



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nitrosamine Implementation Oversight Group (NIOG)

Means of operation and interaction

NIOG - Industry Associations Meeting

31st March 2021



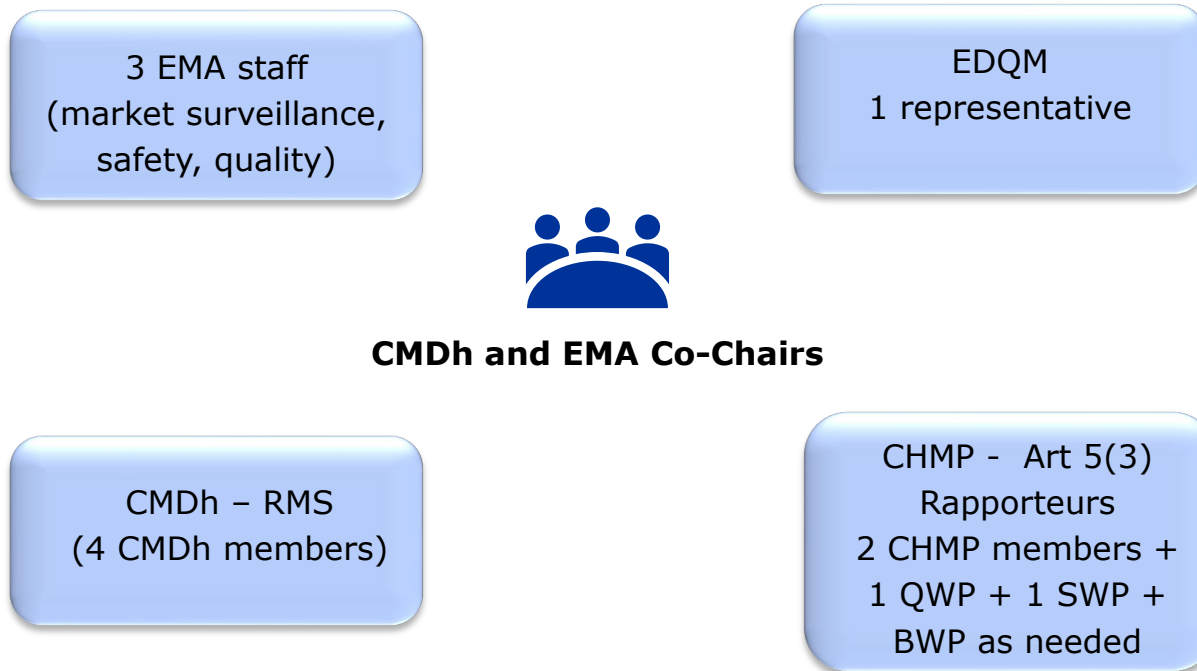


Background

- NIOG (**Nitrosamine Implementation Oversight Group**) established to oversee the implementation of the Article 5(3) CHMP Opinion and report progress to HMA and EMA MB
- Part of EMRN plan for **harmonised implementation of the Article 5 (3)** referral
- Scope: all **human medicines authorised centrally and nationally**
- **NIOG Kick Off meeting** on 10th March 2021, and will continue to meet every 2 months



NIOG Composition





Activities of the NIOG

- Provide non-product specific oversight of the implementation of Article 5(3) - reports progress to the EMRN (e.g. reviewing MAH compliance with call for review timelines, progress with guidance updates, etc)
- Ensure oversight in assessment consistency by gathering new scientific questions related to methodology not captured in existing guidance through escalation of queries from CMDh /CHMP members/EMA/Int. Partners
- Evaluate the need of updating current guidance/Q&A or publishing new scientific guidance
- Support drafting guidance and delivery of training to assessors
- Address any specific matter of the call for review requiring clarification
- Provide a link with stakeholders including dialogue and interaction with pharmaceutical industry



Ways of working





NIOG Interaction with Industry



- NIOG is an **oversight group**
- **High level interaction**, not for in-depth scientific discussions
 - Discuss priorities and topics to engage on
 - Advise on most appropriate fora to follow-up for the topics
 - Monitoring progress of ongoing discussions
 - Liaises with working parties to ensure that topics are appropriately discussed
- **Frequency**: bi-annual NIOG – industry meetings



WP Interaction with Industry

- **Specialised expert** (from WP and industry side) interactions
- In depth discussions via ***nitrosamine only interested parties*** (IP) meetings
- IPs with QWP and SWP, (separately or jointly if required by topic)
- Outcomes to be fed back to **NIOG** and international convergence will be sought
- **Frequency**: interaction will be ***topic driven***, meetings to be organised in May 2021 (follow-up if required)



Next Steps

- **Upcoming IP Meetings**
 - **SWP** - IP meeting: 25th May
 - **QWP** – IP meeting: 26th May (during QWP plenary)
 - **CMDh** - IP meeting 19th May (for outstanding procedural topics, however meeting not dedicated to nitrosamines)
- **Planned NIOG – industry** meeting September/October (**tentative**)



Any questions?

Further information

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