

The Marketing Authorisation Process for Veterinary Medicinal Products in Europe





Before any new animal pharmaceutical product can be placed on the market, a stringent, scientific and independent review has to be carried out by the authorities to ensure it is safe, of high quality and efficacious. Only after this review has been carried out may a product be granted a Marketing Authorisation. This detailed, in-depth process is known as “Registration.”

The EU registration process ensures that only those products of a defined standard, which have been thoroughly tested and carefully reviewed by independent experts, reach the marketplace.

The basis of the review is the data-file, or “Dossier,” which is submitted by the applicant company to the registration authorities.

The data file contains the results of all the studies carried out to assess and demonstrate the safety, quality and efficacy of the product.

This publication contains basic information on what registration is, how it works and what is done to meet the registration criteria.

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WHAT IS PRODUCT REGISTRATION?



*"Animals need medicines too."
IFAH-Europe*

Registration: The Passport to the Market

Imagine yourself emigrating to a new country. You will not be allowed to enter that country until all your details have been checked. For example: the validity of your passport, health status, vaccination record, skills, and whether you can support yourself. Only when your status has been confirmed will you be allowed to enter the country, and even then certain conditions may be applied.

Before an animal health product is allowed to enter the market it, too, must be registered and have its credentials checked. This is a lengthy and complex procedure and is ultimately designed to protect the public, animals and the environment from poor quality or unsafe medicines.

How Registration has evolved

The registration process has its origins in the 1965 EC Medicines Directive, which laid down the criteria of safety, quality and efficacy. In 1981 two EC Directives were published with the intention of improving and harmonising the registration process for medicinal products within the European Union. These were later extended to include vaccines and homeopathic medicines.

In the 1990's, controls were further harmonised and tightened with the introduction of legislation covering residues in food, a centralised registration procedure and the rules for Good Manufacturing Practice.

In 2004, the legislation was amended to increase the efficiency of the procedures, particularly taking into account the 10 new Member States that joined the EU on 1 May 2004, and would therefore have to apply the legislation.

Objectives of Registration

The authorisation process is an exhaustive investigation involving all aspects of the new product. It is based on trial results and data submitted by the applicant company.

The objectives of registration are to ensure:

- the product is **safe** for the animal itself, the consumer of food derived from treated animals, those handling the product, and the environment,
- the product is of consistent **high quality**, does not deteriorate and has the stability to last at least until the expiry date, and,
- the product's **efficacy** conforms with the claims made on its information leaflet and label.

Indeed, successful discovery and development in the laboratory is only the start of the process of bringing a new veterinary medicine to the market.

The three steps of the registration process are briefly reviewed on the following pages.

This will provide an insight into the investment in terms of time, money and effort that is required by companies to obtain a Marketing Authorisation.

Criterion 1: PRODUCT SAFETY



Four Areas of Safety

The safety criteria cover four areas: the **consumer**, the **animal**, the **user** and the **environment**.

1. The consumer

Firstly, for farm animals whose produce will be eaten, safety to the consumer is essential. Studies, often using sophisticated analytical tests, are carried out to guarantee that no harmful residues remain in the food. After treatment with certain substances, it may be necessary to withhold a food animal or its produce from the food chain for a specified period (the Withdrawal Period*).

2. The animal

Safety to the animal patient is also a top priority. Products are rigorously screened at the development stage for any potential adverse side effects, from acute or long-term exposure to the medicine, and clinical symptoms of over-dosage are carefully evaluated.

3. The user

Health and safety at work are very important factors in modern work practices. Those who administer the product must not be put at risk whether they are using it in a feed mill, a veterinary surgery, on the farm or at home. The toxic properties of the product are carefully studied and precautionary advice on safe use is included on the label.

4. The environment

Not only the effects of a substance on animals and users are tested, but the product itself and the excreta of treated animals, whether pets or farm livestock, must be carefully evaluated for any potential impact on the environment.

Registration results in a Marketing Authorisation, granted only after an in-depth, well defined independent scientific assessment. The same system is applied to medicinal products for human use.

Science for Safety

To comply with these safety requirements, an integrated set of studies - including metabolism*, toxicity testing and residue depletion rates - has to be carried out. The outcome of these studies indicates at what dosage and under what conditions the product is safe for the consumer, the animal, the user and the environment.

***Withdrawal Period**

*When medicines are used for food animals, Residue Depletion studies assess the time needed for any residues of a substance or its metabolites (see above), which may still be present in an animal's body, to fall below the level shown to be safe. These include several built-in safety factors. Once this time has been determined, the Withdrawal Period can be established. This **Withdrawal Period** is defined as the minimum time lapse required between the last treatment and the collection of animal produce for human consumption.*

****Metabolism** is the set of chemical reactions that occur within the body, which result in the transformation or breaking down of substances into smaller molecules so that they can either be used by the body or excreted. This takes place in specialised organs, mainly the liver. The transformed molecules are called "metabolites."*

The toxic potential of the substance or its metabolites is assessed and, after multiplication by an appropriate safety factor, a level shown to be safe either for the consumer or, in animal excreta, for the environment, can be established.



Criteria 2 and 3: PRODUCT QUALITY AND EFFICACY

Before they can be put on the market, the efficacy of veterinary products is confirmed by trials under field conditions.

High Standards of Purity and Consistency

Pharmaceutical quality is an essential ingredient of product safety, and requires the product to be manufactured according to specific standards of purity and consistency. These standards apply throughout the production and formulation process. Stability studies ensure that the product retains its potency, efficacy and safety, for the full duration of the shelf-life.

Testing Methods are Continuously Being Improved

The pharmaceutical manufacturer is required to guarantee that a medicine contains only those ingredients that are specified in the data file - nothing more, nothing less - and in exactly the proportions indicated. Analytical test methods used to achieve this are continuously being improved.

The animal health industry has, on own initiative, introduced sterility tests and visual inspection of random samples as additional control measures. As an example of the efforts made to guarantee consistent product quality, water used for dissolving the active substance of a medicine is distilled twice, sterilised and then kept at 85°C until used.

The Product will Live Up to its Claims

Data must also be provided to prove that the product meets a specified level of efficacy in treating or preventing a particular medical condition. Thus the customer can be assured that, when used as directed (correct dose-rate, frequency and duration of treatment), a product will meet its label claims. To support this claim, a product is tested extensively in the laboratory, in disease challenge studies and finally in field trials, which must demonstrate that it works under conditions of practical field use.

The Leaflet is Part of the Product

An animal health product does not consist of the medicine alone. The product name together with its label and leaflet (giving indications, contra-indications, warnings and withdrawal periods) are also essential parts of the product and its registration process. The registration authorities must also approve these and any changes to them.

THOROUGH STUDIES PRECEDE REGISTRATION



Investing in Safety, Efficacy and Quality

The vast range of specific requirements inherent to the animal health sector (large number of different species, different diseases, difficult to administer treatments...) requires a highly significant research effort.

Research and development are time- and cost-intensive. The requirements of safety, quality and efficacy demand complex and exhaustive scientific programmes to provide all the necessary data for regulatory approval. Typically the research and development programmes needed to take a new product from inception to the market cost up to € 50 million and can take between 5 and 11 years to complete.

Much of the time needed for researching and developing the new animal health product is spent on pharmacokinetic*, toxicity and metabolism studies.

Registration itself can take up to three years.

The Jewel in the Crown - Research and Innovation

There is no room for complacency in the battle against disease. Work still remains to be done and many challenges still exist. An example is the prevention and eradication of emerging viral diseases. In addition, pathogenic organisms continuously evolve and new medicines must seek to stay one jump ahead of this development. The search for new antibiotics is a good example of this.

Research and Innovation is a core value of the industry.

New substances and new biological materials are constantly being successfully developed thanks to the steadfast efforts of hundreds of dedicated researchers.

Study Results: The Dossier

All the study results are assembled in a series of files, termed the “dossier” or “data-file.” This is set out in a standard format and contains all the information needed to assess a product’s safety, quality and efficacy.

The manufacturer applying for registration of a new product submits this dossier to the registration authority. The experts and reviewing committee of the authority then carry out a scientific assessment of the dossier.

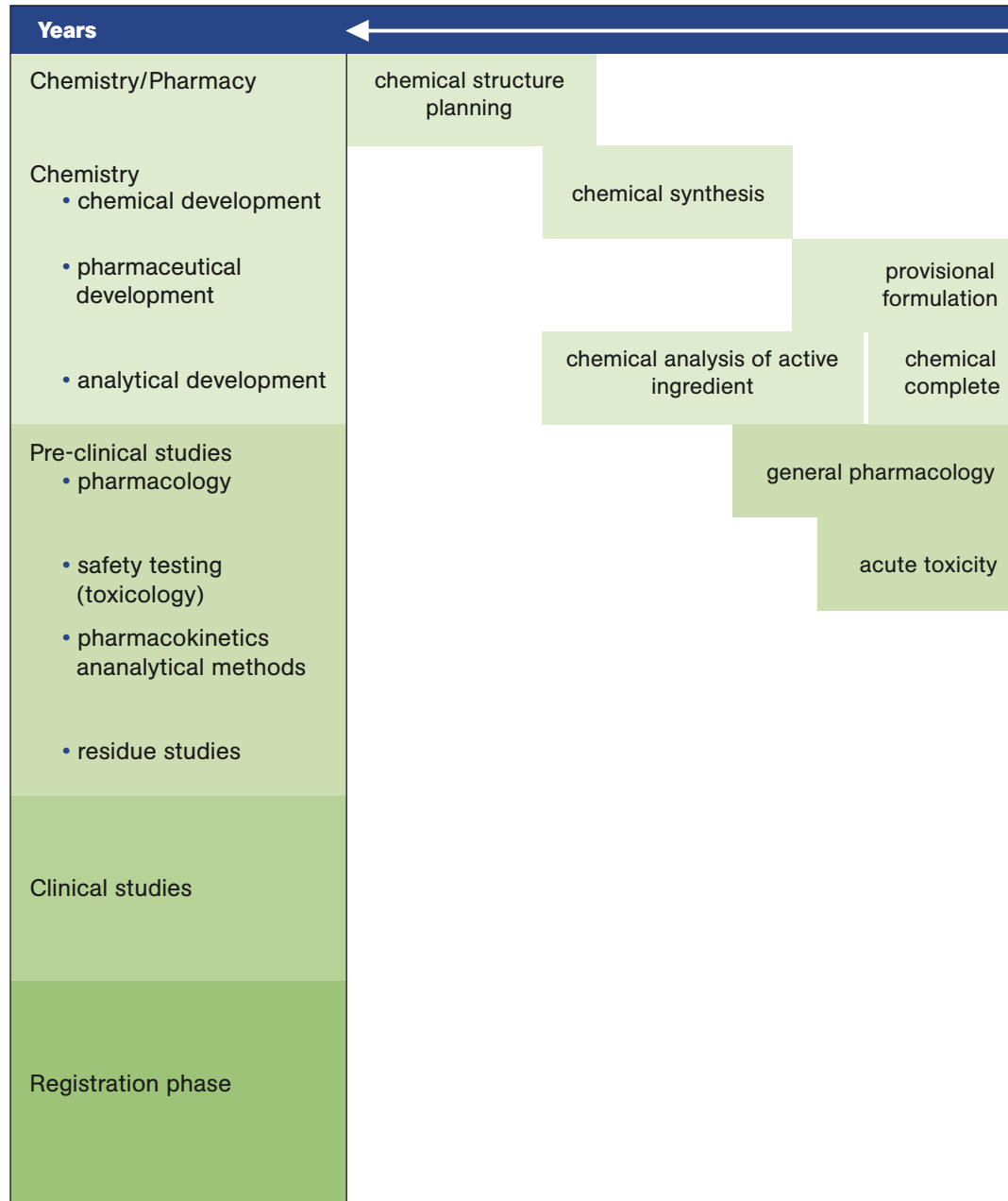
Frequently more data, requiring additional studies, may be requested, extending the total product development time. The manufacturer can elect to appear before the veterinary products committee to present new information in support of its application.

The dossiers are voluminous, and may contain between 5,000 and 10,000 pages for a medicine in a single country for a specific species and treatment. For a registration of a medicine in several countries, the dossier may contain up to 500,000 pages.

**Pharmacokinetics is the study of the rate of absorption and subsequent excretion of a medicine. Medicines may be administered on the skin, via injection, or orally. The active ingredient of the medicine may be absorbed by the skin or the gut. Excretion may be via the urine or faeces.*



DEVELOPMENT OF A NEW ANIMAL HEALTH PRODUCT





5-11





LEGISLATION SHOULD ENCOURAGE INNOVATION

“The political issues encompass two things: predictability and regulatory efficiency.”

IFAH-Europe

Objective Scientific Evaluation

The existing stringent evaluation process is important because it ensures that only safe and effective products of the highest quality are approved for sale in Europe. Equally important is respect for that system. Its independence, objectivity and credibility must not be undermined by non-scientific considerations.

Affordable, Predictable and Objective

The process of research, development and registration of a medicinal product is very expensive and time consuming. Companies, including Small and Medium Sized Enterprises (SMEs) or companies that make niche products, will only risk this substantial commitment to their resources if the entire registration process is:

- **Affordable**
- **Predictable**
- **Objective**

If other criteria, such as socio-economic considerations, are included into the registration process, an impediment to affordability, predictability and objectivity is created.

The criteria need to be transparent. If, in addition to the normal risks of doing business, an unpredictable registration system were to be created, companies would no longer be able to justify the risk of entering the process.

The result would be that companies would be able to commit fewer resources to product development. This would have a detrimental effect on innovative research and the development of new veterinary medicines.

“There is a risk attached to almost everything we do. Even inactivity carries risk. Zero risk does not exist.”

*David Byrne
European Commissioner
for Health and Consumer
Protection
2004*

A Balanced Risk-Benefit Analysis

For any medicine, the potential benefits must be weighed up against the potential risks (see “The Four Areas of Safety,” page 5).

There is no such thing as zero risk in any field. Unfortunately, social pressures sometimes expect that. Inappropriate interference in a proper risk-benefit analysis deprives the marketplace of efficacious products. This restricts the armoury of the veterinarian and hinders his or her ability to combat and treat disease.



Scientific Assessment by Independent Experts

Committees composed of experts carry out official assessment of all data submitted in the “dossiers.” Their knowledge and experience allow them to make objective judgements based on data submitted by manufacturers in support of new products.

A pool of other scientists, who give advice on matters of particular scientific difficulty or interpretation, can be asked to assist these experts.

It is the responsibility of the regulatory authority to assess the safety, quality and efficacy of a new product, and to approve, ask questions, or recommend rejection if an investigation is inadequate.

Under the amended EU legislation published in April 2004, Marketing Authorisations are initially valid for a 5-year period. After this, the company can apply for a renewal. The decision to authorise renewal is mainly based on an Expert Report on the pharmacovigilance record of the product at the time of renewal. Thereafter a Marketing Authorisation does not have to be renewed again, although the authorities can review its safety and benefits profile at any time.

“The Commission needs to receive sound, science-based risk assessments on which to base our food safety policy. Our food scientists must also be clearly independent from policy makers.”

*Romano Prodi
President
European Commission
2001*

Pharmacovigilance

Pharmacovigilance represents the systematic collection, collation and analysis of reports from veterinarians and animal owners of adverse reactions (or events) connected to the use of a veterinary medicinal product.

Manufacturers of medicinal products are required by law to establish and maintain a pharmacovigilance system for their products. This system ensures that all reports of any suspected adverse reactions, or other unexpected effects from the use of the product, are reported to the company.

The company must inform the authorities immediately if any serious suspected adverse reaction is reported. It must also submit regular summary reports of all recorded incidents for examination, even incidents that are only suspected to be related to the use of the product.

IFAH-Europe published its Guide on Good Veterinary Pharmacovigilance Practice in support of pharmacovigilance in April 2004.

REGISTRATION PROCEDURES



The EMEA, London

“The EMEA is a centre of a scientific network connecting all national agencies and exploits all existing scientific expertise.”

David Byrne
European Commissioner
for Health and Consumer
Protection

“The EMEA is now recognised as one of the leading global regulatory agencies. Using expertise drawn from right across the whole European Union, the Agency is committed to ensuring the highest quality advice and assessment based on scientific criteria of quality, safety and efficacy. This is central to our mission to protect human and animal health and provide a competitive environment for the European veterinary and human pharmaceutical industry.”

Thomas Lönngrén
EMEA Executive Director

Registration in Europe Today

Since 1981 there has been a legal framework to harmonise procedures and requirements across the Member States of the European Union (EU). After that date, further measures were taken to abolish the remaining barriers to the free movement of veterinary products within the EU. In 1995 a new European system for authorisation of medicinal products came into effect.

The legislative framework is gradually harmonising the different registration systems that existed in each Member State. From 1993 Member States have been required to recognise the decision of the competent authorities of other Member States.

Until November 2005, three registration procedures for veterinary use are available within the EU:

- **National Procedure**, to obtain a single licence in just one Member State
- **Mutual Recognition Procedure**, to obtain licences in several Member States
- **Centralised Procedure**, to obtain a single pan-European licence.

After November 2005 an additional procedure will be added to complement the Mutual Recognition Procedure. It is the **Decentralised Procedure**.

The choice of procedure is partly restricted (see p.15 and 17). Where allowed, companies may register a product in just one Member State or a selected group of Member States, to deal with localised diseases or species.

For the Centralised Procedure the European Medicines Agency (EMA) was established in 1993.

European Medicines Agency – EMA

Headquartered in London, the EMA's essential task is to provide the best possible scientific advice on the evaluation of the safety, quality and efficacy of medicinal products. This is achieved through the services of its Committee for Veterinary Medicinal Products (CVMP).

The CVMP carries out the scientific evaluation of an application within the EMA (Centralised Procedure) and is made up of scientific experts sent from all of the Member States. The EMA also provides independent arbitration in the event of disputes in the Mutual Recognition Procedure. It shall similarly arbitrate in possible disputes within the framework of the new Decentralised Procedure.

...and in the Future

The legislation for harmonised EU registration procedures provides for its review after 6 years.

Consequently, during 2000, the European Commission took a critical look at how EU procedures function in practice, and in 2001 made proposals for improvements to the legislation. The amended legislation, which was adopted in 2004, will become operational in the Member States from November 2005.

The animal health industry supports the amended legislation as it builds on the success achieved to date. It will encourage harmonised decision making across Europe and will put increased focus on monitoring the safety of products in the marketplace to protect the health of consumers, animals, operators and the environment.

The National Procedure

Each Member State has its own competent licensing authority, in the form of an independent government agency or a department within the Ministry of Health and/or Agriculture.

If a company wishes to license a product in just one Member State, (e.g., for a local disease or species) it can submit an application for Marketing Authorisation to that one national authority.

The dossier is assessed, summarised and reviewed by national experts on quality, safety and efficacy. The outcome of the review is either a recommendation for a license to be granted, a request for further information, or a refusal of approval.

Main EU-Legislative Framework for Registration of Animal Health Products

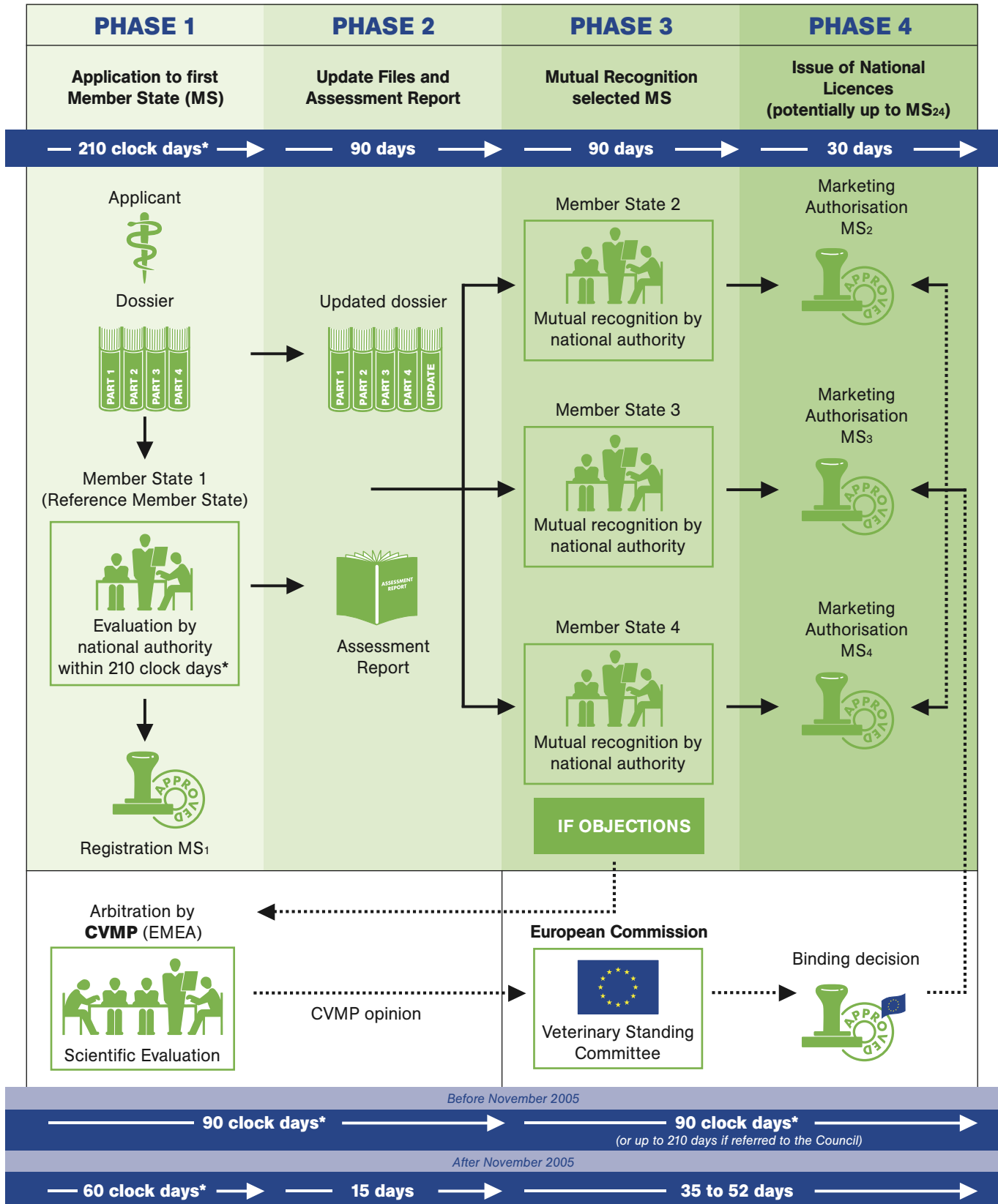
EC Directive 2001/83/EC, as amended by Directive 2004/27/EC (2004)	Basic framework for human medicines registration based on the criteria of safety, quality and efficacy
EC Directive 2001/82/EC (2001) on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC (2004)	Harmonised registration for veterinary products including immunological and homeopathic products; emphasises restriction to the three criteria; establishes the CVMP as the responsible EU-Committee
Annex to Directive 2001/82/EC (2001)	“Norms and protocols” Directive: describes the tests to be carried out to meet safety, quality and efficacy requirements
Council Regulation (EC) No 2377/90 (1990) as amended	Procedure for establishing EU maximum residue limits (MRLs) for substances used in food animals
EC Directive 91/412 (1991)	The principles and guidelines of Good Manufacturing Practice for veterinary medicinal products
Council Regulation (EC) No 726/2004 (2004)	Community Procedures for the [Centralised] authorisation and supervision of human and veterinary medicinal products and establishing a European Medicines Agency (EMA)
Council Regulation (EC) No 297/95 (1995) as amended by Commission Regulation (EC) No 494/2003 (2003)	The fees payable to the European Agency for the Evaluation of Medicinal Products
Commission Regulation (EC) No 540/95 (1995)	The arrangements for reporting suspected unexpected adverse reactions in accordance with the provisions of Council Regulation 2309/93
Commission Regulations (EC) No 1084/2003 (2003) and 1085/2003 (2003)	Procedures for variations to national and centralised Marketing Authorisations
Commission Regulation (EC) No 1662/95 (1995)	Detailed arrangements for implementing the Community decision-making procedures in respect of Marketing Authorisations for products for human or veterinary use

(For more information: <http://pharmacos.eudra.org>)

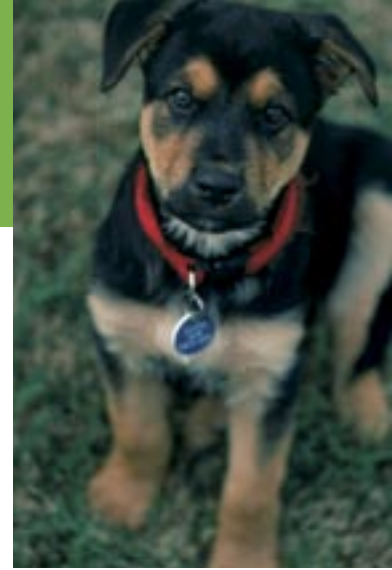




The Mutual Recognition Procedure



* clock days: if questions are sent to the applicant the "clock" is stopped, and it is only started again when answers has been received from the applicant.



The Mutual Recognition Procedure*

Situation until November 2005

A company is obliged to use the Decentralised Procedure, also known as the Mutual Recognition Procedure (MRP), if it wishes to sell a medicinal product in more than one Member State, but not necessarily throughout the EU (some diseases or species are local).

If the product has already been granted a Marketing Authorisation in one or more Member States, then the company can use the MRP to have the existing licence “mutually recognised” in other Member States of its choice.

Under this procedure the dossier has already been examined by one selected national Authority. This “Reference Member State” (RMS) produces an Assessment Report.

The Authorities in the other Member States selected by the company receive a copy of the original dossier and a copy of the Assessment Report. They should then “mutually recognise” the decision of the RMS.

**See diagram opposite*

The Decentralised Procedure*

Situation from November 2005

From November 2005 a new “Decentralised Procedure” will be operational. Unlike the MRP above, the company must use the Decentralised Procedure for a new product that has no Marketing Authorisation to obtain mutually recognised Marketing Authorisation in several or all Member States.

Under this procedure the dossier is sent to one selected national authority. This “Reference Member State” (RMS) then carries out a scientific assessment and produces a draft Assessment Report (no decision is taken yet).

The Authorities in the other Member States selected by the company receive a copy of the original dossier and a copy of the draft Assessment Report. They should then “mutually recognise” the draft decision of the RMS, or reach mutual agreement through discussion.

**See diagram overleaf*

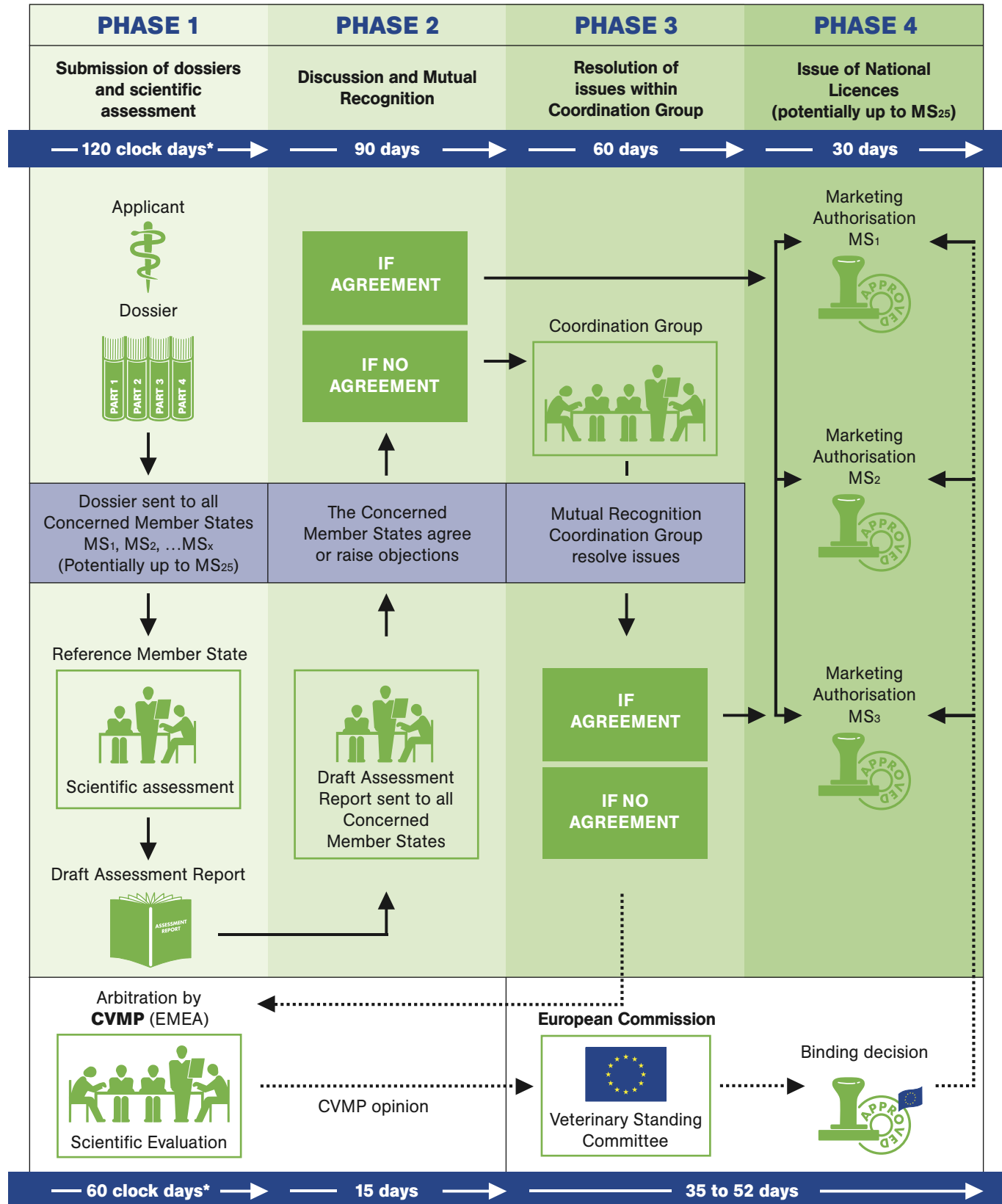
Arbitration

However Member States often ask further questions and, if they cannot reach agreement, the disputed point is passed to the EMEA (CVMP) for the arbitration procedure.

If the objection is valid, the application for mutual recognition is rejected and the company loses its registration in the RMS. If the objection is not considered valid by the CVMP then all the Member States must approve and license the product.



The Decentralised Procedure



* clock days: if questions are sent to the applicant the "clock" is stopped, and it is only started again when answers has been received from the applicant.



The Centralised Procedure

The third route to obtaining a Marketing Authorisation is the Centralised Procedure, leading to a single Marketing Authorisation valid throughout the EU. This Centralised Procedure is compulsory for medicinal products derived from biotechnology as well as for livestock performance enhancers. It is also available at the request of a company for other innovative products.

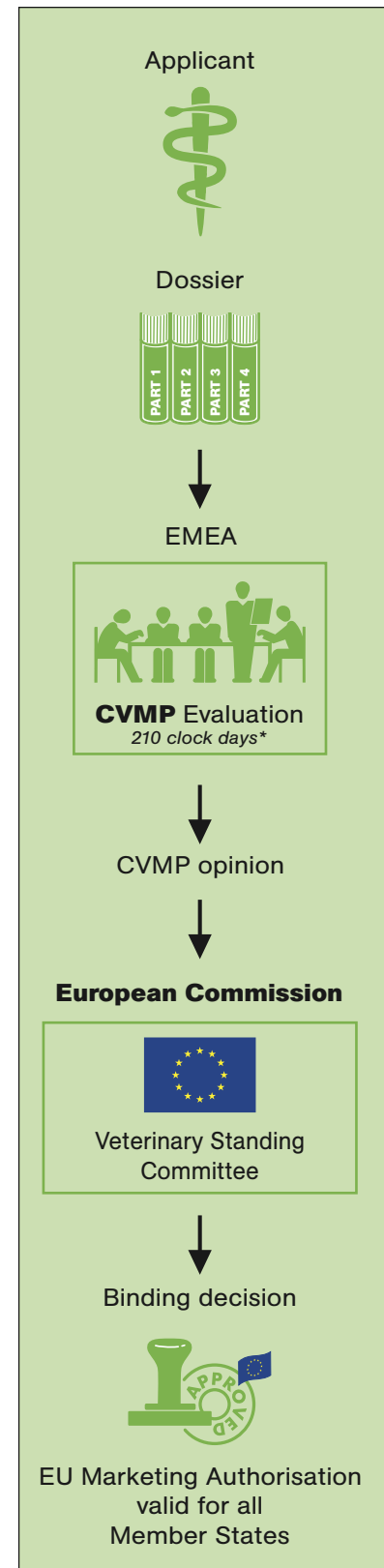
Under this procedure the dossier is submitted directly to the EMEA for a scientific evaluation by the CVMP. The CVMP opinion is transmitted to the European Commission for its opinion, which, if also favourable, proposes a binding decision for authorisation in all Member States of the EU.

However, the European Commission has the right to reject a CVMP favourable opinion.

The Choice of Registration Procedure

IFAH-Europe supports the flexible nature of the European registration procedure. Companies may choose whether to obtain their registration from the national Authorities in one or more individual Member States or centrally, from the EMEA in London. Such a decision clearly depends on whether the company intends to sell the new product throughout the EU or only in certain countries.

The Centralised Procedure



CONSUMER BENEFIT



“Governance, science, society, culture and public media are the main factors in building public confidence and trust in the EU’s system of science based regulation.”

*David Byrne
European Commissioner
for Health and Consumer
Protection
2003*

If we fail to make progress [in understanding risk perception], there is a very real danger that an ‘anti-science’ agenda may take root in European society-leading to a society hampered and restricted by a collective neurosis, lacking in self confidence, resistant to innovation and unwilling to embrace change. We must not be deluded by the sometimes seductive, yet false, notion of a zero risk society.’

*David Byrne
European Commissioner
for Health and Consumer
Protection
2003*

When the registration system in Europe is fair, affordable and predictable, the availability of medicines and vaccines can be maintained to the benefit of our animals. This will help to ensure healthy companion animals and safe affordable food from healthy farm animals.

However, it is not to the consumers’ benefit when:

- registration fees are too high,
- excessive requests for data are received,
- products are banned on not-scientific assessment, and/or
- risk-benefit analysis has not been appropriately undertaken.

Positive Co-operation

IFAH-Europe strongly supports active interaction between the regulatory bodies - at EU and Member State level - and the animal health industry. Such interaction helps to build the mutual confidence and understanding essential for effective operation of the registration procedure. It also helps to build transparency into the registration system. For its part, the industry can provide feedback to the Authorities or the European Commission through IFAH-Europe, particularly on areas of difficulty or non-harmonisation between Member States.

Development of Mutually Agreed Guidelines

A good example of positive co-operation between industry and regulatory authorities is the development of practical guidelines. These guidelines on certain specific aspects of the data requirements assist in the harmonisation of the process in the EU Member States.

The CVMP’s working groups draw up draft guidelines, and IFAH-Europe, acting as the industry representative, provides practical comments and suggestions.

This cooperation recognises that availability of clear, workable guidelines facilitates a good understanding between the regulatory Authorities and the animal health industry regarding what information is required and how it will be evaluated.

Responsibility to Society

The whole issue of regulatory product licensing must also be examined from the consumer’s point of view.

It is clear that the objective of the regulatory process is to protect the public without stalling innovation. Regulatory Authorities and the animal health industry are conscious of their responsibilities to society. They are committed partners in the task of manufacturing products available to the public, which are of high quality, safe and effective to use.



An informed public

The key to an objective opinion is proper information. IFAH-Europe believes that the public's opinion of the regulatory system - and thus its confidence in the quality of food - would be enhanced by a clear understanding of how the system works and how the quality, safety and efficacy of products are assessed.

IFAH-Europe supports the approach to make the registration process more visible to the public, while safeguarding commercially confidential information, so that it can see, hear and appreciate what is being done to protect health, guarantee food safety, and improve animal welfare and the environment. IFAH-Europe and its Members are committed to continue working with the Authorities to help achieve this goal.

“Our survey of pet owners in the UK revealed a low awareness of a formalised pet medicine licensing system, and, subsequently, a high level of owners who were re-assured to learn of the existence of the regulatory system.”

NOAH (National Office of Animal Health), UK

“The most universal needs and expectations of all consumers about the food they consume are its safety, price and availability. The most basic role of government and public policy is to ensure that these fundamental consumer needs are met.”

International Policy Council on Agriculture, Food and Trade

IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe.

It represents both corporate Members and National Animal Health Associations in Europe. These Associations comprise both local and medium-size enterprises (SMEs) and international companies. IFAH-Europe's Membership covers 95% of the European market for veterinary medicinal products.

IFAH-Europe's Mission

IFAH-Europe's mission is to promote a predictable, harmonised, science-based and innovative market place for the provision of quality animal medicines, vaccines and other animal health products, and so contribute to a healthy and safe food supply and to a high standard of health and welfare for animals and people.

As a responsible industry, we want to ensure that our stakeholders understand the work we do and the wide range of benefits we give to society at large. To achieve this, IFAH-Europe, as the voice of the European industry, encourages constructive dialogue with governments, public policy makers, legislators, regulators, non-governmental organisations, the veterinary profession, the food chain, consumers and other stakeholders.

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“Disapproving technologies without proper scientific justification means that the benefits of new technologies to farmers and to consumers will be unnecessarily foregone.”

International Policy Council on Agriculture, Food and Trade



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