**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**](mailto: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 

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| --- |
| **Further comments** |

**General comments**

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| --- |
| **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**

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# Consultation Privacy Notice

Data Controller Name: Department of Health (DoH)

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

Email: [DPO@health-ni.gov.uk](mailto:DPO@health-ni.gov.uk)

Telephone: 028905 22353

Data Protection Officer Name: Charlene McQuillan

Telephone: 028905 22353

Email: [DPO@health-ni.gov.uk](mailto:brendan.g.oneill@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)](http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted) and the [EU General Data Protection Regulation](https://gdpr-info.eu/art-6-gdpr/) (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](https://www.health-ni.gov.uk/topics/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](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-of-access/)

You are entitled to have personal data [rectified if it is inaccurate or incomplete](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-rectification/)

You have a right to have personal data [erased and to prevent processing](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-erasure/), in specific circumstances

You have the right [to ‘block’ or suppress processing](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-restrict-processing/) of personal data, in specific circumstances

You have the right to [data portability](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-data-portability/), in specific circumstances

**You have the right to** [object to the processing](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-object/)**,** in specific circumstances

**You have rights in relation to** [automated decision making and profiling](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/rights-related-to-automated-decision-making-including-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](mailto:casework@ico.org.uk)