Austrian
Federal Office for
Safety in Healthcare
BASG

FACTS

FEDERAL OFFICE FOR SAFETY IN HEALTH CARE

BASG / AGES MEA

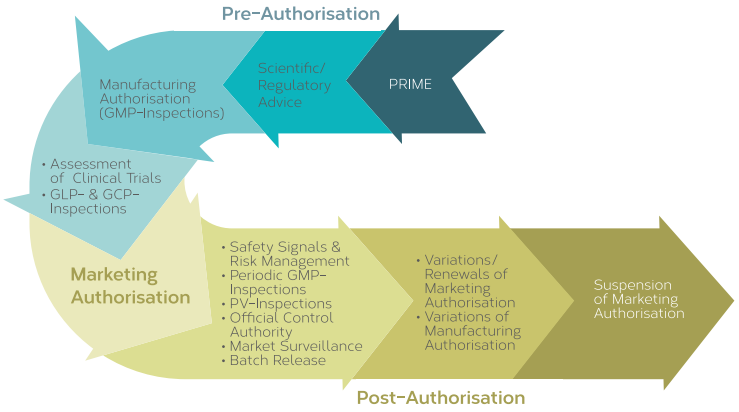
Federal Office for Safety in Health Care (BASG) and Austrian Medicines and Medical Devices Agency (AGES MEA)

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 Social Affairs, Health, Care and Consumer Protection (BMSGPK), carrying out sovereign tasks, including authorisation and control of medicinal products and vigilance of medical devices.

BASG consists of three members appointed by the Federal Minister of Health, one member from BMSGPK 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, Clinical Trial Authorisation, 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 Lifecycle of Medicinal Products

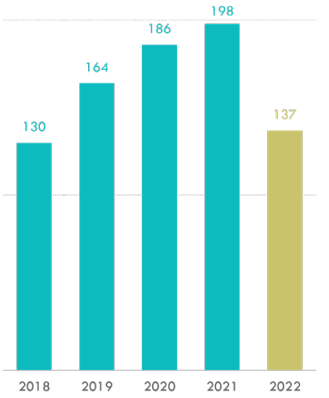
VALUES OF AGES MEA

SCIENTIFIC ADVICE

Scientific advice for applicants

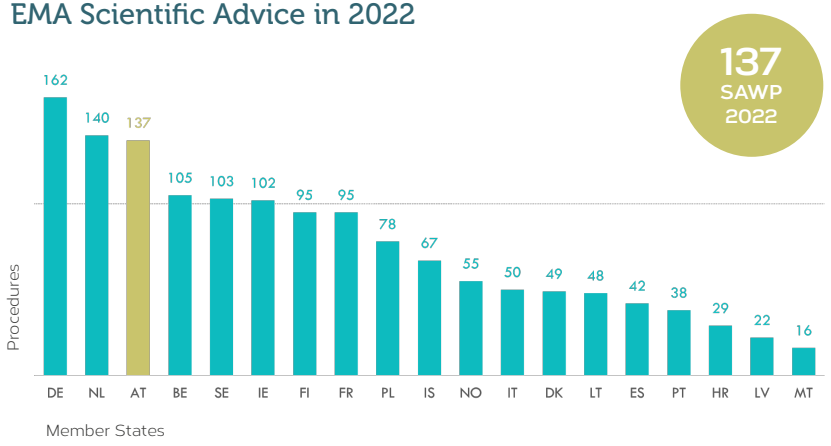
When developing medicines, pharmaceutical companies have the possibility of obtaining scientific advice. Both types of procedures (EMA Scientific Advice/National Scientific Advice) represent defined focal points for AGES MEA and it covers inquiries from the area of new substances (chemical and biological), 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 holds a 3rd place top-position among all EU agencies. This achievement impressively illustrates the extensive know-how available for applicants and customers of AGES MEA to benefit from.

Number of EMA Scientific Advice Procedures

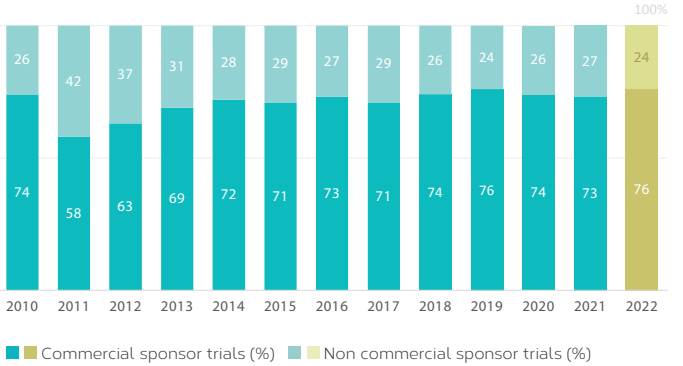


AT-Coordinator
(incl. multinational-teams)

EMA Scientific Advice in 2022



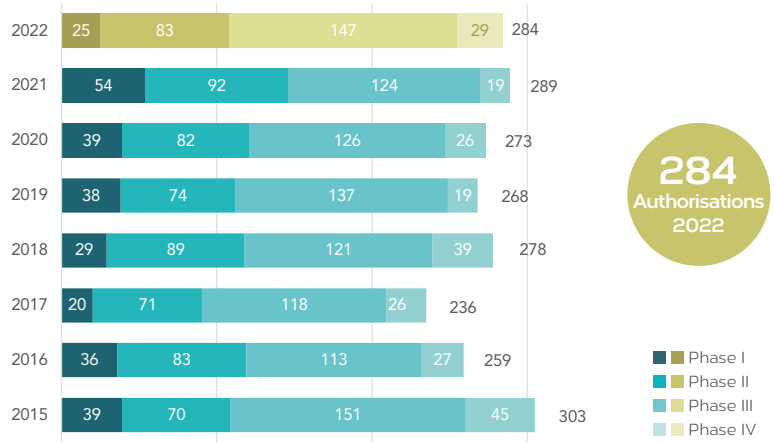
Commercial vs. non-commerical trials in AT



Percentage of commercial versus non-commercial sponsor trials with medicinal products

CLINICAL TRIALS

Authorisation of clinical trials with medicinal products



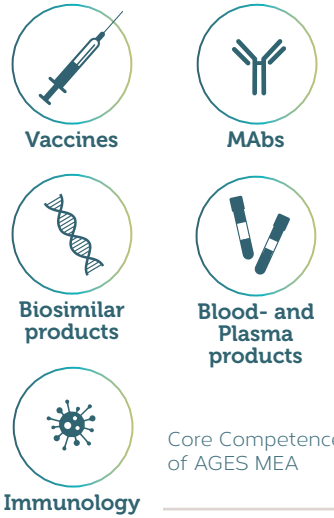
284 Authorisations 2022

Phases of submitted clinical trials

CORE COMPETENCES OF AGES MEA

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, 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

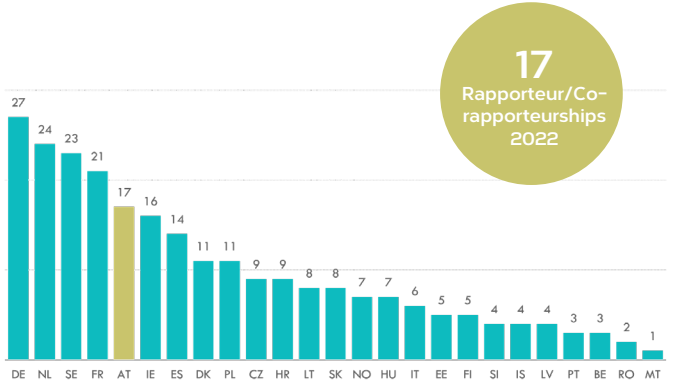
AUTHORISATION AND LIFECYCLE-MANAGEMENT
OF MEDICINAL PRODUCTS

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 MR-/DC-procedures. Since 2009 Austria has constantly occupied a top ten position in benchmarking of European national competent authorities. Recently Austria also entered Top ten in centralised procedures.

This achievement clearly underlines the obvious commitment 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.

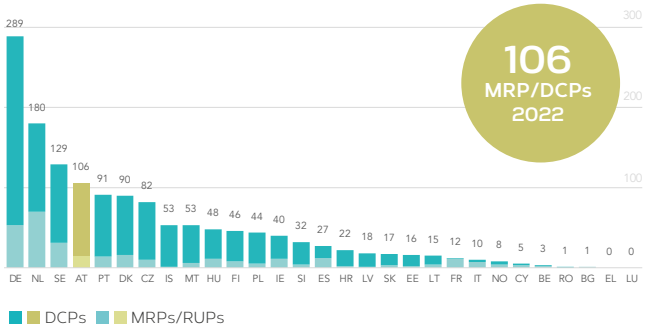
Top ten position in European comparison since 2009

Centralised Procedure

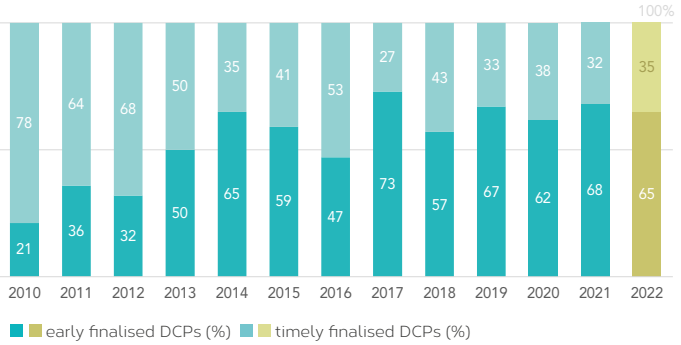


Austria in comparison to other agencies per number of Rapporteur and Co-rapporteurships in the centralised procedure

MR-/DC-procedures

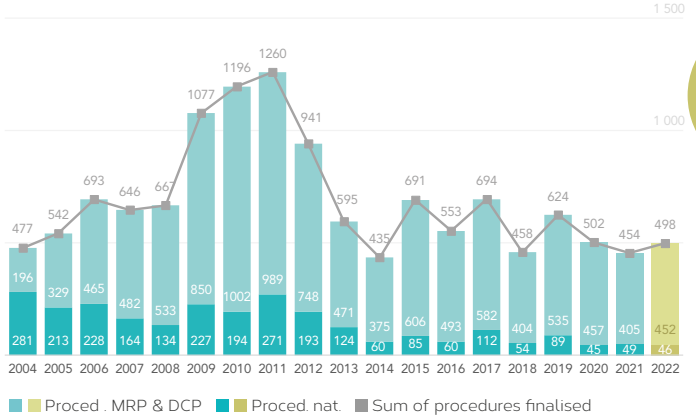


Overview of started human MR- and DC-procedures per RMS 2022



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

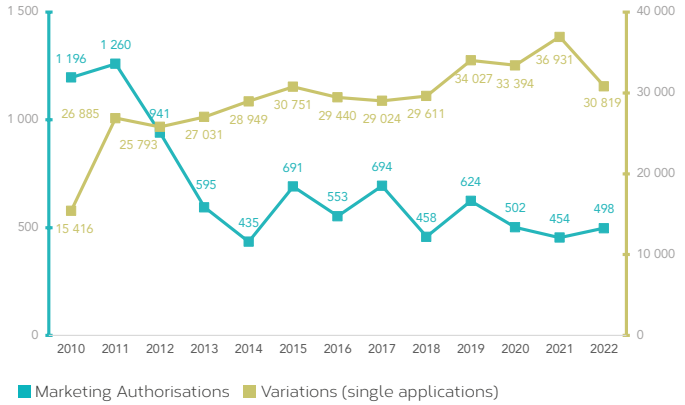
New Marketing Authorisations



498
Marketing authorisations

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

Authorisations and Variations



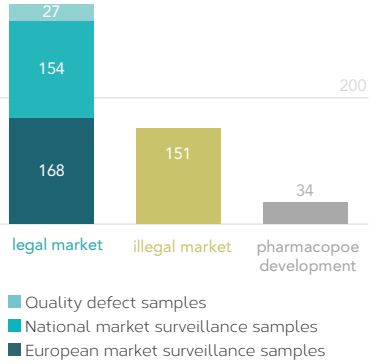
30.819
Variations

498
New Market Authorisations

New Marketing Authorisations vs. Variations

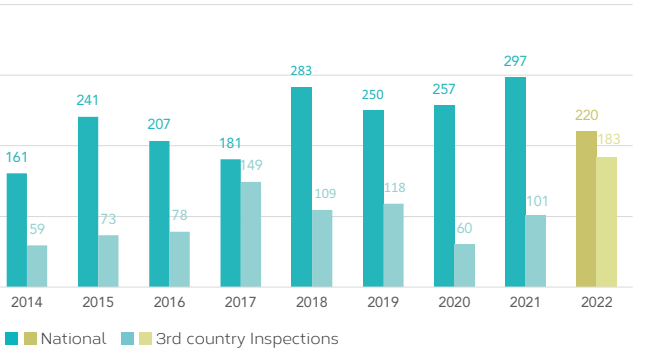
SURVEILLANCE

Market surveillance of Medicinal Products



Market surveillance: sample structure 2022

GM(D)P Inspections



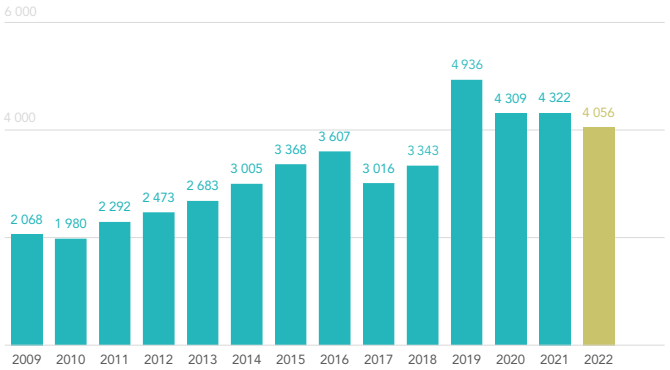
220/183
GM(D)P Inspections

Numbers of national and 3rd country GM(D)P Inspections

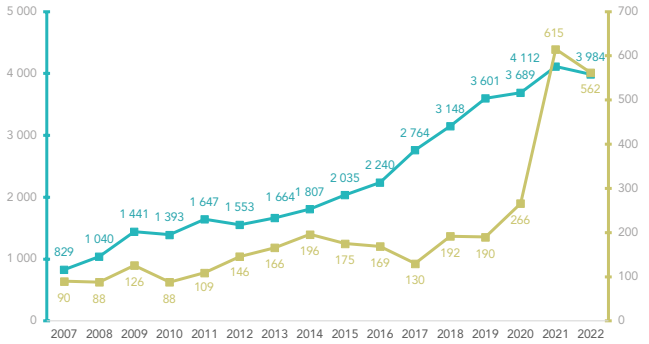
OMCL

Batch Release

4.056
Approvals of plasma pools 2022



Approval of plasma pools 2009-2022



Batch Release of vaccines and Plasma derived medicinal products 2007-2022

CONTACT

BASG & AGES MEA

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