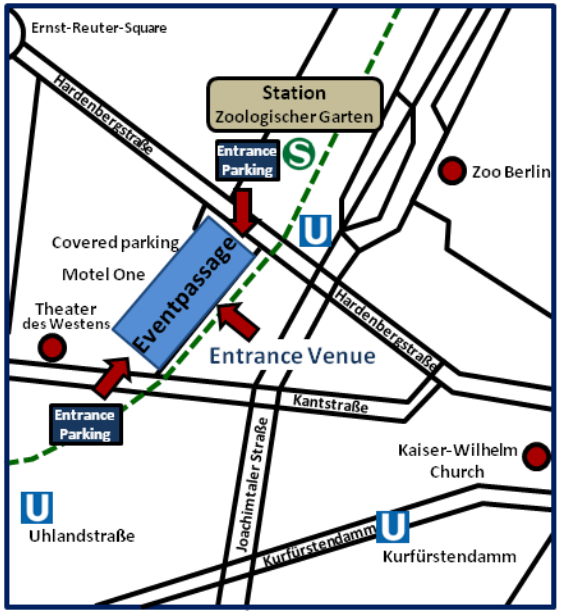
Venue

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 or via phone: +49 (0) 3 40 / 2103 3093

or Cornelia Ibrahim at 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 30th** under:
http://www.umweltbundesamt.de/en/service/dates/workshop-eco-pharmacovigilance-of-veterinary-0

or contact Sabine Sünkler at sabine.suenkler@uba.de

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

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| November 2013

Eco-Pharmacovigilance of Veterinary Medicinal Products

A suitable concept for environmental safety?

International Workshop

4-5 December 2013, Berlin, Germany

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Umwelt Bundesamt

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).

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 Rönnefahrt, 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 Office of Consumer Protection and Food Safety

12.30 Lunch break

13.30 Regulatory overview Part II:
Experiences with environmental risk assessments in the authorization procedure of VMPs
Ines Rönnefahrt, 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 Rönnefahrt, 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

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*