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Review

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 DISCOVERY PROCESS

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.

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, 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

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. 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.

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

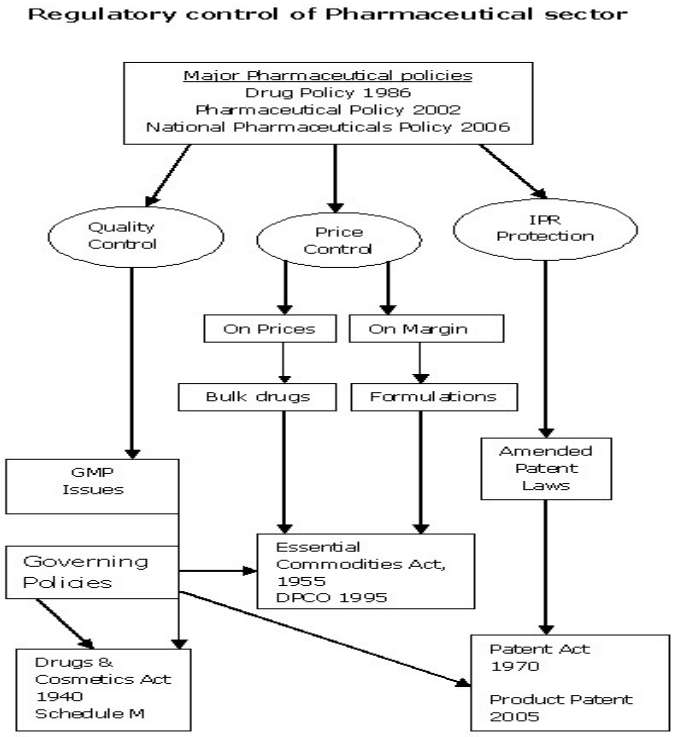
the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).

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

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.



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 ca pability 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.

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 NationsTreaty 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, 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.

Drug policy ofCanada

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 LabourMackenzie 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.

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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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 BCand 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.

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.

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. 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)

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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