6 December 2022
European Medicines Agency

Highlights from the 4th meeting of the Nitrosamine Implementation Oversight Group (NIOG) and Pharmaceutical Industry

30th November 2022

- NIOG and industry stakeholders discussed the 2022 NIOG workplan developments on quality, safety and procedural aspects of the nitrosamine review. In particular, the group reviewed on the recently published policy enabling the use of the temporary universal AI for managing cases where a new nitrosamine is identified and the policy currently under draft enabling the use of interim limits to be applied during CAPA implementation for known nitrosamines. Ongoing discussions on a new approach for determining AIs for nitrosamines were also mentioned.
- Industry challenges with regards to complete the call for review steps (i.e. update risk assessment, testing and remediation activities) by ensuring also continuity of product supply and public health protection were acknowledged. Nevertheless, it was recognised that the policies currently adopted are expected to minimise any risk of shortages or impact to public health.
- The need to develop further scientific knowledge specifically on nitrosamines safety aspects was noted. It is expected that current activities being taken by both regulatory authorities and industry stakeholders as part of different scientific consortia will bring more clarity on such aspects and will promote further policy developments.
- NIOG supported further interactions with industry stakeholders, also through additional scientific meetings with the Quality Working Party and the Non-clinical Working Party experts once additional scientific developments are noted. More engagement with also with international stakeholders was supported in order to ensure global alignment.

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