Medicines

In collaboration with WHO Europe

Facing the Challenges: Equity, Sustainability and Access

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MICHAEL BERNTGEN

PROFILE

Michael Berntgen is Head of the Product Development Scientific Support Department at the European Medicines Agency (EMA), London. This department aims to facilitate timely availability of safe and effective medicinal products by promoting development, research and innovation. It supports medicine development by provision of scientific advice and protocol assistance on products and issues related to drug development – also in collaboration with other decision makers - thereby facilitating that development programmes generate relevant data for later medicine evaluation. Specific measures are available to foster the development of new medicines for orphan diseases and paediatric populations. Furthermore, development of innovative medicines is being stimulated through coordination and management of research projects in liaison with research funding bodies, gathering intelligence from the Business Pipeline as well as conduct of early dialogue with developers on innovation.

Michael is a pharmacist by training and holds a PhD as well as a Master of Regulatory Affairs. From 1999 to 2006, Michael worked in various positions in regulatory affairs in the pharmaceutical industry in Germany and in the UK. In 2006 he joined the German national competent authority BfArM as Scientific Administrator in the Scientific Advice unit. Following this assignment he moved to the European Medicines Agency in 2007 where he initially took up a position as Scientific Administrator in the Therapeutic Group "Anti-infectives" of the Safety and Efficacy sector, followed in September 2009 by the assignment as Head of Rheumatology, Respiratory, Gastroenterology and Immunology in this sector. From September 2013 he was heading the Scientific and Regulatory Management Department until he took over the position as Head of the Product Development Scientific Support Department in September 2016.