HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Advance Notice for Pharmacists

Additional precautionary recall of Valsartan products tomorrow, 11 July 2018

These are Parallel Imported versions of Diovan & Co-Diovan Film Coated Tablets

10 July 2018

Dear Pharmacist,

The Health Products Regulatory Authority (HPRA) wishes to advise you that, as part of our ongoing investigation into the current valsartan impurity issue, additional valsartan-containing products are being recalled as a precautionary measure. This is because additional products have been identified as containing the valsartan active substance manufactured by the company Zhejiang Huahai Pharmaceuticals in China.

These additional products are all in-date batches of various strengths of parallel imported products which are labelled as Diovan and Co-Diovan Film Coated Tablets.

Important Note: The Diovan and Co-Diovan Film Coated Tablet products marketed by Novartis are not affected by this issue and **do not** need to be recalled. Only the Diovan and Co-Diovan products bearing PPA numbers (Parallel Product Authorisations) on their packaging are being recalled. As a result, the volume of packs that will be recalled on this occasion is significantly lower than in the earlier recall of 5 July 2018.

The approach to managing this second phase of the recall has been discussed with the PSI and IPU.

- The recall will start tomorrow, 11 July 2018.
- This is a targeted recall - only those pharmacies that received stock of the affected products from the parallel importer companies **Eurodrug/Imbat, IMED Healthcare and PCO** are directly impacted by this recall action. Therefore, only those pharmacies will receive the recall letter.
- The recall letters stating the exact product names will be emailed to all impacted pharmacies by the three parallel importer companies tomorrow. Printed copies of the letters will also be sent by post.
- All three recall letters will also be uploaded to the HPRA website, at www.hpra.ie/valsartan, tomorrow at 2:30pm, and for ease of reference, there will also be a complete table uploaded to the website at the same time which will contain all of the product details across all three companies.
- Pharmacists who have purchased or hold parallel imported Diovan and Co-Diovan Film Coated Tablet products should check the HPRA website as a matter of importance tomorrow afternoon.

This recall action will be different to the recall action of 5 July 2018 in several ways.

- Not all pharmacies will have stock to be recalled. This is because not all pharmacies will have received stock from the three parallel importer companies Eurodrug/Imbat, IMED and PCO.
- The volume of packs to be recalled here is significantly lower than in the earlier recall.
- Only those pharmacies that received stock of the affected products from Eurodrug/Imbat, IMED and PCO will receive the recall letters from those companies via email and post.

What pharmacists will be asked to do in the recall letters tomorrow:

1. How the recall is discussed with patients may not be straightforward, as patients may not be able to easily distinguish between a parallel imported pack and a non-parallel imported pack.

2. Pharmacies that receive the recall letters from any of the three companies above should, in addition to quarantining and returning any stock of the affected products, start to proactively identify patients to whom they dispensed any of the listed products since 1 January 2018. (It is not likely that any packs dispensed before 1 January 2018 will still be at patient level.)

3. The recall letters will ask pharmacists to contact each patient or their carer to check if the patient still has any of the product impacted by the precautionary recall. If they do, the patient should not stop taking their medicine but should return to their pharmacy with their medicine at an early opportunity, so that the pharmacist can confirm if it is one of the affected products or not. The health risk of abruptly discontinuing this medicine is higher than any potential risk presented by the impurity identified in the active substance.

4. In the event that a pharmacist can definitively determine that a patient does not have one of the concerned products, based on the information supplied by the patient or their carer, then there will be no need for the patient to come back to the pharmacy to have their medicine checked.

5. If a patient brings back one of the affected products, the pharmacist should take it back and dispense an alternative unaffected valsartan-containing medicine to the patient.

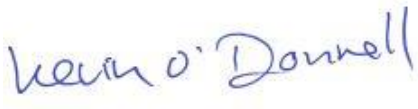
6. In the unlikely event that unaffected valsartan-containing products are not readily available to a pharmacy, the pharmacist should advise the patient to see their doctor at an early opportunity to discuss alternative medicines. Again, it is important to stress that they should not stop taking their medicine in the meantime.

As noted above, information will be published on the HPRA website in relation to this recall tomorrow afternoon, 11 July 2018. This will advise patients that if they have a medicine potentially affected by this second recall, their pharmacist will contact them to discuss the issue but that they should not stop taking their medicine in the meantime.

This continues to be an emerging issue and the HPRA is actively involved with the European Medicines Agency and with other medicines regulators to resolve this issue.

We will keep you informed as the situation evolves.

Yours sincerely,



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