EUROPEAN
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Michael Berntgen is Head of the Scientific Evidence Generation Department at the European Medicines Agency (EMA), Amsterdam. This department aims to support the development of medicines to ensure generation of robust and relevant scientific evidence, also in collaboration with other stakeholders (e.g. patients, HTAs). Activities include the provision of scientific advice and methodology qualification, support to medicines for the paediatric population and for orphan diseases, as well as provision of expertise and support in translational sciences. Furthermore, the department monitors the portfolio related to human medicines, manages the PRIME scheme and facilitates collaboration with downstream decision-makers (HTA bodies and payers), to foster timely access to medicines.

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 and from September 2016 the Product Development Scientific Support Department. In March 2020 he took over the current position as Head of the Scientific Evidence Generation Department.