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NATIONAL DRUG POLICIES- A SYSTEMATIC REVIEW

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ABSTRACT:
National Drug policy is a goal commitments and a guidance of action of drugs. They have different priority of medium goals to long-term goals which is set by the governments for pharmaceutical sectors, and identifies them as different strategies for attaining the goals. This review represents and ensures the adequate supply of the safe and effective drugs of good and better quality, so that every country should have a sound of National Drug Policy as an integral part of its health policy. In different countries there are certain rules and regulation for import and export of drug in various region as well it regulates the law for different developing and developed countries.
Keywords: Health, policy, regulation, Law.

Introduction

Different countries have inadequate supply of drugs according to their health needs, while inadequate use of drugs possesses the problems in both developed countries as well as developing countries. Somehow the reasons are not only financially and in budget concern, but due to lack of infrastructure and human resources.[1, 2]

They also depends on the behaviour of the government bodies, also from prescribers, dispensers as well as consumers a pharmaceutical company .Drug policy ensures an adequate supply of drugs with better quality.[3]

PRINCIPAL AND MECHANISM

National Drug Policy should be based on the principles and the mechanisms which will provide the framework and tools for established good quality, affordable prices, drugs are also prescribed properly and used in very convenient way. Following problems that affect the nation's drug supply system.[4,5]

1. Shortages of needed drugs in rural health centres, while excesses of less useful drugs persists.

2. Generally inefficient management of drug supply to hospitals, health centres and discrepancies, especially problems of stock managements, inventory record keeping and supply ordering.

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3. Mal distribution of drugs in the public sector, favouring hospitals over health centres over dispensaries, with a general bias to urban over rural areas.

4. Inappropriate prescription patterns of drugs by physicians and other health providers, including over prescription and prescription of clinically ineffective or relatively expensive pharmaceutical, related to shortages of needed drugs and to inadequate training of health professionals.

5. Popular demand for drugs, tending to stress inappropriate drugs, related to people's lack of understanding of disease causation and treatment, to prescription patterns and medical practices, to inadequate sources of public information about drugs, and to private advertising.

6. High price of drugs in the private sector, which may reduce access by poorer groups of society to medicines they need.

7. Maldistribution of drugs in the private sector, with focus on urban markets and on high priced brand-name products rather than low-priced generic products.

8. Tendency to prescribe brand-name products rather than generic products, as well as tendency to purchase brand names than generic products. Problems in government's drug supply system, damages, credibility of government health services in general and thereby may decrease utilization.

9. Problem of increasing financial support of government's drug supply system without decreasing access to poorer groups.

13. Pharmaceutical industry is characterized by an unusual degree of market power.

14. The marketing of particular drug in a country does not necessarily reflect the disease pattern of that country.

15. All the information on pharmaceuticals which are developed in developed countries are not necessarily transferred to developing countries.

16. There is inefficient, inadequate or not at all control over quality, entry, registration, marketing, and use of pharmaceuticals in some of the developing countries.

An ideal National Drug Policy should be one which will able to tackle all above problems and should come out with the solutions and mechanisms such that all the essential drugs are made available to entire population at all times, and to ensure safety, efficacy, and quality of medicines.

The Ministry of Health is the natural leader in developing such policy. But other government departments which have roles to play in the procurement, processing, distribution and rational use of drugs - among them those responsible for planning, finance, education, industry and commerce - will need to participate in this work.

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The key elements of an ideal National Drug Policy will be ;[6,7]

1. Selection of essential drugs.
2. Legislation and regulations - licensing and control.
3. Supply - procurement, distribution, storage and local production.
4. Quality assurance.
5. Cost and price of drugs.
6. Patents and trade names.
7. Appropriate drug use - rational drug use, self medication, health education.
8. Drug information and promotion - proper dissimulation of information on drugs and ethical promotion of drugs.
9. Monitoring and evaluation.
10. Manpower and development.
11. Financial resources.

To understand overall impact of operations of TNCs in pharmaceutical supply system of developing countries, it is utmost necessary to study the different aspects of development of new drugs by these firms. The present status of some of the above areas of concerns, such as procurement and distribution of drugs, quantity control ,monitoring and drug legislations in different countries will be discussed in following chapters.

Some of the topics like selection of essential drugs, inappropriate use of drugs, promotional efforts of pharmaceutical industry, dissimulation of information are already covered under Review of Literature for “Genesis of Essential Drug Concept”

PROCUREMENT AND DISTRIBUTION -[8]

In establishing national pharmaceutical services, The most basic requirement must is that patients should have safe, ease and reasonable access to medicine. This implies to well-structured and organized procurement and distribution system. The main objective of policy is to achieve the requirements of population and avail the drugs everywhere in the country.

(a) Procurement and Distribution in Developed Countries –

In developed countries, the drugs is authorized by regulatory authority which are distributed the drugs commercially as well as via intermediate’s and pharmacies and they open accordingly patient need. Some developed countries have control in both public as well private sector. But when there is no control for the establishment of new pharmacy ,then so high population area have less substantially and it indicate the lower figure and if pharmacies in the least densely population area serve more numbers of people which is spread all over the countries.

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According to data in Norway, As per population per pharmacy range vary from 20000 in rural area and 10000 in the Oslo area. For opening the pharmacy in particular areas of populations and nearby pharmacy and the transport facility. One of the unique system of Norwegian pharmaceutical distribution is that, the tax imposed on each pharmacy every year is calculated on the basis of their annual turn-over of individual pharmacy and it is very progressive along with the progress of business.

And most of the tax used for subsidizes the pharmacist, but their profit pattern are not satisfactory due to location where population area is less.

The Wholesaler of pharmaceutical product in Norway is carried out by their state mono-poly i.e Norsk medical depot (NMD). In parallel institute in Hungary also state own is called GYOGYERT, which is key organization in Hungarian drug distribution system (RUD).

In UK the drug distribution is mainly dine by private sectors via manufacture to retailers.

But wholesalers cover costs and earning profits through margin which is allowed for their retail price.

The three different ways in pharmaceutical products which is distribute at retailer level in UK.

(A) Prescription Only Medicines [9,10]

(b) “Pharmacy medicine” (P), it may sold over the counter in pharmacy.

(c) “General sales list medicines” - Pharmaceutical product sold at any shops in village stores .In some developed countries the distribution of pharmaceutical products is regulate by the law on the basis of criteria where population served. They also serve via distance between the pharmacy and transport facility .Ex- Sweden, Denmark, Italy etc.

(1) Public Sector –In developing countries the situation is totally differ, and it is totally based on actual incidents in country. The shortage of essential drugs which leads to the discovery where half of year is supply is shipped .and where no one ask where drug are spoilt and render toxic.

(2) The inadequate supply and distribution of essential drugs are very complex and technical arising from lack of resources. Some of the results are:-[11]

- It takes more years for delivered the drugs because of the administration complexity

Due to the information system doesn’t work properly so, the quantity of drugs cannot be calculated easily.

- If Storage conditions not in proper manure so that drugs are not protected from sunlight, moisture or from any theft.
- If transport doesn’t organize properly, then alternative solutions are not be considered.

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Overall picture of how procurement and distribution system operates in most of the developing countries can be drawn from the study done by John S. Yudikin (1980) in Tanzania. The National Pharmaceutical Company is a government controlled which separately manage from Ministry of Health and they sell 90% of its drugs to private institutions and hospitals.

The individual share of CMS and NAPCO in total annual purchase of drugs in Tanzania is shown in following table 5:

Table no.5: Drug purchase, Tanzania, 1975-1976 (in millions of shillings)

Source of Purchase	Purchaser Government Health Units	Purchaser Non-Government Bodies	Total sales
Central Medical Stores	69.8	8.6	78.4
National Pharmaceutical Company	4.7	66.3	71.0
Total Sales	74.5	74.9	149.4

**Source: Yudkin John S (1980), Int J Health Services 10 (3), p. 457*

(3) Private Sector Distribution –[12]

Private drugs sales are highest seller and distributor in public sector. In developing countries, distribution of drugs through this sector is about total 90%. It is happens in Bangladesh, Nepal and North Yemen

Private sector consists of pharmacy and pharmaceutical outlets may purchase drug from the government import agencies, this is the mono-poly for importation, as Algeria, Sri Lanka, and others directly from foreign suppliers as in Bahrain and other neighboring Gulf Countries or from local wholesaler and manufacturers as in Cameroon, India, Brazil and other industrialized countries.

Mostly drugs distributed by the pharmacy and pharmaceutical outlets is theoretically maintained and control by government, but the practices of some of the country are concern and such controls ensure that the drug which meets the health's and need adequately

Private distribution favors proliferation for brand name product instead of low cost generic product the former fetches more profit to both manufacturer and pharmacy owners.

DRUG REGULATION[13,14]

Medicines are among the most regulated products. All over the world it is impossible to give or sell any medicine if a governmental agency has not given adequate authorization.

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(Called AMM in France, CSM approval in the UK, NDA in USA TGA in Australia, and FDA registration in India and many other developing countries). This can be obtained only by pharmaceutical companies which can demonstrate both the control of quality and satisfactory data showing the efficacy and reasonable safety of the product. The widespread adoption of such regulation is barely 10 years old.

As most of the modern drugs were innovated in developed countries only, all of today's rules and laws regulating drug manufacturing, sale, distribution, advertisement and use were initiated in developed countries.

In all these countries, regulation began as a reaction to therapeutic accidents which aroused public opinion. Because regulations were hastily made to prevent repetition of the accidents which had led to them, they at first differed greatly from one country to another. For instance, in September and October 1937, in the USA, sulfanilamide elixir containing ethylene glycol as a solvent caused deaths of around 100 children. The investigation by the US Congress which followed led to the creation of the FDA

In France, since the beginning of the century, tin oxide had been used empirically to treat skin carbuncles. Until 1952, a preparation of diethyl tin diodide of doubtful stability poisoned about 270 people and caused at least 100 deaths. Public opinion was deeply moved by this accident. As a result France regulation was changed and became more rigorous and formalistic. For example, the strict requirements for batch testing have often been considered to be a protectionist device.

All over Europe, the catastrophe caused by thalidomide in 1959-60 led to the creation of new regulatory systems. The drug was marketed everywhere except in France and in the USA where rigid regulation had already existed and created administrative delays.

All these regulations are based on the same principle, but entail various biases which are due to: different legal customs, the scientific committees that proposed them and which differ in composition; the uneven levels of protection of these markets against imports; and finally the pressure from the public and media.

In Great Britain, for instance, a country of liberal traditions and of strong self-discipline, there was no regulation before thalidomide. In 1964, a tedious and rigorous but voluntary system of regulation was created. But though it was voluntary, all members of the ABPI (Association of British Pharmaceutical Industries) were obliged to comply with it. In 1971, this was replaced by a statutory system of regulation.

In Germany, on the other hand, the country where thalidomide was developed, no regulations were made until EEC rules were imposed in 1972.

In most of the developing countries where there is a pharmaceutical industry, there were no regulations or if they were there they were based on regulations of developed countries (carbon copies of rules). In totally import-oriented countries the condition was still worse as the imports in most of these countries was free and unregulated; and as a result a practice of dumping of banned drugs (in home country) in these countries was very

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common. The recognition of some of the adverse reactions which are common in other part of the world and led to the ban on use of that drug in that part, took many years in other parts of the world.

For example, the use of Ciba-Geigy's Mexaform (Cliquirol) was banned all over the world because of its subacute-mylo optical neuropathy (SMON) but was still in use in India and many other developing countries. In India, Ciba-Geigy itself stopped its manufacturing in 1985, because of international pressure and not because of recognition of this toxicity by Indian Government. Similarly, the drug analgin which is banned in developed countries because of its toxicity is still marketed and used in India. The regulation in developing countries is thus still either inadequate or inefficient.

The regulation of pharmaceuticals, like other regulations, aims also to organize markets. It is often stated that France and USA both countries which have developed strict rules, intended by multiple and complex controls to protect their domestic pharmaceutical industry by preventing foreign companies from entering the market without the help of domestic industry.

The need to limit the cost of drugs is yet another factor observed in some countries like Norway to regulate drugs. Norwegian regulation is extremely restrictive. It requires the demonstration of a genuine medical need for the new drug before its introduction is authorized. According to the Norwegian public authorities, this rule is intended to reduce health costs by limiting the number of drugs available and to enable practitioners to understand existing products better while avoiding the dilution of drug information.

In Sweden, very rigorous clinical trials are required before marketing is authorized and they must be replicated in the country. Such a rule could be misused for a protectionist purpose, especially when the pharmaceutical industry is publicly owned.

As the development of drugs is up till now the domain of very few developed countries, in the rest of the world, the regulation of drugs is mainly the regulation of importation, manufacturing, distribution, storage, sales, advertising, labeling and use of drugs.

Control of imports[15]

In many developing countries, they controlled over imports in many forms regarding trade policy which are permitted for any drugs with some exception like banned ,spurious or some adulterant drugs. This system enable the drug regulatory authorities to determine that what drug should permitted for import and what condition they required. Some of the factors are which they considered like safety, efficacy and quality of drugs. Some additional conditions alike to observe the Good manufacturing practices as well as for drug stability and somehow for climatic conditions for different importing countries like Bahrain and Saudi Arabia. Additional consideration such as registration, restriction on the quantity to be imported, medical needs, Prices are also enforces.

Usually quality, safety and efficacy are the basic conditions, non-observance of which led to cancellation or suspension of license of import. However, different countries provide

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the additional backgrounds for prohibiting, suspending or canceling the imports of drugs. Like Bahrain, import can be cancelled, if price level increases the limits which are accepted in neighboring Arabian countries. In Bolivia, there is prohibition of import of products which is very similar to those products which produce by national pharmaceutical industry.

In India, control over the quality of drugs imported into the country is exercised by restricting the imports through certain specified ports; where the officers of the Central Drug Control Organization collect the samples of imported material and send them to the Central Drug Standard Control Organization for testing with prescribed standards and decision is taken based on the report of the quality whether to allow imports or not. The drugs imported in the country are mostly bulk drugs which are further processed in dosage forms. The percentage of import of final dosage forms is very less, only 0.5% of the total import of drugs. A government organization, State Trading Corporation (public sector undertaking) accounts for nearly 40% of the total import of bulk drugs into the country.

Export of Drugs [16]

The exports of drug is not authorize to be marketed by manufacturer because they do not meet the domestic regulatory standard parameter for those reason which have been generated by fair amount of discussion at that times. The different law of exporting countries specifies the address at that issue. In federal legislation USA, no drug can be export until it is approved by FDA for use in USA.

Some of drug exports by following process they are:-

1) It is specific for foreign purchases.
2) It is not conflicts by law of country, which is intend for export.
3) Shipping package contains the label for export.

In case of Bahrain, law prohibits any exports until and unless sanction by ministry. The condition is impose by most of importing countries like EI Salvador, Arabia countries where the product issue with respect of specialties manufactured and packed in only in abroad.

The policy is designed to measure the assurance of drugs regarding the quality, safety and efficacy subjected to international commerce

The WHO Certificates the drug quality scheme for pharmaceutical products which moves in to the international commerce require member states who participate in the scheme of export drugs to take certain measure to designed and ensure the quality and safety of the drugs.

The monthly bulletin related to drug is issued by WHO , Drugs Information Bulletin, which deals with their policy and their issues of interests for regulatory authorities. It also

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provides information related to toxic effects of drugs as well as monitoring program on adverse reactions to drugs from its office in Upsalla, Sweden.

The UN give a mandate to prepared a list of those products which is banned, withdrawn, restricted or not having approval by various governments. In such case, it is the legislation of import country that prevails.

REGISTRATION OF DRUGS[17]

Many countries now apply for registration of drug.it is fully operational facilities the regulation where the drug should be marketed. Some drug which is not registered so they are not marketed except with prior approval for limited purpose only. It is big confusion between registration and licensing of drugs so they do not have registration of drug accordingly but they having licensing system enable the drugs in market.

In some countries the both systems, licenses which are normally granted for marketing registered products only. The importance of that product is for prescreening the drug which is based on their scientific and some other criteria and procedure for such clinical trial which assure the drug safety. Some countries having various authorities and agency which is trusted with their responsibility for reviewing the applications for registration of drugs that received favorable considerations.

The requirements of Registration generally apply for all the drugs. They are classified into two categories:

(a) Administrative data – It relates the information of matters of the drugs like drug name, manufacturer details and the product status in the country of origin and also other countries.

(b) Pharmaceutical, pharmacological, toxicological, therapeutic and clinical data supported by scientific facts and figures.

LEGISLATION ON QUALITY CONTROL[18,19,20]

Pharmaceutical legislation enforces the responsibility which is generally trusted by which is designated personals such as inspector, who inspects and authorize to inspects the manufacturing process, processing of drug as well as packaging establishments in both wholesaler and retailer. In inspection, they inspect the book and records and they take the samples which is the important function they performed. The facility for analyses the drug which ensuring the quality and safety of drug which is available in market.

Some legal provision permitting their reports and certificates to be accepted as evidence and generally sufficient to dispense analysts from matters of routine. This methods followed for the analysis of drugs or the rationale underling their findings or conclusions.

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Laboratories have different roles for establishing the standard .They established both by administrative and by legal measures.

It is usual to assign specific statutory duties to perform them to specific duties which is performed by specific .The medication laboratory of Finland has legally empowered to obtain the samples, free of cost from manufacturer ,supplier, importers and persons which deals with drugs.

To facilitate the monitoring of drug movement requires the different kinds of system is maintain and they permit its identification of any stage in its productions, storage, distribution and marketing.

The Records must maintain for two-year periods. They contain the name and address of the consignee, date, sold quantity and the lot or control numbers which identifying the batch which is sold must and be included in this records. Similar procedure is followed by India and records of batch number of their production which need to be maintained for a specified period of time.

MONITORING AND EVALUATION[21,22]

The drug should be constantly monitored even after the drug entered in market has they gained the profit in more and more country and establishment for appropriate post market surveillance.

Some national approaches towards to obtain the information related to defective drug. The related information given by physician or drug saler and other information is obtained by voluntarily

Different measures of drugs, when the defective drug has been identified in the market. Among them they are recall of the drug from the market and prohibition of further sales and suspension or cancellation of the registration and marketing license.

The destruction of the defective stocks ,warnings to pharmacists, physicians and consumers for further investigation and legal actions against those responsible for contravening laws and regulations and inspections of production for quality control facilities.

Some of the examples are to illustrated but national approaches in different countries are:-

In Yugoslavia ,the health organization approved the ,drugs medicaments which must notify the federal competent administrative agency .Which gives some adverse side effects occurring in different clinical practices which is not indicated on the label while package insert. Agency is required for an appropriate action on information of receipt of their adverse effect which is detected by different countries. Mainly it give compulsory notification from Austria physician, pharmacist and from those person who engaged in trade to transmit to the federal ministry of health and environmental protection information related to safety of drugs.

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In Italy:-The manufacturer form pharmaceutical company and market drug are required to submit the reports periodically which is concerning about toxicity or any other side effects .

In Nepal:- It provide for recall of drugs when the drugs are not safe and effective in nature

In many of the countries, separate National center is called as phamacovigilance or National Adverse Drug Reaction Monitoring Center (India, Ghana, Sri Lanka) have started based on guidelines which is issued by the WHO Adverse Drug Reaction Monitoring Center which is situated in Uppsala, Sweden.

DISCUSSION & CONCLUSION:-

During last 20 years, the agenda policy for health issue is top reached in many of the countries and have witnessed a major debate on the question of availability of essential drugs. Increasing attention has been paid by Govt.to developing mechanisms to improve the availability and rational use of drugs. With the growing awareness of the need for national drug health policy. Many low income and upper middle in comeiconomies, for different reasons , have tried to rationalized their drugs sector.

During last half decade the pace of pharmaceutical production has increased. The grossly unequal distribution of drugs however, between low , middle economies and high income economies countries has not changed much in last 5 to 6 years . In 1993, 13% of the population living in 12 developed countries consumed nearly 80% of the total world drug consumption, leaving only 20% to rest of the world. In some 2.5 million people or half of the population continues deny to their rights to health and minimum secure for essential medicines .This uneven distribution of drugs consumption is associated with uneven drug production, which is still concentrated and dominated by large transnational corporations situated in few developed countries . In 1993, about 77% of the world pharmaceutical production was concentrated mainly eight high income economies. Only two countries from middle income economies figured in top ten countries in the world pharmaceutical markets. The rise in per capita drug consumption during 1985-1993 is 16 times higher in high income economies than in low income economies

Although many low and middle income economies spent 25 to 75% of their annual health budget and some times more on purchase of drugs , compared to above 10% by many high income economies, the complete health budgets and health their service coverage the countries of low and middle income economies remain severely limited. This highly unsatisfactory situation becomes more serious when very typical nature of pharmaceutical industry undermining national drug policy of poor countries is observed.

Transnational corporations are steadily increases in their size while the numbers are decreases as result of continuous mergers of the companies in a context of intense competition for market. It illustrates the powerful domination of the market .

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Lessons from country experiences :

Since WHO launch the essentials drug concepts and also it rational use of drug for different countries,which is implement by NDPs.

The experience to evaluate and analyses the drug successes and failure. By this assessment they learn from past so plan a strategies for future. In priority such health policy may acquire the public debate in different countries

So they undertake and apply as an exercise.

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