OFFICE OF THE DEPUTY PRIME MINISTER
MINISTRY FOR HEALTH

6th July 2018

Dear Pharmacist,

The Superintendence of Public Health wishes to advise you of a situation that is evolving in all EU Member States regarding a number of valsartan-containing products. This is an emerging issue across Europe which is being closely monitored.

An impurity has been identified in the active substance valsartan, which is used in the manufacture of a number of products. This impurity is N-nitrosodimethylamine (NDMA) and has been classified as a possible human carcinogen. The active substance manufacturer, Zhejiang Huahai Pharmaceuticals, located in China, has reported that the impurity is linked to changes in the manufacturing process. There is currently no evidence that this impurity has caused any harm to patients. However, as a precautionary measure and to prevent further exposure, the local authorities are following closely the situation, through communication with the European Medicines Agency and pharmaceutical companies.

Patients should be advised not to stop taking their valsartan-containing medicines abruptly as the health risk of discontinuing this medicine is high.

We will keep you updated as the situation evolves.

Yours' truly,

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