THE EUROPEAN PHARMACOPOEIA & QUALITY OF MEDICINES

"THE CHALLENGES OF QUALITY REQUIREMENTS FOR FISH VACCINES"

International Symposium organised by the EDQM, Council of Europe
10-11 May 2016

Location: NMBU, Campus Adamstau, 0464 Oslo, Norway
Duration: 1.5 day. **Working language:** English

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PROGRAMME

TUESDAY 10 MAY 2016

8:15-9:30 Registration

9:30-9:35 **Opening Remarks & General Introduction to the Programme**
Catherine Lang, EDQM, Council of Europe

9:35-9:55 **General overview of Fish Vaccination**
Alexandra Adams, University of Stirling, Institute of Aquaculture (UK)

SESSION 1: General Overview on Current Legal Requirements

Moderator: Lukas Bruckner, Specialist of European Pharmacopoeia Expert Group 15V (CH)

9:55-10:10 **EDQM/European Pharmacopoeia (Ph. Eur.): Assuring the quality of medicines**
Catherine Lang, EDQM, Council of Europe

10:10-10:25 **How to use the Ph. Eur. and how to collaborate to the work of Ph. Eur. Group of Experts on 'Veterinary Sera & Vaccines' (15V)**
Catherine Lang, EDQM, Council of Europe

10:25-10:40 **Special focus on Ph. Eur. Monographs for Fish Vaccines**
Céline Lorteau, Chair of Group of Experts 15V, French Agency for Veterinary Medicinal Products (ANSES-ANMV) (FR)

10:40-11:05 *Coffee break*

11:05-11:35 **General approaches 3Rs, alternative methods, consistency of production and humane end-points in the Ph. Eur.**
Lukas Bruckner, Specialist of European Pharmacopoeia Expert Group 15V (CH)

11:35-11:55 **EMA/IWP Guidelines on the Design of studies to evaluate the safety and efficacy of fish vaccines**
Tonje Høy, Norwegian Medicines Agency (NOMA), Member of the Immunologicals Working Party (IWP) & Rapporteur for the Guideline (NO)

11:55-12:15 **Challenges of developing safe and efficacious fish vaccines**
David Verner-Jeffreys, Centre for Environment Fisheries and Aquaculture Sciences (Cefas) (UK)

12:15-12:35 **Potential for future live-attenuated fish vaccines**
Anne Aas-Eng, Pharmaq AS (NO)

12:35-13:00 **Discussion - Questions & Answers**

13:00-14:00 *Lunch break*

SESSION 2a: BATCH POTENCY TEST
Experience with challenge, alternative methods, 3Rs, consistency of production and humane end-points

Moderator: Øystein Evensen, Norwegian University of Life Sciences (NO)

Point of view of Manufacturers

14:00-14:20 **Development of alternative batch potency for new vaccines: HIPRA's experience**
Marta Figa, HIPRA (ES)

14:20-14:40 **Challenge the challenge: development of new potency tests for multivalent fish vaccines**
Marielle van Hulten, MSD Animal Health (NL)

14:40-15:00 *Title to be confirmed*
Anette Kilander, Pharmaq (NO)

15:00-15:45 **Questions & Answers**

15:45-16:00 *Coffee break*

SESSION 2b: BATCH POTENCY TEST
Experience with challenge, alternative methods, 3Rs, consistency of production and humane end-points

Moderator: Tonje Høy, Member of the Immunologicals Working Party (IWP)

Point of view of Academia

16:00-16:30 **Ph. Eur. Expert: Towards *in vitro* methods for potency testing of fish vaccines**
Øystein Evensen, Norwegian University of Life Sciences (NO)

16:30-16:50 **Recent studies related to onset of immunity responses and measurement of antibody responses in Atlantic salmon**
Paul J Midtlyng, Norwegian University of Life Sciences (NO)

16:50-17:30 **Questions & Answers**

Close of day

WEDNESDAY 11 MAY 2016

SESSION 2c: BATCH POTENCY TEST
Experience with challenge, alternative methods, 3Rs, consistency of production and humane end-points

Moderator: Tonje Høy, Member of the Immunologicals Working Party (IWP)

Point of view of Authorities

9:00-9:20 *Title to be confirmed*
Rosario Bullido, Spanish Agency of Medicines and Medical Devices (AEMPS) (ES)

9:20-9:40 *Title to be confirmed*
Rory Cooney, Veterinary Medicines Directorate (UK)

9:40-10:00 *Title to be confirmed*
Ane Kvingedal, Norwegian Medicines Agency (NOMA) (NO)

10:00-10:20 Questions & Answers

10:20-10:45 *Coffee break*

SESSION 3: Round Table Discussion

Moderators: Øystein Evensen, Tonje Høy, Lukas Bruckner

10:45-11:45 Round Table Discussion

- Summary Reports from the Sessions
- Manufacturers' experience and proposals for improvements on current legal requirements
- The need for new monographs/Ph. Eur. texts
- How can the Ph. Eur. better address the needs of its users considering the current regulatory environment in Europe

11:45-12:00 Final Conclusions & Closing remarks
Céline Lorteau
Catherine Lang

Close of the symposium