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11th February 2021

Circular 004/21

Re: Sourcing Exempt Medicinal Products from the United Kingdom*

Dear Pharmacist,

As you are aware, the United Kingdom (UK) has left the European Union (EU). Since 1st January 2021, the UK* is formally a third country and is outside the European Economic Area (EEA). This communication relates to the sourcing of Exempt Medicinal Products (EMPs) from the UK*, in light of its status as a third country.

You will be aware of the legislative provisions in supplying an EMP, i.e. that it must be supplied in response to an unsolicited bona fide request from a Practitioner.[1] Pharmacists are also reminded of the arrangements for the supply of EMPs under the GMS and Community Drugs Schemes. I refer to the PCRS handbook for Pharmacists in this regard (Section 4.3).

EMPs sourced from third countries, including the UK*, need to be sourced through an "authorised operator" (i.e., holder of a manufacturer and import authorisation or a wholesaler distribution authorisation located in the EU/EEA). An authorised operator has a legal obligation to perform certain checks on products they intend to source from a third country supplier and retain records of those sourced and supplied. The checks aim to verify that the proposed supplier of the product is authorised to make that supply, and that the Good Distribution Practice (GDP) requirements pertaining to that supply will be/were met. These checks also help to maintain the security of the supply chain for Irish patients. Authorised operators are also legally required to notify the receipt of EMPs to the notification system operated by the Health Products Regulatory Authority (HPRA). This provides the HPRA a means to identify EMPs in Ireland that may be the subject of a quality defect, recall or a safety issue. In order to facilitate the continued access to EMPs, legislative changes have been made to increase the number of authorised operators eligible to import EMPs from a third country, to include wholesale distributors.

In the interest of maintaining continuity of care for patients, careful management of the sourcing of EMPs is important. In light of the recently changed status of the UK* to a third country, Pharmacists should be aware that the timelines for receiving EMPs sourced from the UK* may vary across the authorised operators that they use. In the event that a Pharmacist has concerns in relation to the expected timeline for receiving an EMP through an authorised operator, consideration should be given to sourcing the EMP through an alternative authorised operator who may be in a position to source the requested EMP within a shorter timeline.

If you have any queries in relation to this information, please email PCRS.ExemptMed@hse.ie.

Yours faithfully,

Shaun Flanagan,
Primary Care Eligibility & Reimbursement

*In accordance with the Northern Ireland protocol, the changed regulatory requirements for the supply of exempt medicinal products from the UK do not apply to the supply of exempt medicinal products from Northern Ireland to the Irish market.

[1]Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended