Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.007

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Regulatory challenges and approaches involved in registration of herbal drugs in European Union

Rajesh Yelugoila
BITS Pilani, India

On April 30th, 2011, hundreds of Herbal Drugs were banned in the European Union. This was a result of European Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC established on 31st March, 2004. Under the regulation of THMPD all herbal medicinal products were required to obtain an authorisation to market within the EU from April 30th, 2011. Prior to this regulation there was no formal EU wide authorisation procedure, hence each EU member state had their own regulations. The proponents of herbal medicine use state that it is impossible to meet the registration requirements for quality and safety under the directive which are similar to those of pharmaceutical products, because of huge costs involved, which may make many manufacturers of herbal medicines to pack off their businesses affecting the supplies of herbal medicine practitioners. They also state that it will make people to buy herbal medicines over the internet, which could be dangerous. The European Commision states that legislation was brought into effect to protect public health by ensuring the safety, efficacy and quality of medicinal products. Even though the herbal drugs are natural, a number of these drugs are dangerous to patients.EC also states that- traditional herbal medicinal products have particular characteristics, notably their long tradition of use. To take account of this, the EU has introduced a lighter, simpler and less costly registration procedure for them, while providing the necessary guarantees of quality, safety and efficacy. For a herbal substance to reach the market it has to fall in any of the following categories- (i) traditional use (ii) well-established use (iii)stand alone or mixed application. Irrespective of the regulatory pathway to access the market, the quality of the herbal medicinal product must always be demonstrated. A herbal Drug could be approved in the EU through the following routes as per the Directive 2004/24/EC (i) Full marketing authorisation (MA) based on the safety, quality and efficacy of the product, aswith any regular medicine (ii) A traditional herbal registration (THR) based on the safety, quality and evidence of traditional use of the product.

Biography

Rajesh Yelugoila has completed his B.Pharmacy from Sree Dattha Institute of Pharmacy, followed by Industry Program in Pharma Regulatory Affairs from Bioinformatics Institute of India. He has worked for about one and half year in Regulatory Affairs department of Neuland Laboratories. At present he is pursuing M.Pharmacy from BITS, Pilani-Hyderabad and he is the author of blog- www.regulatoryone.com.

rajesh.yelugoila@gmail.com