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NATIONAL DRUG POLICY AND STRATEGY

SESSION GUIDE

PLANNING DRUG REQUIREMENTS

ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES
PROGRAMME D'ACTION POUR LES MÉDICAMENTS ET VACCINS ESSENTIELS

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PLANNING DRUG REQUIREMENTS [1]

[1] This document is part of a series of nine session guides: (1) Introduction to a National Drug Policy, (2) Supply System Organization, (3) Selection of Drugs, (5) Procurement Strategies, (6) Systematic Cost Reduction, (7) Financing The Drug Supply, (8) Quality Assurance, (9) Introduction to Proper Drug Use.

This document can be used in conjunction with DAP/86.2 Trainers' Guides.

SESSION GUIDE

SESSION: Planning Drug Requirements

DURATION: 2 hours

RATIONALE: One of the most important decisions in the drug supply cycle is that of determining the order quantities for individual drugs and medical supplies. Most often, order quantities are based on past consumption. However, when consumption data are incomplete or unreliable, when funds are inadequate, when drug utilization patterns seem inefficient or irrational, or when a new program is being established, then a more methodical approach to planning drug requirements is needed. This unit reviews different techniques which can be used to estimate individual drug requirements.

OBJECTIVES: To improve your ability to:

1. Identify at least two methods for estimating annual drug requirements: the consumption method and the epidemiology method.
2. Collect reliable consumption information or estimates of consumption.
3. Organize the analysis of past consumption patterns to identify potential ways to promote cost-effective drug utilization.
4. Perform or supervise the steps necessary to make epidemiologically-based estimates of drug requirements.
5. Use the epidemiologic method of estimating drug requirements to help rationalize drug utilization and, where funds are limited, to set priorities for drug procurement.

PREPARATION: Read the Session Notes.

PLAN:
1. Discussion of what is meant by the term "planning drug requirements."
2. Discussion of your current methods for estimating drug needs.
3. Presentation of the consumption method.
4. Presentation of the epidemiology method.

FURTHER READINGS: Managing Drug Supply, Chapter II.B.

SESSION NOTES

Determining drug requirements is perhaps one of the most difficult responsibilities faced by physicians, pharmacists, and supply specialists who manage pharmaceutical procurement. On the one hand, one would like to avoid perpetuating wasteful or irrational drug utilization by simply ordering on the basis of historical demand for individual drugs. On the other hand, one would also like to avoid creating severe shortages of some items and overstocks of other items by ordering entirely on the basis of some theoretically determined need for individual drugs. Furthermore, lack of reliable information often makes it difficult to determine accurately either historical demand or theoretical need.

Needless to say, there is no "best" way to determine drug requirements. The approach which is taken should be selected on the basis of the drug and health care information available, the purposes of the estimate, and the nature of the drug supply program. Methods for estimating drug requirements fall into two main categories: consumption-based methods and epidemiology-based methods.

Consumption methods rely on analysis of past consumption data which come from existing inventory records or from a survey of recent drug consumption. Epidemiology methods require information about the frequency of common health problems, information about standard treatments, and information about the number of people who will be treated. There are a variety of ways to use each of the methods, and it is possible to use both methods simultaneously in order to compare the results.

A. CONSUMPTION METHOD FOR PLANNING DRUG REQUIREMENTS

In adequately-financed and well-established drug supply programs, drug requirements are usually based on recorded past consumption. However, in essential drug programs and other types of public drug supply programs, a consumption-based approach to determining drug requirements has several drawbacks. These drawbacks include the following:

1. To the extent that there have been shortages of essential items, drug needs will be under-estimated.

2. To the extent that past and current prescribing and dispensing practices are irrational or wasteful, these practices will be supported--if not encouraged--by consumption-based ordering.

3. Estimates of consumption based on supplies issued from the Central Medical Stores may not reflect current drug utilization patterns at the provider level. It may take three months, six months, or even longer before changes in prescribing patterns at the provider level are reflected in stock consumption at the central level.

Despite these drawbacks, there are several advantages to a consumption-based approach to estimating drug needs, including the following:

1. When accurate consumption data are available, the consumption method is the easiest way to determine future drug needs.

2. The consumption method does not require epidemiological data or established standard treatments, either of which can be difficult or impossible to obtain.

3. If consumption data are complete, if stockouts have been recorded and taken into consideration, if prescribing practices remain relatively unchanged, and if the program is not experiencing rapid growth, then consumption-based estimates should result in fewer instances of stockouts or overstocks than the epidemiology method.

The consmmption method has two important steps: data collection and data analysis.

Data Collection -- In an established supply system, consumption data can usually be obtained from the stock card records ("kardexes," etc.). Consumption data can also be

obtained from customs records or import data, other government programs which provide drugs (eg., social security or armed forces in some countries), or from sampling the consumption at selected health facilities.

A method of estimating national consumption by sampling consumption at selected "sentinel" health facilities could be used. A small number of representative sentinel facilities are chosen and consumption records are reviewed for a specified period of time--preferably at least one year in order to include seasonal variations. The facilities should be chosen on the basis of the morbidity pattern, the level of population coverage, the apparent prescribing practices, the adequacy of the drug supply, and the adequacy of information on drug consumption and patient attendance.

An obvious, but frequently overlooked, aspect of data collection is that of assuring consistency in the data. When drugs are ambiguously described, then the data become ambiguous. Consumption should be recorded according to the official generic name. Strengths, package sizes, and the counting unit must be explicitly stated to avoid confusion among those responsible for inputing the data.

Recording of past consumption should also include information about stockouts. To the maximum extent possible, consumption data should be adjusted to reflect the consumption which would have occurred if there had been no stockouts.

Data Analysis — Once consumption data have been collected, they should be reviewed by a Formulary Committee, Pharmacy and Therapeutics Committee, or other qualified committee or individual to determine what adjustments need to be made for the next drug order. This utilization review is the most important part of consumption-based estimates. Utilization review is particularly important when the projected need for drugs exceeds the available funds and cutbacks are required.

There are at least three aspects to be considered during the utilization review:

1. Anticipating Program Growth -- If the program for which drug requirements are being estimated is growing, then this growth needs to be reflected in the drug estimates. Depending on the pattern of growth, next year's drug needs can be based on a straight-line projection (which assumes constant growth) or an "S-curve" projection (which assumes a rapid expansion phase, then a plateau).

2. ABC Value Analysis -- An ABC Value Analysis should be performed to determine where most of the funds are being spent. An ABC Value Analysis categorizes the drugs consumed into three classes (A, B and C) according to the value of the annual usage (unit cost multiplied by the number of units consumed annually). This analysis will be discussed in detail in the session on "Cost Reduction." The analysis itself cannot establish whether or not the expenditures were reasonable, but it should direct the attention of the Formulary Committee, Pharmacy Committee, Chief Pharmacist, or Chief Medical Officer to those few items which account for most drug expenditures. Review of the ABC analysis sometimes suggests items that are being overused and points to areas of potential savings. Figure 1 illustrates the results of an ABC Analysis for one large Ministry of Health supply system.

3. Therapeutic Alternatives Analysis -- Drug consumption can also be reviewed by comparing the utilization of individual drugs within the same therapeutic category. This type of analysis is particularly useful when the unit costs for each item are included. Often a particular item has become popular without regard for its cost relative to therapeutic alternatives. The therapeutic alternatives analysis can suggest substitutions which can result in significant cost savings. Figure 2 is an example of a therapeutic alternative analysis for one therapeutic class.

Figure 1

ABC Value Analysis Year: 1983

CODE	Rank Order	Drug Product Description	WHO Ess. List	VEN Cat.	Total Cost (LC)	% of Total Cost	Cumulative % of Total Cost
		TOTAL - 481 ITEMS			56,040,448	100.00%	100.00%
		CLASS "A" - 37 ITEMS			39,166,166	69.89%	69.89%
		CLASS "B" - 69 ITEMS			11,216,647	20.02%	89.91%
		CLASS "C" - 375 ITEMS			5,657,635	10.10%	100.00%
59111	1	Streptomycine Sulfate Poudre 1 gm.	Y	V	8,363,300	14.92%	14.92%
74060	2	Distilled Water 100%	Y	V	4,640,000	8.28%	23.20%
58162	3	Penicilline G 1M Unit Inj.	Y	V	3,726,250	6.65%	29.85%
58051	4	Chlortetracycline 1%	Y	V	3,333,080	5.95%	35.80%
33061	5	Glucose Perf. Isotonique	Y	V	1,639,478	2.92%	38.73%
68023	6	Insuline Retard I P Z 40 U	Y	E	1,172,979	2.09%	40.82%
70[illegible]	7	Aspirine 500 mg	Y	V	1,161,20[illegible]	2.07%	42.89%
58172	8	Penicilline G+Penicill.GPro 1M Unit	Y	V	1,143,[illegible]	2.04%	44.93%
33072	9	Sodium Chlorure Perf. Isotonique	Y	V	1,053,[illegible]	1.88%	46.81%
59101	10	Rifampicine 150 mg.	Y	E	1,016,1[illegible]	1.81%	48.62%
75117	11	Anti-Spasmodiques (2=Bara.3=Ava)	N	N	785,[illegible]	1.40%	50.03%
59050	12	Ethionamide 250 mg.	Y	E	763,2[illegible]	1.36%	51.39%
58260	13	Sulfaguanidine 500 mg.	N	V	636,792	1.14%	52.52%
58040	14	Chloramphenicol 250 mg.	Y	V	626,327	1.12%	53.64%
58280	15	Sulfamethoxypyridazine	N	V	562,400	1.00%	54.64%
59090	16	Pyrazinamide 500 mg.	Y	E	553,315	0.99%	55.63%
31080	17	Carbazochrome	N	N	515,662	0.92%	56.55%
58163	18	Penicilline G 5 M Unit Inj.	Y	V	514,776	0.92%	57.47%
12091	19	Fluphenazine Retard Inject. 25 mg	Y	N	498,486	0.89%	58.36%
58140	20	Oxytetracycline 250 mg.	Y	V	489,546	0.87%	59.23%
33082	21	Potassium Chlorure 250 mg.	Y	E	489,1[illegible]0	0.87%	60.11%
68021	22	Insuline 40 U	Y	V	471,407	0.84%	60.95%
42050	23	Bromure Butyl d'Hyosine 20 mg.	N	E	453,075	0.81%	61.76%
74680	24	Anti-Infectieux Pulmonaire Enfant	N	N	413,562	0.74%	62.49%
33111	25	Sodium Bicarbonate 14%	Y	E	356,[illegible]	0.64%	63.13%
59040	26	Ethambutol 500 mg.	Y	E	353,290	0.63%	63.76%
46061	27	Vit. B/6 (Pyridox.Chlor.Inj.) 250mg	Y	E	352,755	0.63%	64.39%
68033	28	Glybutamide 500 mg.	N	E	347,726	0.62%	65.01%
74670	29	Anti-Infectieux Pulmonaire Adulte	N	N	343,850	0.61%	65.62%
33024	30	Calcium Gluconate Inject. 10%	N	N	340,[illegible]	0.61%	66.23%
54056	31	Hydrocortisone Injectable 100 mg.	Y	V	324,128	0.58%	66.81%
58420	32	Trisulfamides Sulf(diaz.)(thiaz.)	N	V	301,974	0.54%	67.35%
58182	33	Benzathine Penicilline 600,000 U	Y	V	290,274	0.52%	67.87%
12013	34	Chlorpromazine* 100 mg	Y	E	288,980	0.52%	68.38%
58431	35	Benzathine Benzyl Penicilline 1.2MU	Y	V	287,820	0.51%	68.90%
46130	36	Vitamine K1 Injectable 20 mg.	Y	V	279,963	0.50%	69.40%
75879	37	Antiacide	Y	E	276,006	0.49%	69.89%

Figure 2

Planning Drug Requirements

Therapeutics Alternatives Analysis

SAMPLE DATA ONLY

Year: 1983

Product				Consumption 1984		
CODE	Drug Product Description	Route	WEN Cate.	Total Cost	Cost per Treatment Episode	Number of Treatment Episodes
	MAJOR TRANQUILIZERS					
	AVERAGE COST				7.24	
	TOTAL COST			1,855,374.94		
	PERCENT OF TOTAL EXPENDITURES			3.31%		
12041	Fluphenazine Retard Inject. 25 mg	IV	N	498,486.00	30.12	16,550
12100	Pipotiazine (Estners) Inj.* 100 mg	IV	N	209,461.50	2.82	74,167
12015	Chlorpromazine Inject. 25 mg	IV	N	158,858.00	5.88	27,017
12092	Fluphenazine Decanoate Inj. 25 mg	IV	N	151,587.00	34.13	4,445
12033	Levomepromazine Inject.	IV	N	41,081.60	4.70	8,733
12072	Tri-fluoperazine 100 mg	IV	N	22,784.00	2.56	8,900
12021	Haloperidol Inject.	IV	N	14,365.14	6.24	2,303
12102	Pipotiazine (Estners) Inj. 100 mg	IV	N	14,544.	2.91	5,000
12013	Chlorpromazine* 100 mg	PO	E	288,979.	0.48	607,100
12024	Levomepromazine 100 mg	PO	N	199,390.	1.82	109,775
12030	Levomepromazine 25 mg	PO	N	85,821.	0.70	128,825
12052	Thioridazine 10 mg	PO	N	83,626.	0.58	145,188
12065	Thioridazine 50 mg	PO	N	81,547.4	1.17	69,438
12010	Chlorpromazine 25 mg	PO	E	69,627.6	0.08	856,933
12050	Trifluoperazine 10 mg	PO	N	8,151.	1.48	5,150
12042	Fluphenazine 25 mg	PO	N	8,464.5	1.98	4,275

Thus, the analysis of consumption data is intended to provide insights into utilization patterns. These insights should help to adjust drug orders to reflect anticipated program growth and to encourage more cost-effective drug use. If the analysis suggests ways to improve drug utilization, then these suggestions need to be communicated to prescribers in the form of a Ministry of Health circular, or some other educational format.

B. EPIDEMIOLOGY METHOD FOR PLANNING DRUG REQUIREMENTS

In an adequately-financed drug supply program with reliable inventory control and distribution systems and good prescribing practices, drugs can be ordered on the basis of projections from recorded past consumption. However, when available funds are inadequate for projected needs, when available consumption information is incomplete or unreliable, when prescribing patterns seem inefficient or irrational, when a new supply program is being established, or when an existing program is expanding rapidly, then the epidemiology method may be a more appropriate means of estimating drug requirements.

The epidemiology method requires the following five basic steps:

1. Determine the population to be served.

2. Determine the frequency of each health problem being treated.

3. Establish standard treatments for each health problem.

4. Calculate the quantities of drugs required by multiplying together the first three items.

5. Adjust for available budget.

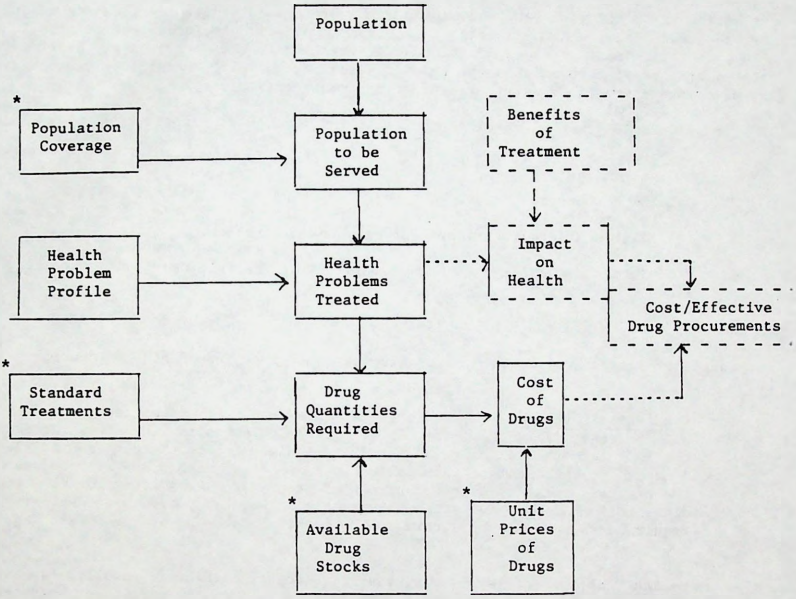
These five steps are represented diagrammatically in Figure 3 and are described briefly below.

1. Population Coverage -- A realistic estimate is needed of the number of patients who will be treated. An estimate of the total population may be useful for determining the long-term theoretical need for drugs. However, for the purposes of placing a drug order, the estimate must reflect the number of people who will be seen in all the health facilities supplied by the program. It is important to know the age distribution of the population being served. For the purposes of estimating drug requirements, the age breakdown can be as simple as, "under age 5" and "age 5 and over."

2. Health Problem Profile -- Next, the frequency of each health problem (symptom, diagnosis, or need for a health service such as prenatal care) must be determined. The health problems must be identified clearly enough to distinguish conditions requiring different types of drug treatment. For example, "ear pain" is not a precise enough category if external ear infections (otitis externa) are to be treated with ear drops and internal ear infections (otitis media) are to be treated with oral antibiotics.

Figure 3

EPIDEMIOLOGY MODEL FOR ESTIMATING DRUG REQUIREMENTS -- CONCEPTUAL FRAMEWORK



*Points of Medical, Pharmacy, or Management Decision or Influence

- - - - = Information and relationships which are difficult or impossible to measure at present.

Getting reliable health problem information is often the most difficult part of estimating drug requirements. There are at least four potential sources for health problem profile data:

a. Existing Government Data - The Ministry of Health, Ministry of Planning, or other government agency may collect usable information on health problems. Before using such data, it must be looked at critically from the viewpoint of its reliability, the specificity with which individual health problems are identified (for example, categories such as "respiratory diseases" are too nonspecific for drug estimates), and the age breakdowns which are available.

b. Survey Data - If existing data are judged to be unusable, another alternative is to conduct a survey at selected health facilities to determine what types of problems are being seen. The survey need not be too detailed, since, for any one country, only twenty to thirty different health problems account for over ninety percent of patients seen by the health service. One advantage to survey is that information on the age-distribution for each health problem can be collected exactly as it is needed for the drug estimate. A survey can be done by looking back at patient registers or by collecting information on patients currently being seen.

c. Comparable Data - Another alternative for obtaining a health problem profile is to use data collected by a private voluntary organization operating within a certain region of the country or data from another country whose health problems are believed to be comparable to those of the population for which the estimate is being made.

d. Expert Panel - A final alternative is to have a panel of doctors, nurses and other experienced health professionals from the country construct a health problem profile based on their experience. Starting without any data, this may be difficult and rather inaccurate. But it may be possible to take existing government data or comparative data from another program and, based on judgments by an expert panel, modify this data to more accurately reflect the health problems of the population being served.

3. Standard Treatments -- A central requirement in using the epidemiology method is that standard treatments be written. Standard treatments are essential for calculating drug requirements with this method. In addition, the process of writing and promoting standard treatments (if they do not already exist) can play an important role in improving drug utilization patterns. For estimation purposes, standard treatments must be specific with regard to dosage, frequency, and duration of treatment. For clinical purposes, however, the standard treatments may reflect a range of treatment regimens. A set of illustrative standard treatments for use in estimating drug requirements is being developed by WHO, but each program must ultimately develop its own standard treatment regimens.

4. Calculation of Quantities Required -- Once the first three steps have been completed, the quantities of drugs required can be calculated by multiplying the number of patients being served by the frequencies of common health problems by the quantities of individual drugs needed to treat each health problem.

5. Adjust for Budget - Depending on the size of the target population, the health profile, the standard treatments, and the drug prices, the final estimate of drug requirements may be higher than the available budget. It is sometimes possible to use the results of the estimate to argue for a higher budget. More often, it is necessary to adjust the drug order to fit the budget. This can be a difficult task for which there is no universally appropriate approach.

Factors which might be considered in making the adjustment include the relative cost-effectiveness of individual drugs in treating specific health problems, the unit costs of individual drugs, the frequency with which specific health problems are encountered, the impact of specific health problems on disability and mortality, and past consumption of individual drugs (if such information is available). In addition, an ABC analysis of the proposed drug order and the establishement of VEN categories of the drugs may be helpful. A VEN system places the drugs into three categories: V = Vital drugs, E = Essential drugs, and N = Non-essential drugs. This system will be discussed in detail in the session on "Cost Reduction."

This five-step estimation process can be applied at the level of the village or community health worker, the mid-level health worker at health centers, or the level of the hospital outpatient clinic where doctors' services are provided.

In theory, the epidemiologic method seems to provide a "truer" estimate of drug requirements. In practice, there are several cautions which should be considered in using this method:

1. Accurate estimates of population coverage and health problem frequencies are often difficult to obtain. Inaccurate estimates can significantly misdirect drug purchases.

2. The process of drafting standard treatments, if they do not already exist, can lead to costly delays in initiating the procurement process.

3. If the standard treatments used to estimate drug needs are not fully communicated to health care providers, and if the standards are not generally adhered to, then drug consumption may deviate significantly from projected drug needs. Thus, it is possible with an epidemiologically-based estimate to create stockouts and overstocks which might not have occurred with consumption-based orders. However, if the standard treatments represent a significant therapeutic improvement, then stock mismatches may represent an acceptable short-term cost of long-term improvements in drug utilization.

Figures 4, 5, and 6 provide an illustration of the epidemiological method which will be discussed during this session.

C. USES FOR ESTIMATES OF DRUG REQUIREMENTS

In addition to providing estimates for use in purchasing new drug supplies for an existing program, estimates of drug requirements derived from the consumption or the epidemiologic method can be used in the following ways:

—to determine order quantities for new or rapidly growing programs;

--to plan health budgets at the local, district, regional, or national level;

--to identify possible ways to improve cost-effective drug utilization;

--to provide information which might be used in negotiating for additional foreign exchange allocations;

--to document the need for specific donor funding;

—to assess the need for specific drug products which may have been offered as gifts.

Further, drug requirements derived from the consumption and the epidemiologic methods can also be used to teach the health workers the discrepancies between real needs (epidemiologic method) and actual demand (consumption method).

Figure 4

Health Problem Profile — Year: 1985

SAMPLE DATA ONLY — Number of Patient Contacts Last Year: 3,123,408
Children Under Age 5 as % of Contacts: 20.00%

Code	Name of Health Problem	Age Group	Treatment Episodes per 1000 Contacts		Number of Treatment Episodes Last Year		Expected Change (% adjustment)	Adjusted Number of Treatment Episodes	
			Medical	Paramedical	Medical	Paramedical		Medical	Paramedical
4.11	Acute diarrhea	<5	220.0	278.4	171,787	652,168			
		>=5	75.0	50.0	58,584	117,128			
14.12	Bacterial skin infections	<5	95.0	125.4	74,181	293,757			
		>=5	15.5	73.6	12,103	172,412			
9.11	Conjunctivitis	<5	50.4	22.6	23,778	52,942			
		>=5	24.0	14.6	18,749	34,201			
15.40	Low back pain	<5	2.5	0.0	1,952	0			
		>=5	36.0	19.4	28,111	45,446			
8.11	Headache	<5	21.0	16.9	16,395	39,589			
		>=5	55.4	62.0	43,259	145,238			
4.32	Heartburn, gastritis	<5	14.0	17.2	10,932	39,922			
		>=5	46.8	30.0	36,544	70,272			
10.12	Otitis media	<5	45.6	60.6	35,607	141,959			
		>=5	13.6	15.7	10,620	36,770			
5.21	Common cold, upper resp.infect.	<5	146.0	166.9	114,004	390,973			
		>=5	50.0	74.0	39,047	173,349			
5.22	Acute tonsillitis	<5	36.0	36.0	28,111	84,332			
		>=5	18.5	15.5	14,446	36,310			

Figure 5. Standard Treatments

SAMPLE DATA ONLY

Health Problem			Treatment Approach									
Code	Name Problem	Age Group	Treat. No.	% of Cases Treated W/ this Trat.	Drug Code	Drug Product Description	Basic Unit (BU)	BU/ Dose	Dose/ Day	Days/ Episode	BU/ Episode	Cost/ Episode
4.11	Acute diarrhea	<5	1	90.0%	76999	ORAL REHYDRATION SALTS	SACHET	1	1	3	3	
			2	10.0%	76999	ORAL REHYDRATION SALTS	SACHET	1	1	3	3	
					36269	SULFAGUANIDINE	TAB	1	6	4	24	
4.11		>=5	1	100.0%		MB DRUG	RX	1	9	4	36	
9.11	Conjunctivitis	<5	1	100.0%	58051	CHLORTETRACYCLINE 1% OPTH	TUBE	1	1	1	1	
9.11		>=5	1	100.0%	58051	CHLORTETRACYCLINE 1% OPTH	TUBE	1	1	1	1	
10.10	Otitis media	<5	1	100.0%	58173	PENI G+PENI PRO 400u	AMP	1	1	5	5	
					7010	ASPIRINE 125 MG SUPP	SUPP	1	4	3	12	
10.10		>=5	1	100.0%	58172	PENI G+PENI PRO 1MU	AMP	1	1	5	5	
					7012	ASPIRINE 500 MG	TAB	2	3	3	18	
5.22	Acute tonsilitis	<5	1	100.0%	58183	BENZATHINE PENI 1,2mu	AMP	1	1	1	1	
5.22		>=5	1	100.0%	58183	BENZATHINE PENI 1,2mu	AMP	1	1	1	1	
5.21	Inter cold, up or resp infect.	<5	1	100.0%	7012	ASPIRINE 500 MG TAB	TAB	1	3	3	9	
5.21		>=5	1	100.0%	7013	ASPIRINE 500 MG TAB	TAB	2	3	3	18	
4.32	Heartburn, gastritis	>5	1	100.0%	41638	MAALOX	TAB	1	4	7	28	
4.32		<=5	1	100.0%	41638	MAALOX	BTL					
14.12	Bacterial skin infections	>5	1	100.0%	58111	NEOMYCIN CREAM	TUBE	1	1	1	1	
14.12		<=5	1	100.0%	58111	NEOMYCIN CREAM	TUBE	1	1	1	1	
15.40	Low back pain	>5										
15.40		<=5	1	100.0%	7012	ASPIRINE 500 MG TAB	TAB	2	3	3	18	
8.11	Headache	>5	1	100.0%	7013	ASPIRINE 125 MG SUPP	SUPP	1	4	3	12	
8.11		<=5	1	100.0%	7012	ASPIRINE 500 MG TAB	TAB	2	3	3	18	

Figure 6. Summary of Drug Requirements Year: 1985

Drug Code	Drug Product Description	Purchase Package Size	Total Needs		Total Cost	Percent of Total Expenditures
			Basic Units	Purchase Units		
7012	ASPIRINE 500 mg tab	Bottle of 1000 tabs	164716	165	16,470.98	0.31%
7013	ASPIRINE 125 mg supp	Box of 12 suppositories	78184	6515	10,833.26	0.18%
59183	BENZATHINE PENI 1,2mu	Box of 50 5-ml amps	24125	483	55,452.91	0.94%
57240	NEOMYCIN CREAM	Box of 25 15-gm tubes	93222	3729	9,322.16	0.16%
58751	CHLORTETRACYCLINE 1 % ophthal	Box of 50 5-gm tubes	17426	349	31,018.89	0.52%
41836	KAOLIN	Box of 24 120-ml bottles	20237	843	49,474.08	0.67%
58172	PENI G + PROCAINE PENI 1m	Box of 100 5-ml amps	29419	294	61,549.72	1.03%
58177	PENI G+PENI PROCAINE 400K	Box of 100 5-ml amps	29388	294	50,275.27	0.84%
75199	ORAL REHYDRATION SALTS	Box of 40 sachets	224106	5603	652,080.06	10.87%
58258	SULFADIAZINE	Box of 40 bottles of 1000 tabs	130416	3	25,683.30	0.43%
	TOTAL				976,859.00	16.28%

Planning Drug Requirements

SHOULD VAJPAYEE GO TO PAKISTAN? EXCLUSIVE OPINION POLL

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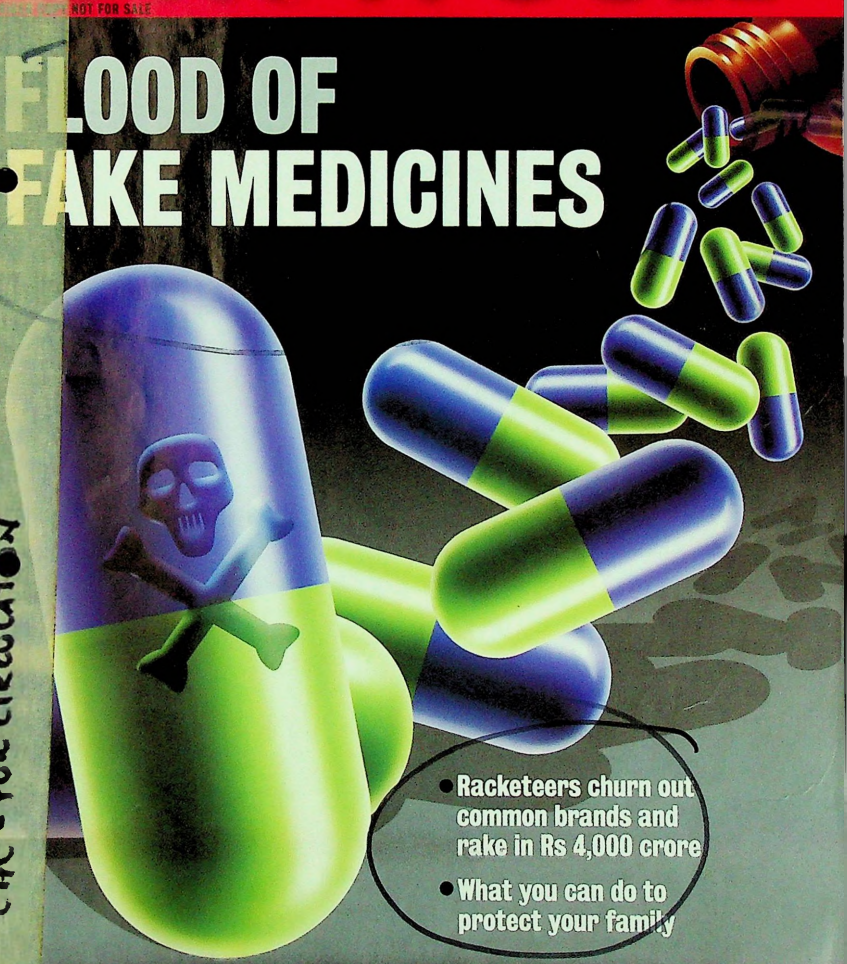
TheWeek

FLOOD OF FAKE MEDICINES

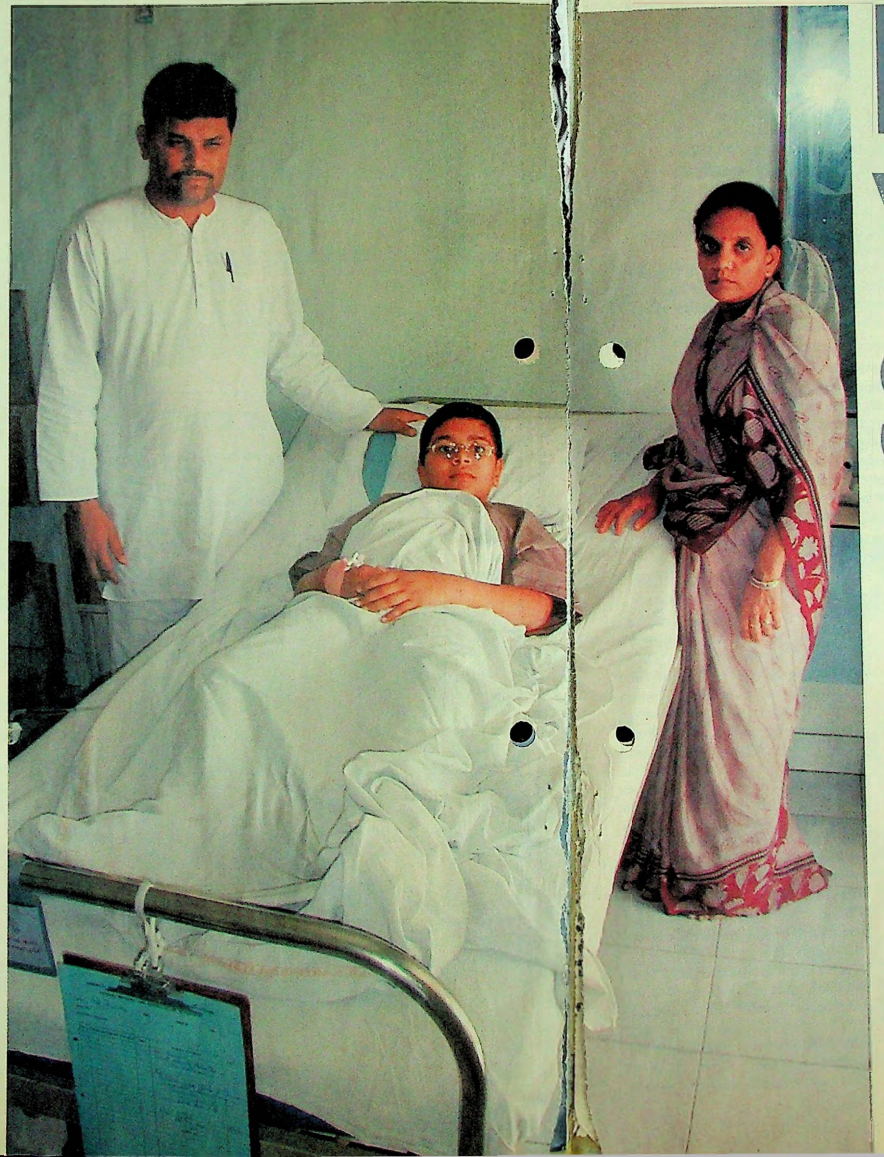


- Racketeers churn out common brands and rake in Rs 4,000 crore
- What you can do to protect your family

According to the WHO, 35 per cent of fake drugs produced in the world come from India, which has a Rs 4,000-crore spurious drug market. About 20 per cent of medicines in the country are fake.

Many common drugs, including those used for headaches and the common cold, are fake or substandard. Of them, 60 per cent have no active ingredient and 16 per cent have harmful ingredients.

A recent raid by the Karnataka Lok Ayukta revealed that authorities were silent about 829 substandard drugs which were being bought and consumed by the public.



KILLING YOU SLOWLY

Many common medicines available in the market are fake

By N. BHANUTEJ/Bangalore
and QUAIED NAJMI/Mumbai

Think twice before you pop that pill. You could be swallowing solidified chalk powder masquerading as paracetamol. Your fever will get worse and you will get stomach pain as bonus. That is, if you are lucky. Things could be much worse. You may be taking that anti-depressant to drive away the blues. In your bad mood, you may not have noticed that the packing looked different: A few hours later, you may be in the grip of a panic attack.

If that does not frighten you, run your eye through these alarming statistics. According to the World Health Organisation, 35 per cent of all fake drugs produced in the world come from India, which has a Rs 4000-crore spurious medicine market. Nearly 20 per cent of the medicines available in the domestic market are fake or substandard. Of these, 60 per cent do not contain any active ingredient, 19 per cent contain wrong ingredients and 16 per cent have harmful and inappropriate ingredients. Spurious drugs appear in commonly known brand names. So be afraid.

"Today fake and substandard drugs harm more persons daily than the SARS virus," said Ajit Singh, chairman of the Associated Capsules Group in Mumbai. Consumers and drug control officials have to grapple with two demons: fake drugs manufactured by seedy underground units, and substandard drugs which come from the stable of reputed companies. Often it is difficult to distinguish between the two. The common factor is that both are harmful.

TRAGIC ORDEAL: Alpesh Mehta,12, (with father and mother) almost died after being injected with a spurious drug

The problem is more acute and widespread than one can imagine. Doubters can peruse these grim findings.

◆ An Army man died in a nursing home in Patna on May 5 after being injected with a substandard drug.

◆ A random test of ciprofloxacin 500 mg tablets (batch no.154 V), an antibiotic manufactured by British Pharma Laboratories of Gujarat, proved that the tablets contained no ciprofloxacin.

◆ Dexamethasone 5 mg (batch no. 145 P) tablets, a life-saving steroid manufactured by the same company, contained no dexamethasone.

◆ Hydrogen peroxide (batch no. 001) solution, manufactured by Medismith of Bangalore, contained no trace of hydrogen peroxide.

◆ Villagers in Madhya Pradesh are usually given fake drugs Conacin and Crocinol in place of the common brand Crocin.

◆ Ampicillin 250 mg capsules, another commonly used antibiotic for respiratory infections, made by Economic Pharma of Mumbai (batch no 5604), contained a powder that had no ampicillin in it.

◆ Paracetamol syrup, usually prescribed to control fever in children, manufactured by Sinclair Pharma (batch no. SP 001), contained no paracetamol at all.

The list goes on and on. The rot runs deep.

This was made amply clear in a recent raid by the Lok Ayukta on the Drugs Control Department of Karnataka. There were a lot of fake drugs in the market and the authorities couldn't care less. The Lok Ayukta discovered that in the last three years, the department had found that 829 commonly known medicines were of poor quality. Still, the department took no action and allowed people to buy and consume the drugs. "This is just the tip of an iceberg," said an official who was anguished at the turn of events. "These are just random samples. What if we had gone looking for fake medicines?"

SPOT THE FAKE ONES

The Organisation of Pharmaceutical Producers of India has some suggestions for consumers

THOSE BUYING MEDICINES SHOULD ALWAYS LOOK FOR:

- The batch number, manufacturing date, expiry date, manufacturing licence number, manufacturer's name/address on the pack before buying any medicine
- Any sloppiness—illegible or badly printed labels, absence of one/all of the above details, faulty sealing and differences in colour of the packing
- Broken tablets/capsules, extraneous matter in liquid preparations, lumps in creams/ointments

TO CURB THE SPREAD OF FAKE MEDICINES:

- Destroy the empty packs/bottles of used or left-over medicines to avoid recycling
- Report to the company which manufactures/markets the product of your doubts about any particular medicine immediately
- The company will lodge complaints either with the local police or the regulatory authorities in the state.
- These two agencies will investigate the matter and initiate appropriate criminal proceedings.

Graphics/MUKESH M.

They would have found it all over the place. To use a cliche, the web of fake medicines spreads from Kashmir to Kanyakumari, though, according to available information, it becomes flimsy down south. The steely filaments of the web are in the northern region, with Bhagirath Palace in Delhi reportedly being the hub of fake medicine trade in south Asia. Indore in Madhya Pradesh is another breeding ground of fake drugs. Nearly 150 small-scale drug manufacturing units operate from garages and hovels here. From Indore, fake medicines have found their way to Russia and Uzbekistan. Medicines are being churned out in slums outside Lucknow and Ahmedabad. They have a thriving market in South Africa, creating huge problems for the health officials there, not to speak of neighbouring countries like Myanmar and Bangladesh.

CROCIN Paracetamol tablets
Batch no. 0100 and S9238
Manufacturer: Smithkline Beecham

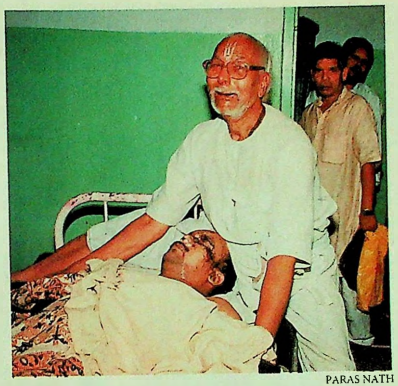
The most established and fast-moving brands are the targets of the drug mafia. Hoechst Marion Roussel Ltd found to its utter shock that 15 per cent of all its products available in the market were fake. Knoll Pharamaceuticals suffered losses worth Rs 75 lakh on three popular brands: Brufen, Entamizole forte and Eptoin. Smithkline discovered that its popular brand Iodex had been duplicated everywhere.

Spurious drugs were being sold in Uttar Pradesh, Bihar, parts of Karnataka and Tamil Nadu.

Unofficial figures gathered by consumer bodies estimate that more than 40 per cent of the medicines which hit the rural market are fake or substandard. The illiterate villager is easy prey to the fake drug mafia which colludes with local doctors and chemists. Many over-the-counter products sold in interior Madhya Pradesh are fake. A villager cannot be expected to distinguish Glysun-D and Glycon-D from Glucon-D. Vips and Vims are balms which officiate for the popular Vicks. In Hyderabad, drug control officials had a hard time distinguishing between Crocin and its fake cousin. The packings were almost the same.

Fake drugs have spread terror in Kashmir, too. In 1999, the drug controller's department in the Valley blacklisted Jackson Pharmaceuticals Ltd after its products were found to be substandard. The company is, however, back in business. The Uttar Pradesh Police raided a dingy house in Lucknow two years ago and seized 300 bottles and 1,000 fake labels of Betadine. The fake drug market thrives in towns like Meerut.

Despite its spread, the pharma companies and authorities do not have any concrete data on the producers of these medicines. Most of the small units operate from hovels and garages. Some of them had been associated with big companies. The general impression is of a shadowy crowd. "No spurious drug manufacturer puts up a nameplate announcing his business and in most cases, these are garage-type operations," said S. Ramesh of the research wing of Associated Capsules Group at Andheri. " It is difficult to catch them as they know all the loopholes of the law," said a doctor. Drug control officials and doctors have much to say about the hot spots and about fake drug manufacturers breeding like mosquitoes, but when one gets down to specifics, they shrug their shoulders.



PARAS NATH

VICTIM: Rakesh Kumar Das was injected with a fake drug

Those who consume the spurious drugs cannot dismiss the problem with a casual expression of resignation. Sometimes they pay with their lives, as in the case of Rakesh Kumar Das, an Army man, who died in a nursing home in Patna after he was administered three injections of Lasix on May 5. His father alleged that his son was injected with a substandard drug. Interestingly, the owner of the nursing home, Dr Ramendra Narayan Singh, does not dismiss the allegation. "Anything can happen in this country,"

Into the lion's den

By NISTULA HEBBAR

In a cramped room in Shakarpur in Delhi, Sanjay Khanna is busy overseeing the production of a batch of fake tablets. His speciality is over-the-counter drugs like paracetomol and disprin. The entire manufacturing unit cost him around Rs 1,00,000, but the profits have more than made up the cost.

What makes fake tablets so profitable? According to Dr C.M. Gulhati, editor of the Monthly Index of Medical Specialities, it is the economics of the situation. A strip of 10 Nimuselide tablets has a sale price of Rs 25.75. The cost of the drug in bulk is Rs 250 per kg—one tablet would be equal to 100 mg. So the cost of 10 tablets would be 25 paise. The cost of printing and packaging a tablet would be about Rs 1.40. Thus the entire tablet is ready for sale at Rs 1.65. Big brands factor in research and development costs, the costs of clinical trials and other overheads. But in fake manufacturing the cost is much less as they skip R&D; they simply lift the formula.

Gulhati is careful in distinguishing between fake and substandard drugs. "Fake drugs may contain the right formula and may just fake the brand, but substandard drugs are from licensed manufacturers where the standardisation procedure has not been followed," he says.

Three years ago, in Shakarpur, the Economic Offences Wing of the Delhi Police had raided a shop, seizing Rs 2,00,000 worth of Nimulid and Glizid tablets. But Khanna is not worried about the law getting to him. "They (the police) will have to pick up the samples first," he says. "We will come to know long before that."

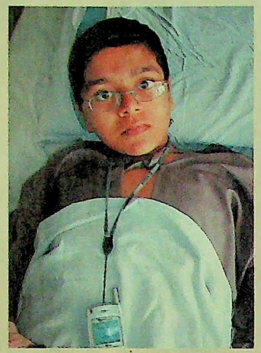
What worried him more was last month's truckers strike that disrupted his supply line between Delhi and Meerut.

Caught in the trap

By QUAIED NAJMI

When disaster struck Lakhpatraj Mehta, 36, it was total and unforgiving. The victims were his two sons, Alpesh, 12, and Aman, 8. While Alpesh nearly lost his life to spurious drugs, Aman died because of alleged medical negligence.

It all began on March 28, 2002, when the three met with a road accident in Pune. Alpesh was admitted to the KEM Hospital while Aman was rushed to the Jehangir Hospital. Mehta claims that 59 doses of Imipanium, a very expensive injection (an ampoule costs Rs 1,850) imported from Holland were administered to Alpesh. All the ampoules were purchased from a private pharmacy store, KM medical store, located in the hospital compound. Though Mehta had noticed that details like the date of manufacture and expiry date were missing, in the heat of the moment he did not report it.



RECOVERING: Alpesh in hospital

After the injections were administered, Alpesh's condition began to deteriorate. His body blackened and he began to bleed. He also developed severe bouts of fits. When there were no signs of improvement even after 55 days, Mehta talked to the doctors. But they insisted that the treatment was proper and that they would give him a total of 120 doses.

Fearing for the boy's life, his family rushed him to another hospital where his treatment schedule was changed. Now he is back on the road to recovery with only a few visits to the hospital.

It was later learnt that the medicine was a counterfeit made in India and passed off as the imported one. It was sold in regular stores at approved rates. Mehta said that he had contacted the Dutch company that manufactures Imipanium and was told that the ideal dosage for a boy of 12 would be 14 to 15 shots, which added fraud to the list of grievances.

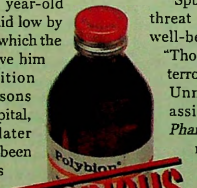
Mehta complained to the FDA in Pune and Mumbai, which has lodged criminal complaints against the pharmacy and its proprietor Jain at Samarth Police Station, Pune. Now, Mehta wants the authorities to institute a CBI enquiry into the drug racket in Pune hospitals. He is determined in his fight despite receiving threats from the drugs mafia. "I am not going to rest until the racket is busted and the culprits are booked," he said.

he said.

Dealing with ill-effects of fake drugs is daily routine for Ahmedabad-based sexologist Dr Paras Shah. "Skin fibrosis due to fake sprays promising penis enlargement is quite common," he said. Gujarat, according to him, is flooded with fake medicines promising wonder cures for sexual problems.

Brij Narayan, a 58- year-old farmer of Bhopal, was laid low by viral fever. But the drugs which the doctors administered gave him no relief. His condition worsened. Finally his sons took him to another hospital, where he got well. It later turned out that he had been given substandard drugs in the first instance.

In Hamidia hospital of the Bhopal Medical College, surgeons face what they call an "anaesthesia problem". Said one: "We are supplied with ketamine hydrochloride injection to be used as anaesthetic agent. Normally 10 mg is enough to make a patient unconscious. But we have to use three to five times more." The particular drug is manufactured at Sanwer Road, Indore.

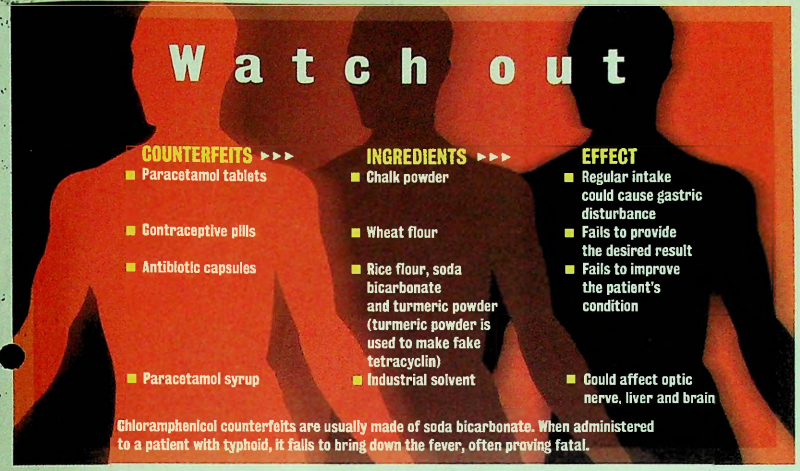


POLYBION SYRUP
B-complex syrup;
Batch no. LR 697.
Manufacturer: E Merck

"Spurious drugs are a major threat to people's health and well-being," said Ajit Singh. "Those who make them are terrorists." According to C.H. Unnikrishnan, senior assistant editor of *Pharmabiz*, some drugs were made of chalk dust, fine sand or limestone powder. "Others are positively harmful," he said.

Sometimes it can cause complications. "A patient who was suffering from a chest disease was being given a syrup," said Dr Amin Wancho of Srinagar. "He complained that it was not helping him. We later found out that it was a substandard drug and it created other problems for him." Sometimes, it can prove fatal: five tribals of Ranchi died five years ago after consuming spurious medicines. Some substandard drugs may contain a small amount of the active ingredients that would build up resistance to a particular drug.

Though physicians express anguish at the prevalence of fake drugs, the fact remains that the racket operates with their connivance, especially in rural areas. A leading doctor in Indore is known to have taken a car as a gift from a dubious



Graphics/MUKESH M.

pharma company. He prescribes its medicines regularly. Dozens of shady pharmaceutical firms in Madhya Pradesh have cut deals with doctors to market their medicines. Some small-time doctors in Gwalior, Sagar, Ujjain and Dewas have gone one step further and have become partners in these units."Small-time doctors perpetuate the spurious drug racket," said V.K. Agnihotri of the Indian Pharmaceutical Alliance.

Veterans of the pharmaceutical industry admit that it had unwittingly played a part in creating this Frankenstein's monster. Some companies neglected "production" handing it over to small-scale units. Over a period, many of the small-scale operators found it more profitable to switch over to producing counterfeit drugs on their own.

GENTAMYCIN EYE DROPS
Batch no. 597
Manufacturer: R.S. Pharmaceuticals

Said Dr C.M. Gulati, editor of *The Monthly Index of Medical Specialties*: "India has inexpensive tableting machinery, which need only a small room. Bulk chemicals are available cheap. Anybody can become a drug manufacturer."

The drug control officers of the states, which are meant to haul up fake drug manufacturers, are universally reviled. "Our drug regulatory authorities have no teeth, few inspectors and even fewer experts," said Prof. Ranjit Roy Chowdhury of the National Institute of Immunology. To be fair, policing by the Drug Control Authority is efficient in Hyderabad, which is a bulk drug capital, but in Karnataka, after the Lok Ayukta raids,

the officials of the authority are seen as being totally corrupt. The same is the case with Madhya Pradesh, Uttar Pradesh and Bihar.

Drug control officials, however, complain that it is not they who lack teeth, but the law. The major problem is that manufacturing fake drugs is not a cognizable offence. It comes under the Drugs and Cosmetics Act, 1940 or the Copyright Act. An accused can only be punished for two or three years and is often let off with a fine of Rs 5,000. Also, identification of fake or substandard medicines is not an easy task and there are many loopholes through which the perpetrators can escape. Drug control officials can rattle their sabres but have to put them back in scabbards.

The Mashelkar committee, set up in 2002, is learnt to have recommended amendment of the act and the setting up of a national drug control organisation.

All this will take time and as of now, the authorities cannot do much. Sensing this, the companies themselves have come up with some defence strategies; it's their money after all. Associated Capsules Group, for instance, came up with t printing the brand nam capsules in a circular fashion not easy to duplicate Laboratories, whose anti-tu drug was widely duplicate getting fewer complaint adopted this method. Omez antacid made by Dr Laboratories, now has a hol the fake drug manufacturer surged ahead by putting tec good use in packing.

For the bewildered cons is no choice but to be well-inf vigilant. He has to exa medicine carefully before ta has to identify tell-tale sign His life may depend on it.

SANJAY AHLAWAT

WARNING NOTE: Dr C.M. Gulati

with NISTULA H
DEEPAK TI
TARIQ BH
LALITA IYE
AJAY UPR
KANHAIAH B
and ANOSH MALEKA

Dark mood

Australia grapples with fake medicine problem

By SACHIDANANDA MURTHY/Canberra

ALLEGRON-25 was a common anti-depressant tablet sold in pharmacies in Australia over the counter. People used it to chase away the blues. Recently, users complained that instead of fighting depression, the tablet intensified the dark moods. They were better off than the users of Travacam, a tablet widely used to fight travel sickness. Australians brave the nine-hour ferry journey from Melbourne to Tasmania by popping Travacam, which was also a favourite in long-distance air travel. But in the last three months, the Therapeutic Drug Administration (TGA), which governs drug standards, found that 19 persons who took the tablet had been hospitalised and 68 others experienced "life-threatening adverse reactions".

These two were among a thousand drugs which were recalled from pharmacies across the country in April and May. The panic persists as the TGA investigators are finding more and more drugs to be spu substandard. Trish Worth, the parlia undersecretary for health, called it "shonky man of medicines" and promised stern action ag makers.

Pan Pharmaceuticals, whose 200 drugs we and production suspended, had tinkered with in a big way. The TGA said that "one of ingredients varied in content from zero to 700 the listed dosage". Patients either got no reli given a seven times higher dosage, which ma them want to jump off planes and trains.

The TGA went on recalling drugs as it disco big companies had given a contract to Pan Phar to manufacture their drugs. Curacel was fined manufacturing counterfeit medicines and a di company was fined $12,000 for switching lab The TGA also found that beef cartilage used drugs was substituted by shark cartilage.

The Australian Self Medication Indus repair the damage done to the 1,424 compar to manufacture over-the-counter drugs. Bu worms led to other cans of worms. If can chicken nugget revealed hard plastic, sai imported from Thailand, contained substan "cause headache, itching and upset stomach

Prime Minister John Howard insisted th had come up only because of the stringent d laws, and said the battle against unscrupu food manufacturers would be waged vigorously.

ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: *THE ROLE OF DATA EXCLUSIVITY*

International Federation
of Pharmaceutical
Manufacturers Associations

Fédération Internationale
de l'Industrie du Médicament

Federación Internacional
de la Industria del Medicamento

FIIM
IFPMA

Dear Reader:

Pharmaceutical and vaccine research and development increasingly promise new therapies and preventions for infectious diseases, including HIV/AIDS, as well noncommunicable diseases, such as cancers, arthritis, heart disease, mental disorders and diabetes. Over 100 HIV/AIDS medicines are in development, including more than 10 vaccines. There are also more than 700 medicines in development for diseases important to a globally aging society – diabetes, arthritis, etc.

For the pharmaceutical industry to invest the billions of dollars, Euros, yen, etc. in these highly risky health care solutions, intellectual property protection is essential. However, patent and trademark protections are not the entire story. This paper corrects for the relative lack of attention given to another important component essential for continued therapeutic progress – the protection of critical information generated by painstaking analysis in the drug and vaccine development process. International treaties, including TRIPS, recognize this area of intellectual property rules, and this paper expands the discussion of data exclusivity rules and implementation.

We thank consultant Dr. Jacques Gorlin for undertaking work in this area.

Dr. Harvey E. Bale, Jr.
Director-General, IFPMA

International Federation
of Pharmaceutical
Manufacturers Associations

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ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY

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I. Introduction

The discovery of a new pharmaceutical compound or vaccine is not sufficient to bring a safe and effective product to the market for use by patients. Rather, the public reaps the benefits of an innovative drug or vaccine only after relevant data, generated in extensive preclinical and clinical trials, demonstrate the drug's safety, quality and efficacy to the satisfaction of regulatory authorities.

The generation of such proprietary data involves a considerable amount of time and expense; the entire drug development process from discovery to marketing takes an average of 10 years and costs, on average, $500 million in industrialized countries.

The protection of test data is a legally required and economically necessary component of the intellectual property package that serves to provide incentives for the development of innovative pharmaceutical products. The Agreement on Trade-Related Intellectual Property Rights (the "TRIPs Agreement") specifically recognizes the "protection of undisclosed information" as being a category of intellectual property subject to protection. Article 39.3 of the TRIPs Agreement provides that:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The intellectual property right reference in Article 39.3 is commonly referred to as "data exclusivity" in the U. S. and "data protection" or "regulatory data protection" in the European Union. Throughout this article, these terms are used interchangeably.[1] Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. It provides the holder with specific rights, namely that the data generated by the holder may not be referred to or used by another person or company for a specific period of time. It does not prevent another company from generating the data. Thus, the right is quite limited in the first instance. However, it has been considered to be of critical importance by countries to provide the necessary incentives for companies to generate the necessary data that accompanies registrational packages for medicinal products.

[1] See glossary of relevant terms in Annex I.

II. Background

1) Definition of the issue

In order to demonstrate a drug's efficacy and safety for its intended therapeutic use, it is necessary for the originator of the drug to conduct extensive testing on animals and humans in pre-clinical and clinical trials as well as toxicology, manufacturing feasibility and other scientific studies. The results of these tests and studies, which are proprietary, are contained in a registration dossier that is submitted to governmental authorities to obtain marketing approval for the drug.

The generation of this confidential registration data involves a very substantial amount of time and expense for the originator; the entire drug development process from discovery to marketing may take as long as fifteen years and cost, on average, $500 million in industrialized countries. The registrational data are provided to the authorities in confidence and are not meant to be referred to by third parties. If these data were immediately available to third parties, there would be no incentive for a company to generate these data in the first instance, unless the investment in terms of both time and costs were protected by another means. In many instances, a patent will cover the pharmaceutical product at issue. However, more and more compounds which are not patent protected (for whatever reason) are being developed and thus data exclusivity in some instances is the only available intellectual property protection right. It is important that governments protect the confidentiality of these data against its unauthorized use or disclosure in order to protect the proprietary interests of scientists and others and to maintain the economic incentives for further pharmaceutical research and development.

However, because of a concern for avoiding repetitive tests and trials on animals and human, governments have sought to limit the originator's proprietary data rights. Therefore, the U. S. and the EU have acknowledged the right of data protection for a certain fixed period of time. After the period has expired, reference to the data is permitted by generic companies. This compromise is viewed as protecting the investment of the originator, while at the same time preventing unnecessary repetitive tests and trials. Arguably, if a country had no data protection law at all, then the data submitted as part of a registrational package should never be permitted to be referred to by a generic company.

The period of data exclusivity is not fixed by the TRIPs Agreement. Earlier drafts of the TRIPs Agreement provided a minimum five year period of

protection. However, this specific minimum time frame was removed from the final version. The time period must be sufficient to protect the originator's investment.

Given the substantial amount of time and resources that is dedicated to obtaining marketing approval and the fact that the data generated in such testing are proprietary and only disclosed by the originator when required by governmental authorities to obtain marketing approvals, governments should be required to protect the data against "unfair commercial use." That is, governments should be required not to disclose nor rely on these data for the marketing approval of generic copies of the pharmaceutical product without the prior approval of the originator for a fixed period of time. Furthermore, governments should be required to protect the data that they receive in a manner that will enable the originators to enforce their rights in every country in the world

2) Patents versus Data Exclusivity

As opposed to a patent right, which gives the right holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product, the protection that governments must accord proprietary test data does not, per se, exclude the copier from running its own tests and submitting the results to the regulatory authorities. Assuming the absence of any intervening patents, a generic alternative may still receive marketing approval, provided that the generic manufacturer conducts its own pre-clinical and clinical trials and independently seeks marketing authorization by the regulatory bodies.

While data exclusivity and patents are the two most critical and, hence, relevant intellectual property rights for the pharmaceutical industry, they are distinct forms of protection; protection of one right is neither dependent on the other nor linked to the other in any intrinsic way and any linkage between the two contravenes TRIPs. The distinctive character of each intellectual property right is reflected in the structure of the TRIPS Agreement, which assigned each right to a separate, parallel section in Part II of the Agreement, Standards concerning the availability, scope and use of intellectual property rights.

3) "Considerable Effort": The logic for requiring data exclusivity

TRIPS Article 39.3 on the protection of undisclosed information contains the logic for requiring protection by governments of registration data. This article recognizes the "considerable efforts" involved in originat-

ing the data; links the protection provided to the data to that "considerable effort" and declares, in essence, that any failure by the government to provide the required protection is "unfair commercial use" of the data. This article relates the protection of the data to the value of the data per se and not to the value of the product or the product in support of which the data were provided to the governments.

While WTO members are obligated to provide protection to proprietary data at a level that is commensurate with their obligations under Article 39.3 of the TRIPS Agreement, many countries—both developed and developing—fail to do so. Some countries do not provide any protection at all for proprietary registration data; other countries provide some protection, but not at the level required by TRIPS Article 39.3; while still others have the statutory basis for the protection but do not enforce the data exclusivity.

4) Protection in the United States, the EU and Switzerland

Most developed countries protect data that are submitted to the regulatory authorities. In practice, abbreviated applications for regulatory approval by subsequent applicants cannot be filed in the United States for five years after the originator's approval. In the EU, Directive 65/65 provides a period of data protection of either 6 or 10 years depending on the Member State at issue. The larger Member States provide 10 years, while the smaller provide only 6 years. However, for products which are approved through the centralized procedure, Regulation 2309/93 provides a 10 year period of data protection (see Article 13.4). During this period of time, no applications that seek to rely on the originator's data may be approved by the regulatory authorities.

While "paper dossiers" (which rely on published scientific literature to demonstrate the efficacy, quality and safety of the competitive drug) are permitted under Directive 65/65, they may only be filed for a drug with an "established medicinal use," which the European Court of Justice has indicated would normally be met only after at least one decade. This loophole has now been closed by Commission Directive 1999/83 (which amends Directive 75/318) and provides that a minimum period of not less "than one decade from the first systematic and documented use of that substance as a medicinal product in the EU" is required for a finding of "well established medicinal use."

In most larger European countries, new chemical entities approved by the national regulatory authorities (the alternative approval process to the

use of the centralized procedure) receive ten years of data exclusivity. As a result of a recently-enacted revision to the Intercantonal Convention on the Control of Medicines, Switzerland now provides ten years of market exclusivity for New Chemical Entities (NCE).

a) In Brief: the Obligation to Provide Data Exclusivity

There appears to be a United States-EU-Swiss consensus that protection of registration data against "unfair commercial use," as reflected in TRIPS Article 39.3, requires governments to prevent reliance, by regulatory authorities or third parties, on the data for the marketing of subsequent versions of the drug during the period of exclusivity without the originator's consent. Where the two regions differ is over the length of the period of data exclusivity. While the United States has a five year period, the EU has a six or ten year period, and Switzerland has a ten year period.[2] [A key difference is also that the US gives (shorter) protection to new indications but the EU does not]. The five year period in the United States is not sufficient for recouping the huge investment of money and time for developing new pharmaceutical products.

b) Data Exclusivity as a Governmental Function

Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function.[3] The authorities may not consider an application for a marketing authorization during the period of data protection. An application relying upon a third party's data may only be submitted after the period of data protection has expired. In the EU, where the periods of data protection differ, the European Commission has made it clear in its "Commission communication on the Community marketing authorization procedures for medicinal products, 1998

[2] For a country without any tradition of protecting test data, the five to ten year periods of data exclusivity may not be enough and may be undercounting the actual length of time that the data should be protected. The periods of time cited for the United States, the EU and Switzerland assume that the data will not be disclosed or relied upon by the regulatory body before the originator of the data receives the marketing approval for the new product. It is critical that any enumeration of the periods of data exclusivity that are required by Article 39.3 include the time after the data is provided but before the marketing approval is granted. As a general rule, this will add three to four years to the five to ten year period cited as the practice in the United States and the EU.

[3] With the proliferation of freedom of information acts, which provide for the public release of governmentally-held information, it is critical that regulatory bodies not disclose proprietary data submitted by originators. At the time of a drugs marketing approval in the US, the Food and Drug Administration compiles a Summary Basis for Approval, which contains conclusionary data and non-proprietary information and is publicly available under the US Freedom of Information Act. Similarly disclosed information is available in Europe. Disclosure of proprietary information in such documents would call into question the protection required under TRIPS Article 39.3.

C 229/4, at C229/13" that "if the [data] protection period in the concerned Member State is longer than in the reference Member State, mutual recognition in the concerned Member State is not possible before the expiry of the 10-year period." (page C 229/13).

Thus, while governments are only required to provide the legal environment in which the patent holder may enforce his right against an infringer, it is another matter with respect to the protection of registration data. It is the government, through its regulatory agencies, and not the originator of the data, that has the responsibility for preventing copiers taking advantage of proprietary data during the period of data exclusivity.

Governments of most developing countries do not protect registration data and freely rely on the data that the pioneer drug companies provide in order to facilitate the expeditious marketing of generic copies of the pioneer drugs. However, this approach may remove the incentive of an innovator to launch in a particular market.

III. Commercial and Economic Rationale for Test Data Confidentiality

As briefly noted above, the generation of the data necessary for the original marketing approval requires a very substantial investment of time, expertise, resources and money. The originators of the drug must be given an opportunity – and the incentive – to recoup the enormous costs involved in generating such data before a competitor is permitted to rely on those data for the approval of the generic alternative.

For example, research-based pharmaceutical companies in the United States invested $21.8 billion in R&D in 1998, a 10% increase over 1997. With forty percent of these R&D expenditures going to pre-clinical functions and thirty percent going towards completing the Phase I, II, and III clinical trials required by the FDA, seventy percent of all R&D expenditures in the United States go to gain regulatory approval.

A new drug costs, on average, $500 million and requires as long as 15 years to develop, if preclinical and clinical trial phases are taken into account. Only three out of ten drugs introduced in the United States from 1980 – 1984 had returns higher than their average after-tax R&D costs. Comprehensive drug testing in the clinical trial stage alone can cost $150 million or more for a single medication, and only 10% - 20% of drugs ever clear the full set of pre-clinical and clinical trials. In stark contrast, a man-

ufacturer of a generic alternative, if it is not required to generate its own test data to gain marketing approval, needs only to invest $1 million to launch a competitor drug, as long as it can demonstrate bioequivalency.[4]

When the later applicant receives the benefit of the data generated by the originator without any investment on its part, the originator is placed at a significant commercial disadvantage. Such a situation undermines the investment potential existing even in countries with strong and effective patent protection, since the results of the originator's tests are immediately available to competitors at no cost. In addition, the burden is placed entirely on the originator to pursue any patent rights; under the data protection scenario, a product is only considered for marketing approval once the period of data protection has passed. Given the imbalance between the cost to the originator of gaining marketing approval for its drug and the copier's cost of coming on to the market, the research-based industry would have a reduced incentive, without such protection, to engage in the important R&D activities that will ultimately benefit patients through the availability of new and innovative drug therapies.

The incentive for developing new drug therapies that is provided by a period of data exclusivity is especially critical when the new drug therapy is not patentable. For example, had generic copies of TAXOL®, (paclitaxel), Bristol-Myers Squibb's anti-cancer drug, which did not have any patents on its active ingredient, been able to be approved immediately, BMS would not have had any incentive to incur the extensive costs (estimated at well in excess of $500 million) to develop, test and bring TAXOL to market.

The fact that both patent protection and data exclusivity provide incentives reflects the dual nature of the drug development process.

- Without the period of market exclusivity provided by a patent, the research-based industry would not have any incentive to undertake the research leading up to the discovery of the innovative drug therapy.
- Without data exclusivity, the originators of the innovative drug would be placed at an unfair commercial disadvantage when compared to their generic competitors, who do not face similar costs of meeting the mandated requirements set by regulatory bodies for drug approval.

[4] Bioequivalency between a generic and a pioneer drug is demonstrated by the bioavailability of the two products. Bioavailability is the extent and rate at which the body absorbs the drug. Scientists measure the time it takes the generic drug to reach the bloodstream. The generic drug must deliver the same amount of the active ingredient in the same time period as the pioneer drug in order to be bioequivalent.

The distinctiveness of the two incentives is recognized in the United States and the European Union, where patent protection and data exclusivity provide, side-by-side, incentives to discover new drug therapies and to undertake the extensive testing required to bring them to market.

IV. Current State of Data Protection

Many developed and developing countries currently fail to provide data exclusivity along the lines mandated by Article 39.3 of the TRIPS Agreement. The forms of the noncompliance range from the total absence of protection to provisions and practices that limit the effective scope of the protection. The following are examples of these practices:

1) Absence of data protection

Countries such as South Africa, Brazil and Israel currently do not have any laws on their books that provide protection for proprietary registration data. Notwithstanding that Articles 78 and 79 of Decision No. 344 of the Andean Pact provide for the protection of registration data, the individual member countries, such as Bolivia, Colombia, and Ecuador, do not provide such protection in their legislation.

2) Linkage of the period of data exclusivity to the life of the underlying patent

Spain links data exclusivity to the life of the underlying patent for the product for which marketing approval is being sought. Linkage of the period of data exclusivity to the life of the underlying patent violates TRIPS obligations, since nowhere in Article 39.3 is there any linkage of the protection for trade secrets to any of the other protections found in Part II of the TRIPS Agreement. Indeed, trade secret protection is entirely independent of other protection and it is not permitted to link the two.

3) Springboarding

Canadian regulatory authorities accept applications for marketing approval of generic copies that rely on the originator's data before the period of data exclusivity expires. Even though the product appears on the market after the period of data exclusivity expires, the review of the dossier occurs during the period of data exclusivity. This practice is a violation of the TRIPS obligation not to rely on the originator's data during the period of data exclusivity.

4) Vague and questionable definitions of data exclusivity

Singapore curtails the five-year period of data exclusivity by starting protection from the date of filing of the originator's pharmaceutical product, rather than from the date of its marketing authorization, which is the standard practice in the United States and the EU. Beginning the count from the date of filing is illogical, since the originator does not reap any commercial benefit from the data exclusivity when its product is awaiting marketing approval and, thus, is not on the market. The effective period of data exclusivity provided in Singapore is thus curtailed by nine to fifteen months.

In addition to its "springboarding" policies, Canada interprets the definition of "reliance" in a strictly literal manner. On November 3, 1998, Justice Evans in *Bayer Inc. v. Attorney General of Canada and Minister of Health*, supported the Government of Canada's contention that if the authorities in the Ministry of Health do not physically open the dossier, then reliance has not occurred. Judge Evans further compounded the problem when he stated that "a period of five years is a long time to grant a de facto monopoly for a drug that is not protected by a patent," thereby confusing the two separate intellectual property rights and erroneously equating patent protection with the period of data exclusivity.

5) Nullification of existing law

Korea had a data exclusivity law on its books but, in May 1997, deleted part of the law that had specified that data on "efficacy" and "domestic use" were required for generic drug applications submitted within the six-year re-examination period. Local clinical trial data or proof of bioequivalency is now no longer needed for a copier drug to enter the Korean market, thereby negating the value of the six-year re-examination period.

6) Permitting on the market "similar" copies of originator drugs that were either approved for marketing abroad or in the country

The Government of Argentina, which previously did not have any statutory protection for registration data, took a step backwards when it passed a data exclusivity law in December 1996, legitimizing the reliance on the originator's registration data submitted to the Argentine public health authorities for use by producers of similar products. Argentina provides for an expedited marketing authorization of a "similar" drug when the originator drug has already been marketed in Argentina or in a number of other (developed) countries. Argentina reportedly will permit the mar-

keting of the generic copy if a certificate of free sale can be provided from abroad for the originator drug.

Argentina claims that such use of certificates of free sale to approve the marketing of a generic copy of the originator's drug does not constitute reliance on the originator's data. A recently enacted law in Israel permits the importation and marketing of any drug that is "similar" to a drug that is already registered in Israel.

7) Unauthorized disclosure of proprietary data embodied in the registration dossier

While TRIPS Article 39.3 permits the disclosure of the data, it only does so if the disclosure is accompanied by steps to ensure that the data are protected against "unfair commercial use." The countries of Eastern and Central Europe, in preparation to join the European Union, are attempting to converge their marketing regulatory requirements with those of the European Union. With the exception of the Czech Republic, these countries are demanding full access to the registration dossiers of the originator drugs, without providing any guarantee that the data will be protected from disclosure. Slovenia reportedly does not take any safeguards to protect registration dossiers against disclosure to generic copiers.[5]

8) Requirement to disclose test data without taking measures to protect confidentiality

Although Japan precludes the issuance of any second approval without full clinical and non-clinical data for six years after the originator's approval, it is not for the purpose of protecting the data but to confirm, during the re-examination period, the efficacy and safety of the approved new drug.

In addition, the Japanese Ministry of Health and Welfare ("MHW") intends to publish a "Summary Basis of Approval" after the approval of each new pharmaceutical product. As the "Summary Basis of Approval" includes all necessary information for examination of such new products by MHW, with a total length of 500 pages or more, the scope of this publication will be significantly greater than the FDA's SBA and the European "Summary of the Product Characteristics", which are about 40-50 pages in

[5] As part of the *acquis communitaire*, Slovenia has decided to link the period of data exclusivity to the life of the underlying patent for the product for which marketing approval is being sought. This violates the TRIPS Agreement. The new data protection law provides a period of six years of data protection from either the initial approval in the EU or Slovenia.

length. Given that a data protection law is not available in Japan, this wide-ranging publication gives rise to doubts about this policy being in compliance with TRIPS.

Furthermore, a "Freedom of Information Act" is to be implemented in Japan from 1 April 2001. Since the Japanese Freedom of Information Act will require the widest range of publication in the world, the Act will give rise to serious doubts about its being TRIPS-compliant, unless it is properly applied.

V. Conclusion

Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. Countries with the leading research-based pharmaceutical industries recognize the strong incentive provided by data exclusivity and have taken steps to ensure that the proprietary registration data that companies are required to submit to gain marketing approval are protected against unfair commercial use and disclosure.

The protection of data embodied in the "non-reliance/non-disclosure" concept is time-related – data exclusivity should be provided for at least ten years from the originator's marketing approval. This time frame is evident from the negotiating history of the TRIPS Agreement and the current practice of countries with leading research-based pharmaceutical industries, such as the European Union and Switzerland.

The obligation to protect registration data against "unfair commercial use" is incumbent upon governments, not the originators of the data. Since January 1, 2000, all WTO member countries – with the exception of only the least developed countries – have been required not only to have TRIPS-compliant protection for proprietary registration data but also to enforce effectively this protection.

As described above, many countries currently either fail to provide such protection or the protection that they provide falls below the levels required by TRIPS. Only with a clear understanding of the data exclusivity issue and a concerted effort by governments, will industries, such as the pharmaceutical industry, that are required to provide registration data to governments have the assurances that their extensive efforts to research, develop and bring new, innovative products to market will not be subject to unfair commercial use.

Glossary of Relevant Terms

The concept of "data exclusivity" is sometimes confused with the concepts of "data privacy" and "trade secrets or business confidential information." The following brief definitions may help to alleviate that confusion:

1. *Exclusivity of Registration Data* – period of non-reliance and non-disclosure that a government must provide to pharmaceutical registration data. Pharmaceutical registration data are the proprietary data generated by scientific research conducted to demonstrate the efficacy and safety of new medicines and submitted to regulatory authorities for marketing approval.

2. *Data Privacy* – individually-identifiable information, e. g., medical background and personal health data, that may not be disclosed or transferred inappropriately without the explicit or implicit authorization of the individual. Unlike registration data, which applies only to those industries such as the pharmaceutical and agro-chemical industries, data privacy applies to all industries.

3. *Trade Secrets or Business Confidential Information* – information deriving its value from not being known to the public, competitors or other parties who may gain benefits from its disclosure or use. To receive protection as a "trade secret," business confidential information must be secret, have commercial value because it is secret and have been subject to reasonable steps taken under the circumstances to keep it secret.

Annex II

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION (TRIPS)

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 below and data submitted to governments or governmental agencies in accordance with paragraph 3 below.
2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices* so long as such information:
   - is secret in the sense that it is not, as a body or in the precise configuration of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
   - has commercial value because it is secret; and
   - has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
3. Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

---

* For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Nature of Obligations under TRIPS Article 39.3

The TRIPS Agreement, which was negotiated as part of the Uruguay Round of trade negotiations in the GATT, the predecessor organization to the World Trade Organization (WTO), was the first international intellectual property agreement to include obligations for the protection of trade secrets, especially the proprietary data submitted by innovators to governments.[6]

Observers have come to realize the growing commercial significance of the incentives provided by a period of data exclusivity for products that were not under patent protection, either because the new chemical entities did not meet the novelty test for a patent from the outset and were, therefore, not patentable or because the chemical entities involved new uses of products whose patents may have expired. Another contributing factor to the emergence of data exclusivity is the expiration of the transition period for TRIPS implementation by the developing countries and the countries of Central and Eastern Europe that are in the process of transformation from centrally-planned into "market, free-enterprise" economies. On January 1, 2000, these countries were obligated to have implemented Article 39.3 together with the rest of the TRIPS Agreement, and any failure to do so exposes them to WTO dispute settlement. Even those countries that will be permitted by the TRIPS Agreement to delay until January 1, 2005 the application of the TRIPS patent obligations to pharmaceutical products--e. g., India, Argentina, and Egypt--were required, as of January 1, 2000, to have their proprietary data protection at the level mandated by the TRIPS Agreement.

Article 39.3 requires a WTO member state to protect registration test data submitted to regulatory authorities against "unfair commercial use and disclosure," except when necessary to protect the public, or unless it can ensure that the data are protected against unfair commercial use. Article 39.3 contains two obligations: protection against disclosure and protection against unfair commercial use. The Office of the General Counsel of USTR defines these two obligations in the following manner:

[6] Although the NAFTA Agreement was concluded in 1992, prior to the completion of the TRIPS Agreement, TRIPS Article 39.3 appeared in its final form in the Dunkel text of the TRIPS Agreement, which appeared in December, 1991. Similarly, while the OECD Council Recommendation concerning the Exchange of Confidential Data on Chemicals was adopted prior to the Dunkel Text -- on July 26, 1983 -- it was only a recommendation to the OECD member states and not a binding international instrument.

> ... With regard to the first requirement, test data must be protected against disclosure to the public (or even within the government) unless such disclosure is necessary for public safety or unless steps are taken to ensure that the data are protected against unfair commercial use.
>
> With regard to the second requirement, ... TRIPS Agreement negotiators understood it [the term "unfair commercial use"] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision.[7]

A similar understanding of the obligation to protect "against unfair commercial use" was contained in a paper presented by New Zealand at the APEC Seminar in 1995:

> Defining 'unfair commercial use' can only properly be done by reference to the context of the complete provision, i. e. the purpose behind the provision. In the light of this we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides. In other words, where undisclosed information is provided to a regulatory authority by an applicant so that the authority can approve the applicant's product, if this information is then used by the authority to approve the product of a second applicant that is, in New Zealand's view, 'unfair commercial use.' In effect, the regulatory authority is giving commercial advantage to the second applicant in that the applicant does not have to generate the data which was required of the first applicant. This can be a significant economic saving.[8]

The negotiating history of TRIPS Article 39.3 supports "non-reliance on the originator's data for a particular period of time" as the definition of the obligation to protect the data against "unfair commercial use." Early drafts of the agreement had specified a period of time during which governments should not rely on such data for the approval of competing products without the consent of the originator of the data. For example, the draft of November 23, 1990 contained the obligation that, "... the data may not be

[7] "The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3," unattributed paper which was drafted by the Office of the General Counsel of USTR for submission in bilateral discussions with Australia, May 1995.

relied upon for the approval of competing products for a reasonable time, generally no less than five years..."

The obligations in Article 39.3 apply to "new chemical entities." "New chemical entity" is a regulatory concept and should not be confused with the "novelty" requirement of a patent. Drug regulatory agencies, such as the U. S. FDA and the national agencies in Europe, define a "new chemical entity" as a new compound with no prior approval as a drug, that has undergone full development and testing, and is proven to be safe and effective. "New chemical entity" status does not relate to the time when the active ingredient was first discovered or synthesized.

[a] *Protection of Undisclosed Information and Control of Anti-Competitive Practices*, APEC TRIPS Seminar: 17-19 May 1995. Presentation by New Zealand.

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DR-1.

Main Identity

From: "Dr. Laing" <laingr@who.int>
To: "INDIA DRUG" <india-drug@usa.healthnet.org>
Sent: Thursday, July 17, 2003 7:13 PM

<BE08203950371C489D4FE2BB2FA3C08D031BEFE6@whqkaki02.who.int>
Subject: [india-drug] Response to Essential Medicines materials for School Health
Sender: owner-india-drug@usa.healthnet.org
Precedence: bulk
Reply-To: india-drug@usa.healthnet.org

Response to Essential Medicines materials for School Health

Dear Dr Sathyanaravanan,

Thank you for your very interesting reply. Many years ago when I was doing work on Plantation health services in South India, I visited some

schools in Tamil Nadu and was very impressed with their school feeding program.

But your response also highlights the problem that I am facing. I am not primarily trying to get materials about school health programs. I am trying to get materials on what children are taught about medicines. The paper that I quoted by Geisler shows that children already know quite a lot and need to know more. Pat Bush at the USP described what children needed to know.
BUT apart from a message from New Zealand I have not heard of materials

that could be used in a school health program.

CMF/FN

Imagine if I had asked for materials about drugs of abuse. I would have

been flooded with materials.

lib. India Drug file

18/7

So if you or your collcagucs have such curricula or materials I would be very interested to see it.

Thank you,

Richard Laing

World Health Organization
CH-1211 Geneva 27, Switzerland
Tel 41 22 791 4533
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E-mail laingr@who.int

DR-1.

ST. JOHN'S NATIONAL ACADEMY OF MEDICAL SCIENCES

INSTITUTE OF POPULATION HEALTH AND CLINICAL RESEARCH

CLINICAL TRIALS DIVISION

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Prof & Head of Medicine & Vice Dean

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Advisors
Dr. K. Srinivasan MD
Prof & Head, Psychiatry

Dr. George D'Souza MD
Professor & Head, Chest Medicine

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    - Trials management
    - Data management
    - Clinical research supplies management
    - Blood and other samples
4) *Our vision for the future*
5) A snap-shot of our major projects

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To RN -> [illegible] given by Denis Xavier.
23/8/03

RJ 5/9/03 → TN

Lib - Resource file (Drugs)

1] AREAS OF OUR WORK AND SOME EXAMPLES

1] CLINICAL EPIDEMIOLOGY IN CARDIOVASCULAR DISEASE

INTERHEART, ICMR Case Control Study, CREATE Registry, OASIS Registry

2] CLINICAL TRIALS

As Coordinating center - CREATE, POISE, VITATOPS, OASIS-5

As Investigating center – HERO 2, DREAM, NN – IGT
and several Phase 4 studies

3] GUIDELINES DEVELOPMENT

Diabetes guidelines for developing countries –CDC Supported study
WHO –Hypertension management at the primary care level

4] HEALTH POLICY

WHO PREMISE

5] TRAINING

Research Methodology Course
Investigators / Clinical Research Coordinators – GCP and Clinical Trial Logistics

2] COLLABORATING AGENCIES

1. World Health Organization
2. NIH/ CDC [Atlanta, USA]
3. Indian Council of Medical Research
4. Academic: McMaster University - Canada, Edinburgh - UK,
   Green Lane Hospital - New Zealand, Royal Perth Hospital – Australia
5. Several Pharmaceutical Companies - Astra Zeneca, Aventis Pharma, Abbott, Novo Nordisk, Pfizer, Sanofi Synthelabo-Recherché, Ranbaxy, Torrent etc.

3| WHAT WE HAVE DEVELOPED

A| PERSONNEL AND INFRASTRUCTURE...

- 1910 sqft of office and storage space
- 6 faculty and 14 research staff
- From 3 departments
- Ability to coordinate large clinical trials and provide total solutions

B| CAPACITY...

1| REGULATORY

- Liaison to obtain Regulatory [DCGI's] approvals for clinical trials
- Import license for drugs and equipment
- Liaison with customs personnel
- Ethics approvals – local / national

2| CLINICAL TRIALS DEVELOPMENT

- Protocol
- Case Report Forms
- Manuals
- Other Study Materials
- Statistical Issues

3| TRIALS MANAGEMENT

- Investigator/ Site / Area Identification
- Documentations
- Investigators Meetings/ Training
- Study Initiation
- Monitoring & Audit
- Study Close Out

4] DATA MANAGEMENT

- Data Base Creation
- CRF Storage [Current / Archiving]
- Data Entry & Quality Checks

5] CLINICAL RESEARCH SUPPLIES MANAGEMENT

- For Drugs & Other Materials
- Storage
- Packaging and Distribution Logistics
- Maintaining Stocks at Centers
- Drugs Accountability
- Drugs Destruction

6] BLOOD AND OTHER SAMPLES

- Temperature Controlled Storage
- Sample Analysis
- Appropriate Destruction

4] OUR VISION FOR THE FUTURE...

- To develop and conduct Clinical Trials and Epidemiological Research with **special relevance** to India and other developing countries
- To achieve world class standards at **'realistic'** costs
- To transform knowledge to better health through policy change

AND HOW ?

- By further developing infrastructure and expertise for total solutions in clinical trials and epidemiological research
- By appropriately disseminating knowledge and advocacy

5] A SNAP SHOT OF OUR MAJOR PROJECTS

TITLE	DESCRIPTION	SPONSOR	STATUS
EPIDEMIOLOGY AND PRACTICE PATTERNS			
INTERHEART	A global case control study to identify the risk factors for Acute Myocardial Infarction in different ethnic populations	WHO, Astra Zeneca, World Heart Federation; Coordinated by McMaster University, Canada.	- Recruitment completed - 282 cases & 563 controls
ICMR Task force study	Risk factors in acute myocardial infarction study. A national multi-centre case control study based in Indian urban hospitals.	ICMR	- **Country coordinator** - Completed - 1000 cases and 2000 controls
CREATE Registry	Prospective observational study of Practice Patterns in Acute MI and Unstable Angina in India.	Aventis Pharma	- **Country coordinator** - 79 centers in India - 13,000 subjects recruited - Target: 20,000
WHO-PREMISE Study	Prevention of REcurrences of Myocardial Infarction and StrokE (PREMISE). Through Community –Based and Health Service Interventions	WHO	- Phase one completed - Plans on for phase two

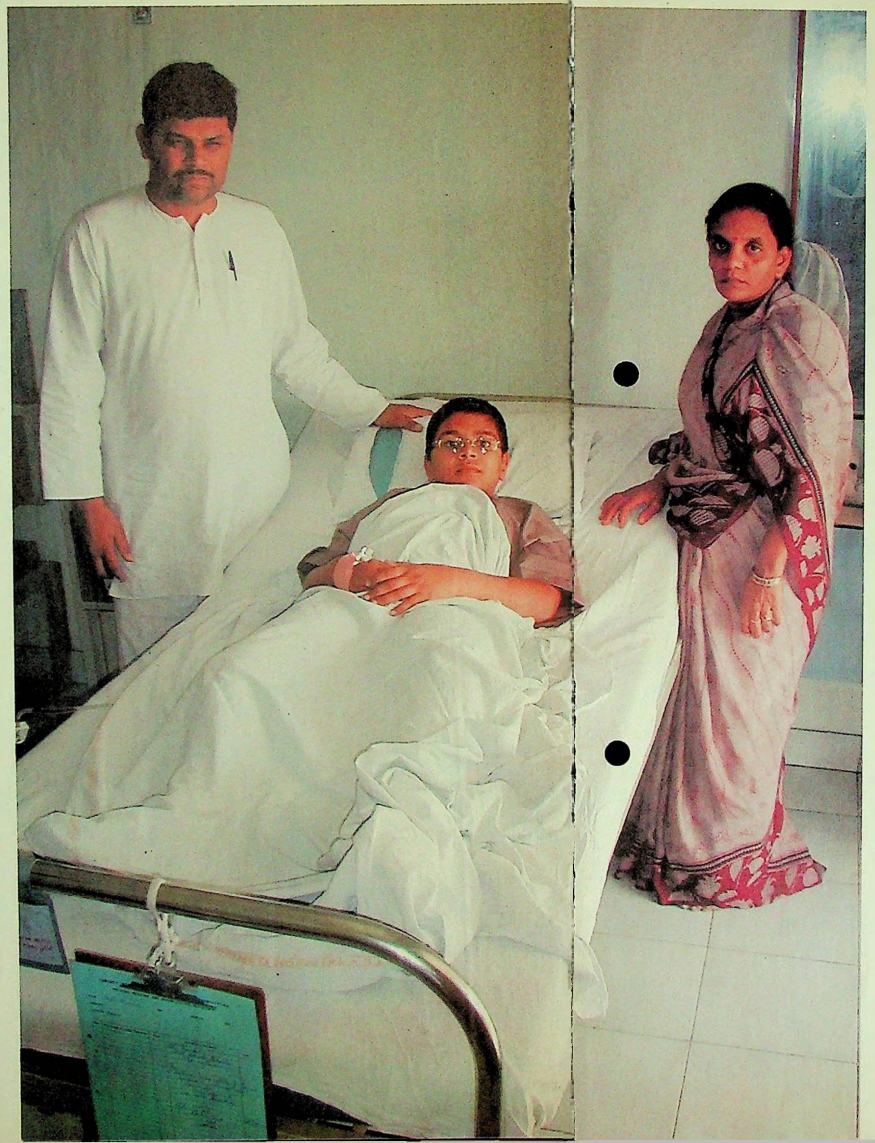
CLINICAL TRIALS			
TITLE	DESCRIPTION	SPONSOR	STATUS
The CREATE Study	A large, simple trial with low molecular weight GIK in patients with acute myocardial infarction	McMaster University, Canada	- **Country coordinator** - 67 centers in India - 4,100 subjects recruited [May 2003] - Target 8000
The DREAM Trial	Diabetes REduction Assessment with ramipril and rosiglitazone Medication	Canadian Institutes of Health Research, Aventis, King, Glaxo-SmithKline.	- Recruitment completed - Follow up ongoing
POISE Study	A large, simple trial of metoprolol versus placebo in patients undergoing noncardiac surgery at moderate and high risk of a perioperative cardiac event	McMaster University, Canada	- **Country coordinator** - Trial to be initiated shortly - 1500 patients from 30 centres
VITATOPS Study	[VITAmins TO Prevent Stroke]. the efficacy and safety of multi-vitamin therapy in secondary stroke prevention	Royal Perth Hospital, Australia	- **Country coordinator** - 500 patients from 20 centres
OASIS-5	A phase 3 international multicenter study in unstable angina / NSTEMI with Fondaparinux,	Sanofi-Synthelabo-Recherche	- **Country coordinator** - 1000 patients - 20 hospitals
GUIDELINE DEVELOPMENT			
DIABETES GUIDELINES PROJECT	A study for the development of low – cost algorithm for management of diabetes in developing countries	World Bank and CDC, USA.	Completed
WHO-HTN Project	A global program on detection, control and follow up of hypertension a the primary care level in middle and low income countries	WHO	- Program development completed - Will be implemented by the WHO in about 30 developing countries

DR-1.

According to the WHO, 35 per cent of fake drugs produced in the world come from India, which has a Rs 4,000-crore spurious drug market. About 20 per cent of medicines in the country are fake.

Many common drugs, including those used for headaches and the common cold, are fake or substandard. Of them, 60 per cent have no active ingredient and 16 per cent have harmful ingredients.

A recent raid by the Karnataka Lok Ayukta revealed that authorities were silent about 829 substandard drugs which were being bought and consumed by the public.



KILLING YOU SLOWLY

Many common medicines available in the market are fake

By N. BHANUTEJ/Bangalore
and QUAIED NAJMI/Mumbai

Think twice before you pop that pill. You could be swallowing solidified chalk powder masquerading as paracetamol. Your fever will get worse and you will get stomach pain as bonus. That is, if you are lucky. Things could be much worse. You may be taking that antidepressant to drive away the blues. In your bad mood, you may not have noticed that the packing looked different. A few hours later, you may be in the grip of a panic attack.

If that does not frighten you, run your eye through these alarming statistics. According to the World Health Organisation, 35 per cent of all fake drugs produced in the world come from India, which has a Rs 4000-crore spurious medicine market. Nearly 20 per cent of the medicines available in the domestic market are fake or substandard. Of these, 60 per cent do not contain any active ingredient, 19 per cent contain wrong ingredients and 16 per cent have harmful and inappropriate ingredients. Spurious drugs appear in commonly known brand names. So be afraid.

"Today fake and substandard drugs harm more persons daily than the SARS virus," said Ajit Singh, chairman of the Associated Capsules Group in Mumbai. Consumers and drug control officials have to grapple with two demons: fake drugs manufactured by seedy underground units, and substandard drugs which come from the stable of reputed companies. Often it is difficult to distinguish between the two. The common factor is that both are harmful.

TRAGIC ORDEAL: Alpesh Mehta,12, (with father and mother) almost died after being injected with a spurious drug

The problem is more acute and widespread than one can imagine. Doubters can peruse these grim findings.

◆ An Army man died in a nursing home in Patna on May 5 after being injected with a substandard drug.

◆ A random test of ciprofloxacin 500 mg tablets (batch no.154 V), an antibiotic manufactured by British Pharma Laboratories of Gujarat, proved that the tablets contained no ciprofloxacin.

◆ Dexamethasone 5 mg (batch no. 145 P) tablets, a life-saving steroid manufactured by the same company, contained no dexamethasone.

◆ Hydrogen peroxide (batch no. 001) solution, manufactured by Medismith of Bangalore, contained no trace of hydrogen peroxide.

◆ Villagers in Madhya Pradesh are usually given fake drugs Conacin and Crocinol in place of the common brand Crocin.

◆ Ampicillin 250 mg capsules, another commonly used antibiotic for respiratory infections, made by Economic Pharma of Mumbai (batch no 5604), contained a powder that had no ampicillin in it.

◆ Paracetamol syrup, usually prescribed to control fever in children, manufactured by Sinclair Pharma (batch no. SP 001), contained no paracetamol at all.

The list goes on and on. The rot runs deep.

This was made amply clear in a recent raid by the Lok Ayukta on the Drugs Control Department of Karnataka. There were a lot of fake drugs in the market and the authorities couldn't care less. The Lok Ayukta discovered that in the last three years, the department had found that 829 commonly known medicines were of poor quality. Still, the department took no action and allowed people to buy and consume the drugs. "This is just the tip of an iceberg," said an official who was anguished at the turn of events. "These are just random samples. What if we had gone looking for fake medicines?"

SPOT THE FAKE ONES

The Organisation of Pharmaceutical Producers of India has some suggestions for consumers

THOSE BUYING MEDICINES SHOULD ALWAYS LOOK FOR:

***The batch number, manufacturing date, expiry date, manufacturing licence number, manufacturer's name/address on the pack before buying any medicine**

***Any sloppiness—illegible or badly printed labels, absence of one/all of the above details, faulty sealing and differences in colour of the packing**

***Broken tablets/capsules, extraneous matter in liquid preparations, lumps in creams/ointments**

TO CURB THE SPREAD OF FAKE MEDICINES:

◆ Destroy the empty packs/bottles of used or left-over medicines to avoid recycling

◆ Report to the company which manufactures/markets the product of your doubts about any particular medicine immediately

◆ The company will lodge complaints either with the local police or the regulatory authorities in the state.

◆ These two agencies will investigate the matter and initiate appropriate criminal proceedings.

Graphics/MUKESH M.

They would have found it all over the place. To use a cliche, the web of fake medicines spreads from Kashmir to Kanyakumari, though, according to available information, it becomes flimsy down south. The steely filaments of the web are in the northern region, with Bhagirath Palace in Delhi reportedly being the hub of fake medicine trade in south Asia. Indore in Madhya Pradesh is another breeding ground of fake drugs. Nearly 150 small-scale drug manufacturing units operate from garages and hovels here. From Indore, fake medicines have found their way to Russia and Uzbekistan. Medicines are being churned out in slums outside Lucknow and Ahmedabad. They have a thriving market in South Africa, creating huge problems for the health officials there, not to speak of neighbouring countries like Myanmar and Bangladesh.

CROCIN Paracetamol tablets
Batch no. 0100 and S9238
Manufacturer: Smithkline Beecham

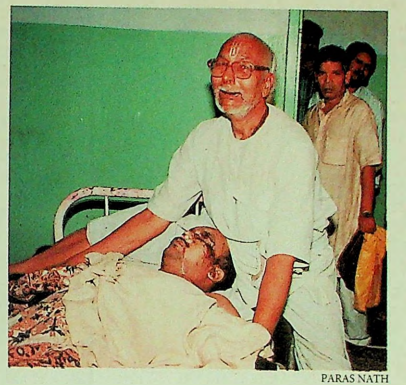
The most established and fast-moving brands are the targets of the drug mafia. Hoechst Marion Roussel Ltd found to its utter shock that 15 per cent of all its products available in the market were fake. Knoll Pharamaceuticals suffered losses worth Rs 75 lakh on three popular brands: Brufen, Entamizole forte and Eptoin. Smithkline discovered that its popular brand Iodex had been duplicated everywhere.

Spurious drugs were being sold in Uttar Pradesh, Bihar, parts of Karnataka and Tamil Nadu.

Unofficial figures gathered by consumer bodies estimate that more than 40 per cent of the medicines which hit the rural market are fake or substandard. The illiterate villager is easy prey to the fake drug mafia which colludes with local doctors and chemists. Many over-the-counter products sold in interior Madhya Pradesh are fake. A villager cannot be expected to distinguish Glysun-D and Glycon-D from Glucon-D. Vips and Vims are balms which officiate for the popular Vicks. In Hyderabad, drug control officials had a hard time distinguishing between Crocin and its fake cousin. The packings were almost the same.

Fake drugs have spread terror in Kashmir, too. In 1999, the drug controller's department in the Valley blacklisted Jackson Pharmaceuticals Ltd after its products were found to be substandard. The company is, however, back in business. The Uttar Pradesh Police raided a dingy house in Lucknow two years ago and seized 300 bottles and 1,000 fake labels of Betadine. The fake drug market thrives in towns like Meerut.

Despite its spread, the pharma companies and authorities do not have any concrete data on the producers of these medicines. Most of the small units operate from hovels and garages. Some of them had been associated with big companies. The general impression is of a shadowy crowd. "No spurious drug manufacturer puts up a nameplate announcing his business and in most cases, these are garage-type operations," said S. Ramesh of the research wing of Associated Capsules Group at Andheri. " It is difficult to catch them as they know all the loopholes of the law," said a doctor. Drug control officials and doctors have much to say about the hot spots and about fake drug manufacturers breeding like mosquitoes, but when one gets down to specifics, they shrug their shoulders.



PARAS NATH

VICTIM: Rakesh Kumar Das was injected with a fake drug

Those who consume the spurious drugs cannot dismiss the problem with a casual expression of resignation. Sometimes they pay with their lives, as in the case of Rakesh Kumar Das, an Army man, who died in a nursing home in Patna after he was administered three injections of Lasix on May 5. His father alleged that his son was injected with a substandard drug. Interestingly, the owner of the nursing home, Dr Ramendra Narayan Singh, does not dismiss the allegation. "Anything can happen in this country,"

Into the lion's den

By NISTULA HEBBAR

In a cramped room in Shakarpur in Delhi, Sanjay Khanna is busy overseeing the production of a batch of fake tablets. His speciality is over-the-counter drugs like paracetomol and disprin. The entire manufacturing unit cost him around Rs 1,00,000, but the profits have more than made up the cost.

What makes fake tablets so profitable? According to Dr C.M. Gulhati, editor of the Monthly Index of Medical Specialities, it is the economics of the situation. A strip of 10 Nimuselide tablets has a sale price of Rs 25.75. The cost of the drug in bulk is Rs 250 per kg—one tablet would be equal to 100 mg. So the cost of 10 tablets would be 25 paise. The cost of printing and packaging a tablet would be about Rs 1.40. Thus the entire tablet is ready for sale at Rs 1.65. Big brands factor in research and development costs, the costs of clinical trials and other overheads. But in fake manufacturing the cost is much less as they skip R&D; they simply lift the formula.

Gulhati is careful in distinguishing between fake and substandard drugs. "Fake drugs may contain the right formula and may just fake the brand. but substandard drugs are from licensed manufacturers where the standardisation procedure has not been followed," he says.

Three years ago, in Shakarpur, the Economic Offences Wing of the Delhi Police had raided a shop, seizing Rs 2,00,000 worth of Nimulid and Glizid tablets. But Khanna is not worried about the law getting to him. "They (the police) will have to pick up the samples first," he says. "We will come to know long before that."

What worried him more was last month's truckers strike that disrupted his supply line between Delhi and Meerut.

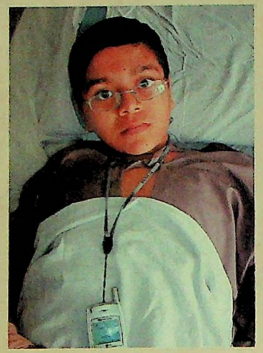
Caught in the trap

By QUAIED NAJMI

When disaster struck Lakhpatraj Mehta, 36, it was total and unforgiving. The victims were his two sons, Alpesh, 12, and Aman, 8. While Alpesh nearly lost his life to spurious drugs, Aman died because of alleged medical negligence.

It all began on March 28, 2002, when the three met with a road accident in Pune. Alpesh was admitted to the KEM Hospital while Aman was rushed to the Jehangir Hospital. Mehta claims that 59 doses of Imipanium, a very expensive injection (an ampoule costs Rs 1,850) imported from Holland were administered to Alpesh. All the ampoules were purchased from a private pharmacy store, KM medical store, located in the hospital compound. Though Mehta had noticed that details like the date of manufacture and expiry date were missing, in the heat of the moment he did not report it.

After the injections were administered, Alpesh's condition began to deteriorate. His body blackened and he began to bleed. He also developed severe bouts of fits. When there were no signs of improvement even after 55 days, Mehta talked to the doctors. But they insisted that the treatment was proper and that they would give him a total of 120 doses.



RECOVERING: Alpesh in hospital

Fearing for the boy's life, his family rushed him to another hospital where his treatment schedule was changed. Now he is back on the road to recovery with only a few visits to the hospital.

It was later learnt that the medicine was a counterfeit made in India and passed off as the imported one. It was sold in regular stores at approved rates. Mehta said that he had contacted the Dutch company that manufactures Imipanium and was told that the ideal dosage for a boy of 12 would be 14 to 15 shots, which added fraud to the list of grievances.

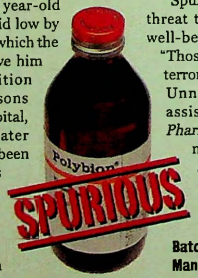
Mehta complained to the FDA in Pune and Mumbai, which has lodged criminal complaints against the pharmacy and its proprietor Jain at Samarth Police Station, Pune. Now, Mehta wants the authorities to institute a CBI enquiry into the drug racket in Pune hospitals. He is determined in his fight despite receiving threats from the drugs mafia. "I am not going to rest until the racket is busted and the culprits are booked," he said.

he said.

Dealing with ill-effects of fake drugs is daily routine for Ahmedabad-based sexologist Dr Paras Shah. "Skin fibrosis due to fake sprays promising penis enlargement is quite common," he said. Gujarat, according to him, is flooded with fake medicines promising wonder cures for sexual problems.

Brij Narayan, a 58- year-old farmer of Bhopal, was laid low by viral fever. But the drugs which the doctors administered gave him no relief. His condition worsened. Finally his sons took him to another hospital, where he got well. It later turned out that he had been given substandard drugs in the first instance.

In Hamidia hospital of the Bhopal Medical College, surgeons face what they call an "anaesthesia problem". Said one: "We are supplied with ketamine hydrochloride injection to be used as anaesthetic agent. Normally 10 mg is enough to make a patient unconscious. But we have to use three to five times more." The particular drug is manufactured at Sanwer Road, Indore.



POLYBION SYRUP
B-complex syrup;
Batch no. LR 697.
Manufacturer: E Merck

"Spurious drugs are a major threat to people's health and well-being," said Ajit Singh. "Those who make them are terrorists." According to C.H. Unnikrishnan, senior assistant editor of *Pharmabiz*, some drugs were made of chalk dust, fine sand or limestone powder. "Others are positively harmful," he said.

Sometimes it can cause complications. "A patient who was suffering from a chest disease was being given a syrup," said Dr Amit Wancho of Srinagar. "He complained that it was not helping him. We later found out that it was a substandard drug and it created other problems for him." Sometimes, it can prove fatal: five tribals of Ranchi died five years ago after consuming spurious medicines. Some substandard drugs may contain a small amount of the active ingredients that would build up resistance to a particular drug.

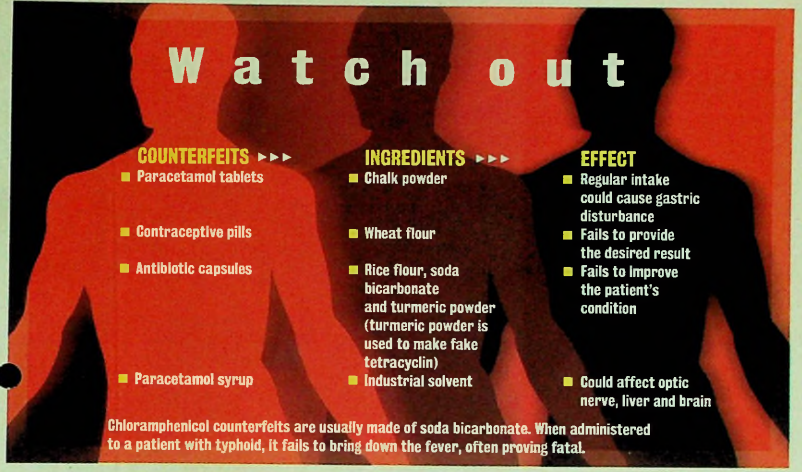
Though physicians express anguish at the prevalence of fake drugs, the fact remains that the racket operates with their connivance, especially in rural areas. A leading doctor in Indore is known to have taken a car as a gift from a dubious pharma company. He prescribes its medicines regularly. Dozens of shady pharmaceutical firms in Madhya Pradesh have cut deals with doctors to market their medicines. Some small-time doctors in Gwalior, Sagar, Ujjain and Dewas have gone one step further and have become partners in these units."Small-time doctors perpetuate the spurious drug racket," said V.K. Agnihotri of the Indian Pharmaceutical Alliance.

Veterans of the pharmaceutical industry admit that it had unwittingly played a part in creating this Frankenstein's monster. Some companies neglected "production" handing it over to small-scale units. Over a period, many of the small-scale operators found it more profitable to switch over to producing counterfeit drugs on their own.

Said Dr C.M. Gulati, editor of *The Monthly Index of Medical Specialties*: "India has inexpensive tableting machinery, which need only a small room. Bulk chemicals are available cheap. Anybody can become a drug manufacturer."

The drug control officers of the states, which are meant to haul up fake drug manufacturers, are universally reviled. "Our drug regulatory authorities have no teeth, few inspectors and even fewer experts," said Prof. Ranjit Roy Chowdhury of the National Institute of Immunology. To be fair, policing by the Drug Control Authority is efficient in Hyderabad, which is a bulk drug capital, but in Karnataka, after the Lok Ayukta raids,

GENTAMYCIN EYE DROPS
Batch no. 597
Manufacturer: R.S. Pharmaceuticals



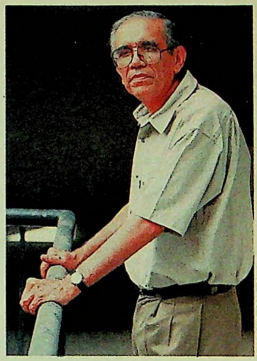
Graphics/MUKESH M.

the officials of the authority are seen as being totally corrupt. The same is the case with Madhya Pradesh, Uttar Pradesh and Bihar.

Drug control officials, however, complain that it is not they who lack teeth, but the law. The major problem is that manufacturing fake drugs is not a cognizable offence. It comes under the Drugs and Cosmetics Act, 1940 or the Copyright Act. An accused can only be punished for two or three years and is often let off with a fine of Rs 5,000. Also, identification of fake or substandard medicines is not an easy task and there are many loopholes through which the perpetrators can escape. Drug control officials can rattle their sabres but have to put them back in scabbards.

The Mashelkar committee, set up in 2002, is learnt to have recommended amendment of the act and the setting up of a national drug control organisation.

All this will take time and as of now, the authorities cannot do much. Sensing this, the companies themselves have come up with some defence strategies; it's their money after all. Associated Capsules Group, for instance, came up with the idea of printing the brand name on the capsules in a circular fashion. This was not easy to duplicate. Lupin Laboratories, whose anti-tuberculosis drug was widely duplicated, started getting fewer complaints after it adopted this method. Omez, a popular antacid made by Dr Reddy's Laboratories, now has a hologram. But the fake drug manufacturers have also surged ahead by putting technology to good use in packing.



SANJAY AHLAWAT

WARNING NOTE: Dr C.M. Gulati

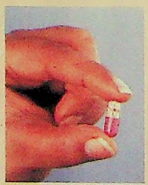
For the bewildered consumer, there is no choice but to be well-informed and vigilant. He has to examine the medicine carefully before taking it. He has to identify tell-tale signs of deceit. His life may depend on it.

with NISTULA HEBBAR/Delhi, DEEPAK TIWARI/Bhopal, TARIQ BHAT/Srinagar, LALITA IYER/Hyderabad, AJAY UPRETY/Lucknow, KANHAIAH BHELARI/Patna and ANOSH MALEKAR/Ahmedabad

Dark mood

Australia grapples with fake medicine problem

By SACHIDANANDA MURTHY/Canberra



ALLEGRON-25 was a common anti-depressant tablet sold in pharmacies in Australia over the counter. People used it to chase away the blues. Recently, users complained that instead of fighting depression, the tablet intensified the dark moods. They were better off than the users of Travacam, a tablet widely used to fight travel sickness. Australians brave the nine-hour ferry journey from Melbourne to Tasmania by popping Travacam, which was also a favourite in long-distance air travel. But in the last three months, the Therapeutic Drug Administration (TGA), which governs drug standards, found that 19 persons who took the tablet had been hospitalised and 68 others experienced "life-threatening adverse reactions".

These two were among a thousand drugs which were recalled from pharmacies across the country in April and May. The panic persists as the TGA investigators are finding more and more drugs to be spurious or substandard. Trish Worth, the parliamentary undersecretary for health, called it "shonky manufacturing of medicines" and promised stern action against the makers.

Pan Pharmaceuticals, whose 200 drugs were recalled and production suspended, had tinkered with Travacam in a big way. The TGA said that "one of the active ingredients varied in content from zero to 700 per cent of the listed dosage". Patients either got no relief or were given a seven times higher dosage, which made some of them want to jump off planes and trains.

The TGA went on recalling drugs as it discovered many big companies had given a contract to Pan Pharmaceuticals to manufacture their drugs. Curacel was fined $84,000 for manufacturing counterfeit medicines and a director of the company was fined $12,000 for switching labels of drugs. The TGA also found that beef cartilage used for vitamin drugs was substituted by shark cartilage.

The Australian Self Medication Industry tried to repair the damage done to the 1,424 companies licensed to manufacture over-the-counter drugs. But the can of worms led to other cans of worms. If cans of frozen chicken nugget revealed hard plastic, salted mackerel, imported from Thailand, contained substances which can "cause headache, itching and upset stomachs."

Prime Minister John Howard insisted that these cases had come up only because of the stringent quality testing laws, and said the battle against unscrupulous drug and food manufacturers would be waged even more vigorously.

DR-1

Main identity

From: "Dr Dabade" <drdabade@sancharnet.in>
To: <drugactionindia@healthyskepticism.org>
Sent: Wednesday, December 10, 2003 11:46 PM
Attach: ATT00070.txt
Subject: [drugactionindia] Deccan Herald

NH/DS - pl. get a cutting from Deccan Herald, 9th Dec. words printed on each line are incomplete

Tuesday, December 09, 2003

Deccan Herald » Edit Page » Full Story

IN PERSPECTIVE

Drug price control: no relief for poor

By GOPAL DABADE

— incomplete

The number of drugs under price control has come down drastically over the years, : affecting public health

In the last few months the media has been so much seized with the issue of substand "spurious medicines", including the sensational news about death penalty for spurio manufacturers that major issues concerning medicines seem to have been totally sid the issue of medicine pricing is much more scandalous and invites equal or even mu attention.

Medicine pricing and its policies have only at times attracted global media attention known example is that, when an Indian drug company, Cipla brought down the pric needed medicines for AIDS/HIV. The price came down from $1000 per person per 350 per person per year.
Even at these prices it has been guessed that Cipla would have made a profit of 200 an Indian drug company exploded the global myth (often perpetuated by giant multi companies, most of them being American and Europe-based) that good and quality cannot be manufactured at low prices. The need for these medicines is immense and Sub-Saharan Africa where the disease is rampant.

Though India has contributed its might to the global challenges of medicine pricing, India the picture is not one of contentment especially for the common man and the p with decreasing government spending on health, increasing deregulation of drug pri expenditure on health has increased tremendously.

Foothold of equity
The National Pharmaceutical Pricing Authority (NPPA) set up in 1997 was establis Government of India to monitor the compliance of the DPCO (Drug Price Control C observed that through these bodies in general the number of drugs under price contr has come down drastically.

The concept of Essential Drugs was realised by the World Health Organisation duri and was strongly based on the foothold of equity which is central to public health ar the people who need the drugs the most are not denied access to them. This concept applied and many developing countries have drawn up their Essential Drugs lists. E are those that satisfy the health care needs of the majority of the population; they sh at all times in adequate amounts and, in appropriate dosage forms, with assured qual

information, and at a cost that the community and individual can afford.

This concept of Essential Drugs of WHO is extremely relevant in the Indian context of people within this country are the below poverty line and many more around it. M emerged as the second commonest cause of rural indebtedness. And also it is estima part of the family's expenses on drugs and diagnostics goes to non-essential or hazar

This is estimated from 60% (the most conservative) to over 90%. Given these situati extremely important that the government implement the Essential Drug Policy on th WHO. The pricing of drugs should not be left to market forces.

Half-hearted gesture

Let us look at the DPCO of 1995, in which the Government of India came out with price control in response to the various emerging public health problems. Unfortuna does not dwell on these major health issues, but on the other hand the list includes d useless and even some hazardous ones. For example the DPCO does not mention an regulation drugs for iron deficiency anaemia, HIV/AIDS, filariasis, coronary artery rheumatic valve heart disease. It also does not mention price regulation for oral rehy cancer drugs and many vaccines (for rabies etc). It also looks half-heartedly at TB b one drug (which is Rifampicin)!

The list on the other hand contains many drugs which are totally unessential like Vit B2, Naproxen (an outdated pain killer) and Sulphadimidine (an outdated anti-infecti forth as the list is quite exhaustive. To add to the misery the list includes even few d Analgin (a pain killer) that are even hazardous.

Successive DPCOs from 1979 onwards have only reduced the number of drugs unde restriction. During 1987 the number of price controlled drugs were 142 and was redu 1995 and in 2003 it is expected to slump to a mere couple of dozens, the reason bein immense pressure from drug manufacturers. These companies have a good excuse, t Government of India has to change its patent laws by 2005. And the multinational d are after the government to change its Patent Act, so that they can make more profit

DR-1.

HAI
Health Action International

BUKO
Pharma-Kampagne

Direct-to-Consumer Prescription Drug Advertising
The European Commission's Proposals for Legislative Change

Health Action International (HAI-Europe), December 2001

The European Union currently forbids advertising of prescription drugs to the public, as do all other countries except the United States and New Zealand. This restriction on advertising is part of the protection offered to the public by prescription-only status.

Last July, the Commission announced a proposal to change the law to allow advertising of prescription drugs to treat AIDS, diabetes and asthma. The key change involves the advertising regulations contained in Articles 86 to 88 of Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use.

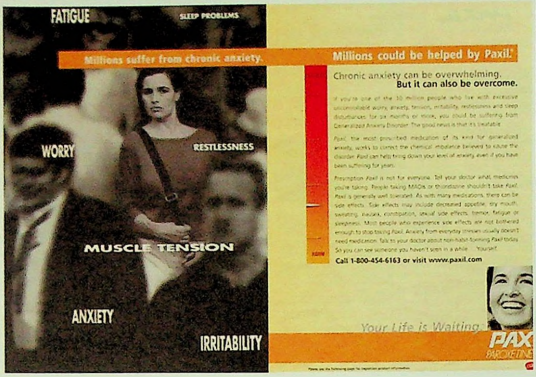
The proposed changes affect only a subset of prescription drugs. However, these are drugs for serious diseases. They would also represent an important 'foot in the door' for direct-to-consumer (DTC) advertising and drug promotion in Europe.

What will these changes mean for public health, for sustainability of national health care services, and for consumer and patient information rights?

This paper discusses the proposed changes, reviews the main evidence on effects of DTC advertising in the US and New Zealand, and concludes with recommendations.

Why maintain the current ban on direct-to-consumer (DTC) advertising of prescription drugs?

- **DTC advertising drives up prescription drugs costs,** threatening the sustainability of national health care services and universal access to health care as a fundamental human right.
- **DTC advertising fails to inform**. It does not provide the impartial, objective information consumers and patients need for informed health care decisions.
- **DTC advertising compromises public safety**. It can lead to rapid widespread exposure to dangerous drugs before risks are fully recognized, as occurred with troglitazone (Rezulin) for diabetes and cisapride (Propulsid) for nighttime heartburn in the US. Additionally, most new drugs are costlier than existing treatments, but few provide any therapeutic advantage.
- **DTC advertising promotes the medicalisation of normal life.** The most heavily advertised drugs are for long-term use by large target audiences, often for mild conditions and 'lifestyle' problems that may not need drug therapy.



Unnecessary Medicalisation

Why shouldn't normal New Yorkers feel anxious two months after the attack on the World Trade Centre, when this ad for paroxetine (Paxil) ran in the *New York Times Magazine*?

"Talk to your doctor about non-habit forming Paxil today," says the ad. The fine print on the back tells another story: discontinuation reactions include depression, somnolence, agitation, tremor, nausea, diarrhea, etc. Withdrawal reactions such as these signal a potential risk of drug dependence.

Why is prescription drug advertising currently forbidden?

Compared with medicines that can be bought over-the-counter (OTC), prescription-only products are generally used to treat more serious diseases, have greater toxicity, and a less well-understood profile of risks and benefits. Prescription-only medicines cannot be bought and sold freely. The aim of laws restricting companies' marketing and advertising rights is health protection.

As prescription drugs often treat serious diseases, restrictions on advertising also take account of the extra vulnerability of people who are seriously ill. Someone in pain, who has been diagnosed with a debilitating illness, or who is caring for an ill family member is vulnerable in a way that is different from someone who is going shopping for a new car or a loaf of bread.

The current legislation reflects both rationales. Article 88 (1) prohibits advertising of prescription-only medicines to the public. Article 88 (2) prohibits all advertisements mentioning a specified list of serious diseases.

What changes is the Commission proposing?

The Commission's proposal would allow manufacturers to advertise treatments for AIDS, diabetes and asthma and other chronic respiratory diseases.

Manufacturers must set up national self-regulatory procedures and submit ads to the European Medicines Evaluation Agency for pre-screening. The Agency, in turn, must examine materials and register any objections within 30 days or the ad can run as submitted. The Agency is also required to maintain a database of ads and write yearly reports, with a detailed review after five years.

Additionally, the Commission is proposing deletion of the section of Article 88 (2) that prohibits advertisements to the public mentioning specified serious diseases: tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other chronic diseases, chronic insomnia, diabetes and other metabolic illnesses. The clause on serious diseases refers to all advertisements, not just prescription-only products. This deletion appears to pave the way for across-the-board advertising of treatments for serious illness.

Are there restrictions on how companies can advertise these products?

The proposal includes no explicit restrictions on media or content, other than conformity to general principles of pharmaceutical advertising listed in Article 87. Article 88 (2), clauses (a) to (f), sets out conditions for how this information would be disseminated. These conditions do not explicitly exclude any media –such as television –nor do they limit target audiences.

The proposal for Article 88 (2) broadly authorizes full product advertisements: "*...This provision applies to product information appended to the marketing authorization as well as to additional related information.*"

A separate clause, already in place, allows Member States to ban the advertising of publicly funded drugs should they choose to do so.

What rationale is presented for these changes?

The Commission states that these changes are being introduced *"in order to respond to the expectations expressed by the patients' groups"*.

The current law does not limit the public's access to drug information; it prohibits *advertising*. Many organizations currently provide drug information to the public. Access to information is often inadequate, but this results from policy decisions not to prioritize patient information, rather than legal barriers.

The Commission has not said which patient groups have requested changes to advertising regulations nor which groups may request advertising campaigns should the change be implemented. The Commission makes no reference to any measures taken to eliminate conflicts of interest. Increasing numbers of patient groups are substantially funded by drug companies, which have a vested interest in DTC advertising.

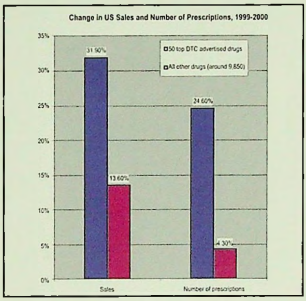
> *"... In July, DG Enterprise proposed to lift the ban for asthma, diabetes and HIV [and] companies will be allowed to impart information promoting "awareness of the availability" of products. Nobody believes it will end there."*
> **- Sarah Boseley, Just Say No to Drug Ads. The Guardian. UK. Dec 10, 2001**

The US experience – drug costs out of control

Spending on DTC advertising has grown exponentially in the US within the last decade, from $55 million in 1991 to $2.5 billion in 2000. If DTCA did not stimulate sales, companies would not be spending more and more each year on this marketing strategy.

Top 50 DTC advertised drugs responsible for large cost increases

- In 2000 over 95% of DTC advertising spending was on 50 drugs;
- These 50 drugs had combined retail sales of $41.3 billion;
- This was nearly one third of total US retail prescription drug spending in 2000;
- These 50 drugs were responsible for **$9.94 billion** of the **$20.8 billion** increase in US retail prescription drug spending from 1999 to 2000, or 47.8% of this increase. (Findlay, 2001)



Source: Figure 1, Findlay, NIHCM, 2001

The bottom line: why does the industry want legislative change?

A US market research firm, PERQ/CHI analyzed the returns on investments for print and television DTC ads in 1999, based on spending and sales data supplied by 25 major manufacturers. On each dollar invested in DTC advertising, the average return was $1.69 for TV ads alone; $2.51 for magazine advertising, and $2.11 for campaigns involving a mix of print and TV ads. (PERQ/CHI, 1999) These are impressive returns – but they also mean impossible costs for public and private drug plans.

"Aggressive direct-to-patient marketing by pharmaceutical companies, high prices for new drugs are making prescription drugs one of the major costs of health care. This issue is not being given the attention it deserves. It's time to put science ahead of marketing."
- Premier Ujjal Dosanjh, May 24, 2000. British Columbia Government News Release. Victoria, B.C., Canada."[Canadians are heavily exposed to cross-border DTCA from the US.]

Can the public find out what drugs are available from DTC advertising?

DTC advertising does not provide an overview of available treatments. Very few drugs are advertised to the public. In the US, over 40% of spending each year goes towards just 10 products. These are mainly new, expensive drugs for chronic or intermittent long-term use by large numbers of people. They exclude off-patent drugs even if these are superior first-line treatments, such as diuretics for uncomplicated high blood pressure. The decision to advertise a drug is a marketing decision, not a public health decision. Sales revenues for the top 10 drugs exceeded US $16 billion last year.

Products with Top DTC Advertising Budgets in 2000

Drug	Condition	DTC Spending Millions US$	Sales Millions US$
Vioxx (rofecoxib)	Arthritis	$ 160.8	$ 1,518.0
Prilosec (omepraxole)	Ulcer/Reflux	$ 107.5	$ 4,102.2
Claritin (loratadine)	Allergy	$ 99.7	$ 2,035.4
Paxil (paroxetine)	Anxiety/Depression	$ 91.8	$ 1,808.0
Zocor (simvastatin)	High cholesterol	$ 91.2	$ 2,207.0
Viagra (sildenafil)	Impotence	$ 89.5	$ 809.4
Celebrex (celecoxib)	Arthritis	$ 78.3	$ 2,015.5
Flonase (fluticasone)	Allergy	$ 73.5	$ 618.7
Allegra (fexofenadine)	Allergy	$ 67.0	$ 1,120.4
Meridia (sibutramine)	Obesity	$ 65.0	$ 113.2
Total		*$ 924.3*	*$ 16,347.8*

Source: Findlay, 2001

"I recently sat in on a focus group sponsored by a drug advertiser... The group remarks were mostly - how can you make statements like this since they wanted to show amazing benefits while downplaying any possible side effects. In the end it was a pure advertising show and all we disliked was overlooked. The ads run now and probably increased sales at the expense of doctors being pressured by regular patients for a drug they really do not need. Needless to say I support more stringent rules in this area."

- John Madura, letter to British Medical Journal, Oct 19, 2001 www.bmj.com/cgi/eletters/323/7318/889#El.1

DTC advertising: an accurate information source?

DTC ads are commonly found to violate US law because they contain inaccurate and misleading information. The US Food and Drug Administration (FDA) directly regulates drug promotion. From 1997 to mid 2001, the FDA sent out 94 notices to companies about DTC advertisements that violated federal regulations, 48 on broadcast and 46 on print advertising. (Ostrove, 2001) In 1998, more than half of products advertised on TV violated regulatory standards. (Koerner, 1999) The most common reasons were exaggeration of benefits and minimization of risks.

New Zealand depends on industry self-regulation, but in a recent spot check (Pratt, 2000), the Ministry of Health found that five of six voluntarily submitted TV ads and a fourth of print ads violated the Medicines Act. This was in spite of voluntary pre-screening by the Therapeutic Advertising Advisory Service. In nearly all cases risk information was absent, incomplete or illegible.

Steven Woloshin and colleagues (2001) examined the content of DTC ads in 10 consumer magazines published in 1998 and 1999. Nearly 9 out of 10 ads "described the benefit of a medication in vague, qualitative terms" and did not provide any evidence to support claims; one-quarter used terms such as 'proven relief, proven effective or clinically proven'; nearly one-fifth cited widespread use as a claim of benefit; and one eighth used personal testimonials.

Researchers in California looked at the educational content of US magazine ads published over a 10 year period, 1989-1998, based on whether the ad mentioned key pieces of information consumers need to know. (Bell et al, 2000) They found the educational value to be minimal:

- 91% did not say the likelihood of treatment success;
- 76% made no mention of other helpful activities, like exercise or diet;
- 73% did not mention any causes or risk factors for the treated condition;
- 71% made no mention of any other possible treatments;
- 64% failed to explain how the drug works.

"The 60-second 'full-product' TV advertisement is misleading because the totality of the images, the music and the audio statements that you present overstate the efficacy of Celebrex...[they] collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence."
- US FDA letter to Searle, Nov 2000

"The graphics of the advertisement show a frustrated woman trying to pull her shopping cart out of its interlocked lineup in front of a store. The concurrent audio states "Think it's PMS? It could be PMDD." The imagery and audio presentation of the advertisement never completely define or accurately illustrate premenstrual dysphoric disorder (PMDD) and there is no clear distinction between premenstrual syndrome (PMS) and PMDD communicated. Consequently, the overall message broadens the indication and trivializes the seriousness of PMDD..."
- US FDA letter to Lilly, Nov 2000

US ads for diabetes, asthma and AIDS, a model for Europe?

Diabetes: blurring the distinction between life-threatening and life-saving

Rezulin (troglitazone) is a diabetes drug, banned in the UK in 1997 because of severe liver toxicity. Rezulin was advertised to the US public for over two years after the UK ban. It was eventually removed from the market in 2000. By that time it had been named as the suspected cause of nearly 400 deaths, 63 from liver failure. (Willman, 2000) US DTC ads for Rezulin stressed its widespread use: *"more than 1,000,000 people have begun using Rezulin to help manage diabetes."* (Woloshin, 2001) These ads made no mention of the UK market withdrawal.

Two new drugs in the same class, Avandia (rosiglitazone) and Actos (pioglitazone) are currently on the US market, and are being advertised to the US public. Health authorities have issued warnings that both drugs can cause fluid retention leading to heart failure.

Any prescription drug may be advertised to the public in the US, even if it is similar to a drug withdrawn for safety reasons or has been associated with serious risks.

These new diabetes drugs have not been shown to save lives. They simply have not been tested for long enough in large enough groups of patients. They were approved for marketing on the basis of their ability to control blood glucose. This effect may or may not translate into long-term health benefits as compared to other drug and non-drug approaches. To quote an independent assessment:

"In patients with type 2 diabetes rosiglitazone improves some surrogate markers and worsens others. Long-term trials are required to know whether this class of drugs reduces morbidity and mortality outcomes." (Therapeutics Initiative, 2000)

AIDS: Unrealistic Expectations of Treatment Success Linked to Risk-taking Behaviours

"Direct-to-consumer advertising may be influencing trends of increasing sexual risk behavior and subsequent STDs including new HIV infections among MSM in San Francisco. Strategies to reduce the possible harmful effects of HIV drug advertising are needed."
-Jim Klausner, San Francisco Department of Public Health

The San Francisco Department of Health warned in early 2001 that it was considering banning DTCA for AIDS drugs within the city limits. A survey of 262 male patients in San Francisco's STD clinics had shown that young men were less likely to practice safe sex because the unrealistic images in DTC ads for AIDS drugs made it seem like AIDS could be effectively controlled. Some adverts showed vigorous men climbing mountains. This is nothing like the reality of life on triple therapy. (Klausner and Kim, 2001)

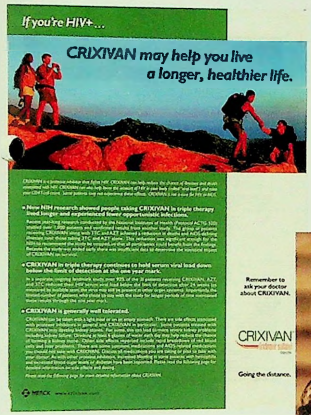
Gay men with higher DTC advertising exposure were more likely to have engaged in unprotected sex with an HIV positive or unknown partner within the last month (27% vs. 16%) and were more likely to believe that triple therapy (HAART) had made HIV infection a less serious disease (25% vs. 17%).

"...You present the statement "Avandia is not indicated for use with insulin" in the audio portion of your 'Real Stories' broadcast advertisement simultaneously with the super "Avandia- Help use the natural insulin in you." This presentation minimizes the communication of the risk of the Bolded Warning by presenting consumers with conflicting messages about the use of Avandia and insulin...In addition your broadcast advertisement is misleading because you fail to present the precaution ...concerning weight gain caused by Avandia...Moreover, your print advertisement is misleading because the risk information is presented under the header "Strengthen your body's own ability to help control blood sugar." This presentation...minimizes the risks associated with Avandia treatment."
US FDA letter to GSK, June 2001

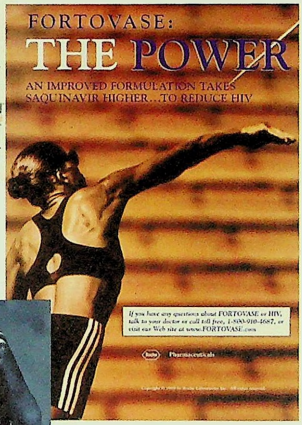
The most important public health message for AIDS is prevention. Unrealistic advertising campaigns for AIDS drugs have interfered with that message in the US. Are there any guarantees that the same companies will behave more responsibly in Europe?

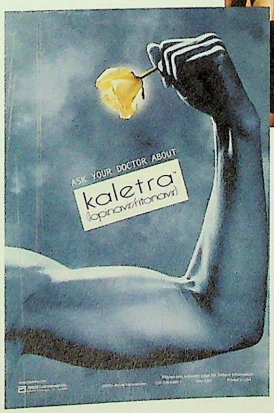
Mistaken Impressions: ad for an asthma drug, Singulair (montelukast)

The US Kaiser Family Foundation published a study on consumer responses to three television DTC ads in November 2001. One of the ads was for an asthma drug, Singulair (montelukast).



Climbing mountains, flexing muscles and throwing a javelin: unrealistic images of the reality of antiretroviral therapy.





Singulair is one of two new oral asthma drugs in a class called leukotriene antagonists. Both are among the top 50 drugs advertised to the US public in 2000. Independent assessments have judged their place in the treatment of asthma to be limited. A 1999 drug bulletin states: *"Average clinical effects are small and would unlikely be detectable by individual patients... [These drugs] cause average clinical benefits that are less than low-dose inhaled glucocorticoids."* (Therapeutics Initiative, 1999)

The Kaiser Foundation study randomly assigned participants to view different ads, then compared knowledge between viewers and non-viewers. They found that more viewers of the Singulair ad knew that there were pills people could take to prevent or limit asthma attacks (71% vs. 36%). However, more Singulair ad viewers came away misinformed about what these pills do: 25% thought they could take a pill rather than use an inhaler during an asthma attack versus 13% of non-viewers. This is dangerous misinformation, as it could delay effective treatment during a potentially life-threatening situation.

The ad says that Singulair doesn't work during an acute attack. However, this voice-over is accompanied by different text on screen and viewers may be distracted. The main emotive message is one of effective relief. Nowhere does the ad even hint that effectiveness is mild or inferior to inhaled steroids, which are also used for prevention. The US FDA allowed Merck to run this ad. The EMEA might similarly allow it. The information it contains is not false. However, the lack of information on relative efficacy is misleading.

In New Zealand, Merck's ad campaign for Singulair included a promotional offer of one month's free medication.(MacKinven, 1999) Nearly 20% of New Zealand's GPs prescribed the drug during its first two weeks on the market. The free promotional offer was criticized as creating an unnecessary strain on patients, since Singulair is expensive and is intended for long-term use.

Advertising only non-subsidized drugs: is this the answer?

Under existing legislation, Member States can choose to impose a ban on advertising of publicly subsidized drugs. If the Commission's proposal is accepted, this clause could be used to avoid paying for the prescriptions stimulated by DTC advertising.

Unsubsidized drugs are products that drug benefit plans have decided not to fund, usually following an evaluation of cost-effectiveness. These drugs tend to be more expensive than equivalent alternatives, relatively ineffective, have a poor risk/benefit profile, or are for 'lifestyle problems' for which drug treatment may not be appropriate.

To allow advertising only of these products creates a perverse incentive for manufacturers. It also adds to the misleading impact of advertising because the public only sees emotive messages lauding the benefits of products that by definition are either overpriced, inferior or unnecessary.

Although the government is not paying for these drugs directly it faces associated costs:

- extra doctor visits
- extra diagnostic tests
- extra health care and hospitalizations from adverse events, especially in the case of additional discretionary drug use.

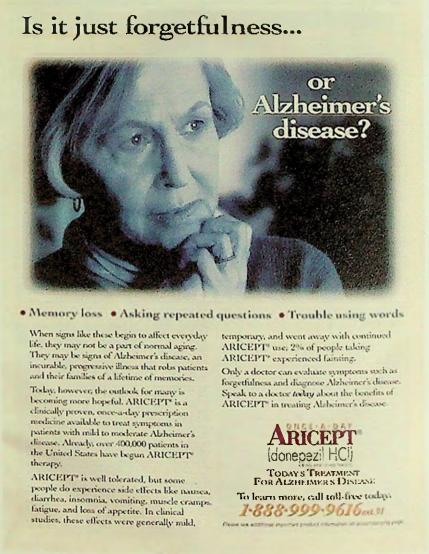
Do DTC ads lead to better health or health care services?

Pharmaceutical industry representatives claim that advertising improves communication between doctors and patients, that it will help untreated patients receive needed care at an earlier date, and that it improves compliance. (Holmer, 1999)

There is no evidence that DTC advertising improves doctor/patient relationships, and surveys of US doctors indicate that opinions are largely negative. (Lipsky, 1997; Time Magazine, 1998)

There is no evidence that exposure to DTC advertising can lead to better health, fewer hospitalizations or lower mortality. The industry claims that patients will see the ads, recognize their symptoms and get earlier treatment and therefore avoid more serious disease. However, there is no research evidence to back this claim. Some market research studies show that ad campaigns increase the number of doctor visits for advertised conditions, but they don't distinguish between people who needed medical care and people who did not have a medical problem and were therefore unlikely to benefit. Ad campaigns cast a wide net in order to maximize sales, often suggesting that common symptoms are signs of serious problems, as in the case of this ad for an Alzheimer's drug. This approach is unlikely to attract only those in need of care.

The effect of DTC advertising on compliance has not been adequately tested. In two surveys by *Prevention Magazine*, between 5% and 8% of respondents said that seeing ads made them more likely to take their medicines. (Prevention, 1998, 1999) Most users of advertised medicines said the ads did not remind them to take the drug. This



survey is frequently cited as evidence of improved compliance although it did not measure behaviour change and failed to mention what types of drugs the respondents were using. If they were symptomatic treatments such as allergy drugs or painkillers, improved compliance is of no health benefit and in some cases can cause serious harm. (Herxheimer, 1998)

Patients with chronic diseases such as AIDS or diabetes are often well informed about their illnesses. For such patients, the key role of ads is to stimulate a switch to newer, more expensive drugs. The US experience shows that this can cause harm: troglitazone was an unnecessarily harmful new drug for diabetes; the leukotriene antagonists for asthma have a limited role in asthma therapy because of unimpressive efficacy; and ads for new AIDS drugs appear to have convinced some younger gay men not to worry about disease prevention.

Recommendations

1. Above all, do no harm

Given the lack of evidence of benefit and considerable evidence of harm from the US experience, prescription drug advertising should not be introduced in Europe for drugs for diabetes, asthma and AIDS. These are serious illnesses for which glossy advertising campaigns are inappropriate and potentially dangerous.

Unless there is clear evidence of lack of harm and of health benefits, the prohibition against direct-to-consumer advertising of prescription drugs should be maintained. The European Union is committed to the precautionary principle. This principle is as relevant to advertising policies with health consequences as to direct chemical exposures.

2. Maintain universal coverage of essential medicines

"Access to health care is a right enshrined in the European Union's Charter of Fundamental Rights and an essential element of human dignity. It must therefore be guaranteed for all."
-European Commission, December 2001

Prescription drug advertising threatens universal health care coverage by pushing drug spending out of control. Annual increases in pharmaceutical costs similar to the US $10 billion (15%) increase last year from sales of DTC advertised drugs would make public and non-profit drug plans unsustainable. Most of these drugs provide little to no advantage compared to existing alternatives. Most are more expensive.

The proposal to advertise only non-subsidized drugs would stimulate widespread use and sales of the least cost-effective products. European consumers would then suffer twice: first by paying out-of-pocket for drugs they mistakenly believe are better; secondly, because they will pay through their taxes for increased doctor visits, diagnostic tests and medical care for those suffering unnecessary adverse effects.

3. Make shared informed health care choices a reality

Patients and the public need independent, comparative information on the pros and cons of all drug and non-drug treatments and the option not to treat. This type of information does not require a change to advertising legislation. It cannot be produced by pharmaceutical companies, which have a vested interest in selling a specific product. However, if informed choice in health care decisions is to become a reality, independent information needs to become an integrated part of national health care systems.

The key issue from a public health perspective is not how to reduce the protection offered by prescription-only status, but how to ensure that the public, throughout Europe, has access to comprehensive, unbiased and reliable medicines information.

References:

Bell RA. Wilkes MS. Kravitz RL. The Educational Value of Consumer-Targeted Prescription Drug Print Advertising. Journal of Family Practice 2000; 49(12):1092-1098

European Commission. Healthcare : Commission proposes three common EU objectives for healthcare and care for the elderly - access for all, high quality, financial sustainability. Press Release. DN: IP/01/1747. Brussels. December 5, 2001

Findlay S. Prescription Drugs and Mass Media Advertising, 2000. National Institute of Health Care Management. Washington DC: Nov 20, 2001 *[www.nihcm.org]*

Herxheimer A. Many NSAID users who bleed don't know when to stop. British Medical Journal 1998; 316:492

Holmer AF. Direct-to-consumer prescription drug advertising builds bridges between patients and physicians. JAMA 1999;281(4):380-2

Kaiser Family Foundation. Understanding the effects of Direct-to-Consumer Prescription Drug Advertising. November 2001: [www.kff.org]

Klausner J, Kim A. Are HIV drug advertisements contributing to increases in risk behavior among men in San Francisco? San Francisco Dept of Public Health. March 14, 2001 [www.surviveaids.org/klausnerabs.html]

Koerner C. US FDA. Division of Drug Marketing, Advertising and Communications. The Regulation of Direct-to-Consumer Promotion of Prescription Drugs. Presentation at Health Canada Multi-Stakeholders' Consultation on Direct-to-Consumer Advertising. Aylmer, Québec. April 14, 1999

Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to-consumer advertising. J Fam Pract 1997 45(6):495-9.

MacKinven M. Pill purveyors go direct. New Zealand Doctor. 17 March 1999, p11

Mintzes B. Blurring the Boundaries: new trends in drug promotion. Amsterdam: Health Action International, 1998

Ostrove N. Division of Drug Marketing, Advertising and Communication. US FDA. Prescription Drug Issues. FDCH Congressional Testimony. Committee on Commerce, Science and Transportation. Washington DC. July 24, 2001

PERQ/CHI,1999. Magazines: a Healthy Diagnosis. [www.magazine.org; accessed Dec 2001]; Calculations based on extra use in exposed consumers vs. unexposed x cost per script x average refill rate/category

Pratt P. Assessment of Regulatory Compliance for Medicines Advertised Direct to Consumer. Medsafe. New Zealand Ministry of Health. Wellington, 2000

Prevention Magazine. National Survey of Consumer Reactions to Direct-to-Consumer Advertising. Rodale Press, 1998; Year two: A National Survey of Consumer Reactions to Direct-to-Consumer Advertising. Rodale Press, 1999

Therapeutics Initiative. Leukotrine Antagonists. Therapeutics Letter 29; University of British Columbia; April/ May 1999 [http://www.ti.ubc.ca/pages/letter29.htm]

Therapeutics Initiative. New Drugs VI. Rosiglitazone. Therapeutics Letter 36; University of British Columbia; July/Aug 2000. [www.ti.ubc.ca/pages/letter36.htm#Rosiglitazone]

Time Magazine. Consumer and Physician Attitudes Towards Direct-to-Consumer Advertising. Time Inc., August 1998

Willman D. FDA: How a New Policy Led to Seven Deadly Drugs. Los Angeles Times. December 20, 2000 [www.latimes.com/news/nation/reports/fda/lat_fda001220.htm]

Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? Lancet 2001; 358: 1141-1146

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BUKO
Pharma-Kampagne

HAI
Health Action International

BUKO Pharma-Kampagne Federal Coordination Internationalism is a network of around 200 German solidarity groups. In 1981 BUKO started a campain against global malpractices in drug marketing by multinational pharmaceutical companies. The focus of the Pharma-Kampagne is to stop unethical drug marketing practices and to foster rational use of drugs all over the world. The Pharma-Kampagne works with medical students, doctors, pharmacists and medical scientists, through campaigns, publications, press work, public debate and dialogue. BUKO Pharma-Kampagne is one of the co-founders of Health Action International (HAI).

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Health Action International (HAI) is an informal network of some 150 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues in more than 70 countries. HAI believes that all drugs marketed should meet real medical needs, have therapeutic advantages, be acceptably safe and offer value for money.

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BUKO Pharma-Kampagne, Bielefeld, July 2002

Nordrhein-Westfälische
Stiftung für Umwelt und Entwicklung

DR-1.

COVER STORY

DRUG TRIALS AND ETHICS

A *Frontline* investigation comes up with new revelations on funding, business connections and conflicts of interest in the Johns Hopkins-linked drug trials at Kerala's Regional Cancer Centre.

R. KRISHNAKUMAR
in Thiruvananthapuram

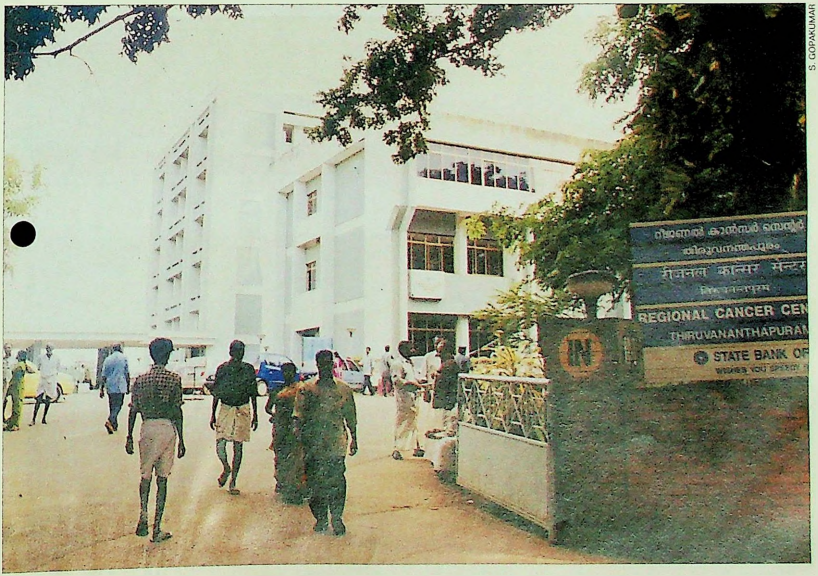
A NON-MEDICAL scientist with a potential anti-cancer "drug" discovery, and links with a "start-up" company. A university holding a patent for the experimental drug. A businessman willing to invest a couple of million dollars in the new company for further development of the drug through trials in human beings. An international contract research organisation that scouts worldwide for opportunities to do clinical research using the drug. An institution in a Third World country willing to conduct trials on its patients for them. These are among the ingredients of what has now come to be known as the "Johns Hopkins-RCC drug trial controversy" in Kerala.

It was on July 30 that the Baltimore-based Johns Hopkins University (JHU) revealed to the media in the United States that the clinical trial of the "experimental anti-cancer drug" developed by one of its faculty members, conducted at the Regional Cancer Centre (RCC) in Thiruvananthapuram, did not have its authorisation. The JHU went on to say that the trial did not have the approval of any of its Institutional Review Boards (IRBs) that ought to have considered whether it would be safe to conduct human trials of the drug.

In an interview to a U.S. newspaper on July 31, the faculty member, Dr. Ru Chih C. Huang, a Biology Professor at the JHU since 1965, said that she was unaware that the university had a requirement to seek internal approval of experiments conducted abroad. She added that she had gone ahead with the clinical trial because it already had the approval of a "similar panel" in the RCC.

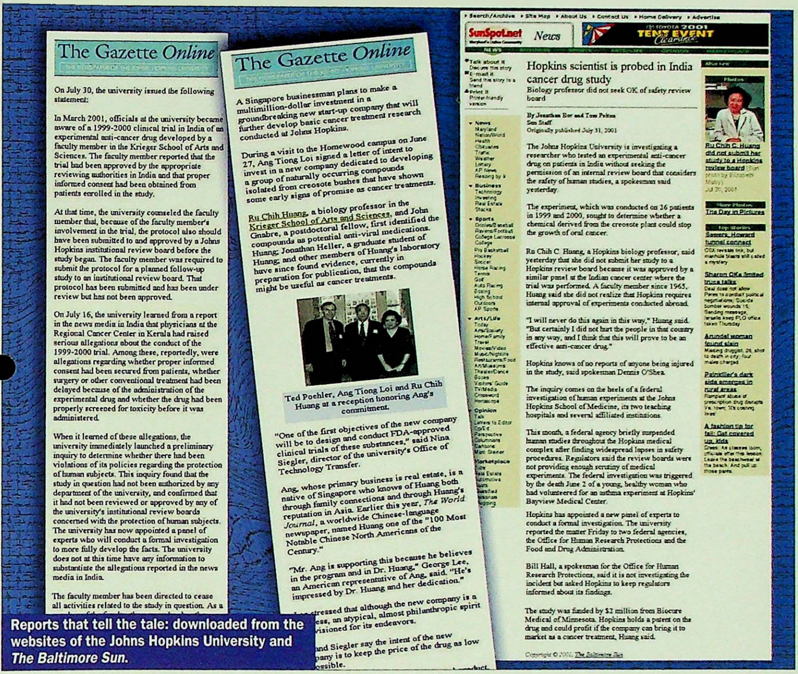
"I will never do this again this way. But certainly I did not hurt the people in that country in any way, and I think this will prove to be an effective anti-cancer drug," Huang, who did not respond to an e-mail message sent by *Frontline*, is quoted as saying in *The Baltimore Sun*.

But perhaps the most significant statements reported in the newspaper as having been made by Huang are that her



S. GOPAKUMAR

The Regional Cancer Centre in Thiruvananthapuram, situated in the Medical College Hospital campus.



The Gazette Online

On July 30, the university issued the following statement:

In March 2001, officials at the university became aware of a 1999-2000 clinical trial in India of an experimental anti-cancer drug developed by a faculty member in the Krieger School of Arts and Sciences. The faculty member reported that the trial had been approved by the appropriate reviewing authorities in India and that proper informed consent had been obtained from patients enrolled in the study.

At that time, the university counseled the faculty member that, because of the faculty member's involvement in the trial, the protocol also should have been submitted to and approved by a Johns Hopkins institutional review board before the study began. The faculty member was required to submit the protocol for a planned follow-up study to an institutional review board. That protocol has been submitted and has been under review but has not been approved.

On July 16, the university learned from a report in the news media in India that physicians at the Regional Cancer Center in Kerala had raised serious allegations about the conduct of the 1999-2000 trial. Among these, reportedly, were allegations regarding whether proper informed consent had been secured from patients, whether surgery or other conventional treatment had been delayed because of the administration of the experimental drug and whether the drug had been properly screened for toxicity before it was administered.

When it learned of these allegations, the university immediately launched a preliminary inquiry to determine whether there had been violations of its policies regarding the protection of human subjects. This inquiry found that the study in question had not been authorized by any department of the university, and confirmed that it had not been reviewed or approved by any of the university's institutional review boards concerned with the protection of human subjects. The university has now appointed a panel of experts who will conduct a formal investigation to more fully develop the facts. The university does not at this time have any information to substantiate the allegations reported in the news media in India.

The faculty member has been directed to cease all activities related to the study in question. As a

The Gazette Online

A Singapore businessman plans to make a multimillion-dollar investment in a groundbreaking new start-up company that will further develop basic cancer treatment research conducted at Johns Hopkins.

During a visit to the Homewood campus on June 27, Ang Tiong Loi signed a letter of intent to invest in a new company dedicated to developing a group of naturally occurring compounds isolated from creosote bushes that have shown some early signs of promise as cancer treatments.

Ru Chih Huang, a biology professor in the Krieger School of Arts and Sciences, and John Gnabre, a postdoctoral fellow, first identified the compounds as potential anti-viral medications. Huang; Jonathan Heller, a graduate student of Huang; and other members of Huang's laboratory have since found evidence, currently in preparation for publication, that the compounds might be useful as cancer treatments.

Ted Poehler, Ang Tiong Loi and Ru Chih Huang at a reception honoring Ang's commitment.

"One of the first objectives of the new company will be to design and conduct FDA-approved clinical trials of these substances," said Nina Siegler, director of the university's Office of Technology Transfer.

Ang, whose primary business is real estate, is a native of Singapore who knows of Huang both through family connections and through Huang's reputation in Asia. Earlier this year, *The World Journal*, a worldwide Chinese-language newspaper, named Huang one of the "100 Most Notable Chinese North Americans of the Century."

"Mr. Ang is supporting this because he believes in the program and in Dr. Huang," George Lee, an American representative of Ang, said. "He's impressed by Dr. Huang and her dedication."

...stressed that although the new company is a ...ess, an atypical, almost philanthropic spirit ...visioned for its endeavors.

...nd Siegler say the intent of the new ...pany is to keep the price of the drug as low ...ossible.

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SunSpot.net News

Hopkins scientist is probed in India cancer drug study

Biology professor did not seek OK of safety review board

By Jonathan Bor and Tom Pelton
Sun Staff
Originally published July 31, 2001

The Johns Hopkins University is investigating a researcher who tested an experimental anti-cancer drug on patients in India without seeking the permission of an internal review board that considers the safety of human studies, a spokesman said yesterday.

The experiment, which was conducted on 26 patients in 1999 and 2000, sought to determine whether a chemical derived from the creosote plant could stop the growth of oral cancer.

Ru Chih C. Huang, a Hopkins biology professor, said yesterday that she did not submit her study to a Hopkins review board because it was approved by a similar panel at the Indian cancer center where the trial was performed. A faculty member since 1965, Huang said she did not realize that Hopkins requires internal approval of experiments conducted abroad.

"I will never do this again in this way," Huang said. "But certainly I did not hurt the people in that country in any way, and I think that this will prove to be an effective anti-cancer drug."

Hopkins knows of no reports of anyone being injured in the study, said spokesman Dennis O'Shea.

The inquiry comes on the heels of a federal investigation of human experiments at the Johns Hopkins School of Medicine, its two teaching hospitals and several affiliated institutions.

This month, a federal agency briefly suspended human studies throughout the Hopkins medical complex after finding widespread lapses in safety procedures. Regulators said the review boards were not providing enough scrutiny of medical experiments. The federal investigation was triggered by the death June 2 of a young, healthy woman who had volunteered for an asthma experiment at Hopkins' Bayview Medical Center.

Hopkins has appointed a new panel of experts to conduct a formal investigation. The university reported the matter Friday to two federal agencies, the Office for Human Research Protections and the Food and Drug Administration.

Bill Hall, a spokesman for the Office for Human Research Protections, said it is not investigating the incident but asked Hopkins to keep regulators informed about its findings.

The study was funded by $2 million from Biocure Medical of Minnesota. Hopkins holds a patent on the drug and could profit if the company can bring it to market as a cancer treatment, Huang said.

Ru Chih C. Huang did not submit her study to a Hopkins review board

Reports that tell the tale: downloaded from the websites of the Johns Hopkins University and *The Baltimore Sun*.

"study was funded by $2 million from 'Biocure Medical of Minnesota'" and that "Hopkins holds a patent on the drug and could profit if the company can bring it to market as a cancer treatment".

On a request for confirmation, one of the correspondents of *The Baltimore Sun* wrote to *Frontline* that the information about the source of funding (Biocure Medical of Minnesota) and the patent (held by the JHU) was obtained by him from Ru Chih Huang in the course of a telephonic interview. The correspondent said that Huang had described the company as a "start-up" and that she had expressed the hope that "Hopkins could make a profit if the drug is brought to the market in four or five years".

Responding to a request for clarification, a spokesperson for the JHU and its Executive Director, Communications and Public Affairs, Dennis O'Shea, wrote to *Frontline*: "Yes, Hopkins does hold a patent on the M4N drug that was used in the study. This patent was assigned to the university by the researcher in routine compliance with the university's technology transfer policy. Such patent assignments are standard operating procedure with any discovery or invention made at Johns Hopkins. The assignment of the patent to the university had nothing to do with the clinical trial in India and it did not in any way alter the researcher's obligation under university rules to submit the proposed trial to an institutional review board."

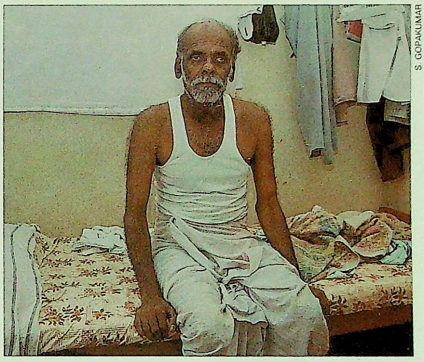
Dr. Ru Chih C. Huang, Biology Professor at the Krieger School of Arts and Sciences, Johns Hopkins University.

O'Shea also said that while the patent application had been filed on October 15, 1999, before the trials, the patent had not been granted until April 10, 2001, well after the trial was completed. Replying to a question on the source of funding for the study, he said that "the source of the funding of the trial remains a focus of the investigation" ordered by the university in the wake of the controversy in India. O'Shea added that the JHU investigation "is being conducted as expeditiously as possible, given the complexity of the facts involved" and that there was no deadline for its conclusion.

However, a report published last year in the JHU newspaper, *The Gazette Online*, gives a clear indication of the funding that Huang's study would have received. On July 3, 2000, the online newspaper (Volume 29, Number 40)

reported that a Singapore-based businessman planned to make "a multi-million-dollar investment in a groundbreaking new start-up company that will further develop basic cancer treatment research conducted at Johns Hopkins".

The report said that real estate businessman Ang Tiong Loi had signed a letter of intent on June 27, 2000 "to invest in a new company dedicated to developing a group of naturally occurring compounds isolated from creosote bushes that have shown some early signs of promise as cancer treatments" in the experiments conducted by Huang and some other members of her laboratory.



S. GOPAKUMAR

M. Gopalan from Tirupur in Tamil Nadu, one of the patients on whom the 'anti-cancer drug' was tested by RCC doctors and who filed a complaint before the State Human Rights Commission regarding the therapy.

THE first-ever human trials of two chemicals, tetra-O-methyl nor-dihydro-guaiaretic acid (M4N) and tetraglycinyl nor-dihydro-guaiaretic acid (G4N) – originally isolated from the creosote bush *Larrea tridentata* at the JHU laboratory by Huang and her co-workers – were conducted between November 12, 1999 and April 8, 2000 on oral cancer patients awaiting surgical treatment at the RCC (*Frontline*, August 17). From available indications, including statements made by a few patients and Dr. V.N. Bhattathiri of the RCC who first brought the issue to public attention, the majority of the 25 patients on whom the trial was conducted had not realised that the injections they received were not part of their treatment but belonged to an experiment to understand the effectiveness of the chemicals in treating some forms of human cancer. Although the RCC claimed that there was no harm done to the patients and that the injections had substantially reduced the extent of the tumours, there was no evidence of continuous monitoring of the patients, most of whom were sent home after the drug-injected tumours were surgically removed.

The Gazette Online report indicates that the letter of intent was signed in April 2000, about two months after the trials at the RCC were completed. It quotes the university's Director of the Office of Technology Transfer, Nina Siegler, as saying that "one of the first objectives of the new company will be to design and conduct FDA (Food and Drug Administration)-approved clinical trials of these substances." This puts a question mark on the approval status of the RCC trials, which had already been completed.

George Lee, a U.S.-based representative of Ang Tiong Lee, is also reported in *The Gazette Online* as saying that although the new company is a business venture, it intends to keep the price of the drug "as low as possible". According to Siegler, the expectation was that the drug could be manufactured "fairly inexpensively" since it was a modification of a natural product. She says: "That still has to be confirmed, as does the product's potential as a cancer treatment, but we are hopeful that if this works out, we might be able to price any resulting drugs in a way that makes them available to all the people of the world and still makes returns for the university and the investor."

The July 2000 report in the JHU's online newspaper also said that the university, which holds the patent rights, will grant an exclusive licence to the new company to [illegible] those inventions and that "there will be contracts between the university and the company for Hopkins to continue work on new drug analogs and clinical development".

Siegler also said that "most of the money will go into clinical trials, not into corporate overhead" and will be "dedicated to seeing if the compound can work in a variety of human cancers", although it would not be "fair" to call it a "virtual company". She also announced tentative plans of the JHU to hire a contract research organisation to help implement clinical trials that received the approval of the FDA.

An earlier report in *The Gazette Online* said that in the latter half of 1998 the JHU had signed an agreement with one of the largest pharmaceutical contract research organisations with offices in about 28 countries, including Ind[illegible] The move was aimed at finding clinical research opportunities for the university's corporate-sponsored clinical drug research. There are indications that the organisation's Indian arm was involved in the drug trials at the RCC.

However, it is yet to be known whether 'Biocure Medical, Minnesota', the company Huang referred to in her interview with *The Baltimore Sun*, is the same as the one proposed through the letter of intent and whether the $2 million funding that she said her study had did indeed come from Ang Tiong Loi. The JHU newspaper report also [illegible]

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Regional Cancer Centre Director Dr. M. Krishnan Nair, who is also Professor and Head of the Department of Radiotherapy.

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Dr. V.N. Bhattathiri, Associate Professor of Radiotherapy at the RCC, whose complaints regarding the drug trials set off the controversy.

tions Ted Poehler, Vice Provost for Research at the university, as saying that the arrangements for the "new start-up" had come with "unusual speed" and that there were "a number of parties, including Ang" who were very impressed with the work Huang and her team had done until then, and "how far they have been able to take it".

Significantly, *The Gazette Online* had also reported that businessman Ang knew Huang "both through family connections and through her reputation in Asia" and that he had decided to support the business because he believed in the programme and Huang. However, the stand of the JHU now, after the RCC trials set off a controversy, is that "the source of the funding for the trial remains a focus of its investigation".

According to RCC Director Dr. M. Krishnan Nair, Huang first approached his institution with the proposal to conduct clinical trials of the new chemicals in June 1998, much before the application for the patent was filed.

In a press statement issued on August 3, following the JHU's denial that it had authorised the clinical trials conducted at the RCC, the cancer centre's Finance Manager (Projects) K.R. Bhaskaran Nair said: "A section of the media has reported that the M4N clinical trials at the RCC were not funded by the Johns Hopkins University. The RCC denies this baseless news report. There is very clear documentary evidence that RCC had received funds from Johns Hopkins University for the clinical trials conducted under the leadership of Dr. Ru Chih Huang (Ordering bank: First Union National Bank, New York; Ordering customer: Johns Hopkins University, Baltimore). This statement is being issued to remove the wrong impression that people may have because of the news report."

Dr. Parvesh Parikh of the Tata Memorial Hospital, Mumbai, who constitutes the one-man commission appointed by the State government to inquire into the controversy, also said that he was in possession of documents that proved that funds had been sanctioned with the authorisation of JHU authorities and that the documents had been signed by the "treasurer" of the university.

After the signing of the letter of intent on June 27, 2000, a few months after the first trials for M4N and G4N (the latter not mentioned in the JHU statements) chemicals were conducted, did Dr. Huang go ahead with the project on her own, without the knowledge of her university, as the JHU statements indicate? Did she obtain funding from sources other than Ang Tiong Loi? If the RCC was to receive only Rs.25 lakhs a year for coordinating the trials in its clinic and in three other hospitals in India, who funded the study at the JHU laboratories until then? Where did the rest of the $2 million from 'Biocure Medical, Minnesota' go?

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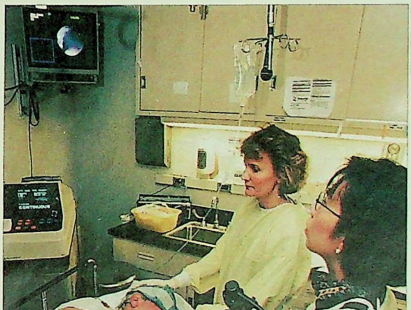
Dr. Parvesh Parikh of the Tata Memorial Hospital, Mumbai (right), who constitutes the one-man inquiry commission appointed by the State government, at a hearing in Thiruvananthapuram.

These are a few of the gaps in the Hopkins-RCC jigsaw puzzle, which remain to be filled by the JHU inquiry. It is unusual that the study by Huang did not attract attention within the JHU because she was a Biology Professor at the university's Krieger School of Arts and Sciences, where hardly any drug research is done. Moreover, she is a non-medical scientist who tested the experimental anti-cancer chemicals earlier only in mice and, ever since the controversy erupted, has been asked by the JHU not to take part in any other human trials. The JHU also asked Huang to cease all activities regarding her current work and stick to basic research in her laboratory.

The gaps in the jigsaw assumed a serious dimension on August 10 when counsel for one of the patients, who had earlier approached the Kerala State Human Rights Commission, produced "RCC documents" before the Dr. Parvesh Parikh inquiry commission. Counsel demanded that the death of two patients within less than 50 days of their participation in the trial in early 2000 was caused by the injections that they received. The relatives of a 60-year-old woman patient who was suffering from "terminal malignancy" told mediapersons, after they deposed before the commission, that the doctors had asked their willingness to include the patient in a new project of the contract research organisation (with which the JHU had signed an agreement in 1998) that would provide her free of cost five doses of the experimental drug, worth Rs.10,000. They said that the woman's condition had worsened before the fifth injection. Dr. Parikh said the commission would inquire into the deaths and go through the entire sequence of events relating to the trials. The commission is expected to submit its report in three weeks. Meanwhile, the inquiry ordered by the Central government is also progressing. ■



GIRI. BUNTONWAR

At the Johns Hopkins University, administering photo dynamic therapy to a cancer patient, a February 1998 picture.

The changing creed

In the global context of unethical practices in research involving human participants, the demand for strict monitoring and laws governing such work becomes more relevant everywhere.

R. KRISHNAKUMAR

THE most significant outcome of the Johns Hopkins-Regional Cancer Centre drug trial controversy could be an increase in public awareness in India about clinical trials and the effect of unseen, market-driven forces that threaten the safety of the patients involved and taunt the objectivity of investigators and the scientific integrity of drug trials.

Unlike in India, awareness about the extent to which academic research has become interlinked with the pharmaceutical and biotechnology industries and other commercial interests and the benefits and risks involved in such alliances is well-established in developed countries like the United States.

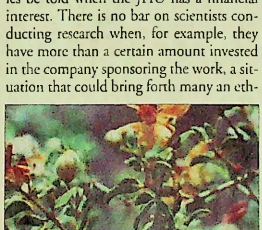
Daniel J. Kevles, Professor of History at Yale University (whose research interests include the interplay of science and society, history of modern biology and scientific fraud and misconduct) explained in an e-mail message to *Frontline*: "Since the 1970s in the U.S., the growth of biomedical research in academia has outpaced the growth of federal funding for its activities. University administrators have increasingly felt the need to turn to private, including industrial biotechnology, sources for support. For this reason, among others, they have fostered close relationships between biomedical firms and the laboratories on their campuses."

The most striking example for well-known academic-research institutions in the U.S. having such links with industry is perhaps the Johns Hopkins University (JHU) itself. Spurred by the fear of being left behind in the race for research funds and top-notch faculty and students, the institution, once dedicated to pure research, is now in the forefront of universities trying to forge partnerships with business.

After the cancellation of federal funds following the death of a "healthy volunteer" participating in an asthma study at the JHU on June 2, the university has remained in media focus with regard to the growing involvement of clinical investigators and research institutions with business. According to a report in *The Baltimore Sun*, the university had filed more patent applications in 1999 than all but two other major research centres in the U.S. Moreover, in recent years the JHU had helped launch 18 companies, and the volume of corporate-sponsored research at its medical school had nearly quadrupled in the last 10 years, the report said.

The point in *The Baltimore Sun* article is in its title – "The changing creed of Hopkins Science". It spoke of how the university's culture was being transformed as it embraced business opportunities, allowed its scientists to be consultants and paid scientific advisers to corporations and to own patents for discoveries developed in its laboratories using corporate funds. Significantly, it focusses on the risks that this new creed brings in its wake, "for the integrity of research, for the safety of patients participating in experiments and for the university's most valuable asset – its reputation".

The report quotes JHU officials as saying that the university's defence against bias in corporate-sponsored research is "disclosure" – the rule that volunteers in drug studies be told when the JHU has a financial interest. There is no bar on scientists conducting research when, for example, they have more than a certain amount invested in the company sponsoring the work, a situation that could bring forth many an ethical dilemma. "Instead, Hopkins officials say they 'manage' financial conflicts of interest by taking steps to discourage abuses – requiring scientists to place stock in escrow and to disclose to patients and publications their financial ties in drug trials," *The Baltimore Sun* report said. However, such a disclosure was conspicuous by its absence in the trial conducted on patients at the RCC by the JHU Biology Professor, Dr. Ru Chih C. Huang.



The creosote bush *Larrea tridentata*, from which the NDGA derivatives were originally isolated.

The JHU provides but one example of the conflicts of interest that face academic institutions in the developed world. Almost all the major universities today face the problem of having to rise above such conflicts of interest and yet are unable to resist the need to relax rules and to lend its name for almost purely commercial ventures. Recently, when the main academic "rival" of the JHU, Harvard University, thought aloud about relaxing its strict conflict-of-interest rules, there was a hue and cry in the U.S. It prompted *The New England Journal of Medicine*, widely regarded as one of medicine's most distinguished and influential journals, to write one of its best-known editorials – "Is Academic Medicine for Sale?" – urging Harvard to encourage other universities to adopt stronger conflict-of-interest guidelines instead of trying to soften its own rules.

All over the world one can find instances of commercial ties and financial requirements leading to unethical practices in research involving human participants, mainly to satisfy the market's need for speedy, cost-effective development of drugs and medical devices. This has also increased the demand for strict monitoring and laws regarding human research, especially in developed nations like the U.S.

On April 18, a U.S. presidential commission, the National Bioethics Advisory Commission, constituted to suggest ways to improve ethical conduct of international clinical trials, recommended a series of steps "to reduce the potential for exploitation of research participants in developing countries, ensuring that studies are responsive to the health needs of the country, and ensuring that post-trial access to successful research products are improved".

According to a press statement issued by the commission soon after its report was presented to President George Bush, its chairman (and president of Princeton University) Harold T. Shapiro said that the potential for exploitation of participants from developing countries by researchers and sponsors from prosperous countries "is cause for a concerted effort to ensure that

protections are in place for all persons participating in international research".

Significant in the context of the JHU-RCC drug trial controversy is the recommendation of the commission that efforts to enhance research collaboration must account for the capacity of the ethics review committee in developing countries to review research, and the need for U.S. researchers and sponsors to ensure that their research projects are conducted "according to ethical standards applied in the U.S".

The research collaborations are also to comply with some basic requirements for the protection of human research participants, such as prior review by ethics review committees, minimisation of risk and having a reasonable risk-benefit ratio, voluntary informed consent by each participant and an equitable distribution of the burdens and benefits of the research.

Prof. Kevles agreed that this was indeed a new area of conflict of interest – of comparative requirements of ethical research conducted in developed and developing countries. "Drug trials tend to be more strictly regulated, and thus more costly, in the U.S. than in developing countries. It is therefore tempting to conduct trials in the Third World," he said.

"THE Hopkins-RCC drug trial controversy is a wake-up call for India," said Dr. K. Mohandas, Director of the Sree Chitra Tirunal Institute for Medical Sciences and Technology. "India is an amalgam. We have the best of institutions and the worst. We have no uniformity of standards in our institutions and the regulatory mechanisms are not often very effective. But because of that we cannot keep away from doing clinical trials, because then we shall not be able to develop our own research and shall be completely sidelined by the rest of the world," he said.

Dr. C.R. Soman, chairman of the activist organisation Health Action by People, said that if the 'Ethical Guidelines for Biomedical Research on Human Subjects' formulated by the Indian Council of Medical Research's (ICMR) Central Ethics Committee on Human Research (CECHR) was accepted and adopted at least by the medical colleges in the country, India could be said to be truly ready for clinical trials. The ethics committee is headed by Justice M. N. Venkatachaliah, former Chief Justice of India.

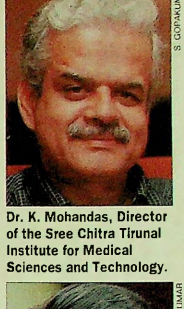
Dr. Soman said that along with the concerns raised about clinical research involving scientists from reputed academic institutions which have commercial ties, multinational pharmaceutical companies are flooding the Indian market with a spate of "new molecules", "a whole range of chemicals". "But the majority in the medical profession is supremely ignorant of this, and drug manufacturers get away with everything. The majority of the doctors are unaware of even the different phases of drug development, or the principles behind the requirement for informed consent," he said.

Dr. Soman said the situation was compounded by the emergence of contract research organisations, "sort of event managers", who took up contracts to organise clinical trials and provide related services from the pre-clinical stage to the marketing of the drug for the pharmaceutical companies. He said: "All they require of the general Indian physician is to dot the 'i's and cross the 't's, and the majority of doctors mechanically do it with no intellectual input from their part."

However, Dr. Soman said, this did not mean that all companies were engaged in such operations. He said that out of self-interest many of them might be meticulous in following ethical norms while conducting clinical trials or introducing drugs into the market. "But there are a lot of imposters."

Dr. Mohandas said: "We really don't know what exactly is happening in the country. We don't know whether testing of drugs or clinical Phase I and II research (to gather data on the safety and efficacy of a drug respectively) is taking place on a large scale even in institutions or clinics not equipped to conduct such experiments. In the absence of a mechanism for monitoring and supervising clinical trials, we do not know the magnitude of the problem. There was this instance when a banned drug, which was used for the treatment of malaria, was tried out as a method of sterilisation in women, and there was a major public campaign by some doctors and activists. It definitely is there, but how big is the problem, we don't know."

However, cardiologist Dr. G. Vijayaraghavan, formerly of Kuwait University, cautioned that it should not be argued that clinical trials conducted on human beings should be stopped forthwith.



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Dr. K. Mohandas, Director of the Sree Chitra Tirunal Institute for Medical Sciences and Technology.

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Dr. C.R. Soman, chairman of the activist organisation Health Action by People.

"What we need to consider is the reason why, despite the widespread conduct of clinical trials all over the developed world, there is not much room left for complaints there," he said. "The answer lies in building up and strengthening institutional checks and balances. Unlike the happenings at the RCC, there are any number of examples of faults and ethical pitfalls in clinical trials being detected effectively by institutional review boards or other monitoring agencies sufficiently early and of even drugs or trials being withdrawn without affecting the faith that a patient has in his physicians," Dr. Vijayaraghavan said.

He added: "Monitoring has to be strengthened at the institutional level based on the well-laid-out principles enunciated in the Helsinki Declaration, the guidelines issued jointly by the Council for International Organisation of Medical Sciences and the World Health Organisation, the ICMR guidelines and so on. Each institution has to establish clear principles to evaluate research on human subjects and specific measures to protect human subjects from possible harm."

Already, according to Dr. Mohandas, there are moves in the right direction. The ICMR is planning to set up training centres in several parts of the country to provide support to institutions and professionals on the ethical issues involved in human research. International workshops are also being organised at the Sree Chitra Tirunal Institute and three universities – in South Africa, Mexico and in the U.S. at Harvard – on ethical guidelines in health research with special reference to international research. The seminar held in Sree Chitra had participants from 15 countries, the majority of them from the Third World. Dr. Vijayaraghavan said: "As long as institutions learn to insist and ensure meticulously that ethical safety guidelines are followed, developing countries like India need not be afraid of international collaborations in human research, pharmaceutical companies or contract research organisations."

Claims and contradictions

There are several unsettled questions that remain at the Johns Hopkins end and the Indian end with regard to the procedural and other aspects involved in the drug trials.

R. RAMACHANDRAN
in New Delhi

THERE are further twists to the controversial anti-cancer drug trials at the Regional Cancer Centre, Thiruvananthapuram, and the business links associated with the Johns Jopkins University's (JHU) joint study with the RCC.

The purpose of the study was to prove in cancer cells the activity that was discovered by the JHU Biology Professor, Dr. Ru Chih C. Huang, and her associates in viruses. The objective was to prove in human trials the inhibition of growth in tumour cells that the JHU team had observed in studies conducted in animals.

Dennis O'Shea, JHU spokesperson, claimed that the university had never "directly" funded the study. However, his claim was contested by the RCC project leader, Dr. Manoj Pandey. According to Pandey, the RCC had received two cheques, signed by JHU treasurer William E. Snow Jr. worth $19,400 and was awaiting the third. Dr. M. Krishnan Nair, RCC Director, is also reported to have stated in March that the project is funded by the JHU. He said that the RCC was to receive Rs.25 lakhs and the amount could later be increased to Rs.1.25 crores. Interestingly, Pandey claimed that the JHU received permission from the U.S. government to import the tissue of Indian cancer patients for study.

O'Shea told the journal *Science*: "I am not saying we know where these funds came from. Just because Johns Hopkins cuts a cheque it does not necessarily mean that it approved the project being funded. Making sense of the financial transactions is a task for the new investigative panel."

O'Shea's remark that the study was not directly funded by the JHU assumes significance in the light of Huang's comments to *Science*. She told *Science* that the funding for the project came entirely from private sources, including the JHU and a Minnesota-based company, Biocure Medical LLC. The company was set up with the objective of designing and conducting clinical trials of compounds derived from nor-dihydro-guaiaretic acid (NDGA).

According to Huang, the supporters of the project have committed about $2.5 million to conduct pilot trials in four places in Asia. Dr. Krishnan Nair had stated that Phase II trials were also to be carried out at, besides RCC, the K.J. Hospital, Kanpur, and the Banaras Hindu University, Varanasi, under the RCC's supervision.

The catch was that let alone the Food and Drug Administration of the U.S., even the JHU's Institutional Review Board (IRB) had not approved the trial although Huang had submitted the protocol for the clinical trials to the IRB early this year. More pertinently, according to a press release issued by the Press Information Bureau (PIB) on behalf of the Union Health Ministry in the wake of the controversy, the approval by the Drug Controller General of India (DCGI) seems to have been granted only in February this year, months after the experiments were conducted.

The PIB press release said that the RCC was granted permission on February 2, 2001, to import M4N (tetra-O-methyl nor-dihydro-guaiaretic acid) from the JHU to undertake a study to evaluate its efficacy in advanced oral and cervical malignancies on the basis of pre-clinical and other relevant data submitted by the RCC Director.

"It is not a retrospective sanction. The proposal came to us only then. We do not know if the trials had been going on earlier," said S. Ramteke, Depury DCGI. On the other hand, Dr. Krishnan Nair had claimed that the initial application for the trial had been submitted to the DCGI on September 12, 1998, and the Ethics Committee of the RCC had granted its permission for the conduct of the study on November 10, 1999. Meanwhile, according to Dr. Krishnan Nair, discussions were held with the DCGI and, based on his verbal consent, the study was commenced.

The DCGI refused to comment on Dr. Krishnan Nair's claim and said that a central committee had been constituted to investigate the issue. When asked about

A demonstration near the Regional Cancer Centre, organised by the 'RCC Protection Forum'.

the granting of sanction after two years of trials, DCGI Ashwini Kumar said: "Clinical trials of new molecules, experimental drugs and so on are new to our country. The systems are still evolving. We shall know whether the trials had been going on since 1999 only after the investigating team submits its report."

Meanwhile, the three-member team constituted by the Union Health Minister to inquire into the controversy was in Thiruvananthapuram waiting for Dr. Pandey to return from the U.S. The committee was expected to submit its report by August 16.

The normal procedure for obtaining approval for clinical trials (Phase I, II and III) is to submit the toxicological data collected from animal experiments to the DCGI. The toxicological data are sent by the DCGI to the Indian Council of Medical Research's (ICMR) Toxicology Committee for evaluation and, if found to be safe, the DCGI gives sanction for Phase I trials.

However, Ranjit Roy Choudhury, chairman of the ICMR Toxicology Committee, said the committee had not received any proposal from the RCC for trials or any data regarding the proposed trials. He added that of late the DCGI did not refer all cases to the committee. Choudhury said that with many new drugs coming into the market, imported and otherwise, the DCGI had begun to refer the data to its expert committee or a chosen set of experts rather than to the ICMR committee.

Regulations with regard to Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Standard Operating Procedures (SOP) are still in the draft stage. However, N.K. Ganguly, Director General of the ICMR, said that the basic regulations governing clinical trials were put in place by the Drugs and Cosmetics Act, 1940 and several clinical trials on new drugs and molecules had been carried out in India in conformity with the Act. Moreover, the ICMR had brought out a base document on Ethical Guidelines for Biomedical Research on Human Subjects in September 2000.

The ICMR document makes clear the legal provision for clinical trials: "The proposed trial should be carried out only after the approval of the DCGI as is necessary under Schedule Y of the Drugs and Cosmetics Act. The investigator should also get the approval of the Ethics Committee of the institution before submitting the proposal to the DCGI. All the guiding principles should be followed irrespective of whether the drug has been developed in this country or abroad or whether clinical trials have been carried out outside India or not."

The DCGI is being evasive when he tries to make a distinction between an experimental drug for a research project and a new drug and says that the regulations for experimental studies do not exist. The Drugs and Cosmetics Act is clear on the definition of a new drug as part of the Rules framed under the Act and it includes any new chemical entity (NCE). Schedule Y of the Act states: "For new drug substances discovered in other countries, Phase I trials [the kind being carried out at the RCC] are not usually allowed to be initiated in India unless Phase I data from other countries are available. However, such trials may be permitted in the absence of Phase I data from other countries if the drug is of special relevance to the health problems of India." Since even Phase I data from the U.S. were not available, on what basis did the DCGI give its approval in February 2001?

According to informed sources in the ICMR, the RCC had applied for a financial grant for the study from the ICMR during 1998-99. The ICMR raised some objections about the proposal and rejected the application. The exact grounds on which the proposal was rejected are not known, according to them. Four and a half years ago, the ICMR had rejected an application for financial grant to conduct a study on foetal tissue transplantation in patients of retinitis pigmentosa under an India-U.S. collaborative research programme at the L.V. Prasad Eye Institute, Hyderabad. The application was rejected on the grounds that undertaking such clinical trials on Indian subjects for an experimental procedure, which were not done on U.S. subjects, was not ethical and hence not acceptable.

In a statement issued then, the ICMR said: "The ICMR stands by the decision unless documentary evidence is provided by the principal investigator that the conduct of such experiments in human beings will be done (or has already been done) on subjects of both countries collaborating in the project, the proposal cannot be considered ethical." Hence, the ICMR may have turned down the RCC's request for financial support because in the RCC-JHU drug trial case too no parallel studies on U.S. subjects were proposed to be done. ■

The misuse of science: Column by Praful Bidwai – Page 96

Dr. M.S. Valiathan, now Honorary Adviser to and formerly Vice-Chancellor of the Manipal Academy of Higher Education (MAHE), was for 20 years Professor of Cardiac Surgery and simultaneously Director of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, the premier institution under the Department of Science and Technology, Government of India. It was under his directorship that one of the earliest institutional ethics committees in the country, with a retired High Court Judge as its chairman, was established at the Sree Chitra Tirunal Institute. The institute needed to ensure strict ethical compliance in order to be commercially successful when it became the first such institution in India to engage in the development of biomaterials and medical devices including the Chitra heart valve. In an e-mail interview he gave **R. Krishnakumar**, Dr. Valiathan spoke about the various aspects of clinical trials in the context of the RCC-Hopkins drug trial controversy. Excerpts:

▶ *Is India really ready for clinical trials?*

Whether India is ready for clinical trials is a vague question. Many institutions are ready and have, in fact, been conducting clinical trials quite well and as per international norms. For example, domiciliary treatment of tuberculosis at TRC (Tuberculosis Research Centre), Chennai. Readiness must be assessed for institutions, not countries.

▶ *Do you think that India is increasingly becoming a favoured destination for human trials? What are the reasons for this?*

Yes, the developing world including India is becoming a favoured destination for clinical trials. You may recall the recent U.S. House legislation which puts restraints on U.S. drug firms conducting clinical trials in the developing countries. The reasons for the popularity of the developing world are the following:

(a) Large population (b) Low cost (c) Legislative vacuum or infirmities (d) Ignorance about the legal and ethical issues of human trials among the public and even health care professionals and (e) Craze among the developing countries to link up with

'Clinical trials should promote health care'

Interview with Dr. M.S. Valiathan.

Western institutions unthinkingly and at any cost.

► *What do you think is a more serious problem today in India – unethical practices involving the kind of first-time trials of chemicals in human beings (as it happened at the RCC) or trials of new or me-too drugs by pharmaceutical companies? Is the latter a pardonable offence?*

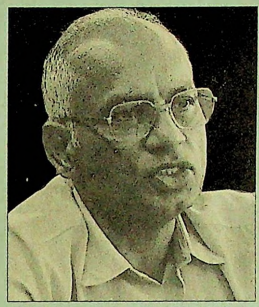
A serious problem arises when medical investigators and companies go about clinical trials without paying the slightest attention to the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council for Medical Research (ICMR). The ICMR document emerged through the effort of the Justice Venkatachaliah Committee which held extensive consultations at the national level. I cannot understand why this document is ignored by investigators and companies. Between the rules of the Drugs Controller General (India) and the ICMR guidelines, the issues of the trial of new chemical entities and that of me-too drugs are fully covered.

► *Cannot Indian institutions, researchers and doctors say no to unethical trials and still "survive"? What do you think are the incentives that make institutions agree to unethical practices?*

Indian institutions can certainly survive the refusal to take part in unethical trials. The reasons for institutions adopting unethical conduct are no different from those which tempt individuals to become corrupt.

► *Is there a general lack of awareness among Indian medical professionals about ethical requirements? How effective are Indian guidelines and laws?*

Yes, there is a serious lack of awareness of ethical guidelines among health care professionals – not doctors alone, administrators, politicians, media, etc. Apart from the ICMR guidelines, the DBT (Department of Biotechnology) has set up a separate set of admirable guidelines on human genome research which is in its infancy in India. Therefore, one cannot claim that we have no guidelines. Of course, guidelines are not laws, but legislation on the basis of guidelines will emerge soon. However, it is a fact that in practice the



BY SPECIAL ARRANGEMENT

guidelines are not often observed. This is no more than another illustration of our scant regard for laws and guidelines in India.

► *Is getting "informed consent" a difficult task in the case of a majority of patients here? What has been your experience? In that case should such people be made "participants" in drug trials at all? Is getting "volunteers" a difficult task here?*

It is not difficult to get informed consent – on the basis of my Kerala experience. It is true that when patients are illiterate and uneducated (not the same thing) and look upon doctors as gods, informed consent would become difficult. Getting volunteers by giving financial incentives is, of course, unethical. Ultimately, the inclusion criteria for subjects, including their ability to give informed consent, should be determined by the principal investigator and his colleagues. Incidentally, the rights of the subjects in a trial are spelt out in the ICMR guidelines.

► *There is a new breed of contract research organisations which act as a sort of "event managers" for the drug companies, organising clinical trials. Do you think they are good or bad for the Indian scene?*

Clinical trials are essential for making progress on many fronts – drugs, devices, vaccines, diagnostic kits, etc. If the trials are restricted too rigidly, there would be little scope for innovation; if unrestricted, there would be chaos and human exploitation. One has to adopt the middle path by sticking to the national guidelines and keeping oneself posted on what is happening in biomedical research at the international level. The human trial should be planned on the basis of an MoU (Memorandum of Understanding) between the firm which developed the product and the medical institution, which would obviously take the approval of its own ethics committee and other approvals as necessary. There is no place for third parties or middlemen in this exercise.

► *What should the country be cautious about and what needs to be done at the practical level when trials involve researchers and resources from developed countries and multinational companies? Are Indian companies and research institutions comparatively better in the matter of sticking to ethical rules?*

As I mentioned earlier, clinical trials are necessary insofar as they promote the interests of health care. The problem is a mismatch between the interests of the group which developed the product and those evaluating it in human subjects. Firms in India and abroad who spend millions on developing products would want to maximise profits; ethics in business is a controversial subject. On the other hand, the evaluating institutions need money and must also protect the interests of patients and subjects. Medical investigators who are approached to take up

clinical trials therefore face serious ethical dilemmas. This is true as much in the affluent countries as it is in India. In the last few years, this issue has become pressing because medical investigators have themselves promoted firms. It is now mandatory for authors of papers for top journals to indicate any direct or indirect links they may have with the firms/industry where the product/process being reported on were developed. In fact, the affiliation is published with the paper.

Lastly, it is no use blaming institutions and firms in affluent countries for exploiting us. We are grown up and should look after our own interests. If we are upright and do a thorough job no one stops us in this and all would be well.

DR-1.

DRUG POLICY
OF
THE NATIONAL CAPITAL TERRITORY
OF
DELHI

The Govt. of National Capital Territory of Delhi
APRIL 1994

Drug Policy of the State of Delhi

A comprehensive statement of the drug policy of the state of Delhi is necessary at this stage in order to provide a strong framework within which the different components would be implemented in the coming years. Such a policy statement would also clearly enunciate the social and economic goals, based on equity and care for the underprivileged, which are sought to be attained through this drugs policy.

The main elements of the policy are the following:

1) All the essential drugs needed for health care should be available at all times at all the health facilities of the state. These drugs should be safe, effective and of good quality.

2) The facilities and manpower needed for providing a good and continuing quality control and assurance system for the drugs being used will be strengthened.

3) The system for procurement, storage and distribution of drugs will be modified to ensure that drugs of good quality, obtained at competitive prices, are always available at the health units.

4) Rational use of drugs will be promoted. Rational use is the use of the most appropriate drug prescribed at the correct dose for the correct length of time. Medicines will be prescribed and ensuring as far as is possible that appropriate drugs only are prescribed will.

5) Doctors at all public health facilities will be encouraged to prescribe drugs by their generic names. Procurement of drugs will also be by generic names.

6) There will be a strengthening of the health education programmes of the government specially relating to drugs. This would promote rational use of drugs and enhance compliance. There would also be an acceleration of the continuing education programmes for doctors and paraprofessional personnel in the field of drugs. This would include establishment of a Drug Information Centre and development of links with non-governmental organization.

7) Research on all aspects of use of drugs will be an integral part of the drug policy in the state so that these results would be continuously utilized to modify the different components of the programme for the benefit of the people. It is important, for example, to collect information as to what is happening at this time. A survey will be carried out by the best available professional consultancies available to understand the strengths and weaknesses of the present system. As each new mechanism will be introduced studies will be initiated to document the impact of such interventions.

It is important to emphasize that all these seven components of the drug policy for the state need to be implemented if the results are to be effective and make an impact:

1) Availability of safe and effective Drugs

2) A Good Quality Control and Assurance System

3) Improved procurement, storage and distribution System

4) Rational Prescribing of Medicines

5) Prescribing by Generic Names

6) Strengthening of Health Education Programmes

7) Research on All Aspects of Drug use

It is the objective of the policy that a limited list of carefully selected drugs will always be available at all health centres and hospitals of the state. These medicines would be procured at reasonable prices thus enabling the drug budget to be used for a much large number of persons then is now available. These drugs would be of good quality and there would be a good are being taken, are of good quality, safe and effective. The prescribing of the drugs would be based on rational pharmacological and therapeutic knowledge and the patients would also be aware of the medicines they are getting and thereby actually take the medicines in the way they should be taken. Information about these essential medicines would also be available to the doctors and paraprofessional staff. Wherever justified additional complementary medicines not on the essential list of drug would be provided through a mechanism established for this purpose. Each hospital, if it so desires could order drugs not on the common list of essential drugs but not more than 10% of the budget spent on drugs.

Steps Being Taken by the Government of Delhi to Implement the New Policy

A series of steps are being taken to implement the drug policy of the state as described above. These are detailed below:

1) Selection of a list of essential drugs

The cornerstone of the drug policy is the selection of a limited number of medicines to be used throughout the state. A list of drugs to be used at the primary health care level and different levels of the health care system is being prepared. Different lists have been prepared for the Outpatients and Inpatients at hospitals. This list will be prepared every year by a Special Committee consisting of eminent experts from the different hospitals in the state and other leading specialists.

2) Pooled procurement of drug for all hospitals in Delhi State-Establishment of a Central Drug Procurement, Storage and Distribution Centre.

Only those drugs on the list of drugs prepared will be procured by a centralized procurement unit which will invite tenders and order the medicines for all hospitals and medical facilities in the state of Delhi. The present practice of every hospital ordering its own drugs will be phased out. All ordering will be carried out by the Central Procurement, storage and Distribution Centre to be established. In the first phase a rate contract will be prepared for the different drugs to be ordered. This will be done by floating tenders and selecting suppliers based on strict criteria such as whether these are actual manufacturers of the medicines, past performance, quality of drugs and prices. This rate contract will be supplied to all hospitals who could then order only from this rate contract. In the next phase the drugs for all hospitals will be ordered centrally

but the medicines will be delivered to the hospitals directly. Finally in the third phase when a computerized procurement, storage and distribution centre has been established all drugs will be ordered by the Centre, stored there and distributed to the different hospitals in the state. The geographical entity of the state of Delhi is such that this is possible and feasible. Modern techniques of drug storage and inventory control will be introduced so that the central unit is aware at any time of the different drugs available at the different hospitals and health care facilities. This would ensure that drugs would not pass their expiry dates and that any imbalances such as shortage of a particular drug at one hospital and unused stocks at another would be identified and corrective measures taken well in time. Checks and counterchecks, such as computerized inventory systems, modern accounting procedures, and surprise checks will be initiated to ensure that losses due to illegitimate activity is kept down to the bare minimum. Training of pharmacists in stores management and improvements in monitoring systems will from an integral part of the system.

3. Preparation of a formulary

To ensure proper and rational use of drugs which in turn would decrease the unnecessary expenditure spent today on medicines a Delhi State Formulary will be prepared. This would provide uptodate information about drugs which are included in the Essential List of Drugs for the state. This formulary would be made available free of cost to all doctors, pharmacists and paraprofessionals in the health field working at state health units. It has been the experience that preparation and use of formularies in different countries have reduced the expenditure on drugs by about fifteen to twenty percent. This formulary would be prepared by a Formulary Committee set up by the State of Delhi and will be updated every year in accordance with the updating of the list of essential drugs. This formulary will consist of information which will help the doctor in prescribing drugs – such as therapeutic indications, contraindications, interactions and side effects associated with each drug.

In addition to the Delhi State Formulary a small pocket book containing names and doses of drugs in the essential list will be printed and provided to all doctors, pharmacists and nurses. This will help them to prescribe and provide drugs only from this list.

4. Quality assurance

The State Drug Control Authority will be considerably augmented and strengthened so that drugs reaching the patient are safe, effective and meet approved specifications and standards. The quality control and assurance system will include managerial, technical and legal aspects. Some of the activities will be (a) strenghening of the Drug Inspectorate Unit (b) strengthening the Quality Control Laboratory and (c) establishing an efficient system for withdrawal from circulation of products which have been found to be below the standard required.

5. Training in Rational use of Drugs

To make certain that the drugs on the test are prescribed will a series of workshops on rational use of drugs would be held throughout the state for all categories of persons involved in prescribing drugs. This will be carried out in collaboration with the staff of medical, nursing and pharmacy institutions in Delhi and organizations such as the medical and pharmacy associations. The government will help in any way it can to implement and strengthen ongoing programmes aimed to introduce the concept of essential drugs in the medical and nursing curriculi so that emerging graduates of the future possess more sensitivity towards rational prescribing than is present at the moment. Much of this training will be imparted while working at the hospitals and health centres in Delhi State.

6. Drug Information

The aim of the policy is to see that practical unbiased information on rational use of drugs and on handling of drugs is provided to all health workers at all levels. Appropriate information will be provided to traditional medical practitioners, retailers, patients and the general public. All available techniques available for such communication using the print, electronic and even, where appropriate, the traditional folk media would be used. Training programmes, workshops, lectures and discussions for different groups of persons would be held. For specialized information on different aspects of drugs it is proposed, in collaboration with the National Informatics Centre and the Delhi Medical Association, to set up a computerized Drug Information Centre. In due course a Delhi State Drug Information Letter will be published. This will contain objective, up-to-date, information about drugs and will be widely circulated.

7. Preparation of Standard Treatment Schedules

In an effort to rationalize prescribing, reduce cost and prevent loss of medicines it is proposed to prepare Standard Treatment Schedules for those drugs being used at the primary health centres and at the Outpatients Departments of hospitals. It would be one more step like the preparation of a list of essential drugs, establishing combined pool procurement, development of a formulary and centralized monitoring of medicines, which would help in using a limited budget for drugs for the maximum number of persons without reducing, in any way, the standard of health care delivered.

8. Drug Advertising and Promotion

Ethical criteria for drug promotion and advertising will be established for the State of Delhi along the lines of such ethical criteria developed by the World health Organisation. Drug promotional activities not in accordance with the law or with such criteria will not be permitted in the state. This will help

to protect the public from being exploited.

9. Research

The type of research will be carried out will be, initially surveys which will enable a picture to be drawn as to what is happening today e.g. how much the expenditure is on the four major groups of high-use drugs like antibiotics, how many people actually are provided medicines, how many people are asked to purchase medicines outside, what kind of medicines and other similar issues. Later, as interventions are introduced the effect of these interventions will be documented. Other studies on drug utilization and on behavioural aspects of patients and the public relating to use of drugs will also be carried out as also studies on drug economics. This type of research – health systems research – will enable the results to be used to modify programmes thereby utilizing such research for the benefit of the people.

10. Monitoring and evaluation

Monitoring and evaluation of the policy and its implementation will be carried out by establishing a monitoring and evaluation mechanism at the Ministry of Health. This unit will study performance in relation to projected activities. Three standing committees would be established; for Selection of Drugs, for Drug Procurement and Stores Management, and for preparing the formulary.

DR-1.

CRITERIA FOR SELECTION OF MANUFACTURES FOR SUPPLY OF MEDICINES TO THE GOVT. OF NCT OF DELHI

1. The manufacturer should have a valid license under the Drugs and Cosmetics Act for Medicines that he intends to tender for supplies.

2. The manufacturer should have a turnover of not less than Rs. 8 crores.

3. The firm should be found satisfactory after inspection by especially approved inspectors.

4. The inspectors selected to assess and audit the manufactures' compliance with Good Manufacturing Practices should be persons with a high degree of competence and credibility from outside the Government.

5. In the interim period, suppliers already on the list would be allowed to continue supplies but if found unsatisfactory during GMP Inspection, their names were to be removed from the list.

6. Random samples picked up by inspectors should conform to approved standards when tested by one of the specially selected testing laboratories.

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GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI

GMP Inspection Form

Part I

(To be filled by the inspecting GMP experts)

1 Names of the inspecting GMP experts :

a) .....

b) .....

2 Dates of inspection : : .....

Part II: Information to be furnished by the unit to be inspected

Any documents attached must be appropriately cross-indexed or identified by the firm. All pages of this part including any attached documents should be signed by firm's representative and handed over to the inspecting GMP experts.

1 Name of the firm : .....

2 Address of the firm's office : .....
(for correspondence purposes) .....
.....
.....

3 Address of the firm's unit or : .....
factory to be inspected .....
.....
.....

4 (a) Name of the contact person : .....

(b) Telephone No. (Off.) : .....
(c) Telephone No. (Res.) : .....
(d) Fax No. : .....
(e) e-mail : .....

5.	(a) Does the firm have any other additional unit manufacturing items mentioned in the R/C or their application	:	Yes/No
	(b) If yes, give address(es) of such other unit(s)	:	....
6.	Year of establishment	:	.....
7.	Annual turn over of the Company	:	.....
8.	(a) Licencing authority (LA) under the Drugs & Cosmetics Act	:	.....
	(b) Licence No(s)	:	.....
	(c) Valid upto	:	.....
9.	Plan of premises at the time of granting licence by LA (Attach line sketches/blue prints and mark clearly the areas allocated for various functions)		.....
10.	(a) Any changes made since the last approval by LA	:	Yes/No
	(b) If yes, give details (Attach additional sheets, if necessary)		
11.	(a) Total land available for the unit to be inspected.	:	.....
	(b) Total area utilized for administration, utilities/facilities, production and quality control	:	.....

(c) Manufacturing areas allocated to various sections :

i) Tablets : .....

ii) Capsules : .....

iii) Oral Liquids :

iv) Oral Powders : .....

v) Injectable preparations : .....

vi) Ophthalmic preparations : .....

vii) Any other dosage form : .....
(If yes, name the category) :

viii) Bulk Drugs : .....
(If yes, name the products) :

d) Is factory centrally air-conditioned: Yes/No

e) If no, indicate areas air-conditioned. Also show clearly in plans attached against items 9 and 10. : .....

12. Products with formulae permitted to be manufactured (list to be attached by the firm) : .....
.....
.....

13. Organisational chart of the firm (Attach separate sheet, if necessary) : .....

14. (a) Total number of employees : Male : .....
Female : .....

(b) Total number of technical personnel : Male : .....
Female : .....

15. Name, qualifications and experience of the head of the Production Deptt. : .....

16. Name, qualifications and experience of the head of the Quality Assurance Department : .....

17. Name, qualifications and experience of the head of the R&D Deptt. : .....

18. Department- or section-wise list of technical personnel engaged in manufacturing/maintenance/quality control functions (Attach list indicating the qualifications, experience and department/section in which working. Also indicate the names of the personnel approved, if any, by the LA) : .....

19. Does a Quality Policy exist in the Company ? If so, attach copy : .....

20. List of Standard Operating Procedures (SOPs) followed in the company. (Use separate sheets, if necessary) : .....

21. List of documents maintained by the Co. in support of GMP compliance. (Use separate sheets, if necessary) : .....

.....
(Signature of the person submitting the information on behalf of the company)

Name .....

Designation .....

Date .....

GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI

GMP Inspection Form

Part III

Observations of the GMP Experts

(Record your observations in brief against each parameter. If space is inadequate, please attach separate sheet and cross-link it suitably.

		Observations
1.	**Location and environment:**	
1.1	Any source of pollution in the neighbourhood ?	Yes/No
1.2	Any open drain, or public lavatory nearby ?	Yes/No.
1.3	Are any products other than drugs manufactured in the same or adjacent building and are these safe ?	Yes/No.
2.	**Factory premises:**	
2.1	Layout and construction	
2.1.1	Are materials of construction satisfactory ?	Yes/No

Observations

2.1.2 Are buildings and facilities/ utilities properly located and constructed for smooth operations and maintenance? Yes/No

2.1.3 Do adequate measures exist to check entry of rodents, insects and birds ? Yes/No

2.1.4 Are lighting and ventilation adequate ? Yes/No

2.2 Adequacy of space:

Are sufficiently large and suitably equipped areas available for:

2.2.1 Receiving and despatching of goods Yes/No

2.2.1.1 Is a separate dispensing area provided ? Yes/No

2.2.2 Storage of raw materials (RMs) Yes/No

2.2.3 Storage of packaging materials (PMs) Yes/No

Observations

2.2.4 Storage of intermediates or semi-finished products — Yes/No

2.2.5 Storage of finished products (FPs) before transfer to main warehouse and distribution — Yes/No

2.2.6 Manufacturing operations for which the firm is licenced ? — Yes/No

2.3 Cleanliness and maintenance

2.3.1 Are floors, walls and ceilings properly constructed and easy to clean, maintain and disinfect ? — Yes/No

2.3.2 Are sewage, trash and other effluents disposed off properly ? — Yes/No

2.3.3 Are areas where penicillin, Cepha or penicilin- or Cepha-based products are manufactured completely separated from areas used for manufacture of other products ? — Yes/No

Observations

2.4 Facilities and utilities:

2.4.1 Are air handling units adequate and properly located and functional ? Yes/No

2.4.2 Is air conditioning system adequate and functional ? Yes/No

2.4.3 Are steam generation facilities adequate and functional ? Yes/No

2.4.4 Is vacuum system adequate and functional ? Yes/No

2.4.5. Is compressed air system adequate and properly functioning ? Yes/No

2.4.6 Is water supply system alright ? Yes/No

2.4.7 Is distilled water quality and supply system alright ? Yes/No

		Observations
2.4.8	Is demineralised water supply system alright ?	Yes/No
2.4.9	Is standby electrical generation provided ?	Yes/No
2.4.10	Are SOPs in existence for regulation of the above actitvities ?	Yes/No
3.	**Personnel:**	
3.1	Are the technical personnel responsible for manufacturing and quality assurance functions adequate in numbers ?	Yes/No
3.2	Does the staff in the above operations have adequate qualifications and experience ?	Yes/No
4.	**Training:**	
4.1	Is personnel engaged in manufacturing, quality assurance, warehousing, cleanliness and maintenance operations periodically trained in accordance with needs ?	Yes/No
4.2	If yes, are any SOPs for training in existence ?	Yes/No

		Observations
4.3	Was documentation in support of such training available for inspection ? If yes, record your observations.	Yes/No
5	**Hygiene and health:**	
5.1	Are medical check ups conducted:	
	(a) on entry of personnel	Yes/No
	(b)periodically thereafter	Yes/No
5.2	Are facilities for changing street clothes, footwear, washing and toilets adequate and satisfactorily maintained	Yes/No
5.3	Are protective steps against likely damage to health due to occupational hazards satisfactory ?	Yes/No
6.	**Technical equipment:**	
6.1	Is equipment for each section adequate ? Please record observations for each section.	Yes/No
	(i)	Yes/No
	(ii)	Yes/No

		Observations
6.2	Are equipments installed in a manner that corrosion is avoided ?	Yes/No
6.3	Are the equipments maintained in a manner that contamination with lubricants, dirt, etc is avoided ?	Yes/No
6.4	Are records of setting up, maintenance and calibration of equipment kept and available for inspection ? If yes, comment on their adequacy	Yes/No
6.5	Are weighing balances appropriate to the quantities to be weighed ?	Yes/No
6.6	Are cleaning SOPs in existence and followed ? Check logs	Yes/No
6.7	Are sequential records of manufactured batches on an equipment available ?	Yes/No
6.8	Are procedures for line clearance for product change over adequate ?	Yes/No

		Observations
6.9	Is equipment status in terms of 'CLEAN', 'IN USE', 'TO BE CLEANED' properly indicated and relevant details of the product, its batch No. etc. noted on the equipment during manufacturing operations ?	Yes/No
7	**Production or manufacturing:**	
7.1	Is master formula (MF) available for each product ?	Yes/No
7.2	Does the MF for each product contain the required details ?	Yes/No
7.3	Is production carried out in accordance with the instructions ?	Yes/No
7.4	Are batch production records (BPRs) maintained in accordance with the MF ?	Yes/No
7.5	Is each step of manufacture duly signed/initialled by the operator and the supervisor in token of compliance with proper 'DOER-CHECKER' drill for manufacturing controls ?	Yes/No

		Observations
7.6	Are alterations to processes recorded and authenticated by competent authorised persons ?	Yes/No
7.7	Do all containers of active RMs, excipients and intermediates bear appropriate labels at all stages of manufacture ? If no, give details	Yes/No
7.8	Are only materials, containers and appliances necessary for the job in hand stored in the vicinity of the manufacturing areas and are these properly labelled with name of the product, batch No., dates, etc ?	Yes/No
7.9	Are containers checked for cleanliness and suitability for packaging before use ?	Yes/No
7.10	Are containers of intermediates and FPs intended for use in the plant or for transport outside closed in such a manner that unauthorised interference is not possible (eg. by sealing, etc.)	Yes/No

		Observations
7.11	Are empty containers freed of old labels and checked immediately prior to use ?	Yes/No
7.12	Do all apparatus/equipment bear appropriate labels to identify the product for which the equipment is used, its batch No , date etc. ?	Yes/No
7.13	Are RMs, PMs and solvents used after approval by the QC Department ? If no, give details	Yes/No
7.14	Are labels on containers of RMs to be used in manufacture checked with regard to identity, quantity and QA approval ? If no, give details	Yes/No
7.15	Are all volume and weight measurements checked by a second person before use ? If no, give details	Yes/No
7.16	Is stage of manufacture clearly indicated on containers ?	Yes/No

		Observations
7.17	Are working instructions available at place of work ? If no, give details	Yes/No
7.18	Do the manufacturing records contain all relevant particulars like :	Yes/No
	a) Batch No. :	
	b) Date of manufacture :	
	c) Names of persons directly responsible for operation and supervision :	
	d) Details regarding apparatus used (eg. eqpt. No., etc) :	
	e) Batch size :	
	f) Yield by weight/volume :	
	g) Percentage of theoretical yield :	
	h) Reasons for abnormal variations, if any	
	i) List of RMs, PMs used with their weights/volumes/quantities and analytical reports under which approved by QA. :	
	j) Description of work carried out	

Observations

k) Details regarding in-process QC checks :

l) Details regarding Quality Assurance approval of FP :

m) Certificate by QA or other authorised person to the effect that everything concerning the batch is in accordance with GMP requirements. :

7.19 Is batch integrity maintained during

a) manufacture : Yes/No

b) packaging : Yes/No

c) stocking : Yes/No

7.20 Is there a system of identification and segregation of rejected batches ? Give details Yes/No

7.21 Is reworking of rejected lots properly documented ? If yes, comment on the same Yes/No

7.22 Is tamper-evident sealing of the finished product done ? Yes/No

		Observations
7.23	Is inert gas used in any operations including packing ? If yes, identify the gas and the products for which used ?	Yes/No
7.24	Is filtration of water, solvents, air, gas, etc during the final stages of manufacture satisfactory ?	Yes/No
7.25	Are plant working instructions available at each place of work ?	Yes/No
7.26	Are written SOPs and specifications for packaging and labelling in existence ?	Yes/No
7.27	Are SOPs for reworking of non-conforming batches in existence ? If yes, check records	Yes/No
7.28	Are appropriate in-process checks carried out by QC personnel and records maintained ?	Yes/No
8	**Warehousing:**	
8.1	Are areas for storage of RMs, PMs and FPs adequate and properly segregated ?	Yes/No

		Observations
8.2	Are all areas clean and orderly ?	Yes/No
8.3	Are the stores protected from entry of rodents, birds, insects, etc. ?	Yes/No
8.4	Are incoming materials properly quarantined into "QUARANTINED" "UNDER TEST", "APPROVED" and "REJECTED" categories with distinct labels for ease of identification ? Check SOP and compliance	Yes/No
8.5	Are areas requiring controlled temperature and humidity adequate ?	Yes/No
8.6	Are FPs requiring controlled temperature and humidity stored properly ?	Yes/No
8.7	Are flammable, corrosive and toxic materials stored separately with proper safety measures ?	Yes/No

		Observations
9	**Standard Operating Procedures:**	
9.1	Are SOPs for various activities in existence ? Check with the list supplied by the firm in Part II	Yes/No
9.2	Are the SOPs adequate and clearly written ?	Yes/No
9.3	Are the SOPs followed ? Please check documentation in support.	Yes/No
9.4	Are the SOPs reviewed periodically ? If yes, what is the frequency ?	Yes/No
10	**Documentation:**	
10.1	Is a duly-approved Quality Policy in existence ? If so, examine it and comment on its adequacy	Yes/No
10.2	Are batch records capable of giving complete history of the batch right from the RM stage to the distribution of the FP ?	Yes/No

		Observations
10.3	Are control documents and control samples readily available ?	Yes/No
10.4	Are control samples and records maintained in accordance with the requirements of the D&C Act and the Rules ?	Yes/No
10.5	Are analytical reports and in-process controls adequately supported by the raw data ?	Yes/No
10.6	Is the data/information recorded concurrently with the operations ?	Yes/No
11.	**Safety**	
11.1	Is a safety manual available ?	Yes/No
11.2	Are safety equipments like helmets, shoes, goggles, gloves, showers, aprons, masks, breathing aparatus, etc available in the factory ?	Yes/No

		Observations
11.3	Is adequate first-aid equipment available at convenient places in the factory ?	Yes/No
11.4	Is periodic first-aid training given to staff ?	Yes/No
11.5	Are electrical connections, wiring etc. checked regularly ?	Yes/No
11.6	Is flame-proof equipment used where flammable solvents or materials are stored or handled during manufacture ?	Yes/No
11.7	Is adequate fire fighting equipment like fire extinguishers, ladders, fire buckets filled with water/sand, etc. available ?	Yes/No
11.8	Is the building safe and provided with emergency exists, escape routes, ladders, etc. ?	Yes/No
11.9	Does the firm maintain accident history/record ? If yes, comment on its adequacy	Yes/No

		Observations
12.	Utilities:	
12.1	Are arrangements for the following adequate ?	
12.1.1	Raw water	Yes/No
12.1.2	Demineralised water	Yes/No
12.1.3	Vacuum	Yes/No
12.1.4	Compressed air	Yes/No
12.1.5	Steam	Yes/No
12.2	Are measuring devices for volume	Yes/No
	temperature	Yes/No
	pressure	Yes/No
	vaccum	Yes/No
	properly calibrated in accordance with the written down procedures ? If yes, record observations against each	

		Observations
13	**Pollution control:**	
13.1	Are arrangements for the following adequate ?	Yes/No
13.1.1	Disposal of solid/semi-solid waste	Yes/No
13.1.2	Disposal of sewerage	Yes/No
13.1.3	Disposal of liquid laboratory waste	Yes/No
13.1.4	Management of gaseous pollutants	Yes/No
13.2	Is effluent treatment plant in existence ? If yes, comment on it	Yes/No
13.3	Are fume hoods of adequate design in existence and used wherever necessary	Yes/No
14.	**Packaging:**	
14.1	Are written procedures and specifications available for:	
	a) Packaging components	Yes/No
	b) Packaging operations	Yes/No
	c) Labels and label control	Yes/No
14.2	Is batch separation maintained during packaging operations ?	Yes/No

		Observations
15.	**Complaints and recalls:**	
15.1	Is a record of complaints/recalls maintained ? If yes, comment on the same	Yes/No
15.2	Are adequate measures taken in such cases and recorded ? If yes, comment	Yes/No
16.	**Summary and recommendations:**	

Signatures of the GMP Experts

1. Name .....
Address .....
.....
.....

2. Name .....
Address .....
.....
.....

GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI

GMP Inspection

SAMPLE RECEIPT FORM

Institution/Company (under inspection) .....

Address .....

.....

Date of inspection .....

Name of representative of the inspected establishment .....

Name(s) of Inspector .....

Name of the Drug sampled .....

Dosage form .....

BatchNo .....

Date of manufacture ..... Date of expiry .....

Place samples (warehouse, production line, packaging section, etc.) .....

No. of samples taken (tins, strips, packets, etc.) .....

1. ..... 2. ....

....

(Signatures and name(s) of inspectors)

Signature and name of representative of the inspected establishment

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Developing Essential Drugs Policies

A Guide for NGOs

Health Action International (HAI)-Europe in collaboration with an international NGO working group

April 1998

Developing Essential Drugs Policies

A Guide for NGOs

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Background

This introduction to non-governmental organisation (NGO) drug policies is the result of the work of an NGO Working Group that saw the need to clarify a number of issues surrounding essential drugs in NGO work. The specific goals of the group were to:

- ensure that internationally agreed standards are translated into appropriate terms for NGOs;
- highlight the components of drug policy that will ensure a sustainable supply of safe and effective drugs and their proper use;
- encourage regular policy review;
- discuss some of the problems and dilemmas which NGOs face in this area;
- provide information about organisations, networks, training opportunities and documentation to support development and implementation.

A first draft of this paper was widely circulated and used during 1996 and 1997. This revised version includes many suggestions from NGOs and individuals who reviewed or used the earlier draft.

1 Introduction

This booklet is an introduction to essential drug policies for NGOs working on health service delivery in developing regions. It is intended for NGO staff working in policy and management positions at regional- or country-levels who could develop and implement an essential drugs policy for their organisation. This booklet is not a comprehensive guide to policy development, nor does it seek to provide the information necessary to develop and manage pharmaceutical projects or programmes.

Section one sets out the basic principles of the essential drugs concept. Section two outlines the key considerations that NGOs should address in developing their own essential drugs policies. It also includes questions that donors should consider in supporting NGO work in pharmaceutical supply. Sections three and four contain a list of contact organisations and references that will enable NGOs to get additional information and technical support.

An essential drugs framework

In 1977, the World Health Organization (WHO) published the first *WHO Model List of Essential Drugs* [1]. This original list identified some 220 essential drugs that a country could use to meet the majority of its people's health problems calling for drug solutions. Since that time, the list has been updated on a regular basis and, when necessary, expanded. It serves as a model for countries in developing their own national lists. At the same time, an essential drugs list is just a starting point. It needs to be developed together with other policies to ensure that essential drugs are effectively managed and used.

[1] Full details and a short description of all publications mentioned in the text are given in section 4 'Key Resources'.

For the past 20 years, WHO has advised countries to base their drug policies on the essential drugs concept. This concept stresses the selection of drugs to meet real public health needs. WHO emphasises that all drugs chosen should be safe, effective, affordable and of acceptable quality. The essential drugs concept implies efficient management of the drug supply and rational use. To date, 51 countries have developed and adopted national drug policies based upon the WHO model and three dozen more countries are in the process of doing so. In addition, more than 140 countries now use an essential drugs list.

"Essential drugs are those that satisfy the health care needs of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms."

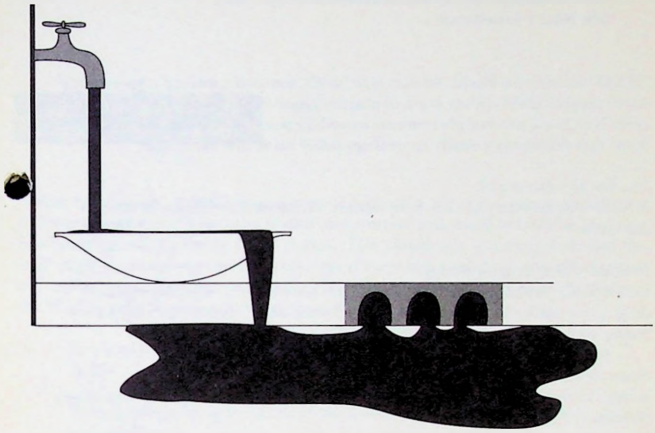
• *The Use of Essential Drugs, WHO (1990)* •

Strengthening NGO effectiveness

Essential drugs policies are based on the WHO essential drugs list and concept. These policies provide the framework for an adequate supply of safe and effective drugs of good quality, at a reasonable price and help to ensure that they are properly prescribed and used. Policies based on the WHO essential drugs concept can help to ensure that scarce resources are well spent and that the best possible use is made of money, medicines and human resources. Essential drugs policies provide a framework which helps to ensure wide access to effective and safe drugs of good quality at low cost.

The essential drugs concept is not only useful at the national level. Its combination of ideas on correct treatment and good management can also be used by local programmes, by hospitals and by NGOs as a framework for developing specific policies for organisations or programmes.

Essential drugs policies based on the WHO concept can also enable NGOs to use their limited resources to manage drugs effectively and meet priority needs. An essential drugs policy can help NGOs provide improved information, education and training, as well as more efficient supply, storage and distribution of drugs. While many NGOs have advocated the adoption of the WHO essential drugs concept by governments, only a few have integrated it systematically into their own practice.



The costs of inefficient drug management are high, while the benefits in terms of better and more cost-effective treatment can be considerable. The potential gains extend beyond the scope of individual NGOs. If more NGOs were to implement the essential drugs concept it would be easier to organise joint services. In Kenya, Nigeria and India, for example, specialised units already undertake joint procurement, training and support for NGOs. Such groups can also link together internationally to gather information and influence policies affecting the welfare of the people they serve.

The Advantages of Having an Essential Drugs Policy
One NGO's Experience

ECHO International Health Services is an NGO, non-profit, medical supply agency which supplies US$4 million worth of pharmaceutical supplies each year for use by other NGOs and national governments around the world. Its staff members have found that developing a clearly stated drugs policy has several advantages:

Uses limited resources well
It helps to protect the end users from financial exploitation and misuse of scarce resources.

Promotes rational drug use messages
Such a policy facilitates discussions with clients and donors on the rational use of drugs in various health care settings, often allowing either much better value for the money available or a reduction in budget requirements.

Assists the development of standards
It helps to encourage the use of standard treatment protocols and rational prescribing policies.

Eliminates confusion
The policy can be clearly stated to clients and donors so that there is no confusion about how ECHO is prepared to help.

Provides clear guidelines for decision making
It justifies the rejection of inappropriate requests or donations even when clients or donors are not willing to engage in a discussion of the reasons behind the policy.

Suggests appropriate funding activities
Using this type of policy as a framework helps ECHO to advise donors who have collected funds but are not sure what kind of drugs to send.

Contributes to sound financial decisions
It provides a solid basis for financial decisions about which products to offer, which should take priority and which are most likely to be in demand or available at lower cost.

• Compiled by Carolyn Green, Senior Pharmaceutical Adviser, ECHO International Health Services, United Kingdom •

Developing Essential Drugs Policies for NGOs

2

Policies based on the essential drugs concept should match the circumstances and needs of different organisations. They must be clear and practical and should be useful in planning, implementing and evaluating health projects. They should take into account the fact that drug supply is a complex process and each stage of the process needs to be critically examined and well managed. The scope and detail of the policy guidelines will depend on the nature of the NGO involved and the answers given to the following questions:

> In what way is the NGO involved in supplying drugs or providing funding for drugs?
>
> What type of training and advocacy work does the NGO carry out regarding drugs and drug policy?
>
> Does the organisation already have a drug policy? Does it need review?

This section identifies and describes key considerations that should be the basis of discussions to develop overall drug policies and essential drugs policy guidelines that are appropriate to an NGO's mandate. The process of developing an essential drugs policy will be different for each NGO. It will depend on the scope and scale of the organisation's operations. For example, an NGO involved in operational work at the country level will need to have detailed systems in place to deal with each component of a drug policy. Ensuring that policies are in line with, and supportive of, national essential drug policies is important. Partnership, collaboration and cooperation are essential for successful policy implementation.

For NGOs providing drugs or funding for drugs to partner organisations in other countries, the policy may be based largely on the need to assess requests for funds and evaluate the implementation of projects. A series of questions are provided at the end of the section that are designed to help NGO and other types of donors assess funding requests using an essential drugs framework.

Assessing needs

Drug policies should reflect overall health priorities and objectives. If drugs are provided without knowledge of the national/regional policy it is possible that the aid provided will undermine national policy or national regulations. In addition, an assessment of the specific local health needs will determine which drugs are selected. If drugs are purchased or provided without adequate knowledge of local health needs there is every chance that money will be wasted on inappropriate drugs and incorrect dosages or quantities. The WHO Action Programme on Essential Drugs (DAP) has details of all national drug policies and publishes a regularly updated list of therapeutic guidelines and national essential drugs lists. In addition information about simple methods of estimating drug requirements can be obtained from the WHO-DAP. (See section 3 for details.)

Drug selection

As well as saving on costs, working with a limited list of essential drugs makes it easier both to quantify needs and to procure and manage drugs more efficiently. Staff members are better able to understand the drugs they are prescribing because there are fewer of them. The limited number also makes it easier for them to communicate this understanding to each other and to patients. An essential drugs list provides a firm foundation on which to introduce standard treatment guidelines, and for training and evaluation of performance.

National essential drugs lists, where they exist, should guide the choice of drugs. Where no national list exists, the most recent version of WHO's *Model List of Essential Drugs* can be used (see section 4). Different levels of the health care system have different requirements. Provincial or district-level facilities will require a fuller list whereas 20 or 30 drugs might be selected for use at the primary health care level. Where drug supply is

extremely limited, the WHO Emergency List can be adapted for use at the primary level. Details of this list can be found in WHO's *New Emergency Health Kit* (see section 4). These two documents are invaluable resources.

Procurement

Choose Generics In general, drugs on the essential drugs list should be generic products; any exceptions to this rule should be justified. Generic drugs are no longer patented. Their risks and benefits are well understood because they have been tried and tested over many years. Because they are not sold under patent they are also usually cheaper than brand-name drugs.

The use of generic names should be encouraged at all stages of procurement, distribution, prescribing and use. Using generic names avoids the possibility of confusion leading to duplication of active ingredients when several drugs are used at the same time. They also simplify training, enabling staff and patients to better recognise and understand the drugs they use.

Bulk Packaging Bulk packages are much cheaper than small packs but they cannot be used in all circumstances.

Location of Manufacture This can be a difficult problem for those involved in choices about drug purchasing. If a local industry is producing good quality drugs at competitive prices then that may be a strong reason to purchase drugs locally. However, problems can arise if either the prices are not competitive or if the quality of the locally produced products is in doubt. Drugs which do not meet the required quality standards should not be bought simply to support local manufacturing. Fortunately, a growing number of national and international NGO low-cost suppliers are an excellent source of reasonably priced drugs of acceptable quality.

Assessing quality

The quality of drug manufacturing is difficult to assess and requires the work of professionals. Some manufacturers, local or foreign, produce drugs with little regard for quality or real costs. Poor control in the manufacturing process can easily produce drugs that do not meet acceptable standards. If the quality of drugs available on the open market is not reliable and if insufficient attention is paid to quality assurance then substandard drugs may be bought which could be dangerous and/or useless.

Factory inspections and laboratory testing are part of systems to assure quality. Laboratory testing has a useful role in quality assurance, but it is expensive, time consuming and often the necessary facilities are not available. It is important therefore to incorporate other aspects of quality assurance.

Get to know your suppliers and exchange information with other NGOs. Every effort should be made to buy drugs from an established, experienced, low-cost supplier. This may be a central medical store, a recognised NGO supplier or a reliable commercial company. The WHO operates a certification scheme which can be used to obtain information about manufacturers and whether or not a drug is used in the country of manufacture.

In general, it is risky to buy drugs on the open market especially from unknown suppliers. It is useful to check where each drug was manufactured and ask to see a sample before making a purchase. The quality of the labelling may help you to know whether the drugs are fake or not - look out for slight spelling mistakes, odd looking addresses and extra labels pasted over old ones. If you have any suspicions do not buy the goods.

Always inspect newly purchased drugs and carry out some basic tests to help identify substandard products. Re-check the labels and ensure that the following are clearly legible: generic name, manufacture and expiry dates, batch numbers, storage requirements, manufacturer's name and address. Check the contents for appearance, looking out for breakages, discoloration, excessively powdery tablets or capsules, injection solutions that are cloudy when they should be clear and so on. Staff should also identify inadequate or damaged packaging. Do the contents of the package look fit for use? Labels should be checked to see if the generic name, the expiry date, and the name and address of the supplier are legible. Is adequate information supplied?

Management, storage and distribution of drugs

Inadequate attention to the management of drugs can result in heavy financial losses. Inventory mistakes leading to understocking or overstocking can be very expensive. The distribution network often develops in a somewhat haphazard way. With better planning of storage points and transport, and with improved inventory control and record keeping, waste in terms of drugs and other supplies, transport and staff time can be kept to a minimum. Donor NGOs can help to ensure that money on pharmaceuticals is well spent by making sure that sufficient funds are allocated to management training activities.

Financing a sustainable drug supply

The cost of drugs and supplies can absorb between 20-40 percent of health budgets and this is a recurrent cost which may require access to foreign exchange. Deciding how to meet these costs is a high priority.

The first step should be to ensure that waste is reduced and that the best possible use is made of the money available. Good assessment, procurement and distribution systems will all reduce waste, as will education and training for prescribers and consumers and the use of treatment guidelines.

If it is necessary to charge fees to recover drug costs and maintain a regular supply of drugs, steps should be taken to ensure that access to care is not seriously inhibited. Often those who are least able to pay are exempted from charges. Many NGO health programmes have experience in administering revolving drug funds. Various options for user charges and other mechanisms for co-payment can be considered. Pre-payment insurance schemes can provide an alternative.

Controlling drug donations

It has become increasingly apparent during the past 10 years that donations of medicines can create more problems than they solve. While some donations are generous and appropriate, many are sent without knowledge of the needs of the recipients or an understanding of the conditions in which they will be used. In many cases, donated drugs are unusable and therefore have to be destroyed. Getting rid of unwanted drugs involves pharmacists or other personnel in dangerous, time-consuming incineration procedures as well as in unnecessary costs.

Donations are given in several ways. Some consist of unused drug samples and returned prescription medicines which are collected by pharmacies in many European countries for redistribution abroad as gifts. In addition, some national governments offer tax incentives to companies donating medicines. Often these medicines are approaching their expiry date when they are sent as donations.

The Consequences of Inappropriate Drug Donations: Two Country Examples

Eritrea 1989 During the war for independence, despite the careful wording of appeals, many inappropriate donations were received. Examples included seven truck-loads of expired aspirin tablets that took six months to burn and 30,000 half-litre bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the terrible smell.

Former Yugoslavia 1994-1995 Of all the donations received by the WHO field office in Zagreb in 1994, 15 percent were completely unusable and 30 percent were not needed. By the end of 1995, 340 tons of expired drugs were stored in Mostar. Most of these were donated by different European nations.

• *Guidelines for Drug Donations (WHO-DAP 96.2)* •

Unfortunately, inappropriate drug donations are common. NGOs such as the World Council of Churches and the International Committee of the Red Cross have led an international effort to improve the standard of donated drugs. Recently WHO published the *Guidelines for Drug Donations* that have been endorsed by many of the major humanitarian organisations active in emergency relief. These guidelines are built around four core principles:

- All donations should be based on an expressed need and unsolicited donations should be discouraged;
- A donation should be given with full respect for the wishes and authority of the recipient;
- There should be no double standards in quality. If the item is unacceptable in the donor country, it is also unacceptable as a donation;
- There should be effective communication between the donor and the recipient.

These guidelines have been developed to be useful for both donors and recipients. NGOs can promote their use and can incorporate the principles into their own drug policies. The Guidelines can be obtained from WHO-DAP (see section 4).

Drugs for use in emergencies

In an emergency, clear policy guidelines are even more crucial. Supplying drugs in an emergency requires care and detailed planning. It is very important that the drugs supplied are the ones which are most needed. Inappropriate donations can cause confusion and hamper the efficiency of an emergency operation. The use of special pre-packaged emergency health kits may often be the most appropriate option for the period of the emergency. Details of emergency kits are given in *The New Emergency Health Kit* (see section 4).

Rational use of drugs

Making sure that the correct drugs are prescribed, dispensed and are used appropriately is of great importance. Efforts put into making sure that essential drugs are available can be wasted if the drugs are not properly used. The essential drugs list, formularies and therapeutic guidelines are important tools but they will have little impact unless they are developed with the involvement of those who will use them and are accompanied by training, supervision and evaluation. Recent studies have shown that the quality of dispensing is often very poor. In many countries, prescribing and dispensing time can be measured in seconds and often no time is taken to explain the drug and use with patients.

Monitoring how drugs are used can be easily assessed using methods described in the WHO manual *How to investigate drug use in health facilities* (see section 4).

Appropriate labelling

All drugs should be clearly labelled in easily read print using the generic name. Labels should be accompanied by clear and correct information for the prescriber, the storekeeper/dispenser and the patient. The label should always include the expiry date. Label information should be written in the local language or in another language understood in the region. Sometimes getting translations of labels takes additional time, but it will help ensure health workers know how to use the drugs correctly.

Drugs procured for Georgia and Azerbadjan by Médecins Sans Frontières were relabelled in Russian by the International Dispensary Association (IDA) which supplied the drugs. This involved a delay of about one month but it helped to ensure that health workers knew how to use the drugs correctly.

• Information collected by Erik Schouten, Médecins Sans Frontières/Health Net International •

Evaluating Funding Requests from NGOs

Some NGOs involved in drug supply provide funding to other NGOs. The questions below are designed to help donor NGOs apply an essential drugs framework in evaluating funding requests. These questions would be applicable and useful for any donor that funds drug supply programmes or projects.

1. What is being requested and for whom?
2. Has there been an assessment of needs?
3. Do the requests match national or local essential drugs lists?
4. Are generic drugs used wherever possible and are generic names used?
5. How does the donor or the recipient assure the quality of the drugs?
6. What level of expertise does the project's staff have?
7. Would additional training or technical support contribute to better management of drugs?
8. Are there adequate facilities for storage and distribution of drugs?
9. What will happen after this supply of drugs has been used?
10. How will the recipients dispose of/destroy any unwanted or unusable drugs?
11. How will the way the drugs are used be monitored?
12. Are there ways in which the project can be helped to become sustainable?
13. Is there a danger that the project might undermine the sustainability of other existing projects?

Where to Obtain Additional Information

3

A comprehensive list of the many organisations working in this field cannot be given, but the following organisations (which are listed in alphabetical order) are a good starting point for anyone working on essential drugs policies. Any of these contacts will provide support, suggestions and information for NGOs involved in drug policy or the provision of essential drugs.

Extra copies of this publication can be obtained from HAI-Europe.

CMC Churches' Action for Health/ World Council of Churches

The CMC works with church-related health institutions and NGOs involved in drug supply and the promotion of rational use of drugs. CMC has worked towards the rationalisation of drug donations and has developed guidelines for drug donations and equipment donations.

CMC Churches' Action for Health/World Council of Churches
P.O. Box 2100
CH-1211 Geneva 2
SWITZERLAND
tel: (+41-22) 791 6061/791 6111
fax: (+41-22) 791 0361

and
The Pharmaceutical Programme
CISS International (Community Initiatives Support Services)
P.O. Box 73860
Nairobi
KENYA
tel: (+254-2) 729 095
fax: (+254-2) 711 918

ECHO International Health Services

ECHO is a non-profit, non-commercial, self-financing medical supply agency committed to providing quality-assured, affordable medical supplies, essential drugs and new or reconditioned medical equipment for health care programmes in developing countries and for disaster relief.

ECHO International Health Services
Ullswater Crescent
Coulsdon
Surrey CR5 2HR
UNITED KINGDOM
tel: (+44-181) 660 2220
fax: (+44-181) 668 0751
e-mail: CS@ECHOHEALTH.ORG.UK

Essential Drugs Project

This organisation was set up by several UK NGOs to promote equitable access to essential drugs and the rational use of all drugs. It provides support and advice to health agencies and NGOs in the UK and collaborates with individuals, groups and networks internationally on a wide range of issues.

Essential Drugs Project
77 Lee Road
Blackheath, London SE3 9EN
UNITED KINGDOM
tel/fax: (+44-181) 318 1419
e-mail: EDP@GN.APC.ORG

Health Action International (HAI)

HAI is a global network of health, development, consumer and other public interest groups in more than 70 countries working for a more rational use of medicinal drugs. HAI represents the interests of consumers in drug policy and believes that all drugs marketed should be acceptably safe, effective, affordable and meet real medical needs.

HAI has three regional coordinating offices:

HAI-Europe
Jacob van Lennepkade 334-T
1053 NJ Amsterdam
THE NETHERLANDS
tel: (+31-20) 683 3684
fax: (+31-20) 685 5002
e-mail: HAI@HAI.ANTENNA.NL

HAI Clearinghouse/Action for
Rational Drug Use in Asia (ARDA)
c/o Consumers International
P.O. Box 1045
10830 Penang
MALAYSIA
tel: (+60-4) 229 1396
fax: (+60-4) 228 6506
e-mail: CIROAP@PC.JARING.MY

HAI/AIS Latin America
Oficina de Coordinación AIS LAC
Aptdo. 41-128
Lima
PERU
tel/fax: (+51-1) 346 1502
e-mail: AIS@AMAUTA.RCP.NET.PE

International Dispensary Association (IDA)
IDA was set up to support health care initiatives in developing countries on a non-commercial basis by supplying high-quality medicines and medical supplies at the lowest possible price.

International Dispensary Association
Postbus 37098
1030 AB Amsterdam
THE NETHERLANDS
tel: (+31-20) 403 3051
fax: (+31-20) 403 1854
e-mail: IDA_SALE@EURONET.NL

International Network for the Rational Use of Drugs (INRUD)
INRUD works through research and training to promote rational drug use. It can provide particular help for those wishing to develop research or training programmes. INRUD does not supply drugs.

International Network for the Rational Use of Drugs
1655 North Fort Myer Drive, Suite 920
Arlington, VA 22209
UNITED STATES
tel: (+1-703) 524 6575
fax: (+1-703) 524 7898
e-mail: INRUD@MSH-DC.ORG

International Society of Drug Bulletins (ISDB)
ISDB encourages the development of high-quality, independent information about drugs and therapeutics and supports the work of independent drug bulletins all over the world. The organisation provides training, information exchange and support for organisations involved in information provision on drugs.

ISDB
P.O. Box 459
75527 Paris Cedex 11
FRANCE
tel: (+33-1) 4700 3320
fax: (+33-1) 4700 2864
e-mail: ISDB@COMPUSERVE.COM

Management Sciences for Health (MSH)
This non-profit organisation supports the development and application of management principles in primary health care and other medical fields. It works with government ministries, international agencies, private organisations and local agencies in more than 50 countries to find solutions to public health problems. MSH has created a 'Drug Management Program' which works with managers and policy makers in developing countries to develop new systems and maximise therapeutic benefits while minimising costs. It provides technical assistance and training in the areas of procurement, logistics, rational use, finance and management information systems.

Management Sciences for Health
Drug Management Program
1655 North Fort Myer Drive, Suite 920
Arlington, VA 22209
UNITED STATES
tel: (+1-703) 524 6575
fax: (+1-703) 524 7898
e-mail: RPM@MSH-DC.ORG

Medecins Sans Frontieres (MSF)
MSF focuses on relief in emergency areas. In addition, they produce several valuable publications.

Medecins Sans Frontières
Max Euweplein 40
1017 MB Amsterdam
THE NETHERLANDS
tel: (+31-20) 520 8700
fax: (+33-20) 620 5170

United Nations Children's Fund (UNICEF)
UNICEF has been active in providing support to governments regarding the acquisition, storage, distribution and rational use of essential drugs. The agency's supply division organises the purchasing of such drugs at low prices.

UNICEF Supply Division
UNICEF Plads-Freeport
DK-2100 Copenhagen
DENMARK
tel: (+45-3) 527 3527
fax: (+45-3) 526 9421
e-mail: SUPPLY@UNICEF.DK

World Health Organization (WHO)
Action Programme on Essential Drugs (DAP)
The Action Programme on Essential Drugs has played a major role in developing and promoting the essential drugs concept. It works to promote the development of national drug policies and to provide leadership and advocacy on drug issues. The programme's staff produces a wide range of materials.

World Health Organization
Action Programme on Essential Drugs
20 Avenue Appia
CH-1211 Geneva 27
SWITZERLAND
tel: (+41-22) 791 2111
fax: (+41-22) 788 0196
e-mail: DAPMAIL@WHO.CH

WHO Division of Drug Management and Policies (DMP)
This division is responsible for programmes in the areas of drug quality and information on safety and efficacy.

World Health Organization
Division of Drug Management and Policies
20 Avenue Appia
CH-1211 Geneva 27
SWITZERLAND
tel: (+41-22) 791 2111
fax: (+41-22) 791 0746

4 Key Resources

The following publications all provide information on various aspects of rational drug use and essential drugs. Copies of the material should be requested directly from the publishers listed. Unless noted, these publications are available only in English. A price indication is given when possible.

General

Managing Drug Supply
Management Sciences for Health (1997)
Available from Kumarian Press, Inc. 14 Oakwood Avenue, West Hartford, CT 06119-2127, USA

This newly revised edition provides a complete overview as well as step-by-step approaches on how to manage pharmaceutical systems effectively.

National Drug Policy

Report of the WHO Expert Committee on National Drug Policies
Ref. no. WHO/DAP/95.9
WHO (1995); English/French; Available from WHO-DAP; Free of charge

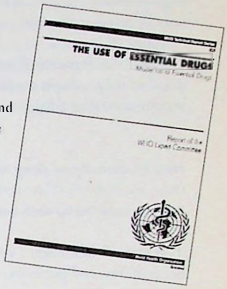
The guidelines cover the major components of drug policy and are intended to provide general principles and strategies that should be adapted to country needs.

Selection and Use

Estimating Drug Requirements. A Practical Manual
Ref. no. WHO/DAP/88.2; WHO (1988); English/ French/Spanish
Available from WHO-DAP; Free of charge

The manual consists of eight training modules which explain the various steps necessary to estimate drug requirements.

The Use of Essential Drugs. Model List of Essential Drugs
(Ninth List, Seventh Report of the WHO Expert Committee)
Technical Report Series No. 867; WHO (1997); English/ French (Russian and Spanish versions to be published shortly); Available from WHO-DAP; Price: fr. 15-/US$13.50, in developing countries Sw. fr. 10.50



The Model List is intended to guide the selection of drugs in situations where the need is great and the resources are small. The list includes information on route of administration, dosage forms, and strengths for some 300 essential drugs.

British National Formulary
Jointly published by the British Medical Association and the Royal Pharmaceutical Society of Great Britain; Available from the Pharmaceutical Press, P.O. Box 151, Wallingford, Oxon. OX10 8QU, UK or from booksellers. Low cost edition for developing countries available from TALC (Teaching Aids at Low Cost) P.O. Box 49, St Albans, Herts, AL1 5TX, UK; Price: UK£5-/US$8.35 plus postage and packing.

This standard UK prescribing manual gives treatment guidelines and UK prescribing costs of generics and branded medicines. It is published twice a year.

Clinical Guidelines Diagnostic and Treatment Manual
Médecins Sans Frontières; English/ French/Spanish/Russian/Arabic/Portuguese
Available from MSF-The Netherlands (see section 3); Price NLG 25-/US$12.50

Guidelines to Rational Drug Use
von Massow, Ndele, Korte
Macmillan (1997); Available from TALC, P.O. Box 49, St Albans, Herts, AL1 5TX, UK or from booksellers; ISBN 0-333-69922-X; Price UK£6.95/US$11.61

Standard treatment guidelines and cost comparisons for essential drugs for developing country use.

Problem Drugs

A. Chetley; HAI/ZED Books (1995); Available from Health Action International (see section 3); English/Spanish (French and Russian versions to be published shortly); Price: NLG 40-/US$20, reduced rates for groups in developing countries

Covers 10 categories of medicines which are commonly used inappropriately. It contains detailed information on the "problem drugs" currently being marketed together with recommendations for action.

How to investigate drug use in health facilities; selected drug use indicators

Order no. 1930049; WHO (1993); English/French/Spanish
Available from WHO-DAP (see section 3)

The manual describes a simple standard methodology for gathering essential data on drug use patterns and prescribing behaviour in health facilities.

How to investigate drug use in communities

Ref. no. WHO/DAP/92.3; Hardon, Brudon-Jakobowicz, Reeler
WHO (1992); English/French; Available from WHO-DAP (see section 3)

This guide provides simple research methods to identify problems in the provision and use of drugs at the community level.

Supply and Marketing

MSH International Drug Price Indicator Guide

Produced annually by Management Sciences For Health (see section 3)
Single copies available free of charge

A regularly updated list which provides an indication of the current generic prices from non-profit suppliers on the international market.

The New Emergency Health Kit

Order no. 1930018; WHO (1990); English/Spanish/French; Available from WHO-DAP (see section 3); Price: Sw.fr.8-/US$2.86, in developing countries Sw.fr. 5.60

This booklet provides information on the development of the kit, now adopted by many organisations as a reliable, inexpensive, appropriate and quickly available source on the essential drugs and equipment urgently needed in a disaster situation. It provides a description of the kit's contents, treatment guidelines and some useful checklists for suppliers and users.

Guidelines for Drug Donations

Interagency Guidelines; Ref. no. WHO/DAP/96.2; WHO (1996); English/ French/Russian/Spanish; Available from WHO-DAP (see section 3)
Free of charge

WHO has developed these Guidelines in collaboration with the major relief organisations. They can help both donors and recipients to maximise the potential benefits of drug donations.

Guidelines on Equipment Donations

CMC Churches' Action for Health/World Council of Churches.
Available from CMC (see section 3); English/French/Spanish/Portuguese

Developed to help donors and recipients maximise the potential benefits of donations of medical equipment.

Ethical Criteria for Medicinal Drug Promotion

WHO (1988); Arabic/Chinese/English/French/Russian/Spanish; Available from WHO-DAP (see section 3); Price: Sw.fr.. 8-/US$2.86, in developing countries Sw.fr. 5.60

The criteria give manufacturers, prescribers and NGOs a framework to ensure that promotional practices are in keeping with acceptable ethical standards.

E-Drug electronic conference

Today approximately 700 health professionals have subscribed to this electronic network that focuses on essential drugs and related topics. No costs are involved and interested individuals can sign up by sending an e-mail message to:
MAJORDOMO@USA.HEALTHNET.ORG
with the following text in the body of the message:
subscribe e-drug <your e-mail address>
The subject heading should be left blank.

Newsletters

Contact
This bi-monthly publication highlights various activities on rational drug use and often contains full reprints of new guidelines and other material. Subscription information available from: CMC/Churches' Action for Health/World Council of Churches (see section 3).
English/French/Spanish/Portuguese

The Essential Drugs Monitor
Published by WHO-DAP, this newsletter provides information on essential drug activities by governments and NGOs. Copies available from WHO-DAP (see section 3).
English/French/Spanish/Russian

HAI News
This publication reports on issues related to rational drug use and includes summaries of work carried out by members of the international HAI network.
Subscription information available from HAI-Asia/ARDA (see section 3).

HAI-Lights
This quarterly newsletter focuses on news affecting HAI groups and interested health and development NGOs working on rational drug use in Europe.
Subscription information available from HAI-Europe (see section 3).

Essential drugs policies based on the WHO concept enable NGOs to use their limited resources to manage drugs effectively and meet priority needs. An essential drugs policy can help NGOs provide improved information, education and training, as well as more efficient supply, storage and distribution of drugs. While many NGOs have advocated the adoption of the WHO essential drugs concept by governments, only a few have integrated it into their own practice.

This booklet aims to help change that. It offers practical advice for NGOs interested in developing and implementing essential drugs policies for their organisation.

HAI
Health Action International

SOCHARA

From: "Aviva" <aviva@netnam.vn>
To: <"pha-exchange@kabi"@healthnet.org:
Sent: Tuesday, February 24, 2004 3:33 PM
Subject: PHA-Exchange> WHO launches intellectual property commission

WHO launches intellectual property commission

The World Health Organisation (WHO) has announced details of a new commission that aims to analyse how intellectual property rights affect the creation of new drugs against 'diseases of poverty' in the developing world.

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) will be led by Ruth Dreifuss, former President of Switzerland. The vice-chair will be R.A. Mashelkar, director-general of India's Council of Scientific and Industrial Research.

Leading economists, lawyers, medics, industry representatives and scientists from across the globe make up the remainder of the 10-person committee (for full list, click here).

The pharmaceutical industry has welcomed the announcement. A statement from the International Federation of Pharmaceutical Manufacturers Associations, which represents more than 60 national industry organisations, says that the Commission is "soundly positioned to delve into issues of intellectual property, its interfaces and linkages with pharmaceutical innovation and public health".

The Commission, which has been set up at the request of last year's World Health Assembly, will review existing research, development and innovation efforts directed at diseases that affect the poor. It will then consider how effectively intellectual property regimes and other incentive and funding mechanisms are stimulating research into new medicines against these diseases.

Governments, UN bodies, other international agencies and private sector and civil-society organisations will be consulted in drawing up the report, which will be presented to the WHO Executive Board in January 2005.

Link to terms of reference of the Commission
http://www.who.int/gb/EB_WHA/PDF/EB113/eeb113id1.pdf

PHA-Exchange is hosted on Kabissa - Space for change in Africa

Main identity

From: "GL München" <mail@gesundheitsladen-muenchen.de>
To: "community health cell" <sochara@vsnl.com>
Sent: Wednesday, November 19, 2003 11:46 PM
Attach: München.jpg
Subject: Re: Thank you once again with a picture

Dear Emmeram, Thanks for the picture. Bavaria + its people are wonderful! Thelma.

Dear Thelma,

another mail from this side.
This time a pic from your presentation in Munich.
You must have some more pictures from sightseeing already.
Did you realise, that the sky is extremely blue ?
That's what people sometimes say about the bavarian sky..
Even the conservatives are coopting the blue sky for their political interests...

Bukofski

Bert 29/11

Greetings

Emmeram
****
Gesundheitsladen München e.V.
MEDIZINISCHES INFORMATIONS- UND KOMMUNIKATIONSZENTRUM
AUENSTRASSE 31
80469 MÜNCHEN
TELEFON 089 / 77 25 65
TELEFAX 089 / 725 04 74
web: http://gesundheitsladen-muenchen.de
e-mail: mail@gesundheitsladen-muenchen.de

Children and drugs

Infancy and childhood is the period of illness Specially in a tropical country like ours. This is also a natural process by which the child's ~~immune Systems~~ interacts with the environment and learns survival. The illness episodes build the immune System in the child. But an episode of illness creates anxiety in the parents who want to care for the child seek medical help. Do children need a wide range of drugs to treat every illness? The answer is a certain NO. Too many drugs are given to children. According to WHO, "two thirds of all drugs used by children may have little or no value". There are chances of the "unnecessary drugs" harming the child as the Blood brain barrier is more permeable and the metabolising & eliminating Organs are Still developing. "children are not ~~Simply Small adults~~" miniature adults. Certain common ~~Instances~~ examples of drug misuse in children ~~Some common examples of drug misuse in children~~.

include: ANTIBIOTICS: most frequently prescribed drug in children. Viruses are more likely to cause respiratory tract infections and diarrhoea. Use of Antibiotics in Most conditions are not indicated unnecessary. But anxious parents and eager to please Med. practitioners join hands in this irrational abuse.

Pain killers and drugs in fever.

Pain in childhood is mainly limb pain, head aches & abdominal cramps are are often self limiting. - They seldom need medication unless they are caused by an illness or condition requiring drugs &.

Fever is one of the most misinterpreted sign. or is regarded as injurious to health. Fever is a protective phenomenon & there is considerable evidence that a variety of human immunological conditions ~~work~~ function better at febrile temp. than at normal ones. Graham Dukes, editor of 'Side effects of Drugs annual' notes that with children " it is often wise and possible to manage a mild pyrexia (fever) without giving drugs at all; on that respect some developing countries are the most enlightened of all". Fever in children is usually due to viral infection and viruses don't respond to antibacterials. or is better managed with simple means of undressing, tepid sponging and fanning.

Antidiarrhoeals; ~~cough~~ & on a typical county ~~we~~ cannot find a child who hasn't had an episode of diarrhoea. In spite of the common knowledge of

Appetite stimulants, vitamins, 'growth' tonic and Brain tonics are other add up to the list of unnecessary medication in childhood.

Simple measure of balanced diet, hygiene and immunisation will keep children healthy & protect them against many sicknesses.

DR - 1

community health cell

From: "sahajbrc" <sahajbrc@icenet.co.in>
To: <pha-ncc@yahoogroups.com>; "ctddsf" <ctddsf@vsnl.com>
Sent: Friday, March 11, 2005 7:33 PM
Subject: Re: [pha-ncc] URGENT: JSA Presentation on issues relating to health rights at the national level

Amit,

You can add that price control of some form or the other is the norm in most countries --with examples etc.(see below from Gulhati's article.) Also you may need to address the argument that we will have universal health insurance and therefore diluting price controls does not matter.

Chinu

United States: Nearly every one is insured against illness. Cost of drugs are reimbursed by insurance companies who keep an eagle's eye on both, prescriptions and prices. If a doctor is found to be unnecessarily prescribing high cost drugs when cheaper alternatives are available, he can loose insurance business. This in effect means he will have to give up profession. Similarly, manufacturers cannot charge more than what they are charging in other countries.

United Kingdom: The entire medical costs are met by the Government through National Health Service. Manufacturers have to negotiate prices with the government. In fact the price control is more rigorous in England than India because there is only one buyer. The NHS pays substantially discounted prices on all medicines. For example Buscopan is sold to NHS at a discount of 42% over the MRP. In any case, individual patients are not concerned.

Belgium (as an illustration of European Community countries): Every resident, including foreigners, get total reimbursement of all medical costs from three government-controlled "mutuelle" who compete with each other but their annual subscriptions are decided by the state and are most reasonable.

The effectiveness of the above measures can be gauged from the fact that US Government is currently prosecuting Glaxo Smith Kline for billion of dollars for overcharging on ranitidine and thus "cheating" USA.

On the other hand in India, the entire system is based on MRP. What about the transfer prices from a related manufacturer or on loan license? There are cases where there is huge difference between the transfer price (price charged by actual manufacturers/loan licensees to the marketers/manufacturer and the MRP

DR-1.

Gist of the Makapur Committee Report on Medicines Purchase and supply for the Government Health Care Institutions in Karnataka

Terms of Reference:

To study the existing set-up, functions and working of the Government Medical Stores and makes specific recommendations with reference to the following:

(1) Qualification of drug requirements (including the basis on which the quantities required are to be assessed).
(2) Procurement and inventory management (including records to be kept computerisation of inventory control, scheduling of purchases and minimum and maximum stock limits to be maintained in respect of each drug).
(3) Distribution of drugs to the Districts (including whether the delivery system or collection system to be followed and in case of the former, whether such delivery is to be done by the Government Medical Stores or the R.C. holders).
(4) Establishment of Sub-stores at the District/ Division level (including whether the sub-stores should only act as a storage and distribution centre ad the present system of centralised procurement should continue or whether the sub-stores should directly procure the drugs from the R.C. holders as per the local requirements and settle the bills on the basis of funds released by the Directorate).
(5) Storage requirements with reference to legal/licensing conditions and the estimated cost.
(6) Staffing pattern and training requirements (financial implications should be assessed in case additional staff is proposed).
(7) Stock and issue Registers to be maintained in the hospitals/centres/ institutions and how the public is to be kept informed about the drugs available in stock.
(8) Whether the present financial limits for supply of drugs to the various institutions needs to be enhanced and if so to suggest the enhanced financial limits together with the additional requirement of funds.
(9) Any other matter incidental to or arising from any of the above terms.

Process adopted: Apart from Internal discussions Discussion with users ; select District Level administrative Health Officers and Personnel from GMS. Visit to Tamil Nadu : discussion with officers of the Tamil Nadu Medical Corporation, visit to district sub –stores and select hospitals

Highlights of the report:

The Report has three main parts: Part 1 reviews and identifies the deficiencies in the existing system of the Medicnes procurement and supply Part 2 reviews the existing system in the Sate of Tamil Nadu Part 3 consists of the recommendations of the committee.

1. Annual identification of the List of Drugs and Its formulation by an expert committee, which includes the Drugs controller and other specialists. The WHO List of essential drugs, and the GOI List to be utilised.
2. Superfluous staff in Group C and Group D; Computerisation of supply orders, receipt of drugs, issue of drugs, collection of vouchers and payment to suppliers; District level warehouses for storage and supply of drugs.
3. Deficiency in the Quality control mechanism of drugs
4. The following specific deficiency has been noted:

a) Delay in finalisation of list of drugs, tender process and of Rate contract.
b) Non-receipt of drugs requirements from all indenting institutions and thereby drugs requirements not quantified in the tender process.
c) The busy Director not able to give required attention.
d) Moderate delay in finalisation of Rate contract
e) Delayed purchases due to non-receipt of requirements / indents.
f) Manual inventory system
g) Inadequate storage facilities
h) Year end purchases by ZP
i) No uniformity in ZP purchases
j) All required drugs not in Rate contract
k) Delay in release of budget to the District Surgeons and other Health Care Institutions.

5. Recommendations:

a) Restructuring the organisation (Upgradation of the post of the Joint Director to Additional Director and providing additional staff - computer operators; Independent quality control wing)

b) Recommendations regarding the job responsibilities of the staff of the GMS

c) Procure and management of Drugs - formation of the therapeutic committee, Tender evaluation committee and empowered committee; functions and responsibilities defined

d) Estimated requirements to be specified in the tender document with a permitted variation of 25%; commensurate with the manufacturing capacity orders to be placed; Generic name drugs to be identified and listed to enable the purchases if any to be made even outside the Rate contract. Committee recommends a list of the drugs following the pattern in Tamil Nadu.

e) Procurement of Drugs: Calendar of events recommended Listing of drugs (August) to Issue of GO by March

f) Tender Process deatiled

g) Procurement and distribution mechanisms: Establishment of District Warehouses (rental or other wise); equipped

h) Distribution of Drugs: Introducing the Pass Book System in duplicate - one with the Health Institution and one with the Warehouse;

i) Inspection of the District warehouse

j) Licensing of the Institutions who store and distribute drugs

k) Recommendations regarding Inventory management

l) Finances: recommendations for Change of the proportion of Medicine finances handled - 90% GMS 10% Individual institutions **or** 10% Individual Institutions 50% by DHO for ZP only by Rate Contract and stored at District Warehouse - ZPs and >100 Beded Institution; 100 beded Instituions - 60% taken back to GMS; Instituions outside the ZP 90% by GMS; PHUs to be made indenting instituions; Increase in Drug budget by 20% The additonal allotment is reserve and is justified and recommended by higher authorities.

m) Expected expenditure is Recurring Rs. 2,20,39,000 and Investment costs Rs: 43,60,000

n) Quality control: establishment at GMS and 1.5% invoice value from the suppliers

o) Training programme

FROM: FMRAI <fmrai@vsnl.net>
DATE: Thu, 22 Jul 2004 17:58:17 +0530
TO: Janswathya Abhiyan <pha-ncc@yahoogroups.com>
SUBJECT: [pha-ncc]

NT To Voice response of CHC ?N/CMF

Dear All,

Giving below a scetch aboout our position on the drug policy which may be presented before the Ministry. This is a pruned thinking which may be remodelled based on the suggestions of JSA meeting and then it may be made specific on each points. This is being proposed for discussion in the JSA meeting at Bhopal.

Amiteva

Pharmaceutical Policy:

Last couple of years Govt. has taken executive decisions in rapid successions for which the first Drug Policy, 1978 has been thoroughly changed. The political good will under which Drug Policy, 1978 was developed is wiped away making the basic tenant of the policy redundant. Present status of the policy reflects virtually scant Govt. control and add to this unwillingness of the past NDA Govt to implement whatever left in the policy has created an anarchy in the pharmaceutical field. It is , therefore needed to prepare and adopt anew policy in the new global regime keeping interest of the people in the foreground.

Lib Drug Policy file

Responsibility:

Excepting industrial part of the policy, all other area should come under the purview of the Health Ministry. Selection of drugs of National Essential Drug List (EDL), quality assurance, Drug Laws etc., should be the exclusive responsibility of the Health Ministry. Issues like drugs prices may be the concurrent responsibility of the Ministry of Chemicals and Fertilisers and the Ministry of Health.

Production:

Govt. used to monitor production of 93 bulk drugs. In order to ensure availability, the Govt. should monitor all drugs which come under national EDL. Govt shall publish production status of all these drugs at least once in a year. Govt. should also establish a cell to estimate need of all the drugs under EDL and should explore shortfall in indigenous production to determine import requirements or expansion of indigenous production. Public sector pharmaceutical units should be given priority for production and a policy to revive this sector should be developed.
A national authority should be constituted for developing policy and monitoring should be prepared which should be provided with statutory power.

National Essential Drug List:

The EDL shops should be prepared by an expert committee every after three years. Experts from different fields of medical profession, consumers, etc.

The list should be popularised with a guideline of use Standard Treatment Guideline) among the users. Its use should be mandatory among Govt., Public Sector Units and for use in reimbursement or for insurance coverage. Drugs under the list should be priced low. Industry should be given incentive for production of these drugs. Prescription of these drugs should be made in generic names.

Quality Control:

Drugs & Cosmetics Act should be amended to ensure quality control. Stringent punishment should be enacted for violation of quality norms. Drug testing laboratories should be established by the Govt. in each states. Consumers of Consumer organisations should be allowed to directly test any drug with doubtful quality with minimum charges in these laboratories. Separate vigilance cell should be created under Drug Control machinery to watch quality of medicines.

Irrational and Hazardous Drugs:

All irrational and hazardous drugs should be withdrawn. Registration system needs to be revamped. All drugs should be re-registered within a regular interval for establishing their therapeutic validity.

Research and Development:

Govt. should involve the research establishments of its own with adequate fund and encourage them for developing cost effective process technology. Any private company which develops new molecules should be encouraged for marketing their drug in the domestic market at cheaper price. Only with this condition, they may be given grants from the Govt.

Third Party Licenses:

The Govt. should abolish Loan/Third Party License system.

Prices:

All drugs under EDL shall be price controlled. Control of price of other drugs should also be covered and mark up shall be kept low based on the annual turnover.

Providing of cost data by the manufacturers should be mandatory. Any violation of price fixed shall be entitled to

sever punishment.

Prices of imported drugs should also be controlled based under the import price documents. Imported medicines may draw more duties than indigenously produced drugs.

Wholesale and retail margins should be determined by the Govt. which should be strictly followed. Like over pricing, under pricing should also be disallowed. Incentive, trade bonus should only be allowed in such a manner that would finally reduce prices to the consumers.

Prices of medicines should be net of taxes and shall be uniform all over the country.

Setup like NPPA should be strengthened with sufficient staff and statutory power.

Pharmacy Act:

Pharmacy Act should be amended so that each shop employ full time qualified pharmacist. More pharmacy colliages should be established to produce adequate number of qualified pharmacists. Preference should be given to qualified pharmacists for granting license to open retail chemist shops.

Pharmaceutical Authority:

A national Pharmaceuticals Athority should be constituted for monitoring production, selection of drugs, pricing, monitoring research, withdrawal of drugs. This committee should include experts from medical practitioners, industry, consumers, academics.

DR-1

JUST PUBLISHED!

World Health Organization
Regional Office for Europe

The EuroPharm Toolbox

A CD-ROM for professional management

By Willem de Boer, Kirsti Bult, Eeva Teräsalmi, Marja Airaksinen, Th. F.J. Tromp, Maaike Smit, and Ida Gustafsen
2005, CD-ROM, English
CHF 100.00/US$ 90.00/EURO 65.00
In developing countries: CHF 70.00/US$ 63.00
Order no.: 13400058

EuroPharm Forum is a joint network of national pharmaceutical associations and the World Health Organization Regional Office for Europe

To implement a new professional service a lot of choices have to be made. This interactive education tool provides a step by step approach to developing national implementation plans for professional programmes. Generalized from the EuroPharm pharmacy-based service programmes, the CD-ROM is designed to stimulate and support practicing pharmacists, health professionals, universities and pharmacy schools as they disseminate and implement best practices in any type of public health services.

The CD-ROM toolbox collates all the EuroPharm Forum model programmes and includes four central elements, i.e. a fictive case study, a real case study, the Forum guidelines and instruments, and country materials.

The fictive case study is a combination of theory and practice. Subjects like defining goals, implementation barriers, risk analysis, activity plan, communication plan, individual motivation plan and feedback are presented and, together with the EuroPharm models, used to create a guide to managing and implementing a best practice programme at national level. The patient education campaign *Ask about your medicines* is used as an example to explain the programme and guides the user through the process of adapting the campaign model to the specifics of his country and takes him through all the stages of developing and implementing such a project.

The real case study for inspiration and motivation is from Finland. It describes the development and use of the *Ask about your medicines* campaign as a tool for professional change, focused on long term goals, as well as objectives and consistent leadership to overcome the barriers that most likely will appear in the process.

The EuroPharm Forum material includes specific practice-oriented programmes within tobacco control, diabetes care, asthma care, hypertension management and patient education, and more general instruments like the communication plan and the feedback system.

The country material includes theories and models used in the EuroPharm Forum member countries and shows for example how the Forum instruments have been used in the specific countries.

729
28/10/05

Publications

WHO, **WHO Press**, 1211 Geneva 27, Switzerland
Tel +41 22 791 24 76 - Fax +41 22 791 48 57 - Email: publications@who.int
Web site: http://www.who.int/bookorders

Leb - Drugs/pharmaceutical resource file
JW 28/10

Contents

Introduction
Reasons for developing the product and how to use it.

Part A
1. How to develop the implementation of the patient education campaign QaM
- A case study on project management
- Theory: Enabling stage
- Theory: Promoting stage
- Theory: Willing stage
- Theory: Doing stage

2. Additional theoretical materials
- Communication plan EuroPharm Forum
- Theory about indicators
- Material Holland and Nimmo
  - Text about leadership and team building
  - Presentation

3. Additional examples of QaM practices (best practices)
- Case Finland
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4. Annex
- EuroPharm QaM 1993
- EuroPharm QaM update 2004

Part B
Theory and models used by EuroPharm Forum but not explained in part A (edited by the project group)
- EFS (feedback system)
- WebBoard conferences
- Cycle of project development and – management

Part C
Theory and models used within the EuroPharm Forum projects
- About the Forum
- Asthma services
- Smoking cessation
- Diabetes care
- Hypertension management
- Pharmacists and HIV/AIDS
- Twinning
- Declarations and resolutions

Part D
Theory and models used in member countries (unedited material)

DR-1.

Indian Express, 26th December, 1994

Marginal rise in drug price likely

EXPRESS NEWS SERVICE

BANGALORE

THE government and the drug manufacturers anticipate a marginal increase in the prices of drugs and pharmaceuticals soon, following the implementation of the modified drug policy of the Centre. The increase in drug prices is also attributed to the entry of multinational companies in a big way.

The indication to this effect was given at a seminar on "Consumers and the New Drug Policy" organised by the Consumers Rights, Education and Awareness Trust (CREAT) here on Sunday. Assistant Drug Controller B G Prabhakumar said the prices of drugs which by and large had remained stagnant since the last few years may increase marginally. However, he ruled out the possibility of abnormal increase in the prices of drugs as feared in some quarters.

Under the modified drug policy adequate care has been taken to check the drug prices he said, adding that the National Pharamaceuticals Pricing Authority to be constituted shortly, will be entrusted with the task of fixation of drug prices.

NATIONAL DRUG AUTHORITY: Mr Prabhakumar disclosed that the modified drug policy also envisages creation of a National Drugs Authority (NDA) the bill on which is pending before Parliament. The proposed authority which will have the task of implementing and supervising the policy effectively will also include consumer representatives.

However, he was sceptical about early functioning of the authority as personnel, including 400 drug inspectors, needed to be recruited. Allaying fears about an abnormal increase in drug prices, either due to the new policy or due to GATT proposals, he said the government had the powers to impose price control measures on the drug industry if the latter resorted to unreasonable increase in prices.

POLICY NOT HELPFUL: Karnataka State Drugs and Cosmetic Manufacturers Association President Jayaprakash Mady complained that the new policy had fallen short of expectations of the pharmaceutical industry.

According to him the industry will face a crisis due to restrictive measures regarding pricing of drugs. "The indigenous drug industry will have to give up research and development activities as they will be starved of funds besides facing a stiff competition from multi-national companies," Mr Mady said.

According to him the net profitability of drug industry was below four per cent and the prices of drugs in India are cheapest in the world. "To invent a new drug Rs 250 crore is needed over a period of 10 years and this will not be possible in the new world trade order" he added.

Mr.Mady urged the government to review the revised policy to make it more realistic and flexible.

CONSUMERS NEGLECTED: Dr Shiradiprasad Tekur of the Community Health Cell said the drug policy and the drug industry have failed to take the needs of consumers into consideration. He alleged that the drug industry, is only profit oriented and has failed to manufacture drugs badly required for people suffering from tuberculosis, anaemia and malaria, which are rampant in rural areas. He criticised the new policy for being silent on irrational and hazardous drugs.

Social Audit Limited
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PRESS STATEMENT

DRUG DIPLOMACY

Decoding the conduct of a multinational pharmaceutical company and the failure of a Western remedy for the third world

A new report from Social Audit

"Senior scientists in the US multinational pharmaceutical company, G.D. Searle, have consistently misinterpreted or misunderstood vital evidence about the hazards of the drug Lomotil for young children."

"Searle has promoted its drug Lomotil for the treatment of infants in the third world — though forbidden by law to do so in the US, since 1973. An overwhelming consensus of informed, independent medical opinion holds that Lomotil should not be used to treat children — and that it is potentially dangerous to do so."

"Searle has defended its promotion of Lomotil for infants with evidence from clinical trials — most of which is irrelevant, and much of which is shockingly bad."

These and other charges are made in a new book, Drug Diplomacy, published today by the British action-research group, SOCIAL AUDIT. The book is co-authored by Charles Medawar, Director of SOCIAL AUDIT — and by Barbara Freese, now a senior year undergraduate student at the University of Minnesota.

Drug Diplomacy examines the allegation that Western and other drugs "are undermining public health in the developing countries". It does this mainly by looking meticulously at the evidence for and against Searle's product Lomotil. Drug Diplomacy also gives a detailed account of recently-ended negotiations between SOCIAL AUDIT and Searle — after which the Company agreed to radically revise its marketing policies for Lomotil, throughout the world.

A Non-Profit Making Company
Registered No: 1042193 England Registered Office: 18 Victoria Park Square, London E2
Chairman: Christopher Zealley Directors: Andrew Phillips Charles Medawar William Osborn USA Oliver Thorold
Anthony Sampson Secretary: Maurice Frankel
Associated with Public Interest Research Centre Ltd

SOCIAL AUDIT's negotiations with Searle ended when the US Company's top scientists and public relations staff came to London, to tell SOCIAL AUDIT that Searle would no longer recommend the use of Lomotil for children aged under two — and to say that the Company would revise its prescribing instructions for physicians, worldwide, to bring them into line with current US recommendations.

But SOCIAL AUDIT is far from satisfied with this. According to Medawar: "to see this as a happy ending is to miss the point almost completely. The point here is not that reason won the day. It is that normally, companies like Searle seem ever ready to abandon reason, and even to pursue ignorance in the search for corporate bliss."

Medawar went on to explain why SOCIAL AUDIT remains "profoundly unhappy" about the present situation:

> "One. This Company's senior scientists continue to stand by evidence from clinical trials — most of which is irrelevant and much of which is shockingly bad. Anyone who can add, subtract and divide would be appalled that Searle could ever have relied on such data — and will be extremely disturbed to know that the Company apparently still does." (See pp. 31 - 44 and p. 32).

> "Two. This case-history clearly suggests that comparable, conspicuously poor evidence is widely accepted at face value. It is alarming that government drug regulatory authorities should have licensed the use of Lomotil for infants, when the evidence in its favour is so dubious — and when the evidence against is so strong. Even the World Health Organisation — which hardly ever criticises named products — has stated that Lomotil, and other antidiarrhoeal drugs like it, are of 'no value' and 'are dangerous in children." (See pp. 11 - 13).

"Three. Lomotil has this disastrous effect in developing countries in spite of the fact that it is a pharmacologically reputable drug. In theory, at least, Lomotil represents an improvement on the thousands, rather than hundreds, of other Western drugs, whose effect in developing countries is mainly to turn things from very bad to very much worse." (See pp. 50 - 56).

SOCIAL AUDIT is looking to the World Health Organisation to control abuse by multinational pharmaceutical companies in the third world — though with obvious misgivings. SOCIAL AUDIT in fact suggests that the WHO "may not be equal to this elementary reform of world health". The report Drug Diplomacy strongly suggests that the WHO's very existence would be jeopardised by business and national interests, if it tried to do so. (See pp. 57 - 63).

NOTES FOR EDITORS AND REVIEWERS

The SOCIAL AUDIT report was largely researched by a young American student, Barbara Freese (21), who worked with SOCIAL AUDIT during a "junior year abroad" in 1981. Drug Diplomacy was largely written by Charles Medawar, who supervised Freese's work — which was undertaken in part-fulfilment of a 4-credit course on "International Relations". Freese had been directed to SOCIAL AUDIT by Ralph Nader — for whom Medawar worked in 1971, and who remains a keen and active supporter of SOCIAL AUDIT's work.

SOCIAL AUDIT is an independent, non profit organisation, concerned with improving government and corporate responsiveness to the public generally. Its concern applies to all corporations and to any government, whatever its politics. SOCIAL AUDIT acts as the publishing arm of PUBLIC INTEREST RESEARCH CENTRE LTD — a registered charity, whose work has been supported by the Joseph Rowntree Social Service and Charitable trusts, the Social Science Research Council, the Ford Foundation and other sponsors. This project was supported notably by the British welfare group WAR ON WANT and by the INTERNATIONAL ORGANISATION OF CONSUMERS UNIONS.

Drug Diplomacy is available from SOCIAL AUDIT at 9 Poland Street, London W1V 3DG. Price: £3.95 plus 35p p&p in the UK. (Elsewhere, add 55p for surface mail to all countries. For air mail post add 90p in Europe and £1.80 for other countries).

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(S.1/2/82)

Consolidated List of

Products

Whose Consumption and/or Sale Have Been

Banned

Withdrawn, Severely Restricted or not Approved by Governments

United Nations

Product name **Sulfaguanidine**

C.A.S number 57-67-0

Scientific and common names, and synonyms
BENZENESULFONAMIDE, 4-AMINO-N-(DIAMINOMETHYLENE)-
N-AMIDINOSULPHANILAMIDE MONOHYDRATE
N1-(DIAMINOMETHYLENE)SULFANILAMIDE
SULFAMIDINUM
SULGINUM

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
DOM	June 1971	Prohibited for import, manufacture, distribution, storage, sale or medical prescription. It has been found to be ineffectual in the treatment of acute bacterial dysentery and in therapeutic use with colon surgery in reducing hospitalization. Furthermore, it has been shown that most strains of Shigella have developed a resistance against this drug in vivo.
IRN	1972	The Ministry of Health has prohibited the importation and production of all drugs containing sulfaguanidine.
THA	Jan. 1975	May only be used in the treatment of diarrhoea.
TUR	4 Mar. 1985	Banned for production and sale having regard to severe adverse reactions.
DNK		Withdrawn from the market by the manufacturer.
VEN		Not approved for use and or sale. Compound currently under study.

WHO comment: Sulfaguanidine, a sulfonamide anti-infective agent, was introduced in 1941 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. Although sulfaguanidine, which is poorly absorbed from the gastrointestinal tract, is no longer recommended in some countries, it continues to be used in others for the treatment of local intestinal infections, including bacterial dysentery, and for pre-operative bowel preparation.

Product name **Sulfamethizole**

C.A.S number 144-82-1

Scientific and common names, and synonyms
BENZENESULFONAMIDE, 4-AMINO-N-(5-METHYL-1,3,4-THIADIAZOL-2-YL)-
N1-(5-METHYL-1,3,4-THIADIAZOL-2-YL)-SULPHANILAMIDE
N1-(5-METHYL-1,3,4-THIADIAZOL-2-YL)SULFANILAMINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
SWE	1 Feb. 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. A combination of adverse reactions and low sales led to this decision.

WHO comment: Sulfamethizole, a sulfonamide anti-infective agent, was introduced in 1953 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. However sulfamethizole, which is rapidly eliminated, retains a place in the treatment of urinary infections in some countries whereas in others its use has been discontinued.

Somatropin (pituitary-derived)

12629-01-5

TRADE AND BRAND NAMES :

Antuitrin growth
Antuitrin-t
Asellacrin
Cb 311
Corpormon
Crescormon
Grorm
Hgh
Human growth hormon
Leutrophin
Nanormin
Nanormon
Phynatol
Phyol
Phyoneon
Protopin
Protropin
Rx 099916
Somacton
Somatonorm
Somatormone
Somatrolin
Somatropin
Sth
22krl

For regulatory information, see page 118

Spironolactone

52-01-7

TRADE AND BRAND NAMES :

Acelat
Aldactone
Aldace
Aldactone 25
Aldactone
Aldactone-a
Aldazida
Aldonorm
Aldopur
Aldospirone
Aldozone
Alexan
Almatol
Alpamed
Altex
Altexide
Aporasnon
Aquarcduct
Carditan
Crk 635
Ct-spiro
Deverol
Diatensec
Digi-aldopur
Dilakton
Dira
Duraspiron
Euteberol
Hokulaton
Hokuraton
Hydrospiron
Idiolaton
Lacalmin
Lactone
Lasilacton
Lasitone
Loractone
Mf 218d
Nefurofan
Noidouble
Osiren
Osyrol
Osyrol-lasix
Penantin
Pirolcaton
Plarenil
Practon 50
Raudazida
Risicordin
Rolactone
Sagisal
Sali-spiroctan
Saluretin
Sas 1060
Sc 9420
Servilactone
Sincomen
Spiresis
Spirelic
Spiridazide
Spiridon
Spirix
Spiro comp
Spiro-f
Spiro-tablinen
Spiroctan
Spirodigital
Spirolang
Spiron
Spironomocompren
Spironone
Spironothiazide
Spiropal
Spiroprop
Spirostada
Spirotone
Spiro50-d
Supraputen
Suracton
Synureticum
Tensollex
Uractone
Urusonin
Verospiron
Xenalone

For regulatory information, see page 119

Sulfaguanidine

57-67-0

TRADE AND BRAND NAMES :

Aseptil-guanidina
Aterian
Coliseptale
Devaguanil
Diacta
Dirkan
Emerin
Ente-rivo simplex
Ganidan
Granidan
Guamide
Guanicil
Guanidan
Guanowept
Guasept
Inorgan
Intestovet
Ordenol
Orgaguanidon
Percural
Resulfon
Ruocil
S-guanidan
Sgd
Shigatox
Suganyl
Sullacarbon
Sulfaglobenicol
Sulfentidine
Sulfogua
Sulgin
Tetrawest
Trisulvet

For regulatory information, see page 121

Product name **Phthalylsulfathiazole**

C.A.S number 85-73-4

Scientific and common names, and synonyms
BENZOIC ACID, 2-[[(4-[2-THIAZOLYLAMINO]SULFONYLPHENYL)AMINO]-CARBONYL]-
4'-[2-THIAZOLYLSULFAMOYL]PHTHALANILIC ACID
6'-(THIAZOLYLAMINOSULFAMOYL)PHTHALANIC ACID

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned. It has been found to be of little or no therapeutic value, its side effects can be harmful, and it is subject to misuse. (Reference: (BGDCO) The Drugs (Control) Ordinance , , 1982)

WHO comment: Phthalylsulfathiazole, a sulfonamide anti-infective agent, was introduced in 1946 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. Although phthalylsulfathiazole, which is poorly absorbed from the gastrointestinal tract, is no longer recommended in some countries, it continues to be used in others for the treatment of local intestinal infections, including bacterial dysentery, and for pre-operative bowel preparation.

Product name **Pipamazine**

C.A.S number 84-04-8

Scientific and common names, and synonyms
10-(3-(4-CARBAMOYLPIPERIDINE)PROPYL)-2-CHLOROPHENOTHIAZINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
USA	July 1969	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to the lack of proof of efficacy and safety for use as an antinauseant and antiemetic for pregnant women.

WHO comment: Pipamazine, which is pharmacologically similar to chlorpromazine, was introduced in 1959 for the treatment of nausea and vomiting. Although it was withdrawn in 1969 by the United States FDA on grounds of lack of proof of efficacy and safety, it remains available in some countries.

Product name **Piperazine**

C.A.S number 110-85-0

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
ITA	1977	Products with anthelminthic indications have been withdrawn due to an unfavourable risk/benefit balance. Since 1975, warnings have been added to the labels concerning the possibility of neurotoxic effects with high dosages. In 1979, the label was revised to advise use on an empty stomach and for short periods of time with long intervals, in order to avoid interaction with nitrites.
SWE	1983	In the light of the carcinogenic and mutagenic potential of piperazine demonstrated in recent studies, discussions between the manufacturers and the Department of Drugs have led to the withdrawal of registration for this drug.
DNK	2 July 1984	Following recent evidence leading to the possibility that carcinogenic nitroso-derivatives may be generated in vivo, preparations containing piperazine have been placed under prescription control. (Reference: (UGLAAD) Ugeskrift for Laeger , 1949 , June 1984)

...[Continued]

Phthalylsulfathiazole

85-73-4

TRADE AND BRAND NAMES :

Aftalyl
Canidis-anti-diarr
Carbidiar
Carbotalin
Colicitina
Coliclase
Cortinen
Crematalil
Cremothalidine
Diaban
Diacolin
Diarrestival
Dienterol
Direver
Disenterol
El-micin
Enteramida
Entero-hermes
Entero-red
Entero-sullina
Entero-loxan
Enterocalme
Enterosteril
Entexidina
Esteraplidin mag
Eugenileed
Fitazil
Ftalil-esteve
Ftalil-septol
Ftalil-tiazol
Ftalysept
Ilentazol
Ingalipt
Intestibla strepto
Intestiazol
Iodentero-neomicina
Logical
Massotalil
Neo-sulfazon
Novosullina
Phtalazol
Phtazol
Porcijec
Septiftalil
Sulfacetil
Sulfathalidine
Sulftalyl
Syptan
Syralbina
Taleudron
Talidine
Talisulfazol
Taloudron
Tamil
Thalazole
Thalinil
Thalistanin
Thalistatyl
Thiazole
Trisulvet
Ultratiazol
Vetoryl

For regulatory information, see page 110

Pipamazine

84-04-8

TRADE AND BRAND NAMES :

Moxnidine
Nausidol
Normetine

For regulatory information, see page 110

Piperazine

110-85-0

TRADE AND BRAND NAMES :

Adelmintex
Adipalis
Adipalit
Adipiazine
Adiver
Ancaris thenium
Ancazine
Antelmina
Antepar
Antepar (b-w)
Anterobius
Anthalazine
Anthelmina
Anticucs
Antiren
Antivermine
Antoban
Arduvermin
Arpezine
Asca-trol no 3
Ascalix
Ascarinex
Ascarivet
Asepar
Askaripar
Averamexan
B-piperazine
Bel-zine
Bioxurin
Brirel
Bryrel
Candizine
Ciperazin
Citrazine
Coopane
Dak
Demovermil
Diatesurico
Dicevermin
Dietelmin
Digesan
Dilaurazine
Dispermin
Diurazina
Divermex
Dowzene
Dyrex
Ecosan
Endorid
Entacyl
Entazin
Equizole-a
Eraverm
Escovermin
Esteropipate
Etaphylline (acetyllinate)
Exelmin
Expoin
Gentiazina
Glycopiparsol
Heksapar
Helmacid
Helmezin
Helmicide
Helmifren
Helmipar
Helmirazine (adipate)
Helmirazine (citrate)
Helmitin
Helmizin
Herb royal round worm treatment
Hexanthelin
Ismiverm
Janes liquid permifu
Jarabe neox
Jetsan supp (adipate)
Justalmin
Kennel-maid
Kihomato
Kontipar
Lamboxil
Lom
Lombricida tropico
Lombrither
Lombrikal
Lombrimade
Lumbrical

...[Continued]

Product name **Neomycin sulfate**

C.A.S number 1405-10-3

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned since it has been shown to cause malabsorption in children and to be of little or no therapeutic value. (Reference: (BGDCO) The Drugs (Control) Ordinance , , 1982)
PHL	July 1982	All anti-diarrhoeal preparations for oral administration containing this product have been banned. Most cases of diarrhoea have been found to be resistant to the drug and its constant use promotes pseudomembranous colitis in infants and children. Neomycin can cause other serious adverse effects including renal damage, neuro-muscular blockage and ototoxicity, possibly leading to deafness in some patients. (Reference: (PHADO) Administrative Order No. 24, July 1982)

WHO comment: Neomycin sulfate, a broad-spectrum antibiotic, was first isolated in 1949 and has subsequently been included in topical, oral and parenteral preparations. Its value in the treatment of diarrhoea is widely questioned although it is still contained in a number of widely available antidiarrhoeal preparations. In some countries the officially approved indications for oral preparations are restricted to the preparation of the bowel prior to surgery and the management of hepatic coma. Topical preparations of neomycin sulfate are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee 722 . , 1985)

Product name **Nialamide**

C.A.S number 51-12-7

Scientific and common names, and synonyms
ISONICOTINIC ACID 2-((-BENZYLCARBAMOYL)ETHYL)HYDRAZIDE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
JPN	Nov. 1974	The Ministry of Health and Welfare withdrew all products containing isocarboxazid and nialamide on the grounds that they lack substantial evidence of efficacy and safety.
IND	1983	Prohibited for manufacture and sale for reasons of health risks associated with use and or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary (Part II-Section 3.I) , , 1983)
CUB		Prohibited from use by the national formulary commission (1982) on grounds of reported toxicity and in view of the availability of other less toxic drugs.
DNK		Withdrawn from the market by the manufacturer.
SAU		Products now controlled by the authorities.
THA		Products have been banned.
VEN		Banned for use and or sale.

WHO comment: Nialamide, a monoamine oxidase inhibitor (MAOI), was introduced in 1959 for the treatment of depressive illness. Subsequently concern regarding potentially serious interactions between MAOIs and foods containing tyramine inspired much restrictive regulatory action. However, MAOIs still retain a place in the treatment of serious depressive illness although there is no international consensus on which compounds should be preferred. Thus nialamide remains available in several countries.

Neomycin sulfate

1405-10-3

TRADE AND BRAND NAMES :

Abilene
Akentect
Amcort
Amphocort
Antibifulle
Apokalin
Aurex
Aurisod
Baneocol
Barriere-mycin
Bastu-angin
Bedermin 100
Benestermycin
Bio-vitastrept
Biodry
Biofradin
Biotur
Biosol
Biosol-m
Bivacyn
Blastoestimulina
Bykanula
Bykomycin
Canaural
Canoral
Cebemyxine
Cefrocyn
Cg 3224
Cicatrex
Cleniderm
Clorpine
Conderm
Conjuctilone
Cornemin
Cortinen
Damapo
Davimycin
Degramycin
Dermadex
Dermicema
Dermo sonerge
Dermolace
Dermosan
Dermovate-nn
Derobion
Dexaamisolone-n
Dexabiotan
Dexacidin
Dexamist
Dexavetaderm
Dia-ject
Diaban
Diacin
Diarest
Dicortineff
Dienterol
Dimicina
Doreplaston/doserf
Dorithicin
Dulcicortine
Duphacerate
Dv 201
Emcortina
Emorex k berna
Enbacin
Endomixin
Enteral
Enteromac
Enteropast
Enterosintex
Eustoporin
Extracort
Febrizene
Fissan
FI 6321 n
Fluonid
Fml-neo-liquifilm
Foille
Forbesotic
Formula 888
Forte
Forticillin
Fradyl
Frakidex
Frakitacine
Gastromycin
Gregoderm
Gustibon
H plus n
Hagrosept
Halicomb
Halog
Heliomycort
Hydro-neo oculos
Hydrocortiderm
I-caps
Idepa
Ido-op
Intradermo caf
Iodenteroôneomicina
Itro
Jenomycin
Kanagotas
Kortikod mepha
Lambiotic
Larmicin
Latodurin
Linitut
Mammanopen
Mastrinal
Medisec neo
Medisec-cloxa
Medri-biotic
Meimyd
Menaderm antiacne
Myacyne
Mycerin
Mycidex
Mycifradin
Myciguent
Mycimist
Mycipo
Mytrex
Naso-neomicin
Nasomixin
Nasydrin
Nefluan
Neimicina roger
Neo decaderm
Neo-analsona
Neo-cantil
Neo-delta-cortef
Neo-hydro
Neo-m
Neo-mantle
Neo-mastitar
Neo-myx
Neo-otosol-hc
Neo-remusin
Neoaristovet
Neobacimyx-h
Neobicin
Neobiotic
Neobrettin
Neobristan
Neocidin
Neocillin
Neoclox
Neocones
Neodecasone
Neofluid
Neointestin
Neolate
Neomac
Neomin
Neomix
Neomycane
Neopenol
Neopt
Neostrep
Neosule
Neosulf
Nifuramicin
Nisocla
Nisoclyn
Nisodyn
Nivemycin
Nodryl
Nokamycin
Noperil
Normoc
Npa
O-biol
Ophthimycin
Optiprime opthcoat
Optison
Optisone
Oribiotic
Otarna
Otcair
Oto vitna
Oto-ftunal
Oto-sinerbe
Otocortison
Otomycin
Panotile
Paralen
Parkeole
Parkesteron
Pervet
Phytacorcin
Pivalone
Polemycin
Poly-pred
Polybactrin-g
Polydexa
Polygynax
Polyspectin
Porcijec
Prednicidin
Prevotec
Propaderm-n
Pulveodil
Pyocidin hc
Quadrex
Renokab
Rino
Rino vitna
Rinofilax
Rinojet
Rovicine
S-thalmic
Sanibiovit
Sanimix
Sanistress
Secantol
Septa
Septomixine forte
Silderm
Siquent neomycin
Sofan
Spersapolymyxin dispersa

...[Continued]

Manufacturer data

Product name **Difurazone** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
		WHO comment: Difurazone, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information to suggest that it remains commercially available.

Product name **Dihydrostreptomycin**

C.A.S number 128-46-1

Scientific and common names, and synonyms
DHSM
DST

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
USA	Sep. 1970	Withdrawn from the market (injectable form) and prohibited for export by the Food and Drug Administration on the grounds of an unfavourable benefit/risk ratio. This antibiotic is considered unsafe due to its ototoxic hazards.
PHL	1972	Dihydrostreptomycin and its salts, singly or in combination, were withdrawn from sale for human use. The drug can cause severe vestibular damage.
ESP	1 Oct. 1983	The Ministry of Health and Consumer Protection has withdrawn approval for dihydrostreptomycin except in oral preparations. (Reference: (ESPMC) Programa Selectivo de Revisión de Medicamentos PHASE I, , Sep. 1983)
DOM		Prohibited for use and/or sale since scientific studies have shown that it can cause deafness.
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
PER		Prohibited for use in its injectable form. It has been found to cause permanent deafness.
		WHO comment: Dihydrostreptomycin, a derivative of the aminoglycoside antibiotic streptomycin with similar antibacterial activity, was first synthesized in 1947 and subsequently used in the treatment of tuberculosis and gram-negative infections. Preparations for systemic use have been widely withdrawn as a result of concern regarding their severe ototoxicity. Dihydrostreptomycin is poorly absorbed from the gastrointestinal tract. It remains available in oral preparations in some countries.

Product name **Dihydroxymethylfuratrizine**

C.A.S number 794-93-4

Scientific and common names, and synonyms
((6-2(5-NITRO-2-FURYL)VINYL)-AS-TRIAZIN-3-YL)IMIDO)DI-METHANOL
BIS(HYDROXYMETHYL)FURATRIZINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
SAU		The withdrawal of nitrofuran compounds is under consideration since they have been superseded by safer and more effective preparations.
JPN	July 1977	Withdrawn from all marketed preparations in 1977 on the grounds that it has been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.

...[Continued]

Legislative or regulative action

Diethylstilbestrol ...[Continued]

TRADE AND BRAND NAMES :

Ragestrol rt83
Remumestrol 2
Rumestrol 1
Rumestrol 2
Rymestrol rt83
Sedestran rt83
Serral
Sexocretin
Sibol
Sintestrol rt83
Stearettes
Stibilium rt83
Stil
Stil-rol
Stilbestrol
Stilbetin
Stilbetine
Stilbette
Stilbilium
Stilboetral
Stilboestroform
Stilboestrol
Stilbofollin rt83
Stilbol
Stilbosol
Stilcap
Stilkap
Stilnestrin
Stilphostrol
Stimplants
Synestrin
Synoestrin
Synthoestrin
Synthofolin
Syntofolin
Tampovagan stilboestrol rt83
Tend-a-water
Tribiotic
Tylosterone
Ut forte
Vagestrol
Vet nutri

For regulatory information, see page 49

Difurazone

804-36-4

TRADE AND BRAND NAMES :

Panzon
Payzone

For regulatory information, see page 50

Dihydrostreptomycin

128-46-1

TRADE AND BRAND NAMES :

Abiocine
Abocillin
Biostrep
Complexobiotico
Dhsm
Diapenin balsamico
Diapenin 3
Diarrestival
Dicromycin
Didrotrenate
Dihydrocidan sulfato
Dihydrostreptofar
Dihydrostreptom
Diidro-pantostrept
Distreptopab
Dreiciclina balsamica
Dst
Entera-strept
Estreptoluy
Helle-strep-forte
Hp 48
Mastigun
Mixtencillin
Retromyopen
Rocopenstrep
Sanstrepto
Solmycin
Solvo-strept
Streptoduocin
Veticar
Veycil-as
Vibriomycin

For regulatory information, see page 51

Dihydroxymethylfuratrizine

794-93-4

TRADE AND BRAND NAMES :

Furatone
Panfuran s

For regulatory information, see page 51

Dimazole

95-27-2

TRADE AND BRAND NAMES :

Asterol
Atelor
Atelora
Aterola
Kesten
Mycotol

For regulatory information, see page 52

Product name **Lobelia**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this drug has been prohibited for use. All prescription chemicals and galenical preparations not included in the latest edition of the British Pharmacopeia or British Pharmaceutical Codex have been prohibited for use. (Reference: (BGDCO) The Drugs (Control) Ordinance , , 1982)
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
		WHO comment: Lobelia comprises the dried aerial parts of lobelia species, the activity of which is due chiefly to the alkaloid lobeline. Although preparations containing lobelia were formerly available for use in the symptomatic treatent of asthma, they are now largely obsolescent as a result of their irritant properties and the availability of more effective preparations.

Product name **Loperamide**

C.A.S number 53179-11-6

Scientific and common names, and synonyms
PIPERIDINEBUTANAMIDE, 4-(4-CHLOROPHENYL)-4-HYDROXY-N,N-DIMETHYL-alpha, alpha-DIPHENYL
4-(P-CHLOROPHENYL)-4-HYDROXY-N,N-DIMETHYL-alpha,alpha-DIPHENYL-1- PIPERIDINEBUTYRAMIDE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL	Nov. 1982	Restricted for use as an antidiarrhoeal drug. Contraindicated in children below two years of age due to the risk of central nervous system damage.
		WHO comment: Loperamide, an inhibitor of intestinal peristalsis, was introduced in 1975 for the treatment of acute and chronic diarrhoea. In many countries its use is discouraged in young children. A WHO Steering Committee has recommended that loperamide should not be used in children below five years of age with acute diarrhoea.

Product name **Lynestrenol**

C.A.S number 52-76-6

Scientific and common names, and synonyms
19 NORPREGN-4-EN-20-YN-17-OL, (17alpha)-
19-NOR-17-alpha-PREGN-4-EN-20-YN-17-OL

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
AUS	1980	High dosage (2.5mg) lynestrenol products were withdrawn following demonstration of a dose-related incidence of mammary tumours in the beagle bitch. It is acknowledged, however, that this species may not offer a reliable model for predicting possible carcinogenicity of progestogens in humans. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee No.90,,)
SAU		Products under control by the authorities.

...[Continued]

Lead oxide and lead salts

TRADE AND BRAND NAMES :

Hiroval Windomethasone

For regulatory information, see page 75

Levamfetamine

156-34-3

TRADE AND BRAND NAMES :

Amphedrine-m Cydril

For regulatory information, see page 75

Loperamide

53179-11-6

TRADE AND BRAND NAMES :

Ami-29
Arret
Blox
Brek
Colifelin
Dissenten
Dissenter
Duplibiot
Elcoman
Firtasec
Imodium
Imosec
Lopemid
Lopemin
Loperan
Loperin
Lopermid
Loperyl
Motilix
Orulop
Pf 185
Pricilone
R-18553
Regulane
Seldiar
Suprasec
Taguinol
Telboc
Tirtasec

For regulatory information, see page 77

Lynestrenol

52-76-6

TRADE AND BRAND NAMES :

Anacylin
Anacylin 101
Anacylin 28
Ancylin
Athilyn
Endometril
Exlutena
Exlution
Exluton
Exluton (a)
Exlutona
Fisioquens
Fysioquens
Lindiol 2.5
Lyn-ratiopharm
Lyndeol
Lyndiol
Lyndiol e
Lyndiolett
Lynoenstrenol
Minette
Mini pregnon
Minilyn
Ministat
Neo-lindiol
Neo-lynobol
Nonovulet
Noracyclin
Noracyclin 22
Normophasic
Org 485-50
Orgaluton
Orgametril
Orgametril
Orgametrol
Ovamezzo
Ovoresta
Ovoresta m
Ovosta
Ovostat
Ovostat-micro
Ovostat-28
Physistat
Pregnon
Pregnon-28
Restovar
Yermonil

For regulatory information, see page 77

Meclozine

569-65-3

TRADE AND BRAND NAMES :

Ancolan
Ancoloxine
Antivert
Bonamina
Bonamine
Bonexyl

...[Continued]

Product name **Acetylsalicylic acid/phenacetin/caffeine (APC)**

Scientific and common names, and synonyms
APC
CAFFEINE,PHENACETIN ACETYLSALICYLIC ACID
PHENACETIN/ACETYLSALICYLIC ACID/CAFFEINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
THA	1983	Banned for manufacture for immediate effect but existing stocks may be sold for a further period of one year. Preparations must be reformulated to contain only acetylsalicylic acid.

Product name **Antirheumatic combinations with glucocorticosteroids**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
AUT	Jan. 1986	Enteral preparations have been withdrawn and parenteral preparations may only be used for very limited indications and under strict medical supervision.
DEU	1 Jan. 1986	Fixed combinations have been withdrawn since concurrent administration of such drugs potentiates adverse effects without increasing benefit.

Product name **Atropine**

C.A.S number 51-55-8

Scientific and common names, and synonyms
alpha H, 5alpha H-TROPAN-3alpha-OL(+ -)-TROPATE (ESTER)
BENZENEACETIC ACID, alpha-(HYDROXYMETHYL)-8-METHYL-8-AZABICYCLO(3.2.1) OCT-3-YL ESTER, ENDO (+ -)

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL	Sep. 1976	Combinations of atropine sulfate with difenoxylate, furazolidone and dimethylpolysiloxane have been disapproved due to possible adverse reactions such as dysuria (from atropine and furazolidone), tachycardia, palpitation and blurring of vision. WHO comment: Atropine, an alkaloid with anticholinergic activity extracted from Atropa belladonna, has been widely used in medicines for centuries. The action taken in the Philippines relates specifically to the use of atropine in combination products. Elsewhere, preparations containing atropine remain available and the substance is included in the WHO Model List of Essential Drugs. (Reference: (WHODI) WHO Drug Information 2 , 1 , 1988)

Product name **Barbiturates in combination**

Scientific and common names, and synonyms
ANALGESICS,BARBITURATES
ANTACIDS/BARBITURATES
ANTIASTHMATICS,BARBITURATES

...[Continued]

Product name **Hexobarbital**

C.A.S number 56-29-1

Scientific and common names, and synonyms
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-(1-CYCLOHEXEN-1-YL)1,5-DIMETHYL
5-(CYCLOHEX-1-ENYL)-1,5-DIMETHYLBARBITURIC ACID
5-(1-CYCLOHEXEN-1-YL)-1,5-DIMETHYLBARBITURIC ACID)

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
SWE	Oct. 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing hexobarbital. **WHO comment:** Hexobarbital is a short-acting barbiturate. See WHO comment for barbiturates.

Product name **Hyoscine methonitrate**

C.A.S number 6106-46-3

Scientific and common names, and synonyms
METHYLSCOPOLAMINE NITRATE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
SWE	June 1981	Hyoscine methonitrate, an antimuscarinic agent, has been withdrawn from appetite suppressant preparations. **WHO comment:** Hyoscine methonitrate, a quaternary ammonium anticholinergic agent, was introduced in 1947 for use as a gastrointestinal antispasmodic. The action taken in Sweden relates to the use of this compound in preparations for suppressing the appetite. Preparations may remain available elsewhere.

Product name **Indalpine**

C.A.S number 63758-79-2

Scientific and common names, and synonyms
2-(3-(4-PIPERIDYL)ETHYL)INDOLE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
FRA	13 July 1985	Following reports of agranulocytosis and severe neutropenia associated with the use of indalpine, the major manufacturer in consultation with the French health authorities decided to suspend the marketing of this drug. (Reference: (FMOPL) Le Moniteur des Pharmacies et des Laboratoires 1666 , , June 1985) **WHO comment:** Indalpine, an antidepressant with serotoninergic action, was introduced in 1983 and marketed exclusively in France. In 1984 its use was associated with cases of leucopenia and agranulocytosis which led to the voluntary suspension of clinical trials in the USA. In 1985 the major manufacturer voluntarily withdrew the drug from the market.

Hyoscine methonitrate

6106-46-3

TRADE AND BRAND NAMES :

Mescomine tn86
Mesconit
Skopolate tn86
Skopyl tn86
Skopyle
Viscope tn86

For regulatory information, see page 69

Indalpine

63758-79-2

TRADE AND BRAND NAMES :

Lm 5008
Upstene

For regulatory information, see page 69

Indoprofen

31842-01-0

TRADE AND BRAND NAMES :

Bor-ind
Endyne
Fenint
Flogosan
Flosin
Flosine
Flosint
Flosyn
Isindone
K 4277
Miantor
Praxis
Reumolene

For regulatory information, see page 70

Iodinated casein strophanthin (neo-barine)

TRADE AND BRAND NAMES :

Coratose

For regulatory information, see page 70

Iproniazid

54-92-2

TRADE AND BRAND NAMES :

Euphozid
Ipropran
Isotamine
Laniazid
Marsilid
Nydrazid
P-1-n forte
Pms isoniazid
Rifamate
Rimactane
Rimifon
Ro 7-1554
Teebaconin
Triniad
Uniad

For regulatory information, see page 70

Isaxonine phosphate

4214-72-6

TRADE AND BRAND NAMES :

Nerfactor
Verfactor

For regulatory information, see page 71

Product name **Griseofulvin** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
CSR		Having regard to recently evaluated reports of carcinogenicity, fetotoxity and teratogenicity in rodents administered very high doses of griseofulvin, the Committee on the Review of Medicines has recommended that all products containing griseofulvin should be restricted in their use to the treatment of dermatophyte infections of the skin, scalp, hair and nails when topical therapy has failed or is considered inappropriate. It also recommends that such products should not be used during pregnancy or for prophylactic treatment.
		WHO comment: Griseofulvin, isolated from a penicillin producing mould, has been widely used as a systemically administered antifungal agent in man for over 20 years. It is effective in dermatophyte infections (including tinea barbae and tinea capitis) but it is inactive against yeasts and bacteria. Evidence that very high doses of griseofulvin are carcinogenic, teratogenic and fetotoxic in laboratory animals has led to an acceptance that it should not be used to treat trivial infections that respond to topical therapy. Oral formulations of griseofulvin are included in the WHO Model List of Essential Drugs (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee 722 . . 1985)

Product name **Guanofuracin**

C.A.S number 300-25-4

Scientific and common names, and synonyms
5-NITROFURFURYLIDENAMINOGUANIDINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
VEN		Not approved for use and or sale.
		WHO comment: Guanofuracin, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information that it remains commercially available.

Product name **Halogenated hydroxyquinoline derivatives**

C.A.S number 148-24-3

Scientific and common names, and synonyms
OXINE
OXYQUINOLINE
8-QUINOLINOL

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
DNK	1978	All halogenated hydroxyquinoline derivatives intended for oral administration have been withdrawn from use. (Reference: (UGLAAD) Ugeskrift for Laeger 140 , 1181 , 1978)
CYP	1980	The Drug Council withdrew all products containing halogenated hydroxyquinoline derivatives intended for internal use due to the possible risk of occurrence of sub-acute myelo-optic neuropathy (SMON) in treated patients.
PHL	Aug. 1980	Withdrawn from the domestic market due to reports of neurological disorders (SMON) with their use in Japan.

...[Continued]

Glutethimide

77-21-4

TRADE AND BRAND NAMES :

Allimid
C "5"
Doriden
Doriden-sed
Doridene
Doridine
Dorimid
Elrodorm
Glimid
Gludorm
Noxyron
Rigenox
Sarodormin
~~Semid~~
Somvit
Tardyl

For regulatory information, see page 64

Griseofulvin

126-07-8

TRADE AND BRAND NAMES :

B-gf
Delmofulvina
Fulcine
Fulcine-s
Fulcine-125
Fulvicin
Fulvicin u/f
Fulvicina
Fungivin
Gelulvine
Greosin
Gricin
Grifulin
Grifulvin
Grifulvin v
Gris-peg
Grisactin
Grisaltin
Grisetulin
Grisefulvin
Griseo
Griseomed
Griseostatin
Grisovin
Grisovin-fp
Grisovina
Grisowen
Grysio
Lamoryl
Lamoryl-novum
Likuoen
Neo-filcin
Norofluvin
Polygris
Sulvina

For regulatory information, see page 64

Halogenated hydroxyquinoline derivatives

148-24-3

TRADE AND BRAND NAMES :

Aci-jel
Cp-cap
Fennosan h 30 tn86
Herrat
Hydroxybenoxopyridine
Oxin tn86
Oxine tn86
Oxyquinoline-rhp
Pedivol
Phenopyridine tn86
Preconsol
Quinoped
Quinophenol tn86
Semori
Serohinol
Superol
Tumex

For regulatory information, see page 65

Halogenated salicylanilides

TRADE AND BRAND NAMES :

Alamin
Annul
Bada
Hilomid
Salinidol
Temasept

For regulatory information, see page 66

Heptabarb

509-86-4

TRADE AND BRAND NAMES :

Heptadorm
Medapan
Medomin
Medomina
Medomine

For regulatory information, see page 67

Product name **Chlorobenzilate** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL		Prohibited for import except in cases of emergency as determined by the authorities.
SGP	Apr. 1984	Importation and sale for local use is banned. This decision was taken to safeguard water sources. (Reference: (MINHS) Ministry of Health , , 1983)
SWE	31 Dec. 1979	Has been withdrawn after mutual discussions between National Products Control Board and the importers because of its carcinogenic effect on experimental animals. (Reference: (PKB) Produktkontrollnaemndens Beslut fraan Den. , , 31 Dec. 1979)
USA	Feb. 1979	Cancellation and denial of registration of chlorobenzilate products for uses other than citrus uses in Florida, Texas, California, and Arizona. Notwithstanding the above, registration of chlorobenzilate products for citrus use in these four states will also be cancelled or denied unless registrants or applicants for new registrations modify the label to include the following: "Restricted use pesticide. For retail sale and use only by certified applicators. Special precautions are to be taken when handling the product and special clothing to be worn." Several scientific studies provided a reliable basis for concluding that chlorobenzilate induces oncogenic effects (i.e. produces tumors) in certain mammalian species and that these laboratory studies and information on human exposure provided substantial evidence that chlorobenzilate poses a risk of cancer and adverse testicular effects. (Reference: (FEREAC) Federal Register 44 , 9548 , 1979)

Bibliographical references

FAO PLANT PRODUCTION & PROTECTION PAPER . 28 . . 1980
FAO PLANT PRODUCTION & PROTECTION PAPER . 26 SUP . . 1980
IARC MONOGRAPH . 30 . 73 . 1983
IARC MONOGRAPH . 5 . 75 . 1974

Product name **Chloroform**

C.A.S number 67-66-3

Scientific and common names, and synonyms

METHANE, TRICHLORO
TRICHLOROFORM
TRICHLOROMETHANE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
DEU	1 Apr. 1986	Prohibited for use as a plant protectant. (Reference: (BGBL) Bundesgesetzblatt IS.363 , , 1986)
PAN	Sep. 1987	Import and use prohibited for agriculture. (Reference: (PANPA) Listado de Productos Agroquimicos Prohibidos , , 1987)

Bibliographical references

IARC MONOGRAPH . SUPPL 4 . 64 . 1982
IARC MONOGRAPH . SUPPL 4 . 87 . 1982
IARC MONOGRAPH . 1 . 61 . 1972
IARC MONOGRAPH . 20 . 401 . 1979
IARC MONOGRAPH . 4 . 239 . 1974
WHO FOOD ADD. . 14 . 24 . 1980

Product name **Chlorofluorocarbons**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
CAN	1 May 1980	The import, manufacture, processing, sale or use of totally halogenated CFCs for use as a propellant in aerosol hair sprays, deodorants and antiperspirants is prohibited for the purpose of subsection 8(2) of the Environmental Contaminants Act. (Chlorofluorocarbon regulations (SOR 80-254)). (Amendment: SOR/81-365 May 7, 1981). Reasons for the control action: Danger of CFCs as a potential depleter of the stratospheric ozone layer. (Reference: (CAGAAK) Canada Gazette Part II 117,1289 , 3 , Apr. 1980)
CAN	May 1981	Under the Environmental Contaminants Act, the import, manufacture, processing, sale or use of chlorofluorocarbons for use as a propellant constituent in aerosol hair sprays, deodorants and antiperspirants is prohibited because of the danger of depletion of the stratospheric ozone layer. (Reference: (CANGZ) Canada Gazette 115 , 1410 , 1981)
NOR	Aug. 1981	In accordance with a Royal Decree of 5 August 1977, it is prohibited to manufacture or import aerosol cans and the like where chlorofluorocarbons are employed as a propellant. The prohibition applies to manufacture both for domestic and export purposes. Certain medicinal products are exempted from this prohibition. These restrictions are based on a 1976 finding by the National Academy of Sciences that chlorofluorocarbons represent a danger to the ozone layer. Chlorofluorocarbons may be exported with no requirement of foreign notification of domestic restrictions on their use.
PHL	1983	Gases being phased out of use due to the threat to the ozone layer.
SWE	1980	Spraying devices containing aerosol propellants in the form of completely halogenated chlorofluocarbons may not be manufactured or imported. (Reference: (SOSFS) Socialstyrelsens Foerfattningssamling 1980:92 , 1 , 1980)
THA		Use in aerosols has been restricted to specific types of drug and cosmetic preparations to protect the stratospheric ozone. (Reference: (MINPT) Ministry of Public Health 26 , , 1981)

Product name **Chloroform**

C.A.S number 67-66-3

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
NGA	1 Feb. 85	Chloroform is not allowed in cosmetic and drug products since 1 Feb. 1985. From that date, import, export and sale of products containing chloroform became illegal. The decision was based on reports from literature of the carcinogenic effects of chloroform on animals and possible hepatotoxic and nephrotoxic effects after prolonged use by humans. (Reference: (AARNO) Administrative Action Reference Number MH.1856/S.3T(112),15 Sep. 1983)

Product name **Chromium**

C.A.S number 7440-47-3

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
ESP	Sep. 1967	Use of the following is prohibited in toys and accessories for children: lead, zinc and potassium alloys which contain more than 10% of these metals, even when coated with inert metals, arsenic and its compounds in whatever quantity, as well as the use of dyes containing antimony, arsenic, copper, mercury, uranium, over 1 per cent of lead, chromium oxide and soluble salts or barium carbonates, cadmium, chromium and zinc. (Reference: (ESPBC) El Codigo Alimentario Espanol, Ch.IX , , Sep. 1967)

Product name **Chlornaphazine**

C.A.S number 494-03-1

Scientific and common names, and synonyms
beta-NAPHTHYLBIS(beta-CHLOROETHYL)AMINE
N,N-BIS(2-CHLOROETHYL)- 2-NAPHTHYLAMINE
NAPHTHYLAMINE MUSTARD

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
DNK	1964	The National Health Service withdrew chlornaphazine, a drug used against lymphogranulomatosis, polycythaemia and chronic leukaemia, as it appeared to be carcinogenic especially in the bladder.
VEN		Not approved for use and/or sale.
		WHO comment: The World Health Organization has no information further to the above regarding preparations containing chlornaphazine or to indicate that they are still commercially manufactured.

Product name **Chloroform**

C.A.S number 67-66-3

Scientific and common names, and synonyms
METHANE, TRICHLORO
TRICHLOROFORM
TRICHLOROMETHANE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
GRC	1976	Not accepted in pharmaceuticals or cosmetics.
TUR	1976	Removed from all cough syrups after a decision by the Ministry of Health based on a review of published information regarding carcinogenicity in rats. Export of this product is prohibited.
JPN	May 1976	Banned by the Pharmaceutical Affairs Bureau in Drugs and Cosmetics for reasons of carcinogenicity.
USA	July 1976	Withdrawn from the market and prohibited for export in drugs and cosmetics by the Food and Drug Administration on the basis of findings of liver cancer in experimental mice and rats by the National Cancer Institute. (Reference: (FEREAC) Federal Register 41 , 26842 , July 1976)
PAN	30 Nov. 1976	The Ministry of Health has banned the sale of pharmaceuticals containing chloroform. (Reference: (PANMR) Ministry of Health Resolution 1843 , , Aug. 1976)
SAU	1977	Sale or supply of any medicinal product containing chloroform has been prohibited by the Drug Committee.
BRA	25 May 1977	Products containing chloroform are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal No.15 , , May 1977)
ITA	1978	Withdrawn from the market owing to suspected carcinogenicity.
CAN	Jan. 1978	National legislation has provided that no manufacturer or importer shall sell a drug for human use that contains chloroform as an ingredient. The Health Protection Branch has reviewed evidence from the National Cancer Institute in the US which suggests that chloroform may be carcinogenic in rats and mice when administered in high doses over prolonged periods. Export of this product is allowed with no requirement of foreign notification regarding domestic restrictions on its use. (Reference: (CANGZ) Canada Gazette , , Nov. 1977)
NOR	Apr. 1978	Prohibited for use in pure form or as an additive to pharmaceutical preparations.

...[Continued]

Product name **Chloroform** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL	Apr. 1978	Prohibited for use as an ingredient in human drugs and cosmetics on the grounds of results of a study by the National Cancer Institute in the United States, suggesting that the substance may be carcinogenic in rats and mice when administered over prolonged periods. (Reference: (PHADO) Administrative Order 341S , , 1978)
DDR	Dec. 1978	Registration approval for preparations containing chloroform has been withdrawn due to a carcinogenic potential. (Reference: (DDCI) Regulation of the Drug Control Institute , , Dec. 1978)
GBR	1979	The Chloroform Prohibition Order has prohibited the sale or supply of any medicinal product containing chloroform. Certain exemptions apply. (Reference: (GBCHL) Chloroform Prohibition Order , , 1979)
NZL	1980	Toothpaste formulations containing chloroform have been voluntarily withdrawn from the market.
DNK	1981	Registered for veterinary use only. (Reference: (DENBH) Danish National Board of Health, Circular Letter , , Sep. 1981)
ETH	1981	Prohibited because of its carcinogenic effects.
ZWE	May 1981	Medicinal products containing more than 0.5% chloroform are prohibited because of the toxicity of the drug. Certain exemptions apply. (Reference: (ZWDCC) Drugs Control Council, News Bulletin (1) , , 1983)
DEU	1982	Prohibited for use and or sale.
BGD	June 1982	Use of chloroform as an excipient in pharmaceutical preparations has been banned due to reported adverse effects.
DOM	1983	Domestic manufacturers and importers have been requested to eliminate this ingredient from their marketed products since pharmacological studies have shown it to be toxic to the liver and the heart, and to be carcinogenic.
BEL	12 Feb. 1983	Prohibited for sale. (Reference: (BELAR) Arrête Royal , , Feb. 1983)
NGA	1 Feb. 85	Chloroform is not allowed in cosmetic and drug products since 1 Feb. 1985. From that date, import, export and sale of products containing chloroform became illegal. The decision was based on reports from literature of the carcinogenic effects of chloroform on animals and possible hepatotoxic and nephrotoxic effects after prolonged use by humans. (Reference: (AARNO) Administrative Action Reference Number MH.1856 S.3T(112),15 Sep. 1983)
CUB		Following the action taken by the US Food and Drug Administration, the National Formulary Commission requested removal of chloroform from pharmaceutical preparations.
THA		The use of pharmaceutical preparations containing chloroform is severely restricted.
VEN		Subject to restricted use and or sale.

WHO comment: Chloroform was formerly widely used in pharmaceutical preparations as a solvent and preservative as well as for its anaesthetic and flavouring properties. By the late 1970s reservations concerning its safety, including positive results in a carcinogenicity screening programme sponsored by the National Cancer Institute in the USA, had led to considerable restrictions in its use in pharmaceutical preparations. While many pharmaceutical products containing chloroform have been withdrawn or reformulated to exclude this substance, it may still be incorporated in toothpastes and other specified products in some countries, subject to statutorily-imposed concentration limits. (Reference: (IARCCD) Chloroform: IARC Monograph (Vol.20) 20 , 401-427 , 1979)

Bibliographical references

IARC MONOGRAPH , SUPPL.4 , 64 , 1982
IARC MONOGRAPH , SUPPL.4 , 87 , 1982
IARC MONOGRAPH , 1 , 61 , 1972
IARC MONOGRAPH , 20 , 401 , 1979
IARC MONOGRAPH , 4 , 239 , 1974

...[Continued]

Chloramphenicol ...[Continued]

TRADE AND BRAND NAMES :

Sanaphenicol
Semicol
Semicoline
Seramycetin
Siccocol
Sirop-amygdalar
Sinicolen
Sificetina
Sinicolina
Sintomicetin
Sintomicetina
Sintomicetine r
Sintomitsin
Sno-phenicol
Snophenicol
Soludectancil
Sopamycetin
Spasmo-paraxin
Spersanicol
Stanomycetin
Strepticine
Streptoglobenicol
Streptophenicol
Subtal supp.
Suismycetin
Sulfaglobenicol
Sulfamycetin
Synthomycetin
Synthomycetina
Synthomycetine
Synthophtone
Tardomyocel
Tega-cetin
Tetra-phenicol oculos
Tetrachlorasone
Tetracol
Tetranfen
Tetraphenicol
Tevcocin
Tifomycine
Tiframilk
Tiromycetin
Toramin
Transicetina
Transpulmycin
Tribiotic
Troc
Trophen
Troymycetin
Tusolone
Tycloran
Unimycetin
Uro-gliscal
Uro-gliscal 500
Urotetten-s
Uroplex 4
Ut forte
Uvomycin
V-crayolan
Vagisept
Variolan
Vetical
Vetophenicol
Viceton
Viklorin
Virogin
Vitaklorin
Vsmpozim
Wintetil
Zoppib spray blu

For regulatory information, see page 32

Chlornaphazine

494-03-1

TRADE AND BRAND NAMES :

Aleukon
Chloronaltina
Erysan
Nafticlorina
Naphthylamine mustard

For regulatory information, see page 34

Chloroform

67-66-3

TRADE AND BRAND NAMES :

Amatuss
Benaled
Benaluss
Benyphed
Broncho-rivo syrup
Chlor-histine
Co-specto
Codacol
Codimal dm
Cotrol-d
Cyprol expectrant
Dalet
Dectuss
Dristan
Eludril
Endal
Expec-c
Fk-tussex
Guanor
Histalix
Hydril
Kentuss
Linctuss
Mc 3
Muflin
Nagalyn
Notose
Orthos kavident
P-m-z
Panosoma
Penta-zine
Phenacol-dm
Phenatuss
Phlogarol
Promex
R 20
Rexahisine
Tussilene-dm

For regulatory information, see page 34

Chloroquine

54-05-7

TRADE AND BRAND NAMES :

Aralen
Aralen hcl
Aralin (diphosphate)
Artrichin
Artrochin
Avloclor (diphosphate)

...[Continued]

Product name **Phthalylsulfathiazole**

C.A.S number 85-73-4

Scientific and common names, and synonyms
BENZOIC ACID, 2-(((4-((2-THIAZOLYLAMINO)SULFONYLPHENYL)AMINO)-CARBONYL)-
4'-(2-THIAZOLYLSULFAMOYL)PHTHALANILIC ACID
6'-(THIAZOLYLAMINOSULFAMOYL)PHTHALANIC ACID

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned. It has been found to be of little or no therapeutic value, its side effects can be harmful, and it is subject to misuse. (Reference: (BGDCO) The Drugs (Control) Ordinance , , 1982)
		WHO comment: Phthalylsulfathiazole, a sulfonamide anti-infective agent, was introduced in 1946 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. Although phthalylsulfathiazole, which is poorly absorbed from the gastrointestinal tract, is no longer recommended in some countries, it continues to be used in others for the treatment of local intestinal infections, including bacterial dysentery, and for pre-operative bowel preparation.

Product name **Pipamazine**

C.A.S number 84-04-8

Scientific and common names, and synonyms
10-(3-(4-CARBAMOYLPIPERIDINE)PROPYL)-2-CHLOROPHENOTHIAZINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
USA	July 1969	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to the lack of proof of efficacy and safety for use as an antinauseant and antiemetic for pregnant women.
		WHO comment: Pipamazine, which is pharmacologically similar to chlorpromazine, was introduced in 1959 for the treatment of nausea and vomiting. Although it was withdrawn in 1969 by the United States FDA on grounds of lack of proof of efficacy and safety, it remains available in some countries.

Product name **Piperazine**

C.A.S number 110-85-0

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
ITA	1977	Products with anthelminthic indications have been withdrawn due to an unfavourable risk benefit balance. Since 1975 warnings have been added to the labels concerning the possibility of neurotoxic effects with high dosages. In 1979, the label was revised to advise use on an empty stomach and for short periods of time with long intervals, in order to avoid interaction with nitrites.
SWE	1983	In the light of the carcinogenic and mutagenic potential of piperazine demonstrated in recent studies, discussions between the manufacturers and the Department of Drugs have led to the withdrawal of registration for this drug.
DNK	2 July 1984	Following recent evidence leading to the possibility that carcinogenic nitroso-derivatives may be generated in vivo, preparations containing piperazine have been placed under prescription control. (Reference: (UGLAAD) Ugeskrift for Laeger , 1949 , June 1984)

...[Continued]

Product name **Piperazine** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
NLD	1 Jan. 1985	The Board of Evaluation of Drugs has concluded that other anthelminthics have a more favourable risk-benefit ratio than piperazine, which may also give rise to potentially carcinogenic nitroso-derivatives. Manufacturers have been requested to withdraw products containing piperazine. (Reference: (NETJAN) Nederlands Tijdschrift voor Geneeskunde 128(41) , , 1984)
THA		The use of pharmaceutical preparations containing piperazine is severely restricted.

WHO comment: Piperazine was first used as a treatment for gout earlier this century and its anthelminthic activity was discovered in 1949. It continues to retain a place in the WHO Model List of Essential Drugs because it is widely available, effective and apparently safe when used on an occasional basis for the treatment of ascariasis infections. It is also considerably cheaper than other anthelminthic drugs. In some countries where ascariasis is not endemic and where piperazine was used predominantly for the treatment of pinworm it has been withdrawn from use on the grounds that other more effective and less toxic drugs are now available. In other such countries, however, piperazine remains available in over-the-counter preparations. Clinical dosages occasionally induce transient neurological signs and concern has been expressed that in some circumstances the drug may generate small amounts of nitrosamine in the stomach. However, it is widely considered that these trace doses are unlikely to give rise to a significant carcinogenic potential. (Reference: (WHODI) WHO Drug Information 1 , 5 , 1983)

Product name **Pipradrol**

C.A.S number 467-80-7

Scientific and common names and synonyms

alpha,alpha-DIPHENYL-2-PIPERIDINEMETHANOL
1,1-DIPHENYL-1-(2-PIPERIDYL)-METHANOL

Legislative or regulative action

Country	Effective Date	Description of action taken grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
DNK		Withdrawn from the market by the manufacturer.
VEN		Not approved for use and/or sale.

WHO comment: Pipradrol, a central nervous system stimulant, was introduced in 1955 for use as an anorexic agent. Pipradrol is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS) United Nations Convention on Psychotropic Substances (IV) , , 1971)

Product name **Pituitary-chorionic gonadotropin (injectable)**

Legislative or regulative action

Country	Effective Date	Description of action taken grounds for decision
USA	July 1972	Gonadotropins of animal origin have been withdrawn from use and prohibited for export by the Food and Drug Administration on grounds of safety and efficacy. In its decision the FDA cited the risk of eliciting antibodies to animal protein, leading to allergic reactions, and the availability of safer and more effective alternatives. (Reference: (FEREAC) Federal Register 37(130) , 13284 , 1972)

...[Continued]

Phthalylsulfathiazole

85-73-4

TRADE AND BRAND NAMES :

[illegible]
Candis-anti-diarr
Carbodiar
Carbotalin
Colicitina
Colicitase
Cortinen
Chemataliil
Chemothalidine
Diaban
Diacolin
Diarrestival
Dienterol
Direver
Disenterol
Elumicin
Enteramida
Entero-hermes
Entero-red
Entero-sulfina
Entero-toxan
Enterocalme
Enterosteril
Entexidina
Esteraplidin mag
Eugeniteed
Filazil
Ftalil-esteve
Ftalil-septol
Ftalil-tiazol
Ftalysept
Ilentazol
Ingalipt
Inrestibla strepto
Intestiazol
Iodentero-neomicina
Logical
Massotalil
Neo-sulfazon
Novosulfina
Phtalazol
Phtazol
Porcijec
Septiftalil
Sulfacetil
Sulfathalidine
Sulftalyl
Syptan
Syralbina
Taleudron
Talidine
Talisulfazol
Taloudron
Tamil
Thalazole
Thalinil
Thalistanin
Thalistatyl
Thiazole
Trisulvet
Ultratiazol
Vetoryl

For regulatory information, see page 110

Pipamazine

84-04-8

TRADE AND BRAND NAMES :

Mornidine
Nausidol
Normetine

For regulatory information, see page 110

Piperazine

110-85-0

TRADE AND BRAND NAMES :

Adelmintex
Adipalis
Adipalit
Adipiazine
Adiver
Ancaris thenium
Ancazine
Anteimina
Antepar
Antepar (b-w)
Anterobius
Anthalazine
Antielmina
Anticucs
Antiren
Antivermine
Antopan
Arduvermin
Arpezine
Asca-trol no 3
Ascalix
Ascarinex
Ascarivet
Asepar
Askaripar
Averamexan
B-piperazine
Bel-zine
Bioxurin
Brirel
Bryrel
Candizine
Ciperazin
Citrazine
Coopane
Dak
Demovermil
Diatesurico
Dicevermin
Dietelmin
Digesan
Dilaurazine
Dispermin
Diurazina
Divermex
Dowzene
Dyrex
Ecosan
Endorid
Entacyl
Entazin
Equizole-a
Eraverm
Escovermin
Esteropipate
Etaphylline (acetylinate)
Exelmin
Exopin
Gentiazina
Glycopiparsol
Heksapar
Helmacid
Helmezin
Helmicide
Helmifren
Helmipar
Helmirazine (adipate)
Helmirazine (citrate)
Helmitin
Helmizin
Herb royal round worm treatment
Hexanthelin
Ismiverm
Janes liquid permifu
Jarabe neox
Jetsan supp. (adipate)
Justalmin
Kennel-maid
Kihomato
Kontipar
Lamboxil
Lom
Lombricida tropico
Lombrifher
Lombrikal
Lombrimade
Lumbrical

...[Continued]

Product name **Medroxyprogesterone acetate/ethinyl estradiol**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
USA		Withdrawn from the market and prohibited for export by the Food and Drug Administration after studies in dogs showed an increased incidence of mammary tumors from the medroxyprogesterone acetate component.

Product name **Meprobamate/diazepines**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
GRC	1980	Withdrawn from the market since the combination is considered unacceptable having regard to the higher incidence of adverse reactions than reported with monocomponent preparations.

Product name **Mepyramine maleate**

Scientific and common names, and synonyms
PAMABROM/PYRILAMINE MALEATE
PYRILAMINE MALEATE/PAMABROM

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
USA	1974	Combinations of pamabrom and mepyramine maleate (pyrilamine maleate) have been withdrawn from the market

Product name **Metoclopramide/polidocanol**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL	Mar. 1983	Disapproved for use in gastrointestinal disturbances since marked liver toxicity limits its therapeutic use.

Product name **Neomycin sulfate/polymyxin bisulfate/nystatin/acetarsol**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
PHL	Sep. 1977	This combination, for use in trichomonal vaginitis, has been disapproved due to the irrational and potentially harmful nature of the combination, which is not shown to be more effective than its individual ingredients given separately in appropriate doses.

Product name **Acetylfuratrizine**

C.A.S number 1789-26-0

Scientific and common names, and synonyms
N-(6-(2-(5-NITRO-2-FURYL)VINYL)-1,2,4-TRIAZIN-3-YL) ACETAMIDE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
SAU		The withdrawal of nitrofuran compounds from the market is under consideration since they have been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.
		WHO comment: Acetylfuratrizine, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information to suggest that it remains commercially available.

Product name **Acetylsalicylic acid (paediatric)**

C.A.S number 50-78-2

Scientific and common names, and synonyms
ASPIRIN
BENZOIC ACID, 2-(ACETYLOXY)-
SALICYLIC ACID ACETATE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
CHE	1986	The Intercantonal Drug Control Office has decided that products containing salicylates should bear on the package a warning against use by children under twelve years of age, except on medical advice. The package leaflets directed to both physicians and patients should additionally include warnings concerning Reye's syndrome in both the sections "Limitations of use" and "Undesirable effects". (Reference: (CHBCM) Bulletin Mensuel 8, , 1986)
IRQ	1986	The National Board for the Selection of Drugs has decided to prohibit the sale of products containing acetylsalicylic acid without a medical prescription. The product information should contain a warning that acetylsalicylic acid should be avoided in children suffering from influenza or chickenpox and that children under 12 years of age should receive acetylsalicylic acid only on medical advice.
NGA	1986	Banned for use in children under the age of 12 years.
ISR	Feb. 1986	The Ministry of Health has ordered that preparations of acetylsalicylic acid intended specifically for children be subjected to prescription control and that all preparations should contain a warning referring to the reported risk of Reye's syndrome in children and young adults with fever due to viral infections.
ITA	June 1986	The Italian Health Council has decided that all products containing acetylsalicylic acid should bear the following warning: "Consult your physician before administering this product to children and teenagers with viral diseases such as influenza or chicken pox. Discontinue use immediately if persistent vomiting or undue sleepiness occurs.".
IRL	9 June 1986	The National Drugs Advisory Board, in agreement with manufacturers, requires that all paediatric dosage forms be available on prescription only. All preparations should carry the warning "This product should not be given to children, particularly those under 12 years of age, without medical advice.".
GBR	10 June 1986	The Committee on Safety of Medicines has advised that acetylsalicylic acid should not be administered to children under 12 years of age except on medical advice. Leading manufacturers have declared their intention to stop supplying paediatric preparations.

...[Continued]

Legislative or regulative action

Product name **Acetylsalicylic acid (paediatric)** ...[Continued]

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
AUS	11 June 1986	The Adverse Drug Reactions Advisory Committee has warned that acetylsalicylic acid should not be given to children and teenagers with fever. The warning does not relate to use for disorders in children and teenagers who do not have fever.
ESP	7 Aug. 1986	The Director General for Pharmacy and Health Products of the Ministry of Health has issued guidelines for package inserts for preparations containing acetylsalicylic acid. A warning should be included stating that the preparation should be administered to children and adolescents with febrile conditions such as influenza or varicella only on medical advice.
HKG	1 Sep. 1986	The Medical and Health Department requires that the product information for all preparations containing acetylsalicylic acid must warn against its use in children under 12 years of age, except on medical advice. Manufacturers are urged to withdraw all paediatric preparations.
DEU	Oct. 1986	The Federal Health Office requires pharmaceutical preparations containing acetylsalicylic acid to bear a warning against use for feverish conditions in children and young people unless on medical advice and only if other measures have failed.
OMN	Dec. 1986	The Central Drug Committee has informed doctors and pharmacists that no products containing acetylsalicylic acid (aspirin) should be given to children under 12 years of age who have chicken pox, influenza or any other febrile illness. Paediatric aspirin preparations will be available only from pharmacies. Products for export containing acetylsalicylic acid should bear the following statutory warning on new packs:"This product should not be given to children, particularly those under 12 years of age, without medical advice."
EGY	1987	The Technical Committee for Drug Control has decided that the product information of all paediatric pharmaceutical products containing acetylsalicylic acid should bear the following warning: "Consult a physician before giving aspirin to children aged less than 12 years, especially in cases of influenza and chickenpox, to avoid risk of Reye's Syndrome." (Reference: (EGYDC) Decision of the Egyptian Technical Committee for Drug control Vol 5(2), 1, 1987)
CHL	2 Feb. 1987	The Institute of Public Health of Chile has decided that all pharmaceutical products containing acetylsalicylic acid should carry a warning on the label that the drug should not be given to children under 12 years of age with febrile viral diseases without consulting a doctor. (Reference: (CHLRS) Resolution of the Minister of Health No 01042 , , Feb. 1987)
DNK	1 July 1987	The National Board of Health has decided that pharmaceutical preparations containing acetylsalicylic acid in paediatric dosages (less than 200mg tablet) should bear the following warning: "Not to be given to feverish children without consulting a doctor ".
SGP	1 Dec. 1987	The Ministry of Health has made it mandatory for all aspirin products to bear the cautionary label: "Caution: not to be given to persons below the age of 16 years except under the direction of a doctor" before the products can be sold in the market. The public is advised not to give their children any medicine containing aspirin unless otherwise advised by the doctor. (Reference: (SGPMA) Medicines Act (Chapter 176). No.S 230 87 , 1078 , Aug. 1987)
SWE	1988	The National Board of Health and Welfare has revised the product information for preparations containing acetylsalicylic acid to recommend that they should not be taken by febrile children under 18 years of age and to indicate that paracetamol is the drug of choice in these circumstances. (Reference: (SSLMS) Information fraan Socialstyrelsens Laekemedelsavdelning Vol.12(6), 145, 1987)
BEL	1 Jan. 1988	The Ministry of Public Health and the Environment requires pharmaceutical products containing acetylsalicylic acid to bear the following warning: "This medicine contains acetylsalicylic acid. Do not use in feverish children without medical advice.". (Reference: (BELMD) Ministerial Decree , , June 1987)
USA	June 1988	The United States Food and Drug Administration has revised the labelling of products containing acetylsalicylic acid to read: "Children and teenagers should not use this medicine for chickenpox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness, reported to be associated with aspirin." (Reference: (FEREAC) Federal Register Vol.53,(111), 21633 , 1988)

...[Continued]

Product name **Acetylsalicylic acid (paediatric)** ...[Continued]

Legislative or regulative action

Country	Effective Date	Description of action taken grounds for decision
NLD		The Board for the Evaluation of Medicines requires information for patients on products containing acetylsalicylic acid to contain the statement: "To be used in children with chickenpox or influenza only on the advice of a doctor."
		WHO comment: Acetylsalicylic acid, a nonsteroidal antiinflammatory, analgesic and antipyretic agent, was introduced into medicine in 1899 and has since been widely available in over-the-counter preparations. Recent studies carried out in the USA have shown an association between acetylsalicylic acid consumption in children and the development of Reye's syndrome (a rare condition characterized by a combination of encephalopathy and liver disorder and usually preceded by an acute viral illness, such as influenza, diarrhoea, or chicken pox). Although these studies were initially criticized for their design, there is now a broad consensus that a link between acetylsalicylic acid and Reye's syndrome has been established, particularly since the reported incidence of Reye's syndrome in the United States has fallen appreciably since the association was first postulated in 1980. In the interim, many drug regulatory authorities have acted to caution against the use of the drug in children and young adults with febrile conditions. Even within this group the risk of exposure is remote and has been estimated to be of the order of 1.5 per million. Acetylsalicylic acid retains a valuable place in medicine and remains in the WHO Model List of Essential Drugs. (Reference: (WHODI) WHO Drug Information 1 , 5 , 1985)

Product name **Acridine derivatives**

C.A.S number 260-94-6

Scientific and common names, and synonyms
EUFLAVINE
PROFLAVINE

Legislative or regulative action

Country	Effective Date	Description of action taken grounds for decision
ITA	1973	These products are only available as topical disinfectants in concentrations not higher than 1%.
DNK	Sep. 1979	Proflavine was withdrawn from all dental-care products in May 1978, following demonstration of mutagenic activity in vitro. Euflavine was similarly withdrawn as of September 1979. No direct evidence exists of any risk to man and the extent to which these substances penetrate mammalian cells is uncertain. Nevertheless, the Registration Board has recommended that the restriction should apply to all acridine disinfectants "that many regard as obsolete and whose safety is questionable".
VEN		Not approved for use and/or sale.
		WHO comment: Acridine derivatives with antiseptic and disinfectant activity, including acriflavine, proflavine and euflavine, were formerly used in the treatment of infected wounds and burns. Such use has largely been discontinued on the grounds that safer and more effective alternatives are now available. Following demonstration of the mutagenic activity of proflavine in 1978 it was withdrawn from dental products in Denmark. Subsequently, euflavine was similarly withdrawn.

Product name **Alclofenac**

C.A.S number 22131-79-9

Scientific and common names, and synonyms
(4-ALLYLOXY-3-CHLOROPHENYL) ACETIC ACID
BENZENEACETIC ACID, 3-CHLRO-4-(2-PROPENYLOXY)-

...[Continued]

Legislative or regulative action

Product name **Acetylsalicylic acid/phenacetin/caffeine (APC)**

Scientific and common names, and synonyms
APC
CAFFEINE,PHENACETIN,ACETYLSALICYLIC ACID
PHENACETIN/ACETYLSALICYLIC ACID/CAFFEINE

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
THA	1983	Banned for manufacture for immediate effect but existing stocks may be sold for a further period of one year. Preparations must be reformulated to contain only acetylsalicylic acid.

Product name **Antirheumatic combinations with glucocorticosteroids**

Legislative or regulative action :

Country	Effective Date	Description of action taken grounds for decision
AUT	Jan. 1986	Enteral preparations have been withdrawn and parenteral preparations may only be used for very limited indications and under strict medical supervision.
DEU	1 Jan. 1986	Fixed combinations have been withdrawn since concurrent administration of such drugs potentiates adverse effects without increasing benefit.

Product name **Atropine**

C.A.S number 51-55-8

Scientific and common names, and synonyms
alpha H, 5alpha H-TROPAN-3alpha-OL(+ /-)-TROPATE (ESTER)
BENZENEACETIC ACID, alpha-(HYDROXYMETHYL)-8-METHYL-8-AZABICYCLO(3.2.1) OCT-3-YL ESTER, ENDO (+ /-)

Legislative or regulative action :

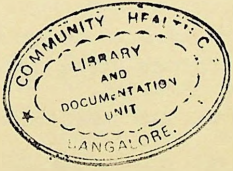
Country	Effective Date	Description of action taken grounds for decision
PHL	Sep. 1976	Combinations of atropine sulfate with difenoxylate, furazolidone and dimethylpolysiloxane have been disapproved due to possible adverse reactions such as dysuria (from atropine and furazolidone), tachycardia, palpitation and blurring of vision. **WHO comment:** Atropine, an alkaloid with anticholinergic activity extracted from Atropa belladonna, has been widely used in medicines for centuries. The action taken in the Philippines relates specifically to the use of atropine in combination products. Elsewhere, preparations containing atropine remain available and the substance is included in the WHO Model List of Essential Drugs. (Reference: (WHODI) WHO Drug Information 2 , 1 , 1988)

Product name **Barbiturates in combination**

Scientific and common names, and synonyms
ANALGESICS/BARBITURATES
ANTACIDS/BARBITURATES
ANTIASTHMATICS/BARBITURATES

...[Continued]

ರೋಗಿಗಳ ಹಕ್ಕು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು
ಹಾಗೂ
ನಿಷೇದಿತ ಔಷಧಗಳ ಪಟ್ಟಿ



ಪ್ರಕಟಣೆ :

ಗ್ರಾಹಕ ಹಕ್ಕು ಶಿಕ್ಷಣ ಮತ್ತು ಜಾಗೃತ ದತ್ತಿ (ರಿ)

239, 5ನೇ 'ಸಿ' ರೆಮ್ಕೋ ಬಡಾವಣೆ, ವಿಜಯನಗರ, ಬೆಂಗಳೂರು – 560 040

ರೋಗಿಗಳ ಹಕ್ಕು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು

ಹೆಚ್ಚುತ್ತಿರುವ ವೈದ್ಯಕೀಯ ನಿರ್ಲಕ್ಷ್ಯದ ಪರಿಣಾಮವಾಗಿ ರೋಗಿಗಳು ನಷ್ಟ, ನೋವು ಮತ್ತು ಕೆಲವು ಸಂದರ್ಭಗಳಲ್ಲಿ ಸಾವನ್ನು ಅನುಭವಿಸಬೇಕಾಗಿದೆ. ಸರ್ಕಾರಿ ಅಥವಾ ಖಾಸಗಿ ಆಸ್ಪತ್ರೆಗಳು ಎಂಬ ಭೇದವಿಲ್ಲದೆ ರೋಗಿಗಳು ಸಂಕಟಕ್ಕೆ ಗುರಿಯಾಗುವ ಸಂದರ್ಭ ಏರ್ಪಟ್ಟಿದೆ. ವೈದ್ಯರ ಅಸಡ್ಡೆ, ಕರ್ತವ್ಯದಲ್ಲಿ ಅನಾಸಕ್ತಿಯ ಪರಿಣಾಮವಾಗಿ, ರೋಗಿಗಳಿಗೆ ಸಮರ್ಪಕವಾದ ಸೇವೆ ದೊರೆಯದೆ, ತಮ್ಮ ಹಕ್ಕುಗಳಿಂದ ವಂಚಿತರಾಗುತ್ತಿದ್ದಾರೆ.

ವೈದ್ಯಕೀಯ ಕ್ಷೇತ್ರದಲ್ಲಿ ಕೆಲವು ಅನೈತಿಕ ವ್ಯವಹಾರಗಳು ನಡೆಯುತ್ತಿದ್ದು, ರೋಗಿಗಳು ತಮಗೆ ಅರಿವಿಲ್ಲದೆ ಕೋಷ್ಟಕ್ಕೆ ಒಳಗಾಗುತ್ತಿದ್ದಾರೆ. ಸರಿಯಾದ ಸಮಯದಲ್ಲಿ ಚಿಕಿತ್ಸೆ ಮಾಡದಿರುವುದು, ಅನಾವಶ್ಯಕ ಔಷಧಗಳನ್ನು ನೀಡುವುದು, ರೋಗಿಗಳನ್ನು ಬೇಡದ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಪಡಿಸುವುದು, ರೋಗಿಗೆ ತಿಳಿಸದೇ ಅವರ ದೇಹದ ಭಾಗಗಳನ್ನು ತೆಗೆದು ಹಾಕುವುದು ಇತ್ಯಾದಿ ಅವ್ಯವಹಾರಗಳ ಬಗ್ಗೆ ವರದಿಗಳು ಹೆಚ್ಚುತ್ತಿದೆ. ಈ ಹಿನ್ನೆಲೆಯಲ್ಲಿ ರೋಗಿಯಾಗಿ ಜನ ಸಾಮಾನ್ಯರು ಅವರ ಹಕ್ಕು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು ಯಾವುವು ಎಂಬುದನ್ನು ತಿಳಿದಿರುವುದು ಅವಶ್ಯಕ.

I. ರೋಗಿಯ ಹಕ್ಕುಗಳು

1. ಪ್ರತಿಯೊಬ್ಬ ವ್ಯಕ್ತಿಗೂ ಸಮರ್ಪಕವಾದ ಆರೋಗ್ಯ ಸೇವೆ ಮತ್ತು ರೋಗ ನಿವಾರಣದ ಹಕ್ಕು.
2. ಜಾತಿ, ಮತ, ಭಾಷೆ ಅಥವಾ ಲಿಂಗ ಬೇಧವಿಲ್ಲದೆ ರೋಗ ನಿವಾರಣ ಹಕ್ಕು.
3. ಲಭ್ಯವಿರುವ ಕಡೆ, ರೋಗಿ ತಾನು ಇಷ್ಟಪಟ್ಟ ವೈದ್ಯರಿಂದ ಅಥವಾ ಆಸ್ಪತ್ರೆಯಿಂದ ರೋಗಕ್ಕೆ ಪರಿಹಾರ ಪಡೆಯುವ ಹಕ್ಕು.
4. ತುರ್ತು ಸಂದರ್ಭಗಳಲ್ಲಿ ಹತ್ತಿರದ ಸರ್ಕಾರಿ ಅಥವಾ ಯಾವುದೇ ಆಸ್ಪತ್ರೆಯಿಂದ ಸೂಕ್ತ ಚಿಕಿತ್ಸೆ.
5. ರೋಗಿಯನ್ನು ಒಂದು ಆಸ್ಪತ್ರೆಯಿಂದ ಇನ್ನೊಂದು ಆಸ್ಪತ್ರೆಗೆ ವರ್ಗಾಯಿಸುವ ಮುನ್ನ. ಈ ವರ್ಗಾವಣೆಯ ಅವಶ್ಯಕತೆಯನ್ನು ತಿಳಿಯುವ ಹಕ್ಕು.
6. ಪರಿಣತ ವೈದ್ಯರಿಂದ ಚಿಕಿತ್ಸೆ ಪಡೆಯುವ ಹಕ್ಕು.
7. ರೋಗಿಯು ವೈದ್ಯರಿಗೆ ನೀಡುವ, ವೈಯಕ್ತಿಕ ವಿಷಯಗಳು, ರೋಗಗಳು, ರೋಗದ ಚಿನ್ಹೆಗಳು, ರೋಗಿಯ ಪರಿಸ್ಥಿತಿ ಮುಂತಾದ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಬೇಕಾದ ಹಕ್ಕು.
8. ಯಾವ ಚಿಕಿತ್ಸೆ ಅಥವಾ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗುವ ಮುನ್ನ ಆ ಪರೀಕ್ಷೆಯ ಬಗ್ಗೆ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುವ ಹಕ್ಕು. ಔಷಧ ಸೇವಿಸಿದರೆ ಅಥವಾ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಿದರೆ ಅದರಿಂದ ಉಂಟಾಗಬಹುದಾದ ತೊಂದರೆಗಳು, ಪರಿಣಾಮಗಳು, ದುಷ್ಪರಿಣಾಮಗಳು, ಯಶಸ್ಸಿನ ಸಾಧ್ಯತೆ, ಸಾವಿನ ಅಪಾಯ ಮುಂತಾದ ವಿಷಯಗಳನ್ನು ತಿಳಿದುಕೊಳ್ಳುವ ಹಕ್ಕು. ಒಂದು ವೇಳೆ ರೋಗಿಗೆ ಈ

ರೋಗಿಗಳ ಹಕ್ಕು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು

ಹೆಚ್ಚುತ್ತಿರುವ ವೈದ್ಯಕೀಯ ನಿರ್ಲಕ್ಷದ ಪರಿಣಾಮವಾಗಿ ರೋಗಿಗಳು ನಷ್ಟ, ನೋವು ಮತ್ತು ಕೆಲವು ಸಂದರ್ಭಗಳಲ್ಲಿ ಸಾವನ್ನು ಆನುಭವಿಸಬೇಕಾಗಿದೆ. ಸರ್ಕಾರಿ ಆಥವಾ ಖಾಸಗಿ ಆಸ್ಪತ್ರೆಗಳು ಎಂಬ ಭೇದವಿಲ್ಲದೆ ರೋಗಿಗಳು ಸಂಕಟಕ್ಕೆ ಗುರಿಯಾಗುವ ಸಂದರ್ಭ ಏರ್ಪಟ್ಟಿದೆ. ವೈದ್ಯರ ಆಸಡ್ಡೆ, ಕರ್ತವ್ಯದಲ್ಲಿ ಆನಾಸಕ್ತಿಯ ಪರಿಣಾಮವಾಗಿ, ರೋಗಿಗಳಿಗೆ ಸಮರ್ಪಕವಾದ ಸೇವೆ ದೊರಯದೆ, ತಮ್ಮ ಹಕ್ಕುಗಳಿಂದ ವಂಚಿತರಾಗುತ್ತಿದ್ದಾರೆ.

ವೈದ್ಯಕೀಯ ಕ್ಷೇತ್ರದಲ್ಲಿ ಕೆಲವು ಅನೈತಿಕ ವ್ಯವಹಾರಗಳು ನಡೆಯುತ್ತಿದ್ದು, ರೋಗಿಗಳು ತಮಗೆ ಅರಿವಿಲ್ಲದೆ ಶೋಷಣೆಗೆ ಒಳಗಾಗುತ್ತಿದ್ದಾರೆ. ಸರಿಯಾದ ಸಮಯದಲ್ಲಿ ಚಿಕಿತ್ಸೆ ಮಾಡದಿರುವುದು, ಅನಾವಶ್ಯಕ ಔಷಧಗಳನ್ನು ನೀಡುವುದು, ರೋಗಿಗಳನ್ನು ಬೇಡದ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಪಡಿಸುವುದು, ರೋಗಿಗೆ ತಿಳಿಸದೇ ಅವರ ದೇಹದ ಭಾಗಗಳನ್ನು ತೆಗೆದು ಹಾಕುವುದು ಇತ್ಯಾದಿ ಅವ್ಯವಹಾರಗಳ ಬಗ್ಗೆ ವರದಿಗಳು ಹೆಚ್ಚುತ್ತಿದೆ. ಈ ಹಿನ್ನೆಲೆಯಲ್ಲಿ ರೋಗಿಯಾಗಿ ಜನ ಸಾಮಾನ್ಯರು ಅವರ ಹಕ್ಕು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು ಯಾವುವು ಎಂಬುದನ್ನು ತಿಳಿದಿರುವುದು ಅವಶ್ಯಕ.

I. ರೋಗಿಯ ಹಕ್ಕುಗಳು

1. ಪ್ರತಿಯೊಬ್ಬ ವ್ಯಕ್ತಿಗೂ ಸಮರ್ಪಕವಾದ ಆರೋಗ್ಯ ಸೇವೆ ಮತ್ತು ರೋಗ ನಿವಾರಣೆಯ ಹಕ್ಕು.
2. ಜಾತಿ, ಮತ, ಭಾಷೆ ಆಥವಾ ಲಿಂಗ ಬೇಧವಿಲ್ಲದೆ ರೋಗ ನಿವಾರಣ ಹಕ್ಕು.
3. ಲಭ್ಯವಿರುವ ಕಡೆ, ರೋಗಿ ತಾನು ಇಷ್ಟಪಟ್ಟ ವೈದ್ಯರಿಂದ ಆಥವಾ ಆಸ್ಪತ್ರೆಯಿಂದ ರೋಗಕ್ಕೆ ಪರಿಹಾರ ಪಡೆಯುವ ಹಕ್ಕು.
4. ತುರ್ತು ಸಂದರ್ಭಗಳಲ್ಲಿ ಹತ್ತಿರದ ಸರ್ಕಾರಿ ಆಥವಾ ಯಾವುದೇ ಆಸ್ಪತ್ರೆಯಿಂದ ಸೂಕ್ತ ಚಿಕಿತ್ಸೆ.
5. ರೋಗಿಯನ್ನು ಒಂದು ಆಸ್ಪತ್ರೆಯಿಂದ ಇನ್ನೊಂದು ಆಸ್ಪತ್ರೆಗೆ ವರ್ಗಾಯಿಸುವ ಮುನ್ನ. ಈ ವರ್ಗಾವಣೆಯ ಆವಶ್ಯಕತೆಯನ್ನು ತಿಳಿಯುವ ಹಕ್ಕು.
6. ಪಡೆಯಿತ ವೈದ್ಯರಿಂದ ಚಿಕಿತ್ಸೆ ಪಡೆಯುವ ಹಕ್ಕು.
7. ರೋಗಿಯು ವೈದ್ಯರಿಗೆ ನೀಡುವ, ವೈಯಕ್ತಿಕ ವಿಷಯಗಳು, ರೋಗಗಳು, ರೋಗದ ಚಿನ್ನಗಳು, ರೋಗಿಯ ಪರಿಸ್ಥಿತಿ ಮುಂತಾದ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಬೇಕಾದ ಹಕ್ಕು.
8. ಯಾವ ಚಿಕಿತ್ಸೆ ಆಥವಾ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗುವ ಮುನ್ನ ಆ ಪರೀಕ್ಷೆಯ ಬಗ್ಗೆ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುವ ಹಕ್ಕು. ಔಷಧ ಸೇವಿಸಿದರೆ ಆಥವಾ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಿದರೆ ಆದರಿಂದ ಉಂಟಾಗಬಹುದಾದ ತೊಂದರೆಗಳು, ಪರಿಣಾಮಗಳು, ದುಷ್ಪರಿಣಾಮಗಳು, ಯಶಸ್ಸಿನ ಸಾಧ್ಯತೆ, ಸಾಮಿನ ಅಪಾಯ ಮುಂತಾದ ವಿಷಯಗಳನ್ನು ತಿಳಿದುಕೊಳ್ಳುವ ಹಕ್ಕು. ಒಂದು ವೇಳೆ ರೋಗಿಗೆ ಈ

ಮಾಹಿತಿಯನ್ನು ತಿಳಿಸುವಷ್ಟು ಸಮಯ ಇಲ್ಲದಿದ್ದಾಗ ಅಥವಾ ರೋಗಿಯನ್ನು ತುರ್ತಾಗಿ ಈ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಪಡಿಸಬೇಕಾದ ಸಂದರ್ಭದಲ್ಲಿ ಇದು ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

9. ರೋಗಿ, ಕಾನೂನಿನ ಪರಿಮಿತಿಯಲ್ಲಿ, ಚಿಕಿತ್ಸೆಯನ್ನು ತಿರಸ್ಕರಿಸಬಹುದು. ಆದರೆ ಹಾಗೆ ತಿರಸ್ಕರಿಸಿದಾಗ ಸಂಭವಿಸಬಹುದಾದ ಪರಿಣಾಮಗಳ ಬಗ್ಗೆ ವೈದ್ಯರಿಂದ ಮಾಹಿತಿ ಪಡೆಯುವ ಹಕ್ಕು.

10. ಯಾವದಾದರು ಪ್ರಯೋಗದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಹಕ್ಕು. ಆದರೆ ಯಾರು ತಮ್ಮ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡಲು ಅಸಮರ್ಥರೊ ಅವರ ಮೇಲೆ ಪ್ರಯೋಗ ಮಾಡಬಾರದು.

11. ಆರೋಗ್ಯ ಸೇವೆಯ ಬಗ್ಗೆ ಮಾಹಿತಿ ಪಡೆಯುವ ಹಕ್ಕು.

12. ರೋಗಿಗೆ, ತನ್ನ ಆರೋಗ್ಯದ ಸ್ಥಿತಿಯ ಬಗ್ಗೆ ಎಲ್ಲ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುವ ಹಕ್ಕು, ವೈದ್ಯರು ಕೆಲವು ಸಂದರ್ಭಗಳಲ್ಲಿ ಕೆಲವು ಮಾಹಿತಿ ನೀಡುವುದರಿಂದ ರೋಗಿಯ ಮೇಲೆ ದುಷ್ಪರಿಣಾಮ ಉಂಟು ಮಾಡಬಹುದು ಎಂದು ತಿಳಿದು ಬಂದಲ್ಲಿ ಆ ಮಾಹಿತಿಯನ್ನು ರೋಗಿಯಿಂದ ತಡೆಹಿಡಿಯ ಬಹುದು. ಆದರೆ ವೈದ್ಯರು ಈ ಮಾಹಿತಿಯನ್ನು, ರೋಗಿಯ ಸಂಬಂಧಿಕರಿಗೆ ಅಥವಾ ಆಪ್ತರಿಗೆ ತಿಳಿಸಬೇಕು.

13. ಚಿಕಿತ್ಸೆ ನೀಡುತ್ತಿರುವ ವೈದ್ಯರ ಮತ್ತು ಅವರ ವೃತ್ತಿ ಮುಂತಾದವುಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿ ಪಡೆಯುವ ಹಕ್ಕು.

14. ಬೇರೊಬ್ಬ ವೈದ್ಯರ ಬಳಿ ಸಲಹೆ, ಸೂಚನೆ ಪಡೆಯುವ ಹಕ್ಕು.

15. ಆಸ್ಪತ್ರೆಯಿಂದ ಮನೆಗೆ ತೆರಳುವ ಮುನ್ನ. ರೋಗಿ ಅಪೇಕ್ಷಿಪಟ್ಟಲ್ಲಿ. ತನಗೆ ನೀಡಿದ ಚಿಕಿತ್ಸೆಯ ವಿವರ, ಪರೀಕ್ಷೆಗಳ ವಿವರ ಮತ್ತಿತರ ಮಾಹಿತಿಯನ್ನು ಲಿಖಿತ ರೂಪದಲ್ಲಿ ಪಡೆಯುವ ಹಕ್ಕು. ಅಲ್ಲದೆ ಬೇರೊಬ್ಬ ವೈದ್ಯರನ್ನು ಈ ಮಾಹಿತಿ ಪಡೆಯಲು ಅಧಿಕಾರ ನೀಡಬಹುದು.

16. ಚಿಕಿತ್ಸೆ ಆದ ನಂತರ ನೀಡುವ ಹಣಕ್ಕೆ ರಸೀದಿಯನ್ನು ಪಡೆಯುವ ಹಕ್ಕು. ಹಾಗು ಆದರಲ್ಲಿರುವ ವಿವರಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿ ಪಡೆಯುವ ಹಕ್ಕು.

17. ರೋಗಿಗೆ ನೀಡುವ ಪ್ರತಿಯೊಂದು ಔಷಧವೂ ಉತ್ತಮ ಗುಣಮಟ್ಟದ್ದಾಗಿರಬೇಕು.

18. ಎಲ್ಲ ಔಷಧಿಗಳು ಸರಿಯಾದ ತಲೆ ಚೀಟಿ (ಲೇಬಲ್) ಹೊಂದಿರಬೇಕು ಮತ್ತು ಔಷಧದ ಹೆಸರನ್ನು ಹೊಂದಿರಬೇಕು.

19. ದೂರುಗಳು, ಕಂದುಕೊರತೆಗಳು ಇದ್ದ ಪಕ್ಷದಲ್ಲಿ ರೋಗಿ ಅದನ್ನು ತಿಳಿಸಲು ಮತ್ತು ಪರಿಹಾರ ಪಡೆಯುವ ಹಕ್ಕು.

20. ವೈದ್ಯರ ಅಥವಾ ಇತರ ಸಿಬ್ಬಂದಿಗಳ ನಿರ್ಲಕ್ಷ್ಯ, ಅನೈತಿಕ ವ್ಯವಹಾರಗಳಿಂದ ನೋವು. ನಷ್ಟ ಉಂಟಾದರೆ ಈ ವಿಷಯದಲ್ಲಿ ವಕೀಲರ ಸಹಾಯ ಸಲಹೆ ಪಡೆಯುವ ಹಕ್ಕು.

21. ಯಾವ ಯಾವ ಪರೀಕ್ಷಾ ವಿಧಾನಕ್ಕೆ ಎಷ್ಟು ಹಣ ನೀಡಬೇಕಾಗುತ್ತದೆ ಎಂಬುದನ್ನು ಸೂಚಿಸುವ ಫಲಕ ಕೇಳುವ ಹಕ್ಕು.

II. ರೋಗಿಗಳ ಜವಾಬ್ದಾರಿಗಳು

1. ರೋಗಿಗಳು ವೈದ್ಯರ ಬಳಿ ಹೋದಾಗ ಸರಿಯಾದ ಮಾಹಿತಿ ನೀಡಬೇಕು. ಅಲ್ಲದೆ ತಮ್ಮ ವೈಯಕ್ತಿಕ ವಿಷಯಗಳು, ಸಂಸಾರದಲ್ಲಿರಬಹುದಾದ ಕಾಯಿಲೆಗಳ ಬಗ್ಗೆ ಸಂಪೂರ್ಣ ವಿವರ ನೀಡಬೇಕು. ವೈದ್ಯರು ಯಾವ ಮಾಹಿತಿ ಕೇಳಿದರು. ಅದಕ್ಕೆ ತಕ್ಕಂತೆ ವಿವರ ನೀಡಬೇಕು. ಯಾವ ವಿಷಯದಲ್ಲಿ ಸುಳ್ಳು ಹೇಳಬಾರದು.
2. ಬೇರೊಬ್ಬ ವೈದ್ಯರ ಬಳಿ ಈಗಾಗಲೇ ಔಷಧಿ ಪಡೆಯುತ್ತಿದ್ದರೆ ಅದನ್ನು ತಿಳಿಸಬೇಕು. ಅಲ್ಲದೆ ಯಾವ ಔಷಧಿಯನ್ನು ಎಷ್ಟು ದಿನಗಳಿಂದ ಸೇವಿಸುತ್ತಿದ್ದಾರೆ ಎಂಬುದನ್ನು ತಿಳಿಸಬೇಕು.
3. ಬೇರೆ ರೋಗಿಗಳ ಹಕ್ಕು ಜವಾಬ್ದಾರಿಗಳನ್ನು ತಿಳಿದಿರಬೇಕು. ಅದಕ್ಕೆ ಚ್ಯುತಿ ಬಾರದಂತೆ ನಡೆದುಕೊಳ್ಳಬೇಕು.

III. ಸಾರ್ವಜನಿಕ ಆಸ್ಪತ್ರೆಗಳಲ್ಲಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳು

1. ಅತಿಯಾದ ಜ್ವರ ಅಥವ ಗಾಯಗೊಂಡ ತುರ್ತು ಸಂದರ್ಭದಲ್ಲಿ ಆಸ್ಪತ್ರೆಗೆ ಒಳರೋಗಿಯಾಗಿ ದಾಖಲಾಗುವ ಹಕ್ಕು.
2. ವೈದ್ಯರಿಂದ ಸಮರ್ಪಕವಾದ ರೋಗ ವಿಧಾನದ ಹಕ್ಕು.
3. ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಮಾಡಿಸಿಕೊಳ್ಳಬೇಕಾದ ಸಂದರ್ಭದಲ್ಲಿ ತಮಗೆ ಇಷ್ಟಬಂದ ವೈದ್ಯರನ್ನು ಸೂಚಿಸುವ ಹಕ್ಕು.
4. ತನ್ನ ರೋಗದ ಬಗ್ಗೆ ಸಂಪೂರ್ಣ ಮಾಹಿತಿ ಪಡೆಯುವ ಹಕ್ಕು.
5. ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ಕೊಠಡಿ (ಆಪರೇಷನ್ ಥಿಯೇಟರ್) ಯನ್ನು ಪರೀಕ್ಷಿಸಿ ಎಲ್ಲಾ ಸೌಲಭ್ಯಗಳೂ ಇದಯೇ ಎಂಬುದನ್ನು ಖಚಿತಪಡಿಸಿ ಕೊಳ್ಳುವ ಹಕ್ಕು.
6. ತೀವ್ರ ಆರೈಕೆಮಾಡುವ ಕೊಠಡಿ (ಇಂಟೆನ್ಸಿವ್ ಕೇರ್ ಯೂನಿಟ್) ಪರೀಕ್ಷಿಸುವ ಹಕ್ಕು.
7. ಪ್ರಯೋಗಾಲಯ, ಪರೀಕ್ಷಣಾಲಯ, ರಕ್ತ ನಿಧಿ ಮುಂತಾದವುಗಳನ್ನು ಪರೀಕ್ಷಿಸುವ ಹಕ್ಕು.
8. ರೋಗಿಗಳ ಹಾಗು ವೈದ್ಯರು ಹಕ್ಕುಗಳು ಮತ್ತು ಜವಾಬ್ದಾರಿಗಳು ಯಾವುವು ಎಂಬುದನ್ನು ಸೂಚಿಸುವ ಫಲಕಗಳನ್ನು ಅಥವಾ ಸೂಚನೆಗಳನ್ನು ಆಸ್ಪತ್ರೆಗಳಲ್ಲಿ ಅಂಟಿಸಿರಬೇಕು ಇಲ್ಲ ತೂಗು ಹಾಕಿರಬೇಕು ಇದೂ ಸಹ ರೋಗಿಯ ಹಕ್ಕು.

IV. ಜವಾಬ್ದಾರಿಗಳು

1. ಕುಟುಂಬ ವೈದ್ಯರನ್ನು ಸಂಪರ್ಕಿಸದೇ, ಅವರ ಅನುಮತಿ ಇಲ್ಲದೆ ಆಸ್ಪತ್ರೆಗೆ ದಾಖಲಾತಿ ಬಯಸಬಾರದು.
2. ಹೊರ ರೋಗಿಗಳಿಗೆ ಇರುವ ಸಮಯದಲ್ಲಿ ಮಾತ್ರ ಆಸ್ಪತ್ರೆಗೆ ಭೇಟಿ ನೀಡಬೇಕು.
3. ವೈದ್ಯರನ್ನು ಕಾಣಲು ಬರುವಾಗ ತಮ್ಮ ಜೊತೆ ಕೇವಲ ಒಬ್ಬ ಸಂಬಂಧಿಕರನ್ನು ಮಾತ್ರ ಕರೆತರಬೇಕು.
4. ಆಸ್ಪತ್ರೆಗೆ ಬರುವಾಗ ಹಿಂದೆ ತೆಗೆದುಕೊಂಡ ಔಷಧಗಳ ಪಟ್ಟಿ ವೈದ್ಯರ ಸಲಹೆ ಮುಂತಾದ ವುಗಳನ್ನು ಕೊಂಡೊಯ್ಯಬೇಕು.

5. ಈ ಮುಂಚೆ ಬೇರೆ ವೈದ್ಯರಲ್ಲಿ ಚಿಕಿತ್ಸೆ ಪಡೆಯುತ್ತಿದ್ದರೆ, ಅವರಿಂದ ಒಂದು ಲಿಖಿತ ಪತ್ರ ಪಡೆದು ಆಸ್ಪತ್ರೆಗೆ ತರಬೇಕು. ಬೇರೊಬ್ಬ ವೈದ್ಯರ ಬಳಿ ಔಷಧ ತೆಗೆದುಕೊಳ್ಳುತ್ತಿದ್ದ ರೋಗಿಯನ್ನು ಅನುಮತಿ ಇಲ್ಲದೆ ಇನ್ನೊಬ್ಬ ವೈದ್ಯ ತನ್ನ ವಶಕ್ಕೆ ತೆಗೆದುಕೊಳ್ಳಬಾರದು.

6. ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ವೈದ್ಯರನ್ನು ಕಾಣುವುದಕ್ಕೆ ಮುಂಚೆ ಅವರಿಂದ ನಿಗದಿತ ದಿನಾಂಕ, ಸಮಯವನ್ನು ಗೊತ್ತಮಾಡಿಕೊಳ್ಳಿ.

V. ಔಷಧಗಳನ್ನು ಕೊಳ್ಳುವಾಗ ಗ್ರಾಹಕರು ಗಮನಿಸಬೇಕಾದ ಅಂಶಗಳು

1. ಯಾವಾಗಲೂ ಅಧಿಕೃತ ಅನುಜ್ಞಾಪತ್ರ (ಲೈಸೆನ್ಸು) ಹೊಂದಿರುವ ಮಾರಾಟಗಾರರಿಂದಲೇ ಔಷಧ ಕೊಳ್ಳಿರಿ.
2. ತಜ್ಞ ವೈದ್ಯರನ್ನು ಭೇಟಿ ಮಾಡಿದ ನಂತರವೇ ಔಷಧಿ ಸೇವಿಸಿ.
3. ಔಷಧಿ ಕೊಂಡಾಗಲೆಲ್ಲಾ ಅಧಿಕೃತ ರಸೀದಿ ಪಡೆಯಿರಿ. ಸರಿಯಾದ ರಸೀದಿ ನೀಡುವುದು ಮಾರಾಟಗಾರರ ಕರ್ತವ್ಯ.
4. ವೈದ್ಯರು ಯಾವ ಔಷಧಿಯನ್ನು ಬರೆದು ಕೊಟ್ಟಿದ್ದಾರೋ ಅದನ್ನೇ ಕೊಂಡಿದ್ದೀರಾ ಎಂಬುದನ್ನು ಔಷಧ ಅಂಗಡಿಯನ್ನು ಬಿಡುವ ಮುನ್ನವೇ ಖಚಿತಪಡಿಸಿಕೊಳ್ಳಿ. ಸಾಧ್ಯವಿದ್ದರೆ, ಮತ್ತೊಮ್ಮೆ ವೈದ್ಯರ ಬಳಿ ಹೋಗಿ ಔಷಧಗಳನ್ನು ತೋರಿಸಿರಿ.
5. ಔಷಧದ ಸೀಸೆ ಅಥವಾ ಪೆಟ್ಟಿಗೆ/ಕವಚದ ಮೇಲೆ ಮುದ್ರಿಸಿರುವ ಬೆಲೆಯನ್ನು ಗಮನಿಸಿ. ಮುಖ್ಯವಾಗಿ, ಔಷಧಿಯನ್ನು ಯಾವ ದಿನಾಂಕದ ಮುಂಚೆ ಸೇವಿಸಬೇಕು ಎಂಬುದನ್ನು ಪರೀಕ್ಷಿಸಿ. ವಾಯ್ದೆ ಮುಗಿದಿದ್ದ ಪಕ್ಷದಲ್ಲಿ ಅದನ್ನು ಹಿಂತಿರುಗಿಸಿ ಬೇರೆ ಪಡೆಯಿರಿ.
6. ಕೆಲವು ಔಷಧಗಳನ್ನು ಶೀತಲ ಪೆಟ್ಟಿಗೆ (ರೆಫ್ರಿಜರೇಟರ್)ಯಲ್ಲಿ ದಾಸ್ತಾನು ಮಾಡಿರಬೇಕು. ಇದನ್ನು ಔಷಧದ ಪೆಟ್ಟಿಗೆ ಮೇಲೆ ಮುದ್ರಿಸಿರಲಾಗಿರುತ್ತದೆ. ಹಾಗೆ ಮಾಡದ ಪಕ್ಷದಲ್ಲಿ ಆ ಔಷಧವನ್ನು ಕೊಳ್ಳಬೇಡಿ.
7. ಔಷಧ ಸೇವಿಸಿದ ನಂತರ ಉರಿ, ಅನಾನುಕೂಲ ಅಥವ ಇನ್ನಾವುದೇ ರೀತಿಯ ಅಹಿತಕರ ಪ್ರತಿಕ್ರಿಯೆ ಉಂಟಾದಲ್ಲಿ ತಕ್ಷಣ ವೈದ್ಯರನ್ನು ಭೇಟಿ ಮಾಡಿ.
8. ಔಷಧ ಸೇವನೆಗೆ ವೈದ್ಯರು ನೀಡಿರುವ ಸೂಚನೆಗಳನ್ನು ತಪ್ಪದೆ ಪಾಲಿಸಿ. ಅಲ್ಲದೆ, ಔಷಧದ ಪೆಟ್ಟಿಗೆ, ಲೇಬಲ್ಲುಗಳ ಮೇಲೆ ಮುದ್ರಿಸಿರುವ ಸೂಚನೆಗಳನ್ನು ಅನುಸರಿಸಿ.
9. ವೈದ್ಯರು ನೀಡಿದಷ್ಟು, ಸೂಚಿಸಿದಷ್ಟು ಮಾತ್ರ ಔಷಧ ಸೇವಿಸಿ. ರೋಗ ಗುಣಮುಖ ಕಂಡಕೂಡಲೇ ಔಷಧ ಸೇವನೆ ನಿಲ್ಲಿಸಬೇಡಿ. ವೈದ್ಯರು ಔಷಧ ಸೇವನೆ ನಿಲ್ಲಿಸುವಂತೆ ಹೇಳುವವರೆಗೂ ಔಷಧ ಸೇವನೆ ಮುಂದುವರಿಸಬೇಕು.
10. ಔಷಧ ಮುಗಿದ ನಂತರ ಅದರ ಪೆಟ್ಟಿಗೆಯನ್ನು ಹಾಗೆಯೇ ಎಸೆಯಬೇಡಿ. ಅದನ್ನು ಸಂಪೂರ್ಣವಾಗಿ ನಾಶಗೊಳಿಸಿ.
11. ಯಾವುದೇ ಔಷಧಿ, ಮಾತ್ರೆಗಳ ಬಗ್ಗೆ ಅನುಮಾನ ಬಂದಲ್ಲಿ ಹತ್ತಿರದ ಔಷಧ ನಿಯಂತ್ರಣ ಅಧಿಕಾರಿಗಳಿಗೆ ದೂರುಸಿಡಿ.

ಕರ್ನಾಟಕ ರಾಜ್ಯ ಔಷಧ ನಿಯಂತ್ರಣಾಧಿಕಾರಿಗಳು
ಅರಮನೆ ರಸ್ತೆ, ಬೆಂಗಳೂರು-560 001
ದೂರವಾಣಿ : 2264760

ವಿ.ಸೂ : ಈ ಮೇಲಿನ ವಿವರಗಳನ್ನು ಪಾಂಡಿಚೇರಿಯಲ್ಲಿ ಮತ್ತು ಮುಂಬಯಿಯಲ್ಲಿ ನಡೆದ ವಿಚಾರ ಸಂಕಿರಣದ ಗೊತ್ತುವಳಿಗಳ ಆಧಾರದ ಮೇಲೆ ಸಿದ್ಧಪಡಿಸಲಾಗಿದೆ.

VI. ನಿಷೇದಗೊಂಡಿರುವ ಔಷಧಗಳು

Consolidated List of Drugs/fixed Dose combination of Drugs Banned by The Central Government Under Section 26A of the Drugs And Cosmetics Act 1940

1. Amidopyrine.
2. Fixed dose combinations of Vitamins with antiinflamatory agents and tranquillisers.
3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
4. Fixed dose combinations of Strychnine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterose and Vitamines.
6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/Chloral hydrate with other drugs.
7. Fixed dose combinations of Iron with Strychnine, Arsenic Yohimbine.
8. Phenecatin.
9. Fixed dose combinations of Anti-histaminics with anti-diarrhoeals.
10. Fixed dose combinations of Penicillin with Sulphonamides.
11. Fixed dose combinations of Vitamins with Analgesics.
12. Fixed dose combinations of Tetracycline with Vitamin C.
13. Fixed dose combinations of Hydroxyquinoline group of Drugs except preparations which are used for the treatment of diarrhoea and dysentry and for external use only.

14. Fixed dose combinations of Corticosteroids with any other drug for internal use.
15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
16. Fixed dose combinations of Ergot.
17. Fixed dose combinations of Vitamins with anti-T.B. drugs except combination of Isoniazide with pyridoxine Hydrochloride (Vitamin B_6).
18. Penicillin Skin/Eye Ointment.
19. Tetracycline liquid oral preparations.
20. Nialamide
21. Proactolol.
22. Methapyrilene, its salts.
23. Methequalone.
24. Oxytetracycline Liquid Oral Preparations.
25. Demeclocycline Liquid Oral Preparations.
26. Combination of Anabolic Steroids with other drugs.
27. Fixed dose combinations of Oesterogen and Progestin (Other than oral contraceptives) containing per table estrogen content of more than 50mg. (equivalent to Ethenyle Estradiol) and of progestin content of more than 3 mg. (equivalent to Norethisterone Anetate)
28. Fixed dose combinations of Sedatives/hypnotics/anxiolytics with analgesic- antipyretics.
29. Fixed dose combinations of Pyrazinamide with other anti- tubercules drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given below.

Drug	Minimum	Maximum
Rifampicin	450mg.	600mg.
INH	300mg.	400mg.
Pyrazinamide	1000mg.	1500mg.

30. Fixed dose combination of Histamine H2-receptor antigonists with antacids except for those combinations approved by the Drugs Controller (India).

31. The patent and proprietory medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.
32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate.
33. Fixed dose combination of Ethambutol with INH other than the following:

INH	Ethambutol
200 mg.	600 mg.
300 mg.	800 mg.

34. Fixed dose combinations of Containing more than one antihistamine.
35. Fixed dose combinations of Anthalmintic with cathetric/purgative except for piperazine.
36. Fixed dose combinations of Salbulamol or any other bronchodilator with central acting anti-tussive and/or, antihistamine.
37. Fixed dose combinations of Laxatives and/or, antispasmodic drugs inenzyme proparations.
38. Fixed dose combinations of Metoclopramide with other drugs except for preparations containing metoclopramide and aspirin/paracetamol.
39. Fixed dose combinations of Centrally acting, antitussive with antihistamine having high atropine like activity in expectorant.
40. Preparations claiming to combat cough associated with asthma containing centrally acting anti-tussive and/or antihistamine.
41. Liquid oral tonic preparations containing glycerophosphates and/or other phosphates and/or central nervous system stimulant and such preparations containing alchol more than 20% proof.
42. Fixed dose combinations of Containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed
44. Dovers Powder I.P.
45. Dovers Powder tablets I.P.
46. Chloral Hydrnte as a drug

Consumer Awareness Series - 2

Rights and Responsibilities of Patients & List of Banned drugs

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PATIENT'S RIGHTS AND RESPONSIBILITIES

PART 1: PATIENT'S RIGHTS:

Section 1: RIGHT TO HEALTH CARE AND HUMANE TREATMENT:-

1. Every individual shall have access to adequate and appropriate health care and treatment.
2. Every patient shall be treated with care, consideration, respect and dignity without discrimination of any kind.
3. A Patient has the right to be treated by fully qualified health care professionals in private or public health care facilities.
4. A Patient has, wherever possible, the right to be treated at a hospital of his choice and to be referred to a consultant of his choice.
5. Every individual shall have the right to prompt emergency treatment from the nearest government or private medical and health facility.
6. Patients have the right to humane terminal care and to die in dignity.
7. A Patient can be transferred to another health care establishment only after an explanation of the need for this transfer and after the other establishment has accepted the patient.
8. A patient has the right to have all identifying information, results of investigations, details of his condition and his treatment kept confidential and not made available to anyone else without his consent.

Section 2: CONSENT:-

1. Before any treatment or investigation, a patient shall have the right to a clear, concise explanation in lay terms of the proposed procedure and of any available alternative procedure. Where applicable, the explanation shall include information of risks, side effects, or after-effects, problems relating to recuperation, likelihood of success, and risk of death. Informed consent of the patient must be obtained prior to the conduct for a treatment or a procedure. In the case of a minor, consent has to be obtained from the parent or guardian. If a patient is incapacitated and any delay would be dangerous, a doctor is entitled to carry out

any neessary treatment or operation after a second opinion is obtained.

2. A Patient has the right to refuse treatment to the extent permitted by law and to be informed of the medical consequences of his decision.

3. Explicit, informed consent is a prerequisite for participation in scientific experimentation. Experimentation must not be carried out on any patient who is unable to express his will.

Section 3: RIGHT TO INFORMATION:-

1. Information about health services (including recent developments in the field) and how best to use them is to be made available to the public in order to benefit all those concerned

2. Information may be withheld from patients in cases where there is good reason to believe that this information would affect the patient's health adversely but, however, the information must be given to a responsible relative.

3. A patient has the right to know the identity and the professional status of the individuals providing service to the patient and to know which professional is primarily responsible for the patient's care.

4. Patients should have the right to seek a second opinion from another physician.

5. Patients should upon request, be able to obtain a copy of summary of their diagnosis, treatment and care including diagnostic results on discharge from a hospital or other establishment. They shallalso have the right to authorise another medical professional to obtain a copy of the same and to inform the patient of the contents.

6. A patient shall have the right to examine and receive an explanation of his bill after any treatment and consultation.

Section 4: THE RIGHT TO ADEQUATE PRESCRIBING INFORMATION:-

1. While prescribing medication, the patient should be informed about the following:-

   Expected outcome, adverse and after effects, chances of success, risks, cost and availability.

2. All drugs dispensed shall be of acceptable standards in terms of quality, efficinacy and safety.
3. All medicines shall be labelled and shall include the pharmacological name of the medicine.

Section 5: RIGHT TO REDRESS GRIEVANCES:-

1. A Patient shall have access to appropriate redressal procedures.
2. A patient shall have the right to legal advice as regards any malpractice by the hospital, the hospital staff or by a doctor or other health professional.

Section 6: RIGHT TO HEALTH EDUCATION:-

1. Every individual shall have the right to seek and obtain advice with regard to preventive and curative medicine, after care and good health.

PART 2: PATIENT'S RESPONSIBILITIES:

1. The patient shall ensure that he or she knows and understand what a patient's rights are and shall exercise those rights responsibly and reasonably.
2. The patient shall ensure that he or she understands the purpose and cost of any proposed investigation or treatment before deciding to accept it.
3. The patient shall accept all the consequences of the his/her own informed decisions.
4. The patient shall provide accurate and complete information which the health professional requires about his or her health and ability to pay for health services.
5. The patient shall establish a stable relationship with and follow the treatment determined by the health professional primarily responsible for the patient's care
6. The patient shall inform the health professional if he or she is currently consulting with or under the care of another health professional in connection with the same complaint or any other complaint.
7. The patient shall so conduct himself or herself so as not to interfere with the well being or rights of other patients or providers of health care.

8. Every individual has a responsibility to maintain his or her own health and that of society by refraining from indulging in high risk behaviour detrimental to health.
9. Every individual has a responsibility to accept all preventive measures sanctioned by law.

Consolidated List of Drugs/fixed Dose combination of Drugs Banned by The Central Government Under Section 26A of the Drugs And Cosmetics Act 1940

1. Amidopyrine.
2. Fixed dose combinations of Vitamins with antiinflamatory agents and tranquillisers.
3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
4. Fixed dose combinations of Strychnine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterose and Vitamines.
6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/Chloral hydrate with other drugs.
7. Fixed dose combinations of Iron with Strychnine, Arsenic Yohimbine.
8. Phenecatin.
9. Fixed dose combinations of Anti-histaminics with anti-diarrhoeals.
10. Fixed dose combinations of Penicillin with Sulphonamides.
11. Fixed dose combinations of Vitamins with Analgesics.
12. Fixed dose combinations of Tetracycline with Vitamin C.
13. Fixed dose combinations of Hydroxyquinoline group of Drugs except preparations which are used for the treatment of diarrhoea and dysentry and for external use only.

14. Fixed dose combinations of Corticosteroids with any other drug for internal use.
15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
16. Fixed dose combinations of Ergot.
17. Fixed dose combinations of Vitamins with anti-T.B. drugs except combination of Isoniazide with pyridoxine Hydrochloride (Vitamin B6).
18. Penicillin Skin/Eye Ointment.
19. Tetracycline liquid oral preparations.
20. Nialamide
21. Proactolol.
22. Methapyrilene, its salts.
23. Methequalone.
24. Oxytetracycline Liquid Oral Preparations.
25. Demeclocycline Liquid Oral Preparations.
26. Combination of Anabolic Steroids with other drugs.
27. Fixed dose combinations of Oesterogen and Progestin (Other than oral contraceptives) containing per table estrogen content of more than 50mg. (equivalent to Ethenyle Estradiol) and of progestin content of more than 3 mg. (equivalent to Norethisterone Anetate)
28. Fixed dose combinations of Sedatives/hypnotics/anxiolytics with analgesic- antipyretics.
29. Fixed dose combinations of Pyrazinamide with other anti- tubercules drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given below.

Drug	Minimum	Maximum
Rifampicin	450mg.	600mg.
INH	300mg.	400mg.
Pyrazinamide	1000mg.	1500mg.

30. Fixed dose combination of Histamine H2-receptor antigonists with antacids except for those combinations approved by the Drugs Controller (India).

31. The patent and proprietory medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.
32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate.
33. Fixed dose combination of Ethambutol with INH other than the following:

INH	Ethambutol
200 mg.	600 mg.
300 mg.	800 mg.

34. Fixed dose combinations of Containing more than one antihistamine.
35. Fixed dose combinations of Anthalmintic with cathetric/purgative except for piperazine.
36. Fixed dose combinations of Salbulamol or any other bronchodilator with central acting anti-tussive and/or, antihistamine.
37. Fixed dose combinations of Laxatives and/or, antispasmodic drugs inenzyme preparations.
38. Fixed dose combinations of Metoclopramide with other drugs except for preparations containing metoclopramide and aspirin/paracetamol.
39. Fixed dose combinations of Centrally acting, antitussive with antihistamine having high atropine like activity in expectorant.
40. Preparations claiming to combat cough associated with asthma containing centrally acting anti-tussive and/or antihistamine.
41. Liquid oral tonic preparations containing glycerophosphates and/or other phosphates and/or central nervous system stimulant and such preparations containing alchol more than 20% proof.
42. Fixed dose combinations of Containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed
44. Dovers Powder I.P.
45. Dovers Powder tablets I.P.
46. Chloral Hydrnte as a drug

TIPS TO CONSUMERS

1. Always buy drugs from a licenced dealer
2. Avoid self modification. Consult qualified Doctors and obtain prescription
3. Insist on Cash bill. The dealer is required by law to issue cash bill for every transaction.
4. Check the drugs before leaving te counter and ensure that what has been dispensed is the one that is prescribed. Preferably go back to the Doctor to show the drug purchased
5. Check expiry date and the maximum retail price printed on the label/container
6. Certain drugs have to be stored in the refrigerator to preserve potency. The storage condition will be mentioned on the label. Refuse to accept if the storage is improper.
7. Report any untoward reaction to your physician
8. Follow the instructions while taking the drugs. Always complete the course of treatment. Do not discontinue in the middle unless advised by your physician
9. Destroy the containers after use or destroy the label before disposing
10. In case of doubt on the quality or price charaged do not hesitate to report to the nearest office of the Assistant Drugs Controller or Drugs Inspector

Bangalore Address:

Drugs Controller Office,
Palace Road, Bangalore-560 001
Phone No: 2264760

Based on the Resulations adopted at the Workshop on Medicine, Media and Consumer Education held at Pondicherry and guidelines issued by Drugs Controller, Karnataka

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