Patients to check if they have prescription-only medicines being recalled

The medicines are believed to be legitimate but were taken out of the regulated medicines' supply chain during distribution and later re-introduced. This means that the correct transport and storage conditions cannot be guaranteed during this period and, while unlikely, could impact their effectiveness.

The medicines are stable at room temperature and there is no evidence that they were tampered with. This means that the risk of these medicines not being fully effective is greatly reduced or negligible. Therefore patients should continue taking their medicine.

Patients can check their medicines by looking for the affected batch numbers on B & S Healthcare labelled packs. The affected medicines are in the original Italian packaging with the UK manufacturer's, B & S Healthcare, label. This recall relates only to B & S Healthcare labelled products.

The Medicines and Healthcare products Regulatory Agency (MHRA) has undertaken a medical assessment of the products to determine whether there is any risk to patients. As a precautionary measure, three medicines are being recalled to a patient level because in the very unlikely event that these products are not fully effective there is a potential risk to patient safety. For these three particular medicines, whilst the likelihood of their effectiveness being compromised is low (because they are stable legitimate medicines), the consequences of a lack of effectiveness could be serious which is why they are being recalled from patients.

If patients have any of these affected products, they should continue taking their medicines and contact their GP practice to arrange a new prescription. Once they have a new prescription, patients should return the affected batches to their pharmacist.

As a precaution, other affected medicines are also being recalled at pharmacy level. Again, patients should continue taking their medicines. If they have any of these affected products, they do not need to arrange a new prescription, but if they have any questions they should speak to their GP or healthcare professional. These medicines are for chronic obstructive pulmonary disease (COPD) (Spiriva Inhalation Powder, Incruse Inhaler, Seebri Breezhaler), psoriasis (Dovobet Gel), and high cholesterol (Provisacor (Crestor)).

B & S Healthcare is carrying out a recall and the UK's medicines regulator, the MHRA, has today issued an alert to pharmacies.

Pharmacies should check for the affected packs in B & S Healthcare labelling,

quarantine and return them to their supplier.

Dr Samantha Atkinson, Director of the MHRA's Inspection, Enforcement and Standards Division, said:

> Making sure the medicines people and their families take are acceptably safe and effective is the primary role of the MHRA and is our highest priority.
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> When we are made aware of potential risks to the security of the supply chain, the MHRA takes action to protect the public.
>
> We continuously strive to ensure the UK's regulated supply chain remains one of the safest in the world.

The recall is taking place as part of an ongoing MHRA investigation.

1. Read the FMD Alert in full on our website.

2. The medicines were parallel imported into the UK by B & S Healthcare from Italy and have been re-labelled in B & S Healthcare labelling. The same batches of products may have been parallel imported legitimately into the UK by other importers. Only those packs in B & S Healthcare labelling are affected by the recall.

3. In the UK, the parallel import licensing scheme allows medicines licensed in another EU Member State to be sold in the UK, as long as the imported product has no therapeutic difference from the same UK product, and as long as the parallel importer is appropriately licensed by the MHRA.

4. The MHRA works with industry and other regulators around the world to track down and prosecute criminals who endanger public safety by selling medicines illegally. In the year 2018/19 we had eight successful prosecutions, with 17 defendants convicted and sentenced, often to terms of imprisonment. We have also obtained confiscation orders worth over £450,000.

5. The MHRA is responsible for regulating all medicines and medical devices in the UK. Underpinning all our work lies robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care (DHSC).