

BASG – Federal Office for Safety in Health Care



2016/2017

Annual Report



Imprint

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Printing

one2print.at, 1060 Vienna

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PROLOGUE

SC Dr. Magdalena Arrouas

Chair BASG, acting Section Director at Ministry of Health



Dear readers,

Since its establishment, the Federal Office for Safety in Health Care (BASG) has continuously succeeded in dealing with the dynamically changing requirements, both on the scientific/regulatory level, as well as on the level of the European Union legislation relevant for Austria, by not only complying with, but also by actively shaping and further developing it.

The structures and processes of the Austrian Medicines and Medical Devices Agency (AGES MEA), which – according to the Health and Food Safety Act – provide the BASG with its technical, organizational and human resources, have already reached a high level of quality and operational maturity. This was reaffirmed in 2017 in a review process conducted by the Heads of Medicines Agencies (HMA), an association of the national regulatory authorities for medicinal products for human and veterinary use in the European Economic Area. The period of the two reporting years 2016 to 2017 was therefore completed very successful.



The structures and processes of the Austrian Regulatory Authority as compared to international standards have reached a high level of quality and operational maturity.

As a consequence, it has also been possible to provide the pharmaceutical industry in Austria with a solid and competent regulatory environment, thus giving a viable basis for sustaining value creation and jobs in this important sector of the economy. Considering international developments, the continuously growing importance of adequate contribution by the public sector for safeguarding the supply of medicines in Austria has also been made possible.

In particular this ensures that the legal and ethical mandate will continue to be fulfilled in the future, especially for the benefit of patients, by ensuring a high level of safety and efficacy for medicines and medical devices in line with the current state of sciences.

As a national competent authority with far-reaching international obligations, the activities of the BASG are not limited to Austria, but must be considered in the increasingly important pan-European context. The BASG and the AGES-MEA are therefore actively involved in constant cooperation with the European Medicines Agency and the other Member States of the EU. The continued positive development of the BASG is of vital interest for the future of the Austrian pharmaceutical location and above all, for the care and safety of our Austrian patients.

SC Dr. Magdalena Arrouas



PROLOGUE

DI Dr. Christa Wirthumer-Hoche

Head of the Austrian Medicines and Medical Devices Agency,
Procedural Member BASG

Dear readers,

Living in a constant process of change, concerning not only medicinal products and medical devices, but also various framework conditions, the Federal Office for Safety in Health Care (BASG) is facing the essential task of keeping pace with these changes by corresponding adaptations and developments.

One topic in our focus has been of course, since the outcome of the EU referendum on 23 June 2016, the Brexit. Vienna submitted

not only a first-class offer to host the European Medicines Agency (EMA) – even though the final decision then was to relocate EMA to Amsterdam – but BASG will also prepare itself to take on even more tasks and works in the future European network.

The Austrian Authority gladly accepts this challenge, even more since BASG is already known to be amongst the top 5 to 10 in Europe, due to its outstanding expertise in many areas of its activity. Especially in the field of scientific advice, Austria ranks first, ex aequo with the UK, and in the field of batch release testing our control laboratory (OMCL) ranks second in the EU.



The mandatory use of the electronic application form (eAF) was well prepared, intensively communicated and ideally implemented.

In order to provide even more specialised expertise, evidently corresponding steps in human resourcing have to be taken. Focusing particularly on education, training is one of our mainstays and especially the very active cooperation with the „EU-Network Training Center“ – an internal training center amongst Regulatory Authorities, in which the Austrian Authority played a leading role in its development right from the outset – is an absolute „MUST“ for all experts working on behalf of the BASG.

The optimization of our regulatory processes will of course also be further promoted. Data regarding economic effectiveness, cost coverage and efficiency of all our services are collected continuously, and new key performance indicators and statistics for management are established.

In March 2017, the European Commission and the US Food and Drug Administration (FDA) signed a Mutual Recognition Agreement (MRA) on inspections for Good Manufacture Practices (GMP) of drug production. 1st November 2017 marked the beginning of mutual recognition of inspections of manufacturing facilities producing drugs for human use between the US and eight European Union Member States. We are proud of Austria being one of these first countries.

This success was facilitated by broad joint and comprehensive

efforts in the quality area, a high level of maturity of the Austrian Medicines Authority's processes, extensive know-how and practical experience of inspectors in the field of GMP as well as continuous evaluation of other inspectorates.

The year 2016 saw also the start of increased communication with an essential stakeholder for medicinal agencies – the patients. Realizing the goal of providing more information and transparency to these customer-group in a targeted manner became a permanent topic that we will of course continue to pursue in the years to come. Numerous legislative amendments at EU level were and are on our door step, such as those for veterinary medicinal products, as well as the implementation of already adopted laws, such as those for clinical trials, medical device legislation, but also the falsified medicines directive. These amendments are all accompanied by massive challenges, inter alia due to the fact that the implementation of new legislation cannot be done anymore without the creation of a special electronic platform, a transnational database or an electronic network.

At the national level, the quality of our e-service portal PHAROS has also been enhanced to further increase the user-friendliness and satisfaction of both, external customers and internal users. The mandatory use of the electronic application form (eAF) was well prepared, intensively communicated and ideally implemented. The automatic data transfer from the eAF now eliminates the need for manual filling in of certain data fields in PHAROS. The integration of the clinical trials in PHAROS was also successfully completed. Since then, these procedures run from submission to approval paperless and without system breaks.

In sense of extending drug surveillance, our unit "Enforcement" was expanded. The unit has been reorganised and equipped with significantly more staff, now enabling a deeper processing of multiple issues from a professional and legal point of view.

This present report provides an excellent overview of the work of the BASG in effort to protect and promote the health of all citizens and animals both in Austria and the EU.

Enjoy reading

DI Dr. Christa Wirthumer-Hoche





Austrian Medicines and Medical
Devices Agency (AGES MEA)

AGES MEA

Austrian Medicines and Medical Devices Agency (AGES MEA) as a business area of the Austrian Agency for Health and Food Safety (AGES)

The Austrian Agency for Health and Food Safety (AGES) is one of Europe's leading expert organisations, striving to minimise risks in areas of public health, animal health, food safety, medical and drug safety and consumer protection.

Founded in 2002, AGES MEA is fully owned by the Republic of Austria and structured in a number of strategic business areas. One of its areas, the Austrian Medicines and Medical Devices Agency (AGES MEA) was established in 2006.



AGES is one of Europe's leading expert organisations, striving to minimise risks in areas of public health, animal health, food safety, medical and drug safety and consumer protection.

Responsibilities of AGES MEA include issuing new marketing authorisations for medicinal products in Austria, as well as the national and European surveillance of medicinal products and medical devices already marketed, in terms of effectivity and possible side effects, also inspecting manufacture, transport and storage. AGES MEA is also monitoring blood- and tissue-vigilance issues.

BASG

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 (BMG), carrying out sovereign tasks, including authorisation and control of medicinal products and medical devices.



The BASG authorises and controls medicinal products and medical 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, providing BASG with necessary resources, staff and infrastructure. When carrying out sovereign activities, the employees of AGES MEA are acting on behalf of BASG.

VISION, MISSION, SELFCONCEPT & VALUES



Vision

We strive to continuously ensure effective and safe medicines and thus contribute to and maintain the highest levels of public health, taking a leading role among medicines agencies in Europe.



Mission

We are the national competent authority for regulation of medicinal products, medical devices, blood and tissue, and a partner to competent authorities and agencies throughout Europe and pharmaceutical industry.



Self-concept

We are dedicated to promoting and protecting both human and animal health by safeguarding and shaping the regulatory and scientific environment to ensure high-quality medicinal products and medical devices with a balanced benefit-risk ratio.

Our scientific and regulatory experts are the knowledge-carriers of our organisation, constantly developing and sharing their expertise and knowledge with the public.

OUR VALUES AND THE WAY WE LIVE THEM



Responsible

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



Objective

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



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.



European

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

Strategic targets

Strategic objectives of the Austrian Medicines and Medical Devices Agency are based on the Vision and Mission, the effectiveness objective Nr. six: "Safe medicinal products and medical devices" of AGES, the quality objectives in the framework of the strategy AGES 2016–2020 and the objectives of BASG:

1

Ensuring sustainable and successful positioning on the market and within the EU network

- 1.1 Recognise and incorporate future-oriented developments
- 1.2 Participate actively in shaping relevant committees
- 1.3 Lead and competently assess regulatory procedures

2

Maintaining an active communication

- 2.1 Communicate decisions in a transparent way
- 2.2 Keep stakeholders proactively informed
- 2.3 All Under One Roof (AUOR) is known to all applicants as a unique selling proposition (USP) of AGES MEA

3 Acting in a customer- and service-oriented way

- 3.1 Define corresponding quality criteria
- 3.2 Create added value for customer
- 3.3 Conduct dialogue with relevant stakeholders
- 3.4 Institute Surveillance is going to be developed further in a customer-oriented way, making use of guidelines for stakeholder engagement. Additionally, tools for market analysis and -survey are implemented for full scale impact assessment of the pharmaceutical market.

4 Using resources (infrastructure, human- and time-resources) an efficient and effective manner

- 4.1 Take consistent decisions
- 4.2 Further expand and optimise process management on an ongoing basis
- 4.3 Procedures for EU rapporteurship and RMS activities of AGES MEA are – in due consideration of quality of assessment – optimised in terms of processing times and costs. The amount of procedures is stable.
- 4.4 The process “clinical trials” is implemented by AGES MEA according to the recent EU Regulation
- 4.5 Enforcement activities of AGES MEA are expanded and the cooperation with other authorities is strengthened.

5 Developing IT landscape

- 5.1 Implement European and national requirements promptly
- 5.2 Establish BASG as central data hub and platform for Austria

Quality Management

- ▶ The complete Austrian Medicines and Medical Devices Agency, which is a business area of the Austria Agency for Health and Food Safety (AGES), was certified in 2010 by Quality Austria according to ISO 9001.
- ▶ The Official Medicines Control Laboratory (OMCL) of the Federal Office for Safety in Health Care was accredited in 2002 as testing laboratory according to ISO/IEC 17025 by Akkreditierung Austria as conformity assessment body No. 198. The current scope of accreditation is published at <http://www.en.bmwf.gv.at/technicalaffairsandsurveying/Akkreditation>. The quality system of the OMCL is additionally subject to periodic audits by the OMCL network, which assess additionally to ISO 17025 compliance the implementation of Quality Management Guidelines of the network.
- ▶ Accreditation of all inspection activities according to ISO/IEC 17020 was laid down in 2016, but the standard is still used as an internal requirement. Besides ISO/IEC 17020, the quality system implements requirements of the Compilation of Community Procedures, which is the basis for international recognition of inspection results (e.g., in the framework of the Mutual Recognition Agreement with the USA)
- ▶ The pharmacovigilance system considers the requirements of GVP module I as well as the Commission Implementing Regulation (EU) 520/2012.

Compliance to these standards is verified by mutual audits of the European and international regulatory network.



Authorised medicinal products with new active ingredient



Number of authorised medicinal products with a new active pharmaceutical ingredient in the last eight years

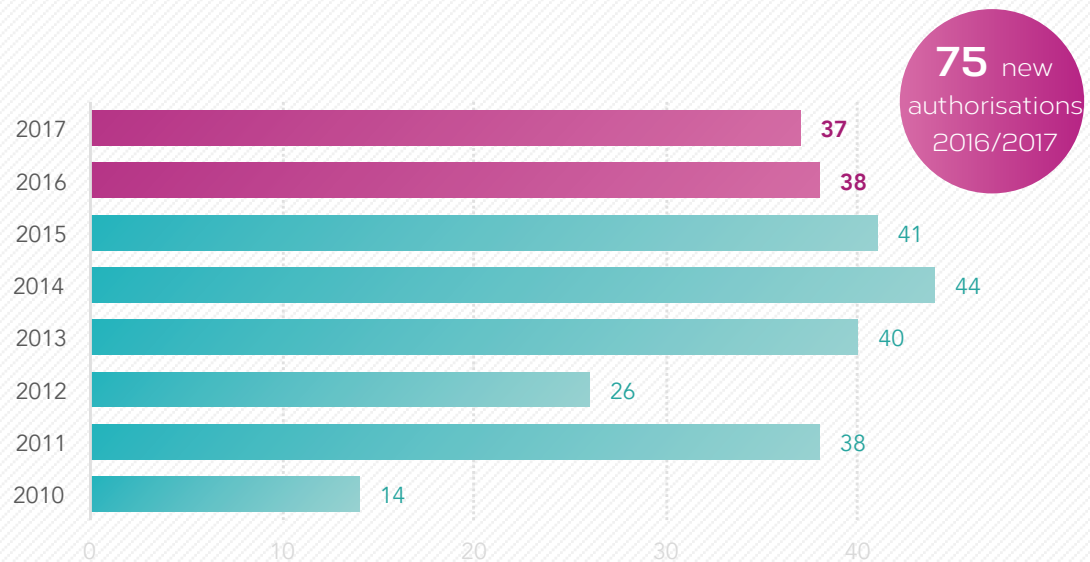
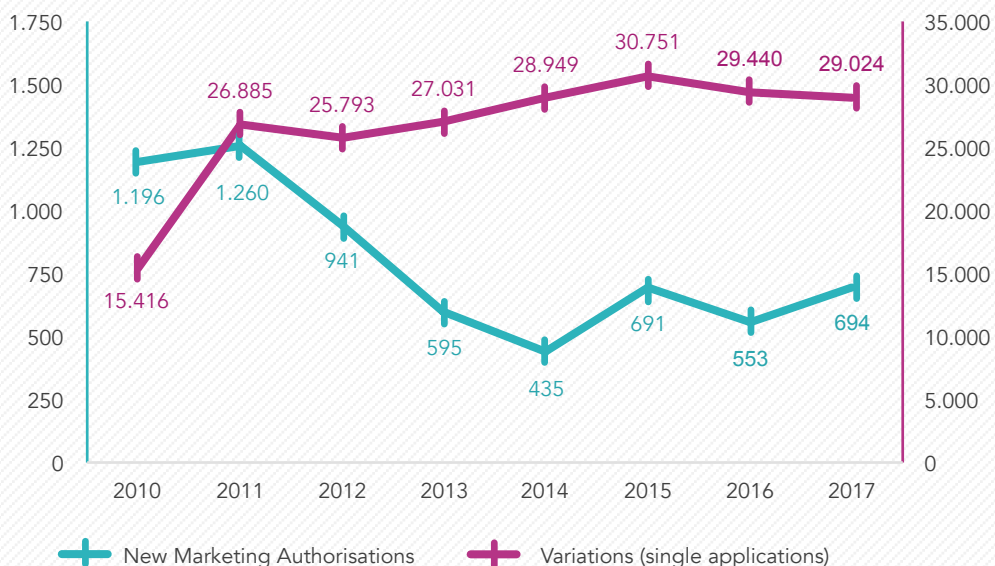


Fig. 1
Number of authorised medicinal products with a new active pharmaceutical ingredient

New Marketing Authorisations vs. Variations

Since 2011 the number of applications for new marketing authorisations in Austria and in Europe generally decreases. However, the number of variation applications remains relatively steady over the past years. Since the beginning of 2014 lifecycle services in Austria are covered by an annual fee. This minimises the administrative burden substantially and facilitates predictable costs for the industry.

New Marketing Authorisations vs. Variations



58.464

Variations
2016/2017

1.247

New Market
Authorisations
2016/2017

Fig. 2
New Marketing
Authorisations
vs. Variations

Austria as Reference Member State (RMS)

Austria – strongly positioned as RMS

For years Austria has held a top ten position as RMS in the EU ranking for European authorisation procedures. In 2016 and 2017, the BASG/AGES MEA holds 8th position in finalised procedures for human medicinal products. In herbal medicines, Austria has established itself in the excellent 1st place for finalised and started procedures.

Despite the decreasing number of new marketing authorisation applications on the European level, Austria could steadily enhance its procedure numbers as RMS over the last years and has recently allocated the 850th procedure number.

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

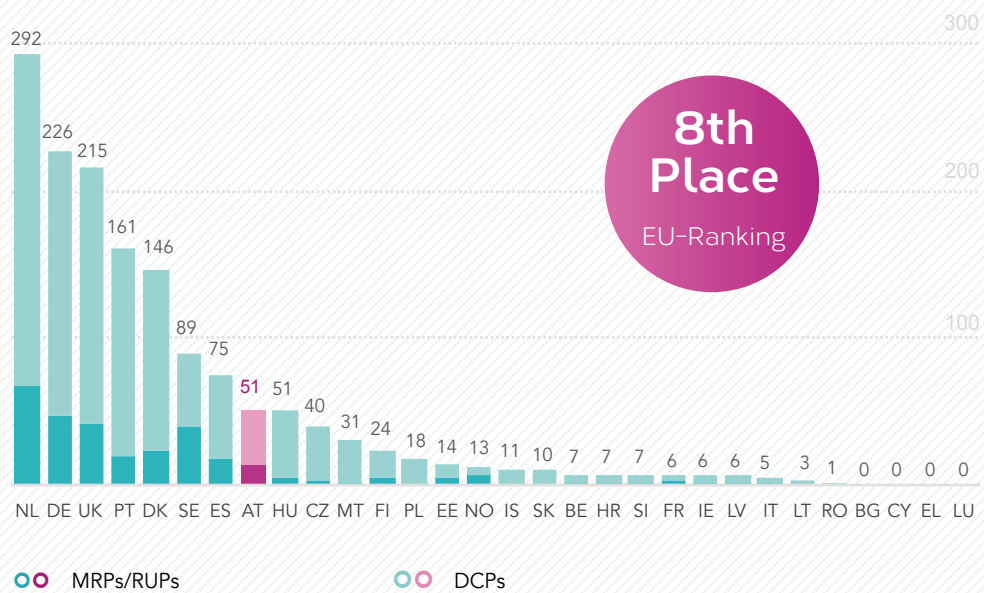


Fig. 3
Overview on finalised human MR- and DC-procedures per RMS 2017

Overview on finalised herbal MR- and DC-procedures per RMS

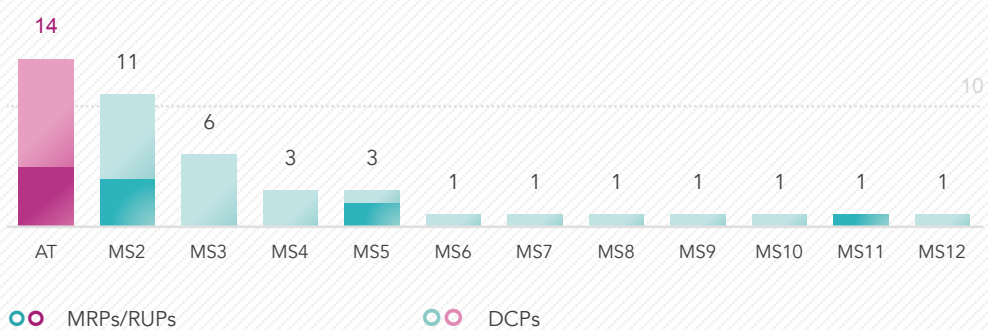
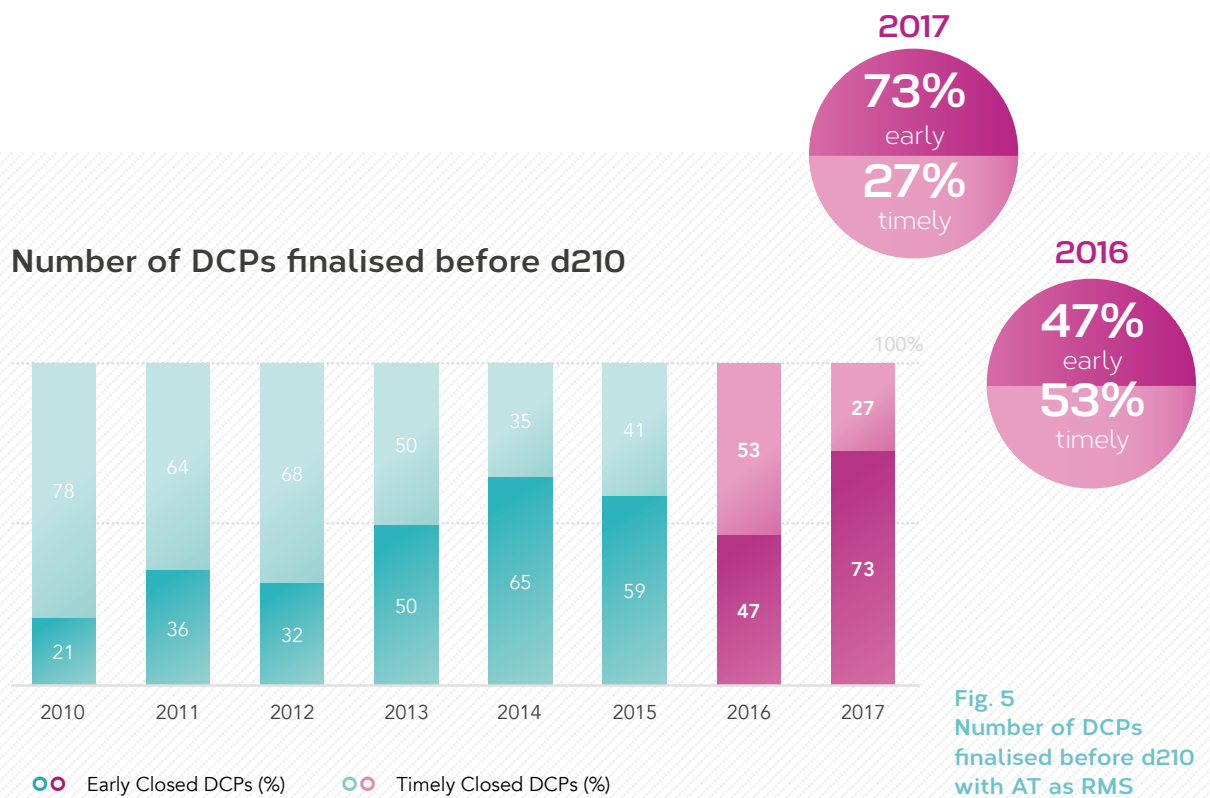


Fig. 4
Overview on finalised herbal MR- and DC-procedures per RMS 2016 and 2017

Austria – convincing with its case management

Austria convinces with its “case managers” as a reliable and competent interface between applicants, assessors and other European national agencies. They guarantee an optimised information flow between all parties involved and the procedure duration is thereby kept as short as possible. Hence it was possible to finalise a significant amount of procedures before Day 210.



High level of expertise

An analysis of procedures led by Austria as RMS highlights the assessors' expertise. In 2016 and 2017, Austria has most frequently acted as RMS for medicinal products with the ATC codes N, C, J, and G. The majority of the procedures corresponds to generic applications followed by hybrid applications; this is comparable to the EU-wide distribution by application types.

ATC Codes of procedures with AT=RMS

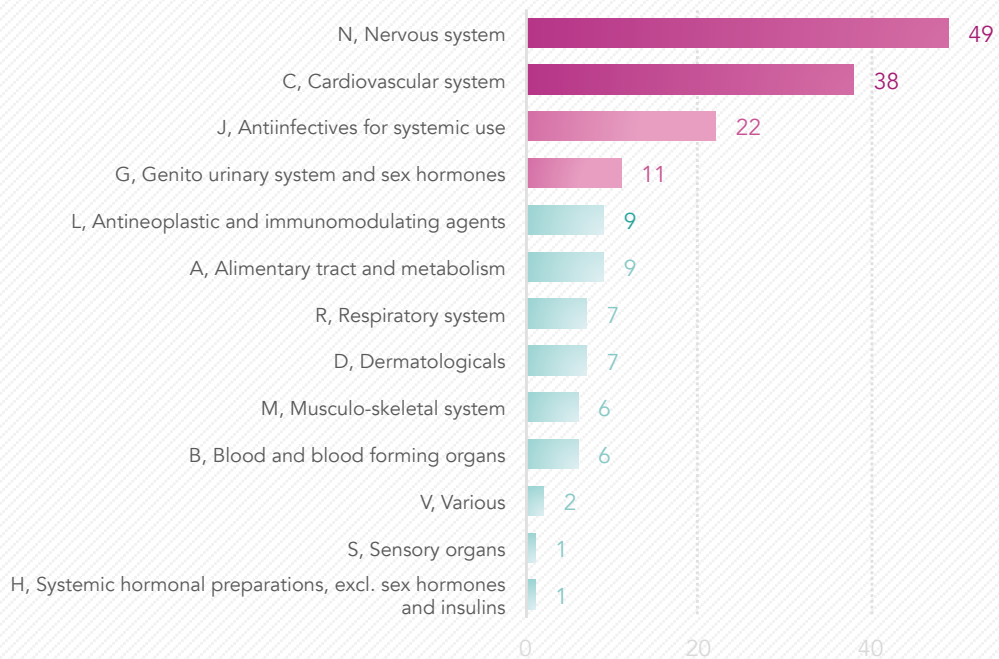


Fig. 6
ATC Codes of
procedures with
AT=RMS

Legal basis of procedures with AT=RMS

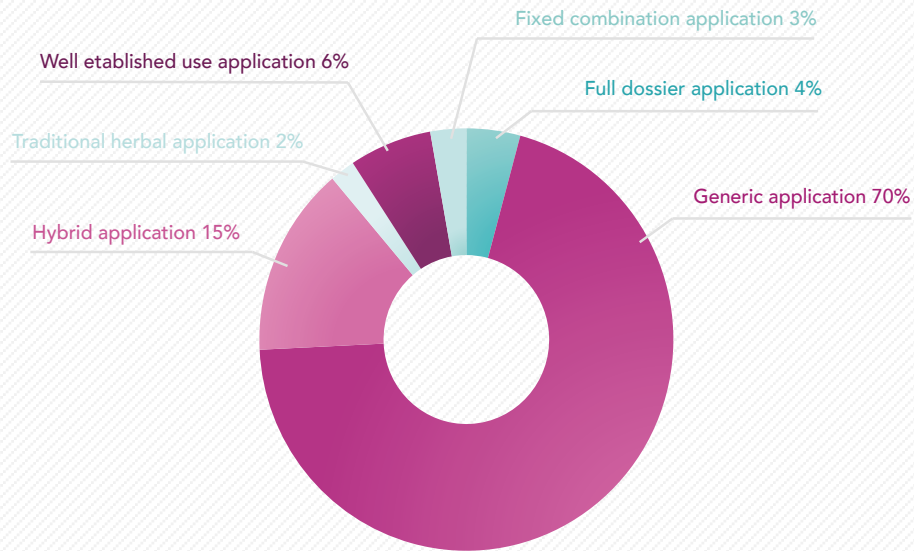


Fig. 7
Legal basis of
procedures with
AT=RMS finalised
in 2010-2017

Number of started MRPs/DCPs with AT=RMS at product level

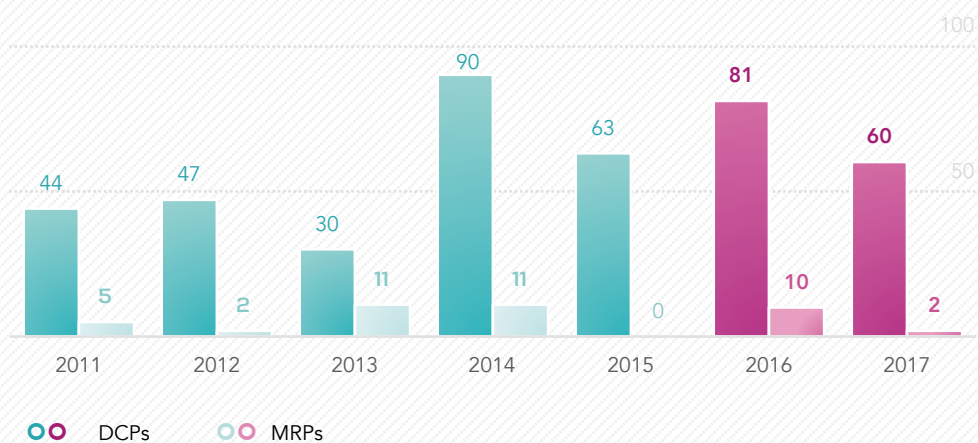


Fig. 8
Number of started
MRPs/DCPs
with AT=RMS at
products level



Austria will take over the role as RMS in as many procedures as possible within its existing resources. The process of slot allocation has continuously been optimised in order to guarantee the best possible planning of applications and efficient utilisation of expert resources. In order to make the availability of the respective expert teams visible, a slot matrix has been published on our website.

<https://www.basg.gv.at/en/medicines/marketing-authorisation-procedure/mrpdcp-authorisation/>

DCP slot requests and -bookings are possible at any time, whether long term or short term, depending on the availability as shown in the slot matrix. Requests for Mutual Recognition-, Repeat-Use and Line Extension Procedures may also be submitted at any time. In addition, applicants can sign up for the UpToDate newsletter issued by BASG/AGES MEA in order to receive by e-mail the latest news respective to European procedures.

https://www.basg.gv.at/index.php?id=abo_newsletter

BASG is the most active national competent authority involved in the assessment of Certificates of Suitability (CEPs)

In order to avoid multiple assessments of identical active substance documentations by different authorities during the different procedures, documentation on an active substance can be submitted to the European Directorate for the Quality of Medicines & HealthCare (EDQM). After a positive, centralised assessment by two assessors from different national competent authorities and one EDQM assessor, a Certificate of Suitability (CEP) is granted; the CEP certifies that the quality of the active substance in question has been adequately documented. Future application dossiers only need to include a copy of the CEP rather than an extensive active substance documentation, eliminating the need for repeat assessments of the active substance.

Furthermore, the same procedure is in place to evaluate TSE (Transmissible Spongiform Encephalopathy) risk of active substances and excipients and hereby helps to guarantee TSE-free products.



To avoid multiple assessments, documentation on an active substance can be submitted to the EDQM.

Austria highly participates with its assessors in the CEP working party of the EDQM and has been the leading national competent authority within Europe – as counted by contributed assessor days – since 2013. In 2016 and 2017, eleven experienced assessors have been sent to Strasbourg (ten responsible for chemical evaluations and one assessor responsible for TSE evaluation) .

In addition Austria (together with eight other countries) is represented in the Technical Advisory Board and, as a result, can actively participate in professional and strategic decisions. Furthermore, an Austrian delegate is also member of the “Ad Hoc Committee” and thereby involved in discussions and decisions as regards CEP suspensions and withdrawals.

Scientific Board

The Scientific Board is an official committee of the Advisory Board on Medicinal Products to the Federal Ministry of Health and advises in matters related to the approval and safety of medicinal products. The Scientific Board has three scheduled face-to-face-meetings and several further ad-hoc discussions each year, all chaired by the Head of the AGES MEA. Currently, the Scientific Board consists of 35 members – representing a wide scope of expertise, coming mostly from university hospitals – appointed by the Federal Minister of Health.












Permanent items on the agenda include discussions on open approvals and variation processes in which the decision is not clear as yet, moreover issues of Pharmacovigilance, as well as topics of current events.



The Scientific Board of BASG/AGES MEA is representing a wide scope of expertise.

BASG dialogues

In 2016 and 2017 the BASG/AGES MEA organised several BASG dialogues. These information and discussion meetings have already a long tradition and are recognised by representatives of industry, interest groups and other stakeholders as well visited events.

	Fit for PSUR-Repository?	30.05.2016
	Dialogue with patients: How to get useful information. (In cooperation with EUPATI)	09.06.2016
	Pharmacovigilance – Update	15.09.2016
	Reporting of side-effects & News from clinical trials	13.10.2016
	News from veterinary medicinal products authorisation	08.11.2016
	Implementation of EU-Telematics-strategy in Austria and recent news from IDMP/SPOR	29.11.2016
	Marketsurveillance in Austria	30.11.2016
	New OECD-guideline for IT-based systems in GLP	01.12.2016
	Focus addictive drugs	12.01.2017
	Pharmacovigilance – Update	13.06.2017
	Brexit – Chances and challenges	13.09.2017
	IDMP/SPOR/CESSP	07.11.2017
	Meet the Case Manager	09.11.2017





Services of the Federal Office for
Safety in Health Care / Austrian
Medicines and Medical Devices
Agency

Scientific Advice

Pharmaceutical companies have the opportunity to apply for Scientific Advice (SA) from regulatory authorities regarding questions related to development of medicinal products. These SAs may be requested either at the European level (at the European Medicines Agency, EMA) or directly at BASG/AGES MEA.

In 2016 a total of 112 EMA SA procedures have been assessed on behalf of the Austrian agency. Austria belonged to the top 2 member states in the European comparison. The year 2017 brought a further increase to a completion number of 167 procedures. 74 percent of the procedures were handled exclusively by experts from the BASG/AGES MEA. The remaining 26 percent were assessed by external colleagues of the Department of Clinical Pharmacology at the Medical University of Vienna.

Also in 2017, 15 requests for national scientific advice (NASA) procedures were finalised compared to 22 in 2016. Feedback on the customer satisfaction confirmed excellent results. The questions covered criteria like waiting period between application of a NASA and advice meeting as well as adequacy of responses and expertise provided.

Number of EMA Scientific Advice Procedures

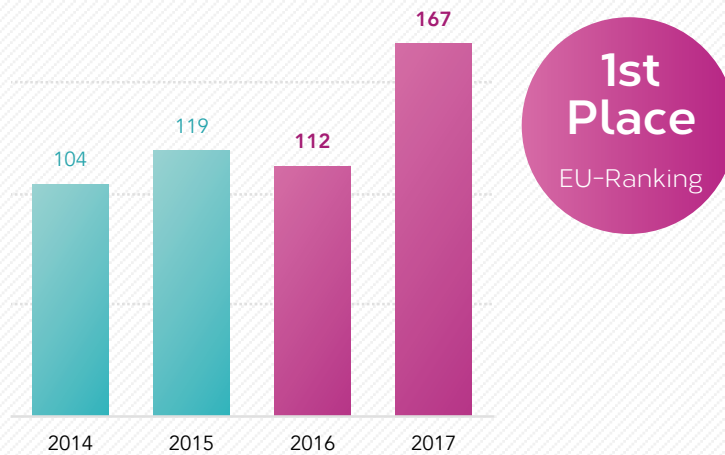


Fig. 9
Number of EMA
Scientific Advice
Procedures from
2014–2017

Clinical Trials

After the organisational harmonisation of clinical trials with medicinal products and clinical investigations with medical devices in 2016, the management of applications was successfully integrated in the overarching IT System PHAROS. Additionally, substantial resources had to be invested in the preparations for the Regulation (EU) 534/2014 for clinical trials. This included contribution in working groups on the European level as well as national preparations for the Regulation coming into force. Especially the activities regarding the development of the EU portal and database proved to be a challenging task.

Clinical trials with Medicinal Products

The general decline in the number of submissions continued through 2016 and 2017. In 2017 only 235 clinical trial applications were submitted for approval, which is an all-time low.

While in 2016 the decline was seen for phase III and phase IV trials, in 2017 fewer submission were made for phase I and phase II trials. The proportion of commercial to non-commercial trials remained stable at 70 percent to 30 percent in favour of commercial trials. In the EU in general 60 percent of the trials submitted for authorisation are conducted by commercial sponsors.



The general decline in clinical trial applications continues.

Phase distribution of clinical trials with medicinal products

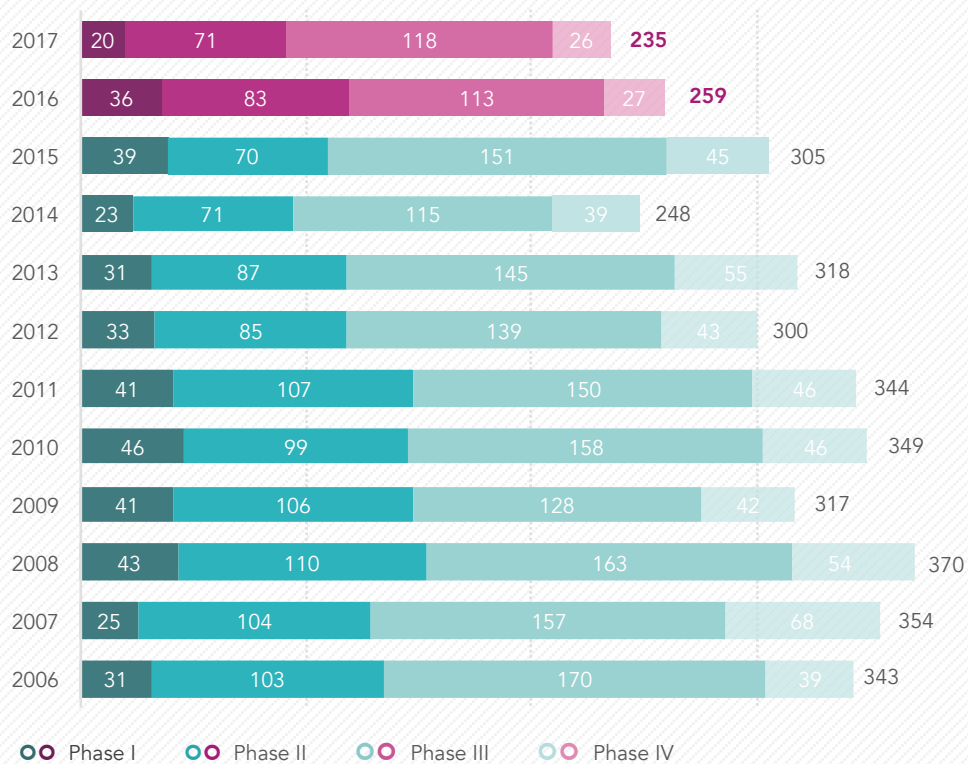


Fig. 10
Phase distribution
of clinical trials with
medicinal products

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

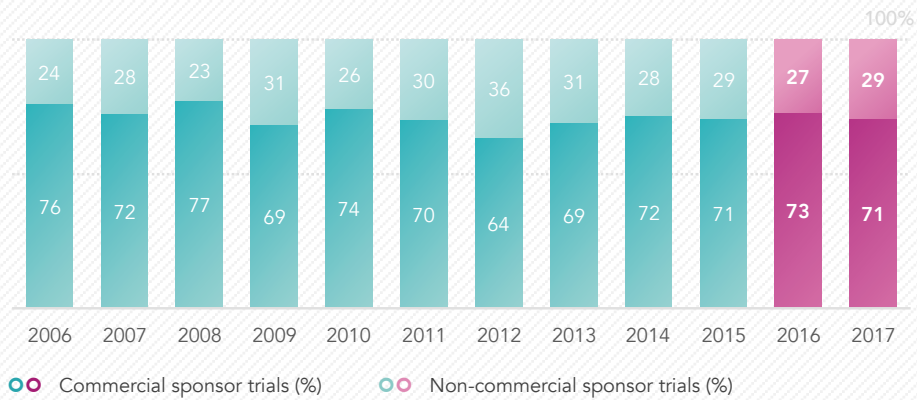


Fig. 11
Percentage of commercial versus non-commercial sponsor trials with medicinal products

In preparation for the Clinical Trial Regulation in 2016 a pilot project was initiated to prepare for the future process. The project was developed together with major Ethics Committees in Austria and so far ten initial applications have been authorised.

In 2016/2017 for clinical trials ongoing in Austria 666/575 Annual Safety Reports (ASRs) or Development Safety Update Reports (DSURs), were submitted and reviewed following a risk-based approach. Austria also participated in 18/36 procedures as part of the

Lifecycle procedures in clinical trials with medicinal products

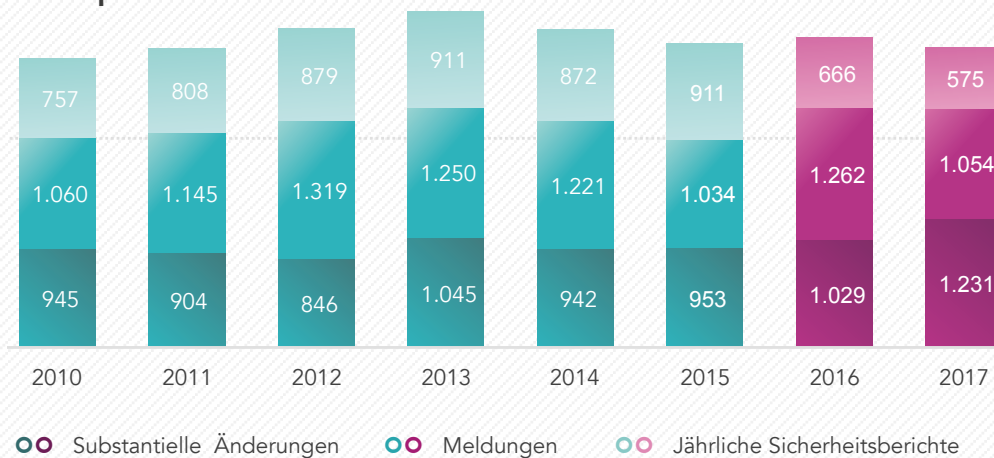


Fig. 12
Lifecycle procedures in clinical trials with medicinal products

ASR Assessment Pilot Project of the Clinical Trial Facilitation Group (CTFG). The purpose of this pilot is to establish the work-sharing process for the future review of annual safety reports that will be required according to article 44 of the Clinical Trial Regulation.

As part of the Voluntary Harmonisation Procedure (VHP, see <https://www.basg.gv.at/en/medicines/prior-to-authorisation/clinical-trials/vhp/>) 209/191 clinical trial applications and 453/487 substantial amendments were assessed. Austria participated in 53/49 procedures as concerned member state and lead 2/1 rapporteurships as reference member state. Additionally, Austria participated in 150/188 substantial amendments, managing 8/11 as rapporteur. Two applications for authorisation of Compassionate Use were approved, one in 2016 and one in 2017. The number of Non-Interventional Studies (NIS) notified according to the ordinance for notification of NIS in 2016 and 2017 was similar to previous years.

Austria

- ▶ Active participation in the preparations for the implementation of the Clinical Trial Regulation
- ▶ 54 procedures as part of the ASR Assessment Pilot Project
- ▶ 53/49 first application procedures within the „Voluntary Harmonisation Procedure“
- ▶ 3 rapporteurships within the „Voluntary Harmonization Procedure“
- ▶ Participation in 338 substantial amendments, 19 as rapporteur



Reporting of Non-Interventional Studies

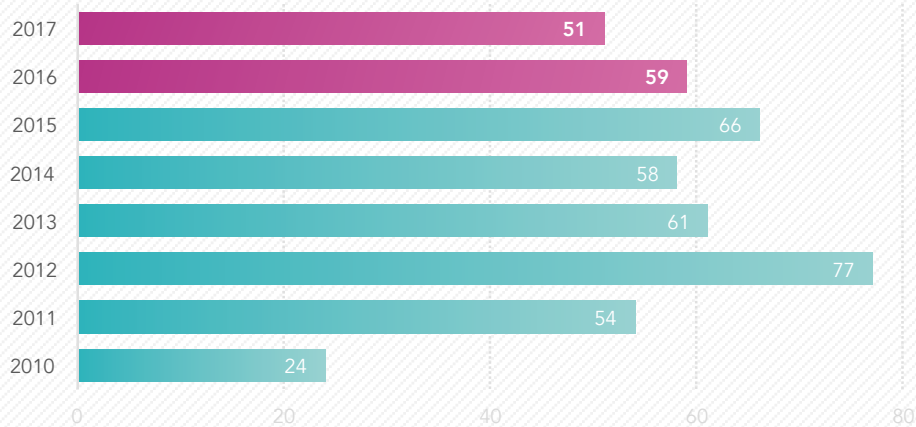


Fig. 13
Reporting of Non-Interventional Studies

Clinical Investigations with Medical Devices and Performance Evaluations of In-Vitro Diagnostica

As part of the go-live of the common IT system and the ordinance for electronic submission a web-based electronic application form for studies according to the Medical Devices Act was developed and successfully implemented. After a decline in 2016 the number of applications returned to that of previous years in 2017.

In 2016/2017 54/93 initial applications were submitted to the BASG, 9/10 being applications for performance evaluations of IVDs. For ongoing clinical studies 62/80 substantial amendments, 144/233 other notifications and 19/12 safety reports were submitted.

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

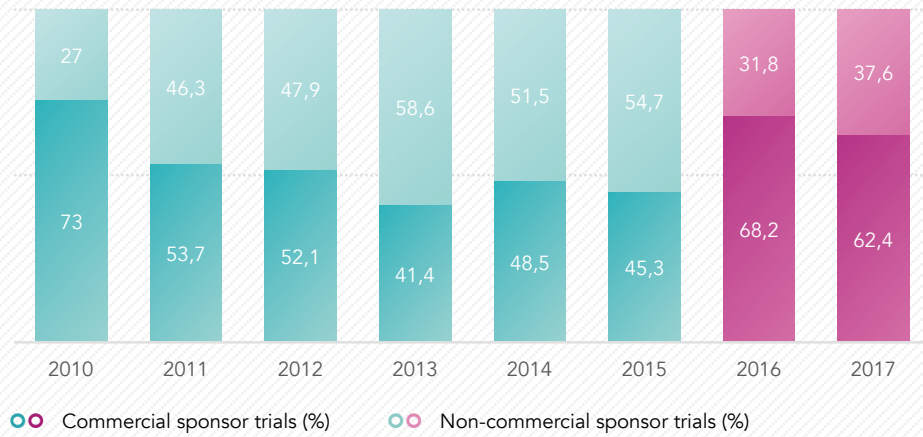


Fig. 14
Percentage of commercial versus non-commercial sponsor trials with medicinal devices

Distribution of study applications per class of medical device/IVD

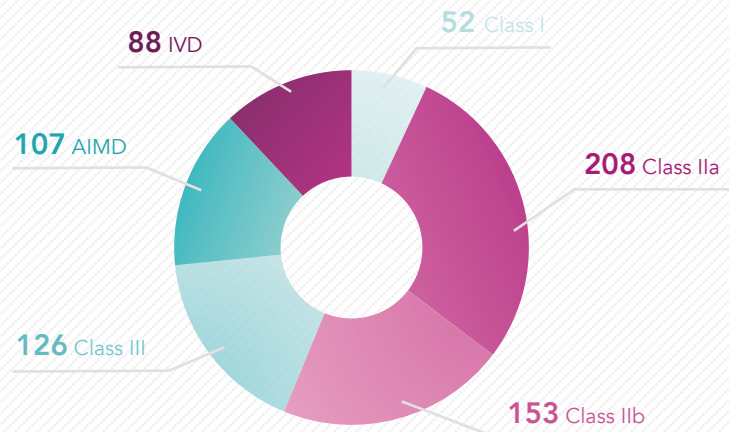


Fig. 15
Distribution of study applications per class of medical device/IVD

Lifecycle procedures in clinical trials with medical devices /IVDs

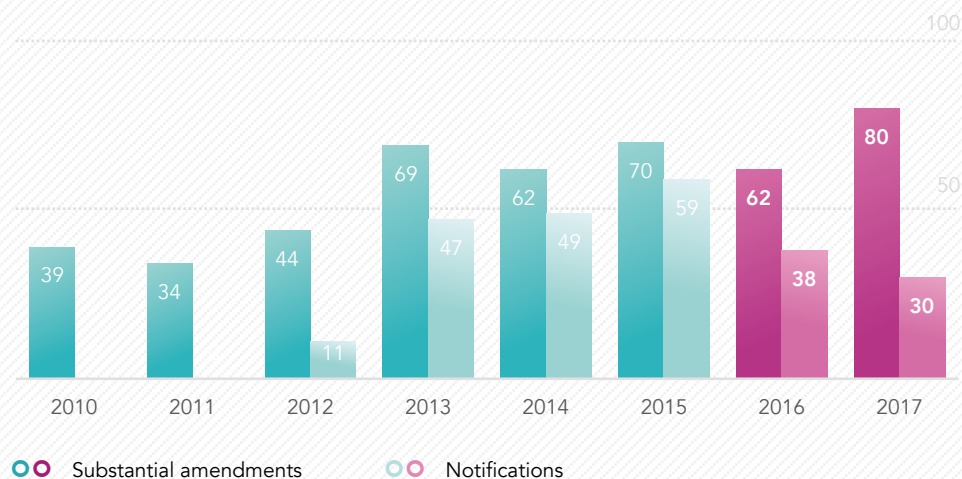


Fig. 16
Lifecycle procedures
in clinical trials
with medical
devices /IVDs

Marketing Authorisations

By the end of 2017 10.822 medicinal products have been approved, of which 87 percent were products for humans and the rest for animals. 1.321 authorised human medicinal products can be dispensed without prescription. Furthermore, there are 3.944 medicinal products registered.

In 2016 and 2017 484 resp. 621 human and 69 resp. 73 veterinary medicinal products were newly authorised by the BASG/AGES MEA, whereas marketing authorisations of 384 resp. 385 human and 54 resp. 82 veterinary medicinal products have been withdrawn. In 107 resp. 165 cases, the distribution as parallel import has been approved.

By the end of 2017 the product information has been published online by BASG/AGES MEA (<https://aspreregister.basg.gv.at>) for 11.562 medicinal products.



National

In 2016 and 2017, 53 resp. 98 national marketing authorisations were issued for human use and 7 resp. 14 for veterinary use. Furthermore, the BASG/AGES MEA has implemented registrations for 43 resp. 31 homeopathic, ten resp. ten traditional herbal and two resp. one pharmacy-owned medicinal products.

MRP/DCP

In 2016 and 2017 431 resp. 523 human and 62 resp. 59 veterinary medicinal products were authorised in Austria. Austria acted as RMS for 65 resp. 69 products and for one veterinary product each year. Austria was involved in 366 resp. 454 human products) as well as in 61 resp. 58 veterinary products) as Concerned Member State (CMS).

In 2016 and 2017, a RMS transfer towards Austria has been performed for 86 products.

29 resp. 80 medicinal products were conditionally approved in 2016 and 2017 – the national marketing authorization is issued in such cases on the basis of the English product information texts finalised within the DCP/MRP. Before marketing, the German product information texts need to be submitted by the MAH and approved by the BASG/AGES MEA.

Authorised human Medicinal Products

Medicinal Product Type	Legal Base	Number 2016	Number 2017
Biological Medicinal Products	Full application (Article 8(3) of Directive No 2001/83/EC)	144	101
	Generic application (Article 10(1) of Directive No 2001/83/EC)	-	1
	Informed consent application (Article 10c of Directive No 2001/83/EC)	1	1
	Known active substance (Article 8(3) of Directive No 2001/83/EC)	192	219
	New active substance (Article 8(3) of Directive No 2001/83/EC)	1	7
	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	1	10
	Well-established use application (Article 10a of Directive No 2001/83/EC)	28	35
Homeopathic Medicinal Products	Homeopathic marketing authorisation procedure (Article 16 of Directive No 2001/83/EC)	613	615
Medical Gases	Generic application (Article 10(1) of Directive No 2001/83/EC)	1	1
	Well-established use application (Article 10a of Directive No 2001/83/EC)	30	32
Herbal Medicinal Products	Fixed combination application (Article 10b of Directive No 2001/83/EC)	3	3
	Full application (Article 8(3) of Directive No 2001/83/EC)	81	58
	Generic application (Article 10(1) of Directive No 2001/83/EC)	2	2
	Known active substance (Article 8(3) of Directive No 2001/83/EC)	26	30
	Well-established use application (Article 10a of Directive No 2001/83/EC)	87	96
Radiopharmaceuticals	Full application (Article 8(3) of Directive No 2001/83/EC)	18	17
	Generic application (Article 10(1) of Directive No 2001/83/EC)	7	8
	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	1	1
	Known active substance (Article 8(3) of Directive No 2001/83/EC)	2	2
	New active substance (Article 8(3) of Directive No 2001/83/EC)	2	2
	Well-established use application (Article 10a of Directive No 2001/83/EC)	14	13
Chemical Medicinal Products	Fixed combination application (Article 10b of Directive No 2001/83/EC)	220	246
	Full application (Article 8(3) of Directive No 2001/83/EC)	664	576
	Generic application (Article 10(1) of Directive No 2001/83/EC)	4,176	4,382
	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	482	516
	Informed consent application (Article 10c of Directive No 2001/83/EC)	48	56
	Known active substance (Article 8(3) of Directive No 2001/83/EC)	1,430	1,427
	New active substance (Article 8(3) of Directive No 2001/83/EC)	2	8
	Well-established use application (Article 10a of Directive No 2001/83/EC)	892	934
Medicinal Products according to Pharmacopoeia Monograph	§ 9c National Medicines Act	14	14
Total		9,182	9,413

Authorised human Medicinal Products

Medicinal Product Type	Legal Base	Number 2016	Number 2017
Allergen Manufacturing	Allergens production process	67	67
Pharmacy's own registration	Pharmacy's own registration	723	718
Homeopathic Medicinal Products	Homeopathic simplified registration procedure (Article 14 of Directive No 2001/83/EC)	2.926	2.956
Herbal Medicinal Products	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	200	203
Total		3.916	3.944

Authorised veterinary Medicinal Products

Medicinal Product Type	Legal Base	Number 2016	Number 2017
Biological Medicinal Products	Full application (Article 12(3) of Directive No 2001/82/EC)	135	115
	Informed consent application (Article 13c of Directive No 2001/82/EC)	1	1
	Known active substance (Article 12(3) of Directive No 2001/82/EC)	33	42
	New active substance (Article 12(3) of Directive No 2001/82/EC)	2	6
Medicated Feedingstuffs	Full application (Article 12(3) of Directive No 2001/82/EC)	13	13
	Generic application (Article 13(1) of Directive No 2001/82/EC)	5	6
	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	2	2
	Known active substance (Article 12(3) of Directive No 2001/82/EC)	1	1
Homeopathic Medicinal Products	Homeopathic marketing authorisation procedure (Article 19 of Directive No 2001/82/EC)	88	100
Chemical Medicinal Products	Fixed combination application (Article 13b of Directive No 2001/82/EC)	29	35
	Full application (Article 12(3) of Directive No 2001/82/EC)	446	389
	Generic application (Article 13(1) of Directive No 2001/82/EC)	402	423
	Generic, hybrid or similar biological application (Article 13 of Directive No 2001/82/EC)	2	2
	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	137	134
	Informed consent application (Article 13c of Directive No 2001/82/EC)	11	7
	Known active substance (Article 12(3) of Directive No 2001/82/EC)	54	69
	New active substance (Article 12(3) of Directive No 2001/82/EC)	1	7
	Well-established use application (Article 13a of Directive No 2001/82/EC)	56	57
Total		1.418	1.409

Further information

	Number 2016	Number 2017
New Marketing Authorisations for human Medicinal Products	484	621
Withdrawals of human Medicinal Products	384	385
New Marketing Authorisations for veterinary Medicinal Products	69	73
Withdrawals of veterinary Medicinal Products	54	82
Marketing Authorisations for OTC human Medicinal Products (total)	1.333	1.321
Registrations for for OTC human Medicinal Products (total)	3.849	3.877
Parallel imports (total)	107	165

Overview of authorisation procedures finalised positively over the last years

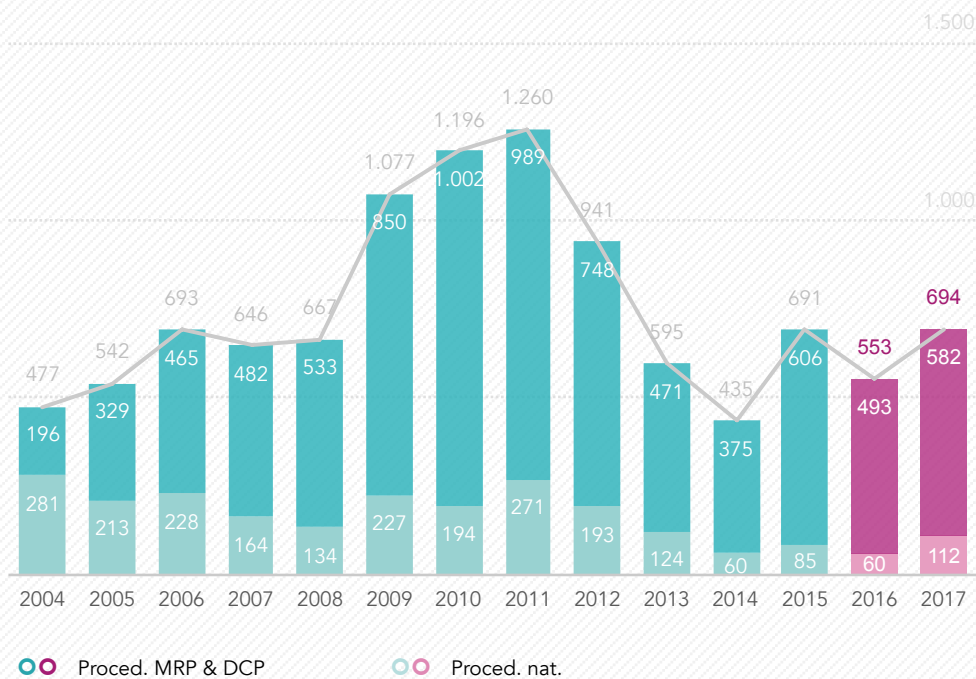


Fig. 17
Overview of authorisation procedures finalised positively over the last years

Centralised Procedures (human Medicinal Products)

In 2016 and 2017, the BASG/AGES MEA participated in the assessment of 20 centralised procedures and eight peer reviews for new active substances, as well as biosimilars and generics.

In 2016 and 2017, EMA appointed the BASG/AGES MEA as Rapporteur for 13 (seven rapporteur- and six co-rapporteurships) and 16 centralised procedures (twelve rapporteur- and four co-rapporteurships), respectively.

This ensured, that the BASG/AGES MEA was able to position itself in eighth and second place (together with four other member states) in total number of rapporteurships in 2016 and 2017, respectively.

Regarding veterinary medicinal products in 2016/2017 BASG/AGES was involved in the assessment of five centralised procedures regarding vaccines and generics and eight peer reviews regarding vaccines, maximum residue limits (MRL) and environmental risk assessment (ERA).

When applying for centralised procedures BASG/AGES was appointed once Rapporteur and twice Co-Rapporteur (in each case in multinational assessment teams) for centralised procedures regarding veterinary vaccines and twice Co-Rapporteur (in each case in multinational assessment teams) for generics.

Austria's Rapporteur and co-rapporteurships 2016

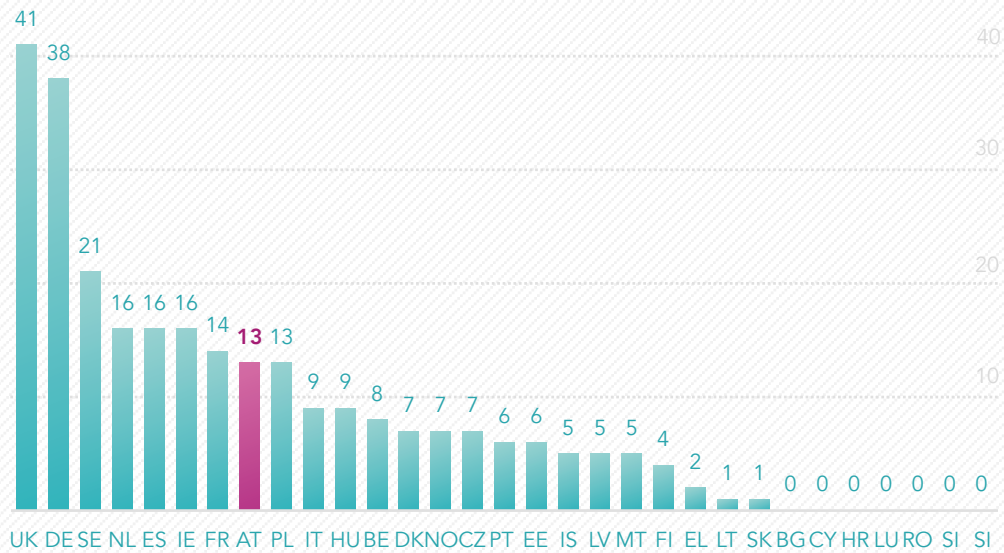


Fig. 18 Austria in comparison to other agencies per number of Rapporteur and co-rapporteurships in the centralised procedure 2016

Austria's Rapporteur and co-rapporteurships 2017

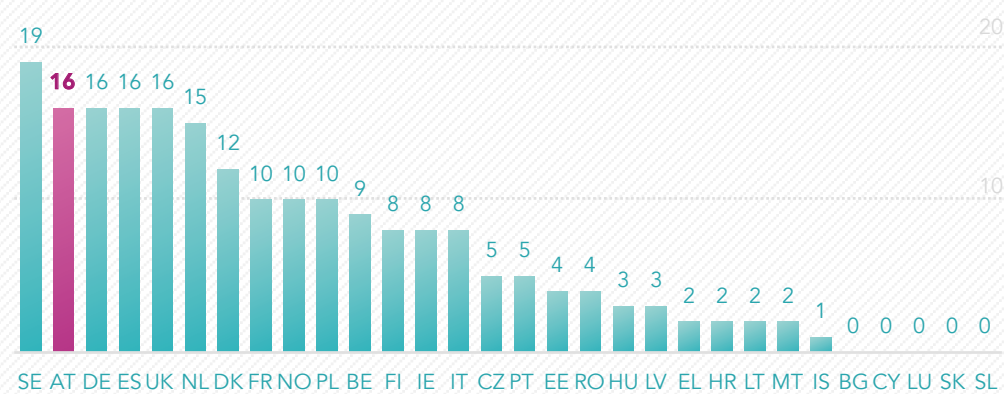


Fig. 19 Austria in comparison to other agencies per number of Rapporteur and co-rapporteurships in the centralised procedure 2017

Variations

Medicinal products are underlying permanent variations, which need to be submitted by the marketing authorisation holder and to be examined by the BASG/AGES MEA. In 2016 and 2017, 8.178 resp. 7.781 applications for variations were submitted, corresponding to a number of 27.972 resp. 27.201 individual variations.

Number of individual variations covered in applications (human)

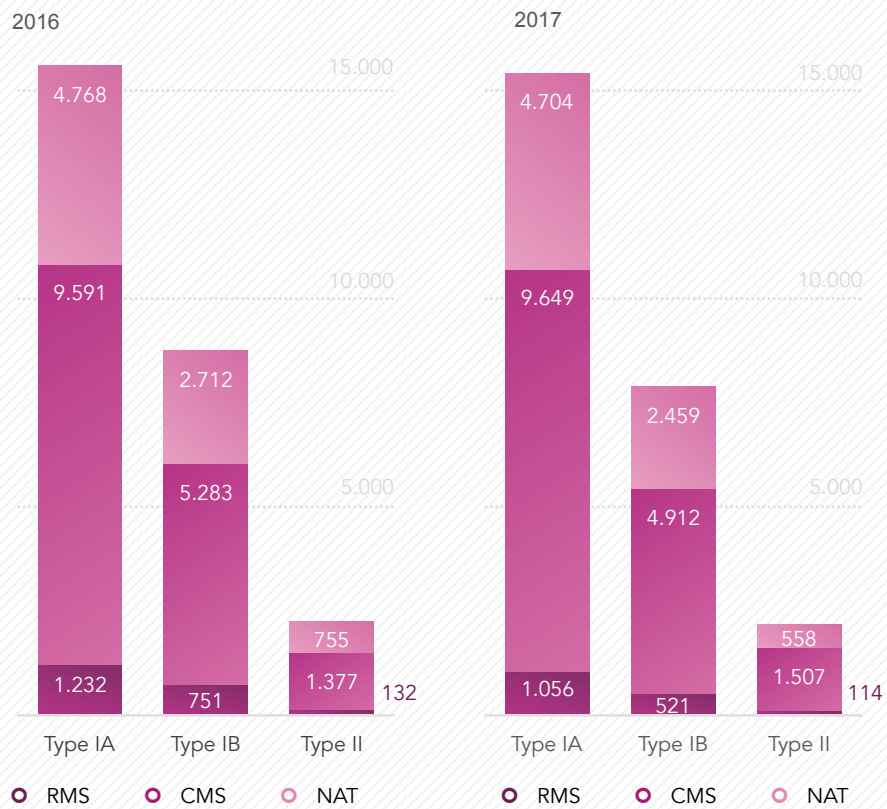


Fig. 20
Number of individual variations covered in applications (human)



Changes of medicinal products are examined in line with the Variation Regulation (EC) No. 1234/2008.

Number of individual variations covered in applications (veterinary)

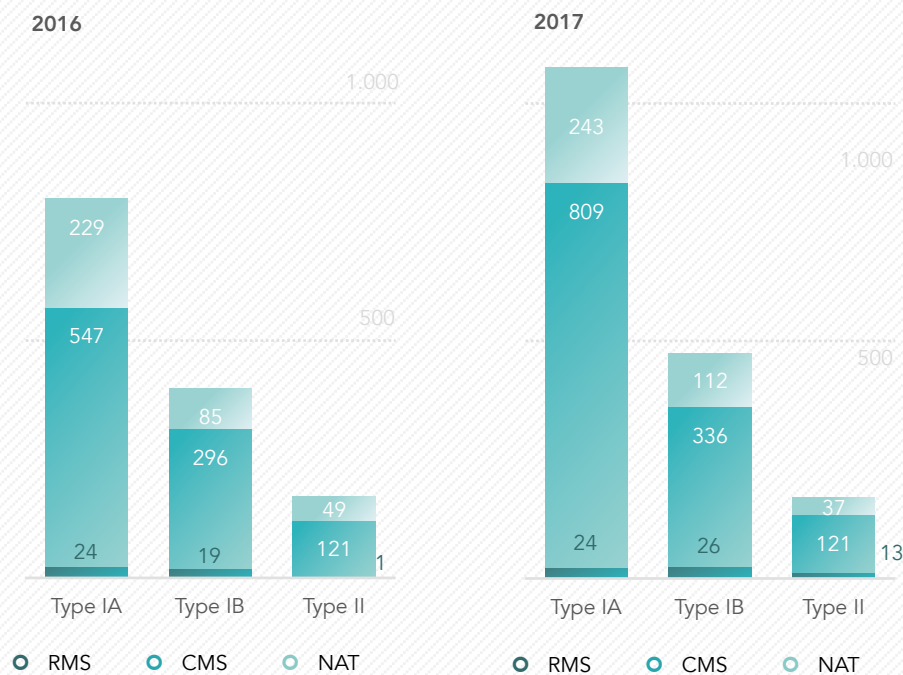
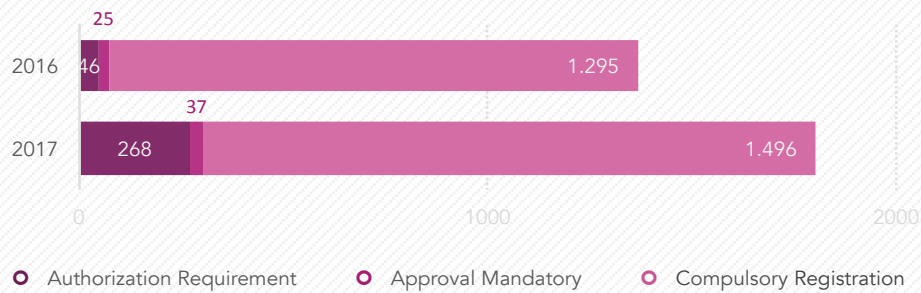


Fig. 21
Number of individual variations covered in applications (veterinary)

1.163 resp. 1.215 variations (corresponding to 1.468 resp. 1.823 individual applications) were additionally submitted in the national procedure in accordance with §24/25 AMG (Austrian Medicinal Products Act).

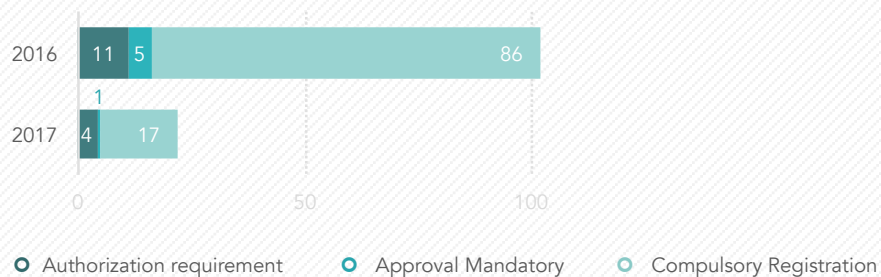
Number of individual variations covered in applications according to AMG § 24/25 (human)

Fig. 22
Number of individual variations covered in applications according to AMG § 24/25 (human)



Number of individual variations covered in applications according to AMG § 24/25 (veterinary)

Fig. 23
Number of individual variations covered in applications according to AMG § 24/25 (veterinary)



Further submissions in 2016/2017



Fig. 24
Further submissions in 2016/2017

703 Notifications according Art 61(3) Dir. 2001/83 EC

Paediatric Medicines

In total 174 new PIP submissions (Paediatric Investigation Plans) have started at the PDCO (Paediatric Committee) at EMA in 2015. BASG/AGES MEA contributed to the assessment in eight of these (five as rapporteur, three as peer reviewer). In addition PDCO received 237 requests for modifications of earlier agreed PIPs, 17 of these with contributions from BASG/AGES MEA (nine as rapporteur, eight as peer reviewer).

Pharmacovigilance

Several measures were initiated in the last years in order to educate health care professionals about their reporting obligations regarding pharmacovigilance issues. Trainings, periodical publications as well as distribution of educational material contributed to the increased cooperation and information exchange between stakeholders regarding pharmacovigilance.

21.723
Individual Case
Safety Reports
2016/2017



Austria acts as lead member state for 50 active substances and completed 744 signal detections in 2016 and 2017.

10.132 Individual Case Safety Reports (ICSRs – initial and follow-up reports) for medicinal products for human use have been reported in 2016, 11.591 in 2017.

Until November 2017 all case reports from health care professionals, patients and marketing authorisation holders were submitted by BASG/AGES MEA to the European Pharmacovigilance database “Eudravigilance”. Since November 2017 marketing authorisation holders send their reports directly to the Eudravigilance database, these are then rerouted to the BASG/AGES MEA.

Signal detection and validation enables early identification of associated risks and ensures safe and adequate use of medicinal products for human use. According to the implementing regulation 520/2012/EC, worksharing should be performed within the EU for signal management of medicinal products being authorised in several member states, as well as for active substances included in several medicinal products. As part of that worksharing, Austria acts as lead member state for 50 active substances and completed 744 signal detections in 2016 and 2017.

Pharmakovigilance reports, human. Initial reports by different reporters

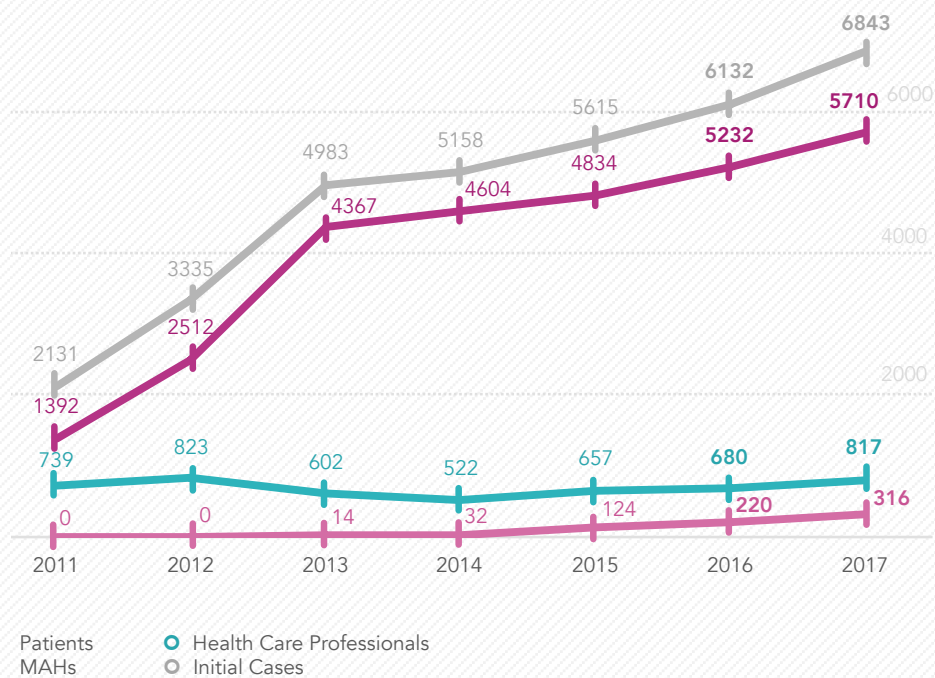


Fig. 25
Pharmakovigilance reports, human. Initial reports by different reporters

PSUSA-procedures (Human Medicinal products)

Since 2015, PSUSA-procedures could be further expanded with AT in the role of the lead member state: BASG/AGES MEA positioned itself successfully on the eight rank.

PSUSA: Lead Member States, total since 2015

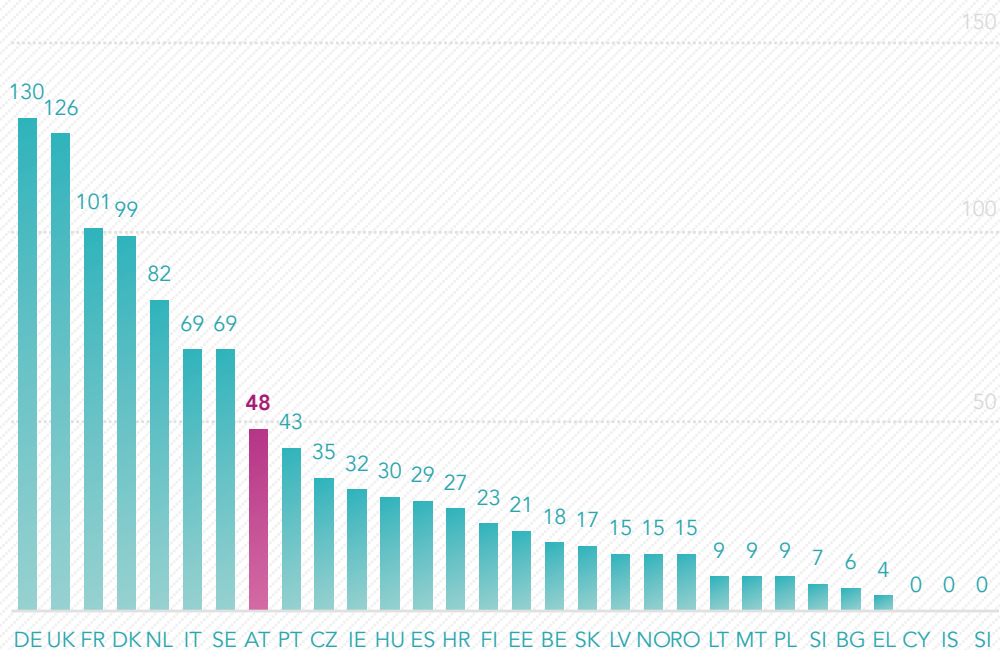


Fig. 26
PSUSA: Lead
Member States,
total since 2015

Related to PRAC(Co-)Rapporteurships, AT was able to place itself among the top ten EU countries.

PRAC-(Co-) Rapporteur appointments for initial applications 2016

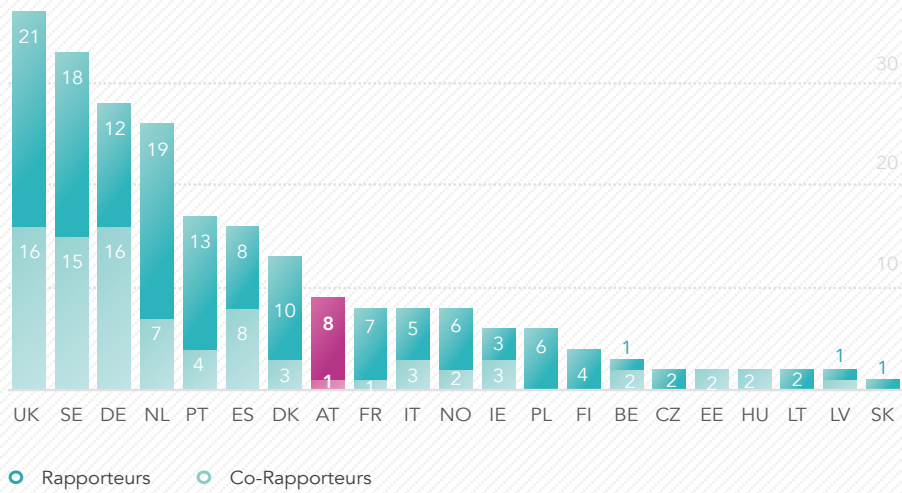


Fig. 27
PRAC-(Co-) Rapporteur appointments for initial applications 2016

PRAC-(Co-) Rapporteur appointments for initial applications 2017

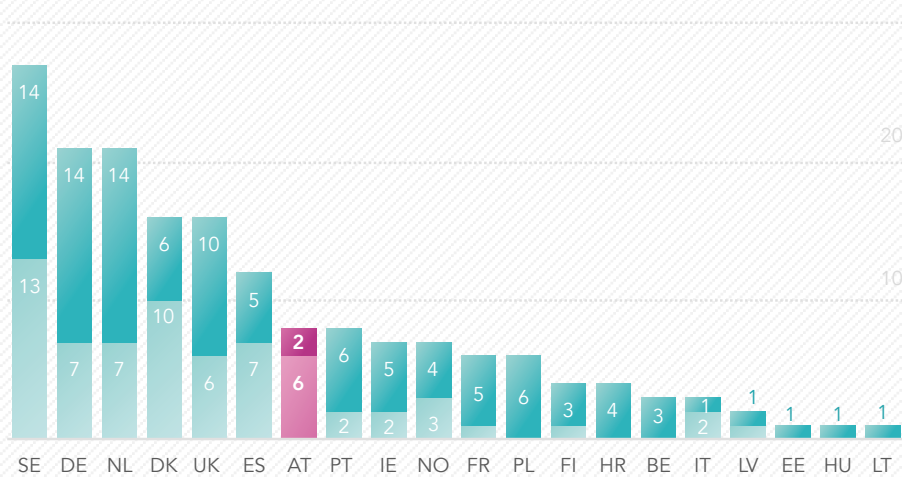


Fig. 28
PRAC-(Co-) Rapporteur appointments for initial applications 2017

Pharmacovigilance – veterinary

In 2016 and 2017, a total of 1.484 PSURs (Periodic Safety Update Reports) regarding veterinary medicinal products have been assessed. Thereof 296 national PSURs, 31 PSURs as RMS and 11 PSURs as PSUR Reference Member State (P-RMS) have been assessed. Within the assessment of the procedures under the PSUR worksharing, Austria acts as P-RMS for currently a total of 14 substances.

Nationally approved veterinary vaccines are still assessed nationally and not as part of the PSUR worksharing, a common Data Lock Point (DLP) was agreed however.

In 2016 and 2017, a total of 282 initial reports (382 reports including follow-up) on adverse reactions of veterinary medicinal products were reported and forwarded to the EMA EudraVigilance Veterinary database (EVVET). As in recent years, most adverse reactions have been reported to be related to vaccines and antiparasitics. Most adverse reactions in 2016 and 2017 were reported in dogs and cats – followed by adverse reactions in cattle and pigs.

Reports on horses, rabbits, birds (chickens) and small pets or exotic pets occurred only rarely.

In 2016 and 2017, four cases of adverse reactions in humans by use of veterinary medicinal products were reported („User safety“).



1.484
PSURs



282
Initial
Reports

Import of medicines

The purpose of monitoring the importation is to allow patients to be provided with products that are not available or licensed in Austria if there is a medical need. The request for a foreign medicine is made by the treating physician via a pharmacy. In addition, the Federal Office oversees the import of raw materials and intermediates that are sourced or manufactured abroad and are to be finished in Austria. This ensures that the quality level required by law can be verified and that imports can be stopped if necessary.

Importation and marketability licences, importation notifications

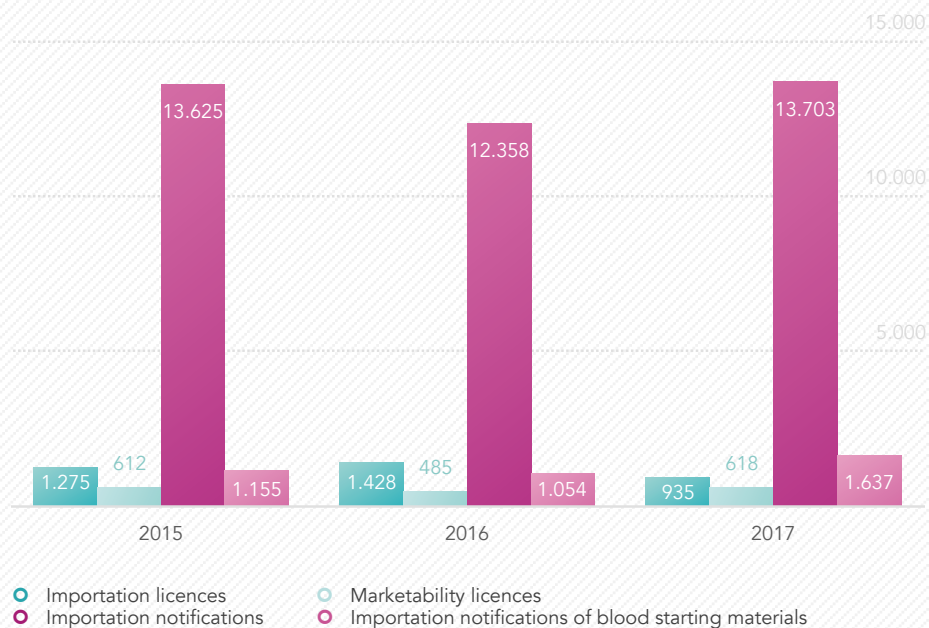


Fig. 29
Importation and marketability licences, importation notifications

Enforcement

In 2017, 83 cases were registered in the area of enforcement. In 2016 the number was 93 cases. 45 (54 percent) of these cases were completed in 2017. Prioritised was the search for illegal drugs, their production and commercialisation, illegal distance sale and falsified medicines. In addition illegal incidents in the tissue, medical devices and drug market were followed up.

In 2017 32 enforcement inspections (2016: 23) were carried out and 9 charges were filed with the prosecution authorities or notified to the criminal intelligence services (2016: 12).

Overview of cases in the area of enforcement

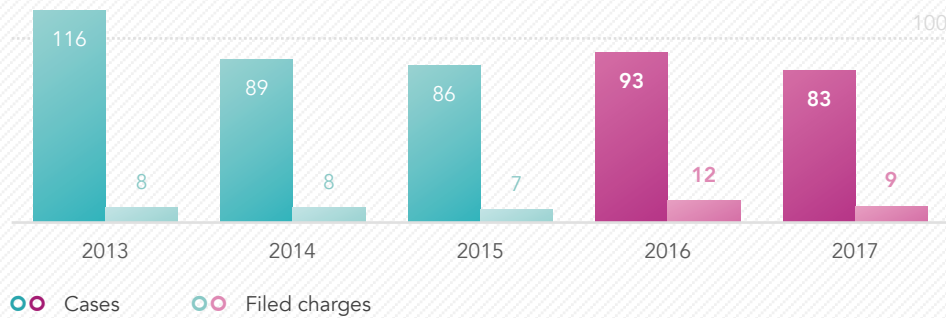


Fig. 30
Overview of cases
in the area of
enforcement

Enforcement inspections

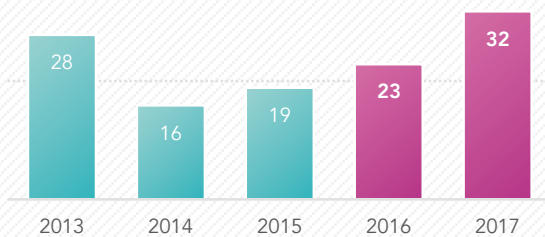


Fig. 31
Enforcement
inspections

Market surveillance

The main task of the market surveillance is the analytical control of medicinal products sampled from the market. The assessment of risk signals from other departments of the AGES MEA and the EDQM (European Directorate for the Quality of Medicines) is used to generate the annual sampling plan.

The sampling plan contains mainly three kinds of samples:

- ① **Quality control of legal medicines**
(see highlights from the surveillance of the legal market)
- ② **Quality control of illegal medicines**
(see highlights from the surveillance of the illegal market)
- ③ **Samples for the elaboration of monographs for the European Pharmacopoeia and the Austrian Pharmacopoeia**
(see highlights from the elaboration of monographs)

All samples are classified according to the four-level-scale of the EDQM (see chart)

EDQM-Skala

- Ⓐ **A** (all complies) = sample ok
- Ⓘ **I** (issues) = sample ok but issues identified
- Ⓞ **O** (out of specification) = result slightly deviates from manufacturers specification
- Ⓢ **S** (serious) = result deviates significantly from manufacturers specification, immediate action necessary (health risk or violation of law)

Market surveillance: sample structure 2016/2017

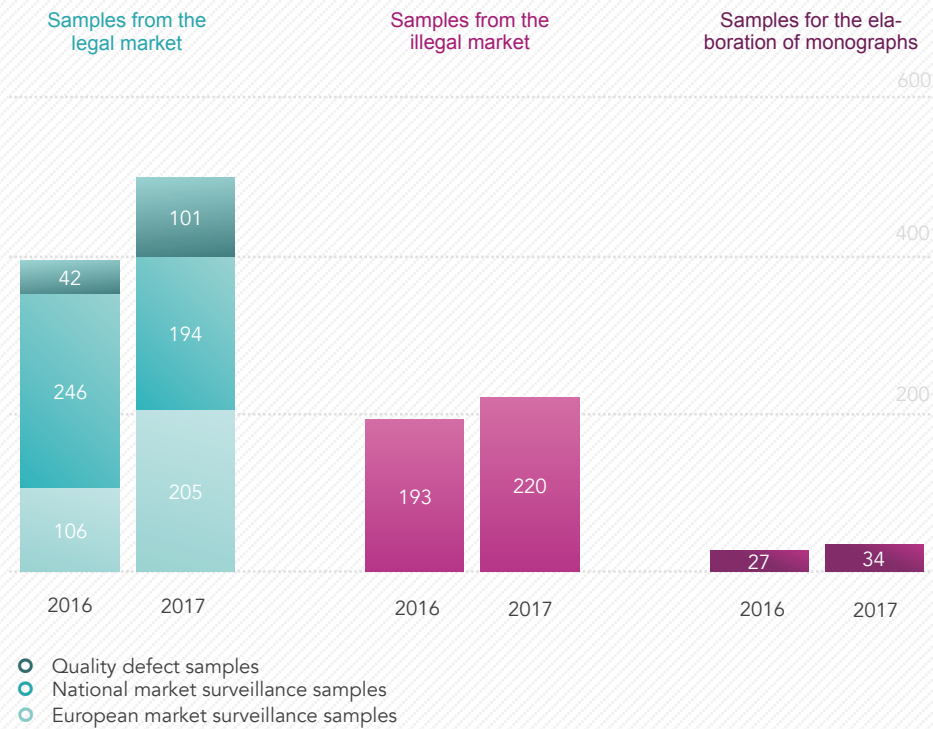


Fig. 32
Market surveillance:
sample structure
2016/2017

Market surveillance: results of samples from the legal market 2016/2017

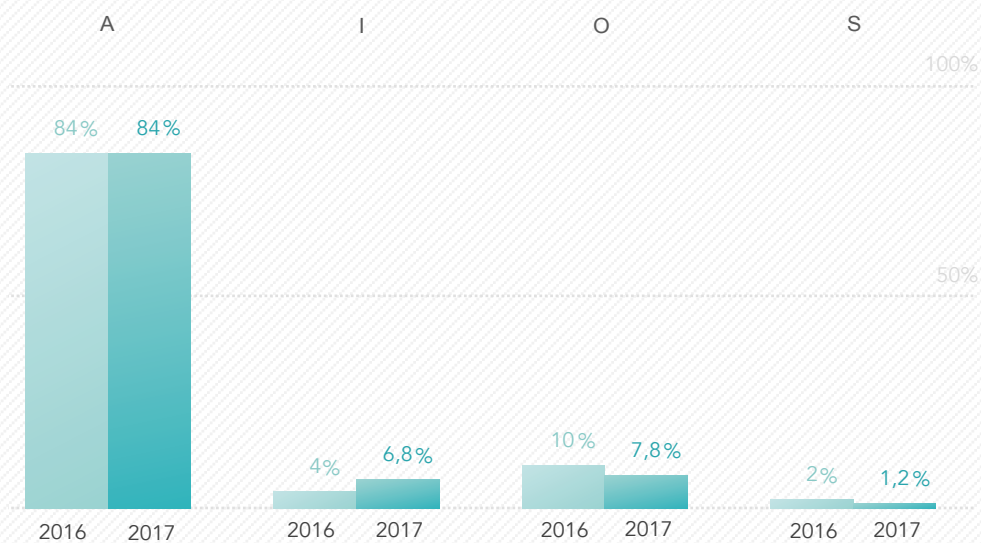


Fig. 33
Market surveillance:
results of samples
from the legal
market 2016/2017

Market surveillance: results of samples from the illegal market 2016/2017

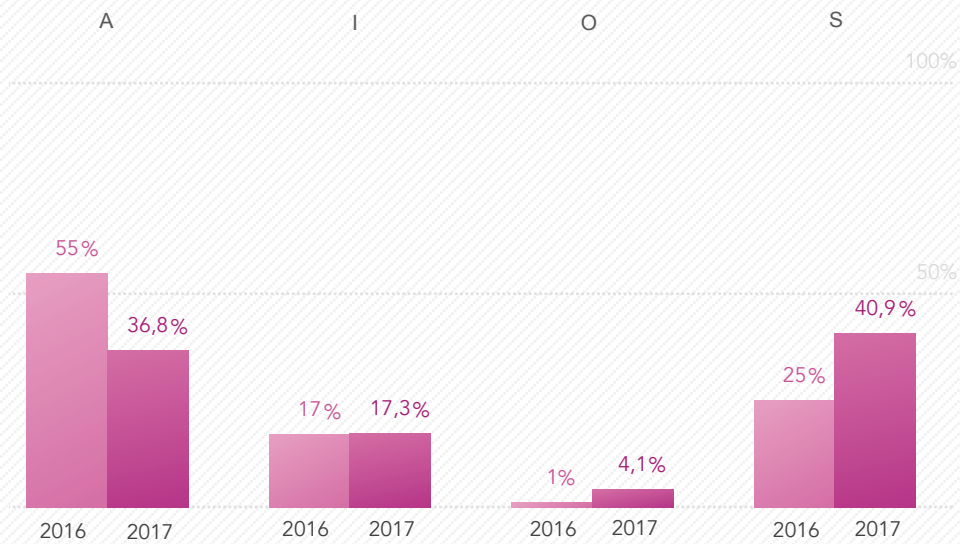


Fig. 34
Market surveillance:
results of samples
from the illegal
market 2016/2017

Highlights from the surveillance of the legal market

Incoming reports concerning quality defects of medicinal products are evaluated and categorised according to class of risk. In cases of health risks, samples are analytically examined.

101 samples were analyzed in 2017, the results showed six "serious findings", 34 of the tested medicines were licensed as Mutual Recognition Products, six as Central Authorised Products.

6

„serious findings“

Highlights from the surveillance of the illegal market

193 samples under suspicion to be illegal medicines were analyzed in 2017. In 72 cases (37 percent) immediate action was recommended because of potential health risks or violation of law.

In addition 27 samples from schools in suspect to be illegal narcotics were tested. 18 of them (67 percent) were proved to contain illegal substances.

Highlights from the elaboration of monographs for the European Pharmacopoeia and the Austrian Pharmacopoeia

Austrian Pharmacopoeia (ÖAB)

The Austrian Pharmacopoeia contains monographs for medicines not described in the European Pharmacopoeia and which are manufactured primarily by Austrian manufacturers and paid by the consumers. After an OMCL proposal the Austrian Ministry of Health started the revision of old ÖAB, which dated back to 1961, in 2007. In the Austrian Pharmacopoeia Expert Group the OMCL chairs and is responsible for the publication of the draft monographs for public consultation. In the 2018 edition 100 percent of the monographs are new or revised. Also the Austrian pharmacopoeia contains a growing number of finished products.

European Pharmacopoeia (Ph. Eur.)

A special challenge for the OMCL was the development of the Finished Product Monograph of Dronedarone Hydrochloride and Dronedarone Tablets for the European Pharmacopoeia.

Quality defects

In 2016 and 2017, 247 and 257 quality defects and product defects without health hazards and 206 and 222 Rapid Alert Notifications were processed, respectively. 38 and 40 percent, respectively, of the notifications (quality defects, product defects, recalls) came from the marketing authorisation holders and manufacturers, followed by pharmacies (31 and 37 percent, respectively). Additionally, six and twelve percent, respectively, were reported internally. Eight and ten percent, respectively, were received from other authorities (eg the European Medicines Agency). Six percent and seven percent, respectively, of the reports were submitted by the users and patients, one percent in both years by wholesalers / distributors and one percent through the Rapid Alert System



In 2017, 257 quality defects and 222 Rapid Alert Notifications were processed.

Quality defects and product recalls

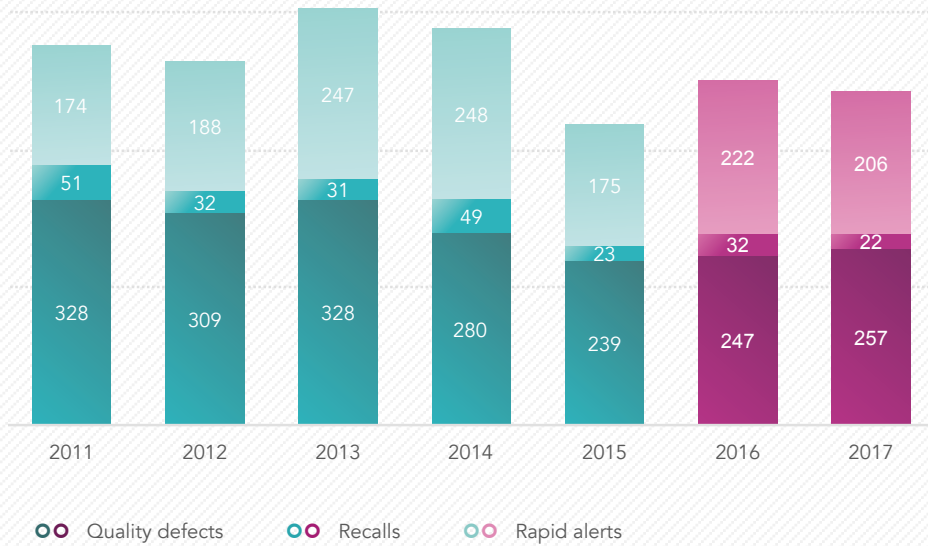


Fig. 35
Quality defects and product recalls

Origin of the reports of quality defects and product recalls

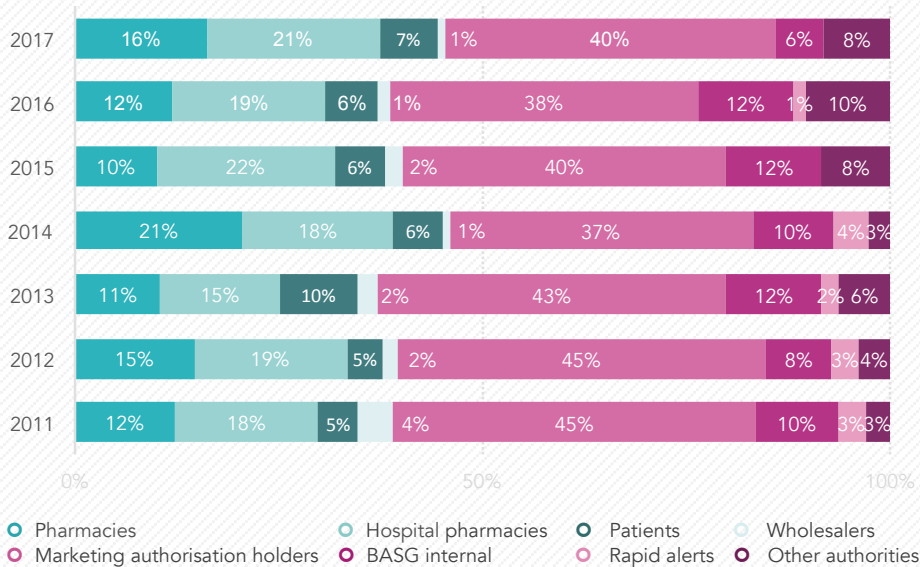


Fig. 36
Origin of the reports of quality defects and product recalls

In 2016, 68 percent and in 2017, 75 percent of the Rapid Alert Notifications were relating to recalls, 32 and 25 percent, respectively, were relating to GMP / GDP Non-compliance reports. For 32 and 22 quality defects, respectively, a recall had to be carried out to ensure patient safety and in three cases, several countries have been informed via the Rapid Alert System on quality defects.

Medicine shortages

In 2016 and 2017, 77 and 147 medicinal products, respectively, were reported as medicine shortages.

Medicine Shortages

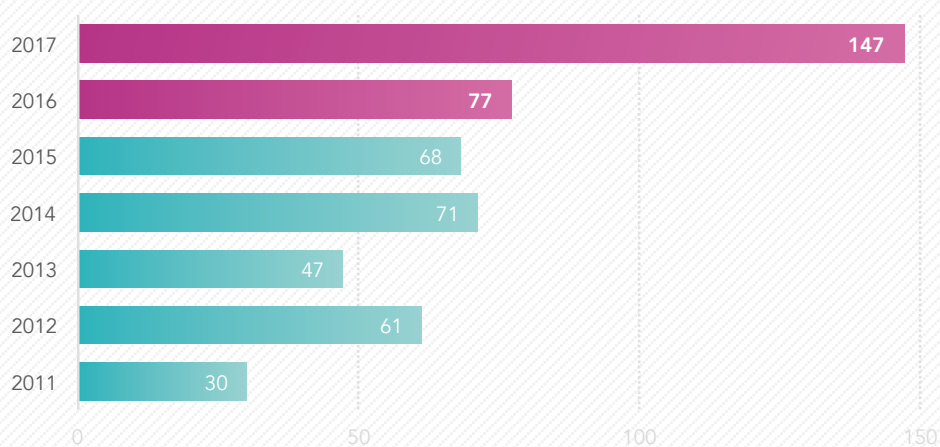


Fig. 37
Medicine Shortages

Inspections

The GMP (Good Manufacturing Practice) inspections as well as inspections according to the Blood- and Tissue Safety act are the basis not only for a manufacturing license according to the respective laws. On the other hand these periodic inspections are intended to verify the quality standards of medicines, blood and tissue products in accordance with legal requirements (see also section Blood and Tissue).

Compliance with applicable legislation is confirmed by an appropriate certificate. Generally it is distinguished between application and routine inspections. In total in 2016 137 applications and in 2017 127 applications were filed pursuant to Medicinal Products Act. In 2016 and 2017, in total 285 and 329 GM(D)P-inspections, respectively, were carried out. 78 and 146, respectively, of them in third countries (especially in the USA). 146 of them in third countries (especially in the USA). Most of the inspections in the USA were relating human plasma where the BASG/AGES MEA has a key role within Europe with a longstanding inspection experience. This activity involves close cooperation with other European agencies and the EMA. The need to assess compliance with regulatory requirements in advance of inspections (inspections of design qualifications) was performed on seven occasions. In 2016/2017, respectively, were six and ten GLP inspections as well as five and three bioequivalence trial inspections done.

Inspections of Good Clinical Practice (GCP) in Clinical Trials

In 2016 and 2017 BASG conducted 11 and 13 inspections of clinical trials in Austria. In addition four inspections were performed on request of the European Medicines Agency (EMA). Inspectors had to travel to countries like the USA, India or Africa.

In 2016 and 2017, inspections of pharmacovigilance systems were carried out in seven Austrian marketing authorization holders, five of which were considered to be separate systemic inspections, two were carried out in the context of the „Periodic Surveillance for Compliance with the Provisions of the Pharmaceutical Rules (GMP)“.

Numbers of domestic and third country GM(D)P inspections

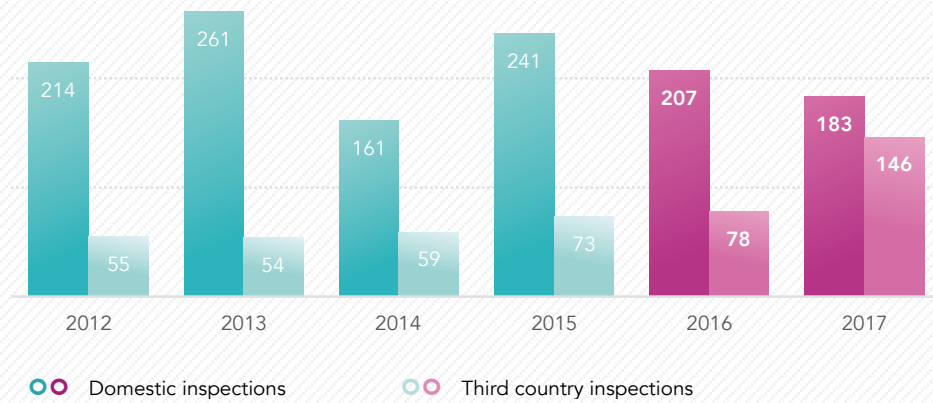


Fig. 38
Numbers of domestic
and third country
GM(D)P inspections

Inspections of plasma facilities

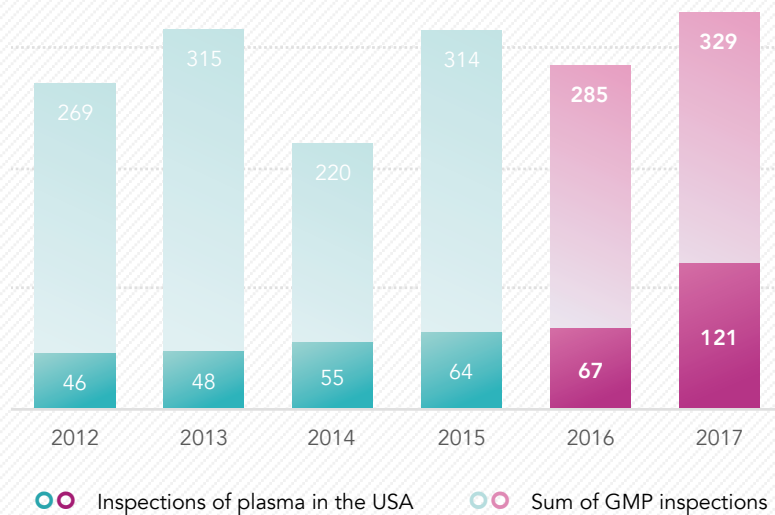


Fig. 39
Inspections of
plasma facilities

Approval of Plasma Pools / Batch Release of Vaccines

Altogether 3.016 pools of human plasma for fraction were approved in 2017 (minus 16.4 percent compared to 2016 due to increased pool sizes for one manufacturing site). All of them were tested negative for markers of hepatitis B, C and HIV1/2. Pools for the manufacturing of Human Plasma pooled and treated for Virus Inactivation were also tested negative for HAV and HEV and below the limit specification for Parvo B19 virus.

These results indicate that the measures for the avoidance of human pathogens in the starting material for plasma fractionation are well implemented in the manufacturing processes. These measures are an essential part for protecting against viral contamination in medicines derived from human plasma.

3.016
Pools of
human plasma
for fraction

Approval of plasma pools 2007–2017

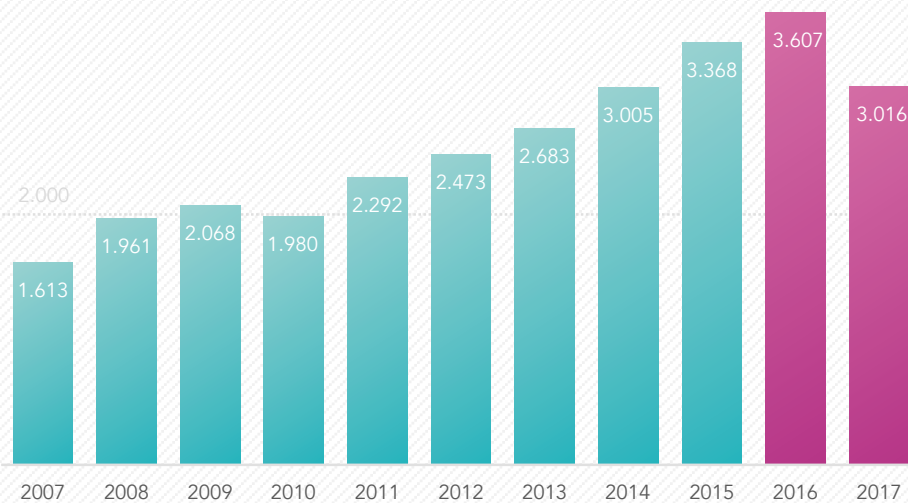


Fig. 40
Approval of plasma
pools 2007–2017

In 2017 2.764 batch releases of plasma derived medicinal products were applied for and approved without objection, which is a gain of 23.4 percent compared to 2016.

Batch release of plasma derived medicinal products 2007-2017

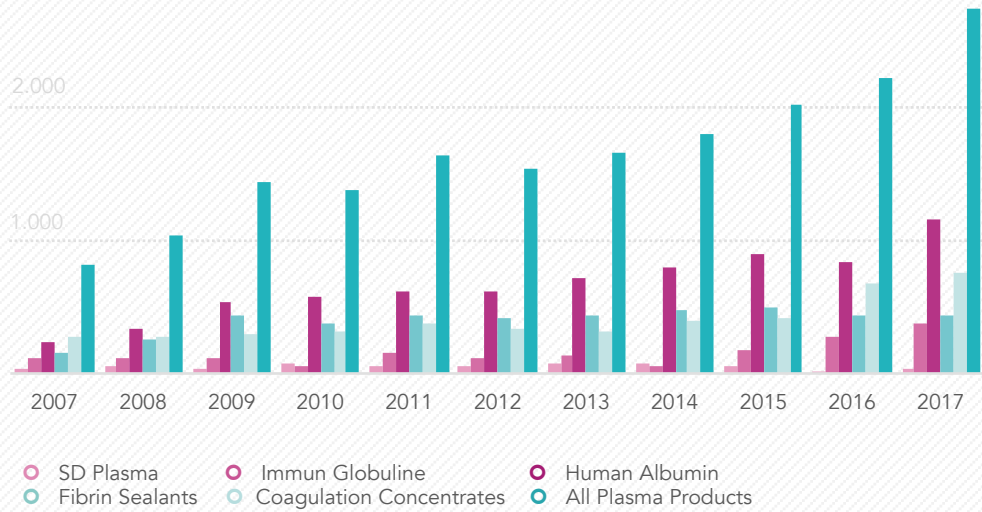


Fig. 41
Batch release of plasma derived medicinal products 2007-2017

The total number of released vaccine batches decreased compared to 2016 by 23 percent. For tick borne encephalitis virus vaccines the number decreased by 22.8 percent and the release of meningococcal group C vaccines decreased by 11.9 percent. Additionally, vaccines for clinical studies were released by AGES.

With respect to Directive 2010/63 on the protection of animals used for scientific purposes and the Austrian Tierversuchsgesetz 2012, the OMCL is active in the field of replacement, reduction and refinement of tests performed in animals. Therefore, the OMCL participates in the VAC2VAC project of the Innovative Medicines Initiative 2 program (www.vac2vac.eu), in working groups of the European Pharmacopoeia and directly interacts with manufacturers.

Batch Release of vaccines 2007–2017

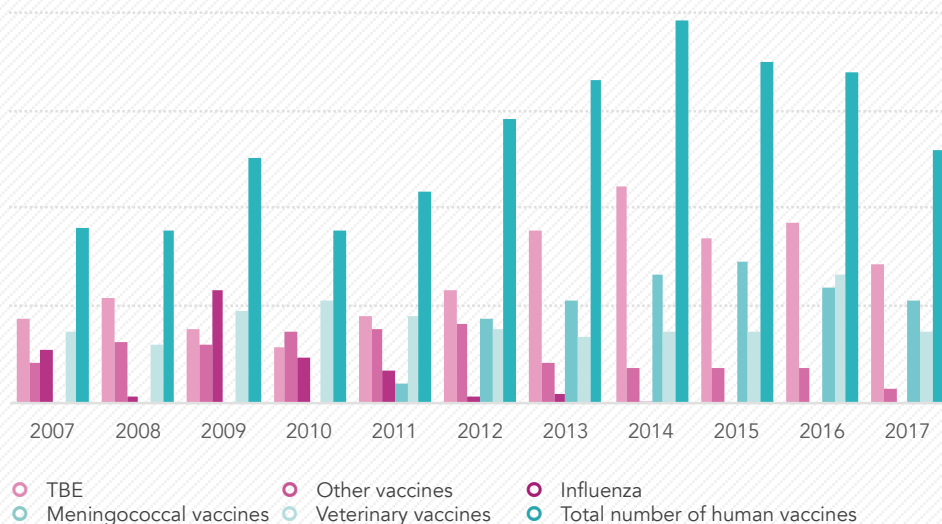


Fig. 42
Batch Release of vaccines 2007–2017

Medical Devices

Market Surveillance – Vigilance – Free Sales Certificates

The area of expertise includes market surveillance, vigilance and issuance of free sale certificates. These activities should ensure that only safe and effective medical devices are placed on the market and put into service.

The range of tasks in the field of market surveillance extends from delineation and classification of medical devices, complaints and reports related to risks arising in connection with medical devices to conduction of inspections of manufacturers or operators of medical devices. In 2016, 322 market surveillance cases were registered and 13 inspections were conducted. The number of market surveillance cases remained nearly the same with a number of 331 cases in 2017. In 2017 18 manufacturers were inspected, whereas the majority of manufacturers were affected by the closure of a notified body.

Vigilance includes capturing and assessing incidents and the relevant field safety corrective actions with medical devices. 1.171 incidents and 1.173 field safety corrective actions were registered in 2016. The total number of cases remained at a constant level, including 1.271 incidents and 1.065 field safety corrective actions in 2017.

As a service for the exporting medical device industry it is possible to apply for a free sale certificate. In 2016, based on 247 applications 635 free sale certificates were issued. In 2017 these numbers increased to 284 applications and 760 issued free sale certificates.

Furthermore, seven applications for certificate of exemption and 347 enquiries were registered in 2016. The number of applications remained stable in 2017. Four applications for certificate of exemption and four on delineation of a device have been submitted. In 2017 the number of enquiries significantly increased to 455.

Medical devices may be moved freely between member states once placed in the European Market. Therefore, European cooperation and communication is essential for safe and effective medical devices on the common market. To foster the cooperation and communication on the European level, Austria took the lead on an EU-funded market surveillance project. Within this project it was evaluated, whether manufacturers of medical devices – intended to be reprocessed – fulfil the legal requirements by providing adequate information on how to reprocess them safely and properly and by validating the process of cleaning, disinfecting and sterilizing. This project was successfully completed in 2017. In parallel Austria participates actively in another EU-funded project, named „Market Surveillance of Medical Devices“, which was initiated in 2016. The project focuses on joint inspections and clinical process and resource development.

Inquiries concerning medical devices

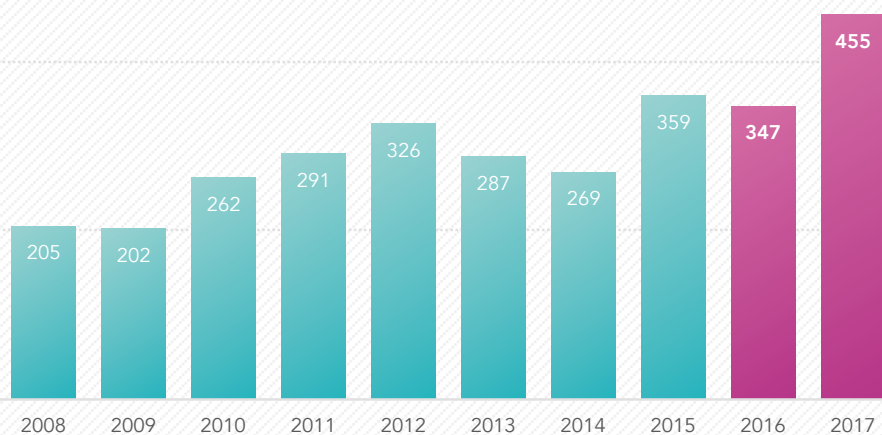
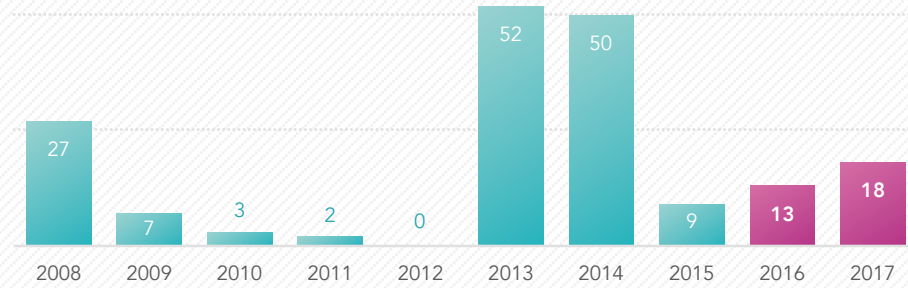


Fig. 43
Inquiries concerning
medical devices

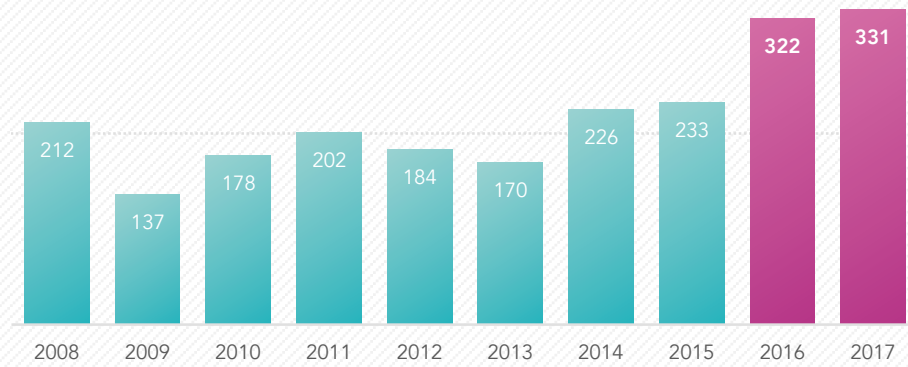
Medical device Inspections

Fig. 44
Medical device
Inspections



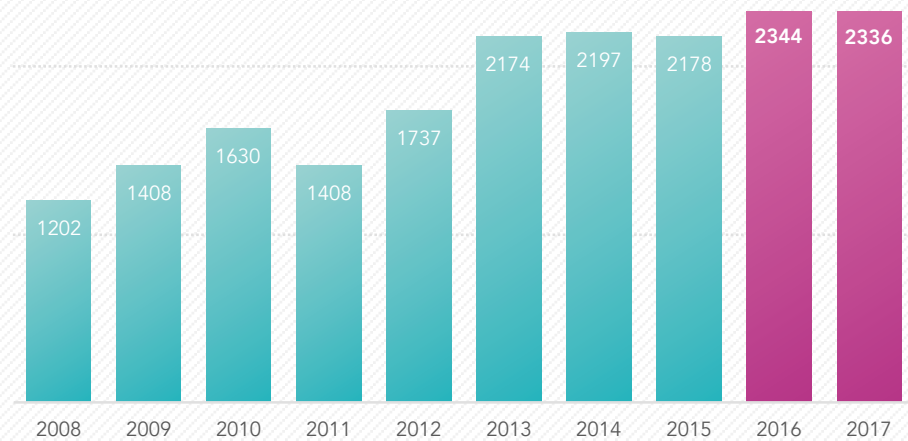
Cases in medical device market surveillance

Fig. 45
Cases in medical
device market
surveillance



Cases in medical device vigilance

Fig. 46
Cases in medical
device vigilance
(incidents + field
safety corrective
actions)



Blood and Tissue

The area of expertise includes inspections according to the blood safety act and tissue safety act as well as receipt and evaluation of haemovigilance and tissue vigilance notifications including determination/surveillance of necessary measures within Austria and the EU network.

Despite the ever increasing workload in routine vigilance and inspection activities, BASG/AGES MEA took again an active role in the relevant European expert network in order to facilitate further harmonisation and information exchange.

Since 2015 AGES is an associated partner of the EU joint action project „Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation – VISTART” and has been participating in the development of inspection guidelines, joint inspections and in the preparation of standards for harmonised vigilance reporting.

Blood Safety (Haemovigilance)

Haemovigilance reports

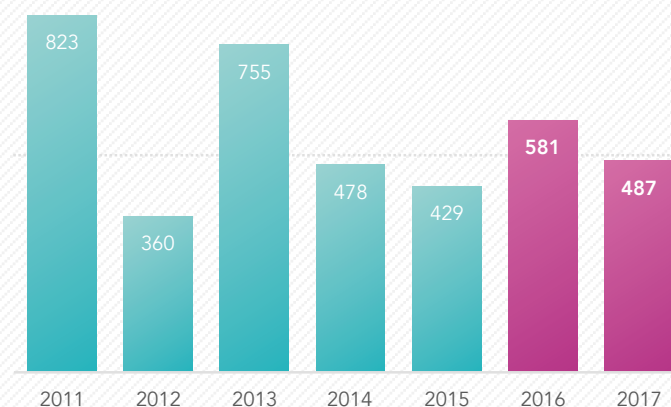


Fig. 47
Haemovigilance
reports

The reports received in 2016 comprised 50 serious adverse transfusion reactions, 47 serious adverse reactions during donation and 26 serious adverse events during manufacturing (product defects).

In 2017 41 serious adverse transfusion reactions, 53 serious adverse reactions during donation and 22 serious adverse events were reported.

41 reports of near-miss events were received in 2016, 31 in 2017. Detailed information can be found in the annual haemovigilance report via the following link: <https://www.basg.gv.at/en/news-center/publications/reviews/spezielle-berichte/>

Tissue Safety

Tissue and cells vigilance reports

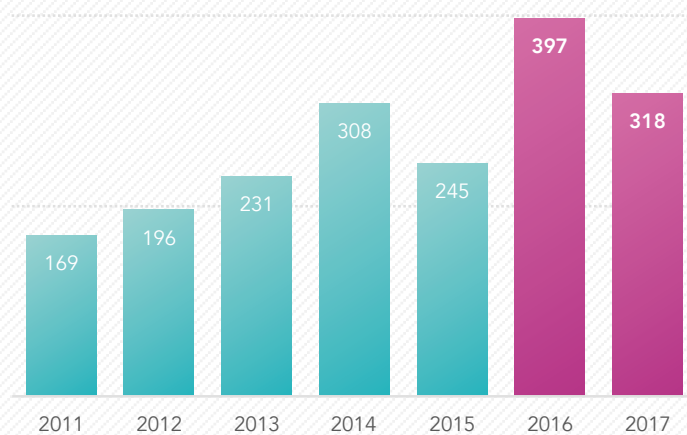


Fig. 48
Tissue and cells
vigilance reports

Regarding tissue vigilance reports in 2016, four of those comprised suspected serious adverse reactions and 10 suspected serious adverse events related to procurement or application of human tissues or cells. In 2017 seven suspected serious adverse reactions and 17 suspected serious adverse events were reported.

Validated reports as well as annual reports were sent to the European Commission. The Commission report was published and can be obtained via <https://www.basg.gv.at/en/news-center/publications/reviews/spezielle-berichte/>

Furthermore the accumulated report of the annual activities of tissue establishments can be found using the above mentioned link.

In 2016 a total number of 62 inspection procedures were performed, 17 of these were applications according to the tissue safety act, 45 were routine (periodical) inspections. In 2017 a total number of 88 inspections were performed, 34 relating to applications.

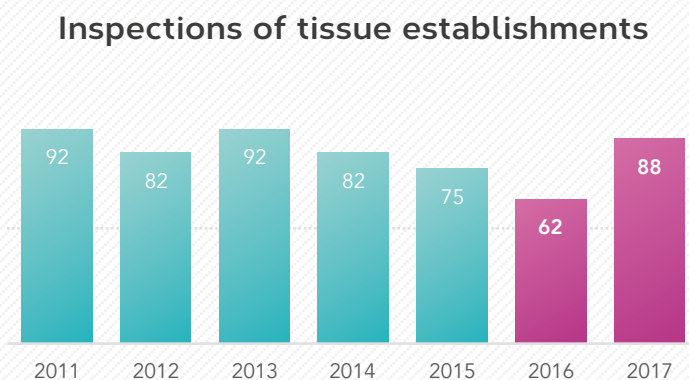


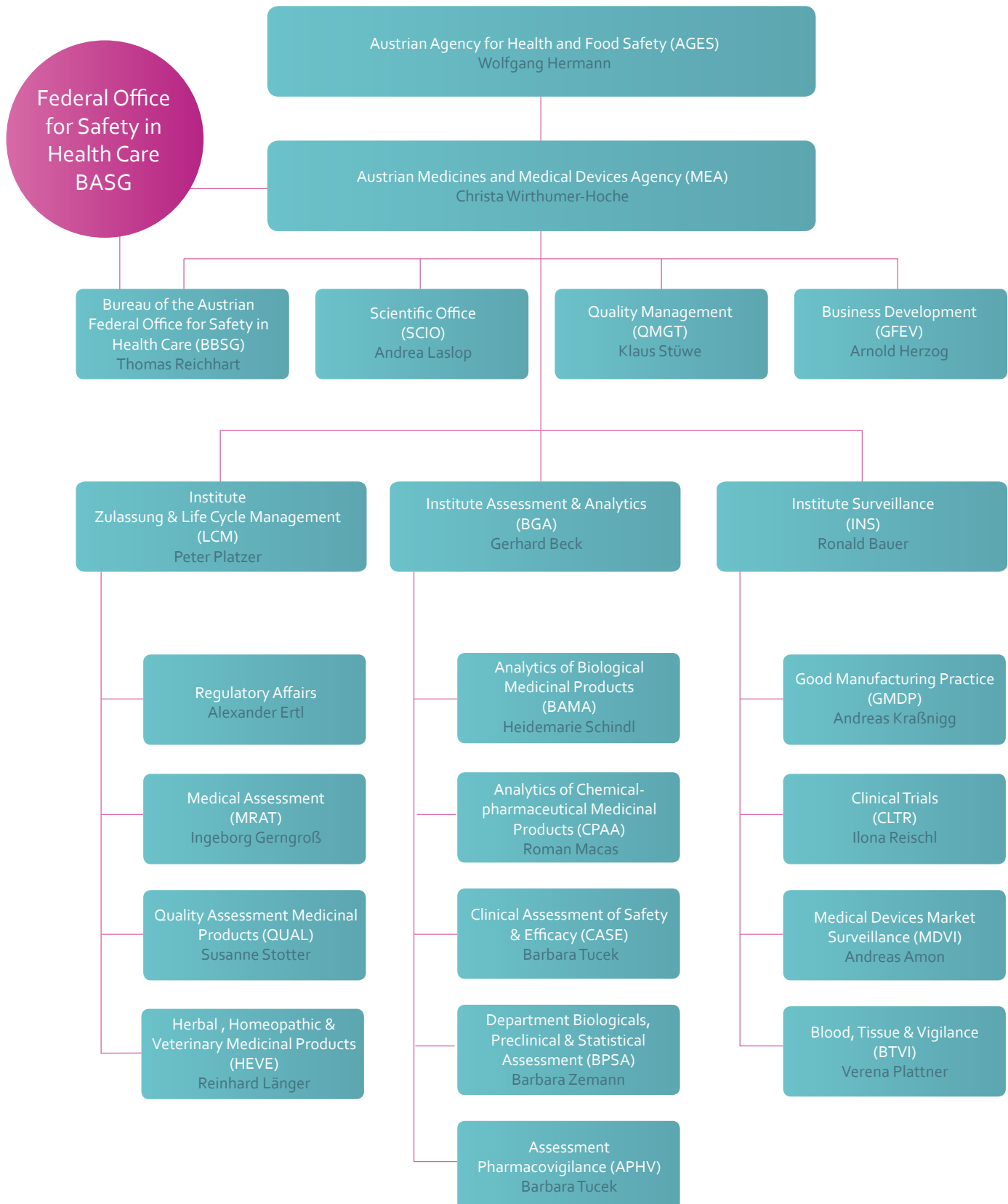
Fig. 49
Inspections of tissue establishments



3

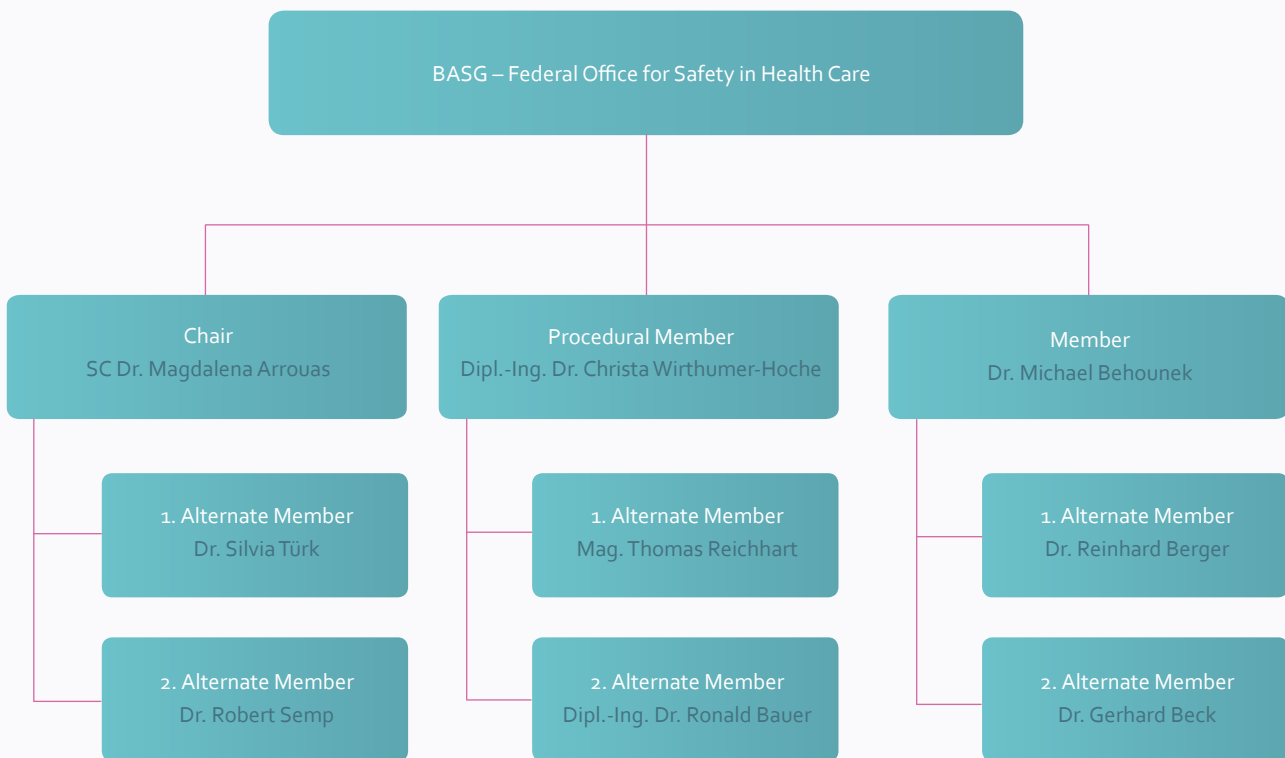
Organisation

Organisation



BASG – Federal Office for Safety in Health Care

The BASG consists of three members:





4

Annex



Committee activities

The boards and commissions where the Austrian Medicines and Medical Devices Agency (AGES MEA)/Federal Office for Safety in Health Care is represented, can be viewed on the BASG website at the following link:

<https://www.basg.gv.at/ueber-uns/basg-und-ages-mea/gremialtaetigkeiten/>

Scientific Publications

Scientific publications created with involvement of the Austrian Medicines and Medical Devices Agency (AGES MEA)/Federal Office for Safety in Health Care, can be viewed on the BASG website at the following link:

<http://www.basg.gv.at/news-center/publikationen/wissenschaftliche-publikationen/>

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