

Pharmaceutical Policy

Part-I

Principals of a Pharmaceutical Policy

Needless to mention here that conceptually in health we, in India had always been showing instances for good policy. It was in the Bhore Committee who provided concepts for prioritizing primary health care which was much later taken up in Alma Ata by WHO. Similarly the Concept of Essential Medicines evolved and first such list was created by Hathi Committee. One also need to know that after creating good policy the Govt. happily shelved all these policies and reversed whatever good the policy stipulated.

Much later than the Hathi Committee's report was produced and landmark recommendations were proposed, WHO in its Nairobi meeting recommended for medicine policy to be prepared for the nations. It is particularly necessary for the developing nations because of the fact that they are resource wise and technologically deficient. Even with numerous constraints, a nation can with appropriate policy provide better access to essential medicines. WHO defines medicine policy as follows.

“A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field.”

Basic Components:

After number of application and much debate in the WHO experts level, certain basic criteria for a pharmaceutical policy was defined. These components are interlinked and inseparable. Due to complex situation in our pharmaceutical marker which is considered to be one of the most developed in the developing countries, certain other components defined by the WHO experts are also needed to be included. WHO primarily defined the following components for policy construction.

Components:	Objectives:	Access	Quality	Rational use
Selection of essential drugs		X	(X)	X
Affordability		X		
Drug financing		X		
Supply systems		X		(X)
Regulation and quality assurance			X	X
Rational use				X
Research		X	X	X
Human resources		X	X	X
Monitoring and evaluation		X	X	X

X = direct link; (X) = indirect link

Demands estimation- policy framework should contain this vitally needed component by finding out the morbidity and mortality of various prevalent diseases. Having done this, the steps come

to estimate medicines required to meet challenges posed by these diseases. The country then can plan about the procurement target of the medicines.

Procurement- most of the countries in the developing world do not have medicine production capability. Therefore they require import and gradual development of production facilities. Some small countries like Sri Lanka with a proper medicine procurement policy are effectively providing cheap medicine policy. Some countries combine both- by developing state run medicine production units together with import had been managing their need. India is a remarkable exception who had achieved near self reliance in medicine production.

List of Essential Medicines: Developing countries suffer most by procuring expensive if not irrational medicines by spending a great lot from their limited resources. This pitiable situation can be overcome with careful selection of medicines. WHO published and regularly upgrades list of essential medicines. Each country should prepare their own list to meet the therapeutic need of their majority of population.

There are many factors involved in preparation of such list. For example, cost benefit factors, risk-benefit factor and appropriate use of the medicines under the list. This attracts the necessity of rational use of medicines.

Pricing: this is a single factor which emerged as prime cause of hindering the access to essential medicines. Multinational medicine companies have created real crisis in the recent time by selling medicines at very prices which most of the poor can not afford. Prices of HIV/AIDS medicines, cardiovascular medicines, medicines for chronic diseases, etc are sold in the developed countries at very high prices. In addition, TRIPS agreement had also inflicted restrictive patent clauses to safeguard interest of the multinational medicine companies. Many nations are now are utilizing the flexibility of TRIPS agreement and the Doha declaration to contain price rise and availability of cheaper medicines.

Guidelines for marketing: In view of the unethical business practices by the pharmaceutical companies, it has become increasingly necessary to legislate and enforce code of marketing of medicines.

Medicine Legislation:

To control production, procurement, distribution, pricing quality assurance and marketing extensive legislation is vitally essential. Many countries could not legislate effective regulation since they could not withstand pressure from the pharmaceutical industry. Mere legislation is not enough. Enforcement of legislation and strict implementation are essential for streamlining the entire medical system often desired by the big pharmaceutical companies to be left unbridled.

Campaign and education:

Policy should provide due importance to medical education to eradicate preexisting distorted medical culture. Even the end user of medicines sometimes influences use of medicines. Large number medical misbelieve among common people prevent rational use. It is not only creation of appropriate set up or regulation but popularization of the policy requires wide participation of people.

“Recent progress in a number of countries shows that access to essential medicines can be improved through stronger partnership among governments, pharmaceutical companies and civil society, including consumers, working together to ensure universal access to essential medicines. The role of pharmaceutical companies, ranging from multinationals to generic manufacturers to national distributors,

is critical in this effort.” [Delivering on the Global Partnership for Achieving the Millennium Development Goals- United Nations Report on MDG]

Making a pharmaceutical policy is not enough. Success of the policy fully depends on its application, monitoring and regular updating.

“A national drug policy involves a complex process of development, implementation and monitoring. First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties. Finally, the effect of these activities is monitored and the programme adjusted if necessary. Throughout the process careful planning and the involvement of all parties are needed, and the political dynamics have to be considered at all times.” [Guidelines of Pharmaceutical Policy-WHO]

PART-II

Status of Pharmaceutical Policy in India

India’s first pharmaceutical policy was formulated in 1978 without involving medicine prices which of course was declared as Drugs Prices Control Order (DPCO) in 1979- this policy was aimed to help development of Indian national sector pharmaceutical companies keeping the public sector medicine companies in the prime position. Repercussion of this policy was found remarkable to the extent the national pharmaceutical companies successfully competed the multinationals whose share of pharmaceutical market slumped from 80% to 24% within a decade. Medicines price also came down though temporarily within 5 years of working of the policy. As well Indian companies became 8th largest medicine producers of the world with a credit of capturing substantial export market. Even now the countries in Africa and south east Asia are much benefited with economic prices of medicines they import from India.

As far as working of the policy in domestic ambiance, the Govt. made all attempts to dilute the important component of the policy either by mid term executive decisions or by bring changes in the policy itself. Major departure from the policy was shift of importance to the public sector medicine companies. These companies together were the largest medicine producers in Asia. Almost all public sector medicine companies were thus made to become sic and then some of them were closed. Recent instance is the conspiratorial outcome of closure of three vaccine producing public sector medicine companies.

Though after much delay the Govt. prepared a National List of Essential Medicines (NLEM) in 1993, yet the list was not made effective let alone popularizing it. Only recently following a public interest litigation when the Supreme Court ordered that all medicines under the NLEM Govt. proposed that they would follow the court order. This list was supposed to be used by the Govt. institutions and the public sector undertaking, but it never happened. Certain State Govt.s sometime attempt to follow the list. Due to lack of campaign and no compulsions attached the list remains as mere historical document.

Monitoring of production data of major bulk medicines has been abandoned in the recent times. Demand estimation, import quantification and ensuring availability are now foregone chapter. This has been fully liberalized and market forces in no time created anarchy to the extent that whatever regulatory controls exist are openly flouted by the industry. Today except a few, no multinational medicine company produced medicines in India. Taking advantage of third party manufacturing allowed by the Govt., multinationals and large Indian pharmaceutical companies

are now producing medicines from small scale companies resulting to closure of numerous production units and flooding the market with spurious or fake medicines.

Quality of medicines is now posing a large threat. Even a sparse random survey by the Govt. laboratories show that medicines of many reputed companies failed to meet the Govt. stipulated standard (see drugscontrol.org). another most worrying concern has become overwhelming presence of irrational medicines in the market. Perhaps largest numbers of fixed dose combination (FDCs) of medicines are available in India. Recent announcement of the Drugs Controller General of India (DCGI) on 295 FDCs as unapproved show only tip of the whole menace. All FDCs are considered as new drug per definition in the Drugs and Cosmetics Act, 1940. Here the state drugs control authorities have been happily granting approval of anything and everything prepared in combination. The DCGI list is faulty and contains very little irrational combinations. On top, the order but not notification of DCGI left enough scope for the pharmaceutical industry to stall its application by court order.

Most pitiable condition is found in the price control area. The United Nation’s report release in August, 2008 expressed concern on medicine prices.

“Access to essential medicines in developing countries, however, is far from adequate.”

“Information available in a number of countries suggests the existence of large gaps in the availability of medicines in both the public and private sectors as well as a wide variation in prices—much higher than the international reference prices (IRPs)—which render essential medicines unaffordable to poor people. New World Health Organization (WHO) estimates show that public sector availability of essential medicines covers only one third of needs, while private sector availability covers about two thirds. The prices people pay for lowest-priced generic medicines vary from 2.5 to 6.5 times the IRPs in the public and private sectors, respectively.”

Control of prices on medicines which was on 387 bulk medicines has been successively reduced to only 74. This even was proposed to be given up with a plea that market forces would automatically through competitiveness regulate prices. This notion has miserably failed. The same report of the United Nation gave the following table

Margins between producer and consumer prices in the public and private sectors (*percentage*)

Country	Public Sector Mark-up	Private Sector Mark-up
China	24-35	11-33
El Salvador		165-6894
Ethiopia	79-83	76-184
India		29-694
Malaysia	19-46	65-149
Mali	77-84	87-118
Mongolia	32	68-98
Morocco		53-93
Pakistan		28-35
Uganda	30-66	100-358
Tanzania	17	56

Even now the Govt. had been relying on the market forces to determine prices. Recent study of prices of medicines shows that the question of wide variety of difference of same medicines in different brands is not being addressed by the Govt. So also Govt. despite definite complaints on

flouting the ceiling prices of medicines of hundreds of pharmaceutical companies has not taken any suitable action.

Part-III

Proposed National Pharmaceutical Policy (Part-A) 2006

The UPA Government as assured in their Common Minimum Programme tried to formulate a new policy. The policy draft was uploaded in internet as a part of the policy which avoided medicine pricing. A brief critic of the draft is given here. The policy has now put on hold an all probability this Govt. will not be able to promulgate this policy.

Aim of the policy: statement that the Govt. would try to ensure availability of quality medicines at reasonable price announced from 1986 policy till date had failed miserably. Most important question arises in this concern is medicines prices policy revised version of which is yet to be developed by the Govt. hence it is immature to say Govt. envisions to fulfilled the desire of access to essential medicines by all. But while drafting the Part-A of the policy, the Govt. had dealt with many components of medicines pricing. In this area Govt is yet hesitant to take any decision.

Under the given situation revamping of the pharmaceutical policy has become much important since a rain of anarchy exists in the pharmaceutical industry. Govt. needs to address the following in their policy objective

To monitor production and pricing of all medicines.

To ensure indigenous production of all essential medicines.

To weed out all irrational medicines in phases within certain period.

To control prices of all essential medicines.

To ensure quality of medicines and to adopt appropriate legislation.

To establish strong regulatory control for unbiased information on medicines.

To develop a process of dissemination of unbiased information on medicines.

To encourage and implement rational use of medicines.

To provide right to the users for redressal of complaints.

Most of the above features are missing from the policy. These areas in the previous policies were left to the industry resulting to a nearly lawless situation and the industry took everything they do was granted.

2. Production: While estimating the future prospect of medicine industry data used in the policy'06 are highly inflated. For example, pharma market has not been anywhere near Rs. 50,000 crores in 2004-2005. Yet another highly expanded figure for prospect of the market in 2010 has been estimated to Rs. 1,00,000 crores of which bulk drugs would constitute Rs. 25,000 crores. Never in the past, pharma market expanded to double (100% growth) in five years. This examination might have been made following industry data which is highly inflated. If one considers ORG data, it is certain to conclude that the domestic market is degrowing in real unit terms; parallelly import of both bulk drugs and finished formulation has jumped up all time high.

It is also important to note that in the policy'06 no separate mention has been made for estimation and production of vaccines and sera. These are mostly needed by Govt.'s program of eradication of diseases, and require onetime use and are generally low priced. Govt. needs to ensure their availability since industry being not interested to invest in this area, there is always short supply.

Therefore the policy should clearly spell about monitoring mechanism for production of essential medicine, sera and vaccine. This should be integral part of the functioning of the NADT.

3. Past Approach: While analyzing the past approach, the policy draft has not made any self critical review. As if only due to the court cases the DPCO has failed and the Govt. was also forced to review National Essential Drug List. Govt. in the past announced that the price control basket would be small while remaining drugs would be left to the market forces who would compete among themselves resulting to reduction of prices. This has failed, instead this approach of the Govt. has allowed chain reaction of increase in prices, highly differential prices among brands and large discounts to the trade. The draft policy mentioned eleven areas regarding important developments after liberation process in 1991. Excepting in two- import and VAT no significant development has been found in the other areas during this period. Liberation of industrial licensing (no licensing); for foreign direct investment (100% FDI) and automatic technology agreement have not caused any significant increase in FDI. In the R&D area, domestic companies could not develop or introduce any new chemical entities. Whatever molecules or new drug delivery system was invented was sold to foreign multinational companies. New system of excise duty on MRP has not helped to reduce prices of medicines but allowed shifting of industries away from Mumbai, Gujarat and Hyderabad. Modification/expansion of schedule M of Drugs and Cosmetic Act has caused closure of small scale units. In Maharashtra alone 700 small scale companies have been shut down.

4. New Policy Initiative: The Draft Policy recommends that the comprehensive area of drug regulations and price control shall be bestowed to a single statutory authority is welcome. In fact this proposal was made by the activists since a long time back. National Authority on Drugs and Therapeutics (NADT) replacing the presently exerting CDSCO which has limited power is also appropriate. The Draft Policy also suggested for formulation of a task force for merger of NPPA and NDA to bring them under the umbrella of NADT. It is therefore required that the policy should propose for a new bill to enforce the process.

It is also required to form separate drug court for quick redressal of the cases of violation of quality standard, counterfeiting and many other areas directly concerned to the consumers.

5. Intellectual Property Rights including data Protection: this portion of the policy deals with the options available in the amended Patents Act but does not spell any thing in the impending marketing of high priced newly patented medicines and complications that may arise in production of generic medicines. Much interest has been shown for data protection ignoring the fact that this would become counter productive to produce generic medicines particularly in the perspective that increase in export of medicines is the outcome of Indian companies ability to export generic medicines.

6. Clinical trials and Drug Development: All the recommendations made in this chapter are aimed to facilitate Clinical Trial Outsourcing (CRO). Temptation before the helpless Indian industry in the product patent regime is diversification of manufacturing activity to clinical trials of the new molecules developed by the foreign multinationals. This would not cater the need of people for manufactured products. Present Schedule Y of Drugs and Cosmetics Act is not fully compliant to international covenants to protect abuse of human, genetic piracy and above all standards of biosafety. Therefore the policy should propose to review of Schedule Y to make it compliant to international standards.

7. Anti cancer drugs and anti-HIV/AIDS medicines: All the recommendations made in the policy are vital and welcomed. Recommendations for drugs for life threatening diseases are good but in absence of specific definitions, there may be chances of confusion and litigation.

8. Patented Drugs: Proposal for price negotiation is correct but while performing so global indicator of prices should be compared. Wherever effective drugs of reasonable price exist, the patented medicines having no reasonable therapeutic advantage but are very expensive should not be allowed for introduction in the Indian market.

9. Trade margin and Excise Duty: All proposals made in the policy draft are acceptable.

10. Maximum Retail Price: It is acceptable that MRP inclusive of all taxes should be mentioned in the sales pack but it should be available in the same price in all states (after all states adopts VAT system)

11. Drugs and Therapeutic (Regulation) Act: Surprisingly provision made in this chapter is inadequate. This authority should be given right to raid, investigate, confiscate or cease activities of any organisation producing or dealing with medicines whenever complaints on serious violation are received. Price list should also be available to public. Despite several assurances from the Govt. no comprehensive proposal has emerged out of the policy.

12. Strengthening of NPPA: Proposals made on revamping of NPPA is welcome but present structure of NPPA is not sufficient to cope up with the work of cost data compilation, check up and approval of price revision, etc. within a short time. Expansion of NPPA even after its merger with NDA is vital. The policy should also suggest for expansion of NPPA structure.

13. Bulk Procurement System for Drugs by Govt.: No elaborate declaration in this chapter is required. The policy should direct the Central/State Govts. And public sector undertakings to prepare procurement policy with certain given guideline in the policy. Though described later in the policy, it is necessary to mention here again the purchase preference to pharma public sector undertakings.

14. Lower Prices of Bulk Procurement & Promotion of Generic name: Proposal is acceptable. No amount of policy imposition will be successful for mere mention of generic names unless consumers are educated and the system of orientation of prescribers attitude are taken up as well.

15. Control on Pharmaceutical Brands: Steps suggested in the policy is appreciated. The policy has not taken into consideration of wild proliferation variety of combination medicines. Sometimes these are called as brand extension. Policy should make provision to check approval of such combinations. It is necessary to declare that approval of combination of medicines should be discouraged and unless of a text book reference and therapeutic validity no combination should be allotted.

16. Quality certification of Drugs: Medicines are totally different from any other commodities. It is not acceptable that some medicines with Agmark or something like ISI mark and others with different (inferior) quality will be available simultaneously. When the matter of life is concerned, no medicine beyond proven variance in active substances in quantity, bioavailability, etc. should be allowed. Therefore all manufacturers shall be responsible to maintain minimum quality standard declared by the Govt.

17. On Loan or Third Party Manufacturing: statement made in the policy that ‘a higher price is associated with better quality’ is not correct. With scope of loan or third party manufacturing allowed by the Govt. most of the top selling brands which of course bear higher prices are manufactured by the small scale units. This system has made the brand holding companies not responsible for the quality assurance of their products. The policy should recommend abolition of such third party manufacturing system.

18. Strengthening of Pharma PSUs, Purchase preference to Pharma PSUs, Consumer Awareness: Proposals made in these chapters are acceptable.

19. Scheme for providing Accessibility of drugs to BPL: The policy has dealt elaborately in this chapter. Proposal of Rashtrya Swasthya Bima Yojna and utilisation of National Illness Assistance Fund is welcomed. Certain additions in this proposal would be as follows. In addition to the Govt. doctors, some private practitioners may be authorised like ESIS to treat the BPL patients.

Integration of the Bima Yojna and National Illness Assistance Fund is not clear.

According to the National Health Policy document only 20% to 25% of all people in our country use modern medicine and 65% of the population do not have access to essential medicines (The World Medicine Situation, WHO). Many people who are marginally above BPL are may not be able to meet the high cost of therapy. It is therefore needed to plan for another tier for them where medical insurance system with subsidised premium can be established.

20. Health Cess: Medicines in India is already burdened with several taxes. The taxation starts right from the fine chemicals, bulk drugs to formulations. Tax component of medicines are very high. Imposition of another 2% as health cess would increase this burden. Instead this cess if at all be imposed shall be applicable to the sales turnover of the manufacturers (other than the SSI) and should never be imposed on the users.

21. R & D in Pharmaceuticals: For the first time elaborate proposal on R & D in the areas of human resource development, fiscal incentives, PRDSF and development of orphaned drugs have been made in the pharmaceutical policy. All these are welcomed but the area which is not considered as to how they would benefit people as end result. It is therefore needed that when sizable public fund of Rs. 150 crores would be provided to private institutions for R & D, any new molecule developed thereof should be marketed in India at cheaper price much below the price like other patented medicines.

22. Subsidy for Implementation of Schedule M for GMP: Providing low interest fund for borrowing by the SSI to implement Schedule M provisions is welcome but the policy did not indicate the source of such fund.

23. Drug Prices Monitoring and Awareness fund: Proposal is good. Pending claim on DPEA is enormous. A paltry sum of which is only recovered while rest are pending in court cases. It is necessary to establish separate judicial machinery for quick disposal of the amount recoverable.

24. Pharma Parks: This can be the part of the policy but may form a recommendation from the Govt. to Central/State Govt.s

25. Pharma Export: The commercial aspect of pharma export also can not be a part of the policy, instead the policy should recommend formation of a committee by the Govt. to assist Pharmexil to deal with the situation of TRIPS obligation and its impediments.