3 March 2020
EMA/105779/2020

Update on nitrosamines in EU medicines

EU and national authorities are continuing their work to prevent and manage the presence of nitrosamine impurities in EU medicines.

Nitrosamines are classified as probable human carcinogens (substances that could cause cancer) based on animal studies. They are present in some foods and water supplies and are not expected to cause harm when ingested at very low levels. In the few medicines where they have been found, the risk to patients is expected to be low.

A review by EMA's human medicines committee (CHMP) is currently considering evidence on how a nitrosamine called *N*-nitrosodimethylamine (NDMA) came to be present in some batches of ranitidine (a medicine for heartburn and stomach ulcer).

In addition, EMA and national authorities are assessing the impact of recent tests which found NDMA in some EU batches of metformin medicines, used for diabetes.

Further results from tests on metformin in the EU are being awaited. In line with previous advice, patients should continue taking their metformin medicines as usual. The risk from not having adequate diabetes treatment far outweighs possible risks from low levels of nitrosamines.

As metformin is considered a critical medicine, EMA and national authorities are cooperating closely to avoid possible shortages so patients can continue to get the treatments they need.

An ongoing procedure aimed at providing guidance to companies on how to deal with nitrosamines in medicines is currently gathering evidence and considering opinions from leading experts in the EU. As a result of this procedure, which began in September 2019, measures to evaluate and mitigate the risk of nitrosamines are being implemented across the EU.

Authorities in the EU are also conducting an exercise to determine what lessons can be learnt from the presence of nitrosamines in sartans, which came to light in mid-2018. The lesson learnt group is currently finalising recommendations to prevent and better manage the presence of impurities in the future.

EMA will continue working closely with national authorities, EDQM[1] and international partners and will take all necessary measures to protect the quality of medicines in the EU.

[1] The European Directorate for the Quality of Medicines and HealthCare

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