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Highlights from the second meeting of the Nitrosamine Implementation Oversight Group (NIOG) and pharmaceutical Industry

- The NIOG and Industry stakeholders discussed the progress of the call for review recommended by CHMP article 5 (3) scientific opinion and the progress and achievements of the 2021 workplan agreed by NIOG and Industry during the first meeting in March 2021.
- Step 1 of the call for review requiring the evaluation of a potential risk of presence of nitrosamines in human chemical and biological medicinal products has now concluded. For centrally authorised products (CAPs) the response rate received was high (98% for chemical medicines and 92% for biological medicines). All products for which a potential risk of nitrosamines contamination was identified are now going through the confirmatory testing phase. This corresponds to 16% of CAPs with chemical API for which a response is expected by September 2022 and 1% of CAPs with biological API for which a response is expected by July 2023. Industry expressed concerns on possible challenges in terms of testing capacity and timelines.
- Since March 2021, the engagement and the scientific discussion between Industry and European regulators has intensified especially through dedicated meetings with the Quality Working Party (QWP) and the Safety Working Party (SWP). This allowed to progress with most of the topics included in 2021 workplan such as the policy on confirmatory testing, approach in case of presence of multiple nitrosamines, approach for dealing with dis-harmonisation of limits and facilitate reporting of the call for review. Where a position was reached, the related published guidance was updated or is in the process of being updated.
- More industry scientific data is needed in order to progress on critical topics such as the approach for mutagenicity assays, Structure-Activity Relationship studies, root cause investigations and extrapolation of Acceptable Intake limits from other substances. These topics, along with other quality, safety and multidisciplinary topics will prioritised as part of the 2022 workplan.
- More agile topic related scientific discussions between industry and regulators could be considered provided that there is sufficient relevant new information and scientific data to justify such interactions. Nitrosamines International discussions (including at ICH level) amongst Regulators and Industry stakeholders is supported from EU perspective and being explored.

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