



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 March 2021  
EMA/167020/2021

## Nitrosamine Implementation Oversight Group - Industry Associations Meeting

31 March 2021 – Teleconference, 15:00 - 17:00, CET

### Agenda

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

| Item | Preliminary draft agenda                                                                                                                                                                                                           | Lead                                                                         | Mins |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------|
| 1.   | Welcome and introduction                                                                                                                                                                                                           | Co-Chairs                                                                    | 10'  |
| 2.   | Presentation on NIOG mandate, means of operation and interaction                                                                                                                                                                   | EMA – Andrei Spinei                                                          | 30'  |
| 3.   | NIOG Workplan and prioritisation, overview of topics for interaction with industry <ul style="list-style-type: none"><li>Quality topics</li><li>Multidisciplinary topics</li><li>Safety topics</li><li>Procedural topics</li></ul> | EMA – Robert Bream, Rhys Whomsley, Maria Filancia                            | 30'  |
| 4.   | Call for review - status update and identified challenges at-Round Table <ul style="list-style-type: none"><li>Products containing chemically synthesised APIs</li><li>Products containing biological APIs</li></ul>               | EFPIA, Medicines for Europe, AESGP, EUCOPE, APIC<br><br>EuropaBio, PPTA/IPFA | 30'  |
| 5.   | A.O.B.                                                                                                                                                                                                                             | All                                                                          | 15'  |
| 6.   | Conclusion and next steps                                                                                                                                                                                                          | Co-Chairs                                                                    | 5    |

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# List of participants

## **EMA**

Evdokia Korakianiti

Marie-Helene Pinheiro

Monika Mayr

Andrei Spinei

Robert Bream

Rhys Whomsley

Stefano Ponzano

Maria Filancia

Robin Ruepp

Gilija Cesnule

## **CHMP**

Martina Weise, CHMP member (*apologies*)

Kristina Dunder, CHMP member

## **CMDh**

Kora Doorduyn van der Stoep, CMDh Chair

Susanne Winterscheid, CMDh Vice Chair

Priscilla Schoondermark

Nicole Kavanagh

Laura Galatti

Andrzej Czesławski

## **QWP**

Blanka Hirschlerova

## **SWP**

Leon van Aerts

Louise Frederikke Swaffield Bang-Lauritsen

**EDQM**

Helene Bruguera

Michael Wierer

**Industry participants****EFPIA**

Ron Ogilvie

Matt Popkin

Andrew Teasdale

Graham Cook

Andreas Hartmann

Sylvie Meillerais

Nigel Hamilton

Alison Dawson

Andrew Lennard

Jim Harvey

Giovanna Rizzetto

**AESGP**

Steven Hesp

Fatima Bicane

Sharon Porter

Karen Foster

Sampriti Roy

Isabel Veiga

Christelle Anquez-Traxler

Klavdija Kmetič

**APIC**

Sabina Jurca

Ajda Podgorsek

Tony Storey

### **EuropaBio**

Anne-Regine Herboth

Robert A. Jolly

Nicola Squillacciotti

Bruno Mouton

### **EUCOPE**

Bertrand Fournier

Fatma Kandemir

Martina Wong

Maren von Fritschen

### **Medicines for Europe**

Koen Laenen

Schmidt Jurema

Mark King

Valerie Niddam

Gordon McIntyre

Jonathan Rousell

Marina Couva

Marcela Caltova

Thuroch O'Críodain

Jozsef Balla

### **PPTA**

Philip Lienbacher

Natalia Osmanova

Mary Gustafson

### **IPFA**

Khatija Suleman

Richard Schmitz

Françoise Rossi