New restrictions on exports to tackle HRT shortages

The government has confirmed new restrictions on the export of all variations of HRT products, some of which currently face supply shortages due to manufacturing issues.

The restrictions will stop some medicine wholesalers from 'parallel exporting'. This is when companies buy medicines meant for UK patients and sell them on for a higher price in another country, potentially causing supply problems.

Around 360,000 prescriptions of HRT are dispensed a month to relieve symptoms of the menopause. Currently, some HRT drugs are being parallel exported. The new restrictions will end this practice to ensure people can still access the medicines they need.

Nineteen HRT drugs will be subject to export restrictions to ensure that alternatives remain available for the HRT drugs that are in short supply. Similar measures are in place in other European countries, including France and Spain.

New restrictions for a further 5 medicines, including all adrenaline autoinjectors and hepatitis B vaccines, have also come into force to protect supplies of these products for patients.

A full list of the medicines that cannot be parallel exported from the UK has been published.

The Department of Health and Social Care (DHSC) has been working closely with affected suppliers to monitor the situation and reduce the potential impact on patients. The new measures will further reduce the impact on patients.

DHSC has written to holders of wholesale dealer licences to tell them that the government will exercise its powers to stop parallel exporting of medicines that are needed for UK patients.

Companies that parallel export a medicine that is on the list may face action from the Medicines and Healthcare products Regulatory Agency (MHRA).

The government has also introduced serious shortage protocols for the antidepressant fluoxetine, to further protect UK patients from medicine shortages. This means pharmacists can supply an alternative strength or pharmaceutical form of fluoxetine when patients have a prescription for the 10mg, 30mg and 40mg capsules, which are currently in shortage.

The serious shortage protocol will be in place while manufacturing issues mean the drug is temporarily in short supply, to ease pressure on the supply chain.

Serious shortage protocols are drawn up with senior, specialist doctors and pharmacists and are approved by national experts, including the Chief Pharmaceutical Officer and the National Medical Director at NHS England.

Medicine shortages do occasionally occur in the UK. DHSC has existing, well-established processes to deal with and resolve shortages. The new parallel export restrictions and serious shortage protocol will support this approach.

The medicine supply chain is complex and highly regulated, so problems can arise for a variety of reasons, including manufacturing issues or problems with raw ingredients.

Health and Social Care Secretary Matt Hancock said:

I know how distressing medicine shortages can be for those who rely on drugs like HRT and it's absolutely crucial patients can always access safe and effective treatments through the NHS.

The new measures we're introducing today will help us ensure patients get the medicines they need and the high-quality care they deserve.

Helping the NHS is a priority for this government, and people should be fully reassured that we will always act to ensure that there is an adequate supply of the medicine you need.

Dr Rick Greville, Director of Supply Chain at the Association of the British Pharmaceutical Industry, said:

The decision to take precautionary measures to protect medicines supplies will be very much welcomed by our members.

It means that these stockpiles of medicines which companies have built over previous months are better protected and available for use only by the NHS patients for which they were intended.

Companies can now work with the department to identify any problem areas.