From the Chief Medical Officer
Professor Sir Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: cmooffice@health-ni.gov.uk

HSS(MD)13/2025

Our Ref: HSS(MD)13/2025
Date: 17 April 2025

FOR ACTION
Chief Executives, Public Health Agency/HSC Trusts/NIAS,
Chief Operating Officer, SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

MHRA LETTER- WINDSOR FRAMEWORK: INFORMATION FOR NORTHERN IRELAND HEALTHCARE PROFESSIONALS

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued a letter to healthcare professionals in Northern Ireland following the implementation of new arrangements for medicines under Windsor Framework from 1 January 2025.

The attached letter**, 'Windsor Framework: Information for Northern Ireland Healthcare Professionals' (Annex A)** issued by the MHRA on 9 April 2025 clarifies what product information now applies in Northern Ireland for medicinal products. Product information includes Summary of Characteristics (SmPC), Patient Information Leaflets (PIL) and patient safety updates. As medicine licensing has changed under the new arrangements, all product information approved by the MHRA, including those authorisations previously only applicable to Great Britain, apply UK-wide.

Although there will be a period of overlap in the supply chain where EU packs released by a qualified person (QP) before 1 January 2025 and UK-wide authorised packs QP released from 1 January 2025 can be supplied to patients in Northern Ireland until their expiry date, healthcare professionals in Northern Ireland should refer to the UK product information which is available at: **https://products.mhra.gov.uk/**.

Healthcare professionals responsible for the prescribing, dispensing and supply of medicines in Northern Ireland should note the information and advice provided in this letter (**Annex A**).

Yours sincerely

PROFESSOR SIR MICHAEL McBRIDE
Chief Medical Officer

PROFESSOR CATHY HARRISON
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, SPPG (*for onward distribution to SPPG Pharmacy and Medicines Management Team and community pharmacists*)
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, SPPG
Family Practitioner Service Leads, SPPG *(for cascade to GP Out of Hours services)*
Medical Directors, HSC Trusts *(for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads)*
Nursing Directors, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers including independent hospitals*)
Regional Medicines Information Service, Belfast HSC Trust
Regional Pharmaceutical Procurement Service, Northern HSC Trust
Professor Kenda Crozier, Head of School of Nursing and Midwifery QUB
Andrea Shepherd, Head of School of Nursing, Ulster University
Heather Finlay, CEC
Maurice Devine, Open University
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, Ulster University
Professor Gavin Andrews, Head of School, School of Pharmacy, QUB
Postgraduate Pharmacy Dean, NI Centre for Pharmacy Learning and Development, QUB
Michael Donaldson, Head of Dental Services, SPPG *(for distribution to all General Dental Practitioners)*
Raymond Curran, Head of Ophthalmic Services, SPPG *(for distribution to Community Optometrists)*
Trade Union Side
Clinical Advisory Team
Louise McMahon, Director of Integrated Care, SPPG
Dr Camille Harron, NIMDTA
Prof Pascal McKeown, QUB
Prof Alan Smyth, QUB
Prof Louise Dubras, Ulster University

Annex A

Medicines & Healthcare products Regulatory Agency

Department of Health & Social Care

9 April 2025

Windsor Framework: Information for Northern Ireland Healthcare Professionals

The Windsor Framework's arrangements for human medicines came into effect on 1 January 2025, introducing a UK-wide licensing regime and the disapplication of EU Falsified Medicines Directive safety features for medicines marketed and supplied in Northern Ireland (NI).

This means that from this date, all medicines released by a Qualified Person (QP) onto the NI market will now be approved and licensed on a UK-wide basis by the Medicine and Healthcare products Regulatory Agency (MHRA) and will be supplied in same packs across the whole UK. This includes novel and innovative medicines which, under the original NI Protocol, had to be authorised for NI by the European Commission (EC).

What does this mean for product information?

Prior to 1 January 2025, for all novel and innovative medicines, healthcare professionals in NI should have been referring to the product information published by the European Medicines Agency (EMA), including Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL).

From 1 January 2025, as a consequence of the new licensing arrangements, product information that was approved by the MHRA for medicines authorised in Great Britain, will now apply across the UK. This includes current or any future updated product literature (SmPC and PIL) and any new safety information issued by the MHRA.

There will be a period of overlap in the supply chain where EU packs QP released before 1 January 2025 and UK-wide authorised packs QP released from 1 January 2025 can be supplied to patients in NI until their expiry date. Healthcare professionals should refer to the UK product information which is available at: https://products.mhra.gov.uk/

Additionally, where a difference in product literature (SmPC and PIL) could lead to a significant change of clinical practice in NI, affecting patient safety, healthcare professionals may be notified via a Direct to Healthcare Professional Communication (DHPC) from the marketing authorisation holder.

Annex A

Medicines & Healthcare products Regulatory Agency

Department of Health & Social Care

New supplementary guide

We have published a supplementary guide with frequently asked questions, to inform healthcare professionals, particularly prescribers and pharmacists, about key changes in the following areas:

- 'UK Only' labelling requirement for outer packaging
- 2D barcodes and serial numbers
- Summary of Product Characteristics and Patient Information Leaflets

Further information

Visit the MHRA Windsor Framework Hub for a range of information and resources which explain the main changes introduced by the Windsor Framework for medicines.

If you have any questions or need any support, please email the Department for Health and Social Care at: windsor.framework@dhsc.gov.uk