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Product Recall

Parallel imported Co-Diovan 80mg/12.5mg Film-coated Tablets, Co-Diovan 160mg/12.5mg Film-coated Tablets & Co-Diovan 160mg/25mg Film-coated Tablets which have been Parallel Imported by IMED Healthcare Ltd

Product Name	PPA Number	Marketing Authorisation Holder Name	Batch Numbers
Co-Diovan 80mg/12.5mg Film-coated Tablets	PPA1463/043/001	**IMED Healthcare Ltd**	All in-date batches
Co-Diovan 160mg/12.5mg Film-coated Tablets	PPA1463/043/002	**IMED Healthcare Ltd**	All in-date batches
Co-Diovan 160mg/25mg Film-coated Tablets	PPA1463/043/003	**IMED Healthcare Ltd**	All in-date batches

July 11th, 2018

Dear Pharmacist,

We wish to advise that the above valsartan-containing products parallel imported by IMED Healthcare Ltd. are being recalled with immediate effect.

Please note that Co-Diovan 80mg/12.5mg Film-coated Tablets, Co-Diovan 160mg/12.5mg Film-coated Tablets and Co-Diovan 160mg/25mg Film-coated Tablets marketed by Novartis are not affected by the impurity issue and are therefore not included in this recall action.

The reason for the recall is as follows:

- An impurity has been identified in the valsartan active substance used in the above 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.

Pharmacists are requested to perform specific actions in relation to contacting patients - see below for details.

This continues to be an emerging issue and the HPRA is actively involved with the European Medicines Agency and with other medicines regulators to manage this issue. At present, the risk is theoretical and there is no direct evidence of harm having been caused by this impurity.

Our records show that your pharmacy was supplied units of one or more of the above products and, on that basis, we kindly request that you perform the following actions:

1. Immediately quarantine any units from the above products which you have in your pharmacy.
2. Please contact IMED Healthcare Ltd on 1 800 864 864 / 01 880 9180 to arrange return of the quarantined units within the next 7 days. Credit will be arranged at that time.

As noted above, patients do need to be contacted by their pharmacist in relation to this recall action. We request that you also perform the following actions:

3. Please check your dispensing records to identify patients to whom any packs of the above parallel imported products were dispensed since **1 January 2018.** (It is not likely that any packs dispensed before 1 January 2018 will still be at patient level.)

4. If any patients are identified during this check, please do the following:

    a. Please contact the patient or their carer to check if they still have any IMED Healthcare Ltd product impacted by the precautionary recall. If they do, please advise that 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. They should be advised that the health risk of abruptly discontinuing this medicine is higher than any potential risk presented by the impurity identified in the active substance.
    b. In the event that you 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 is no need for the patient to come back to your pharmacy to have their medicine checked.
    c. If a patient brings back one of the affected products, please take it back and dispense an alternative unaffected valsartan-containing medicine to the patient.
    d. In the unlikely event that unaffected valsartan-containing products are not readily available to your pharmacy, please 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.

If you have supplied units of the above products to another pharmacy or clinic, please forward a copy of this letter to them so that they can perform the requested actions.

Further information on this issue is available on the HPRA website, at www.hpra.ie, and this is being updated as the HPRA's investigation continues.

Should you have any queries in relation to the recall, please contact me using the contact details below.

Yours sincerely,

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