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Role of regulatory affairs in pharmacovigilance: Marketing authorizations and new pharmacovigilance legislation in EU: Important changes, challenges and options

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Abstract

The relationship between the pharmaceutical industry and government is an important determinant of the government approach to managing pharmaceuticals at the national and EU level. Some issues such as aspects of Marketing Authorization have been harmonized and are uniform across EU member states. New Pharmacovigilance legislation was adopted by the European Parliament on 22 September 2010 and came into force in July 2012. The legislation takes the form of new Directive-amending the requirements of 2001/83/EC and a Regulation 1235/2010 that amends Regulation (EC) 726/2004. Together these will bring about a number of changes to strength the way in which the safety of medicines for human use is monitoring in EU. There are three main area of change: enhanced monitoring of the benefits and risk of medicines in post-authorization-significant impact on the area of Marketing Authorization Applications and maintenance- companies need to implement an integrated environment between Pharmacovigilance and Regulatory Affairs; replacement of the Pharmacovigilance Working Party with Pharmacovigilance Risk Assessment Committee; an increased level of transparency of safety information. For all these major changes transitional period will be setting up with specific reporting requirements until EMA can ensure the functionalities of EudraVigilance database.

New Pharmacovigilance legislation has some major achievements: clarification of roles and responsibilities of various stakeholders, strengthening of the risk-adjusted approach, improvement of transparency, strengthening and clarification of procedures in relation to the use of PASS and RMP, involvement of patients.

Biography

Nathalia Valkova has competes her PharmD from Medicine University of Sofia, Bulgaria after defend a research thesis of Pharmacoepidemiology. She joined Regulatory Affairs and Pharmacovigilance within the Pharmaceutical Industry in Dec 2009, taking on increasing responsibilities in Salvis Pharma Drug Safety.