Info Day for micro, small and medium-sized enterprises (SMEs)

EMA support for SMEs under the new Veterinary Medicinal Products Regulation

28 October 2021, 10:00-16:00 CEST

Virtual meeting

Background and objectives

The info day provides an overview of EMA initiatives supporting SMEs and service providers operating in the veterinary medicines sector.

It highlights platforms for early dialogue with EMA, the range of support that companies can access to optimise their development plans and the experience of companies with marketing authorisation applications.

The event also focuses on the impact on SMEs of the implementation of the Veterinary Medicinal Products Regulation (EU) 2019/6, which will become applicable on 28 January 2022. It includes a presentation of the Union Pharmacovigilance Database and a demonstration of the Union Product Database.

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Chaired by Ivo Claassen and Constantinos Ziogas (EMA)

Introduction

10:00 – 10:05	**Joining and technical checks**	**5'**
10:05 – 10:15	**Welcome and introduction** *Ivo Claassen and Constantinos Ziogas (EMA)*	**10'**

Session 1: EMA's support for SMEs developing innovative veterinary medicines

10:15 – 10:30	**Overview of EMA initiatives supporting SMEs** *Clément Provansal (EMA)*	**15'**
10:30 – 10:45	**Early support to innovation** *Frida Hasslung Wikström (Chair of the Scientific Advice Working Party)*	**15'**
10:45 – 11:00	**The role of Novel Therapies and Technologies Working Party** *Susana Casado (Vice-chair of the Novel Therapies and Technologies Working Party)*	**15'**
11:00 – 11:10	**Q&A**	**10'**

Session 2: Planning a successful marketing authorisation application

11:10 – 11:25	**Pre-submission: need for Maximum Residue Limits (MRL) evaluation for biologicals** *Sebastien Girault (EMA)*	**15'**
11:25 – 11:45	**Path to marketing authorisation: SMEs' experience and considerations** *Susan Kennedy (Triviumvet) and Almudena Pradera (Equicord)*	**20'**

11:45 – 12:00	**Q&A** *with invited panellist G. Johan Schefferlie (Vice-chair of the CVMP)*	15’
12:00 – 12:10	**Coffee break**	10’

Session 3: Veterinary Medicinal Products Regulation (VMP-Reg) – towards 28 January 2022

12:10 – 12:30	**Status update on EMA implementation of the VMP-Reg** *Jordi Torren Edo (EMA)*	20’
12:30 – 12:50	**Limited markets: what is in for SMEs?** *Susanne Thiele (EMA)*	20’
12:50 – 13:00	**Q&A**	10’
13:00 – 14:00	**Lunch break**	60’

Session 4: Post authorisation - Pharmacovigilance

14:00 – 14:15	**Changes in pharmacovigilance, signal detection and surveillance** *Jos Olaerts (EMA)*	15’
14:15 – 14:45	**Introduction to Union Pharmacovigilance Database (EVVet3)** *Laura Descalzo (EMA)*	30’

Session 5: Union Product Database (UPD)

14:45 – 15:30	**Introduction to the UPD system and demo of functionalities** *Jana Schalansky and Ana Rosula Vicente (EMA)*	45’

Session 6: Q&As

15:30 – 15:50	**Participants’ questions** *Ivo Claassen (EMA)*	20’

Conclusion

15:50 – 16:00	**Closing remarks** *Ivo Claassen and Constantinos Ziogas (EMA)*	10’