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POLICIES THAT LOADED AGAINST THE POOR

A short critique of drug policies of India

By

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Background

Evaluation of current drug policy of India is incomplete, unless we historically examine the evolution of different drug policies in India. The drug policy of India is not a stand-alone document as many dimensions of it are an extension of different national and international policies like national health policy and international trade agreements. With the current world order of dominated by the principle of liberalization and globalization, various international policies and trade agreements have a definite impact on the drug scenario not only in India, but also throughout the world.

Previous Drug Policies of India

Historically, pharmaceutical sector in India has passed through different eventful stages. The post-independence scenario was marked by high drug price- one of the highest in the world making most people inaccessible to allopathic medicines. 90% of our market share was handled by either imports or produced by multinational companies in India. However this was the time country had gone through the worst health profiles in the post-independence era. The life expectancy at birth was just 36.7 years and our Infant Mortality Rate [IMR] was equally bad at 146[Today our life expectancy at birth is 65 years and IMR is 70]. Millions of deaths were occurring on the account of infectious diseases like Small Pox, Malaria, Tuberculosis etc.

The period after 1970 was a significant period in the history of pharmaceutical sector in India, especially the drug industry in India. The two important government policies laid the foundation for these developments. Through a Drug Price Control Order [DPCO], drugs used in common diseases were brought under the price control by setting a ceiling on their retail prices. This made possible the availability of medicines rather cheaply. The second important policy was the Indian Patent Act of 1970, which recognized the process patents, not the product patent. [Product patent is given to researchers when a new drug is discovered. Once the chemical is known it is rather easy for others to manufacture the same drug through different processes. Each of these processes can be registered as process patents]. Supplementing with these two policies, other government policies like imposing high tariffs on import of medicines, limiting the investment choices of foreign companies has helped in developing the Indian pharmaceutical industry and a better accessibility of medicines.

Over these years, Indian pharmaceutical sector has become one of the fast growing one in the world. Today it has a market share of 85% of bulk drugs and 70% of domestic formulations. In the year 1992 our drug export amounted to 12.8 billion compared to an import of 8 billion. However this does not mean that all were perfect with the drug scenario. If we carefully analyse, the comparative advantage [through the above-mentioned policies] enjoyed by our pharmaceutical companies over their counterparts in other developing countries, were only partially transferred to the people of this country. If we look at the prices of off-patented medicines, we can see that many of them priced higher than even those in the developed world. A flourishing industry with little quality assurance measures has lead to condition in which India has become the home of largest formulations in the world. We have about 70,000 drug formulations compared to just over 3000 in all of Scandinavian countries. Most of them are unnecessary, hazardous and costly drugs. Unethical and intensive promotional strategies adopted by the pharmaceutical companies coupled with the declining values in the medical practice has created a situation in which any unnecessary drug can be produced and marketed. Menace due to the black-market of counterfeit and sub-standard drugs are equally disturbing.

Changes in the government policies towards liberalization and globalization in early 90s had its impact in the pharmaceutical sector also. To promote further investment in the industry government had abolished the industrial licensing. However the decision to reduce the price control from 142 bulk drugs to 73 drugs proved to be disastrous in the following years. This has lead to spiraling of drug prices as the market share of medicines under price control was reduced to around 40%. By then India has become a signatory to WTO after Uruguay round of talks held between 1986 to 1994. According to this all developing countries had to comply with TRIPS [Trade Related Intellectual Property Rights] agreement within 10 years starting from January 1st 1995. TRIPS agreement stipulates a strong product patent rule that was benchmarked against the stringent patent rules of United States of America. This has happened with out much national level debate and deliberations on the issue of affordability of drugs in the future. Though the government issued an Ordinance in 1995 to comply with TRIPS,

subsequently they could not pass the Bill in the parliament as by then various Civil Society Organizations started to protest against this anti-people move. The period between 1995 to 2002 saw many different government policies in the pharmaceutical sector, almost all of them were to promote the industry by allowing foreign investments and profiteering by the industry.

National Pharmaceutical Policy 2002

Change in the name of the policy for the first time from drug policy to pharmaceutical policy is justified by most of the policy prescriptions in the document. The name 'drug' is often linked to patients and a policy document that ignores the patients and promote profiteering by the industry rightly choose have its title as 'Pharmaceutical policy 2002'. After all, a policy prepared by the Ministry of Chemicals and Fertilizers with the involvement of industry representatives can not be expected to be different. Long pending demand by the activists for the active role of ministry of health in the formation of drug policies went in deaf years in this time too. As a result what we have is a policy that formed to support the industry and silent on many important issues related with drug accessibility, rational use of medicines etc.

A severe blow this time has come in the form of further reduction in the span of drug control. The new criteria set by the government allowed majority of drugs to move out of the price control. Now the price control is reduced to about 35 drugs from 74, which means 75% of the medicines in the market are out of price control. Authorities have been giving at least two rationales the price decontrol. One, Price relaxation will help the industry to increase its revenue, which in turn can be invested in research and development [R&D]. Second justification is that once the price control is removed, market mechanisms will stabilise the drug prices. Both these arguments are groundless. We were given the same explanations in 1995 when the prices were first decontrolled. Even after 7 years investment in research and development is only 2% of industries total turn over. Even if some resources flows, it will be mostly towards the diseases of the affluence as indicated by global priority in health research. Internationally it is acknowledged as 90-10 gap in health research, which indicate that 90% of total resources in health research is directed towards the diseases affecting the 10% of the world's population. Similarly the argument that market mechanism would stabilise the drug prices may not work, as patients [consumers] have little choice in the selection of the drug from the market other than what is suggested by the doctor. We know for sure that any costly drug can be pushed through the market, if the supplier resorts to intensive promotional strategies.

Though millions are likely to be costed out by the new pharmaceutical policy, the industry responded well to the Pharmaceutical Policy 2002 by showing immediate sharp increase in the share prices of most of the pharmaceutical manufacturers in the national and international markets.

National Health Policy 2002

National Health policy is supposed to be the lead document to spell out the national policies concerning health including the broad issues related with drugs.

However our national health policy is a very weak document, as far as policies pertaining to medicines are concerned. It came out as a support document to the Pharmaceutical policy. Like the Pharmaceutical Policy 2002, National Health Policy is also very conspicuous by the absence of any policies to address the major issues like drug affordability, drug quality control, rational use of drugs etc. Perhaps the only important suggestion in whole of the document is the proposal to have a central funding to make Essential drugs available at Primary Health Centres throughout the country. Even this is below the optimum level required and also remains to be seen how much would be actually allocated for.

International Trade agreements

The new world order of globalization and liberalization has brought all countries in the world vulnerable to international trade agreements and legislation. One of the most visible and inhuman impacts of these trade laws would be in the pharmaceutical sector in the form of TRIPS agreements. This is an example how the trade laws can prevent the new technologies that have the potential to improve the life of millions of unhealthy can be prevented from reaching them. This is happening when at least 11 million deaths from preventable or curable diseases are occurring annually in the world. Half of them are children. A significant portion of them can be avoided if they have access to medicines. According to WHO estimate 1/3 of the world's population is deprived of essential medicines.

As we discussed earlier Trade Related Intellectual Property Rights or TRIPS agreement of WTO, recommends a harsh product patent of 20 years of monopolistic marketing rights to discoverer of the technologies. In pharma sector this will have a definite adverse affect on the life of the poor, as many new generation medicines will be highly inaccessible. The comparison of prices of ciprofloxacin in India and Pakistan can throw some light in to the magnitude of the problem. Price of this medicine in Pakistan, which has a product patent legislation, is five times more than that in India. The emergence of newer diseases, resurgence of older diseases that are thought to be controlled in the past and multi drug resistant infections are going to be high priority public health issue of the future world especially in the developing world. All these conditions will require new medicines. The significance of the issue of accessibility to new generation medicines to fight against the future public health emergencies should be viewed in this context.

In fact, TRIPS agreement had provided some flexibility under its 'article 31', which allows a limited provisions for compulsory licensing of patented medicines by the countries in public health emergencies. For dubious reason's 'the Second Patents Amendment Bill' passed by the Indian parliament in May 2002 failed make use of the flexibility available within the TRIPS agreement under article 31. We could have included enough provisions to have compulsory licensing in public health emergencies. Right now what is given is highly restrictive and is clearly in the advantage of patent holder.

What is happening in India is in not in the interest of people of this country. This is the case with most developing countries. Many who knew of the dynamics of the industry campaign lead by the multinational companies are not surprised at the turn of

events. The influence of Pharmaceutical Researchers and Manufacturers of America [PhRMA -world's richest and most politically influential organization] on US Trade Representatives is the power behind the industry campaign. Over the years many countries including India have come under the threat of US trade rules on behest of PhRMA.

What can we do as Civil Society Organisations?

Drug prices are already on an increase and the days to come will prove how much exactly it would be. Immediate spurt in the drug prices will be on the account of price decontrol and within few years the combined effect of new patent rules and price decontrol are going to cost out millions of poor and sick in our country. We should not spare any opportunity to counter these policies as they are unjust, anti-poor and are in the interest of national and multinational corporate houses.

We strongly believe and recommend that unless we take the issue to the people of this country, little is going to be achieved. The issue needs to be politicised for the benefit of poor and sick in this country. In most developed, an increase in drug prices in range of 10% or 20% is a political issue and can even bring down the governments. Here we [common people] hardly talk about it, despite the drug prices multiply in short periods.

It is not asking you to come out in the street and protest. Instead start talking about these issue too in different forums. I am really optimistic about the proposed 'Bihar level network for rational drug use'. We need to realise it, expand it to like minded people and should be made effective.

Thank You

[Christian Medical Association of India [CMAI] has been campaigning for rational use of medicines for last few decades. The major activity is the promotion of rational use of drugs in the mission hospitals through various publications and rational drug use training workshops. A quarterly publication called 'Rational Drugs' with a circulation of over 5000' copies has been a motivation for rational drug use in the mission hospital circles for over a decade. CMAI's recent organisational reform resulted in the formation of a Policy Advocacy & Research Group as a formal CMAI structure to evaluate policies, bring forward evidences and campaign for people centered policies. This document is an attempt to support the campaign for access to medicines and people centered drug policies in India].