

8 September 2022 EMA/735626/2022 European Medicines Agency

## Highlights from the 8<sup>th</sup> meeting of the Nitrosamine Implementation Oversight Group (NIOG)

- NIOG reviewed the scientific gaps on quality and safety/toxicological aspects and agreed on the need to also survey international authorities and industry interested parties.
- NIOG discussed approaches to manage cases of products with nitrosamines during the implementation of the corrective actions by companies in order to balance patient safety and availability of medicines.

NIOG noted the upcoming meetings of the Quality Working Party and the Non Clinical Working Party with Industry Stakeholders and expected topics to be discussed. The NIOG also discussed the topics that may be raised during the next meeting between the group and interested parties currently being planned.

