

## INSTITUTES

### Assessment & Analytics

#### Dr. Gerhard Beck

Traisengasse 5  
A-1200 Vienna  
Phone: +43 50 555-36300  
gerhard.beck@ages.at

#### OMCL Biological Medicines

DI Heidemarie Schindl  
Possingergasse 38  
A-1160 Vienna  
Phone: +43 50 555-36304  
heidemarie.schindl@ages.at

#### Chemical-Pharmaceutical Medicines

Mag. Roman Macas  
Spargelfeldstraße 191  
A-1220 Vienna  
Phone: +43 50 555-36940  
roman.macas@ages.at

### Surveillance

#### DI Dr. Ronald Bauer

Traisengasse 5  
A-1200 Vienna  
Phone: +43 50 555-36400  
ronald.bauer@ages.at

### Marketing Authorisation of Medicinal Products and Life Cycle Management

#### Mag. Dr. Peter Platzer

Traisengasse 5  
A-1200 Vienna  
Phone: +43 50 555-36570  
peter.platzer@ages.at

### AGES Medicines and Medical Devices Agency

Traisengasse 5  
A-1200 Vienna  
Phone: +43 50 555-36111

#### Head of the Agency

##### DI Dr. Christa Wirthumer-Hoche

Phone: +43 50 555-36000  
Traisengasse 5  
A-1200 Vienna  
christa.wirthumer-hoche@ages.at

#### IT/PHAROS/e-services

georg.neuwirther@ages.at

### Imprint

Publisher:  
AGES GmbH (Austrian Agency for Health and Food Safety)  
Spargelfeldstraße 191 | A-1220 Vienna | Austria

Photos: Photodisc Inc, Shutterstock  
© Ryan McVay, leungchopan

All rights reserved. The reproduction of texts and data including their (digital) storage and use on optic and electronic data carriers is subject expressly to AGES' prior written consent.



HEALTH FOR HUMAN,  
ANIMALS AND PLANTS



AGES MEDICINES AND  
MEDICAL DEVICES AGENCY

ACTIVITIES AND LOCATIONS

## AGES MEA - AUSTRIAN MEDICINES AND MEDICAL DEVICES AGENCY

### A business segment of AGES

Responsibilities of the Austrian Medicines and Medical Devices Agency (AGES MEA) include issuing marketing authorisation for medicinal products (human and veterinary), assessing the efficacy and safety of medicinal products and medical devices, market surveillance, inspection eg. of manufacturers and clinical trials.

When carrying out sovereign activities, the employees of AGES MEA are acting on behalf of the Federal Office for Safety in Health Care - BASG. The BASG is directly subordinate to the Austrian Federal Ministry of Health - BMG, representing the owner of AGES, the Republic of Austria.

The quality assurance system used by AGES MEA implements the requirements of ISO 9001, as well as ISO 17025 for OMCL testing activities.

### Values of AGES MEA

#### • WE ARE RESPONSIBLE

We are committed to working in the interest of the health of humans, animals and plants in a sound and responsible manner. We stand by our actions and decisions.

#### • WE ARE OBJECTIVE

We are guided by facts, we are impartial and act with integrity.

#### • WE ARE COMPETENT

We do the right things and we do them in a service- and results-oriented manner. As a team, we strive for innovation, interdisciplinarity and excellence.

#### • WE ARE EUROPEAN

We live and promote the European idea. We actively participate in shaping the European regulatory environment, thereby contributing to safeguarding health in Europe.

### Help and scientific advisory services for applicants

When developing medicines, pharmaceutical companies have the possibility of obtaining scientific advice from the Medicines and Medical Devices Agency. Both types of procedures (EMA Scientific Advice/National Scientific Advice) represent specified focus areas. In the case of enquiries from the field of generics but also biotechnology and monoclonal antibodies (MAbs), as well as the development of biosimilars, the Medicines and Medical Devices Agency ranks amongst the leading medicines agencies within the EU. With regard to the number of scientific advice procedures carried out, it occupied a Top 3 spot among all EU agencies as early as 2008, this position being confirmed again in 2014. This achievement illustrates impressively the extensive know-how available for applicants and customers of the Medicines and Medical Devices Agency to benefit from.

### Approval procedure - Main areas of focus

The Medicines and Medical Devices Agency conducts a scientific-technical assessment of the chemical, pre-clinical and clinical data of the application for marketing authorisation. This assessment determines the outcome of the decision regarding the approval of a medicine. In recent years emphasis has been placed on these features both with regard to the approval of generics (more than 90 % of all licensing applications), as well as in the field of biotechnology. Plasmaderivates, vaccines, biotechnological therapies - such as monoclonal antibodies (MAbs), biosimilars and the fields of immunology and ophthalmology are all core competencies of the Medicines and Medical Devices Agency.

### Austria as Reference Member State (RMS) - The role within the EU in procedures of mutual recognition and decentralised licensing

The Medicines and Medical Devices Agency plays a sustained and leading role as Reference Member State (RMS) in the evaluation of European authorisation and licensing procedures. For years now, Austria has been in the EU Top 10 for mutual recognition and de-centralised authorisation procedures (MRP/DCP). Since 2009 Austria has constantly occupied at least 7th place in overall European comparison.

This achievement clearly underlines the obvious commitment on the part of the Austrian medical authority to be at the forefront of helping to shape matters at a European level - both in the interest of applicants and of public health.

### Activities of AGES MEA relating to the life cycle of a medicine

- Scientific advice
- Admission of clinical trials
- Marketing authorisation and life cycle management of medicinal products
- Pharmacovigilance
- Quality of medical (pre- and post- marketing authorisation)
- Inspections
- Market surveillance of medicinal products (legal and illegal market)
- Market surveillance and vigilance regarding medical devices
- Haemovigilance and tissue vigilance
- Participation in national and international pharmaceutical boards