



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

[By Email]

Castle Buildings
Upper Newtownards Road
BELFAST
BT4 3SQ

Tel: 028 9052 2799

Email: karen.simpson@health-ni.gov.uk

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Dear Colleague

CONSULTATION ON PROPOSED AMENDMENTS TO THE PHARMACEUTICAL SERVICES REGULATIONS (NI) 1997

I am writing to seek your views on proposed amendments the Department of Health proposes to make to the Pharmaceutical Services Regulations (Northern Ireland) 1997 (referred to in this consultation as “the Pharmaceutical Regulations”) as part of the response to the current pandemic emergency. The proposals, however, will also apply to any future pandemics. A copy of the proposed draft amending Regulations is attached to this email.

The Pharmaceutical Regulations set out the legislative framework for the delivery of community pharmaceutical services in Northern Ireland, including the terms of service for chemists. The proposed amendments mainly relate to the terms of service and are detailed below and specifically relate in a period where a disease being or in anticipation of a disease being imminently pandemic and a serious risk or potentially a serious risk to human health, such as Covid-19.

Medicine Home Delivery Service

It is proposed that, in order to deal with the current pandemic, and any other pandemics that may follow, each pharmaceutical contractor must ensure that a home delivery option is in place for delivery of prescription items to eligible patients. Home delivery would support the current shielding strategy that has been put in

place to limit the spread of Covid-19. It would require adhering to the following hierarchy:

- using the home delivery option that the eligible patient themselves has put in place (for example, a relative, neighbour, or volunteer collecting the prescription);
- the pharmacy delivering the items itself;
- the pharmacy finding another pharmacy who will deliver it, the first pharmacy having dispensed it; or
- the pharmacy sending the prescription form to another pharmacy, that does arrange deliveries, for them to dispense and deliver the item.

Varying core and supplementary opening hours for community pharmacies

It is further proposed as part of the current pandemic response but potentially available in the event of any pandemic, that the Health and Social Care Board (HSCB), with the agreement the Department, would be able to vary core and supplementary opening hours for community pharmacies that have statutory terms of service, for a period specified in an announcement.

This would enable the HSCB to arrange, for example, for a pharmacy to close for a certain amount of time to the public so that it could focus on dispensing, and potentially another pharmacy to be open for longer to deal with the reduced capacity in the locality. This new power to require a pharmacy to open in an emergency is a realistic option if a contractor is intending to close a pharmacy where the HSCB considers it essential for patients and the public, and is maintaining other pharmacies in the wider area.

Other amendments

Other proposed amendments to the Pharmaceutical Regulations mainly support the changes detailed above. Where the HSCB has made an announcement to the effect that specified terms of service of chemists are suspended in specified circumstances for a limited period, it is proposed that during that limited period the suspended terms will not form part of the arrangements to provide pharmaceutical services which

chemists have with the HSCB. Similarly, if the HSCB has made an announcement to the effect that a specified term of service need not be complied with in specified circumstances for a limited period, enforcement action cannot be taken against chemists in relation to noncompliance with that term in that period. There are also ancillary provisions dealing with amendment and withdrawal of advice and announcements.

Implementation and Guidance

The HSCB commissions pharmaceutical services in Northern Ireland and will be responsible for implementing the new provisions. If any of the provisions are deemed appropriate, the HSCB will be responsible for producing guidance and ensuring contractors and GPs are aware of the amendments and are signposted to the guidance.

Consultation

As required by the primary legislation governing the Pharmaceutical Services Regulations (NI) 1997, the Department is conducting a consultation on the proposed changes. Given the current emergency situation, the consultation period needs to be reduced to ensure there is no delay in making the Regulations. The targeted consultation will be for **ten working days**. A copy of the consultation document will also be published on the Department's website. A list of consultees is attached at Annex 1.

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, any proposals have 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 policy 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 changes have been subject to an initial screening and it is not expected that implementation of this policy will present any specific or differential rural impacts. 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 proposed amendments impose no costs on charities, social economy enterprises or the voluntary sector. The proposals may ultimately have an impact on retail pharmacy businesses, however these are enabling amendments to the existing legislation at this stage.

Furthermore, if the circumstances so permit, before any of these powers would be used consideration would be given to the financial implications.

Freedom of Information

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

Responding to this consultation

I should be grateful for any comments on these proposed changes by **5:00 pm on Wednesday 20th May**. A response pro forma is provided below. Nil responses are not required.

Yours sincerely

Karen Simpson

Karen Simpson
Medicines Policy Branch
Department of Health
Castle Buildings
Stormont
Belfast
BT4 3SQ

Email: Karen.Simpson@health-ni.gov.uk

Part A

Consultation questions

Q1. Given the current emergency situation, do you agree with the Department's proposal to amend the Pharmaceutical Services Regulations (NI) 1997 to provide for the options that each pharmaceutical contractor must have a home delivery option in place for delivery of prescription items to eligible patients? Medicine home delivery will ensure community pharmacy contractors can further support any shielding strategy used to limit the spread of Covid-19.

Yes No Don't know / no views

Question 1

We are reasonably content with this proposal but would recommend it is given further consideration.

In some circumstances, pharmacists are able to provide a home delivery service. However, there are times, when due to staff shortages/pressures and logistical difficulties, home delivery is not possible.

This challenge has become particularly acute in our experience with the current covid-19 pandemic and the extra pressures it has placed on pharmacists. We are therefore uncomfortable with the use of the term '*must*' in this context and would recommend it is replaced with '*should*'.

In addition, the obligation creates issues around the onus of accountability and where it lies should a pharmacist be legally obliged to pass on a prescription to a person or another pharmacy via a third-party home delivery service. Where would liability lie should something go wrong e.g. a dispensing error or delivery to the wrong address? The change would also have implications for pharmacy professional indemnity insurance cover. There will also be GDPR implications where patients' private information needs to be shared, where consent would be difficult to obtain.

There is also the matter of future-proofing, where home delivery service could be applied in another, future pandemic. While in the current covid-19 pandemic, we know already which patient group shielding refers to, there is the possibility that a different pandemic/virus could affect a much larger group of shielded patients e.g. all males or all patients with hypertension. We would question if this demand on pharmacists would be feasible, if for example, half of the population was shielded. In addition, there may be difficulties for pharmacists to identify members of the shielded cohort.

Please note that the detail of our above response does not take into account the 'hierarchy' outlined in the text set out on page 2 of the consultation response

document but is **based solely on the legislation** The Pharmaceutical Services (Amendments Relating to the Provision of Pharmaceutical Services During a Pandemic etc.) Regulations (Northern Ireland) 2020.

Q2. Given the current pandemic response, and the need to respond to any future pandemics, do you agree with the Department's proposal to amend the Pharmaceutical Services Regulations (NI) 1997 to permit the Health and Social Care Board (HSCB) with the agreement of the Department, to be able to vary core and supplementary opening hours for community pharmacies that have statutory terms of services, for a period specified in an announcement?

Yes No Don't know / no views

We agree with the proposal that contractors' hours may be changed by the Board as per point 4B of the legislation. However, in doing so, we would point out the need for the Board to ensure the pharmacy network and provision of service remain protected and uncompromised, particularly within rural areas.

We would further request that a common sense approach, taking into account staff availability, safety and concerns about staff wellbeing, be applied in future and that opening hours are negotiated with a representative committee of chemist contractors before any changes are introduced.

Q3. Do you agree with the other proposed amendments to the Pharmaceutical Services Regulations (NI) 1997, as described in the correspondence above in relation to the terms of service for chemists.

Yes No Don't know / no views

We agree with the proposals to suspend certain terms of service in specified circumstances where it is in the public health benefit.

We would seek reassurance that the suspension of terms of service would be temporary and reviewed regularly to ensure the appropriate delivery of pharmaceutical services.

With regard to the suspension of enforcement action, this would be a sensible measure for the time of the pandemic, however this suspension would need to be reviewed regularly to provide reassurance and protection of the public.

General comments

Any additional general comments

Pharmacy Forum(NI) is pleased to have the opportunity to comment on the changes proposed. We would stress that our priority is to ensure community pharmacy, and the wider professional body, is enabled to provide the best possible pharmaceutical service to the population, not least during times of pandemic and other health emergencies.

While the proposals in the document are well-intentioned, we urge care not to create unintended consequences in the drafting of these proposed regulations.

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 actions/proposals set out in this consultation document 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 actions/proposals set out in this consultation document 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 recommendations 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 1 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 actions/proposals set out in this consultation document 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

We would point out the need to protect the pharmacy network and provision of service, particularly within rural areas.

APPENDIX

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: <https://ico.org.uk>

Annex 1

LIST OF CONSULTEES

The Health and Social Care Board
The Pharmaceutical Society of Northern Ireland
Community Pharmacy NI
British Medical Association
Royal College of General Practitioners
The Patient and Client Council
Ulster Chemists' Association
National Pharmacy Association
Pharmacists' Defence Association
Pharmacy Forum NI