

IMPF Policy Notes for Parliamentarians On Access to Medicines



**Indian Medical Parliamentarians' Forum
Centre for Legislative Research and Advocacy**

Indian Medical Parliamentarians' Forum (IMPF)

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IMPF Policy Notes for Parliamentarians On Access to Medicines

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Preface

On behalf of Indian Medical Parliamentarians' Forum (IMPF), we are pleased to present the 'IMPF Policy Notes for Parliamentarians on Access to Medicines'. Access to medicine is an integral element of right to health. In India right to health is a fundamental right within the purview of right to life guaranteed under Article 21 of our Constitution. Ensuring medicines more affordable and accessible to patients is the benchmark of achieving the principles of right to health. Hence, our laws and policies need to create a facilitative environment for the realization of right to health by enhancing access to medicines.

Over the years, India has emerged not only as a cheap producer of generic drugs but also as a prominent supplier of generic drugs worldwide. Hence, many termed India as a pipeline for global generic supply or the poor man's pharmacy. The Indian Patents Act 1970 and implementation of Hathi Committee Report are said to be major law and policy measures that facilitated the growth of domestic pharmaceutical industry in the 1980s. In 90s the industry started exporting to the developing and developed country markets. However, the self-sufficiency and export potential did not improve the situation of access to medicines within India. According to WHO World Medicines Situation Report, only 33 percent of Indian population has access to modern medicines. In other words, it means that approximately 660 million people in India do not have access to medicines. This data conveys that growth of industry does not automatically improve the access situation in a country.

This limited success in the access may get worse in the light of changing international and national trade regime. As a member of WTO, India has amended its Patent Act to introduce product patent regime. Further, there is also growing demand from multinational pharmaceutical companies and big Indian companies to introduce data exclusivity. Both product patent and data exclusivity delay the introduction of generic drugs and insulate the market from competition. This would result in higher price. This begs the question: how effective is our price control and monitoring mechanism?

There have been several access barriers; this policy note attempts to highlight certain issues, which have direct and indirect implications on access to medicines. The articles in this volume deal with the main issues of enhancing access to medicines,

which include regulation, pricing, branding, intellectual property rights and promotional strategies. However, this does not include the issues of social barriers to access. We hope that this policy note would adequately inform and help the Members of the Parliament and policy makers address these issues inside the Parliament and other appropriate policy making bodies with an objective to bring changes in the relevant laws and policies.

IMPF Policy Notes on access to medicines is the first in the series, which is being brought out by the support of the Centre for Trade and Development (Centad). We would like to acknowledge and extend our gratitude to the Centad for their valuable support. We are grateful to each one of the authors for their write-ups in this policy note. We also reaffirm our deep appreciation towards the Centre for Legislative Research and Advocacy (CLRA) for its initiative to carry forward the IMPF responsibilities.



R. Senthil
Convener-Secretary



M. Jagannath
Chairperson

Lack of Controls Compromise Access to Medicines

Access to essential medicines is a major determinant of health outcomes. In developing countries, economic constraints lead to low affordability of essential medicines. Very definite estimates are difficult to compile, but different sources estimate that around 50 to 80 percent of the Indian population are not able to access all the medicines that they need. Even if we consider the lower figure, this is an untenable situation that needs remedial measures. India being the fourth largest producer of drugs in the world and exports medicines to over 200 countries, clearly local production or availability is not major constraint.

Thus any vision on universalization of access to essential medicines, in such a situation, would have to look at economic constraints that compromise access. It is estimated that the total expenditure on medicines in India is in excess of Rs 25,000 crores or, to put it in another way, Rs 1,800 for every family in the country. It is easy to comprehend that an expenditure of this magnitude would place a major burden on the finances of poor families. Several studies indicate that the proportion of medicine costs to total health costs is higher in poorer countries, and so among the income poor within these countries. Thus clearly, compromised access due to economic constraints adversely affects health outcomes in the country, and especially of the income poor.

While there are several factors responsible for at least half of the Indian population being denied access to medicines, two major areas of concern stand out. The first relates to price control measures implemented by the Government. Following the recommendations of the Hathi committee, the Government of the day announced the first comprehensive Drug Prices Control Order, in 1979, bringing 378 medicines under price control. In 1986 the Government, in a new Policy, reversed many features of the 1978 Policy. The span of price controls was reduced, greater profitability was allowed, imports were liberalised and various production control measures were scrapped. In 1994, the Government announced its new policy on Drugs and Pharmaceuticals, and continuing the trend set in 1986, the policy further reduced the span of price controls. The progressive decontrol of drug prices can be seen from the following table:

Poily	No. of Drugs under Price Control	Profitability Allowed for drugs under price control	Approx. percentage of drug market under price control
1978	378	40-75%	85%
1986	166	75-100%	60%
1994	74	100%	25%

The relaxation of price controls on drugs has been justified on the grounds that such controls are unnecessary when adequate competition exists in the market. This contention, however, does not stand scrutiny. Unlike other consumer goods, there is no direct interaction between the patient and the market, but mediated through doctors and chemists. Drug companies, through several promotional strategies – many of them unethical – are able to lure doctors and chemists to push their products irrespective of the price or actual therapeutic benefit. The fact that market competition seldom stabilises the prices of medicines is borne out by the fact that there is a wide variation in prices of different brands of the same generic medicine. At times this variation is to the extent of 500 to 1000 percent. Often, the top selling brand is also the most expensive. Comprehensive price control on all essential drugs is necessary to stabilise drug prices, ensure accessibility and check companies from profiteering.

It is estimated that 50 percent of drugs prescribed are irrational, or inessential or hazardous or a combination of the three. This acts as a major drain on the finances of the poor and further compromises their access to drugs which they actually need. The estimated drain on such useless or harmful medicines is the tune of Rs 10,000 crore per year, or almost Rs 1,000 per family per year. Remedies for this situation are not difficult to suggest. A periodic review of all medicines in the market, their scientific scrutiny, weeding out of useless and irrational drugs, strict norms for licensing of new drugs, and implementation of a strict code of conduct on the promotional practices of drug companies, are all practices that many countries follow. The fact that we are not able to do this in India point to both a lack of will and complicity of drug control authorities with unscrupulous drug companies.

- Dr. Amit Sen Gupta

All India Peoples Science Network, New Delhi

Pharmaceutical Policy: Ensure Participation and Informed Policy Making

The purpose of a national policy is to express the vision and political commitment of a government on a particular theme. Often, various interest groups attempt to influence the policy making in order to reflect their interests in the policy. Pharmaceutical policy is not an exception and many interest groups, especially industry associations, are in forefront to protect the commercial interest. As a result of economic liberalization, in 2002 National Drug Policy has been renamed as National Pharmaceutical Policy (NPP). This change in nomenclature got reflected in its content. The NPP clearly focuses on how to facilitate a growth strategy to the industry while listing down access to medicines as one of its objectives. This shift in the focus should be rectified in order to ensure access to medicines.

Currently, a six member Group of Ministers (GoM) is deliberating on the contents of new NPP. Even though it deals with various aspects relating to pharmaceutical industry ranging from regulation, tax regime, and R&D promotion to pharmaceutical education, the main point of contention is on the price control/monitoring mechanism. One of the main reasons behind the new NPP is the intervention of Supreme Court (SC). SC stayed the implementation of the price control mechanism proposed in the NPP 2002, as it proposed to reduce the number of drugs under price control from 74 to 34, which was challenged by concerned individuals and public interest groups. As a result of SC staying the implementation of the new price control proposals in the NPP 2002, the Drug Price Control Order 1995 (DPCO) is currently in force, which covers only 74 drugs. SC directed that the government “*shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control*” and is “*further directed to review drugs which are essential and life saving in nature.*” The SC has not disposed the petition and still retains the opportunity to scrutinize the new NPP in order to find out how far the government has followed its direction.

In the recent past, the Government appointed two committees (2004 and 2005) and a parliamentary committee (2004) pointed out jumble *raj* existing in the pharmaceutical prices and the ineffectiveness of the existing price control mechanisms to check such practices. These reports clearly state that competition alone fails to bring down the price in the market and the government should play a role in keeping the house in order. Prior to the referral to the GoM the Ministry of Chemicals and Petrochemicals did a series of consultation with industry including a Task Force consisting only industry members. Meanwhile, government encouraged the industry

to announce voluntary price cut without any significant success. The draft policy framed after consulting with the industry is now referred to GoM. The concerned individuals and public interest groups did not get a chance to comment on the content of this draft.

According to newspaper reports, the policy recommends inclusion of all 354 drugs in the National List of Essential Medicines under price control. However, the clauses of exceptions in the policy would reduce the number of drugs from 354 to less than 200. Critiques also point out that the exception clauses also gives room for pharmaceutical companies to escape the price control after making small changes in the existing drug. Further, the inclusion of only essential drugs under price control will also not offer an effective solution, because the most effective and commonly used drugs are outside the essential drug list. Since beginning, DPCO gives the National Pharmaceutical Pricing Authority (NPPA), responsible for the implementation of DPCO, the authority to monitor the pricing of all drugs. However, NPPA does not invoke this power with a few exceptions in the last six months. Therefore, there is an urgent need to bring monitoring of prices of drugs outside the DPCO and enforce price control if the price crosses the affordability limit. Another, important lacuna reported by the press is with regard to the approach towards controlling of prices of patented drugs. The policy is believed to propose price negotiation with companies on the pricing of patented drugs. Negotiation as an initial approach is fine. However, the draft policy is silent on the fallback strategy in case of failure of negotiation. One expects that the policy should spell out the stick along with carrot. Price control is considered as an important policy option to ensure access to medicine in the post-TRIPS period, where the product patent regime is in force. Therefore, there is an urgent need to have a re-look on the proposed price control and monitoring mechanisms to address the challenges of product patents.

Till date, the GoM had only one meeting and announced the intention of hearing all stakeholders including industry and public interest groups. However, GoM has not fixed any date for such hearings. Further, in order to create an informed participation and debate the draft policy should be made available to the public. In the absence of its availability in the public domain, one cannot expect informed debate. Even though the policy is considered to be the domain of the executive, the participation of parliament in the process should be ensured. A deliberation and audit of the policy by the members of parliament would ensure an informed and participatory policy making.

- K M Gopakumar
Centad, New Delhi

Indian Pharmaceutical Market: Certain Issues of Concern

India has a vast pharmaceutical market, and is rightly celebrated in international circles for making medicines very affordable and low-priced. But within India, it is a scenario of unaffordability and poor access amid plenty. Competition does not work in India's pharmaceutical formulations market.

The notion of a free market in pharmaceutical and health services is a contradiction in terms. India's pharmaceutical sector has been a "free" market in a different sense for a long time: one could make all kinds of irrational drugs from fresh human placenta, animal liver and cattle blood as also arbitrary combinations of different kinds of medicines and sell them at arbitrarily high prices.

Some other features of this "free" market:

- In India, the same drug is sold at vastly different prices by equally reputed companies and often by the same company.
- Brand leader is often the price leader! That is, the most popular brand of a drug is also often the highest priced.
- Medicines are the only commodity in which the end-user (the paying patient) does not decide what to buy and at what cost. The purchaser of medicines is extremely vulnerable. The doctor prescribes and the patient pays.
- The asymmetries in information, in the doctor-drug company interface, as much as in the doctor-patient and drug company-patient, is what leads to market failure. That is why even in market economies, all issues related to drugs including their prices are the subject of regulation by their Governments.
- Pharma is the only sector in India (and probably in the world) where government tender procurement prices are 1-3% of the retail market prices! For example, for the Tamil Nadu Government, a drug company bids to supply Albendazole 400 mg tablets, a medicine for worms, at a mere 35 paise per tablet, while brands of this drug sell for Rs 12 in the market.
- India's pharmaceutical markets are full of unnecessary, unscientific and therapeutically useless drugs. We need to immediately weed out all these drugs by allowing only drugs as per the WHO essential drug list or the Government's own National List of Essential Medicines (NLEM) 2003.
- At least 60 percent of the top-selling 300 drugs are not in the NLEM. Therefore

two-thirds of drugs sold in India are not essential drugs by the Government's own definition.

And from the users' point of view:

- A serious indictment of the pharmaceutical industry is the lack of public health relevance of many of these top-selling preparations. Take the case of preparations for iron deficiency anaemia, which is one of India's most prevalent public health problems. There is not a single preparation in the top 300, which has the ingredients for an anaemia preparation as mentioned in the NLEM.
- The major crisis of drugs in India is one of availability (in the public systems), access and affordability to the poor and the middle class.
- India has the largest number of people, an estimated 649 million, without access to essential medicines (*World Medicines Report 2004*, WHO).

Price Control: Never Ending Debate

The Seventh Report of the Standing Committee on Chemicals & Fertilizers, 2005-06 (*Availability and Price Management of Drugs and Pharmaceuticals*), Fourteenth Lok Sabha states:

The Committee's examination revealed that though, there is a provision that a strict watch will be kept on the movement of the prices and the Government may determine the ceiling levels beyond which increase in prices would not be permissible, this provision has seldom been applied. In this context, some of the State Governments have also informed that when the cases of high prices of anti-cancer drugs, Antibiotics, Nutraceuticals and Cetrizine were referred to the National Pharmaceutical Pricing Authority (NPPA), the latter conveyed its helplessness in curtailing the high prices. The Committee members are unhappy over this unsatisfactory state of affairs and desire that the situation should be remedied forthwith. They therefore, recommend that for the category of drugs for the same therapeutic use, the Government should determine a reasonable ceiling beyond which increase in prices may not be allowed.

Several other expert committees set up by the Government of India, in post-liberalization times, have also stressed the importance of drug price regulation. For instance: the Drug Price Control Review Committee of 1999, the Sandhu Committee of 2004, and a Task Force appointed by the PMO in 2005 and chaired by Dr. Pronab Sen from the Planning Commission, the Commission on Macroeconomics and Health 2004, etc. However industry does not want controls of any kind and in accordance with the wishes of the pharma industry, the number of drugs in the price control basket has come down over the years from over 347 in 1979 to 74 in 1995. It would have been less than 30 if the Pharmaceutical Policy 2002 were not stayed by the Supreme Court. The Court directed the Government of India to first decide the basket of essential drugs to be put under price regulation and a methodology thereof.

- In India, unlike in the developed countries, expenditure on medicines constitutes a large proportion (50%) of total medical expenditure. About 80-90% of this expenditure is out-of-pocket expenditure by the people since the government spends a very small proportion on medicine procurement.
- There is no social security or other “safety nets”.
- Majority of Indians are below or near poverty-line. Expenditure on medicines is a very important cause for indebtedness before and after hospitalization.

The Report of the Standing Committee on Chemicals & Fertilizers, 2005-06, Fourteenth Lok Sabha observed that the Government should determine a reasonable ceiling beyond which increase in prices may not be allowed. Several other expert committees set up by the Government of India, in post-liberalization times, have also stressed the importance of drug price regulation.

- S. Srinivasan & Dr. Anurag Bhargava

S. Srinivasan is with Low Cost Standard Therapeutics (LOCOST), Baroda



“Branded Generic” Medicines: Licensed to Loot

No standard medical or English dictionary gives the meaning of Branded Generics. It is a peculiar terminology coined and used in India alone. What does it mean?

As per Drugs and Cosmetics Rules, all schedule H medicines can only be prescribed by duly registered medical practitioners and sold by licensed retail chemists only on presentation of doctors’ prescription.

As per global practice, pharmaceutical manufacturers in India are expected to convince doctors about the benefits of their brands so that they are patronized by the medical profession and prescribed.

In defiance of this legal and ethical practice, many drug companies in our country offer huge discounts to chemists to push their brands to patients. These have been nicknamed “Branded Generics.” The aim is to (a) sell prescription products without prescription particularly in the semi-urban and rural areas, (b) to replace prescribed brands with highly profitable brands in which the chemists have vested interest and (c) to recommend therapy and dispense the same to lay people.

Needless to say all such actions are illegal and potentially dangerous for patients. There are many diseases where the change of a brand, even when the medicine remains the same, can pose serious problems due to bio-equivalence differences (the amount of medicine that reaches the blood in a particular time frame) such as theophylline used in asthma and carbamazepine used in the treatment of epilepsy. There is also huge number of substandard medicines in the market since the government is unable to monitor over 20,000 manufacturers churning out 60,000 brands.

How can some drug companies offer huge, unprecedented discounts to chemists? There are two reasons. Firstly, the manufacturing cost of most medicines is very low compared to their retail price. For example, the cost of producing 10 tablets of cetirizine, used to control allergy, is barely Rs 1.50 while the retail price of major brands such as Cetrizet (Sun Pharma), Cetzine (GlaxoSmithKline), Alerid (Cipla) and Incid-1 (Bayer) is in the region of Rs 30. Take another medicine. The cost of manufacturing 10 tablets of nimesulide 100 mg is less than Rs 1.40 while the retail price of brands with large sales such as Nise (Dr. Reddy's Lab.) and Nimulid (Panacea) is over Rs 29 (exclusive of local taxes). Thus in just two medicines, there is a profit margin of about 2000%. Interestingly, nimesulide was discovered in America but not approved for use by Americans! With a total sale of about Rs 160 crores, a globally discarded drug like nimesulide is giving profits of over Rs 150 crores every year to the pharma industry. No wonder at least 10 out of 40 richest Indians on Forbes list are owners of drug companies.

Such huge, vulgar profits mean that different companies employ different methods. It is much simpler to offer large discounts to chemists via "branded generic" route. For example, some brands of cetirizine and nimesulide are sold to chemists for less than Rs 4 per 10 tablets while the printed maximum retail price (MRP) is in the region of Rs 25 to Rs 26. Chemists sell such brands at a price which is determined by the "look" of the purchaser. In one survey, the price charged for 10 tablets of the same brand of nimesulide (Nicip) was Rs 10 by one chemist and Rs 15 by another chemist. Yet another chemist charged the full MRP of Rs 25! All these chemists had purchased the strip for Rs 4 only.

What is the answer? The Ministry of Chemicals and Fertilisers has done a survey of prices of three medicines: nimesulide, cetirizine and omeprazole and has come to the conclusion that vulgar profiteering is going on. Yet instead of bringing all these medicines under Drug Price Control Order (DPCO), the Ministry has sought to reduce margins paid by the manufacturers to the chemists. This will only help pharmaceutical companies to make even more profits and not the patients.

- **Dr. Chandra M. Gulhati**

Editor, Monthly Index of Medical Specialties (MIMS)

Industry and Unethical Drug Promotion

“When a great profession and the forces of capitalism interact, drama is likely to result. This has certainly been the case where the profession of medicine and the pharmaceutical industry are concerned. On display in the relationship between doctors and drug companies are the grandeur and weaknesses of the medical profession – its noble aspirations and its continuing inability to fulfil them. Also on display are the power, social contributions, and occasional venality of a very profitable industry whose products contribute in important ways to the health and longevity of the American people but that at times employs methods that are deeply troubling and even criminal” (David Blumenthal, “Doctors and Drug Companies,” *NEJM*, 21 October 2004).

In the west sales promotion expenditure is very large. The above article published in *NEJM* mentioned that in 2002, the industry expended 33 percent of its revenues on selling and administration. In 2001, one company Novartis reported spending 36 percent of its revenues on marketing alone. The marketing expenditures of the drug industry have been estimated variously at \$ 12 to 15 billion yearly, or \$ 8,000 to 15,000 per physician. Average expenditure on research and development by the pharmaceutical industry in India is only 2 percent of the sales turnover while they spent nearly 20 percent or in real terms Rs 5,000 crores for sales promotion. This amount, of course, is realized from sales of medicines. Justification of such large expenditure is questionable since prices of medicines are rising.

All medicine companies thrive by sales of new medicines which may be molecule or manipulate version of same molecule or even combination of existing molecules. What happens if such propensity remains uncontrolled can be cited from the fact that in our country it is said that more than 60,000 brands of medicines containing more than 1000 different chemical entities are sold in the market. It is also established that about 70 percent of such medicines are either irrational or injurious to health. Major vehicle of these sales is sales promotion or marketing.

To develop a pharmaceutical company in India, it is not necessary to build a medicine production unit. In fact, almost all large multinational medicine companies in India have closed their production units and their brands are now produced mostly by the small scale sector pharmaceutical factories. However, all medicine companies have to set up marketing machinery to promote their brands.

Real competition is visible in the area of marketing. The primary objective of promotion is to come up with stunts and surprises. In absence of any therapeutic validity of very large number of irrational medicines, the industry promotes them with false or distorted claims. Their propaganda literatures misquote medical journals

or quote certain evidences which have no much recognition. Most effective promotional method is gifts and other inducements. A joint US-Australian study ("A National Survey of Physician-Industry Relationships," *NEJM*, 26 April 2007) revealed that 25 percent of doctors have received direct payment from pharmaceutical producers and 94 percent of practicing doctors have some relationship with drug industry. Many instances where large sum of money have been paid to the doctors are not unavailable in our country. No conferences of the professional organisations are held without substantial sponsorship by the medicine companies.

Whatever favour made to the doctors has significant effect on the outcome in the prescription. Proliferation of large number of irrational medicines had been thus possible in our country. Many countries have enforced ethical criteria for promotion of medicines. Certain industry organisations have also prepared code of conduct for promotion and marketing, but they are inadequate and provide no or insignificant measures for violation. Unless a strict control on the promotion of medicines is enforced by the Government, marketing of irrational medicines shall remain unchecked and spread further.

- **Amitava Guha**

Federation of Medical & Sales Representatives' Associations of India

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Drug Prices: The Tax Angle

If media reports and representations from the small scale (SSI) medicine manufacturers are to be believed, the cumulative effect of certain decisions, taken independently by the ministries of finance and chemicals, are damaging the future prospects of 5,000 and odd small-scale pharmaceutical industries of the country. It is also resulting in the increase of drug prices, thereby throwing doubts over the success of the policy measures that were intended to be people-friendly.

The first decision, taken by chemicals ministry two years ago, was to make the printing of maximum retail price (MRP) on medicines inclusive of all taxes mandatory. The intention was noble, as the earlier practice of MRP exclusive of taxes had resulted in medicine prices varying from region to region. The decision also helped the creation of confidence in the minds of the consumer with regard to medicine prices. It was welcomed by the medicine trade sector as they were saved from the task of calculating taxes and duties on each and every transaction.

On the face of it, the other decision, taken by the finance ministry, was also people friendly. The ministry had announced a change in the manner of calculating

excise duty on medicines. Instead of levying excise duty on ex-factory value of medicine, the new valuation was based on MRP with 40 percent abatement to factor in the post-manufacturing expenses. The idea was to discourage the companies from printing unreasonably high MRP (which used to be passed on to the trade as higher margins) as high MRP, now, will mean higher taxation. It was also expected that the move would increase the revenue generation from this sector as ex-factory value used to be just a fraction of the actual selling price.

These two decisions would have worked well, but for another policy initiative – allowing tax holidays in hill states to attract new investments in these industrially backward regions – that negated the benefits derived from the earlier decisions.

The SSI drug units' problem is actually a cumulative effect of these three policy initiatives. While the first two directives focused on linking taxation to MRP and thereby controlling medicine prices, the third one, which allowed tax-free existence, provided an escape route for bigger pharmaceutical companies or pharmaceutical companies that had the financial muscle to shift from traditional manufacturing centres to excise-free zones.

Today, over 50 percent of the country's Rs 30,000 crore worth medicine production is happening in tax-exempt states. In addition to their own manufacturing facilities, pharmaceutical companies also utilise the services of contract manufacturers in these areas to outsource medicines that are immune to taxation. The prices of these medicines can go high, as there is no taxation on MRP. Since high MRP also means high profit margins for the entire supply chain – manufacturer, distributor, retailer – products from hill states, though costlier, are being pushed by the retailers in the country. The effect of this is two fold. One, the prices of medicines goes up. Two, local SSI drug makers numbering over 5,000 who did not have the funds to shift base to excise-free states are losing their traditional markets. On one hand, they cannot increase MRP of their medicines, as they will be liable for higher taxes. On the other, they cannot print less MRP (means less trade margin) as the trade is looking for more profits.

The prices of all medicines, except the ones whose prices are not fixed by the government's medicine price fixing body – the National Pharmaceutical Pricing Authority (NPPA), have been affected. On the fiscal front, this movement of existing units from taxable zones to tax-free zones is feared to result in a dip in tax collections.

In other words, the twin objectives, to reduce the prices of medicines and to increase the excise collections from pharmaceutical sector, both are unlikely to materialise. In addition to this, it has also made survival difficult for thousands of pharmaceutical companies. The continued existence of small pharmaceutical firms is important, as they are the ones that wholly cater to the needs of the local markets. While major Indian drug companies are going global, the SSIs, which employees

several lakhs of people, are purely India centric. The existence of several competing brands also serves as an automatic check on price increase.

The immediate objective of the government should be to see that the MRP of medicines from the excise-free states are kept under check and medicines made available to public at reasonable cost. If required the NPPA should be asked to invoke the public interest clause -10(b)- enshrined in the Drugs Price Control Order (1995) more frequently and fix the prices of all medicines where prices are known to have gone high. The government should also give a serious look into the problems faced by SSI pharma units and launch time-bound assistance programmes to put them back on rails.

Alternatively, the policy makers have to chalk out a solution to end the discrimination being faced by units outside excise-free zones, without killing the units that have gone up-hill to cash in on the fiscal incentives. A balanced approach needs to be taken.

- Suresh Kurup
Member of Parliament, Lok Sabha

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Hazardous Drugs and Dubious and Irrational Drug Combinations: Need for Fresh Approach to Drug Regulation

Pharmaceutical policies in India talk of regulation of **prices** and **quality** of drugs. But there is one other basic issue, that of the **content** of drugs, which has never been addressed. In most countries of the world, the drug regulatory administration restricts the approval, manufacture and sale of drugs in the market to only those which are of scientifically proven efficacy, and with acceptable safety profile. This is not the case in India. Hazardous drugs long withdrawn from other parts of the world are allowed to be manufactured and promoted here.

The drug controller general's office (DCGI) approves new drugs and combinations in a laissez-faire manner. It has approved 70,000 formulations in the market, a figure without parallel in the world. While only 30 combinations of different drugs have been considered rational by the WHO, there are about 130 fixed dose combinations of Nimesulide itself in India!

Waste of precious resources and danger to health

A large part of the domestic market in drugs (more than 30,000 crores) is towards the sales of drugs which are irrational. For instance:

- i. A narcotic (codeine) containing irrational cough suppressant is the top selling brand in India
- ii. The top selling preparation for anaemia in India (Dexorange) launched in 1971 was allowed till 2000, to contain haemoglobin obtained from slaughterhouse blood, which is used only to feed dogs abroad. Only after years of persistent protests, was this preparation banned acknowledging the fact that it lacked therapeutic rationale and could be hazardous.
- iii. Nimesulide, an analgesic not approved in the USA (the country of its discovery) and the UK, is also banned in the European Union for use in children below 12 years of age. Yet more than 80 brands of Nimesulide preparations for children are allowed to be sold in India.
- iv. A large number of irrational preparations are sold as tonics and health supplements. Protein 'supplements' derived from milk and groundnuts are allowed to be sold for Rs 600 per kg. A 'tonic' sold by one multinational has only fresh liver extract and alcohol.

While we talk of death penalty for **spurious** drugs, why do we not address the issue of these dubious drugs, which waste people's money and endanger their health?

Need to go beyond the fragmented and partial approach in drug regulatory system

There is an urgent need to bring all drug related regulatory issues under the control of a single administrative body like a National Drug Authority. This has been suggested by numerous committees and policy documents over the past 32 years, the latest being the Pronab Sen Committee in 2005. At present at one level, the regulatory system is fragmented between Ministries at the Union government level, and between the Centre and the States at another. The pharmaceutical policy, an important operational tool of the National Health Policy, is prepared by the Ministry of Chemicals. This results in the policy failing often to address priorities of public health. Pricing of drugs is dealt by the National Pharmaceutical Pricing Authority (under the Ministry of Chemicals). Approval and quality standards are dealt with by the Drug Controller General of India (under the Ministry of Health).

Numerous problems occur because of misgovernance and lack of infrastructure, at the level of the States. State Drug Controllers approve drug combinations, which can only be done at the DCGI office, leading to the plethora of irrational combinations in the market. The Mashelkar committee noted that only 7 states in the entire country have reasonably equipped and functioning drug testing laboratories.

The current approach to drug regulation is **partial**. For example, drug price regulation is contemplated for only **some** drugs and not others. Companies then shift production from price controlled preparations to those falling outside the list. This is in fact worse for the consumer, and to prevent this all drugs in a particular therapeutic category should be under a system of price regulation and monitoring. The issues related to unethical trials, irrational preparations, unethical and wasteful promotion, illegal prescriptions by chemists do not find mention in the policy.

The pharmaceutical policy should back its regulatory provisions with an effective legislation and allocation of judicial powers to the drug regulatory authorities. Currently action against offenders is marked by long delays due to litigation.

- Dr. Anurag Bhargava

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Compulsory Licensing: Suggestions for Change

The Paris Convention, TRIPS Agreement, and Doha Declaration on TRIPS and Public Health stipulate provisions on compulsory licensing for implementation by member countries of the World Trade Organisation in their national patent systems. The developing countries have not made full use of stipulations in these three documents mentioned above. The various possibilities for ensuring the working of patents under certain contingencies to meet the demands of the relevant products, particularly in the area of healthcare, are dealt here. India has ignored certain important provisions in the amending process of its national Patents Act 1970

Compulsory licensing system

The question of constraints that would emerge after the implementation of TRIPS has been a subject of serious concern and was discussed in the TRIPS Council of the

World Trade Organisation during 2001. The issue was further debated in the Doha Ministerial Conference held in November 2001, leading to Doha Declaration on TRIPS Agreement and Public Health. There are nine possibilities of structuring grant of compulsory licences arising from the TRIPS Agreement and the Paris Convention, and as clarified in the Doha Declaration on Public Health. These are discussed below.

Voluntary licence

The amended Indian Patents Act 1970 does not provide for a voluntary licensing system. This provision should be available in the Patents Act to meet the needs of those patentees who do not promote their patented products but interested in realising royalty. The provision of a voluntary licence in the Patents Act and incentives to patent-holders would help.

Authorisation for meeting government requirements

Article 31 of the TRIPS Agreement provides for the use of patented substances to meet government requirements. Appropriate provision does exist in the amended Indian Patents Act 1970 in Section 100 thereof.

Compulsory licence due to abuse of patent rights by the patent-holder

Article 8 of the TRIPS Agreement and article 5A of the Paris Convention deal with the abuse of patent rights by the patentees, and provide suitable measures for governments to take. The grounds of abuse could be stipulated as any one of the following:

1. That the reasonable requirements of the public have not been satisfied.
2. That the patented invention is not available at a reasonably affordable price.
3. That the same is not being worked to meet demand in different regions.

The validity of the above grounds would be examined by the Controller of Patents in consultation with the patent-holder, after apprising him of the abuse. The Indian Patents Act in this respect needs to be suitably modified.

Compulsory licence due to unsuccessful attempts at obtaining a voluntary licence

Article 31(b) provides for a compulsory licence due to unsuccessful attempts by an enterprise to obtain a voluntary licence on reasonable commercial terms and conditions from the patent-holder. This is an important provision for an effective role for domestic enterprises and must be incorporated into the national Patents Act.

Compulsory licence due to national emergency

The TRIPS Agreement in Article 31(b) also deals with situations of national emergency or other circumstances of extreme urgency. The formulation of provision in the Patents Act should be made.

Compulsory licence due to circumstances of extreme urgency (health emergency, environment emergency, etc)

Under circumstances of extreme urgency including prevention or control of HIV/AIDS, malaria, tuberculosis or any other epidemic among human beings or animals, the government may notify the urgency, and thereafter the Controller of Patents can grant compulsory licences to the interested enterprises. Relevant provision should be provided in the Patents Act.

Compulsory licence in cases of public non-commercial use

The TRIPS Agreement in Article 31(b) also deals with public non-commercial use, the circumstances of which are totally different from other contingencies. The relevant formulation in the Patents Act should be made.

Compulsory licence to remedy anti-competitive practices

Utilizing article 31(k) of TRIPS, remedial measure can be taken if the patentee is resorting to anti-competitive practice as evidenced and determined after judicial or administrative process.

Second patent for an invention involving important technical advance

Article 31 (l) provides that if an important technical advance of considerable economic significance over the first patent has been justified by an interested enterprise to the satisfaction of the Controller of Patents, a compulsory licence may be granted to that enterprise in consultation with the first patent-holder.

If all the above possibilities are suitably provided in the national patent law, it would be possible to strengthen the competitive environment. In the Indian Patents (Second Amendment) Act 2002, certain possibilities that are available have not been incorporated nor adequately provided.

Working of patented inventions

The Indian Patents Act 1970, in Chapter XVI, specifically deals with the 'Working of Patents, Compulsory Licences and Revocation'. But other sections of this chapter leave some ambiguities that ought to be rectified through further amendments to the Patents Act 1970. So also, with regard to Section 92, dealing with grant of compulsory licensing during circumstances of national emergency and circumstances of extreme urgency, section 117A provides for an appeal to be filed, with the Appellate Board. This stipulation needs reconsideration.

Royalty payments

Article 31(h) of TRIPS provides that the right-holder shall be paid adequate remuneration but is not specific about the rate of royalty to be paid. The non-amended Patents Act 1970 provided a ceiling of 4 percent on royalty payments, which has been deleted in the amended Act.

Conclusion

Patents to protect innovation should be supported, but the system should not be used as a device to restrict competition and allow the creation of monopolies. The originators of inventions should get their just rewards by way of suitable royalties. The doors should be opened for obligatory licensing involving domestic enterprises in the production of patented drugs. The lives of patients have to come before the patents of drug companies, and that is the fulfilment of the objectives of the National Health Policy and international human rights laws.

- **B.K. Keayla**

National Working Group on Patent Laws, New Delhi



Spurious Drugs: The Other Side of the Story

A public-interest-litigation filed by a senior executive of a leading domestic pharmaceutical company (in his individual capacity) and the media coverage that followed has once again brought the issue of spurious drug presence in domestic market to the centre-stage. While the PIL, being considered by Delhi high court, is against the delay in the passage of the spurious drug bill in the Parliament, the media reports, as usual, put the blame for spurious drug marketing on Delhi's Bhagirath Place, the biggest wholesale market for medicines in Asia. It goes on to suggest that the one-in-five medicines purchased in India could be spurious - an indirect attempt to allege that 20 per cent of Indian drugs are spurious.

While there is no question about the need to put an end to the spurious drug menace, there is an urgent need to re-visit the issue in a manner that explains the actual problem. The projected magnitude of the problem is a debatable issue and this is not the first time one has seen interest groups trying to conjure up such percentages to magnify spurious drug presence in India. The previous government had even set up a high-level committee headed by Dr R.A. Mashelkar, then CSIR chief, to understand the seriousness of spurious drugs problem and suggest remedial measures. The accusation at that time was that 30 percent of Indian drugs were spurious. The whole argument was based on a report of WHO, which WHO promptly denied having ever written. The issue calmed down after Mashelkar committee found the spurious drug presence in the country to be miniscule. However, the committee recommended for strengthening the Drugs and Cosmetics Act to provide severe penal actions against spurious drug makers. The delay in clearing the amendment needs to be admitted and the government should take speedy action in this regard.

At the same time, one should not forget that the campaigners are cleverly mixing up issues like spurious drugs, counterfeit drugs or look-alike drugs, not-of-standard drugs and unaccounted inter-state movement of drugs to magnify the problem of 'spurious drug'. While these are issues that call for serious attention from the industry point of view, public health concerns are more in the case of spurious drug where the patient is denied the medicine. By mixing up intellectual property issues (trade mark violations), tax violations (inter-state movements) and technical issues (storage problems can make drugs sub-standard) and genuine spurious drug manufacturing, the campaigners are seriously threatening the existence and credibility of Indian small-scale drug manufacturing sector. By inflating the problems, the campaigners are also helping multinational drug firms in their attempts to lobby for further strengthening of intellectual property norms as a remedy to India's spurious, counterfeit problems. For the same reason, any attempt to blow out of proportion, the issue of counterfeiting or spurious drug making should be opposed.

Of the 10,000 odd registered drugs manufacturing units less than 200 are big. The rest are either manufacturing medicines for a limited area or are doing contract jobs for bigger drug companies. The media allegation that SSIs, who are troubled by the new manufacturing standards prescribed by the health ministry, may resort to manufacturing of spurious drugs is thus damaging the reputation of thousands of registered units that supplies life saving medicines to most parts of the country. The small-scale manufacturers have repeatedly challenged its detractors to prove one such instance where registered units are found to be producing spurious drugs.

Spurious drug manufacturing, being a clandestine activity, is very difficult to be traced by drug officials who track the registered manufacturing and sales channels for compliance of quality and marketing standards. The best way of tracking the spurious drug penetration is through the feedback companies receive from the extensive field force network. The companies are indeed on this job and leading Indian pharmaceutical manufacturers and multinational pharmaceutical companies are known to be doing a commendable job in this regard. While government needs to strengthen its official network, squarely blaming the ministry for the alleged spurious drug presence is not desirable.

The blacklisting of Indian manufacturers in Nigeria was an instance highlighted by the media as an example of spurious drug manufacturing in India. Interestingly, the Nigerian issue has more to do with the registration norms of that country and the porous borders it has with its African neighbours than spurious drugs. Most of the companies blacklisted by Nigerian companies are not supplying medicines to that country and therefore not registered there. The medicines, however, are exported to their neighbouring countries from where it reaches Nigeria through (allegedly) illegal channels.

It should be noted that 'counterfeit drugs' has been the main reason given by the office of the United States Trade Representative (USTR) for the inclusion of

India in the special watch list of countries whose intellectual property protection do not match US expectations. Any irresponsible allegation on the presence of spurious drugs in India can only prove as an assertion of USTR allegations. As majority of Indian pharmaceutical industry and health NGOs feel, any move towards further tightening of Indian patent laws taken under US pressure, can have long term adverse impact on the accessibility and affordability of life saving medicines not only to Indian population, but also to vast patient population in the developing world. One needs to be more responsible while making allegations that can seriously affect Indian medicine making capability.

Our attempt should be to ensure adequate supply of quality medicines at affordable prices in required quantities. The presence of a vibrant pharmaceutical industry – both domestic as well as multinational, private as well as public – is therefore essential. The spurious drug bill, to be tabled in the Parliament soon, should be scrutinised keeping this aspect in mind. Nothing in the law should lead to a total wipe out of the small-scale sector.

- **Dr. R. Senthil**

Member of Parliament, Lok Sabha

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Clinical Trial Industry in India

India is fast turning into a major hub of global clinical research if the growing presence of multinational drug majors like Pfizer, Johnson and Johnson, GSK, Merck, Eli Lilly, etc in Indian clinical research space is any indication. All big companies either own clinical research facilities (such as Pfizer and Eli Lilly), or outsource clinical research services from contract research organizations (CROs) in the country. As per a McKinsey estimate, Indian clinical trial industry is to be worth Rs 5,000 crores by 2010.

The shift in MNC interest towards India for clinical development is primarily due to the rising costs of clinical development and the dwindling numbers of successful drug discoveries in the developed countries. The companies are left with no other choice but to outsource part of the clinical research from low cost destinations. The preference for India is not because of the cost advantage, but also the presence of quality manpower and a host of other factors like a revised patent law that recognizes product patent, introduction of good clinical practices, rich patient pool, talented medical faculty, and its bio informatics strengths.

An Ernst & Young study, commissioned by FICCI, says that India will contribute 1,00,000 patients towards clinical research, and will need not less than 3,000 clinical trial sites, over 50,000 clinical research professionals and a regulatory body that can handle over 400 clinical trial applications in near future.

Acknowledging the growing business opportunities in this segment, the finance ministry has announced fiscal concessions that are expected to benefit over 100 CROs actively involved in India. The health ministry has recently come out with guidelines and checklists that companies need to follow for receiving approvals for multi-centric global clinical trials. By and large, the stage has been set for big time clinical trials in India.

However, the public health concerns related with the conduct of clinical trials are yet to be addressed completely. The plans for accrediting CROs to distinguish the best ones from the dozens of newly emerging CROs are yet to materialize. The functioning of the institutional ethical committees is yet to be foolproof. The regulatory mechanism, to track the conduct of illegal and unethical clinical trials, is far from perfect. The clinical trial registry, intended to bring in transparency in the conduct of clinical trials in the country, is also in its infancy. While World Health Organisation (WHO) wants pharmaceutical companies to disclose significant data on ongoing clinical trials, India is yet to take its decision on the regulatory need for such public disclosure.

Another major grey area is the case of Indian subjects and the benefits they are to derive out of the successful completion of the drug trial. The government has to ensure that the medicines that have been developed with the help of clinical trials conducted in India should be made affordable to Indian public. There should also be strict regulations on conducting clinical trials on Indian subjects for diseases that are not major threats to Indian population.

The compensation that should be provided to Indian subjects in the eventuality of any adverse result should also be clearly defined. Until such measures are in place, Indian public and public interest groups are to continue with their apprehensions of being turned “guinea pigs” to further commercial interests of pharmaceutical companies. The government should also speed up the preparation of the bill that specifically looks at the protection of human volunteers subjected to the clinical trials.

Serious consideration should also be given to the industry demands for the establishment of a central committee of experienced researchers for policy implementation, comprehensive policy guidelines for clinical trials, rules and regulations for toxicology studies and a host of fiscal incentives.

- Dr. Karan Singh Yadav
Member of Parliament, Lok Sabha

Restricting Patents to New Chemical Entities: A Public Health Necessity

Has the Government forgotten its promise to Parliament?

In March 2005, when India's Patent Act was being amended in compliance with the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), Parliamentarians had raised important concerns about the impact of the amendments on access to medicines and treatment. To address some of these concerns Parliament included key public health safeguards in India's patent law such as Section 3(d) which is aimed at preventing evergreening, i.e., the practice of pharmaceutical companies to extend patent monopolies by making minor improvements in or finding new uses for existing drugs.

However, Section 3(d) allows patents for even improvements or new uses if the company asking for the patent can show increased efficacy. A restriction to new chemical entities would make patent standards even more stringent; fewer patent monopolies mean greater generic competition that is critical for ensuring access to treatment and medicines in India. When this issue was raised by Parliamentarians, that in the interests of public health, patents should not be given to improvements or new uses at all, the Commerce Minister, Mr. Kamal Nath, promised Parliament that the issue of limiting patents to new chemical entities would be closely examined to ensure this was TRIPS compatible.

Thus, in April 2005, the Commerce Ministry convened a Technical Expert Group on Patent Law Issues (TEG), chaired by Dr R.A. Mashelkar, to examine this issue. Interested groups representing views of industry, academia, and civil society from India and abroad made submissions to the TEG, arguing on the many differing perspectives of this complicated legal issue. Nearly two years later, in December 2006, the TEG submitted its report which concluded, without offering any legal analysis and in the most perfunctory manner, that limiting patents to new chemical entities was not TRIPS compatible. The only reason the TEG gave was that it was not in the "national interest" which it interpreted as the interest of Indian companies; ironically the domestic pharmaceutical industry has strongly criticized the report.

Immediately, the TEG report came under intense criticism from civil society, media, and academia for failing utterly in fulfilling its mandate. Then, in February 2007, reports in the Hindu and the Times of India revealed that the main conclusions of the TEG report were lifted verbatim and without acknowledgement from a submission that was funded by a coalition of multinational pharmaceutical companies. In the resulting furore and controversy, the TEG withdrew its report, and Dr. Mashelkar resigned from his position as chair.

The importance of this issue and of the enormous impact of the TEG actions can be seen from a critical case in the Chennai High Court where Novartis is suing the government for the denial of its patent application for imatinib mesylate - a crucial anti cancer drug. Novartis sells this drug for Rs 1,20,000 per patient per month while Indian generic companies sell it for Rs 8-10,000 per patient per month. The Chennai Patent Controller found that the drug was a new form of an already known drug and hence was not entitled to a patent. Novartis then dragged the Indian Government to court over its public health safeguards in Section 3(d). In the course of the case, Novartis tried to cite the TEG report claiming that it supported its stand.

The issue of the unavailability and un-affordability of drugs is no doubt a complex one. However, it is clear that 20 year monopolies on drugs have a severe adverse impact on peoples' access to treatment. The case of HIV treatment illustrates what is also true for every other disease - in 2001 the entry of Indian generics led to a nearly 100% reduction in HIV drug prices from \$10,000 to \$130 per year. The right to health and life of all persons is enshrined in Article 21 of the Indian Constitution and it is a matter of great urgency that Parliament re-examine the issue of limiting patents to new chemical entities.

In the weeks following the TEG report's withdrawal and Dr. Mashelkar's resignation, there has been no word from the government as to how it plans to proceed on this matter. And the longer the government takes in keeping its promise to Parliament to resolve this issue, more and more patents are being granted on essential medicines that may otherwise not have been granted, putting the health of the public in jeopardy.

- Chan Park & Kajal Bhardwaj
Lawyers Collective HIV/AIDS Unit, New Delhi

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Patients Oppose Patent Applications for AIDS Drugs

Patents in India Endanger Global Availability of Affordable Medicines

In 2006 and 2007, the Indian Network of People Living with HIV/AIDS (INP+) and the Delhi Network of Positive People (DNP+), represented by the Lawyers' Collective HIV/AIDS Unit officially submitted their legal oppositions to several patent applications on AIDS drugs filed in the Delhi, Chennai, Kolkata and Mumbai

patent offices by multinational pharmaceutical companies. These oppositions are based on technical and health grounds.

These networks are objecting to the patenting of AIDS drugs, because the patent applications are not for a new invention but simply the improvements/derivatives of existing drugs. The granting of such patents will risk increasing the cost of anti-retroviral treatment, thereby increasing further the burden on developing countries.

The new patent regime in India

Two years ago, India changed its patent law to comply with the World Trade Organization's TRIPS Agreement that governs trade agreements and intellectual property rights. One year later in 2006, India granted its first ever patent to Roche on a drug used in hepatitis C treatment. Public interest groups are deeply concerned that this would set a precedent leading to the patenting of other essential medicines including anti-retrovirals.

There are many patent applications of essential medicines waiting to be approved or rejected, including anti-retrovirals and drugs for treating mental illness, tuberculosis and opportunistic infections. Therefore, decisions made by Indian patent offices are a question of life and death for people living with HIV/AIDS who rely on the availability of affordable AIDS drugs and other essential medicines made by Indian generic manufacturers.

Public health safeguards in Indian Patent Law

However, one provision of the Indian law states that any interested party can oppose a patent before it is granted in a "pre-grant opposition" process. Such oppositions have been filed against numerous patent applications on essential medicines that do not warrant patents under Indian law. Indian cancer patients in 2005 opposed a Novartis patent application for Gleevec, an anti-cancer drug, on the grounds that the application claimed a new form of an old drug. In response, the Swiss pharmaceutical company, Novartis filed cases against the Government of India, Indian generic companies and the Cancer Patients Aid Association (CPAA) challenging the rejection of its patent application under Section 3(d) of the Patents Act, 1970.

Section 3(d) of the Patents Act, 1970 was included by the Indian parliament to prevent abuse of the patent system. It has now become one of the most important public health provisions in India's patent law as it prevents pharmaceutical companies from obtaining patents on a new form of an old drug and protects manufacture of these essential drugs by Indian companies.

Earlier in the 1990s, Glaxo succeeded in extending its monopoly on the drug Zidovudine by obtaining a patent in many developed and developing countries for a new use, i.e., HIV/AIDS treatment, which led to the denial of AIDS treatment to millions in the developing world, till Indian companies produced generic versions in the absence of product patents in India.

India while complying with the TRIPS agreement and introducing a product patent regime for new drugs that were invented, also coupled its law with the Section 3(d) to refuse patents on discovery of new uses or forms of older drugs. The introduction of Section 3(d) of the Patents Act, 1970 has given hope to many who rely on affordable generic drugs manufactured by Indian companies for continuing their life.

International medical humanitarian organization Médecins Sans Frontières (MSF), members of the European Parliament, US Senators, and nearly a quarter of a million people from over 150 countries have expressed their concern about the negative impact Novartis actions could have on access to medicines in developing countries, and have called on the company to immediately cease its legal action in India.

- **Leena Menghaney**

Medicines Sans Frontiers (MSF), New Delhi

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Data Exclusivity and Pharmaceuticals

As on date, generic drug manufacturers in India are not required to carry out elaborate and expensive drug testing procedures (clinical trials) as long as their product is a bioequivalent of the drug of the patent holder (patentee). They can rely on the earlier test data (originator data) submitted to the drug regulator, proving the safety and efficacy of the drug. Drug trials are prohibitively expensive and constitute a major proportion of the drug development costs; this exemption helps reduce the costs associated and facilitates introduction of cheaper versions of a drug faster.

Data exclusivity in the context of drugs and pharmaceuticals refers to restricting access to such test data submitted to the drug controller by the patentee. The same would increase not only the drug development costs (which will be translated into the price of the product) but also the time taken to introduce cheaper generic substitutes. The exclusivity period begins after the expiry of the patent term, usually extending for 3-5 years. Requiring the generics to replicate time consuming tests for a bioequivalent necessarily implies extending the patent monopolies beyond the patent term.

Proponents of data exclusivity want the Indian Parliament to amend the Drugs and Cosmetics Act, 1940 to protect test data from subsequent use by generics. They

urge that India is obligated to do so under Article 39.3 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which requires signatories to (a) protect data submitted as part of marketing approval, against unfair commercial use, and (b) prevent authorities from disclosing the test data.

However, disclosure of data by the authorities is permitted, if due precautions are taken to prevent unfair commercial use or if disclosure was necessitated in public interest. As is evident from the language, the TRIPS agreement envisages 'data protection' and not 'data exclusivity' and that too against 'unfair commercial use'. Data exclusivity as opposed to data protection implies that the authorities cannot disclose the data of the patentee. Data protection as defined under TRIPS on the other hand allows governmental authorities the discretion to disclose the data in public interest.

The concept of data exclusivity is often confused with that of patents. A patent is granted for an invention and confers a right on the patentee to exclude others from manufacturing the said drug. This is considered to be a patentee's reward for the time and money invested in drug development. Test data submitted to the drug regulator however helps ascertain the safety and efficacy of the drug for public consumption. Hence, whereas a patent is private right conferred to reward innovation, the requirement to submit test data is necessitated to protect public health and public interest.

The move to interpret data protection as data exclusivity goes against the regulator's discretion to disclose data submitted in public interest as mentioned in Article 39.3 of the TRIPS agreement. The drug regulator acts in public interest when it relies on pre-existing test data of a bioequivalent formulation for marketing approval. The same prevents duplication of tests, which are bound to give similar results and hastens the entry of generics once the rights of a patent holder expire. This in turn ushers in competition and leads to a reduction in drug prices, hence promoting access.

Bypassing an interministerial committee, the Chemicals and Fertilizers Secretary and Joint Secretary, submitted a report on the issue of conferring data exclusivity on test data on 31 May 2007 (popularly quoted as the Satwant Reddy Report). The report recommends the introduction of data exclusivity for traditional medicines and pharmaceuticals. Ironically, the report also observes that introduction of exclusivity would delay the entry of generics and continue to keep the drug prices high through the exclusivity period. It is feared that such an interpretation would have serious consequences for public health and access to medicines. Hence, greater parliamentary deliberation on the issue is the need of the hour.

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International Nonproprietary Names for Pharmaceutical Substances and Their Usage in India

International Nonproprietary Names (INNs) are internationally recognized names for pharmaceutical substances recommended by the World Health Organization (WHO). INNs are universally applicable generic names for drugs and thus help reduce confusion in drug nomenclature. The generic name allows an understanding of the drug even when that individual drug is not known, and is a vital piece of information that is compulsory on a medicine label. INNs are nonproprietary in nature and hence should not be used to coin brand names. However, many pharmaceutical companies use brand names coined from INNs. This practice dilutes the INN system and hampers the creation of new INNs since brand names are protected as proprietary names under trademark laws. To address this issue, in 1993 the World Health Assembly of WHO adopted Resolution 46.19 exhorting Member States to devise appropriate policies and regulations for the use of INNs.

Usually, an INN consists of two parts – a randomly selected, fancy term and a stem. Stems are those parts of a group of pharmacologically related INNs that indicate the relationship between two pharmaceutical substances using a common element or compound. The purpose of having common stems in INNs is to identify the common elements that are present in different molecules. Hence, INNs of different drugs that are pharmacologically related have a common stem. For example, *glimepiride* and *glicazide* are INNs for two pharmaceutical substances used to treat diabetes, and their familial relation can be identified by the common stem *gli-*. There is no authoritative interpretation on what constitutes a common stem. However, each stem has its own technical definition that explains its function.

In India, the trademark registration of words declared as INNs or those deceptively similar to INNs are prohibited under Section 13(b) of the Trade Marks Act, 1999. Nevertheless, there are instances of brand names derived from INNs being used as trademarks in India. In view of the requirements of the Resolution 46.19 of 1993, WHO has requested the Drugs Controller General of India (DCGI) to take appropriate measures to address this situation. However, little progress has been made in implementing this Resolution. INN protection letters issued by the WHO to the DCGI show that brand names have been coined from INNs primarily by small pharmaceutical companies. However, a survey conducted among the leading pharmaceutical companies in India shows that even these companies have coined about 10% of their brands from INNs. Leading companies have largely concentrated on deriving brand names from INNs in therapeutic areas such as diabetes, and cardiovascular and antihypertensive drugs.

The use of INNs in brand names can lead to confusion within brand names, particularly in cases where the brand names become more popular than the generic names. This increases the danger of pharmacists giving the wrong medicine to patients as two brands derived from the same INN stem may sound and look alike. However, it can also be argued that if the objective of INNs is to ensure that there is no confusion regarding the names of pharmaceutical substances, the use of INNs in brand names may be promoting that objective rather than violating it. Using brand names that are totally unrelated to the INN (e.g., AZ-1 for azithromycin and AZ for albendazole) can create further confusion in a country such as India, where anarchy prevails in the medicine market due to the proliferation of brand name drugs, many of which are irrational combination drugs. Using totally unrelated brand names would help only big pharmaceutical companies with marketing clout recall brand name among prescribers and end users. Small and medium scale companies will have to spend more money to build up a unique brand name, which will be reflected in even higher prices and probably eventually wipe them out.

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Drug Information for Consumers in India

Every consumer has right to obtain information on any consumable goods and services. Thus drug information is basic right of the consumer. The pharmaceutical sector is unique regarding drug consumption, as the choice is made not by the patient but by the doctor prescribing medication. However, this does not take away the right to obtain drug information to the ultimate consumers. Information on medication and treatment helps the consumer become aware, make informed choices with respect to his/her health, and brings about the practice of rational drug use. Consumer drug information would include not only general advise on health and diseases but also specific information on drug composition, brand and generic names, indications and contraindications, rational and irrational drug combinations, price comparisons, dosage, side effects, precautions, drug use in special conditions such as pregnancy, storage conditions, expiry date, and dietary habits associated with the medication. Apart from drugs, information must also be provided on medical devices, other forms of treatment and on the disease/medical condition itself. The manner in which

information is communicated is as important as the substance of the information. The information must be accurate, basic and comprehensive, reliable, accessible, and user-friendly.

Generally speaking, the main sources of consumer information on drugs are healthcare workers (doctors, pharmacists, and nurses), the drug regulatory authority, civil society organizations, mass media and pharmaceutical companies and so on. In India people are mainly depending on doctors and pharmacists for obtaining information. Often doctors and pharmacists fail to provide information to people. Currently, there is no single source or database dealing exclusively with consumer drug information. The multiplicity of sources of information makes it difficult for consumers to identify the most accurate and reliable source. Even on the internet there is no comprehensive database of accurate and reliable drug information, which can be easily understood by consumers. Enough information is not being disseminated in local languages. Likewise, the traditional drugs and medical devices are particular areas where information is not being provided. It is also necessary that a comprehensive database of drug information should be developed by the Government as a source of reliable and accurate information for consumers. Such a database should be made publicly available, including on the internet. In the absence of accurate and reliable information, consumers in India fail to exercise choice. This asymmetry in information in turn makes compromises in the competition in pharmaceutical market.

Though there exist a variety of laws and policies addressing different aspects of drug information (such as labelling and advertising), these are spread around in many statutes including Drugs and Cosmetic Act, Drugs and Magic Remedies (Objectionable Advertisements) Act, Consumer Protection Act and The Monopolies and Restrictive Trade Practices Act and the Competition Act. However, there is no comprehensive coverage on this issue. Further, there is an urgent need to streamline the implementation of existing laws and code conducts for dissemination of information on drugs to consumers. For instance, the code of conduct of Indian Medical Council insists doctors to make prescription in generic names there is little monitoring of its implementation. There is also a need to identify the gaps in the existing law and policy framework in order to enhance the dissemination of accurate and reliable drug information. For instance, neither National Health Policy nor National Pharmaceutical Policy deals on this issue directly. The new Pharmaceutical Policy can make significant contribution to this direction.

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