



# SME Office NEWSLETTER

Information for SMEs on the EU regulatory environment for medicines.  
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## EMA's relocation

EMA's business continuity plan entered its fourth phase on 1 January 2019 to ensure that EMA can continue its core activities to the same quality while it is physically relocating to the Netherlands ([Link](#)). These include the highest priority activities (authorisation, maintenance and supervision of medicines; ongoing Brexit preparedness and implementation activities; preparation for implementation of new veterinary legislation) and other activities listed in [Annex 1 of the business continuity plan](#).

EMA staff will gradually move into a temporary building in Amsterdam, called the Spark building. As of 11 March 2019, all EMA face-to-face meetings will take place at the Spark building until EMA moves into its permanent building. EMA has published an [Orientation Guide for Industry](#) on the Spark Building, which includes details on how to get to the building, facilities, and the arrangements for pharmaceutical companies attending scientific meetings. More information can be found on the EMA website ([Link](#)).



## United Kingdom's withdrawal from the European Union

### Brexit-related variations

EMA is encouraging marketing authorisation holders to submit Brexit-related type IA and type IB variations as early as possible in March 2019, to enable EMA to confirm compliance with regulatory and legal requirements by 29 March 2019. Please refer to the EMA practical guidance ([EMA/478309/2017 Rev. 4](#)) and to the dedicated news item for more details ([Link](#)).

### Batch control testing

The European Commission (EC) published on 25 February 2019 a notice related to the "Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products" ([Link](#)). Guidance for marketing authorisation holders for centrally authorised products on how to implement the exemptions provided in the notice is also available ([Link](#)). The scope of exemptions stated in the EC communication is limited in time and only applies in case there is no withdrawal agreement.

### Updated Brexit related guidance

Updated Brexit-related guidance for companies have been published on EMA's website : EC/EMA questions and answers ([Link](#)), EMA practical guidance ([EMA/478309/2017 Rev. 4](#)) and EC/EMA notice to marketing authorisation holders ([Link](#)). Changes are highlighted in the documents. The dedicated webpage on Brexit-related guidance for pharmaceutical companies should be consulted regularly ([Link](#)).

## New Medical Devices legislation

**R**egulation (EU) 2017/745 on Medical Devices ([MDR](#)) and Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices ([IVDR](#)) changed the European legal framework for medical devices, introducing new responsibilities for EMA and for national competent authorities. They will come into full effect in May 2020 for medical devices and May 2022 for in vitro diagnostic medical devices, following a transition period. A questions and answers document has been published on 28 February 2019 ([EMA/37991/2019](#)). It provides guidance on the implementation of Article 117 of the medical devices regulation ([Regulation \(EU\) 2017/745](#)), which stipulates that marketing authorisation applications for medicines with an integral medical device must include the results of the device's assessment of conformity by a notified body. EMA will publish further updates to the Q&A document addressing other requirements for various categories of devices. More information can be found on the EMA website ([Link](#)) and in the dedicated press release ([Link](#)).

## Big data

**E**MA and Heads of Medicines Agencies (HMA) have established a joint task force to investigate the role of 'big data' in the context of medicines development and regulation in the EU. The task force has published a report setting out recommendations on the generation and acceptability of evidence derived from big data, sources and formats, methods for processing and analysis and expertise available in the EU regulatory network ([EMA/105321/2019](#)). This also includes a definition of the term 'big data'. The public consultation is open until 15 April 2019. For more information, please consult EMA website ([Link](#)) and the outcome of surveys of national competent authorities and pharmaceutical industry ([Link](#)).



## Orphan medicines

**T**he EC has launched a consultation on a revision of the guideline on the content and format of applications for orphan drug designation and the transfer of designations between sponsors. It provides supplementary advice to sponsors to take into account EMA's online web portal ([IRIS](#)), which was launched in 2018 to submit applications for designations as orphan medicinal products. Companies

developing orphan medicinal products are encouraged to provide their comment by 28 April 2019 ([Link](#)).

## Advanced Therapy Medicinal Products

**A** new multidisciplinary guideline for investigational advanced therapy medicinal products in clinical trials has been released for consultation until 1 August 2019 ([EMA/CAT/852602/2018](#)). It provides guidance on the structure and data requirements for a clinical trial application and addresses development, manufacturing and quality control as well as non-clinical and clinical development of investigational ATMPs.

## Parallel distribution

**S**ince 11 February 2019, parallel distributors are required to use [IRIS](#), EMA's secure online platform for the management of product-related regulatory procedures, for parallel distribution processes (i.e. submission of notifications of parallel distribution and access to the public register of parallel distribution notices). The IRIS quick guide to registration has been updated to reflect these changes ([Link](#)), a guide to the portal for parallel distribution industry users ([Link](#)) and online training sessions are also available ([Link](#)). In view of the launch of this new module and in the context of EMA's relocation to the Netherlands, EMA is temporarily suspending the submission of parallel distribution annual updates until 30 April 2019. Further details can be found under this [Link](#).

## Good Manufacturing Practices

**T**he Swiss Agency for Therapeutic Products, Swissmedic, has started in 2019 to enter information on GMP compliance and manufacturing authorisations of Swiss manufacturers into the European Union's EudraGMDP database ([Link](#)) for all new or renewed manufacturing authorisations. Swissmedic now also issues GMP certificates using new templates, which replace paper documents. This latest development is part of the mutual recognition agreement between the EU and Switzerland, operational since June 2002. More information can be found in the dedicated press release ([Link](#)).

Two further Member States, Poland and Slovenia, have now been included into the mutual recognition agreement for GMP inspections between EU and the US ([Link](#)). More information can be found under this [link](#) and in the corresponding Q&A ([EMA/885291/2018](#); [EMA/866364/2018](#)).

## Falsified medicines

As of 9 February 2019, most prescription medicines and some over-the-counter medicines for human use in the European Union are required to have a unique identifier (a two-dimension barcode) and an anti-tampering device on their outer packaging. These mandatory safety features are a key measure of the Falsified Medicines Directive ('FMD') ([Directive 2011/62/EU](#)) which is part of the EU's strategy to strengthen the security of the supply chain of medicines. The safety features are implemented through a delegated regulation ([Commission delegated regulation \(EU\) 2016/161](#)) that came into effect on 9 February 2019. For more information, please refer to the corresponding Q&A document ([Link](#)), the implementation plan ([Link](#)) and to the dedicated news item ([Link](#)).

## Electronic Product Information

A public consultation on draft key principles which will form the basis on which the electronic product information (ePI) for human medicines will be developed and used in the European Union ([Link](#)) has been launched by EMA, the Heads of Medicines Agencies (HMA) and the European Commission (EC) on 31 January 2019. The draft key principles have been prepared in consultation with stakeholders (patients, healthcare professionals, regulators, pharmaceutical industry) in a workshop which took place on 28 November 2018 (Presentations, recording and meeting report are available under this [link](#)). SMEs are encouraged to submit comments via an [online form](#) by 31 July 2019. More information can be found in the dedicated press release ([Link](#)) and in the product information requirements webpage ([Link](#)).

## Pharmacovigilance

A new GVP chapter on paediatric pharmacovigilance came into effect on 8 November 2018 (chapter IV, [EMA/572054/2016](#)). It provides guidance on how to make best use of existing tools and processes to address the specific needs and challenges of safety monitoring of medicines used in children. In addition, it advises on how to adapt regulatory requirements to the paediatric population. Further information can be found in the dedicated press release ([Link](#)) and in the introductory cover note of the GVP ([Link](#)).

New or updated guidance have been published or updated:

- Guidance on the format of the risk management plan (RMP) in the EU ([EMA/164014/2018 Rev.2.0.1](#));
- Q&A on signal management ([EMA/261758/2013 Rev 3](#));

- EudraVigilance registration manual ([EMA/507439/2018 Rev. 1](#));
- Q&A on Eudravigilance registration ([EMA/404930/2018](#));
- Documentation for Eudravigilance registration ([EMA/503894/2018](#));
- Instructions on how to change the qualified person for pharmacovigilance and responsible person for Eudravigilance ([EMA/503895/2018](#));
- Guidance on the query support options offered by EMA on EudraVigilance and Pharmacovigilance related queries ([Eudravigilance support guide](#));
- Q&A from stakeholders on the new EudraVigilance System ([EMA/679813/2018](#));
- Guidance document on the query support options offered by the EMA on EudraVigilance and Pharmacovigilance related queries ([Link](#)).



## Scientific guidelines for human medicines

### Patient registries

A revised guideline on studies to support marketing authorisation applications for medicines intended for haemophilia patients with factor VIII deficiency came into effect on 1 February 2019 ([EMA/CHMP/BPWP/144533/2009 Rev. 2](#)). A guideline on factor IX deficiency has also been released for consultation until 30 June 2019 ([EMA/CHMP/BPWP/144552/2009 rev. 2 Corr. 1](#)). The revisions introduce changes in relation to the investigation of recombinant and human plasma-derived factor VIII and factor IX haemophilia medicines in previously untreated patients, where in this small subset of patients data should be collected from patient registries rather than from small clinical trials. More information on the practical implementation of the guidelines is available in a questions and answers document ([Link](#)). Further details can also be found in the dedicated press release ([Link](#)).

A discussion paper on methodological and operational considerations in the use of patient disease registries for regulatory purposes has been released for consultation ([Link](#)) until 30 June 2019.

### Clinical trials

A guideline on the content, management and archiving of the clinical trial master file (CTMF) has been published ([EMA/INS/GCP/856758/2018](#)). It provides guidance on the requirements of the current legislation ([Directive 2001/20/EC](#) and [Directive 2005/28/EC](#)), ICH E6 Good Clinical Practice Guideline ([Link](#)), as well as prospectively considering specific requirements of Clinical Trials Regulation (EU) No. 536/2014 with respect to the TMF.

### Quality guidelines

A guideline describing the information on quality aspects to be included in the product information of vaccines for human use will enter into force on 1 May 2019 ([EMA/CHMP/BWP/133540/2017](#)).

A revised guideline on the requirements for quality documentation of biological investigational medicinal products (IMPs) in clinical trials came into force on 1 November 2018 ([EMA/CHMP/BWP/534898/2008 rev. 1](#)). It addresses documentation requirements on the biological, chemical and pharmaceutical quality of IMPs containing biological/biotechnology derived substances and lists examples of modifications which are typically considered as 'substantial'.

A revised guideline on Active Substance Master File Procedure (ASMF) will enter into force on 17 June 2019 ([Link](#)). It clarifies the responsibilities of the marketing authorisation holder in providing information on the sections 'control of active substance' and the 'reference standard', and introduces changes to annex 2, 3 and 4.

A draft guideline on quality and equivalence of locally applied and locally acting medicinal products for cutaneous use has been released for consultation until 30 June 2019 ([CHMP/QWP/708282/2018](#)). It details guidance on the quality of topical products not covered by other guidelines, and equivalence testing of topical products in lieu of therapeutic equivalence clinical trials.

A draft guideline on the pharmaceutical use of different grades of water in the manufacture of active substances and medicinal products for human and veterinary use was released for consultation until 15 May 2019 ([EMA/CHMP/CVMP/QWP/496873/2018](#)). It has been updated to reflect the changes in the European Pharmacopoeia monographs. It replaces the Note for Guidance on quality of water for pharmaceutical use ([CPMP/QWP/158/01](#), [EMA/CVMP/115/01](#)), and the position statement on

the Quality of Water used in the production of Vaccines for parenteral use ([EMA/CPMP/BWP/1571/02 rev.1](#)).

An ICH guideline on a framework to facilitate management of post-approval chemistry, manufacturing and controls (CMC) changes in a more efficient manner across the product lifecycle was adopted ([EMA/CHMP/ICH/804273/2017](#)). It aims to strengthen quality assurance and reliable product supply, including proactive planning of supply chain adjustments.

The following questions and answers have also been published or updated:

- Quality of medicines ([Link](#));
- Bovine spongiform encephalopathies and vaccines ([Link](#));
- Haemagglutination Inhibition test for qualification of influenza vaccine inactivated seed preparations ([Link](#)).

### Non clinical guidelines

A draft guideline on the non-clinical data to be submitted in applications for marketing authorisations or clinical trials for the non-radioactive part of radiopharmaceuticals has been released for consultation until 30 June 2019 ([EMA/CHMP/SWP/686140/2018](#)). It replaces the non-clinical part of the Note for Guidance on Radiopharmaceuticals/Eudralex 3AQ20a and 3Q21a. For quality aspects, 3AQ20a has been replaced by the 'Guideline on Radiopharmaceuticals' (EMA/CHMP/QWP/306970/2007).

A revision of the guideline on the environmental risk assessment (ERA) of human medicines has been released for public consultation until 30 June 2019 ([EMA/CHMP/SWP/4447/00 Rev. 1](#)). It clarifies when ERA studies are required and provides technical guidance to increase consistency in assessment, and a definition of 'endocrine active substances' which includes all compounds that affect development or reproduction. More information can be found in the dedicated press release ([Link](#)).

### Clinical guidelines

A revised guideline defining the requirements to waive clinical trials with clinical or pharmacodynamic endpoints in the demonstration of therapeutic equivalence for locally applied, locally acting gastrointestinal products will enter into force on 1 May 2019 ([CPMP/EWP/239/95 Rev. 1](#)). It also defines the *in vivo* bioequivalence studies and *in vitro* equivalence tests necessary to demonstrate therapeutic equivalence.

A guideline on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation will come into effect on 1 July 2019 ([EMA/CHMP/458101/2016](#)). The new guidance provides details on what to include in a PBPK modelling



report, when it is intended for regulatory submissions. It also clarifies the supportive data needed to qualify a PBPK platform for the intended use.

The questions and answers document on modelling and simulation for paediatrics ([Link](#)) and pharmacology and pharmacokinetics ([Link](#)) have also been updated.

A draft revised guideline on the evaluation of medicines indicated for the treatment of bacterial infections ([EMA/844951/2018 Rev. 3](#)) has been released for consultation until 31 July 2019. It merges guidance on the evaluation of medicinal products indicated for treatment of bacterial infections ([CPMP/EWP/558/95Rev.2](#)) and its addendum ([EMA/CHMP/351889/2013](#)). It was revised to take into account scientific advice in the field, discussions with international regulatory authorities to include recommendations for primary endpoints, primary analysis populations and non-inferiority margins in trials to support certain infection site-specific indications for use.

A guideline on the evaluation of medicinal products indicated for prophylaxis or treatment of respiratory syncytial virus (RSV) disease will come into effect on 1 May 2009 ([EMA/CHMP/257022/2017](#)). The guidance covers the development of vaccines, monoclonal antibodies and directly acting antiviral agents and focuses on the assessment of safety and efficacy in populations most likely to develop RSV lower respiratory tract infection and severe RSV disease, including infants, toddlers and older adults.

A draft guideline on the clinical investigation of medicinal products for the treatment of gout has been released for consultation until 1 August 2019 ([EMA/CHMP/774470/2018](#)). It provides guidance on the development of new urate-lowering and anti-inflammatory treatment options, including details on study design, inclusion criteria, primary endpoints and trial duration.

A draft paediatric addendum to the guidelines on the clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic (VTE) disease has been released for consultation until 30 June 2019 ([EMA/CHMP/763438/2017](#)). It includes specific guidance relating to endpoints and imaging techniques adapted according to the localisation of VTE, methodological issues of clinical trials and the possibility to extrapolate efficacy and safety from data in adults.

A concept paper on the revision of the guideline on the evaluation of anticancer medicinal products has been released for consultation until 14 April 2019 ([EMA/CHMP/755489/2018](#)). It proposes to review aspects relating to biomarkers, which have resulted in novel development strategies and definitions of biomarkers-based indications.

## Scientific Advice (human)

### Public information on scientific advice

In June 2018, EMA started to provide information on scientific advice received during product development, in European Public Assessment Reports. The initiative, initially focusing on PRIME products, is now extended to all types of products.



### Pre-submission and authorisation processes

EMA has published a booklet describing the journey of a medicine for human use authorised through EMA, from initial research to discussions on patient access across the EU ([Link](#)). It describes how EMA supports medicine development by with scientific advice and how it assesses a medicine's benefits and risks once it receives an application for marketing authorisation. All steps involved in these processes, including the involvement of patients, healthcare professionals and other external experts, as well as principles guiding the scientific discussions are outlined.

## Regulatory guidance

### Fees for applications to EMA

Adjusted fees for all applications, except for pharmacovigilance procedures, will be coming into effect on 1 April 2019. EMA will publish full details of the revised fees (including an updated explanatory note on fees) at the end of March, once the amended regulation has been adopted by the European Commission and published in the Official Journal of the European Union. Fees charged for pharmacovigilance procedures in accordance with [Regulation \(EU\) 658/2014](#) are expected to be revised in 2020, taking into account the 2018 and 2019 inflation rates.

### Mobile technologies in product information

A revised guidance document on mobile scanning and other technologies in the labelling and package leaflet of centrally authorised medicinal products has been published ([EMA/493897/2015 Rev. 1](#)). It covers the use of mobile technologies to access a dedicated platform maintained by the Marketing Authorisation Holder or a national competent authority with information on medicinal products. The list of contact points in Member States to review national versions of the content of mobile scanning ([EMA/358267/2015, Version 4](#)) and an updated declaration form for providing this information have also been updated ([EMA/493921/2015 Rev.1](#)).

### Checklist to facilitate validation for initial marketing authorisation applications

A new validation checklist for initial marketing authorisation applications (MAA) was published on 12 February 2019 ([Link](#)). EMA is encouraging applicants to submit it as part of the MAA, which aims at making the validation process more efficient. More information can be found under this [link](#).

The following guidance documents have also been updated:

- Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' ([EMA/CHMP/302620/2017 corr. 1\\*](#));
- Pre-authorisation guidance ([EMA/821278/2015](#));
- Post-authorisation guidance ([EMEA-H-19984/03 Rev. 80](#));
- Procedural advice for users of the centralised procedure for similar biological medicinal product ([EMA/940451/2011](#));
- Procedural advice for users of the centralised procedure for generic/hybrid applications ([EMEA/CHMP/225411/2006](#));
- Q&A documents on Type IA variations ([Link](#)), Type IB variations ([Link](#)), Type II variations ([Link](#)), on PSUR ([Link](#)) and on Paediatric Investigation Plan ([Link](#));
- Q&A on pre-submission queries service ([Link](#));
- Q&A on worksharing ([Link](#));
- Q&A on post-authorisation efficacy study ([Link](#));
- Q&A on post-authorisation measures ([Link](#));
- Q&A on annual re-assessment ([Link](#)).

## Regulatory science strategy to 2025 for human and veterinary medicines

In December 2018, EMA published its draft '[Regulatory Science to 2025](#)' strategy for a six-month public consultation. The initiative sets out detailed plans for advancing the Agency's

engagement with regulatory science over the next five years. It covers both human and veterinary medicines across a broad range of subjects, many of which are applicable to SMEs. The [consultation](#) will remain open until 30 June 2019 (comments to be submitted via an [online questionnaire](#)). More information can be found in the dedicated press release ([Link](#)).



## Antimicrobials used in animals

An updated scientific advice on the public health impact of the use of antibiotics in animals was released for consultation until 31 March 2019 ([EMA/CVMP/CHMP/682198/2017](#)). It elaborates on a risk-based categorisation of antimicrobials according to their use in animals and the possible development of antimicrobial resistance.

## Veterinary Medicines

### New legislation for veterinary medicines

The European Parliament adopted the final texts of the new veterinary medicines regulation ([Link](#)) and the corresponding update of [Regulation 726/2004](#) concerning the regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products. The new regulation intends to increase the availability of veterinary medicinal products, reduce administrative burden, stimulate competitiveness and innovation in the veterinary sector, improve the functioning of the internal market and address the public health risk of antimicrobial resistance. The regulation is a new standalone set of rules covering all aspects of veterinary medicines (at national and centralised level) that will replace [Directive 2001/82](#) and the veterinary product-specific articles currently included in [Regulation 726/2004](#). The new veterinary medicines regulation will become applicable by end of 2021.

## Veterinary scientific guidelines

A revised guideline on the implementation of risk assessment to control elemental impurities in veterinary medicinal products came into effect on 27 November 2018 ([EMA/CVMP/QWP/631010/2017-Rev.1](#)). It outlines a phased implementation for the submission of risk assessments required by the European Pharmacopeia. A reflection paper providing information on how such risk assessment may be conducted for elemental impurities in products authorised or to be authorised in the European Union has also been released for consultation until 31 August 2019 ([EMA/CVMP/QWP/153641/2018](#)).

A revised guideline on study design, conduct and evaluation of bioequivalence studies for pharmaceutical forms with systemic action and in vitro dissolution tests will come into effect on 1 July 2019 ([EMA/CVMP/O16/2000-Rev.3](#)).

A guideline on assessment and control of DNA reactive impurities in veterinary medicines and of their mutagenic potential ([EMA/CVMP/SWP/377245/2016](#)) will come into effect on 1 July 2020.

A draft guideline for allergen products of biological origin, used for the treatment or specific immunotherapy or in vivo diagnosis of immunoglobulin E (IgE)-mediated allergic diseases in horses, dogs and cats was released for consultation until 31 August 2019 ([EMA/CVMP/IWP/170689/2016](#)). It sets out recommendations on quality (production and control), and clinical testing regarding safety and efficacy.

A revised guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease will come into effect on 1 July 2019 ([EMA/CVMP/IWP/105506/2007 Rev. 1](#)). It was revised to take into account changes considered necessary following a review of stakeholders experience. An accompanying Q&A document addresses topics raised by stakeholders not specifically addressed in the revised guideline ([EMA/CVMP/IWP/466888/2017 Rev. 1](#)).

## Minor use minor species/limited market

A revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market entered into force on 1 January 2019. It was updated in light of experience gained by the Agency and the Committee for Medicinal Products for Veterinary Use (CVMP) ([EMA/308411/2014-Rev.1](#); see also revised guidance ([EMA/CVMP/388694/2014-Rev.2](#))).



## Regulatory guidance for veterinary products

The following guidance documents have been updated:

- Eudravigilance access policy or veterinary medicines (coming into effect in 2021) ([EMA/113700/2008-Rev.1](#)) – revised to align field access specifications for each stakeholder to the data fields of Veterinary ICH international standards, and implemented in the updated EudraVigilance Veterinary system;
- Use of approved pictograms on the packaging of products authorised via centralised procedure, mutual recognition or decentralised procedure – revised to add new species ([EMA/776723/2017 rev. 1](#));
- Practical guidance on centralised type IA and IB variation application form ([EMA/631179/2018](#)) and corresponding checklist ([Link](#)).

## Other news

**P**resentations, reports and/or videos of the following events have been published:

- A common data model for Europe - Why? Which? How? – EMA Workshop report ([Link](#)) - 12/2017;
- European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting ([Link](#)) - 22/10/2018;
- SME Info day for micro, small and medium-sized enterprises: regulatory toolbox for medicines and combined devices developers ([Link](#)) – 26/10/2018 – video published;
- Multi-stakeholder workshop Heads of Medicines Agencies (HMA)/EMA task force on availability of authorised medicines ([Link](#)) - 09/11/2018 – report published;
- Fourth industry stakeholder platform on research and development support ([Link](#)) – 23/11/2018;
- Stakeholder workshop on support to quality development in early access approaches, such as PRIME and breakthrough therapies ([Link](#)) – 26/11/2018;

- EMA/HMA/EC workshop on electronic product information (ePI) ([Link](#)) – 28/11/2018;
- Multi-stakeholder workshop on EMA's veterinary regulatory science to 2025 ([Link](#)) - 06/12/2018;
- 16<sup>th</sup> Joint European Medicines Agency/European network for Health Technology Assessment dialogue meeting ([Link](#)) - 07/12/2018;
- Industry stakeholder meeting on Brexit and the operation of the centralised procedure for human and veterinary medicinal products ([Link](#)) – 28/01/2019.

### Publication of interest

'European regulatory experience with advanced therapy medicinal products', Nature review drug discovery, that provides an analysis of scientific advice and marketing authorisation received for ATMPs up to June 2018 ([Link](#)).

### Other report of interest

Sales of veterinary antimicrobial agents in 30 European countries in 2016 - Trends from 2010 to 2016 Eighth ESVAC report ([Link](#)).



## Registered SMEs

Currently, 1704 companies have SME status assigned by the Agency.

The names and profiles of these companies are published in the Agency's public [SME Register](#).

If you would like to have your company details included in the SME Register, you must first apply for SME status at the Agency.

See the [Applying for SME status](#) section of the SME Office pages on the Agency's website for information on how to do this.

### About the SME Office

The SME Office was set up within the European Medicines Agency to address the particular needs of smaller companies.

The Office has dedicated personnel who can help SMEs by:

- responding to practical or procedural enquiries;
- setting up briefing meetings to discuss their regulatory strategy;
- organising info days and training sessions.

### Need more information?

Visit the European Medicines Agency website:

<http://www.ema.europa.eu>

In particular, these sections may interest you:

[SME Office](#)

[Pre-authorisation \(human medicines\)](#)

[Pre-authorisation \(veterinary medicines\)](#)

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