



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2022
EMA/171422/2022

Agenda – 3rd meeting of the Nitrosamine Implementation Oversight Group – Industry Associations

4th May 2022 – teleconference, 4PM-6PM, CET

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

Item	Final agenda	Initials	Mins
1.	Welcome and introduction	Co-Chairs	5
2.	Adoption of the agenda	Co-Chairs	5
3.	Q&A update on latest scientific developments (root causes) and testing requirement simplification	RB	25
4.	Risk of N-Nitroso-API formation <i>NIOG presentation</i> • Communication of risk <i>Industry presentation</i> • <i>What is the role of the industry associations in sharing nitrosamine risk information?</i> • <i>How does industry share information between industry members to support the call for review?</i>	RB/RW/AS Industry	20 20
5.	Update on progress of call for review step 2 and step 3 for medicines with chemical active substance	Tour de table per EU Trade organisation	30
6.	Organisation for future IP meetings with QWP and/or SWP experts on nitrosamines	MM	5
7.	Harmonised approach to post-authorisation procedures: submission of nitrosamine risk assessment	MM	5
8.	A.O.B	All	5

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