European Vaccine Manufacturers

ANIMAL WELFARE AND VACCINE DEVELOPMENT

Currently, safe and efficacious vaccines are available for 26 infectious diseases and new vaccines with major potential for improving health are in the pipeline. Intensive efforts are under way to develop effective vaccines for AIDS, meningococcal conjugate ACYW135, malaria, tuberculosis, dengue, leishmaniasis, and enteric diseases, among others.

Unlike medicines that are used to cure diseases, vaccines are given to large numbers of healthy people with the aim of preventing life threatening or serious disease. Therefore, regulatory authorities require that vaccines be extensively tested all along their development process to ensure they are safe.

Vaccine research and development is a lengthy and complex process and it can take up to 12 years to develop a new vaccine. The first phase of vaccine Research and Development corresponds to the development of a vaccine candidate against a specific disease. The candidate is designed and improved through various tests and projections. In a second phase, researchers conduct animal studies to measure the immune response induced by the vaccine but also to check the safety of the vaccine
A small proportion of the research and development process involves animals but it is essential for solving current and future challenges for public health. Alternatives to animal testing such as computer modelling and simulation have significantly reduced the reliance on animals and the number of animals needed.

Only after the vaccine candidate has been proven in animal models to have excellent safety records and promising data regarding efficacy, the authorities will allow it to be tested on human beings during "clinical trials." The clinical data obtained in the clinical trials must prove to the regulatory authorities that the vaccine is safe and effective in preventing a disease before a marketing authorisation is delivered. The competent authority bases its decision on the clinical trial results, but also on a review of the manufacturing process as well as on an inspection of the plant where the vaccine is manufactured.

Once authorised, vaccines still have to be tested. First of all, vaccines are biological products, and as such, differ considerably from other medicines. Biological products are very sensitive to change and are strictly regulated and controlled throughout the manufacturing process. Second, public trust in the safety and efficacy of vaccines is a determining factor for the success of immunization programs, and thus for the achievement of public health goals.

Therefore, after a vaccine is licensed for public use, authorities require from manufacturers to keep monitoring vaccines quality and safety through “batch release testing”. The competent authority requires all manufacturers to submit samples from each vaccine lot produced before its release. Manufacturers must also give the results for vaccine safety, potency, and purity.

The use of animals in batch release testing constitutes a regulatory obligation and represents around 80% of the total number of animals used in the vaccine industry. Progress is constantly being made to reduce animal use, especially by replacing *in vivo* by *in vitro* testing and the vaccine industry is working with public authorities on ways to rationalise Batch Release testing.

Vaccine manufacturers' efforts and commitment to animal welfare contributed to reduce the global number of animals of 18% over the past 5 years, whereas there was a significant increase of activity (+20% for Production and +17% in Research & Development). Despite the significant progress already made, alternative methods are not available for everything, and the use of animals is crucial for research, development and batch release testing.

The development of new and reliable alternative methods is hampered by the lack of understanding of the detailed biological process involved in immunisation and the complex interactions that occur in a living body. Achieving the goal of replacing animals in many types of vaccine testing will require significant advances in scientific knowledge and techniques. However, improved manufacturing practice thanks to new analytical/monitoring tools and strong quality systems, together with Good Manufacturing process inspections, should lead to decrease the number of biological and quality control testing.

The Vaccine industry aims to discover and develop vaccines that will help to control and eliminate life-threatening infectious diseases . To do so, properly controlled animal use will continue to be necessary. The vaccine industry hopes that the review of Directive 86/609 will take into account the research and regulatory needs and put forward a balance text that will favour research and innovation in Europe.

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