Austrian
Federal Office for
Safety in Healthcare
BASG

FACTS

FEDERAL OFFICE FOR SAFETY IN HEALTH CARE

BASG/AGES MEA

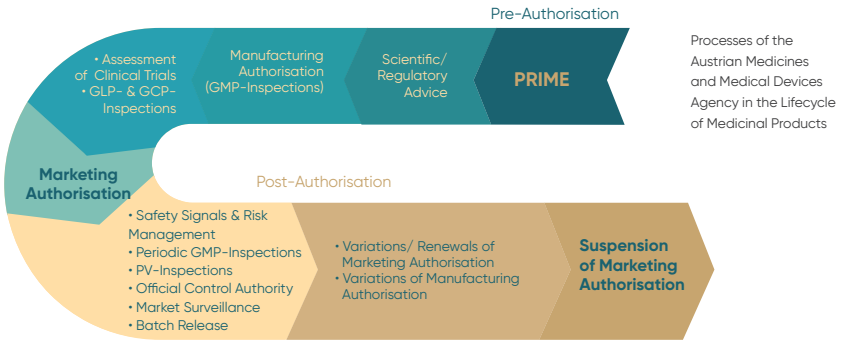
Federal Office for Safety in Health Care (BASG) and Austrian Medicines and Medical Devices Agency (AGES MEA)

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, inspection in accordance with 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

RESPONSIBLE | OBJECTIVE | COMPETENT | EUROPEAN

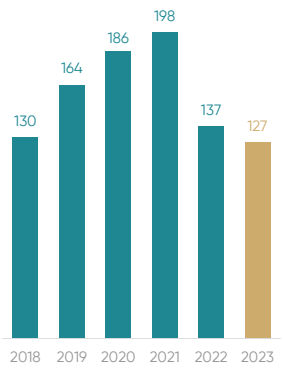
SCIENTIFIC ADVICE

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 requests from the area of new substances (chemical and biological), but also from the development of biosimilars and generics. AGES MEA is consistently ranked among the leading medicines agencies within the EU. With regard to the number of scientific advice procedures it holds 2nd 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.

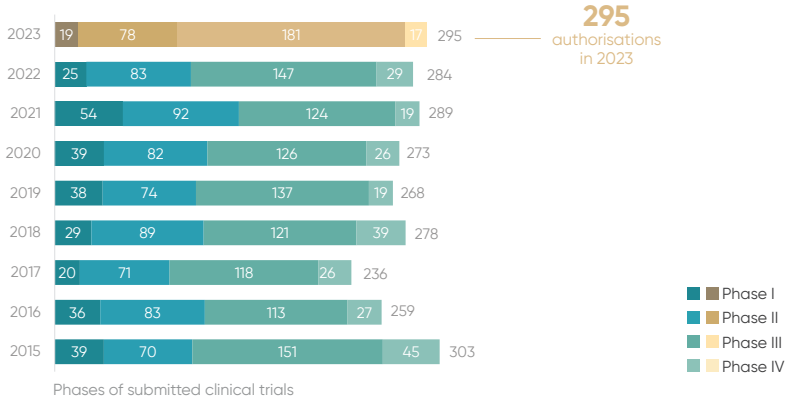
Number of EMA Scientific Advice Procedures

AT-Coordinator (incl. multinational-teams)



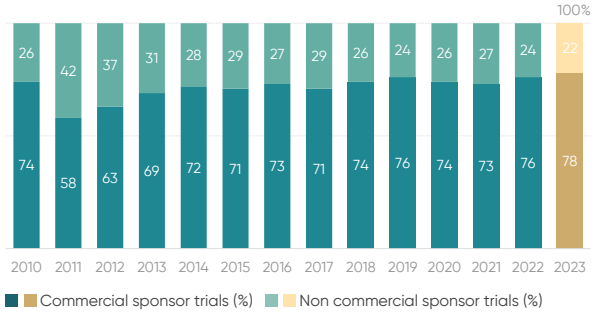
CLINICAL TRIALS

Authorisation of clinical trials with medicinal products



Phases of submitted clinical trials

Commercial vs. non-commerical trials in AT



22% non commercial &

78% commercial in 2023

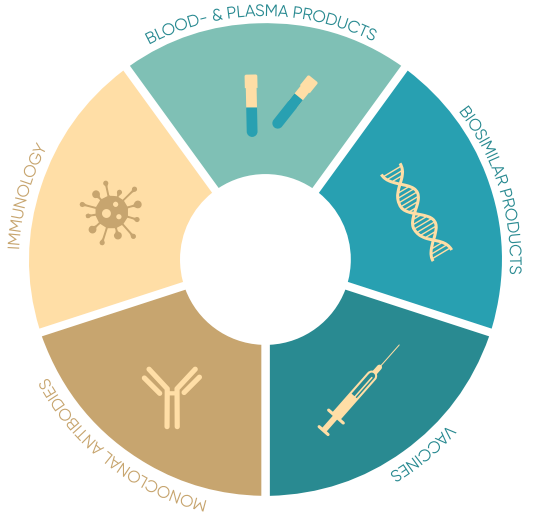
Percentage of commercial versus non-commercial sponsor trials with medicinal products

CORE COMPETENCES OF AGES MEA

Approval procedure - Key areas of focus

AGES MEA carries out the scientific assessment of the quality preclinical and clinical data of the marketing authorization application. This assessment determines the outcome of the decision on the approval of a medicinal product. In recent years, the focus has been on the approval of both generic and biotechnological drugs. Blood- and plasma products, vaccines, monoclonal antibodies (MAbs), biosimilars and the field of immunology are AGES MEA's core competencies.

Core Competences of AGES MEA



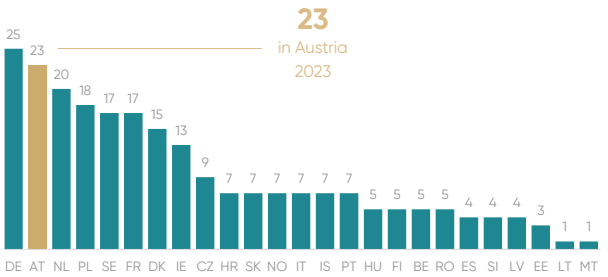
AUTHORISATION AND LIFECYCLE-MANAGEMENT OF MEDICINAL PRODUCTS

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 Mutal 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 medicines 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.

„Austria has been in the EU Top 10 in MR-/DC-procedures since 2009"

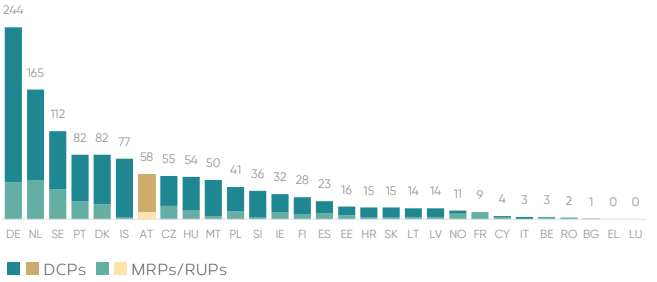
Centralised Procedure

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

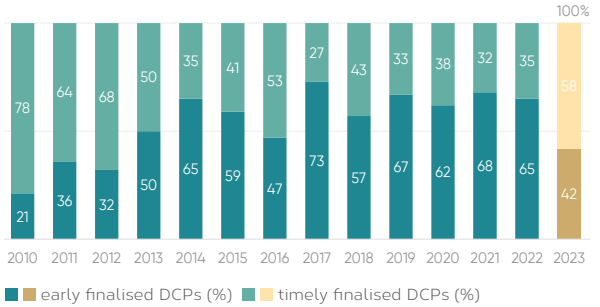


MR-/DC-procedures

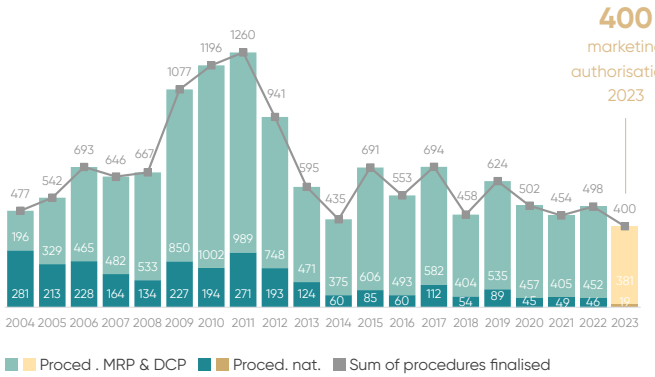
Overview of finalised human MR- and DC-procedures per RMS 2023



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

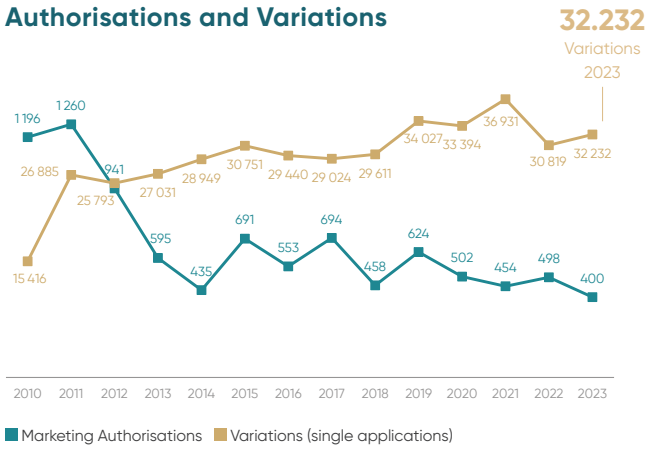


New Marketing Authorisations



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

Authorisations and Variations

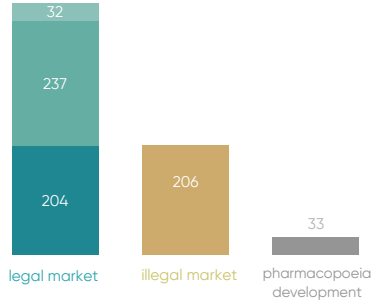


New Marketing Authorisations vs. Variations

SURVEILLANCE

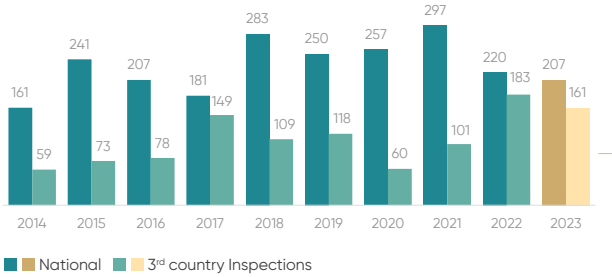
Market surveillance of Medicinal Products

Market surveillance: sample structure 2023



GM(D)P Inspections

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

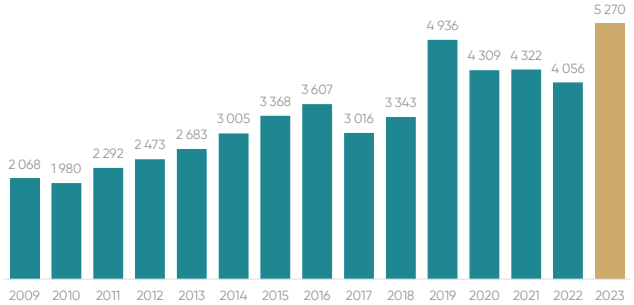


207/161
GM(D)P Inspections

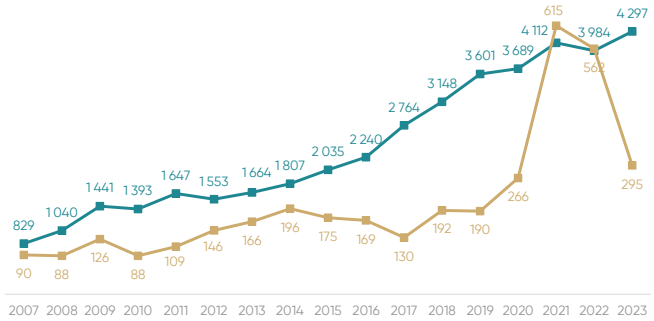
OMCL

Batch Release

5.270
Approvals of plasma pools 2023



Approval of plasma pools 2009-2023



Batch Release of vaccines and Plasma derived medicinal products 2007-2023

CONTACT

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