5th Global Animal Health Conference 2016

Workshop

Good Regulatory Practice for the Marketing Authorisation of Veterinary Products in an Asian Context

14-16 November 2016
The Lalit Hotel, New Delhi, India

BILL & MELINDA GATES foundation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

OIE
WORLD ORGANISATION FOR ANIMAL HEALTH

GALVmed
Protecting Livestock – Improving Human Lives

INFAH

DIA DEVELOP INNOVATE ADVANCE

Health for Animals
global animal medicines association

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The Workshop Team

Claire Davidson, Davidson · Ryan · Dore Partnership

Ruby Singh, FDA

Kevin Rice, FDA

Jean-Pierre Orand, ANSES

David Murphy, EMA (CVMP)

David MacKay, EMA

Gilly Cowan, GALVmed

Elisabeth Erlacher-Vindel, OIE

Erik de Ridder, Elanco

Philippe Sabot, Merial

Rick Clayton, HealthforAnimals

Jason Todd, EMA

Ken Noda, MAFF, Japan

Yuko Hosoda, MAFF, Japan

Workshop timings, moderator and agenda

Monday, 14 November – Wednesday, 16 November 2016

Timing: From Monday lunchtime to Wednesday lunchtime.

Moderator: the workshop discussions will be moderated by Claire Davidson, Davidson ▪ Ryan ▪ Dore

Workshop delegates will be encouraged to actively participate in the discussions in each of the workshop sessions, and to share your knowledge, your experience and your local practice.

Workshop Overview

Global organisations interested in promoting animal health, such as OIE, GALVmed and the World Bank, have recognised the importance of good governance in the regulation and control of veterinary products (VPs) and the part this plays in supporting socio-economic development as well as public health through good animal health. This workshop will cover the main elements of a regulatory system for the marketing authorisation of veterinary products, looking at sharing best practice, and how this can be adapted for local implementation under local conditions.

The relationship between animal health and access to veterinary products underpins the need to ensure the regulatory environment is enabling for manufacturers of veterinary products. A common element running through the sessions will be the value, in terms of efficient use of resources and encouraging market development, of working to international standards and guidelines and regulatory convergence, particularly on a regional basis.

Workshop Aims

The aim of this workshop is to share knowledge and understanding of good regulatory practices and to promote further close cooperation amongst a regional network of regulatory agencies. This serves the wider aim of promoting animal health and contributes to the One Health approach.

Conference Objectives

Specific objectives are to review and discuss:

- The essential elements of a regulatory system for the marketing authorisation of veterinary products and the opportunities for stimulating the entry of new quality assured, safe and effective products on the market.
- The roles of legislation and guidance documents, and alignment with international standards.
- Good manufacturing practices (GMP), authorisation procedures for veterinary products and pharmacovigilance.
- The benefits and hurdles of mutual recognition of marketing authorisation processes from other regions with internationally recognised regulatory systems, including GMP.
- The benefits and hurdles of the formation of regional organisations to pool resources and the advantages of alignment with international standards.
- The processes necessary for market control of veterinary products. How to tackle falsified products? What are the critical elements and where should resources be focussed?

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Workshop

Monday, 14 November 2016

11:30 REGISTRATION

12:30 WELCOME LUNCH

14:00 INTRODUCTION TO THE WORKSHOP

14:10 SESSION 1

GENERAL

Regulatory lead: **Ruby Singh**, FDA

Assisted by: **Philippe Sabot**, Merial Animal Health

1. Identifying the main characteristics of a credible, effective and fair authorisation system
2. How can we overcome hurdles, such as capacity problems and lack of specialist expertise?
3. What are the ways to cooperate with other authorities (such as work-sharing and mutual recognition) and what are the benefits and risks from a national perspective?
4. How and why should we improve stakeholder interaction?

Discussion, Questions and Answers

15:30 COFFEE BREAK

15:50 SESSION 2

LEGISLATION AND GUIDANCE

Regulatory lead: **Ken Noda**, MAFF, Japan

Assisted by: **Yuko Hosoda**, MAFF, Japan and **Elisabeth Erlacher-Vindel**, World Organisation for Animal Health (OIE)

1. Legislation: the law, its development, implementation and revision; the difference between regulations and guidelines
2. International standards: codes and guidelines; what is their relation with regional or national guidelines?
3. Other guidance and Pharmacopoeia: where can they be found? What can they provide?
4. Preparing guidelines; flexibility versus clarity; public consultation process; access to scientific advice; how is animal welfare protected (3Rs)?

Discussion, Questions and Answers

17:30 CLOSE

18:30 DINNER

Tuesday, 15 November 2016

09:00 SESSION 3

GMP/MANUFACTURE

Regulatory lead: **Jason Todd**, EMA

Assisted by: **Philippe Sabot**, Merial Animal Health

1. Quality Control and GMP; the role of the qualified person (QP); release of products and certificate of analysis

Discussion, Questions and Answers

2. Inspections and certification; how an auditor gets qualified; inspections of manufacturing sites by Authorities

Discussion, Questions and Answers

10:30 COFFEE BREAK

10:50 SESSION 4

AUTHORISATION PROCEDURES

Lead: **Gilly Cowan**, GALVmed

Assisted by: **Philippe Sabot**, Merial Animal Health

1. Dossier structure and experts:
   - Are there common global dossier "formats" for veterinary products and also for veterinary biologicals?
   - Experts' qualifications and experts reports;
   - Regulatory Experts - conflicts of interest
   - Harmonisation and mutual recognition; acceptance of data from other regions; how to establish confidence in the dossiers or licences from other regions or countries.

Discussion, Questions and Answers

2. The scientific review process:
   - Timelines and organisation
   - Fast-track procedures; exceptional circumstances
   - Inter-acting with the applicant
   - Internal guidelines and tools for consistency and transparency of an assessment (SOPs, templates)
   - Appeal procedure: how can it be done in a fair and objective way?

Discussion, Questions and Answers

12:45 LUNCH

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14:00 SESSION 5

LOGISTICS

Regulatory lead: **Kevin Rice**, FDA

Assisted by: **Erik de Ridder**, Elanco

1. Application forms and dossier submissions: paper or electronic?
2. Confidentiality and transparency: the balance between commercial confidentiality of submitted dossiers and the public interest; attracting commercial investment
3. Effective information and records management; archiving and security
4. Invoicing fees: "fee for service"

Discussion, Questions and Answers

15:20 COFFEE BREAK

15:50 SESSION 6

POST AUTHORISATION PROCEDURES AND MARKET CONTROL

Regulatory lead: **Jean-Pierre Orland**, ANMV Anses

Assisted by: **Erik de Ridder**, Elanco

1. Changing or updating the dossier; variations, the different types and their respective use
2. Quality control of veterinary medicinal products, including GMP inspection, control of distribution systems
3. Tackling illegal import, falsified and counterfeit products

Discussion, Questions and Answers

17:30 CLOSE

18:30 DINNER

Wednesday, 16 November 2016

09:00 SESSION 6 CONTINUED

Regulator: **David Murphy**, EMA (CVMP)

Assisted by: **Rick Clayton**, HealthforAnimals

4. Safety surveillance in the market: pharmacovigilance and its implication.

Discussion, Questions and Answers

09:40 SESSION 7

KEY ENABLING FACTORS

Regulatory lead: **David MacKay**, European Medicines Agency (EMA)

Assisted by: **Philippe Sabot**, Merial Animal Health

1. Encouraging investment: enabling market access; what prevents companies bringing products to market; protection of technical documentation
2. Benefits of regulatory convergence and harmonisation; Regional cooperation
3. Prioritisation and best use of resources

Discussion, Questions and Answers

11:00 COFFEE BREAK

11:20 OPEN Q&A SESSION

12:00 SUMMARY AND CLOSURE OF WORKSHOP

12:30 LUNCH

Pre-Conference Dinner

Wednesday, 16 November 2016

18:00 NETWORKING DRINKS

19:00 PRE-CONFERENCE DINNER

Dinner Speaker: **Avni Malhotra,** Country Director, Heifer International, USA

For any further information please contact Carolin Dörflinger from DIA at the following address:
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