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

Proposed Amendments to the Human Medicines Regulations 2012

Patient Group Directions

CONSULTATION REPORT

October 2022

Contents

Section 1: Summary of the Consultation

Introduction

1. On the 17th December 2021 the Department of Heath launched a public consultation on a proposed amendment to the Human Medicines Regulations 2012 (HMRs) in relation to the authorisation of Patient Group Directions (PGDs) as a consequence of the planned closure of the Health and Social Care Board (HSCB) on 31st March 2022. The consultation closed on the 14th January 2022.

Background

2. PGDs provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor). 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.

3. Part 12, Chapter 1, Regulation 213 in the HMRs states that in Northern Ireland the 'Health Authority' is defined as the "Regional Health and Social Care Board" i.e. the HSCB. The HSCB had been the commissioning body in Northern Ireland, responsible for General Practitioner (GP) services and Community Pharmacy (CP) services. These commissioning functions moved to the Department of Health on 1st April 2022. The Department therefore issued a consultation prior to the transfer of functions, for a proposed amendment to the HMRs to expressly designate the Department of Health as a 'Health Authority.'

4. 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 (MRG) carry out inspection and enforcement activities on his behalf. Following legal advice on the matter, administrative arrangements were put in place to mitigate against any potential conflict with the extant role the Department holds in enforcement of the HMRs, and the adoption of a commissioning function that the Department could potentially be required to take enforcement action against.

5. These administrative arrangements were to separate the enforcement responsibilities under HMRs from the development and authorisation functions of PGDs. The newly formed Strategic Planning and Performance Group (SPPG) within the Department will be responsible for the development and authorisation functions of PGDs.

Consultation

6. The Department took forward a full public consultation. The primary legislation governing the HMRs, namely the Medicines and Medical Devices Act 2021 (MMDA) provides that before making changes to the HMRs the "relevant

authority" must carry out a public consultation, and the Department of Health is named as the relevant authority within the MMDA. The consultation sought views on the proposals to expressly amend "Health Authority" from the "Regional Health and Social Care Board" to the "Department of Health", and on the administrative arrangements to separate the enforcement responsibilities under HMRs from the development and authorisation functions of PGDs.

7. The questions asked were as follows:-

POLICY

Question No.	Question
No.1	Do you support the proposed amendment to the HMRs to designate the Department of Health in Northern Ireland as a 'Health Authority' and de facto because of this also an NHS body, in place of the HSCB which is to close on 31st March 2022 and allow statutory functions in relation to PGDs to become the responsibility of the Department from 1st April 2022?
No.2	Do you support the administrative arrangements the Department of Health in Northern Ireland will put in place to separate the enforcement responsibilities under the HMRs from the development and authorisation functions of PGDs, to allow the Department to be designated as a Health Authority?
	Any additional general comments?

EQUALITY AND HUMAN RIGHTS

Question No.	Question
No.1	Are the proposed changes to provisions relating to PGDs likely to have an adverse impact on any of the nine equality groups identified under section 75 of the Northern Ireland Act 1998? If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.
No.2	Are you aware of any indication or evidence – qualitative or quantitative – that the proposed changes may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.
No.3	Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.
No.4	Are there any aspects of these proposals where potential human rights violations may occur?

RURAL IMPACT

Question No.	Question
No.1	Are the proposed changes likely to have an adverse impact on rural areas? If yes, please provide comment on how these adverse impacts could be reduced or alleviated.

8. Responses were received from:
   - Community Pharmacy NI;
   - Pharmacy Forum NI; and
   - British Medical Association.

9. Community Pharmacy NI and Pharmacy Forum NI used the consultation response template (shown in Annex A). The British Medical Association (BMA) forwarded a letter seeking further clarity on the details of the consultation. A response to this letter was issued by the Department on the 6th January 2022.

10. The views of all respondents and the Department's response to those views are set out in Section 2.

Section 2: Responses Received and Departmental Response

POLICY

Q1. Do you support the proposed amendment to the HMRs to designate the Department of Health in Northern Ireland as a 'Health Authority' and de facto because of this also an NHS body, in place of the HSCB which is to close on 31st March 2022 and allow statutory functions in relation to PGDs to become the responsibility of the Department from 1st April 2022?

Summary of responses received:-

Two of the consultees agreed with the intention of the proposal for measures to be put in place to ensure continuity in respect of the legality and operation of PGDs following the closure of the HSCB. However, both these consultees also noted this agreement was caveated with issues to be addressed that were detailed in the second response on the administrative arrangements to be put in place. The third consultee noted the intention of the proposals but sought further clarity on the administrative arrangements.

Department's Response:-
The Department welcomes the views and the endorsement of the policy intent for measures to be put in place to allow for the statutory functions in relation to PGDs to become the responsibility of the Department from 1st April 2022, and notes this agreement is caveated with further consideration of issues to be addressed with regards the administrative arrangements.

Q2. Do you support the administrative arrangements the Department of Health in Northern Ireland will put in place to separate the enforcement responsibilities under the HMRs from the development and authorisation functions of PGDs, to allow the Department to be designated as a Health Authority?

Summary of responses received:-

All three organisations that responded to the consultation wanted further details on the proposed administrative arrangements. The consultation document clarified that the newly formed Strategic Planning and Performance Group (SPPG) within the Department will be responsible for the development and authorisation functions of PGDs, and that this Group would be separate from the Medicines Regulatory Group who carry out inspection and enforcement activities on behalf of the Minister. One of the consultees asked for the Terms of Reference for the newly formed SPPG. The other two consultees also asked for further details on the administrative arrangements and questioned whether having SPPG and MRG within the same Department, would be an adequate way to ensure appropriate separation of MRG's

enforcement responsibilities from SPPG's development and authorisation responsibilities.

Department's Response:-
The Department is made up of several groups each headed by a Grade 3. Each Group is then in turn made up of various Directorates each of which consists of various branches. Groups within the Department, including SPPG, do not have a Terms of Reference. A link to the Department's management structure can be found at https://www.health-ni.gov.uk/doh-management-and-structure

SPPG's development and authorisation responsibilities for PGDs will fall under a different Group command to those of MRGs enforcement responsibilities. This is the administrative arrangement agreed by the Department to demonstrate how these functions will be separated in order to mitigate against any conflict of interest, perceived or otherwise. Responsibility for signing off on PGDs, on behalf of the Health Authority is to be undertaken by the Grade 3, as the head of SPPG.

The consultation asked for General Comments

Summary of responses received:-

Two of the consultees used the general comments section to seek assurances that any PGDs authorised by the HSCB would remain valid following closure of the HSCB.

Department's Response:-

The transitional provision at Schedule 4 Part 2 2(2) of the Health and Social Care Act (Northern Ireland) 2022 provides for any pre-existing PGDs that are in force prior to the dissolution of the HSCB to continue to have effect to the same extent and subject to the same provisions as if it had been done by, or in relation to the Department.

EQUALITY AND HUMAN RIGHTS

Only two consultees responded to the Equality and Human Rights questions. These were the consultees that had completed the response questionnaire. No issues were raised by either organisation and the questions have been grouped together for ease of reference for consideration and response.

Q1. Are the proposed changes to provisions relating to PGDs likely to have an adverse impact on any of the nine equality groups identified under section 75 of the Northern Ireland Act 1998? If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

Q2. Are you aware of any indication or evidence – qualitative or quantitative – that the proposed changes may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

Q3. Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

Q4. Are there any aspects of these proposals where potential human rights violations may occur?

Summary of Responses

Both consultees indicated 'No' to questions 1 and 2 and indicated 'Don't know/No views' to questions 3 and 4.

Department's Response:-

The Department notes the responses.

RURAL IMPACT

Only two consultees responded to the Rural Impact questions. These were the consultees that had completed the response questionnaire. No issues were raised by either organisation

Q.1 Are the proposed changes likely to have an adverse impact on rural areas? If yes, please provide comment on how these adverse impacts could be reduced or alleviated.

Summary of Responses

One consultee indicated No to question 1 and the other consultee indicated "Don't know/No views'.

Department's Response:-

The Department notes the response.

Section 3: Next Steps and Way Forward

Following the consultation, the Department of Health decided to pause on making any expressed amendments to the Human Medicines Regulations 2012 on the authorisation of PGDs prior to the HSCB closing on 31st March 2022. Although support was given to the proposals in principle from those who responded to the consultation, they also wanted further consideration to be given on the matter. The transitional provision Schedule 4 Part 2 2(1) of the Health and Social Care Act (Northern Ireland) 2022, has been identified as an enabling provision to allow the Department to act as the Health Authority to sign off PGDs in the interim.

Health and Social Care Act (Northern Ireland) 2022 (legislation.gov.uk)

A paper was prepared for the Department's Top Management Group in early March this year, to set out the issues and agree a number of recommendations on the administrative arrangements for the authorisation of PGDs. It was agreed the current roles, responsibilities and functions related to the development, management and signing of PGDs would remain within the SPPG. SPPG would sit in a different Group command to Medicines Regulatory Group who had enforcement responsibilities.

It is a regulatory requirement that the approving Health Authority approves the use of the PGD. The sign-off on behalf of a Health Authority is usually undertaken by the Clinical Governance or Patient Safety lead of that organisation, although this person does not have to be a health professional, they will hold a position of authority in the organisation.

As SPPG will retain their current roles in relation to PGDs, it was agreed that responsibility for signing off on PGDs, on behalf of the Health Authority is to be undertaken by the Grade 3, as the head of SPPG.

The Department plans to take forward an expressed amendment to be named as the "Health Authority" in the HMRs at the earliest opportunity.

Annex A

Consultation Response Questionnaire

CONSULTATION RESPONSE FORM

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

Please indicate your answer to the questions by placing an **X** by your selection. You can also provide further comments in the free text field.

Please send responses electronically using the response sheet below and email address below.

Responses to be sent by e-mail to: Pharmacyconsultations@health-ni.gov.uk

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

Respondent details

I am responding:	as an individual	☐
	on behalf of an organisation	☐

Name: _____

Job Title: _____

Organisation: _____

Address: _____

_____

Tel: _____

_____

e-mail: _____

Part A

Consultation questions

Q1. Do you support the proposed amendment to the HMRs to designate the Department of Health in Northern Ireland as a 'Health Authority' and de facto because of this also an NHS body, in place of the HSCB which is to close on 31st March 2022 and allow statutory functions in relation to PGDs to become the responsibility of the Department from 1st April 2022?

Yes ☐ No ☐ Don't know / no views ☐

Further comments

Q2. Do you support the administrative arrangements the Department of Health in Northern Ireland will put in place to separate the enforcement responsibilities under the HMRs from the development and authorisation functions of PGDs, to allow the Department to be designated as a Health Authority?

Yes ☐ No ☐ Don't know / no views ☐

Further comments

General comments

Any additional general comments

Part B

Equality Implications

Section 75 of the Northern Ireland Act 1998 requires the Department to "have due regard" to the need to promote equality of opportunity between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation; between men and women generally; between persons with a disability and persons without; and between persons with dependants and persons without. The Department is also required to "have regard" to the desirability of promoting good relations between persons of a different religious belief, political opinion or racial group.

The Department has also embarked on an equality screening exercise to determine if any of these recommendations are likely to have a differential impact on equality of opportunity for any of the section 75 groups. We invite you to consider the recommendations from a section 75 perspective by considering and answering the questions below. Answering these questions will contribute to the completion of the Department's Screening template and the screening outcome.

Q1. Are the proposed changes to provisions relating to PGDs likely to have an adverse impact on any of the nine equality groups identified under section 75 of the Northern Ireland Act 1998? If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

Yes ☐ No ☐ Don't know / no views ☐

Comments:

Q2. Are you aware of any indication or evidence – qualitative or quantitative – that the proposed changes may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

Yes ☐ No ☐ Don't know / no views ☐

Comments:

Q3. Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

Yes ☐ No ☐ Don't know / no views ☐

Comments:

Q4. Are there any aspects of these proposals where potential human rights violations may occur?

Yes ☐ No ☐ Don't know / no views ☐

Comments:

Part C

Rural Impact

The Rural Needs Act (NI) 2016 became operational on the 1st June 2017 and 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.

Q1. Are the proposed changes likely to have an adverse impact on rural areas? If yes, please provide comment on how these adverse impacts could be reduced or alleviated.

Yes ☐ No ☐ Don't know / no views ☐

Comments:

Appendix 1

Freedom of Information Act 2000 – Confidentiality of Consultations

The Department will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. Before you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential. If you do not wish information about your identity to be made public, please include an explanation in your response.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Secretary of State for Constitutional Affairs' Code of Practice on the Freedom of Information Act provides that:

- the Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;
- the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature;
- acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see web site at:

http://www.informationcommissioner.gov.uk/

Appendix 2

Consultation Privacy Notice

Data Controller Name: Department of Health (DoH)

Address: Castle Buildings, Stormont, BELFAST, BT4 3SG

Email: DPO@health-ni.gov.uk

Telephone: 028905 22353

Data Protection Officer Name: Charlene McQuillan

Telephone: 028905 22353

Email: DPO@health-ni.gov.uk

Being transparent and providing accessible information to individuals about how we may use personal data is a key element of the Data Protection Act (DPA) and the EU General Data Protection Regulation (GDPR). The Department of Health (DoH) is committed to building trust and confidence in our ability to process your personal information and protect your privacy.

Purpose for processing

We are encouraging organisations and institutions to respond to the consultation. We will process personal data provided in response to consultations for the purpose of informing the strategy. We will publish a summary of the consultation responses and, in some cases, the responses themselves but these will not contain any personal data. We will not publish the names or contact details of respondents, but will include the names of organisations responding.

For the purpose of this consultation the only data we will process is the information provided by the individual when they respond to the consultation, as follows:

Name

Email address

Name of organisation (if responding on behalf of an organisation)

Lawful basis for processing

The lawful basis we are relying on to process your personal data is Article 6(1)(e) of the GDPR, which allows us to process personal data when this is necessary for the performance of our public tasks in our capacity as a Government Department.

How will your information be used and shared

We process the information internally for the above stated purpose. We don't intend to share your personal data with any third party. Any specific requests from a third party for us to share your personal data with them will be dealt with in accordance the provisions of the data protection laws.

How long will we keep your information

We will retain consultation response information until our work on the subject matter of the consultation is complete, and in line with the Department's approved Retention and Disposal Schedule Good Management, Good Records (GMGR).

What are your rights?

You have the right to obtain confirmation that your data is being processed, and access to your personal data

You are entitled to have personal data rectified if it is inaccurate or incomplete

You have a right to have personal data erased and to prevent processing, in specific circumstances

You have the right to ‘block’ or suppress processing of personal data, in specific circumstances

You have the right to data portability, in specific circumstances

You have the right to object to the processing**,** in specific circumstances

You have rights in relation to automated decision making and profiling.

How to complain if you are not happy with how we process your personal information

If you wish to request access, object or raise a complaint about how we have handled your data, you can contact our Data Protection Officer using the details above.

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner at:

Information Commissioner’s Office

Wycliffe House

Water Lane

Wilmslow

Cheshire SK9 5AF

casework@ico.org.uk