FACTS

Federal Office for Safety in Health Care

Austrian
Federal Office for
Safety in Healthcare
BASG

BASG / AGES MEA

Federal Office for Safety in Health Care (BASG) and Austrian Medicines and Medical Devices Agency (AGES MEA)

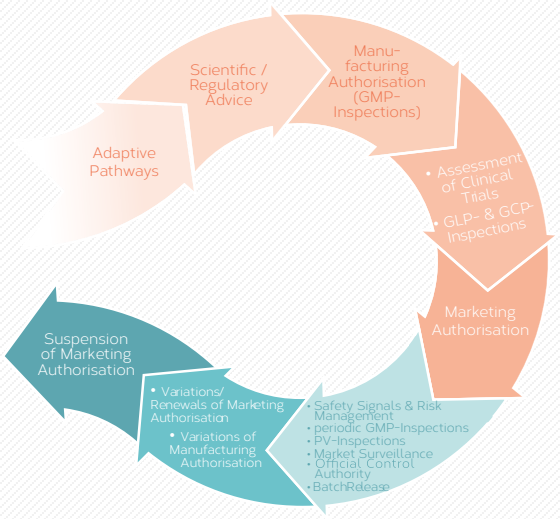
The Federal Office for Safety in Health Care (BASG) and the Austrian Medicines and Medical Devices Agency (AGES MEA) were both set up in January 2006. The BASG is directly subordinated to the Austrian Federal Ministry of Health and Women (BMGF), carrying out sovereign tasks, including authorisation and control of medicinal products and vigilance of devices.

BASG consists of three members appointed by the Federal Minister of Health, one member from BMG and from AGES MEA each. The third member is the head of the AGES MEA.

AGES MEA is therefore closely linked to the BASG, constituting two of its members, providing BASG with necessary resources, staff and infrastructure. When carrying out sovereign activities, the employees of AGES MEA are acting on behalf of BASG.

Responsibilities of AGES MEA include providing Scientific Advice, inspecting according to GMP, GLP and GCP, assessing dossiers for new marketing authorisations of medicinal products, as well as European surveillance of medicinal products and medical devices already marketed, in terms of efficacy and possible side effects, i.e. pharmacovigilance, and all processes related to Lifecycle-Management. AGES MEA is also monitoring blood-and tissue-vigilance issues.

Processes of the Austrian Medicines and Medical Devices Agency in the Life-Cycle of Medicinal Products



SCIENTIFIC ADVICE

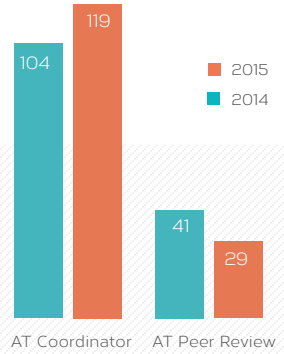
Scientific advice for applicants

When developing medicines, pharmaceutical companies have the possibility of obtaining scientific advice from AGES MEA. Both types of procedures (EMA Scientific Advice/National Scientific Advice) represent specified focus areas. In the case of enquiries from the field of new substances (chemical and bio), but also from the development of biosimilars and generics, AGES MEA ranks consistantly amongst the leading medicines agencies within the EU. With regard to the number of scientific advice procedures it occupied the 1st place-top-position among all EU agencies. This achievement illustrates impressively the extensive know-how available for applicants and customers of AGES MEA to benefit from.

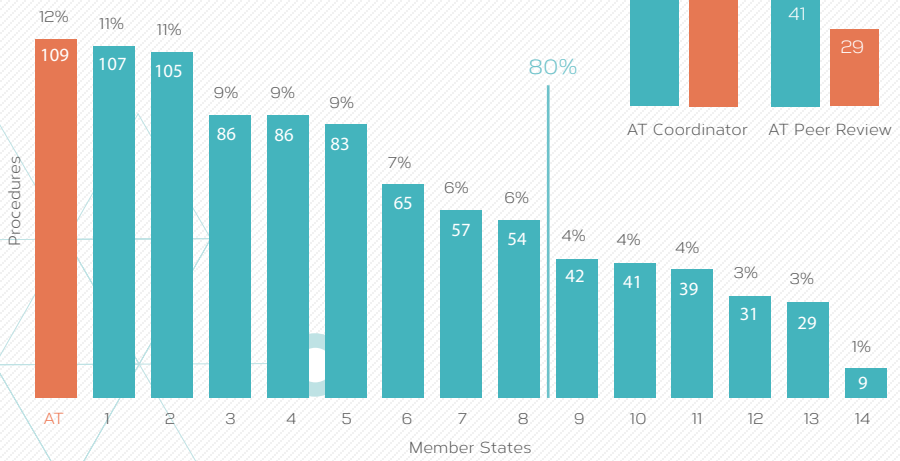
VALUES OF AGES MEA

- WE ARE RESPONSIBLE
- WE ARE OBJECTIVE
- WE ARE COMPETENT
- WE ARE EUROPEAN

Number of EMA Scientific Advice Procedures

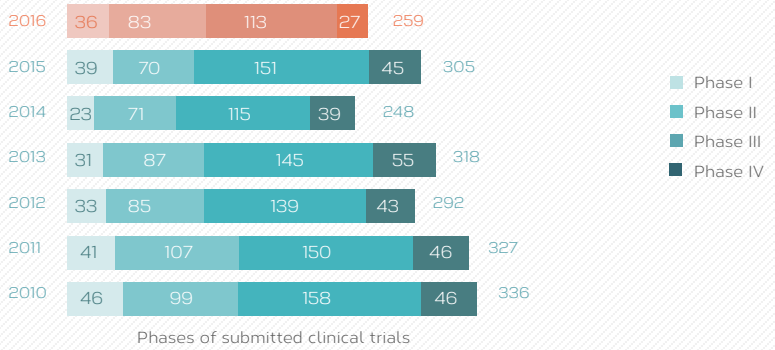


SAWP - Scientific Advice in 2015



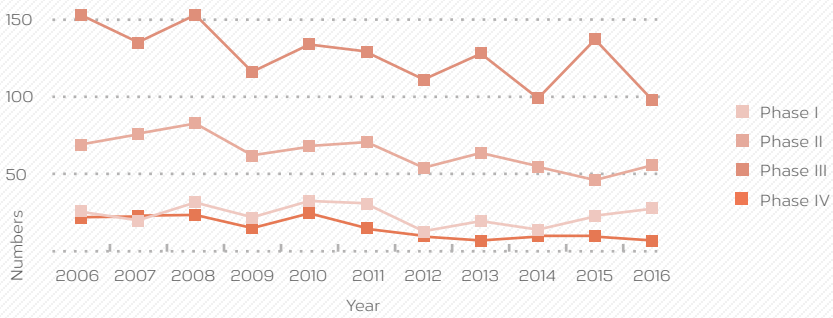
CLINICAL TRIALS

Authorisation of clinical trials

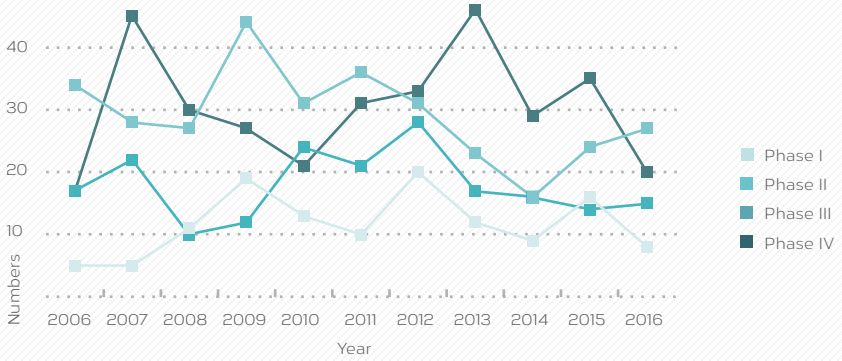


Phases of submitted clinical trials

Commercial Trials in AT



Academic Trials in AT



MARKETING AUTHORISATION

Approval procedure - Main areas of focus

AGES MEA conducts a scientific 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 national authorisation applications), as well as in the field of biotechnology. Blood- and plasma products, vaccines, monoclonal antibodies (MAbs), biosimilars and the field of immunology are all core competencies of the AGES MEA.

Core competences of AGES MEA

- BLOOD- AND PLASMA PRODUCTS
- VACCINES
- BIOSIMILAR PRODUCTS

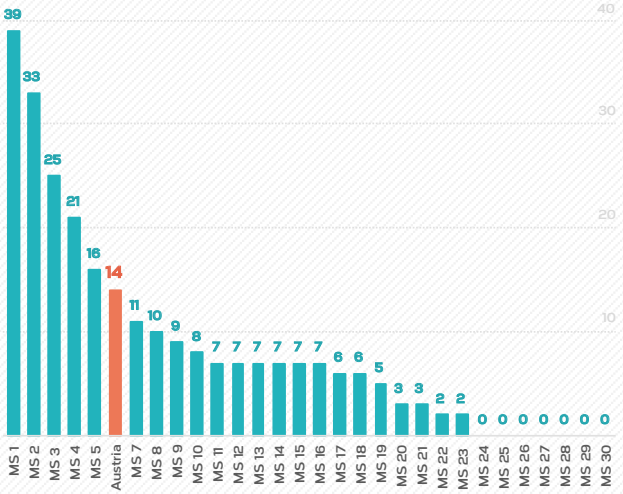
AUTHORISATION AND LIFECYCLE-MANAGEMENT OF MEDICINAL PRODUCTS

AGES MEA plays a sustained and leading role as Rapporteur in the centralised procedure (CP) and as Reference Member State (RMS) in the evaluation of mutual recognition and de-centralised authorisation procedures (MRP/DCP). For years now, Austria has been in the EU Top 10 in MRP/DCP procedures. Since 2009 Austria has constantly occupied a top ten place in the overall European comparison. Recently Austria also entered Top ten in centralised procedures. 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.

Top ten place

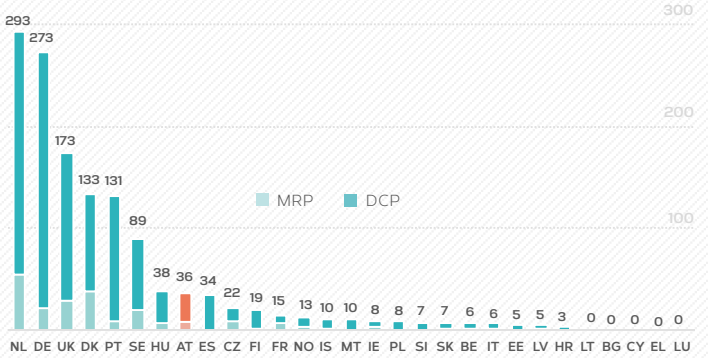
in European comparison since 2009

Centralised Procedure

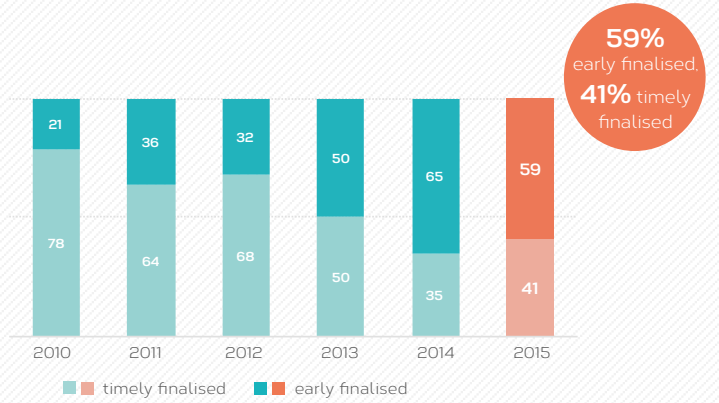


Austria in comparison to other agencies per number of Rapporteur and Co-rapporteurships in the centralised procedure

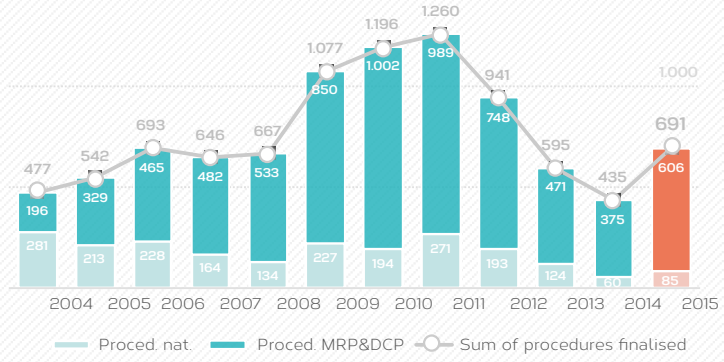
MRP/DCP Procedure



Overview on finalised human MR- and DC-procedures per RMS 2016



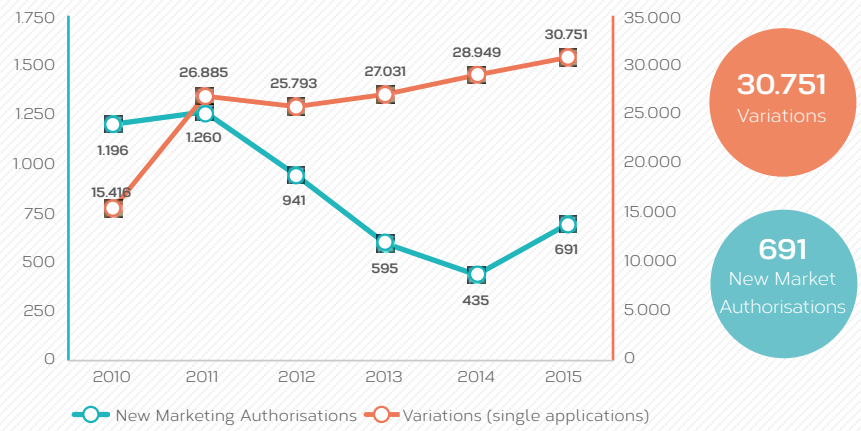
Fast processing, time kept as short as possible, many DCP procedures can be finalised before day 210



Marketing authorisations issued over the last years national vs MRP/DCP

OMCL

Authorisations and Variations

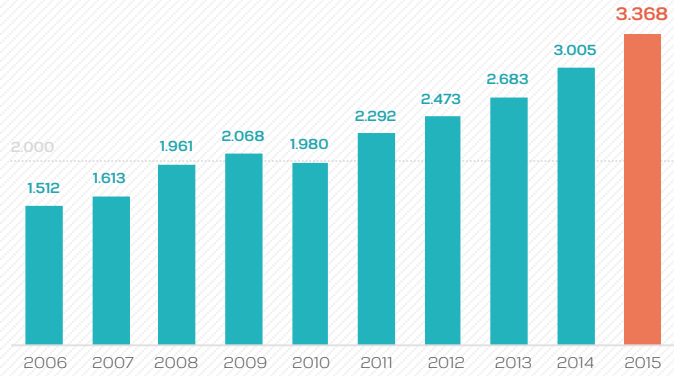


30.751 Variations

691 New Market Authorisations

New Marketing Authorisations vs. Variations

Batch release

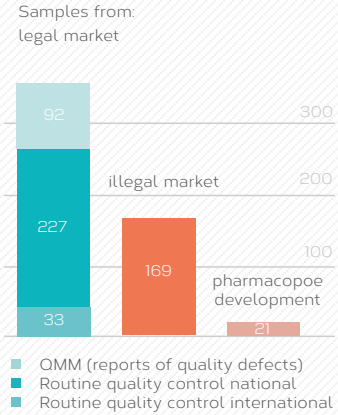


Approval of plasma pools 2006-2015

SURVEILLANCE

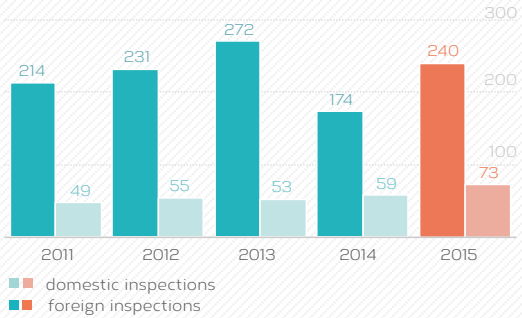
Market surveillance

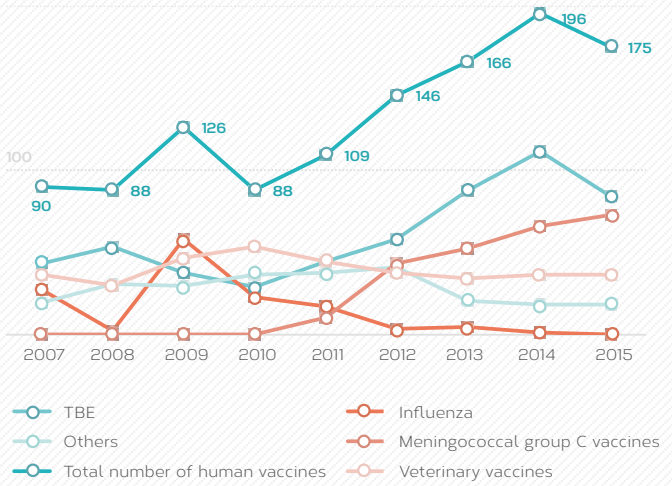
Market surveillance: sample structure 2015



Inspections

Numbers of domestic and foreign countries inspections





Batch Release of vaccines 2007-2015

CONTACT

BASG & AGES MEA

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