Update on medicines containing valsartan from Zhejiang Tianyu

20/08/2018

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Company no longer authorised to manufacture valsartan active substance for EU medicines due to presence of NDMA

The company Zhejiang Tianyu is no longer authorised to manufacture the valsartan active substance for EU medicines following the suspension of its CEP – a certificate verifying that the quality of its valsartan meets European requirements.

The suspension of the certificate by the European Directorate for the Quality of Medicines and Healthcare (EDQM) comes after the detection of low levels of N-nitrosodimethylamine (NDMA) in the valsartan produced by the Chinese company.

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

The levels of NDMA found so far in batches of valsartan from Zhejiang Tianyu are considerably lower than levels found in the active substance from Zhejiang Huahai, which triggered a recall of several valsartan medicines in July 2018. The certificate for Zhejiang Huahai had already been suspended and the company is also not permitted to supply valsartan active substance to the EU.

National medicines authorities are currently taking appropriate actions in their countries. Actions being taken, which are precautionary, include recalling and stopping the distribution of medicines containing valsartan from Zhejiang Tianyu. For further information, contact the relevant national authorities.

EMA's review of valsartan in relation to NDMA is continuing and the Agency is working closely with the EDQM, international partners and national authorities in the EU.

The EDQM is a Directorate of the Council of Europe created in 1964 which sets standards for the quality of medicines and their active substances in European countries.

EDQM is in charge of issuing CEPs, which manufacturers can use to demonstrate that the quality of their active substance is suitably controlled and complies with European regulatory requirements. More information about the procedure for issuing CEPs is available on the EDQM website.

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.