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

- The NIOG met to review the progress of the call for review recommended by CHMP article 5 (3) scientific opinion and the progress and achievements of the 2022 workplan agreed by NIOG and Industry during the first meeting in December 2021.
- NIOG noted that with the "call for review" entering the final steps for chemical medicines (deadline 26 September 2022), there is an increase in reporting from MAHs, together with an increase in reporting for new nitrosamines. Therefore there is a need to focus efforts of regulators where it is of most impact. A dedicated drafting group was formed and will work on a proposal to be agreed at committee level.
- NIOG noted the recent scientific developments on the root cause of formation of certain active substance related nitrosamines in the presence of trace nitrites from excipients and expressed the need to rapidly share information with all MAHs. An updated question and answer on root causes to more clearly highlight this risk was supported.
- NIOG further discussed the engagement and collaboration with International authorities for quality and safety related topics and supported working closer with International Partners for setting AI limits for substances of common interest.

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