John Barber, J Pharmacovigilance 2014, 2:5
http://dx.doi.org/10.4172/2329-6887.S1.012

OMICS Group Conferences
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3rd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
October 27-29, 2014 Hyderabad International Convention Centre, India

European risk management plans: Current experience of the generics sector

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In July 2012, the new European Pharmacovigilance legislation started to come into effect. One of the changes brought in, was the requirement for all new generic marketing authorisation applications (MAA) to include a risk management plan (RMP). Prior to July 2012, a generic MAA could be submitted with a waiver statement that no RMP was required. This therefore imposed a significant change on generic companies. There is now just over two years experience with the preparation, assessment and implementation of RMPs for generic medicines. During this time, a number of issues and concerns have arisen. The aim of this session will be to review some of these issues and concerns and to look at how they may be addressed.

Biography

John Barber is currently the QPPV for Dr. Reddy's Laboratories Europe, a role he has been in since April 2010. Prior to that, he was Global Clinical Pharmacovigilance Manager for Glenmark Pharmaceuticals, during which he initiated the development of the company's Pharmacovigilance quality management system for its clinical development programme. He was previously employed by Alliance Pharmaceuticals, a specialist UK pharmaceutical company, where he was latterly Director of Scientific Affairs. In this role, he was responsible for Pharmacovigilance, medical information and clinical development. He also has experience as an information analyst with ICI Pharmaceuticals, Roche and Glaxo Wellcome. He is currently the Immediate Past President of the UK Pharmaceutical Information and Pharmacovigilance Association (PIPA) and is a lead on Pharmacovigilance issues for the British Generics Manufacturers Association (BGMA). By education, he is a pharmacologist, attaining a BSc (Hons) from the University of Liverpool.

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