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Update on review of valsartan medicines following detection of impurity in active substance

Assessing potential impact on patients is priority

EMA's review of valsartan medicines in relation to an impurity found in the valsartan active substance manufactured by Zhejiang Huahai Pharmaceuticals is now underway.

The impurity – N-nitrosodimethylamine (NDMA) – is classified as a probable human carcinogen which, based on results from laboratory tests, may cause cancer with long-term use.

Over the past two weeks, national medicines authorities have been recalling medicines containing valsartan from Zhejiang Huahai, and these medicines should no longer be available in pharmacies across the EU.

While further assessment is needed, there is no immediate risk and patients taking valsartan are advised not to stop their treatments unless they have been advised to do so by their pharmacist or doctor. Healthcare professionals should follow specific advice from national authorities concerning medicines in their country.

It is still too early to provide information on the longer term risk NDMA may have posed for patients. EMA has made this aspect of the review a priority and will update the public as soon as new information becomes available.

EMA will consult toxicology experts to better understand the impact that use of medicines containing the NDMA impurity may have on patients. The review will also seek to establish how long and at what levels patients might have been exposed to NDMA.

NDMA is an unexpected impurity that was not detected by routine tests carried out by Zhejiang Huahai. EMA is now gathering details of the company's manufacturing processes, following changes introduced in 2012 that are believed to have produced NDMA as a side product.

EMA is also working closely with national authorities to evaluate whether other medicines containing valsartan (other than those being recalled) could also contain the same impurity.

Further information about the review of valsartan, including the questions being addressed to companies, is available on EMA's website.

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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.

The review covers all medicines that contain valsartan supplied by Zhejiang Huahai Pharmaceuticals. As a precaution, the review will also consider whether other valsartan medicines may be affected.

More about the procedure

The review of valsartan medicines in relation to NDMA found in the active substance from Zhejiang Huahai Pharmaceuticals was triggered by the European Commission on 5 July 2018 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.