EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25th June 2021
EMA/INS/GMP/324282/2021

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

- The NIOG took note of CHMP decision on the PKWP question concerning the use of Rifampicin with nitrosamine impurities in healthy patients as part of clinical drug-drug interaction trials. The CHMP agreed to the NIOG position that rifampicin with nitrosamines above the Acceptable Intake (AI) should not to be used in healthy volunteers. The CHMP decision has been published in the CHMP minutes at the following link.
- NIOG was informed of the discussions on scientific progress as presented at the QWP and SWP Industry Party (IP) meetings organised on 26th and 31st May, respectively.

  The NIOG will continue monitor the scientific progress on topics discussed at the SWP and QWP expert groups and will discuss any proposals for updating guidance, as necessary.
- NIOG took note of the progress on the call for review to MAHs concerning the risk of nitrosamine impurities in human medicinal products, CAPs and NAPs, as per the Article 5(3) scientific opinion.
- NIOG discussed and reviewed new topics and priorities recently added to the workplan at the proposal of industry and EU regulatory network authorities.
- NIOG noted the ongoing topics and developments concerning nitrosamines as discussed with partner international regulatory authorities 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 September 2021.

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