



To: holders of a wholesale dealer licence

3 October 2019

Dear licence holder,

Re: Restrictions on parallel export and 'hoarding' of medicines under regulation 43(2) of the Human Medicines Regulations 2012

The Department of Health and Social Care (DHSC) is writing to all holders of wholesale dealer licences to remind them of their obligations under regulation 43(2) of the Human Medicines Regulations 2012 to ensure the continued supply of medicinal products so that the needs of patients in the UK are met. It is important that patients get the medicines they need and that medicines are not diverted to other countries or hoarded (held back) when they are needed to treat patients in the UK. We are asking all licence holders to review their business procedures against their legal obligations.

In order to assist with this, we have today published a list of medicines that are needed to meet the needs of UK patients and therefore cannot be supplied for parallel export or parallel distribution from the UK. This letter explains those restrictions and provides guidance on the obligations of licence holders under regulation 43(2) of the Human Medicines Regulations 2012 in relation to the parallel export of medicines as well as hoarding medicines.

Parallel export of medicines

Parallel export is the practice of buying medicines already placed on the market in the UK in order to sell them in another country in the European Economic Area (EEA) where they are repackaged and relabelled in accordance with the requirements of the importing country. Anyone holding a wholesale dealer licence can parallel export a medicine but in practice parallel export is undertaken by a small group of licence holders. Sometimes the parallel export of a medicine can lead to or exacerbate supply shortages in the exporting country. Shortages of medicines can pose serious risks to patients and lead to increased difficulty of sourcing medicines and mitigating risks to patients.

Several EU member states have implemented measures to prevent the parallel export of specific medicines where this is necessary to meet the needs of patients in their country. Those measures are based on Article 81 of EU Directive 2001/83/EC which has been transposed into UK legislation in relation to wholesale dealers at regulation 43(2) of the Human Medicines Regulations 2012. This places an obligation on wholesalers to ensure, within the limits of the licence holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met. Pursuant to regulation 42(1) of the Human Medicine Regulations 2012, this has effect as a provision of the wholesale dealer licence and applies equally to the holder of a manufacturer licence under regulation 39(8) of the Human Medicines Regulations 2012.

Criteria for restricting the parallel export of a medicine

In order to ensure the continuity of supply to patients in the UK, a list of medicines that cannot be parallel exported has been published on <https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk>. A medicine will only be included on this list if the following criteria are met:

- a) the medicine is required to meet the needs of UK patients;
- b) the medicine is either being parallel exported or is at threat of being parallel exported; and
- c) the export of that medicine is either contributing to, or may contribute to, a shortage of that medicine in the UK.

It will be for the Secretary of State for Health and Social Care to decide whether a medicine meets the criteria outlined above and the list of medicines that cannot be parallel exported will be reviewed and updated on an ongoing basis. When a medicine no longer meets the criteria, it will be removed from the list.

Breach of the conditions of the wholesale dealer licence

It is up to the licence holder to consult the list of medicines published on <https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk> before supplying a medicine for parallel export. The restrictions apply from midnight at the start of the day after the medicine is added to the list. Any sales for parallel export that take place after that will be considered a breach of regulation 43(2) of the Human Medicines Regulations 2012. However, if a final agreed purchase order has been received from an importer abroad before the restriction applies, then the medicine can still be supplied.

A breach of regulation 43(2) may lead to regulatory action by the Medicines and Healthcare products Regulatory Agency (MHRA). This could include (i) an immediate suspension of the licence or suspension of the supply of certain products under the licence and/or (ii) a 28-day notice proposing to vary the licence to restrict or prevent export activity as necessary. Any continuation of the offending activity would constitute a criminal offence under regulation 34(1), read together with regulation 18(1), of the Human Medicines Regulations 2012.

'Hoarding' of medicines

DHSC is also aware of instances where holders of a wholesale dealer licence have been holding back stock of a medicine when that medicine has been in short supply. For the avoidance of doubt, this is also considered to be a failure to ensure the continued supply of medicinal products so that the needs of UK patients are met in breach of regulation 43(2) of the Human Medicines Regulations 2012. Any stocks of medicines included in the parallel export restriction may therefore also not be withheld or 'hoarded' and doing so may similarly lead to regulatory action being taken as outlined in the previous paragraph.

Further queries

A Q&A document is attached to this letter and the list of medicines that cannot be parallel exported can be found on <https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk>. Any queries can be directed to parallelexports@dhsc.gov.uk.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'S.O.', with a horizontal line underneath.

Steve Oldfield

Chief Commercial Officer
Department of Health and Social Care (DHSC)