Rational Drug Bulletin

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Editorial

Community Development Medicinal Unit [CDMU] began its activity by procuring essential medicines and distributing them among the NGO member organizations on non-profit basis. CDMU is committed to implement the concept of Essential Medicine & Generic Medicine with Standard Treatment Guidelines. Major conflict developed when the demand profile from member organizations widely differed from the essential medicines procured by CDMU. This necessitated CDMU's effort for campaign for rational use of medicines (RUM). CDMU took steps to develop and initiate publication called Rational Drug Bulletin [RDB] in the year 1991. In the year 2007 CDMU tried to enhance membership of the bulletin. An intense effort was given to provide information about medicines to the member organization. Later, it was found that take home message of many of the articles published in the RDB were not cleared to the members. Therefore CDMU redesigned RDB to make it acceptable to the members and also sustainable. RDB will again start its journey in newer form from 1st January 2014. From the present issue the Rational Drug Bulletin will also be available as e-bulletin. Readers can enroll his / her email id at CDMU website: www.cdmuindia.org to get regular issues of the bulletin.

We apologize for not being able to publish Rational Drug Bulletin for last 3 years. We realized since long that unbiased rational medical literature is very essential. In the present world with fast-changing concepts of medicine, information on medicines may play a key role in therapeutics; however, for the consumer, getting the unbiased scientific information is a real problem. Therefore the need of such initiatives is growing, and it is important that we must sustain the effort. Medicines sold in India are largely irrational. The questions of ethics were neglected and the market forces have succeeded in making many medical professionals ignorant of evidence-based practice, resulting in irrational therapeutics. In this bulletin, we wish to continue to uphold the practice of ethical, scientific knowledge dissemination along with rational, cost effective approach towards treatment regimen. Objective of RDB is to achieve Rational Use of Medicine in our society.

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The Struggle for Rational Drug Policy

Dr. Punyabrata Gun

In 1975, a Parliamentary Committee on Drug and Pharmaceutical Industry submitted its report. The committee, widely known as Hathi Committee by the name of its chairman Congress MP Jaishuklal Hathi, was appointed by the Government of India to analyze the Indian drug industry.

In its unique recommendations, the committee suggested a restricted list of 116 essential drugs with which one can treat most of the diseases of the majority of the Indian population. It recommended the measures to be implemented to ensure their production. It recommended a gradual shift from brand names to generic names, and it asked for price control measures to make life-saving drugs and essential drugs affordable while all the irrational drugs were eliminated. It recommended that public sector play a leading role in drug production and certain drugs be reserved to encourage the growth of Indian drug companies. The committee decried the role played by multi-national drug companies and recommended immediate dilution of foreign equity in drug companies up to 40% and progressively to 26%. In fact, it recommended the nationalization of foreign drug companies.

In 1977, the World Health Assembly decided that the major social goal of governments and WHO should be the attainment by all people of the world by the year 2000 of a level of health that would permit them to lead a socially and economically productive life. As medicines are very important for health care, WHO released its 1st Model List of Essential Medicines in 1977.

In 1982, in Bangladesh a military government took the initiative to formulate a national drug policy. It appointed an 8-membered expert group for this purpose. The key features of the Bangladesh National Drug Policy 1982 are:

- Fixed Dose Combinations were banned
- Use of codeine in different preparations was banned
- Cough mixtures, throat lozenges, gripe water, tonic, enzyme mixtures were withdrawn
- If sufficient raw materials are produced in country, then their importation would be not allowed
- Antacids and Vitamins were kept reserved for national industries, while the MNCs were asked to concentrate their resources to develop and formulate drugs requiring higher technology
- No foreign brands were allowed to be manufactured under license, if the same or similar products were already manufactured in Bangladesh
- Harmful or unnecessary Drugs were banned: 1099 were banned with immediate effect. 146 drugs were allowed to be sold till 30.6.1983.

The expert group recommended:

- Formulation of an Essential Drug List (EDL) of 150 drugs for the country
- While products patent must not be allowed, process patent could be allowed for limited period

Government would control prices of finished drugs, raw materials, packaging materials and intermediates

Drug administration has to be strengthened and adequately manned.

Movement in India for Rational Drug Policy

These developments in the world, in a neighboring country, and in India itself influenced heath-activists in India to intensify their struggle for a rational drug policy. They got themselves organized in various organizations. All India Drug Action Network (AIDAN) was founded in 1982. It has since been active in the campaign for a rational, people oriented drug policy and rational use of drugs.

In 1983, at Dalli-Rajhara in Chhattisgarh, iron ore-miners founded a hospital in memory of their martyrs. *This Shaheed Hospital was probably the first institution where the principles of rational therapy were put into practice in a large scale.*

In Gujarat, LOCOST (Low Cost Standard Therapeutics) was founded in 1983. Initially it used to procure essential generic drugs from the indigenous manufacturers and to supply them to NGOs and people's organizations after rigid quality checks. Later it started to manufacture several essential generics. It has been very active in the advocacy of a people-oriented drug policy and rational therapeutics.

In 1984, in West Bengal, Drug Action Forum, WB was formed. It came out with a Bengali booklet 'Oshudher janya manush na manusher janya oshudh?'(Whether medicines are for the people, or the people are for the profiteering of the drug companies?). West Bengal Voluntary Health Association financially helped in its production. In 1984 West Bengal Voluntary Health Association set up a Central Drug Marketing Unit to supply affordable generics to its member organizations. For more effective service Community Development Medicinal Unit (CDMU) was constituted in 1986 as an autonomous unit. Besides procurement-storage-distribution of essential medicines, it promotes the concept of essential medicines. In 1995, the workers of Kanoria Jute Mill began a people's health program in Chengail of Howrah district in West Bengal. Shramajibi Swasthya Udyog, an organization of doctors and health workers, has developed the program as a model of rational primary and secondary care. It has combined rational techniques of diagnosis, rational use of investigations with rational use of medicines.

Among the other notable organizations active in this field outside West Bengal are Kerala Shasthra Sahitya Parishad, Lok Vidyan Sangathana, Delhi Science Forum, Voluntary Health Association of India, Medico Friends Circle, Jana Swasthya Abhiyan, Drug Action Forum-Karnataka, Janaswasthya Sahayog of Chhattisgarh, etc.

The present scenario

India has been named as the 'Pharmacy of the World'. It ranks third if the total volume of drugs produced is considered. It ranks fourteenth if the total value of drugs produced is considered as drug price is less in India than in many other countries. Still essential medicines are inaccessible to the majority of the Indian population. It is a problem of poverty amidst plenty. Drug costs are about 40-80 percent of the health care costs. Health care is the second most common reason for rural indebtedness. There are more than one lakh drug formulations available in the Indian market. A great many of them are irrational and unscientific. Regulation by drug authorities is poor, corrupt and inefficient. Ruling over a public interest litigation filed by AIDAN, the Supreme Court has compelled the government to come out with a Drug Price Control Order in 2013. The 348 medicines listed in the National List of Essential Medicines, 2011 are brought under price control. But the price control is not based on the cost of raw material, cost of production and cost of packaging. Ceiling price of a particular drug has been decided simply by calculating the average of the prices of the brands of the said drug having 1% or more of market share. As the drug market is dominated by the high-cost brands, this measure will nominally reduce the price of the high-cost brands while increase the price of the low-cost ones, thus making the task of the healthcare professionals trying to find an economic option for their patients more difficult than it is today.

The struggle for free essential medicines for all should go on….

The High Level Expert Group on Universal Health Coverage, constituted by the Planning Commission has shown that a mere 0.5% of GDP increase in governmental spending on health can provide free essential medicines to all of India's citizens.

The group recommended:

- At least 15% allocation of public funding for health to drugs; State must procure all EDL medicines;
- Separate AYUSH[1] EDL, with centralized procurement at state level;
- Prescription & Dispensing in accordance with Standard Treatment Guidelines (STG);
- A two-bid open transparent tendering process;
- Ensuring quality generic drugs;
- Warehouses at every district level;
- An autonomous procurement agency for drugs, vaccines & diagnostics;
- A system of empanelled laboratories for drug quality testing;
- Enactment of transparency in the tender procedure.
- Prompt payments.

Various organizations and individuals working in the field of public health in West Bengal have formed a forum in 2012: People for Health Care. The forum is organizing awareness camps and workshops of activists to raise the demand of *Free Essential Medicines for All*. The struggle must continue till there is health for all.

Medicine cost

Dr. Anjan Adhikari

Anyone who has purchased prescription medications has probably wondered why they cost so much? As the reason of high price, the drug companies usually point to the cost of research. The media responds with figures showing that the companies spend more on marketing than they do on research. Then what is the real situation?

The first step in the development of drugs is the discovery of a new compound (natural or synthetic) that affects a medical condition. Initial phase of drug development involves research of the chemical and biological properties, exploration of the compound to determine its kinetics & dynamics, how it will be absorbed, distributed, metabolized and eliminated from the body, what will be its efficacy. But the most important issue is the safety of the drug or medicine. Preliminary evaluation of new drug starts in the laboratory using cells on plates (tissue cultures) and animals. If the new compound is safe and effective in animals, the next phase is testing in a small number of healthy human volunteers to confirm the information available from the animal studies and to gain further information on the effects of the compound. Finally, the new compound will be tested diseased persons.

The regulatory authority evaluates the new drug as per the criteria, and then approves the drug or medicine for marketing. Drugs or medicines are concerned with, safety and efficacy which are the most important parameters to be considered. But cost of the medicine is also an important factor. Pricing of drug is directly related with the accessibility of the drug to the common people, more in the developing and underdeveloped countries. Higher price of medicines will jeopardize the implementation of the concept of rational use of medicines in the societies. Studies revealed one-third of the global population lacks access to the medicines need. In the poorest countries of Africa and Asia, this figure may rises upto 50%. They simply cannot afford to purchase the medicines. On the contrary, industrialized countries generally have social security and/or insurance schemes covering the cost of the drugs. But people in poorer countries pay the full cost of the drugs from their own pocket. Price of drugs or medicines may vary considerably from country to country, even among different cities within a country. Common people don't have any information regarding the price structure or where to find the best prices for their medicines. It is also very difficult for the common people to understand the intricate factors relating to the drug price. The same is often true to some extent for the government authorities and health care system managers.

Drug prices vary for various reasons and in various situations. Cost of medicine may differ in its original branded form to its generic form, price may differs depending upon the place from where it is bought from; it is different in a public clinic, a charitable dispensary, and in a private

pharmacy. Price of a same medicine may even differ in urban or rural settings of a country. So, the picture of drug pricing is very gloomy. It is impossible for the common people to know what should be the 'best price' of a drug and where to find it. From the procurement price of a drug, to the sell price, there can be a 100 % or more difference – based on tariffs, taxes and retail mark-up & obviously on profit.

Pharma industry generally argues with the following justification for high drug cost:

- New drugs are innovative and are valuable to society
- Drug Research & Development costs are high
- Producing drugs is risky
- Drug companies donate millions dollars of free drugs
- Good value; impossible to put a value on good health

Cost of medicines is a flexible concept. Drug prices vary even for a single drug, in different hospitals of a city. The key players of the pharmaceutical supply chain, who can play an important role in framing the cost of medicine, are-

- Branded Manufactures
- Innovative Pharmaceutical Firms
- Generic Manufacturers
- Wholesalers/Distributors
- Retailers
- Governmental
- Non-Profit Sellers

Factors affecting the cost of medicines ?

Study revealed that that one-third of the population of the developing world's, unable to purchase essential medicines. Essential medicines are "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." Actually there are a number of factors affecting the drug price in any country. Followings are few factors:

- Prices of patented drugs
- Prices of generic drugs
- Monopolistic pharma industry
- Retail and wholesale market
- Composition of total population
- Prescribing habits of physicians
- Use of Essential drugs
- Use of Standard Treatment Guidelines
- Medicine use pattern in the society
- Using newer drug therapy instead of older drugs
- Other legal, regulatory & social factors

One important factor of drug price is the availability and use of Generic medicine in the country. Generic drugs have the same chemical composition as branded drugs and sold under their non-proprietary name. For example paracetamol, a painkiller is the generic name, or non-proprietary name, for branded drugs like Crocin and Calpol. The drug paracetamol (10 tablet strip) prescribed in its generic name may cost Rs. 2/- (Rupees Two only), while a branded version of paracetamol may cost Rs. 11/-

(Rupees Eleven Only) or more. The price difference of generic and branded may be up to 90%. A study in United States of America proved that with increase in the number of manufacturer of generic drugs, there would be reduction in the medicine prices. But still today generic medicines are not popular in India. There are various reasons for their unpopularity. There is a distinct lack of awareness about generic drugs. Since they are cheap, people don't buy them believing them to be of inferior quality. They pay more money for branded drugs.

Access to medicines in any society depends on four factors: Rational selection and use of medicines, Affordable prices, Sustainable financing, Reliable health and supply systems. Affordable price is the issue which can be influenced by various financial, regulatory and even social conditions. Steps to be taken to ensure affordability of medicines include:

- Reducing taxes, tariffs and margins on essential drugs
- Ensuring provision of special low prices (by equitable pricing or granting voluntary license to a local manufacturer) for purchasers in low-income countries
- Find cheaper sources of supply
- Developing national drug pricing policies
- Promoting competition for multi-source products
- Promoting use of Generic medicines, Essential medicines
- Implementation of the concept of Standard treatment protocols
- Scientific and rational procurement policy including quantification
- Using open competitive purchasing methods
- Monitoring by the regulatory authority & Governmental agencies about the prices of drugs
- Ensuring proper distribution system, from manufacturer or importer to consumer. Price of drugs must be competitive and efficient.
- Monopolies (e.g. a single importer or wholesaler) or near monopolies at any point in the distribution system should be discouraged.

Drug companies are like other companies in that they manufacture products that must be sold for a profit in order for the company to survive and grow. They are different from other business companies because the drug business is very risky. For instance, only one out of every ten thousand discovered compounds actually becomes an approved drug for sale. Much expense is incurred in the early phases of development of compounds that will not become approved drugs. In addition, it takes about 7 to 10 years and an average cost of 500 million dollars to develop each new drug. These expenses must be covered by the revenue from compounds that successfully become approved drugs. Moreover, after a drug is approved, millions of dollars are spent on marketing. Drug companies spend a lot of money on marketing because of the stiff competition they face from other drug companies for their drugs. In a nutshell, the price paid by a patient for a medication must cover the costs of developing new compounds that become approved drugs and compounds that fail to become drugs, as

well as marketing, post-marketing studies, and a profit.

India approved a new drug pricing policy designed to increase the number of drugs deemed essential that are subject to price caps. After going through various twists and turns over the years, as well as being in the cold storage for some time, the National Pharmaceutical Pricing Policy 2012 has been finalized. The objective of the new policy is to ensure the availability of essential medicines "at reasonable prices". The new price caps will initially be applied on imported drugs that are on the "essential" medicines list. The latest policy will extend price restrictions to 348 "essential" drugs, including cancer and HIV medicines that weren't covered under the previous policy that set prices for 74 drug compounds and their combinations. While the government's efforts to bring more drugs under price control are aimed at making medicines affordable for the poor, local and foreign producers argue that there is enough competition to ensure that drugs sold in India are among the cheapest in the world. Further, the department of pharmaceuticals draw a new drug price control order (DPCO 2013) enlisting the ceiling prices. The ceiling price (which will cap the drug price) will be revised every five-years, or as and when the NLEM [national list of essential medicines] will be updated or revised.

In many countries medicines account for over half of total health expenditures and are often unavailable and unaffordable to consumers who need them. Up to 90% of the population in developing countries still buys medicines through out-of-pocket payments, and are often exposed to the risk of catastrophic expenditure. Equitable access to quality pharmaceuticals is an essential component of health system strengthening and primary health care reform, particularly in low and lower-middle income countries. Sustainable and efficient financing of medicines and affordable prices are therefore essential to ensuring access to medicines, and are two of the building blocks in the WHO [World Health Organization] access to medicines framework.

Drug Alert

No benefit of Paracetamol with Ibuprofen FDC

The Fixed Dose Combination [FDC] of paracetamol with Ibuprofen [sold as Combiflam, Flexon, Ibuclin, etc] is no better than either paracetamol or ibuprofen taken alone in relief of muculo-sketal pain according to a double blind, randomized controlled trial under-taken at the Department of Emergency Medicines, stony Brook University, New York. A total of 90 patients were administered either ibuprofen 800 mg or paracetamol 1 g or FDC of both. There was no difference in the relief of pain among the three groups. Side effects of FDC are more by consuming two drugs together than individual ingredients.

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