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The characteristics of the current drug policies in India, Nepal and Bangladesh

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■ The characteristics of the national drug policy in India

Introduction to the Indian national drug policy

The current Indian national drug policy has its roots in two documents originated in the 70-ties and the 80-ties of the XX. century. Although the first National Drug Policy was declared in 1978, it has been revised thrice since then, in 1986, 1994 and 2002 [3]. Also, in 1986 another document on the Indian drug policy, titled “Measures for Rationalisation, Quality Control and Growth of Drugs and Pharmaceutical Industry in India” was evolved [1]. The drug policy has been implemented under some legal acts related mainly to the fields of health care, family welfare, scientific research and development, and industry. It emerged from the findings of the Hathi Committee (a committee commissioned to study the operations of multinational drug companies vis-à-vis indigenous companies and public sector undertakings). The committee’s recommendations were released in 1975 and they included:

- 1) nationalisation of multinational units,
- 2) diluting foreign equities of companies coming under the Foreign Equity Regulations Act,
- 3) earmarking some drugs for public sector undertakings,
- 4) strengthening R&D (research & development) activities,
- 5) abolishing brand name drugs,
- 6) issuing licenses for formulations of only 117 drugs which the committee considered sufficient for the treatment of the majority of diseases in India,
- 7) measures for drug quality control,
- 8) disseminating unbiased drug information to prescribers and consumers,
- 9) monitoring of adverse drug reactions [3].

The national drug policy of India ensures access, quality and rational use of drugs [2] and its main objectives are as under [1]:

- 1) ensuring abundant availability of life saving and prophylactic medicines, at reasonable prices and of good quality,
- 2) strengthening the system of quality control over drug production and promoting the rational use of drugs in the country,
- 3) creating an environment conducive to channelling new investment into the pharmaceutical industry to encourage cost-effective production with economic sizes and to introduce new technologies and new drugs,
- 4) strengthening the indigenous capability for production of drugs.

In 1979 the Drug Prices Control Order was declared, which brought 347 drugs under price control [1]. The industrial licensing has been made easy and is granted keeping in consideration that the basic stage manufacture is achieved and undue imports are discouraged. The latter is achieved through tariff mechanism and EXIM (EXPORT IMPORT) Policy [1]. However, licensing related to formulations has been abolished except in cases of specific cells/tissues targeted formulations [1]. The R&D sector has been regarded as thrust areas of exports. In view of GATT accord and changes in patent laws, the subject matter of basic research in drug sector has assumed greater importance. The foreign technology agreements are permitted for all the items in the pharmaceutical sector to encourage the introduction of newer and more efficient technologies [1]. It has to be emphasized that in India the pricing issues receive more attention because of the pressure of the industry and the GATT agreement and due to the fact that one of the main objectives of the Indian

policy is to strengthen the domestic pharmaceutical industry [5]. Pharmaceutical companies play a significant role due to existence of high rate of morbidity and mortality from diseases of deprivation and communicable diseases. The responsibility of pharmaceutical sector is shared by two ministries, the Department of Chemicals and Petrochemicals under the Ministry of Industry and the Directorate of Drugs Control under the Ministry of Health and Family Welfare [3].

India's pharmaceutical industry is one of the most highly regulated industries in the country. Price controls have a strong effect on profitability in the industry [7]. Government of India has set up an independent National Pharmaceutical Pricing Authority to carry out the price fixation for the bulk drugs and the formulations. This authority looks into the list of drugs under the price control and implementation of provisions of Drugs (Prices Control) Order. The Government will hold the power of review and reclaim the prices of medicines in case of unreasonable rise of prices of medicines [1].

Today in India about 20,000 firms have licences to produce pharmaceuticals. Of these, about 200 units are responsible for over 40% of total drug production [3]. These are engaged in production of complete range of formulations (medicines ready for consumption by patients) and 350 bulk drugs (chemicals having therapeutic value used for the production of formulations) [1]. Good Manufacturing Practices (GMP), quality control and rational use of drugs are taken care of. Drug Control Organisation has been strengthened by establishing sub-zonal offices. Screening of irrational or harmful drugs is an ongoing exercise and 44 categories of formulations have been banned so far and the definition of new drugs has been widened and guidelines issued on clinical trials. Five leading hospitals at Pondicherry, Chandigarh, New Delhi, Bombay and Lucknow have been identified as Adverse Drug Reaction Monitoring Centres [1].

Pharmaceutical pricing in India

The Drug Prices Control Order (DPCO) of 1979 divided the drugs brought under the price control into four categories according to how essential they were deemed to be, allowing maximum profit margins to the least essential drugs. The idea was that the lower profit margins from life-saving and essential drugs (Categories I and II) would be compensated for by the higher margins for Categories III and IV drugs. However, the result was that drug companies decreased and even stopped the production of life-saving and essential drugs and concentrated on the more profitable ones [3]. In India, every year hundreds of people still die from malaria for which chloroquine is a cheap but effective remedy; thousands go blind due to lack of vitamin A, and millions suffer from endemic goitre due to iodine deficiency. India has also the largest number of people suffering from tuberculosis and leprosy in the world. The 1987 Drug Prices Control Order reduced the number of price controlled drugs from 347 to 142 and increased the maximum profit margins for these drugs. Moreover, the 1995 DPCO also decreased

the number of some drugs essential for public health, like ferrous sulphate for anaemia and most of drugs for tuberculosis, malaria, leprosy, rheumatic heart disease, rabies vaccine, cancer and tetanus [3]. This resulted in decrease of the number of essential drugs reaching the poor. Moreover, Indian markets are flooded with over 100,000 formulations and there is no system of central registration of these formulations. These drugs are sold under numerous brand names rather than their generic names, resulting in phenomenal increase in drug prices [3]. Although the ceiling prices are fixed for the drugs for commonly marketed standard sizes of price-controlled formulations [1], the pharmaceutical policy of 2002 calls for further relaxation of production and price controls. It is expected that less than 40 drugs will remain under price control [3]. So, while in 1979 there were 347 drugs under price control, in 2004 the number dropped to 74. This has resulted in exorbitant price rises [4]. In India it was noted that the increase in the price of the basket of drugs was linked to the New Drug Price Control Order and that the quality of the drugs in the basket was comparatively poorer than the quality of drugs in general. This seems to reflect a shift in the practice of the industry, the essential drugs under generic name being left for production to small manufacturers, most of which did not enforce the GMP (Good Manufacturing Practices) [5].

Pharmaceutical supply systems and quality assurance in India

Since 1983, the government has issued various orders banning several harmful and/or useless formulations marketed in India, but to little effect [3]. Despite the phenomenal growth of the drug industry during the past five decades, the availability of modern drugs is still low. For example, in 1984 only 5% to 6% of the population could afford the modern drugs they needed. Another 25% had limited access to essential drugs [3]. Moreover, a majority of people living in rural areas and urban slums, the main victims of endemic and epidemic diseases, had little or no access to modern drugs. The market structure of the Indian pharmaceutical industry is skewed with a small number of large firms and many smaller pharmaceutical companies. The large private sector includes domestic manufacturers, foreign controlled companies (with more than 25% equity held by a foreign company) and smaller private firms. Therefore, pharmaceutical policy in India is perceived as industrial policy, not a health policy [7].

Most of the Indian drug manufacturers are privately owned, small-scale and many of them use problematic quality assurance systems and procedures. On the other hand, due to strict regulations, some of the Indian manufacturers have proven their ability to take a product from API (active pharmaceutical ingredient) to finished dose form at a level of quality suitable for use in regulated markets [7]. The quality of drugs, mainly in the private sector, remains an important problem in India [5]. There is a considerable variability in the quality of drugs throughout the country. About one in 10 of all private pharmacies reported quality violations, with most of the

“out of quality” drugs being manufactured by smaller firms. Each Indian state is responsible for quality assurance activities and there is wide variation in implementation [7].

Rational use of drugs in India

In the absence of a clear, comprehensive and rational drug policy, a distorted pattern of drug production and the proliferation of non-essential, irrational and harmful drugs can be still observed in India. The All India Drug Action Network (AIDAN) is a network of civil society organisations, that has been campaigning for a rational drug policy for the last two decades [3]. The government has taken little initiative to fulfill its statutory function to monitor manufacturers’ promotional literature and has taken no steps to supply objective and unbiased drug information to prescribers. Some constituent bodies publish drug information bulletins for prescribers. However, representatives of pharmaceutical companies are the only source of information to prescribers in remote areas [3]. The picture in terms of accessibility to essential drugs is not impressive.

Pharmaceutical research in India

Accordingly to the TRIPS (Trade-Related Aspects of the Intellectual Property rights) compliance of 2005, Indian pharmaceutical companies now have to patent pharmaceutical products. This will likely provide access to international technology, R&D and global marketing but it may also result in rising drug prices and intra-country competition from the many indigenous drug companies. Indian pharmaceutical companies will have to develop their own “know-how” and R&D centers to cope with what will be fierce global competition within and outside the Indian market for branded medicines. As companies like Ranbaxy Laboratories and Dr. Reddy’s Laboratories are pushing to expand their exports and are increasing their spending on R&D with hopes of becoming more important players worldwide, the traditional business models for Indian drug makers will not work much longer. The responsibility to stimulate R&D and promote local industry is most often discussed in terms of industrial, rather than health, policy. This seems to be also the approach by the International Finance Corporation (IFC). Most of the pharmaceutical industry projects supported by the IFC focus on exports rather than seeking to satisfy internal health needs or address affordability problems [7].

Final remarks on Indian drug policy

India is well on its way to becoming a global “innovation-intensive pharmaceutical giant”, helped by the fact that policy makers and the government are planning to increase national spending on pharmaceuticals R&D [6]. The following problems have been recently highlighted with regard to the future of the Indian drug policy:

1) the need to review the hypotheses on policy process,

- 2) the identification of specific policy innovations from the cross-national approach that could improve the design and the implementation of pharmaceutical policy,
- 3) the ways to improve the political feasibility of implementing those innovations within specific political contexts [5].

Drug and health activist organisations have recently intervened in a petition challenging the government’s recent move to further curtail the number of drugs under price control. At the heart of these efforts is the principle of entitlement. Neither the Constitution nor the National Health Policy guarantees the right to health or to medical care including affordable and appropriate drugs. The community of health professionals must recognise this right and help people exercise it [3].

The ensuring the effective implementation of a policy requires continuous tending, caring, revising and weeding, much like a garden. Lack of attention during the phase of implementation can result in a policy falling into disrepair or even reversal. In many ways, the most difficult challenges occur during implementation, when the goals and mechanisms of a policy must be put into practice [5].

■ The characteristics of the national drug policy in Nepal

Objectives and major components of the national drug policy of Nepal

Nepal is a landlocked country in the South East Asia Region with its borders as China and India. It is one of the low income countries in the region and harbours a population of about 27 million. The government of Nepal has formulated the National Drug Policy in 1995, in consistency with the National Health Policy of 1991. This policy has been designed in order to ensure the access, quality and rational use of the drugs in the country. The main objective of the National Drug Policy is “To maintain, safeguard and promote the health of people by making the country self-reliant in drug production; ensuring the availability of safe, effective, standard, and quality drugs at affordable price in quantities sufficient to cover the need of every corner of the country; and to manage effectively all the drugs-related activities including production, import, export, storage, sale, supply and distribution” [8]. The other objectives include the establishment and promotion of the national pharmaceutical companies’ production capacity thereby promoting the domestic drugs. It also focuses on development of human resources for the pharmaceutical sector along with establishing the quality control lab for the testing, analyzing and standardization of drugs. The policy also has the objective of monitoring the uniformity of the drug prices and promotion of the Ayurvedic, homeopathic and other forms of traditional medicine.

Several policy strategies have been developed and implemented to achieve the objective set by the National Drug Policy. The strategies are basically developed as per the WHO’s guideline and they cover all the basic components needed in a National Drug Policy. These

strategies for the improvement of drug use are broadly educational, managerial, economic and regulatory.

Selection of essential drugs and ensuring a proper supply system is one of the components. The policy aims to develop a list of essential drugs to be used at different levels of health facilities in the country, in accordance with the WHO's concept of essential drugs. For proper supply system the procurement, storage and distribution strategies are formulated. The procurement is supposed to be done by opening tenders and from authorized pharmaceutical companies identified by the Government of Nepal. The procurement should be done as per the generic names of the drugs. The procurement, storage and distribution of drugs should be carried out by qualified pharmacy personnel. For the sustainability of the supply, of the required drug volume, the strategy of partial and full cost sharing has been adopted and will be expanded in a phase wise manner throughout the country. The policy has also provided the room for the introduction of modern and scientific methods for the proper supply and distribution of drugs and for necessary changes for the betterment.

Regulation and quality assurance is another component required in a National Drug Policy. The drugs quality should be monitored regularly. The National Drug Policy of Nepal mentions the development of National Medicines Laboratory as an independent national quality control lab and phase wise extension of the five regional drug testing labs throughout the country. The policy mentions that the drug registration in Nepal will be based on the scientific facts and standards. The drugs not meeting the given standards will be banned. The certificate of the "Good Manufacturing Practices (GMP)" as per the WHO is compulsory for the registration of imported drugs, while the standards of "The National Code of Drug Manufacturing Conduct" are to be followed by the manufacturers of domestic drugs. The drug registration is supposed to be updated regularly and for the imports of drugs a specific custom point has been set.

Rational use and education is another major component of the National Drug Policy of Nepal. The provision for the regular training of the health workers prescribing drugs in various levels of health facilities on "Standard Drug Treatment Schedule" exists and the health workers should follow the schedule of their level while prescribing drugs. This promotes the rational use of drugs. It has been mentioned that for the promotion of the rational use of drugs necessary training modules and guidelines will be developed and pharmacists and other health personnel at hospitals will be trained on the production technology, quality assurance and GMP. "Drug Information System" for providing the information details on drugs is to be developed in an effective manner. The involvement of the private sector in providing information on drugs and their rational use is also necessary. The National Antibiotic Control Committee is the body responsible for the prudent use of the antibiotics, while the National Antibiotics Therapeutics Advisory Committee provides necessary advice on different antibiotics.

Human resource development and promotion of national drug companies, as a component in the National Drug Policy, relates to the development of pharmacy personnel from the academic and non-academic institutions and it puts the domestic pharmaceutical companies, domestic drugs and importation of the needed pharmaceutical machineries into the national priorities.

Promotion of traditional medicines is another unique component. There are various plans set up for the promotion of the traditional medicines such as the Ayurvedic medicines and homeopathic medicines in Nepal. Some of them are: development of needed human resources; development of formulary on dosages; scientific evaluation of safety, efficiency and efficacy.

Regular research and development has been planned. Regular randomized clinical trials of new drugs are supposed to be performed by the Nepal Health Research Council under the Ministry of Population and Health. Researches on new technologies are planned to be conducted regularly.

Monitoring and evaluation and seeking technical cooperation is also an essential component of the National Drug Policy of Nepal. Plans for the regular monitoring of the policy implementation are mentioned, as well as that with co-operation of national and international organization, training and technology exchange activities in the pharmaceutical sector will be conducted.

Implementation of the national drug policy in Nepal

The National Drug Policy of Nepal has been developed as per the WHO guidelines. Accordingly to the WHO it is recommended to all the countries to formulate and implement a comprehensive national drug policy. As a rule, the national drug policy should show the evidence of commitment for achieving the desired goals and provide guidance to reach the goals. The broad objective of the national drug policy is to promote equity and sustainability of the pharmaceutical sector. Other basic objectives are to ensure the access, quality and rational use of drugs. A national drug policy should fit with the country situation, national health policies and political priorities. It should fit within the framework of a national health policy and a particular health system and it should be consistent with broader health objectives [9].

The comprehensiveness is the strength of the National Drug Policy of Nepal. It has been developed in consistency with the National Health Policy and it has covered the three major areas of access, quality and rational use. The approaches are developed and refined within the national political context. The guidelines and appropriate checklists are properly developed. Some of the examples are:

- 1) the guidelines for drug donation,
- 2) the guidelines for the ethical promotion of medicines (this includes several rules to be followed by pharmaceutical companies while promoting their drugs, such as sample medicine provision, sponsoring health workers or programs, etc.),

3) the guidelines on labelling or stability of pharmaceutical products.

The lists of drugs banned in Nepal also exists and the list of psychotropic and narcotic substances is updated. The record keeping of administered psychotropic and narcotic drugs is a mandatory practice. Other important points of the National Drug Policy are the several criterions to be fulfilled within the process of the new company registration, which are designed to prohibit the entry of poor quality companies. There are some special forms developed by the Department of Drug Administration to monitor the quality and safety of drug use in the country. Examples of them are: the Adverse Drug Reaction Form, the Sample Submission Form and the Auditors Notebook for GMP [10].

Not surprisingly, what happens in most of the countries, the implementation of the policy is not fully working as expected. Though the National Drug Policy is in place, the question: "Does it function properly?" needs to be answered, as most often the policies might limit themselves to the paper itself.

The rules set by the drug policy in Nepal are not found to be implemented fully. There exists the lack of concerns for financing and pricing issues. The prices of drugs are not found consistent all over the country and the difficult topographical features of the country worsen this situation further. The difference in performance due to the geographical situation of the country has not been addressed by the National Drug Policy. It is always difficult to supply the drugs in the remote areas, for the hard to reach populations. Also a standard storage system might not be available which will lower the shelf life of the drugs. Though effort has been made to prepare the list of essential drugs to promote the rational use in every level of the government health facilities, least attention has been paid towards the private sector. The private health facilities and clinics are not obliged to follow the essential drug lists used in the government health facilities and this might result in the irrational drug use. There is a need to address this issue in the National Drug Policy.

Another example of poor implementation of the National Drug policy of Nepal is the weak regulation of the drugs which can be sold without prescription (OTC drugs). The OTC drugs usage is often likely to be irrational in Nepal. Also, the pharmacies generally do not have the appropriately trained and qualified human resources. Though it has been mentioned in the policy that the different clinical trials will be carried out for introduction of new drugs, nothing much has been done in this sector.

Conclusions on the national drug policy of Nepal

National Drug Policy of Nepal is very much consistent with the National Health Plan and envisages the concept of equitable access, good quality and rational use. It incorporates basically four major strategies, i.e. educational, managerial, economic and regulatory – for achieving the objectives set forth. As Nepal follows a competitive market system, where both domestic and

foreign manufacturers compete, the implementation of the policy should be strengthened further. Focus has to be given in enforcing the regulatory measures and production of the necessary human resources to carry out tasks as reflected by the policy. The affordability and price uniformity of the drugs should also be taken as point of high priority, as about one third of the country population lives below the national poverty line and this population might not be able to access the drugs it needs. There is much to be done in the area of increasing community awareness of effects, risks and benefits resulting from the use of drugs and also in the area of promoting the rational drug use. The quality control labs need to be extended so that quality checks can be done regularly. Thus, the Department of Drug Administration under the Ministry of Health and Population of Nepal, as well as other key stakeholders, such as pharmaceutical companies, health workers and consumers, should all play an effective role in implementation of the National Drug Policy. Only this way the objectives set by the National Drug Policy would be met, contributing to the improvement of health status of the population.

■ The characteristics of the national drug policy in Bangladesh and its role in development of the national pharmaceutical industry

Introduction to the pharmaceutical policy of Bangladesh

In most of the low income countries where out-of-pocket expenditure is the major source of health care financing, pharmaceutical expenditure usually is the largest part of the healthcare expenditure. Moreover, in both developed and developing countries, recent pharmaceutical inventions and innovations are some of the main reasons for global increase of healthcare costs [11]. Bangladesh is one of these low income countries in South East Asia, having more than 80% of its healthcare expenditure spent out-of-pocket [12]. The total healthcare system is fairly inadequate to provide even minimal coverage to the population. The current GDP of the country is 488 USD *per capita* and state is investing only 3% of its GDP to the healthcare sector [12, 13]. Only 28.4% of the total healthcare expenditure is contributed by the state and whole remaining part is paid out-of-pocket [12]. Almost 80% of the out-of-pocket expenditure is spent on pharmaceutical products. Because of their high prices, the pharmaceutical products are often not accessible to the ordinary people. As a result, the complete cycle of treatment is quite a rare experience for the poor people.

Bangladesh has had the pharmaceutical policy introduced in 1982 under a military regime. The existing drug policy is quite old and insufficient to meet the current challenges, faced by the pharmaceutical sector as well as the whole national healthcare sector. Although a preparation of a new drug policy has been finalized in 2004, at the official level, this document is yet to be passed by the national parliament. Official version of the latest drug policy is not yet available publicly.

The aim of this chapter is to describe the characteristics of the pharmaceutical policy of Bangladesh and to explain the role of this policy in development and regulation of the national drug industry and practices related to drug use and management. This chapter also covers these issues of pharmaceutical policy that are related to ensuring the adequate access to the necessary drugs for all citizens of the country. The overall discussion is based on the drug ordinance of 1982 as the latest drug policy is still not accessible [14].

Healthcare system of Bangladesh in brief

Due to very low investment of GDP on health, the overall healthcare status in Bangladesh is not good. Bangladesh achieved a significant improvement in various health care indicators in recent years but overall healthcare system is still in a primitive condition. The majority of the disease burden is due to the nutritional disorders of children and various infectious diseases but also there is a growing trend of incidence of non-infectious diseases, like cardiovascular ones and diabetes. There are two basic types of healthcare sub-systems in Bangladesh – public and private. Within the private healthcare system there are organizations which are private for-profit and not-for-profit. In public hospitals patients are supposed to get services almost free of cost, except a very minimum user fee, but in reality the public hospitals are lacking many resources, like diagnostic services or medicines. It is almost given that only prescription is possible to be received in a public hospital instead of the drugs. It means that patients have to buy necessary drugs and medical supplies. The Ministry of Health and Family Welfare, as the department of the government which is responsible for looking after the whole healthcare system, has three major wings. They include three directorate offices covering health, family planning and affairs related to drugs and diagnostics. The directorate of drug administration is the highest regulatory authority for the pharmaceutical sector in Bangladesh. The mission of this organization is to ensure that the common people have an easy access to the useful, effective, safe and good quality essential drugs and also other drugs, at affordable prices. Currently there are three streams of drug producers in Bangladesh: Allopathic, Homeopathic, Unani and Ayurvedic. There is a total of 807 drug manufacturers, including 231 Allopathic, 204 Ayurvedic, 295 Unani and 77 Homeopathic drug producers [14].

Evolution of drug policy in Bangladesh

The basic drug policy was introduced in unified India in 1940 by the colonial British administrations. As it was introduced by the British government, the inherent intention and most of the clauses of the drug policy were actually in favor of expanding British market in this sub-continent. Bangladesh was a part of Pakistan after gaining independence of India from British colonial regime and further in 1971 Bangladesh became an independent country. Unfortunately Bangladesh had no drug policy

until May 1982. With some amendments, Bangladesh was following that primitive drug policy developed by British administration.

Before introduction of the Drug (Control) Ordinance of 1982, the drug regulations were being very weakly enforced. Before the Drug Ordinance of 1982, there were in total 4,170 brands of drugs which were produced by the modern pharmaceutical companies under the regulations of the Drug Act of 1940. As part of the existing industry did much progress by that time and also the medical professionals had progressed at a significant pace, the drug Act of 1940 was considered grossly out-dated and inadequate to meet the needs of healthcare system. It was especially inadequate for controlling the prices of pharmaceutical raw materials and processed drugs. As the drug policy was not updated properly, it also failed to prevent the appearance of substandard and spurious drugs on the market. There were also present problems of unethical promotion performed by pharmaceutical companies and proliferation of harmful and useless drugs. Surprisingly, it was found that most of the drugs on the market were useless, unnecessary and even harmful in some cases. From 166 licensed pharmaceutical companies only eight multinational pharmaceutical companies produced 75% of the total supply of drugs. The drug manufacturers did not bother to ensure supplies of essential and life saving drugs to the common people of Bangladesh, one of the least developed and poorest countries in the world. Many pharmaceutical companies were involved in production of unnecessary and marginally useful drugs of doubtful value, such as vitamins, tonics, enzymes, alkalisers, gripe waters, cough mixtures, etc. To stop the production of these useless, unnecessary or harmful drugs, to control the import of drugs, to ensure the basic health needs of the poor and vulnerable people, to stop the misuse and dispatch of foreign currency, an eight member expert committee was formed on 27 April 1982. According to its recommendations, the National Drug Policy (NDP) was promulgated on 12 June 1982. For many reasons the previous drug policy was inefficient to meet the country's needs. There were identified at least five prominent causes to replace the former drug policy by a newer one:

- 1) problems related to the price control,
- 2) huge number of unnecessary drugs on the market,
- 3) presence of outdated and harmful drugs,
- 4) absolute dependency of the country on the multinational pharmaceuticals companies,
- 5) lack of initiatives to grow local industries.

To combat these problems and to develop a strong local industry, first drug policy was introduced by a military government in June 1982. In reality, it was not a well developed drug policy with a proper vision but nevertheless it had some positive impact. Initially there were 13 objectives and 16 regulatory clauses in the policy document and later on additional eight objectives were included. The basic idea of the drug policy was to ensure the access to the essential medicines, to the general population at reasonable prices and to develop a strong and modern local pharmaceutical industry sector. The objectives in the policy document were as follows:

- 1) to ensure the availability of essential drugs at reasonable prices,
- 2) to control the prices of imported drugs,
- 3) to gradually stop the imported and locally manufactured unnecessary drugs,
- 4) to promote local industry set up to attain the essential drugs production,
- 5) to prohibit importing and manufacturing of injurious drugs,
- 6) to abolish unethical advertisement and promotion of drugs,
- 7) to control prices of raw materials,
- 8) to ensure that all companies, including multinational ones, will obligatorily produce the essential drugs,
- 9) to establish the drug courts,
- 10) to ensure legal punishment for any violation of the drug rules or in case of adulteration of the pharmaceutical products,
- 11) to strengthen the system of procurement, storage and distribution of drugs,
- 12) to give the priority to provide legal and financial coverage for the industrial establishment by local initiatives,
- 13) to take gradual steps to produce and sell all medicines under their generic names instead of the trade names.

There were 16 additional clauses as drug rules or criteria to be maintained by pharmaceutical companies in the country. These 16 criteria were mostly related to the production and promotional practices. For example, all kinds of fixed dose combination (FDC) preparations were banned as these combinations were not properly graded and might cause toxic effects to the patients. All kinds of narcotic drugs were extremely restricted in use and only the pharmaceutical companies, which were owned by the country government, were allowed to produce them. Some substances were also banned to be used in any preparations, for example the codeine or its derivatives were on such a negative list. To make the drug policy more uniform to all sectors, some important recommendations were adopted, including the selection of essential drugs and their classification, the preparation and publishing of the national formulary, the development of an independent registration system for the Ayurvedic, Unani and Homeopathy medicines or the establishment of one national and a few regional drug testing laboratories.

After the introduction of the drug policy there was a serious enforcement of the regulatory rules in the initial few years. This enforcement resulted in emergence of the new era in the pharmaceutical sector development. The total number of registered products, both locally produced and imported, was 4,340. Out of a total of about 4,000 brands of allopathic drugs in the market, the Drug (Control) Ordinance cancelled the registration or license of 1,742 brands manufactured or imported into Bangladesh. These drugs were considered as unnecessary or even injurious ones. Out of these 1,125 were locally produced drugs and 617 were imported drugs. Several companies registrations were cancelled or suspended for not maintaining the due quality and the appropriate

production practices. During that period, altogether 212 pharmaceutical companies were in the sector; 48 companies were suspended and nine companies were totally liquidated. Even multinational companies were also facing problems with compliance to the new regulations and some of them had to leave their operations due to the lessened profitability. Small drug retailers were also under the monitoring umbrella of the drug policy, because one of the objectives of the drug policy was to develop the drug retailers chains owned by the trained pharmacists.

The pharmaceutical policy impact on the drug industry in Bangladesh

One of the most remarkable aspects of the development of the pharmaceutical industry in Bangladesh is the emergence of local companies in wake of the Drug Control Ordinance of 1982. The policy provided additional legislative power to control this sector and to provide appropriate legal coverage. The Drug Ordinance of 1982 had played the supreme role in development of the national pharmaceutical market and the national pharmaceutical industry. In reality this drug policy ultimately "reversed the pyramid". Before 1982 there were 212 pharmaceutical companies in the country and out of them only eight Multi National Companies (MNC-s) were producing 75% of the total market production. The remaining 204 companies produced only 15% of the market share [15]. After two decades the total picture has been changed to show reversed proportions: in the recent yearly statistics the number of pharmaceutical companies is almost the same, with a marginal increase (231), but currently the local companies produce almost 95% of the market share and the remaining part is produced by MNC-s. Earlier Bangladesh had to import pharmaceutical products made by 122 foreign companies from 23 different countries. Now the Bangladeshi local pharmaceutical companies export their drugs to 52 different countries, including the USA, the UK and many other developed and developing countries [14]. The market volume increased several hundred folds. Currently the pharmaceutical market size is almost 537 million Taka per quarter, that means almost 500% growth from the pre – drug policy time. After establishing the national drug testing institute, the rate of testing newer drugs has increased and at the same time the rate of using the sub-standard drugs has also decreased significantly.

Constraints and challenges of the national drug policy of Bangladesh

The prominent limitation of the current drug policy is that it is more than two decades old and it urgently needs to be updated. During these two decades both national and international perspectives of the healthcare system have changed a lot. The number of essential drugs has been raised enormously and these new drugs should be included into the Bangladeshi essential drugs list as soon as possible. Also the prices of the locally made generics and the innovative molecules should be reviewed to broaden accessibility for the poor people. The WHO and

some other international organizations have developed specific features of drug policy for the low income countries and they should be reviewed and incorporated. The pharmaceutical marketing expenditures are rising and that leads to the increases of drug prices in the local market [16].

The number of companies producing traditional medicines is quite high but still the market shares of these companies are not high. As a low-income country, Bangladesh is enjoying some extra benefits and exemptions from TRIPS and other international business agreements. According to the TRIPS agreement, Bangladesh will be able to produce many innovative drugs from 2016. However, Bangladesh has no backup industries involved in making raw materials and necessary machineries, therefore the country may not be able to grab this opportunity. The current drug policy is not suitable to support the development of these kinds of backup industries and to facilitate the further development of the local pharmaceutical industry.

To ensure more accessibility to the essential drugs for the poor people of the country, the list of the essential drugs should be updated immediately. The price controls should be adopted not only in relation to the essential drugs but also to some special drugs, e.g. the oncological ones.

The Drug Ordinance of 1982 has created quite favorable conditions both for the Bangladeshi patients and the local industry. It is expected that the forthcoming drug policy will reflect the international recommendations of essential drugs and at the same time it will be still or even more favorable for developing the local pharmaceutical industry along with the establishment of the supportive industrial sector.

■ The concluding remarks on features of the national drug policies of India, Nepal and Bangladesh

The three countries of the Indian sub-continent have undergone significant changes in the recent decades. India has become a pharmaceutical giant producing drugs which are exported not only to other countries in the Asian region but also to many developing and developed countries worldwide. The adherence to the GMP standards or maintaining the appropriate quality in the processes of drug production are no longer problems for many Indian companies and they promote their successful performance on the international drug market. Neighboring Nepal focuses mainly on its internal market and makes efforts to accommodate to the challenges brought by advances in the area of modern health care. Bangladesh is making efforts to provide equitable and affordable but basic health care coverage for the poor majority of its population and has some successes in this task.

The pharmaceutical policies in all of these three countries have important places as the very specific parts of the broader national health policies. To some extent all of these drug policies are lead by the guidelines established by the WHO for national drug policies worldwide. It

seems that Bangladesh should make the biggest efforts in order to up-date its drug policy and to fit better into the changing landscape of contemporary health care and global economy of the XXI. century. Still struggling to provide the most basic help for its poorest citizens, Bangladesh in its own way is bravely entering markets of the richest countries of the world, offering them its home produced pharmaceuticals. Bangladesh is also thinking about reaching the full compliance with the international agreements on the intellectual property rights – something too difficult to imagine some time ago. Nepal has quite well organized and planned pharmaceutical services and this country is probably just in the eve of reformulating its drug policy originated more than a decade ago.

Interestingly to the countries of the West, the role of the traditional medicines, like Ayurvedic or homeopathic ones, is not decreasing on the Indian sub-continent. To the contrary, they all have their important places in the official drug policies and in some way they are even prioritized and their use is unchangeably popular within the wide populations.

■ Streszczenie:

Charakterystyka współczesnych polityk lekowych Indii, Nepalu i Bangladeszu

Słowa kluczowe: polityka lekowa, przemysł farmaceutyczny, dostępność leków, reformy opieki zdrowotnej, Bangladesz, Indie, Nepal

Artykuł charakteryzuje polityki lekowe trzech krajów subkontynentu indyjskiego: Indii, Nepalu i Bangladeszu. Wszystkie spośród tych polityk mają swoje głębokie źródła w czasach kolonialnych, gdy ta część świata znajdowała się pod panowaniem brytyjskim, oraz odnoszą się do złożonej problematyki azjatyckich krajów rozwijających się. Indie kładą coraz większy nacisk na innowacyjność i stają się „globalnym gigantem farmaceutycznym”, prowadzącym ekspansję nawet na rynki krajów bardziej od siebie rozwiniętych. Wysiłki Nepalu skupiają się przede wszystkim wokół problematyki wewnętrznej; kraj ten podejmuje wyzwania związane z unowocześnieniem opieki zdrowotnej. W Bangladeszu kładziony jest nacisk na to, aby w sposób sprawiedliwy i przystępny zapewnić podstawowe świadczenia zdrowotne dla bardzo biednej większości swojej populacji. Na całym subkontynencie indyjskim mają bardzo duże znaczenie leki wywodzące się z medycyny tradycyjnej, w tym takich jej gałęzi, jak Ayurveda lub znacznie młodsza homeopatia. Wymienione charakterystyki mają swoje odzwierciedlenie w krajowych politykach lekowych. Wszystkie trzy kraje omawiane w artykule znajdują się na różnych etapach zaawansowania we wdrażaniu ochrony praw własności intelektualnej, która odnosi się również do leków. Do pilnych i priorytetowych zadań polityk zdrowotnych a także lekowych tych krajów należy wciąż zapewnienie obywatelom dostępu do leków podstawowych, określanych przez WHO jako *essential drugs*.

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