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'PARADOX OF HUMAN RIGHTS' - NEED FOR REGULATION OF COMMERCIALIZED INDIGENOUS SYSTEMS OF MEDICINES IN INDIA *

ABSTRACT

As the title suggests, this dissertation emphasises on the need of medicine regulatory system in a civil society. The paper studies the Medicine regulatory system in India and suggests some reforms in the regulatory system of India. As we can see that consumer of medicines are not well aware of all the prevailing regulatory provision related to drugs. The authors will first discuss about the history and growth of drugs over the time. We will study that how these drugs have emerged over a period of time and how they have managed to capture a bigger market area. Further, we will see that how these drugs regulations have become effective. Then, various guidelines and rules which are followed to regulate these drugs. In the Indian context, the architecture of drug regulation is designed as a classic command and- control system in which the regulator prescribes standards, distributes licences and then undertakes inspection to check for compliance. The Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 framed thereunder structures the whole medicine regulatory system in India. The provisions of the Drugs and Cosmetics Act, 1940 do not apply to medicines and substances exclusively used or prepared for the use in accordance with Ayurvedic, Sidha & Unani systems of medicines. Previously, there was no such commercialization of ayurvedic drugs but with the passage of time it is deeply commercialized. In India, more than half of the population believes on the consumption of ayurvedic drugs, hence they have captured huge market place. But, still there is a lack of regulation to keep an eye on quality, supply and demand of these drugs. Thus, authors at last taking into account the commercialisation of these indigenous system of drugs by profit-centered firms suggests the need to bring Ayurvedic, Sidha & Unani drugs within scope of the 1940 Act. The authors will discuss the above mentioned topics as well a number of other sub-topics related to the main theme in this paper.

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Key words- Ayurvedic, Sidha & Unani, indigenous, drugs, pharmaceutical, regulations, medicine, commercialisation, profit-centered firms.

INTRODUCTION

Drugs or pharmaceutical[1] products have several attributes, which are unique and differentiate them from ordinary consumers' products. In most cases, the patients are not equipped with the specialised knowledge needed to make an independent assessment of the safety, quality and efficacy of the medicines. In most instances, consumers are not in a position to make decisions about when to use drugs, which drugs to use, how to use them and to weigh potential benefits against risks as no medicine is completely safe.[2] The manufacturing, distribution & sale of drugs require special knowledge and expertise to take informed decisions about all aspects of medicines. Given the asymmetry of information between the manufacturers, the doctors who prescribe drugs and patients who ultimately consume them, the need for regulatory supervision is widely acknowledged amongst all stakeholders in the realm of public health.

HISTORY OF MEDICINES REGULATION

Medicines are perhaps as old as mankind and the concepts how their quality has to be ensured has evolved gradually over the time. For example, Mithridates VI (120 BC), King of Pontus, concocted a compound preparation called "Mithridatium" which included 41 individual components and was held as a panacea for almost all diseases. It took until 1540 when in England the manufacture of Mithridatium and other medicines was subjected to supervision under the Apothecaries Wares, Drugs and Stuffs Act.[3] The Act was one of the earliest British statutes on the control of medicines and it established the appointment of four inspectors of "Apothecary Wares, Drugs and Stuffs". This could be seen as the start of pharmaceutical inspections. History of Pharmacopoeias, the official books of drug quality standards, probably dates back to one of the proclamations of the Salerno Medical Edict issued by Fredrick II of Sicily (1240), and ordered apothecaries to prepare remedies always in the same way – *forma curiae*. The first Pharmacopoeias as we know them today stared to appear in Europe from 16th century e.g. the first Spanish Pharmacopoeia was issued in 1581. The standards for the manufacture of Mithridatum were established in England in The London Pharmacopoeia only in 1618.

The modern medicines regulation started only after breakthrough progress in the 19th century life sciences, especially in chemistry, physiology and pharmacology, which laid a solid

[1] Drugs, pharmaceuticals and medicines have been used inter-changeably in the article.

[2] C.J. van Boxtel, B. Santoso and I.R. Edwards, 'Drug Benefits and Risks' 67 (2nd Edition, IOS Press and Uppsala Monitoring Centre, 2008).

[3] History of Medicines regulation http://www.ganfyd.org/index.php?title=History_of_medicines_regulation [Accessed on 21st October at 10:15 PM].

foundation for the modern drug research and development and started to flourish after the second World War. Unfortunate events have catalysed the development of medicines regulation more than the evolution of a knowledge base. In 1937 over 100 people in the United States died of diethylene glycol poisoning following the use of a sulfanilamide elixir, which used the chemical as a solvent without any safety testing. This facilitated introduction of The Federal Food, Drug and Cosmetic Act with the premarket notification requirement for new drugs in 1938. However, in countries with poor regulatory environment even recently medicines contaminated with diethylene glycol have killed patients. The second catastrophe that influenced the development of medicines regulation far more than any event in history was the thalidomide disaster. Thalidomide was a sedative and hypnotic that first went on sale in Western Germany in 1956. Between 1958 and 1960 it was introduced in 46 different countries worldwide resulting in an estimated 10,000 babies being born with phocomelia and other deformities. The role of this disaster in shaping the medicines regulatory systems is not hard to underestimate.[4]

WHAT MAKES MEDICINES REGULATION EFFECTIVE?

Drug regulation is a public policy response to the demands of public health and the changing needs of pharmaceutical industry. Thus, the objective of regulatory control is a question of achieving a 'balance' between protecting and promoting public health and facilitating the industry vis-à-vis compliance with regulatory standards.[5] Medicines regulation varies from countries to countries but uniformly incorporates several mutually reinforcing activities all aimed at promoting and protecting public health. Medicines regulation demands the application of sound medical, scientific and technical knowledge and skills, and operates within a legal framework. Regulatory functions involve interactions with various stakeholders (e.g. manufacturers, traders, consumers, health professionals, researchers and governments) whose economic, social and political motives may differ, making implementation of regulation both politically and technically challenging. Medicines regulation has administrative part but far more important is the scientific basis for it. All medicines must meet three criteria: be of good quality, safe and effective.

[4] Lembit Rägo, Budiono Santoso, 'Drug Regulation: History, Present and Future' 2008 http://www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf [Accessed on 21st October, 2016 at 10:50 PM].

[5] Ratanawijitrasin and Wondemagegnehu, 'Effective drug regulation : a multicountry study' (World Health Organisation, Geneva, 2002).

According to WHO (World Health Organisation) principle medicines regulatory functions are listed in the below:-[6]

- Licensing of the manufacture, import, export, distribution, promotion and advertising of medicines;
- Assessing the safety, efficacy and quality of medicines, and issuing marketing authorization;
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medicines;
- Controlling and monitoring the quality of medicines on the market;
- Controlling promotion and advertising of medicines;
- Monitoring adverse reactions to medicines;
- Providing independent information on medicines to professionals and the public.

MEDICINES REGULATION IN INDIA

The Indian pharmaceutical sector has come a long way, being almost a small sector before 1970 to a vital supplier of healthcare products, serving almost 95 per cent of the country's pharmaceuticals needs. It ranks 3 rd in the world in terms of production volume and 13th in domestic consumption value. Indian Pharmaceutical industry grew at 15.7% during December 2011. The Industry today is in the front rank of India's science based industries with wide ranging capabilities in the complex field of drug manufacture and technology.[7]

In the Indian context, the architecture of drug regulation is designed as a classic command and-control system in which the regulator prescribes standards, distributes licences and then undertakes inspection to check for compliance. This has a number of positive attributes including clarity in regulatory standards, which makes it easier to apply and to spot instances of non-compliance. During the first three decades after the turn of the century, India was largely dependent on imported drugs. Lack of regulations meant that there was a high quantity of adulterated, spurious and substandard drugs in the market. The Drugs and Cosmetics Act in 1940 (hereinafter referred as 'the 1940 Act') was enacted to address this problem. The constitutional scheme also takes cognizance of health related issues and enlists Public Health

[6] WHO Policy Perspectives on Medicines (Issue no 7, 2003) http://apps.who.int/iris/bitstream/10665/68391/1/WHO_EDM_2003.2.pdf [Accessed on 21 October, 2016 at 11:48 PM].

[7] Sarda Rohit R., Ladkat Nilesh B., Khodade Ravikiran B., Chaudhari Pallavi M.and Kasture Pramod 'The Indian Pharmaceutical Industry; Evolution Of Regulatory System And Present Scenario' (International Research Journal of Pharmacy, 2012) http://www.irjponline.com/admin/php/uploads/1164_pdf.pdf [Accessed on 21st October, 2016 at 11:36 PM].

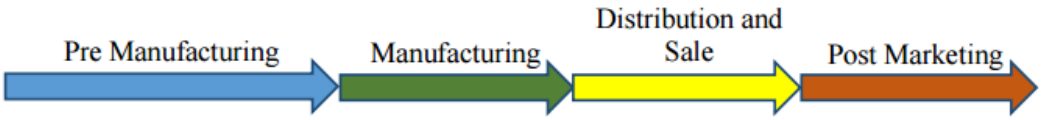
as a subject matter of State List.[8] Though the entry being enumerated in list 2, Union Parliament is empowered to make laws on it by virtue of Article 249, 250, 252 & 253 of The Constitution of India.[9] The constitutional position is such that although abovementioned provisions may lead to a central legislation, it does not diminish the powers of state governments to exercise control over that area of governance. This position is reflected in the 1940 Act. The legal basis for the enactment of the 1940 Act was Section 103 of the Government of India Act 1935 (equivalent to Article 252 of the Constitution in terms of legal effect).

The 1940 Act regulates about import, manufacture and sale and distribution of drugs. The 1940 Act focuses solely on the imported products and this is the reason behind the lack of exports in the country. Additionally it gives a key to the purpose for the division of regulatory powers between the centre and the state governments. Authorizing of drug imports was viewed as crucial and more imperative and, thus is the transmit of the central government, where as the manufacture, sale and distribution of drugs are not critical and fall under the ambit of state government. The nature and size of the administrative part in 1940 decided this division of responsibility. From that point forward, there has been a sensational change in the segment, without any alteration in the division of the regulatory responsibility. Throughout the years, India has originated as a production pivot for generic medicine, and this needs better better regulatory focus and measures to be contributed on authorization and enforcement. Notwithstanding, both these functionaries are to a great extent outside the domain of the central government and fall precisely in the ability of state governments. Another cynosure of the 1940 Act is the large body of rules, the Drugs and Cosmetics Rules, 1945, that are adjoined to the Act. The Act itself solely provides the bare structure and the principles that have been altered and revised consistently. There has been a focus on subordinate enactment prompting to progressively confounded arrangement of rules that are hard to track, understand and interpret. This section, hence, is portrayed by absence of legitimate assurance experienced by both regulates and regulators alike.

[8] The Seventh Schedule to the Constitution of India (henceforth, the Constitution) lists the distribution of legislative subject matters across three lists – List 1 (Union list); List 2 (State list) and List 3 (Concurrent list). Entry 6 in the State List refers to "Public health and sanitation; and hospitals and dispensaries." This subject matter forms the legal basis for the regulation of pharmaceuticals in India.

[9] **Article 249:** Power of Parliament to legislate with respect to a matter in the State List in the national interest.
Article 250: Power of Parliament to legislate with respect to any matter in the State List if a Proclamation of Emergency is in operation.
Article 252: Power of Parliament to legislate for two or more States by consent and adoption of such legislation by any other State
Article 253: Legislation for giving effect to international agreements.

Distribution of Regulatory Functions along the Drug Product Life Cycle



STAGE	CLINICAL TRIALS	NEW DRUG APPROVALS	MANUFACTURING	DISTRIBUTION AND SALE	POST MARKETING SURVEILLANCE
Regulatory Functions	• Applications online in the Clinical Trials Registry - India (CTRI) • Approval of applications • Good Clinical Practices • Inspections • Registration of Ethics Committee • Serious Adverse Events (SAE)	• 12 Subject Expert Committees (SECs) for deliberation on new drug applications for grant of marketing licence • Import of new drugs (Registration of foreign manufacturers and grant of licence to import)	• Application for Licence to manufacture (Generics and those with marketing licence) • Inspection of Good Manufacturing Practices (WHO-GMP/Schedule M) • Grant of Licence to Manufacture • Collection of Samples, testing and prosecution for Non-Compliance	• Application for Licence to distribute and sell • Inspection of Good Distribution Practices (GDP) and sale premises • Grant of Licence to distribute and sell • Prosecution for Non-Compliance	• Periodic Safety Update Reports (PSURs) required to be submitted (Schedule Y of the Drugs and Cosmetics Rules) for new drugs granted marketing licence • Banning of Drugs considered harmful or sub-therapeutic under Sec. 26A of the DCA • Pharmacovigilance Programme of India (PvPI) is the national co-ordinating centre for collecting Adverse Drug Reaction Reports from Adverse Drug Monitoring Centre(AMCs)

Source: Administrative Structure and Functions of Drug Regulatory Authorities in India published by Indian Council for Research on International Economic Relations (2015).

AYURVEDIC, SIDHA & UNANI SYSTEM OF DRUGS EXEMPTED UNREASONABLY

The provisions of the Drugs and Cosmetics Act, 1940 do not apply to medicines and substances exclusively used or prepared for the use in accordance with Ayurvedic & Unani systems of medicines. That Drugs & Cosmetics Act, 1940 classifies the Ayurvedic, Sidha & Unani Drugs on the following grounds:-

i) The Act exempts *Vaidyas* and *Hakims* who manufacture Ayurvadic, Sidha & Unani drug for the use of their own patients by virtue of Section 33EEA of the impugned Act.

ii) The Central Government can't regulate or restrict manufacture of Ayurvadic, Sidha & Unani drugs in public interest contrary to other drugs.

iii) The quantum of penalty for offences is less severe with regard to Ayurvadic, Sidha & Unani drugs than other drugs.

The exclusion of medicines and substances exclusively used or prepared for the use in accordance with Ayurvedic, Sidha & Unani systems of medicines from the ambit of provisions

of Drugs & Cosmetics Act, 1940 is totally unreasonable and irrational. Our Constitution forbids class legislation but permits reasonable classification provided that it is founded on an intelligible differentia which distinguishes persons or things that are grouped together from those that are left out of the group and the differentia has a rational nexus to the object sought to be achieved by the legislation in question.[10] The Test of Reasonable Classification says that the classification must be based upon intelligible differentia that distinguishes persons or things that are grouped from others that are left out of the group. Secondly, this differentia must have a rational relation to the object of classification. There should be a relation between the differentiations to the object of the classification.[11] The classification by the impugned act though is based on intelligible differentia i.e. indigenous drugs and non-indigenous drugs but is not having direct nexus with the object of the act.

The 1940 Act, which is the major medicine regulatory system in India, aims to regulate drugs thereby promoting public health at large. The object of the act is to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment.[12] To achieve this object, all the drugs should be treated on equal footing since all the drugs are intended as preventive or curative[13] and there exist no reason for classifying Ayurvedic, Sidha & Unani drugs looking at object of the act.

SUGGESTION

The exclusion of medicines and substances exclusively used or prepared for the use in accordance with Ayurvedic, Sidha & Unani systems of medicines from the ambit of provisions of Drugs & Cosmetics Act, 1940 is totally unreasonable and irrational. The 1940 Act, which is the major medicine regulatory system in India, aims to prevent sub-standards in drugs thereby promoting public health at large.

The preparation of Ayurvedic and Unani drugs is no longer confined to Vaidyas & Hakims for their patients but has been commercialised by firms. In fact, developments in ayurveda during the past two centuries through organised production of medicine, institutionalisation of education and professionalisation of clinical practice have often been parallel to, or a response to developments in biomedicine in India. Manufacturing in ayurveda has passed from small-scale physician outlet to petty/cottage production and later to the industrial scale, emerging as a

[10] In Re Special Courts Bill, (1979) 1 SCC 380.

[11] Chiranjit Lal Choudhury v. The Union of India [1950] 1 SCR 869; See also: Ram Krishna Dalmia and others v. Sri Justice S. R. Tendolkar [1959] 1 SCR 279.

[12] Chiman Jagjivandass Sheth v. State of Maharashtra, AIR 1963 SC 665.

[13] A.S.P. Kurup v. Union of India, 1984 FAJ 36 (Ker).

competing alternative to the biopharmaceutical market. An analysis of ayurvedic manufacturing industry is germane for the simple reason that we are more or less ignorant about the dynamics of this thriving industry in the 21st century. The pluralistic healthcare market is of great relevance as a strong parallel to allopathic generic medicine market in the contemporary context. An estimate (Gautam et al 2002) shows that about 84% of the domestic market for Indian system of medicine is for ayurveda, 13% for homeopathy and 3% for unani and siddha. Ayurvedic and unani products for bulk sales (i.e., 30039001) have gone up in a substantial scale in the past seven years. It has marked 39% growth during this period, more than 5% annually.[14] Ayurveda industry in India has seventy percent share of formal Medicine Market which makes it a big player in the Medicine market and thus lead to commercialization. It originated over 5000 years ago and is the world's oldest health care systems. Recently, National Research Development Corporation (NRDC), an Enterprise of the Department of Scientific & Industrial Research, Ministry of Science & Technology, Govt. of India, New Delhi and M/s Dabur India Ltd., New Delhi have entered into License Agreements for commercialization of Ayush-64, an ayurvedic formulation for treatment of Malaria and Ayush-82, an ayurvedic Formulation for management of Diabetes both developed by Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, an Autonomous body of the Ministry of AYUSH (Ayurveda, Yoga and naturopathy, Unani, Siddha and Homeopathy).[15]

There is a growing tendency on the part of certain manufacturers to market preparations containing partly modern drugs & partly Ayurvedic Unani drugs under names which simulate Ayurvedic or Unani preparations thus making it difficult to exercise control over them under the Drugs & Cosmetics Act, 1940. The Udupa Committee's report on Ayurveda Research Evaluation, 1958 discloses that costly raw material such as gold, musk, saffron, pearl etc. which are component ingredients are either not used or subsided by artificial products.[16] For these reasons, it is suggested to bring Ayurvedic, Sidha & Unani drugs within scope of The 1940 Act.

CONCLUSION

[14] M S Harilal, 'Comercialising Traditional Medicine' Indian Systems of Medicine (Economic & Political Weekly, Vol. 56, 2009).

[15] Ministry of science & Technology, 'Agreement for Commercialisation of an Ayurvedic Formulation for Treatment of Malaria and an Ayurvedic Formulation for Treatment of Diabetes' http://pib.nic.in/newsite/PrintRelease.aspx?relid=136569 [Accessed on 23rd October, 2016 at 7:50 PM].

[16] Udupa Committee Report, 1958 http://www.communityhealth.in/~commun26/wiki/images/7/7f/Udupa_Committee_report_1959.PDF.pdf [Accessed on 24th October, 2016 at 8:34 PM].

The ayurvedic sector is undoubtedly emerging as medicine-centred as opposed to its basic orientation that was patient-centred, characterised as the pre-eminence of the "pharmaceutic episteme". It is evident that as an industry, ayurveda has huge potential, but what industrialisation of medicinal production will do to the system of medicine, however, remains to be examined. A major concern is the failure of regulation systems, which may hamper the spread of ayurvedic therapeutic tradition and its clinical value in future. The exclusion of indigenous systems from the ambit of medicine regulatory system has no rational basis and is a danger for public at large. The classification has no direct nexus with the object of the 1940 Act i.e. to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment rather the impugned classification runs contrary to object to be achieved by the act. Also taking into account the commercialisation & taking over of these indigenous systems of drugs by large capitalist & profit-cantered firms, the Ayurvedic, Sidha & Unani system of drugs should also be within scope of the 1940 Act.