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

Indian Federation of Animal Health Companies
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)

Melanie Leivers, EMA

Gilly Cowan, GALVmed

Glen Gifford, OIE

Erik de Ridder, Elanco

Philippe Sabot, Merial

Rick Clayton, HealthforAnimals

Jason Todd, Veterinary Medicines Directorate

Ken Noda, JMAFF

Atsushi Yamamoto, JMAFF

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.

Conference Hashtag on Twitter

Join the conversation on Twitter, using **#GAHC**

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.

Workshop 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 (REGENCY)

Monday, 14 November 2016

11:30 REGISTRATION

12:30 WELCOME LUNCH (REGENCY)

14:00 INTRODUCTION TO THE WORKSHOP

Rick Clayton, HealthforAnimals

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 (REGENCY)

15:50 SESSION 2

LEGISLATION AND GUIDANCE

Regulatory lead: **Ken Noda**, JMAFF

Assisted by: **Atsushi Yamamoto,** MAFF, Japan and **Jean-Pierre** Orand, 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 regulation?
3. Guidance and guidelines: where can they be found? What can they provide?
4. Preparing guidelines; flexibility versus clarity; development and public consultation process; access to scientific/legislative advice; how is animal welfare protected (3Rs)?

Discussion, Questions and Answers

17:30 CLOSE

18:30 DINNER (BALUCHI RESTAURANT)

Tuesday, 15 November 2016

09:00 SESSION 3

MANUFACTURING OF VETERINARY MEDICINAL PRODUCTS: SOME CONTROLS FOR INDUSTRY AND REGULATORY AUTHORITIES

Regulatory lead: **Jason Todd**, EMA

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

1. Some controls on manufacturers
2. Approval and inspection

Discussion, Questions and Answers

3. Some controls at manufacturers' level
4. Quality control and product release

Discussion, Questions and Answers

5. Some controls for regulatory agencies
6. Inspection programmes and qualification, training and impartiality of inspectors

10:30 COFFEE BREAK (REGENCY)

10:50 SESSION 4

AUTHORISATION PROCEDURES

Lead: **Gilly Cowan**, GALVmed

Regulatory lead: **Rishendra Verma**

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'
     i. Experts appointed by the Applicant
     ii. Experts appointed by the Regulatory Authorities

Discussion, Questions and Answer

2. 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

3. The scientific review process:
   - Timelines and organisation
   - Inter-acting with the applicant
   - Fast-track procedures; exceptional circumstances
   - 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

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12:45 LUNCH (REGENCY)

14:00 SESSION 5

LOGISTICS

Regulatory lead: **Kevin Rice**, FDA

Assisted by: **Erik de Ridder**, Elanco Animal Health (Eli Lilly Company)

1. Application forms and dossier submissions: paper or electronic?
2. Efficient information and records management; archiving and security
3. Confidentiality and transparency: the balance between commercial confidentiality of submitted dossiers and the public interest; attracting commercial investment
4. Invoicing fees: fees to support the regulatory program

Discussion, Questions and Answers

15:20 COFFEE BREAK (REGENCY)

15:50 SESSION 6

POST AUTHORISATION PROCEDURES AND MARKET CONTROL

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

Assisted by: **Erik de Ridder**, Elanco Animal Health (Eli Lilly Company)

1. Changing or updating the dossier; variations, the different types and their respective use
2. Official quality control of veterinary products, tackling illegal import, falsified and counterfeit products
3. Import, distribution and retail of vet products, GDP inspection, control of distribution systems
4. Surveillance

Discussion, Questions and Answers

17:30 CLOSE

18:30 DINNER (ALFRESCO, OUTSIDE 24/7 RESTAURANT)

Wednesday, 16 November 2016 (REGENCY)

09:00 SESSION 6 CONTINUED

Regulatory lead: **David Murphy**, EMA (CVMP)

Assisted by: **Rick Clayton**, HealthforAnimals

5. Safety surveillance in the market

Discussion, Questions and Answers

09:40 SESSION 7

KEY ENABLING FACTORS

Regulatory lead: **Melanie Leivers**, 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 (REGENCY)

11:20 SESSION 7 CONTINUED

Antimicrobial resistance 10'

Somu Kumar Ambat, Access Consulting Group

Discussion, Questions and Answers

12:00 SUMMARY AND CLOSURE OF WORKSHOP

Rishendra Verma, Indian Veterinary Research Institute

12:30 LUNCH (REGENCY)

PRE-CONFERENCE DINNER (REGAL)

Wednesday, 16 November 2016

18:00 REGISTRATION

19:00 NETWORKING DRINKS

19:30 DINNER SPEECH

SOCIO ECONOMIC DEVELOPMENT PROGRAM FOCUSING SMALL RUMINANT

Avni Malhotra, Country Director, Heifer International, India

20:00 PRE-CONFERENCE DINNER

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Conference Fees, Travel, Accommodation and Living

- There is no registration fee, conference fee or workshop fee.
- There is no fee for the pre-conference dinner, the conference lunch and coffee breaks.
- Visa applications, travel and accommodation for academia, government and government agency employees will be covered by the conference funder. We kindly ask industry attendees to bear the costs of their travel and accommodation arrangements.

Registering

If you are interested in attending the Pre-Conference Workshop or the Global Animal Health Conference 2016, please complete your application online:

http://gahc.diaonline.events/

We only have a limited number of places available. Please note that your registration is not valid until you have received a confirmation email by DIA.

Visa Application: Apply at your earliest convenience

You are required to possess a valid international travel document in the form of a national passport with a valid visa. We encourage you to contact the Indian embassy in your respective country for further details and to apply for your visa as soon as possible. We strongly recommend that you follow their requirements due to strict application laws. We will be happy to provide an invitation letter to all attendees whenever needed, so please don't hesitate to ask.

Practical Assistance

The conference organisers will provide practical assistance with travel and accommodation for academia, government and government agency employees, this includes:

- Reserving hotel rooms according to your needs
- Reserving flights via an on-line booking tool
- Arranging transfers between the airport and the hotel
- Providing an invitation letter if needed

Vaccination

Please check the recommended vaccinations and medications with your doctor (ideally, 4-6 weeks) before your trip.

Special thanks to our sponsors.

For any further information please contact Carolin Dörflinger from DIA at the following address:
Carolin.Doerflinger@diaglobal.org