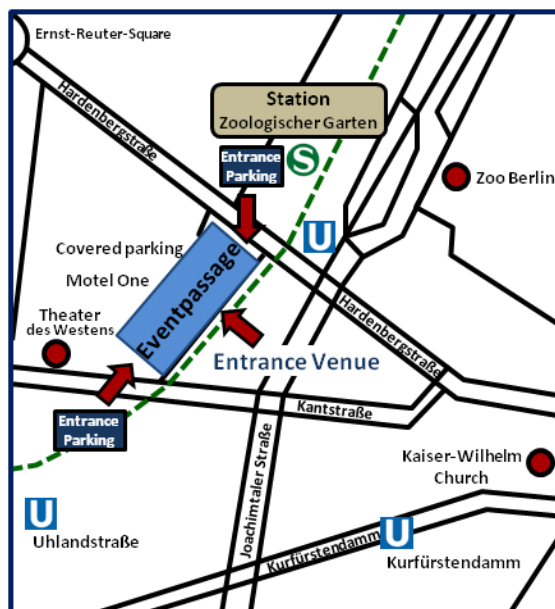


## Venue

The Workshop will take place at “Eventpassage” which is located close to the train station “Zoologischer Garten” in the city centre of Berlin. From this station it takes you just 5 min to walk to the venue. The address of the venue is Kantstraße 8, D-10623 Berlin (located in the building of the hotel Motel One).



## How to find us:

Take Bus No. X9 from Airport Berlin Tegel (TXL) to station “Zoologischer Garten”. From Airport Berlin Schönefeld (SXF) you will get there by train no. RE7 or no. RB 14.

If you arrive by car parking is available at “Parkhaus am Zoo” for a 13 € day ticket.

## Contact

For further information on the workshop please contact Ines Rönnefahrt at [ines.roennefahrt@uba.de](mailto:ines.roennefahrt@uba.de) or via phone: +49 (0) 3 40 / 2103 3093

or Cornelia Ibrahim at [cornelia.ibrahim@bvl.bund.de](mailto:cornelia.ibrahim@bvl.bund.de)

You will find more information also on our website: <http://www.umweltbundesamt.de/en/service/dates/workshop-eco-pharmacovigilance-of-veterinary-0>

## Registration

Please register until **November 30<sup>th</sup>** under: <http://www.umweltbundesamt.de/en/service/dates/workshop-eco-pharmacovigilance-of-veterinary-0>

or contact Sabine Sünkler at [sabine.suenkler@uba.de](mailto:sabine.suenkler@uba.de)

Please consider that the venue has limited capacity. The participation of the workshop is free of charge.

Editor | Umweltbundesamt  
Wörlitzer Platz 1, 06844 Dessau-Roßlau  
[www.umweltbundesamt.de](http://www.umweltbundesamt.de)

| November 2013

## Eco-Pharmacovigilance of Veterinary Medicinal Products

A suitable concept for environmental safety?



**International Workshop**  
**4-5 December 2013, Berlin, Germany**

## Background

The quality, efficacy and safety of medicinal products are ensured by a complex system of pre- and post market control. Once placed on the market medicinal products are monitored in a comprehensive pharmacovigilance system in order to detect and to manage risks. In principle, this also applies to environmental safety: All new veterinary medicinal products in the EU are subject to an assessment of potential environmental risks in the pre market control. However, there is a discrepancy between the general obligation to report on environmental problems in the post authorization surveillance and the question how to fulfill this obligation.

## Workshop description

The workshop consists of introductory presentations which are followed by discussions in three working groups focused on individual aspects of the problem. The objective of the workshop is to review the current state of eco-pharmaco-vigilance of veterinary medicinal products and to discuss opportunities to enhance the system. To disseminate the obtained results the conclusions of the scientific discussion will be published in a workshop report.

## Who should attend?

You are kindly invited to a workshop hosted by the Federal Environment Agency and the Federal Office of Consumer Protection and Food Safety. It is open to experts from industry, science and regulatory agencies active in the field of assessment, surveillance and management of environmental risks of veterinary medicinal products (VMPs).

## Time Wednesday, 4 December 2013

- 10.30 Registration
- 11.00 Welcome  
*Adolf Eisenträger, Federal Environment Agency*  
*Sabine Gärtner, Federal Ministry for the Environment, Nature Conservation and Nuclear Safety*  
*Cornelia Ibrahim, Federal Office of Consumer Protection and Food Safety*  
*Ines Rönnfahrt, Federal Environment Agency*
- 11.30 Occurrence, fate and effects of VMPs in the environment: What are the problems?  
*Alistair Boxall, University of York, U.K.*
- 12.00 Regulatory overview Part I:  
Legal basis and experiences with pharmacovigilance of potential environmental problems  
*Cornelia Ibrahim, Federal Agency of Consumer Safety, Germany*
- 12.30 Lunch break
- 13.30 Regulatory overview Part II:  
Experiences with environmental risk assessments in the authorization procedure of VMPs  
*Ines Rönnfahrt, Umweltbundesamt, Germany*
- 14.00 Challenges and opportunities of post market surveillance: fate and effects monitoring  
*Dirk Jungmann, Technical University of Dresden*
- 14.30 Introduction to working groups  
*Ines Rönnfahrt, Umweltbundesamt, Germany*
- 14.45 Coffee break
- 15.15 Working groups  
WG 1 Pharmacovigilance of potential environmental problems: state of the art & visions

- WG 2 Which concepts complement pharmacovigilance to ensure environmental safety of VMPs? Is there a need for adjustment?
- WG 3 Challenges and opportunities of post market environmental surveillance: How can environmental monitoring support pharmacovigilance?
- 17.30 Short feedback from working group discussions
- 17.45 End of Day 1

## Time Thursday, 5 December 2013

- 09.00 Working groups
- 10.00 Presentation of working group results  
10.00 – 10.20 WG 1  
10.20 – 10.40 WG 2
- 10.40 Coffee break
- 11.00 Presentation of the working group results  
11.00 – 11.20 WG 3
- 11.20 Plenary discussion
- 13.00 Lunch break
- 14.00 Summary and conclusions of the Workshop
- 15.00 End of workshop

### Chairs of the workshop:

*Adolf Eisenträger, Federal Environment Agency*  
*Cornelia Ibrahim, Federal Office of Consumer Protection and Food Safety*