DR-35.1

Explanatory Note on
Peoples Charter for ~~Healthcare~~ Access to Essential Medicines

Withdrawal of the Government from Health Care

A series of policy changes by the government -- including some that are on the anvil -- will have a direct effect on access to medical care in the country. The Insurance Regulatory Authority Act, for example, is designed to facilitate the introduction of private health insurance, and also to allow entry to MNCs in the health sector. It, moreover, allows the government to legitimise its withdrawal from investing in health care.

Public expenditure on health care has been a major casualty of the process of economic liberalisation and structural adjustment policies. Central allocation to State governments for health has declined, thereby forcing many States to procure loans from lending agencies such as the World Bank. Such loans are invariably associated with conditionalities that are directed at a transformation of the public health system. Such a transformation is sought to be achieved through mecahisms such as introduction of user charges, purchase of medicines through global tenders, farming out of primary health care centres to NGOs -- in others words, mechanisms for privatisation of the public health infrastructure and delivery system.

In many States we already witness the shift of administrative responsibilities in health care delivery to NGOs and other private organisation, thus minimising the role of elected representatives. This will further facilitate the privatisation of the health infrastructure. Implementation of such prescriptions, put forward by the World Bank, has led to utter chaos in the public health infrastructure in countries in S.America and Africa -- a fact that is admitted to even by the World Bank.

Investment by the government on health care (less than two percent of the budget) in India is one of the lowest in the world. Per capita investment in health is only Rs.57 a year and 87% of health care costs are paid for privately. Notwithstanding this the government has not only reduced expenditure for disease eradication programmes, it has also reduced the number of programmes covered. We see today a resurgence of communicable diseases, and while old diseases like tuberculosis, malaria, kalaazar flourish anew, newer diseases have started manifesting themselves -- including the looming threat of an AIDS epidemic. What is urgently required is not a cutback on existing programmes but a major expansion of diseas control programmes.

Abandonment of Price Controls

While access to drugs constitutes only a part of measures required to confront a major public health crisis, it is still a necessary part. Recent policies that have been announced by the government are poised to further cut access to essential medicines, especially for the poor. In the recent budget the government has announced its intention to slash the number of drugs under price control. Moreover, such changes are being mooted not by the Ministry of Health or even the Ministry of Chemicals, but by the Finance Ministry.

The move to further reduce the span of price control is directed at improving the health of the industry and not the Indian people. Since the introduction of the first comprehensive drug policy in 1978, all subsequent policies have pandered to the needs of the industry. While the 1978 policy had 343 drugs under price control, this was reduced to 166 in 1987 and further to just 73 in 1994. Profitability allowed in controlled categories was increased in this period from 40-75% in 1978,

Peoples Charter for Access to Essential Medicines

Most of the people of our country are deprived from proper healthcare. The government has ignored this basic necessity for survival. The following are therefore demanded from the government:

1. No privatisation of the public healthcare system.
2. More per capita budgetary expenditure on healthcare.
3. Increase the number of National Diseases Eradication Programmes and enhanced budgetary support to each programme.
4. Revitalise public sector drug companies.
5. Develop a public distribution system for cheaper essential drugs.
6. Formulate a rational drug under the aegis of the Health Ministry.
7. Ensure production and availability of all drugs in the national Essential Drug List.
8. Control import of bulk drugs and finished formulations and rationalise duties on imports. Restrict import keeping in view the needs of domestic producers.
9. All drugs should be assessed periodically, in order to ban hazardous and irrational drugs.
10. Formulate a new Drug Prices Control Order to bring all essential drugs under price control.
11. No change in the fundamentals of the Indian Patents Act,1970 that allow domestic manufacture of patented drugs to counter monopoly, high prices and imports.
12. Utilisation of third party licensing by big companies to evade taxes, reduce employment and utilise cheap labour should be stopped.
13. Uniform tax structure for all drugs, maximum retail price should be inclusive of all taxes.
14. Strengthen quality control mechanisms to stop proliferation of spurious and sub-standard drugs.
15. Enquire into corrupt practices by drug companies involving tax and duty evasion.
16. All government purchases should be made through a central procurement system, based on the list of essential drugs.

to 75-100% in 1987 and finally to 150% in 1994. It is now proposed that just 15-20 drugs will be kept under price control -- thereby virtually making the whole policy of price control redundant. We already have a situation where the prices of essential drugs like anti-TB, anti-leprotics, cardiovascular drugs, etc. are rising at a significantly higher rate than the rate of inflation, and the situation can only worsen as price control is further relaxed. Many drug companies are known to openly flout the existing DPCO by not submitting cost-data to the National Pharmaceutical Pricing Authority (NPPA). The pharmaceutical industry has openly expressed its displeasure over the NPPA (constituted about 5 years ago) and the new pricing policy might decide to scrap the NPPA. A new Drug Price Control Order, in fact, needs to do quite the opposite of what is being proposed -- increase the span of price controls, so that all essential drugs are put under price control.

Skewed R&D Policy

Almost two years back the Govt. had appointed two committees -- one to prepare policy guidelines towards R&D and the other to review the existing Drug Price Control Order (DPCO). The committee on R & D, among other recommendations, proposed the setting up of a corpus fund of Rs.150 crores for the pharmaceutical industry. In India the private sector had done little R&D for drug development, while major R&D work has been largely done in public funded institutions like CSIR laboratories. While the specific mechanisms for setting up the corpus fund are awaited, it is apprehended that this fund would be created by imposing higher taxes on drugs. Thus the private sector, in spite of its poor record in R&D, will be allowed another largesse by the government. Instead it would make much better sense for the government to invest in strengthening public funded R&D.

Revitalise the Public Sector

Even today there is a large infrastructure for manufacture of drugs in the public sector. Of these, the production units of Hindustan Antibiotics Ltd. have been rented out to private enterprises, who are making profit out of it. The Indian Drugs and Pharmaceuticals Ltd. (IDPL), once the largest company in the pharmaceutical sector in India, has been lying idle since 1996 and the BIFR had recommended that the company be wound up. HAL and IDPL, in the formative years of the drug industry in India were the largest manufacturing units in the country and played a major role in the country become self reliant in the area of production of essential drugs. Moreover these two companies pioneered production of drugs from the basic stage in the country, and were the first to challenge the monopoly of MNCs in the early. Unfortunately the same conditions which led to these companies becoming sick still exist -- corrupt and inept management at the highest levels coupled with a lack of direction. sixties Today, faced with a change in the patent system and a renewed challenge from the Multinational Sector, these public sector units (IDPL, HAL as well as Bengal Chemical, Bengal Immunity and Smith Stanistreet) still have a major role to play. Given the will and the vision these public sector units can be revitalised and can play an important role in making available life saving and essential drugs at cheaper prices.

Public Distribution System

It is estimated that 60-70% of the Indian people have little or no access to medicines primarily because they cannot afford such medicines and the public health system is woefully adequate. In such a situation the government needs to establish a public distribution system for drugs, through which all essential drugs at subsidised prices (where necessary) should be distributed.

Ensure Rational Drug Use

A large number of hazardous and irrational drugs are sold in the market. Sale of such drugs are not only a major health hazard, but it also deflects scarce resources away from essential medicines. Such a situation has been made possible because there is no real drug policy in existence -- merely a pricing and licensing policy. Companies, as a consequence, are able to sell these medicines with the help of their high-pressure unethical marketing. A rational drug policy under the aegis of the Health Ministry (and not the Industry Ministry) is the first necessary step to remedy this situation. Such a policy needs to prioritorise drug needs of the country on the basis of a list of essential drugs, ensure production of quality drugs at cheaper prices and minimise import. The policy should also devise means to ensure rational drug production and usage.

Stop Unethical Promotion

Steps are required to put a check on the unethical promotion of drugs. In spite of assurances the government is yet to enforce the 'Criteria of Ethical Promotion of Pharmaceuticals' prepared by the WHO. In the recent years there is a noticeable tendency towards marketing of expensive new drugs, most of which have little or no advantage over older and cheaper drugs. These drugs, many of them being imported, are marketed with the help of lucrative inducements offered to a section of the medical profession and chemists. Therefore a rational drug policy should include mechanisms to ensure ethical drug promotion and prevent the import of non-essential drugs.

Reverse Import Liberalisation

Following the liberalisation of imports, multinational drug companies are closing down their production units in the country. They are either importing their products from their parent companies or getting them manufactured in the small scale sector. This has led to a sharp increase in imports in the last two years, while closure of large production units has caused unemployment of thousands of workers. While mergers, acquisitions and brand selling has flourished, there is no significant investment in the industry. All these have led to increasing unemployment and loss of job security in the pharmaceutical sector. Liberalised imports have also forced the closure of many medium scale bulk drug companies who face competition from cheaper imported bulk drugs. Urgent measures are required to stop unrestricted import of bulk drugs through appropriate duty structures that favour domestic manufacturers.

Save the Indian Patents Act, 1970

The Indian Patents Act of 1970 was instrumental in helping the country achieve self reliance in the production of drugs. It helped Indian companies introduce new drugs within 2-3 years of their introduction in the global market, that too at prices that were one-tenth or less of global prices. It also encouraged the development of process technologies for a large majority of essential drugs, principally in public funded institutions. Today the government is poised to change the Indian Patents Act in order to "honour" its obligations at the WTO. Changes envisaged will reverse most of the benefits of the earlier Act. It is of vital importance that the new Act retain licensing provisions that allow domestic manufacturers to manufacture patented drugs if monopolies are created, if prices are high, or if domestic manufacture is nit done by the original patentee. Various other safegaurds need to be built in to see that all the gains of the 1970 Patents Act are not frittered away. Today many developing countries, who amended their Patent Acts in accordance with the TRIPS accord are faced with exorbitant prices for new drugs -- a situation that has brought the whole continent of Africa, reeling under the onslaught of an AIDS epidemic, to the brink of a disaster. Many of these countries are today prepared to come together and unitedly

demand a revision of the TRIPS accord. The issue has also led to the building of an unparallelled global coalition that is prepared to question the TRIPS accord. India has, arguably, the most developed pharmaceutical industry in the developing world. Instead of rushing in to amend its Patents Act in a foolhardy manner, India needs to provide leadership to the rising tide of discontent all over the globe, against the TRIPS accord.

Stop Third Party Manufacture

The government allows large companies to get their drugs manufactured in the small scale sector, even if they have the capacity to manufacture such drugs. This opportunity is being misused by many large companies, some of whom have even closed down their factories. This facility for "third party manufacturing" allows big companies to utilise exemptions provided to the small scale sector and also to reap the benefits of cheap labour costs in the small scale sector. Moreover, such manufacturing leads to poor quality control and increases the presence of sub-standard and spurious drugs in the market. Many large companies, however, are content to reap profits as mere traders, leaving the manufacturing to the large, unorganised and poorly monitored small scale sector.

Stop Tax and Duty Evasion, Rationalise Taxes

Unregulated manufacturing also allows large scale defaults in the payments of taxes and duties. This leads to crores of revenue being lost by the government. While the practice is widely known, the government has refused to act till date. Because the tax structure varies in among different states, it too promotes illegal trade in drugs across state borders. Moreover, in the absence of a clear tax structure, consumers are charged in accordance with the arbitrary whims of retail chemists. This situation can be remedied by having an uniform tax structure, and by clearly printing the price of drugs on packages, inclusive of all taxes.

Centralised Drug Procurement

The government is a major purchaser of drugs and if government purchases are co-ordinated it can provide it with a major bargaining handle to push down drug costs. Such a procedure is in place in many countries, including many developed countries, and should be introduced in India too.

To

The Hon'ble President of India

New Delhi

Sir,

We, the people of India note with serious concern the health care situation in our country is reaching a serious deteriorating condition. We therefore request that the following Charter may please be seriously considered by the Government of India and necessary policy decisions may be taken at your behest.

Peoples Charter for Access to Essential Medicines

1. No privatisation of the public health care system.
2. More per capita budgetary expenditure on healthcare.
3. Increase the number of National Diseases Eradication Programmes and enhanced budgetary support to each programme. — Comprehensive Health Care
4. Revitalise public sector drug companies.
5. Develop a public distribution system for cheaper quality essential drugs.
6. Formulate a rational drug policy under the aegis of the Health Ministry.
7. Ensure production and availability of all drugs in the national Essential Drug List.
8. Control imports of bulk drugs, intermediates and finished formulations and rationalise duties on imports. Restrict import keeping in view the needs of domestic producers.
9. All drugs should be assessed periodically, in order to ban hazardous and irrational drugs.
10. Formulate a new Drug Prices Control Order to bring all drugs under price control and to reduce prices of essential drugs.
11. No change in the fundamentals of the Indian Patents Act,1970, that allow domestic manufacture of patented drugs to counter monopoly, high prices and imports.
12. Utilisation of third party licensing by big companies to evade taxes, reduce employment and utilise cheap labour should be stopped.
13. Uniform tax structure for all drugs, maximum retail price should be inclusive of all taxes.
14. Strengthen quality control mechanisms to stop proliferation of spurious and sub-standard drugs.
15. Enquire into corrupt practices by drug companies involving tax and duty evasion.
16. All government purchases should be made through a central procurement system, based on the list of essential drugs.
17. No Foreign Direct Investment (FDI) be allowed in the pharmaceutical sector, except where there is clear indication that such investment will be accompanied by transfer of technology not available in the country.

Thanking you,
Yours faithfully,

SL No.	Name	Place	State	Signature

DR-35. 2

International Symposium on TRIPS
And Access to Medicines
Organised by National Working Group on Patent Laws
& Medecins Sans Frontieres (MSF)

New Delhi, June 4, 2001

NEW DELHI STATEMENT

INTRODUCTION

1. The National Working Group on Patent Laws (India) in association with Medecins Sans Frontieres (MSF), Geneva, jointly organised, on June 4,2001, an International Symposium on TRIPS and Access to Essential Medicines. Over seventy-five senior experts including twentythree from abroad participated in the day long Symposium.

   Critical issues relating to TRIPS Agreement were deliberated upon in the following sessions:

Session I	International Senario on TRIPS
Session II	Issues of Implementation & Review of TRIPS
Session III	Implications of TRIPS for R&D and Technology Dissemination
Session IV	Pharmaceutical Industry in India and Future Role in Ensuring Access to Essential Medicines
Session V	Implications of TRIPS for Health Care

In the Concluding Session indepth discussions were held on all the issues stated above.

2. Participants from India, representing various organisations, included Dr. Nitya Nand, Mr. S.P. Shukla, Dr. Arun Ghosh, Prof. Prabhat Patnaik, Prof. Ashok Parthasarathy, Dr. Pushpa M. Bhargava, Dr. Vandana Shiva, Dr. Gopakumar Nair, Mr. Dilip G. Shah, Mr. B.K. Keayla, Mr. Dinesh Abrol, Dr. Biswajit Dhar, Dr. Amit Sengupta, Dr. Mira Shiva, Dr. N.N. Mehrotra, and Mr. Amitava Guha. Partcipants from abroad included Dr. James Orbinski, Ms. Ellen 't Hoen, Prof. Jerome H. Reichman, Prof. Fredrick M. Abbott, Mr. James Love, Dr. Graham Dukes, and Dr. Zafar Mirza. The thrust of most of the presentations at the symposium was that the TRIPS agreement is singularly insensitive to the needs of the developing countries. In fact it is an instrument for the preservation and accentuation of inequalities between the developed and developing countries. Laws and policies related to health and pharmaceuticals and those related to the patent system in any country have to be so linked that they cater to the needs of the poor. India could give a lead in this respect.

CRITICAL ISSUES

3. Certain critical issues were identified by experts who spoke at the symposium, which can form the basis of a common approach in the ongoing review of the TRIPS agreement. The need for caution was emphasised on the process of implementation of the TRIPS agreement by developing countries. The need to introduce amendments in their respective national legislations with utmost care and necessary safeguards was underlined.

4. Participants at the symposium expressed concern at the trend in intellectual property protection, that is increasingly skewing the balance of the rights of patent holders and consumers; in favour of the former. Speakers noted that the TRIPS agreement on manifold issues marks a fundamental shift in this balance, as well as a shift in global attitudes where private profits are put ahead of social benefits. This is further fueled by dependence of economies in the developed world on industries that require strong intellectual property protection. Of the fifteen most profitable industries today at global level, six are from the pharmaceutical sector and five from the information technology sector. It was also pointed out that intellectual property protection allows such industries to create monopolies, not only over production, but also in the control of knowledge.

5. The net result of this trend, in the pharmaceutical sector, has been high cost of medicines and the consequent denial of access to medicines to the income poor across the globe. Further, it has also led to a situation where medicines required to treat diseases that predominantly occur among the poor are not researched at all.

   Instead drugs that are being researched are drugs used for "lifestyle" diseases like impotence, baldness, obesity, etc. It was underlined that while the pharmaceutical industry claims that high prices are explained by the massive expenditure on R&D, the truth is that drugs they actually research have little relevance to real medical needs. Moreover, the kind of profits that big pharmaceutical MNCs generate are an indication of profiteering and not just legitimate profit making.

6. Speakers at the symposium also stressed on the need to utilise provisions available in the TRIPS agreement to ensure production of cheap drugs by domestic manufacturers in the developing countries. For this, legislations in the developing countries need to have licensing and other provisions that prevent abuse of monopoly positions by MNCs and also allow imports of drugs from the global market at competitive prices. It was also pointed out that the next few years are going to be crucial, as developed countries challenge laws enacted by the developing countries like Brazil in the WTO dispute settlement mechanism. The resolution in WTO of the complaint made by the US against Brazil for violation of the TRIPS agreement because the former has included provisions that allow it to produce cheap anti-AIDS drugs by licensing domestic manufacturers, is being seen as crucial in the context.

IMPLEMENTATION OF TRIPS

7. India is in the process of implementing the TRIPS agreement through introduction of the Patents (Second Amendment) Bill 1999 — subsequently referred to a Parliamentiary committee for examination and report. In this regard it was pointed out that the constitutional guarantees in the fundamental rights to its citizen regarding "Right to Life" has special significance in the implementation of the agreement. It was emphatically stressed that the Constitution of India should not in any way be violated in the process of harmonising the existing Indian patent system with the TRIPS agreement. It was also pointed out that the August, 2000 Resolution of the Sub - commission of UN Commission on Human Rights should also be taken note of. This Resolution requests all governments and national, regional and international economic forums to take national human right obligations and principles fully into account in international economic policy formulation. This Resolution also notes that actual or potential conflicts exists between the implementation of the TRIPS agreement and the realisation of economic, social and cultural rights. These cautions needs to be specifically taken note of by the Parliamentary committee in their delebrations on the Patents (Second Amendment) Bill, 1999.

8. Both foreign and Indian experts pointed out the need to utilise, to the maximum, "flexibilities" that can be interpreted to be availaible in the TRIPS agreement while amending domestic laws with a view to implementing the agreement. They felt that such flexibilities are available in Articles 7, 8, 30 and 31, if the said Articles are interpreted liberally. The necessity to incorporate the following safeguards, while amending the patent system, was specifically pointed out:

8.1 The provision in TRIPS where imports are treated at par with domestic production should not be interpreted to mean that that working of the patent is a non-issue. While an interpretation of the said provision may absolve the patent holder from the obligation of working the patent in the country where the patent is taken, it should also be ensured that the patents are worked by domestic enterprises by providing them legal rights through compulsory licences to work the patents;

8.2 The compulsory licensing system for commercial purposes, provided for in article 31, should be made fool-proof. After an offer of reasonable terms and conditions and also after waiting for a reasonable period for response from the patent holder, it should be legally possible for the Controller to automatically grant a compulsory licence. In order to avoid any ambiguity in this respect, the quantum of royalty and the maximim waiting period can be stipulated (say 8% or above of royalty on annual ex-factory sale turnover and 150 days waiting period). If these conditions are satisfied by an enterprise desirous of taking a compulsory licence, the said licence should be issued as a legal right for the enterprise and the Controller will issue the licence within 100 days. There should be clear-cut provision in this regard in the Patents Act

so as to ensure smooth application of the compulsory licensing system to achieve the desired objective;

8.3 Article 30 dealing with limited exceptions to the exclusive rights available to the right holder should be used to provide for total freedom for undertaking R&D activity on the patented subject matter. Strongest support in this regard, thus far has come from the WTO ruling in a case involving Canada and the European Union on the implementation of "Bolar" type exception. The formulation of the new Section 107A in the Patents (Second Amendment) Bill in India needs to be reformulated to achieve total freedom for R&D and for taking marketing approval from concerned authorities on patentable subject matter. The actual marketing of the patented product will be undertaken only after the expiry of the patent term or after obtaining compulsory licence.

8.4. The definitions of 'novelty', 'industrial application' and 'inventive step' to qualify granting of patent need to be specifically elaborated so that infructuous claims are not entertained. Similarly, the list of inventions not patenable as such, should clearly include formulations based upon off-patented molecules. Further, formulations based upon changes in dosage form and new uses should also be specifically exclude from the scope of patentability as new products. Patenting of life-forms, including micro-organisms, should also be outside the scope of patentability. The aspect is still being debated internationally.

8.5 The issue of parallel imports is an important one for developing countries. Suitable provision has to bo made to ensure that the people have access to cheaper medicines and also to harness the country's capabilities to cater to the needs of other developing countries which do not have a developed pharmaceutical industry. Availability of medicines from other countries at cheaper prices should be provided in the law as the cause for parallel imports.

The above are a few issues which need to be specifically provided for in the Patents Amendment Bill in India. Similarly, these issues are also relevant for other developing country for suitably stipulating in their respective laws.

REVIEW OF TRIPS AGREEMENT

9. As regards the review of TRIPS agreement, the spirit of Articles 7 and 8 should be specifically reflected in different Articles in the substantive Section 5 of the TRIPS agreement. This will help in the smooth transfer and dissemination of technology for developing countries like India. It will also help the application of intellectual property rights in a manner conducive to social and economic welfare and the balancing of rights and obligations. Similarly, it would also be possible to implement provisions necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance. It will also be possible to

provide for appropriate measures to prevent abuse of intellectual property right by the right holders.

The patent term of 20 years, provided for in the TRIPS agreement, is too long a period in the context of fast changes in the product cycle making patented products unimportant within a short duration. This results in ensuring that there is virtually no role for the generic industry on the expiry of patent term of 20 years. A review of TRIPS needs to question the 20 year patent period.

BEYOND TRIPS

10. Speaker also emphatically argued that:

10.1 A rational international system of intellectual property rights and obligations has, by definition, to represent the interests and aspirations of the people of each country. Such a system must be in harmony with the entire spectrum of national laws enacted through national political processes. The system must have maximum flexibility so as to enable it to realise specific development objectives of each country concerned. The key to flexibility in the intellectual property regime lies in providing scope for the strengthening of the technological capabilities of developing countries. This, in fact, happens to be one of the stated objectives of TRIPS.

10.2 There can be no uniform set of standards and norms of equal validity or relevance applicable to a wide range of developing countries that are obliged to respond to the imperative of their respective cultural and socio-economic needs. The holding of a global monopoly of patents, representing a massive stock of science and technology, by a group of industrialised countries is no justification for common standards and norms to be demanded from developing countries as a price for being admitted to a global multilateral system of trade and exchange. If adequate flexibility is not made available within the framework of TRIPS, the whole system is likely to become unsustainable.

10.3 The TRIPS proposals aim at reserving the domestic markets of the developing countries for the manufactured goods of the developed countries. Implementation of the TRIPS Agreement would arrest the promotion of indigenous technological capabilities. They would constrain research and development of frontier technologies in these countries. Educational and training institutions of developing countries will end up producing graduates whom these countries will not be able to absorb. The TRIPS proposals would strengthen the vicious circle of limited scientific and technological activities creating conditions for brain-drain.

11. For developing countries, in particular, it is essential that:

    11.1 The supremacy of national laws on intellectual property protection be maintained;

    11.2 The national laws of developing countries must increasingly influence and decisively change the international regime of rights and obligations. They must enable developing countries to breath freely in order to grow and develop their potential on a continuing basis;

    11.3 In their national laws on intellectual property protection, developing countries must balance rights granted to foreign owners of technology with adequate obligations on them. Only then will they obtain much needed technology under fair terms and conditions in conformity with their public interest requirements

12. Technology, which is based on both scientific progress as well as accumulated skills and experience is a common heritage of humanity. The present global patent regime allows appropriation of technology or private gains. The directions outlined above will open up the possibilities for a progressive decommercialization of technology, thereby enabling developing countries to accelerate the pace of their technological transformation.

13. In order to demonstrate their good faith, the developed countries should agree to the resumption of negotiations on the UNCTAD Code of Conduct on Technology and participate in them with enough political will in order to complete them expeditiously.

FORGING OF A GLOBAL COALITION

14. The widely evocative issue of access to anti-retrovirals, i.e. the drugs that are used to treat AIDS patients, has played a major role in the way the international community today sees the pharmaceutical industry. Treatment of AIDS with a combination of drugs - - called Highly Active Anti-retroviral Treatment (HAART) – has decreased mortality from AIDS by 84% in developing countries. Unfortunately less that 5% of AIDS infected people across the globe have access to such treatment currently, because the estimated cost of treatment by HAART is about $12,000 per person per year. At present rates Zimbabwe, Uganda and Ivory Coast would require to spend 265%, 172% and 84% of their respective Gross National Products, just to buy drugs to treat all their AIDS patients! This issue has been the rallying point of a major global campaign that today is demanding a closer, critical look at the TRIPS agreement.

15. Condemnation of the role of transnational pharmaceutical companies reached a crescendo due to the lawsuit brought against the South African government in Pretoria's High Court by 39 pharmaceutical companies. The law suit targeted a

legislation by South Africa – the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 - - which allowed the country access to cheaper anti-AIDS drugs. The 1998 lawsuit was supported by the US Government, which placed South Africa on the Special 301 Watch List, and the European Union, which wrote to then Vice President of South Africa, Mbeki, to express its concern about the legislation. The move by the pharma majors evoked a massive counter-response across the globe, led by Medecins Sans Frontieres (MSF). The companies suffered a major defeat when, in April, 2001 the companies capitulated to mounting anger and disgust over their conduct and agreed to withdraw the case unconditionally.

16. About two months back Brazil moved a resolution at the UN Human Rights Commission, which was approved by 52 votes in favour, 0 against and 1 abstention (USA). The resolution, among other things called upon States at the international level, to ensure that "the application of international agreements is supportive of public health policies which promote broad access to safe, efficient and affordable preventive, curative or palliative pharmaceuticals and medical technologies....." Today many national governments in third world countries are backing protests and demonstrations against the WTO in general and the TRIPS regime in particular.

17. Countries in Africa, Latin America and Asia, as well as organisations campaigning for access to cheap anti-AIDS drugs see India as a potential source of cheap drugs. In March 2001, an Indian company, Cipla announced that it would offer the combination of anti-AIDS drugs at a cost of $600 per patient per year, and later announce that they could bring down cost to $ 350 for supply of these drugs to MSF. Cipla's offer was matched within weeks by two other companies, Hetero Drugs and Ranbaxy. These offers are, till date, by far the cheapest that have been made anywhere in the world. In other words, Indian companies are now offering drugs to treat AIDS at prices that are one fortieth of global prices! Such a precipitous fall in prices can revolutionise AIDS treatment in developing countries, and save millions of lives.

18. The defeat for the 39 pharmaceutical companies in South Africa is not the end of this serious issue. Every country that has tried to interpret the TRIPS Agreement in a manner that allows access to cheaper drugs for its people is faced with a hostile reaction from the US. But it has led to the building of an unprecedented global coalition against the use of TRIPS to deny the poor access to drugs.

19. The issues here are complex. On one side, the WTO has to considered the future of humanity; on the other hand, there is also the moot question as to who is going to pay for the highly expensive treatment required for AIDS. The same issue arises in respect of tropical diseases which afflict a large segment of people across the world; and the problem herein is intimately connected with the issue of funding research and development in regard to diseases common in developing countries, which are least able to afford the expenditure involved in promoting original research. This issue has also to be specifically addressed to by the World Health

Organisation with the World Trade Organisation and the large transnational corporation.

20. The Indian Parliamentary Committee which is deliberating on the amending Bill for changes in the Indian Patents Act 1970 has an important task. It needs to look beyond the needs of India alone — the new Bill has to be so formulated that it becomes a model for other developing countries. The Bill must also enable the Indian pharmaceutical industry to meet, not only domestic needs, but also the needs of many other developing and least developed countries of access to essential medicines at competitive prices.

DR-35.5

Bad Medicine: Impact of TRIPS on Medical Care

Paper presented at the
International Symposium on TRIPS and Access to Medicines
June, 4, 2001, New Delhi

Intellectual property is an explicitly modern notion. The first patent law was enacted in 1623, and the precursor of modern copyright laws - the Statute of Anne - came into being in 1710 in England. Intellectual Property Rights are state-mandated monopolies. The idea behind such rights is that the fundamentals of an invention are made public while the inventor for a limited time has the exclusive right to make, use or sell the invention. Discoverers and inventors are thought to deserve special reward or privilege because of the benefit of their discoveries or inventions to society. Public good is not considered a reward in itself, and, true to classical economic theory, certain incentives are believed to be necessary to encourage invention or innovation.

It can legitimately be argued that the notion of IPR is built on a contradiction: in order to promote the development of ideas, it is necessary to reduce the freedom with which people can use them. This contradiction is a running thread in all debates on IPRs, and is sought to be resolved in laws related to IPRs by attempting a balance between public interests and rights of the inventor. Two contrasting interests, that often manifest as contrasting opinions -- as reflected in the following statements.

> "The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed -in every country- of the economic and social consequences of the TRIPs Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents."
> *UNDP Human Development Report 1999*

> "The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D".
> *IFPMA, ASEAN Workshop on TRIPS, Jakarta, May 2000*

While IPR laws have always been a compromise between these two contrasting positions, in the last few decades the resolution of the underlying contradiction has tended to increasingly favour the latter position. How this has happened is, in a manner, embedded in the history of the development of human enterprise in the last 300 odd years.

Redefining Property

Throughout much of human history, the possession and distribution of property was mediated by the use of force. This mediation was later codified in the form of laws which

sanctified the concept of private property. These laws were primarily directed at real estate, a form of property that is local by definition and, as the name implied, was very real. The Industrial Revolution and industrial modes of production led to the necessity of redefining "property". Tools acquired a new economic value and, thanks to their development, it became possible to duplicate and distribute them in quantity. To encourage their invention, copyright and patent laws were developed. These laws were geared towards getting mental creations into the world where they could be used - and could enter the minds of others - while assuring their inventors compensation for the value of their use. The earliest Patent laws were an expression of the need to ensure that innovations did not die away with the original inventor -- in other words they were designed to promote disclosure and dissemination of knowledge. However, the systems of both law and practice which emerged were based on physical expression. Thus what was protected as intellectual property was an expression of an idea -- a technological artifact, a piece of music, a work of literature, etc.

Since it is now possible to convey ideas from one mind to another without ever making them physical, ideas themselves are sought to be given ownership, and not merely their expression. And since it is likewise now possible to create useful tools that never take physical form, there is a move towards patenting abstractions, sequences of virtual events, and mathematical formulae - the most unreal terrain imaginable.

We are now entering an era where major parts of the world economy are based on ideas and knowledge, i.e. goods that take no material form. The central distinction between information or knowledge or ideas and physical property is that information can be transferred without leaving the possession of the original owner. Unlike physical goods, there are no physical obstacles to providing an abundance of ideas. Intellectual property can thus be conceived as an attempt to create an artificial scarcity in order to give rewards to a few at the expense of the many.

IPRs today bring into force another kind of dilemma. Open ideas can be examined, challenged, modified and improved. But IPRs, by converting scientific knowledge into a commodity, arguably inhibits science. There are innumerable examples to show that IPRs have been used to suppress innovation. Companies may take out a patent, or buy someone else's patent, in order to inhibit others from making use of new ideas. As far back as in 1875, the US company AT&T collected patents in order to ensure its monopoly on telephones: an act that is beleived to have slowed down the introduction of the radio by almost 20 years. In a similar fashion, General Electric used control of patents to retard the introduction of fluorescent lights, which were a threat to its market of incandescent lights.

We also see the development of a new contradiction -- information or ideas are sought to be commodified at the same time as technology makes it possible to exchange ideas in a radically free environment. If ideas are to be exchanged in the marketplace, the basic assumption of the marketplace as it is with regard to physical objects -- that value is based on scarcity -- should hold good. But this is precisely contrary to the nature of information, which may -- in many cases -- increase in value with dissemination.

Monopoly as a Facilitator of Creativity?

Central to the projected utility of Intellectual Property Rights is the notion that creation is facilitated by the provision of a temporary monopoly. This notion had a certain kind of validity in the context in which the concept of IPRs developed. The earliest Patent and Copyright Laws were geared, to an extent, to benefit the individual artisan, or the author of a literary piece or a musical score. In the last hundred years, however, protection of IPRs has acquired a radically new connotation. We are no more talking about protecting the property of a single, or a group of artisans who have labored to produce an useful artifact. Intellectual products, today, are social products. With the institutionalisation of the concept of IPRs individual creators ceased to be the beneficiaries, and were replaced by large corporate interests. In practice, today, most individual creators do not actually stand to gain from protection of intellectual property. When employees of corporations and governments have an idea worth protecting, it is usually copyrighted or patented by the organisation, not the employee. Since intellectual property can be sold, it is usually large corporate entities who benefit.

Today, IPRs help create monopolies of a different order, and thereby place enormous power at the disposal of a handful of corporations. It is a power that allows corporations not only to reap huge profits, but more importantly, to determine the direction of research. Microsoft, for example, with its virtual monopoly over software that is used on Personal Computers (PCs) has consistently obstructed the development of new products by its competitors. A handful of Pharmaceutical corporations, given their monopoly over the control of knowledge, can decide the kind of drugs that will be developed -- drugs that can be sold to people with the money to buy them. Thus on one hand we have the development of "life-style" drugs, i.e. drugs like viagra which target illusory ailments of the rich. On the other hand we have a large number of "orphan" drugs -- drugs that can cure life threatening diseases in Asia, Africa and S.America, but are not produced because the poor cannot pay for them.

Rent Incomes to the Fore

To understand how IPRs have become a major instrument of Capitalist development, it would be instructive to trace the changing stance of the US on IPRs. Until 1891 the United States did not recognize foreign copyrights. The U.S. made the transition from "pirate" to "police" over the past 100 years and today the United States has become the international advocate of strong intellectual property protection. This advocacy has been the motivating force behind the inclusion of intellectual property rights in the GATT, the United States-Canada Free Trade Agreement, NAFTA, and numerous other treaties.

In the mid-80's the United States was faced with waning industrial competitiveness, which hurt U.S. companies and U.S. trade internationally. As a consequence it began searching for new areas of commerce which would maintain U.S. dominance in the world market. Around this time several intellectual property dependent industries, namely information technology, entertainment (records, films, and books) and pharmaceutical

who were becoming extremely important contributors to the U.S. economy. All these sectors were heavily IPR dependant as they dealt in products where the development costs were high but the replication costs were small These were sectors where, in order to maintain high levels of returns, monopoly "rent" incomes had to be protected thought the mechanism of strong Intellectual Property Protection.

The importance of the knowledge based sectors to the US (and global) economy can be gauged from the performance of large companies today. Among the top fifteen companies (**Table 1**) with the highest returns (profits) on Revenues (turnover), six are pharmaceutical companies -- Microsoft, Cable and Wireless, E.I. du Pont de Nemours, Eli Lilly, Glazo Wellcome, Roche Group, Bristol-Myers Squibb, Novartis and Pfizer. Five are from the information technology sector -- Microsoft, Cable and Wireless, Telefonos de Mexico, Intel and Textron. Yet, none of these figure anywhere among the top 100 in terms of turnover. Microsoft is 216th in the list in terms of turnover, but has the highest return on revenues (39.4%). Clearly rent incomes, today, are one of the major driving forces of the economies of the developed countries.

Table 1: Top Performing Companies (Highest Return on Revenues)

Company	Revenues rank	1999 Profit as % of Revenue
Microsoft	216	39.4
Cable and Wireless	315	38.8
E.I. du Pont de Nemours	123	27.6
Eli Lilly	485	27.2
Telefonos de Mexico	482	26.1
Volvo	305	25.8
Intel	116	24.9
Glazo Wellcome	349	21.3
Roche Group	239	20.9
Petronas	311	20.8
Bristol-Myers Squibb	206	20.6
R.J.Reynolds Tobacco	436	20.6
Novartis	192	20.5
Pfizer	285	19.6
Textron	428	19.2

Source: Fortune 500

Redifining the Victim

Clearly, with Rent incomes becoming important, the legitimisation of a strong IPR regime became a necessity. How this was done is a fascinating story. In the 1980s the

U.S International Trade Commission (ITC) did a study for the USTR which asked American businesses to estimate the amounts they lost per year to piracy. The ITC survey "proved" that international "piracy" was costing American industries millions, if not billions, per year. Countries singled out for action, as a result of these findings, were largely developing countries in Asian, S.America and Africa. Here a caveat may be added, that what the ITC termed as piracy was actually Intellectual Property Laws of sovereign countries, decided upon by their sovereign governments.

The moral high ground was sought to be occupied with the plea for protection of creative and innovative work. The US now posed the whole issue as an organized effort by foreign countries, especially those located in Asia (China, India, Thailand, Malaysia, etc.), to systematically usurp American creativity and technological knowledge. The innocent victims were American companies, such as Microsoft, or Walt Disney, or Merck. Gradually the U.S. introduced the concept of unfair trade practices alongside that of alleged IPR violations in countries like India. It was repeatedly said that the lack of strong international intellectual property laws hindered international trade. By this virtual sleight of hand the U.S. (with the support of Europe and Japan) introduced IPRs as an issue in trade negotiations in the Uruguay Round of GATT negotiations in 1986.

The success achieved by the U.S. in making IPR a trade issue and its subsequent incorporation in the WTO agreement overturned the very basis of trade negotiations, where classically the developing nations were considered victims and special considerations were taken to remedy their problems. In the new version, the roles are reversed. The U.S. is a victim and the developing countries are the hostile aggressors which threaten the very foundation of America -- its creativity and ideas. Finally, large Multinational Corporations came to be characterised as the victims of Third World piracy. Thus, the whole concept of Intellectual Property has finally come a full circle -- from the initial notion of the protection of an individual's rights and the notion of disclosure of information, IPRs now mean protection of the rights of corporations and a bar on the free flow of information.

High Risk Activity?

Let us now look at the pharmaceutical industry in greater detail. The principal arguments of the pharmaceutical industry that has seduced even neutral observers are related to its claims that it invests huge amounts in the development of new drugs and hence deserves returns for such investments. And further that new product development is a risky business, which needs to be "adequately" compensated. Notwithstanding the initial controversies regarding inclusion of TRIPS in the GATT negotiations, this argument has converted IPRs into the "holy cow" of trade negotiations, that nobody dare tamper with. So, while concerns may be raised about how to ensure a modicum of fairness towards consumers, the TRIPS accord itself is being projected as being inviolable. Thus attempts at seeking a better balance between Patent rights and consumer interests are often limited to looking for possibilities within the TRIPS accord.

Suppose, however, we confront the argument squarely. R&D costs on drug development are difficult to compute as industry would always like to pad R&D costs to get tax benefits. Industry estimates are that global annual R&D investment is to the tune of $56 billion. Other estimates indicate that this is a gross overestimate. The US National Science Foundation estimates that R&D expenditure in the pharmaceutical industry, in the US, was 9.8 billion dollars in 1996 (**Table 2**). Projecting this to global current expenditures, we would be looking at a figure of around 20-25 billion dollars. Even this does not reflect just drug development costs, as R&D expenditures on company balance sheets are padded to include a whole range of peripheral costs in order to avail of tax benefits (which could be up to 40-45% in the US).

Table 2: R&D Expenditure -- US (in million $)

Year	Pharmaceutical R&D Costs	Total (all sectors) R&D Costs
1986	3,658	87,823
1988	4,906	97,015
1992	7,944	119,110
1993	9,146	117,400
1994	9,633	119,595
1995	10,215	132,103
1996	9,773	144,667

Source: US National Science Foundation, Division of Science Resources Studies, Research & Development in Industry, 1995-96

The quantum of R&D expenditure is a relatively minor issue. In fact what the industry never says, but is widely known, is that large pharmaceutical companies spend substantially more on promotion than on R&D. The important point to be underscored is that after the claimed investments are made on R&D the pharmaceutical sector has consistently been the most profitable sector. A perusal of the profitability in different sectors based on data from the top 500 globally, shows that profitability in the pharmaceutical sector is way ahead of all other sectors (**Table 3**).

Table 3: Profitability by Industrial Sector (1999)		
Sector	**Net Profits as % of Assets**	**Net Profits as % of Revenues**
Pharmaceuticals	14.7	18.3
Beverages	11.1	10.1
Tobacco	8.0	8.5
Specialty Retailers	6.0	2.6
Telecommunications	5.5	10.2
Computers, Office Equipment	4.9	6.6
Food	4.8	2.2
Aerospace	4.1	4.3
Petroleum Refining	4.0	3.6
Forest & Paper Products	3.8	4.2
Food & Drug Stores	3.7	1.9
Chemicals	3.6	3.3
Wholesalers	3.5	1.2
Airlines	3.4	3.4
Electronics, Electrical Equipment	2.9	3.0
General Merchandisers	2.8	1.4
Energy	2.3	2.2
Publishing, Printing	2.3	2.5
Motor Vehicles & Parts	2.2	2.2
Utilities: Gas & Electric	2.1	2.5
Entertainment	2.0	5.6
Health Care	1.9	2.8
Diversified Financials	1.5	11.1
Mail, Package, Freight Delivery	1.1	1.7
Securities	0.9	10.7
Industrial & Farm Equipment	0.8	0.9
Mining, Crude Oil Production	0.8	1.0
Banks: Commercial and Savings	0.6	5.4
Insurance: P & C	0.6	3.5
Insurance: Life, Health	0.5	2.3
Engineering, Construction	0.4	0.5
Railroads	0.4	1.3
Trading	0.4	0.2
Metals	-0.7	-0.4
Source: Fortune 500		

Did someone say, high risk? Clearly pharmaceutical companies are able to hedge whatever risks there may be, very successfully. Profitability in the sector is almost double that of the sector which is second on the list -- telecommunications (a sector which

incidentally did much worse in 2000). Such trends mean that profits of individual companies have soared and the top 14 pharmaceutical companies earned net profits to the tune of 33 billion dollars in 1999 (**Table 4**). To look at it in another way, if profit margins of top pharmaceutical companies were to have been less by a third of current levels -- which would still make them more profitable than any other sector -- a benefit of about 11 billion dollars could have been passed on to consumers. That is in fact more than the projected 10 billion dollars that are required to provide access to anti-AIDS drugs to all HIV positive patients in the world! What we see taking place in the pharmaceutical sector is profiteering, driven by rent incomes through Patent protection, and not legitimate returns on investment.

Table 4: Profitability of Top Global Pharmaceutical Corporations (1999)

Rank	Company	Revenues $ million	Profits $ million
1	Merck	32,714	5,890
2	Johnson & Johnson	27,471	4,167
3	Novartis	21,609	4,432
4	Bristol_Myers Squibb	20,222	4,167
5	Astra-Zeneca	18,445	1,143
6	Roche Group	18,349	3,837
7	Pfizer	16,204	3,179
8	Glaxo Wellcome	13,738	2,930
9	Smithkline Beecham	13,562	1,704
10	American Home Products	13,550	-1,227
11	Aventis	13,438	-1,035
12	Abbott Laboratories	13,178	2,446
13	Warner Lambert	12,929	1,733
14	Eli Lilly	10,003	2,721

Source: Fortune 500

There is a truism about pharmaceutical consumption -- those who need drugs the most are the least likely to be able to pay for them. So even if it is claimed that efforts by the pharmaceutical industry places life saving drugs in the market, the mere presence of such drugs does not ensure access. This is a fact that has been consistently highlighted in the campaign on ant-AIDS drugs and needs little elaboration here. It needs to be underlined, however, that as we move towards poorer countries as well as towards the income poor in rich countries, drug costs form a higher proportion of total medical costs. For example, in countries such as China, Indonesia, and Thailand, this share ranges from 35-45%. In several African countries, it is believed to exceed 50% [*Public-Private Roles in the Pharmaceutical Sector, 1997, WHO*]. US Cost of prescription drugs is about 10% of health care costs but have risen much more rapidly than physician costs and costs of

hospitalisation. Moreover, in developing regions, a much larger percentage of drug costs are paid for privately (**Table 5**).

Table 5: Regional Comparison of Private Expenditure on Pharmaceuticals

	Total Pharmaceutical Expend.		Pvt. as % of Total
	Per capita (US$)	% GDP	
Sub-Saharan Africa	8	0.9	65
Asia	12	0.6	81
Middle East	27	0.7	74
Latin America	26	0.9	72
Mkt.Economies	138	0.6	40

Source: Selected Topics in Health Reform and Drug Financing, WHO

However high drug prices, as a consequence of strong patent protection, is not an issue that need divide the developed and developing countries. The pharmaceutical industry has posed the issue as a contradiction between developing countries that wish to manufacture "pirated" drugs and developed countries that want to protect legitimate profits of their pharmaceutical companies. High drug costs concerns people living in developed countries too, in fact now more than ever before. It affects the poor and marginalised across the globe. In the US, for example, it has a major effect the aged who live on welfare. As the population of the aged increases drug costs cut into welfare budgets, and a crisis situation is not far away. A 1998 report estimated that, in the US, prices for the 50 drugs most used by seniors increased faster than the rate of inflation in the past five years, with increases in 1998 four times the rate of inflation. Annual prescription drug spending has grown from $559 in 1992 to $1205 in 2000.

Innovations for Whose Benefit?

High prices, driven by rent incomes are just one part of the story. The other part of the story is that drugs which sell in the market have little to do with the actual medical needs of the global population. As there is nobody to pay for drugs required to treat diseases in the poorest countries, or even to treat the poor in developed countries, such drugs are rarely researched. Research and patenting in pharmaceuticals are being driven by the search for the next "blockbuster" drug -- which in industry parlance means a drug with global sales of over one billion dollars. This is a major reason for the trend towards global mergers, as individual Cos. wishing to retain the huge growth rates from the 1970s to the 90s, try to pool resources for R&D. As a consequence, we are looking to a situation, where 10-12 conglomerates will survive as "research based" companies. The bulk of drug manufacturing will be done by smaller companies. In the US today, this trend is already discernible. While the volume of sales of large pharmaceutical companies has stagnated in the past decade, the sales of small companies producing generic drugs

has shown a double digit growth. However the profitability of these companies have not suffered -- rather they have increased. Clearly these companies are able to thrive on "rent incomes" made possible by strong IPR protection, while not enhancing their manufacturing activities.

The frantic search for the next "blockbuster", consequently, skews drug development in favour of new drugs for which there are buyers who are willing to pay prohibitive amounts. Attempts are also focused at carrying out minor modifications on proven "blockbuster" in order to maintain dominance over particular market segments after the patent on the original money-spinner runs out. Thus Schering has recently introduced its "son of Claritin" to replace its anti-allergic drug, Claritin, (loratidine) that produced returns to the tune of 9 billion dollars in the last decade. Eli Lily tried the same with its hugely succesful anti-depressant drug, Prozac, (fluoxetine) by trying to introduce R-fluoxetine -- an attempt which failed in the penultimate stage due to the "new" drug's unacceptably high cardiac effects.

This trend has converted the whole business of new drug development into farcical exercise with tragic consequences. The basic qualification for the next "blockbuster" is that it should be possible to sell it in the market, not that it should address real medical needs. Hence, more and more drugs being introduced are "copycat" drugs or drugs like Pfizer's Viagra that address "lifestyle" needs and not medical needs and do not significantly alter prevalent therapeutic practices (**Table 6**).

Table 6: Assessment of New Drugs Introduced Between 1981-2000

Category	Number	Percent
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an important therapeutic innovation but has certain limitations	67	2.96
Product has some value but does not fundamentally change the present therapeutic practice	192	8.51
Product has minimal additional value, and should not change prescribing habits except in rare circumstances	397	17.59
Product may be a new molecule but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product	1427	63.23

Product without evident benefit but with potential or real disadvantages	58	2.57
Editors postpone their judgements until better data and a more thorough evaluation of the drug is available	109	4.83
Total	2257	100
Source: Prescrire International		

The problem, thus, is not merely one of high prices. Consumers are being forced to pay higher prices based on the specious plea that these prices are warranted because of high research costs. But the drugs that are being introduced do not address real medical needs in an overwhelming majority of cases. What, one may legitimately ask, then justifies such high research costs -- the burden of which are finally passed on to consumers.

It also needs to be noted that many new drugs are initially researched in public funded institutions. For a major proportion of newly introduced drugs it is virtually impossible to trace the precise step which is innovative. Beta-blockers, H2-blockers, Taxol, ACE inhibitors -- therapeutic groups which spawned a host of "blockbusters" were initially researched in public funded institutions.

It is but natural that an industry driven by rent incomes will bypass the needs of the income poor across the globe. The most severely affected are the poor living in developing countries. Tuberculosis kills half a million people in India alone, but the last new anti-TB drug was introduced more than two decades back. Just four per cent of drug research money is devoted to developing new pharmaceuticals specifically for diseases prevalent in the developing countries. Some drugs developed in the 1950s and 1960s to treat tropical diseases, on the other hand, have begun to disappear from the market altogether because they are seldom or never used in the developed world. These drugs are termed, appropriately, as "orphan" drugs.

The pharmaceutical industry argues that patented drugs constitute less than 10% of drugs that are being used in developing countries. The statement is possibly true when taken at its face value. But what it hides is the fact that this is because drugs addressing the real medical needs of developing regions are seldom addressed by pharmaceutical companies. So the reason why so few commonly used drugs in developing countries are under patents is not because new drugs are not necessary, but because pharmaceutical countries do not develop appropriate drugs.

Patents make for Bad Science

Strong patent protection now extends to protection of test data generated by companies while researching new products. The pharmaceutical industry argues that granting data exclusivity for test data is crucial, since the development of these data is expensive. Allowing other companies to rely on data developed by the innovator, instead of having

to develop their own clinical data, would give them an unfair economic advantage. But the net result is that there is less and less disclosure of information when patents are filed. We now have an emerging trend that is contrary to the standard argument in favour of strong patent protection: that such protection ensures early disclosure of innovations and thus promotes faster dissemination of knowledge.

"Full disclosure" usually means providing enough detail for a "person skilled in the same or the most clearly related area of technology to construct and operate" the patented object. Strong patent protection is now moving the pendulum away from the concept of "full disclosure" and it is a matter of grave concern for the scientific community. Can information provided by patients acting in the public interest legitimately be considered the intellectual property of a pharmaceutical company? In practice, to support the marketing of their new products, most manufacturers make some of their intellectual property generally available by publishing some of the reports upon which their successful licensle applications were based. Unfortunately, these reports are not generally representative of all the evidence. A report in 1980 showed that studies submitted in support of applications for new licenses for drugs in which side-effects had been shown were less likely than others to be published. There have been a number of recent instances of suppression of vital information by companies. Clearly, patents have ceased to be a vehicle of dissemination of knowledge and have become the tools to constrain its spread -- quite the antithesis of what good science requires.

Patents Retard Domestic Industries in Developing Countries

Domestic industries outside the developed countries have been able to develop in places where strong patent production has not been allowed. India is representative of such a situation, where the Indian Patents Act of 1970 allowed the development of a strong vertically integrated pharmaceutical industry. It was facilitated by the ability of Indian companies to develop and market generic versions of patented drugs. The issue is not just that it allowed cheaper versions of patented drugs to be sold in the Indian market. More importantly, it led to the development of world class manufacturing facilities in a developing country.

Today the campaign on access to drugs draws strength from Indian companies like Cipla who are offering anti-AIDS drugs at one tenth to one fortieth of the prices being charged by large pharmaceutical countries. It also draws strength from the ability of Brazil to indigenously manufacture 8 out of the 12 anti-AIDS drugs and also to distribute them to all those who require these drugs. Let us not forget that this could not have happened if the TRIPS accord had been signed in 1975 and not in 1995! It is this that we stand to lose as we move towards "harmonised" standards of strong patent protection.

It is also this that is sought to be taken away by large pharmaceutical companies through the medium of TRIPS. Notwithstanding the rhetoric, the TRIPS accord was not pushed through to access markets of developing countries. These markets represent just a fraction of the global market -- India, for example, accounts for 0.8% of the market, in contrast to 33%, 24% and 20% for the US, Europe and Japan respectively. Rather the

TRIPS agreement became a necessity to protect the markets of large pharmaceutical companies in the developing world against competition from cheaper generic drugs manufactured in countries like India and Brazil. TRIPS in other words is not about "free" trade, but has to do with protection of markets in developed countries.

The Way Forward

I have attempted in this paper to suggest that financial returns for large pharmaceutical companies is evidence of profiteering and not just legitimate profit making. The intent has also been to show that patenting leads not only to high prices but also to the wrong kind of research, to inhibition of research, and also to stifling of domestic industries in developing countries. The next logical step would be to suggest that the patent system which perpetuates such a situation be taken apart and be replaced by a new system, that brings back a balance between the rights of the inventor and public interest.

The issue of access to AIDS drugs is, arguably, the weakest link in the TRIPS accord and the emerging global patenting system. The tremendous evocative appeal of the "Access Campaign to AIDS Drugs" lends it the potential to delegitimise the TRIPS agreement.

However, to effectively strike at the "weakest link" the campaign for access to cheap medicines has to look beyond AIDS and beyond the TRIPS framework. The "access campaign" must eventually extend itself to cover access to all essential medication and draw in interest groups from across the globe. While, tactically, the foregrounding of the AIDS issue is correct, there is the danger that the pharmaceutical industry might try a damage limitation exercise and agree to view the issue as an exception. As evinced by the recent (April, 2001) WTO/WHO meeting in Norway, such an exercise has already been initiated. The slogan of "differential pricing" is being used to suggest that the TRIPS framework may allow lower prices to be charged for ant-AIDS drugs. At some point there may be a grudging acceptance that exception may be made in a few other cases too.

This is by no means a satisfactory solution. The pharmaceutical industry would still ensure that the agreement continues to hold in the case of most therapeutic groups, and also that their prime markets remain secure. The solution only partially addresses just one part of the many problems associated with the TRIPS accord.

The campaign needs also to look beyond the TRIPS framework. While arguing for a more "liberal" interpretation of the TRIPS language to ensure better access, it is also necessary to understand that the TRIPS agreement was arrived at on the basis of submissions of the pharmaceutical industry. It is an agreement designed to promote monopolies and hinder competition. The campaign needs to look beyond TRIPS, and use the present momentum to force its renegotiation. The minimum that such a renogotiation must demand is the incorporation of provisions that automatically promote competition in all markets, and curb the monopoly over knowledge that the present TRIPS regime allows. Such a demand is not really something "revolutionary". Prior to the passage of the Kefauver-Harris drug law in 1962 in the US, Senator Kefauver's original idea was to have automatic compulsory licensing after three years at 8% royalty. [*Richard Harris' "The*

Real Voice"]. Though the proposal was shelved, it was something that was seriously debated upon.

The chink in the armour of TRIPS is visible. The pharmaceutical industry has never been as much on the defensive as it is today. Never before has public perception been as hostile to wards the industry. Never before has such a large unity been forged on the issue of patents in pharmaceuticals. The question really is, can we capture the moment?

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Considering all these aspects, bulk drugs will be kept under price regulation in accordance with the following critera:-

(i) The total MAT value of any particular bulk drug is more than Rs.2000 lakhs (Rs. 20 Crores) and the percentage share of any of the formulators is 50% or more.

(ii) The total MAT value of any particular bulk drug is less than Rs.2000 lakhs (Rs. 20 Crores) but more than Rs.500 lakhs (Rs. 5 Crores) and the percentage share of any of the formulators is 90% or more.

The above mentioned modified methodology and criteria are the best available, keeping in view the inherent constraints with respect to access to and availability of turnover data of large variety and range of bulk drugs. This modified methodology meets the requirement that the bulk drugs for price control should be identified on the basis of extent of usage and the absence of sufficient competition in both high selling and low selling formulations. On this basis, criteria have been enunciated in sub para (vi) of para 10.B II(a) the Note.

On the basis of the data worked out from the ORG-MARG of March, 1999 for the application of the above mentioned methodology and on the basis of the application of criteria stated in sub-para (f) above, there would be about 37 bulk drugs under price control and the retail market coverage on account of formulations of these drugs is estimated to be around 25% of the total retail trade reported in ORG-MARG of March 1999. This span of control is considered reasonable keeping in view the overall objective of the "Pharmaceutical Policy – 2001" aiming at ensuring adequate availability at reasonable prices and also creating an environment conducive to channelising new investments into pharmaceutical R&D and industry.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX. IV

SOME OF THE MODELS FOR WORKING OUT THE MAXIMUM ALLOWABLE PRICE

[Refer sub-para (f) of para 10.B.II on p. 8 of the Note]

The DPCRC's observation that the present methodology of microanalysis for price determination of bulk drugs through cost-cum-techno-economic study needs to be reviewed in the context of the liberalized economic regime, is a profound observation. The pharmaceutical industry has been averse to such studies for the reasons of maintaining secrecy with regard to their technology and process details. Moreover, as the price fixed on the basis of such a study is a normative price and not the actual price, it creates problems for some producers of so called "quality" drugs. The industry has been consistently representing against the present system. Hence, for calculating the "maximum allowable price" of bulk drugs, it is proposed to allow the working out of the prices of major manufacturers of a bulk drug, which is under price control, in a given period of time on the basis of invoices submitted to the Central Excise Authorities on which the Central Excise Duty is paid. The data could also be collected from the top 4 or 5 formulators (as per ORG) of the concerned bulk drug. The average purchase price for the concerned bulk drug could be determined for price regulation on this basis also. Similarly, for bulk drugs, which are imported, the average of the landed cost in a given period of time shall be considered. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Chemicals and Petrochemicals can take into account market based data and arrive at an average "maximum allowable price" for the bulk drug on the basis of this data. If this is not possible the NPPA can devise its own methodology. Once the average price is determined for a bulk drug, it would be notified and shall be considered for revision from time to time. Under the Pharmaceutical Policy-2001, the flexibility to use market based data would be available to determine the "maximium allowable price" of bulk drugs. TheDepartment of Revenue and the Customs and Central Excise formations all over the country shall assist the Department of Chemicals & Petrochemicals and its attached office, the National Pharmaceutical Pricing Authority, to get the data/invoices/information as deemed necessary for conducting the above study from time to time. The Department of Revenue be advised to take necessary steps in facilitating this procedure.

I.No.N/7/2000-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX.V

STATEMENT ON PHARMACEUTICAL POLICY - 2001

[Refer paras 9, 11 and 13(ii) on p.4-5 &10 of Note]

INTRODUCTION

The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

2. The process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are: -

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.
- Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and

formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.

- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.

- Extending the facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology.

- Introduction of the Patents (Second Amendment) bill in the Parliament. It, inter-alia, provides for introduction of product patent regime and the extension in the life of a patent to 20 years.

3. The impact of the policies enunciated, from time to time, by the Government has been salutary. It has enabled the pharmaceutical industry to meet almost entirely the country's demand for formulations and substantially for bulk drugs. In the process the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 1999-2000, drugs and pharmaceutical exports were Rs.6631 crores out of a total production of Rs.19,737 crores. However, two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy - 2001. A reorientation of the objectives of the current policy has also become necessary on account of these issues:-

(a) The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and

(b) The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

4. It is against this backdrop, that Pharmaceutical Policy – 2001 is being enunciated.

F.No.5/7/2000-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

OBJECTIVES

5. The main objectives of this policy are:-

(a) Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.

(b) Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.

(c) Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.

(d) Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.

(e) Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

APPROACH ADOPTED IN THE REVIEW

6. In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by this Department by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR.

7. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards) :-

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,
- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India.

F.No.6/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

8. The recommendations of the PRDC in so far as they relate to the Pharmaceutical Policy have been taken into account while formulating the proposals on pricing aspects.

9. The Pharmaceutical Research & Development Committee has recommended in its report, submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). Necessary action in this regard has been initiated.

10. As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO,1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy – 2001".

11. It has emerged that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and canvass opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally.

12. In view of the steps already taken and in the light of the approach indicated in the foregoing paragraphs, the decisions of the Government are detailed below :-

I. <u>Industrial Licensing</u>

Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of

(i) bulk drugs produced by the use of recombinant DNA technology,

(ii) bulk drugs requiring in-vivo use of nucleic acids as the active principles, and

(iii) specific cell/tissue targetted formulations.

II. Foreign Investment

Foreign investment upto 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing.

III. Foreign Technology Agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

V. ENCOURAGEMENT TO RESEARCH AND DEVELOPMENT (R&D)

(a) In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF.

(b) Royalty receipts obtained on sales or assignment of Indian intellectual property, including a patent held by a research-intensive company, meeting gold standards, would be fully exempt from income tax.

(c) Expenditure on consumables as well as on equipment directly used in R&D by a research-intensive company, meeting gold standards, would be allowed to be written off for purposes of Income Tax within a period of one year.

(d) Exemption to a research-intensive company, meeting gold standards, from payment of import duties on chemicals, bio-chemicals, special consumables, equipment and spares, as specified by the Government from time to time, required by it for R&D in its own facility.

VI. PRICING

(a) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. These principles would be applied for developing the criteria for selection of bulk drugs for price regulation under the Pharmaceutical Policy – 2001. The identification of bulk drugs for price regulation would be based on the following methodology :-

(i) The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion., as in the past, therefrom of sera & vaccines, blood products, combinations etc. would form the total basket out of which selection of bulk drugs would be made for price regulation.

(ii) The ORG-MARG data of March 1999 would form the basis for determining the span of price control as suggested by DPCRC.

(iii) The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March 1999).

(iv) The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

(v) The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator

(vi) in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.

(vi) Bulk Drugs will be kept under price regulation if:-

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2000 lakhs (Rs. 20 Crores) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2000 lakhs (Rs. 20 Crores) but more than Rs.500 lakhs (Rs. 5 Crores) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

(vii) All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:-

In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

(b) Maximum Allowable Post-manufacturing Expenses (MAPE)

(i) Maximum Allowable Post-manufacturing Expenses (MAPE) will be 100% for indigenously manufactured formulations.

(ii) For imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit shall not exceed fifty percent of the landed cost.

(c) Pricing of Formulations

(i) For Scheduled formulations, prices shall be determined as per the present practice.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(ii) An R&D intensive company achieving "the gold standards" would qualify for an additional cost of 5% of ex-factory cost in determination of the prices of Scheduled formulations manufactured by it.

(d) Ceiling prices

Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all importers/formulators, including those in small scale sector or marketing under generic name, to follow the price so fixed.

(e) Exemptions

(i) A manufacturer producing a new drug in the country, not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) Any formulator may represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient , on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(f) Pricing of Scheduled Bulk Drugs

(i) For a Scheduled bulk drug, there shall be a price notified as the "maximum allowable price" for being adopted while fixing the prices of formulations containing that bulk drug.

(ii) The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest, and also to conduct cost cum techno-economic study, if it considers it necessary to do so, as per present practice.

(g) Monitoring

(i) To have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is, in the present context, extremely important as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, decided to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(h) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

VII. QUALITY ASPECTS

The Ministry of Health & Family Welfare would

(i) progressively benchmark the regulatory standards against those adopted in developed countries, for manufacturing,

(ii) progressively harmonize standards for clinical testing with international practices,

(iii) streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D, and

(iv) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

VIII. PHARMA EDUCATION AND TRAINING

The National Institute of Pharmaceutical Education and Research (NIPER) has been set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, Government's endeavor will be to upgrade the standards of pharmacy education and R&D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

DR-35.4

DRAFT NOTE FOR THE CABINET COMMITTEE ON ECONOMIC AFFAIRS

SUBJECT: Pharmaceutical Policy - 2001

INTRODUCTION

The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

2. The process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are: -

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.

SECRET

National Pharmaceutical Policy - 2001
(Draft)

- Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.
- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.

APPROACH ADOPTED IN THE REVIEW

3. Two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy - 2001. A reorientation of the objectives of the current policy has also become necessary on account of these issues :-

(a) The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and

(b) The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

4. In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by this Department by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR. The Committee has given its report and its recommendations are summarized in Annex. I.

5. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards) :-

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,

- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India.

6. The recommendations of the PRDC in so far as they relate to the Drug Policy have been taken into account while formulating the proposals on pricing aspects.

7. The Pharmaceutical Research & Development Committee has recommended in its report, submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). This Committee recommended that the fund would be created by collecting a surcharge of 1% of the maximum retail price of all the formulations sold within the country and could be expected to generate around Rs.100 crore annually. However, the Ministry of Finance has, in lieu of the surcharge, agreed to allocate Rs. 150 crores as Plan Fund for creation of the R&D fund. This proposal is being pursued through Expenditure Finance Committee separately.

8. As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO,1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The summary of these recommendations is at Annex.II. These recommendations have been examined in this Department.

9. The domestic drugs and pharmaceutical industry needs reorientation in order to meet the challenges and canvass opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally. The Statement on

Pharmaceutical Policy – 2001 (Annex. V) incorporates these objectives and measures.

10. In view of the steps already taken, as enumerated in paragraph 2 above and in the light of the approach indicated in the foregoing paragraphs, the proposals for inclusion in the Statement of Pharmaceutical Policy – 2001 are detailed below :-

A. PROPOSALS ALREADY APPROVED

I. Industrial Licensing

Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of

(i) bulk drugs produced by the use of recombinant DNA technology,
(ii) bulk drugs requiring in-vivo use of nucleic acids as the active principles, and
(iii) specific cell/tissue targetted formulations.

II. Foreign Investment

Foreign investment upto 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 10.A.I above, kept under industrial licensing.

III. Foreign Technology Agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 10.A.I above, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

B. PROPOSALS SUBMITTED FOR CONSIDERATION

I. ENCOURAGEMENT TO RESEARCH AND DEVELOPMENT (R&D)

(a) In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board on the lines of the Technology Development Board to administer the utilization of the PRDSF.

(b) Royalty receipts obtained on sales or assignment of Indian intellectual property, including a patent held by a research-intensive company, meeting gold standards, would be fully exempt from income tax.

(c) Expenditure on consumables as well as on equipment directly used in R&D by a research-intensive company, meeting gold standards, would be allowed to be written off for purposes of Income Tax within a period of one year.

(d) Exemption to a research-intensive company, meeting gold standards, from payment of import duties on chemicals, bio-chemicals, special consumables, equipment and spares, as specified by the Government from time to time, required by it for R&D in its own facility.

II. PRICING ASPECTS

(a) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. These principles would be applied for developing the criteria for selection of bulk drugs for price regulation under the Pharmaceutical Policy – 2001. However, the DPCRC's recommendation regarding the new criteria for ascertaining the mass consumption nature of a bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies. After due consideration of various options in this regard, the Department proposes that the identification of bulk drugs for price regulation should be based on the following methodology :-

(i) The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion., as in the past,

therefrom of sera & vaccines, blood products, combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.

(ii) The ORG-MARG data of March 1999 would form the basis for determining the span of price control as suggested by DPCRC.

(iii) The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March 1999).

(iv) The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

(v) The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.

(vi) Bulk Drugs will be kept under price regulation if:-

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2000 lakhs (Rs. 20 Crores) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2000 lakhs (Rs. 20 Crores) but more than Rs.500 lakhs (Rs. 5 Crores) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

(The rationale for indicating threshold values of MAT and the criteria enunciated in sub-para (vi) above is given in Annex. III.)

(vii) All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:-

In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price

movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

(b) Maximum Allowable Post-manufacturing Expenses (MAPE)

(i) Maximum Allowable Post-manufacturing Expenses (MAPE) will be 100% for indigenously manufactured formulations.

(ii) For imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit shall not exceed fifty percent of the landed cost.

(c) Pricing of Formulations

(i) For Scheduled formulations, prices shall be determined as per the present practice.

(ii) An R&D intensive company achieving "the gold standards" would qualify for an additional cost of 5% of ex-factory cost in determination of the prices of Scheduled formulations manufactured by it.

(iii) The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in case of Scheduled drugs, will continue.

(iv) The present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Prices Control) Order, 1995, would be done away with. However, in case of non-Scheduled formulations, DPCRC has recommended that the difference between the first sale price of a formulator and the retail price printed on the label be limited to forty percent of the latter. The matter was considered and it was felt that such a ceiling may not be made obligatory but be enforced through internal guideline to NPPA.

(d) Ceiling prices

Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all importers/formulators, including those in small scale sector or marketing under generic name, to follow the price so fixed.

(e) Exemptions

(i) A manufacturer producing a new drug in the country, not produced elsewhere, if developed through indigenous R&D, would

be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient , on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

(f) Pricing of Scheduled Bulk Drugs

(i) For a Scheduled bulk drug, there shall be a price notified as the "maximum allowable price" for being adopted while fixing the prices of formulations containing that bulk drug.

(Some of the models for working out the "maximum allowable price" are detailed in Annex. IV.)

(ii) The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest, and also to conduct cost cum techno-economic study, if it considers it necessary to do so, as per present practice.

(g) Monitoring

(i) The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will

increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(iii) The other recommendations of DPCRC like giving powers to drug control authorities to dispose of small and petty offences etc., will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable. Monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.

(h) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

III. QUALITY ASPECTS

(a) The DPCRC's recommendation that the requirements of "Good Manufacturing Practices" prescribed under the Drugs & Cosmetics Act and Rules made thereunder be upgraded to the levels prescribed for WHO/GMP certification is acceptable. The Ministry of Health & Family Welfare will be advised

(i) to progressively benchmark the regulatory standards against

those adopted in developed countries, for manufacturing.
(ii) to progressively harmonize standards for clinical testing with international practices.
(iii) to streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D.

(b) to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals, Ministry of Health and Family Welfare would (a) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and (b) establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center.

11. On the assumption that the proposals indicated above will be approved, a Draft Statement entitled "Pharmaceutical Policy -2001" has been prepared (Annex.V) for the public announcement.

12. Comments of the Departments of Industrial Policy & Promotion, Biotechnology, Health, Indian Systems of Medicines and Homeopathy, Scientific & Industrial Research, Science & Technology, Revenue, Economic Affairs, Expenditure and the Planning Commission were called for and their views alongwith the comments of this Department thereon are at Annex. VI.

13. The approval of the Cabinet Committee on Economic Affairs is requested to the following :

(i) Proposals contained in para 10 B above relating to Encouragement to Research and Development (R&D), Pricing and Quality of Drugs and Pharmaceuticals.
(ii) Draft Statement titled "Pharmaceutical Policy - 2001" (at Annex.V) for public announcement.

14. A Statement on Implementation Schedule is given at Appendix –I.

15. This note has been seen and approved by the Minister (C&F).

(Sharad Gupta)
Joint Secretary to the Government of India

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX. I.

RECOMMENDATIONS OF PRDC
[Refer para 4 on p.2 of the Note]

S.N.	Action Point	Responsibility for action
1.	Establishment of a Drug Development Promotion Foundation	Dept. of C&PC
2.	Revamping and modernization of CDSCO	Min. of Health and Dept. of C&PC
3.	Establishment of the Pharmaceutical R&D Fund.	Min. of Finance and Dept. of C&PC.
4.	Establishment and operationalisation of GMP/GLP/GCP Monitoring Authority	Dept. of Science and Technology, ICMR, DCG (I)
5.	Amendments to the Indian Patent Act.	Min. of Industry and Dept. of C&PC.
6.	Establishment to the Income Tax Act for tax exemptions on royalty and licensing from abroad and export of pharma R&D	Min. of Finance & Dept. of C&PC.
7.	Amendments to the custom duty structure to exempt imports for pharma R&D from custom duty	Min. of Finance & Dept. of C&PC.
8.	Amendments to legislation etc. for contract research use and import of animals for pharma R&D.	Min. of Welfare & Dept. of C&PC.
9.	Establishment of a tenable system of quality assurance for indigenous system of medicines.	Dept. of ISM
10.	Establishment of a new drug discovery infrastructure	Dept. of C&PC, CSIR, ICMR, DST, DBT, & Dept. of ISM.
11.	Documentation and digitization of indigenous knowledge systems	CSIR, ISM, ICMR and Dept. of C&PC
12.	Human Resource Development for New Drug Discovery and ISM.	CSIR, ICMR, Dept. of ISM, DBT, DST, Universities & Dept. of C&PC.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX.II

DRUG PRICE CONTROL REVIEW COMMITTEE

SUMMARY AND RECOMMENDATIONS

[Refer para 8 on p. 3 of Note]

The Committee held detailed deliberations to review the existing drug price control mechanism in the country keeping in view the terms of reference assigned to it by the Government. Apart from studying details in regard to pricing systems prevalent in various countries, two separate teams visited (a) Canada, France and Egypt and (b) U.S.A. and Mexico to have first hand information on the price regulatory systems operating in these countries. Both the teams had extensive discussions with various interest groups namely manufacturers, trade, pharmacists and Government officials of these countries. Also, the Committee constituted a group consisting of Dr. Rakesh Mohan, Dr. Amit Mitra, Dr. S. M. Jharwal, Shri Sharad Gupta, Shri K. M. Kaul and Dr. P. V. Appaji to look into the present criteria of selection of drugs for price control and the current price determination mechanism and to suggest modifications/alternatives to make the system of price control simpler and more transparent. Based on the suggestions received from industry associations, consumer interest groups, voluntary health organisations, trade, State Governments and some experts, and inputs received from teams and the group mentioned above, the Committee makes the following recommendations alongwith relevant observations :

1. The committee noted that the Indian Pharma Industry has registered an impressive growth over the years and has been expanding its market beyond the national frontiers. But in the changing trade and regulatory scenario at the international level much more needs to be done to make available the required medicines in abundance to the masses. Of late, increasing incidence has been observed of the diseases such as malaria, Diarrhoea, T. B., Sexually Transmitted Diseases (STDs), Hepatitis-B, Whooping cough (pertussis), measles, amoebiasis, diabetes mellitus and mood disorders. To deal with the various diseases, the public funding available in India for healthcare facilities and products is abysmally inadequate. Currently only about 3.5% of the total outlay of the states is spent on health needs. The available data reveal that the per capita expenditure on medicines is less than Rs.5.00 in many states.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

The role of the state assumes special significance since the proportion of the people below poverty line is more than one third of the total population. The fact that these people do not have the means to meet the expenditure even on minimum calorie level required implies that the expenditure on medicines which is of emergent nature is much beyond their capacity. Further, for the large segment of the population above poverty line, the problem is compounded in the absence of rational private health care, adequate and affordable public health care and health insurance cover because they are not able to meet the entire expense out of their pocket.

2. The Committee noted that in most other countries, the regulation of the drug prices is considered necessary to contain public expenditure due to government's role in funding social health and insurance schemes that cover hospital and out-patient drugs. The price regulations are used as an instrument to keep their health budgets within reasonable limits. In these countries, a substantial proportion of the population is covered through health insurance and public health schemes. As a result, the consumers are not affected directly by the high prices of drugs or high costs of medical services, but are made to pay for the increased prices / cost through high insurance premium. As opposed to this, a substantial proportion of the population in India is market dependent and have to meet all their expenses out of their own pocket on this account, making price regulation of pharmaceutical products in the market unavoidable.

3. In India, in view of a large segment of the population being poor, the reach of the health coverage being inadequate, non-availability of appropriate medical insurance coverage, price inelastic demand, market imperfections and inadequate consumer awareness, the Committee considers it necessary to continue formal regulation of the prices of pharmaceutical products and medicines for some more time till public expenditure on health care for those who cannot afford is increased and an alternative system is developed for others. However, it is pertinent to point out that the pharmaceutical industry is perhaps the only knowledge based and highly technology oriented manufacturing industry in the country which is under a formal price control regime. This is mainly because the financial provisions in the budgets of Central and the State Governments are too inadequate to cater to the needs of the ailing people. The Committee expresses serious concern on this aspect and feels that the budgetary provision should progressively be raised. Further, there is an urgent need to expand public health care, supply of essential drugs and the health insurance cover, both by the governmental and the non-governmental organisations, as prevailing in the developed countries.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

Such an alternative arrangement should be made fully operative within a period of next five years.

4. The present system of product-based price control has been in existence in this country since long with progressive decontrol in terms of the number of drugs as well as their share in the total pharma market. For the reasons stated above, the Committee is of the view that this system should continue, for the time being, but with simplified methodologies and procedures to take cognizance of the changed circumstances of liberalisation ushered into the Indian economy. For the purpose of determining span of control and pricing of the drugs identified for price control, the Committee recommends that:

(i) The approach to price control based on selectivity be continued and applied across-the-board to all the drugs used in the country irrespective of their therapeutic use. The guiding factors to identify specific drugs should be (i) mass consumption nature of the drug and (ii) absence of adequate competition in such drugs. This approach will also ensure that the important drugs needed for National Health Programmes, where adequate competition does not exist, are covered for the purposes of price control.

(ii) The Committee considered the suggestion that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. While the Committee feels that the above approach is desirable, it calls for an objective and careful assessment for identifying "low cost drugs", as the per day cost of a medicine varies depending on dosage form, patients condition, variation in the prescribed dosage, price difference in various brands, etc. The Committee is of the opinion that the price of the largest selling pack of a brand be taken as the basis to determine the low cost nature of a medicine for which the cost of maximum prescribed dose per day (irrespective of age and ailment) may be considered and the cost per medicine per day so worked out should not be more than Rs.2.00. This criteria is reasonable because for a short duration treatment of 10 days, it amounts to only about 1.5 per cent of the monthly per capita income and for long duration, it will be about 5 per cent. In common man's perception, this expenditure is same as that for a cup of tea. However, the prices of such drugs would need to be monitored so that these prices are not allowed to go up beyond acceptable limits.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) The committee noted that the criteria of mass consumption laid down in the Drug Policy, 1994 had come under criticism on account of non-exclusion of "export value" from the turnover of a bulk drug. The main argument against the non-exclusion of the "export value" was that it does not truly reflect the mass consumption nature of the drug in the domestic market and unduly inflates the turnover of a drug with high export share. However, it was reported that the value of exports was not segregated for the reasons of the fluctuating nature of export. In this regard, the Committee feels that if the criterion of "bulk drug turnover" is to be applied, non-exclusion of the export turnover of a drug from the total turnover for the purpose of assessing the mass consumption nature of a drug in a more liberalised regime, is not a sound accounting method. Therefore, identification of a drug for keeping it under price control may be decided on the basis of its consumption in the domestic market which would comprise domestic production and imports less exports.

(iv) The turnover level of Rs. 40 million stipulated in the Drug Policy as modified in 1994 may be updated on the basis of general rate of inflation (WPI – All commodities). With a view to undertaking such an exercise the Committee collated the data available from the Annual Report of the Department of Chemicals & Petrochemicals, the periodical returns/data received from manufacturers by NPPA and observed that the data were inadequate Therefore, the Committee issued a public notice in the national news papers (Hindi and English) requesting the manufacturers to furnish the data for the year 1998-99 on production and exports (quantity and value) of both the bulk drugs and formulations. However, the response was poor and the attempts to update the data did not succeed. Therefore, the committee felt that the available data were not complete to work out the turnover, as defined above.

5. In view of the above, the committee considered an alternative method based on the sales turnover of formulations (brand wise) in various categories as given in the monthly retail store audit report on the pharmaceutical market by a leading and reputed organisation, namely, ORG-MARG. The ORG-MARG provides, on a monthly basis, the data on moving-annual total (MAT) representing the sale value during a twelve month period for each of the formulation pack marketed by different manufacturers. The formulations with their sale value are categorised as per their clinical/therapeutic/chemical classification. For the purpose of judging mass consumption nature of a bulk drug, any brand based on a given drug having specified minimum value of MAT could be considered as a mass consumption drug. Secondly, to judge the level of competition, if the market share of a brand in a specific category is found to be higher

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

than the maximum stipulated share, such drug may be considered as having inadequate competition. By adopting the above criteria, the specific bulk drugs may be identified based on the composition of the selected brands.

6. The group constituted by the committee to consider an appropriate methodology has made the following suggestions, with which the committee agrees:-

(i) The minimum MAT value of a brand for the purpose of determining the mass consumption nature of the drug may be considered as Rs.10 crores.

(ii) Secondly, a brand with 10 per cent or more share in a given category may be treated as having inadequate competition.

(iii) Identify the brands having MAT value of Rs.10 crores and above with a share of 10% or above in the group/category (there are approximately 180 categories in ORG). For this purpose, the March, 1999 issue of the ORG-MARG Report which provides firm data for the year, 1998-99 be used.

(iv) Exclude all brands having Ayurvedic and other products which are not covered under DPCO.

(v) Exclude the multi-ingredient based brand formulations.

(vi) List out the bulk drugs contained in each of the brand products so selected for the purpose of identifying the bulk drugs to be included under price control.

(vii) From the list of bulk drugs so worked out, the low cost drugs may be eliminated on the basis of "per day cost of a medicine" worked out based on the maximum retail price (MRP) of the top selling pack of the brand from which the concerned bulk drug was identified. As stated earlier, the per day cost of a medicine should not exceed Rs.2.00 for being considered as "low cost medicine".

7. The committee recommends that the above methodology be adopted for identification of specific bulk drugs to be put under price control. Accordingly, the Government would need to undertake an exercise to arrive at a list.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

8. **Methodology for fixation/determination of prices of bulk drugs**

(i) For determining the price of a bulk drug, three alternatives were considered viz. (i) The cost-cum-techno-economic study (ii) Market price data and (iii) Import price data. It was felt that the present methodology of micro analysis for price determination through cost-cum-techno-economic studies needs to be reviewed in the context of the liberalised regime, wherein the prices are likely to be determined by the market forces. The Committee also took note of the fact that the industry has been averse to such studies for the reasons of maintaining secrecy with regard to their technology and process details. This would become a more legitimate concern particularly in the context of introduction of product patents. Therefore, the committee recommends that the market price data would be a better method to determine realistic prices as compared to that based on cost-cum-techno-economic studies.

(ii) For the purpose of determining the price of a bulk drug, the committee recognizes that a system of price related information would have to be evolved since there is no single source of data which can be relied upon. The possible sources of information could be the chemical/drug industry journals, purchase documents available from formulators, import data as available from DGHS, the Central Excise authorities and Annual Cost Audit Report etc The Government may develop a suitable method to work out a representative price of a bulk drug based on an averaging appropriate to the available data.

(iii) The committee also recognizes that in the liberalised regime, the prices of bulk drugs would be more prone to fluctuations and, therefore, there may be requests from the manufacturer for frequent revision in the prices. Such changes in the prices, if allowed, are bound to result in undue uncertainty in the market which would neither be in the interest of the industry nor the consumers. Therefore, after having determined the price based on a weighted average market price, taking into account a reasonable duration and source of data availability, revision in the bulk drug prices may be effected on an yearly basis and the prices so determined may be notified for the purpose of pricing of formulations based on it, every year in the first week of June on the basis of data pertaining to the preceding financial year and statutory changes announced in the budget for the current year. Provided, however that, with a view to keeping the prices within reasonable limits, annual increase may not be allowed beyond a limit which may be prescribed by the Government on the basis of the rate of inflation during the preceding year measured in terms of WPI of all commodities.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) In case the price to be notified on the basis of weighted average market price of a drug as calculated under (iii) above is not acceptable to a drug producer(s), at his request and on adequate information being provided, the government may require a cost cum techno-economic study to be undertaken as an exceptional measure. Further, such a study shall be undertaken only in situations where (i) Anti-dumping proceedings are initiated and / or (ii) Public interest is involved. Where ever, such cost-cum-technical studies are to be undertaken, the present method may be adopted. The two-third cut-off criteria in respect of the estimated production of a drug to determine its price has generally been found to be with a sound economic rationale as the price so fixed covers bulk of the production i.e. more than 66 percent. This also encourage cost efficient production while discouraging cost inefficient ones. Further, capacity utilisation may be taken at 80 per cent or actual whichever is higher, so as to be in line with criteria adopted by the financial institutions for the purpose of appraising proposals for granting financial assistance.

9. **Methodology for determining the prices of formulations.**

(i) The Committee also deliberated on the suggestion that instead of the prices of bulk drugs, the prevailing market prices (MRP) of the formulation packs containing any of the drugs identified for price control may be taken as the bench-mark price and notified. Revision in the notified prices in future were suggested to be allowed within the limit of rate of inflation measured in terms of CPI for industrial workers/agricultural labourers. It was also suggested that the price changes for the controlled formulations may be reviewed by the Government every year for taking necessary corrective measures.

The Committee considered the above suggestion and felt that the following problems are likely to be encountered in this regard :

(a) This method would provide automaticity in the price fixation method for formulations and provide incentive to the manufacturers to revise their prices upwards. The concept of automaticity in pricing was considered in the Drug Policy on an earlier occasion and was not found to be desirable.

(b) Secondly, as the basis of price determination of controlled drugs (cost-plus) and decontrolled drug formulations (market forces) differ, it would not be appropriate to take the prevailing market prices as the bench mark. In this regard, the suggestion of the industry for grant of one time increase on the prices of controlled formulations, based on inflation factor, to bring these at par with the decontrolled formulations (now to be brought under price control) might unduly increase the prices.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(c) Thirdly, the prices of new introductions with different pack sizes and different strength/compositions than those notified as bench mark formulations would need to be fixed afresh rendering the system more complex and disputable.

In view of the above, the Committee felt that a cautious approach needs to be adopted at this stage. However, based on a further review after about three years i.e. before the TRIPS provisions come into existence, this suggestion may be reexamined for its feasibility keeping in view the observed changes in the availability, price situation and rationalisation of phrama products.

(ii) Therefore, the present method of determination of the prices of both imported and indigenous formulations on the basis of formula given in para 7 of DPCO, 1995 may continue. However, for the indigenously produced formulations the Committee has noted that the existing methodology does not account for expenses on account of (a) maintenance of quality by observing WHO certification etc. and (b) improved packaging to check counterfeiting, maintenance of quality during the shelf life, etc. These elements involve capital investment and recurring expenditure. Presently, a large number of manufacturers in the country do not have WHO certification. However, recovery of the expenditure incurred on these elements through increased MAPE will not be correct as per the established accounting principles since MAPE covers only the post manufacturing expenses. Nevertheless, the Committee feels that due weightage needs to be given to these elements of cost while working out the prices of the formulations. With a view to reducing the rigorous by moving from the micro analysis to the macro assessment, the committee recommends that an additional eight per cent cost be allowed on the products manufactured under WHO-GMP certification and additional upto two per cent for improved packaging, on application by a manufacturer, to compensate for these costs over and above the ex-factory cost worked out based on the existing methodology as given in para 7 of the DPCO, 1995. Further, recognizing that there is a need to improve the GMP standards to standards such as US-FDA/MCA for encouraging exports, the Committee suggests that an appropriate provision to meet higher expenses on this account may be allowed through a further three per cent of the Ex-factory Cost, over and above other provisions suggested above.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) As regards the question of providing incentive for R&D, the Committee noted that the Pharmaceutical Research and Development Committee (PRDC) is considering to lay down certain criteria for the identification of Units/Industry engaged in R&D activities alongwith required measures. Subject to the recommendations of that Committee, a further additional cost of five per cent of ex-factory cost over and above that recommended under para (ii) above, may be allowed to companies which undertake basic research for new drug discovery, provided they have actually spent a minimum percentage of their sales turnover, as may be prescribed, for this purpose. Such an incentive may be provided based on a certificate by a designated technical authority. The Committee recognises that the proposed incentives to the manufacturers with US-FDA/MCA certification and the R&D certified companies shall be availed of by a small number of companies. These incentives, nevertheless, were considered desirable to provide positive signals to the investors in such activities. Further, the Committee feels that any price rise on account of these or WHO-GMP standards is expected to be offset by the benefits to consumers through improved quality and security from the spread of spurious drugs in the market.

(iv) With a view to introducing a simplified procedure, a suggestion was made for appropriate neutralization, based on WPI/CPI of Conversion Cost (CC), and Packing Charges (PC) and Packing Material (PM) Cost. Based on the deliberations, the committee recommends that the CC&PC be neutralized on the basis of CPI for industrial workers. Further, the PM Cost be neutralized on the basis of WPI for all commodities. For the neutralization of these costs, the improvement in Process Loss (PL) needs to be kept in view.
However the government needs to notify the norms every year as required in the previous DPCOs .

(v) During the deliberations, the Committee felt that the imported finished formulations, patented or otherwise, be brought under price control. However, this may not be GATT/WTO compatible. Nevertheless, the price of new introductions in the country would need to be watched and monitored. The Committee, therefore, recommends that the prices of patented drug formulations, including those granted with EMR, introduced in the country shall be under price control and the marketing approval under the Drugs & Cosmetics Act should be issued only after the applicant has obtained price approval from the Government. When it is not feasible to determine a reasonable price under the existing methodology/formula, an alternative methodology including reference pricing corrected for relative per capita income level may be developed by the Government.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

10. Monitoring & Enforcement

(i) The committee recognizes the objectives of the Drugs Price Control Order in the given socio-economic conditions in the country and the need to enforce and monitor the provisions to adequately protect the consumers' interest. The Committee is of the view that effective monitoring systems would have to be established to move away from the "controlled regime" to the "monitoring regime" in a medium and long term perspective.

(ii) The Committee noted with concern that the enforcement of various provisions of Drugs and Cosmetics Act is still not uniform throughout the country and spurious and substandard counterfeit drugs find their way into the market. It was also reported that different yardsticks are adopted by State Licensing Authorities for granting manufacturing approval of drug formulations. This leads to proliferation of formulations and pack sizes. The Committee feels that the systems and criteria adopted for granting drug licences and formulation approvals need to be made uniform. The Committee recommends that the Good Manufacturing Practices (GMPs) requirements prescribed under the rules for manufacture of drugs be upgraded to the levels prescribed for WHO-GMP Certification Scheme . This needs to be achieved within a period of 2 years, say by December, 2001, after which no manufacturing license under the Drugs and Cosmetics Act be renewed or granted to units not conforming to the minimum prescribed WHO-GMP standards.

(iii) Further, the committee is informed that under the provisions of "The Drugs and Cosmetics Act" such activities constitute a cognizable offence with appropriate penal provisions including imprisonment since it involves human health and life. The committee feels that the relevant provisions be enforced in their letter & spirit. The Committee also recommends that WHO-GMP be made a basic criterion for granting a drug license to manufacture a drug in the country.

(iv) Further, for effective enforcement, the following steps are recommended :

(a) Provide powers to the Drugs Control Authorities to dispose off small & petty offences/contravention's by compounding provision for such offences in the DPCO. This would obviate the necessity of launching prosecutions in minor cases.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(b) The Government should develop an appropriate mechanism to study the price movements of drugs marketed in the country in both controlled/decontrolled categories and develop a price index for pharma products to review the price situations on monthly/quarterly basis to take corrective measures. In the case of imported bulk drugs and formulations, the prices need to be monitored more closely in the light of the changes in the international trade regime. This would help in determining the cases of dumping and under/over invoicing to protect the interest of the industry and consumers.

(c) The Committee recognizes that in the liberalised regime, a reliable data base would go a long way in evolving appropriate and timely policy measures. The Government should develop a data bank on pharmaceutical sector. A simplified format may be prescribed in the DPCO to collect the required information.

(d) The availability and price situation be reviewed by holding periodical meetings with the consumer interest groups, industry and trade.

(e) Import of formulations falling under the price decontrolled category be monitored effectively according to a format to be prescribed in DPCO. This should indicate the quantity, c.i.f. price, customs duty paid and the MRP of the product for each imported consignment.

11. Miscellaneous

(i) Dispose off the review petitions filed by the manufacturers with in a given time frame, say two months after receipt of complete information.

(ii) The Committee has noted with concern that presently there is no system of prescription audit, through which it could be ascertained whether the hospitals/doctors prescribe more expensive and non-essential drugs instead of low priced essential drugs. However, the committee was informed that there is a tendency to prescribe high cost medicines despite the availability of cheaper and equally effective substitutes. The Committee feels that this tendency needs to be curbed through a coordinated effort by the Department of Chemicals & Petrochemicals and Ministry of Health by developing an appropriate prescription audit mechanism with active support of Indian Medical Association.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) The Committee has noted that in addition to product-wise price control on selected drugs, there are limits, stipulated in the DPCO, 1995 on profits of a pharmaceutical company as percentage of its sales turnover. It was also noted that this provision of controlling overall profitability of a company was intended to check unreasonable increase in the prices of pharmaceutical products not under price control. It was reported to the committee that it has not been practicable for the government to meaningfully monitor the profitability of each and every company. At the same time, this provision has reportedly adversely affected the scope of increased investment in R&D. As the thrust of the economic policy is towards providing flexibility under the conditions of market economy, the Committee is of the view that there is no need to have dual control on pharmaceutical companies. Therefore, the Committee recommends that the provision limiting profitability of pharmaceutical companies be done away with.

(iv) As a medium and long term strategy, adequate health insurance cover, both by the public and private sector, needs to be provided so that the dependence on price control measures could progressively be reduced.

(v) To curb indiscriminate imports, there is need to strengthen procedures and rules under Drugs & Cosmetics Act so as to provide for a registration system for import of pharmaceutical products into the country.

(vi) As per available reports, eight percent margin is provided to the wholesalers and sixteen per cent to the retailers on the scheduled formulations. For non-scheduled formulations, the companies are at liberty to decide the trade margin. It is reported that the prevailing normal trade margin in respect of the decontrolled formulations is 20 per cent for retailers and 10 per cent for wholesalers. In view of this, the present stipulation of 16 per cent margin on scheduled formulations to the retailers needs to be retained.

(vii) It has also been observed that some of the manufacturers tend to provide unduly high trade margins, adversely affecting the consumer interest. Therefore, the committee is of the view that to discourage unethical practices by the players, the difference between the first sale price of a formulation by the manufacturers and the retail price printed on the label be limited to a maximum of 40 percent of the MRP in the case of decontrolled formulations.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(viii) As brought out earlier there is (a) absence of rational private health care (b) inadequate public health care and (c) inadequate health insurance cover in the country. Therefore, the committee recommends that there is an urgent need to expand public health care by progressively raising the budgetary provision, improve supply of essential drugs and accelerate the process of providing health insurance cover, both by the governmental and non-governmental organisations and that such an arrangement should be made fully operative within a period of next five years..

(ix) Further, the Committee has observed that several manufacturers are providing bonus offers/schemes for promotion of their products. Such schemes/offers lead to higher prices for the consumers apart from the possibility of compromise on quality of the product, resulting in proliferation of substandard products in the market. Therefore, the committee is of the view that such practices be discouraged through effective monitoring for taking corrective measures.

F.No.6/7/2000 PLI
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ANNEX-III

RATIONALE FOR THRESHOLD VALUES OF MAT
[Refer sub-para (vi) of para 10.B.II(a) on p.6 of the Note]

Presently, there are 74 bulk drugs under price control and the retail market coverage is estimated to be 38-40% approximately. These drugs were kept under control on the basis of turnover criteria of Rs.400 lakhs or more, which was based on 1989-90 data. This, in terms of value of formulations, works out to Rs.1600 lakhs on the basis of "the ratio of value of consumption of bulk drug for production of formulations to the value of formulations produced as 1:4" adopted in Chapter V of the Report of the working group on Drugs and Pharmaceuticals for the Ninth Five Year Plan Period (1997-98 to 2001-02).

Data used at the time of promulgation of DPCO 1995 was of the year 1989-90. For this reason value of formulations arrived at above would require correction for inflation since then. Further correction would be required there on account of the fact that now we are considering only single ingredient formulations where as all formulations comprise of single as well as multi-ingredient formulations. On the basis of increase in the Wholesale Price Index (WPI) for Drugs and Medicines from 140.4 points in 1989-90 to 320.9 points in 1998-99, the value of all the formulations i.e. Rs.1600 lakhs, calculated above, would come to Rs.3657 lakhs. Further, the MAT-Value for all formulations as per ORG-MARG of March, 1999 is Rs.1190946 lakhs (Rs.11909.46 crores), whereas the MAT-Value of all the single ingredient formulations works out to Rs.603283 lakhs. On this basis, the value of Rs.3657 lakhs of all formulations corresponds to Rs.1852 lakhs in terms of the total single ingredient formulations. Hence, the threshold limit of Rs.2000 lakhs appears reasonable for bringing drugs under price control, which would mean that if, for any bulk drug, the MAT-Value of all its single ingredient formulations is above Rs.2000 lakhs, then it could be considered for price control.

Under the liberalised industrial, trade and economic policies, the availability of bulk drugs is not as problematic as it was earlier when import policy was quite restrictive. There are large number of formulators for a bulk drug. However, an analysis of ORG-MARG data indicates that in majority of cases, major share of the retail market is with 3-5 formulators only. Rest of the formulators have rather low shares. In view of these factors, it is not prudent to define competition in terms of number of bulk drug manufacturers and number of formulators in relation to a particular bulk drug.

Pharmaceutical Policy - 2001
Yes to Increased Profits, No to Health!

Anant Phadke

The draft Note for the cabinet committee on Economic Affairs, titled 'Pharmaceutical Policy 2001', follows the old pattern of exclusively focussing on economic issues related to the drug industry. It primarily deals with pricing of drugs, profitability.

This time, the additional concern is increased focus on making the India drug industry on par with the international standards. Despite our repeated demand that the health ministry be actively involved in the preparation of the pharmaceutical policy, this draft 'Pharmaceutical Policy 2001' has been prepared only by the Ministry of Chemicals and Fertilizers, with total exclusion of issues of rationality of drug production.

Main Features of 'Pharmaceutical Policy 2001'

Briefly speaking this 'Note' has the following features -

1. Complete Surrender To The MNCs

It enumerates sanctifies the 'liberalization' steps taken since 1991- abolition of industrial licensing barring a few exceptions; dereservation of the 5 drugs hitherto reserved for the public sector and opening of the public sector to foreign competition; automatic approval of foreign investments even for 100% foreign collaboration; automatic approval of foreign Technology Agreements.

Industrial licensing has been abolished except for three technologies – recombinant DNA technology, in vivo nucleic acid use, specific cell/tissue targeted formulations.

2. Increased Incentives And Provisions For Research For Enhanced International Competitiveness

a) Permission to increase prices by five percent extra for drug companies which comply with suggested 'gold standards' of –

- investing at least 5% of the turnover of the company in R and D, atleast 10 crores per annum for innovative research,
- employing at least 100 research scientists in India,
- of having at least 10 patents for research done in India

b) Setting up of Pharmaceutical Research and Development Support Fund (PRDSF) with the Ministry of Finance contributing Rs. 150 crores as 'Plan Fund' for the creation of the 'R & D fund'

c) To enhance international competitiveness, certain measures will be taken, like mandatory WHO/Good Manufacturing Practices Certification Scheme, attaining international standards for clinical testing.

For products manufactured under WHO-GMP certification, additional 8% cost be allowed in estimating cost of production) and further upto 2% for improved packing.

(We have to see in detail, as to whether all the details of the WHO-GMP certification standards are relevant to Indian conditions. There can not be any compromise on minimum standards. But beyond this, in pursuit of promoting exports, if standards are set on par with developed countries, the drug prices would go further out of the reach of the majority of people in India. Hence, we should question this move.)

3. Reduced Span Of Price-Controlled Drugs

Only about 37 bulk drugs accounting for about 20% of the market-sale, would be under price-control, as compared with the 74 bulk drugs accounting for about 40% of the market being under price-control today and 343 drugs under price-control in 1985. Newer, 'liberal' criteria for selection of bulk drugs under price-control have done this trick.

4. Increased Profitability

- The Maximum Allowable Post-manufacturing Expense (MAPE) would be 100% for indigenously manufactured drugs. Currently only class IV. i.e. totally 'inessential ' drugs are allowed 100% MAPE.

- For imported formulations, the selling price can be upto 150% of the landed costs.

- The present provision as per the Third Schedule of the Drug Price Control order 1995, of limiting the profitability of drug companies, would be done away with.

- There would be some exemptions (see section B2.2) even for the limited number of 37 bulk drugs to be under price control.

Thus overall, the drug companies have been given a free hand to jack up prices.

The above four are the main provisions in brief, of the 'Pharmaceutical Policy 2001.' There are a few other provisions, which are of not much significance.

What Should Be Our Critique?

Our response to this draft note should be two fold : raising issues on both the health and economic aspects.

A. The Health Aspect of the Drug Policy

On the health aspect, we should strongly protest against the exclusion of the policy issues related to the rationality/irrationality of various drug-formulations sold in India. Secondly we should once again bring forth our following demands about the socio-medical rationality of drug production in India.

1. Eliminate all drugs and formulations not recommended by standard text-books and other authorities
2. Eliminate al Fixed Dose Combinations not recommended. by standard text-books and other authorities.
3. Priority and incentives to the production of Essential Drugs, especially to drugs for Primary Health Care.
4. Abolish all brands names. Drugs to be sold only under generic name, with the company's name in the bracket.
5. Review of all the drugs every three years to eliminate obsolete drugs.
6. Strict ethical guidelines for drug-research.
7. Commercial production of any drug claimed to be Ayurvedic, should be allowed only after the scrutiny of its rationality by the council for Indian System of Medicine.
8. Strict regulations for ethical promotion and marketing of pharma-products. We have formulated details about this in our earlier deliberations and demands.
9. Proper system of post marketing surveillance for adverse drug reactions.
10. Proper system of Compulsory Continuing Medical Education (CMIE) for medical and paramedical professionals in rational therapeutics.

The above is only a reiteration in brief, of our main demands as regards the medico-social rationality of drug production in India.

We need to once again forcefully put forth these demands and point out that the 'Pharmaceutical Policy 2001' does not even mention any of these crucial aspects of drug policy.

B. Economic Aspects of Drug Policy

B1. Self reliance

Self-reliance, which was one of the principal concerns of the Hathi committee report and which was an important element of the earlier drug-policy statements, does not even find a mention in this 'Note'! For the current decision makers,a globalized economy means complete domination by the foreign multinationals. We have to expose and oppose this spineless, shameless prostration before the imperialists. We should continue to argue for restrictions on majority owned foreign companies in the production of those drugs for which know how exists with the Indian companies. Foreign companies be allowed only if they are willing to provide superior know how at reasonable cost, to the Indian companies.

In today's globalized economy, distinction between and the consequences of the role of 'Indian' and 'foreign' companies has been blurred to a certain extent. But there is no case for throwing over board, the concept and strategy for self-reliance. Complete domination by foreign MNCs is nether inevitable nor of course desirable.

B2 Price-Control

We have argued for price-control on drugs for two valid reasons –

1. Drugs are part of essential commodities, are life-saving.
2. The consumer has no choice, but has to buy medicines once the doctor prescribes it. Hence consumer resistance is very low in purchase of medicines.

No amount of so called liberalization would negate the above rationale. Hence the need for control of drug prices continues. The drug price control is today too complicated because of the plethora of thousands of irrational fixed dose combinations being marketed. If all these irrational fixed dose combinations are weeded out, price-control will be far less complicated.

2.1 Criteria For Price-Controlled Drugs

Even within the existing drug production pattern, there is no case for further concessions to the drug industry by reducing the number of drugs to be price controlled. We should oppose further decontrol of drug prices by concretely exposing the irrational nature of the new measures of further price decontrol.

The new formula for deciding which **bulk-drugs** will be price-controlled, is as follows -

For **bulk-drugs** with a sale of Rs. 5 to 20 crores, the drug will be price-controlled if a formulator controls more than 50% of the market.

For **bulk-drugs** with a sale of above 20 crores, the drug will be price controlled if a formulator controls more than 90% of the market.

Even if price control is to be restricted to drugs which are produced or sold monopolistically, both these figures of cut off sale value and of percent control by one formulator are arbitrary. There should be no cut off value for sales figures. Any drug be subject to price-control, whatever may be its sale, if it is produced or sold monopolistically. Secondly, the cut off value to decide monopolistic control can not be set arbitrarily at 50% or 90% control by one formulator. Internationally, it has been established that if more than half of the market of a product is controlled by five or less number of companies, the product is deemed to be under monopolistic control. This criterion be applied to the bulk drug market in India, if it is decided that price control is restricted only to drugs which are monopolistically controlled.

The above formula is for bulk drugs, from which Ayurvedic drugs have been excluded. The method for controlling prices of **formulations** would continue as before, as per the 1995 DPCO.

B 2.2 Liberal Exemptions

Certain drugs would be exempt from price-control. The criteria for exemption are liberal, at the cost of the consumer. These criteria are

a. Fifteen year exemption for new drugs developed though indigenous R & D.
b. Exemption till expiry of the patent for
    i) drugs whose process has been patented under the Indian Patent Act 1970.
    ii) Formulations involving new drug delivery systems registered under IPA 1970.

As per the DPCO of 1979, some drugs were allowed only 40% mark up. Hence the drug companies were clamouring for exemption of certain drugs from price control. But now, as per the new proposed policy, all indigenously manufactured drugs would enjoy 100% MAPE. Secondly these will be monopoly due to the patent coverage so that the prices will not be brought down by competition, below the levels decided by the new limit of 100% MAPE. Hence, now there is no case for exemption from price-controls, if the MAPE is raised to 100%.

c. 'Cost per day per medicine' being less than Rs. 2/-.

This would mean commonly used essential drugs like aspirin, paracetamal, iron-folic acid, furazolidone, B'comples, etc. will all go out of price-control! This exemption should also be stoutly opposed. The fact that drug companies have been selling 75 mg. tablet of Aspirin at 75 paise per tablet, when the price should not be more than 20 paise, per day, shows once again that they cheat, exploit consumers whenever there is a chance. Removing price-control on those essential drugs whose per day cost is less Rs. 2/- is simply unacceptable.

B 3 Other Measures.

Other provisions as regards ceiling prices, fixing prices of Scheduled Bulk Drugs, drug price monitoring, Drug Price Equalization Account (DPEA) do not require any fresh comments.

Thus overall, the new drug policy titled 'Pharmaceutical Policy 2001' is pro-industry, anti-people and devoid of any medico-social rationality. We should oppose it in whatever way possible.

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Fair copy, please
CM
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Pharmaceutical and Drugs Policy

There is need a pharmaceutical and rational drug policy, which would reflect our concerns for the health of the people and the economy of the drug industry. Drugs are meant to maintain and restore the health of the people. This primary concern should not be lost sight of in any policy. At the same it is necessary to ensure that the essential drugs are produced in sufficient quantities. The essential drugs must be available, accessible and affordable. They must be utilised in a rational manner.

The National Policy must be enunciated ..... jointly by the Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilizers, to reflect the concerns for the health of the people and the industry.

Situation: Because of the GATT decisions and the formation of WTO, the Indian Patent Act, 1970 is being amended to fall in line with the demands of the larger multinational ~~procedures~~ of drugs in the developed countries. This will adversely affect the manufacturers in the country, who are able to produce drugs of reasonable quality at much lower prices than the multinationals (eg. , the anti-retroviral drug packages in the management of HIV infection and AIDS). There is need to ensure a certain amount of self-reliance which would call for support for the local industry. The use of drugs in the country is irrational. This starts with the manufacture and marketing of irrational drugs and irrational combination of drugs, ~~and~~ the prescriptions and the usage.

There has been large scale reduction in the number of drugs under price control. This has been followed by unwarranted increases in the price of the drugs ~~act~~ of price control.

Public Sector:

The public sector had been active in the production of essential drugs, including the antibiotics. In recent times, they have fallen into disrepute because of mismanagement. The remedy is not to dismantle them or to privatize them but to ensure better management. The public sector needs to be strengthened as the sector responds to the health needs of the people and not necessarily to profit making only. A vibrant public sector would ensure that the country/state is not ~~wonder~~ the mercy of the private sector.

Private Sector: Indian economy has been a public - private mix. The private sector has a role. It is competitive, though not so much in the health sector. Brand loyalty is created; questionable promotion methods are used by which the prescriber (agent for the user) prescribes only certain brands. It is necessary that the private sector is regulated carefully: monitored and corrections applied without delay.

Span of Price Control With profit as the main guiding factor for the private sector, there is always a tendency to increase the profits, while profitability is needed (otherwise no industry will be interested in continuing the manufacture), it is necessary to curb pro fiteering and drive the drugs beyond the access of the majority of the people, especially the poor, and the government.

All essential drugs should continue to be under price control, ensuring availability and affordability.
One way of reducing the price of drugs is to have them under generic name, instead of the brand name.

The National Pharmaceuticals Pricing Authority must ensure early fixing of the prices; automatic ~~ant...~~ Revisions may be made based on the consumer Price Infix / Wholesale Price Index.

Import of drugs: Self - reliance is the key word to ensure availability and affordability. But, with the new patent regime, many of the newer drugs will have to be imported. The cost of the these imported drugs will be very high.

Care must be taken to ensure that only drugs which do not find ~~them~~ their counterparts locally manufactured are imported. These should not be merely 'me - too' drugs. They should have specific indications, not met by drugs already available, less adverse and side effects and are cheaper.

Quality of drugs: We must be alert on the quality of drugs produced in the country or imported from abroad. It is a good idea for the industry to join the WHO Good Manufacturing Practice Scheme. This is not merely to boost export but to ensure that the people receive good quality drugs.

Post marketing surveillance is essential to ensure that only quality drugs are in circulation.

Rational Use of Drugs:

The Rational Use of Drugs has many facets. It starts with the manufacture of rational drugs. Irrational drugs and irrational combinations of drugs should not be produced. The relevant authorities must ensure that such drugs are not available in the market. No banned drugs should be available. The legislation must ensure it; the law must be implemented. The prescribes must be knowledgeable; hence, there is need for proper education and continuing updating in the proper use of drugs.

The users also should become aware of the need for rational use of drugs. Addition of new drugs or their formulation must be based on real need. At the same time, obsolete drugs must be eliminated.

Research:

Research is necessary to bring out newer drugs needed for the health of the people. This requires that increased incentives must be provided for investment in Research and Development. The policy must serve this purpose. Research and Development should

// Banned drugs should not be allowed to be produced even for export. A recent court decision allowed such production. This is ethically wrong. When we have decided that a particular drug or its combinations are bad for use in the country, it is not correct to produce it for export.

form an integral part of the activities of the manufacturers, the larger ones independently and the smaller ones conjointly. It is good to have the Pharmaceutical Research and Development Support Fund. The industry must contribute to it. There is no reason why Government should contribute Rs. 150/- crores towards such a fund. Government should encourage in other ways, such as helping in the patenting of the new products and processes and making available protocols for human experimentation and drug trials.

Study on new drugs must follow all the ethical guidelines. The basic ethical principles are beneficence, non - male... justice and antinomy and must be observed in all phases of the ~~eterical~~ trials.

Promotion of drugs

The industry must follow the revised WHO ethical guidelines for promotion of drugs. The Governments (central and State) and the profession must ensure that the guidelines are followed. The prescribers are agents of the patients and other users and not of the industry

Pharmaceutical Policy - 2001

A Critique

Dr Anant Phadke

The Draft 'Note' submitted before the Cabinet Committee on Economic Affairs, titled 'Pharmaceutical Policy 2001', follows the old pattern of exclusively focussing on economic issues related to the drug industry. It primarily deals with pricing of drugs, and profitability.

This time, the additional concern is the increased focus on making the Indian drug industry on a par with the international standards. Despite our repeated demand that the health ministry be actively involved in the preparation of the pharmaceutical policy, the draft has been prepared only by the Ministry of Chemicals and Fertilizers, with total exclusion of issues of rationality of drug production. The various groups working in the field of health as well as activists need to register their opposition to the draft policy in chorus so that the policy gets rationalized.

Briefly put, the 'Note' has the following features:

Complete Surrender To The MNCs

The 'Note' enumerates the sanctities of the 'liberalization' steps taken since 1991 — abolition of industrial licensing barring a few exceptions; dereservation of the 5 drugs hitherto reserved for the public sector and opening-up of the public sector to foreign competition; automatic approval of foreign investments even for 100% foreign collaboration; and automatic approval of Foreign Technology Agreements.

Industrial licensing has been abolished except for three technologies — recombinant DNA technology, *in vivo* nucleic acid use, specific cell/tissue-targeted formulations.

Increased Incentives and Provisions for Research for Enhanced International Competitiveness

a) Permission to increase prices by five percent extra for drug companies which comply with suggested 'gold standards' of

- investing at least 5% of the turnover of the company in R and D, at least 10 crore per annum for innovative research,
- employing at least 100 research scientists in India,
- having at least 10 patents for research done in India

b) Setting up of Pharmaceutical Research and Development Support Fund (PRDSF) with the Ministry of Finance contributing Rs. 150 crore as 'Plan Fund' for the creation of the 'R & D fund'

c) To enhance international competitiveness, certain measures will be taken like mandatory WHO/Good Manufacturing Practices Certification Scheme, attaining international standards for clinical testing and so on.

For products manufactured under WHO-GMP certification, additional 8% cost be allowed in estimating cost of production and further upto 2% for improved packing.

We have to see in detail whether all the details of the WHO-GMP certification standards are relevant to Indian conditions. There cannot be any compromise on minimum standards. But beyond this, in pursuit of promoting exports, if standards are set on a par with developed countries, the drug prices would go further out of the reach of the majority of people in India. Hence, we should question this move.

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Only about 37 bulk drugs, accounting for about 20% of the market-sale, would be under price-control, as compared with the 74 bulk drugs accounting for about 40% of the market being under price-control today and 343 drugs under price-control in 1985. Newer, 'liberal' criteria for selection of bulk drugs under price-control have done this trick.

Increased Profitability

- The Maximum Allowable Post-manufacturing Expense (MAPE) would be 100% for indigenously manufactured drugs. Currently, only category II &III. drugs are allowed 100% MAPE.
- For imported formulations, the selling price can be upto 150% of the landed costs.
- The present provision, as per the Third Schedule of the Drug Price Control Order 1995, of limiting the profitability of drug companies, would be done away with.
- There would be some exemptions (see section B2.2) even for the limited number of 37 bulk drugs to be under price control. Thus, overall, the drug companies have been given a free hand to jack up prices.

Besides the above main provisions there are a few other provisions, which are not of much significance.

What Should be Our Response?

Our response to this draft note should be twofold : raising issues on both the *health and economic aspects*.

HEALTH ASPECTS OF THE DRUG POLICY

We should strongly protest against the exclusion of the policy issues related to the rationality/irrationality of various drug-formulations sold in India. We should once again bring forth the following demands about the socio-medical rationality of drug production in India.

- Eliminate all drugs and formulations not recommended by standard textbooks and other authorities
- Eliminate al Fixed Dose Combinations not recommended by standard textbooks and other authorities.
- Give priority and incentives to the production of Essential Drugs, especially drugs for primary health care (PHC).
- Abolish all brand names. Drugs are to be sold only under generic names, with the company's name in the bracket.
- Review of all the drugs every three years to eliminate obsolete drugs.
- Strict ethical guidelines for drug-research.
- Commercial production of any drug claimed to be Ayurvedic should be allowed only after the scrutiny of its rationality by the Council for Indian Systems of Medicine.
- Lay down strict regulations for ethical promotion and marketing of pharma-products. We have formulated details about this in our earlier deliberations and demands.
- Device a proper system of post-marketing surveillance for adverse drug reactions.
- Evolving proper system of Compulsory Continuing Medical Education (CMIE) for medical and paramedical professionals in rational therapeutics.

ECONOMIC ASPECTS OF DRUG POLICY

Self-reliance

Self-reliance, which was one of the principal concerns of the Hathi Committee Report and which was an important element of the earlier drug-policy statements, does not even find a mention in the 'Note'! To the current decision-makers, a globalized economy means complete domination by the foreign multinationals. We have to expose as well as oppose this spineless, shameless prostration before the imperialists. We should continue to argue for restrictions on majority-owned foreign companies in the production of those drugs for which know-how exists with the Indian companies. Foreign companies should be allowed only if they are willing to provide superior know-how at reasonable cost, to the Indian companies.

Self-reliance, which was one of the principal concerns of the Hathi Committee Report and which was an important element of the earlier drug-policy statements, does not even find a mention in this 'Note'! To the current decision-makers, a globalized economy means complete domination by the foreign multinationals.

Complete domination by foreign MNCs is nether inevitable nor desirable.

Price-Control

We have argued for price-control on drugs for two valid reasons.

- Drugs are part of essential commodities, they are life-saving.
- The consumer has no choice, but has to buy medicines once the doctor prescribes it. Hence consumer resistance is very low in the purchase of medicines.

No amount of so-called liberalization would negate the above rationale. Hence the need for control of drug prices continues. The drug price control is today too complicated because of the thousands of irrational fixed-dose-combinations being marketed. If all these irrational fixed-dose-combinations are weeded out, price-control will be far less complicated.

Criteria for Price-Controlled Drugs

Even within the existing drug production pattern, there is no case for further concessions to the drug industry by reducing the number of drugs to be price-controlled. We should

oppose further decontrol of drug prices by concretely exposing the irrational nature of the new measures of further price decontrol.

The new formula for deciding which bulk-drugs will be price-controlled is as follows

- For bulk-drugs with a sale of Rs. 5 to 20 crore, the drug will be price-controlled, if a formulator controls more than 50% of the market.
- For bulk-drugs with a sale of above 20 crore, the drug will be price controlled if a formulator controls more than 90% of the market.

Even if price-control is to be restricted to drugs which are produced or sold monopolistically, both these figures of cut-off sale value and of percent control by one formulator are arbitrary. There should be no cut-off value for sales figures. Any drug be subject to price-control, whatever may be its sale, if it is produced or sold monopolistically. Secondly, the cut-off value to decide monopolistic control cannot be set arbitrarily at 50% or 90% control by one formulator. Internationally, it has been established that if more than half of the market of a product is controlled by five or less number of companies, the product is deemed to be under monopolistic control. This criterion should be applied to the bulk drug market in India, if it is decided that price control is restricted only to drugs which are monopolistically-controlled.

The above formula is for bulk drugs from which Ayurvedic drugs have been excluded. The method for controlling prices of formulations would continue as before, as per the 1995 DPCO.

Liberal Exemptions

Certain drugs would be exempt from price-control. The criteria for exemption are liberal, *at the cost of the consumer.* These criteria are

a. A fifteen-year-exemption for new drugs developed though indigenous R & D.

b. Exemption till expiry of the patent for

i) drugs whose process has been patented under the Indian Patents Act (IPA) 1970.

ii) formulations involving new drug delivery systems registered under IPA 1970.

As per the DPCO of 1979, some drugs were allowed only 40% mark-up. Hence the drug companies were clamouring for exemption of certain drugs from price control. But now, as per the proposed policy, all indigenously manufactured drugs would enjoy 100% MAPE. Secondly, there will be monopoly due to the patent coverage so that the prices will not be brought down by competition, below the levels decided by the new limit of 100% MAPE. Now there is no case for exemption from price-controls, if the MAPE is raised to 100%.

c. 'Cost per day per medicine' being less than Rs. 2/-.

This would mean commonly used essential drugs like aspirin, paracetamol, iron-folic acid, furazolidone, B'complex, etc. will all go out of price-control! This exemption should also be stoutly opposed. The fact that drug companies have been selling 75 mg. tablet of aspirin at 75 paise per tablet, when the price should not be more than 20 paise, per day, shows once again that they cheat, exploit consumers whenever there is a chance. Removing price-control on those essential drugs whose per day cost is less Rs. 2/- is simply unacceptable.

Other Measures

Other provisions as regards ceiling prices, fixing prices of Scheduled Bulk Drugs, Drug Price Monitoring, Drug Price Equalization Account (DPEA) do not require any fresh comments.

Thus overall, the new drug policy titled 'Pharmaceutical Policy 2001' is pro-industry, anti-people and devoid of any medico-social rationality. We should oppose it in whatever way possible. ■

(The author is with CEHAT, Pune 411 009)

HONOURED

The World Health Organization, Geneva, has appointed Dr Abhay Bang on the Global Steering Committee for the Research on Tropical Diseases. Dr Abhay Bang is the director of a voluntary organization. SEARCH which has been working for the last 15 years in the Gadchiroli District in Maharashtra on the health problems of one lakh rural and tribal population.

AWARDED

The Karnataka Government has conferred Pathanjala Swarna Padaka Award to Dr B N Brahmacharya for the year 2000. He has rendered yeoman service in the field of Nature Cure and Yoga over 30 years. He is the Hon. Consultant at Prakruthi Jeevana Kendra, a charitable trust at Malleswaram, Bangalore.

Pharmaceutical Policy - 2001
Yes to Increased Profits, No to Health!

Anant Phadke

The draft Note for the cabinet committee on Economic Affairs, titled 'Pharmaceutical Policy 2001', follows the old pattern of exclusively focussing on economic issues related to the drug industry. It primarily deals with pricing of drugs, profitability.

This time, the additional concern is increased focus on making the India drug industry on par with the international standards. Despite our repeated demand that the health ministry be actively involved in the preparation of the pharmaceutical policy, this draft 'Pharmaceutical Policy 2001' has been prepared only by the Ministry of Chemicals and Fertilizers, with total exclusion of issues of rationality of drug production.

Main Features of 'Pharmaceutical Policy 2001'

Briefly speaking this 'Note' has the following features -

1. Complete Surrender To The MNCs

It enumerates sanctifies the 'liberalization' steps taken since 1991- abolition of industrial licensing barring a few exceptions; dereservation of the 5 drugs hitherto reserved for the public sector and opening of the public sector to foreign competition; automatic approval of foreign investments even for 100% foreign collaboration; automatic approval of foreign Technology Agreements.

Industrial licensing has been abolished except for three technologies – recombinant DNA technology, in vivo nucleic acid use, specific cell/tissue targeted formulations.

2. Increased Incentives And Provisions For Research For Enhanced International Competitiveness

a) Permission to increase prices by five percent extra for drug companies which comply with suggested 'gold standards' of –

- investing at least 5% of the turnover of the company in R and D, atleast 10 crores per annum for innovative research,
- employing at least 100 research scientists in India,
- of having at least 10 patents for research done in India

b) Setting up of Pharmaceutical Research and Development Support Fund (PRDSF) with the Ministry of Finance contributing Rs. 150 crores as 'Plan Fund' for the creation of the 'R & D fund'

c) To enhance international competitiveness, certain measures will be taken, like mandatory WHO/Good Manufacturing Practices Certification Scheme, attaining international standards for clinical testing.

For products manufactured under WHO-GMP certification, additional 8% cost be allowed in estimating cost of production) and further upto 2% for improved packing.

(We have to see in detail, as to whether all the details of the WHO-GMP certification standards are relevant to Indian conditions. There can not be any compromise on minimum standards. But beyond this, in pursuit of promoting exports, if standards are set on par with developed countries, the drug prices would go further out of the reach of the majority of people in India. Hence, we should question this move.)

3. Reduced Span Of Price-Controlled Drugs

Only about 37 bulk drugs accounting for about 20% of the market-sale, would be under price-control, as compared with the 74 bulk drugs accounting for about 40% of the market being under price-control today and 343 drugs under price-control in 1985. Newer, 'liberal' criteria for selection of bulk drugs under price-control have done this trick.

4. Increased Profitability

- The Maximum Allowable Post-manufacturing Expense (MAPE) would be 100% for indigenously manufactured drugs. Currently only class IV. i.e. totally 'inessential ' drugs are allowed 100% MAPE.

- For imported formulations, the selling price can be upto 150% of the landed costs.

- The present provision as per the Third Schedule of the Drug Price Control order 1995, of limiting the profitability of drug companies, would be done away with.

- There would be some exemptions (see section B2.2) even for the limited number of 37 bulk drugs to be under price control.

Thus overall, the drug companies have been given a free hand to jack up prices.

The above four are the main provisions in brief, of the 'Pharmaceutical Policy 2001.' There are a few other provisions, which are of not much significance.

What Should Be Our Critique?

Our response to this draft note should be two fold : raising issues on both the health and economic aspects.

A. The Health Aspect of the Drug Policy

On the health aspect, we should strongly protest against the exclusion of the policy issues related to the rationality/irrationality of various drug-formulations sold in India. Secondly we should once again bring forth our following demands about the socio-medical rationality of drug production in India.

1. Eliminate all drugs and formulations not recommended by standard text-books and other authorities
2. Eliminate al Fixed Dose Combinations not recommended. by standard text-books and other authorities.
3. Priority and incentives to the production of Essential Drugs, especially to drugs for Primary Health Care.
4. Abolish all brands names. Drugs to be sold only under generic name, with the company's name in the bracket.
5. Review of all the drugs every three years to eliminate obsolete drugs.
6. Strict ethical guidelines for drug-research.
7. Commercial production of any drug claimed to be Ayurvedic, should be allowed only after the scrutiny of its rationality by the council for Indian System of Medicine.
8. Strict regulations for ethical promotion and marketing of pharma-products. We have formulated details about this in our earlier deliberations and demands.
9. Proper system of post marketing surveillance for adverse drug reactions.
10. Proper system of Compulsory Continuing Medical Education (CMIE) for medical and paramedical professionals in rational therapeutics.

The above is only a reiteration in brief, of our main demands as regards the medico-social rationality of drug production in India.

We need to once again forcefully put forth these demands and point out that the 'Pharmaceutical Policy 2001' does not even mention any of these crucial aspects of drug policy.

B. Economic Aspects of Drug Policy

B1. Self reliance

Self-reliance, which was one of the principal concerns of the Hathi committee report and which was an important element of the earlier drug-policy statements, does not even find a mention in this 'Note'! For the current decision makers,a globalized economy means complete domination by the foreign multinationals. We have to expose and oppose this spineless, shameless prostration before the imperialists. We should continue to argue for restrictions on majority owned foreign companies in the production of those drugs for which know how exists with the Indian companies. Foreign companies be allowed only if they are willing to provide superior know how at reasonable cost, to the Indian companies.

In today's globalized economy, distinction between and the consequences of the role of 'Indian' and 'foreign' companies has been blurred to a certain extent. But there is no case for throwing over board, the concept and strategy for self-reliance. Complete domination by foreign MNCs is nether inevitable nor of course desirable.

B2 Price-Control

We have argued for price-control on drugs for two valid reasons –

1. Drugs are part of essential commodities, are life-saving.
2. The consumer has no choice, but has to buy medicines once the doctor prescribes it. Hence consumer resistance is very low in purchase of medicines.

No amount of so called liberalization would negate the above rationale. Hence the need for control of drug prices continues. The drug price control is today too complicated because of the plethora of thousands of irrational fixed dose combinations being marketed. If all these irrational fixed dose combinations are weeded out, price-control will be far less complicated.

2.1 Criteria For Price-Controlled Drugs

Even within the existing drug production pattern, there is no case for further concessions to the drug industry by reducing the number of drugs to be price controlled. We should oppose further decontrol of drug prices by concretely exposing the irrational nature of the new measures of further price decontrol.

The new formula for deciding which **bulk-drugs** will be price-controlled, is as follows -

For **bulk-drugs** with a sale of Rs. 5 to 20 crores, the drug will be price-controlled if a formulator controls more than 50% of the market.

For **bulk-drugs** with a sale of above 20 crores, the drug will be price controlled if a formulator controls more than 90% of the market.

Even if price control is to be restricted to drugs which are produced or sold monopolistically, both these figures of cut off sale value and of percent control by one formulator are arbitrary. There should be no cut off value for sales figures. Any drug be subject to price-control, whatever may be its sale, if it is produced or sold monopolistically. Secondly, the cut off value to decide monopolistic control can not be set arbitrarily at 50% or 90% control by one formulator. Internationally, it has been established that if more than half of the market of a product is controlled by five or less number of companies, the product is deemed to be under monopolistic control. This criterion be applied to the bulk drug market in India, if it is decided that price control is restricted only to drugs which are monopolistically controlled.

The above formula is for bulk drugs, from which Ayurvedic drugs have been excluded. The method for controlling prices of **formulations** would continue as before, as per the 1995 DPCO.

B 2.2 Liberal Exemptions

Certain drugs would be exempt from price-control. The criteria for exemption are liberal, at the cost of the consumer. These criteria are

a. Fifteen year exemption for new drugs developed though indigenous R & D.
b. Exemption till expiry of the patent for
    i) drugs whose process has been patented under the Indian Patent Act 1970.
    ii) Formulations involving new drug delivery systems registered under IPA 1970.

As per the DPCO of 1979, some drugs were allowed only 40% mark up. Hence the drug companies were clamouring for exemption of certain drugs from price control. But now, as per the new proposed policy, all indigenously manufactured drugs would enjoy 100% MAPE. Secondly these will be monopoly due to the patent coverage so that the prices will not be brought down by competition, below the levels decided by the new limit of 100% MAPE. Hence, now there is no case for exemption from price-controls, if the MAPE is raised to 100%.

c. 'Cost per day per medicine' being less than Rs. 2/-.

This would mean commonly used essential drugs like aspirin, paracetamal, iron-folic acid, furazolidone, B'comples, etc. will all go out of price-control! This exemption should also be stoutly opposed. The fact that drug companies have been selling 75 mg. tablet of Aspirin at 75 paise per tablet, when the price should not be more than 20 paise, per day, shows once again that they cheat, exploit consumers whenever there is a chance. Removing price-control on those essential drugs whose per day cost is less Rs. 2/- is simply unacceptable.

B 3 Other Measures.

Other provisions as regards ceiling prices, fixing prices of Scheduled Bulk Drugs, drug price monitoring, Drug Price Equalization Account (DPEA) do not require any fresh comments.

Thus overall, the new drug policy titled 'Pharmaceutical Policy 2001' is pro-industry, anti-people and devoid of any medico-social rationality. We should oppose it in whatever way possible.

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DR-35

DRAFT NOTE FOR THE CABINET COMMITTEE ON ECONOMIC AFFAIRS

SUBJECT: Pharmaceutical Policy - 2001

INTRODUCTION

The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards "promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive." The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

2. The process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are: -

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.

SECRET

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F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

- Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.
- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.

APPROACH ADOPTED IN THE REVIEW

3. Two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy - 2001. A reorientation of the objectives of the current policy has also become necessary on account of these issues :-

(a) The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and

(b) The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

4. In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by this Department by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR. The Committee has given its report and its recommendations are summarized in Annex. I.

5. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards) :-

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,

- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India.

6. The recommendations of the PRDC in so far as they relate to the Drug Policy have been taken into account while formulating the proposals on pricing aspects.

7. The Pharmaceutical Research & Development Committee has recommended in its report, submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). This Committee recommended that the fund would be created by collecting a surcharge of 1% of the maximum retail price of all the formulations sold within the country and could be expected to generate around Rs.100 crore annually. However, the Ministry of Finance has, in lieu of the surcharge, agreed to allocate Rs. 150 crores as Plan Fund for creation of the R&D fund. This proposal is being pursued through Expenditure Finance Committee separately.

8. As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO,1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The summary of these recommendations is at Annex.II. These recommendations have been examined in this Department.

9. The domestic drugs and pharmaceutical industry needs reorientation in order to meet the challenges and canvass opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally. The Statement on

Pharmaceutical Policy – 2001 (Annex. V) incorporates these objectives and measures.

10. In view of the steps already taken, as enumerated in paragraph 2 above and in the light of the approach indicated in the foregoing paragraphs, the proposals for inclusion in the Statement of Pharmaceutical Policy – 2001 are detailed below :-

A. PROPOSALS ALREADY APPROVED

I. Industrial Licensing

Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of

(i) bulk drugs produced by the use of recombinant DNA technology,
(ii) bulk drugs requiring in-vivo use of nucleic acids as the active principles, and
(iii) specific cell/tissue targetted formulations.

II. Foreign Investment

Foreign investment upto 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 10.A.I above, kept under industrial licensing.

III. Foreign Technology Agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 10.A.I above, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

B. PROPOSALS SUBMITTED FOR CONSIDERATION

I. ENCOURAGEMENT TO RESEARCH AND DEVELOPMENT (R&D)

(a) In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board on the lines of the Technology Development Board to administer the utilization of the PRDSF.

(b) Royalty receipts obtained on sales or assignment of Indian intellectual property, including a patent held by a research-intensive company, meeting gold standards, would be fully exempt from income tax.

(c) Expenditure on consumables as well as on equipment directly used in R&D by a research-intensive company, meeting gold standards, would be allowed to be written off for purposes of Income Tax within a period of one year.

(d) Exemption to a research-intensive company, meeting gold standards, from payment of import duties on chemicals, bio-chemicals, special consumables, equipment and spares, as specified by the Government from time to time, required by it for R&D in its own facility.

II. PRICING ASPECTS

(a) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. These principles would be applied for developing the criteria for selection of bulk drugs for price regulation under the Pharmaceutical Policy – 2001. However, the DPCRC's recommendation regarding the new criteria for ascertaining the mass consumption nature of a bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies. After due consideration of various options in this regard, the Department proposes that the identification of bulk drugs for price regulation should be based on the following methodology :-

(i) The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion., as in the past,

be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient , on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

(f) Pricing of Scheduled Bulk Drugs

(i) For a Scheduled bulk drug, there shall be a price notified as the "maximum allowable price" for being adopted while fixing the prices of formulations containing that bulk drug.

(Some of the models for working out the "maximum allowable price" are detailed in Annex. IV.)

(ii) The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest, and also to conduct cost cum techno-economic study, if it considers it necessary to do so, as per present practice.

(g) Monitoring

(i) The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will

increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(iii) The other recommendations of DPCRC like giving powers to drug control authorities to dispose of small and petty offences etc., will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable. Monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.

(h) <u>Drug Price Equalization Account (DPEA)</u>

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

III. <u>QUALITY ASPECTS</u>

(a) The DPCRC's recommendation that the requirements of "Good Manufacturing Practices" prescribed under the Drugs & Cosmetics Act and Rules made thereunder be upgraded to the levels prescribed for WHO/GMP certification is acceptable. The Ministry of Health & Family Welfare will be advised

(i) to progressively benchmark the regulatory standards against

those adopted in developed countries, for manufacturing.

(ii) to progressively harmonize standards for clinical testing with international practices.

(iii) to streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D.

(b) to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals, Ministry of Health and Family Welfare would (a) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and (b) establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center.

11. On the assumption that the proposals indicated above will be approved, a Draft Statement entitled "Pharmaceutical Policy -2001" has been prepared (Annex.V) for the public announcement.

12. Comments of the Departments of Industrial Policy & Promotion, Biotechnology, Health, Indian Systems of Medicines and Homeopathy, Scientific & Industrial Research, Science & Technology, Revenue, Economic Affairs, Expenditure and the Planning Commission were called for and their views alongwith the comments of this Department thereon are at Annex. VI.

13. The approval of the Cabinet Committee on Economic Affairs is requested to the following :

(i) **Proposals contained in para 10 B above relating to Encouragement to Research and Development (R&D), Pricing and Quality of Drugs and Pharmaceuticals.**

(ii) **Draft Statement titled "Pharmaceutical Policy - 2001" (at Annex.V) for public announcement.**

14. A Statement on Implementation Schedule is given at Appendix –I.

15. This note has been seen and approved by the Minister (C&F).

(Sharad Gupta)
Joint Secretary to the Government of India

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX. I.

RECOMMENDATIONS OF PRDC
[Refer para 4 on p.2 of the Note]

S.N.	Action Point	Responsibility for action
1.	Establishment of a Drug Development Promotion Foundation	Dept. of C&PC
2.	Revamping and modernization of CDSCO	Min. of Health and Dept. of C&PC
3.	Establishment of the Pharmaceutical R&D Fund.	Min. of Finance and Dept. of C&PC.
4.	Establishment and operationalisation of GMP/GLP/GCP Monitoring Authority	Dept. of Science and Technology, ICMR, DCG (I)
5.	Amendments to the Indian Patent Act.	Min. of Industry and Dept. of C&PC.
6.	Establishment to the Income Tax Act for tax exemptions on royalty and licensing from abroad and export of pharma R&D	Min. of Finance & Dept. of C&PC.
7.	Amendments to the custom duty structure to exempt imports for pharma R&D from custom duty	Min. of Finance & Dept. of C&PC.
8.	Amendments to legislation etc. for contract research use and import of animals for pharma R&D.	Min. of Welfare & Dept. of C&PC.
9.	Establishment of a tenable system of quality assurance for indigenous system of medicines.	Dept. of ISM
10.	Establishment of a new drug discovery infrastructure	Dept. of C&PC, CSIR, ICMR, DST, DBT, & Dept. of ISM.
11.	Documentation and digitization of indigenous knowledge systems	CSIR, ISM, ICMR and Dept. of C&PC
12.	Human Resource Development for New Drug Discovery and ISM.	CSIR, ICMR, Dept. of ISM, DBT, DST, Universities & Dept. of C&PC.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX.II

DRUG PRICE CONTROL REVIEW COMMITTEE

SUMMARY AND RECOMMENDATIONS

[Refer para 8 on p. 3 of Note]

The Committee held detailed deliberations to review the existing drug price control mechanism in the country keeping in view the terms of reference assigned to it by the Government. Apart from studying details in regard to pricing systems prevalent in various countries, two separate teams visited (a) Canada, France and Egypt and (b) U.S.A. and Mexico to have first hand information on the price regulatory systems operating in these countries. Both the teams had extensive discussions with various interest groups namely manufacturers, trade, pharmacists and Government officials of these countries. Also, the Committee constituted a group consisting of Dr. Rakesh Mohan, Dr. Amit Mitra, Dr. S. M. Jharwal, Shri Sharad Gupta, Shri K. M. Kaul and Dr. P. V. Appaji to look into the present criteria of selection of drugs for price control and the current price determination mechanism and to suggest modifications/alternatives to make the system of price control simpler and more transparent. Based on the suggestions received from industry associations, consumer interest groups, voluntary health organisations, trade, State Governments and some experts, and inputs received from teams and the group mentioned above, the Committee makes the following recommendations alongwith relevant observations :

1. The committee noted that the Indian Pharma Industry has registered an impressive growth over the years and has been expanding its market beyond the national frontiers. But in the changing trade and regulatory scenario at the international level much more needs to be done to make available the required medicines in abundance to the masses. Of late, increasing incidence has been observed of the diseases such as malaria, Diarrhoea, T. B., Sexually Transmitted Diseases (STDs), Hepatitis-B, Whooping cough (pertussis), measles, amoebiasis, diabetes mellitus and mood disorders. To deal with the various diseases, the public funding available in India for healthcare facilities and products is abysmally inadequate. Currently only about 3.5% of the total outlay of the states is spent on health needs. The available data reveal that the per capita expenditure on medicines is less than Rs.5.00 in many states.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

The role of the state assumes special significance since the proportion of the people below poverty line is more than one third of the total population. The fact that these people do not have the means to meet the expenditure even on minimum calorie level required implies that the expenditure on medicines which is of emergent nature is much beyond their capacity. Further, for the large segment of the population above poverty line, the problem is compounded in the absence of rational private health care, adequate and affordable public health care and health insurance cover because they are not able to meet the entire expense out of their pocket.

2. The Committee noted that in most other countries, the regulation of the drug prices is considered necessary to contain public expenditure due to government's role in funding social health and insurance schemes that cover hospital and out-patient drugs. The price regulations are used as an instrument to keep their health budgets within reasonable limits. In these countries, a substantial proportion of the population is covered through health insurance and public health schemes. As a result, the consumers are not affected directly by the high prices of drugs or high costs of medical services, but are made to pay for the increased prices / cost through high insurance premium. As opposed to this, a substantial proportion of the population in India is market dependent and have to meet all their expenses out of their own pocket on this account, making price regulation of pharmaceutical products in the market unavoidable.

3. In India, in view of a large segment of the population being poor, the reach of the health coverage being inadequate, non-availability of appropriate medical insurance coverage, price inelastic demand, market imperfections and inadequate consumer awareness, the Committee considers it necessary to continue formal regulation of the prices of pharmaceutical products and medicines for some more time till public expenditure on health care for those who cannot afford is increased and an alternative system is developed for others. However, it is pertinent to point out that the pharmaceutical industry is perhaps the only knowledge based and highly technology oriented manufacturing industry in the country which is under a formal price control regime. This is mainly because the financial provisions in the budgets of Central and the State Governments are too inadequate to cater to the needs of the ailing people. The Committee expresses serious concern on this aspect and feels that the budgetary provision should progressively be raised. Further, there is an urgent need to expand public health care, supply of essential drugs and the health insurance cover, both by the governmental and the non-governmental organisations, as prevailing in the developed countries.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

Such an alternative arrangement should be made fully operative within a period of next five years.

4. The present system of product-based price control has been in existence in this country since long with progressive decontrol in terms of the number of drugs as well as their share in the total pharma market. For the reasons stated above, the Committee is of the view that this system should continue, for the time being, but with simplified methodologies and procedures to take cognizance of the changed circumstances of liberalisation ushered into the Indian economy. For the purpose of determining span of control and pricing of the drugs identified for price control, the Committee recommends that:

(i) The approach to price control based on selectivity be continued and applied across-the-board to all the drugs used in the country irrespective of their therapeutic use. The guiding factors to identify specific drugs should be (i) mass consumption nature of the drug and (ii) absence of adequate competition in such drugs. This approach will also ensure that the important drugs needed for National Health Programmes, where adequate competition does not exist, are covered for the purposes of price control.

(ii) The Committee considered the suggestion that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. While the Committee feels that the above approach is desirable, it calls for an objective and careful assessment for identifying "low cost drugs", as the per day cost of a medicine varies depending on dosage form, patients condition, variation in the prescribed dosage, price difference in various brands, etc. The Committee is of the opinion that the price of the largest selling pack of a brand be taken as the basis to determine the low cost nature of a medicine for which the cost of maximum prescribed dose per day (irrespective of age and ailment) may be considered and the cost per medicine per day so worked out should not be more than Rs.2.00. This criteria is reasonable because for a short duration treatment of 10 days, it amounts to only about 1.5 per cent of the monthly per capita income and for long duration, it will be about 5 per cent. In common man's perception, this expenditure is same as that for a cup of tea. However, the prices of such drugs would need to be monitored so that these prices are not allowed to go up beyond acceptable limits.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) The committee noted that the criteria of mass consumption laid down in the Drug Policy, 1994 had come under criticism on account of non-exclusion of "export value" from the turnover of a bulk drug. The main argument against the non-exclusion of the "export value" was that it does not truly reflect the mass consumption nature of the drug in the domestic market and unduly inflates the turnover of a drug with high export share. However, it was reported that the value of exports was not segregated for the reasons of the fluctuating nature of export. In this regard, the Committee feels that if the criterion of "bulk drug turnover" is to be applied, non-exclusion of the export turnover of a drug from the total turnover for the purpose of assessing the mass consumption nature of a drug in a more liberalised regime, is not a sound accounting method. Therefore, identification of a drug for keeping it under price control may be decided on the basis of its consumption in the domestic market which would comprise domestic production and imports less exports.

(iv) The turnover level of Rs. 40 million stipulated in the Drug Policy as modified in 1994 may be updated on the basis of general rate of inflation (WPI – All commodities). With a view to undertaking such an exercise the Committee collated the data available from the Annual Report of the Department of Chemicals & Petrochemicals, the periodical returns/data received from manufacturers by NPPA and observed that the data were inadequate Therefore, the Committee issued a public notice in the national news papers (Hindi and English) requesting the manufacturers to furnish the data for the year 1998-99 on production and exports (quantity and value) of both the bulk drugs and formulations. However, the response was poor and the attempts to update the data did not succeed. Therefore, the committee felt that the available data were not complete to work out the turnover, as defined above.

5. In view of the above, the committee considered an alternative method based on the sales turnover of formulations (brand wise) in various categories as given in the monthly retail store audit report on the pharmaceutical market by a leading and reputed organisation, namely, ORG-MARG. The ORG-MARG provides, on a monthly basis, the data on moving-annual total (MAT) representing the sale value during a twelve month period for each of the formulation pack marketed by different manufacturers. The formulations with their sale value are categorised as per their clinical/therapeutic/chemical classification. For the purpose of judging mass consumption nature of a bulk drug, any brand based on a

given drug having specified minimum value of MAT could be considered as a mass consumption drug. Secondly, to judge the level of competition, if the market share of a brand in a specific category is found to be higher

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

than the maximum stipulated share, such drug may be considered as having inadequate competition. By adopting the above criteria, the specific bulk drugs may be identified based on the composition of the selected brands.

6. The group constituted by the committee to consider an appropriate methodology has made the following suggestions, with which the committee agrees:-

(i) The minimum MAT value of a brand for the purpose of determining the mass consumption nature of the drug may be considered as Rs.10 crores.

(ii) Secondly, a brand with 10 per cent or more share in a given category may be treated as having inadequate competition.

(iii) Identify the brands having MAT value of Rs.10 crores and above with a share of 10% or above in the group/category (there are approximately 180 categories in ORG). For this purpose, the March, 1999 issue of the ORG-MARG Report which provides firm data for the year, 1998-99 be used.

(iv) Exclude all brands having Ayurvedic and other products which are not covered under DPCO.

(v) Exclude the multi-ingredient based brand formulations.

(vi) List out the bulk drugs contained in each of the brand products so selected for the purpose of identifying the bulk drugs to be included under price control.

(vii) From the list of bulk drugs so worked out, the low cost drugs may be eliminated on the basis of "per day cost of a medicine" worked out based on the maximum retail price (MRP) of the top selling pack of the brand from which the concerned bulk drug was identified. As stated earlier, the per day cost of a medicine should not exceed Rs.2.00 for being considered as "low cost medicine".

7. The committee recommends that the above methodology be adopted for identification of specific bulk drugs to be put under price control. Accordingly, the Government would need to undertake an exercise to arrive at a list.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

8. Methodology for fixation/determination of prices of bulk drugs

(i) For determining the price of a bulk drug, three alternatives were considered viz. (i) The cost-cum-techno-economic study (ii) Market price data and (iii) Import price data. It was felt that the present methodology of micro analysis for price determination through cost-cum-techno-economic studies needs to be reviewed in the context of the liberalised regime, wherein the prices are likely to be determined by the market forces. The Committee also took note of the fact that the industry has been averse to such studies for the reasons of maintaining secrecy with regard to their technology and process details. This would become a more legitimate concern particularly in the context of introduction of product patents. Therefore, the committee recommends that the market price data would be a better method to determine realistic prices as compared to that based on cost-cum-techno-economic studies.

(ii) For the purpose of determining the price of a bulk drug, the committee recognizes that a system of price related information would have to be evolved since there is no single source of data which can be relied upon. The possible sources of information could be the chemical/drug industry journals, purchase documents available from formulators, import data as available from DGHS, the Central Excise authorities and Annual Cost Audit Report etc. The Government may develop a suitable method to work out a representative price of a bulk drug based on an averaging appropriate to the available data.

(iii) The committee also recognizes that in the liberalised regime, the prices of bulk drugs would be more prone to fluctuations and, therefore, there may be requests from the manufacturer for frequent revision in the prices. Such changes in the prices, if allowed, are bound to result in undue uncertainty in the market which would neither be in the interest of the industry nor the consumers. Therefore, after having determined the price based on a weighted average market price, taking into account a reasonable duration and source of data availability, revision in the bulk drug prices may be effected on an yearly basis and the prices so determined may be notified for the purpose of pricing of formulations based on it, every year in the first week of June on the basis of data pertaining to the preceding financial year and statutory changes announced in the budget for the current year. Provided, however that, with a view to keeping the prices within reasonable limits, annual increase may not be allowed beyond a limit which may be prescribed by the Government on the basis of the rate of inflation during the preceding year measured in terms of WPI of all commodities.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) In case the price to be notified on the basis of weighted average market price of a drug as calculated under (iii) above is not acceptable to a drug producer(s), at his request and on adequate information being provided, the government may require a cost cum techno-economic study to be undertaken as an exceptional measure. Further, such a study shall be undertaken only in situations where (i) Anti-dumping proceedings are initiated and / or (ii) Public interest is involved. Where ever, such cost-cum-technical studies are to be undertaken, the present method may be adopted. The two-third cut-off criteria in respect of the estimated production of a drug to determine its price has generally been found to be with a sound economic rationale as the price so fixed covers bulk of the production i.e. more than 66 percent. This also encourage cost efficient production while discouraging cost inefficient ones. Further, capacity utilisation may be taken at 80 per cent or actual whichever is higher, so as to be in line with criteria adopted by the financial institutions for the purpose of appraising proposals for granting financial assistance.

9. **Methodology for determining the prices of formulations.**

(i) The Committee also deliberated on the suggestion that instead of the prices of bulk drugs, the prevailing market prices (MRP) of the formulation packs containing any of the drugs identified for price control may be taken as the bench-mark price and notified. Revision in the notified prices in future were suggested to be allowed within the limit of rate of inflation measured in terms of CPI for industrial workers/agricultural labourers. It was also suggested that the price changes for the controlled formulations may be reviewed by the Government every year for taking necessary corrective measures.

The Committee considered the above suggestion and felt that the following problems are likely to be encountered in this regard :

(a) This method would provide automaticity in the price fixation method for formulations and provide incentive to the manufacturers to revise their prices upwards. The concept of automaticity in pricing was considered in the Drug Policy on an earlier occasion and was not found to be desirable.

(b) Secondly, as the basis of price determination of controlled drugs (cost-plus) and decontrolled drug formulations (market forces) differ, it would not be appropriate to take the prevailing market prices as the bench mark. In this regard, the suggestion of the industry for grant of one time increase on the prices of controlled formulations, based on inflation factor, to bring these at par with the decontrolled formulations (now to be brought under price control) might unduly increase the prices.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(c) Thirdly, the prices of new introductions with different pack sizes and different strength/compositions than those notified as bench mark formulations would need to be fixed afresh rendering the system more complex and disputable.

In view of the above, the Committee felt that a cautious approach needs to be adopted at this stage. However, based on a further review after about three years i.e. before the TRIPS provisions come into existence, this suggestion may be reexamined for its feasibility keeping in view the observed changes in the availability, price situation and rationalisation of phrama products.

(ii) Therefore, the present method of determination of the prices of both imported and indigenous formulations on the basis of formula given in para 7 of DPCO, 1995 may continue. However, for the indigenously produced formulations the Committee has noted that the existing methodology does not account for expenses on account of (a) maintenance of quality by observing WHO certification etc. and (b) improved packaging to check counterfeiting, maintenance of quality during the shelf life, etc. These elements involve capital investment and recurring expenditure. Presently, a large number of manufacturers in the country do not have WHO certification. However, recovery of the expenditure incurred on these elements through increased MAPE will not be correct as per the established accounting principles since MAPE covers only the post manufacturing expenses. Nevertheless, the Committee feels that due weightage needs to be given to these elements of cost while working out the prices of the formulations. With a view to reducing the rigorous by moving from the micro analysis to the macro assessment, the committee recommends that an additional eight per cent cost be allowed on the products manufactured under WHO-GMP certification and additional upto two per cent for improved packaging, on application by a manufacturer, to compensate for these costs over and above the ex-factory cost worked out based on the existing methodology as given in para 7 of the DPCO, 1995. Further, recognizing that there is a need to improve the GMP standards to standards such as US-FDA/MCA for encouraging exports, the Committee suggests that an appropriate provision to meet higher expenses on this account may be allowed through a further three per cent of the Ex-factory Cost, over and above other provisions suggested above

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) As regards the question of providing incentive for R&D, the Committee noted that the Pharmaceutical Research and Development Committee (PRDC) is considering to lay down certain criteria for the identification of Units/Industry engaged in R&D activities alongwith required measures. Subject to the recommendations of that Committee, a further additional cost of five per cent of ex-factory cost over and above that recommended under para (ii) above, may be allowed to companies which undertake basic research for new drug discovery, provided they have actually spent a minimum percentage of their sales turnover, as may be prescribed, for this purpose. Such an incentive may be provided based on a certificate by a designated technical authority. The Committee recognises that the proposed incentives to the manufacturers with US-FDA/MCA certification and the R&D certified companies shall be availed of by a small number of companies. These incentives, nevertheless, were considered desirable to provide positive signals to the investors in such activities. Further, the Committee feels that any price rise on account of these or WHO-GMP standards is expected to be offset by the benefits to consumers through improved quality and security from the spread of spurious drugs in the market.

(iv) With a view to introducing a simplified procedure, a suggestion was made for appropriate neutralization, based on WPI/CPI of Conversion Cost (CC), and Packing Charges (PC) and Packing Material (PM) Cost. Based on the deliberations, the committee recommends that the CC&PC be neutralized on the basis of CPI for industrial workers. Further, the PM Cost be neutralized on the basis of WPI for all commodities. For the neutralization of these costs, the improvement in Process Loss (PL) needs to be kept in view.
However the government needs to notify the norms every year as required in the previous DPCOs .

(v) During the deliberations, the Committee felt that the imported finished formulations, patented or otherwise, be brought under price control. However, this may not be GATT/WTO compatible. Nevertheless, the price of new introductions in the country would need to be watched and monitored. The Committee, therefore, recommends that the prices of patented drug formulations, including those granted with EMR, introduced in the country shall be under price control and the marketing approval under the Drugs & Cosmetics Act should be issued only after the applicant has obtained price approval from the Government. When it is not feasible to determine a reasonable price under the existing methodology/formula, an alternative methodology including reference pricing corrected for relative per capita income level may be developed by the Government.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

10. Monitoring & Enforcement

(i) The committee recognizes the objectives of the Drugs Price Control Order in the given socio-economic conditions in the country and the need to enforce and monitor the provisions to adequately protect the consumers' interest. The Committee is of the view that effective monitoring systems would have to be established to move away from the "controlled regime" to the "monitoring regime" in a medium and long term perspective.

(ii) The Committee noted with concern that the enforcement of various provisions of Drugs and Cosmetics Act is still not uniform throughout the country and spurious and substandard counterfeit drugs find their way into the market. It was also reported that different yardsticks are adopted by State Licensing Authorities for granting manufacturing approval of drug formulations. This leads to proliferation of formulations and pack sizes. The Committee feels that the systems and criteria adopted for granting drug licences and formulation approvals need to be made uniform. The Committee recommends that the Good Manufacturing Practices (GMPs) requirements prescribed under the rules for manufacture of drugs be upgraded to the levels prescribed for WHO-GMP Certification Scheme . This needs to be achieved within a period of 2 years, say by December, 2001, after which no manufacturing license under the Drugs and Cosmetics Act be renewed or granted to units not conforming to the minimum prescribed WHO-GMP standards.

(iii) Further, the committee is informed that under the provisions of "The Drugs and Cosmetics Act" such activities constitute a cognizable offence with appropriate penal provisions including imprisonment since it involves human health and life. The committee feels that the relevant provisions be enforced in their letter & spirit. The Committee also recommends that WHO-GMP be made a basic criterion for granting a drug license to manufacture a drug in the country.

(iv) Further, for effective enforcement, the following steps are recommended :

(a) Provide powers to the Drugs Control Authorities to dispose off small & petty offences/contravention's by compounding provision for such offences in the DPCO. This would obviate the necessity of launching prosecutions in minor cases.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(b) The Government should develop an appropriate mechanism to study the price movements of drugs marketed in the country in both controlled/decontrolled categories and develop a price index for pharma products to review the price situations on monthly/quarterly basis to take corrective measures. In the case of imported bulk drugs and formulations, the prices need to be monitored more closely in the light of the changes in the international trade regime. This would help in determining the cases of dumping and under/over invoicing to protect the interest of the industry and consumers.

(c) The Committee recognizes that in the liberalised regime, a reliable data base would go a long way in evolving appropriate and timely policy measures. The Government should develop a data bank on pharmaceutical sector. A simplified format may be prescribed in the DPCO to collect the required information.

(d) The availability and price situation be reviewed by holding periodical meetings with the consumer interest groups, industry and trade.

(e) Import of formulations falling under the price decontrolled category be monitored effectively according to a format to be prescribed in DPCO. This should indicate the quantity, c.i.f. price, customs duty paid and the MRP of the product for each imported consignment.

11. Miscellaneous

(i) Dispose off the review petitions filed by the manufacturers with in a given time frame, say two months after receipt of complete information.

(ii) The Committee has noted with concern that presently there is no system of prescription audit, through which it could be ascertained whether the hospitals/doctors prescribe more expensive and non-essential drugs instead of low priced essential drugs. However, the committee was informed that there is a tendency to prescribe high cost medicines despite the availability of cheaper and equally effective substitutes. The Committee feels that this tendency needs to be curbed through a coordinated effort by the Department of Chemicals & Petrochemicals and Ministry of Health by developing an appropriate prescription audit mechanism with active support of Indian Medical Association.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(iii) The Committee has noted that in addition to product-wise price control on selected drugs, there are limits, stipulated in the DPCO, 1995 on profits of a pharmaceutical company as percentage of its sales turnover. It was also noted that this provision of controlling overall profitability of a company was intended to check unreasonable increase in the prices of pharmaceutical products not under price control. It was reported to the committee that it has not been practicable for the government to meaningfully monitor the profitability of each and every company. At the same time, this provision has reportedly adversely affected the scope of increased investment in R&D. As the thrust of the economic policy is towards providing flexibility under the conditions of market economy, the Committee is of the view that there is no need to have dual control on pharmaceutical companies. Therefore, the Committee recommends that the provision limiting profitability of pharmaceutical companies be done away with.

(iv) As a medium and long term strategy, adequate health insurance cover, both by the public and private sector, needs to be provided so that the dependence on price control measures could progressively be reduced.

(v) To curb indiscriminate imports, there is need to strengthen procedures and rules under Drugs & Cosmetics Act so as to provide for a registration system for import of pharmaceutical products into the country.

(vi) As per available reports, eight percent margin is provided to the wholesalers and sixteen per cent to the retailers on the scheduled formulations. For non-scheduled formulations, the companies are at liberty to decide the trade margin. It is reported that the prevailing normal trade margin in respect of the decontrolled formulations is 20 per cent for retailers and 10 per cent for wholesalers. In view of this, the present stipulation of 16 per cent margin on scheduled formulations to the retailers needs to be retained.

(vii) It has also been observed that some of the manufacturers tend to provide unduly high trade margins, adversely affecting the consumer interest. Therefore, the committee is of the view that to discourage unethical practices by the players, the difference between the first sale price of a formulation by the manufacturers and the retail price printed on the label be limited to a maximum of 40 percent of the MRP in the case of decontrolled formulations.

SECRET

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

(viii) As brought out earlier there is (a) absence of rational private health care (b) inadequate public health care and (c) inadequate health insurance cover in the country. Therefore, the committee recommends that there is an urgent need to expand public health care by progressively raising the budgetary provision, improve supply of essential drugs and accelerate the process of providing health insurance cover, both by the governmental and non-governmental organisations and that such an arrangement should be made fully operative within a period of next five years..

(ix) Further, the Committee has observed that several manufacturers are providing bonus offers/schemes for promotion of their products. Such schemes/offers lead to higher prices for the consumers apart from the possibility of compromise on quality of the product, resulting in proliferation of substandard products in the market. Therefore, the committee is of the view that such practices be discouraged through effective monitoring for taking corrective measures.

F.No.6/7/2000-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX-III

RATIONALE FOR THRESHOLD VALUES OF MAT

[Refer sub-para (vi) of para 10.B.II(a) on p.6 of the Note]

Presently, there are 74 bulk drugs under price control and the retail market coverage is estimated to be 38-40% approximately. These drugs were kept under control on the basis of turnover criteria of Rs.400 lakhs or more, which was based on 1989-90 data. This, in terms of value of formulations, works out to Rs.1600 lakhs on the basis of "the ratio of value of consumption of bulk drug for production of formulations to the value of formulations produced as 1:4" adopted in Chapter V of the Report of the working group on Drugs and Pharmaceuticals for the Ninth Five Year Plan Period (1997-98 to 2001-02).

Data used at the time of promulgation of DPCO 1995 was of the year 1989-90. For this reason value of formulations arrived at above would require correction for inflation since then. Further correction would be required there on account of the fact that now we are considering only single ingredient formulations where as all formulations comprise of single as well as multi-ingredient formulations. On the basis of increase in the Wholesale Price Index (WPI) for Drugs and Medicines from 140.4 points in 1989-90 to 320.9 points in 1998-99, the value of all the formulations i.e. Rs.1600 lakhs, calculated above, would come to Rs.3657 lakhs. Further, the MAT-Value for all formulations as per ORG-MARG of March, 1999 is Rs.1190946 lakhs (Rs.11909.46 crores), whereas the MAT-Value of all the single ingredient formulations works out to Rs.603283 lakhs. On this basis, the value of Rs.3657 lakhs of all formulations corresponds to Rs.1852 lakhs in terms of the total single ingredient formulations. Hence, the threshold limit of Rs.2000 lakhs appears reasonable for bringing drugs under price control, which would mean that if, for any bulk drug, the MAT-Value of all its single ingredient formulations is above Rs.2000 lakhs, then it could be considered for price control.

Under the liberalised industrial, trade and economic policies, the availability of bulk drugs is not as problematic as it was earlier when import policy was quite restrictive. There are large number of formulators for a bulk drug. However, an analysis of ORG-MARG data indicates that in majority of cases, major share of the retail market is with 3-5 formulators only. Rest of the formulators have rather low shares. In view of these factors, it is not prudent to define competition in terms of number of bulk drug manufacturers and number of formulators in relation to a particular bulk drug.

Considering all these aspects, bulk drugs will be kept under price regulation in accordance with the following critera:-

(i) The total MAT value of any particular bulk drug is more than Rs.2000 lakhs (Rs. 20 Crores) and the percentage share of any of the formulators is 50% or more.

(ii) The total MAT value of any particular bulk drug is less than Rs.2000 lakhs (Rs. 20 Crores) but more than Rs.500 lakhs (Rs. 5 Crores) and the percentage share of any of the formulators is 90% or more.

The above mentioned modified methodology and criteria are the best available, keeping in view the inherent constraints with respect to access to and availability of turnover data of large variety and range of bulk drugs. This modified methodology meets the requirement that the bulk drugs for price control should be identified on the basis of extent of usage and the absence of sufficient competition in both high selling and low selling formulations. On this basis, criteria have been enunciated in sub para (vi) of para 10.B II(a) the Note.

On the basis of the data worked out from the ORG-MARG of March, 1999 for the application of the above mentioned methodology and on the basis of the application of criteria stated in sub-para (f) above, there would be about 37 bulk drugs under price control and the retail market coverage on account of formulations of these drugs is estimated to be around 25% of the total retail trade reported in ORG-MARG of March 1999. This span of control is considered reasonable keeping in view the overall objective of the "Pharmaceutical Policy – 2001" aiming at ensuring adequate availability at reasonable prices and also creating an environment conducive to channelising new investments into pharmaceutical R&D and industry.

F.No.M/7/2000-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF CHEMICALS & PETROCHEMICALS

ANNEX. IV

SOME OF THE MODELS FOR WORKING OUT THE MAXIMUM ALLOWABLE PRICE

[Refer sub-para (f) of para 10.B.II on p. 8 of the Note]

The DPCRC's observation that the present methodology of microanalysis for price determination of bulk drugs through cost-cum-techno-economic study needs to be reviewed in the context of the liberalized economic regime, is a profound observation. The pharmaceutical industry has been averse to such studies for the reasons of maintaining secrecy with regard to their technology and process details. Moreover, as the price fixed on the basis of such a study is a normative price and not the actual price, it creates problems for some producers of so called "quality" drugs. The industry has been consistently representing against the present system. Hence, for calculating the "maximum allowable price" of bulk drugs, it is proposed to allow the working out of the prices of major manufacturers of a bulk drug, which is under price control, in a given period of time on the basis of invoices submitted to the Central Excise Authorities on which the Central Excise Duty is paid. The data could also be collected from the top 4 or 5 formulators (as per ORG) of the concerned bulk drug. The average purchase price for the concerned bulk drug could be determined for price regulation on this basis also. Similarly, for bulk drugs, which are imported, the average of the landed cost in a given period of time shall be considered. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Chemicals and Petrochemicals can take into account market based data and arrive at an average "maximum allowable price" for the bulk drug on the basis of this data. If this is not possible the NPPA can devise its own methodology. Once the average price is determined for a bulk drug, it would be notified and shall be considered for revision from time to time. Under the Pharmaceutical Policy-2001, the flexibility to use market based data would be available to determine the "maximium allowable price" of bulk drugs. TheDepartment of Revenue and the Customs and Central Excise formations all over the country shall assist the Department of Chemicals & Petrochemicals and its attached office, the National Pharmaceutical Pricing Authority, to get the data/invoices/information as deemed necessary for conducting the above study from time to time. The Department of Revenue be advised to take necessary steps in facilitating this procedure.

(ii) An R&D intensive company achieving "the gold standards" would qualify for an additional cost of 5% of ex-factory cost in determination of the prices of Scheduled formulations manufactured by it.

(d) Ceiling prices

Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all importers/formulators, including those in small scale sector or marketing under generic name, to follow the price so fixed.

(e) Exemptions

(i) A manufacturer producing a new drug in the country, not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) Any formulator may represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient , on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

F.No.5/7/2000-PI.I
GOVERNMENT OF INDIA
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(f) Pricing of Scheduled Bulk Drugs

(i) For a Scheduled bulk drug, there shall be a price notified as the "maximum allowable price" for being adopted while fixing the prices of formulations containing that bulk drug.

(ii) The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest, and also to conduct cost cum techno-economic study, if it considers it necessary to do so, as per present practice.

(g) Monitoring

(i) To have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is, in the present context, extremely important as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, decided to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(h) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

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VII. QUALITY ASPECTS

The Ministry of Health & Family Welfare would

(i) progressively benchmark the regulatory standards against those adopted in developed countries, for manufacturing,

(ii) progressively harmonize standards for clinical testing with international practices,

(iii) streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D, and

(iv) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

VIII. PHARMA EDUCATION AND TRAINING

The National Institute of Pharmaceutical Education and Research (NIPER) has been set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, Government's endeavor will be to upgrade the standards of pharmacy education and R&D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

DR - 35.

GLOBALISATION AND ITS IMPACT ON THE INDIAN PHARMACEUTICAL INDUSTRY

D. P. DUBEY

Given by Sri Dubey
for

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	products			
5.	Hoffman La Roche	Syntex Lab.	1994	$ 5.3 bn.
6.	Eli Lyly	PCS Health System	1994	$ 4 bn.
7.	Sandoz	Gerber	1994	$ 3.7 bn.
8.	Smith Kline Beecham	Sterling	1994	$ 2.9 bn.
9.	Glaxo	Burroughs Wellcome	1995	$ 14.2 bn.
10.	Hoechst	MMD Roussel	1995	$ 7.2 bn.
11.	Pharmacia	Upjohn	1995	$ 7 bn.
12.	Rhone-Poulenc Rorers	Fison	1995	$ 2.7 bn.
13.	BASF	Boots	1995	$ 1.3 bn.
14.	Ciba Geigy	Sandoz	1996	$ 30.1 bn.
15.	Hoffman la Roche	Cornage Ltd.	1997	$ 11 bn.
16.	Hoechst A.G.	Rhone Poulenc	1998	
17.	Astra	Zeneca	1998	$ 67 bn.

(Source :- Compilation from reports published in various news papers at different times)

TABLE - V

Percentage of drug production and world population in some countries

Country	% of world Drug production.	%world population
USA	28.2 %	4.7 %
Germany	7.7 %	1.5 %
France	7.1 %	1.1 %
U. K.	3.4 %	1.1 %
Brazil	1.7 %	2.8 %
India	1.2 %	16.1 %

(Source :- Business Standard February 19, 1997)

Conclusion :

The present Govt. at centre is bringing a bill in the winter session of the Parliament to change Indian Patent Act 1970. The change in the Act is not in the interest of the people of the country. Now the patent has become an object of business instead of development. Considering the wide gap of industrial and technological development between developed and developing countries monopoly rights through patent system should not be allowed to the rich nations. Today 85% of the patents are being controlled by TNCs of rich nations. "Globalisation is hurting poor people, not just the poor countries. In this process poor country and poor people will become increasingly marginalised," says the 1997 world development report of UNDP.

The question is why this pressure and hurry ? The main aim to imp[illegible] the conditionalities of WTO and the attempt to change Indian Patent Act is that MNCs need more markets and are eyeing Asia the largest continent of the world where 60% of the world population lives but contributes only 20% of the world pharma business. With high rate of population growth it is expected that the need of the drugs will tremendously increase in the third world countries including India in the next millennium. India contributes 16.1% of world population, but produces only 1.2% of world drug production (See table-V). Hence the MNCs are trying to have more control on the pharmaceutical markets of the developing nation.

Developed countries are always backing their own big companies to capture markets in other countries even at the cost of the interest of the people there. The United States has successfully battled for the inclusion of strict intellectual property rules in international trade agreements such as NAFTA and GATT. Often the U.S. position has literally been drafted by PhRMA. These trade agreements disregard public health consideration and have forced dramatic change in the intellectual property rules world over. Still PhRMA is not satisfied. And when PhRMA is not happy the office of U.S. Trade Representative (USTR) is not happy," says the editorial comment of Multinational Moniter.

The above comments clearly indicate intention of the USA and other rich nations. Unfortunately, the Govt. of India is dancing to their tune. Against this, it is necessary to develop and launch broad based movement every where with the active support of people hailing from all walks of life forcing the government to change their stand.

TABLE IV

Some TOP Pharma Company mergers in the world

Name of Company	Name of Company	Year of merger	Value of transaction
1. Dow Chemials	Marion Labs	1986	$ 6.21 bn.
2. Bristol Myers	Squibb Corp	1989	$ 12.09 bn.
3. Beecham group of Company	Smith, Kline & French	1989	$ 7.9 bn.
4. American Home	American Cynamide	1994	$ 9.7 bn.

GLOBALISATION AND ITS IMPACT ON THE INDIAN PHARMACEUTICAL INDUSTRY

Globalisation is a process which involves economic inter-dependence of countries world wide removing all barriers for economic integration as if the whole world is a single village. Obviously, in this process the rich nations with their superior financial power, control the scenario and on the other hand the poor and the developing nations are forced to integrate surrendering their economic independence knowing fully well, what they are forced to accept is really prejudicial to their own interest. In this process, the world financial institutions like world Bank, IMF and now the WTO advance the interest of the rich countries only. The draconian policies of World Bank and IMF under structural adjustment programme resulted in the net transfer of $178 billion between 1984 and 1990 from poor countries to the commercial banks of rich nations. (Source : UNDP Human Development Report 1994). William Shakespeare introduced us to Shylock, the one man bank and his method of debt extraction. The process of IMF, World Bank is more organised, ruthless and heinous today than Shylock's. The Transnational Corporations (TNC) of rich nations are practically controlling the world finances. Today, the whole world is colonised by Global finance and the TNCs supported by the neo-colonial structure including World Bank, IMF and WTO are controlling the financial situation world-wide. Government of third world countries are powerless against global finance and are unable to control its movement within their own national boundaries.

The situation of the world drug industry is no different. "Operating at the behest of the Pharmaceutical Research and Manufacturers Association (PhRMA) for a decade and a half, U.S. Government has waged a ruthless crusade to force third world countries to adopt straight jacketting intellectual property rules at the expense of protecting public health", says the editorial comment in the June '98 issue of Multinational Moniter, a journal published from Washington.

The structural adjustment programme introduced by Government of India at the behest of IMF, World Bank and WTO created serious impact on India's drug industry, health care system, on the workers engaged in the industry and ultimately on the people of the country. These reform policies are mainly the reduced role of the Government, cut in subsidy in social sector, increase in administered prices, liberalisation of trade by increasing tariff rate providing incentive for foreign investment, privatisation of public sector, equating foreign companies with Indian companies de-regulating the labour market etc. This is aimed at withdrawal of the state initiative from social and welfare sector like health, education, public distribution etc.

In the following paras I shall deal on how the workers of the drug industry and the people of our country are affected by the impact of globalisastion.

Drug Industry situation prior to Indian Patent Act, 1970 : At the time of independence, total drug production in our country was around 10 corers. At

that time MNCs taking the help of colonial "Patent and Designs Act, 1911" exploited the drug market of our country. They were engaged mainly in import of drugs from their country of origin. Between 1947-57, 99% of the 1704 drugs and pharmaceutical patents in India were held by foreign MNCs. During that time the MNCs controlling 80% of the market did not come forward with financial investment and technological help to establish drug production centres in India. Drug prices in India was one of the highest in the world. In 1954, first Public Sector drug company Hindusthan Antibiotic Ltd. (HAL) was established with the help of WHO and UNICEF. Indian Drugs and Pharmaceutical Limited (IDPL) was established in 1961 with help from Soviet Union. The establishment of these two public sector units and coming into force of the Drug Policy of 1978 had been mainly responsible for the availability of drugs and medicines at relatively lower price in India. The country became almost self sufficient in production of drugs.

Indian Patent Act 1970 :

The Patent Bill was first introduced in the Parliament in 1967, but the Patent Act, 1970 came into force only in 1972.

Indian Patent Act 1970 which is in operation in our country does not allow product patent on medicines, agricultural products and atomic energy. This is the most suitable patent act for the developing world. Here, process patents are allowed for 5-7 years. Mainly with the help of Indian Patent Act 1970 India is today selfsufficient in production of basic drugs covering various group of drugs. Indian scientists developed new processes for 107 drugs. Indian companies are now among the world leaders in the production of bulk drugs from basic stages. At present, the prices of drugs in India is comparatively economical than many other countries. As per UNIDO, India is identified to produce its own drug needs with its own technology and manpower indigenously. After 1970, many new drug firms were established by Indian businessmen. At present, around 23 thousand small, big, medium factories are producing drugs in India.

Attempt to change Indian Patent Act 1970 is a part of this globalisation programme. The imposition of unequal trade treaty like World Trade Organistion (WTO) is a step towards globalisation in favour of the MNC's of rich nations. With its help, the market of the developing nations is forced open for the developed countries. Most of the developing countries were forced to sign WTO agreement without realising its implication; as a result, developed countries are always winner. Already, at the dictates of IMF, World Bank and WTO Govt.. of India is slackening all checks and controls to invite the MNC's in all industries including pharmaceutical industry. FERA and MRTP Acts have been amended. Customs duties and corporate taxes have been lowered down. Relief, concessions and facilities have been extended to MNC's as that of Indian companies. All these, already, had adverse impact on the indigenous drug industry. As per the requirement of WTO guideline for product patent regime, the availability of new drugs in our country may be delayed depending on the desire of patent holder. As per

More over, the number of workers engaged in these units have been reduced drastically. When IDPL was established it had a strength of more than 15,000 workers. Today, it has been reduced to less than 7,000.

With pharmaceutical industry taking a leap towards biotechnology development world-wide, only the public sector drug companies, with the backing of the Central Government, could have faced the challenge effectively from the MNCs in the new situation.

Mergers and Acquisitions :

International and national level mergers, acquisitions and take covers have now become a common phenomenon in the pharmaceutical industry. Internationally American Home Product merged with Cyanamid, SKB with Sterling, Rhone Poulenc took over Fashions, BSF with Boots, Glaxo with Burroughs Welcome, Ciba Geigy with Sandoz, Warner Hindustan with Parke Davis, Hoechst with Rhone Poulenc etc. are some of the examples of big take avers. By mergers and acquisitions these companies became further bigger with more financial power at their disposal over their competitors. (See Table for top pharma merger of the world)

In the coming days, with the help of international financial companies MNCs will capture and take control of Indian companies to control Indian market.

To match the situation created by international mergers and take overs, Indian companies are adopting the same path. For example Wockhardt took over Merind and Tata Pharma, Ranbaxy took over Croslands, Nicholas Piramal took over Roche, Boehringer, Sumitra Pharma. Inevitable results are job loss of workers. Because of over lapping of job large number of workers are declared excess. After merger Glaxo-Welcome and Ciba-Sandoz announced reduction of 15 thousand and 10 thousand of work force respectively world-wide. Upjohn and Pharmacia decided to close 24 of their 57 plants in different countries after merger.

Some companies are adopting 'Buy and Grow' method. They are taking over some popular brands and increasing their business. SKB took over Crocin from Duphar, Ranbaxy tool over 7 leading brands from Gufic, Dr. Reddy's Lab purchased 6 products of Dolphin and two each from Pfimex and SOL Pharma. Sun pharma purchased all leading brands of NATCO,after selling the popular brands the companies are becoming sick and closing their shutter throwing the workers in the street.

Governments permission to MNCs to come to India with 100% equity have threatened the existing companies with same origin and their workers.

Through the process of mergers, acquisitions and take overs MNCs will gradually perpectuate their grip on the Indian industry in the creation of limited number of mega companies having monopoly control and domination world wide. In absence of competition people will have to pay any price as it happens in the sellers market.

Knoll Pharma (Boots)	1995	All workers aruond 600
Smith Kline Beecham	1995	208
E. Merck	1995	194
Rhone Poulenc	1996	700
Hindusthan Ciba Geigy	1993	907
Duphar Interfran	1996	154
Bayer	1996	590
Abbott	1996	All workers
Roche	1996	All 320 workers
Boehringer Mannheim	1997	All 335 workers
Park Davis	1997	All 650 workers
Pfizer	1995	215
Unichem	1997	All workers

(Source : Annual reports of respective companies and interaction with the office bearers of the union.)

Thus, the total payment on voluntary retirement scheme by some of the firms like Glaxo, Hoechst, Pfizer, Knoll Pharma, Rhone Poulenc, Park davis, Smith Kline Beecham, Duphar, Bayer etc. are more than 200 cores in last three financial years. The main important thing is employment opportunities in these units have been reduced for ever.

Impact on Public Sector :

With the reduced role of the state under globalisation the public sector drug companies are faced with serious problems including imminent closures. Public sector drug companies like Indian Drugs and Pharmaceuticals Ltd. (IDPL), Hindusthan Antibiotics Ltd. (HAL), Bengal Chemicals and Pharmaceuticals Ltd. (BCPL), Bengal Immunity (BI) and Smith Stanistreet Pharmaceuticals Ltd. (SSPL) played an important role in the production of essential drugs at affordable price. Under the globalistion process the role of Public sector has been marginalised and they have been made sick. Attempts have been made to either privatise or close them. The Penicillin Plant in HAL, the biggest in the country, has been handed over to Priv[illegible] hands. Its Streptomycin plant also has been leased to a private company for manufacture of other drugs. IDPL which is having the biggest pharmaceutical plant in Asia is closed from 1996 for want of proper financial assistance from the government. The public sector drug companies used to supply raw materials to the small scale sector companies. Now, these companies are facing difficulties in procuring raw materials. Similar is the fate of BCPL, B.I. and SSPL. These three units were taken over by the government after they were made sick by the private owners. Proper utilisation of their capacity could not be made due to lack of will on the part of the government, mismanagement at the administrative level and high level corruption.

It is not because of any inherent weakness but due to lack of political will, deliberate efforts to destroy them, corruption and mismanagement these public sector units have been rendered commercially unviable.

the guidelines, product patent is granted for 20 years and process patent for another 20 years. At present, newer drugs are made available in our country within 4-6 years time. Prices of the drugs will go up by 5 to 10 times as it is evident from the prices of drugs in India and other countries like Pakistan, U.K. and U.S.A. where product patent is in force. Ranitidine is sold by Glaxo in India at Rs7.20. The same product is sold by the same company in Pakistan at Rs. 65, in U.S.A. at Rs 545. Similarly, anti-viral drug Aciclovir costs in India at Rs. 33.75 while the same drug is sold in Pakistan at Rs. 363. There are many such examples. The drug prices in U.S.A., U. K. and other developed countries have gone up so high that the health care expenditure in those countries is predominantly funded by insurance companies at a very high premium. In those countries people cannot think [illegible]treatment without insurance coverage. Product patent regime will definitely hamper India's drug export as countries will be forced to purchase from patent holders only.

Dilution of Drug Policy and Drug Price Increase :

Unlike consumer goods, drugs are not purchased by the preference of a person, but on a doctors' prescription. Consumers have no choice of their own on this matter.

Prices of the drug are increasing by leaps and bounds along with the prices of other commodities in recent times. The drug manufacturers are flouting the Drug Price Control Order (DPCO).The DPCO was first introduced in 1970. In 1970 most of the drugs were under price control. In 1987 this was diluted and number of drugs which were restricted to 347, in 1987 it was brought down to 163 drugs and in 1994 only 73 drugs were under DPCO. Even then the industry is not happy; they want the control to be abolished totally. They have already demanded decontrol of 17 bulk drugs and further recommended full decontrol within 3 years time (Economic Times 28th September' 98). Whereas many developed countries of Europe control drug prices directly. In U.K., Government determine the profit level of drugs [illegible]pplied by individual company. The company has to reimburse the excess [illegible]rofit to the department of health.

Recent study shows that prices of many life saving bulk drugs have gone up steeply. Drugs policies in our country are decided not by the need of our people, pattern of disease or by the purchasing capacity of the people, but by the profit motive of the industry and Central Government is playing the role of silent onlooker.

We are giving below the prices of twelve essential drugs before the liberal decontrol of DPCO in 1995 and today.

Table I

Name of the drugs.	For treatment	Packing	Price		Percentage increase.
			1995	1998	
Diazepam	Depression	10's	3.13	9.50	204%
Ampicillin	Antibiotic	4's	12.85	23.15	80%

Cephalexin	Antibiotic	10's	45.07	113.15	151%
Ethambutol	Anti T.B. Drugs	10's	5.92	33.00	457%
Rifampicin	----do----	10's	24.00	64.00	167%
Pirazinamide	----do----	10's	17.01	46.95	176%
Lignocaine Hcl	Anaesthetic	30 ml.	4.16	12.40	198%
Promethaxine Hcl	Anti allergic	10's	1.25	3.23	158%
Antacid liq.	Gastritics	200 ml.	13.00	23.00	77%
Oxyfedrine HCl	Angina pectoris	10's	10.44	21.41	105%
Discopyramide Phosphate	Cardiac problem	10's	16.50	50.46	206
Dipyridamole	Anti anginal	10's	2.00	4.73	137%

The above list is only indicative. Hundreds of such examples can be given.

Further, under WTO agreement with the imposition of products patent regime, the prices of all new drugs (Patented) will go up without any control of domestic law. DPCO will become further irrelevant and Indian people's accessibility of newer drugs will be restricted only to the rich elite of the country. We are giving below the high prices of some of the new drugs introduced in 1977 in Indian market.

Table II

DRUG	COMPANY	STRENGTH	PACK	PRICE
Sporanox	Ethnor	100 mg	4 Tab.	173.00
Lumicil	Novertis	250 mg	14 Cap	1247.00
Sparlex	Sun Pharma	200 mg	6 Tab	154.00
Rispid	Panacea	50 ml	1mg/ml cap	141.00
Livial	Infar		28 Tab	1225.00
Pipracil	Cyanamid	2 G	Vial	215.78
Arnate	Mesco Pharma	50 mg	12 Tab	180.00
Adno ject	Inca	3 mg	2 ml.vial	210.00
Roxisara	Sarabhai	300 mg	6 Tab	165.00
Celex	Glaxo	250 mg	4 Tab	14[illegible]

(Source : Paper of A Guha, placed in the seminar held at Delhi in May, 1998)

World-wide concern has been expressed with the sharp rise of drug prices. In this dilution WHO's goal of "Health for all by 2000 AD" will remain a distant dream.

Moreover, with the rapid development in technology, more number of new drugs are being introduced. Experts say that very few of them are having theraputic advantages over the existing drugs. "Out of 348 new drugs introduced by 25 big US companies during 1981 to 1988 only 3 percent made important potential contribution while 84 percent made little or no potential contribution" said US federal authority. Hence the introduction of new costly drugs should be properly monitored by the central Government.

MASS KILLING OF JOBS :

With the reduction of the customs duties of foreign imports many drugs manufactured in India have become unviable even in Indian market than the foreign goods. As a result, the owners of these factories are closing down their units throwing the workers out of employment. Messrs. Boehringer Mannheim, and Parks Davis who were the lone producer of Chloramphenicol in India stopped their production as its prices from the international market were cheaper than the cost of Indian production. M/s. Sarabhai Chemicals closed their vitamin 'C' plant due to similar reason. Like Chloramphenicol and vitamin 'C' many other drugs like paracetamol, metronidazole, ampicillin, amoxycillin etc. are available at a cheaper price in our country from the international import because of the lowering down of the customs duties and Indian factories have been closed and workers are on the street. Not only the workers but for the above drugs our country became dependent on foreign supply.

In their attempt to shift the production to the third party manufacturing, already, Hindustan Ciba Geigy, Roche, Abbot, Boehringer Mannheim, Boots, Park Davis, Unichem etc. have closed their factories by offering VRS to all workers and sold the land of their factory premises at a premium price. Apart from these closures, Pfizer, Rhone Poulenc, Hoechest, Glaxo etc. reduced their work force. Crores of rupees have been spent to give VRS amount. These companies are manufacturing their products with the help of loan license. Some of the companies have opened new smaller factories in new places and appointed workers with less wages and more work load. More casualworkers are being appointed. In last two years times in Mumbai-Thane region of Maharashtra around 30,000 workers lost their jobs in pharmaceutical industry.

Apart from the factory workers the distribution workers are gradually being replaced by C&F agency system. In this system, original company does not have any responsibility of the workers. They are employed by agents with more work load and less wages. In the last decade around 15 thousands distribution workers lost their jobs in the pharmaceutical industry. Moreover, through the agency system Government is deprived of central sales tax.

In the marketing also the field workers or the sales promotion employees are facing tremendous attacks in the name of franchise, co-marketing, appointment of communicator etc. many permanent sales promotion employees are losing their jobs. Many others are appointed in the name of so called executives to remove them from the fold of the union. More casual and contractual workers are being recruited.

Table III

Company	Year	Reduction of work force
Glaxo	1995	1564
Hoechst	1996	1049

Revised version to be available for workshop on PPO2 + EGL on 25/11/02

DISCUSSION PAPER –PHARMA POLICY 2002

by Naveen Thomas

1) BEGINNING WITH A LIE:

"The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid"

DRUG POLICY 1986 OBJECTIVES:

- ensuring abundant availability, at reasonable prices, of essential life saving and prophylactic medicines of good quality;
- strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
- creating an environment conducive to channelising new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs, and
- strengthening the indigenous capability for production of drugs.

THE POLICY DOES NOT ADDRESS THE ABOVE OBJECTIVES ANYWHERE IN THE NEW POLICY. INFACT IT GOES AGAINST THESE OBJECTIVES IN MOST PLACES.

2) TRUTH REVEALED:

"However, the drug and pharmaceutical industry in the country today faces new challenges on account of: **1) liberalization 2) globalisation 3) new obligations undertaken by India under the WTO Agreements**.

These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards **1) promoting accelerated growth of the pharmaceutical industry and 2) towards making it more internationally competitive**".

THE RHETORIC IN THE FIRST FEW LINES ARE RECTIFIED IN THE SUBSEQUENT LINES.

3) CAN'T CONTROL, SO LEAVE IT!

- It is interesting to quote from the background note circulated by the government to the DPCRC prior to its deliberations. "DPCO is used as one of the essential instruments to achieve the objective of essential medicines of good quality, at reasonable prices, for the required health care of the masses. It has been an evolutionary process, which has been taking cognisance of ever-emerging new factors and their resultant effect on the availability of drugs at reasonable prices... controls have been gradually diluted with the promulgation of each subsequent order. However, the common feature of price control has been the principle of selectivity with the aim of product-wise price control, mainly based on the extent of mass usage of drugs."
- The key "ever-emerging new factor" that the note identified was the inadequate machinery to administer the price control orders, leading to the concept of selectivity. It further observed that the determination of criteria for the selection of drugs under price

non-tariff barriers removed
FDI - very low in reality - ? exports 1/3rd of 20,000 cr
how much repat.
of leading 10 cos - India - 4 are Indian, rest MNC's.

control was a ticklish problem because of the need to strike a balance between the interests of the consumer and the manufacturer. "Therefore," the note said, "certain working principles were evolved and applied across the board... Industry, keen to get rid of price controls altogether, has time and again questioned these working principles... To make matters worse, industry has not been forthcoming in providing data to substantiate their claims."

- The failure to evolve an effective mechanism to monitor the pharmaceutical industry's adherence to the DPCO, coupled with the liberalisation of the economy, has led the government to advance the dubious argument - at the behest of pharmaceutical companies - to justify the removal of price controls that market mechanism and competition will help check and stabilise drug prices. The questionable premise of selectivity on mass usage principle for price control has been further used to whittle drastically the list of drugs under price control.
- Soon after the 1995 round of decontrol and the resultant reduction in the number of drugs under price control, the prices of drugs went up. Indeed, the policy statement makes the observation: "Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-scheduled formulations." But it ends up - based on that very dubious market figures - diluting the DPCO.

4) WHAT HAPPEN WHEN THERE IS DECONTROL?

- An analysis carried out by the Delhi Science Forum (DSF) on the impact of the 1995 decontrol throws up some interesting facts about the "market behaviour". The price movement of 28 essential drugs - eight under price control and 20 outside it - showed that out of the eight controlled drugs there was a decrease in six of them. On the other hand, the prices of the 20 drugs showed an increase in excess of 10 per cent and in some cases in excess of 20 per cent. More interestingly, the DSF analysis showed that in all segments there were wide variations in the prices of different brands of a given formulation and the top-selling brand in any formulation is not the cheapest one, sometimes twice as expensive. This is proof enough that the market mechanism does not stabilise drug prices and the market share of a brand is not dependent on its price. In fact, the very reason for putting in place a price control mechanism was this atypical market behaviour in the case of pharmaceuticals.
- The DSF also analysed the increase in prices of 50 top-selling drugs between February 1996 and October 1998. It showed that the average increase in the case of brands under price control was 0.1 per cent whereas that in the case of brands outside price control was 15 per cent. It was also found that the price rise was not a one-time increase owing to an escalation in raw material costs but was indicative of a trend of continual increase in the prices of decontrolled drugs, Amit Sen Gupta of the DSF said.

5) INDIA HAS THE CHEAPEST DRUG PRICES. MYTH OR REALITY???

- Sen Gupta said that there was a prevailing myth that drug prices in India were the lowest in the world. "This is at best a partial truth. Drugs that are still patent-protected are much cheaper in India than elsewhere because of the 1970 Patents Act and we have lost this advantage after its amendment in the wake of TRIPS (Trade-Related aspects of Intellectual Property Rights). But for many off-patent drugs, which account for 80 to 85 per cent of the current drug sales in the country, prices are higher in India than in Sri Lanka and Bangladesh and even in Canada and the United Kingdom. In the United

States, the U.K. and so on, there are effective price control mechanisms and bodies to monitor drug prices.

6) DPCO – A POLITICAL TOOL?

- When we argued that the change in the Patents Act would result in an increase in prices, the government said that it would use the mechanism of DPCO to keep the prices in check. Now that the Patents Act has been amended, the TRIPS argument is being used to dismantle the DPCO, confirming our fears."

7) WHAT HAPPENS WHEN SELECTION OF DRUGS FOR PRICE CONTROL IS BASED ON MARKET FORCES INSTEAD OF PEOPLE'S HEALTH NEEDS?

- For example, an anti-diabetic drug, listed as an essential drug but required to be taken only once a day, might be low in volume as well as value. Conversely, a very expensive drug, low in volume sales, could show up as having a high turnover. Similarly, a reasonably low-priced essential drug, but consumed in large quantities, might be missed out because the total turnover could still work out to be low. So the bottom line should be that the selection should be based on health need - namely, the list of essential drugs - and not on market behaviour which, in the case of drugs, does not follow the norms of other consumables. But this has been the problem with the Indian drug policy over the past four decades, in which the inputs of the health sector are never reflected in the policy articulated by the Department of Chemicals and Petrochemicals which in turn is influenced by the industry lobby.

- In arriving at the selection criteria, the present policy statement has rejected the new criterion recommended by the DPCRC to ascertain the mass consumption nature of a bulk drug on the basis of the top-selling brand, on the grounds that it gives rise to anomalies. Yet, the policy does not offer any justification as to the final set of criteria that has the effect of keeping three-fourths of the drugs in the market out of price control.[1]

8) POLICY WAS MADE IN A DATA VACCUM.

- The policy statement admits **that no reliable data exist** to ascertain mass consumption and the absence of sufficient competition in respect of a particular bulk drug - the two criteria used for the selection of controlled drugs. However, says the document, in the absence of any exhaustive and comprehensive information, the ORG-MARG data are the best available. According the ORG-MARG database, 23 drugs belong to the first selection criterion, Rs.25 crores turnover and 50 per cent market share of any formulator, and 12 belong to the second. However, the NPPA is expected to come out with the final list of controlled drugs in May, which may include other drugs in addition to those on the ORG-MARG list, in particular the "less than Rs.2 cost per day per medicine" category.

[1] The basic data source that the DPCRC has used is the "Retail Store Audit for Pharmaceutical Market in India", published by ORG-MARG in March 2001, which lists all major brands and their sale estimates on an all-India basis.

9) PROMOTING FORMULATIONS AT THE COST OF BULK DRUGS.

- In addition to making higher profit margins for the manufacturer possible, the policy has done away with the **ceiling on profitability on formulations** that existed until now (vide the Third Schedule of DPCO 1995). In case of bulk drugs, the manufacturer has been allowed a 4 per cent higher rate of return over the existing 14 per cent on net worth or 22 per cent on the capital employed. Considering that more and more manufacturers are moving away from bulk drug manufacture to formulations, this provides an additional windfall. With no restriction on imports, pharmaceutical imports (which is largely of bulk drugs) have been rising at the rate of 29.3 per cent while exports (which are mainly of formulations) have been increasing at the rate of 18 per cent, according to the data of the Centre for Monitoring of Indian Economy (CMIE).

10) LOGIC DEFIES LOGIC.

- That the government should indulge in such massive decontrol exercise **"to promote accelerated growth and improve competitiveness"** defeats logic because pharmaceutical stocks, even during the current slowdown of rest of industry (except for the automobile sector), were the most robust in the last quarter of 2001. Now, with the announcement of the new policy, the pharmaceutical stocks, in particular those of multinational corporations (MNCs), have further shot up.

11) COUNTER PRODUCTIVE MOVE.

- THE move to allow 100 per cent automatic foreign investment in the pharmaceutical industry is not likely to bring any large investment for production or technology or R&D, as MNCs are able to widen their markets now through imports alone. Further, Indian firms are increasingly turning into trading houses for MNC products. The existing MNCs have already shut their bulk drug production and R&D units. And the impending change in the patent regime will only aggravate this trend when the indigenous drug industry and R&D base would be completely eroded because of the removal of competition and the absence of any regulatory framework. While the new policy includes some measures on the R&D front based on the recommendations of the Mashelkar Committee or the PRDC, the policy puts forward no clear strategy that will counter this disturbing trend.

12) R & D – BASIC PREMISE QUESTIONABLE.

- However, the basic premise on which the Mashelkar Committee worked remains questionable. Indeed, this premise is one of the chief arguments used by the DPCRC to dilute the DPCO under the new policy. The committee had observed that stiff price control measures under the DPCO left little scope for the firms to generate resources for R&D. This argument is dubious because the progressive reduction in the control span under the DPCO - down to 40 per cent after 1995 - does not result in any corresponding increase in R&D spending by the pharmaceutical companies. The overall R&D expenditure by the Indian drug industry (comprising about 150 companies) remains at a meagre 2 per cent of the total turnover. There is no guarantee, points out Sen Gupta, that the control relief will be channelled into R&D and not used to fatten the balance sheets of individual companies.

13) GOLD STANDARDS – TOO COSTLY?

- DPCO 1995 provided several incentives to drug manufacturers for R&D, which exempt them from price control. But the companies that have qualified for this price control exemption on grounds of indigenous R&D efforts over the years are fewer than the fingers on one hand. Interestingly, the Mashelkar Committee had set certain 'gold standards' for a company to qualify as an R&D-intensive company eligible for price benefits under the DPCO. Considering that hardly any company has qualified for exemption from the DPCO even without such standards being set, it is highly unlikely that such 'gold standard' companies would emerge as desired by the committee. Now that most drugs have been put outside DPCO controls, the DPCO does not any longer offer an incentive for R&D.

14) HRD, EDUCATION, QUALITY CONTROL – A FOND HOPE?

(1 para at the end)

- The policy makes only cursory remarks about the aspects of quality control and education and human resource development, which should actually have received greater attention, especially with the increase in the spread of spurious drugs in the market. With licensing completely abolished, it is going to be even more difficult to keep a check on quality. The policy has endorsed the recommendation of the Mashelkar Committee to establish a new structure for the Central Drug Standard Control Organisation (CDSCO) under the MoHFW. With no clear indications of where the funding and manpower will come from, the hope of establishing a network of "world class" CDSCO laboratories can at best be a fond hope, if not mere rhetoric, like the rest of the policy document with matters regarding healthcare.

15) INDUSTRY RESPONSE TO POLICY - GOVT. HAS SHOW LARGESSE

- The secretary general, Indian Pharmaceutical Alliance, and former director, Pfizer, D. G. Shah, said, "The two criteria that have been considered are steps in the right direction. For drugs of mass consumption where there is inadequate competition, there is a need for price control. Where there is already enough competition, the large number of drugs has brought prices down over the years".
- According to Mr. Shah, "The size of the pharmaceutical industry is around Rs. 20,000 crores and the government felt that where the sales of a drug exceeds Rs. 25 crores, it qualifies as mass consumption. In the case of monopoly, the Monopolies and Restrictive Trade Practices (MRTP) Act prescribes 66 per cent market share but they have chosen to go for 50 per cent market share".

16) POLICY BASED ON PVT. DATA - MOTIVATED?

- Mr. Shah felt that at least it is a positive step. "Earlier which drugs come under price control was a subjective criteria and the database used to determine the drugs was not disclosed. One of the industry's demands was that the database used should be in the public domain and accordingly, the ORG-MARG March 2001 list was used. The criteria now are only arithmetical and there is no subjectivity. This shows transparency and there can be no favouritism. The focus is the consumer and the fine print of the policy is now awaited".

who are their promoters

17) OVER-RULING GOOD SENSE

- PP 2002s overall emphasis has been on reducing the price control to facilitate industry's investment in R and D and help small units to comply with the Schedule M requirements. However, by reducing the span of price control, the PP 2002 overrules the suggestion of the Drugs Price Control Review Committee (DPCRC) of 1999. The DPCRC had recommended that in the absence of health cover for majority of the population in the country, price controls should be continued till the government expenditure on health rises to a substantial level and the availability of essential drugs is improved. Neither of these has been achieved, yet PP 2002 has recommended that price controls should be reduced.

18) BIG FRY WITH SMALL FRY – PROTECTION TO WHOM?

- There are about 24,000 pharmaceutical units (including loan licensees) in the country [GITCO 2000][2] of which only about 300 are estimated to be large-scale units. The rest 23,700 are in the small and medium scale sector.
- **Impact of DPCO :** DPCO is applicable to all units irrespective of their size and turnover. In practice the impact of DPCO is relatively greater on the small-scale units than on the large units because of the differences in production volume between the two [Lalitha 2001][3]. Larger units with wide range of production of items have the advantage to balance the production between the items under price control and those, which are not. Since most of the small units do not have such flexibility, they get adversely affected. Also, larger units have the capacity to argue their case with the government to justify the higher prices based on their cost of production or other reasons and charge higher prices. Smaller units have also cited reducing profit margin due to DPCO as one of the reasons for not complying with the Schedule M[4] requirements of the Indian Drugs and Cosmetics Act.

19) ARBITRARY AND INNEFFECTIVE:

- PP 2002 states that besides the list of drugs under DPCO, a bulk drug will be kept under price regulation if (a) the total moving annual total (MAT) sales value of any bulk drug is more than Rs 25 crore and the percentage share of the formulators is 50 per cent or (b) the MAT value of a bulk drug is less than Rs 25 crore but more than Rs 10 crore and the percentage share of the formulator is 90 per cent or more. These cut-off figures are purely arbitrary. It is a known fact that the subsidiaries of large companies are commonly used to split the production and sales of the parent firm to escape from such ceilings fixed by the government. This makes it difficult for the regulating authority to cast a wide net to bring other drugs under control.

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[2] GITCO (2000): 'Industrial Status, Sickness Level and WTO Impact Study: Drugs and Pharmaceutical Sector', Gujarat, August.

[3] Lalitha, N (2001): 'Product Patents and Pharmaceutical Industry', a report submitted to the Indian Council of Social Science Research, New Delhi.

[4] Schedule M provides guidelines on quality aspects to be adopted in drug manufacturing which covers various stages from procurement of raw materials to the final stage of packing the finished formulations. Also known as the Good Manufacturing Practices (GMP), the central government has stipulated that all existing units will have to comply with the GMP requirements by December 2003, failure of which will lead to cancellation of its licence and closure of the unit. While GMP is a must for all the units, it is imperative for units functioning on contract basis for a parent unit especially in the context of the WTO regime. Though GMP compliance will provide the units a relative advantage in the context of exports over units which do not comply, critics observe that not all the conditions are relevant. It is estimated that a minimum of Rs 40 lakh will be required to comply with the requirements and in some cases it may necessitate shifting to new premises. This may force some of the units to exit. However, whether the reduction in the span of control would result in improved compliancy rate will have to be observed in the next few years.

20) TRIPS AND PHARMA

- Assuming that a product has effective protection for a period of 12 years, it means that domestic producers will enjoy absolute monopoly status for 12 long years and reap a monopoly profit. Two major apprehensions of adopting the TRIPS Agreement in the pharmaceutical sector were regarding the higher prices of the patented products and their accessibility. By providing a blanket exemption from price control, the government is making the access to drugs difficult. It appears that 'who patents the product' matters more for the government than what is patented. Rather than exempting drugs from price control, providing easy access to credit, promoting venture capital funds and streamlining the procedures would help in promoting innovations.

21) POLICY DOES NOT DEAL WITH THESE:

- Product development requires different levels of expenditure and facilities compared to the infrastructure available in public funded laboratories today, which possibly are good for the initial phase of discovering new molecules. Unfortunately, economic liberalisation has meant a squeeze on public spending on medical and biotechnology research in general, which in any case was only a little over 2 per cent of the overall government R&D expenditure. But there is no mention of improving public-funded R&D in the new policy statement.

- A main issue with the pharmaceutical drugs in India is that in the place of 452 drugs (279 that appear on the National Essential Drug List 1996 and 173 considered important by the ministry of health and family welfare), there are about 80,000 formulations in the market, a sizeable percentage of which is considered to be irrational combination drugs. Easy entry of drugs, absence of prescription and sales by generic drugs and thorough scrutiny to examine the therapeutical contribution of a product before allowing entry in the market are the reasons for the mushrooming growth of irrational combinations in the country. Monitoring of prices at retailer level - not done

- Such irrational combinations have created two kinds of problems in the country. One is that the patients are prescribed unnecessary drugs, which besides causing side effects also result in increasing the cost of treatment and duration of treatment. This often happens in the private health care. In the public health care, absence of effective implementation of a Essential Drug Policy (EDL) has resulted in irrational combinations being procured in the hospitals and essential drugs are often in short supply. This obviously results in poor people buying the required medicines from the open market, which they should have normally got free of cost. Hence, it has been suggested that the EDL should be at least in the government health care to ensure adequate supply of essential drugs. Both these crucial aspects of pruning and weeding the irrational combinations and implementation of EDL have not found a place in PP 2002. Ideally, the policy should have dealt more on the subject of the availability of essential drugs. This is essential in the context of reducing price controls and foreign competition.
- PP 2002 does talk about ceiling prices for formulations. However, the problem is monitoring these prices at the retailer level. The policy admits that while the price of the bulk drugs is brought down through price control, its effect on formulations is not felt immediately and companies continued to charge higher prices and hence suggests stricter monitoring. Here unless the consumer cares to compare the prices of similar combinations (normally the patient goes by what has been prescribed), the pharmacist is going to dispense only the high priced drugs.

VOICE - study of UP & Kar - price on package varies. Delhi.

- **One-Sided :** The problem with the pharmaceutical policy 2002 is it is one-sided echoing mostly the business interests and fails to reflect the health needs or the approaches to the health-related issues in the economy. The policy does not suggest ways of improving the domestic production of anti TB drugs, antimalarial, CNS stimulants or antileprotics, where the supply is less than the actual demand.
- The policy does not mention facilitating contract research, which will be useful in reducing the initial costs for the domestic R and D firms and help concentrating on commercial development of a product. Industry should also be encouraged to collaborate with academic institutions to improve R and D. Presently the collaboration between academics and industry in India is at a low level, which needs to be drastically improved by paying attention to the IPR issues. These aspects need a more detailed discussion in the policy and government support.
- Improving the availability of essential drugs most of which are off-patent should be the immediate concern of the government, besides weeding out irrational combinations.
- Adopting generic sale of drugs and effective implementation of essential drug policy will automatically lead to reduction in the prices of drugs.

SUGGESTIONS

- The upshot is that to meet the emerging challenges, in the wake of globalisation and the impending new product patent regime on the one hand and the new developments in the area of biotechnology on the other, there is no substitute for **enhanced public spending in drug R&D.** Even in advanced countries such as the U.S., significant R&D in pharmaceuticals is still public-funded. Indeed, what the country needs is a paradigm shift in medical research, drug development in particular, with a national-level strategic planning and new institutional mechanisms in public funded R&D.

ANNEXURE

The prices of vitamins, aspirin and ciprofloxacin will now be decontrolled while maxformin, norfloxacin, salbutamol sulphate, ibuprofen, cinarbin, pentazocine, bisacodyl, chlorophenarmin and streptomcyin are among the new drugs which will come under price control. Among bulk drugs which will remain on the controlled list are the anti-TB drug rifampicin, betamethazone and aminacin sulphate. Companies likely to benefit from the developments are Ranbaxy, Pfizer and Glaxo. Novartis, Knoll and German Remedies are among those whose products will continue to remain under price control.

Cipla's Ciplox and Ranbaxy's Cifran will now come out of price control. With Ranbaxy's Histac also out of DPCO, up to 80 per cent of Ranbaxy's portfolio will be out of the new DPCO. E Merck's Polybion, Glaxo's Zinetac and Zevit and SmithKline's Septran are likely to come out of the list.

Among those to have entered the list are Novartis' Voveran which contributes nearly 20 per cent to the company's turnover and enjoys 51 per cent of the diclofenac market and Otrivin which has a 95 per cent market share in xylometazoline market. Aventis' Daonil and Pfizer's Dolonex could be included in the list. GlaxoSmithKline's Dilosyn is the only methdilazine product in the market and would qualify for control as it is a Rs. 13 crore brand.

As per ORG data for March 2001, formulations of 23 molecules have turnover in excess of Rs. 25 crores with a single manufacturer having market share of more than 50 per cent.

The older molecules like amikacin sulphate, betamethasone, cefotaxime, erythromycin, framycetin, glipizide, ibuprofen, metronidazole, norfloxacin, chloroquine, phenytoin, piroxicam, prednisolene, proridone iodine and rifampicin will continue under price control and only eight molecules are relatively new.

The ORG data also show that formulations of 12 molecules have annual turnover of more than Rs. 10 crores with a single manufacturer having market share in excess of 90 per cent. In this category, barring streptomycin, pentazocine, phenobarbitone and quindiodochlor, all eight molecules are new.

Apart from the 35 molecules, a few more could come under control when the government decides on the basis of surveillance of price of movement of the list of 180 essential drugs prepared and forwarded by the Union Health Ministry.

Molecules with turnover more than Rs. 25 crores and with a market share of 50 per cent

Bulk drug	Brand	Company
Amikacin	Mikacin	Aristo
Betamethasone	Betnesol	GSK
Cefixime	Taxim-O	Alkem
Cefotaxime	Taxim	Alkem
Chloroquine	Lariago	IPCA
Diclofenac	Voveran	Novartis
Erythromycin	Althrocin	Alembic
Fexofenadine	Allegra	Aventis
Framycetin	Sofradex	Aventis
Glibenclamide	Daonil	Aventis
Glipizide	Glynase	USV
Ibuprofen	Brufen	Knoll
Metformin	Glucophage	Franco Indian
Metoclopramide	Perinorm	IPCA
Metronidazole	Metrogyl	Unique/Lakar
Nandrolone	Decadurabolin	Intas
Norfloxacin	Norflox	Cipla
Pheniramine	Avil	Aventis
Phenytoin	Eptoin	Knoll
Piroxicam	Dolonex	Pfizer
Povidone Iodine	Betadine	Win Medicare
Prednisolone	Wysolone	Wyeth
Rifampicin	R-cin	Lupin

Source: pharmabiz.com

Molecules with turnover ranging from Rs. 10-25 crores with a market share of 90 per cent

Bulk drug	Brand	Company
Acarbose	Glucobay	Bayer
Betahistine	Vertin	Duphar
Bisacodyl	Dulcolax	German Remedies
Dydrogesterone	Duphaston	Duphar
Lignocaine	Xylocaine	Astra
Methdilazine	Dilosyn	GSK
Norethinderone	Regesterone	Novartis
Pentazocine	Fortwin	Ranbaxy
Phenobarbitone	Gardenal	Rhone Poulenc
Quiniodochlor	Enteroquinol	East India
Streptomycin	Ambistrin	Sarabhai
Xylometazoline	Otrivin	Novartis

NATIONAL HUMAN RIGHTS COMMISSION
SARDAR PATEL BHAVAN
NEW DELHI

Case No.778/96-97/NHRC

Name of the Complainant : Indus Hospital Shimla Referred by the Himachal Pradesh State Human Rights Commission, Shimla

Case No.158/6/96-97/NHRC

Name of the Complainant : Suo Motu cognizance of the Press Clipping in the 'Indian Express' dated 9.9.1997

CORAM:

JUSTICE SRI M.N VENKATACHALIAH, CHAIRPERSON
JUSTICE SRI V.S. MALIMATH, MEMBER
SRI VIRENDRA DAYAL, MEMBER

8.0 BROAD FINDINGS AND RECOMMENDATIONS

8.1 General

(1) Fungal contamination in IV fluids is a serious health risk. Glucose/nutrients in the fluid provide an excellent medium for microbial growth. Fungal contamination can occur through contaminated ingredients during manufacture, or cracks/leakage of faulty containers during transportation and/or storage. Gross fungal contamination can be detected by visual observation as suspended, white to blackish, cotton-like matter. A Cautionary labelling regulation provides for the hospital staff to visually inspect and examine the IV fluids before administration to patients. It goes to the credit of the hospital staff at the Indus Hospital in Shimla and the Ram Manohar Lohia (RML) Hospital in Delhi to have spotted the fungal contamination before administering the defective IV fluids to patients.

(2) The purpose of the present investigation has been to examine: (a) critical steps during manufacture, transportation or storage of LVPs upto the stage of administration to patients vulnerable to fungal contamination; (b) to identify the possible cause(s) or failures which lead to the observed contamination; (c) suggest checks/counter-checks/measures to minimize, if not to completely eliminate, occurrence of such lapses, and (d) in case it still happens and complaint is received, suggest reporting system which must be in place to minimize consequences and to prevent recurrence of such happenings.

(3) Unfortunately there is no reliable mechanism for obtaining a feed back on the magnitude of the fungus problem in IV fluids in India. Though fungal contamination in IV fluids is a serious health risk, neither the manufacturer, or the regulatory authorities or hospitals have adequate record-keeping which could indicate the extent of the problems. Rather a certain percentage of defectives due to fungal contaminated bottles is taken as an acceptable norm. This mindset needs a change. We must aim for zero-defective batches. Fungus infested LVP is not common any were in the developed countries. As per the Gold Sheets, in the USA no recall of LVPs took place after early 70's. Similarly, Australia has not recorded such recall after the early 90's.

8.2 Core Healthcare Limited

(1) Core Healthcare's manufacturing operations are located at two separate spacious sites, Sachana and Rajpur near Ahmedabad.

(2) Core Healthcare manufactures IV products by the world-class Rommelag technique of Blow-Fill-Seal technology. As per the Company, manufacturing processes are validated for aseptic filtration prior to filling, sterilization of the Blow-Fill-Sealed containers and leak testing of filled containers

However, fungal contamination as reported has occurred very likely during storage, transportation, due to defective containers and/or damage incurred. The manufacturer does not have a proper system of monitoring the quality of the product particularly from the angle of contamination after the product leaves the manufacturing plant. The Batch Production Records of the manufacturer invariably show no evidence of damaged stocks. Further, the informal free replacement of defective stocks by the Company's field staff has under-played the problem as no records of such transactions are made available. In fact, in the absence of data on defectives, it seems that the extent of this problem is under-reported.

A. (a) Sachana and Rajpur plants have different levels of practices: while Sachana plant is state-of-the art, Rajpur plant is older and has inherent drawbacks of design

(b) Containers with weak neck could have cracked during transportation and storage creating leakage

(c) Weak secondary packing of corrugated shippers could have further aggravated the problem especially when stacking was higher than desirable height which could have damaged the containers due to heavy weight

(d) Manufacturer's warehousing facilities in Delhi, are shoddy and not rodent-free; rodent can damage shippers which can damage containers

B. (e) The batch records contain information related to manufacturing. But the records on market complaints, distribution, quarantined or recalled batches at company's warehouses is not easily accessible

(g) Lack of system in attending to complaints from hospitals and lack of ownership for removal of rejected goods from the hospital stores

(h) Important processes like sterile aseptic filling with broth fill and container suitability are not validated regularly

(4) There is an immediate need for the manufacturers to take up improvement of system involved in the management of quality of LVPs as a major project and bring about improvement results in the shortest possible time-frame so as to make LVPs a defect-free product. Blow-Fill-Seal equipment is a purpose-built machine that contains an extrusion, moulding, filling and sealing station to produce product under aseptic conditions. As with any machinery, function is directly related to training and the validation exercises required to establish the operating limits of this machinery. In reviewing this issue there are several areas of manufacturing and validation that should

be examined: extrusion process, cycle time, MDPE plastic granules, and sterilization.

The manufacturer must aim at getting a defect-free product during the entire supply chain management including manufacture, transportation and storage on the lines of the Six Sigma programme adopted by the electronics industry. Six Sigma is a standard of quality which has only 3.4 defects per million opportunities for error. The quality improvement within manufacturing of LVPs can be achieved by using tools and technology for high speed repetitive process of Blow-Fill-Seal technology.

The manufacturer must benchmark to international standards to raise standards of quality. It is not just the manufacturing process which is important. It involves the whole culture and attitude towards every function in the supply chain. Benchmarking involves finding the best-in-class for any world-standard. To institutionalize this culture, an extensive training programme must become the central focus.

Present mindset of LVP manufacturers is to measure defect in terms of percentage		LVP manufacturers need to move towards perfection
<u>defects per million</u>		<u>defects per million</u>
1% = 10,000	→	6 Sigma = 3.4
2% = 20,000	→	5 Sigma = 233
3% = 30,000	→	4 Sigma = 6200
4% = 40,000	→	3 Sigma = 66,803
5% = 50,000	→	2 Sigma = 308,733
6% = 60,000	→	1 Sigma = 697,700

Industry must change mindset of measuring defects from percentages to Sigma levels.

It is well recognised that the fungal contamination in plastic containers develops due to microleaks. Therefore, select critical materials/processes which affect the integrity of the container during manufacture, transportation and storage and require special attention are:

(a) Material of construction, weight, size, shape of container

(b) Sterilization cycle

(c) Leak test in during production and also during storage

(d) Secondary packaging system

(e) Mode of handling and transportation

(f) Stacking of the corrugated shippers at the company's warehouse, MSD and hospital stores

(g) Environmental and rodent control measures during storage, etc.

The continuous management of change for quality in the manufacture of LVPs in plastic containers should be achieved for which the following programme is suggested:

(a) For each critical process, from raw material to customer map the process, break down operations into steps and tasks, chart the flow of work, identify tasks that are prone to error, identify measurement points and measure processes and defect levels. If a task adds no value, discontinue. Form partnerships with suppliers and customers, e.g. manufacturers, transporters, depots and hospital stores. Mapping is only successful when it is done by the people actually involved in the process. Empowered teams are perhaps the most powerful force in making quality part of the supply chain process.

b) The next step is to carry out annual review and record defects for each and every process. These measurements of defects become part of continuous improvement model. From measurement move to analysis. The team may use techniques ranging from brainstorming to sophisticated pareto analysis or root cause identification. The analytical results, in turn, are used to solve the problem and devise an action plan. This is where training becomes so important.

(c) Institutionalize the solutions. Apply new procedures at each appropriate step of the process. Then the process starts all over again. It is a closed loop. Thus, it is a process of continuous improvement-of continuous learning. It includes the supplier and the customer.

(d) Finally, set goals. No quality programme can succeed unless tough goals are set and are measured. For instance, initial goal could be a 10 times improvement in quality in five years.

(e) Goal should be towards approaching zero defects in LVPs and maximum customer satisfaction.

(5) The various processes involved in the IV fluid life cycle and steps where quality is to be addressed by the manufacturer alone or through partnership with hospital, FDA or MSD etc. for manufacture, storage, and distribution are described in the following flow charts 5 (a) and (b).

5 (a)

INTRAVENOUS FLUID LIFE CYCLE

STEPS TO ADDRESS CRITICAL QUALITY MEASURES

WATER SYSTEM & OTHER INPUTS	Multicolumn WFI* production system is a must. Storage of WFI at 80°C and continuous recirculation required. Water system must be validated. Regular monitoring for bioburden endotoxin must be done Regular in-process control must be performed
COMPOUNDING	Area must meet specified cleanliness level. Environment must be monitored and controlled. 0.2µcartridge filtration is a must. CIP/ SIP* processes must be validated. Manufacturing system must be of closed type. Regular in-process control must be performed.
FILLING BFS - TECHNOLOGY	CIP/ SIP processes and container weight must be validated. 0.2µcartridge filtration is a must,before filling. Bioburden of filled containers before terminal sterilization must be performed for each batch. Regular in-process control must be performed Media fill must be performed, atleast once a year or when any changes are made in the system
FILLING OPEN -TECHNOLOGY (PVC/GLASS)	Area must meet specified cleanliness level. Environment must be monitored and controlled. CIP/ SIP processes must be validated. Cleaning, sterilization process of containers & closures must be validated. Personnel monitoring must be performed Regular in-process control must be performed Media fill must be performed atleast once a year or when any changes are made in the system.
TERMINAL STERILIZATION	Validation of sterilization process must be performed. Sterilization technology must be automatic & equipped with recording device. Quality of input steam and water must be monitored & controlled. Regular in-process control must be performed.
INSPECTION LABELLING PACKING & STORAGE	Leak testing procedure must be validated Visual inspection by trained personnel with regular change after every 2 hrs. Quality of corrugated boxes & their transport worthiness must be validated.
DESPATCH	Predespatch inspection must be performed. Despatch bay must protect the goods being loaded from weather effect. Loading operation must be supervised appropriately.

5 (b)

INTRAVENOUS FLUID LIFE CYCLE

PARTNERSHIP	STEPS TO ADDRESS CRITICAL AREAS
Manufacturer & FDA	**DESPATCH FROM MANUFACTURER'S SITE** — To strengthen FDA monitoring at manufacturer's site.
Manufacturer & Transporter	**TRANSPORTATION** — Careful selection of transporter to be made. Basic training to be given to transporter on handling of goods. Strict & continuous monitoring to be done of transport services.
MSD FDA Manufacturer	**DISTRIBUTORS** **MSD HOSPITAL STORES** **STOCKIST** **RETAILER** — Good Waterhousing Practices training to be imparted to the concerned personnel. FDA to increase periodic monitoring. Manufacturer must initiate post-marketing surveillance.
Hospital	**CUSTOMER** — Reuse of Intravenous sets must be banned. Only ETO* sterilised & disposable IV* sets must be used. All LVPs* must be inspected for integrity of theproduct before use.
Hospital FDA Manufacturer	**COMPLAINTS** — Batch must be quarantined to "Not for sale" or "Not for use" area. Concurrent information to manufacturer. Thorough investigation & testing must be carried out. To recall batch, if found defective.

*CIP : Clean-In-Place
ETO : Ethylene Oxide
IV : Intravenous
LVPs : Large Volume Parenterals
SIP : Steam-In -Place
WFI : Water For Injection

(6) In BFS technology Medium Density Polyethylene (MDPE) granules cannot withstand conventional sterilizing temperatures. Therefore, for producing LVP in MDPE container, the time a product is to be heat treated depends not only on the temperature but also pre-sterilization count (Bioburden) and the heat resistance of the micro-organism. This means that one cannot see the sterilization as an isolated process but one must consider the whole preparation and packaging process and should be able to prove the Sterility Assurance Level (SAL) required. Therefore, whenever a significant alteration in the composition of the product, packaging, premises, equipment or process takes place, the process warrants revalidation. Whenever a change is made, the manufacturer must set workable standards for bottle weight/ size/shape and secondary packings and validate them. It is recommended that at least 3000 units of production be included in each broth-fill trial. As target is zero growth, anything above 0.1% of units contaminated should be considered unacceptable. Any contamination should be investigated. Broth fill studies should be carried out once in a year.

(7) The manufacturer must create and implement procedures for effective and immediate handling of market complaints and recall of defective batches. If any container in a batch is found to be contaminated the rest of the supply must be quarantined till it is cleared after adequate examination and review. If the contaminated bottle on examination is found "intact", the entire batch must be rejected. Integrity of container systems plays an important role in the assurance of sterility. Even if one "intact" bottle is found contaminated with fungus the entire batch has to be rejected. There has to be zero tolerance of defectives. In such cases, the entire manufacturing process has to be revalidated which includes validation of container systems.

(8) The manufacturer must educate their own personnel and their customers with the Standard Operating Procedures (SOPs) for storage and transportation of such products. The customers, i.e. the MSD and hospitals in this case, should also be provided with detailed SOP on handling and storage of the LVPs to reduce the possibility of damage after receipt of the products in the MSD warehouse, hospital stores, dispensaries and wards. Regular training should be imparted to concerned personnel on storage and handling of such products after receipt from the manufacturer/supplier.

8.3 RML Hospital, New Delhi

(1) Visit to the RML Hospital stores in Delhi indicated deficient facilities, poor documentation and ineffective quarantine system for defective stocks. Handling of the shippers was rough particularly at the receiving station of the RML Hospital. Rodent control measures were practically non-existent in the stores. Location of the stores and storage conditions were generally far from satisfactory. The setting up of a hospital pharmacy and

warehousing facilities seems to have received the lowest priority at the planning stage of the hospital. The warehouse is located in the basement with open pipelines and ducting running over storage racks.

(2) The cautionary labelling on the containers to the effect that "if the container is found leaking or the solution is hazy or contains visible solid particles, the contents should not be used" has prevented use of defective I V fluids by the hospital staff. However, the documentation in respect of such defects, procedures for handling of market complaints and recalls are inadequate for tackling the complaints in an effective manner.

(3) There is no centralised hospital pharmacy set up under the charge of a qualified pharmacist for procurement, storage and issue of IV fluids. Heads of Radiology and Blood Banking look after this important activity resulting in misuse of precious time of medical experts and not providing the value addition which a pharmacist is qualified to provide and manage these tasks effectively.

(4) The importance of proper hospital pharmacy administration for procurement, storage, manufacturing, dispensing and distribution etc., of medicaments by professionally competent and legally qualified pharmacists was highlighted in the report of the Expert Committee on Hospital Pharmacy by Drugs Control Department, Government of Mysore in 1967. The report also recommended that a post of Deputy Director (Pharmacy) be created in the health services department of the state drugs control set up.

Even the report of the Hospital Review Committee for Delhi hospitals set up by Ministry of Health, Family Planning and Urban Development in 1968, recommended an effective organisation for quality control of drugs supplied to hospitals.

The Report of the Committee of Drugs and Pharmaceutical Industry headed by Shri Jaisukhlal Hathi in 1975, recommended that a chief pharmacist with at least a graduate in pharmacy degree should be appointed for maintaining quality of drugs supplied to patients in hospitals. **It is unfortunate that till now these recommendation have not been implemented**. It is high time that it is done.

(5) There is urgent need to set up a full fledged Hospital Pharmacy Department under the Head of Hospital Pharmacy, who should be at least a post-graduate in Hospital Pharmacy and reporting directly to the Medical Superintendent (M.S). He/she must be a member of the Drug Therapeutics Committee of the hospital.

(a) The Head of Hospital Pharmacy, with approval and support of the M.S. must develop policies and procedures for Procurement of

multisource medical items and their inventory control, receipt, handling, storage, quality control, distribution and dispensing etc. Systems, such as, just-in-time (JIT) to reduce inventory levels and consequently reduce requirement of large warehousing space, should be encouraged. The need for purchase of LVPs and other medical supplies from intermediaries like the MSD, the Kendriya Bhandar and Super Bazaar should be reviewed.

(b) The Head of Hospital Pharmacy with the approval and co-operation of the Hospital pharmacy and Therapeutics Committee must develop a Hospital Formulary to achieve the following including IV fluid requirements:

- Selection of drugs
- Distribution of drugs
- Safe administration of drugs
- Rational use of drugs
- Labelling, including cautionary labelling
- Recall of drugs
- Reporting of drug product defects

(c) The Head of Hospital Pharmacy, in addition, develop written policies and procedures for reports on all medication errors and adverse drug reactions (ADRs) and set up computerized Drug Information Service.

(6) The hospital must be required to document and report directly to the manufacturer and the concerned drug control authorities any instance of sub-standard LVP for speedy follow up action.

(7) The hospital staff must be trained in documentation and disposition of fungus-contaminated IV fluids.

(8) The hospital must be provided with warehousing facilities wherein proper environmental controls are made and entry of rodents is effectively checked. Facilities should be regularly inspected and accredited by the regulatory authorities. The hospital must lay down guidelines for the Good Warehousing Practices. The concerned staff in the warehouse must be trained in the Good Warehousing Practice guidelines being proposed in the Appendix-1.

(9) As per the Directorate General of Health Services, Govt. of India, New

Delhi, all consignments of drugs including LVPs to Government Hospitals are required to be tested by the testing laboratories approved by the State Drug Control Administration. This practice is counter productive because inspection and testing of 3-5 bottles from a batch cannot assure sterility of the entire batch. Also quality cannot be inspected . It has to be built in to the finished product during manufacture by following GMPs and carrying out adequate quality control checks at critical steps of manufacture and distribution. Neither the staff of hospitals or of a public testing laboratory were equipped with adequate knowledge of sampling procedures. Attention to this has been drawn in sub-para (11) of para 1.3. A poorly maintained laboratory, defective record keeping and weak quality culture make things worse. Further, the approved testing laboratories visited lacked adequate space, competent staff, documentation and validation of equipments, etc. Everything is taken as routine and the working culture was far from satisfactory.

8.4 Indus Hospital, Shimla

(1) Indus Hospital has a hospital pharmacy for indenting, receipt, storage and distribution of LVPs.The problem of fungus contamination in the products of M/s Core Parenterals was first brought to the notice of the Drug Control Department of Himachal Pradesh by the enlightened management of Indus Hospital on November 30, 1995. Thereafter when the Quality Control Committee of Indus Hospital again detected fungus in the products manufactured by M/s Core Parenterals they reported the matter to the State Human Rights Commission on April 23, 1996.

(2) The Expert Committee visited the Indira Gandhi Hospital in Shimla, and the Government Analyst Laboratory at Kandaghat where the samples were referred for analysis by the Drug Control Department of Himachal Pradesh. Table 2 (a) summarizes the results of the sterility tests performed on samples from defective batches by the Government Analyst at Kandaghat drawn by the Drug Control Department of Himachal Pradesh.

(3) The time taken for sterility testing by the Government Analyst in Himachal Pradesh was 1-5 months. It was also not clear as to why the drug control administration in HP did not send for analysis certain batches allegedly containing fungus to the Government analyst. Similar situation must be prevailing in other states. At the time of the visit to the Government Analyst's Laboratory at Kandaghat, the sterility testing facilities were not operational and was used for storing furniture. Question therefore arises as to how can

the laboratory carry out its sterility testing programme under such circumstances?

2 (a)

Government Analysist Reports - Kandaghat

Product	*Batch No.*	*Date of Manufacturing*	*Date of Expiry*	*No. of bottles with fungus*	*Sample No.*	*Date of receipt*	*Date of Report*	*Findings*
5% Dextrose Injection	*E-01-1071*	*N A*	*N A*	*N A*	*SML-96/9*	*30.04.96*	*21.05.96*	*Sample Does Not Pass Sterility*
5% Dextrose Injection	*E-01-1224*	*May-94*	*Aug-99*	*3*	*SML-96/10*	*30.04.96*	*20.05.96*	*Fails Sterility and Fungus*
5% Dextrose Injection	*E-01-2004*	*Dec-94*	*Nov-99*	*2*	*SML-96/11*	*30.04.96*	*20.05.96*	*Fails Sterility and Fungus*
5% Dextrose Injection	*F-01-1093*	*Feb-94*	*Jan-99*	*3*	*SML-95/189*	*02.01.96*	*01.05.96*	*Std. Quality*
5% Dextrose Injection	*F-01-0459*	*N A*	*N A*	*N A*	*SML-95/190*	*02.01.96*	*01.05.96*	*Std. Quality*
Irrigasol	*E-35-1295*	*N A*	*N.A*	*N A*	*SML-95/191*	*02.01.96*	*01.05.96*	*Std. Quality*
R/L Injection	*F-40-1513*	*N A*	*N A*	*N A*	*SML-95/192*	*02.01.96*	*01.05.96*	*Std. Quality*
5% Dextrose	*F-01-0496*	*Aug-94*	*Jul-96*	*1*	*N A*	*N A*	*N A*	*Not Sampled*
Improdex	*E-23-3127*	*Dec-93*	*Nov-96*	*2*	*N A*	*N A*	*N A*	*Not Sampled*

(4) The Government Analyst Report does not mention if containers were damage or they were intact whenever the sample failed in sterility thereby making it difficult to decide whether to quarantine or recall the remaining stocks from the market. It may be noted that sample drawn from the defective bacthes sent to the Central Drugs laboratory (CDL) at Calcutta by the Drug Control Administration at H.P. were declare to be of standard quality by CDL

(5) The recommendations mainly pertain to the Drug Control Administration and are reported in the Chapter under Central and State Drug Control Organisations.

8.5 Central and State Drug Control Organisations

(1) In view of the serious health hazards due to microbiological contamination in sterile preparations, requirements were laid down in Schedule 'M' to the Drug and Cosmetic Rules in which the GMPs to be followed in the manufacture, storage and distribution are included. The Drug Control Authorities are expected to monitor the compliance to Schedule M provisions in the manufacture and quality control of such preparations through tightened inspections to reduce the chances of failure of the systems or accidental contamination. A review of Schedule 'M' of the Drugs and Cosmetics Rules with a view to improving current GMP guidelines for manufacture, storage and distribution of IV fluids revealed that

(a) The existing schedule is very general and lacks specific guidelines for LVP manufacture.

(b) Schedule M having been adopted a decade back, a review should be undertaken in consultation with the manufacturers of LVPs (both glass and plastics) and regulatory authorities.

(c) Looking at the current international trends in manufacturing, quality control and distribution, the existing requirements of Schedule M are less than adequate from the point of view of harmonizing them with other international practices.

(2) In accordance with the Drugs and Cosmetics Rules, grant or renewal of a manufacturing licence for LVPs is now done by the Central Licence Approving Authority (CLAA) (approval by the Central Government) after joint inspection with the State Licencing Authority and necessary recommendation by the State Licencing Authority. Similarly the CLAA also gives permission for manufacture of additional products. WHO Certification Scheme is operated by the CLAA and State drug control authorities. Routine enforcement of the complaint investigation is done by the State Drug Control Authorities. This joint responsibility, which exists

in monitoring of quality of IV fluids in India lacks infrastructure, adequate number of trained people as well as clearly defined roles. The Gujarat State Drug Control Authorities do not have even the infrastructure for routine enforcement and inspection of manufacturers which is required to be undertaken twice a year. The six-monthly statutory audit and inspection of plants of Core Healthcare by FDA Gujarat have not been carried out regularly. The register of such inspections maintained at the Core Healthcare plant at Sachana did not reveal specific investigation for fungus contamination although such a major problem was reported from time to time. The government drug control machinery should adequately monitor the quality of LVP's. Regular audits and statutory inspections are not undertaken due to lack of manpower and other resources. This is an area of major concern and steps must be taken to focus attention on preventive action.

(3) Whenever a batch is suspected to be deficient in quality, the entire process of reporting and complaint handling is long and bureaucratic. It involves lengthy correspondence between the hospital and the Drug Control Department. The manufacturer is informed later.

(4) The specifications and test methods for an appropriate grade of polymer to be used in the manufacture of plastic containers is not defined in the Indian pharmacopoeia. In the absence of such requirements, the manufacturer can use any grade of material leading to quality problems later.

(5) The regulatory must change from its present reactive role of discussing concerns to proactive role of influencing the industry, hospital, MSD, distributors, retailers, approved testing laboratories etc. to provide defect-free LVPs to the patients as per 5 (a). The proactive role once adopted shall definitely manage the present concerns also.

(6) Efforts must be made to bring Schedule M and the GMP requirements in line with international standards with the following objectives:

(a) To elaborate the entire chapter on sterile preparations and to make the same more specific.

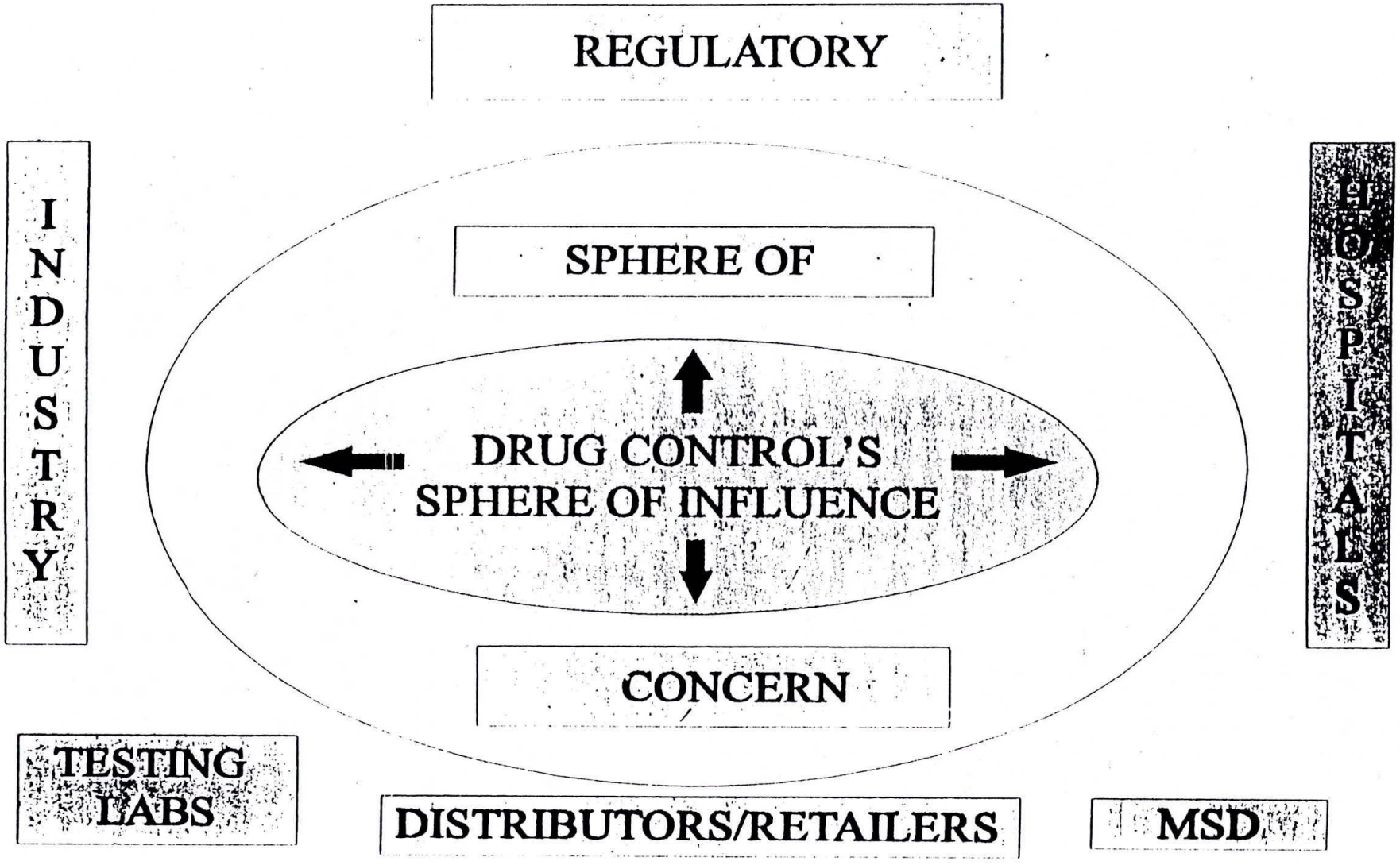
(b) To include the BFS technology for the manufacture of LVPs which is used in India today.

(c) To up-grade the entire Schedule M wherever necessary keeping in mind the present GMP requirements.

(d) To separate GMP requirements for LVPs as an exclusive chapter which is fully specific and in-line with cGMP practices as followed in India and the developed countries.

5 (a)

DRUG CONTROLS'S SPHERE OF INFLUENCE



(e) To provide an opportunity to LVP manufacturers in India to up-grade practices to international standards.

(f) To provide guidelines to LVP manufacturers and distributors so as to improve the quality standards of such products.

(g) To provide guidelines to regulatory bodies, public testing laboratories, hospitals, MSD etc. for monitoring the LVP product quality.

To carry out amendment to the Schedule M, a committee may be constituted in consultation with the manufacturers of LVPs (both glass and plastics). Once the changes are finalised, they should be implemented in a dynamic time-bound manner. The proposed ammendment to Schedule 'M' is enclosed in the Appendix-2

(7) The member of total manufacturers of LVPs are about 175 (both glass and plastics) compared to the large number of about 25,000 total pharmaceutical manufacturers in India. The Central Government must immediately take steps to examine the entire system of licencing (including loan licencing), new product approvals, certification and complaint handling under effective Central Government control through CLAA or other suitable means. The present dual system of control does not appear to be very effective. A mechanism must also be created so that speedy grant of free-sale and such other certificates for export purpose are available and the manufacturers are not put to any undue hardships.

It is also necessary to expand the sphere of influence of the regulatory authorities beyond manufacturers to include hospitals, MSD, Government testing laboratories, approved testing laboratories, distributor/retail outlets etc. where periodic inspection and certification are required to ensure quality of LVPs.

Enough infrastructure and facilities do not exist with either CLAA or even the FDA in Gujarat so that once in six months statutory audit of every manufacturer's premises is carried out and record of any market complaints during the period are examined thoroughly. The Drug Inspectors must be imparted adequate training for carrying out audit and inspection. To focus on these issues, a post of Director (Pharmaceutical Services) may be created under the DCGI at the center. Simultaneously, a post of Deputy Commissioner or Deputy Director (Pharmaceutical Services) be created under the Director, Health Services at state levels. The Drug Control Departments need to strictly enforce the provisions of the Drug and Cosmetics Act so that the consumer is protected against sub-standard LVPs.

(8) A GMP Certification Scheme for LVP manufacturers on the lines of WHO Certification Scheme for exports must be made mandatory for domestic requirements. Let us have only one quality standard of LVP manufacture

both for domestic and export requirements. There must be pre-inspection audits by the manufacturer prior to grant of GMP certification by the Drug Control Authority.

(9) All contamination-related quality complaints must be reviewed by the Hospital, the concerned Drug Control Organization and the Manufacturer within 72 hours and suspected stocks must be quarantined immediately pending further testing or market recall of batches.

8.6 Approved Testing Laboratories

(1) Ensure upgradation of the quality of the approved testing laboratories without any delay. As per the current practice, result of testing of a few bottles is inadequate in number and cannot guarantee the quality of the entire batch. Such an activity provides only a false psychological satisfaction and needs to be reviewed.The statutory sampling must be in accordance with the appropriate statistical sampling procedures.

8.7 Medical Stores Depot

(1) In 1996, the Government of India constituted an Expert Committee under the chairmanship of Shri C.R. Vaidyanathan to examine the procedure for the purchase of drugs and medicines through the MSD and suggest measures for streamlining the procedures. The Expert Committee made important recommendation for procurement, organisational set-up, computerisation, inventory control and monitoring, date expired goods, drug formulary, quality control etc.

(2) As per information available, the total requirement of Government hospitals of IV fluids per annum in Delhi is 10 lac bottles per annum. The Government hospitals purchase their requirements through either the MSD or Kendriya Bhandar. On receipt from the manufacturer, the MSD stores bottles in their own warehouse which is not a rodent-free facility. Bringing stocks to hospital require further local transhipment which involves unnecessary handling and storage.

(3) The MSD must immediately take steps to upgrade their warehouse facilities and make them free of rodents and pests.

(4) Purchasing system must be modified so that while the hospitals continue to place orders for their IV fluids requirements through MSD, they receive the stocks directly from the manufacturers. On a longer term, there is a need to review the outdated and cost in effective roles of MSD, Kendriya Bhandars and Super Bazars in procurement of manicines including IV fluids for hospitals. Possibilities for large hospitals to deal directly with the manufacturers and negotiate annual contract and indent IV fluids on a monthly basis or even just-in-time must be explored. This will not only

eliminate bureaucratic purchase procedures and extra handling but also save costly warehouse space of MSD. It is must be understood that chronic quality problems can be eliminated or at least minimized by removing wasteful activities in the process.

SOME OF THE MEDICINE WHICH BANNED IN ALL OVER THE WORLD BUT ARE SOLD IN INDIA

In our country we have only 515 medicines, which are sold by 3000 different names. These medicines are banned in all of the countries of the world and the production and selling of those is considered as a crime. Doctors and Scientists have said that these medicines are dangerous and can produce paralysis, cancer, blindness, and produce many other dangerous sickness. This medicine makes the immune system of the man weak and the man can die.Here are names of some of the medicines which are banned all over the world but are sold here without any restriction.

Sr.	NAME OF THE MEDICINE	BANNED IN COUNTRIES	EFFECTS
01.	Oxyfin Botazon, Oxypoz, Larjesic, Neurojesin, Sungril, Oxyzen, Parabutazon, Kliocvinal, Phynil Butazon, Actimal, Aljiril, Aristopyrin, Butacartidan, Butaproxyvan,	Britain, Japan, Germany,Sweden, Finland, America, Italy,Bangladesh, Australia,Maylasia, Israel, Jordan	By taking a small amount of this medicine the intestine get small Punctures and can cause blood cancer.These medicines have taken more than 15000 lives. It has been given 'B' where it is banned
02.	Ambkvinal, Eliqueen, Embijayam Fort, Emicure, Emicleen, Emigil Plus, Choloropectiden, Dyedoqueen, Introgyem, Aydojol, Aydocyclin, Metaqueen, Neutrojyem, Aydohydroxyqueen, Queenijol, Analjin,	Japan, Norway, Sweden,Germany, Denmark, Nepal,Bangladesh, Spain, France,Sri Lanka	Paralysis in legs, blindness Because of these10000 people got paralysed in Japan
03.	Beralgun Buskapan, Butaljin Farjesic Marlajin Oxypoz Sinaljesic Jimaljin	Australia, Austria, Belgiun,Billi, Denmark, France,Grease,Israel,Italy,Japan,Korea,Mexico, Nepal,Sweden,America,Britain,Germany,	It destroys the White Blood Cells in the body of the human body due to it the structure of the bones and the

	Altrajin Finoljin Pamajin	Denmark, Nepal,	muscles of the human beings gets effected and can cause death of a person
04.	A.T.Fort, Mayestrojanfort, Orosekronfort, Orgalotin, Ostron, S.G.Fort, Cholorostrap, Cuper Strap, holoromfenical and Straptamysin, Introstrap, Intestostrap, Straptophinakle,	Australia, Austria, Belgiun, Denmark, Greece, Italy,New Zealand, Norway,South Africa, Thailand, Britain, Singapore,America, Germany, Bangladesh	If it is given to a pregnant woman then makes the child handicap .It also effect in the production of the white blood Cells in the body of the human
05.	Drooling Drooling, Dekadyurabolin, Brufen, Ivabolin, Novaljin, Aspirin, Kaimer, Kaimoral, Kaimoral Fort, Alfapsin,	Bangladesh, Britain and all of the country of the world	It effects the immune system of the body and the person soon dies
06.	Acetophenetideen, Fenasitin, Acromysine, Docabolin, Histaprade, Pericart, Parydron, Irgofen, Mygril, Mygrenil, Stiptoment,	Canada, Chili, Cyprus, Denmark etc	They effects the liver of the humans The Vitamin present in these medicines only increase the cost of the medicine and nothing other than that.
07.	Tetracyclene Thoron Trynarjick Restil Kamaslip Plasidox 2 Plasidox 10 Plasidox 5	Bangladesh, Denmark, Italy, Jayen, New Zealand, Peru,Greece, Italy, Norway, Spain,Venezuela, Bangladesh, Nepal etc.	The colour of the teeth of the children gets brown and gives severe damage to the body

List of Drugs Banned by the Government of India under Section 26A of the Drugs & Cosmetics Act 1940

A. G.S.R. 578(E) Dated 23.7.83

1. Amidopyrine
2. Fixed dose combinations of Vitamins with anti-inflammatory agents and tranquilisers.
3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
4. Fixed dose combinations of Strychine and Caffeine in tonics
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/Chloralhydrate with other drugs.
8. Phenacetin
9. Fixed dose combination of anti-histaminics with anti-diarrhoeals.
10. Fixed dose combinations of Pencillin with Sulphonamides.
11. Fixed dose combination of Vitamins with Analgesics
12. Fixed dose combination of Tetracycline with Vitamin C
13. Fixed dose combination of Hydroxyquimoline group of drugs with any other drug except for preparations meant for external use.
14. Fixed dose combination of Cotricosteroids with any other drug for internal use.
15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
16. Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, Analgesics, Antithistamines for the treatment of migraine, headaches.
17. Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).
18. Pencillin Skin/Eye Ointment.
19. Tetracycline Liquid oral preparations.
20. Nialamide
21. Practolol
22. Methapyrilene, its salts.
23. Methaqualone
24. Oxytetracycline Liquid Oral preparations.
25. Demeclocycline Liquid Oral preparations.
26. Combination of Anabolic steroids with other drugs.
27. Fixed dose combinations of Destrogen and Progestin (other than oral contraceptive) containing per tablet estrogen content of more than 50mcg. (equivalent to Ethinyl Estradiol) and of Progestin content of more than 3mg.(equivalent to Norethisterone Acetate) and all fixed dose combination injectable preparations containing synthetic oestrogen and progestorone.
28. Fixed dose combination of Sedatives/hypnotics/anxiolytics with analgesic -antipyretics.
29. Fixed dose combination of Pyrazinamide with other antitubercular drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given below:-

Drugs	Minimum	Maximum
Rifampicin	450mg	600mg
INH	300mg	400mg
Pyrazinamide	100mg	1500mg.

30. Fixed dose combination of histamine H2-receptor antagonists with antacids except for those combinations approved by the Drugs Controller, India.
31. The Patent and Proprietary medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.
32. All Pharmaceutical preparations containing chloroform exceeding 0.5% w/w or v/v whichever is appropriate.
33. Fixed dose combination of Ethambutol with INH other than the following:-

INH	Ethambutol
200mg	600mg
300mg	800mg

34. Fixed dose combination containing more than one entihistamine.
35. Fixed dose combination of anthelmintic with cathetric/purgative except for Piperazine.
36. Fixed dose combination of Salbutamol or any other Bronchodilator with centrally acting antitussive and/or antihistamine.
37. Fixed dose combination of laxatives and/or antispasmodic drugs in enzyme preparations.
38. Fixed dose combination of Metoclopramide with other drugs except for preparations containing Metoclopramide and aspirin/paracetamol.
39. Fixed dose combinations or centrally acting antitussive with antihistamine having high atropine like activity in expectorants.
40. Preparations claiming to combat cough associated with asthma containing centrally acting antitussive and/or an anti-instamine.
41. Liquid oral tonic preparations containing glycerophosphate and/or other phosphates and/or central nervous system stimulant and such preparations containing alcohol more than 20° proof.
42. Fixed dose combination containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed.
43. Chloral Hydrate as a drug. (Tooth Pastes/tooth powders containing tobacco cosmetics)
44. Dovers Powder I.P
45. Dovers Powder tablets I.P. (Nox-11014/1/83-DMS & PFA)

B. G.S.R. 731 (E) dated 30.09.94

46. Antidiarrhoeal formulations containing Kaolin or Pectin or Attapulgite or Activated Charcol.
47. Antidiarrhoeal formulations containing Phthalyl Sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole.
48. Antidiarrhoeal formulations containing Neomycin or Sceptomycin or Dihydrostreptomycin including their respective salts or esters.
49. Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing Diphenoxylate or Loperamide or Atrophine or Belladonna including their salts or esters or metabolites Hyoscyamine or their extracts or their Alkaloids.
50. Liquid oral antidiarrhoeals or any other dosage form for pediatric use containing halogenated hydroxyquinolines.
51. Fixed dose combination of antidiarrhoeals with electrolytes.

C. G.S.R 57(E) dated 07.02.95

52. Patent and Proprietary Oral Rehydration Salts other than those conforming to the following parameters:
    a) Patent and Proprietary Oral Rehydration Salts on reconstitution to one litre shall contain
    Sodium - 5o to 90 millimoles.
    Total Osmoloarity - 240 to 290 milliosmoles.
    Dextrose Sodium Molar ratio - Not less than 1:1 and not more than 3:1
    b) Patent and Proprietary cereal based Oral Rehydration Salts on reconstitution to one litre shall contain:-
    Sodium - 50 to 90 millimoles.
    Total osmolarity - Not more than 290 milliosmoles.
    Precooked rice - equivalent to not less than 50gms and not more than 80 gms as total replacement of Dextrose.
    c) Patent and Proprietary Oral Rehydration Salts (ORS) may contain aminoacids in addition to Oral Rehydration Salt conforming to the Parameters specified above and labelled with the indication for "Adult Chloleratic Diarrhoea only".

D. G.S.R. 633(E) dated 13.09.95

53. Fixed dose combination of Oxyphenbutazone or Phynylbutazone with any other drug.
54. Fixed dose combination of Analgin with any other drug.
55. Fixed dose combination of dextropropaxyphene with any other drug other than anti-spasmodics and/or nonsteroidal anti-inflamatory drugs (NSAIDS)
56. Fixed dose combination of drug, standards of which are prescribed in the Second Schedule to the said Act with an Ayurvedic, Siddh or Unani drug.

E. G.S.R. 499(E) dated 14.8.98

57. Mepaerine Hydrochloride (Quinacrine and its salts) in any dosage form for use for female sterlisation or contraceptives.
58. Fenfluramine and Dexofenfluramine.

F. G.S.R.702(E) 14.10.1999

59. Fixed dose combinations of Vitamin B_1 B_6, and B_{12} w.e.f. 1.1.2001
G. G.S.R. No. 170(E) dated 12.3.2001.
60. Fixed dose combination of Nitrofurantoin and Trimethoprim
61. Fixed dose combination of Phenobarbitone with any anti-asthamatic drugs
62. Fixed dose combination of Phenobarbitone with Hyoscin and/or Hyoscyamine
63. Fixed dose combination of Phenobarbitone with Ergotamine and /or Belladona
64. Fixed dose combination of Haloperidol with any anti-cholinergic agent including Propentheline Bromide.
65. Fixed dose combination of Nalidixic acid with any anti-amoebics including Metronidazole.
66. Fixed dose combination of Loperamide Hydrochloride with Furazolidone.
67. Fixed dose combination of Cyproheptadine with Lysine or Peptone.

Annexure 1

PHARMACEUTICAL POLICY-2002

INTRODUCTION

The basic objectives of Government's Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

2. The process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are: -

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.
- Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and

  formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.
- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.
- Extending the facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology.
- Introduction of the Patents (Second Amendment) bill in the Parliament. It, inter-alia, provides for the extension in the life of a patent to 20 years.

3. The impact of the policies enunciated, from time to time, by the Government has been salutary. It has enabled the pharmaceutical industry to meet almost entirely the country's demand for formulations and substantially for bulk drugs. In the process the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 1999-2000, drugs and pharmaceutical exports were Rs.6631 crores

out of a total production of Rs.19,737 crores. However, two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy-2002. A reorientation of the objectives of the current policy has also become necessary on account of these issues:-

a. The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and
b. The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

4. It is against this backdrop, that Pharmaceutical Policy-2002 is being enunciated.

OBJECTIVES

5. The main objectives of this policy are:-

a. Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
b. Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
c. Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
d. Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
e. Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

APPROACH ADOPTED IN THE REVIEW

6. In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by this Department by the name of Pharmaceutical Research and Development Committee (PRDC) under the Chairmanship of Director General of CSIR.

7. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards) :-

- Invest at least 5% of its turnover per annum in R&D,
- Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,
- Employ at least 100 research scientists in R&D in India,
- Has been granted at least 10 patents for research done in India,
- Own and operate manufacturing facilities in India.

8. The recommendations of the PRDC in so far as they relate to the Pharmaceutical Policy have been taken into account while formulating the proposals on pricing aspects.

9. The Pharmaceutical Research & Development Committee has recommended in its report submitted inter-alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF). Necessary action in this regard has been initiated.

10. As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO, 1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals & Petrochemicals was set up in 1999, which has given its report. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy - 2002".

11. It has emerged that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and harness opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally.

12. In view of the steps already taken and in the light of the approach indicated in the foregoing paragraphs, the decisions of the Government are detailed below :-

I. Industrial Licensing

Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of

i. bulk drugs produced by the use of recombinant DNA technology,
ii. bulk drugs requiring in-vivo use of nucleic acids as the active principles, and
iii. specific cell/tissue targetted formulations.

II. Foreign Investment

Foreign investment upto 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing.

III. Foreign Technology Agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to in para 12.I above, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

V. ENCOURAGEMENT TO RESEARCH AND DEVELOPMENT (R&D)

(a) In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF.

(b) With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in pharma R&D, appropriate fiscal incentives would be provided.

VI. PRICING

(a) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. However, the DPCRC's recommendation regarding the new criteria for ascertaining the mass consumption nature of a bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies.

In this context, it may be noted that there is no tailor made data available for the purpose of ascertaining the mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. There is only one source namely, "Retail Store Audit for Pharmaceutical Market in India" published by ORG-MARG, which lists out all major brands and their sale estimates on All India basis. This publication contains data for single ingredient as well as multi-ingredient formulations. However, it does not give complete description of all the ingredients of the pharmaceutical product listed therein.

Hence, there is need to obtain information in regard to composition of each brand, dosage form wise and pack wise, from various other publications / sources, viz.,

(a) Indian Pharmaceutical Guide (IPG)

a. Current Index of Medical Specialities (CIMS).
b. Monthly Index of Medical Specialities (MIMS).
c. Drug Today
d. Information provided by some manufacturers
e. Label composition as indicated on market samples.

Though none of these sources can be said to be exhaustive and comprehensive in regard to market information, yet under the given circumstances, these are the best available. It has also been noted that the sale value of any combination formulation is not directly relatable to a single particular bulk drug forming part of the combination formulation. Combination formulations involve too many variables, viz., strength of a particular bulk drug and its proportion with respect to other bulk drugs used in the combination formulation, price difference between bulk drugs used in combination formulation, pack sizes, dosage forms etc. In view of these facts, ORG-MARG sales

data for combination formulations does not yield information in regard to mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. Also, it is to be borne in mind that processing of such data, which requires cross-checking with other publications and sources of information in regard to composition of each brand, dosage form-wise and pack-wise may involve instances of omission / commission.

In view of above, it would be logical to conclude that although ORG-MARG sale estimates available in regard to all single-ingredient formulations of a particular bulk drug would not yield the sale value of that bulk drug in the form of all its formulations, yet it would adequately reflect the mass consumption nature of that bulk drug in the form of single ingredient formulations, which may be used as a practical indicator for formulating the policy.

The Department through NPPA, with the help of NIPER has developed the desired database for single ingredient formulations from the retail store audit data as published by ORG-MARG. On this basis, the Department proposes to undertake the exercise of identifying the bulk drugs of mass consumption nature and having absence of sufficient competition according to the following methodology: -

i. The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion., as in the past, therefrom of sera & vaccines, blood products, combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.

ii. The ORG-MARG data of March 2001 would form the basis for determining the span of price control as suggested by DPCRC.

iii. The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March 2001).

iv. The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

v. The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.

vi. Bulk Drugs will be kept under price regulation if:-

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000 lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

vii. All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:-

In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

(b) Maximum Allowable Post-manufacturing Expenses (MAPE)

Maximum Allowable Post-manufacturing Expenses (MAPE) will be 100% for indigenously manufactured formulations.

(c) Margin for Imported Formulations

For imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit shall not exceed fifty percent of the landed cost.

(d) Pricing of Formulations

(i) For Scheduled formulations, prices shall be determined as per the present practice. The time frame for granting price approvals will be two months from the date of the receipt of the complete prescribed information.

(ii) The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in case of Scheduled drugs, will continue.

(iii) The present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Prices Control) Order, 1995, would be done away with. However, if necessary so to do in public interest, price of any formulation including a non-Scheduled formulation would be fixed or revised by the Government.

(e) Ceiling prices

Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those marketing under generic name, to follow the price so fixed.

(f) Exemptions

(i) A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.

(ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patent Act, 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

(iv) The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed Rs. 2/- per day, under intimation to the Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient, on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2/- per day, obtain the necessary price approval.

(g) Pricing of Scheduled Bulk Drugs

i. For a Scheduled bulk drug, the rate of return in case of basic manufacture would be higher by 4 per cent over the existing 14 per cent on net worth or 22 per cent on capital employed. The time frame for granting price approvals will be 4 months from the date of the receipt of the complete prescribed information.

ii. The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest.

(h) Monitoring

(i) The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(iii) The other recommendations of DPCRC like giving powers to drug control authorities to dispose of small and petty offences etc., will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable. Monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.

(i) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

VII. QUALITY ASPECTS

The Ministry of Health & Family Welfare would

(i) progressively benchmark the regulatory standards against the international standards for manufacturing,

(ii) progressively harmonize standards for clinical testing with international practices,

(iii) streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D, and

(iv) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective net work of drugs standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

VIII. PHARMA EDUCATION AND TRAINING

The National Institute of Pharmaceutical Education and Research (NIPER) has been set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, Government's endeavor will be to upgrade the standards of pharmacy education and R&D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

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DR-35.

Indian Pharmaceutical Scene

It is essentially the story of Drug Industry, Govt. and common man rather than common man and remedy to his ill health

* 70,000 - 80,000 formulations
* 20% sub-standard or spurious drugs - Govt, 80% Inessential
* Formulation - Irrational, Hazardous, Bannable
* Shortage of Essential and Life-Saving Drugs
* Non-availability of unbiased information
* Unethical Medical Advertising
* Irrational Prescribing practice of Medical profession induced by drug-doctor axis
* Inadequate drug legislation / Drug Control
* 50% of the drugs sold without prescription
* Beginning - Urea stibamine, vaccines, bulk drug production
* Indian Independence

Indian Patents Act 1970

- 12 years of protracted debate and deliberations
- National Interest > Patentee Interest
- Drugs / Defence Equipment / Food & Agriculture
- Process Patents 5 -7 years - To prevent monopoly capital
- Out of 3.5 lakh patents, 84% belonged to developed nations
- This has necessitated I.P.A.
- Increased Bulk drug Production ; Decreased drug Prices

Hathi Committee Report, 1974

◊ Too many inessential drugs - combination

◊ Shortage of essential drugs

◊ Poor quality control

◊ Technology to produce essential drugs available

◊ MNCs doing only Formulation activity

◊ Brand names - Double Standards

◊ Aggressive Sales Practice

◊ R & D Activity

Recommendations

- Essential drugs for Primary Care
- Generic Names
- Distribution of quality control
- Equity of Foreign participation, Phasing out of MNC's
- Bulk drug production Self reliance
- Communication with health professionals, researchers and planners
- NDA
- Result - WHO Essential Drug List, Bangladesh Drug Policy

- ♦ 1985 Rajiv Gandhi's New Economic Policy
- ♦ 1986 New Drug Policy - Bonanza for MNCs
- ♦ 1994 NDP to suit DDT - WTO

DDT

- 1947 GATT - 1986 Uruguay 1991 DDT
- Drug, Agriculture, biotechnology , Educative , Research Computer
- Amendment of Laws Patent & Constitution
- DDT accepted on 31 December '94 - without information
- Product patent
- No restriction on foreign equity
- No restriction in the area of investment
- No licensing No export obligation No obligation to use locally available material
- Foreign investment on par with Indian companies, leading to more inessential drugs

All India Drug Action Network

Consists of numerous health, consumer, legal aid and human rights organizations and Peoples' Science Movements. It is a loose network of academicians, professional social activists, individuals and organisations who are deeply concerned about the drug issue and implementation of Rational Drug Policy.

1. Academy of Young Scientists
2. Association for Consumer Action on Safety and Health (ACASH), Bombay
3. Arogya Dakshata Mandal, Pune
4. Catholic Health Association of India, Secunderabad
5. Community Development Medical Unit, West Bengal
6. Consumer Education & Research Centre, Ahmedabad
7. Consumer Guidance Society of India, Mumbai
8. Drug Action Forum - W. Bengal
9. Bodhi -West Bengal
10. Drug Action Forum - Karnataka, Bangalore
11. Delhi Science Forum, Delhi
12. Kerala Sastra Sahitya Parishat, Kerala
13. LOCOST, Baroda
14. Lok Vigyan Sanghatana, Pune
15. Medico Friends' Circle, Pune
16. Voluntary Health Association of India, Delhi

Books

1. A decade after Hathi Committee: Dr. B. Ekbal
   Kerala Sastra SahityaParishat
2. The Politics of Essential Drugs: Dr. Zafarullah Choudhary
   Vistar Publication, New Delhi: M32, Greater Kailash Market, Part I, New Delhi - 110 048
3. The Rational use of Drugs: Community Development Medicinal Unit (CDMU), 41/1B Garcha Road, Calcutta - 700 019.

Journals

1. BODHI: Editor, Bodhi, 254, Lake Town, Calcutta - 700 089, India. {Tel. & Fax (91) (33) 534 4878
2. ESSENTIAL DRUGS MONITOR: Editor, E.D.M., W.H.O, CH 1211 Geneva 21, Switzerland
3. FRCH NEWSLETTER: Foundation for Research in Community Health {FRCH}, 3-4 Trimiti B Apartments, Aundh Park, Pune -7
4. DRUG DISEASE DOCTOR: DD 35, SEBA, Sector I, Salt Lake, Calcutta - 700 064.

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Community Health Cell, 367, Srinivasa Nilaya,
Jakkasandra I Main, I Block Koramangala,
Bangalore - 560 034. Ph: 5531518

Drug Action Forum - Karnataka

It is a voluntary organisation established in 1986 and was registered in 1990.

Works towards establishing a rational drug policy for the country through educating consumers, medical profesionals, health and drug policy makers.

We are a group of 10-15 people actively involved with the activity. There is no paid staff in our organisation. Activities include lectures, publishing on Rational Drug Use for General Public, Doctors, etc.

Works closely with the All India Drug Action Network, Voluntary Health Association of India.

Supreme Court Litigation

Drug Action Forum Karnataka
NCCDP
Voluntary Health Asociation of Karnataka

Advocate Prashanth Bhushan
17th August 1993
DTAB Functioning Banned Drugs.

Problems

Attendance in the Court
Keeping in touch with the others
Supplying Drug Information

Consumer Protection Act 1986

Milestone in the history of socio-economic legislation in the country.

Simple, speedy and extensive redressal to the consumer's grievances.

Three tier quasi-judicial machinery at the national, State and district levels.

- Protect the rights of the consumer
- It covers all sectors - Private, Public and co-operative
- The provisions of the Act are compensatory in nature
- The right to be protected against the marketing of goods which are hazardous to life and property.
- The right to be informed about the quality, quantity, potency, purity, standard and price of goods so as to protect the consumer against unfair trade practice.
- The right to be heard and to be assured that consumer's interest will receive due consideration at the appropriate forum
- The right to seek redressal against unfair trade practices as unscrupulous exploitation of consumers
- Right to consumer education

Complaint

- Suffered a loss or damage as a result of unfair trade practice
- Goods suffer from one or more defect
- No fee for filing a complaint
- Complaint can be sent by post
- Complainant and opposite party should appear before the Commission for hearing
- Does not include any service provided free of charge or under a contract of personal service
- Medical Service and doctors have been brought under CPA through Govt. Hospital and others - providing free services have been excluded
- Informed consent:
- Do not go beyond the point of your skill
- Keep yourself abreast about latest developments
- In cases of medico-legal implications, inform the police
- Never overstate your qualifications
- Publicity is prohibited
- Keep the patients' interest paramount
- Therapeutics - use drugs judiciously