23 June 2020
EMA/303870/2020

European regulators make recommendations drawing on lessons learnt from presence of nitrosamines in sartan medicines

The European medicines regulatory network[1] has issued recommendations on impurities in medicines following the conclusion of an exercise to draw on lessons learnt from the presence of nitrosamines in a class of blood pressure medicines known as sartans.

The recommendations aim to clarify the roles and responsibilities of companies involved in the manufacture of medicines and to amend guidance on controlling impurities and good manufacturing practice. The recommendations also cover the management of impurities once detected, communication with patients and healthcare professionals, and international cooperation. The full recommendations are available on EMA's website.

The network noted that nitrosamines were not previously recognised as potential impurities in sartan medicines, and these recommendations will help both regulators and companies better prevent and mitigate the risks of these and other impurities in the future.

Nitrosamines are classified as probable human carcinogens (substances that could cause cancer) based on animal studies.

Regulators in the EU first became aware that they were present in some sartan medicines in mid-2018. The discovery led to swift regulatory action, including the recall of medicines and measures to stop the use of active substances from certain manufacturers. A subsequent EU review, which concluded in April 2019, established the sources of nitrosamines and set out new manufacturing requirements for sartans.

Although the exercise focused on nitrosamines in sartans, the recommendations will help reduce the risk of impurities being present in other medicines and ensure that regulators are better prepared to manage cases of unexpected impurities in the future.

In September 2019, EMA launched an Article 5(3) procedure to provide additional guidance to companies that make and market medicines in the EU. The recommendations of the lessons learnt exercise will complement the outcome of this Art 5(3) procedure which will provide the key scientific opinion on the presence of nitrosamine impurities in human medicines containing chemically synthesised active substances.

[1] The network comprises the European Commission, the European Medicines Agency, national competent authorities in the European Economic Area and the European Directorate for the Quality of Medicines & HealthCare.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Reviewing practices on the basis of experience is one of the ways the authorities in the EU ensure that medicines in the EU are of the highest quality. EU authorities will continue working closely with the European Directorate for the Quality of Medicines & HealthCare and international partners and will take necessary measures to protect and reassure patients.