EXPRESS Pharma

www.expresspharmaonline.com FORTNIGHTLY INSIGHT FOR PHARMA PROFESSIONALS 16 - 31 December 2011

new! Thermo Scientific
Revco UxF Series -86°C Freezers

Thermo SCIENTIFIC

Herbal pharmacovigilance: India vs global outlook

__Rajashri Survase-Ojha__, director and founder, and __Onkar Deshmukh__, RA Associate, Raaj Global Pharma Regulatory Affairs Consultants write on the need to expand pharmacovigilance regulations from the pharmaceutical arena to the herbal sector

Rajashri Survase-Ojha
Director & Founder,
Raaj Global Pharma Regulatory Affairs Consultants

WHO defines 'pharmacovigilance' as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related difficulties. It is high time we practised pharmacovigilance for herbal products as well. We need to look at the herbal drug regulations of India in comparison with those of highly regulated markets which have been looking upon herbal products as a 'medicine'. It appears that the Indian regulations on herbal medicines are lagging behind the times and this article aims to serve as a reminder of this fact.

Now, the above statement begs the question: what kind of regulations? The answer is: pharmacovigilance of herbal preparations or products in the first place. Pharmacovigilance of 'pharma medicines' on a global level has already begun. Amazingly, there are no any cast-iron regulations in the herbals segment. There is a myth that herbal medicines do not have adverse effects and hence consumed by patients on their own. However, this is not true and herbal products are also likely to have adverse effects if taken without proper guidance.

The underlying principle of pharmacovigilance should definitely not be narrowed down to only chemical or pharma drugs and herbal products also need to be included under the aegis of pharmacovigilance, in India and globally as well.

Global scenario

The total herbal market is of $ 62 billion, out of which India's

EXPRESS Pharma Subscribe Online

PALL Life Sciences

SEMINARS ON:
• DRUG POLYMORPHISM
• DRUG DISSOLUTION TESTING
• GENOTOXIC IMPURITIES
14-16 DEC 2011
HYDERABAD, INDIA

INSTACOAT™

involvement has, surprisingly, remained very nominal at just about $ 1 billion. The major contributor is the European Union with 45 per cent [$ 28 billion] share of the total market. North America makes up 11 per cent [$ 6.9 billlion]. 16 per cent [$ 9.8 billion], 19 per cent [$ 10.8 billion], and 4.1 per cent [$ 2.4 billion] of the herbal market is held by Japan, ASEAN countries and rest of EU respectively. Though, India has a minor share in the herbal parma market, it has a very good standing in the global market and is recognised as one of the mega bio-diverse countries of the world.

WHO anticipates that the global market for herbal products to grow upto $ 5 trillion by 2050. India, one of the developing countries, despite its bio-diversity and huge prospects of benefits, lacks efficient pharmacovigilance for herbal products.

Herbal drug authorisations in Europe are quite identical to new drugs approval in US, where medicines are acknowledged for safety, effectiveness and quality. In UK, the committee for the safety of medicines and Medicines and Healthcare products Regulatory Agency's (MHRA) 'yellow card' scheme for ADR reporting is the primary method of monitoring the safety of herbal medicines. This scheme helps MHRA monitor the safety of all medicines and vaccines that are on the market. UK MHRA asks patients and health professionals to fill the yellow card to get the required information on ADRs. Moreover, yellow card reports that they receive are weighed up, simultaneously, with supplementary resources of information such as clinical trial data, medical literature or data from international medicines regulators in order to identify previously unrevealed safety issues or side effects.

The India story

Onkar Deshmukh
RA Associate,
Raaj Global Pharma Regulatory Affairs Consultants

On the other hand, Indian Central Drugs Standard Control Organisation [CDSCO] has the same system as the yellow card scheme which is for 'voluntary' reporting of ADRs, but by healthcare professionals only. If truth be told, the awareness of the above system in India has not been observed for the common public. Hence, they are unaware about 'where' and 'why' to report. The responsibility of Indian Health Authority is to spread this information across the country to make this system successful and effective. UK government introduced this system in 1964 and made it a legal liability for pharma companies to impart the results of the reports they receive about the assumed serious side effects of their products. These reports are made on 'yellow card' reporting forms. Besides, they have set up a website dedicated for such reports and it is made available to everyone,

including the common public. On the contrary, it has been perceived that, in India this information is open to healthcare professionals only and I doubt many of them really pay special attention or are vigilant on the same. Furthermore, India does not have any individual websites that actually coach everyone on the importance of pharmacovigilance along with the help of healthcare professionals.

US also brought in the 'MedWatch' programme for reporting the adverse reactions of all medicines and made it compulsory for the drug/biologic/human cell, tissues and cellular and tissue-based product manufacturers, distributors, and packers. In the same way, India should also introduce such pharmacovigilance programmes, principally for herbals.

The number of adverse reactions to herbal drugs reported or recorded in the National Pharmacovigilance Programme in India is quite insignificant. The strong faith, that herbal or ayurvedic medicines are safe, is one of the causes for this situation. However, it is a myth caused by ignorance about facts and the concept of pharmacovigilance, amongst the herbal practitioners or healthcare individuals with regards to herbal products.

To illustrate, recent studies on this matter have revealed the actual extent of unawareness about herbal pharmacovigilance. This investigation revealed the frame of mind of many herbal practitioners wherein they claimed,'herbal products do not have any kind of adverse effects' and few believed that there are any. This leads to improper manufacturing methods and prescriptions without any logic. Some people experienced unwanted reactions after prescription but they did not report the same and this is where lack of pharmacovigilance can be noticed.

Proper training for pharmacovigilance

If people had been trained on how, why, what and where to report such unwanted reactions, they would have certainly helped the regulatory authority to help themselves. Even if the National Pharmacovigilance Programme has heartened accounting of all suspected drug-related adverse events including those caused by herbal/traditional/alternative medicines, the integer of reports related to herbal drugs has been extremely bad. A great many challenges, which rule out the identification and reporting of adverse reactions to herbal drugs can be identified in terms of detection, assessment and deterrence. This includes falling short of quality assurance and control in the manufacture of herbal preparations, which in turn becomes confusing and deters the spotting of adverse reactions. However, patients get allopathic medicines at the same time, which might also be contributing to those unexpected reactions. The gist of the matter is that a person skilled in

pharmacovigilance rarely has a handle on herbal science while an expert in herbals is not skilled in the science of pharmacovigilance. In addition to that, pharmacovigilance does not get any coverage in the BHMS, MBBS or pharmacy curriculum, both at the undergraduate and post graduate level.

If weighed against the regulated global market, it all boils down to the need for the introduction of pharmacovigilance in the curriculum at the under-graduate and postgraduate level in India as stated above and promoting studies on the safety of herbal drugs. The reporting of ADRs concerning herbal products in India must be made compulsory. Moreover, balanced and easily accessible drug information ought to be made available.

The Traditional Knowledge Digital Library launched by the Government of India is an example of how ancient knowledge available in the ancient scriptures can be made digitally accessible. Healthcare professionals should give their best, not only in reporting the adverse reactions but also by being more confident in the assessment of the same. Pharmacy or ayurvedic colleges can directly share their involvement in national pharmacovigilance programmes so as to make new talents more responsive in this field.

In a nut shell, we know many hazards have already been reported in India on account of not practicing pharmacovigilance in herbal pharma products and hence exercising the same is the need of the hour. Effectual regulations in this area would do a world of good and help avert a 'herbal disaster'.

References:

1. Geneva: World Health Organization; 2004. WHO guidelines on safety monitoring of herbal medicines in Pharmacovigilance systems; p. 19.
2. Wal, P., Wal. A., Gupta, S., Sharma, G., [2011] J young pharm, Pharmacovigilance of herbal products in India, Jul-Sep 3[3], 256-258.
3. UK MHRA, Yellow card: Helping to make medicines safer. Available from: http://yellowcard.mhra.gov.uk/
4. Central Drugs Standard Control Organization, Adverse drug reaction reporting.
5. Global Herbal Market. Available from www.dsir.gov.in/

FEEDBACK: We would love to hear from you -- what you like about our content, what you dont, and even how you think we can improve. Please send your feedback to: *editorial.ep@expressindia.com*

The Express Group

© Copyright 2001: The Indian Express Limited. All rights reserved throughout the world. This entire site is compiled in Mumbai by the Business Publications Division (BPD) of The Indian Express Limited. Site managed by BPD.