Review Article

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REGULATORY STATUS OF POST MARKET MONITORING OF HERBALS IN INDIA AND CANADA: A REVIEW

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ABSTRACT

Herbal medicines are widely used across the globe for primary health care. There is a common belief that the herbal medicines are safe and free from any side effects. As the use of herbal medicines has increased, so too have the reports of poor quality drugs, suspected toxicity and adverse events. Manufacturing and approval of herbal medicines are regulated in most of the countries. The safety and efficacy of herbal products are critically determined by their quality. An appropriate regulatory mechanism is also highly essential for post market monitoring of herbals for its safe effective use. The present review highlights and compares the status of post market monitoring of herbals in India and Canada.

Keywords: Herbal, Post marketing, India, Canada, Regulations, GMP

INTRODUCTION

Herbal medicines are traditionally considered harmless since these belong to natural sources. However, this is not true as there are several case reports of adverse reactions to herbal drugs mentioned in published literature.[1] GMP therefore remains one of the most important tools to ensure that the manufacturing process is carried out to meet the prescribed standards, quality control measures are adequately adopted, and the finished products are of acceptable quality before they are released for sale.[2]Adverse effects may arise followed by the usage of herbal medicines that are prepared by selection of wrong plant species or mixed with adulterants or in contraindication with other medicinal products or contaminated with hazardous and toxic substances or by its misuse by the public as well as health care providers etc. Therefore, analysis of adverse events related to the use of herbal medicines is more complicated than in the case of conventional pharmaceuticals. Furthermore, herbal medicines are often used for self-care; thus, there is a great need to educate consumers and public in their proper use. This article reviews the mechanisms for effective monitoring and regulation of marketed herbal drugs for its effective safe use, in India as well as Canada.

INDIA

India is having a well-recorded and well-practiced knowledge of traditional herbal medicine which includes indigenous systems of medicine like Ayurveda, Siddha and Unani (ASU drugs).[3] In India, traditional medicines are governed by the Drugs and Cosmetics Act of 1940 and Rules of 1945.[4] Regulatory authority, manufacturers and public are to play a crucial role in post market monitoring of herbals for safe effective use.

Role of Regulatory Authority

WHO recommends that each country or area should adopt a regulatory system to manage the appropriate use of herbal medicines. Adopting a regulatory mechanism has always helped in ensuring that herbal medicines have acceptable quality, safety and efficacy[5].

In India, AYUSH under Government of India is the department which regulates manufacture, sale or distribution of ASU medicines. Manufacture, sale or distribution of any drug can be prohibited at any time by the Government, notifying in the Official Gazette for public interest. Section 33EED of the Drugs and Cosmetics Act empowers the Government to prohibit manufacture, sale or distribution of ASU drugs under particular conditions. The ASU drugs likely to involve risk in human beings or animals and which are not having claimed therapeutic value shall be prohibited in the country. The Government must be satisfied with clear evidence before enacting the power under Section 33EED. The inspectors appointed by the Central or State Government under Section 33G of the act are empowered to conduct visit and surprise checks to enforce the provisions of the act and to institute prosecution actions if required against the ASU drugs in the market, which violates regulatory provisions of the law.

Role of manufacturers

Good Manufacturing Practices is a tool evolved by WHO and various countries in individual to ensure the quality and safety of marketed herbal medicines. Schedule T of the Drugs and Cosmetics Act, 1940 illustrates the Good Manufacturing Practices to be followed by the manufacturers of ASU medicines in India. The schedule stipulates the manufacturers to maintain a market complaint record to register all reports of market complaints received regarding the products sold in the market.

They are also entitled to carry out an investigation regarding the complaints received and shall take corrective action to prevent recurrence of such market complaints. The manufacturer shall enter all these details and data received on such market complaints in the record. Once in a period of six months, the manufacturer shall submit the record of such complaints to the licensing authority concerned. The Register shall also be available for inspection during any inspection of the premises by the regulatory authority. Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

Literature inserted inside the product package should indicate the name, address of the manufacturing unit and telephone number for reporting of any adverse drug reaction by physicians or patients. On receipt of such Adverse Drug Reaction report, it will be the responsibility of the manufacturer to ensure the recall of the product from the market.

Pharmacovigilance for ASU medicines

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of the adverse effects of drugs or any other possible drug-related problems.[6] The objective is to extend safety monitoring and detect drug adverse events that have previously been unrecognized despite evaluation in clinical trials.[7]It is aimed to improve patient care and safety by preventing the adverse drug reactions. To put the pharmacovigilance system for ASU drugs in proper place, the department of AYUSH recognized the Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurveda University, Jamnagar as National Pharmacovigilance Resource Centre for ASU drugs (NPRC-ASU) in India considering the guidelines of WHO for the safety issues of herbal medicines. The National Pharmacovigilance Programme is coordinated by the National Pharmacovigilance Resource Centre (NPRC-ASU) under the guidance of National Pharmacovigilance Consultative Committee (NPCC-ASU).The committee comprised of regulatory authorities, administrative heads of National Institutes and technical persons. It shall have the responsibility of monitoring and regulating administrative and financial aspects related to the programme. Further, National Pharmacovigilance Technical Advisory Committee (NPTAC-ASU) is a technical committee and is mainly concerned with reviewing and analyzing the Adverse Drug Reactions reported at different levels and to suggest proper remedial measures. There are many Regional Pharmacovigilance Centres (RPC) for ASU medicines functioning under NPRC-ASU and also, many peripheral Pharmacovigilance Centres are working under RPCs. The pharmacovigilance report sent by the peripheral Pharmacovigilance centers is collected by the Regional Pharmacovigilance Centres to carry out causality analysis. The collected information will be kept confidentially. The data will be statistically analyzed by the National Pharmacovigilance Centers and forwarded to Department of AYUSH, Government of India.[8]

Advertising

Nowadays advertisements are seen more in the media and newspapers with regard to ASU medicines. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 controls prohibited advertisements of drugs which alleged to possess magic qualities as remedial measure or matters connected therewith. It enacted as per the Gazette of India, Act No.21 of 1954. The act enacted with the intension to control self-medication by the public. The act also restricts persons as well as companies to take part in the advertisements which either mislead or gives false impression to the true character of a drug. The regulatory authority is responsible to monitor and detect such advertisements which violate the provisions of the act and to institute prosecution against the offenders.

CANADA

All natural health products (NHPs) sold in Canada are subjected to the Natural Health Products Regulations, which came into force on January 1, 2004. The Regulations ensures safety, efficacy and of high quality of wide range of natural health products for Canadians. To be legally sold in Canada, all natural health products must have a product license, and the Canadian sites that manufacture, package, label and import these products must have site licenses also.

In order to ensure safety and high quality products, Good Manufacturing Practices are also followed and flexibility is also given to manufacturers, packagers, labellers, importers and distributors to implement quality systems appropriate for their product lines and businesses.[9]

The post-market issues of greatest concern are characterized as those involving poor quality or contaminated products, adulterated products and deceptive or misleading advertising practices. Health Canada employs a number of active and collaborative methods to aid in mitigating this issues.[9]

Role of regulatory authority

Natural Health Products Programme of Health Canada administers the Natural Health Products Regulations (NHPR) and consists of three directorates which include Natural and Non-Prescription Health Products Directorate (NHPD), Marketed Health Products Directorate (MHPD) and Health Products and Food Branch Inspectorate (HPFBI). Each directorate has its own specific roles and administers the Natural Health Products Regulations in Health Canada. The sale of NHPs for commercial purposes in Canadian market is controlled and regulated by NHPD which is the main directorate of the Natural Health Products Program. The assessment and issuance of Natural Health Products and Site Licenses are governed by NHPD. The MHPD is functioning as a scientific regulatory authority for Health Products Vigilance in Canada. Functions of MHPD include reviewing and analyzing marketed health products safety data, conducts risk/benefits assessments of marketed Health Products, provides policies to effective regulation of marketed health products etc. The responsibility of MHPD also includes the management of adverse reactions involving NHPs. An adverse event followed by the consumption of Health Products is encouraged to report to MHPD immediately. The regulations with regard to Natural Health Products are enforced and implemented for the compliance, including investigations and product recalls are carried out by HPFBI. It also handles consumer and industry complaints or concerns regarding licensed or unlicensed NHPs or sites.

The minister can issue orders to stop further sale of Natural Health Products in Canada to importers, licensees, distributors etc., if he feels that the product is unsafe under the recommended conditions of use. He also entitled to suspend the product licenses of a Natural Health Product, if he is satisfied with reasonable grounds that the licensee contravened the

regulations or any provisions of the act concerned or raised any misleading of false claims in the application for, or amend a product license.

Surveillance

As per the Natural Health Products Regulations, license holders are required to monitor the adverse effects of their products following usage by their consumers. They must report any adverse effects, if detected, to the Authority concerned as soon as possible. Also, the consumers have to play an equal role in detecting and reporting the serious side effects of the products to their health care providers or Health Canada directly. The system of reporting adverse effects of NHPs is very important as it helps Health Canada to monitor the safety on public Health and to make changes in product safety information, issue public warnings and advisories, and/or recall unsafe products from the market.

Market Authorization Holders are also required to submit reports to the Canada Vigilance National Office by either email or fax of their products concerned.

Section 24 of the Natural Health Products Regulations require the licensee to submit a case report for every serious adverse reaction of the natural Health Products concerned to the Minister, occurring inside the Country. It must be reported within 15 days, after the date on which the reaction came under the notice of the licensee.It is also stipulated that a case report for each serious unexpected adverse reaction that occurs inside or outside the country must be provided within 15 days, after the day on which the reaction came under the notice of the licensee.

Licensees shall also prepare and keep an annual summary report, containing the adverse reactions that are detected in concise. The report shall also include a critical analysis of every adverse reaction that is occurred inside the Country

Licensees who are started to recall the natural health products from market shall be entitled to submit all relevant details connected with the concerned product to the Minister within three days after the date on which the recall is started.

Advertising

Only health products that Health Canada authorizes for sale in Canada may be advertised. Specific requirements exist for advertisements of prescription drugs to consumers. Health Canada is the national regulatory authority for health product advertisements. The advertisements must not be false, misleading or deceptive in nature and are to be ensured by the department. The advertisements will be reviewed and pre-cleared by independent agencies. The department may intervene in the incidents like an illegal advertisement of prescription drugs to publics or, promotion of unauthorized health products or if the resolution is not achieved through independent agencies complaints mechanisms etc. product license holders are responsible for ensuring that all advertising is in the terms of market authorization.

Table 1: Comparison of regulatory status of post market monitoring of herbal medicines in India and Canada

	India	Canada
Legal Status	• Regulated as Ayurveda, Siddha and Unani Medicines as Indigenous system of medicines. • Homoeopathic medicines as a separate class.	• Regulated as Natural Health Products including Homoeopathic medicines.
Law	• Drugs and Cosmetics Act 1940 and Rules 1945	• Natural Health Products regulations
Regulatory authority	• Department of AYUSH, Government of India	• Natural Health Products Programme (includes Natural Health Products Directorate(NHPD), Marketed Health Products Directorate(MHPD) and Health Products and Food Branch Inspectorate (HPFBI)
Adverse Reaction monitoring	• Regulators, manufacturers and public are involved in reporting of adverse reaction. • Market complaint register is to be maintained by the manufacturer	• Regulators, manufacturers and public are involved in reporting of adverse reaction.
Pharmacovigilance for herbals	• Pharmacovigilance concept exists for herbals.	• Not exists
Advertising	• Regulation exists. • Special Act, Drugs and Magic Remedies (Objectionable Advertisement) Act exists.	• Regulated under Natural Health Products Regulations

CONCLUSION

Traditional medicine, particularly herbal medicine playing important role in maintain of health in rural and remote areas. Though the herbal medicines are marketed under proper regulatory framework, post market monitoring for safety, efficacy and side effects are highly essential to safeguard the health of end users. The involvement of regulators, manufacturers and public are highly essential to identify the unwanted effects of herbal medicines in the market. In India, the concept of pharmacovigilance for herbals is evolved and controlled by separate agency whereas reporting system of adverse events to the department is followed by Health Canada. Pharmacovigilance is to be strengthened to ensure the safety of marketed drugs worldwide. Provisions in legislation are also laid down in the statute of both countries to control false or misleading or deceptive advertisements with respect to herbal drugs. In India, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 is exclusively framed to control unethical and unwanted advertisements of herbal drugs.

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