

# PHARMACEUTICALS

## Current situation

The pharmaceutical sector is extensively regulated at the European Union's level in the dual interest of ensuring the highest possible level of public health and patient confidence in safe, effective and high-quality medicinal products, while continuing to develop a single EU-wide market for pharmaceuticals in order to strengthen European pharmaceutical industry's competitiveness and research capability.

To guarantee the highest possible level of public health and to secure the availability of medicinal products to citizens across the European Union all medicinal products for human and animal use have to be authorised either at the Member States or at Community level. Special rules exist for the authorisation of medicinal products for paediatric use, orphan drugs, herbal medicinal products, vaccines and clinical trials.

The European Medicines Agency (EMA), established in 1994, is a decentralised body of the European Union. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use that must undergo a scientific authorisation procedure. Under the centralised procedure, companies submit a single marketing authorisation application to the EMA. Once granted, the authorisation is valid in all EU and EEA-EFTA states (Iceland, Liechtenstein and Norway).

Additionally, the Agency also plays a role in stimulating innovation and research in the pharmaceutical sector. It gives scientific advice and protocol assistance to companies for the development of new medicinal products and publishes guidelines on quality, safety and efficacy testing requirements.

Approximately 425,000 laboratory animals are used in the European Union every year to produce vital human and veterinary vaccines which are invaluable in preventing diseases. Laboratory animals used include dogs, cats, horses, hamsters and guinea pigs.

Vaccines are of biological origin and have the potential to vary from batch to batch. Consequently, vaccines are tested for batch-to-batch consistency and many of these tests involve animals. Although veterinary vaccines are used to protect animals, this is at the expense of large numbers of other animals that are used in quality control tests before vaccines are released onto the market. There is enormous potential for replacing or refining many of the tests that cause the most suffering, and there is also scope for discontinuing some tests altogether.

The International Council on Animal Protection in Pharmaceutical Programs (ICAPPP) was formed to promote animal protection in pharmaceutical testing guidelines developed internationally through discussions among Japan, Europe, and the United States under the banner of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and other similar harmonisation programmes.

The ICH was established in 1990 to align regulatory requirements across the USA, The European Union and Japan. It brings together the regulatory authorities and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

EMA contributes to the EU's international activities through its work with the European Pharmacopoeia, the World Health Organisation, and the ICH and VICH (for veterinary medicines) conferences. ICAPP has *Interested Party status* at the EMA.

## Legislation

The basic rules defining the framework for pharmaceutical medicinal products in the EU date back to 1965 (Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products). Since then a score of Community legislation has followed with the aim of achieving a single EU-wide market for pharmaceuticals. In 2001 the legislation regulating medicinal products was codified into two main directives: Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2001/82/EC on the Community code relating to veterinary medicinal products. These Directives set the rules for the placing on the market of medicinal products destined for human and veterinary use respectively. The primary purpose of these rules for the production and distribution of medicinal products are to safeguard public health, without hindering the development of industry and trade in medicinal products within the Community.

Vaccine testing is also regulated by these two directives, as vaccines are biological and their results can vary. Many of these quality control tests involve infecting animals with serious diseases, which causes considerable suffering. The EU legislation specifies that vaccines are tested in accordance with the monographs of the European Pharmacopoeia, which works under the aegis of the Council of Europe which, having 49 member countries, cannot be expected strictly to align its activities with EU law.

## Future Action

- More humane, alternative ways of testing must be sought. Some manufacturers and regulators are already working on these issues, but a more consolidated approach is urgently required.
- Regulators, policy makers and manufacturers must find new ways of testing essential vaccines through the development and use of alternatives to tests on animals and by cutting the red tape as currently it can take more than 10 years for alternative tests to be approved. It is important unnecessary tests on animals are stopped and there is a greater effort to reduce the numbers of animals used and levels of suffering until new methods can be developed.