**CONSULTATION ON PROPOSED AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012 IN RELATION TO PATIENT GROUP DIRECTIONS AS A CONSEQUENCE OF THE PLANNED CLOSURE OF THE HEALTH AND SOCIAL CARE BOARD ON 31ST MARCH 2022**

In Northern Ireland as part of a major programme of work to transform its health and social care system, as set out in ***Health and Wellbeing 2026: Delivering Together***, the Health and Social Care Board (HSCB) is to close and its functions will migrate to a newly formed Strategic Planning and Performance Group (SPPG) within the Department of Health and its staff to the Regional Business Service Organisation. It is planned, subject to the necessary legislation being in place, that this will be completed by 31st March 2022.

In light of the organisational changes taking place as a result of the HSCB closure, amendments are required within the Human Medicines Regulations 2012[[1]](#footnote-1) (HMRs) that relate to the supply of medicines in accordance with Patient Group Directions (PGDs). The specific statutory functions in relation to PGDs will become the responsibility of the Department of Health from 1st April 2022.

For a PGD to be lawful, it must be developed and approved by a doctor (or dentist) and a pharmacist. It must also be approved by the agency that has commissioned the service. This agency must be specifically designated within the HMRs.

Within the HMRs, the definition of “Health Authority” in respect of Northern Ireland in Regulation 213 is defined as the Regional Health and Social Care Board (HSCB). The Department is currently not listed as a ‘Health Authority’ in the Regulations. Therefore, as the specific statutory functions in relation to PGDs will become the responsibility of the Department from 1st April 2022, the Department needs to be designated as a ‘Health Authority’ and an amendment to the Human Medicines Regulations is therefore being proposed.

**Patient Ground Directions (PGDs) and the HSCB**

A PGD is a written instruction for the sale, supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The supply and/or administration of medicines under a PGD cannot be delegated – the whole episode of care must be undertaken by the health care practitioner operating under the PGD.

HSCB commissions a range of activity, which is facilitated by the establishment of PGDs:

* The delivery of vaccination services in primary care
* The provision of medicines by paramedics in GPOOH services
* The provision of prescription only medicines through various extended services in community pharmacy

In order for these services to function successfully, a PGD must be signed off appropriately. The HMRs provide a body with the legislative powers to sign off a PGD. *Part 12, Chapter 1, Regulation 213* states that in Northern Ireland the ‘Health Authority’ is defined as the HSCB. The HSCB is currently the commissioning body, which is responsible for General Practitioner (GP) services and Community Pharmacy (CP) services. These commissioning functions are to move to the Department of Health on 1st April 2022.

To allow the Department to have the same powers under the HMRs as the HSCB currently has as Health Authority and de facto because of this also an NHS body for the purpose to be legally able to authorise a PGD, it is proposed to amend the definition at Regulation 213 with regards “Health Authority” to the Department of Health. This will allow for a seamless transition of commissioning functions in relation to PGDs to migrate to the Department.

Administrative Arrangements

It is also recognised that the Minister of the Department of Health has extant powers of enforcement under the HMRs and officers of the Department’s Medicines Regulatory Group carry out inspection and enforcement activities on his behalf. Following legal advice on the matter administrative arrangements are being put in place to mitigate against any potential conflict with the extant role the Department holds in enforcement of HMRs and the adoption of a commissioning function that the Department would then potentially have to take enforcement action against.

These administrative arrangements will separate the enforcement responsibilities under HMRs from the development and authorisation functions of PGDs. The newly formed SSPG within the Department will be responsible for the development and authorisation functions of PGDs.

Legislative powers

The Medicines and Medical Devices (MMD) Act 2021 provides the powers to amend and update the HMRs. The MMD Act requires a public consultation on any changes to HMRs when using the powers of the Act. The MMD Act also stipulates that the appropriate authority when making regulations an assessment needs to be carried out whether regulations would contribute to the objective of safeguarding public health, and have regard to a number of factors. This assessment is attached at Annex A.

Summary

Due to the important nature of these services, it is imperative that PGDs can continue to be issued in an appropriate and timely manner. The purpose of consultation is to seek views on the proposed change to the HMRs to designate the Department of Health in Northern Ireland as a ‘Health Authority’ and allow statutory functions in relation to PGDs to become the responsibility of the Department from 1st April 2022.

**Equality and Human Rights considerations**

In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with section 75 of the Northern Ireland Act 1998, this proposed amendment been equality screened and a preliminary decision has been taken that a full EQIA is not required. This preliminary decision is subject to change following analysis of feedback received during this consultation.

The Department has also considered the policy from a Human Rights perspective and has provisionally concluded that this amendment will not engage any of the rights.

**Rural Impact**

The Rural Needs Act (Northern Ireland) 2016 places a duty on public authorities, including government departments, to have due regard to rural needs when developing, adopting, implementing or revising policies, strategies and plans and when designing and delivering public services. The proposed amendment to the HMRs has been subject to an initial screening and it is not expected that this will present any specific or differential rural impacts, as it is mainly a technical amendment. This preliminary decision is subject to change following analysis of feedback received during this consultation.

**Regulatory Impact**

The Department has conducted an initial screening and considers that a regulatory impact assessment is not appropriate. The amendment required to the HMRs imposes no additional costs on charities, social economy enterprises or the voluntary sector.

**Freedom of Information**

Please see Appendix 1 to the consultation response document concerning the confidentiality of responses to consultations.

**Consultation Privacy Notice**

Please see Appendix 2 to the consultation response document concerning consultation privacy notice.

**Responding to this consultation**

A consultation Questionnaire is provided separately and can be accessed alongside this consultation at: [Consultations | Department of Health (health-ni.gov.uk)](https://www.health-ni.gov.uk/consultations)

Responses can be sent by email to: Pharmacyconsultations@health-ni.gov.uk

**The deadline for consultation responses is 5.00 pm on 14th January 2022**

**Annex A**

**Legislative basis for the Consultation and the assessment of the matters set out in section 2 of the Medicines and Medical Devices Act 2021**

The Medicines and Medical Devices Act 2021 (‘the Act’) received Royal Assent on 11th February 2021. We propose to make the legislative changes under consultation in this document, under Part 2 of the Act, which provides powers to make regulations about human medicines.

This consultation is conducted in line with the consultation requirement in section 45(1) of the Act.

Section 2 of the Act states that patient safety must be the overarching objective of the appropriate authority when making regulations. Section 2 requires that when assessing whether regulations would contribute to the objective of safeguarding public health, the appropriate authority must have regard to three factors:

1. The safety of human medicines
2. The availability of human medicines
3. The likelihood of the relevant part of the United Kingdom being seen as a favourable place which to –
4. Carry out research relating to human medicines
5. Conduct clinical trials, or
6. Manufacture or supply human medicines.

We have assessed the proposals against each of these factors, outlined below.

1. **Patient safety: how does this consider patient safety?**

These proposed changes are to maintain continuity in terms of provision of these medicines. We therefore do not consider there to be an impact on patient safety from the changes.

1. **Availability**

These proposed changes aim to maintain continuity in terms of access of medicines supplied using PGDs. These changes would mean medicines can continue to be available without patients being negatively impacted.

1. **The likelihood of the relevant part of the United Kingdom being seen as a favourable place which to Carry out research relating to human medicines, Conduct clinical trials, or Manufacture or supply human medicines**

In Northern Ireland, these proposed changes seek to maintain continuity of provision and therefore we do not expect them to negatively impact on the favourability of the UK.

1. The Human Medicines Regulations 2012. Available at: <http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/made> [↑](#footnote-ref-1)