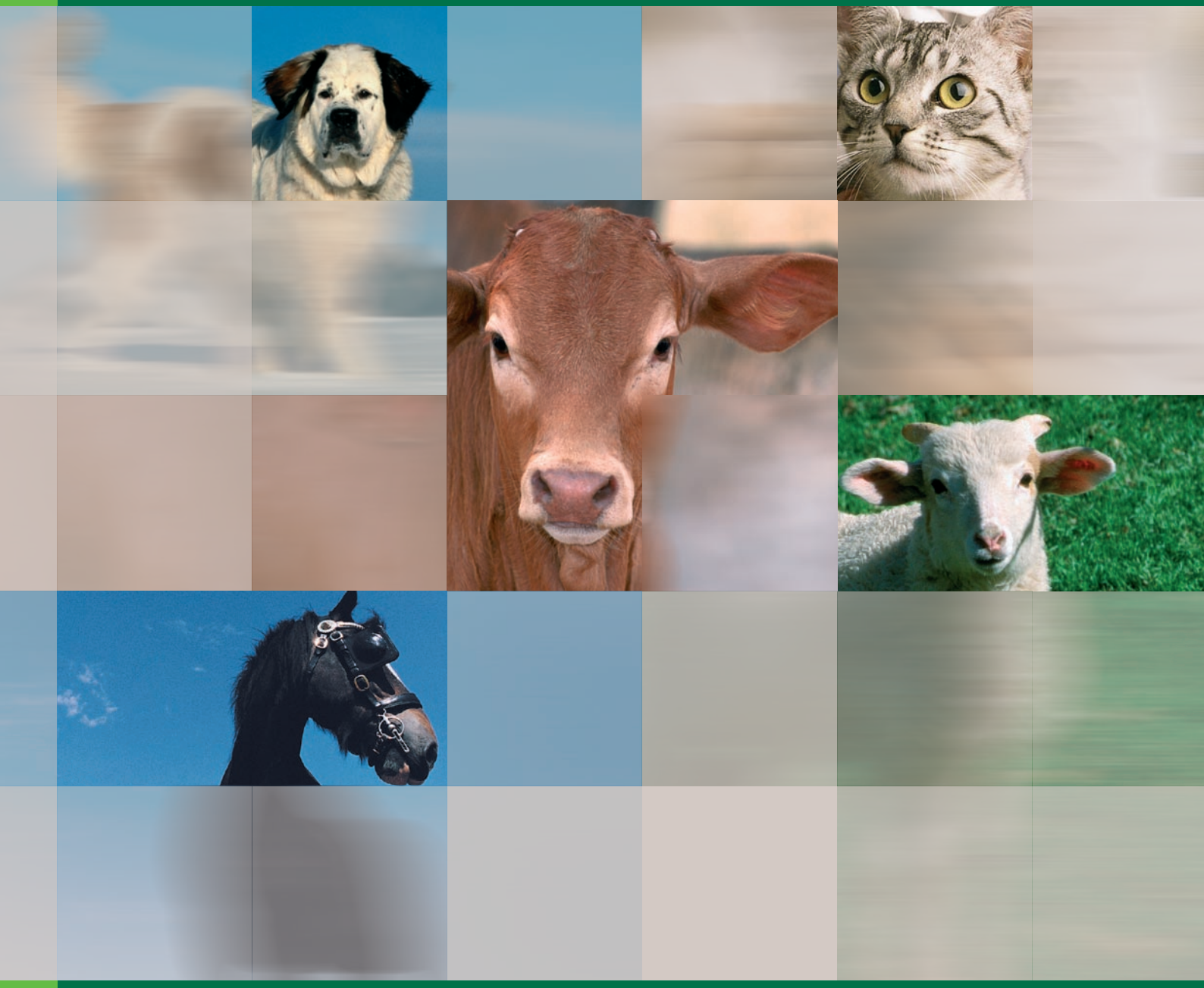
Europe IFAH
Representing the European Animal Health Industry

LEAFLET 01

The Marketing Authorisation Process for Veterinary Medicinal Products in Europe



IFAH-Europe - Improving the quality of life for animals and people

In the European Union, an effective and rigorous examination and registration system exists for placing veterinary medicinal products on the market.

IFAH-Europe supports this system and highly recommends that it be respected for the safety that it provides to both consumers and animals alike.

This leaflet provides a summary of the registration system of veterinary medicinal products in the Europe Union.

What does Product Registration mean?

Registration is the precondition for placing a product on the market

Before any new veterinary medicinal product can be placed on the market, it must receive a Marketing Authorisation. Such an authorisation is granted only after stringent, independent scientific review by the competent authorities, and indicates that the product is registered for sale.

The registration process for human and veterinary medicinal products dates back to the 1965 European Community Medicines Directive, which laid down three basic criteria on which decisions regarding marketing authorisation are based. They are: **safety, quality** and **efficacy**. Over the past 40 years, requirements in terms of these three criteria have been updated continually in line with advances in scientific knowledge.

The process requires applicants to submit data supporting the safety, quality and efficacy of a product in a detailed 'Dossier', which is reviewed by an independent scientific committee working on behalf of the governmental agency. The scientific review examines all aspects of the product, and includes a detailed risk-benefit analysis. Only after passing this review and being declared **safe, of high quality and efficacious**, may a product be offered for sale.

The safety and efficacy of the product are monitored closely following its entry into the marketplace, under statutory post-marketing surveillance or 'Pharmacovigilance' programmes. The quality is monitored via Good Manufacturing Practice inspections and sampling and testing programmes. The authorities have the right to restrict conditions of use or even withdraw a product from the market if they believe it poses any risk to consumers, users, animals or the environment.

Research & Development

Veterinary pharmaceutical companies invest continuously in the research and development of new, improved products to fight animal disease and to meet the challenge posed by emerging new diseases. Bringing a new product to market can take between 5 and 11 years (with the Marketing Authorisation process alone taking 1.5 to 3 years), and can cost up to € 50 million. That level of investment is similar to the cost involved in the development of a human medicine, but the market for veterinary medicines is some 40-times smaller and is much more fragmented.

Putting Safety first

All aspects of risk are considered during the registration process. Safety is the number one priority. If there is any doubt about either the quality of the data in a dossier or the safety of the product concerned, Marketing Authorisation will either be refused, or will be granted subject to the imposition of additional safety requirements. Instructions governing the use of a product, safety warnings, and controls on the distribution and use of veterinary medicines also enable effective risk management. The effectiveness of these measures is monitored throughout the life of a product under the pharmacovigilance system.

Criteria for Registration – Safety, Quality and Efficacy

Safety

In order to qualify for Marketing Authorisation, a product must be demonstrably safe for:

- animals;
- consumers of animal produce;
- users (farmers, veterinary surgeons, pet owners etc.); and
- the environment.

These criteria are imposed stringently, and companies must conduct in-depth studies and provide detailed data demonstrating the safety of their products. Scientific assessment of this information errs on the side of caution in order to maximise the safety of registered products. Where medicines for use in food producing animals are concerned, studies are undertaken to determine a 'Withdrawal Period' – that is, a period after treatment during which the animal cannot enter the food chain. Withdrawal periods may range from one day to as much as six months or more. Additional safety factors are always applied during the establishment of a Withdrawal Period.

Quality

A manufacturer must demonstrate not only the quality of a finished product, but also the consistent quality of the raw materials and manufacturing processes involved in its production. The product must be stable, which means that its quality and efficacy are ensured at least until the stated 'best before' date.

Efficacy

The manufacturer must substantiate claims for the effectiveness of a product. It must demonstrate in detailed field trials that the product is effective in preventing or treating a medical condition, in accordance with statements made on product labelling and information sheets.

About the Procedure: A Single Market for Veterinary Medicines

Each EU Member State has its own independent regulatory authority, authorised to perform independent scientific evaluations of veterinary medicinal products. In addition, there is a pan-EU regulatory agency for human and veterinary medicines (European Medicines Agency, or EMEA), based in London, UK.

To ensure that the EU operates as a single market, the registration requirements for all EU Member States have been harmonised. However, some medicines are only needed in certain Member States (some diseases are localised, or only occur in very hot or very cold conditions). The system is therefore flexible, and includes three different routes through which a Marketing Authorisation may be obtained.

National Procedure

If an applicant wishes to market the product in just one Member State (for example, a national company that intends to market a product only in its own territory), it applies for authorisation to the official regulatory authority in that country alone.

Decentralised Procedure

If an applicant wishes to market the product in more than one Member State, and does not wish to use, or is not eligible for, the Centralised Procedure (see below), then it may use the Decentralised Procedure. Under this procedure the data dossier is submitted to one national authority, which carries out a scientific evaluation. This is later sent to other Member States, requesting 'mutual recognition' of the draft opinion (new products) or decision (existing products) of the national authority of the first Member State.

Centralised Procedure

If an applicant wishes to market its product throughout the EU, it may use the Centralised Procedure. Under this procedure, dossiers are submitted directly to the EMEA, and resulting EU-wide Marketing Authorisations are valid in all Member States. Use of the Centralised Procedure is compulsory for certain biotechnology products, while applicants may request its use for other innovative products.

Packaging – An Integral Part of the Product

Packaging is regarded as an integral part of the product, and must also be reviewed and approved by the authorities. The packaging material contains detailed information on ingredients, dosage and what the product can and cannot be used for. Any future changes to packaging must also be checked and approved by the authorities.

Use of Products

A product can only be placed on the market after it has been independently reviewed and received a Marketing Authorisation. Veterinary surgeons are only allowed to use authorised medicinal products in accordance with the indications stipulated on packaging material. Only if no authorised product is available for a particular animal species, or the treatment of a particular illness, veterinary surgeons may - under specific circumstances - use products authorised for use in other species, for conditions not specified on the product label, or human medicines. These exceptions are necessary in order to safeguard animal welfare where no authorised medicine is available.

Pharmacovigilance, or continuous In-Use Monitoring

Once a product receives a Marketing Authorisation and is placed on the market, it is the role of veterinary health professionals and indirectly the animal owners to report any suspected adverse in-use reaction or lack of efficacy they may encounter. These reports are submitted to the manufacturer and to the regulatory authorities. Serious issues are followed up immediately, and all suspected adverse reaction reports are collated periodically and checked for trends or increases in incidence rates. Where necessary, corrective action is taken (a product may have new warnings added to its label, or may be suspended or withdrawn from the market, or further studies may be required to investigate a problem). This continual in-use monitoring is called 'Pharmacovigilance'.

Marketing Authorisations are valid initially for a period of five years, after which the applicant can apply for a renewal. The decision to renew a product's Marketing Authorisation is based on a re-assessment of its risk-benefit profile, taken following consideration of an Expert Report on its pharmacovigilance record.

Getting the right Balance

The European registration system clearly benefits people and animals alike, ensuring that only safe, high quality and efficacious products reach the market. It is vital that requirements imposed by the system are proportionate, however, and that risk-benefit analysis involves consideration of issues such as animal health and welfare. A proportionate, balanced approach will ensure that the rights of animals and their owners are respected, as well as those of the public. Consumers must be protected, but sick animals should not be denied access to medicines unnecessarily.

In Conclusion

Developing new veterinary medicinal products and bringing them to market is both time-consuming and expensive. If registration procedures become too burdensome, too lengthy or too unpredictable (for example, if Marketing Authorisation is denied or withdrawn on non-scientific grounds), animals and those responsible for their care would be denied access to the full range of modern medicines potentially available to them. Equally, time and money spent by manufacturers to meet changing standards for existing medicines means that less resources are available to invest in the research and development of new or improved products.

To ensure that manufacturers continue investing in the development of new medicines at levels sufficient to drive innovation, it is essential that the Marketing Authorisation process remains both scientifically based and predictable.

The EU possesses an effective and rigorous registration system. IFAH-Europe supports this system and calls for full recognition of the protection it provides for consumers and animals alike. IFAH-Europe also believes strongly that the introduction of non-scientific considerations into the Marketing Authorisation process must be avoided at all costs if the independence, objectivity and credibility enjoyed by the system is to be protected.

A comprehensive brochure entitled 'The Marketing Authorisation Process for Veterinary Medicinal Products in Europe' has been published by IFAH-Europe and can be ordered free of charge by using the following e-mail address: info@ifahsec.org.

For more information, contact:

IFAH-Europe

Representing the European
Animal Health Industry

Rue Defacqz, 1,
1000 Brussels,
Belgium

Tel: +32 (0)2 543 75 60
Fax: +32 (0)2 537 00 49
E-mail: info@ifahsec.org
www.ifahsec.org/Europe

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