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Design and Development of National Drug Regulatory System and Policies

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Abstract: Regulation of drugs encompasses a variety of functions. Key functions include licensing, inspection of manufacturing facilities and distribution channels, product assessment and registration, adverse drug reaction (ADR) monitoring, QC, control of drug promotion and advertising, and control of clinical drug trials. Each of these functions targets a different aspect of pharmaceutical activity. All of these functions must act in concert for effective consumer protection. Quality of drugs available to the public is the main aim of drug regulation. If regulatory goals are to be achieved, appropriate structures must be established and appropriate activities carried out to achieve the desired goals. Comprehensive and up-to-date laws, unified but independent organization, competent human resources, freedom from political and commercial influence, adequate and sustainable financial resources, clear and transparent standards and procedures, outcome-oriented implementation and systematic monitoring and evaluation are critical components contributing to effective drug regulation.

Keywords: Quality, Adverse Drug Reaction, Clinical Drug Trials.

INTRODUCTION

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes pre-clinical research (microorganisms/animals) and clinical trials (on humans) and may include the step of obtaining regulatory approval to market the drug

Introduction to regulatory affairs in pharmaceutical industry

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents.

This department is responsible for knowing the regulatory requirements for getting new Products approved. They know what commitments the company has made to the regulatory agencies where the product has been

approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified.[1]

Importance of regulatory affairs

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

Inadequate reporting of data may prevent a timely positive evaluation of marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse1 failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company for better, or worse Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.

The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

Responsibility of Regulatory Affairs Professional's

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records,[2] in appropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

Need of regulatory affairs in the pharmaceutical industry

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in

executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

In India import, manufacturing, sale and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945 (hereinafter refer as Act) made there under. At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act. Any substance falling within the definition of drug (Section 3b of the Act) required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (Rule 122 E of the Act), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. The application for Registration and import can be made to the Licensing Authority under the Act i.e. to the Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi by the Local Authorized Agent of the foreign manufacturer having either manufacturing or sale License or by the foreign manufacturers 'having a whole sale License in the country[3]

A regulatory process, by which a person/organization/sponsor/innovator gets authorization to launch a drug in the market, is known as drug approval process.

In general, a drug approval process comprises of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies.

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs.

The new drug approval is of two phase process - the first phase for clinical trials and second phase for marketing authorization of drug. Firstly, non-clinical studies of a drug are completed to ensure efficacy and safety, and then application for conduct of clinical trials is submitted to the competent authority of the concerned country. Thereafter, the clinical trials can be conducted (phase I to phase IV). These studies are performed to ensure the efficacy, safety and optimizing the dose of drug in human beings. After the completion of clinical studies of the drug, then an application to the competent authority of the concerned country for the approval of drug for marketing is submitted. The competent authority review the application and approve the drug for marketing only if the drug is found to be safe and effective in human being or the drug have more desirable effect as compare to the adverse effect

Even after the approval of new drug, government should monitor its safety due to appearance of some side effects, when it is used in larger population.[4] The interactions with other drugs, which were not assessed in a pre-marketing research trial and its adverse effects (in particular populations) should also be monitored.

Major bodies regulating drugs and pharmaceuticals

The principal regulatory bodies entrusted with the responsibility of ensuring the approval, production and marketing of quality drugs in India at reasonable prices are:

The Central Drug Standards and Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licences to manufacture the above-mentioned products;

The National Pharmaceutical Pricing Authority (NPPA), which was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals; periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines; maintains data on production, exports and imports and market share of pharmaceutical firms; and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.[5]

The Department of Chemicals and

Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. The responsibilities assumed by this body are relatively broader and varied in comparison to the other two bodies. The main aspects of pharmaceutical regulation are thus divided between the above two ministries. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy. However, other ministries also play a role in the regulation process. These include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for drug approval entails the coordination of different departments, in addition to the DCGI, depending on whether the application in question is for a biological drug or one based on recombinant DNA technology. Issues related to industrial policy such as the regulation of patents, drug exports and government support to the industry are governed by the Department of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers. With respect to licencing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests. State drug controllers have the authority to issue licences for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).[6]

Prevailing Mechanisms

This sub-section primarily focuses on major regulatory policies and mechanisms in relation to drug pricing and development of standards for ensuring safety and efficacy.

In India, drug manufacturing, quality and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. This act has witnessed several amendments over the last few decades. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals.

Some of the important schedules of the Drugs and Cosmetic Actsi include: Schedule D: dealing with exemption in drug imports, Schedule M: which, deals with Good Manufacturing Practices involving premises and plants and Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs.[7,8]

In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.

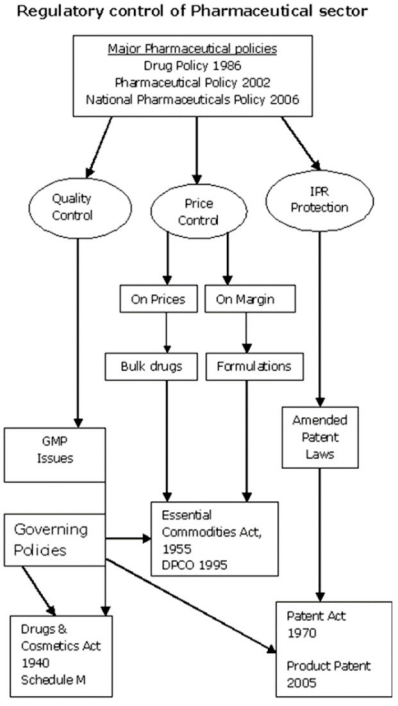

Fig 1: Regulatory Control of Pharmaceutical Sector

Temporal Progression of Drug Policies & Acts

The Patents Act of 1970, Drug Price Control Order 1970 and Foreign Exchange Regulation Act 1973 played a significant role in terms of the building of indigenous capability with regard to manufacture of drugs. The New Drug Policy of 1978 provided an added thrust to indigenous self-reliance and availability of quality drugs at low prices.DPCO 1987 heralded the increasing liberalization in the industry. One of the important features of this act was the reduction of the number of drugs under price control to 143.

The major objective of DPCO 1995 was to decrease monopoly in any given market segment, further decrease the number of drugs under price control to 74 and the inclusion of products manufactured by small scale producers under price control list.

In 1997, the National Pharmaceutical Pricing Authority was constituted in order to administer DPCO and deal with issues related to price revision.

The Pharmaceutical Policy 2002 carried forward earlier governmental initiatives in terms of ensuring quality drugs at reasonable prices, strengthening of indigenous capability for cost-effective production, reducing trade barriers and providing active encouragement to in-house R&D efforts of domestic firms.[9]

In 2003, the Mashelkar Committee undertook a comprehensive examination of the problem of spurious and sub-standard drugs in the country and recommended a series of stringent measures at Central and state levels. The regulatory body came in for censure with the committee noting that there were only 17 quality-testing laboratories, of which only seven laboratories were fully functional.

The National Pharmaceuticals Policy 2006, among other initiatives, has proposed a slew of measures such as increasing the number of bulk drugs under regulation from 74 to 354, regulating trade margins and instituting a new framework for drug price negotiations in a move to make drugs more affordable for the Indian masses.

A **drug policy** is the policy, usually of a government, regarding the control and regulation of drugs considered dangerous, particularly those which are addictive. Governments try to combat drug addiction with policies which address both the demand and supply of drugs, as well as policies which can mitigate the harms of drug abuse, and for medical treatment. Demand reduction measures include prohibition, fines for drug offenses, incarceration for persons convicted for drug offenses, treatment (such as voluntary rehabilitation, coercive care, or supply on medical prescription for drug abusers), awareness campaigns, community social services, and support for families. Supply side reduction involves measures such as enacting foreign policy aimed at eradicating the international cultivation of plants used to make drugs and interception of drug trafficking. Policies which may help mitigate the effects of drug abuse include needle exchange and drug substitution programs, as well as free facilities for testing a drug's purity.

Drugs subject to control vary from jurisdiction to jurisdiction. For example, heroin is regulated almost everywhere; substances such as qat, codeine and even Tamiflu are regulated in some places, but not others.

Most jurisdictions also regulate prescription drugs, medicinal drugs not considered dangerous but that can only be supplied to holders of a medical prescription, and sometimes drugs available without prescription but only from an approved supplier such as a pharmacy, but this is not usually described as a "drug policy".

International treaties

The International Opium Convention, signed in 1912 during the First International Opium Conference, was the first international drug control treaty. It went into force globally in 1919 when it was incorporated into the Treaty of Versailles in 1919. A revised Convention was registered in League of Nations Treaty Series in 1928. It also imposed some restrictions—not total prohibition—on the export of Indian hemp (cannabis sativa forma indica). In 1961 it was superseded by the international Single Convention on Narcotic Drugs to control global drug trading and use. The Convention banned countries from treating addicts by prescribing illegal substances, allowing only scientific and medical uses of drugs. It did not detail precise drug laws and was not itself binding on countries,[10,11] which had to pass their own legislation in conformance with the principles of the Convention.

Drug policy in counters

1. **Drug policy of Australia;**

Australian drug laws are criminal laws

and mostly exist at the state and territory level, not the federal, and are therefore different, which means an analysis of trends and laws for Australia is complicated. The federal jurisdiction has enforcement powers over national borders.

Illicit drug use in Australia is the recreational use of prohibited drugs in Australia. Illicit drugs include illegal drugs (such as cannabis, opiates, and certain types of stimulants), pharmaceutical drugs (such as pain-killers and tranquillisers) when used for non-medical purposes, and other substances used inappropriately (such as inhalants).According to government and community organisations, the use and abuse of illicit drugs is a social, legal and health issue that creates an annual illegal market estimated to be worth A$6.7 billion

Drug use in Australia;

The Australian government enacted numerous policies in response to illicit drug use. During the 1980s, it was one of the first countries to enact the policy of "harm minimisation", which consists of three pillars: "demand reduction", "supply reduction" and "harm reduction". This policy is still in effect as of 2012 and the following outlines are contained in the The National Drug Strategy: Australia's integrated framework document:

- supply reduction strategies to disrupt the production and supply of illicit drugs, and the control and regulation of licit substances. It involves border security, Customs and prosecuting people involved in the trafficking of illicit substances.
- Demand reduction strategies to prevent the uptake of harmful drug use, including abstinence orientated strategies and treatment to reduce drug use; This involves programs promoting abstinence or treating existing users.
- Harm reduction strategies to reduce drug-related harm to individuals and communities. It is a policy that is a "safety net" to the preceding two policies. The threefold model accepts that demand prevention and supply prevention will never be completely effective, and if people are involved in risky activities, the damage they cause to themselves and society at large should be minimised. It involves programs like needle & syringe programs and safe injecting sites, which aim to prevent the spread of disease or deaths from overdoses, while providing users with support to reduce or stop using drugs.[12]

2. **Drug policy of Canada;**

Canada's drug regulations are covered by the Food and Drug Act and the Controlled Drugs and Substances Act. In relation to controlled and restricted drug products the Controlled Drugs and Substances Act establishes eight schedules of drugs and new penalties for the possession, trafficking, exportation and production of controlled substances as defined by the Governor-in-Council. Drug policy of Canada has traditionally favoured punishment of the smallest of offenders, but this convention was partially broken in 1996 with the passing of the Controlled Drugs and Substances Act.

Until 1908 the use of narcotics, opiates especially, in Canada was unregulated.[2] From the 1850s onwards, Chinese immigrants came to British Columbia in droves, establishing opium dens in their isolated communities. Canadian employers saw the Chinese immigrants as a source of cheap labour, and the government viewed opium consumption as another way to gain revenue, imposing a tax on opium factories in 1871. However, with the decline of the gold rush in the 1880s resentment towards the Chinese grew, as unemployed Canadians could not compete with cheap Chinese labour. Additionally, Japanese immigration to Canada began to rise sharply, resulting in demonstrations against Asian labour. In 1907, there was a particularly large demonstration against Asian immigrants in Vancouver's Chinatown. In response to the demonstrations, Deputy Minister of Labour Mackenzie King travelled to British Columbia and interviewed two opium merchants. King was concerned with the growing numbers of white opium users and believed that Canada had to set the precedent on drug use worldwide. The following year the government enacted the Opium Act of 1908, which made it an offence to import, manufacture, possess or sell opium, while not making it an imprisonable offence. The same year, Parliament passed the Proprietary and Patent Medicine Act 1908, prohibiting the use of cocaine in medicines and requiring pharmaceutical companies to list on the label the ingredients of any medicine if heroin, morphine, or opium was part of the contents.[13]

The 1908 drug law created a black market for opium, and law enforcement officials believed that the only way to stop this black market was through imprisonment for offenders, so the Opium and Drugs Act 1911 was passed by Parliament. This created harsher penalties for drug offenders and also expanded the list of prohibited drugs to include morphine and cocaine, while cannabis was included in 1923. During World War I, all provinces enacted prohibition, a decision repealed in all areas except Prince Edward Island by 1929. In 1921 the penalties of the Opium and Drugs Act were expanded to provide for a seven-year prison sentence for crimes committed under the Act. The amendment also made it an offence to be in a building that contained narcotics, notably shifting the burden of proof to the defendant for this crime. Whipping and deportation became penalties for violations of the 1911 Act in 1922.

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3. Drug policy of India;

The major drug laws of India are the Narcotic Drugs and Psychotropic Substances Act (1985) and the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act (1985).

Narcotic Drugs and Psychotropic Substances Act;

The Narcotic Drugs and Psychotropic Substances Act, commonly referred to as the NDPS Act, is an Act of the Parliament of India that was assented to by President Giani Zail Singh on 16 September 1985, and came into force on 14 November 1985. The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha on 23 August 1985. It was passed by both the Houses of Parliament and it was assented by the President on 16 September 1985. It came into force on 14 November 1985 as The Narcotic Drugs and Psychotropic Substances Act, 1985 shortened to NDPS Act). Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance. The Act has been amended twice - in 1988 and 2001. The Act extends to the whole of India and it applies also to all Indian citizens outside India and to all persons on ships and aircraft registered in India.

Under one of the provisions of the act, the Narcotics Control Bureau was set up with effect from March 1986. The Act is designed to fulfill India's treaty obligations under the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

India had no legislation regarding narcotics until 1985. Cannabis smoking in India has been known since at least 2000 BC and is first mentioned in the *Atharvaveda*, which dates back a few hundred years BC. The Indian Hemp Drugs Commission, an Indo-British study of cannabis usage in India appointed in 1893, found that the "moderate" use of hemp drugs was "practically attended by no evil results at all", "produces no injurious effects on the mind" and "no moral injury whatever". Regarding "excessive" use of the drug, the Commission concluded that it "may certainly be accepted as very injurious, though it must be admitted that in many excessive consumers the injury is not clearly marked". The report the Commission produced was at least 3,281 pages long, with testimony from almost 1,200 "doctors, coolies, yogis, fakirs, heads of lunatic asylums, bhang peasants, tax gatherers, smugglers, army officers, hemp dealers, ganja palace operators and the clergy."

Cannabis and its derivatives (marijuana, hashish/charas and bhang) were legally sold in India until 1985, and their recreational use was

commonplace. Consumption of cannabis was not seen as socially deviant behaviour, and was viewed as being similar to the consumption of alcohol. Ganja and charas were considered by upper class Indians as the poor man's intoxicant, although the rich consumed bhang during Holi. The United States began to campaign for a worldwide law against all drugs, following the adoption of the Single Convention on Narcotic Drugs in 1961. However, India opposed the move, and withstood American pressure to make cannabis illegal for nearly 25 years. American pressure increased in the 1980s, and in 1985, the Rajiv Gandhi government succumbed and enacted the NDPS Act, banning all narcotic drugs in India.

4. Switzerland

The national drug policy of Switzerland was developed in the early 1990s and comprises the four elements of prevention, therapy, harm reduction and prohibition.[19] In 1994 Switzerland was one of the first countries to try heroin-assisted treatment and other harm reduction measures like supervised injection rooms. In 2008 a popular initiative by the right wing Swiss People's Party aimed at ending the heroin program was rejected by more than two thirds of the voters. A simultaneous initiative aimed at legalizing marijuana was rejected at the same ballot.

Between 1987 and 1992, illegal drug use and sales were permitted in Platzspitz park, Zurich, in an attempt to counter the growing heroin problem. However, as the situation grew increasingly out of control, authorities were forced to close the park.

5. United Kingdom

Drugs considered addictive or dangerous in the United Kingdom (with the exception of tobacco and alcohol) are called "controlled substances" and regulated by law. Until 1964 the medical treatment of dependent drug users was separated from the punishment of unregulated use and supply. This arrangement was confirmed by the Rolleston Committee in 1926. This policy on drugs, known as the "British system", was maintained in Britain, and nowhere else, until the 1960s. Under this policy drug use remained low; there was relatively little recreational use and few dependent users, who were prescribed drugs by their doctors as part of their treatment. From 1964 drug use was increasingly criminalised, with the framework still in place as of 2014 largely determined by the 1971 Misuse of Drugs Act.

Until 1916 drug use was hardly controlled, and widely-available opium and coca preparations commonplace.

Between 1916 and 1928 concerns about the use of these drugs by troops on leave from the First World War and then by people associated with the London underworld gave rise to some controls being implemented. The distribution and use of morphine and cocaine, and later cannabis, were criminalised, but these drugs were available to addicts through doctors; this arrangement became known as the "**British system**" and was confirmed by the report of the Departmental Committee on Morphine and Heroin Addiction (Rolleston Committee) in 1926. The Rolleston Report was followed by "a period of nearly forty years of tranquillity in Britain, known as the Rolleston Era. During this period the medical profession regulated the distribution of licit opioid supplies and the provisions of the Dangerous Drugs Acts of 1920 and 1923 controlled illicit supplies." The medical treatment of dependent drug users was separated from the punishment of unregulated use and supply. This policy on drugs was maintained in Britain, and nowhere else, until the 1960s. Under this policy drug use remained low; there was relatively little recreational use and few dependent users, who were prescribed drugs by their doctors as part of their treatment.

It has been argued that the main legal innovations between 1925 and 1964 were in response to international pressures, not domestic problems.

in the 1960s a few doctors prescribed large amounts of heroin, some of which was diverted into the illegal market. Also substances such as cannabis, amphetamines and LSD started to become significant in the UK.

In 1961 the international Single Convention on Narcotic Drugs was introduced. To control global drug trading and use, it banned countries from treating addicts by prescribing illegal substances, allowing only scientific and medical uses of drugs. It was not itself binding on countries, which had to pass their own legislation.

Following pressure from the US, the UK implemented the Drugs (Regulation of Misuse)

Act in 1964. Although the Convention dealt with the problems of drug production and trafficking, rather than the punishment of drug users, the 1964 Act introduced criminal penalties for possession by individuals of small amounts of drugs, as well as possession with intent to traffic or deal in drugs. The police were soon given the power to stop and search people for illegal drugs.

In 1971 the Misuse of Drugs Act (MDA) was passed, continuing measures in previous legislation, and classifying drugs into classes A (the most highly regulated), B, and C. Penalties for trafficking and supply were increased in the 1980s.[15]

In 1991 a new phase of UK drug legislation started with an attempt to integrate health and criminal justice responses via Schedule 1A6 Probation Orders. This reduced the separation between medical and punitive responses that had characterised the British system in the past

Legislation

A. 1868 – Pharmacy Act. First regulation of poisons and dangerous substances. Limited sales to chemists.
B. 1908 – Poisons and Pharmacy Act. Regulations on sale and labelling, including coca.
C. 1916 – Defence of the Realm Act 1914 (Regulation 40B). Sale and possession of cocaine restricted to "authorised persons".
D. 1920 – Dangerous Drugs Act. Limited production, import, export, possession, sale and distribution of opium, cocaine, morphine or heroin to licensed persons.
E. 1925 – Dangerous Drugs Act. Controlled importation of coca leaf and cannabis.
F. 1928 – Amendment to Dangerous Drugs Act criminalising possession of cannabis. Doctors continued to be able to prescribe any drugs as treatments, including for addiction.
G. 1964 – Dangerous Drugs Act, following UN 1961 Single Convention. Criminalised cultivation of cannabis.
H. 1964 - Drugs (Prevention of Misuse Act) criminalised possession of amphetamines.
I. 1967 – Dangerous Drugs Act. Doctors required to notify Home Office of addicted patients. Restriction on prescription of heroin and cocaine for treatment of addiction.
J. 1971 – Misuse of Drugs Act. Introduced classes A, B, and C of drugs. Created offence of "intent to supply". Increased penalties for trafficking and supply (14 years imprisonment for trafficking Class A drugs). Established the Advisory Council on the Misuse of Drugs (ACMD).
K. 1985 – Controlled Drugs (Penalties) Act. Maximum penalty for trafficking Class A drugs increased to life imprisonment.
L. 1986 – Drug Trafficking Offences Act. Making suspects aware of an investigation criminalised. Police could compel breaches of confidentiality, and could search and seize.
M. 1991 – Criminal Justice Act, Schedule 1A6: a probation order could have attached a condition of attending drug treatment.
N. 1998 – Crime and Disorder Act. Created the Drug Treatment and Testing Order (DTTO).
O. 2000 – Criminal Justice and Court Services Act. People charged with certain offences could be tested for drugs by police. Created the Drug Abstinence Order, the Drug Abstinence Requirement. Introduced testing for prisoners released subject to supervision.
P. 2003 – Criminal Justice Act. Bail restricted for people charged with certain offences if test indicates Class A drug use. Created the generic Community Order, replacing the DTTO with the Drug Rehabilitation Requirement.
Q. 2003 - Anti-Social Behaviour Act. Premises used for Class A drugs supply could be closed.
R. 2005 – Drugs Act. Introduced drug testing on arrest. Classified psilocybin mushrooms as drugs. Required treatment assessment could not be refused. Penalties for dealing near schools increased.
S. 2006 – Police and Justice Act. Punitive conditions can be attached to conditional cautioning.
T. 2007 – Drugs Act 2005 (Commencement No. 5) Order 2007 (S.I. 2007/562)
U. 2008 – Controlled Drugs (Drug Precursors) (Intra-Community Trade) Regulations 2008 (S.I. 2008/295)
V. Controlled Drugs (Drug Precursors) (Community External Trade) Regulations 2008 (S.I. 2008/296)
W. 2008 – The Misuse of Drugs Act 1971 (Amendment) Order 2008 (S.I. 2008/3130)
X. 2009 –The Misuse of Drugs (Designation)

(Amendment) (England, Wales and Scotland) Order (SI 2009/3135)

Y. 2009 –The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations (SI 2009/3136)

Z. 2009 –The Misuse of Drugs Act 1971 (Amendment) Order (SI 2009/3209)[16]

DISCUSSION

I) National drug regulatory system and policies

1. Introduction

Essential drugs are not used to their full potential

Health is a fundamental human right. Access to health care, which includes access to essential drugs, is a prerequisite for realizing that right. Essential drugs play a crucial role in many aspects of health care. If available, affordable, of good quality and properly used, drugs can offer a simple, cost-effective answer to many health problems. In many countries drug costs account for a large share of the total health budget.

Despite the obvious medical and economic importance of drugs there are still widespread problems with lack of access, poor quality, irrational use and waste. In many settings essential drugs are not used to their full potential.

Lack of access to essential drugs

An increasing number of pharmaceutical products are available in the world market, and there has been rapid growth in both drug consumption and expenditure. However, many people throughout the world cannot obtain the drugs they need, either because they are not available or too expensive, or because there are no adequate facilities or trained professionals to prescribe them. Although hard data are unavailable, WHO has estimated that at least one-third of the world's population lacks access to essential drugs; in poorer areas of Asia and Africa this figure may be as high as one-half.[2] Millions of children and adults die each year from diseases that could have been prevented or treated with cost-effective and inexpensive essential drugs.

Poor quality

In many countries drug quality assurance systems are inadequate because they lack the necessary components. These components include adequate drug legislation and regulations, and a functioning drug regulatory authority with adequate resources and infrastructure to enforce the legislation and regulations. Without these, substandard and counterfeit products can circulate freely. In addition, inappropriate handling, storage and distribution can alter the quality of drugs. All these factors may have serious health consequences and lead to a waste of resources.

Irrational use of drugs

Even people who have access to drugs may not receive the right medicine in the right dosage when they need it. Many people buy, or are prescribed and dispensed, drugs that are not appropriate for their needs. Some use several drugs when one would do. Others use drugs that carry unnecessary risks. The irrational use of drugs may unnecessarily prolong or even cause ill-health and suffering, and results in a waste of limited resources.

Persistent problems and new challenges

These problems have persisted despite all the work done to improve access to essential drugs, to ensure drug quality and to promote rational drug use. The reasons are complex and go beyond simple financial constraints. To understand them it is necessary to look at the characteristics of the drug market, and to study the attitudes and behaviour of governments, prescribers, dispensers, consumers and the drug industry. Health sector development, economic reform, structural adjustment policies, trends towards liberalization, and new global trade agreements all have a potential impact on the pharmaceutical situation in many countries. They may also affect the ultimate goal of achieving equity in health.

Changes in the patterns of disease and drug demand also represent major challenges. The rise of new diseases, such as acquired immunodeficiency syndrome (AIDS), the re emergence of other diseases and increasing drug resistance of potentially fatal diseases, such as malaria and tuberculosis, all contribute to increased spending on drugs and growing pressure on health resources. Changes in life expectancy and in lifestyles have led to an increase in chronic diseases and diseases of the elderly, and an increase in the need for drugs to treat these chronic diseases.

A national drug policy as a common framework to solve problems in pharmaceuticals

Experience in many countries has shown that these complicated and interdependent problems can best be addressed within a common framework, as piecemeal approaches can leave important problems unsolved and often fail. In addition, the different policy objectives are sometimes contradictory, and so are the interests of some of the stakeholders. On the basis of this experience, WHO recommends that all countries formulate and implement a comprehensive national drug policy (NDP).

1.2 National drug policy

A commitment to a goal and a guide for action

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

A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

The policy document should be developed through a systematic process of consul-tation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment must be built.

Why is a national drug policy needed?

A national drug policy is needed for many reasons. The most important are:

- to present a formal record of values, aspirations, aims, decisions and medium- to long-term government commitments;
- to define the national goals and objectives for the pharmaceutical sector, and set priorities;
- to identify the strategies needed to meet those objectives, and identify the various actors responsible for implementing the main components of the policy;
- to create a forum for national discussions on these issues.

The consultations and national discussions preceding the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document.

The main objectives of ensuring equitable access, good quality and rational use are usually found in all national drug policies, but clearly not all of these policies are the same. The final definition of objectives and strategies depends on the level of economic development and resources, on cultural and historical factors, and on political values and choices. The guidelines set out here are intended to help countries develop and implement a comprehensive policy framework that is appropriate to their own needs, priorities and resources.

A national drug policy is an essential part of health policy

A national drug policy cannot be developed in a vacuum it must fit within the framework of a particular health care system, a national health policy and, perhaps, a programme of health sector reform. The goals of the national drug policy should always be consistent with broader health objectives, and policy implementation should help to achieve those broader objectives.

The health policy and the level of service provision in a particular country are important determinants of drug policy and define the range of choices and options. On the other hand, the drug situation also affects the way in which health services are regarded. Services lose their credibility if there is no adequate supply of good quality drugs, or if these are badly prescribed. Thus the implementation of an effective drug policy promotes confidence in and use of health services.

There are also economic arguments. In many countries a large proportion of health care spending is on drugs. Health care financing is therefore closely related to drug financing. It is

very difficult to implement a health policy without a drug policy.

Objectives of a national drug policy

In the broadest sense a national drug policy should promote equity and sustainability of the pharmaceutical sector.

The general objectives of a national drug policy are to ensure:

The more specific goals and objectives of a national policy will depend upon the country situation, the national health policy, and political priorities set by the government. In addition to health-related goals there may be others, such as economic goals. For example, an additional objective may be to increase national pharmaceutical production capacity.

It is critical that all the drug policy's objectives are explicit, so that the roles of the public and private sectors and of the various ministries (health, finance, trade and industry) and government bodies (such as the drug regulatory authority) can be specified.

Importance of the essential drugs concept

The essential drugs concept is central to a national drug policy because it promotes equity and helps to set priorities for the health care system. The core of the concept is that use of a limited number of carefully selected drugs based on agreed clinical guidelines leads to a better supply of drugs, to more rational prescribing and to lower costs.

The reasons are clear. Essential drugs, which are selected on the basis of safe and cost effective clinical guidelines, give better quality of care and better value for money. The procurement of fewer items in larger quantities results in more price competition and economies of scale. Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs. Training of health workers and drug information in general can be more focused, and prescribers gain more experience with fewer drugs and are more likely to recognize drug interactions and adverse reactions.

By the end of 1999, 156 developed and developing countries had national or institutional lists of essential drugs for different levels of care, in both the private and public sectors; 127 of these lists had been updated in the previous five years, and 94 were divided into levels of care. There is substantial evidence that the use of national lists of essential drugs has contributed to an improvement in the quality of care and to a considerable saving in drug costs.

1.3 Key components of a national drug policy

A national drug policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy (access, quality and rational use). The policy should balance the various goals and objectives, creating a complete and consistent entity. For example, access to and to lower costs.

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As can be seen from the Table, most components cannot be linked to one objective only.

Selection of essential drugs

Drug selection, preferably linked to national clinical guidelines, is a crucial step in ensuring access to essential drugs and in promoting rational drug use, because no public sector or health insurance system can afford to supply or reimburse all drugs that are available on the market. Key policy issues are:

1. the adoption of the essential drugs concept to identify priorities for government involvement in the pharmaceutical sector, and especially for drug supply in the public sector and for reimbursement schemes;
2. procedures to define and update the national list(s) of essential drugs;
3. Selection mechanisms for traditional and herbal medicines.

Affordability

Affordable prices are an important prerequisite for ensuring access to essential drugs in the public and private sectors. Key policy issues are:

- government commitment to ensuring access

through increased affordability;
- for all drugs: reduction of drug taxes, tariffs and distribution margins; pricing policy;
- for multi-source products: promotion of competition through generic policies, generic substitution and good procurement practices;
- For single-source products: price negotiations, competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, "early workings" of patented drugs for generic manufacturers and parallel imports.

Drug financing

Drug financing is another essential component of policies to improve access to essential drugs. Key policy issues are:
- commitment to measures to improve efficiency and reduce waste;
- increased government funding for priority diseases, and the poor and disadvantaged;
- promotion of drug reimbursement as part of public and private health insurance schemes;
- use and scope of user charges as a (temporary) drug financing option;
- use of and limits of development loans for drug financing;
- guidelines for drug donations.
- Supply systems

The fourth essential component of strategies to increase access to essential drugs is a reliable supply system. Key policy issues are:
- public–private mix in drug supply and distribution systems;
- commitment to good pharmaceutical procurement practices in the public sector;
- publication of price information on raw materials and finished products;
- drug supply systems in acute emergencies;
- inventory control, and prevention of theft and waste;
- disposal of unwanted or expired drugs.

Regulation and quality assurance

The drug regulatory authority is the agency that develops and implements most of the legislation and regulations on pharmaceuticals, to ensure the quality, safety and efficacy of drugs, and the accuracy of product information. Key policy issues are:
- government commitment to drug regulation, including the need to ensure a sound legal basis and adequate human and financial resources;
- independence and transparency of the drug regulatory agency; relations between the drug regulatory agency and the ministry of health (MoH);
- stepwise approach to drug evaluation and registration; definition of current and medium-term registration procedures;
- commitment to good manufacturing practices (GMP), inspection and law enforcement;
- access to drug control facilities;
- commitment to regulation of drug promotion;
- regulation of traditional and herbal medicines;
- need and potential for systems of adverse drug reaction monitoring;
- international exchange of information.

Rational use

The rational use of drugs means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Irrational drug use by prescribers and consumers is a very complex problem, which calls for the implementation of many different interventions at the same time. Efforts to promote rational drug use should also cover the use of traditional and herbal medicines. Key policy issues are:
- development of evidence-based clinical guidelines, as the basis for training, prescribing, drug utilization review, drug supply and drug reimbursement;
- establishment and support of drugs and therapeutics committees;
- promotion of the concepts of essential drugs, rational drug use and generic prescribing in basic and in-service training of health professionals;
- the need and potential for training informal drug sellers;
- continuing education of health care providers and independent, unbiased drug information;
- consumer education, and ways to deliver it;
- financial incentives to promote rational drug use;

- regulatory and managerial strategies to promote rational drug use.

Research

Operational research facilitates the implementation, monitoring and evaluation of different aspects of drug policy. It is an essential tool in assessing the drug policy's impact on national health service systems and delivery, in studying the economics of drug supply, in identifying problems related to prescribing and dispensing, and in understanding the sociocultural aspects of drug use. Key policy issues are:

- the need for operational research in drug access, quality and rational use;
- The need and potential for involvement in clinical drug research and development.

2.0 The national drug policy process

Formulating a national drug policy

By the end of 1999, 66 countries had formulated or updated their national drug policy within the previous 10 years. Very often an acute emergency or an important political change created a window of opportunity to start the policy formulation process. In some countries this was a change to a government committed to reform; in other countries it was an economic or political change, such as the sudden devaluation of the CFA (Communauté financière d'Afrique) franc, or the collapse of the Union of Soviet Socialist Republics, which created the need to harmonize and improve certain aspects of the pharmaceutical system. Other factors could be a political drive towards expansion of the local industry or the implementation of global trade agreements.

Step 1: Organize the policy process

The ministry of health is the most appropriate national authority to take the lead role in formulating a national drug policy. The first step is to decide how to organize the development process that will identify the structure of the policy, its major objectives and its priority components.

At this stage it is important to identify all the interested parties that need to be involved, the necessary resources, and how these can be obtained. The need for assistance from WHO, donors or countries with relevant experience should also be assessed. This stage can be carried out within the ministry of health with support from a small committee of selected experts.

Step 2: Identify the main problems

In order to set realistic objectives a thorough analysis and understanding of the main problems in the pharmaceutical sector are needed. There are various ways of carrying out an initial situation analysis.

One successful approach has been to bring together a small team of experts, some of whom should have performed similar analyses in other countries. These experts should come not only from the ministry of health but also from other disciplines and backgrounds. They should be asked to examine the situation systematically, to identify the main problems, to make recommendations about what needs to be done and what can be done, and to identify possible approaches. They should act as impartial advisers. Once they have formulated their recommendations, these can be discussed at one or more multidisciplinary workshops, in order to formulate consolidated advice to the government. Examples of such reports are available from the WHO Department of Essential Drugs and Medicines Policy.

Step 3: Make a detailed situation analysis

A more detailed situation analysis of the pharmaceutical sector and its components may be needed. This should further analyse the source of the problems, in order to identify potential solutions, choose the most appropriate strategies, set priorities, and serve as a baseline for future systems of monitoring and evaluation.

Step 4: Set goals and objectives for a national drug policy

Once the main problems have been defined, goals can be set and priority objectives identified. For instance, if one of the priority problems is lack of access to essential drugs, one of the priority objectives should be to improve the selection, affordability and distribution of essential drugs.

The selection of appropriate strategies to achieve the objective is more complex, since it may involve choosing from among very different approaches. A workshop involving a small number of key policy-makers may be helpful. The

situation analysis should justify the choices and serve as the basis for decisions.

Once the main objectives and strategies have been outlined, they should be discussed with all interested parties. Broad consultation and careful consideration of conflicting interests and structural constraints are necessary to set achievable objectives and to formulate appropriate strategies to attain them.

Step 5: Draft the text of the policy

Once a thorough analysis of the situation and an outline of the main goals, objectives and approaches have been completed, a draft text of the national drug policy should be prepared. It should set out the general objectives of the policy. In most countries this will be to ensure that essential drugs are accessible to the entire population; that the drugs are safe, efficacious and of good quality; and that they are used rationally by health professionals and consumers. The specific objectives should also be described, followed in each case by the strategy to be adopted. Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process. Examples of national drug policy documents from other countries may be consulted.

Step 6: Circulate and revise the draft policy

The draft document should be widely circulated for comments, first within the ministry of health, then in other government ministries and departments, and finally to relevant institutions and organizations outside the government, including the private and academic sectors. Endorsement by government sectors responsible for planning, finance and education is important since the successful implementation of many elements of the policy will depend on their support as well. Once this wide consultation is complete, the draft document should be revised in the light of the comments received, and finalized.

Step 7: Secure formal endorsement of the policy

In some countries the document can then go to the cabinet or parliament for endorsement. In others it will remain an administrative document that serves as a basis for implementation plans and changes in the law and regulations. In some countries the entire national drug policy document has become law. This is a powerful demonstration of political commitment but it can also cause problems, as future adjustments to the policy may become difficult. It is therefore recommended that only certain enabling components of the policy are incorporated into law, without too many operational details.

Step 8: Launch the national drug policy

Introducing a national drug policy is much more than a technical task. To a large extent the policy's success will depend on the level of understanding of different sectors of society, and on their support for its objectives. The implications and benefits for all interested parties should therefore be stressed.

The policy should be promoted through a clear and well-designed information campaign. Public endorsement by respected experts and opinion leaders can be very useful. Information should be disseminated through a variety of channels to reach different target groups. The media can play a major role in ensuring public understanding and support for the policy. Some countries have organized high profile launches.

3.0 Legislation

3.1 Importance of legislation and regulations

A legislative framework is needed in order to implement and enforce the various components of a national drug policy, and to regulate the activities of the different parties in both the public and private sectors. Permitting the circulation of poor-quality, ineffective products and harmful ingredients in a country has an impact on the population's health and on the national economy. Lack of legislation and regulations on other aspects of pharmaceuticals, such as financing, supply and the use of drugs, affects cost-effectiveness in health delivery.

Two types of legal framework cover pharmaceuticals. Laws are passed by a country's legislative bodies, and are formulated in general terms to meet current and future needs. Regulations enable government authorities to set out in more detail how the laws should be interpreted, and how they will be implemented and enforced. Regulations can be changed more easily than laws, and create the necessary flexibility in a changing environment. In some countries, regulations require only the approval of the head of a ministry or department.

Legislation and regulations ensure that the responsibilities, qualifications, rights and roles of each party are defined and recognized (including those of medical practi-tioners, pharmacists and the drug regulatory authority). They also create the legal basis enabling the regulatory control of activities such as drug manufacture, import, export, marketing, prescribing, dispensing and distribution, and the enforcement of such laws and regulations.

The purpose of the legislation is therefore the same as that of the drug policy: to ensure that only safe, effective, quality drugs are produced, imported and distributed, and that these drugs are made available, as well as managed and used appropriately.

4.0 Selection of essential drugs

Essential drugs

The selection of essential drugs is one of the core principles of a national drug policy because it helps to set priorities for all aspects of the pharmaceutical system.

WHO has defined essential drugs as "those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at a price the individual and the community can afford". This is a global concept that can be applied in any country, in the private and public sectors and at different levels of the health care system.

Essential drugs concept

The concept of essential drugs is that a limited number of carefully selected drugs based on agreed clinical guidelines leads to more rational prescribing, to a better supply of drugs and to lower costs. The reasons are obvious:

- Essential drugs which are selected on the basis of safe and cost-effective clinical guidelines lead to more rational prescribing,[16] and therefore to higher quality of care and better value for money;
- Training of health workers and drug information in general can be more focused;
- Prescribers gain more experience with fewer drugs, and recognize drug interactions and adverse reactions more easily;
- Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs;
- The procurement of fewer items in larger quantities results in more price competition and economies of scale.

All of this is even more important in resource-poor situations where the availability of drugs in the public sector is often erratic. Under such circumstances measures to ensure a regular supply of essential drugs will result in real health gains and in increased confidence in health services.

5. Affordability

5.1 Challenges

New essential drugs are often expensive

Affordable prices are important for both public and private sectors. The issue of affordability is becoming more important because resistance to well-known anti-biotics, which are widely available as generic products, is increasing. New essential drugs for the treatment of some infectious diseases, such as malaria, tuberculosis and HIV/AIDS, are often very costly.

Market failure

In a perfect market, buyers and consumers are left to transact their business, and the balance between supply and demand results in a reasonable price. However, conditions for such markets are rarely met in pharmaceuticals because of the following factors:

- Information imbalance. The patient knows less than the prescriber or the dispenser about the efficacy, quality and appropriateness of the drug. This can result in misleading advice and miscommunication, and ultimately inappropriate drug use. For markets to work properly both buyers and sellers should have complete information.
- Failure of competition. This occurs when market power is created through exclusive rights, such as patents and trademarks, and when production is concentrated in a small number of suppliers.

II) Drug financing

1 Challenges

Inadequate resources

Ensuring stable and adequate financing for health care is becoming increasingly difficult as a result of the combined effects of economic

pressures, continued population growth and the growing burden of disease. Health care resources are stretched by the demographic shift to older populations, with more costly chronic diseases, the emergence of new diseases such as AIDS, and the resurgence of older diseases, such as tuberculosis and malaria, which need increasingly costly drugs because of growing resistance to the earlier drugs.

Achieving equity

Market-oriented "Laissez-faire" policies are not geared to protecting the needs of the poorest people, and without government involvement the poor may be denied access to drugs. Ensuring access to essential drugs, particularly in remote areas, can be a major challenge to those involved in developing and implementing drug policy.

III) Supply systems

Who has responsibility for the supply system, and how it should be structured, are important choices with many political and economic ramifications. It is very important that the drug policy defines the future supply system and the role of the government. There are several options, and which one is chosen will depend on existing structures, the balance between public and private sectors, and other factors.

In some countries problems with the central medical stores and the public supply system have been overcome by contracting some of the work out to private operators while maintaining a centralized structure. For example, the transport of drugs can often be left to the private sector. In other countries different structures are used. An autonomous or semi-autonomous agency is set up to serve as a supply agency not directly managed by the government. The objective of such a system is to combine the efficiency of the private sector with the public health approach and the economies of scale that can be achieved in a centralized system.

Further options include direct delivery systems or primary distributor systems. In a direct delivery system drug prices are established by tender, but drugs are supplied directly to facilities. A primary distributor system is one in which contracts are negotiated with a single prime vendor who supplies and distributes directly to districts or major facilities.

A well-coordinated supply system will ensure that public funds available for drug purchases are used effectively to maximize access, to obtain good value for money and to avoid waste. This will increase confidence in health services and promote attendance by patients. There needs to be good coordination between these central elements of the supply system. Failures at any point of the drug supply system can lead to shortages or to waste. Both the health and the economic consequences can be serious.

IV) Drug regulation

The drug regulatory authority (DRA) is the agency that develops and implements most of the legislation and regulations on pharmaceuticals. Its main task is to ensure the quality, safety and efficacy of drugs, and the accuracy of product information. This is done by making certain that the manufacture, procurement, import, export, distribution, supply and sale of drugs, product promotion and advertising, and clinical trials are carried out according to specified standards. Several of these functions also contribute to efforts to promote rational drug use.

Drugs of poor quality can have serious health and economic consequences. There are many ways in which the quality of a drug may be unacceptable or poor. Drugs may not contain the right active ingredients in the quantities stated on the label; they may contain no active ingredient at all, or contain substances that could be harmful. The quality may have deteriorated because of poor storage conditions, contamination or repackaging; or the drug may simply have passed its expiry date.

Apart from the medical consequences of ineffective treatments or toxic effects, money is wasted because of the extra costs to the health care system. Considerable wastage may also occur if drugs are not packaged and stored properly, so that new stocks must be procured. There is also a more general psychological effect. If people do not have confidence in the quality of the drugs they receive, they may lose confidence in the drug policy and the health services as a whole.

V) Important of promote rational use;

All drugs, including essential drugs, can be used irrationally. Irrational use is widespread in both developing and industrialized countries; it occurs in public and private sector health

facilities and in the home. Many of the gains of efficient selection, procurement and distribution can be lost by irrational prescribing and by lack of adherence to treatment by the patient.

Irrational drug use has both medical and economic consequences. In medical terms, inappropriate treatment may lead to unnecessary suffering and death, to iatrogenic disease and hospital admissions, and to increased antimicrobial resistance. Irrational drug use also decreases public confidence in the health care system and attendance rates of curative and preventive services. Economically, irrational drug use leads to an enormous waste of resources and to unavailability of essential drugs in other areas where they may be needed.

i) Challenges

Complexity of the issue

The factors that influence drug use are many and interrelated. Changing complex practices that are embedded in cultural and social beliefs and shaped by knowledge, attitudes, infrastructure and economic interests is very difficult. No single approach is likely to work, and some interventions may produce unintended effects. A combi-nation of strategies tailored to the needs of the different groups and different environments is needed.

Conflicting interests

Policies to promote rational use are often controversial and may be opposed for various reasons. Prescribers, and particularly those who also dispense, may have a financial interest in prescribing more drugs or drugs with the highest profit margins; they may resent any interference with their freedom to prescribe. They may also derive a certain status from prescribing many newly marketed or expensive drugs. Pharmacists and drug sellers have a financial interest in increasing the volume of their business; producers want to increase their sales and their marketing practices may conflict with the goals of rational use. Consumers and prescribers may believe that interventions to encourage rational use are intended to cut costs rather than to improve therapy. It is important to identify and consider all these various interests, which are basic barriers to change.

CONCLUSION

This review synthesizes experience with drug regulation in order to draw generic conclusions from the strengths and weaknesses of different systems and identify features affecting the performance of drug regulation. In drug regulation, the government acts as the guardian of the public by controlling private powers for public purposes. Ensuring the safety, efficacy and quality of drugs available to the public is the main aim of drug regulation. If regulatory goals are to be achieved, appropriate structures must be established and appropriate activities carried out to achieve the desired goals. Comprehensive and up-to-date laws, unified but independent organization, competent human resources, freedom from political and commercial influence, adequate and sustainable financial resources, clear and transparent standards and procedures, outcome-oriented implementation and systematic monitoring and evaluation are critical components contributing to effective drug regulation.

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