Workshop on good regulatory practice for the registration of VMPs in an Asian context

Introduction

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5th Global Animal Health Conference and Workshop 2016

Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

Organising Committee:

The Workshop Team

Workshop Moderator: Claire Davidson,

Session 1:	Ruby Singh, FDA, USA (with help from Philippe Sabot, Merial)
Session 2:	Ken Noda and Atsushi Yamamoto, MAFF, Japan, and Jean-Pierre Orand, ANSES, France
Session 3:	Jason Todd, Veterinary Medicines Directorate, UK (with help from Philippe Sabot, Merial)
Session 4:	Gilly Cowan, GALVmed and Rishendra Verma, Regulatory expert, India (with help from Philippe Sabot, Merial)
Session 5:	Kevin Rice, FDA, USA (with help from Erik de Ridder, Elanco)
Session 6a:	Jean-Pierre Orand, ANSES, France (with help from Erik de Ridder, Elanco)
Session 6b:	David Murphy, European Medicines Agency (with help from Rick Clayton, HealthforAnimals)
Session 7:	Melanie Leivers and David Mackay, European Medicines Agency

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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.

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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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Objectives

to review and discuss – *share knowledge and experience*

- The essential elements of a regulatory system
- The roles of legislation and guidance documents
- Authorisation procedures, GMP and pharmacovigilance
- Mutual recognition - benefits and hurdles
- Formation of regional organisations - benefits and hurdles
- Market control of veterinary products