



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



# Applying for EU marketing authorisation

For medicinal products  
for veterinary use



Medicines can be authorised throughout the European Union (EU) by means of a single application procedure ('centralised procedure').

### **The centralised procedure**

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The European Medicines Agency is responsible for the scientific evaluation of applications for centralised marketing authorisations.

Once granted, the centralised marketing authorisation is valid in all EU Member States. This allows the marketing-authorisation holder to market the medicine and make it available for administration to animals throughout the EU. Information on the medicine will be available in the Member States in the local language; during the assessment, all data and communications are in English only.

### **What type of data need to be submitted?**

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Companies wishing to obtain a marketing authorisation need to provide the Agency with an application that includes a comprehensive package of data (a 'dossier') establishing that the medicine meets the required quality, safety and efficacy standards; the safety of the medicine with regard to people coming into contact with the medicine and to the environment must also be demonstrated.

For veterinary medicines intended for food-producing animals (e.g. cattle, pigs, poultry, horses, bees, rabbits and fish), the safety to consumers also needs to be studied. The Agency does not conduct any studies, nor is it involved in any animal testing.

### **How long does the authorisation procedure take?**

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Upon submission of a valid marketing-authorisation application, the evaluation takes up to 210 days. This 'active' time can be interrupted ('clock stop') to allow applicants to prepare responses to questions from the Committee for Medicinal Products for Veterinary Use (CVMP). At the end of the procedure, the CVMP issues a scientific opinion on whether or not the medicine should

be authorised, which is then transmitted to the European Commission, which has the ultimate authority for granting the marketing authorisation within 67 days after receipt of the CVMP opinion.

For food-producing animals, a maximum residue limit (MRL) must be established for the active substance(s) and species before an authorisation can be issued, to allow the setting of a withdrawal period for food derived from these animals. If no MRL exists, an MRL application has to be submitted first.

### **Which veterinary medicines *must* be centrally authorised?**

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All veterinary medicines derived from biotechnology and other high-tech processes must be evaluated by the Agency via the centralised procedure. Veterinary medicines intended primarily for use as performance enhancers must also be centrally authorised.

### **Which products may *optionally* be centrally authorised?**

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For medicines that do not meet the above description, companies can submit an application to the Agency, provided the medicine is a new active substance in veterinary medicines, constitutes a significant therapeutic, scientific or technical innovation, or is in any other respect in the interest of animal health at EU level.

Immunological veterinary medicines for the treatment of animal diseases that are subject to EU prophylactic measures are also eligible, as are generics of centrally authorised products.

For medicines that fall outside the scope of the centralised procedure, authorisation via the decentralised, mutual-recognition or national procedures should be used, depending on the number of countries in which authorisation is sought.

To find out whether a product can be evaluated under the centralised procedure, companies should submit to the CVMP an 'eligibility request'.

## **Can I get pre-submission advice from the Agency?**

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The Agency's website provides detailed advice on procedural, regulatory and legal aspects of a submission, which applicants are encouraged to consult.

Once it is clear that a product is eligible for the centralised procedure, companies should inform the Agency in writing approximately 7 months in advance of their intended submission date.

Applicants are strongly recommended to obtain procedural and regulatory advice from the Agency through a pre-submission meeting with the Agency's product team. A successful pre-submission meeting should help applicants to submit applications that conform to the requirements and can be processed speedily. These meetings also enable applicants to establish contact with Agency staff closely involved with the application as it proceeds.

For small- or medium-sized companies, the Agency provides additional support via a dedicated SME Office.

Furthermore, scientific guidance is published on the data, tests and studies required in support of the dossier for an authorisation application.

For more detailed scientific questions, in particular on the design of studies, or on deviations from published study requirements, it is also possible to request 'scientific advice' from the CVMP.

## **How is my product evaluated?**

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The evaluation of centrally authorised products is done by the CVMP, involving members from the 28 EU Member States and from Iceland and Norway. For each product, the CVMP appoints two rapporteurs to lead and coordinate the evaluation.

## Steps involved in obtaining an EU marketing authorisation

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- Submission of eligibility request.
- Pre-submission meeting.
- Notification of intention to submit an application.
- Appointment of rapporteurs.
- Submission of the application.
- Scientific evaluation by the CVMP.
- CVMP scientific opinion.
- European Commission decision on the marketing authorisation.

### Useful information

On the European Medicines Agency's website ([www.ema.europa.eu](http://www.ema.europa.eu)):

Home > Regulatory > Veterinary medicines:

- Pre-authorisation
- Scientific advice
- Maximum residue limit (MRL) applications
- SME office
- Scientific guidelines

On other websites:

[Regulation \(EC\) No 726/2004.](#)

['The rules governing medicinal products in the European Union', Notice to Applicants, Volume 6A, Chapter 4: Centralised Procedure.](#)



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### **Further information**

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#### **European Medicines Agency**

30 Churchill Place  
Canary Wharf  
London E14 5EU  
United Kingdom

**Telephone** +44 (0)20 3660 6000

**Send a question** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

**Website** [www.ema.europa.eu](http://www.ema.europa.eu)