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Austrian Agency for Health and Food Safety



Günter Waxenecker is the head of the Austrian Medicines and Medical Devices Agency (AGES MEA) since 2023 and also a procedural member of the Federal Office for Safety in Health Care (BASG). He is responsible for scientific advice procedures, marketing authorisations of medicinal products, clinical trials of medicinal products and medical devices, pharmacovigilance and vigilance in the field of medical devices, blood and tissues, quality of medicinal products, inspections and market surveillance of medicinal products and medical devices on the Austrian market.

He is a member of the EC Pharmaceutical Committee and the EMA Management Board, member of the Executive Steering Group on Shortages and Safety of Medicinal Products and co-chair of the European Shortage Monitoring Platform.

Günter Waxenecker joined the Austrian Medicines and Medical Devices Agency in 2007 as an assessor for medicinal products focusing on the non-clinical assessment and quality of biopharmaceuticals in the context of clinical trial approvals, scientific advice procedures and marketing authorisation applications. He worked as a group leader and coordinator of the non-clinical working group at AGES MEA and was subsequently responsible for the non-clinical, methodological/biostatistical and quality aspects of biopharmaceuticals as head of unit. He has been a member of the CHMP Non-Clinical Working Party and has acted as Rapporteur for the third revision of the ICH S5 Guideline on Detection of Toxicity to Reproduction for Human Pharmaceuticals.

Günter Waxenecker studied Food Science and Biotechnology and holds a Masters degree in Drug Regulatory Affairs. Before joining the National Competent Authority, he worked as project leader and programme manager for SMEs in Vienna. He is also a lecturer in various Austrian master programmes.