Update on review of valsartan medicines due to detection of NDMA

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EMA reviewing valsartan produced by another company Zhejiang Tianyu

As part of the ongoing review of valsartan medicines, EMA has learnt that low levels of N-nitrosodimethylamine (NDMA) have been detected in the valsartan active substance manufactured by a second company, Zhejiang Tianyu.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

The NDMA levels detected in batches of valsartan from Zhejiang Tianyu are much lower than levels seen in the active substance from Zhejiang Huahai, which triggered a recall of several valsartan medicines in July 2018.

EMA is working closely with international partners to review the impact of the NDMA detected in valsartan from Zhejiang Tianyu and will communicate as soon as additional information becomes available.

There is no immediate risk to patients. Patients should not stop taking any valsartan medicines without consulting their doctor or pharmacist.

A list of medicines containing valsartan from Zhejiang Tianyu will be available from national medicines authorities.

More about the medicine

Valsartan is an angiotensin-II-receptor antagonist used to treat hypertension (high blood pressure), recent heart attack and heart failure. It is available on its own or in combination with other active substances.

Medicines containing valsartan as the only active substance have been authorised in the EU via national authorities. Nine products containing valsartan in combination with other active substances have been authorised centrally.

More about the procedure

The review of valsartan medicines in relation to the presence of NDMA in the active substance was triggered by the European Commission on 5 July 2018 under Article 31 of Directive 2001/83/EC.

The review is being carried out by the 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.