

## Dear Ladies and Gentlemen,

Since the second Veterinary Pharmacovigilance Symposium in Berlin in 1997 extensive developments have been seen in this field. Veterinary medicinal products (VMPs) are often simultaneously authorised in European as well as in other countries worldwide. Thus, a close pharmacovigilance network connecting users of VMPs, pharmaceutical industry, and competent authorities has become essential to meet European and international safety standards set by legislation. This is not only a precondition for free trade of animals and animal products in a global market but also for consumer safety and animal welfare.



One of the most impressive advancements applies to international harmonisation including electronic exchange of pharmacovigilance data. Numerous working groups are compiling standardised protocols for data collection and transfer to be used all over the world – the current stage of proceedings being an issue of this symposium.

Regulatory and clinical aspects of pharmacovigilance will be presented by representatives of competent authorities, universities, and veterinary practitioners. Signal detection is considered a promising tool to produce hypotheses on adverse effects, and for the present a challenge to statisticians and assessors.

This conference provides an excellent opportunity to meet pharmacovigilance experts from all over the world, exchange views and experience on recent and future developments, challenges and pitfalls, socialise, and start collaborations.

I am looking forward to welcoming you to Berlin in December 2010 at the 3rd Pharmacovigilance Symposium.

Dr. Helmut Tschiersky-Schöneburg

## PROGRAMME

### 13 December 2010

(10:00 – 18:00, Registration from 09:00)

#### Welcome Address

Dr. Helmut Tschiersky-Schöneburg  
*Federal Office of Consumer Protection and Food Safety, Germany*

#### Greetings and Introduction

Prof. Dr. Thomas Heberer and Dr. Cornelia Ibrahim  
*Federal Office of Consumer Protection and Food Safety, Germany*

#### Session 1: International Harmonisation in the Field of Pharmacovigilance

##### Composing Harmony from Dissonance

Dr. Margarita Brown  
*Food and Drug Administration, Centre for Veterinary Medicine, USA*

##### Post Marketing Regulation of Veterinary Medicinal Products in Japan – Adverse Event Reporting System and a Prospect for International Harmonisation

Kaoru Eguchi  
*National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan*

##### View from an OIE Expert

Ana Isabel de Vasconcelos Batalha  
*World Organisation for Animal Health, France*

#### Session 2: Different Approaches to Pharmacovigilance in Europe, Part 1

##### Special Impacts of the Danish Pharmacovigilance System

Lisbet Vesterager Borge  
*Danish Medicines Agency, Denmark*

##### The Spanish Way – Pharmacovigilance with Limited Resources

Dr. Ramiro Casimiro  
*Agencia Española de Medicamentos y Productos Sanitarios, Spain*

#### Session 3: Different Approaches to Pharmacovigilance in Europe, Part 2

##### Species- and Breed-Related Adverse Drug Reactions: Experience from the Swedish Veterinary Pharmacovigilance System

Dr. Hans Tjälve  
*Läkemedelsverket – Medical Products Agency, Sweden*

##### Pharmacovigilance in Ireland – Case Studies from a Small Pharmacovigilance System

Lisa Woods  
*Irish Medicines Board, Ireland*

#### Session 4: Pharmacovigilance Inspections

##### Veterinary Pharmacovigilance Inspections – Working Together to Make Pharmacovigilance More Effective

Caroline Evans  
*Veterinary Medicines Directorate, United Kingdom*

##### Pharmacovigilance Inspections... Time to Panic?

Dr. Marie-Odile Hendricks  
*Pfizer Animal Health, United Kingdom*

#### Session 5: Cooperation with Universities in the Field of Pharmacovigilance

##### Veterinary Pharmacovigilance Centres – the French Experience

Dr. Xavier Pineau  
*Veterinary Pharmacovigilance Centre of Lyon, France*

##### Cooperation with Universities in the Field of Pharmacovigilance – the Swiss Way

Dr. Cedric Müntener  
*Swissmedic, Swiss Agency for Therapeutic Products, Switzerland*

##### Cooperation with the University of Leipzig – VETIDATA

Dr. Henry Otilie  
*University of Leipzig, Germany*

##### Cooperation with the National Pharmacovigilance Centres in Germany

Prof. Dr. Manfred Kietzmann  
*University of Veterinary Medicine Hannover – Foundation, Germany*

#### Conference Dinner

### 14 December 2010

(09:00 – 17:00)

#### Session 6: Electronic Exchange of Pharmacovigilance Data

##### Centralisation of Pharmacovigilance Data in the EU, Challenges and Opportunities

Dr. Jos Olaerts  
*European Medicines Agency, United Kingdom*

##### Electronic Exchange of Pharmacovigilance Data: the Industry Journey so far and the Look ahead to the Future

Sylvie Meillerais  
*International Federation for Animal Health Europe, Belgium*

##### Applying HL7 and ISO Standards to Veterinary Pharmacovigilance

Nic Pillinger  
*Assured Information Systems, United Kingdom*

#### Session 7: Signal Detection

##### An Approach to Signal Detection

Michelle Nicholson  
*Health Canada, Canada*

##### Signal Generation in Veterinary Pharmacovigilance Databases

Marietta Rottenkolber  
*University of Munich, Germany*

##### Signal Detection and Data Mining in Animal Health Pharmacovigilance from Industry Perspective

Dr. Tatty Hodge,  
*Pfizer Animal Health, USA*

## PROGRAMME

### Session 8:

#### Clinical Aspects of Pharmacovigilance

##### Epidemiological Aspects of Bovine Neonatal Pancytopenia

Prof. Dr. Wolfgang Klee  
*University of Munich, Germany*

##### Haemorrhagic Diathesis in Calves – Regulatory Aspects

Dr. Klaus Cussler  
*Paul-Ehrlich-Institut, Germany*

##### Pharmacovigilance of Bluetongue Vaccination – Experience with a Decreed Vaccination in Farm Animals

Dr. Lukas Bruckner  
*Institute of Virology and Immunophylaxis, Switzerland*

##### Pharmacovigilance from a Veterinary Practitioner's Point of View – Why Do We Have Underreporting and How Can We Change this?

Dr. Rainer Schneichel  
*Bundesverband Praktizierender Tierärzte (bpt), Germany*

### Session 9:

#### Risk Management – Risk Communication

##### Risk Identification and Risk Management in Pharmacovigilance

Dr. Kevin Woodward  
*AFF Woodward Consulting, United Kingdom*

##### Authority Perspective on Risk Management Concerning Veterinary Medicinal Products – Background, Status and Reflections

Dr. Fia Westerholm  
*European Medicines Agency, United Kingdom*

##### Exchange of Information – Established Ways and New Approaches

Dr. Cornelia Ibrahim  
*Federal Office of Consumer Protection and Food Safety, Germany*

#### Closing Remarks

### Venue

NH Hotel Berlin Friedrichstraße  
Friedrichstraße 96  
10117 Berlin  
Germany

### Registration

Registration to the symposium is made via online registration or email directly to:

#### Federal Office of Consumer Protection and Food Safety (BVL)

Ms. Karen Lieske  
Mauerstraße 39-42  
10117 Berlin  
Tel. +49 (0) 30 18 444 300 01

Email:

[pharmacovigilance-symposium@bvl.bund.de](mailto:pharmacovigilance-symposium@bvl.bund.de)

Online registration:

[www.bvl.bund.de/pharmacovigilance-symposium](http://www.bvl.bund.de/pharmacovigilance-symposium)

Registration deadline:

Please register by 30 November 2010 and be aware that on-site registrations and cash payments are not possible.

### Registration Fees

Industry.....	450.00 EUR
Authority, University.....	250.00 EUR
Student .....	150.00 EUR

Registration fee includes:

- admission to the lectures
- morning and afternoon coffee breaks and lunch breaks
- conference dinner on 13 December 2010
- copy of the proceedings.

### Cancellation and Refunds

Cancellations of confirmed registrations are subject to a charge of 100.00 EUR per participant provided the cancellation is received before 30 November 2010. After this date no refunds will be made.

### Bank Transfer

Registration fees must be in EUR currency. Payments can be made, without charges for the beneficiary, as follows:

#### Bank data for international transfer

Bank: Deutsche Bundesbank, Filiale Saarbrücken  
BIC: MARKDEF1590  
IBAN: DE81590000000059001020  
Account holder: Bundeskasse Trier

#### Payment from a German bank account

Bundeskasse Trier  
Deutsche Bundesbank, Filiale Saarbrücken  
BLZ 590 000 00  
Konto-Nr. 590 010 20

Please note the following reference number on your money transfer form:

**915019002864 – BEW03138450**

After receipt of payment you will receive a confirmation of registration via email.

### Hotels

Rooms have been allocated in the below-mentioned hotels. Please make your reservation individually and refer to the code “BVL” when booking. Please be aware that the allocated hotel accommodations are limited and are on a first-come, first-served basis.

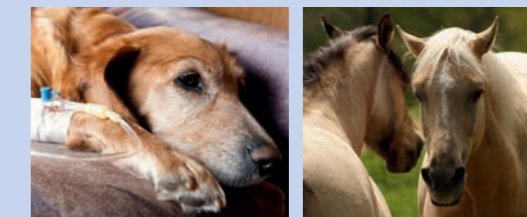
- NH Berlin Friedrichstraße  
<http://www.nh-hotels.de>
- Hotel Gendarm nouveau  
<http://www.hotel-gendarm-berlin.de>
- Hilton Berlin, Domhotel GmbH  
<http://www.hilton.de/berlin>
- Sofitel Berlin Gendarmenmarkt  
<http://www.sofitel.com>
- NH Berlin-Mitte  
<http://www.nh-hotels.de>



Federal Office of  
Consumer Protection  
and Food Safety

## 3<sup>RD</sup> INTERNATIONAL SYMPOSIUM ON VETERINARY PHARMACOVIGILANCE

13 – 14 December 2010  
Berlin, Germany



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VETERINARY DRUGS

**Pharmacovigilance**  
for Quality, Efficacy and Safety of  
Veterinary Medicinal Products

