HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Product Recall

A number of Valsartan-containing Film Coated Tablet Products See Appendix 1 for the Product List

July 5th, 2018

Dear Pharmacist,

The Health Products Regulatory Authority (HPRA) wishes to advise you that the batches of valsartan-containing film coated tablet products listed in Appendix 1 are being recalled with immediate effect.

This is a precautionary recall action and is being conducted to pharmacy level. Note that specific advice in relation to this issue is also being given by the HPRA to patients (see below for details).

Not all valsartan-containing medicines are affected by the recall. There are alternative valsartan-containing medicines and other treatments available to patients. Switching existing patients to alternative valsartan-containing medicines which are not on the list in Appendix 1 should be feasible at present, given current stocks. However, the situation may change and prescribers may have to consider other treatment options for patients requiring such medicines.

The reason for the recall is as follows:

- An impurity has been identified in the valsartan active substance used in the listed medicinal products; this impurity is N-nitrosodimethylamine (NDMA) and it has been classified as a probable human carcinogen. At present there is no evidence that this impurity has caused any harm to patients; however, this recall action is being undertaken as a precautionary measure to prevent any further exposure to the impurity in the affected medicines whilst the investigation is ongoing.

- The active substance manufacturer, Zhejiang Huahai Pharmaceuticals, located in China, has reported that the impurity is linked to changes made to the manufacturing process.

This is an emerging issue. At present, the risk is theoretical and there is no direct evidence of harm having been caused by this impurity. The HPRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact on patients who have been taking these medicines. In this regard, work is currently ongoing at a European level to better understand the potential impact of this impurity, and as a precautionary measure at this time, this recall is being undertaken.

Please perform the following actions:

1. Immediately quarantine any units from the batches / products listed in Appendix 1 which you have in your pharmacy. For hospital pharmacies, this includes wards, clinics and any other relevant locations within your hospital.

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