EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Highlights from the 13th meeting of the Nitrosamine Implementation Oversight Group (NIOG)

- NIOG adopted the quality and safety updates implemented in Q&A revisions, clarifying the applicable Acceptable Intake (AI) limit to different administration routes, acceptability of *in vivo* study types and the expectations for the submission of variations to shelf-life and storage conditions as needed to comply with the interim limit during CAPA implementation.
- NIOG was informed on the latest non-clinical developments with a focus on the addendum to ICH M7.
- NIOG discussed the timeframe of the applicability of the Less than lifetime (LTL) limit and recommended a case-by-case approach to the evaluation by the relevant authorities on whether potential timelines extensions (exceeding the 3-year time period from establishment and publication of the initial AI) could be granted.
- NIOG agreed on a communication reminding MAHs of their responsibilities to monitor and mitigate nitrosamines risks throughout the lifecycle of their products.
- NIOG adopted for publication a report that provides and overview of the European Medicines Regulatory Network response to the presence of nitrosamine impurities in human medicines. The report covers all activities since the discovery of nitrosamines in sartans in 2018.

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