

30th September 2021 EMA/INS/512114/2021

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

- The NIOG discussed the QWP and SWP nitrosamine expert groups developments on the workplan topics following the IP meetings in May 2021. NIOG agreed to the proposals for update to nitrosamine guidance proposed by QWP and its nitrosamine expert groups.
- The group was informed of submissions received for the call for review to MAHs of chemical and biological human medicinal products following the deadline to step 1 phase for biological products in July 2021.
- NIOG discussed and reviewed progress on topics in the NIOG workplan.
- NIOG took note of topics of common interest with international partner regulatory authorities discussed at the Nitrosamines International Strategic Group (NISG) as well as the Nitrosamine International Technical Working Group (NITWG).
- The next NIOG meeting is expected to take place in November 2021, with date to be confirmed.

