# VETERINARY GENERICS IN THE EU

**22 & 23 September 2010, Conf. No. V9-8210** **W**

MANAGEMENT FORUM

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If you have NOT received confirmation seven days after registering, please contact Registration Department.

## REGISTRATION INFORMATION

**Dates**
22 September 2010 Start: 09.30 – Finish: 17.15
23 September 2010 Start: 09.00 – Finish: 15.45

**Registration & Coffee**
22 September 2010 09.00

**Venue**
The Rembrandt Hotel, 11 Thurloe Place, London SW7.

**Directions**
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

**Accommodation**
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £133.92 (Superior), £152.18 (Executive) both including English breakfast. Excluding VAT – subject to availability.
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
**All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.**

**Fee**
**£1,200 + VAT.** The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

**Conference No. V9-8210**

**Discounted Rates**
Available on application for personnel from non-profit making organisations and registered charities.
**Group discount available on request.**

**Cancellation Policy:**
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
**NB: Cancellations must be received in writing by registrations@management-forum.co.uk.**

In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

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**ANNUAL SEMINAR**

MANAGEMENT FORUM

# VETERINARY GENERICS IN THE EU

## Benefits in Attending:

- **Clarify** what we mean by a generic
- **Understand** Article 13 applications
- **Comply** with the Quality requirements for veterinary generics
- **Gain** an understanding of the principles of bioequivalence
- **Discuss** the significance of Global Reference Product and European Veterinary Medicinal Product
- **Discover** how to process a Generic Application through DCP or MRP
- **Understand** the requirements for Detailed and Critical Summaries for generics
- **Understand** the legal base of regulation of generic veterinary medicinal products in the EU
- **Discuss** the challenges with approvals of Articles 13.1 and 13.3 ('generic') dossiers
- **Review** requirements of the new Annex 1 for Article 13a ('bibliographic') submissions
- **Discover** how to make an Article 13 application work

Chairman:
**Ray Harding** Consultant, Cyton Biosciences Ltd.

Speakers:
**Anne Nallen** Nallen Regulatory Consulting
**Dr Inge Sandberg** Technical Director European Group for Generic Veterinary Products (EGGVP)
**Lesley Johnson** Head of Pharmaceuticals and Feed Additives, Veterinary Medicines Directorate

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The CPD Certification Service

**22 & 23 September 2010**
**The Rembrandt Hotel, London**

## INTRODUCTION

Directive 2004/28 came into force in October 2005, amending Directive 2001/82, and brought with it significant changes to the regulation of generic veterinary medicines in the European Union. This also applies to so-called 'branded generics' that are often authorised by way of Article 13a ('bibliographic dossiers') as well as to true generic products authorised according to Article 13.1. These changes have lead to implications for both manufacturers of generic veterinary medicines and for research-based companies that seek to protect their products from competition.

This seminar will cover the authorisation of generics in detail and look at requirements of the newly-revised Annex 1 of Directive 2009/9 together with opportunities for applicants arising from the new legislation.

## BENEFITS IN ATTENDING

This seminar will examine the experience gained in implementing the legislation to provide valuable advice to all in the animal health industry. The difficulties of authorisation of generic products will also be addressed. The seminar will provide an opportunity to hear the views and latest experience of regulatory and industry experts in the implementation of the legislation and procedures. In addition, it will provide a valuable forum for those planning the authorisation of generic veterinary medicines to discuss the detailed requirements.

## WHO YOU WILL MEET

- **Regulatory Affairs Managers and personnel from animal health companies responsible for business development, strategic marketing and licensing of veterinary medicines in Europe.**
- **This is a key opportunity to network with other animal health professionals who have experience in this field.**

## CHAIRMAN

***Ray Harding*** Consultant, Cyton Biosciences Ltd.

## SPEAKERS

***Dr Inge Sandberg*** Technical Director for European Group for Generic Veterinary Products (EGGVP).

***Anne Nallen*** Nallen Regulatory Consulting.

***Lesley Johnson*** Head of Pharmaceuticals and Feed Additives, Veterinary Medicines Directorate.

**A Certificate of Attendance for Professional Development will be given to each participant who completes the course.**

## PROGRAMME

### Day One — 22 September 2010

09.30 **Chairman's Welcome and Introduction**
*Ray Harding*

09.45 **Article 13 Applications**
- What is a generic?
- Legal Framework in the EU
- New provisions of Annex1 (Directive 2009/9) and dossier requirements

*Ray Harding*

10.45 **Discussion**

11.00 **Coffee**

11.15 **Quality Requirements for Generics**
*Anne Nallen*

12.00 **Bioequivalence: Current Guideline Explained**
- How to conduct a bioequivalence study
- Proof of bioequivalence
- Exemptions from requirement to provide bioequivalence

*Ray Harding*

12.30 **Discussion**

13.00 **Lunch**

14.00 **Significance of Global Reference Product and European Veterinary Medicinal Product**
- Impact on data exclusivity periods
- Impact on licensing of generics

*Anne Nallen*

14.45 **Processing a Generic Application Through DCP or MRP**
- Filling in the Part 1
- Choice of Reference Product
- Harmonisation of the SPC

*Anne Nallen*

15.30 **Discussion**

15.45 **Tea**

16.00 **View of an Applicant: Making an Article 13 Application Work**
- Informed consent
- Bibliographical files
- 'Generic' products

*Dr Inge Sandberg*

17.00 **Discussion**

17.15 **End of Day One**

### Day Two — 23 September 2010

09.00 **Chairman's Welcome and Brief Review of Day One**
*Ray Harding*

09.15 **Data Protection and Generic Veterinary Medicines**
- The current legal base of the regulation of generic veterinary medicinal products in the EU: Article13
- How the current legislation provides for generic products
- Requirements of newly-revised Annex 1 (Directive 2009/9)
- Principles of data protection in Article 13

*Ray Harding*

10.00 **Problems with Generic Products**
*Lesley Johnson*

11.00 **Discussion**

11.10 **Coffee**

11.30 **New CVMP Guideline on Bioequivalence Studies**
- Principles of bioequivalence studies
- In-vivo and in-vitro bioequivalence studies
- Exemptions from bioequivalence studies

*Ray Harding*

12.15 **Discussion**

12.30 **Lunch**

13.30 **Requirements of Annex 1 (Directive 2009/9) for Generic and Bibliographic Dossiers**
*Ray Harding*

14.15 **Discussion**

14.30 **Tea**

14.45 **Requirements for 'Detailed and Critical Summaries' for Article 13 Applications**
*Ray Harding*

15.30 **Discussion and Chairman's Closing Remarks**

15.45 **End of Forum**