22 January 2024
EMA/INS/GMP/30231/2024
European Medicines Agency

Highlights from the 6th meeting of the Nitrosamine Implementation Oversight Group (NIOG) industry partners (IP)

- The NIOG informed Industry stakeholders on the updated process-flow notification for establishment of acceptable intake (AI) limit for nitrosamines in human medicines following both CAPs and NAPs.
- The NIOG presented the updates to the Nitrosamine guidance since the last meeting in July 2023, as well as the planned procedural updates that will be published in the next revision of the Questions & Answers on nitrosamines in human medicines. These concern analytical methods, testing and reporting requirements for non-mutagenic nitrosamine impurities (NMI) as well as requirements for submission of results from Ames tests.
- Industry stakeholders raised questions to NIOG on implementation of Carcinogenic Potency Categorization Approach (CPCA) and enhanced Ames test (EAT) approaches, also considering the EU harmonised assessment and any differences on implementing recommendations by competent authorities at national level, enabling discussions to address the practical elements.
- In the context of a request from industry stakeholders to consider applicability of the less than lifetime (LTL) approach to new and ongoing marketing authorisation applications, industry stakeholders were requested to bring forward any examples of such applications that would benefit from this approach and informed that such discussions can happen at working party IP level. NIOG reiterated that the LTL approach is for use by NCA for authorised products when necessary to avoid shortages.
- NIOG encouraged collaboration within industry associations to share data and maximise resources for *in vivo* and *in vitro* studies supporting the toxicological profiling of nitrosamines.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union