



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17/12/2021

EMA/535229/2021

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Agenda - Nitrosamine Implementation Oversight Group - Industry Associations Meeting

08th December 2021 – Teleconference, 2PM – 4PM, CET

Co-Chairs: Evdokia Korakianiti (EMA) & Susanne Winterscheid (CMDh)

Item	Preliminary draft agenda	Name	Mins
1.	Welcome and introduction	Co-chairs	5
2.	Adoption of draft agenda	Co-chairs	5
3.	EMA status update on call for review	EMA- Maria Filancia	10
4.	EMA update on progress of NIOG Workplan and discussion on outstanding issues to prioritise in 2022 - Quality topics - Safety topics - Multidisciplinary topics - Procedural topics	EMA- Rob Bream, Rhys Whomsley, Robin Ruepp	50
5.	• Short update on progress of call for review	Tour de table per EU Trade organisation	30
	• Industry update on workplan and priorities for 2022	1 cross-industry lead speaker	
6.	A.O.B	All	15

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Item	Preliminary draft agenda	Name	Mins
7.	Conclusions and next steps	Co-chairs	5

List of participants

EMA

Evdokia Korakianiti

Marie-Helene Pinheiro

Monika Mayr

Robert Bream

Rhys Whomsley

Maria Filancia

Robin Ruepp

Linda Malaguti

CHMP

Martina Weise (apologies)

Kristina Duncer (apologies)

CMDh

Kora Doorduyn van der Stoep, CMDh Chair

Susanne Winterscheid, CMDh Vice Chair

Priscilla Schoondermark (apologies)

Laura Galatti

Andrzej Czesławski

Nicole Kavanagh

QWP

Blanka Hirschlerova

SWP

Leon van Aerts

BWP

Mats Welin

CTFG

Robert Klaus

EDQM

Helene Bruguera

Michael Wierer

Industry participants**EFPIA**

Joel Bercu

Jim Harvey

Andreas Hartmann

Andreas Czich

Matt Popkin

Ron Ogilvie

Andrew Teasdale

Achim Lueckel (apologies)

Sandra Johanssen

Krista Dobo

AESGP

Christelle Anquez

Sharon Porter

Sampriti Roy

Lawrence Steedman

Fatima Bican

Brigit Ewert (apologies)

Karen Foster

APIC

Ajda Podgorsek-Berke

Hilde Merete Hagen

Mohan Ganapathy

EuropaBio

Sylvie Meillerais

John Nicolette

Stephane Guillet

Lionel Mavoungou

Stephen Jones

Alison Dawson

EUCOPE

Jonathan Dormer

Nazia Noor (apologies)

Fatma Kandemir

Thomas Brückner

Medicines for Europe

Camille Andries (Secretariat)

Sabrina Conti (Secretariat)

Valerie Niddam-Hildesheim

Gordon McIntyre

Jonathan Rousell

Marina Couva

Jurema Schmidt (apologies)

Stefan Gimmel

Mark King

Jozsef Balla

PPTA

Evelina Kozubovska

Richard Schmitz

Dominika Misztela (apologies)

IPFA

Françoise Rossi