

# Workshop

An effective tool to strengthen the environmental safety of medicinal products:

## Monograph system for active pharmaceutical substances

A one-day meeting hosted by the German Federal Environment Agency (UBA) and the French Agency for Veterinary Medicinal Products/ ANSES. The proposed monograph system for environmental data will be discussed in light of the Commission`s report "Study of environmental risks of medicinal products" and the Commissions`s proposal for a new Regulation on Veterinary Medicinal Products. The aim is to allow participants to share a larger understanding of benefits as well as to discuss the design and possible implementation steps of the monograph system.

Date: 26 November 2014

Venue: Science14 Atrium, 14b Rue de la Science, 1040 Brussels, Belgium

### Agenda

09.00 - 09.10	Welcome and Introduction
9.10 – 09.25	Proposal on a new Regulation for veterinary medicinal products: state of play Ariane Vander Stappen (DG Health and Consumers)
9.25 – 09.40	Strategic approach to pollution of water by pharmaceutical substances: update and next steps Peter Korytar, Helen Clayton (DG Environment)
09.40 – 10.00	Practical experiences with Environmental Risk Assessment of veterinary medicinal products and impact on Marketing Authorizations Mathilde Harvey (ANSES, France)
10.00 – 10.20	Monograph system of active pharmaceutical substances: necessity, challenges and perspectives Ines Rönnefahrt (UBA, Germany)
10.20 – 10.40	Sharing Data for a Common Goal: Legal, Cultural and Logistic Considerations Tom Hargreaves (Blue Frog Scientific Limited, United Kingdom)
10.40 – 11.00	Coffee break
11.00 – 12.30	Working groups I  WG 1 What are the benefits of a monograph system? WG 2 How could a Monograph system be designed? WG 3 How could a monographs system on active pharmaceutical substances be implemented into the legislative framework?
12.30 - 13.30	Lunch break
13.30 – 14.00	Working groups II (summarizing results)
14.00 – 15.45	Feedback from working group discussions & Plenary discussion
15.45 – 16.00	Conclusions
16.00	End of workshop

