Registration details

Who should attend?

Experts from EU institutions, national ministries/ competent authorities, industry associations and other stakeholders are welcome to discuss the benefits and challenges of the different approaches and to contribute proposals for putting it into practice.

Registration

Please fill in the following online form to register for the workshop:
http://registration.ecologic-events.eu/monograph-workshop

Registration is open **by 2 June 2017**.
There is no registration fee.

Contact

For content related questions or requests, please contact Dr. Ines Rönnefahrt (UBA) via **monograph-workshop@uba.de** or via phone: 0049 (0)340-2103-3093.

For questions or requests concerning participation and organisational matters, please contact the organising team of Ecologic Institute at: **logistics-monograph-workshop@ecologic-events.eu**.

Publisher:
Umweltbundesamt
Postfach 14 06
06813 Dessau-Roßlau
Tel: +49 340-2103-0
info@umweltbundesamt.de
Internet: www.umweltbundesamt.de

Photo:
Front page: Ines Rönnefahrt

Date: May 2017

How to achieve an appropriate Environmental Risk Assessment Of Veterinary Medicinal Products Workshop
07 June 2017 - Brussels

For our Environment

Umwelt Bundesamt

Background

On 10 September 2014 the European Commission (COM) adopted a proposal for a Regulation on Veterinary Medicinal Products (VMPs). During the ongoing review of the EU legislation the necessity to improve the environmental risk assessment (ERA) of VMPs with a special focus on so called legacy products has been identified. Many legacy VMPs entered the market before an environmental risk assessment was introduced into the VMP authorisation procedure by the relevant EC legislation. Therefore, substantial information on environmental effects is missing for such legacy VMPs or at least not available to all EU competent authorities. A need for better knowledge on environmental effects of VMPs has also been brought up within the context of water protection.

Within its decision on the proposal for a regulation on VMPs from 10 March 2016 the European Parliament (EP) has asked the COM to "...present a report to the European Parliament and the Council on a feasibility study of a substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products...".

One of the most promising approaches seems to be a compilation of quality checked data for the environmental risk assessment of active pharmaceutical substances in substance based data files. Applicants could refer to such a data file instead of generating environmental data on their own; a fair sharing of costs will have to be provided for. In 2015 the German Environment Agency (UBA) initiated a research project in order to considerer different scenarios in a kind of 'impact assessment', e.g. the 'ERA master file concept' and an alternative approach, not based on substances but on products, as proposed by industry.

Workshop description

In this workshop different approaches are presented and discussed together with aspects of an effective procedural organisation and legal aspects. The workshop also addresses the possible benefits for the environment, eventual reduction in administrative burden by data sharing and any impact the system may have on applicants, agencies, national competent authorities, the European Medicines Agency (EMA) and other stakeholders. The workshop is a follow-up of the one held in November 2014 in Brussels. It is being hosted by the German Ministry for the Environment, Nature Conservation, Building and Nuclear Safety and the German Environment Agency (UBA).

Venue

The workshop will be held at the **BIP, the Visitor Centre of the Brussels-Capital Region (Rue Royale 2-4, 1000 Brussels, Belgium)**. The venue is located on the Place Royale, in the heart of the Mont des Arts, Brussels museum quarter and easily accessible by both car and public transport.

The BIP is reachable via:

- Metro stations Parc and Brussels Central
- Metro station Trone if you come from Brussels South Station (Gare du Midi / Zuid)
- Bus 38 and 71 stop "Koning - Royale"
- Tram 92 and 93 stop "Koning - Royale"

Agenda

10:30 – 11:00 Registration & coffee	
Welcome and Setting the Scene Rodrigo Vidaurre, Ecologic Institute, Germany	'5
Opening Words Sinikka Hinrichsen, German Ministry for Environment, Nature Conservation, Building and Nuclear Safety, Germany	'10
Pharmaceuticals in the environment: veterinary medicines Ariane van der Stappen, European Commission, DG Santé	'20
ERA of VMPs: Background and State of the Art Jutta Klasen, German Environment Agency, Germany	'20
ERA of VMPs: The journey and the way forward Christel Van den Eede, IFAH Europe, Belgium	'20
EGGVP views on Generics and Ecotoxicology Elsa Vecino, EGGVP, Belgium	'20
The ERA Master File Concept Ines Rönnefahrt, German Environment Agency, Germany	'20
Discussion	'20
13:15 – 14:15 Lunch	
Impacts and implications of an ERA for veterinary medicinal products Anke Joas, bipro, Germany	'20
World Café	'90
16:10 – 16:30 Coffee Break	
Wrap up and overall discussion	'45
Summary and further actions	'15
17:30 End	