



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/529177/2021
20 September 2021

Draft agenda – Veterinary 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

Co-Chairs: Ivo Claassen – Constantinos Ziogas

Speakers: tbc

Time	Topics
10:00	Connection to virtual room and technical checks
10:05	Welcome and introduction
	<ul style="list-style-type: none">Welcome address and opening remarks
10:15	Session 1: EMA's support for SMEs developing innovative veterinary medicines
	<ul style="list-style-type: none">Overview of EMA initiatives supporting SMEsEarly support to innovationThe role of Novel Therapies Working Party
	Q&A
11:10	Session 2: Planning a successful marketing authorisation application
	<ul style="list-style-type: none">Pre-submission: need for MRL evaluation for biologicalsPath to marketing authorisation: SMEs' experiences and peer-to-peer considerations
	Q&A
12:00	<i>Coffee break</i>

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Time	Topics
12:10	Session 3: Veterinary Medicinal Products Regulation (VMP-Reg) – towards 28 January 2022
	<ul style="list-style-type: none"> • Status update on EMA implementation activities on Veterinary Medicinal Products Regulation (VMP-Reg)
	<ul style="list-style-type: none"> • Limited markets: what is in for SMEs?
	Q&A
13:00	<i>Lunch break</i>
14:00	Session 4: Post authorisation: Pharmacovigilance
	<ul style="list-style-type: none"> • Changes in pharmacovigilance, signal detection and surveillance
	<ul style="list-style-type: none"> • Introduction to Union Pharmacovigilance Database (EVVet3)
	Q&A
14:45	Session 5: Union Product Database (UPD)
	<ul style="list-style-type: none"> • Introduction to the UPD system and demo of functionalities
15:30	Q&A session
15:50	Closing remarks