Medicines & Healthcare products Regulatory Agency

Export of UK medicines and the new Windsor Framework (Northern Ireland) labelling requirements

Dear colleague

We are writing to you to explain some changes to the packaging for all medicines licensed in the UK, which will be coming into effect from 1 January 2025, and to reassure you that these medicines can still be exported from the UK to other countries and territories.

The changes are coming about as a result of the Windsor Framework – an agreement negotiated between the European Union and the UK Government in February 2023, about Northern Ireland – one of the four countries that make up the UK. For medicines, the agreement means that medicines currently authorised under Regulation (EC) No 726/2004, (broadly those under the EU Centralised Procedure) will now come under UK law, and the Falsified Medicines Directive will not apply to any UK medicines.

In addition, from 1 January 2025, all medicines on the UK market must be labelled with 'UK Only' to prevent onward movement of UK medicines into any part of the European Union, while ensuring medicines use the same packaging and labelling across the UK. There are no changes to the regulatory standards applied by the UK's Medicines and Healthcare Products Regulatory Agency's (MHRA) in licensing medicines.

The MHRA would like to reassure you and other regulators that the inclusion of 'UK Only' on packaging does not mean that goods cannot be exported from the UK to other non-EU countries or territories. Medicines featuring 'UK Only' on their packaging may continue to be exported after the implementation of the Windsor Framework to any country or territory where the import of those medicines is compliant with local legal requirements or provisions.

There is no restriction on Marketing Authorisation holders exporting from the UK at any time. When there are shortages in the UK market, export by other types of companies is restricted and the UK's Department for Health and Social Care publishes a list of medicines banned from export, which is regularly updated.

The MHRA also requires that any company exporting medicines should be able to show proof that they have followed both UK laws and the laws of the country receiving the medicines.

We hope this information is helpful. Please do contact us at partnerships@mhra.gov.uk if you have any questions about this.