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CONSUMER ALERT!

Phenyl butazone - oxyphenbutazone

HAZARDOUS DRUGS

Prepared for:

Drug Action Network core group meeting at Sevagram

30 - 31 July 1984

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U. K.:

On 6th March 1984, U K banned Phenylbutazone.
On 3rd April 1984 Ciba Geigy withdrew Oxyphenbutazone, a breakdown product of phenylbutazone from U K market.

In Germany 65 such drugs have been banned, and use of another 206 severely restricted.

In Finland, manufacturers have been asked to withdraw these drugs.

In U S the Public Citizen Health Research Group has asked the department of Health and Human Services for an imminent danger ban.

Japan has severely restricted the use of these drugs.

IOCU has sent world wide consumer alerts. Norway, Federal Republic of Germany, Italy, Australia, Sweden, Finland and Bangladesh have severely restricted their sales.

It is not that, we have not been concerned about the misuse of these antiinflammatory agents and their irrational combinations, prior to the knowledge of these bans. We feel that after receiving unbiased authentic information about the extent of the adverse effects related to these drugs, it is our responsibility to alert others. The public needs to be informed of their dangers realizing that a significant number of patients to buy the drug over the counter unwarned and uninformed.

We are using this as yet another case where, double standards have existed in the drug information given to doctors in the West and to our own doctors.

The total annual turn-over of the two products of phenylbutazone and Oxyphenbutazone (BUTAZOLIDIN & TANDRIL of Ciba Geigy's) fetch 200 million Swiss-Francs ie. £ 65 million ie. Rs 1170 million and these drugs have been in the market since 1952 and 1960 respectively and are well known). It is very unlikely that, Ciba Geigy will withdraw these products from the third world, specially after having already stated their decision to withdraw Mexaform(Clioquinol) and Dianabol(Anabolic Steroid) from the world market. Withdrawing Butazolidin and Tandril at this point would lead to a financial set-back. It is unlikely that Ciba Geigy will give in very easily toconsumer pressure- a stand already made clear by the makers of Butazolidin and Tandril.

What are these drugs used for?

Phenylbutazone and Oxyphenbutazone are non-steroidal antiinflammatory drugs which also have mild anti-pyretic and analgesic properties. They give only SYMPTOMATIC RELIEF and

"Phenylbutazone and oxyphenbutazone should not be used unless the urine had been examined for protein and a blood examination and had shown that white cells and platelet counts were within the normal range. B M Ansell, Prescribers Journal, 1969, 8, 120 in Martin dale- the extrapharmacopia, 28th edition, 1982. A routine urine and blood test prior to usage of the drug is recommended. In view of the additonal costs this may not always be possible forthe poorer patients. An extra caution and restrain in the utilization of these drugs is therefore, indicated.

In India the drugs have been recommended by certain manufacturers for minor problems and feeble conditions. Gifford 1973 has been quoted in MIMS editorial, November 1982 that according to Pharmacology books "Phenylbutazone as an antipyretic and an analgesic is relatively inferior to aspirin" Phenlbutazone as an antiinflammatory agent, is effective, but serious toxicity limits its use in long term therapy. In rheumatoid arthritis, phenylbutazone has a limited role and should be used primarily for acute exacerbations not relieved by other measures.

WHAT ARE THE DANGERS ASSOCIATED WITH THE USE OF PHENYLBUTAZONE OXYPHENBUTAZONE?

Bone Marrow Toxicity:

Aplastic anaemia or pancytopenia ie. total bone marrow shut down which is fatal in over 50% cases. Agranulocytosis, which is a severe depression of white blood (granulocyte cell production - fatal in about 35% cases). Leukaemia which is a cancer of bone marrow; Gastro intestinal bleeding or peptic ulceration - fatal in about 20% cases.

Other risks are liver damage Hepatitis in less than .1% cases access to liver. It is mainly hepato-cellular necrosis. Hepatitis usually starts within 4 weeks of starting treatment but in 20% cases can be started upto or even after 1 year. Cholestatic jaundice occurs in less than 3% cases. Serum sickness type of hyper-sensitivity, ulcerative stomatitis, nephritis(kidney failure) thrombocytopenia(depletion of platelet count) are other serious side effects, though some of these are much rarer.(Ref: Phenylbutazone and hepatitis-Fowler P D Woolfe D, Alexander S Rheum Rehabilitation, 14, 17, 1975).

MIMS editorial adds that "because of its sodium and chloride retention properties, phenylbutazone can increase plasma volume by as much as 50%, thus straining cardiac functions and occassionally causing acute pulmonary edema. Since, toxic effects are more pronounced in the senior citizens, the drug is contraindicated for use in geriatic patients."

The seriousness of the Problem:

A STUDY IN SWEDEN OF DRUG INDUCED BLOOD DYSCRASIAS ATTRIBUTED PHENYLBUTAZONE AS THE DOMINANT CAUSE.(Drug induced dyscrasias in Sweden Battinger L E & Westerholm N, British Medical Journal, 3 339 1973).

Incidence of bone marrow aplasi due to phenylbutazone and oxyphenbutazone is assessed as 1 in 33000 to 1 in 99000. Aplasie anaemia or agranulocytosis were quoted as underlying or contributing causes of death. In 376 death certificates in the year October 1974 to September 1975, the mortality rate was estimated as 2.2 per 100,000 cases.

The study of fatal bone marrow depression with special reference to phenylbutazone and oxyphenbutazone- Inman W H W, British Medical Journal I-1500 (1977). The effect of bone marrow depression is serious. Drug induced agranulocytocis- phenylbutazone. Pisciotta A V Drugs 15 132 (1978) Drug induced bone marrow depression by phenylbutazone, British Medical Journal 4, 490 (1973).

Ciba Geigy's adverse effects department at its head office in Basle in one its internal memos in February 1983, gave it findings of 1182 reported deaths from these drugs ... 2724 ... detailed patient reports of other adverse effects. Well over ½ of these deaths were from bone marrow toxicity including leukemia, gastro-intestinal bleeding or perforated ulcers. Of the 6716 cases of undesirable side effects reported on the drug, 777 persons have known to have died with Butazolidin between 1952 and 1981. Of 4165 cases of side effects reported with Tandril, 405 persons are reported to have died. 199 cases of serious undesirable effects and 18 deaths have been reported in Japan.

After 12 years, the receipt of the first report of adverse reaction to Butazolidin from Great Britain, came from West Germany indicating that identification of adverse reactions come along only with experience and a high degree of alertness and suspicion about possible adverse reactions. In third world countries, adverse reaction reporting is depressingly inefficient, as are the controls on potentially hazardous dr... Double standards in giving the drug information to the health personnel makes matters worse.

Phenylbutazone and oxyphentubazone is poorly tolerated by many patients. Even if diarrhowa, nausea, nervousness, insomnia are associated with the drug, it is ignored that the potential fatality cannot be overlooked. Some type of side effect is noted in 10 to 45 % of patients and medication may have to be discontinued in their cases. Its use should be limited to short term therapy of not more than a week during any one treatment period. Even then, the incidence of disturbing the side effects is about 10%. Phenylbutazone has a limited role in the therapy of rheumatoid arthritis. It is primarily used for relief of acute exacubations of the disorder that are not relieved by the other measures.

Goodman Gillman; 5th Eidition
Chapter- 17.

According to Martindale : "Although phenylbutazone is effective in almost all rheumatic disorders including ankylosing spondylitis, osteo arthritis, rheumatoid arthritis and reitusdeseas, it is GENERALLY RESERVED FOR USE IN THE TREATMENT OF RHEUMATIC DISORDERS where less toxic drugs have failed.

- Martindale; 28th Edition

In 1975, a study was done in U.K. to determine the true incidence as opposed to the reported incidence ofdeaths due to aplastic anaemia, and agranulocytosis in people using phenylbutazond or oxyphenbutazone. In U.K. even where all death certificates mentioning a drug have to be reported to the Government Drug Authority, only 1 out of 4 deaths due to drugs were found to have been reported. It was only because of the study, that the relationship of the drugs and death could be found. According to Oldver Gillie, medical correspondent, Sunday Times, states "In Britain where the 2 drugs have been used comparitively cautiously, 512 deaths associated with them have been recorded between 1964 and 1980. But, the real total is probably at least double that world-wide, as reported in the Ciba Geigy internal report (Ref: Dr Hanssen) which records 1182 deaths associated with the drug upto 1982.

Since it is impossible that almost half of these deaths occured in Britain alone, many deaths must have gone unrecorded in other countries and the actual figures would certainly run into many thousands, giving Butazolidin and Tandril amongst the highest death total for any drug".

Scrip. No. 854; December 12, 1983;
pg.18.

In U.K. the death rates were found to be 22 deaths per million users of phenylbutazone, and 38 deaths per million users of oxyphenbutazon. Dr Sidney Wolfe uses the companies own estimates of patient exposure world-wide ie.75 million users of phenylbutazone, 66 million users of oxyphenbutazon to estimate the number of patients that must have been affected. Using the U.K. study result and their mortality rate due to these drugs as the basis, he estimates the following;

with phenylbutazone, about 75 million people exposed by 22 deaths per million ie. about 1650 deaths.

with oxyphenbutazone, about 60 million people exposed by 38 deaths per million ie. 2280 deaths. Total= 3930 deaths(ie. 1650+2280)

World wide from aplastic anaemia and agranulocytisis; 3930 deaths must have occured many of which went unreported. The internal document shows that aplastic anaemia and agranulocylosis constituted 37.8% of the deaths. If 3930 deaths constitutes only 37.8% of total deaths, then the total number of the deaths due to these drugs would be approximately 10,400 ie. 10,400 deaths world-wide merely due to use of 2 drugs. If we try to extend this to other brands that are available in the market, then there would definately be more deaths. By mid 1982, 311 deaths in U.S. were reported. It is known that only one in ten deaths due to these drugs get reported. In other words total deaths would be over 3100.

According to Dr Olle Hanssen another Ciba Geigy's internal memo has stated in light of the dangers of the drug and "the presence of many newer equally effective non-steroidal anti-inflammatory drugs now available in the market with comparatively less toxicity, that it is reasonable and necessary that the risk and benefit ratio of Butazolidin and Tandril should be carefully reassessed for the indications of all forms of inflammatory and degenerative arthritis as promoted, to see if such promotions are justified".

Malayasia:

Consumer association of Penang report based on discussions with University Hospitals, Pharmacologists reports that phenylbutazone and oxyphenbutazone are amongst the 5 drugs accounting for the majority of the adverse drug reactions suffered by patients, admitted into the hospital. Consumer Association of Penang has demanded an immediate recall of the drug from the market for the safety and health of the Malayasian Consumer.

Japan:

Mainichi Daily News which is a Japanese newspaper dedicated to International understanding covered the news in its headlines on 9th February, 1984. Ciba Geigy's antiinflammator pain killing drugs killed 1182 in the world.

INTERNAL DOCUMENTS OBTAINED : BAN IS CALLED FOR

The newspaper covered the issue daily in its morning as well as in the evening issue, including a strong editorial. The headlines on February 11, stated that the Government ignored findings of courts in drug poisonings. Apparently, two litigations took place about 10 years ago. Investigations should have been done. About 15 deaths in Japan due to these drugs have so far been recorded. . pharmaceuticals Co. stocking preparations of Ciba Geigy's declared withdrawal according to Mainichi, February 10. February 12th- Mainich; "Documents of side effects ordered severe restrictions being decided is possible for all drugs containing these drug".

India:

Pune Journal of on-going Education : In this issue no. of 37, June 81, in a letter to the Managing Director of Ciba Geigy, the Journal had raised strong objection against their new product parazolandin (parasolandin being a combination of paracetamol and phenylbutazone) for indicating it for conditions like fever.

C E R C:

CERC prepared a document on irrational and hazardous anti-inflammatory agents including phenylbutazone and oxyphentazone combination with amidopyrines. They had submitted this to the Drug Control Authorities and demanded their ban. It is important for us to be constantly aware that the situation in India is more serious than the countries mentioned earlier.

1. We have these drugs available over the counters in any dosage for any duration of time with our (falsely continuing to believe in the sanctity and magic of western medicine.
2. Patients are rarely given any warnings by their doctors and if they buy the drugs over the counter they can rarely make head or tail of the medical literature inserts.
3. Phenylbutazone and oxyphenbutazone have been available often in deadly combinations with amidopyrine, analgin, paracetamol, diazepan, Vitamin B, dextrapropoxyphene acetominophe which makes the combination.

Phenyl butazone and oxyphenbutazone are dangerous drugs.

93.2

VOLUNTARY HEALTH ASSOCIATION OF INDIA

D-9/334 (h)
a:25.8.82

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USING TETRACYCLINE FOR CHILDREN AND PREGNANT WOMEN

Introduction: The question of Syp.tetracycline for paediatric usage is not merely one of discolouration of the teeth. More importantly, it is the question of SELLING AND PRESCRIBING A POTENTIALLY HARMFUL DRUG WITHOUT GIVING ADEQUATE INFORMATION TO THE PATIENT. It is also a question of the over use or misuse of a drug in trivial conditions when, more often than not, it is not required; and of attempting to deal with childhood infection with pills, while the causes of the infection and increased susceptibility are allowed to remain untouched.

Looking at the drugs we prescribe or consume makes us realise the necessity to know more about these drugs - not from the drug representative but from authentic medical literature and the experience of others. Realization of this discrepancy in the information from the drug companies and their medical literature enhances our reponsibility in this regard to the patients.

RATIONAL THERAPEUTICS IS KNOWLEDGEABLE PRESCRIBING OF THE MOST EFFECTIVE, LEAST COSTLY, MOST NON-TOXIC, EASILY AVAILABLE DRUG in the RIGHT QUANTITY, for the RIGHT DURATION and for the RIGHT PROBLEM in the RIGHT WAY.

IT IS THE RESPONSIBILITY OF HEALTH PERSONNEL TO ENSURE THAT THE RIGHT DRUGS ARE PRODUCED AND MADE AVAILABLE TO THOSE WHO MOST NEED THEM, AND THAT HAZARDOUS OR IRRATIONAL DRUGS ARE THROWN OUT OF THE MARKET.

Ensuring that people get at least the minimum required to be healthy is our MAIN CONCERN. We realize that drugs can play only a small part in keeping people healthy. Therefore, by demolishing some of the myths surrounding the unquestionable healing properties of all drugs, we hope more and more individuals will begin to look beyond pills for a cure for their ills.

The manufacture of Tetracycline for paediatrics is supposed to be banned from January 1982. The date of the ban on marketing of the drug has not yet been fixed. The reasons for banning the manufacture are:

1. DENTAL DISCOLOURATION

"Children receiving long or short term therapy with tetracycline may develop brown discolouration of the teeth. The larger the dose of the drug, relative to body weight, the more severe is the deformity, the deeper the colour, and the more intense the hypoplasia of enamel". The quantity received is more important than the duration. Mild darkening of the permanent teeth occurred in 3 of 14 children who received 5 courses of the drug, whereas 4 of 6 who received eight courses had moderate darkening of the enamel.

(Ref: Grossman,E.R., Walchick,A; Freedman,H.: Tetracycline and Permanent Teeth: the Relationships between doses and tooth colour: Paediatrics: 1971, 47, 567-570).

"The risk of this is highest when the tetracycline is given to neonates and babies prior to the first dentition".

"If given between the ages of 2 months and 5 years - pigmentation of the permanent teeth may develop."

The earliest characteristics of this defect is yellow fluorescence probably due to the formation of a tetracycline-calcium orthophosphate complex; with time this progresses to permanent brown pigment.

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a:25.8.82

2. CATABOLIC EFFECT

"Tetracyclines exert a catabolic effect, perhaps due to a generalized inhibition of protein synthesis in mammalian cells".

"Administration of 2.5 to 3 gms. of Chlortetracyclines given to undernourished adults results in weight loss, increased urinary nitrogen excretion, negative nitrogen balance, and elevated servum non protein nitrogen concentration."
(Goodman Gillman: page 1188, 6th Ed)

Gocke, T.M., Jackson,G.G.,Grigsby,M.E., Love,B.D. Jr, and Finland,M.

"Some effects of antibiotics on nutrition in man, including studies of the bacterial flora of the faeces". Arch. Intern.Med. 1958, 101,476-513.

In India the majority of children who would receive tetracycline are malnourished or bordering on malnutrition. They would be repeatedly picking up infection - more often viral but bacterial infections as well. Additionally, how much of this drug would get prescribed by different doctors or consumed anyway, we don't know.

3. BONE GROWTH

According to Goodman, Gillman, 6th Edition (1980), Tetracycline are deposited in the skeleton of the human foetus and young child. A 40% depression of bone growth, as determined by the measurements of fibula, has been demonstrated in premature infants treated with these agents. (Cohlan, S.Q., Bevelander,G., and Tiamsic, T.: Growth Inhibition of Prematures Receiving Tetracyclines - Clinical and Lab.investigations. Am. J. Dis. Child 1963, 105, 453-461).

4. Tetracycline induced diarrhoea is not exactly uncommon - and that supra-infection by other organisms may occur sometimes.

5. "Tetracycline may cause increased intracranial pressure and tense bulging of the fontanels (pseudo tumor cerebri) in young infants, even when given in usual therapeutic doses".
(Ref: Goodman, Gillman)

Increased intracranial pressure presents itself with severe headache, vomiting, loss of function of certain cranial nerves, and limbs and if severe, even death. The figures of the common or rare this entity is are not available to us right now.

6. The ingestion of out dated and degraded tetracycline is known to cause Fanconi Syndrome - a clinical picture characterized by nausea, vomiting, polyuna (increased passage of urine, polydipsea - increased thirst, acidosis, protienuria glycosuria and aminoacidune (passage of proteins, glucose and aminoacids in urine).

Our drug control of sales of hazardous drugs, sales of out-dated products is not exactly good and whether the problems created by out-dated tetracycline is more than discolouration of the teeth would be interesting to know.

PREGNANT WOMEN

Liver Damage: According to Gooman,Gillman: "Pregnant women appear to be particularly susceptible to severe, tetracycline-induced hepatic damage".
Schultz, J.G., Adamson, J.S.,Jr: Workman,W.W.,and Morman,T.D.
Fatal Liver Disease after intra-venous Administration of Tetracycline in High Dosage. N.Eng.J. Med. 1963: 269, 999-1004.

"Jaundice appears firs, and azotemia acidosis and irreversible shock may follow. Although hepatic fat is increased during pregnancy, the quantity appears to be even greater after exposure to a tetracycline.

"Disseminated intravascular coagulation has been reported in a pregnant woman who developed hepatic renal failure after given only 2 doses

of 100mg each of tetracycline intramuscularly (Pride, G.L., Cleary R.E. & Hamburger, R.J. Disseminated intravascular coagulation associated with tetracycline induced hepato renal failure during pregnancy. Am.J. Obst. Gynae. 1973, 115, 585-586). This may be a rare phenomenon.

"Treatment of pregnant patients with tetracyclines may produce discolouration of teeth in the offspring. Ingestion of the drug between mid-pregnancy to about 4-6 months of post natal period is dangerous for deciduous anterior teeth (temporary front teeth) and from 6 months to 5 years of age for the permanent anterior teeth. Children up to 7 years may be susceptible to this complication of tetracycline therapy".

(Weyman,J. Tetracycline and Teeth. Practitioner 1965, 195,661-665)

The argument offered for continuing its use is that Tetracycline is cheap, easily available.

In Australia, the Drug Evaluation Committee has recommended the banning of all tetracyclines in paediatric formulas.

In Belgium, the Philippines, Italy and the U.S.A. the drug has been banned from Paediatric formulas. In addition, there is the compulsory warning: Not to administer in pregnancy and to children below 8 years.

The International Organization of Consumer Unions has listed Tetracycline as one of the 44 problem drugs, rated as a widespread serious problem.

Tetracycline is a more expensive drug than penicillin or sulphonamides. It is a bacteriostatic drug. For many infections it is not so good. The yellowness of the teeth can be seen only months or years later, and it lasts all through the patient's life.

A mother should not be given tetracycline after four months of pregnancy, nor should a child be given the drug if he is below 7 years, unless his life is in danger.

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93.3

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D-10/340(b)
LCD/25.5.84

Rationality in Banning Fixed Dose Combinations

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Hathi Committee (1975) appointed by Government of India pointed out that the medicinal needs of the people in India can be met by only 116 drugs. However, over 25,000 drug formulations continue to be sold and prescribed in India. Many of these formulations are unnecessary variations of identical basic drugs sold under different brand names or without any proven therapeutic effect or they are too toxic for human consumption. Unless there is a clear cut proven therapeutic superiority or a fixed dose combination, such combinations not only put financial hardship to poor patients but also expose the patients to the undesirable effects of the unnecessary medicament(s) of such formulations. Dr H Mahler, The Director General of WHO feels that 98 % of the drugs available in the developing world are not essentials hence not required. The Drug Technical Advisory Board (DTAB) of India has recently (1982) recommended the weeding out of the following fixed dose combinations with an uniform cut off date of March 31, 1983.

1. Fixed dose combination of amidopyrine.
2. Fixed dose combinations of vitamins with antiinflammatory agents and tranquilizers.
3. Fixed combinations of atropine with analgesics and antipyretics.
4. Fixed dose combinations of strychinine and caffeine in tonics.
5. Fixed dose combinations of yohimbine strychnine and testosterone and vitamins.
6. Fixed dose combinations of iron with strychnine and arsenic and yohimbine.
7. Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.
8. Fixed dose combinations of ayurvedic, unani drugs with modern drugs.
9. Fixed dose combinations of phenacetin.
10. Fixed dose combinations of antihistaminics with antidiarrhoeals.
11. Fixed dose combinations of penicillins with sulphonamides.
12. Fixed dose combinations of vitamins with analgesics.
13. Fixed dose combinations of tetracycline with vitamins C.
14. Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.
15. Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for the treatment of asthma.
16. Fixed dose combinations of chloramphenicol except with streptomycin.
17. Fixed dose combinations of ergot except combinations of its alkaloid ergotamine with caffeine.
18. Fixed dose combinations of prophylactic vitamins with anti-TB drugs except combinations of INH with vitamin B_6 .

The rational for the undesirability of the above said fixed dose combinations can be based on the forthcoming arguments andfacts.:

1. Fixed Dose Combinations of Amidopyrine:

Fixed dose combinations of amidopyrine(amidopyrine) are irrational because amidopyrine is an outdated and obsolete drug as it causes bone marrow depression leading to agranulocytosis which may be fatal(Beaver 1965). Even though it has marked antipyretic and analgesic properties, its "over the counter" sale in the United States had been prohibited since 1938(Moodbury 1970). In view of the recent development of newer and safer antipyretic analgesics, it is in public interest to drop out amidopyrine altogether from physicians armamentarium.

2. Fixed Dose Combinations of Vitamins with Antiinflammatory Agents and Tranquilisers:

The addition of vitamins to antiinflammatory agents and tranquillisers in fixed dose combinations does not yield any proven increases in the therapeutic effects of these combinations. In a way they are just like placesbos but certainly enhance the cost of formulations. In most of the patients requiring either antiinflammatory or antipsychotic therapy, vitamin deficiency is not an usual associated feature even in our country where malnutrition is so prevalent. Hence vitamin supplementation with these drugs is both a waste of vitamins as well an unnecessary financial burden for the patients.

3. Fixed Dose Combinations of Atropine with Analgesics and Antipyretics:

Analgesics and antipyretics reduce the raised body temperature to normal(antipyresis).But Atropine is known to cause hyperpyrexia (ie. it may raise the body temperature). Hence such combinations is therapeutically antagonistic and is therefore irrational. Furthermore, even in cases of visceral pain (eg. colics), where atropine may be advised with the idea of its antispasmodic property, simultaneous administration of an antipyretic analgesic, which is ineffective against visceral pain has hardly any therapeutic advantage. All the more such combinations unnecessarily expose the patients to the potential toxicity of antipyretic analgesics.

4. Fixed dose Combinations of Strychnine and Caffeine in Tonics:

Fixed dose combinations of strychnine and caffeine in tonics areundesirable because strychnine (formerly used as an appetiser) is now an obsolete drug and its enthusiastic use in tonics may even induce convulsions particularly in susceptible individuals. Similarly caffeine though, has a mild CNS stimulant effect leading to little temporary mood elevation and relief from fatigue, has no tonic effect on the body. Furthermore caffeine products mild physical dependence and habitual use of this drug in tonics may cause psychological and physical dependence for such formulations.

5. Fixed Combinations of Yohimbine, Strychnine with Testosterone and Vitamins:

Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins are irrational because yohimbine is no longer regarded as therapeutically useful aphrodiasiac in man even when mixed with methyltestosterone(Laurance,1980). Furthermore, yohimbine should not be used therapeutically because of its side effects viz Central excitation, raised blood pressure, increased heart rate. Strychnine is also now an obsolete. Vitamins do not play any therapeutic role(except in deficiency diseases) and simply act as placebo, of course, giving the psychological boost to the patient.

6. Fixed dose Combinations of Iron with Strychnine, Arnica and Yohimbine:

Strychnine, arnica and yohimbine combinations are used as stimulant appetizers. In most of the patients (except women) generally there is no deficiency of iron because iron is adequatly stored in the liver. However, in very specific anaemic cases supplemental iron therapy may be given separately. To add iron in these formulations is irrational and may be just for the purpose of increasing the price of the formulation or to seek patient rights for the formulations.

7. Fixed dose combinations of Sodium Bromide/Chloral Hydrate with other drugs:

Fixed dose combinations of sodium bromid/chloralhydrate with other drugs can now be considered irrational because both these drugs are now obsolete due to their toxic manifestations. Bromides on prolonged administration replace the chloride ions of the body. Because of the slow onset of action, cumulative poisoning, manifesting as conjunctivitis, GIT symptoms, dermatitis and mental disturbances is likely to occur. Further their exeeding slow onset of action and low potency make these bromides unreliable hypnotics.

Chloral hydrate, being an irritant of the mucous membranes, causes gastritis leading to a variety of GIT symptoms eg. nausea vomitting flatulence and epigastric distress. Chloral hydrate can even cause hepatic and or renal damage! In view of the recent and more safer hypnotics there is now no justification of prescribing chloral hydrate to patients.

8. Fixed dose combinations of Ayurvedic and Unani drugs with Modern drugs:

The modern (Allopathic) drugs are well, standardised and their standardization methods are official. In case of ayurvedic and unani drugs, official standardization methods are not available at present. Therefore, it does not argue well to have a combination of ayurvedic and/or unani drugs with modern drugs bevause of the standardization problems of the resulting formulations. In view of the lack of authentic repeatable research data on the efficacy of fixed dose combinations of ayurvedic and unani drugs with modern drugs, there is no justification of such formulations to be sold for use by the general public.

9. Fixed dose combinations of Phenacetin:

Phenacetin is gradually loosing its importance because it causes kidney damage when used in large amounts or for long periods. Hence it has no place in routine analgesic, antipyretic and antiinflammatory therapy. Therefore, fixed dose combinations of phenacetin are outdated and hazardous. Formulations containing aspirin with phenacetin and often with caffeine are promoted with claims that they provide greater analgesic effect and/or cause fewwer side effects than does aspirin alone. In most controlled clinical trials such claims have not been found correct.

10. Fixed dose combination of Antihistaminics with Antidiarrhoeals:

The fixed dose combinations of antihistaminics with antidiarrhoeals is rational, only in certain specific cases where the diarrhoea is due to allergy(like protein allergy). In these specific cases, the antihistaminics may be prescribed separately so that such combinations are not irrationally used in the treatment of all other types of diarrhoea. Routine use of these

combinations is not only a waste of antihistaminic drugs but also it exposes the patients to the undsirable effects of this class of compounds.

11. Fixed dose combinations of Sulphonamides with Penicillins:

Even though sulphonamides and penicillins individually do have important role in the therapy of infections. The combination of penicillin with sulphonamides is undesirable. This is because the antagonism of the antibacterial effect may result when bacteriostatic (Sulphonamides) and bactericidal(Penicillin) agents are given concurrently,(Jawetz and Gunnison, 1953). In addition oral combinations may even induce penicillin sensitivity.

12. Fixed dose combinations of Vitamins and Analgesics:

In the fixed dose combinations of vitamins with analgesics, the vitamins do not play any therapeutically beneficial role and rather act as placebo. Therefore, such combinations are therapeutically irrational. Since such formulations are likely to be misused by the patients and if administered for long periods because of their vitamin contents, such combinations are likely to expose the society to a veriety of undesirable effects of analgesics.

13. Fixed dose combinations of Tetracyclines with Vitamin C:

There is no specific therapeutic indication of giving tetracylines and vitamin C together because tetracyclines ... does not cause any specific vitamin C deficiency. Therefore, this combination is of no therapeutic superiority and may be produced by drug companies just for enhancing the cost of their product. Further, in inffective conditions where tetracyclines are indicated, vitamin C deficiency is not an usual associated feature, such formulations should not be routinely employed.

14. Fixed dose combination of Hydroxyquinolines group of Drugs except preparation which are used for the treatment of Diarrhoea and Dysentery:

Halogenaled hydroxyquinolines are indicated only in intestinal infection like amoebiasis. So the combination of hydroxyquinoline with some other antidiarrhoeal and antidysentery drugs like enzymes for the treatment of dyspepsia is undesirable because hydroxyquinolines may induce Subacute Myelooptic neuropathy(SMON). Due to this toxic manifestation the use on this drug in clinical practice has been abandoned in many advanced countries. The clinical use of these formulations for such simple conditions like dyspepsia exposes these patients to the risk of SMON and hence should not be employed.

15. Fixed dose combinations of Steroids for Internal use except combinations of steroids with other drugs forthe treatment of Asthma:

In view of the acute onset of the benefical effect of steroids in a large number of clinical conditions, their use has tremendously increased in recent years. However, fixed dose combinations of steroids with other drugs are objectionable as it is extremely important to adjust the steroid dose to the minimum that produces the desired effect and the dose of the other drug if altered, not on the patients need for it (other drug) but on his need for steroid. In view of the widespread use of such combinations, the patients are exposed to toxic cumulative effects of these drugs. However, in case

of asthma, since immumological factors play an important role and adrenal steroids cause nonspecific reducation of the response to the antigen antibody reactions, the fixed dose combinations of steroids with other drugs in the treatment of asthma is therapeutically rational and justified.

16. Fixed dosecombinations of Chloramphenicol except with Streptomycin:

Chloramphenicol is a drug of choice only in the treatment of enteric fever and gastroenteritis. Its combination with streptomycin in the treatment of gastroenteritis is therapeutically justified because this combination has been found therapeutically superior to either of these drugs alone in the treatment of mixed infections of the gastrointestinal tract. But combination of chloramphenicol with other drugs(like tetracycline) is irrational because both the drugs have almost the same antimicrobial spectrum and also because chloramphenicol is more toxic as it may cause aplastic anaemia.

17. Fixed dose combinations of ergot except combinations of its Alkaloid Ergotamine with Caffeine:

Ergot alkaloid, ergotamine is effective in the treatment of migrains because it is a vasoconstrictor agent and prevents the rhythmic distension of extracranial arteries.

Caffeine may be allowed in combination also because of its vasoconstrictor effect on intracranial vessels. However the combination of ergotamine with other drugs(like paracetamol, prochlorperazine etc) have no therapeutic advantage and hence irrational.

18. Fixed dose combination of Prophylactic vitamins with antitubercular drugs except combinations of I N H with vitamin B_6:

Fixed anti tubercular drug (except INH) are irrational becuase in these combinations, the vitamines have on therapeutic role to play (of course unless there is a vitamins deficiency) and they simply act as placebo and might give some psychological boost to the patient. However, because INH causes vitamin B6 deficiency, its combination with vitamin B6 is rational and therapeutically justified.

Another drug combination which has been recently banned in this country after a much hue and cry from the medical experts is that of Estrogen Progesterone (E P combinations). These combinations were used for test for pregnancy. The use of E P hormonal preparations were banned in U S A by the Food and Drug Administration (FDA) in 1975 because these preparations were found to seriously damage the foetus.

It is often alleged that drug companies levy a heavy burden on the common man by charging more and more through their dubious multiple drug formulations which are their patented products. For example, the real pain killer in most ofthe analgesic tablets is aspirin, the market is flooded with a number of costlier pain killers containing in addition salicylamide, caffeine and quinine sulphate, which have no proven synergistic efficacy. Similarly, amongst anti-cold ointments, only menthol is said to be of any real therapeutic value. Here too, other ingredients of dubious value like camphor, turpentine and thymol are often added in order just to put in market a new formulation and thus increase the price of such a patented formulation.

In our opinion such anti-social problems must be tackeled at all levels. The responsible persons of the society in the medical and health field, like doctors and pharmacists should keep a close watch on the drugs banned inthe developed countries and also on the drugs which on clinical trials have not been found safe and effective. These responsible men should convey all the clinical information on such drugs or their combinations to the appropriate authorities of the Government of India. Though the Drug Technical Advisory Board(DTAB), Drug Consultative Committee(DCC) and Director General of Health Services(DGHS) have been entrusted with this job by the Government of India but other responsible men in the medical field will also have to keep a vigil so that there is no oversight on the part of the official machinery and the harmful and obsolete drugs from developed countries are not dumped in our country any longer. The World Health Organization(WHO) should also play an effective role inthis regard and ensure that only safe and effective drugs are sold to member countries. In addition, the government must adopt the recommendations of WHO on essential generic preparations. In a developing country like ours, the goal must be to ensure availability of essential drugs to patients and health education to all about safe water, sanitation and finally sufficient nutritious food.

However, the major problem lies in the fact that a large number of drug formulations in India have not been adequately evaluated for their safety and this again emphasises the need to exercise strict quality control . This becomes much more significant in the light of the recent statement by the Government in Rajya Sabha that 17.5% of the drug manufactured and sold in the country in the last three years were found to be substandard.

Over all, if employment of such fixed dose combinations aids the busy physician and does not significantly represent a lessoning of his individualized orientation to his patient and are rational from the therapeutic point of view, they are a boon to therapeutics otherwise a curse to the patient and the society.

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HAZARDOUS, BANNED, BANNABLE AND DUMPED DRUGS

(Prepared for Drug Action Core Group meet at Wardha 30-31st July '84 as a Background paper for discussion)

The issue of dumped drugs for past few years has been much in the news. The multinationals involved in manufacture and sales of such drugs have received their dure share of condemnation. Foreign government policies which provided the scope for exports of such hazardous products have been condemned by many of us eg. the Clayton Amendment Act and the U.S. Resolution.

It is well known that sales of medical technologies and drugs is a commercial enterprise, the motivation is profit making and not 'service' or 'welfare work'.

Realizing all this the question arises as to how much as citizens of India, can we expect our drug control authorities to safe guard our interests. The pressure from the drug industry is immense. It is not merely money power but political connections & influence over the medical lobby. Many of the so called medical experts are in their pay roll, many others are conducting 'scientific studies' sponsored by the companies, attending conferences sponsored by the companies, receiving gifts and samples from the companies. This affiliation is not unexpected. Inspite of knowing this our expectations from our drug control authorities is high. After all our pharmaceutical industry is the most developed in the third world, (ie according to UNIDO it belongs to Category 5,- developed enough to be self sufficient).

We have demanded that our imports, production and sales should give priority to essential, life saving drugs over irrational and hazardous drugs. This being along with WHO's guidelines for Essential drugs programme. The drug industry and its supporters allege that concept of essential drugs is only for struggling, least developed third world countries and not for a country like India, with its well developed industry and high and advanced level of medical expertise .However, this same lobby puts India in the category of less developed countries when it comes to the issue of banning drugs and drug control, claiming that consideration of hazards over efficacy are luxuries which we cannot afford!

However, consumers anywhere in the world have a right to expect that irrational hazardous drugs are not issued licences and that licenses of such banned drugs should be withdrawn as soon as possible, bans implemented, and that all drugs in the market are quality controlled. We have 20% substandard drugs ie. in 5 will not be effective With increasing number of spurious drugs floating in the market, the problem is beginning to take dangerous proportion.

Since 1980 we've been concerned about this issue of dumped and hazardous drugs. We widely circulated the list of combination drugs recommended for being weeded out and printed it in our special issue of HFM on Drugs April-June 1981. Since then the story of the drug ban has got more and more convoluted and fascinating. Our earlier belief is only reconfirmed that the government is not serious about controlling the sale of

hazardous drugs. The budget allocation for ensuring this, the expertise, technical personnel, quality control labs, qualified drug inspectors, mechanism to keep the health personnel and the public informed about these drugs has remained depressingly inadequate. Inspite of all the hue and cry raised by health and the consumer groups, nothing very much has happened.

The health of the nation seems to be relatively unimportant, as indicated by decreasing health budget. The Central Drug Contrl authorities allege that they have no real powers where implementation is concerned as this depends entirely on the state drug control authorities. They argue that they have inadequate budget and infrastructure.

Expenditure on Health as a percentage of total plan

Programme	FYP I 1951-56	FYP II 1956-61	FYP III 1961-66	FYP IV 1969-74	FYP V 1974-79	FYP VI 1980-85
Health sub-total to plan	3.83	3.04	2.79	2.74	1.73	1.87

One glance at what is happening to the health budget is enough to indicate the priorities health care is receiving in our welfare state.

We have 600 drug inspectors in the country (Hathi Committee has recommended). The required number is one for 25 drug units and 100 chemist shops. Only Maharashtra, Gujarat and Kerala have the stipulated number of drug inspectors and an adequate drug control mechanism.

In this paper we will not touch upon the extent of the problem of substandard and spurious drugs and the name-sake action being taken against those involved in their produce and sales.

Our focus will be on what has happened to the drugs recommended for being weeded out in 1980. In 1980 the Drug Consultative Committee a statutary body consisting of medical experts under Section 7 of the Drugs and Cosmetics Act(Central act 23 of 1940) nominated a subspecial committee to go into the rationality of 34 categories of fixed dose combination drugs. They were to study whether these drugs should be withdrawn or allowed to be manufactured and sold.

The criteria used by the Committee is very sensible and straightforward.

A Sub Committee of the Drugs Consultative Committee, comprising state drug controllers, has laid down well thought out and rational yardsticks to determine the desirability of combinations of drugs. As per these norms, combinations of drugs should only be allowed in the following cases:

a) If there is synergistic action
b) Where there is corrective action
c) When two or more drugs are normally prescribed together and taken by the patient simultaneously.
d) When the dosage of each of the drugs need not be individualized.
e) Where a fixed dose combination would ensure better

patient compliance due to convenience of administration.

f) Where two or more drugs, prescribed separately, may lead to non ingestion of one of the drugs, thus adversely affecting the health of the patient.

Conversely, fixed dose combinations of drugs should not be permitted under the following circumstances:

a) Where adverse interactions may occur
b) When one of the combined drugs becomes toxic on prolonged use
c) When abrupt withdrawal of one of the drugs caused withdrawal symptoms
d) If sub therapeutic doses are used in the absence of clinically demonstrable synergism
e) When pharmacokinetic behaviour of the individual agents is grossly different.

The criteria used by Bangladesh for banning 1742 drugs is given in the appendix 1.

We'll just look at what was involved in attempts to ban a few drugs eg. Amidopyrines, High dose E P drugs, Paediatric tetracyclin. Steroid combinations are dealt with later under ambiguity is the name of the game.

The sub committee submitted its report, recommended a ban of 23 combination drugs and giving their reasons for recommending the ban. 16 categories of these drugs were recommended for immediate weeding and 7 of the categories to be weeded over a specified time. Over 500 brand drugs would thus be affected (This list of 23 combinations and the reasons are attached in the appendix). This report was presented to the DCC at a special meeting on 10.10.81 and later to DTAB and Ministry of Health and Family Welfare which accepted it in 1981. The DTAB(Drug Technical Advisory Board) a Statutary body under section 5 of the Drugs and Cosmetics Act Central Act 23 of 1940 recommended banning of 18 fixed dose combination(list attached as appendix 2)

Under section 23 P of the Drugs and Cosmetics act 1940 the Central government has had the powers to issue such directions to the State governments as required to execute the Drug act. Under section 18 of the act the state government has had the power to 'prohibit manufacture,distribution and sale of drugs by a gazette notification.

These drugs were randomly selected from the Pharmaceutical Guide. Out of these 350 brands 44 brands were marketed by foreign sector, 8 by public sector and 298 by private sector. A point to note is that most of these drugs were being produced by private Indian companies and not multinationals. This was to be : inphased : discontinuation. According to the authorities"the purpose was to give time limit to firms who may have already purchased the bulk drugs for manufacturing the formulations". What compassion and consideration shown to the drug companies?

AMIDOPYRINE

The Drug Controller of India(DCI) by DO No.1273/77 DC directed the State Drug Controller to ban the fixed dose combination of amidopyrine on effect from 3.2.82. Orders were issued to stop manufacture from 1st July '82 and sale by October 31st '82. This ban was later extended further to 31.3.83.

The DCI through his DO No. 19013/8/81D dated 22.4.82 directed the State Drug Controllers to ban the manufacture of fixed dose combinations from 30.9.82 and their sales from 31.3.83. Sequal to V C Gare panel report government decision to withdraw 350 unnecessary drugs was taken.

When Maharashtra FDA did ban amidopyrines, the multinational most affected managed to get a stay order on the grounds that the drug was allowed to be marketed in other states by their state FDA's. In 1980 33 formulations of amidopyrine produced by 20 so manufactures were in the market. Multinationals and other big drug houses highly trusted by the public such as Suhrid Geigy, Sandoz, Suhudgeigy, Unichem, Ethnor, Thems, Indon were involved. Most of these drugs were being sold without adequate warning.

As Praful Bidwai on 19th August 1980 stated in the Financial Times Harmful drugs production still not stopped,' reluctant to lose their market share, these companies have merely continued to produce and market amidopyrine and are continuing to sell their preparations without even an additional warning about the drugs side effects.

Mukaram Bhagat Centre for Education and Documentation, in 'Aspects of Drug Industry in India' gives the example of Tamilnadu government medical list for government hospitals in which drugs like amidopyrine, phenacetin and analgin are very much included even when they were considered harmful and been disallowed.

PHENACETIN AND HOLOGENATED HYDROXYQUINOLINE:

Ban of fixed dose combinations of phenacetin and hologenated and hydroxyquinoline was to be effective from 1.11.82. The date of the ban of fixed dose combination of amidopyrine, phenacetin and halogenerated hydroxyquinolines was extended to 31.3.83 through DO No. X19013/8/81-D dated 13.8.82.

In 1979 January the Drug Controller of India had issued an order to gradually phase out amidopyrine as always 'phased discontinuation' process was not meant to be implemented as there were no specific DEADLINES.

HIGH DOSE OF E P DRUGS:

Through another DO No. 12-48/79-DC dated 26.6.82 the DCI directed the State Drug Controllers to ban the manufacture of high dose estrogen and progesterone combination from 31.3.83 and their sales from 30.6.83.

M/S Unichem Labs Bombay (OP 2927/82 of writ petition 2928/82), M/S Nicholas Labs Bombay and M/S Organon (now known as Infar (India)Ltd Calcutta filed writ petitions in Bombay and Calcutta high courts against the DCI's instructions to ban these drugs, their contention that Central government has no powers to ban the drugs. The high court of Bombay and

Calcutta have granted stay orders and these products continue to be available in the market.

Even though section 10A and 26A of the amedned Drugs and Cosmetics Act (April '82) empower the Central Government to prohibit import, manufacture and sale of any drugs considered harmful/toxic or irrational etc. Since the matter regarding high dose E P drugs was in the court, these drugs have NOT been included in the gazette notification of the DCI issued on 23.7.83 banning 22 fixed dose combinations.

What is absolutely objectionable is the fact that(this is inspite of the act of the Drug Controller of India's earlier instruction dated 26.6.82 banning the production and sales of high dose E P drugs from 31.3.83 and 30.6.83) M/S Organon (INDIA) Ltd have managed to obtain extention of licences to manufacture these products for another 2 years.

A sample of high dose E P drugs from Calcutta with manufacturing date 31.12.83 indicates that the ban is not merely being flaunted by Organon but by other drug companies manufacturing these products.

The misuse of these drugs for hormonal pregnancy tests and for attempting to induce abortions continues massively.

PAEDIATRIC TETRACYCLIN

Manufacture of Paediatric tetracyclin drops was to be banned from 1.5.82, no date was then given for marketing. Paediatric tetracyclin have since been banned on paper. They are still available, OTC, without warning.

Paediatric tetracyclin ban too does not figure in the gazette notification of July 23rd 1983.

On April '82 the Drugs and Cosmetics Act was amended whereby the Central Government and the Central Drug Control Authorities were given specific powers to 'ban the import, manufacture and sale of drugs in public interest'.(This was mentioned in the Drug Action Network Newsletter October '82)

Section 3(b)(i) was substituted and section 10A and 26A were inserted in the act. This came into effect from 1.2.83. This means that had our Central Drug Control authorities wanted it, gazette notifications banning the manufacture and sale of these drugs could have been undertaken immediately under the powers invested in it under section 26A of the act exercised.

The implications of this delay have been that certain drug companies have challenged the drug Controller of India's authority to ban these drugs. Some of them have even got stay order against specific bans, making these bans ineffectual and the whole drug control authority of our nation a laughing stock. The drug control authorities see their role as mainly advisory and hence don't feel particularly perturbed. Actually to come to think of it no one in the Health Ministry at Centre or State level seems to be particularly perturbed.

Allowing this extended time period, during which imports manufacture and sales have continued amounts to 'arbitoriness and discrimination' under article 14 of Constitution of India

according to Vincent Panikulangara since these drugs would be dumped in the market, substitutes withheld. With our efficiency of drug control mechanism, products in the chemists shops will continue to be sold and never withdrawn.

According to Section 26A of the Drugs and Cosmetics Act 1940

> "Without prejudice to any other provisions contained in this chapter, if the central government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then that government may, by notification in official gazette prohibit the manufacture, sale or distribution of such drug or Cosmetic".

Under section 10A of Drugs and Cosmetics Act of 1940 also there is a mandate that following a gazette notification imports of injurious drugs can be banned.

> Article 47 of the Constitution of India lays down that
> "The State shall regard the raising of the level of nutrition and standard of living of its people and the improvement of public health as among its primary duties and in particular the state shall endeavour to bring about prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health".

Under section 53 P the DCI directed the State Drug Controllers to ban the 20 fixed-dose combinations. The State Drug Controllers under section 18 of the act could exercise their power and prohibit their manufacture and sales by issuing a gazette notification. According to Vincent Panikulangara, the State Drug Control authorities are guilty of not exercising their power and taking responsibility. They have thus violated section 18 and 33 of the Drugs and Cosmetics Act and violated the fundamental right of the public citizens to health and life under section 21 of the Constitution of India. Article 14 of the Constitution is also violated by their having acted in a arbitrary and discriminatory manner contrary to public interest in favour of the Drug companies.

Kerala High Court Judge Mr Potti's judgement on Vincent Panikulangara's writ petition speaks for itself.

> "As between the lives of the citizens of this country on the one hand and loss that may result to the manufacturers and traders by the immediate ban on the manufacture and sales on the other, the government had chosen to view the latter as of more concern". It is the duty of the state to protect its citizens from injury and harm especially

when the injury is not inevitable".

Acting Chief Justice P Subramanian Potti and Justice Paripuran Kerala High Court, in their directive to the Union of India to release the list of brand names of banned drugs.

In October 1982 M/S Nicholas(India)Ltd Bombay filed a writ petition in Bombay High Court against the decision to ban the fixed dose combination of aspirin and vitamin C. The Bombay high court after the hearing of the respondent ruled that State Drug Control authorities has no power under Section 18 of the Drugs and Cosmetics Act to stop the manufacture and sale of these products.(The high court ruled that it would be open to the respondents as and when the law has been enacted to pass any fresh order as it is considered necessary in accordance with the law after following procedures prescribed by the government).

Subsequent to the Drug Amendment Act coming into force on 1.2.83 the manufacturers have again gone to court challenging the central government and sections 26A and 10A of on grounds of "LACK OF OBJECTIVE CRITERION for such ban".(A special handout on Rationale of the ban is available with us).

The Commissionor of FDA Maharashtra State(which is supposed to be having the best drug control mechanism) had informed the DCI that in the light of the ruling given by the Bombay High Court "it would not be possible for him to take any action to stop the manufacture and sale of any of the fixed dose combinations in question".(Letter dated 9 June 1984 by Drug Controller of India to us).

It was probably the above as well as Vincent's writ petition against the state and central drug control authorities for not having used their power that forced DCI to issue the gazette notification. A point to note is that drugs banned earlier and at different types make the brand banned list. E P drugs are not included in the gazette notification.

The ambiguidty of the wording of the gazette notification hit us early, when we attempted to compile the banned brand list. It was not clear whether for eg. in Category 4 include
- any drug containing yohimbine or strychnine would be banned (as neither of the two were considered to have therapeutic value and infact could lead to serious side effects as stated even by the DCC).
- or the ban was applicable to drugs containing both yohimbine and strychnine.
- or to yohimbine and strychnine with testesterone or vitamins
- or ONLY to drugs which contained all 4 ie. yohimbine, strychnine, testesterone and vitamins.

Another doubt was regarding criteria 12 ie. whether it could effectively deal with sterbid and antihistamines combination which could be indicated for allergy as well as asthma. First of all DCC had recommended a ban of all steroid combinations. Making this exception would obviously encourage misuse. After all doesn't the microscopic print in the medical literature for high dose E P drugs now-a-days say only secondary amenorrhea and isn't it true that it is mostly used for pregnancy testing and attempting abortion, changing the indication

on paper of a hazardous drug won't alter its use. Similarly allowing steroid combination for asthma won't prevent their misused for other conditions.

The DCC had recommended banning of all fixed dose steroid combination, DTAB decided to prohibit manufacture of fixed dose combination of bronchodilators, antihistaminics and tranquillizers with corticosteroids as early as October 4, 1980.

Dr B Shankaranand, the then DGHS, chairing a meeting had said "The current medical practice in all the developed countries is to give corticosteroids separately and fixed dose combinations of corticosteroids with other drugs are being discouraged".

Prof. Harkishan, Singh of the Department of Pharmaceutical Sciences Punjab University stated that there existed "published evidence to show that cortico steroids taken in small doses over longer periods are more harmful than if taken in larger doses over shorter time".

The Drug Consultative Committee comprising of all state Drug Controllers entrusted the responsibility of evaluating 34 categories of fixed dose combination, on basis of their rationality to a sub-committee. The sub committee comprising of some distinguished medical experts recommended a ban on steroid combinations. The Committee warned against compulsory intake of steroid because the "fixed dose combinations of steroids for internal use can produce serious side effects viz fluid and electrolyte disturbances, hyperglyceria glycosuria, increased suscesptibility to infection including TB, peptic ulcers, osteoporosis, steroid myopathy, cushings syndrome and Hersutism, combination with bronchodilators etc.".

On December 31, 1981, the Drug Technical Advisory Board constituting of exactly the same members reversed its own earlier decision. It felt that there was a need for getting wider medical opinion and further details and allowed the sales of these products.

Dr Gulati MIMS Editor in his editorial MIMS India Vol.2 No.3 February 1982 writing about the "somersault on steroids" says "they must have had very extraordinary reason to

a) reverse their own earlier decision
b) ignore the advise of DCC
c) consider the opinion of the whole battery of eminent and distinguished medical specialists from research institutions as inadequate so as to ask further details and wider medical opinion".

It would be interesting to find out how and why this change in their stand on fixed dose combinations of steroids took place. We would very enthusiastically have undertaken this exercise, had obtaining information such as this, been a less tedious, less time energy consuming and less frustrating affair.

The Kerala High Court judgement, in response to Vincent Panikulangara's writ petition OP 8439/1982 had directed the Central and State Drug control authorities "to publish the list of trade/brand names and the names of the manufacturers of these drugs. This was in 1982. Repeated requests for the same have been made to the Central Drug Controllers office. Some of the Drug Action networkers have been requested to do the same at the State level.

Excuses were made that the drugs have been licenced and registered with State health authorities and the centre allegedly has no clue about the various formulations and brands involved. The drug control mechanism is so inefficient that even to obtain just the list of, these products has taken more than one year. To ensure their ban or 'quality control' would definitely take a century.

It should be noted that the drug ban will be applicable for lesser drugs than what we had anticipated. Inspite of the presence of irrational and hazardous ingredients only those drugs will be banned that contain all the ingredients mentioned in the various categories eg. under category 5 -only those drugs containing all the following ie. yohimbine + strychnine + Testesterone + Vitamins will be affected.

According to Dr Das Gupta, Asst.Drug Controller the banned brand list will be ready in about 3 months. We had prepared our own black lists of banned or bannable drugs as far back as 1982 which have been circulated amongst the health care institutions in the voluntary sector and drug action networkers. These black lists have been for

1) Clioquinols, hydroxyquinolines ie. mexaform and Co
2) Amidopyrines - abalgen Ergopyrine
3) Paediatric tetracyclin
4) Diphenexylate - lomotil etc.
5) Anabolic steroids
6) Penicillin and streptomycin)
7) Chloramphenicol and streptomycin) In DCC recommendations
8) High dose E P drugs
9) Antiinflammatory agents and steroids etc.

(Background papers based on the above underlined drugs had been prepared and are available).

2-3 attempts at compiling the banned brand list based on drug banned by the gazette notification have been made. Three things have prevented us from widely circulating them.

i) Our expectations from our drug control authorities to make them available at least after the Kerala High Court judgement and Supreme Court writ petition.
ii) The difficulty in obtaining the drug list of formulations from the State Drug Control authorities.
iii) The process of reformulation of various drugs taking place with our not having any information as to
   a) which drugs were being formulated and sold as reformulating?
   b) Which drugs were being reformulated but their banned formulations under the same BRAND existed were sold unscrupulously in the market?
   c) Which were the hazardous banned drugs still being manufactured and sold as such?

Our health and drug control authorities get extremely upset when we mention the achievements of Bangladesh in their attempts towards a Rational Drug Policy. Inforced to mention Bangaldesh again. It should be noted that after the issuing of the Promulgation banning 1742 drugs in June 1982 the time period given to the drug companies of 3, or 6 or 9 months was given to withdraw these products from the market, to destroy these products even their export to other countries was strictly prohibited. We on the other hand have failed to implement a recommended ban by our own government committees and banned by our own drug controller. The drugs banned were mere few hundred, not over a 1000. The time period given was for the

drug companies to complete the manufacture of their formulations and sell off their stocks. The stocks surprisingly like Medusas head never seem to finish off.

Nepal, Pakistan, Malaysia, Sri Lanka and Banghdesh feel that clioquinol (hydroxyquinoline) formulations have no significant therapeutic value and can have major side effects. They have decided to ban these drugs. Ciba Geigy makers of mexaform have announced their plans to withdraw the drug from international market. We continue to allow them to be sold and promoted under more than 90 brands (including those produced by our public sector.)

The Drug campaigners from Bangladesh, Sri Lanka have complained about the outrageous smuggling in of these banned products from India. Our continuing to allow the manufacture and sales of these hazardous and irrational products is not merely hazardous to the health of our people, it also creates problems for our littler neighbours who are attempting to rationalize their drug policies, in the interest of their people.

If our government authorities cannot make all that goes with ensuring good health, available to its 700 million people it has no business to allow irrational and hazardous drugs to be inflicted upon them.

We will compile our own banned brand list and while the game playing goes on between the health, drug control authorities of centre and state, the drug industry and the high courts we will ensure that all these drugs are BOYCOTTED by health personnel as well as consumers.

The DCI had in one of his meetings last year pointed out that unhygienic conditions in the public hospitals, lack of clean water, sanitation quackery and unethical practices by medical personnel were greater problems than continuing sales of few hazardous drugs.

We want to make it clear that the issue here is not merely of banning a few hazardous and irrational drugs but it is to focus on what is going on in the name of 'health care'. It is to high light that when causes of ill health lie elsewhere in primarily dealing with them alone will there come about a significant change in the health status and quality of life of our people? There are no effective pills against poverty and the diseases of poverty. To deny people their right to health care is bad enough, but to let loose 'garbage and trash in the name of medical care is is inexcusable, inflaunting and totally unacceptable.

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Duplicate

Rationality in Banning Fixed Dose Combinations

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Hathi Committee (1975) appointed by Government of India pointed out that the medicinal needs of the people in India can be met by only 116 drugs. However, over 25,000 drug formulations continue to be sold and prescribed in India. Many of these formulations are unnecessary variations of identical basic drugs sold under different brand names or without any proven therapeutic effect or they are too toxic for human consumption. Unless there is a clear cut proven therapeutic superiority or a fixed dose combination, such combinations not only put financial hardship to poor patients but also expose the patients to the undesirable effects of the unnecessary medicament(s) of such formulations. Dr H Mahler, The Director General of WHO feels that 98 % of the drugs available in the developing world are not essentials hence not required. The Drug Technical Advisory Board (DTAB) of India has recently (1982) recommended the weeding out of the following fixed dose combinations with an uniform cut off date of March 31, 1983.

1. Fixed dose combination of amidopyrine.
2. Fixed dose combinations of vitamins with antiinflammatory agents and tranquilizers.
3. Fixed combinations of atropine with analgesics and antipyretics.
4. Fixed dose combinations of strychinine and caffeine in tonics.
5. Fixed dose combinations of yohimbine strychnine and testosterone and vitamins.
6. Fixed dose combinations of iron with strychnine and arsenic and yohimbine.
7. Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.
8. Fixed dose combinations of ayurvedic, unani drugs with modern drugs.
9. Fixed dose combinations of phenacetin.
10. Fixed dose combinations of antihistaminics with antidiarrhoeals.
11. Fixed dose combinations of penicillins with sulphonamides.
12. Fixed dose combinations of vitamins with analgesics.
13. Fixed dose combinations of tetracycline with vitamins C.
14. Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.
15. Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for the treatment of asthma.
16. Fixed dose combinations of chloramphenicol except with streptomycin.
17. Fixed dose combinations of ergot except combinations of its alkaloid ergotamine with caffeine.
18. Fixed dose combinations of prophylactic vitamins with anti-TB drugs except combinations of INH with vitamin B_6 .

The rational for the undesirability of the above said fixed dose combinations can be based on the forthcoming arguments andfacts.:

1. Fixed Dose Combinations of Amidopyrine:

Fixed dose combinations of amidopyrine(amidopyrine) are irrational because amidopyrine is an outdated and obsolete drug as it causes bone marrow depression leading to agranulocytosis which may be fatal(Beaver 1965). Even though it has marked antipyretic and analgesic properties, its "over the counter" sale in the United States had been prohibited since 1938(Moodbury 1970). In view of the recent development of newer and safer antipyretic analgesics, it is in public interest to drop out amidopyrine altogether from physicians armamentarium.

2. Fixed Dose Combinations of Vitamins with Antiinflammatory Agents and Tranquilisers:

The addition of vitamins to antiinflammatory agents and tranquillisers in fixed dose combinations does not yield any proven increases in the therapeutic effects of these combinations. In a way they are just like placesbos but certainly enhance the cost of formulations. In most of the patients requiring either antiinflammatory or antipsychotic therapy, vitamin deficiency is not an usual associated feature even in our country where malnutrition is so prevalent. Hence vitamin supplementation with these drugs is both a waste of vitamins as well an unnecessary financial burden for the patients.

3. Fixed Dose Combinations of Atropine with Analgesics and Antipyretics:

Analgesics and antipyretics reduce the raised body temperature to normal(antipyresis).But Atropine is known to cause hyperpyrexia (ie. it may raise the body temperature). Hence such combinations is therapeutically antagonistic and is therefore irrational. Furthermore, even in cases of visceral pain (eg. colics), where atropine may be advised with the idea of its antispasmodic property, simultaneous administration of an antipyretic analgesic, which is ineffective against visceral pain has hardly any therapeutic advantage. All the more such combinations unnecessarily expose the patients to the potential toxicity of antipyretic analgesics.

4. Fixed dose Combinations of Strychnine and Caffeine in Tonics:

Fixed dose combinations of strychnine and caffeine in tonics areundesirable because strychnine (formerly used as an appetiser) is now an obsolete drug and its enthusiastic use in tonics may even induce convulsions particularly in susceptible individuals. Similarly caffeine though, has a mild CNS stimulant effect leading to little temporary mood elevation and relief from fatigue, has no tonic effect on the body. Furthermore caffeine products mild physical dependence and habitual use of this drug in tonics may cause psychological and physical dependence for such formulations.

5. Fixed Combinations of Yohimbine, Strychnine with Testosterone and Vitamins:

Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins are irrational because yohimbine is no longer regarded as therapeutically useful aphrodiasiac in man even when mixed with methyltestosterone(Laurance,1980). Furthermore, yohimbine should not be used therapeutically because of its side effects viz Central excitation, raised blood pressure, increased heart rate. Strychnine is also now an obsolete. Vitamins do not play any therapeutic role(except in deficiency diseases) and simply act as placebo, of course, giving the psychological boost to the patient.

6. Fixed dose Combinations of Iron with Strychnine, Arnica and Yohimbine:

Strychnine, arnica and yohimbine combinations are used as stimulant appetizers. In most of the patients (except women) generally there is no deficiency of iron because iron is adequatly stored in the liver. However, in very specific anaemic cases supplemental iron therapy may be given separately. To add iron in these formulations is irrational and may be just for the purpose of increasing the price of the formulation or to seek patient rights for the formulations.

7. Fixed dose combinations of Sodium Bromide/Chloral Hydrate with other drugs:

Fixed dose combinations of sodium bromid/chloralhydrate with other drugs can now be considered irrational because both these drugs are now obsolete due to their toxic manifestations. Bromides on prolonged administration replace the chloride ions of the body. Because of the slow onset of action, cumulative poisoning, manifesting as conjunctivitis, GIT symptoms, dermatitis and mental disturbances is likely to occur. Further their exeeding slow onset of action and low potency make these bromides unreliable hypnotics.

Chloral hydrate, being an irritant of the mucous membranes, causes gastritis leading to a variety of GIT symptoms eg. nausea vomitting flatulence and epigastric distress. Chloral hydrate can even cause hepatic and or renal damage! In view of the recent and more safer hypnotics there is now no justification of prescribing chloral hydrate to patients.

8. Fixed dose combinations of Ayurvedic and Unani drugs with Modern drugs:

The modern (Allopathic) drugs are well, standardised and their standardization methods are official. In case of ayurvedic and unani drugs, official standardization methods are not available at present. Therefore, it does not argue well to have a combination of ayurvedic and/or unani drugs with modern drugs bevause of the standardization problems of the resulting formulations. In view of the lack of authentic repeatable research data on the efficacy of fixed dose combinations of ayurvedic and unani drugs with modern drugs, there is no justification of such formulations to be sold for use by the general public.

9. Fixed dose combinations of Phenacetin:

Phenacetin is gradually loosing its importance because it causes kidney damage when used in large amounts or for long periods. Hence it has no place in routine analgesic, antipyretic and antiinflammatory therapy. Therefore, fixed dose combinations of phenacetin are outdated and hazardous. Formulations containing aspirin with phenacetin and often with caffeine are promoted with claims that they provide greater analgesic effect and/or cause fewwer side effects than does aspirin alone. In most controlled clinical trials such claims have not been found correct.

10. Fixed dose combination of Antihistaminics with Antidiarrhoeals:

The fixed dose combinations of antihistaminics with antidiarrhoeals is rational, only in certain specific cases where the diarrhoea is due to allergy(like protein allergy). In these specific cases, the antihistaminics may be prescribed separately so that such combinations are not irrationally used in the treatment of all other types of diarrhoea. Routine use of these

combinations is not only a waste of antihistaminic drugs but also it exposes the patients to the undsirable effects of this class of compounds.

11. Fixed dose combinations of Sulphonamides with Penicillins:

Even though sulphonamides and penicillins individually do have important role in the therapy of infections. The combination of penicillin with sulphonamides is undesirable. This is because the antagonism of the antibacterial effect may result when bacteriostatic (Sulphonamides) and bactericidal(Penicillin) agents are given concurrently,(Jawetz and Gunnison, 1953). In addition oral combinations may even induce penicillin sensitivity.

12. Fixed dose combinations of Vitamins and Analgesics:

In the fixed dose combinations of vitamins with analgesics, the vitamins do not play any therapeutically beneficial role and rather act as placebo. Therefore, such combinations are therapeutically irrational. Since such formulations are likely to be misused by the patients and if administered for long periods because of their vitamin contents, such combinations are likely to expose the society to a veriety of undesirable effects of analgesics.

13. Fixed dose combinations of Tetracyclines with Vitamin C:

There is no specific therapeutic indication of giving tetracylines and vitamin C together because tetracyclines ... does not cause any specific vitamin C deficiency. Therefore, this combination is of no therapeutic superiority and may be produced by drug companies just for enhancing the cost of their product. Further, in inffective conditions where tetracyclines are indicated, vitamin C deficiency is not an usual associated feature, such formulations should not be routinely employed.

14. Fixed dose combination of Hydroxyquinolines group of Drugs except preparation which are used for the treatment of Diarrhoea and Dysentery:

Halogenaled hydroxyquinolines are indicated only in intestinal infection like amoebiasis. So the combination of hydroxyquinoline with some other antidiarrhoeal and antidysentery drugs like enzymes for the treatment of dyspepsia is undesirable because hydroxyquinolines may induce Subacute Myelooptic neuropathy(SMON). Due to this toxic manifestation the use on this drug in clinical practice has been abandoned in many advanced countries. The clinical use of these formulations for such simple conditions like dyspepsia exposes these patients to the risk of SMON and hence should not be employed.

15. Fixed dose combinations of Steroids for Internal use except combinations of steroids with other drugs forthe treatment of Asthma:

In view of the acute onset of the benefical effect of steroids in a large number of clinical conditions, their use has tremendously increased in recent years. However, fixed dose combinations of steroids with other drugs are objectionable as it is extremely important to adjust the steroid dose to the minimum that produces the desired effect and the dose of the other drug if altered, not on the patients need for it (other drug) but on his need for steroid. In view of the widespread use of such combinations, the patients are exposed to toxic cumulative effects of these drugs. However, in case

of asthma, since immumological factors play an important role and adrenal steroids cause nonspecific reducation of the response to the antigen antibody reactions, the fixed dose combinations of steroids with other drugs in the treatment of asthma is therapeutically rational and justified.

16. Fixed dosecombinations of Chloramphenicol except with Streptomycin:

Chloramphenicol is a drug of choice only in the treatment of enteric fever and gastroenteritis. Its combination with streptomycin in the treatment of gastroenteritis is therapeutically justified because this combination has been found therapeutically superior to either of these drugs alone in the treatment of mixed infections of the gastrointestinal tract. But combination of chloramphenicol with other drugs(like tetracycline) is irrational because both the drugs have almost the same antimicrobial spectrum and also because chloramphenicol is more toxic as it may cause aplastic anaemia.

17. Fixed dose combinations of ergot except combinations of its Alkaloid Ergotamine with Caffeine:

Ergot alkaloid, ergotamine is effective in the treatment of migrains because it is a vasoconstrictor agent and prevents the rhythmic distension of extracranial arteries.

Caffeine may be allowed in combination also because of its vasoconstrictor effect on intracranial vessels. However the combination of ergotamine with other drugs(like paracetamol, prochlorperazine etc) have no therapeutic advantage and hence irrational.

18. Fixed dose combination of Prophylactic vitamins with antitubercular drugs except combinations of I N H with vitamin B_6:

Fixed anti tubercular drug (except INH) are irrational becuase in these combinations, the vitamines have on therapeutic role to play (of course unless there is a vitamins deficiency) and they simply act as placebo and might give some psychological boost to the patient. However, because INH causes vitamin B6 deficiency, its combination with vitamin B6 is rational and therapeutically justified.

Another drug combination which has been recently banned in this country after a much hue and cry from the medical experts is that of Estrogen Progesterone (E P combinations). These combinations were used for test for pregnancy. The use of E P hormonal preparations were banned in U S A by the Food and Drug Administration (FDA) in 1975 because these preparations were found to seriously damage the foetus.

It is often alleged that drug companies levy a heavy burden on the common man by charging more and more through their dubious multiple drug formulations which are their patented products. For example, the real pain killer in most ofthe analgesic tablets is aspirin, the market is flooded with a number of costlier pain killers containing in addition salicylamide, caffeine and quinine sulphate, which have no proven synergistic efficacy. Similarly, amongst anti-cold ointments, only menthol is said to be of any real therapeutic value. Here too, other ingredients of dubious value like camphor, turpentine and thymol are often added in order just to put in market a new formulation and thus increase the price of such a patented formulation.

In our opinion such anti-social problems must be tackeled at all levels. The responsible persons of the society in the medical and health field, like doctors and pharmacists should keep a close watch on the drugs banned inthe developed countries and also on the drugs which on clinical trials have not been found safe and effective. These responsible men should convey all the clinical information on such drugs or their combinations to the appropriate authorities of the Government of India.Though the Drug Technical Advisory Board(DTAB),Drug Consultative Committee(DCC) and Director General of Health Services(DGHS) have been entrusted with this job by the Government of India but other responsible men in the medical field will also have to keep a vigil so that there is no oversight on the part of the official machinery and the harmful and obsolete drugs from developed countries are not dumped in our country any longer. The World Health Organization(WHO) should also play an effective role inthis regard and ensure that only safe and effective [illegible] drugs are sold to member countries. In addition, the government must adopt the recommendations of WHO on essential generic preparations. In a developing country like ours, the goal must be to ensure availability of essential drugs to patients and health education to all about safe water, sanitation and finally sufficient nutritious food.

However, the major problem lies in the fact that a large number of drug formulations in India have not been adequately evaluated for their safety and this again emphasises the need to exercise strict quality control . This becomes much more significant in the light of the recent statement by the Government in Rajya Sabha that 17.5% of the drug manufactured and sold in the country in the last three years were found to be substandard.

Over all, if employment of such fixed dose combinations aids the busy physician and does not significantly represent a lessoning of his individualized orientation to his patient and are rational from the therapeutic point of view, they are a boon to therapeutics otherwise a curse to the patient and the society.

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Source: The Eastern Pharmacist-June '83.

Circulated by the Voluntary Health Association of India
for Drug Action Net Workers for information
and necessary action.

DRUGS CONTAINING IRRATIONAL COMBINATIONS OF CHLORAMPHENICOL AND STREPTOMYCIN

DCC A-14

	BRAND	DRUG HOUSE
*	Basi	
*	Basiplon	Khandelwal
*	Basiplon Suspension	Khandelwal
*#	Chlorostrep Kapseals	Parke-Davis
*#	Chlorostrep Suspension	Parke-Davis
*#	Enterostrep	Dey's
*#	Enterostrep 'C'	Dey's
*#	Enterostrep Suspension	Dey's
*	Ifistrep	Unique
*	Ifistrep Suspension	Unique
*	Reofin	Rallis
*	Retostrep with [illegible]omycin	Retort
*#	Strepto-Paraxin	Boehringer-knoll
*#	Strepto-Paraxin Pediatric	Boehringe-knoll
*#	Streptophenicol	Mercury
*#	Streptophenicol Syrup	Mercury

Drugs containing Penicillins and Streptomycins

DCC - A-15

Bistrepen	Alembic
Bistrepen Forte	Alembic
Dicrysticin-S	Sarabhai
Dicrysticin-S '800'	Sarabhai
Dicrysticin-S Forte	Sarabhai
Hemacillin-S	SP LTD
Munomycin	Glaxo
Omnamycin	Hoechst
Penicillin Streptomycin	IDPL
Penmyn	Sarabhai
Penstrep	MSD

Combiotic CL
Injection: Each ½ gm contains Streptomycin sulfare 0.5 gm, Procaine Pencillin G 300,000 units, Sod. Pencillin G 100,000 units

Combiotic Forte
Injection: Each 1 gm contains Streptomycin Sulfate 1 gm, Procaine penicillin G 300,000 units, Sod Pencillin G 100,000 lac units

(The drugs containing Penicillin and Streptomycin have been taken from the Pharmaceutical Guide 1981)

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DRUGS CONTAINING ANALGIN

	BRAND	DRUG HOUSE
*#	Anadex	Concept
*#	Baralgan	Hoechst
*#	Benalgis	Franco-Indian
*	Combigesic	Unloids
#	Cemizol Inj	IDPL
*#	Cibalgin Compositum	Ciba-Geigy
#	Conaril	Citadel
#	Dolagin +	Pharmed Gujarat
*	Eucrasil	Eisen
*	Eucrasil-5	Eisen
*	Eucrasil Forte	Eisen
#	Fargesic	PharEast
#	Fargesic Syrup	PharEast
#	Maxigesic	Ethico
#	Medalgin	Medoz
#	Medalgin Syrup	Medoz
#	Neogene	Anglo-French
#	Novalgin	Hoechst
#	Novalgin Injection	Hoechst
*	Promalgin	Uniloids
*#	Sedyn-A-Forte	M M Labs
*	Spasmizol	IDPL
*	Spasmizol Drops	IDPL
*	Spasmizol Inj.	IDPL
*#	Ultragin	Manners
*#	Ultragin Syrup	IDPL
*#	Ultragin Inj	IDPL
*#	Zimalgin	Rallis

DCC- A 7

* MIMS APRIL 1982

\# CIMS MAY 1982

DRUGS CONTAINING PHENACETIN

*	Capherin	Mercury
#	Dolopar	Micro
*#	Dolviran	Bayer
*#	Treupel	German Remedies
*#	Veganin	Warner

DCC A-13

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\# CIMS MAY 1982

THE BLACK LISTED DRUGS

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Some Brands DRUGS CONTAINING ANALGIN

	BRAND	DRUG HOUSE
*#	Anadex	Concept
*#	Baralgan	Hoechst
*#	Benalgis	Franco-Indian
*	Combigesic	Unloids
#	Cemizol Inj	IDPL
*#	Cibalgin Compositum	Ciba-Geigy
#	Conaril	Citadel
#	Dolagin +	Pharmed Gujarat
*	Eucrasil	Eisen
*	Eucrasil-5	Eisen
*	Eucrasil Forte	Eisen
#	Fargesic	PharEast
#	Fargesic Syrup	PharEast
#	Maxigesic	Ethico
#	Medalgin	Medoz
#	Medalgin Syrup	Medoz
#	Neogene	Anglo-French
#	Novalgin	Hoechst
#	Novalgin Injection	Hoechst
*	Promalgin	Uniloids
*#	Sedyn-A-Forte	M M Labs
*	Spasmizol	IDPL
*	Spasmizol Drops	IDPL
*	Spasmizol Inj.	IDPL
*#	Ultragin	Manners
*#	Ultragin Syrup	IDPL
*#	Ultragin Inj	IDPL
*#	Zimalgin	Rallis

* MIMS APRIL 1982

\# CIMS MAY 1982

DRUGS CONTAINING PHENACETIN

*	Capherin	Mercury
#	Dolopar	Micro
*#	Dolviran	Bayer
*#	Treupel	German Remedies
*#	Veganin	Warner

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DRUGS CONTAINING IRRATIONAL COMBINATIONS OF STEROIDS AND ANTI INFLAMMATORY AGENTS

BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	CONTRAINDICATIONS & SPL. PRECAUTIONS
* Butacort (PCI)	Prednisolone 1.5mg Phenylbutazone 100mg	10-2.09 1000-64.80	Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis	Oedema or hypertension where there is danger of cardiac decompensation, renal and hepatic disease, peptic ulceration, blood dyscrasias. May potentiate coumarin-type anticoagulants, oral hypoglycarmics and sulphonamieds. Check blood regularly. (See Sec. 5C)
* Butapred (Biochem)	Prednisolone 2mg phenylbutazone 100mg, salicylamide 300mg, dried alum, hydrox gel 20mg	10-4.40 500-142.47	Rheumatoid arthritis, ankylosing spondylitis, gout and superficial vein thrombosis. Extra articular rheumatism fibrositis, tensoynovitis, bursitis, painful shoulder and acute arthritis of any joint, osteoarthritis.	(As above)
* Deltaflamar (Indoco)	Dexamethasone 0.25mg oxyphenbutazone 75mg dried alum, hydrox 150mg, mag trisilicate 100mg	10-5.50	Rheumatic and allied conditions.	(As above)
* Ingapred - (Inga)	Phenylbutazone 50mg prednisolone 1.25mg	10-1.23	Rheumatoid arthritis, Still's disease gout, ankylosing spondylitis, osteoarthritis.	(As above)

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Sec. 5C :- Corticosteroids are contra-indicated in tuberculosis, local or systemic infections unless controlled by chemotherapy, active peptic ulcer, psychoses, osteoporosis, renal dysfunction, diabetes mellitus, glaucoma, hypertension, myasthenia gravis, thrombo-embolic disorders, congestive heart failure and pregnancy.

BRAND & DRUGS HOUSE	INGREDIENTS	COST	INDICATIONS	CONTRAINDICATIONS & SPL. PRECAUTIONS
* Thilozone-P (Unique)	Phenylbutazone 125mg dexamethasone 0.37mg mag. trisillicate 150mg	10-2.64 500-99.17 10-2.64	Rheumatoid arthritis, osteoarthritis, spondylosis, myositis, fascitis, tendinitis, gout	Peptic ulcer, blood dyscrasias, cardiac/ renal/hepatic insufficiency. (See Sec 5C)
*# Triactin (Pharmed)	Prednisolone 1.75mg mag. trisillicate 150mg phenylbutazone 0.1g	10-2.80	Rheumatoid osteoarthritis, ankylosing spondylitis, osteoarthritis, gout, painful joints.	Oedema or hypertension where there is danger of cardiac disease, peptic ulceration, blood dyscrasias. May potentiate coumarin type anticoagulants, oral hypoglycaemics and sulphonamides. Check blood regularly. (See Sec. 5C)
*# Triactin-D (Pharmed)	Dexamethsone 0.25mg phenylbutazone 100mg mag. trisillicate 150mg	10-2.80	(Same as above)	(Same as above)
# Arumin (MPI)	Paracetamol 0.15g dexamethasone 0.25mg phenylbutazone 0.1g chloroquine phos. 25mg	10-6.65 10 x 10-66.50		

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Sec 5C:-Corticosteroids are contra-indicated in tuberculosis, local or systemic infections unless controlled by chemotherapy, active peptic ulcer, psychoses, osteoporosis, renal dysfunction, diabetes mellitus, glaucoma, hypertension, myasthenia gravis, thrombo-embolic disorders congestive heart failure and pregnancy.

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BRANDS CONTAINING DIPHENOXYLATE (LOMOTIL)

Antidiarrhoeals

*# Lomotil (Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.025mg	.10- 1.84	Symptomatic relief of diarrhoea	Children above 2 yrs 0.25mg of diphenoxylate hcl/kg body-wt daily in divided doses	Atropine intolerance and jaundice, hypersensitivity to diphenoxylate hcl, diarrhoea associated with pseudo membraneous enterocolitis
*# Lomotil Liquid(Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.025mg, alcohol 0.79 ml/5ml	20ml-2.22 60ml-6.59		(Same as above)	
*# Lomofen (Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.25mg, furazolidone 50mg	10- 1.97	Bacterial diarrhoea with gastro-enteritis or food poisoning	(Same as above)	Hypersensitivity to active ingredients ingredients, entero-colitis. Hepatic disease, ulcerative colitis and patients on narcotics, addicting drugs or MAOIs alcoholic beverages, G-6PD def.
# Lomofen Susp. (Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.025mg, furazolidone 50mg	60ml-6.75			(Same as above)
# Lomomycin (Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.025mg, neomycin sulph. 250mg	10- 5.50	Diarrhoea of bacterial origin associated with gastro-enteritis.	Children above 2yrs Corresponds to 0.25 mg, diphenoxylate hcl/kg body wt. in divided doses	(Same as above)
# Lomomycin Liquid(Searle)	Diphenoxylate hcl 2.5 mg, atropine sulph. 0.025mg, neomycin sulph. 250mg	60ml-10	(Same as above)	(Same as above)	(Same as above)

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BRANDS CONTAINING TETRACYCLINE

ANTIBIOTICS

BRAND & DRUG HOUSE	INGREDIENTS	COST	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
Ificyclin Paed. drops (Unique)	Tetracycline 100mg/ ml	5ml- 1.81 10ml- 3.35		In childhood it can cause permanent discolouration of the child's teeth and therefore prolonged use should be avoided.
Ificyclin Syrup (Unique)	Tetracycline 100mg per 5ml	25ml- 2.44 50ml- 4.39 450ml-32.24		
Linemett Syrup (Mercury)	Tetracycline 125mg per 5ml	30ml- 3.18 60ml- 5.87	333mg - 1g 8-12 hourly. Children: 20mg/kg body-wt in divided doses daily.	Renal failure. Prescribed with caution to children under 6 years.++(See Sec. 7A)
*Lupicyclin Syrup (Lupin)	Tetracycline 125mg	30ml -4.60 60ml- 8.13 500ml-41.17	250mg 6 hourly. Children: 20-40mg/kg body-wt in divided doses.	++(See Sec.7A)
*Mysteclin-V Paed.Drops (Sarabhai)	Tetracycline hcl 100mg, amphotericin B 20mg/ml	10ml- 2.91		++(See Sec. 7 A)
*Sandocycline Susp. (Sandoz)	Tetracycline 125mg, broxyquinoline 200mg, brobenzoxaldine 40mg/ 5ml	60ml- 6.05	2.5-10ml 6 hourly according to age. See Lit.	Renal disease. Concurrent admin. of other hepatotoxic drugs. ++(See Sec. 7A)

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* (MIMS)

++Sec 7A : Tetracyclines should not be used in the latter half of pregnancy or in children upto 12 years of age. Use with extreme caution in impaired renal or hepatic function; dosage should be reduced accordingly. The simultaneous administration of milk supplements containing salts of calcium, magnesium or iron should be avoided.

BRAND & DRUG HOUSE	INGREDIENTS	COST	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
*# Subamycin Paed. Syrup (Dey's)	Tetracycline 125mg/5ml	40ml- 4.91	12.5-25mg/kg body-wt daily in 4 divided doses	++(See Sec 7A)
*" Subamycin Paed Drops(Dey's)	Tetracycline 100mg/ml	5ml- 2.71 10ml- 3.47	[illegible]	"
*# Terramycin Soluble Tabs (Pfizer)	Oxytetracycline hcl 50mg;	25 -3.15	Children: 20mg/kg body wt in equally divided doses every 6 hourly	"
*# Terramycin Syrup(Pfizer)	Oxytetracycline 125 mg/5ml	30ml-3.70 60ml-6.32	20-55mg/kg body wt daily in 4 divided doses.	"
*# Terramycin Paed Drops(Pfizer)	Oxytetracycline 100 mg/ml	5ml- 2.58 10ml-3.59		"
*# Terramycin I M Inj.(Pfizer)	Oxytetracycline 50mg 125mg/ml	50mg:2ml-1.06; 10ml-3.59 125mg:2ml-1.17	200-400mg daily in divided doses every 6-12 hrs. Children: 7-10mg/kg body wt daily.	"
* Terramycin I V Inj. (Pfizer)	Oxytetracycline	3ml- 2.90	250-500mg 12 hourly. Maximum 250mg 6 hrly. Children: 10-20 mg/kg body wt. daily in 2 divided doses. Maximum 30mg/kg body wt. daily in 3-4 divided doses.	"
* Trycin (MSD)	Tetracycline hcl 250mg	-2.20	250mg 6 hrly. Children: 25-60mg/kg body wt. daily in 4 divided doses.	

* MIMS # CIMS

++ SEC 7A : Tetracyclines should not be usd in the latter half of pregnancy, or in children upto 12 years of age. Use with extreme caution in impaired renal or hepatic functin; dosage should be reduced accordingly. The simultaneous administration of milk supplements containing salts of calcium, magnesium or iron should be avoided.

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BRAND & DRUG HOUSE	INGREDIENTS	COST	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
# Alcyclin Paed. S Drops (Alembic)	Tetracycline hcl 100mg/ml (approx 20 drops)	5ml- 2.27 10ml-3.05	10-30 mg per kg body wt. daily in 4 equally divided doses according to severity of infection	Prolonged and frequent use in children
# Alcyclin-O (Alembic)	Oxytetracycline equiv. to anhydrous oxytetracycline 50mg, lidocaine 2% per ml vial and 250mg per 2ml with lidocaine 2%	250mg: 10 x 2ml-13.94	Children and infants: 10-15mg per kg body wt per day in 2-3 equal divided doses i.m. 250mg: lamp deep i.m. every 9-12 hrs	

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STATEMENT SHOWING THE CATEGORIES OF FIXED-DOSE COMBINATIONS RECOMMENDED BY THE SUB-COMMITTEE OF THE DRUGS CONSULTATIVE COMMITTEE FOR BEING WEEDED OUT

A. Categories of fixed-dose combinations to beweeded out immediately.

CATEGORY	REASONS FOR WEEDING OUT
1. Fixed dose combinations of Steroids	Fixed dose combinations of Steroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:- (a) The adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn. (b) It is difficult to titrate the dose of the steroid when it is present in fixed dose combinations with other drugs.
2. Fixed Dose Combinations of Ami-dopyrine	Ami-dopyrine is considered toxic because:- (a) It causes high incidence of agranulocytosis. (b) In some individuals, it may cause a sharp fall of total leueocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug.
3. Fixed Dose Combinations of Chloramphenicol	Fixed Dose combinations of Chloramphenicol with any other category of drug is considered harmful for the following reasons and should not be allowed - (a) Chloramphenicol is the commonest drug which causes pancytopenia and peripheral blood changes including Leucopenia, Thrombocytopenia and aplasia of the bone marrow. This reaction is not related to dose and when done, marrow aplasia is complete; the fatality rate is almost 100%. (b) Patients receiving chloramphenicol must be checked repeatedly for blood studies which is however generally done in the case of patients receiving fixed dose combinations of Chloramphenicol.

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4. Fixed Dose combinations of Ergot

Fixed dose combinations of Ergot with Quinine, Ethinyl estradial, etc. should not be allowed. Such combinations are considered harmful for the following reasons:

(a) They may cause uncontrollable bleeding and may lead to serious consequences.
(b) They may cause many harmful side effects.

5. Fixed Dose combinations of Vits. with anti-inflammatory Agents & Tranquilizers.

Fixed dose combinations of Vits. with anti-inflammatory agents and tranquilizers should not be allowed. Such combinations are considered irrational for the following reasons:

(a) There is no definite role of Vitamins in the management of inflammatory disorders and therefore a fixed dose addition of Vitamins in such preparations will be irrational.

(b) Similarly there is no rationale for adding Vitamins to tranquilizers.

6. Fixed Dose combinations of Atropine in Analgesic Anti-pyretics.

Fixed dose combinations of atropine in analgesic antipyretic should not be allowed as atropine may reduce efficacy of antipyretics by blocking sweating response.

7. Fixed Dose combinations of Analgin

Fixed dose combinations of any category of drug with analgin in oral dosage form are considered generally harmful as analgin is potentially a toxic drug and may cause agranulocytosis except for some combinations which may have therapeutic rationale e.g. with neurovitamins. However, fixed dose combinations with analgin in injectable form may be continued to be allowed as these are generally meant to combat an acute attack of pain, and injectables are less likely to be misused.

8. Fixed Dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins

Fixed dose combinations of Yohimbine and Strychnine in a formula containing Testosterone and Vit.B.12 should not be allowed. Such combinations are considered harmful and irrational for the following reasons:

(a) Yohimbine easily penetrates the CNS and can cause central excitation including rise of B.P. and heart rate, hyper-excitability and tremour.

(b) There is no convincing evidence regarding the aphrodisiac effect of Yohimbine and the drug has no proven therapeutic value.

(c) There is no rational basis for the use of strychnine in therapy and therefore no justification for the use of it in any proprietary medicine.

(d) There is a very narrow margin between the therapeutic dose and the toxic dose of strychnine.

9. Fixed dose combinations of Iron with Strychnine, Arsenic, Yohimbine

Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine should not be allowed as there is no rationale of such combinations and such a combination can cause harmful side effects.

10. Fixed dose combination of Sodium Bromide/Chloral Hydrate with other drugs

Fixed dose combinations of sodium Bromide/Chloral Hydrate with any category of drug are considered irrational and harmful for the following reasons:

Use of both Sodium Bromide and Chloral Hydrate have become obsolete, as there safer hypnotic drugs available today and their therapeutic concentration in blood is very close to their toxic levels.

11. Fixed dose combinations of Tetracycline, Analgin with Vitamin C

Fixed dose combinations of Tetracycline, Analgin, etc. with Vit.C should not be allowed as there is no rationale of such combinations.

12. Fixed dose combinations of Ayurvedic drugs with modern drugs

Fixed dose combinations of Ayurvedic drugs and potent allopathic drugs like Stilboestrol could be very harmful and there is no adequate evidence of safety of the interaction of drugs of these two systems of medicine.

13. Fixed dose combination of Phenacetin

Fixed dose combinations of any category of drugs with Phenacetin should not be allowed, as the question of banning Phenacetin because of its potential toxicity (nephropathy, methemoglobinemea, hemolytic anemia as a consequence of chronic over dosage) is under active consideration of the Government.

14. Fixed dose combinations of Chloramphenicol with Streptomycin	Fixed dose combinations of Chloramphenicol with Streptomycin should not be allowed as Chloramphenicol being potentially a toxic drug its use should be kept restricted to enteric fever only.
15. Fixed dose combination of Penicillin with Streptomycin	Fixed dose combination of penicillin with streptomycin should not be allowed.
16. Fixed dose combinations of more than one anti-histaminics	Fixed dose combinations of more than one anti-histaminics in oral dosage form should not be allowed as the differences between their action is but marginal.

B. Categories of fixed dose combinations to be weeded out over a specified time. ..

Category	Reasons for weeding out
1. Fixed dose combinations of Anti-histaminics in anti-diarrhoeals.	Fixed dose combinations of sedative anti-histaminics in anti-diarrhoeal preparations may be permitted provided all ingredients are in adequate therapeutic doses.
2. Fixed dose combinations of Penicillin with Sulphonamides	Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons: (a) The combination of penicillin, a bactericidal drug and sulphonamide, a bacteriostatic drug may cause antagonism. (b) There is risk of development of bacterial resistance to both the drugs.
3. Fixed dose combinations of anti-histaminic with tranquilizer.	Fixed dose combinations of anti-histaminics having patent sedative preparations (for example, diphenhydramine dimenhydrinate, tripelennamines, pyrelamine, Antazolin methapyrilline, etc). with tranquilizers are considered irrational for the following reasons: Such combinations may cause enhanced sedation, which may interfere with the patient's day time activity and dull the mind and slow the reflex activity.

4. Fixed dose combinations of tranquilizers, Anti-Histaminics and Analgesics

Fixed dose combinations of Tranquilizers with anti-histaminics and analgesics in oral dosage form are considered irrational for the following reasons:-

(a) Such combinations may cause a lot of unwanted sedation, which may interfere with the patient's day time activity and dull the mind and slow reflexes.

(b) There may not be many clinical situations which would need a fixed dose combination of these 3 categories of drugs and there will be unnecessary drugging. However, fixed dose combinations of these drugs in injectable form may be allowed as injectables are not likely to be misused.

5. Fixed dose combinations of Vitamins with Analgesics

Fixed dose combinations of high dose Vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.

6. Fixed dose combinations of Paracetamol with Anti-histaminics and tranquilizers.

Fixed dose combinations of Paracetamol with anti-histaminics and tranquilizers should not be allowed as there is hardly any clinical situation which should demand a fixed dose combination of anti-pyretic, an anti-histaminic and tranquilizer. However, fixed dose combinations of paracetamol with anti-histaminics and paracetamol with tranquilizers may be allowed provided the formula contains an adequate dose of such ingredient.

7. Fixed dose combinations of prophylactic Vitamins in anti-TB Drugs.

Fixed dose combinations of Vitamins in prophylactic doses in anti-TB drugs should not be allowed as such combinations lack rationale. However, combinations having a therapeutic rationale such as INH + B6 may be allowed.

93.5

STATEMENT SHOWING THE CATEGORIES OF FIXED-DOSE COMBINATIONS RECOMMENDED BY THE SUB-COMMITTEE OF THE DRUGS CONSULTATIVE COMMITTEE FOR BEING WEEDED OUT

A. Categories of fixed-dose combinations to beweeded out immediately.

CATEGORY	REASONS FOR WEEDING OUT
1. Fixed dose combinations of Steroids	Fixed dose combinations of Steroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:- (a) The adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn. (b) It is difficult to titrate the dose of the steroid when it is present in fixed dose combinations with other drugs.
2. Fixed Dose Combinations of Ami-dopyrine	Ami-dopyrine is considered toxic because:- (a) It causes high incidence of agranulocytosis. (b) In some individuals, it may cause a sharp fall of total leucocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug.
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Fixed dose combinations of Vits. with anti-inflammatory agents and tranquilizers should not be allowed. Such combinations are considered irrational for the following reasons:

(a) There is no definite role of Vitamins in the management of inflammatory disorders and therefore a fixed dose addition of Vitamins in such preparations will be irrational.

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Fixed dose combinations of Yohimbine and Strychnine in a formula containing Testosterone and Vit.B.12 should not be allowed. Such combinations are considered harmful and irrational for the following reasons:

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(b) There is no convincing evidence regarding the aphrodisiac effect of Yohimbine and the drug has no proven therapeutic value.

(c) There is no rational basis for the use of strychnine in therapy and therefore no justification for the use of it in any proprietory medicine.

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	Category	Reasons for weeding out
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2.	Fixed dose combinations of Penicillin with Sulphonamides	Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons: (a) The combination of penicillin, a bactericidal drug and sulphonamide, a bacteriostatic drug may cause antagonism. (b) There is risk of development of bacterial resistance to both the drugs.
3.	Fixed dose combinations of anti-histaminic with tranquilizer.	Fixed dose combinations of anti-histaminics having patent sedative preparations (for example, diphenhydramine dimenhydrinate, tripelennamines, pyrelamine, Antazolin methapyrilline, etc). with tranquilizers are considered irrational for the following reasons: Such combinations may cause enhanced sedation, which may interfere with the patient's day time activity and dull the mind and slow the reflex activity.

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Fixed dose combinations of Tranquilizers with anti-histaminics and analgesics in oral dosage form are considered irrational for the following reasons:-

(a) Such combinations may cause a lot of unwanted sedation, which may interfere with the patient's day time activity and dull the mind and slow reflexes.

(b) There may not be many clinical situations which would need a fixed dose combination of these 3 categories of drugs and there will be unnecessary drugging. However, fixed dose combinations of these drugs in injectable form may be allowed as injectables are not likely to be misused.

5. Fixed dose combinations of Vitamins with Analgesics

Fixed dose combinations of high dose Vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.

6. Fixed dose combinations of Paracetamol with Anti-histaminics and tranquilizers.

Fixed dose combinations of Paracetamol with anti-histaminics and tranquilizers should not be allowed as there is hardly any clinical situation which should demand a fixed dose combination of anti-pyretic, an anti-histaminic and tranquilizer. However, fixed dose combinations of paracetamol with anti-histaminics and paracetamol with tranquilizers may be allowed provided the formula contains an adequate dose of such ingredient.

7. Fixed dose combinations of prophylactic Vitamins in anti-TB Drugs.

Fixed dose combinations of Vitamins in prophylactic doses in anti-TB drugs should not be allowed as such combinations lack rationale. However, combinations having a therapeutic rationale such as INH + B6 may be allowed.

Dup.

MS-cb/D-10.340/
25.8.1982

ANABOLIC STEROIDS FOR GROWTH

BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
* Adroyd (Parke-Davis)	Oxymetholone 5mg	15-9.04	Underweight or asthenic patients convalescence from acute infectious diseases, major surgical procedures-pre-and post-operatively, chronic debilitating illness; osteoporosis, fractures and decubitus ulcers, severe burns	Occassionally 20-30mg daily may be required. Usually for 10-21 days but not more than 90 days. Ped. dosage: see Lit.	Prostatic carcinoma. Although Adroyd has a low degree of androgenicity, very young and preadolescent individuals are usually sensitive to the masculinising effects of androgens. Due to this, they should be under medical supervision during therapy and the drug withdrawn if masculinising effect develop. Adroyd should be used with caution in cardiac disease, hepatic dysfunction, nephritis and nephrosis.
* Anabolex B12 (Cipla)	Methandienone 2mg Vit B12 50mcg ferric amm. cit 50mg/ml	5ml-6.23	Loss of appetite and weight loss with anaemia. Growth disorders in children	15-10 drops daily for 4-6 weeks	Continuous treatment should be limited to a max. of 4 weeks with intervals of 1-2 months between courses.
*# Dianabol (Ciba-Geigy)	Methandienone 25mg	1ml-5.70	Negative nitrogen balance, protein malnutrition, convalescence, wasting diseases, osteoporosis, growth retardation, aplastic anaemia, red-cell aplasia.	1ml-i.m. weekly. For intensive therapy 1ml on alternate days	Prostatic cancer, severe liver insufficiency, severe nephrosis, pregnancy and lactation. Should not be given continuously for persons periods exceeding 4 weeks. High doses in women may produce menstrual cycle disorders, hirutism, deepening of voice. In children, premature ossification of epiphyses and virilisation may occur.

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BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
*# Dianabol Tabs (Ciba-Geigy)	Methandienone 1mg and 5mg	1mg: 20- 5.53 5mg: 10- 6.02	(Same as Dianabol)	Male: 5mg daily. Maint. therapy: 2.5mg daily. See Lit. Female: 2.5mg daily. Maint: 1-2mg daily. See Lit.	(Same as Dianabol)
*# Dianabol Drops (Ciba-Geigy)	Methandienone 1mg per ml	5ml-5.50	(")	Children: 0.01-0.04mg/kg body wt for not more than 4 weeks	(")
# Durabolin (Organon)	Nandrolone phenyl-propionate; 10mg and 25mg	10mg-13. 25mg-21.85	Protein loss following surgery trauma, burns, infectious diseases or following prolonged corticosteroid therapy, uraemia due to acute and chronic renal failure, general debility, osteoporosis, aplastic anaemia, inoperable mammary carcinoma, under weight children and fractures.	i.m. 25mg every week in acute renal failure upto 50mg weekly and in chronic renal insufficiency upto 50mg twice weekly. Children: 10mg every week	(See lit)
# Deca Durabolin	Nandrolone decanoate 10mg and 25mg	10mg: 1amp -9.28 25mg: 1amp 8.53	i.m. 25mg every 3 weeks. In acute renal failure upto 50mg weekly and in chronic renal insufficiency upto 10mg every 3 weeks. Children: 10mg, every 3 weeks		

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N.B. Dianabol has been deleted from the June issue of MIMS and is withdrawn by Ciba-Geigy.

BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
*# Evabolin (Concept)	Nandrolone phenyl-propionate 25mg Vit.E 100mg/2ml	2ml-7.06	Convalescence, to promote growth in undernoursihed children adjuvant to steroid therapy. Osteoporosis, hypoproteinaemia, Haemolytic anaemias.	2ml-4ml i.m. once weekly	Carcinoma of prostate, pregnancy, male breast carcinoma.
* Neurabol H (Cadila)	Vit B1 60mg B6 27.5mg Hydroxycobalamin 100mcg, nandrolone phenylpropionate 25mg/2ml	2ml-4.42	General debility, osteoporosis, weight loss, refractory anaemias, neuritis, neuralgias.	2ml i.m. every week	Prostatic carcinoma, pregnancy, B1 sensitive patients.
*# Orabolin (Organon)	Ethylestrenol 2mg;	20-13.34	Osteoporosis, weight loss, debility, anorexia, burns, during steroid therapy	1 tab twice daily. In serious conditions dosage may be increased	Pregnancy, prostatic carcinoma, male breast carcinoma. Severe liver dysfunction.
*# Orabolin Drops (Organon)	Ethylestrenol 2mg per ml	5ml-6.56	Body wt upto 10kg	Body-wt upto 10kg: 10-20 drops. 10-20kg: 20-40 drops 20-30kg: 40-50 drops More than 30kg: 50-60 drops. All daily	
* Trinergic (Unichem)	Methandienone 5mg Vit B1 10mg, B6 10mg B12 30mcg	20-12.71	Malnutrition and under nutrition convalescence, old age anorexia nervosa, neurological disorders, extensive burns, severe injuries		Continuous treatment should be limited to a max. of 4 weeks with intervals of 1-2 months between courses.
* Trinergic Inj. (Unichem)	Methandienone 25mg Vit B12 500mcg/ml	1ml-2.96	(Same as above)	1ml once or twice weekly.	(Same as above)

BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	DOSAGE	CONTRAINDICATIONS & SPL. PRECAUTIONS
*# Unabol (Unichem)	Nandralone phenyl propionate 25mg/ml	1ml-7.01	Negative nitrogen balance, old age, osteoporosis, bone fractures, during prolonged corticosteroid therapy, to promote weight gain	25mg weekly	@ Carcinoma of prostate, pregnancy, male breast carcinoma
*# Winstrol (Cosme Farma)	Stanozolol 2mg	30-12.46	Poor protein anabolism, osteoporosis, convalescence, aplastic anaemia., during corticosteroid therapy	2-4mg thrice daily just before or with meals. Children 3-6 years: 1mg twice daily; 6-12yrs: 2mg thrice daily	Pregnancy, carcinoma of prostate, severe liver disease. Pre-pubertal children where it may lead to stunting of growth. Use lower dosage in young females to minimise androgenic side-effects. Impaired cardiac and renal function.
* Aquaviron B12 (Nicholos)	Free testosterone 25mg, VitB12 500mcg per ml	1ml-4.75	Depressed debilitated male patients	1ml i.m. twice weekly for about 6 weeks; diminish frequency as conditions improves	Prostatic carcinoma
*Aquaviron Inj	Free testosterone 25mg/ml	1ml-2.50	Male: hypogonadism, organic impotence, ennuchism, delayed puberty, premature senility Female: metropathia haemorrhagica menorrhagia, frigidity, inoperable breast carcinoma	Male: 1-2ml every 1-2 weeks diminishing the doseas patient improves Female: 1-2ml daily until bleeding stops. Not more than 200mg in one month	

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MS-cb/D-10:343/

Information on some of the unwanted drugs 'Banned Abroad' (Dumped in the Third World)

Drug Banned	Brands	Reason for Banning	Countries in which banned
Clioquinol	Mexaform Enteroquinol	Blindness Sub acute myelo optic neuropathy 10,000 - 30,000 afflicted in Japan presenting with pain, paralysis blindness and in extreme cases death Until banned in Japan in 1970	US, UK, Japan, New Zealand
Lomotil for infants		WHO - Risks of treatment outweigh benefits - paralytic ileus leading to inacurate assessment of fluid loss and toxemia if assiciated gut infections	(see dear doctor series of social audit)

93.7

MS-cb/D-10:343/

Some of the unwanted/dumped drugs

Generic Drug	Brands and Preparation	Reason for Banning	Countried in which banned
Analgin Dip Dipyone	90 brands sold in India	Fatal agronulocytisis blood dyscreaseas	Analgin market in India FIVE ERORES ANNUALLY.
	Labels for Dipyrone in US should be restricted for its antipyretic effects in serious life threatening situations.	American Medical Association "Because ~~of~~ Dipyrone (analgin) may produce fatal Agranulocytosis and other blood dyscrasias its use as a general analgesic antiarthritic antipyretic cannot be condoned. Permissable only for febrile convulsions where parential preparations needed and in Hodgkins when fever cannot be controlled." Dr Satoskar -'50% of aplastic anemia here is due to this drug.' In India Hoechst claims Novalgin to be 'patent, non salycilate, analgesic, antipyreitc, antispasmodic, anti-inflammatory, anti rheumatic agent for all kinds of pain, rheumatic fever, rheumatoid arthritis, relief of colics. Literature enclosed says although danger of agranulocytosis is remote, it has to be borne in mind and a white cell count should be done if patients condition so warrants."	

...3/-

Drug banned	Brands and Preparation	Reason for Banning	Countries in which banned
Amidopyrine		incriminated with stomach cancer and bone marrow suppression	U.S.A.(banned in 1938) U.K., Germany, Japan, Switzerland.
Phenacetin		Renal damage converted to paracetamol for painkilling action - other by products cause toxicity so why not use PARACETAMOL	
Tetracyclin (Paediatric drops)		For pregnant mothers and for children upto eight years - discolouration of teeth, their early decay, the incorporation of drug in the bones causing disorders Several antibiotic syrups decompose rapidly with time and are therefore sold exclusively as granules to be reconstituted before use, but in third world ready to use syrup preparations freely available.	Banned in most countries Market in India of Tetracyclin drops Rs. five crores.
Pregnancy tests in which estrogen progestrone mixtures are administered		Associated faetal malformation	US,UK, Sweden, Finland, Singapore
Alpha Hydroxy, Progestrone Caproate	Prolution Depot being advocated for prevention and treatment of abortion, prolonged treatment with adequate dosage recommended to maintain pregnancy	Foetal malformation specially spinal cord defect	US(Banned in 1973) UK According to Dr Satoskar "proof of prevention of abortion unclear but most shocking is its use as long term contraceptive.

Nos used in DCC/DTAB/Gazette Notification respectively	Category Banned	Name of the Drug	Drug House	Content	Source	Available in the market or
		Nandril	Nectrine			
		Neoril	ICC			
		Nermygin	Alkem			
		Neurodin	Medo Chem			
		Neurogesic	Beckcem			
		Neuroxy	Galaxy			
		Neurovon	Veniyon			
		Nibidril	Nibin			
		Onalpam	Khandelwal			
		O P D	Cifiss			
		Ophen	Bombay Tablet			
		Olgin	Artichem			
		Oxalpam	Nibin			
		Oxamol	Nutri Thera			
		Oxalgin	Cadila			
		Oxal	Dia Pharma			
		Oxylar	Lark			
		Oxydon	Healer			
		Oxydril	Dynamic			
		Oxytod	Entod			
		Oxypyron	Thio Pharma			
		Oxymide	Cadila			
		Oxybutal	Eros			
		Oxypam	Cyper			
		Oxypam Plus	Eros			
		Oxy-Triaction	Pharmed			
		Oxyrin	Themis			
		Oxyryl Plus	Tablets			
		Oxidine	"			
		Oxypose	Simis			
		Oxone-A	Rank			
		Oxydrex	Plazma			
		Oxidigin	Oasis			
		Oxigin	Min			
		Oxypyrin	Monokem			
		Oxin	Axar			
		Oxymol	Bio Med			
		Oxyphen	B P Labs			
		Oxyphenbutazone	Acron, Acila, Alma, Arora, B P Labs, Belco, Bombay Drug, Chemical & Pharma, Cooper, Cyper, Deepharma, Fairdeal, Ganesh, Indica, Kanpha, KSDP, Kent, Lark, Lupin			
		Paramin	Artichem			
		Parazine	Albert David			
		Prrin	Artichem			
		Pentoxy	Penta			
		Phenabid	IDPL			
		Phenzyn-A	Pasteur			
		Placidin	Lupin			
		Primoxyphen	Prim			
		Prolyn	Mercury			
		Prestigesic	Syntheco			
		Prestigen	Stadchem			
		Primoxyphen	Prim			
		Reducin	Unique			
		Referin	Mac Mohan			

Nos used in DCC/DTAB/Gazette Notification respectively	Category Banned.	Name of the Drug	House	Content	Source	Available the mar or
		Reparil	Fairdeal			
		Rilifon	Shree			
		Roxypam	Lancet			
		Sanoxymol	Sanitex			
		Sidril	Sims			
		Suganril	S G Pharma			
		Tendazone	Crystal			
		Thiodril	Thio Kof			
		Trigerzin	Trigger			
		Tromalgin	La Pharma			
		Tromin	Rays			
		Tromagesic	Themis			
		Venco Oxypamol	Veniyon			
		Vikrapyrin	Vikrant			
		Virgonalgin	Virgo			
		Zeroxyl	Medoz			
		Zonalgin	Febro			
	Anabolic Steroids:					
		Adroyd	Parke Davis	-Oxymetholone	MIMS	
		Anabolex B12	Cipla"	-Methandienone Vit B12,Ferric amm ci	"	
		Dianabol	Ciba Geigy	Methandienone-	Both	
		Dianabol Tabs	"	"	"	
		Dianabol Drops	"	"	"	
		Durabolin	Organon	Nandrolone phenylpropionate	CIMS	
		Deca Durabolin		-Nandrolone decanote	"	
		Evabolin	Concept	-Nandrolone phenyl propionate,Vit E	bot	
		Neurabol H	Cadila	-Bit B1,B6,Hydroxycobalamin,nandrolone phenyl propionate	MIMS	
		Orabolin	Organon	Ethylestrenol	both	
		Orabolin Drops	"	"	"	
		Trinergic	Unichem	-Methandienone, Vit B1,B6,B12	MIMS	
		Trinergic Inj.	"	Methandienone,Vit B12		
		Unabol	"	-Nandralone phenyl propionate	bot	
		Winstrol	Cosme Farma	-Stanozolol	"	
		Aquaviron B12	Nicholas	-Free testosterone,Vit B	MIMS	
		Aquaviron Inj		-Free testosterone	"	

CLASS VI

Irrational combinations of Tonics, cough syrups etc.

eg. Vitamin B Complex,Liver extract and iron
" " , Vitamin C " " etc.

(Would like to get your views and help from you)

DCC A1

MS-cb/D-10.340/
25.8.1982

DRUGS CONTAINING IRRATIONAL COMBINATIONS OF STEROIDS AND ANTI INFLAMMATORY AGENTS

BRAND & DRUG HOUSE	INGREDIENTS	COST	INDICATIONS	CONTRAINDICATIONS & SPL. PRECAUTTONS
* Butacort (PCI)	Prednisolone 1.5mg Phenylbutazone 100mg	10-2.09 1000-64.80	Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis	Oedema or hypertension where there is danger of cardiac decompensation, renal and hepatic disease, peptic ulceration, blood dyscrasias. May potentiate coumarin-type anticoagulants, oral hypoglycarmics and sulphonamieds. Check blood regularly. (See Sec. 5C)
* Butapred (Biochem)	Prednisolone 2mg phenylbutazone 100mg, salicylamide 300mg, dried alum, hydrox gel 20mg	10-4.40 500-142.47	Rheumatoid arthritis, ankylosing spondylitis, gout and superficial vein thrombosis. Extra articular rheumatism fibrositis, tensoynovitis, bursitis, painful shoulder and acute arthritis of any joint, osteoarthritis.	(As above)
* Deltaflamar (Indoco)	Dexamethasone 0.25mg oxyphenbutazone 75mg dried alum, hydrox 150mg, mag trisilicate 100mg	10-5.50	Rheumatic and allied conditions.	(As above)
* Ingapred - (Inga)	Phenylbutazone 50mg prednisolone 1.25mg	10-1.23	Rheumatoid arthritis, Still's disease gout, ankylosing spondylitis, osteoarthritis.	(As above)

* MIMS

Sec. 5C :- Corticosteroids are contra-indicated in tuberculosis, local or systemic infections unless controlled by chemotherapy, active peptic ulcer, psychoses, osteoporosis, renal dysfunction, diabetes mellitus, glaucoma, hypertension, myasthenia gravis, thrombo-embolic disorders, congestive heart failure and pregnancy.

COMMUNITY HEALTH CELL
47/1, (First Floor) St. Marks Road
BANGALORE - 560 001

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BRAND & DRUGS HOUSE	INGREDIENTS	COST	INDICATIONS	CONTRAINDICATIONS & SPL. PRECAUTIONS
* Thilozone-P (Unique)	Phenylbutazone 125mg dexamethasone 0.37mg mag.trisillicate 150mg	10-2.64 500-99.17 10-2.64	Rheumatoid arthritis, osteoarthritis, spondylosis, myositis, fascitis, tendinitis, gout	Peptic ulcer, blood dyscrasias, cardiac/renal/hepatic insufficiency. (See Sec 5C)
*# Triactin (Pharmed)	Prednisolone 1.75mg mag.trisillicate 150mg phenylbutazone 0.1g	10-2.80	Rheumatoid osteoarthritis, ankylosing spondylitis, osteoarthritis, gout, painful joints.	Oedema or hypertension where there is danger of cardiac disease, peptic ulceration, blood dyscrasias. May potentiate coumarin type anticoagulants, oral hypoglycaemics and sulphonamides. Check blood regularly. (See Sec. 5C)
*# Triactin-D (Pharmed)	Dexamethsone 0.25mg phenylbutazone 100mg mag.trisillicate 150mg	10-2.80	(Same as above)	(Same as above)
# Arumin (MPI)	Paracetamol 0.15g dexamethasone 0.25mg phenylbutazone 0.1g chloroquine phos.25mg	10-6.65 10 x 10-66.50		

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* MIMS
\# CIMS

Sec 5C:-Corticosteroids are contra-indicated in tuberculosis, local or systemic infections unless controlled by chemotherapy, active peptic ulcer, psychoses, osteoporosis, renal dysfunction, diabetes mellitus, glaucoma, hypertension, myasthenia gravis, thrombo-embolic disorders congestive heart failure and pregnancy.

DRUGS CONTAINING IRRATIONAL COMBINATIONS OF CHLORAMPHENICOL AND STREPTOMYCIN

	BRAND	DRUG HOUSE
*	Basiplon	Khandelwal
*	Basiplon Suspension	Khandelwal
*#	Chlorostrep Kapseals	Parke-Davis
*#	Chlorostrep Suspension	Parke-Davis
*#	Enterostrep	Dey's
*#	Enterostrep 'C'	Dey's
*#	Enterostrep Suspension	Dey's
*	Ifistrep	Unique
*	Ifistrep Suspension	Unique
*	Reofin	Rallis
*	Retostrep with Neomycin	Retort
*#	Strepto-Paraxin	Boehringer-knoll
*#	Strepto-Paraxin Pediatric	Boehringer-knoll
*#	Streptophenicol	Mercury
*#	Streptophenicol Syrup	Mercury

Drugs containing Penicillins and Streptomycins

Bistrepen	Alembic
Bistrepen Forte	Alembic
Dicrysticin-S	Sarabhai
Dicrysticin-S '800'	Sarabhai
Dicrysticin-S Forte	Sarabhai
Hemacillin-S	SP LTD
Munomycin	Glaxo
Omnamycin	Hoechst
Penicillin Streptomycin	IDPL
Penmyn	Sarabhai
Penstrep	MSD

Combiotic - CL
Injection: Each ½ gm contains Streptomycin sulfare 0.5 gm, Procaine Pencillin G 300,000 units, Sod. Pencillin G 100,000 units

Combiotic Forte
Injection: Each 1 gm contains Streptomycin Sulfate 1 gm, Procaine penicillin G 300,000 units, Sod Pencillin G 100,000 lac units

(The drugs containing Penicillin and Streptomycin have been taken from the Pharmaceutical Guide 1981)

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DRUGS CONTAINING ANALGIN

	BRAND	DRUG HOUSE
*#	Anadex	Concept
*#	Baralgan	Hoechst
*#	Benalgis	Franco-Indian
*	Combigesic	Unloids
#	Cemizol Inj	IDPL
*#	Cibalgin Compositum	Ciba-Geigy
#	Conaril	Citadel
#	Dolagin +	Pharmed Gujarat
*	Eucrasil	Eisen
*	Eucrasil-5	Eisen
*	Eucrasil Forte	Eisen
#	Fargesic	PharEast
#	Fargesic Syrup	PharEast
#	Maxigesic	Ethico
#	Medalgin	Medoz
#	Medalgin Syrup	Medoz
#	Neogene	Anglo-French
#	Novalgin	Hoechst
#	Novalgin Injection	Hoechst
*	Promalgin	Uniloids
*#	Sedyn-A-Forte	M M Labs
*	Spasmizol	IDPL
*	Spasmizol Drops	IDPL
*	Spasmizol Inj.	IDPL
*#	Ultragin	Manners
*#	Ultragin Syrup	IDPL
*#	Ultragin Inj	IDPL
*#	Zimalgin	Rallis

* MIMS APRIL 1982

\# CIMS MAY 1982

DRUGS CONTAINING PHENACETIN

*	Capherin	Mercury
#	Dolopar	Micro
*#	Dolviran	Bayer
*#	Treupel	German Remedies
*#	Veganin	Warner

* MIMS APRIL 1982
\# CIMS MAY 1982

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27.8.1982

DRUGS CONTAINING HYDROXYQUINOLINE

BRAND	DRUG HOUSE
Ambactin-4	B C P W
Amoebindon	Indon
Aldiamycin	Alkem
Aldiamycin Suspension	Alkem
Alliquin	Standard Pharmaceuticals
Amebys	Napha
Ambilan	Swastik Pharmaceuticals
Amoechin	Universal Drug House
Antidar	Dextromed
Bioxyl	Bio-Drug
Chlorambin	Anglo-French
Colon	Emsons
Davoquin	Albert David
Dequinol	Dey's Medical Stores
Dependal	S K & F
Dysenchlor	S G Chemicals
Digichlor	T H P
Diodoquin	Searle
Di-Iodohydroxyquin	Semit
Di-Iodohydraxyquinoline	T H P
Di-Iodohydroxyquinoline	Fairdeal
Di-Iodohydroxyquinoline	Usan
Di-Iodohydroxyqunoline	Baropharn
Dinochlor	Bengal Immunity
Dinoquin	Bengal Immunity
Diorcin	Cos Pharma
Dystrindon	Indon
Dysental	Quality Pharmaceuticals
Dysentol	Bronkal Pvt Ltd
Dysentriad	GDA Chemicals
Enteroton	I N D C
Entro Iodochlor	Bombay Tablet
Embaquin	M & B
Entrokin	Bengal Chemicals
Entroquinol	Indo-Pharma Lab
Entero-vioform	Ciba-Geigy
Intestopan-In	Sandoz
Faircolin	Fairdeal
Fairdiquin	Fairdeal
Floraquin	Searle
Furoquinol	Chogule
Histoquin	Zandu
Idosulpain	Indo Pharma
Indoquin	Indoco
Intestopan-Q	Sandoz
Intestopan Suspension	Sandoz
Labrody	Labros Chemicals
Lumigyl Caplets	Ethico
Mebinol Complex	MAC Labs
Mexaform	Ciba-Geigy
Neoquin	Sunways
Moebagym	Ebers
Phenipan	Sandoz

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BRAND	DRUG HOUSE
Quiniform	Albert David
Quinogel Compound	Acilla
Stadmed Entrozyme	Stamed
Sulfaquinol	Comteck
Sulphaquino-Bael	Standar Pharmaceuticals
Sulphazyme	INDC
Uni-Dys	Unichem
Yodchin Sulpha	Duphar, Navaratna

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D-9/330(c)
LCD;a.24.9.84

Sub: Banned Brand Drug List.

Dear Friends,

The banned brand drug list is being sent to you. The list is divided into 5 classes.

Class I: Drugs banned under gazette Notification of 23rd July 1983.

Class II: Drugs that should have got banned under the same notification but were not because of the existing ambiguity of wording . eg. See Category 4 which is strychnine Yohimbine, testesterone and tonics. Any drug containing yohimbine and strychnine or testesterone in tonics is just as irrational as a drug containing all the 4(obviously the number of drugs affected this way are much less.

Class III: Drugs recommended for withdrawal by the Drug Consultative Committee(Original list attatched -Appendix A)

Class IV: Drugs that were banned independently ie. drugs which had no relation with Drug Consultative Committee recommendation.

Class V: Problem drugs that should be severely restricted if not banned. eg. Anabolic steroids for children,Phenyland oxyphen butazones.

Class VI: Irrational combination of tonics,cough syrups etc. To be compiled by friends in the Drug Action network.

The sequence used is that given in the Gazette Notification. The three obliques x/x/x inddcate DCC/DTAB/Gazette Notification to facilitate cross checking. If there are any errors they are unintended.

You are requested to review the list, add/substract/modify according to most recent information. There is no machinary for sharing unbiased drug information or we as health personnel and consumers would not have to spend time on this. If this list makes some of the drug companies upset, we cannot help it, they had more than 2 years to compile and disseminate a more accurate,more up-to-date, more impressive banned brand drug list.

The list is as comprehensive as we can make it.
Note: - It is possible that some brands have been reformulated. eg. Some APCs may now contain Paracetamol instead of Phenacetin which drug companies have actually done so and withdrawn their earlier APCs containing phenacetin. We do not know you can of course double check the contents on the container.

After the Kerala High Court Judgement 1982 a directive had been given to State and Central health authorities to make the banned brand drug list available to the Public. It is end of September '84. This list is made in Public Interest.Use it in whatever ways you can, share the information with others. Information and knowledge are powerful tools for action.

YOU ARE REQUESTED TO BOYCOTT THESE PRODUCTS,AS THEY ARE DANGEROUS AND/OR IRRATIONAL. We have a right to safeguard our health and that of our people.

Prepared specially for Drug Action Networkers and VHAI members with help from Dr Rane and Dr Anil Pilagaonkar of Arogya Dakshata Mandal. Late Mr Agacy, Cynthia Brown have helped with the earlier 'Black Lists'. For the final version we owe our thanks to Alphonse.

In solidarity,

Dr Mira Shiva
Coordinator
Low Cost Drugs & Rational Therapeutics, VHAI

D-9/330(c)
LCD.a.20.9.84

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BANNED BRAND DRUG LIST

Note:
Banned drug list is being divided into 6 classes:

1. Drugs banned under the Gazette Notification
2. Drugs that should have been banned under Gazette Notification in absence of the ambigious wording, or modification.
3. Drugs that were recommended for being weeded out by DCC and were not weeded out.
4. Those drugs that were banned earlier separately. eg. E P drugs.
5. Problem Drugs that should be severely restricted if not banned. eg. Butazolidine Tandril, Hydroxyquinoline, Anabolic steroids for children.
6. Irrational combinations of Tonics.
   eg. Vitamin B Complex Liver extract and iron.

Drugs belonging to Class I are being dealt with first, the sequence used for the various categories is based on the sequence as in Gazette Notification.

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drugs.	Drug House	Content	Source	Available in the market or not
	CLASS I					
2/1/1	Amidopyrine and its combinations.				Pharma'81	
		Adysmene	Ethnor		"	
		Alergin	Cipla			
		Aristapyrin	Aristo		"	
		Arthrex	Gajiar's			
		Biopyrin	Biochem			
		Bipipyrin	B P Labs			
		Bitapyrin	Bombay Tablet			
		Butapyrin	Inga			
		Butarin	Themis			
		Cibalgin	Ciba			
		Dolorindon	Indon			
		Eropyrin	Eros			
		Esgipyrin	S G Chemicals			
		Meparin	Mercury			
		Naphapyrin	Napha			
		Nectapyrin	Nectarin			
		Neo-Spasmindon	Indon			
		Optalidon	Sandoz			
		Oripyrin	Indo Pharma Labs			
		Phenorin	Jagson Pal			
		Phenylbutazone & Amidopyrin	Pharmakab			
		Predapyrin	Eros			
		Pyrindon	Indon			
		Rumipyrine	Uniloids			
		Spasmerin	Mercury			
		Spasmindon	Indon			
		Spasmo Cibalgin	Ciba			
		Theraphen	Therapeutic			
		Uni-spasm	Unichem			
		Vegamin	Warner		MIMS'83	
		Dolviran	Bayer		"	
		Codopyn	Stadmed			
		Apidin	IDPL			
		Trevpel	German Remedies		CIMS '83	

Nos used in DCC/DTAB/Gazette Notification respectively	Categor Banned.	Name of the Drug.	House	Content	Source	Available in the market or not.
5/2/2	Fixed dose combinations of Vitamins with anti inflammatory agents and tranquillisers:					
		Placidin Spasms Proxyvon	Lupin Wockhardt	Dicyclomine HCL, Dexhopro-xhphene HCL, Acetaminophen, Cloriazephoxide		
		Sudhinol-M-C compound	Ranbaxy	Dexnopropoxyhene, Napeylate, Paraxetamol diazepham		
		Tylenol with codeine	Ethnor	Acetaminophen, Corcintamok-troprophyhen, Paracetamol, diazephem		
		Walagesic	Cater Wallace			
		Conaril	Citadel	Analgin, Coedine, phos		
		Paranal	TTR Pharma	", Ponacetamol, diazepam		
		Sedyn-A-Forte	[illegible]			
		Equagesic	Wyeth			
		Diligan	Uni-UCB	Meclozine HCL, Nicotinic acid; Hydroxizine HCL		
6/3/3	Fixed dose combinations of Atropine in Analgesics And Antipyretics:					
		Antispasmin	Stadmed	Ethel morphine nec Phenolphtha lein. Phenobar-bitone, Amidopyrin, Atrophine mothonitrate.	MIMS'87	
		Prydonnal	Eskaylab	Paracetamol, Hyoscyamine, scopolamine HBr, Phenobarb Atropin sulph.		
		Spasmolysin	Standard	Analgin, Atropin methonitrate, Papaverine HCL, Diazepam.		

Nos used in DCC/DTAB/Gazette Notification respectively 1980/82/83	Category Banned.	Name of the Drug.	House	Content	Souce	Available in the market or not.
0/4/4		Fixed dose combinations of Strychnine and Caffeine in tonics.				
8/5/5		Fixed dose combinations of Yohimbine and strychnine with Testosterone and Vitamins.				
9/6/6		Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.				
10/7/7		Fixed dose combinations of Sodium Bromide Chloral hydrate with other drugs.				
		Gynodex	Retort	Ext.aletris, Ext.Vibunum Ext. hyoscyamus, Ext.of ovary, Ext.of placenta, Sodium bromide.		
13/9/8		Phenacetin and its combinations:				
		Antispam	Cooper		Pharma'83	
		Asthimindon	Indon		"	
		Bellaspin	Nibin			
		Cyperdine	Cyper			
		Dolviran	Bayer			
		Espico	Kirti			
		Influenza Tabs	Dey's, Acila			
		Phenacin	Kirti			
		Qinarsol	Cipla			
		Spasmindon	Indon			
		Spasmon	Semit			
		Vencospasmin	Veniyon			
		Capherin	Mercury		MIMS '82	
		Dolopar	Micro		CIMS 82	
		Treupel	German Remedies		Both	
		Veganin	Warner			
		(Continued on Page.12)				
1/10/9		Fixed dose combinations of anti histaminics with anti diarrhoeals.				
		Clorambin	AFD	Light Kaolin, Pectin, meomycinsulph, di iodohydroxyquin, line belladona, Chloraphenaramin, mebate.		
2/11/10		Fixed dose combinations of Pencillin and Sulphonamides.				
		Crystastrep	Dey's			
		Penitriad	M & B			
		Penivoral Trisulfas-	Franco Indian			
		Pentid-Sulfas	Sarabhai			
		Sipromide V	Alembic			
		Stanpen-S	SP Ltd.			
5/12/11		Fixed dose combinations of vitamins with Analgesics:				
		Micropyrin	Nicholas	Acetysalicylic acid, Vit.C		
		Phenabid	IDPL	Oxyphenbutazone, Vit. C.		

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	House	Content	Source	Available in the market or not.
0/13/12	Fixed dose combinations of Tetracycline with Vitamin C.					
0/14/13	Fixed dose combinations of Hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only.					
1/15/14	Fixed dose combinations of steroids for internal use except combination of steroids with other drugs for the treatment of Asthma.					
		Cortihist	Ingo	Prednesolone, chlorpheneamine Maleate		
		Perideca	Merck Sharp & Dohme	- Dexame theone, cyproheptadine.		
		Aquivorn B12	Nicholas	Free testosterone, vit.B12		
		Mixogen	Infar India	- Ethinyl oestradiol, testosterone Oestradiol monobenzoate, " phyenylpropionate, Testosterone propionate " phenylpropionate, isocaproate.		
		Pasuma 'Strong'	-Merck	Methyl testosterone, vit.E, Caffeine, recephedrine HCL(tab		
		Testiobion	Merck	Testosterone, Vit.E(inj) " , vit.E, B6, B12.		
		Disecron Forte	Nicholas.	Progestrone, Oestradiol, benzoate		
		(a)Senso	Vilco	Methyltestosterone, Vit.E, Caffeine		
		(b)Theragran-GR	Sarabhai	Ethnyl oestradiol, Methyl testosterone, Vit.A, B1, B12, Vit.D, E,		
		(c)Geriatone	Wyeth	Ethinylestradiol, methyl testostrone, Vit B1, B12, folic acid, c, dried ferrous sulf.		
		(d)Trinergic	Unichem	Methandienone, Vit B1, b6, B12(capsule) Methandienone, Vit B1, B6, B12(inj		
		Other oral(contraceptives) are combinations of 2 or more steroids.				
		Dexabolin	Infar India	- Dexamethozone, ethynloestrenol.		
		Docabolin	"	Nandrolone phenylpropionate, desoxycorticosterone phenylpropionate.		
		((Duoluton	German Remedies			
		E P Forte	Unichem			
		Menstrogen	Infar India			
		Norlestrin	Parke Davis			
		Orasecron Forte	-Nicholas			
		Orgalutin	Infar India			
		Osterone	Lyka			
		Ovral	Wyeth			

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug	House	Content	Source	Available in the market or not
		Ovulen	Searle			
		Lyndiol	Infar India			
		Minivlar ED	-German India			
		Norcyclin	Ciba Geigy			
		Orlest-28	Parke Davis			
		Ortho Novin	-Ethnor			
		Ovral L	Wyeth			
		Primovrar	German Remedies))			

3/16/15 Fixed dose combinations of chloramphenicol for internal use except combination of chloramphenicol and streptomycin:

Chloramphenicol & Sulphonamides:

Diastrep	Sunways	
Enteromycetin Sulfa	- Dey&s	
Kemisulfan	Carlo Erba	

4/17/16 Fixed dose combinations of Ergot:

Ergatap	Mercury	Ergot prep.
Cafergot	Sandoz	Ergotamine tartrate, Caffein
Ergophen	Inga	Ergotamine tarterate, Belladonna dry#ect, henc
Ingagen	Inga	Ergotamine tarterate
Ingagen-M	"	Methyl ergotamine maleate
Migranil	Inga	Ergotamine tarterate, Bella-dona dry ext. Paracetamol
Migril	Welcome	Ergotamine tarterate, cyclizine HCL, caffeine
Vasograin	Cadilla	Ergotamine tarterate, caffeine, paracetamol, pro-chlorperazine, maleate.

7/18/17 Fixed dose combinations of Vitamins with anti TB drugs except combination of Isoniazide with Pyridoxine Hydrochloride(Vit.B6):

Anticox 450	-Unichem	Rifampcin, INH, B6
Anticox 600	Cadilla	Rifampicin, INH, B6

0/0/18 Pencillin skin/eye ointment:

0/0/19 Tetracycline liquid oral preparations:

Ificyclin Paed.drops	-Unique	-Tetracycline	
Ificyclin syrup	-Unique	"	
Linemett syrup	-Mercury	"	MIMS
Lupicyclin syrup	-Lupin	"	"
Mysteclin-V Paed drops	-Sarabhi-T,	amphotericin"	
Sandocycline susp.	-Sandoz	-", broxyquinoline,	
Subamycin Paed syrup	-Dey's	brobenzoxaldine	

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	Drug House	Content	Source	Available in the market or
		Subamycin Paed drops	-Dey's	Tetracycline	CIMS & MIMS	
		Terramycin soluble Tabs	- Pfizer	Oxytetracycline	"	
		Terramycin syrup	- "	"		
		Terramycin Paed drops	- "	"	"	
		Terramycin IM Inj	- "	"	"	
		terramycin IV Inj	- "	"	"	
		trycin	- MSD	Tetracycline	MIMS	
		Alcyclin Paed S drops	-Alembic	"	CIMS	
		Alcyclin-O	- "	Oxytetracycline " lidocaine, anhydrous oxytetracycline.		

0/0/20 Nialamide:

	Niamid	Pfizer	Pharma-'79

0/0/21 Practolol:

0/0/22 Methapyrilene, its salts.

Capqu	Roc	Pharma '83

CLASS II

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	Drug House	Content	Source	Availability at the moment or not
0/0/0		Amidopyrine				
5/2/2		Fixed dose combinations of (vitamins) anti inflammatory agents and tranquillisers:				
		Butaproxyron	Wockhardt			
		Flamar P	Indoco			
		Maxigesic	Ethico			
		Rumatin	Nool			
		Drugs containing Vitamins and anti inflammatory agents:				
		Ranodine	Ranbaxy			
		Micropyrin	Nicholas			
		Phenabid	IDPL			
0/0/0		Fixed dose combinations of Atropine in Analgesics and Antipyretics.				
0/0/4		Fixed dose combinations of strychnine and Caffeine in tonics:				
		Ciltone	Buphar			
		Orheptal	Merck			
		Santevini	Sandoz			
		Tenophos	Rallis			
		Toniazol	Boehringer Knoll			
		Aminovin Tonic	-Smith Stanstreet			
		Eunova	German Remedies			
		Mynberrys	Juggat Pharma			
		Ranbaxy's tonic	-Ranbaxy			
		Acetyisalic acid	-Alcid -Bengal Immunity			
		Antiflu	SP Ltd.			
		APC	-Boots, CPL, Dey's, IDPL, Opil, Kemp Khandelmal, Nectarine, Pharmakab, Semit, Swastik.			
8/5/5		Fixed dose combinations of Yohimbine and Strychnine with testosterone and vitamins:				
		Gavarine	Gavert			Pharma '83
		PMT	Cadila			
		Sensa	Vilco			
		Vigotab	Jagson Pal			
		Yohimbine	Atul			
		Yohimbine & Strychnine				
		Nectarine Pearles	-Nectarine			
		Pasuma Strong	E Marck			
		Emetine & Strychnine				
		Strembin	Usan			
9/6/6		Fixed dose combinations of iron with strychnine, arsenic and yohimbine.				
10/7/7		Fixed dose combinations of sodium bromide chloral hydrate with other drugs.				

Nos used in DCC/DTAB/Gazette Notification respectively 1980/82/83	Category Banned.	Name of the Drug.	Drug House	Content	Source	Any other matter
13/9/8	Phenacetin and its combinations:					
1/10/9	Fixed dose combinations of anti histaminics with anti diarrhoeals.					
2/11/10	Fixed dose combinations of penicillin with sulphonamides					
5/12/11	Fixed dose combinations of vitamins with analgesics.	Mitacin	Nicholas.			
6/13/12	Fixed dose combinations of tetracycline with vitamin C.					
0/14/13	Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only.					
1/15/14	Fixed dose combinations of steroids for internal use except combination of steroids with other drugs for the treatment of asthma.					
3/16/15	Fixed dose combinations of chloramphenicol for internal use except combination of chloramphenicol and streptomycin.					
4/17/16	Fixed dose combinations of Ergot.					
7/18/17	Fixed dose combinations of vitamins with anti TB drugs except combination of Isoniazide with pyridoxine hydrochloride (Vit. B6).					
0/0/18	Pencillin skin/eye ointment.					
0/0/19	Tetracycline liquid oral preparations.					
0/0/20	Nialamide					
0/0/21	Practolol					
0/0/22	Methapyrilene, its salts.					

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	Drug House	Content	Source	Available in the market or not

13/9/8 Phenacetin and its combinations

Acetylsalicylic Acid, caffeine &Phenacetin:

Alcid	Bengal Immunity	Pharma'83
Antalgin	Medinex	
Antiflu	SP Ltd	
APC	Acila, Ama, Arora, Belco, Bengal Immunity, Bombay Drug House, BP Labs, Chemical & Pharma, Deepharma, Cooper, Dey's, Eros, Forstar, Hima, Ganesh, H Jules, IDPL, Inga, Cyper Pharma, Kanpha Labs, Nectarine, Nymph, Panacea, Phamakab, Sanitex, Sarvodaya, Semit, Stamac, Tablets, Teecee,	
Apidin	IDPL	
Apihist	Bombay Tablet	
Apocine	Mediproducts	
Aselgin	Gavert	
Bodryl	Parke Davis	
Capherin	Mercury	
Capramin	Glaxo	
Capsin	BC, L	
Codral	Burroughs Wellcome	
Colithan CPA-	Fairdeal	
Dolorin	Cal Chem	
Dristan	Whitehall	
Flucut	Emkay	
Histacap	ICC	
Influenza Tabs-	Panacea	
Ingacin	Inga	
Nylacin	Nymph	
Painkill	Paras	
Panalate	Forstar	
Prolene Comp.65-	Stadmed	
Relaxin	Franklin	
Salurin Forte	Alma	
Supacin	Nymph	
Veganin	Warner Hindustan	
Verafen	Pharmakab	
Verindon	Indon	
Wescogesic	Wesco	

Acetylsalicylic Acid, codeine & phenacetin:

Antadone	SPLtd
Cocodin	Cooper
Codalgin	THP
Coditon	Nymph
Cododon	Nectarine
Codopin	Stadmed
Codophene	Gavert
Codopyrine	Glaxo
Codotab	Jagson Pal
Codral	Burroughs Wellcome
Dardona	Baidyanath
Dolorin	Cal Chem
Laspin	Lark
Salijon	Smith
Thiocodine	Thio Kof
Treupel	Homburg
Vaganin	Warner.

CLASS III

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	House	Content	Source	Available in the market or No
7/0/0	Clitone:		Dupari	Vit.B, Nicotinamide, Penthenol, Sodglycero phos. mangsulph, caffeine, liver fraction with B12, B Nicotinamide, Cal.pantho-thenali, cupicichl, quinine hcl, sod glycereo, caffeine alcohol, mang chl		
	Orheptal:		Merck			
15/0/0	Pencillin & Streptomycin					
		Bistrepen	Alembic			
		Bistrepen Forte	-Alembic			
		Dicrysticin-S	-Sarabhai			
		Dicrysticin-S800	- "			
		" S Forte	- "			
		Hemacillin-S	SP Ltd			
		Munomycin	Glaxo			
		Omnamycin	Hoechst			
		Penicillin Streptomycin	- IDPL			
		Penmyn	Sarabhai			
		Penstrep	MSD			
		Campicillin C	Cadila			MIMS '83
		Carbelin	Lyla			"
		Crys-4	Sarabhai			"
		Crystapen & Granules	- Glaxo.			"
7/0/0	Analgin :					
		Aarelgin	Ramsons			Pharma'83
		Adgesic	Ethico			
		Adol	Acila			
		Algesin-O	Alembic			
		Algiril	P & B Labs			
		Alpox	Alps			
		Anacet	Semit			
		Anadex	Concept			
		Analag	A TaCC			
		Analgin	Acila, Acron, Alembic, Alkem, Alma, Apex, A TaCC, Arora, Arya, Associated Products, Bengal Health, Belco, Bombay Drug House, BP Labs, Biochem, Carewell, Chemical & Pharma, Comet, Cooper, Cyper Pharma, Deepharma, DWD, Emcee, Fairdeal, Forstar, Govert, Ganesh, Haffkine, Hima, H Jules, IDPL, Ifiunik, INDC, Indica, Inga, Indian, Inventa, ICCO, Kanpha, KSDP, Lark, Medinex, Medirose, Medisearch, Nulife, Nymph, Paam, Nectarine, Panacea, PCI, Pharmakab, Prakash, Pulymar, Ranbaxy, Rays, Remedies(I), Sanitex, Sarvodaya, Semit, SIRI, Smith, Stamac, Tablets, Tarachem, Teecee, Veniyon, Vidarbha.		

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	House	Content	Source	Available in the mark or n
		Analpar	Thio-Kof			
		Anamol	Heiko			
		Anapiron	Roc			
		Anmol	Medirose			
		Anoxy	West Coast			
		Avalgin	Tharachem			
		Belgin	Belco			
		Benalgis	Franco Indian			
		Biogin	Bio-Med			
		Bitalgin	Bombay Tablet			
		Butacortindon-Indon				
		Butagin	Alkem,Tablets			
		Butaphen Plus-Biochem				
		Butaster	West Coast			
		Canapar	U S Vitamin			
		Capagin	Kon Test			
		Cartagin	Indochem			
		Celgal	Veco			
		Cemizole	IDPL			
		Cetalgin-D	Optho			
		Dadhalgin	Dadha			
		Dexabutalgin -Monoekem				
		Dexabutazone -Stadchem				
		Diapar	Navil			
		Dicigesic-N	DCI			
		Dicolgin	Kanpha			
		Dipralgin	PCI			
		Dizalgin	Franklin			
		Dolagin	Pharmed			
		Dolo-Neurobin -E Merck				
		Doloril-A	Indica			
		Dolotril	Saima			
		Doloxan	Shree			
		D-Pyrone	B P Labs			
		Duogesic	Sanderson			
		Dubactin	Tablets			
		Dypalgin	P & B Labs			
		Ebejlam	Ebers			
		Epagin	Kon Test			
		Eucrasil	Eisen			
		Fargesic	Phar-East			
		Fevozone	Alpha			
		Flunil	Excel			
		Gavalgin	Gavert			
		Geecoprin	Paam			
		Ginol	Nibin			
		Histarin	La Pharma			
		Iccalgin	ICCO			
		Indalgin	Indus			
		Indo-Analgin-Indochem				
		Inflagin	Kanpha			
		Inflar	Navil			
		Jemjesic	Jems			
		Kanamol	Kent			
		Kanopar	Kanpha			

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	House Content	Source	Available in the market or no
		Kapaxgin	Kaptab		
		Kelgin	Kee Pharma		
		Kepoxgin	Kanpha		
		La-Pyrin	La Pharma		
		Largesic	Lark		
		Medalgin	Medoz		
		Metabutadec	Supreme		
		Metoxyl	Acron		
		Micron Plus	Wesco		
		Molgin	Dia Pharma		
		Monalgin	Monokem		
		Myalgin	Shree		
		Mylogin	Chemical & Pharma		
		Neorin	Themis		
		Nivelgin	Nictarine		
		Novapam	Fetro		
		Nurolgit	Nulife		
		Nycin	Nymph		
		OAD	Amee		
		Orphalgin	Biddle Sawyer		
		Oxal	Dia Pharma		
		Oxalgin	Cadila		
		Oxidigin	Oasis		
		Oxigin	Min		
		Oxydril-DS	Lymamic		
		Oxymol	Bio Med		
		Oxynal	Euphoric		
		Oxypose	Sims		
		Oxypyron	Thio Pharma		
		Oxyzol	Medirose		
		Palgin	Chemo Pharma		
		Pamagin	Alkem		
		Pamolgin	Paam		
		Panalgin	Carewell		
		Parageic	Radicals		
		Paralgenol	Veco		
		Paralgicin	Stadchem		
		Paralgin	Emcee		
		Paralgin	Godama		
		Paralgin	Stamac		
		Par Analgin	Bombay Tablet		
		Paranalgin	Gavert		
		Parladim	Fourts		
		Parazoll	Ganesh		
		Penalfine	La Pharma		
		Penalgin	Tarachem		
		Petragin	Thio Pharma		
		PFI	Medi		
		PRC	Alkem		
		Predniphenol-6-	Gavert		
		Primdril	Prim		
		Pyragesic	Jamsons		
		Quikalgin	Synthiko		
		Referin	Mac Mohan		
		Repalgin	Rays		
		Resin	Assam Pharma		

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	Drug House	Content	Source	Available in the market or not.
		Ricofast	Plazma			
		Rumalgin	Shree			
		Rumasol	Excel			
		Selectagesic	Supreme			
		Rupalgin	Rup			
		Shormetal-D	Themis			
		Spalcin	Martel Hammer			
		Spanil	Grosons			
		Spasaron	Kon Test			
		Spasmatac	A Tac			
		Spasmate	Terce			
		Spasmo	Enkay			
		Spasmo-Amidozone	Suprachem			
		Spasmolyrin	Standard			
		Spasmogin	Indochem			
		Spasmlan	Ador			
		Sterpose A N	Sterfil			
		Sunalgin	Medinex			
		Supralgin	Sarvodaya			
		Synalgesic	Geoffery Manners			
		Trialgin-D	Osseisule			
		Trigerzin	Trigger			
		Trigin	Biox			
		Tromalgin	La Pharma			
		Trypin	Healer			
		Uniprox	Unicure			
		Vespanil	Veco			
		Virgonalgin	Virgo			
		Wespalgin	West Coast			
		Zinalgin	TCF			
		Zonalgin	Febro			
14/0/0		Chloramphenicol with Streptomycin:				
		Basiplon	Khandelwal			
		Bichlorfenin	Medinex			
		Caristrep	Carewell			
		Cemistrep	Suprachem			
		Cilastrep	Acila			
		Chloramphenico Streptomycin-Sarvodaya,HA,Tablets				
		Chlorocin Strep	Jagson Pal			
		Chlorostrep Kapseals -Parke Davis				
		Chlorostreptoseal INDC				
		Chlorosulf	Ranbaxy			
		Chlorosoin	Dolphin			
		Cooperstrep	Cooper			
		Conti Strep	Continental			
		Dee Strep	Deepharma			
		Dycos	Dynamic			
		Glucostrep	Gluconate			
		Glycostrep	Glyco Remedies			
		Gravostrep	La Grandel			
		Ifistrep	Unique			
		Intestostrep	East India			
		Listrep	Lister			

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned	Name of the Drug	House	Content	Source	Available in the market or not
M		Medistreps	Medirose			
		Medostrep	Medoz			
		Monostrep	Monokem			
		Niscostrep	Nishikam			
		O-Strep	Optho			
		Paam Strep	Paam			
		Pharmastrep	Pharmakab			
		Phenistrep	PCI			
		Phenistrep	Usan			
		Phermceostrep	Pharma Medico			
		Prom	Duff			
		Ranstrepcol	Ranbaxy			
		Redstrep	Duff			
		Rhofin	Rallis			
		Strepcol	New Life			
		Strephenicol	H Jules			
		Streptachlor	Forstar			
		Streptokep	Remedies(I)			
		Streptochlor	Mac'			
		Streptophenicol	Mercury			
		Streptosain	Sain			
		Streptovil	Vilco			
		Sunstrep	Sunchem			
		Vecostrep	Veco			
		Vinystrep	Healer			
		Wilostrep	Dadha.			

CLASS IV

Nos used in DCC/DTAB/Gazette Notification respectively. 1980/82/83	Category Banned.	Name of the Drug.	House	Content	Source	Available in the market or no

Those drugs that were banned separately eg. E P drugs Ban on 22nd June 1982 DO No.
and Hydroxyquinoline DO No. X 19013/8/81-D dated 13.8.82 withdrawal delayed to 31.3.83 order changed to combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.

E P Drugs:

E P Forte	Unichem	Hydroxyprogesterone, acetete, ethninylestradiol, hydroxyzine hcl	CIMS '83
Cumority			
Secrodyl	Allenbury's		
Lut-Estron Forte-	Mac	Progesterone, oestradiol dipropion	CIMS "
Menstrogen Forte-	Organon-	Estradiol benzoate Progestertone	"
Gestaplon	Khandelwal-	progesterone, estradiol benzoate	MIMS'83
Orasecron Forte-	Nicholas-	Ethisterone, Ethinyl ostradiol	CIMS "
Disecron Forte-	Nicholas-	Progesterone, Oestradiol benzoate	"

Di-Iodohydroxyquinoline:

Amebiotic	Pfizer	Pharma'83
Amecure	Excel	
Amicline	Griffon	
Amidochlor	Therapeutic	
Amidys	Sarvodaya	
Amitrig	Trigger	
Amocidol	Saima	
Amoebin	Penta	
Ameobindon	Indon	
Bioquin	Stadchem	
Chlorambin	AFD	
Colon	Emsons	
Combiasis	Usan	
Davoquin	Albert David	
Diazole	Godama	
Digichlor	THP	
Dinoquin	Bengal Immunity	
Diodoquin	Searle	
Diodys	Cadila	
Di-iodohydroxyquin-	Semit	
Di-iodohydroxyquinoline-	Alma	
Di-iodohydroxyquinoline-	Apex, Arora, Associated Products, Belco, BP Labs, Bombay, Cadila, Cooper, Cyper, Haffkine, H Jules, ICCO, Ifinnik, Indica, Indian Research, Indon, Ganesh, Kanpha, KSDP, Nectrine, Nymph, Paam, Pharmakab, Pharma Products, Sarvodaya, Stamac, Tablets, Teecee,	

Nos used in DCC/DTAB/Gazette Notification respectively	Category Banned.	Name of the Drug.	Drug House	Content	Source	Available in the market or
		Di-Metrazole	Supreme			
		Eroquin	Eros			
		Eroquin-F	"			
		Farnid	Phar East			
		Floraquin	Searle			
		Furaquin	Revers			
		Furogil	Saima			
		Glucoline	Gluconate			
		Histoquin	Zandu			
		Indosulpain	Indo Pharma			
		Intestren	Nishkam			
		Iodocycline	Smith			
		Iodoquin Comp.	Indoco			
		Jemeobic	Jems			
		Kentizole	Max & Kent			
		Kentroquin	Kent			
		Kequinsabl	Kee Pharma			
		Lumigyl	Plazma			
		Metroquin	Vita Nova			
		Moebagyl	Ebers			
		Mexogil	Kanpha			
		Mexogyl	Medix			
		Nid	Tercee			
		Nivembin	M & B			
		Novonidagyl	P & B Labs			
		Nutrozyne	Cipla			
		Quincycline	Bombay Drug			
		Quinildine	Gavert			
		Quinogyl	Synthico			
		Quinomycin Forte	Medley			
		Quinopect	Saima			
		Quinozol	Heiko			
		Quinsentry	Ramsons			
		Rayquinol	Rays			
		Saril	TCF			
		Stambiquin	Stamac			
		Sulfa Kaotin Forte	Rays			
		Sulphachin	IRI			
		Sulphazyme	INDC			
		Thiozyme	Thio Kof			
		Tricodys	Medinex			
		Tryquin	Ramson			
		Uni Dys	Unichem			
		Vagiquin	Cifiss			
		Veniquin	Veniyon			
		Zolaquin	Pulymar			
		Iodochlorhydroxyquinolinez				
		Alliquin	SP Ltd			Pharma '83
		Ambarid	N I Pharma			
		Ambiquinol	Emcee			
		Amebide TC	Roberts			
		Ambizyme Forte	Emcee			
		Amoechin	UDH			
		Amygil Plus	Emcee			
		Andocin	Angel Pharma			
		Antidys	Remedies(I)			
		Aremzyme	Roberts			

Nos used in DCC/DTAB/Gazette Notification respectively	Category Banned.	Name of the Drug.	House	Content	Source	Available in the market
		Baidyanath Eczema Malham	Baidyanath			
		Baidyanath Isabhael	"			
		Bradex-Vioform	Ciba			
		Chloropectidin	Cal Chem			
		Clogil	M R Labs			
		Corto Quinol	East India			
		Cosmezem	Cos Pharma			
		Curogyl	Shree			
		Darmadar	Stamac			
		Davoquin	Albert David			
		Deaquin	Cadila			
		Depedal	Eskay			
		Dermo Quinal	East India			
		Dequinol	Dey's			
		Diacheck	New Life			
		Diarzole	Monopax			
		Digichlor	THP			
		Diogyl	Searle			
		Dysentol	Quality			
		Dysentol	Bronkol			
		Enapec	A TaCC			
		entakon	Kon Test			
		Entrobael	INDC			
		Entero Quinol	East India			
		Entero-Vioform	Ciba			
		Enterotone	INDC			
		Entromin	Panacea			
		Entroquin	Indo Pharma			
		Entrozyme	Stadmed			
		Entrozyvit	Amava			
		Forquin	Medirose			
		Fungrin P	Saico			
		Gestro Quinol	Prakash			
		Gquin	Grosons			
		Iodochlorhydroxyquin	-Alma, Associated Products, Arora, Cooper, ICC, Haffkine, Nymph, Panacea, Semit, Stamac, Tablets, United, Apex, ICC, Kanpha, Deepharma			
		Iodocortindon	Indon			
		Indochlora HCL	Paam			
		Idofur	Nymph			
		Iofur	Apex			
		Metroquin	Rays			
		Mexaform	Ciba			
		Nudy's Comp.	NuLife			
		Ompectol	Ramsons			
		Pectocin	Thio Pharma			
		Protoquit	PCI			
		Protozide	India Health			
		Quinidochlor	NCPW			
		Quinidochlor	Amava, AtaCC			
		Quinizole	Min			
		Quinodochlor	Forstar			
		Quinoform	Albert David			
		Stamaquin	Stamac			

Nos used in DCC/DCTAB/Gazette Notification respectively	Category Banned	Name of the Drug	House	Content	Source	Available in the Market or not
		Stomazole	Kanpha			
		Sulpha quino Bael	-SP Ltd			
		Tolnacomb	Sterfil			
		Uni Dys	Unichem			
		Uni Enzyme	"			
		Vencosarin SN	Veniyon			
		Viodochlor	Therapeutic			
		Vilco 12-21C	Vilco			
		Vioform	Ciba			
		Wesco Dys	West Coast.			

CLASS V:

Problem drugs that should be severely restricted if not banned. eg. Butazolidines, Anabolic steroids for children etc.

Phenylbutazone:

Acetazohe	IRI	Pharma '83
Actimol	Pharmed	
Acapyrin	Usan	
Algesin	Alembic	
Amphiyrin	PCI	
Aquapyrine	Vidarbha	
Arcon	Alkem	
Arcure	NuLife	
Arogopyrin	Arora	
Aristopyrin	Aristo	
Arthozolin	Remedies	
Baripyrine	Sanitex	
Beesopyride	Enkay	
Bipipyrin	BP Labs	
Bitapyrine	Bombay Tablet	
Butadol	Osler	
Butacort	PCI	
Butadez	Cadila	
Butamol	Angel Labs, Ganesh	
Butanyl	THP	
Butapyringa	Inga	
Butasule	Franklin	
Butascarbisone	Ganesh	
Butapred	Biochem	
Butarin	Themis	
Butaster	West Coast	
Cartagin	Indochem	
Celgal-P	Veco	
Cepyrin	Chemical & Pharma	
Coirtazolin	PCI	
Dadhapyrin Tabs	Dadha	
Decapyrine	Delta Pharma	
Delta Jagozolodin	-Jagsonpal	
Dexabutarin	Themis	
Dexabutazone	Stadchem	
Dexabutalgin	Monokem	
Dexaphenalgin	Sims	

Nos Used in DCC/DTAB/Gazette Notification respectively	Category Banned.	Name of the Drug	House	Content	Source	Available in the market or not.
		Dexapyrin-D	Sarvodaya			
		Dexapyrin	Ganesh			
		Dicipyrin	DCI			
		Ebeflam	Ebers			
		Erobutol	Eros			
		Esgipyrin	SG Pharma			
		Gavazone	Gavert			
		Gecopyrine	Paam			
		Gravodine	La Grande			
		Inapyrin	INDC			
		Intasolone	ICC			
		Jagopyrine	Jagson Pal			
		Jagzolodin	"			
		Kebutacine	Kee Pharma			
		Medicopyrine	Medi			
		Medopyrin	Medoz			
		Omdex	Ramsons			
		Oripyrine	Indo Pharma			
		Orthodex	Saima			
		Pamapyrin	Galpha			
		Pancy	Lister			
		Parazone	New Life			
		Parazolandin	SG Pharma			
		Phemol-D	Pharmakab			
		Phenamide	Nibin			
		Phenidopyrin	Sterling			
		Phenorin	Jagson Pal			
		Phenopyrine	Cooper			
		Phenylbutazone	Acila			
		Phenylbutazone	Albert David			
		Phenylbutazone	Apex, Bleco, B P Labs, Bombay Drug, Cyper, Cooper, Chemical & Pharma, Deepharma, Ganesh, Inga, Indica, Kanpha, Nectarine, Nishkam, Nymph, PCI, Sain, Sarvodaya, Semit, Stamac, Tablets, Veniyon			
		Phenylbutazone& Amidopyrine	Cooper, Cyper, Deepharma, Ganesh, Pharmakab, Albert David			
		Prenovil	Navil			
		Predniphenol-6	Gavert			
		Pulrheuma	Pulymar			
		Pyrine	ICCO, Cyper, Deepharma			
		Remaril	Albert David			
		Ribopyrine	ICCO			
		Rumalgin	Shree			
		Rhumalcort	Galpha			
		Rhumagon	Stamac			
		Rumatril	Carewell			
		Rumarem	Robert			
		Rumatison	Siri			
		Rumicort	INDC			
		Rumin	"			
		Sanipyrine	Sanitex			
		Teraphen	Therapeutic			
		Thilopyrin	Unique			
		Thiozone	"			
		Thiopyrin	Thio Kof			

Nos used in DCC/DTAB/Gazette Notification respectively	Category Banned.	Name of the Drug	Drug House	Content	Source	Available in the market
		Triactin	Pharmed			
		Triactin-D	"			
		Trigxyl	Trigger			
		Udypyrine	UDH			
		Vencogegic	Veniyon			
		Oxyphenbutazone:				
		Actgesic	Thio Pharma		Pharma '83	
		Algiril	P & B Labs			
		Alophen	Alpha			
		Amidozone	Suprachem			
		Anox	Shanberg			
		Anoxy	West Coast			
		Arden	Adonis			
		Arodil	Arora			
		Bestophen	Evans			
		Broxyl	Min			
		Butacortindon	Indon			
		Butadex	Cadila			
		Butagin	Tablets			
		Butanil	INDC			
		Butaphen	Biochem			
		Buta Proxyvon	Panama			
		Cetazone-D	Ganesh			
		Coxin	Carewell			
		Cypadril	Cyper			
		Dafenoxyn	Dadha			
		Delta Flamar	Indoco			
		Dexopam	Bombay Drug			
		Diazeril	West Coast			
		Disflam	Standard Organic			
		Doloflam	Vilco			
		Doloril-A	Indica			
		Doloxam	Shree, Healer			
		Febrogesic	Febro			
		Flamar	Indoco			
		G-Oxyl	Grosons			
		Inflandril	Medix			
		Inflar	Navil			
		Infladol	Nishkam			
		Inflamak	Novus			
		Inflarid	Radicals			
		Inflagin	Kanpha			
		Infla Proxycap	Kanpha			
		Inflavan	Kandelwal			
		Inotimee	Keepharma			
		Intaryl	Geno			
		Jagril	ICC			
		Jamril	Jamsons			
		Kapflam	Kaptab			
		Kapoxgin	"			
		Kentigesic	Max & Kent			
		Largesic	Lark			
		Maxigesic	Ethico			
		Metrozole	Supreme			
		Metrozole-F	"			
		Monoril	Monokem			

VOLUNTARY HEALTH ASSOCIATION OF INDIA

D-9/334-(a.1)
19.8.1982: a

C - 14 Community Centre,
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New Delhi 110 016

BACKGROUND PAPER PREPARED BY VHAI FOR DRUG-INFORMATION+SHARING TO PREPARE FOR ACTION

THE CLIOQUINOL CONTROVERSY

Demanding its ban. A Just Demand. Or, Just a Demand?

We are grateful to our friends in IOCU, Penang, Social Audit, UK, for some valuable information they sent to us.

Historical Background

Hydroxyquinolines were introduced into the Swiss Pharmacopëa in 1900 as a topical and antiseptic agent. In the 30's it became a focus of interest when its potential as an intestinal amoebicide was investigated.

It was around 1932 that classical animal studies established the "therapeutic potential of the halogenated hydroxyquinolines as lumenal amoebicides".

i) Ref: Leake, C.D. (1932) Chemotherapy of Amoebiasis. Journal of American Medical Association - 98. 195-199.

The initial clinical trial of clioquinol was conducted in the U.S.A. in 1933.

ii) David, N.A., Johnstone, H.G., Reed, A.C., Leake, C.D., 1933. The Treatment of Amoebiasis with todochlorhydroxy-quinoline (vioform N.N.N). Journal of American Medical Association. IOU. 1658 - 1661.

Data cited in this report suggested "the compound might have a useful spectrum of action against other enteropathogenic protozoa and bacteria".

Since then "halogenated oxyquinoline derivatives HOQ" have been popularly used for prophylaxis and treatment of gastroenteritis, amoebiasis, travellers' diarrhoea (HOQ include a todochlorhydroxyquinoline, proxy quinoline, halquinol, diiodohydroxyquinoline, chlorquinaldol, chiniofon).

In 1934 the first proprietary preparation was promoted to the public for treatment of amoebic dysentery and simple diarrhoea.

As a result of a chance clinical observation, hydroxyquinolines became established for twenty years for the treatment of acrodermatitis enteropathica (a rare skin disorder) until it was shown that it acted by rectifying the underlying selective malabsorption of zinc by forming an absorbable chelate and it was replaced by zinc.

WHEN WERE THE INITIAL OBSERVATIONS ABOUT CLIOQUINOL RELATED PROBLEMS NOTICED?

According to Dr. Ole Hansen, in 1935, the very first year after CIBA (of Switzerland) had started marketing the drug - "a report from doctors in Argentina describing exactly the same side effects as the Japanese cases in the 60's and 70's was received by CIBA".

"From internal documents in 1939, from Switzerland and documents released in the courts in Japan, it was discovered that experiments of the drugs with cats and dogs had proved fatal".

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"In the early 60's, a Swiss and a Swedish veterinarian reported to CIBA GEIGY that they had found dogs with diarrhoea treated with Enterovioform had died, in seizures".

According to Dr.Ole Hansen "attempts to hide facts, deny facts," (e.g. denial that the drug is absorbed) and attempts to convince doctors not to publish their negative experimental findings have been made throughout by CIBA GEIGY, the producers of Mexaform and Enterovioform.

Even before or during epidemics of SMON in Japan, several reports regarding systemic toxicity following partial absorption with oral administration was recorded.

Cases of optic atrophy were observed in a small proportion of children receiving the treatment for acrodermatitis enteropathica - this was prolonged in high dosage treatment. Since earlier, children never survived without treatment, optic atrophy as a late manifestation of the disease could not be excluded.

In 1964, reversible and unusual gait changes were noted in 20 out of 4000 institutionalized patients on long term treatment.

(Ref: Gholz, L.M., Arons, W.L.(1964): Prophylaxis and Therapy of Amoebiasis and Shigellosis with Iodochlorhydroxyquin. American Journal of Tropical Medicine and Hygiene.13;396-401).

Convulsions in laboratory mice on high dosages was reported in 1969 and in "domestic dogs and cats treated for diarrhoea in veterinary practice".

A reversible confusional state had been described following acute dosage in man.

Five personal observations of "transient global amnesia after clioquinol" have been reported in the Journal of Neurology, Neurosurgery and Psychiatry 1979: 42, 1084-1090 by M.Mumenthaler, H.E.Kaiser, A. Meyer and T.Hess from the Department of Neurology, University of Berne and Basel, the State Hospital, Lucerne and the Department of Internal Medicine, Berne, Switzerland.

According to WHO's Drug Information: Jan-March 1978, though sporadic cases for about 6-7 years were reported, it was only after three decades of use of "clioquinol in the treatment and prophylaxis of diarrhoea in Japan that SMON was recognized as a distinct clinical entity in 1964 (Tsubaki, T., Toyokura, Y., TSU Kagoshi, H. (1965). Sub-acute Myelo Optic Neuropathy following abdominal symptoms - A clinical and pathological Study, Japan Journal of Medicine: 4, 181-184).

HOW USEFUL IS CLIOQUINOL?

There is no evidence to sugges that clioquinol is effective in the prophylaxis of travellers' diarrhoea.

British National Formulary, 1981

The claim for the value of clioquinol in the prevention and treatment of that nebulous ragbag "travellers' diarrhoea" do not withstand critical examination.

The Lancet (1977)

The Committee (on Safety of Medicines,UK) has reviewed the data relating to the efficacy of clioquinol in the treatment of diarrhoea and considers "that there is inadequate evidence to support the claim".

Pharmaceutical Journal (30.7.77)
page 597.

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The drug was excluded from consideration by a WHO expert committee convened in 1977 to prepare a model list of "essential drugs" on the grounds that the risks of treatment out-weighed the potential benefits.

(Ref: WHO 1975: Selection of Essential Drugs. Techn.Ref.Series 615, page 14).

The editorial in the Journal of American Medical Association 10th April 1972, page 273 stated:

".....in the 40 years that clioquinol has been available only one study which is not entirely convincing, has shown it to be effective in preventing travellers' diarrhoea whereas one other prospective study has shown it to be no more effective than a placebo....."

"Hydroxyquinolines are active only on organisms present within the intestinal lumen. Used alone, therefore, they are active only in the absence of significant tissue invasion - a development that cannot be excluded with certainty even in patients with asymptomatic amoebiasis".

PDT/DI/78.1 WHO:Drug Information.
Jan-March 1978

Anti-diarrhoeal drug blinds and damages brain - M.V.Kamath, Times of India, 20th June 1977.

"The scientific evidence for the value of clioquinol in the treatment of prevention of traveller's diarrhoea is scanty".

According to Dr. P. C. Pandiya of Jaipur, then President of the Pharmacy Council of India. "The Indian brand of Mexaform contains 2 more drugs (besides Iodo chloro hydroxyquinoline the basic drug - phanquone and oxyphenonuim - and has come to be used not only for travellers' diarrhoea but diarrhoea of all descriptions including that due to indigestion".

"The dramatic relief is due to oxyphenonuim which reduces the spasm of the intestines and bowel movements and thus markedly reduces abdominal pain and discomfort".

The Hathi Committee had included clioquinol in the analogous list of essential drugs, "Due to its low cost in relationship to alternative treatment and having regard to the paucity of documented evidence of SMON within the country".

But in India Hydroxyquinolines are supposed to be obtained only under prescription (like many other drugs). How much this restricts the vigorous selling of the drugs over the counter is well known to all of us.

WHAT IS SMON?

SMON stands for Subacute Myelo Optic Neuropathy.

"In its classical form the condition was characterized by the prodermal gastro-intestinal symptoms considered to be of neurogenic origin.

- an ascending numbness of both legs associated with severe and persistent dyaesthesiae.
- frank myelopathy revealed by exaggeration of reflexes extensor plantar responses a sensory level nn the trunk and sphincter disturbances could also occur and the combination of exaggerated patellar reflexes and absent ankle jerks was considered to be a characteristic finding.

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Disturbances in visual acuity developed but they were not usually an early manifestation.

The increase in the number of SMON cases reported annually was substantial. In 1965 - 451 cases were reported and in 1969 the number went up to 2340.

(PDT/D1/77.4 page 10): WHO Drug Information. 1977

"Females and elderly were particularly vulnerable and formed a high proportion of patients who also suffered from serious chronic diseases".

(Ref: Sobur, I., Ando, K., (1969) - Review and Comment on Myelo - Neuropathy Accompanied by Abdominal Symptoms, Paisnin Igakn 24, 2390 - 2397.

More reports were received in summer -

"A correlation between the use of clioquinol and the occurrence of SMON in a series of 171 patients was first reported in 1971".

(Ref: Tsubaki T. Honma; Hoshi, M.(1971): Neurological Syndrome Associated with Clioquinol: Lancet 1, 696 - 697.

This was following the discovery of a green compound - later identified as an iron chelate of clioquinol on the tongue of some patients and in the urine and faeces of others by Professor Tsubaki of Sigata, Japan.

Regarding the effects of SMON which, according to some clioquinol sympathisers, have allegedly been due to idiosyncrotic causes the relationship between SMON and Clioquinol has unequivocally been shown.

According to the WHO report the fact that some 15% of the victims had apparently never taken clioquinol may merely reflect the difficulty in obtaining precise drug histories from patients; alternatively, it may indicate the existence of other factors in the etiology of the disease, or that SMON may not always be readily distinguishable on clinical grounds from other neuropathies.

Pharmaceutical Journal
30.7.77: page 597

Similarly, the reasons for having detected less number of cases before 1955 could be attributed.

- to a low detection rate
- the absence of an unidentified aetiological co-factor
- relatively low volume of sales
- relatively low dosage and duration of treatment
- or to the existence of poorly absorbed formulations

The effect of particle size and presence of emulsifying agents on the absorption of clioquinol, could have a bearing on the discrepant results of long term toxicity test on animals.

Social Audit's leaflet on Cliquinol:

"Bad information means bad medicine" has this to say about SMON:

"Clioquinol has caused thousands of cases of SMON a condition involving continuous pain, paralysis, blindness and, in extreme cases, death. In Japan, cases of SMON reached epidemic proportions - affecting an estimated 10,000 - 30,000 people before the drug was banned there in 1970".

The casual relationship between clioquinol and SMON has even been accepted by the Japanese courts.

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WHAT IS THE INCIDENCE OF SMON OUTSIDE JAPAN?

According to a Lancet editorial of the 28th May 1977, page 596, "the companies deny that the neurological damage from clioquinol is a serious risk outside Japan and identical abnormalities of the nervous system have been reproduced in animals".

According to the Journal of the American Medical Association: "The absence of epidemics in other countries does not invalidate the conclusion that clioquinol is neurotoxic. Clinicians from England, Australia, Switzerland, Sweden, Denmark, the Netherlands, and the USA, have described patients who developed neurological symptoms while taking these compounds.

The clinical symptoms of these patients were like the one that characterized SMON".

Journal of the American Medical Association
23rd July, 1973: Page 296

According to an international survey on recent reports concerning intoxications with halogenated oxyquinolines derivatives - "A survey of the literature has proved that 86 cases were reported as SMON or intoxication of halogenated oxyquinoline derivatives (including suspected cases in 47 articles published outside Japan from January 1970 to February 1977).

According to Dr. N. H. Wadia in his article: "Some Observations on SMON" from Bombay in the Journal of Neurology, Neurosurgery and Psychiatry 1977: 40, 268-275 where he reported 9 cases of SMON by retrospective study of their hospital records from 1967-71 and prospective search from March 1972 till 1977.

> "In 1977 it would be imprudent totally to ignore the Japanese experience. If the factor which makes for the reported difference in SMON prevalence is genetic, SMON may never appear in India in epidemic form. But, if the factor is environmental or infective then the change in the Indian environment may result in the appearance of SMON".
>
> (The above study was funded by CIBA-GEIGY).

CIBA GEIGY one of the two main manufacturing companies of hydroxyquinolines has collated details of about 200 possible cases - published as well as unpublished.

The total number of cases of SMON reported from outside Japan is less than 100, of these a high proportion are from Australia.

CLIOQUINOL - RESTRICTIONS, BANS, BOYCOTTS

Hydroxyquinolines are sold in more than 100 countries. In some, there is a ban on its sale while in others sale is restricted to prescriptions.

Some of the countries which have imposed restrictions are Australia, Denmark, Venezuela and Norway. In the Federal Republic of Germany, Finland, France, "Traveller's Diarrhoea" has been deleted from recommended indications and the compound has been placed on prescription.

MORE SPECIFICALLY:

SWEDEN: At first, HCQ was accepted for treatment of acrodermatitis

..6/-

enteropathica. Later, however, Sweden totally withdrew it and replaced it by zinc salts, which is considered safer and more efficacious.

In the summer of 1976, Dr. Ole Hansen proposed that all CIBA GEIGY products should be boycotted in Sweden as the company continued to market or promote their products of Enterovioform and Mexaform in spite of conclusive evidence showing their relationship with SMON.

In 1977, the boycott started with doctors writing to the Swedish medical journals protesting against the continued sales of clioquinol. Thanks to the information obtained by a Swedish free-lance journalist from the CIBA GEIGY's internal documents.

On September 27, 1981 the Swedish newspapers published that for each individual drug, CIBA GEIGY lost 25% of their market in Sweden. CIBA GEIGY is said to have lost 75 million Swedish Kroner during the boycott years. In 1980, this was equivalent to the total turnover of CIBA GEIGY (Sweden).

The boycott by the Swedish doctors and the public was their way of contributing to the developing countries, fulfilling their responsibility towards all peoples in preventing drug suffering.

38 individuals afflicted with serious side effects by taking Mexaform, sued CIBA GEIGY for damages in Sweden. CIBA GEIGY and Eraco agreed to pay 1.8.million Swedish Kroner as damages in an out of court settlement according to the Economic Times of the 14th April 1982.

JAPAN

About 10,000 persons are reported to be suffering from SMON in Japan. The number of suits in various parts of the country in September 1979, according to the Japan Times, was 5200.

It took more than 8 years and 4 months after the first SMON damage suit was brought against the State and three pharmaceutical companies (CIBA GEIGY - Japan -Takeda Chemicals and Tanabe Selyakulo) for the Tokyo district court to reach two decisions:-

1) Clioquinol causes SMON
2) CIBA GEIGY et al. were liable in failing to pass on information about the dangers of clioquinol.

Regarding the demand for appropriate instructions and a warning for doctors and patients, the company has argued:

> "It is however not possible to achieve complete uniformity of the information for the doctors and patients, because in different countries there are different rules which are usually laid down by the local health authorities".
>
> (Dr.J. Sobotkiewicz: Statement at Geneva Press Conference on SMON). Proc. of 28th April 1980: p.34.
>
> (If there were no rules, more such drugs would be let loose on the public; and, in countries where the rules are lax, the people are obviously at the mercy of some unscrupulous drug industries who knowingly take full advantage of these rules).

Some of the SMON victims who have won their cases are using part of their money to fight against needless drug induced suffering. According to Michiko Kinoshita, a SMON victim from Japan, in an interview with the New Internationalist, January 1981:

> "We want our fight against clioquinol in Japan to help secure assistance for SMON victims in other countries, just as thalidomide litigation in Europe and the USA helped gain assistance for thalidomide victims in Japan".

../-

U.S.A. According to the National Drug Regulations, 1961, the use of clioquinol for amoebic dysentery is restricted. The maximum dose recommended is : 22.5 gm. for 10 days.

BANGLADESH The Bangladesh Government on June 12, 1982, acting on the advice of an Expert Committee, banned the manufacture, import, distribution and sale of 1707 drugs, which were considered irrational and harmful. Mexaform and Enterovioform and all products containing hydroxyquinolines have also been banned.

(A lesson India can follow from its small neighbour!)

ENGLAND In 1973, the UK saw no reason to restrict the sale of HOQ. However, in 1977, it was felt that oral clioquinol should be available only on prescription.

(Ref: Pharmaceutical Journal 1977: 106,219)

In 1977, the Lancet had said:

"The time has come to halt free sales of clioquinol (i.e.enterovioform) and similar drugs for vague intestinal ailments and to demand good evidence before their use for other purposes is allowed to continue".

In London, in May 1978, the Sunday Times and BBC television covered in a programme the clioquinol dangers. This was following the briefing of a medical journalist and a TV producer by Dr. Ole Hansen.

Questions were raised in the parliament a few weeks later and just two months after the press and TV coverage, the Ministry of Health demanded that all bottles from pharmacies be withdrawn and the texts on the bottles and leaflets be altered. Even though these drugs are formally on prescription only, they have just disappeared from the market in England.

(The role of the press and Government Health Ministry needs to be noted and appreciated).

A point to note:

The Medical authorities in Britain had said: "This (SMON) is no problem in Britain". Fortunately, in spite of them, these drugs have disappeared from the market in Britain.

INDIA According to the Hathi Committee, HOQ are supposed to be prescription drugs, but they can be obtained in any amount over the counter without prescription, without adequate warning. Even if the details of the warning were not written in such small print the English-knowing population being so small, the caution hardly succeeds in warning most of the consumers. Therefore, banning of dangerous drugs is the only solution in the absence of adequate control.

OUR PLAN OF ACTION

1. Distribution of this briefing document amongst our drug core groups and discussion at the Drug Workshop.
2. Sending its summary to the Central and State Drug Controllers and Health Ministers.
3. Sending it to various medical and pharmacology heads for discussion and feedback.

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4. Dissemination of this information via Health For The Millions, to our members, asking them not to prescribe this drug.

5. Dissemination to our journalists friends and consumer activists.

6. Demand for a warning which can be understood by consumers.

Caution - The use of this drug may lead to blindness, loss of the function of your legs, loss of bladder control or constant pain in the legs.

(Myelopathy, optic neuritis are meaningless for a consumer - as long as we can not ensure sales of potentially toxic drugs without a prescription, it becomes our responsibility to ensure adequate warning).

7. Demand that a cheaper alternative be made available.

8. Letters to MIMS, CIMS, IMA JOURNAL.

9. Try to get figures of SMON or suspected SMON cases from our colleagues in neurology or eye departments in the larger teaching colleges, PGI, NIMHANS, AIIMS.

10. Keep pressure on the Drug Controller to get Clioquinol banned and make alternatives easily available at low cost.

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   Kiyohiko Kalthaira, Ph.D, Tokyo Medical and Dental University. Medical Research Institute.

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4. Transient Global Amnesia after Clioquinol. Fiver personal observations from outside Japan.

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7. The SMON Syndrome: Utusan Konsumer' March 1982
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   N.H.Wadia, Department of Neurology, J.J.Hospital, Byculla.

9. SMON Victims Plaintiffs Make Compromise Accord:

   Japan Times Sunday (Sept. 16. 1979)

10. Journal of Neurology, Neurosurgery and Psychiatry, 1977, 40 - 268-275
11. Goodman Gillman

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ALTERNATIVES

Nitronidazoles like Metronidazole (INN)
Finidazole (INN)

PROS

- have amoebicidal action in the tissues as well as in the intestinal contents.

- they are fairly well tolerated by the majority, therefore Metronidazole can be used for amoebic dysentery as well as hepatic amoebiasis.

CONS

Occasional reports of neuropathy and mutogenic an. carcinogenic potential in animal models (of uncertain relevance to man), has led to statutory requirements for warning labelling in the USA and India.

- Metronidazole is relatively costly.

/Since / Metronidazole is extensively absorbed in the small intestines and hence for greater and adquate action in addition a lumenal amoebicide/should be routinesly /it prescribed.

Diloxanide furoate

PROS - is highly effective against nonsymptomatic carriers.

- in 95% cases eradication of organisms has been reported

- regarding its use in acute amoebic dysentery divergent results have been obtained - concurrent use of tissue amoebicide whenever possible is recommended.

Paromnmycine Aminoglycoside

Antibiotic - Is effective both for symptom less causes and acute amoebic dysentery.

CONS

High cost

Troublesome diarrhoea

Carbasone arsenical and Glycobiarsol gave unimpressive performance - isolated fatalities attributed to carbasone.

- occasionally - evidence of cumulative toxicity.

- the choice of lumenal amoebacide should be based on its effectiveness.

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IS A PATIENT A CONSUMER ?

R.C. GOYAL

Introduction

Till recently, if any dispute regarding negligence on the part of the doctors or hospitals was raised in a Court of Law, it was either filed under the Law of Torts to claim damages, or under Sections 304 A, 336, 337 and 338 of the Indian Penal Code to get the negligent punished. However, after the introduction of the Consumer Protection Act, 1986, a drastic change has taken place. We find a number of complaints being filed by patients and their heirs in the District Forum, and State/ N nal Commissions created under the Consumer Protection Act, 1986, against individual doctors and hospitals for negligence of one sort or another.

There can be a number of reasons for this change, but the main reasons are :

- Increasing knowledge of one's rights as a patient;
- Doctors and hospitals are no more held in high esteem as before;
- No cost is involved if a complaint is filed in the District Forum or State/National Commission, since a patient can make out his case and argue it himself;
- A complaint is decided within a short span of three to four months under the Consumer Protection act while it usually takes years in the Civil/Criminal Courts.

Benefits to Consumer

There are a few reasons for keeping medical services under the purview of the Consumer Protection Act. These are:

- There are cases of medical practitioners dealing casually with their patients because these doctors are negligent and callous by nature. The Act may serve as a deterrent to these doctors.
- The Act provides speedy, easy and cheap remedy to aggrieved patients against negligent doctors, enabling them to claim compensation.

Negative Impact on Consumers and the Medical Profession

On the other hand, there are many good reasons for excluding medical services from the Consumer Protection Act. These are:

- To decide, whether a patient is a consumer or not, one shall have to give importance not to the letter of the law but to the spirit behind it. Otherwise, by extending the definition of the term 'consumer' to users of hospitals, nursing homes and private practitioners, one will invite a flood of irresponsible litigation, especially since the services of the Commissions are available free of costs to all complainants.
- It will hamper doctors from giving their best out of fear of mishaps, unwanted litigation, huge compensation claims etc.
- In every area of medicine, junior doctors need to be trained and all senior doctors need to extend their expertise. This introduces specific risks and raises distinct ethical issues. Senior surgeons may well be the best of surgeons but the nature of medical care and the need to train surgeons for the future means that the former must allow their juniors to perform some of the procedures for which they are responsible. The delegation of these duties is based on an assessment of the ability of the juniors to perform the operations concerned. As a result even if a junior doctor's work is supervised, it will leave the senior doctor's judgement of the clinical problem or the junior's ability open to criticism.
- Doctors will cease to rely on their own clinical diagnosis and will resort to practising defensive medicine. To reduce the risk of litigation, they will put patients through different tests - radiology, pathology, etc. which will prove expensive to the patients. The patient who comes in with a headache of one day's duration may be advised X-ray views of the skull, to seek the opinion from an Opthalmologist, a C.T. Scan and an M.R.I. scan, lest the doctors miss a brain tumour. He has to have a series of test results to justify his course of action and pass the buck if things go wrong and he finds himself dragged to a consumer court.

Series of tests — No ethical or medical justification.

- Pioneering surgeons use techniques that others would not attempt. Because of the nature of their work, these surgeons are vulnerable to emotive appeals about the use of patients as guinea pigs. Though they treat their patients with respect, care and expertise, yet their actions can be painted in a bad light before the general public.
- There are certain specialist doctors who work in high risk areas such as neurosurgery, traumasurgery or heart surgery and who regularly have fatalities. However, this is merely a reflection of the risk of the surgery they are prepared to undertake. Now they may think twice about working in these high-risk areas because of the Consumer Protection Act being applicable to them.
- The learned members of the District/State National Commission are likely to commit errors in their orders while granting compenstion/award in the cases of hospitals/ nursing homes/doctors due to lack of medical knowledge in general and in particular with regard to instant decisions which are frequently taken by doctors during emergency treatment and at the time of an operation.

  Example: When an obstetrician conducts a delivery in a labour room, she has to take many instant decisions, such as during foetus distress. At that time, her prime duty is to save the mother as well as the foetus but sometimes she has to devote her entire energy in saving either the mother or the foetus, whichever is more viable. Similarly, she has to decide instantly whether to conduct a normal delivery, forceps delivery or caesarean keeping in view the condition of the mother as well as of the foetus. In most cases, patients and their family members misunderstand the whole issue due to lack of medical knowledge. Not to talk of the patient and his family members, if the decision taken by the obstetrician is discussed with a doctor of any speciality other than obstetrics, even he may not be able to justify the decision of the concerned obstetrician. Such an issue was rightly appreciated in appeal by the Tamil Nadu State Commission against the order of the Thanjavur District Forum. In this case, the obstetrician was directed to pay Rs.50,000/- as a fine for taking a wrong decision by the District Forum. However the State Commission set aside the order because one of the members of the State Commission was also an obstetrician and could understand the difficult situations in which an obstetrician has to take instant decisions when two lives are at stake.
- Patients usually go to doctors with implicit faith and doctors generally respond with a feeling of responsibility. Treating this service as a purely commercial one will do more harm than good. Even if it is assumed that this profession has become commercial, it still cannot be termed as a trade or commerce.
- Insurance companies have increased their premiums on the premise that medical professionals are subject to a large number of claims under the Consumer Protection Act. Naturally, doctors have started charging more from their patients to cover the enhanced insurance premium.
- There is no comparison between a doctor and a trader. The consumer law is meant to protect consumers from those traders whose intention is to defraud. In all doctors-patient cases, the doctor intends to cure and at times fails to cure. The intention of the doctor is never malafide and when something does go wrong,

it is never intentional or preplanned.

- A doctor's professional reputation is one of his most valuable assets, as dear to him as his professional skill. The consumer court may provide an easy method for blackmailing and the doctor may opt to settle out of court. Thus the Act can be held as a weapon to blackmail an honest doctor. It will encourage unscrupulous operators and waste valuable time and energy of professionals.
- When a person goes to a hospital for treatment, there is always some risk. Every surgical operation involves risks. It would be wrong and indeed bad law to say that simply because a misadventure or mishap occured, the hospital and the doctors are liable.
- It is an admitted fact that allopathic medicines are generally useful but at the same time they are also harmful as they may also have side effects. Thus while curing one illness, the use of some medicines causes another illness through no fault of the treating physician.
- In most cases which lead to litigation under the Consumer Protection Act there is lack of communication between doctors and their patients. Doctors often do not realise that patients and their family members are anxious to know about the nature of the illness and line of treatment, and seek assurance of full recovery. Sometimes doctors do not find time to explain the situation to them because of their busy schedule.

The points discussed above will ultimately lead to a situation of 'patient selection' by doctors. They will select and treat only those patients who would not create a legal problem for them. In other words they would treat only 'clean' cases. Thus the ultimate sufferers will be the patients.

Recommendations

- The Parliament should reconsider the provisions of the Act in the interest of one and all and redefine 'consumer' and 'service' so that doctors and hospital authorities do not become subject to frivolous litigation. Urgent intervention in this connection is required by the Medical Council of India and the Indian Medical Association. More than a hundred cases have been filed against doctors and they have been asked to pay damages amounting to as much as Rs. one lakh to ten lakhs.
- Aggrieved patients could file suits for compensation in Civil Courts. If the Civil Courts are over-burdened with cases, as they clearly are, the government can constitute separate Civil Courts to hear medical cases for quick disposal. This is being suggested for two main reasons:
  - Under the Consumer Protection Act, 1986, one can file a complaint against a doctor of a hospital in the District/State/National Consumer Forum without making any payment. If people had to file their cases in the Civil Courts under the Law of Torts, they would have to pay Court fees at the time of filing a suit and will think twice before filing frivolous cases.
  - The President and Members of the District State/National Forums are not conversant with the medical profession and its intricacies. Therefore they can easily commit a mistake in concluding whether there is any negligence involved or not. If separately constituted Civil Courts were to hear such medical cases again and again, they would soon begin to understand the medical intricacies involved.
- To discourage false complainants, there should be a provision in the Act to deposit 10 percent of the claimed amount as security in the government treasury at the time of filing a complaint before the Consumer Forum. If he wins, he gets back his deposit otherwise he loses it.
- When a patient files his claim before the Consumer Forum, he must give an undertaking that if his application is found frivolous and is dismissed, he will pay for the entire expenses incurred in defending the claim, compensation for time lost, damages for loss of reputation and mental torture and agony undergone by the defending doctors and hospitals. At the same time the Consumer Forum should be liberal in awarding costs while dismissing the complaint so that false complainants do not get undersired encouragement under the Act.
- If, because of pressure from the consumer associations or for any other reason, the government is not willing to make drastic changes in the Act such as keeping patients out of the purview of the Act or constituting separate Civil Courts for dealing with the grievances of patients, the government can make slight modifications in the Act. They should nominate a medical person with the same specialisation as the doctor in the case.

as an ad-hoc member of the Consumer Forum. Or, before registering a complaint in the Consumer Forum, a show-cause notice should be issued to the other party, i.e., the hospital or the doctor or both as the case may be, and then refer the complaint as well as the reply to a team of medical experts. On their advice, the complaint may be either rejected or entertained for trial.

- Members of the various Consumer Forums should look into complaints against doctors/ hospitals sympathetically as they do not intentionally provide deficient service to patients.
- Advocates should discourage patients who come to them to file frivolous complaints.
- Patients should give serious thought before entering into litigation against doctors. They should carefully consider whether they were really given deficient service or whether it was the only alternative remedy available to their doctor.
- The press should not give undesired, exagerated publicity to doctor-patient matters because it will further harm the relationship. If any news of deficient service is brought to the knowledge of the public, it's coverage should be objective.
- The government should issue a notification to exclude patients from the definition of the word 'consumer' and medical services from the word 'service' as given in the Consumer Protection Act, keeping in view the pros and cons of the application of the Act on them.

Conclusion

If there are still occasional lacunae in treatment, the remedy is not in demoralising those providing the requisite services nor in diverting their attention from the provision of such services to dealing with a spate of irresponsible litigation - which will certainly result from the wider and more flexible interpretation of the terms 'consumer', 'service' and 'hiring for a consideration' in the Consumer Protection Act. This type of interpretation would become counter-productive and would defeat the very purpose of the legislation.

In a case of demonstrable 'negligence', it is not that a patient would be deprived from seeking justice. Recourse is always available to him in a Civil Court where suitable compensation can be provided to the aggrieved and also in a Criminal Court where the negligent can be punished.

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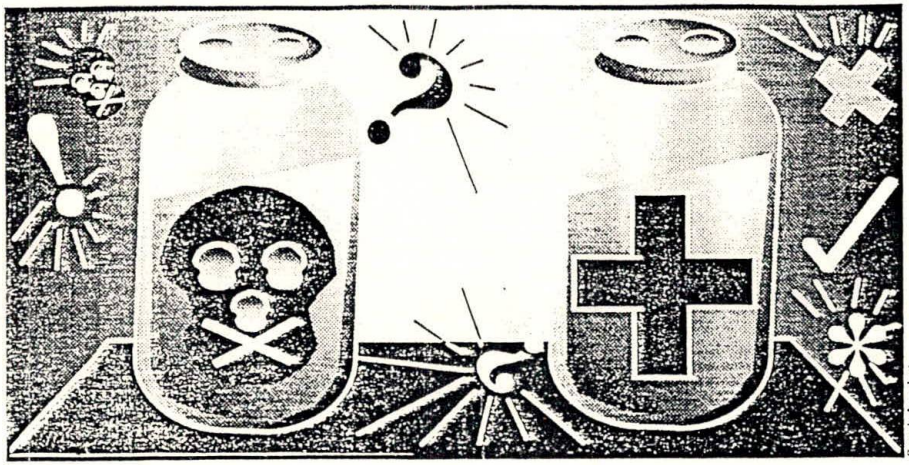
Dr. R.C. Goyal has been writing regularly on a variety of issues ranging from 'Is a Patient a Consumer' to 'Role of Counselling in Management and Lord Ram as a Counsellor.' Dr. Goyal is presently working with Holy Family Hospital, New Delhi.

Blood or death banks ?

Despite the fact that blood banks, whether public, voluntary or private have been screening blood, increasing instances of supplying infected blood has raised doubts about the safety norms followed in these banks, writes Y G MURALIDHARAN



Satish Avachat

THANKS to Consumer Protection Act, two recent cases filed in the Delhi and Maharashtra Consumer Redressal Fora against hospitals for administering contaminated blood during treatment, has brought to fore the safety of blood supplies by blood banks across the country.

The first case relates to a Delhi housewife, Indu Rahi who was admitted to Safdarjung Clinic in August 89 for delivery of a child. As she required a ceasarian operation, she was asked to arrange for blood. Unfortunately, blood was procured by a private blood bank which made all the difference. Three months later, when she complained of fever and vomitting, her blood test showed that she was HB and AG positive as a result of receiving contaminated blood.

On appeal by the patient, the Delhi Consumer Redressal Forum held the Sunil Blood Bank and Transfusion Centre (which supplied the blood) guilty of supplying infected blood and was asked to pay Rs.20000 as damages to the complainant. While it is easy for a blood bank to pay damages and absolve its responsibility, it will not be so for the patient who has to suffer till her death.

Blood banks which are supposed to save human lives are fast turning to be death traps. Despite the fact that blood banks, whether public, voluntary or private have been screening blood, increasing instances of supplying infected blood has raised doubts about the safety norms followed in these banks. The reports of more and more people contracting malaria, jaundice, syphilis and even AIDS due to transfusion of unsafe blood, is an indication of the murky business that goes on in blood banks.

While a few diseases arising due to administering contaminated blood is curable, what is of great concern is getting infected by that dreaded disease AIDS, as it happened in the case of Sunita Heganavar (26) of Kohlapur. She was given four units (bottles) of blood as part of a surgical operation. All the units were supplied by the blood bank maintained by Miraj Medical Centre, which is authorised by the Maharashtra Food and Drug Administration (FDA).

Out of four units of blood, three were screened and found safe. However, the fourth was not subjected to regular tests. Before the hospital administration could find that the fourth unit of blood was contaminated, the damage had been done. Now Sunita, her husband, her daughter (born after the operation) all are infected with the virus [illegible] that causes AIDS. She has appealed to the Maharashtra Consumer Redressal Forum claiming Rs.10 lakh as damages plus medical treatment. The final verdict is awaited.

What is alarming is that a number of instances of administering blood without screening have been hushed up or have gone unnoticed.

The increasing number of diseases due to transfusion of contaminated blood may be attributed to several reasons. One to the ever increasing demand for blood and secondly, as a result of this, a mushrooming in blood banks that pay scant regard to safety aspects.

To date, there is no accurate statistics about blood business in the country. According to one estimate, the country requires nearly 50 lakh units of blood per year.

Out of this, 19 lakh bottles is obtained from volunteers. By WHO norms, India requires 42 lakh units of blood against the availability of 20 lakh. For the rest, patients have to depend on professional donors. Obviously the demand and supply doesn't match — guaranteeing a market for those who sell blood as their only means of survival.

Poverty coupled with unemployment leading to migration to cities in search of jobs, has led young men taking to selling blood for their survival. Most blood banks have touts, who prey on poor, desperate villagers and offer them money in exchange of blood. Even in the case of donors, reliable statistics are not available.

However, World AIDS (July 92) reports that there are nearly 30,000 professional blood donors in India. Each donor sells roughly 15 units (one unit is 350 ml) of blood a month from Rs.25 to Rs.500 depending upon the category of blood. The Professional Blood Donors Welfare Association claims that they cater to 80 per cent of the country's needs.

But the sting lies in the fact that many of these professional donors are carriers of HIV.

According to the National Aids Control Organisation (NACO) statistics 14.87 per cent of the country's estimated 15 lakh HIV infected cases are professional blood donors. Another category of blood donors who sell plasma to blood products manufacturers are also responsible for getting and spreading HIV.

In order to bring down instances of HIV infected blood being given to patients, professional blood donors were extensively tested for HIV in 1985. Though none of them were found HIV positive, the situation is not so in 1994.

Despite the fact that blood business in the country is playing havoc with the lives of the innocent patients, nothing has been done to stop this menace. Four years ago, Ms. A.F. Ferguson and Co., carried a survey and found that there were 1018 blood banks in the country. Of these, 378 do not have a mandatory licence from the government. Again 326 out of 378 unlicenced blood banks are the ones owned by the government itself. The committee also found that half the banks it surveyed were not carrying out all the critical tests against blood infections.

Elaborate rules which runs to seven pages have been framed under the Drugs and Cosmetics Act for establishing and maintenance of blood banks. These provisions include minimum area of 100 square metres, equipments like sphygmomanometers, refrigerators, weighing machines, disposable plastic packs, blood collection bottles, emergency equipments etc., More importantly, blood banks should ensure that blood supplied confines to the standards laid down in the current edition of Indian Pharmecopoeia.

According to FDA regulations every unit of blood has to be tested for four diseases — malaria, hepatitis, syphilis and HIV — before being released for use. It should be remembered that no blood transfusion is completely free from infection and there is no test completely reliable. While the shelf life of whole blood is between 21-30 days, there is what is called 'window period' of 45-90 days when the incubating virus does not reveal its presence in the test. So it is possible, for a person to give blood up to 45 days after exposure to HIV, without the virus being detected.

All blood banks are also required to send samples of every unit of blood collected to one of the Government Surveillance Centres. This is done the same day that the blood is drawn and the results are back within 24 hours. There are 180 zonal blood testing centres spread in 112 cities. In Bangalore there are two zonal centres and two surveillance centres.

The conditions of licensed private blood banks are not encouraging. Many blood banks use domestic refrigerators for storage which cannot ensure the standard of four degree centigrade temperature, as prescribed by the drugs and cosmetics rules. They often take up to five units of blood a day from a single professional donor, but use five different names in order to evade regulations which limit donors from giving no more than one unit every 12 weeks.

Blood banks seldom check the donor's Haemoglobin count. Medical standards stipulate that the donors count should not be below 12.5 gm. While such persons could be at risk by giving blood, the receipient would hardly benefit. It is not surprising that the Project Director of National AIDS Control Organisation, monitoring blood supplies termed these blood banks as 'money spinnig rackets' whose aim is to supply as many bottles as possible from as few donors as possible.

The government has drawn up a plan to clean up the 1018 blood banks through a series of measures. The NACO will set up 30 blood component separation units in major cities. A central legislation to control the blood banks, standardising the quantity of blood in commercial banks, total ban on tapping professional blood donors in all government hospitals and fixing a standard selling price of blood under the Drug Price Control Order, are some of the steps to be taken to control blood business.

Despite all these plans, the fact remains that demand for blood can be met only by encouraging voluntary donations. As of now, there is no strong effort either by the government or social organisations to promote or campaign for voluntary blood donations. There is an urgent need to create an awareness among the people about the need for blood donation. Many misconceptions exist about blood banks and thanks to ignorance, India with a population of 850 million people collect just 20 lakh units, whereas Japan with a population of 120 million collects 80 lakh units a year. And only 10 to 15 per cent of blood comes from centres that have proper AIDS testing facilities.

Another reason for shortage of blood is that blood is not used judiciously. In many of the cases, where blood transfusion is needed it is only a part of the blood that is to be transfused. Whole blood transfusion is needed only in case of heavy loss of blood as in accidents. For instance, anaemics just need red blood corpuscles, haemophiliacs Factor 8 and burn victims need plasma. Unfortunately, all these patients are given whole blood as we do not have adequate facilities to break down blood.

Another way to minimise HIV infection as also the menace of professional donors, is to go in for 'autologus transfusion' wherein one's own blood is drawn and administered. Under this system one or two units of blood is taken from the patient before surgery and replaced with the same after or during surgery. Of course this is subject to other medical conditions.

Very recently, the National Plasma Fractionation Centre at Bombay introduced, what is called the "Fractionation system", a unique way of multiplying the benefits of one blood unit. Under this system, plasma is fractionated into three products i.e. albumin of five and 20 per cent, Factor IX and immunoglobulin. While albumin is used as a volume expander, Factor IX is used for bleeding disorders and immunoglobulin is used to raise the level of antibodies in the treatment of Hepatitis A. The equipment costing Rs.3.5 crore is presently available only in this centre in the whole of South East Asia.

The need of the hour is to make blood banks more responsible and accountable. Licence should not be granted unless all the requirements are compiled with.All said and done, the one debate that remains undecided is that should untested blood be given to a patient in case of emergency? Over to you dear doctors.

PRESCRIBING DRUGS

Questions to ask yourself before writing a prescription.

1. Need	: Is this drug really necessary
	: Is it being given to make the patient feel that something is being done?
2. Aim	: What aim is to be achieved by this drug?
	: What disorder of function is to be corrected?
	: What symptom/s have to be relieved?
3. Knowledge	: What is the approved or generic name?
	: What class does it belong to?
	: What are its characteristics?
	: Do I have the requisite experience or knowledge to use it?
	: Have I weighed the potential toxic effects against the benefit?
4. Route and Dosage	: By what route, in what dose and at what intervals is the drug to be given and why? In what form/s does the drug come?
5. Alternatives	: Have I selected the best agent available for this particular purpose?
	What other remedies might have been chosen?
	How do these compare in effecacy, safety, cost?
6. Duration	: For what period of time, days weeks or months will it be advisable to continue therapy?
	When and how could a decision be made to stop?
7. Observations	: What observations can be made to judge whether the aim has been achieved?
	When should they be made and by whom?
	What laboratory investigation if any would help in this assessment?
8. Elimination	: How is the drug eliminated?
	Will the patients illness change the usal pattern of distribution, effects or elimination of the drug?
9. Unwanted effects	: What are the side effects or toxic effects of the drug?
	Are they acceptable?
	How frequent are they?
	How can they be modified/managed?
10.	:Have I checked for the following:
	a. Possible allergic risks
	b. Possible idiosyncratic reactions
	c. Patients drug diet which may interfere with the drug
	What precautions can I take to ensure continuation of therapy

11. Contraindications : Are there any conditions in which this drug is contraindicated?

Are these 'absolute' or 'relative'?

Are there any drugs which should be avoided when the patient takes this treatment?

Which and why?

12. Patient point of view : What does the patient believe about the drug?

What has he been told about it? and

What has he remebered?

Does he need additional information?

13. Patient reliability : Does his relative need additional information?

Is the patient reliable for this type of therapy?

Will he need/get proper supervision by relatives or attendants?

14. Cost : Is the drug the cheapest drug of that type?

If not could a cheaper drug do the job as well?

15. Finally is there anything else I need to know about this drug?

Adapted from;

i. A Herxheimer : The Lancet II 1186-1187, 27th Nov.1976

ii. Formulary and Therapeutic guide-Kurji Holy Family Hospital

iii. Prescribing drugs - MNAMS Handout, Dept of Pharmacology, St.John's Medical College, Bangalore.

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ADVANTAGES OF ESSENTIAL DRUGS ON FINGERTIPS

Preparing a rational list of essential/restricted drugs has several advantages: medical, economic, social and administrative.

Medical advantages

* It is medically, therapeutically and scientifically soumd, and it ensures rational use of drugs.

* It limits the use of irrational and hazardous drugs and decreases the risks of iatrogenesis. (Doctor-induced illness)

Economic advantages

* It is economically beneficial to the nation because it prevents wastage of scarce resources on non-essentials.

* The economics of scale achieved in the larger production of priority drugs brings down their prices.

* It curtails the aggressive marketing of non-essential formulations.

* It is economically beneficial to the patient because it prevents wastage on irrational and non-essentials.

Social advantages

* It responds to the real health needs of the people.

* It facilitates the dissemination of correct information about the drugs to health personnel, medical practitioners and consumers in general.

* It makes it imperative to draw up priorities to meet the most urgent needs of the people for essential health care.

Administrative advantages

* It is organizationally sound because it makes quality control easier because of the limited number of drugs to be mentioned.

* It facilitates the streamlining of production, storage and distribution of drugs, because of the smaller number of drugs involved.

* It helps in the clear identification of the drugs.

* It facilitates the fixing of prices as well as the revision/withdrawal of excise duties, sales tax, etc.

Source: AIDAN

MARKETING OF PHARMACEUTICALS

Dr.ARUN BAL, ACASH

Even in the remotest part of the world people consume drugs.These drugs are part of the armamentorium of the medical practioners and healers at every level and are universally perceived to have powerful effects.Drugs are treated quite differently from other consumer items in all the societies.It is quite common in the most advanced soceities also to see that the consumers, though otherwise well informed and aware of his\her rights, purchase and consume the drugs without even a routine enquiry about its price,quality and necessity.Another aspect of the drugs marketing which is specific only for the drugs is that the consumer usually has no choice of the selection.This is partly because of the technical nature of the subject.However the marketing of the drugs affects the consumer financially,and many a times physically also.The gap in per capita drug consumption between the developed and the developing countries is considerable.In India we have approximately 60 000 drug formulations while WHO essential drug list mentions only 277 drugs.Approximately 55% drugs in the market are either irrational,inessential or hazardous.The total turnover of the drug industry is Rs.5500 crores which is slated to increase to Rs.16000 crores at the end of 8th five year plan.This enormous increase in the production of the drugs over the years has not been able to improve the availability of the drugs for the common man.The availabilty of the drugs for the common man continues to be as low as 20-30% of the population.A number of publications have discussed at length the inappropriateness of the expensive and often ineffective products consumed in the developing country.The vital resources of the developing countries are being used for products that are not essential at a time when the large section of the population is without access to even most basic drugs.Under the National Tuberculosis Control Programme the anti tuberciular drugs, which are of category one as per the DDPCo of 1986, are suppuosed to be available to all registered patients at the District and Taluka level Tuberculosis control centers.In a recent personal experience in two taluka level centres, it was found that the number of registered tuberculosis patients was 250 and 210 while the doses available were only 2 and 4 respectively which were taken away by the staff of the centres . This forces the poor patients to buy the drugs from the market.WHO estimates that some 500 million dollars have been mobilised to support national drug policies in the developing countries but this amount is only 5% of the amount being spent by the industry on the drug promotion worldwide.In India we have 20000 drug manufacturing units.Indian Pharmaceutical industry is categorised as category IV by

UNIDO.This means the technologically most advanced pharmaceutical industry.This obvious contrast of technologically advanced industry with the ever increasing drug production with poor availability of the essential drugs is perplexing at first.However when one goes in the deetails of the situation it is obvious that some other factors are at play which have made situation so difficult.

Over the last few years we have winessed number of tragedies causing deaths due to the substandard, spurious and hazardous drugs beuing marketed in the country.In spite of all the policy decisions, seemingly people oriented, the spate of tragedies has not abated.Is this an aberration or a deep rooted problem?It is obvious that the wrong kind of the drugs are being maketed.For years the industry has justified the high prices of the drugs with the argument that this is necessary for the research and developement of the new drugs for the various diseases.However over the last decade even the people connected with the industry have admitted that the marketing departmenrt of the companies and not the reseaerch departments, decide the production and marketing patterns of the companies.On the avarage 5-10% of the turnover is spent on on the R&D while 15 to 20% spent on the marketing of the drugs.Of the 348 new drugs from 25 largest US drug companies bedtween 1981 and 1988 the FDA said that at the time of introduction only 3% made imporatant contribution to the existing therapies,13% made modest potential contribution while 84% made little or no potential contribution.Glaxo advertising in UK of Fortum (Ceftizidime) ,a powerful antibiotic, mentions that the drug may be used when there is no time to wait for the sensitivity test. In case of powerful antibiotic like Fortum is it ehical to allow and promote the marketing which may cause indiscriminate use?Similarly newer forms of advertising are dificult to monitor.These include Video ads which are circulated through TV stations.In 1991 US FDA warned Ciba Geigy Ltd regarding its product Actigall which was claimed to avoid gall stone surgery.Many a times the slides about certain products prepared by the company but used for scientific discussions are prepared with the specific purpose of promoting the product than the scientifin enquiry.WHO essential drug list has received poor response from the industry.Head ofUS Pharmaceutical Manufaturers Association said that it would be poor buisiness practice to support essential drug list. The vice president of International Federation of Pharmaceutical Manufacturer`s Association remarked ` you cant expect us to support the policies which run counter to our own interests`.Indian goverment is signatory to various international agreements regarding adoption of essential drugs list of WHO.Inspite of these agrements the correct application and execution of essential drug list remains to be a distant dream.There are number of instances of mercenary attitude adopted by the industry while marketing the drugs in various

countries.These instances are well documented and need no recounting.However it would be wotrh while to narrate some of the instances of the marketing in Indian context.

High Dose Oestrogen Progestrone Drugs

This group of drugs were being marketed in India for many years.These drugs were used mainly to diagnose pregnancy and to delay the onset of the menstrual period.However over the years the drugs were proved hazaerdous and were banned in the developed countries and many of the developing countires.In India the sale of these drugs was about 7-8 crores rupees per year.These drugs were known to cause foetal ananmolies.On orders from Supreme Court the drug controller of India was forced to hold the public enquiry in four metropolitan cities in India to collect the public evidance about the hazardous nature of the drug.The overwhelming evidance about the hazardous nature of these drugs forced the government to ban these drugs.This was the first instance of a drug banned after public enquiry in India.The industry perceived this as an adverse trend for the future of the industry.The campaign for ban on High Dose Oestrogen Progestrone drugs did not end after the ban order was issued by the government.The injections of these drugs were used more than the tablets.The industry was marketing agressively the injections relying on the fascination for the injections in the soceity.The ban gezette notification mantioned ban on only the tablets.The voluntary organisations were again forced to move the court to secure the corredct ban order.Here also the industry and government nexus was obvious.The counsel of the drug controller was not breifed by the government and the task was left to the voluntary oraganisations .

Anabolic Steroids

Anabolic steroids are synthetic androgenic hormones.The primary use of androgens is to deal with impaired functioning of testis known as hypogonadism.However androgen have significant effects on muscle mass and body weight.When administered to patients with hypogonadism,it was assumed but never proved that the androgen in pharmacological doses could promote growth of muscle mass above normal levels.This was based on a wrong assumption that anabolic and androgenic actions are different.A standard texbook of Pharmacology by Satoskar states that various studies have shown that there is no lack of anabolic drive in patients recovering from the illness The use of anabolic drugs in such condition is highly questionable.In India anabolic steroids are being marketed by the industry for many indications which are highly irrational.Infar (India) ltd. a subsidiary of multinational Organon Ltd. markets Anabolic steroids in India.This company used to hold CME programmes in collaboration with Indian Medical Association.These programmes were being held

in five star hotels accompanied by lunch\dinner.The company used these programmes to promote the irrational product instead of scientific discussion.The enclosures to this paper details one such incident.This company used to pay even some doctors to spy on the voluntary organisations.

ANALGIN\DIPYRONE

Analgin\Dipyrone is an analgesic or painkiller.One of the widely used analgesic in India,this drug is banned all over the developed world and whereever it is available its use is highly restricted.In India one of the main manufaturers of this drug is Hoechst Ltd.In 1988 this compoany started marketing the drug for treatment of fever in children and the company booklet claimed that analgin has direct smooth muscle relaxing action.As the enclosures to this paper would reveal the company on repeated enquiries could produce some papers which were of 1950`s and did not sunstantiate the claims made by the company.Analgin continues to be used in India on large scale and such false cliams many a times go unnoticed .

M\S Glaxo (India)ltd and the recent court cases

In october 1993 FDA,Maharashtra issued orders for Glaxo to close its plant in Worli,Bombay for ten days for gross violation of provisions of Drugs and Cosmetics Act.The violations found by FDA were of grave nature.The rejects from the assembly line in Glaxo`s Worli plant were being only dumped in refuge dump in the factory premises.These were then being lifted by the scrap dealer employed by the company and sold in the market.The FDA officials found that the code numbers as well as the labels of Glaxo Ltd. in possession of the scrap dealer.Subsequent to the order of the FDA, Glaxo Ltd filed an appeal with the Health Minister which was rejected.However the company went into appeal to High Court which was also rejected.The papers in possession of ACASH reveal that the abovementioned offence was not the solitary instance.FDA had found that Glaxo Ltd was indulging into many gross violations of the provisions of Drugs and Cosmetic Act.Some of these were:
Inadequet check of raw material Industrial gelatine used for making blank capsules.The industrial Gelatine is known to contain many impurities like zinc,lead,arsenic ect.The significance of this violation is that in JJ Hospital glycerol tragedy similar violation of rules was not noticed and the industrial glycerine was allowed to be used for medicinal purpose leading to the deaths of many patients.Salbutomol Inhaler marketed by Glaxo Ltd for treatment of Asthama is supposed to contain 100 microgrammes of Salbutomol.However the FDA analysis showed that the particular batch which had pasased the company`s quality control contained only 4 microgrammes of Salbutamol.Inj.Fortum (Ceftazidime) is a costly antibiotic

marketed by Glaxo Ltd.FDA enquiry found that the company was not conducting Pyrogen test for this antibiotic.Susequently ACSH wrote to the parent company in UK but received an ambigous reply.The British Medical assaociation took up the matter with the parent company in UK but also received similar reply.FDA also found many violations of Drugs and Cosmetics Act by other companies namely Boots (India)Ltd and German Remedies.These companies were using the raw material which had already expired.The Glaxo Ltd has atlast realised the futility of pursuing legal cases and has closed down its Worli plant for ten days.

These are not isolated instances to shrugged off as an abberrations of othereise perfect system of drug productiop,distribution and use.There is no denying that the pharmaceutical industry has made important contribution to the public health over the last 0 years through the developement of many life saving drugs. The performance of the industry is usually measured in terms of profit and production.However the pharmaceutical industry is different from the other consumer industries.Its performance also needs to be measured in the terms of social accountability and the benefit\risk retio of its products.Its products affect lives of millions of consumers.If the performance of Indian Pharmaceutical industry is measured against these parametrs it would appear to be dismal.It has always discliamed the responsibility for marketing hazardous products while taking credit for technological acheivement.It always blames the goverment for allowing the marketing of dangerous drugs while convieniently forgetting the sinister role played by its lobbyist to influence the policy makers.The deafening silence of the medical profession regarding marketing of hazardous drugs and the marketing strategies of the industry encourages the industry to continue to market these drugs.It would be worthwhile to point out here that in case of Glaxo Ltd. none of the professional associations of Medical profession in India raised their voice while British Medical Association took up the matter with the parent company of Glaxo in UK.

Marketing of Pharmaceuticals is an important aspect of the healthcare in context of developing countries.Vital resources of the poor people are being spent on irrational inesential drugs instead on the necessities like food and clothing.Consumer activists,media,medical profession need to join the hands to correct the situation in the larger interest of the national health.Unless this is done on priority basis the oft repeated slogan of Indian Government ` Health for All by 2000 AD` is likely to turn into `Wealth for Few by 2000 AD.

VII.

DRUG INFORMATION AND ETHICAL MARKETING

Perhaps the most crucial component of a rational drug policy is to ensure that accurate and unbiased information about drugs is available to consumers and to medical practitioners. The manufacturers have the primary responsibility of making such information available in respect of the drugs produced by them. This is the area where there is maximum confusion. There is ample evidence to show that drug producers as a rule either suppress vital information relating to their products, or deliberately provide wrong information.

The situation prevailing in India in this regard is truly incomprehensible. A glaring example is provided by the recent case of the judgement of the Kerala High Court on writ petition No. OP 8439/1982 in which the Court directed the Central and State Drug Control Authorities "to publish the list of trade/brand names and the names of the manufacturers of (these) drugs" (which have been banned). This directive has not been complied with, on the excuse that the drugs have been licenced and registered with State health authorities and the Centre has no clue about the various formulations and brand involved.

The current practice is to notify the banning of a drug through a Gazette Notification. Surprisingly, the Gazette Notification indicates the generic name of the drug whichare being banned, whereas the products are all marketed under trade names. Moreover, the notifications are generally couched in such ambiguous language that it is normally impossible to gather whether the ban becomes applicable if any one of the drugs in the general category is present in a combination, or whether all the drugs have to be present in combination for the ban to become applicable. Similar ambiguities are created by not clarifying e.g. whether steriod combinations means only non-sex steroids or sex-steroids also.

Ban of all steroid combinations except for asthma saw no drugs being banned in reality - just a change of indications on paper. (See Table 8.1).

Such ambiguities favour only the drug trade.

It should be the responsibility of the Drug Control Authorities to :

- screen all promotional literature for false information (e.g. recommending Lomotil for children under two years of age),

- monitor prescription guides which are used by doctors (e.g. MIMS & CIMS) to ensure that information contained in these guides is accurate.

- inform health personnel and consumers of the W H O ' s recommendations for an essential drugs list.

- provide information to the general public about drugs which are banned abroad - giving the reasons for their being banned or restricted.

- ensure that proper cautions about side-effects and contra-indications are provided along with the products in the appropriate local language.

- ensure that labelling of products are clear.

- ensure that international non-proprietory names (generic names) are used on all products.

DOUBLE STANDARDS

A growing phenomenon, which is assuming menacing proportions is the manufacture, import, distribution and sale of drugs in India (and other Third World countries) which have either been banned, withdrawn from the market, or heavily restricted in the parent country of the Pharmaecautical Company. In spite of knowing the reasons for the ban abroad, the Company not only continues to sell the product in India, but makes false claims about its safety.

The main reason for such unethical marketing practices is the weakness of legislation in India and the practical absence of a strong administrati machinery.

The menacing proportions of the problem of dumping banned drugs in developing countries caused the Non-aligned Summit to adopt a Resolution (see Tab 2.3) at its meeting in Colombo in 1976.

CONFERENCES, SEMINARS, ETC.

It is well known by now that Pharmaceutical Companies agree to defray the expenses of national and international conferences, seminars and scientific sessions. They host these meetings in the most lavish settings and shower the participants with expensive gifts. Obviously, the burden of these frightful extravaganzas are eventually borne by the poor consumers who have to pay higher prices for dubious products.

On a less visible level, pharmaceutical companies vie with one another to bribe doctors and chemists to promote their products. These incentives take many forms : expensive gifts graded according to the volume of sales, sponsorships for "study tours" abroad, or even straight cash incentives.

The giving of free samples and occasional "give-aways" has become a ·ı ine practice.

In contrast to this system adopted by the Government of India, the British Government sends individual notifications to all health institutions and medical practitioners, and gives detailed information about the reasons for a particular drug being withdrawn from the market. (See Table 8.1)

UNETHICAL MARKETING PRACTICES

In the absence of coherent policies, and the even more glaring absence of adequate monitoring and control machinery, India provides a wide-open market for pharmaceutical products. The competition is fierce. The profit-making objective is over-riding. Industry has no inclination or time to consider ethical alternatives. A close look at some of the practices indulged in by the pharmaceutical industry will suffice to show that ethics is the first casualty of competition.

Examples can be adduced by the thousands, but a few are given here only by way of being indicative :

- Glaxo Laboratories cited the authority of 'Lancet' to promote its sales of Ostocalcium B-12, even though there was no such endorsement of the product in Lancet.

- Boehringer-Knoll quoted UNICEF and used their logo to promote the use of streptomycin-chloramphenicol combination for diarrhoea treatment, whereas UNICEF actually promotes simple oral re-hydration therapy for most common diarrhoeas.

- Franco-Indian Laboratories misquoted Goodman and Gilman to promote their tonic, whereas Vitamin B-12 has no role in ordinary anaemia.

- S.G. Chemicals misquoted Goodman and Gilman and Martinadale to promote a combination of two dangerous drugs analgin and oxyphenbutazone, whereas, in fact, the texts warn against the use of this dangerous combination.

Banned in letter, not in spirit

The high dose EP combination drugs case offers a classic example of how medicines with proven negative effects on the foetus can remain indefinitely on the market, even after being banned. It also shows the six long years of effort made by concerned individuals and groups to get the stay order obtained on the ban by drug manufacturers vacated. More recent cases of banned drugs, fixed dose Chloramphenicol Streptomycin combinations and combination steroids offer grim testimony to an ongoing struggle.

The high dose estrogen-progesterone (EP) combination drugs case is a fascinating story of how India's drug consumer movement matured over six trying years in its struggle to get a once-banned drug re-banned - and against all odds. Not only does this story reflect the powerful resistance put up by the drug industry in collusion with a galaxy of gynecologists but also raises the discouraging question of the lacunae in drug legislation rendering impossible the implementing of a ban order in the virtual absence of a drug monitoring network and a communication link reaching out to chemists, doctors and unsuspecting consumers.

E.P. combination drugs are synthetic female hormone preparations which, in the absence of other substitutes, were propagated for use in the diagnosis and treatment of gynecological disorders during the 40s and 50s. Its issue was raised seriously for the first time in India in 1975 after a number of countries had already banned such high dosage combinations completely or had banned their use in pregnancy testing. The controversy then had centred around their association with congenital malformations of the foetus in women who had used them in the early stages of pregnancy.

The use of synthetic female hormones in pregnancy testing is based on a simple principle - a woman who misses her period due to reasons other than pregnancy would menstruate if injected with the female hormones. When the Australian Department of Health withdrew from the market a number of hormone pregnancy test (HPT) preparations both for their questionable safety and increasing availability of reliable alternatives, WHO informed all governments of this action. As a consequence, the government of India banned the use of these drugs as pregnancy tests, making it obligatory for the manufacturers to print a caution on the packaging in 1976.

Born with defects

In 1979, a furore resulted when a study conducted by Dr. B. Palaniappan, Professor of obstetrics and gynaecology at Kilpauk Medical College, Madras, highlighted the fact that high dose EP drug combinations were being taken by women in the mistaken belief that they could terminate an unwanted pregnancy. Of 52 mothers who had given birth to babies with congenital defects, 31 per cent had taken hormonal preparations during early pregnancy, often with a view to terminating it. The issue was re-examined by the government in consultation with concerned departments and professionals but the drugs remained on the market, albeit with a strong caution against use in pregnancy testing.

In practice, however, most manufacturers ignored this directive, and these drugs were readily sold by chemists over-the-counter for pregnancy tests and also as abortifacients. Such mass scale misuse of the drugs led a number of women and health groups to reopen this issue as one directly affecting women and a campaign spearheaded by Voluntary Health Association of India, Medico Friend Circle and Arogya Dakshata Mandal was launched on March 8th, 1982. Various groups pressed for various strictures ranging from rigid implementation of the "warning" rule to a complete ban of such drugs. As result of the campaign, the issue was reopened at the governmental level. On 18th March, 1982, the Drugs Controller first issued a directive for strengthening the warning on the packages and later directed that all EP formulations (other than oral contraceptives in low doses) would be banned for manufacture with effect from 31st December, 1982 and for sale from 30th June, 1983.

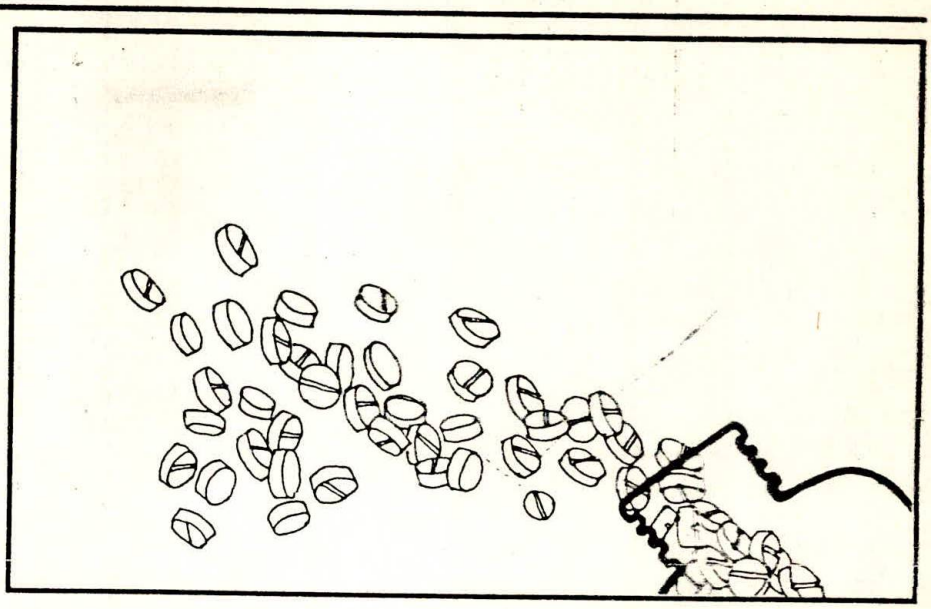
Where profits rule

To allow the manufacture of a hazardous drug for almost another one year before effecting its ban was to ignore the urgency of the lives at stake. Not surprisingly, the drug industry took advantage of this callous laxity to keep this profit-earning drug, with an annual sales of Rs 7 crores, well entrenched in the market. Aware that its market lay essentially in pregnancy testing and abortion induction and only marginally

in treating gynaecological disorders such as secondary amenorrhoea (long delay in menses), it sought and obtained stay orders against the ban in the Calcutta and Bombay High Courts on the technical grounds that the ban could be effective until the Drugs and Cosmetics Act itself was amended.

The ban order was effected on the extremely grave charge that high dose EP drug combinations could result in the birth of deformed babies if consumed by pregnant women. Yet, a stay lasting several years, was obtained on mere technical grounds permitting a hazardous drug to circulate in a free and open market comprising largely of an illiterate and ignorant public. The moral dilemma deepens when we add to an ill-informed public a large number of unqualified or ignorant prescribers and dispensers, a weak drug control infrastructure and drug manufacturers who have consistently failed to warn consumers in regional languages against its use during pregnancy, knowing full well the real dangers involved in self-prescription. The extent of the risk involved can be seen from the fact that roughly 6-12 lakh mothers could be affected by this exposure.

Campaigners who worked for the ban were hard put to establish that what was recommended was not a ban on all hormone preparations, a premise used by the drug representatives to mislead the consumers. High dose estrogen-progesterone fixed combinations were not to be confused with low dose combinations used for contraception. Once propagated for use in India in the 40s and 50s in the treatment of gynaecological disorders, the use of high dose EP drugs was no longer rational when only a small percentage of patients required hormonal preparations in the treatment of amenorrhoea, the major causes being directly traceable to malnutrition, anemia, tuberculosis and psychological stress. The issue that needed to be underscored was that under the guise of treating secondary amenorrhoea requiring female hormones, high dose EP drugs continued to be used mainly in pregnancy testing where the chunk of the profit lay.



In an obvious bid to counter the risks alleged and get the ban order rescinded, the Organisation of Pharmaceutical Producers of India (OPPI) put forth the following argument to the Drug Controller in a letter dated August 4, 1982 : "We are by no means defending the use of such drugs for pregnancy tests, but reiterating that if ---- a few uninformed individuals do use them for this purpose, the risk involved does not call for a total ban on these drugs." That the magnitude of risk is large can be seen from the categorical condemnation of these drugs in pregnancy testing by authoritative sources all over the world. Besides foetal malformations, these drugs have given false positive results in one out of five cases with 10 per cent cases resulting in unwanted abortions.

Views from foreign experts

Specific responses sought from experts from other countries proved revealing. Quoted below are some letters received on the issue :

Prof. M.D. Rawlins, Professor of clinical pharmacology, University of Newcast upon Type : "It is my view....that there is no place for high dose oestrogen-progesterone combinations either as therapeutic agents or as diagnostic tests. The epidemiological evidence demonstrating the risks of EP preparations are substantial; 'proof' would require a prospective randomised study which would be quite unethical to perform".

Dr. Stephen Franks, Senior lecturer in reproductive endocrinology, St Mary's Hospital Medical School, London:" I feel strongly that there is no justification for the use of these drugs in amenorrhoea, menstrual irregularities and other gynae disorders. If menstrual regulation is required in patients who have irregular or no periods then the treatment of choice is either the conventional low dose oestrogen-progesterone or progesterones alone. I might add that there is very little literature in the most reputable journals of gynaecology on the use of the high dose pill for amenorrhoea or other gynaecological problems. The reason is obvious : there seems little point in conducting trials on preparations containing high doses of steroids (with well recognised spectrum of side effects) when low doses of the same drugs or alternative agents are effective and widely available."

If the above responses are not sufficient to counter OPPI's second claim favouring high dose EP drugs for treating various menstrual disorders in the absence of substitutes in India, ICMR in 1982 had made the following recom-

mendation in consultation with concerned experts : "Fixed dose combinations of oestrogens and progesterones may be totally banned in the country, even for the treatment of secondary amenorrhoea as other substitutes are available for its management."

To ban afresh

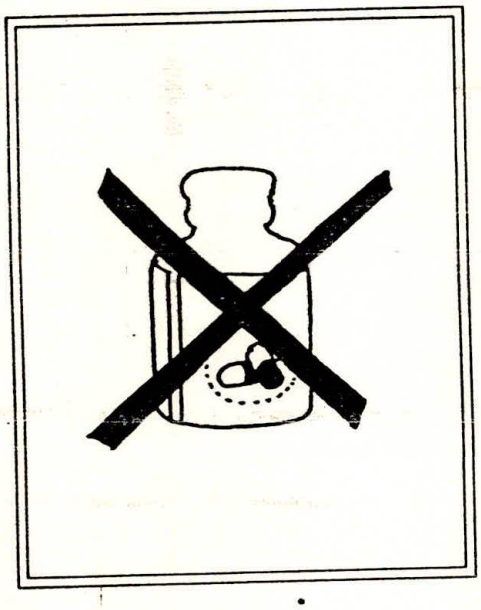
In 1984, Vincent Panikulangara, an advocate, filed a public interest litigation in the Supreme Court challenging the continuation of the production and sale of EP drugs in the country. When the matter came up for hearing in November 1986, the judges expressed surprise over the stay orders passed by the High Courts and came down heavily on the Drug Controller for delay and inaction on a matter concerning public health. The Drug Controller was directed to hold an inquiry on the issue through a public hearing soliciting the views of interested individuals, experts and consumer groups. The Drug Controller's opinion and the report of the hearing were to be submitted within six months.

Public notices for the hearings were inconspicuously inserted in newspapers and failed to state in clear terms that they were being held to decide whether or not to ban high dose EP drugs. The drug companies were shrewd enough to use professional bodies like the Federation of Obstetric Gynaecology Society of India(FOGSI) to act as their spokesman. Till the very end, FOGSI supported the stand of the drug manufacturers in stating that the drug was essential and absolutely safe. The statements of many eminent gynaecologists appeared based on personal anecdotal experience unsubstantiated by a single well designed study establishing statistical scientific evidence.

After a delay of several months following the four public hearings, a ban order was passed by the government. The Gazette Notification issuing the ban was released on 15th July, 1988. But no move was made to inform the chemists, medical professionals and ignorant consumers about the banned drug, clearly stating the brands and their manufacturers. Neither were any orders issued to recall banned products from the market, underscoring the apprehension that the consumption of the hazardous drug would continue for a long time even after the ban had been effected.

Permitting the manufacture and sale of high dose EP drugs as single ingredients in the same dose would be ridiculing and sabotaging the ban. If these drugs continue to be sold, both the manufacturers and the drug control authorities have to be held responsible. An unenforced drug ban is as bad as no ban at all. If this could happen to a watertight case like high dose EP, one shudders at the effects of other hazardous drugs doing their round in an uncontrolled market.

When ban orders are stayed



Withdrawal of hazardous and irrational drugs from the Indian market has proven to be an extremely difficult task. The story of combinations of steroids and Chloramphenicol-Streptomycin are yet more cases in point. Since the formulation of the new Drug Policy in 1986 these were literally the only drugs for which Gazette Notifications were issued by the Drug Controller of India, banning them on 3rd November, 1988.

The fact that a sub-committee of the Drugs Consultative Committee reviewing 34 combination drugs in 1986 had recommended that these two combinations be **immediately** weeded out is now history. This fact would never had been known if it weren't for the diligence of rational drug campaigners.

Several attempts were made to dilute these recommendations. From the original decision to weed out **"all** steroid combinations," the Drug Technical Advisory Board in 1982 watered it down to "all steroid combinations except for bronchial asthma". Full use was made of this loop hole. All products containing steroid combinations continued to sell and be used and misused for all kinds of senseless indications eg. insect bites, vague allergies, food poisoning etc. The chemists and doctors were not **warned** about the change in the indications nor the reasons for the change. In other words, most doctors and chemists were not even aware of the Gazette notification. It soon became clear that notifications issued by the drug control authorities and alterations made in the product literature by some manufacturers aimed to ensure "legal coverage" but not necessarily the "warning and stoppage" of misuse. No medical doctor who has

been prescribing a product for several years feels the need to read the package insert each time unless the warning is printed outside. Moreover, most doctors dont even get to see the medicines they prescribe as these are dispensed by the chemist or the hospital pharmacy.

Steroids

Since doctors prescribe drugs under brand names, many are unaware of the content and dosage of the various ingredients i.e. even the presence of steroid in a combination is sometimes not known. The tragedy becomes evident when one considers that many of the conditions for which these drugs are administered are chronic conditions requiring treatment for long periods. Prolonged use of steroids, according to therapeutic guidelines, should be preferably avoided because of the many associated side effects. Some of the known side effects are suppression of pituitary and adrenal gland functioning, high blood sugar and a predisposition to diabetes. Due to the suppression of the immune system, there is also a predisposition to infections such as tuberculosis, a thinning of bones leading to fractures, peptic ulceration, myopathy (muscle weakness), fluid and salt retention leading to hypertension, central obesity with "moon face" and "buffalo hump", behavioral disturbance, "steroid psychosis", hair growth on the face in women, acne etc. Besides the above, danger also lies in an abrupt stoppage of steroids since the suppressed adrenal gland fails to take up its normal functions immediately, leading to an abrupt fall in blood pressure and a sudden collapse which could prove fatal. Steroid doses have to be therefore administered according to need which may not be possible in fixed dose combinations. Also, it is crucial that stoppage of steroids following prolonged treatment be done gradually. Many patients taking steroid combinations for years for the treatment of asthma, arthritis, allergies etc. are often not aware that they are taking steroids, as no special warnings are given.

Withdrawal of irrational drugs from the market has proven extremely difficult ....

Unless considered life saving, systemic administration of corticosteroids is contra indicated (use not recommended) in patients with peptic ulcers, brittle bones, psychoses or severe psychoneurosis. They should also be used with great caution when patients suffer from congestive heart failure, diabetes, infectious diseases, chronic renal failure, uremia (high levels of urea in blood) or are elderly. Use of corticosteroids may mask the symptoms to such an extent that a true diagnosis becomes extremely difficult to make.

Many chronic asthmatic patients, unfortunately, are not even aware of the difference between a bronchodilator (air passage dilator) alone and a bronchodilator in combination with a steroid. Steroids do give relief in asthma and can be life saving in acute cases but creating dependency on them for mild attacks when more effective and safer alternatives exist is medical malpractice and drug misuse.

Several countries eg. Bangladesh, Turkey, Denmark, Saudi Arabia, Venezuela, Italy, Australia, Belgium, Greece, Norway, New Zealand, Singapore, Thailand, USA, India, Nepal etc. have either banned, withdrawn or severely restricted these fixed dose combinations of steroids.

On **3rd November 1988**, after much rethinking, these fixed dose combination drugs were ultimately banned eight years after they were initially recommended for "immediate weeding out" in 1980.

Ironically, history has repeated itself. The manufacturers have gone to court and obtained stay orders against the ban. Two years after the ban order, fixed dose combinations of steroids continue to be freely sold and there appear no signs of any attempt to get these stay orders revoked.

Since many old stocks continue to be sold in smaller towns and villages, a list of some formulations of fixed dose combinations of steroids is given below even though some manufacturers have decide to stop their production:

Brand Name	Content	Manufacturer
Betaklor	Betamethasone Chlorpheneramine	Velco
Betneton	Betamethazone Chlorpheneramine	Glaxo
Cortina	Dexamethasone Chlorpheneramine amine	Lupin
Cortophen	Prednisolone Chlorpheneramine	Uniloids
Histacort	Chlorpheneramine Prednisolone	SIRIS
Histapred	Prednisolone Chlorpheneramine	Wyeth
Kenamina	Triamcinolone	Sarabhai

Chloramphenicol-Streptomycin

The story of Chloramphenicol-Streptomycin is another woeful tale. While Chloramphenicol is meant for typhoid and Streptomycin for tuberculosis, a combination of these two has been promoted and sold for diarrhoea. Because the majority of diarrhoeas are viral based, antibiotics have no role to play in their treatment. An irrational drug combination only detracts from the main line of treatment which is oral rehydration. Besides being an economic waste, it also has a dangerous potential for causing fatal toxicity i.e. agranulocytosis in which the white cell count falls, making a person prone to infection, a condition which could prove fatal.

The emergence of drug resistance is yet another alarming problem. If Chloramphenicol is used for trival infections such as diarrhoea, a patient can become resistant to its effectiveness in the cure of typhoid for which it is actually meant. Not surprisingly, resistance of typhoid to Chloramphenicol has been reported from several parts of India. In the dysentery epidemic in West Bengal a few years ago, some 2000 children died as the bacteria, shigella, became resistant to Chloramphenicol as well as to many other drugs. Ironically, this drug is sold in an irrational combination with Streptomycin, rendering the latter unavailable for the treatment of tuberculosis which affects 10 million people in our country.

The Chloramphenicol Streptomycin combination along with Steroid combinations were banned on 3rd November, 1988. Together, they remain on the market due to stay orders obtained by the manufacturers. On this subject of the continued role of banned drugs which came up for public litigation as early as 1982, while pronouncing his judgement, Justice Potti said : " As between the profits of the manufacturers and the health of the consumers, the government has considered the former of greater importance."

What has been the fate of other drugs recommended for elimination since 1986? The Drug Price Control Order of 1986 only made prices more remunerative for the manufacturers.

For consumers, however, doubts loom large about the economy, safety and efficacy of these drugs.

For consumers, however, doubts loom large about the economy, safety and efficacy of these drugs. If stay orders can be obtained recurrently on banned drugs, it is difficult to envisage action on other hazardous drugs beginning with identification and then a painfully prolonged historical process of battling for their ban.

A list of banned Chloramphenicol-Streptomycin combination drugs is given below :

	Brand	Manufacturer
1.	Basiplon	Khandelwal
2.	Bichlorphenin	Medinex
3.	Chemistrep	Suprachem
4.	CHLOROSTREP SUSPENSION	Parke Davis
5.	Chlorocinstrep	Jagson Pal
6.	Chlorostrep Kapseals	Parke Davis
7.	Chlorostreptoseal	INDC
8.	Chlorsoin	Dolphin
9.	Cilastrep	Acila
10.	Contistrep	Continental
11.	Cooperstrep	Cooper
12.	Chloramphenicol Pharma and Streptomycin	Indiana
13.	Chloramphenicol and Streptomycin	Sarvodaya
14.	Chloramphenicol and Streptomycin	H.A.
15.	Cyperstrep	Cyper Pharma
16.	Diastrep	Sunways

VI

HAZARDOUS AND IRRATIONAL DRUGS

There are about 8,000 pharmaceutical units in India, which are producing approximately 60,000 drug formulations. many of these formulations are known to be irrational and even hazardous.

MOST DRUG COMBINATIONS ARE IRRATIONAL

* they increase cost unnecessarily
* they increase chances of drug interaction
* they make quality control difficult
* they make drug pricing and price control difficult
* they make monitoring of adverse drug reactions difficult
* they confuse consumers and medical practitioners alike.

The WHO List of Essential Drugs which consists of 250 drugs contains only seven combinations.(Technical Report Series 722, 1985)

In 1980, the Drug Consultative Committee, a statutory body constituted under Section 7 of the Drugs and Cosmetics Act (Act 23 of 1940), nominated a sub-committee of experts to study the rationality of 34 categories of fixed dose combination drugs. This sub-committee was to recommend to the DCC whether these combination drugs should be allowed or withdrawn.

The sub-committee formulated norms to allow combinations of drugs. These were :

a) if there is synergistic action
b) where there is corrective action
c) when two or more drugs are normally prescribed together and taken by the patient simultaneously
d) when the dosage of each of the drugs need not be individualized.
e) where a fixed-dose combination would ensure better patient compliance due to convenience of administration

f) where two or more drugs, prescribed separately may lead to non-ingestion of one of the drugs, thus adversely affecting the health of the patient

Conversely, norms for NOT allowing fixed dose combinations were formulated as follows :

a) where adverse interactions may occur
b) when one of the combined drugs becomes toxic or prolonged use
c) when abruspt withdrawal of one of the drugs may cause withdrawal symptoms
d) if sub-therapeutic doses are used in the absence of clinically demonstrable synergism
e) when pharmacokinetic behaviour of the individual agents is grossly different.

34 categories of combination drugs were evaluated and on the basis of these criteria, the sub-committee recommended a ban on 23 combination drugs and gave reasons for recommending the ban. Sixtten categories of these drugs were recommended to be weeded out immediately, while 7 of the categories were recommended to be weeded out over a specified period.

The list of 23 combinations to be weeded out is given on pg.

The sub-committee submitted its report to the Drug Consultative Committee on the 10 October 1981. It was also presented to the Drug Technical Advisory Board, and to the Ministry of Health and Family Welfare, which accepted these recommendations in 1981. The Drug Technical Advisory Board (a statutory body constituted under Section5 of the Drugs and Cosmetics Act of 1940) recommended banning of eighteen fixed dose combination drugs. It decided to prohibit the manufacture of fixed dose combinations of bronchodilators. antihistaminics and tranquilizers with corticosteroids as early as October 1980.

By some incomprehensible logic, the Drug Technical Advisory board, consisting of exactly the same members reversed its decision on December 31, 1981 and allowed the sale of the products which it had earlier considered

to be dangerous. At this point of time, it claimed that it was necessary to obtain wider medical opinion.

The Editor of MIMS in his editorial in the issue of February 1982 (Vol. 2 No.3) on the "somersault on steroids" said that "they must have had very extraordinary reason to

- reverse their own earlier decision
- ignore the advice of the Drug Consultative Committee
- consider the opinion of the whole battery of eminent and distinguished medical specialists from research institutions as inadequate so as to ask for further details and wider medical opinion."

The consumer who is exposed to these hazardous drugs is entitled to know the reason/s for the volte-face. This has, however, not been forthcoming.

RECOMMENDATIONS FOR WITHDRAWAL OF HAZARDOUS, IRRATIONAL AND THERAPEUTICALLY USELESS DRUGS

* All existing drugs available in the Indian market should be screened by an appropriate, impartial authority, such as the National Drug Authority recommended by the Hathi Committee.
* Those drugs which have life-threatening or serious side-effects, and for which safe alternatives are available should be banned with immediate effect.
* No fixed dose combinations should be allowed if an alternative single ingredient drug is available, except in accordance with the norms laid down by WHO.
* Information regarding the action taken by other countries to ban hazardous and irrational drugs, and their reasons for doing so (together with supporting medical/research evidence) should be made available to the public.

* The criteria for the withdrawal of hazardous and/or irrational drugs which have an unacceptably high risk factor, which are prepared in sub-therapeutic doses, or which are marketed in irrational combinations, should be widely publicized for the benefit of medical practitioners and the general public. The criteria used by the Scandinavian countries,Sri Lanka,Bangladesh,Mozambique etc. can be used as guidelines (see Appendix)

* Once a decision is made that a particular drug or drug combination is hazardous or irrational or useless, immediate steps must be taken to destroy all existing stocks and to stop further production immediately.

* Legislation should be suitably modified to ensure that Courts do not grant stay orders against decisions to destroy existing stocks of hazardous drugs, or to stop further production of such drugs forthwith. This is necessary in the interest of public health.

* After screening by the proposed National Drug Authority, only those drugs which are approved, should be re-registered with the Government. All other products should be withdrawn from the market, and further production banned. In line with the practice followed by other countries, it should be made mandatory for all drugs to be re-registered periodically e.g. every five years.

Laws that protect

Various laws exist for the protection of public health. But a lack of knowledge or a neglect of their provisions often results in drug induced ill health. Dr S.G. KABRA describes some of the cases that suffer due to a neglect or a non implementation of the law and the efforts made to bring breaches before law courts.

There are several laws, the provisions of which are meant to regulate health care facilities for the benefit of the public. Indifference to or neglect of these legal provisions engenders a tacit nexus between offenders and the authorities. It is therefore necessary to identify these legal provisions to create awareness and to evolve a strategy to ensure that the authorities entrusted with the enforcement of these provisions do in fact do so. Enumerated below are several laws with a direct bearing on public health.

Drugs and Magic Remedies (Objectionable Advertisement) Act,1954

Its statement of objects and reasons :

"In recent years there has been a great increase in the number of objectionable advertisements in newspapers or magazines or otherwise relating to alleged cures of venereal diseases, sexual stimulants and alleged cures for diseases and conditions peculiar to women. These advertisements tend to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances or to resort to quacks who indulge in such advertisements for treatments which cause great harm. It is necessary in the public interest to put a stop to such undesirable advertisements. This bill is intended for this purpose."

Taking into account specific provisions, Section 3 of the Act states :

"Subject to the provisions of this Act, no person shall take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

a) promoting miscarriage in women or prevention of conception in women; or
b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
c) the correction of menstrual disorder in women; or
d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule,* or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act.

(* The Schedule appended to the Act lists 54 diseases, disorders and conditions which cannot be advertised.)

Section 4 of the Act states :

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains matter which : a) directly or indirectly gives a false impression regarding the true character of the drug; or b) makes a false claim for the drug; or c) is otherwise false or misleading.

No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes in Section 3. Under Section 9A of this Act, an offence punishable under this Act is a cognizable one.

A test case

Offending advertisements are a very common feature in the print media in India. To invoke the provisions of this Act, we initiated a test case in a magistrate's court in Ajmer against the then Editor and Publisher of The Hindustan Times, Delhi (Khushwant Singh and Dr Hans Raj respectively) for an advertisement by Dr Sablok which appeared in the newspaper. The case was registered only after letters written to the editor, drawing attention to the provisions of the Act went unheeded, the advertisements appearing unchecked. Though the case was ultimately dismissed through default, it did succeed in ensuring that all three defendants

appear in court whenever required through the execution of a bond and surety. The case also succeeded in establishing the following :

* The offence is cognisable. Any court in whose jurisdiction a newspaper or magazine is sold or circulated has jurisdiction in the case if the offence is deemed to be committed locally and the cause of action local

* The editor and publisher along with the advertizer are all equally liable to offence.

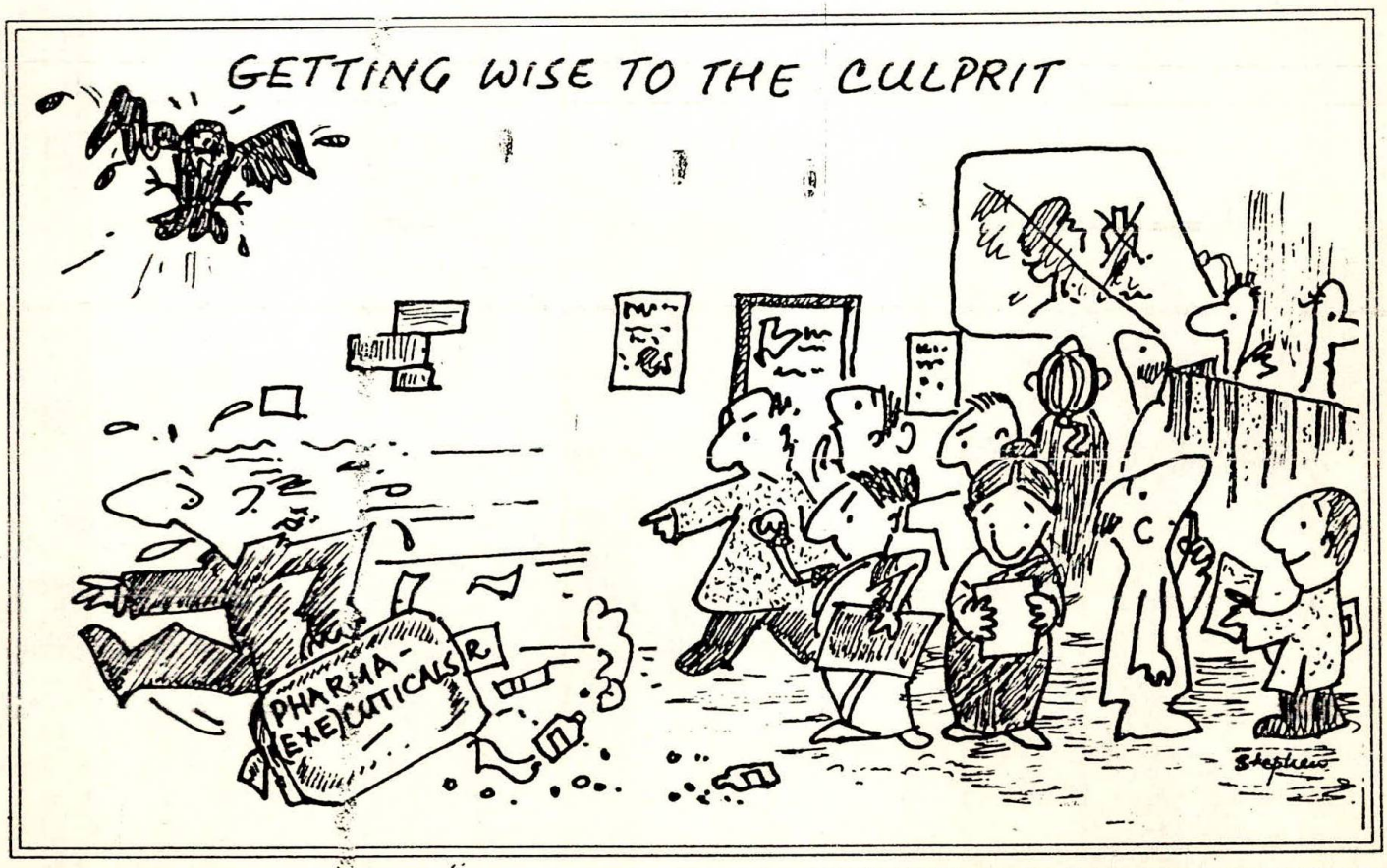
Efforts at implementation

After my deputation to SDM Hospital, Jaipur, I wrote letters to the Director, Health Services, Inspector General of Police and Health Secretary of Rajasthan, drawing their attention to the provisions of the law and its breach. There was no response. Marudhar Mridul, a leading lawyer of Rajasthan, agreed to file a writ petition which was decided on September 1989. The Hon'ble Mr. Justice SN Bhargava issued a directive to the Inspector General of Police, Rajasthan, to establish a special cell to monitor such advertisements in the print media and initiate prompt action against the offenders. Some cases have been registered by the police. Some of the newspapers have stopped carrying such advertisements. Much still remains to be done to fully get the court's order implemented.

Drugs and Cosmetics Act

This Act provides for the control and regulation of safe production, distribution and sale of drugs and cosmetics. Powers to enforce the provisions of the Act are vested in the State Drugs Controllers whose activities are coordinated by the Drug Controller of India who in turn ensures the uniform application of its provisions throughout the country.

Despite its existence, precious little has been done to implement its provisions. A case in point is drug induced blindness. Eye drops and ointments with steroid content are widely used for allergic conjunctivitis. Due to prolonged use of eye drops, I have known several cases turn blind through drug induced glaucoma and cataract. Though every text book of medicine and pharmacology mentions that steroids should not be used for prolonged periods, no warning to this effect is written on preparations. The implications are specially ominous when one considers the fact that self medication is a very common phenomena. Even well meaning parents regularly administer eye drops to children, oblivious of the dangers. The six year old son of a compounder first put me on the trail which led me to compile over 18 cases of blindness in



one year due to prolonged use of steroid - containing eye drops. None had been warned.

Letters were written to apprise the Drug Controllers of Rajasthan and India of the cases in point. Articles were written in the lay press, giving case histories of the patients to highlight the dangers of steroids in eye medicines. One such article which appeared in Rajasthan Patrika, a Jaipur daily, attracted the attention of the local government. A committee of experts was appointed to investigate the facts and to submit their report.

The committee recommended that all steroid eye preparations should carry a warning that the medicine's prolonged use may lead to blindness due to cataract, glaucoma or fungal infection. The State government forwarded the recommendations to the State Drugs Controller, who in turn, instead of acting under the provisions of the law, forwarded it to the Drugs Controller of India. The Central Drugs Controller returned it to the State Drugs Controller, agreeing with the recommendations of the Committee. The State Drugs Controller still did not act. Even the report of the Committee was not made public.

A writ petition was then filed in the High Court on 20th January 1989. Hon'ble Mr. Justice Mahendra Bhushan Sharma and Mr. Justice I.S. Israni directed the Drugs Controller of Rajasthan to ensure the printing of the necessary warning on all steroid-containing eye preparations. Their lordships quoted extensively the specific rules under which the State Drugs Controller had the power to implement the provisions so as to allay any impression to the contrary.

Though a number of steroid preparations now carry a warning, many still do not. Despite a large number of cases brought to his notice, no public warning was issued by the Drugs Controller against the prolonged use of steroid-containing eye drops. Partially implemented, the court order has not been followed in true spirit.

Banned and bannable drugs

According to a writ petition filed under the Drugs and Cosmetics Act, the decisions of the Drugs Consultative Committee and the Drugs Technical Advisory Board, the highest technical bodies under the Act, once accepted and communicated by the government, are binding on all health authorities and government doctors. A drug that has been declared harmful or irrational by the technical bodies cannot be purchased or prescribed by any government authority. This is irrespective of the fact that government orders prohibiting manufacture and sale of the drug might have been stayed by a court. Prohibiting the manufacture and sale of a drug and directing all government doctors **not** to prescribe a drug found to be harmful are two different consequences that flow from the decisions of the two technical bodies.

An interesting observation made by the court during the hearing was that a stay order by one High Court is not automatically binding on the other High court. Evidence of banned drugs still being purchased, prescribed and reimbursed by health authorities was produced before the court. The case is still pending before it.

Atomic Energy Act, 1962

The Atomic Energy Regulation Board constituted by the Central Government under the provisions of the Act have codified the mandatory safety provisions for diagnostic x-ray units. The safety code details the mandatory measures necessary to prevent unnecessary exposure to radiation. Yet no state government machinery exists to ensure that these safety provisions are followed. The result : no x-ray units follow them. With commercialisation of diagnostic x-rays and their rapid proliferation, there is grave danger to the population. After having written to all authorities bringing to their notice the mandatory provisions and having failed to persuade them to fulfill their responsibilities under the Act, a writ petition has been filed in the High Court with notices issued to the central and concerned State government.

The Indian Medical Council Act and the Medical Degrees Act

Provisions of these two Acts have been invoked to prevent advertisements and unethical practices, professional misconduct and the use of unrecognised or fake degrees by doctors. The State Medical Council must be made to do its duty to regulate and supervise the professional conduct of the doctors registered with it and to ensure ethical standards of medical practice.

The Insecticides Act.

The provisions of this Act have been invoked to prevent the availability of the deadly pesticide, aluminium phosphide, in the open market. Numerous articles have been written to bring to light a large number of deaths that result every year from aluminium phosphide. All the concerned authorities have been warned. Questions have been raised and answered in parliament. Though there are widespread assertions on the illegality of open market sale of aluminium phosphide, nothing has been done to prevent it. A writ petition, it is felt, should now be filed to prevent thousands of deaths due to this deadly pesticide.

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III

CONCEPT OF ESSENTIAL DRUGS

Confusion abounds in the minds of the consumers, health personnel and policy makers as regards **drug demands** and wants created by market forces as opposed to genuine drug needs.

The concept of essential drugs aims at providing much needed help in this selection process and in the way out of the 'pill jungle'. There is an urgent need for a clear understanding for what is meant by **rational, essential** and **priority drugs.**

The WHO Expert Committee on Essential Drugs attempted to provide guidelines to member countries to help them draw up a list of essential drugs:

> "It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population".
>
> "Drugs included in such a list would differ from country to country depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources and genetic, demographic and environmental factors". (See Annexure 3.1).

It is evident, therefore, that the key elements in the concept of essential drugs are that, that they be

- RATIONAL
- SCIENTIFICALLY PROVEN
- THERAPEUTICALLY EFFECTIVE
- ECONOMICAL and
- SOCIALLY ACCEPTABLE

Drugs have a definite role in health care. They are meant to help people and not to serve economic interest.

According to Health Action Internation (HAI) an international pressure group working towards rational drug policies and rational drug use, all drugs must:

1. **MEET REAL MEDICAL NEED**
   This means that their use is likely to improve the quality or extent of medical care.

2. **HAVE SIGNIFICANT THERAPEUTIC VALUE**
   This means that they must do what is claimed for them, and that patients will benefit from that.

3. **BE ACCEPTABLY SAFE**
   This means that their likely benefits must far outweigh risks.

4. **OFFER SATISFACTORY VALUE FOR MONEY**
   This favours the introduction and use of drugs which work as well as other medicines, but cost less.

AIDAN reiterates the above and it feels that the **Selection of Drugs** from amongst the different therapeutic categories should be based on

MEDICO SOCIAL JUSTIFICATION:
it should keep in mind -

- THERAPEUTIC EFFICACY
- SAFETY
- COST OF TOTAL COURSE OF DRUG TREATMENT NOT MERELY UNIT COST OF A DRUG
- EASE OF ADMINISTRATION
- LIMITED POTENTIAL FOR MISUSE
- INDIGENOUS PRODUCTION
- EASE OF TRANSPORT. STORAGE
- LONG SHELF LIFE

ESSENTIAL DRUGS RELATED DEFINITIONS

In drawing up the essential drug programme, it will be helpful to bear in mind the following concepts :

RATIONAL DRUGS are those drugs which are accepted world-wide and included in the standard text books of medicine and pharmacology.

ESSENTIAL DRUGS are those selected by each country according to health needs to its people. The 'Criteria of selection of essential drugs' suggested by WHO have been accepted by over 80 countries. In addition to these criteria, Norway has based the selection of essential drugs on **"efficacy", "safety"** and **"medical need".** This **medical need** clause precludes the registration of any new drug which is not "more effective" than one that is already in use, and which is not **safer** and **cheaper** than drugs currently used.

PRIORITY DRUG LIST are drawn from among the essential drug list to give priority to drug **production, distribution** and **availability for use** in diseases having

- greater mortality (death)
- greater morbidity (illness)
- severe sequelae (after effects)
- communicability (T.B,Leprosy)

and for use in national programme such as T.B. and Malaria eradication, Blindness control, Goitre control, Immunization, etc.

GRADED ESSENTIAL DRUG LIST drugs are needed for different levels of health personnel and health institutions. Bangladesh prepared such a graded list of essential drugs which indicated 12 drugs for use at village level; an additional 33 drugs for use at "thana" level; and 105 drugs for restricted and specialized use. (See Annexure 3.3).

ADVANTAGES OF THE CONCEPT OF ESSENTIAL DRUGS

Preparing a rational list of essential/restricted drugs has several advantages; medical, economic, social and administrative.

MEDICAL ADVANTAGES

- It is **medically, therapeutically** and **scientifically sound,** and it ensures rational use of drugs.
- It **limits** the use of irrational and **hazardous** drugs and **decreases** the risks of **iatrogenesis.**
- It **improves** the possibility of **monitoring adverse drug reactions** in patients.

ECONOMIC ADVANTAGES

- It is economically beneficial to the nation because it **prevents wastage of scarce resources** on **non-essentials.**
- The **economies of scale** achieved in the larger production of priority drugs **brings down their prices.**
- It **curtails** the **aggressive marketing of non-essential formulations.**
- It is economically beneficial to the patient **because it prevents wastage on irrational** and non-essentials.

SOCIAL ADVANTAGES

- It **responds** to the **real health needs** of the **people.**
- It facilitates the **dissemination of correct information** about the drugs to health personnel, medical practitioners and consumers in general.
- It **makes it imperative to draw up priorities** to meet the most urgent needs of the people for essential health care.

ADMINISTRATIVE ADVANTAGES

- It is **organizationally sound** because it **makes quality control easier** because of the limited number of drugs to be monitored.

- § It facilitates the streamlining of production, storage and distribution of drugs, because of the smaller number of drugs involved.
- § It helps in the clean identification of the drugs.
- § It facilitates the fixing of prices as well as the revision/withdrawal of excise duties, sales tax etc.

*****

RATIONAL DRUG USE

Drugs are the hallmark of Modern Medicine. The 'healing professions' throughout the ages have always used 'natural' or 'synthetic' products for their medicinal value, to treat various common ailments of people. Drugs, however, have never in the past dominated the medical scene as they have done in the second half of this century. Today, the 'pill for every ill' culture is well established. It has ensured that we are probably the most 'drugged generation' of all times. Not a very healthy thought!

Throughout the centuries, philosophers, social activists and concerned doctors have warned against the dangers and problems of overuse or misuse of drugs by doctors and the people.

The Indian Situation

The Indian Council of Medical Research and the Indian Council of Social Sciences Research set up a joint study group to study the health situation in India and evolve an alternative strategy for our commitment to 'Health for All by 2000 AD'. This high powered expert committee had some very interesting things to say about the present situation of drugs and prescribing practices, in their Report published in 1981.(1)

"One of the most distressing aspects of the present health situation in India is the habit of doctors to over prescribe glamorous and costly drugs with limited medical potential. It is also unfortunate that the drug producers always try to push doctors into using their products by all means - fair or foul. These basic facts are more responsible for distortions in drug production and consumption than anything else."

Irrational Drug Use - Some dimensions

To understand the principles of Rational Drug Use, one needs to first identify and appreciate the elements of irrationality in the present situation. A spate of reports appearing in our newspapers and periodicals high-light these elements. Of all of them, however, the report of the recent 'Lentin Commission' and its shocking findings are the most telling.

Irrationality in drug use arises out of three sets of factors:

A. Irrationality in drug production, marketing and availability.

B. Irrationality in prescribing practices of doctors and health workers.

C. Irrationality in drug use by the consumber public.

All these taken together result in the situation we find ourselves today.

A. Irrationality in drug production, marketing and availability.

* Industrial Policy

Drug policy continues to be part of the industrial policy and not part of the health policy. Industrial growth and profit margins determine the policy and not health needs of the people.

* Over abundance

There is a plethora of drugs produced in the country. The Hathi Committee recommended 116 as essential and the WHO says 200 are necessary. At present there are over 70,000 formulations in the country.

* Quality of drugs

Twenty percent of the drugs available in the country are substandard and spurious. Many are adulterated. Many are old and being sold after the expiry dates are over.

Turmeric powder in tetracycline and poor quality intravenous fluids have been reported. The substandard 'glycerol' in J.J.Hospital highlighted by the Lentin report is another example.

* Unwanted drugs

The formulations available include the following:

i. Banned drugs: Drugs which have been banned in many countries such as Lomotil and Clioquinol.

ii. Irrational combinations:

Formulations which have combinations that are antagonistic or irrational. The Hathi Committee had suggested weeding out of atleast 23 such groups of preparations. These were finally banned by a gazette notification in July 1983 but continue tobe available.

iii. Hazardous or Bannable drugs: Hazardous drugs which should not be available without prescription or adequate medical supervision. Preparations containing analgin, oxyphenbutazone and cortico-steroids are the commonest examples (Refer A to Z of Drug use - page 31)

iv. Drugs promoted for indications that are not clinically proven or are potentially dangerous, eg., promotion of EP Forte combinations for pregnancy testing and induction of abortion even when there is well documented evidence that risk of foetal deformity is increased by the use of these preparations. (now banned since 1988 June 30)

v. Costly Drugs: Drugs which are inflated in cost by inclusion of costly, additional, often unnecessary ingredients or by cosmetic embellishments in manufacture and packaging. Tonics and high protein foods especially baby foods are good examples.

* Wrong Priorities

There is over-production of unimportant drugs or drugs for the rich while drugs for some common health problems are in short supply. Tonics, vitamins, horomne preparations and high protein substitutes are being produced in wasteful abundance while drugs for leprosy and tuberculosis (two major public health problems) are produced at one third and one fourth of actual requirements. Similarly Vitamin A and many vaccines urgently required for child care programmes are frequently in short supply.

* Over-the-counter sales

Sale of drugs over-the-counter without doctor's prescriptions or the necessary statutory checks are not at all uncommon. This results from inadequate drug legislation and even more inadequate drug controls. Over-the-counter unauthorised sales of prescription drugs which now-a-days do not even have the precautionary product information make the situation even more hazardous.

* Escalating Prices

Price control policies have been both inadequate and ineffective and hence the cost of drugs has been constantly escalating. With liberalization policies of the present government this is bound to increase further. The purchasing power of majority of our patients is limited. With increasing prices, patients are forced to buy only part of a prescription or go in for sub-standard alternatives promoted by the drug shops.

B. Irrational Drug Prescribing

Doctors, nurses and health workers often prescribe or administer drugs irrationally. The types of irrational drug prescribing has been classified as follows: (4)

Type of irrational drug use	Occurs if a drug is prescribed when:
1. Extravagant prescribing	A less expensive drug would provide comparable efficacy and safety
	Symptomatic treatment of mild conditions divert funds from treating serious illness
	A brand name is used where less expensive equivalents are available.
2. Overprescribing	The drug is not needed
	The dose is too large
	The treatment period is too long
	The quantity dispensed is too great for the current course of treatment

Type of irrational drug use	Occurs if a drug is prescribed when:
3. Incorrect prescribing	The drug is given for an incorrect diagnosis
	The wrong drug is selected for the indication
	The prescription is prepared improperly
	Adjustments are not made for co-existing medical, genetic, environmental or other factors.
4. Multiple prescribing	Two or more medications are used when one or two would achieve virtually the same effect.
	Several related conditions are treated when treatment of the primary condition will improve for cure the other conditions.
5. Under prescribing	Needed medications are not prescribed
	Dosage is inadequate
	Length of treatment is too brief.

There are many background factors which lead to such prescribing practices.

a. Inadequate training

Doctors, nurses, pharmacists and health workers may be inadequately trained in the use of drugs. The training may be theoretical and not geared to the practice of prescribing in the real life situation. Technical minutiae may be stressed at the cost of information on cost, social context and hazard.

b. Inadequate continuing education

The doctor, pharmacist, nurse or health workers in field practice are inadequately supported by a process of continuing education by their professional associations and training institutions. Once graduation is over, there is little opportunity to refresh one's knowledge of drugs and medical matters through unbiased sources of information.

c. Unethical medical advertising

Medical advertising of drugs has been more often than not, found to be full of unproven claims of efficacy. In addition, promotional literature all over the world by the same company for the same drug has been found to be vastly different. Facts are withheld or modified. Statistics are used in a biased manner. Drug company sponsored misinformation is not uncommon.

d. Prescribing for prestige/power

Doctors especially often prescribe extravagantly as a sign of 'prestige' and 'power'. In India people often consider a good doctor to be one who gives a long, costly prescription, in keeping with his list of degrees. Many doctors succumb to this cultural status symbol. A vicious cycle is maintained thereby.

e. Busy outpatients

Many of our institutions are understaffed especially those run by the government. The queues at the out-patient clinic are long and there is a heavy rush. Lack of time to make a good clinical judgement often results in an irrational prescription including drugs for all eventualities.

f. Inducements by medical companies

Misinformation is not the only method by which doctors are made to prescribe irrationally by medical companies. Sales promotion includes a host of practices such as unethical trade discounts, bribes, gifts, sponsorship for conferences and travel. The commercial proposition induces many doctors to prescribe unethically.

g. Unauthorised prescribing

Health workers and practitioners of other non-allopathis systems of medicine are often by virtue of their training unauthorised to prescribe all the drugs in the medical armamentarium. Health workers may be trained to prescribe only a few drugs. Too often they get a larger number of drugs and dispense them to get the community's approval and get greater prestige. Many traditional medicine practitioners, dispense allopathic drugs with little background training or knowledge.

h. Drugs as a substitute for caring

Drugs have become a symbol of the new medical culture, where treatment is primarily drug oriented and all other aspects of 'caring' and nursing of the patient are relegated to the back ground. When simple home remedies like hot water gargles and nursing procedures can provide relief to many symptoms of the patients, doctors prefer to prescribe symptomatic drugs instead, thus increasing drug consumption irrationally.

i. Drug use by Consumer Public-irrational dimensions

i. Self-medication.

Medication by patients themselves is not an uncommon problem. Either they are too poor to consult doctors or because of the easy availability of drugs they medicate themselves, encouraged by the pharmacists, advertisements, peer group information or advice of family members. A survey conducted by the National Institute of Nutrition in the twin cities of Hyderabad and Secunderabad covering 10 percent of the 330 retail Pharmaceutical shops showed that self-medication rate was an alarming 46 percent.

ii. Use of unutilized drugs.

It is a very common habit among the consumer public to take a medicine, not as the doctor has directed by just enough to feel better. This is often the case with antibiotics and particularly for children. Unused medicine is kept in the home pharmacy and given to one or other of the children or family member who gets the same symptoms, next. Unused or unutilized portion of prescribed medicine is often kept beyond expiry date. If proper storage precautions are not taken, it may also get denatured. Use of such medicines is a major cause of untoward reactions.

iii. Inadequate labelling or storage of medicine.

Medicines prescribed by doctors are often inadequately labelled by the dispensing pharmacist. Storage instructions are not very clearly explained to the patient. The medicine cupboard is often a source of irrational drug use. Children may have access to it and this may lead to accidential poisoning.

iv. Peer group exchange

Consumers of drugs often advise relatives, friends and neighbours about the benefits a particular prescribed drug has given them. They are advised to take these drugs for what is thought to be a similar complaint or disease. This peer group exchange is often the cause of much irrational drug use by the lay public.

v. Status symbol drugs

Capsules, injections and tonics have become status symbol drugs. They are thought to be more effective and also being costlier are considered to be of greater prestige value. Patients often demand or pressurise their doctors to prescribe one or more of these and doctors often comply with the request to retain the patient and family in their practice.

vi. Multiple consultations

Patients often go to many doctors seeking quick relief of their symptoms. The doctors are not often aware that consultation with them is one of many such concurrent events. Generalists and Specialists may both be consulted. Practitioners of different systems may be consulted simultaneously. Different medicines given by different doctors are then consumed with the hope of getting relief. When relief does occur it is not easy to decide which medicine brought it about.

Multiple prescriptions then become a way of life when symptoms recur. Many drugs may potentiate one another. Others may work at cross purposes. When the consultation is of plural systems the confusion is worse.

vii. Inadequate Consumer Awareness

Probably one of the key factors for irrational drug use by consumers is the absence of awareness of drug use, misuse and the effects of overuse. Consumer education is next to absent in India. Due to loopholes in the existing laws, precautionary product information is not supplied with the medical products. The media, the medical profession, the educational system and the social welfare agencies concentrate on the misuse of psychotropic substances and drug abuse. Misuse, overuse or abuse of commonly prescribed drugs is not considered to be an adequately serious problem for consumer education. The problem is further compounded by a large illiterate population and the need of such efforts to be in multiple languages when they do get organized.

Rational Drug Use

* Means practice of socially conscious, relevant and scientifically sound medicine.

* Emphasises the selective use of drugs based on

- Essentiality
- Efficacy
- Safety
- Easy availability
- low cost
- Ease of administration
- Adequate quality
- Preferably of indigenous production

* Recognises the concept of essential drugs and the concept of graded lists for different levels of health personnel.

* Recognises the non-role of drugs in certain conditions and the role of alternative systems of medicine in some other conditions.

* Accepts a conscious decision not to use certain drugs which are hazardous or bannable or banned and use all others only when they are really needed.

* Means prescription with awareness, to avoid as far as possible iatrogenesis which includes

- drug induced problems,
- drug interactions,
- adverse drug reactions and
- emerging drug resistance.

* Recognises the rights of health personnel and consumers to unbiased drug information and its effective communication.

Drugs have allayed pain and suffering over the centuries. They have helped many live more comfortable, productive and meaningful lives. All of us committed to the health movement must ensure that drugs should continue to play their limited but useful role in medical service.

And it will only be if

The public;
Governments;
drug industries;
planners;
health professionals;
medical colleges;
pharmacy colleges;
nursing colleges;
drug controllers;
pharmacists;
journalists and media persons;
and
teachers and educators;

Commit themselves to promoting a Rational Drug Use.

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VOLUNTARY HEALTH ASSOCIATION OF KARNATAKA

"RATIONAL DRUG THERAPY"

What is Rational Drug Therapy?

Rational Drug Therapy is the art and science of prescribing the best suited drugs to individuals who need them, not to those who merely want them.

The Drugs used will be

* Efficient
* Safe (With low incidence of side effects)
* Low Cost
* Easy to administer

The person who prescribes will have knowledge, skill and concern for the patient. Rational Drug Therapy requires firstly accurate diagnosis.

Are a number of tests necessary for accurate diagnosis?

No, not always. Tests are time consuming. They also add to the cost of treatment. Ordering many tests is a poor substitute for accurate history taking and physical examination.

What prevents accurate diagnosis?

Situations like an over crowded O.P.D. Accurate diagnosis is only possible where doctors can spend enough time with the patient.

In choosing a drug what are the points one should consider?

For most illnesses use the cheaper preparations as the drug of first choice.

Use more expensive ones for those who do not respond to the first drug or those who develop adverse reactions to it.

Consider all aspects together

Some times a poor patient can afford only a less powerful drug. In a life threatening situation cost will not be the main consideration.

Remember these

Most potent drugs are not necessarily the best.

The most rational drug therapy in a given situation is not always the ideal.

When do doctors become irrational in their use of drugs?

According to WHO, there are 75 ways doctors misuse drugs. The commonezt is overuse of drugs. They prescribe?

* Too large quantities
* For too long duration
* Entirely unnecessary drugs
* Too many drugs at the same time for the same problems

What happens when patients overuse drugs?

The following are the results of overuse of drugs:

* Waste of drugs
* Wastage of money
* Increased chances of adverse reaction due to toxicity and drug interaction
* Confusion in the minds of patient.

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Why do some doctors over prescribe?

Doctors over prescribe when they do not have enough time and facilities to do a proper diagnosis. They try to make the patients happy by over prescribing.

Sometimes doctors do not have enough knowledge of drugs and their prescribing principles, due to lack of continuing education.

At other times it is the patients who pressurize doctors into overprescribing. Because many patients believe that a good doctor gives heavy prescriptions.

Very often advertising and sales promotion techniques used by the drug companies influence the doctors. They often receive incomplete information and excessive amount of samples.

By prescribing a drug where none is needed doctors try to retain the patient's good will.

Some doctors prescribe the latest drugs just to prove that they are update.

Often tie ups exist between local chemists, shops and doctors Accordingly, doctors advise you to go to a particular chemist or prescribe a particular product more often.

Are there times when doctors also underprescribe drugs?

Yes, Doctors sometimes do fail to prescribe sufficient of the right kind of medicines. This is because:

* The medicines are too costly for the patient

* The doctors do not have enough information on the drugs

* Non-availability of drugs (Anti T.B.,Leprosy drugs)

Drugs are being rapidly added. Medical information therefore is radically changed every ten years.

From where do the doctors get their information on drugs?

As WHO says "Drug advertising and contacts with representatives of pharmaceutical firms are often the main sources of information for a physician on drugs and some time the only ones. Such information is always influenced by commercial interest. The basic theme of promotional material is that a drug will provide the answer to a distressing clinical problem. Little attention is given in aiding the physician to use his clinical judgement. Unfavourable aspects and complications of such treatment rarely receive sufficient attention".

In developed countries, there is one drug representative for every 30 doctors and in developing countries eg.Tanzania, one for every 4 doctors. No wonder most of the profits made by drug companies is from third world countries. According to Tom Heller in Poor Health, Rich Profits some of the multinationals have been comfortably overpricing their products anywhere 20% to 6000%.

Drug companies also try to influence the doctors through gifts, calendars and posters. They usually fund medical conventions, dinners and so on.

Do you mean to say that doctors do not receive impartial information on drugs?

Yes unfortunately there has been no organised attempt to give doctors impartial information. Any information on drugs become all the more difficult to get in rural areas.

Information on drugs is certainly available in the pharmacological text books. However, brand names of these drugs and the comparative impartial analysis of the brand named drugs are not available to the prescriber.

What about the training the doctors receive? Does it not help doctors to make the right choice of drugs?

Unfortunately medical training does not train the future physician to judge a preparation critically. Encyclopaedic knowledge of pharmacology does NOT include rational drug therapy (where cost is an important criterion)

NOR does it include conscious "immunization against the half truths of persuasive industrial advertising".

NOR does it give due importance to non drug therapies, and is not open to other simple and effective form of therapy.

There are 30,000 brand or trade named drugs in India, many of them are "me too" drugs i.e. being very similar to the ones they are supposed to have replaced. Many are combination drugs. The various doses of the drugs combined are very different from recommended doses in the pharmacology books and therefore very irrational. Since most doctors do not have time to open the pharmacology books, they accept what the drug representative or the accompanying literature has to say about the drugs. Even information regarding the combination drugs banned by the Government is not known to many.

What steps are needed to rationalise the use of drugs in the Market?

Initially the following three steps need to be taken.

1. Elimination of imitative drugs for which adequate therapies already exist in the market which are cheap as well as effective.
2. Elimination of ineffective drugs-those having irrational combinations and drugs of unproven efficacy.
3. Elimination of drugs for which the toxic effects are unacceptably high and the use of which needs to be more severely limited than is actually the case.

Such an approach called a rationalized rather than an essential drug list allocates different priorities to different kinds of drugs based on therapeutic need, efficacy, cost and available resources. The drugs easily obtainable within the country should be grouped into three categories according to priority.

What are these three categories?

1. First line main drugs needed by primary health care units of the country. These products would be relevant to the diseases of wide prevalence and would include pharmaceutical care. Such drugs should number 50 to 60 and meet 80 to 90% of the total health needs of the developing country.

2. Second line drugs would be available at district and regional hospitals and would be needed for cases not responding to first line drugs, or that are so severe that second line drugs should be used immediately. They would also be needed for less prevalent conditions. This list may be longer than the first but quantities needed would be much less.

3. Finally the third line drugs would be available only for specialised tertiary care. What is meant by basic drugs refers to first line drugs while all the drugs taken together may be called the rationalised list of drugs.

.....4

How do patients use their drugs?

A WHO working group report on Rational Drug Therapy, 1975, lists following reasons for patients failing to take drugs properly:

* Failure to obtain prescribed drugs
* Failure to take prescribed drugs sufficiently long or at all
* Failure to follow physician's instructions
* Seeking treatment from more than one doctor
* Self medication with potent drugs

What can a doctor do in such situations?

The prescriber needs to keep in mind the drug-taking behaviour of the population; their attitude towards prescription of drugs; their simplicity; illiteracy and gullibility to believe anything the doctor says.

The doctors in turn has by force of habit come to believe everything the smooth taking drug representatives and drug firms claim. This too is irrational. Merely writing a prescription even if it is medically sound is not rational drug therapy. The doctor's responsibility does not end there. The patient has to be given clear instructions and explanations as required. The patient needs motivation, reassurance and follow up if need be. The role of non drug therapies also needs to be learnt by the doctor, and their use conveyed to the people. The doctor's role is of an educator and liberator. The doctor needs to liberate the patient from drugs and disease and not encourage slavish dependency on either the drugs or the doctor.

SOURCE : "HEALTH FOR THE MILLIONS"

April - June 1981.

DR-12.

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DRUG SITUATION IN INDIA

DANGEROUS PROFITEERING

MY IDEA OF A BETTER ORDERED WORLD IS ONE IN WHICH MEDICAL DISCOVERIES WOULD BE FREE OF PATENTS AND THERE WOULD BE NO PROFITEERING FROM LIFE OR DEATH".

- Indira Gandhi
at World Health Assembly (1981)

The pioneers in establishing the drug industry in the country were P.C.Ray and T.K.Gujjar. At the time of Independence, the total pharmaceuticals sale was Rs.10 crore.

Over the years, the multinationals have gained strong roots in the Indian Drug Industry and repatriate huge amounts out of this country. On the whole, the contribution of these drug manufacturing units towards producing life-saving and essential drugs has been very little. The Indian drug industry floods the market with about 70,000 formulations, yet 40,000 children go blind every year because of Vitamin A Deficiency.

Most of drugs produced are unessential and many of them have been banned in developed countries.

Unlike other commodities in the market for which the market is open and common through the mass media, the drug companies' main concern are doctors, wholesalers and retail chemists.

It is obvious that the drug companies use high pressure marketing techniques, and thus non-essential drugs are sold. An analysis shows that 52 multinationals in 1978-79 spent only Rs.1.56 crore on research, but Rs.15.34 crore was spent for marketing.

Though the drug companies approach the doctors through medical representatives, they extensively advertise in professional medical journals also.

The Indian Council of Medical Research and the Indian Council of Social Sciences Research set up a joint study group to study the health situation in India and in the report have rightly said, "Eternal vigilance is required to ensure that the health care system does not get medicalised, that the doctor-drug producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health".

Regarding the drug-pushing strategy of drug companies, the ICMR and ICSSR study states. "It is unfortunate that the drug producers always try to push doctors into using their products by all means - fair or foul. These basic facts are more responsible for distortions in drug production and consumption than anything else".

After having known about banned drugs, bannable drugs, unessential drugs and the promotional techniques of,

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drug companies, let us see what our drug policy has to offer. The following observations are worth noting.

1. The drug policy of our country is prepared by the Ministry of Petroleum and Chemicals, and the Health Ministry is in no way involved.

2. The policy announced as on January 3, 1986, did make a brief mention about banning of drugs. But no thought had been given to the loopholes in the ban orders.

3. No attempt has been made by the policy about abolition of brand names and introducing generic names.

4. No attempt was made to make a list of essential drugs.

5. The 1986 drug policy increases the cost of essential drugs. The increase in price is even one hundred percent for some products.

6. The policy encourages more formulations by delicensing certain drugs and also its formulations.

7. The drug policy makes no mention about restrictions that need to be put on the promotional material of drug companies.

In short, the drug policy is more a pricing policy than making it a people's policy.

A committee set up under the guidance of Jaisukhlal Hathi made certain useful recommendations. None of these has been fully implemented. The following are the highlights of the recommendations.

1. All multinational companies should be nationalised.

2. Generic names should be used, instead of using trade names, brand names.

3. Production of single drugs.

4. Elimination of irrational drug combinations

5. Indian National Formulory must be revised in order to keep the medical profession will informed.

6. Distribution of drugs being an important factor, a National Drug Authority of India (NDA) should be set up.

7. A list of 117 essential drugs were drawn up by the committee.

8. The Indian sector of drug industry should be helped to obtain self-sufficiency.

Former judge of the Supreme Courpt Justice Krishna Iyer is on record as stating. "Government is allergic to the Hathi committee report and dithers, delays, shies and even retreats, allowing the hefty drug industrialists to hold to ransom people's health. Pharmaceutical imperialism practised by covert and overt disinformation, trade terrorism and brain-washed professionalism is a menace to a patriotic drug policy".

In the context of the entire drug issue, a lesson has to be learnt from a small neighbour, Bangladesh. In fact, the country took up the entire idea of a drug policy from the Hathi committee.

The Indian drug industry should cease to exist as a profit - making industry and the concern should be for health of the people. Drugs have a role to play in the health care system

MEDICATION AS A SUBSTITUTE FOR CARING

Perhaps the biggest reason for overuse of medicines, however, is that docotors and health workers often find it easier to hand out medicine than to give the time and personal attention that people need.

About 4 out of 5 illnesses are self limiting. This means people get well whether they take medicine or not. Most health problems can be better managed without medication. What often will help people most is friendly adivce and understanding support.

However, many doctors and health workers get into the habit of giving everyone medicine for any and every problem they have. The less curable the problem, the more medicines they give.

At the same time, people have come to expect medicine every time they visit a doctor or health worker. They like to believe that "there is a medicine for everything". They are disappointed if the doctor or health worker does not give them any, even when medicines will do no good and the health worker carefully explains why.

So a 'Vicious Circle' results in which the doctor always gives medicine because the 'patient' always expects (or demands) it, because the doctor always gives it. The prescribing of a medicine becomes both the symbol and the substitute for human caring. This problem especially common in places where doctors nurses, and health workers are over worked. The result is not only a costly overuse of medicine, but a failure to meet human needs on human terms.

- Helping Health Workers Learn
David Werner and Bill Bower.

"The physician who sets about to treat a disease without knowing anything about it is to be punished even if he is a qualified physician; if he does not give proper treatment, he is to be punished more severely, and if by his treatment the vital functions of the patient are impaired, he must be punished most severely".

- Koutilya Arthashastra.
