



**30 May 2016, Strasbourg, France**

## **EDQM International Symposium on 'The Challenges of Quality Requirements for Fish Vaccines', 10-11 May 2016, Oslo, Norway**

As part of the ongoing efforts of the European Pharmacopoeia Commission to replace *in vivo* with *in vitro* methods and its significant efforts to reduce the number of animals used to test vaccines, a symposium directed towards fish vaccine manufacturers, regulatory authorities and academia has taken place at the Norwegian University of Life Sciences in Oslo.

This symposium was attended by 83 participants, who included officials and experts from 14 countries, as well as representatives from European licensing authorities, academia and manufacturers of vaccines intended for fish. The symposium was dedicated to discussing the current requirements with a focus on alternative methods being used or under development, to replace the challenge batch potency test. The audience discussed the opportunity to introduce humane endpoints in [European Pharmacopoeia](#) (Ph. Eur.) monographs for fish vaccines, and to revise the four monographs already published [*Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids* (1521), *Cold-water vibriosis vaccine (inactivated) for salmonids* (1580), *Vibriosis vaccine (inactivated) for salmonids* (1581), *Yersiniosis vaccine (inactivated) for salmonids* (1950)]. The potential need for new Ph. Eur. monographs such as a general monograph dedicated to vaccines intended for fish, and individual monographs for fish vaccines, for example for the Mediterranean region or for other fish diseases, was also discussed.

The scientific programme was composed of general [presentations](#) followed by presentations from industry, academia and regulatory authorities on alternative methods to the challenge batch potency test and discussions on how to help manufacturers to develop them. Manufacturers were in favour of replacing the current challenge test by alternative methods, not only for animal welfare reasons but also because alternative methods are cheaper, more robust and allow shortening the time needed for release. Some manufacturers had already investigated alternative methods while others had just started.

If there was full support from the participants to move towards alternative testing for fish vaccines, it was also recognised that replacement of the batch potency test by alternative tests was an exercise that took companies a lot of time and resources for well-established, safe and efficacious vaccines. In this context, suggestions were made as to how information and experiences on the recent advances that have been made with regard to alternative methods for the batch potency test could be further shared between manufacturers, and how academia, EDQM, [World Organisation for Animal Health](#) (OIE) or other interested parties could help. The discussions were very constructive, and many good ideas were put forward. In light of the outcome of the symposium, the European Pharmacopoeia Commission would decide on future developments.

**Contact:** Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe  
Tel.: +33 (0) 3 88 41 28 15 - E-mail: [caroline.letarnec@edqm.eu](mailto:caroline.letarnec@edqm.eu)

**Note for the Editor:** Further information is available on the internet site [www.edqm.eu](http://www.edqm.eu)

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in Member States<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.



<sup>1</sup>There are thirty-eight members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

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