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EMA review of impurities in sartan medicines

The European Medicines Agency (EMA) is reviewing the blood pressure medicines candesartan, irbesartan, losartan, olmesartan and valsartan in relation to impurities found in some batches of these medicines.

The impurities are N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA). Both NDEA and NDMA belong to the class of nitrosamines and are classified as probable human carcinogens (substances that could cause cancer) based on animal studies.

The review will evaluate the root cause for the presence of these impurities, their possible impact on patients and what measures can be taken to reduce or eliminate these impurities from future batches.

Some medicines covered by this review are no longer available in the EU. Medicines containing valsartan made by Zhejiang Huahai in China have been recalled by national authorities. Medicines containing valsartan from another company Zhejiang Tianyu are no longer being distributed in the EU.

EMA has published preliminary risk estimates for patients who took affected valsartan medicines containing NDMA. Further risk estimates will be made available as the review progresses.

Although the review initially was focused on valsartan medicines, it was expanded as a precautionary measure to include other 'sartan' medicines with a similar chemical structure in September 2018 following the detection of very low levels of NDEA in some batches of losartan.

EMA will provide regular updates on its website.

More about the medicine

Candesartan, irbesartan, losartan, olmesartan and valsartan belong to a class of medicines known as angiotensin-II-receptor antagonists (also known as sartans).

The medicines are used to treat patients with hypertension (high blood pressure) and those with heart failure or who have had a recent heart attack. They work by blocking the action of angiotensin II, a hormone that constricts blood vessels and causes blood pressure to rise.

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More about the procedure

The review of valsartan medicines was triggered by the European Commission on 5 July 2018 under Article 31 of Directive 2001/83/EC. On 20 September 2018, the review was extended to include medicines containing candesartan, irbesartan, losartan and olmesartan.

The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.