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European Medicines Agency

Nitrosamine Implementation Oversight Group

Terms of Reference

1. Scope

The Nitrosamine Implementation Oversight group has the primary responsibility to oversee the implementation of the Article 5(3) CHMP Opinion relating to nitrosamine impurities in human medicines and to provide progress updates to the European Medicines Regulatory Network Authorities.

2. Membership

The NIOG is composed of CHMP, CMDh, EDQM and EMA representatives as follows:

Organisation	Member	Back-up
EMA (Chair)	Evdokia Korakianiti, Evdokia.Korakianiti@ema.europa.eu	
CMDh (Co-Chair)	Susanne Winterscheid, Susanne.Winterscheid@bfarm.de	Marta Marcelino marta.marcelino@infarmed.pt
CHMP	Kristina Dunder, kristina.dunder@lakemedelsverket.se	
CMDh	Priscilla Schoondermark, p.schoondermark@cbg-meb.nl	
CMDh	Nicole Kavanagh, nicole.kavanagh@hpra.ie	
CMDh	Laura Galatti, l.galatti@aifa.gov.it	
CMDh	Pawel Pawlowski, pawel.pawlowski@urpl.gov.pl	

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Organisation	Member	Back-up
CMDh	Zuzana Fliegerova, Zuzana.Fliegerova@sukl.gov.cz	
QWP	Blanka Hirschlerova, blanka.hirschlerova@sukl.gov.cz	Maryam Mehmandoust, maryam.mehmandoust@ansm.sante.fr
NcWP	Marianne Schmidy, Marianne Schmidt mnsc@dkma.dk	
BWP (ad hoc)	Mats Welin, mats.welin@mpa.se	
CTCG (observer)	Gernot Hirn, gernot.hirn@ages.at	
EDQM	Helene Bruguera, helene.BRUGUERA@edqm.eu	
EMA	Robert Bream, Robert.Bream@ema.europa.eu	Ciaran Joyce, ciaran.joyce@ema.europa.eu
EMA	Rhys Whomsley, Rhys.Whomsley@ema.europa.eu	Francisca van Doesum-Wolters, francisca.vandoesumwolters@ema.europa.eu
EMA	Robin Ruepp, robin.ruepp@ema.europa.eu	
EMA	Stefania Ragone ,stefania.ragone@ema.europa.eu	Ana Coelho, ana.coelho@ema.europa.eu
EMA	Vasili Dabouras, vasilios.dabouras@ema.europa.eu	
EMA Secretariat	Rubén Lindo del Rey, ruben.lindo@ema.europa.eu	
EC	Romain Rotival, romain.rotival@ec.europa.eu	

3. Organisational and administrative support

The EMA Inspection Office will provide the secretariat for the group as follows:

- Organisation of teleconferences
- Minute taking
- Coordination of correspondence

The group will virtually meet ad hoc as needed to discuss policy-driven updates. The frequency will be reviewed and adapted when necessary.

The group will meet with pharmaceutical industry stakeholders to discuss regulatory and scientific developments concerning nitrosamines (not conclusively covered in the Article 5(3) referral).

4. **Mandate**

The European Medicines Regulatory Network have agreed on a harmonised implementation of the CHMP Opinion pursuant to Article 5(3) of Regulation (EC) No 726/2004 for nitrosamine impurities in human medicines. Further details on the harmonised implementation are available at the following link. As part of this process, the EMRN have agreed the following mandate for the NIOG:

- providing non-product specific oversight of the implementation of the CHMP Article 5(3) Opinion;
- reporting progress to the EMRN in terms of MAHs' compliance with the call for review to MAHs' timelines, progress with the updating of guidance, etc;
- ensuring oversight in assessment consistency by gathering new scientific questions related to methodological aspects not captured in existing guidance, identified through escalation of queries from the CMDh, the CHMP, EMA, international partners;
- evaluating the need for updating current guidance/Q&As, or publishing new scientific guidance;
- providing support to the drafting of guidance and to the delivery of training to assessors;
- addressing any specific matter of the call for review to MAHs requiring clarification;
- providing a link with stakeholders, including initiating and maintaining a dialogue and interaction with pharmaceutical industry.

5. **Workplan**

The NIOG will operate in accordance with a workplan derived from topics raised by relevant stakeholders:

- Committees and working parties of the EMRN
- International regulatory partners (via NISG and NITWG)
- Pharmaceutical industry associations

The NIOG workplan will be supplemented with new topics raised by relevant stakeholders, should these arise.