

## **To the attention of interested persons**

The National Agency for Medicines and Medical Devices has requested precautionary recall from the Romanian market of all medicinal products containing valsartan manufactured by the Zhejiang Huahai Pharmaceuticals manufacturers in China, pursuant to recent identification of impurities introduced by the active substance manufacturing process.

The active substance manufactured by this Chinese company has been used by several medicinal product manufacturers and similar recalls are ongoing on EU level as well.

The following are currently recalled from pharmacies in Romania:

- VALSARTAN ZENTIVA 80mg film-coated tablets
- VALSARTAN ZENTIVA 160mg film-coated tablets
- VALSARTAN TORRENT 80 mg, film-coated tablets
- VALSARTAN TORRENT 160 mg, film-coated tablets
- VALSARTAN HIDROCLOROTIAZIDA TORRENT 160mg/12,5mg, film-coated tablets
- VALSARTAN HIDROCLOROTIAZIDA TORRENT 80mg/12,5mg, film-coated tablets

Valsartan containing medicinal products are dispensed based on prescription and they are used for high blood pressure control as well as by patients with recent heart attack.

Patients using medicinal products currently included in the recall should not stop their treatment and should advise with their pharmacist or doctor.

At present, there is no proof of the impurity affecting patients but recall of respective products is a precautionary measure pending completion of investigations.

The European Medicines Agency (EMA) and national competent human medicinal product authorities are working together to investigate the possible presence of the impurity in other valsartan containing medicinal products and its potential impact on patients.