Report on the Consultation on Draft Provision of Services Guidance

This report was considered by the Council of the Pharmaceutical Society NI at its meeting of 26th January 2021, with Council approving the recommendations outlined within.

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1. About the Pharmaceutical Society of Northern Ireland

1.1 The Pharmaceutical Society NI is the regulatory body for pharmacists and pharmacies in Northern Ireland.

1.2 Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality, safe care to patients.

1.3 It is our responsibility to protect and maintain public safety in pharmacy by:

- setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register and the standards for pharmacy premises;
- maintaining a publicly accessible Register of pharmacists and pharmacy premises;
- handling concerns about the Fitness to Practise of pharmacists, acting as a complaint's portal, acting to protect the public and maintaining public confidence in the pharmacy profession; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

2. About the Consultation

2.1 The Council of the Pharmaceutical society NI consulted on draft Guidance on the Provision of Services. The consultation ran for 12 weeks from **08 July 2020 to 12 noon on 30 September 2020**.

2.2 The draft guidance was developed to primarily provide help to pharmacists when considering their obligations under Principle 1 of the Code – *Always put the patient first* – and Standard 1.1.5 – *If, for any reason you are unable to provide a professional service, you have a professional responsibility to take reasonable steps to refer the patient or service user to an appropriate alternative provider for the service they require*.

2.3 The proposed guidance covered the following three main areas relating to the provision of services:

- the impact of a pharmacist's religion and/or beliefs on their willingness to provide a specific service;
- a patient or service user is violent, threatens violence or is verbally abusive; and
- the medicine, service or medicinal device is not currently in stock or available.

2.4 The consultation was accompanied by a phase 1 Equality Assessment, which was published alongside the consultation on our website.

3. Consultation Engagement

3.2 **Correspondence with key stakeholders**: All registrants and key stakeholders were emailed details of the consultation and instructions on how to respond. Reminder emails were also sent out as the consultation period neared its conclusion.

3.3 **Website:** The consultation document and the Proposed Guidance on the Provision of Services were available to download from the website along with a response form 08 July 2020 to 30 September 2020.

3.4 **Facebook and other media**: the consultation document was advertised on our Facebook page over the consultation period.

4. Purpose of Report – approach and analysis

4.1 This report provides a summary of the responses to the consultation.

4.2 No differential weighting was given to responses, and all responses were read and considered. Comments and points from individuals were considered alongside the views of organisations. Where the views of a particular organisation were considered to be particularly relevant to a question or issue this has been highlighted in the report.

4.3 In the report, comments and direct quotes are attributed to the consultee category to which they fit i.e. individual pharmacist. With regards to organisations, we have in most instances directly attributed comments/quotes.

4.4 The report considers the direct responses to the consultation questions alongside the comments provided by respondents. It identifies themes emerging from the comments and provides analysis on those themes, making recommendations to Council.

5. Consultation Document

5.1 The Consultation document outlined how to respond to the consultation; provided the 13 consultation questions; and provided a supporting rationale for the proposals.

6. Respondents

6.1 The Pharmaceutical Society NI received 23 responses. An overview of the responses can be found in Figure 1. A list of respondents can be found at Appendix 1.

Figure 1 - Respondents			
Individuals		**Organisations**	
Pharmacists	6	Pharmacy Representative Body	3
Undergraduate Students	0	Patients/Public Representative Body	2
Pre-registration Students	0	Government Department	0
Community Pharmacy Owner	0	University	0
Member of Public	7	Regulatory Body	1
Other Healthcare Professional	0	Health and Social Care Organisation	1
Other	0	Other	3
Total	**13**	**Total**	**10**
Overall Total	**23**		

7. Overview of how respondents' answered consultation questions[1]

Figure 2 - Overview of how respondents' answered consultation questions
<u>Question 1:</u> Does Section 1 (Introduction) of the draft Guidance clearly set out the purpose of the document?

[1] This table represents the basic statistical analysis of the responses to the 5 conusltation questions and should be considered in conjunction with the comments and themes identified in the remaining sections.

Yes	No	Unsure	Did not answer
14 (82.4%)	1 (5.9%)	2 (11.8%)	6

Question 2: Does Section 2 (Legal Framework) of the document clearly set out the basic legal framework within which this Guidance sits?

Yes	No	Unsure	Did not answer
13 (76.5%)	0 (0%)	4 (23.5%)	6

Question 3: 1. Is the information provided in Section 2 (Legal Framework) appropriate?

Yes	No	Unsure	Did not answer
12 (70.6%)	0 (0%)	5 (29.4%)	6

Question 4: Should any further information be included in Section 2 (Legal Framework)?

Yes	No	Unsure	Did not answer
4 (23.5%)	7 (41.2%)	6 (35.3%)	6

Question 5: Is the Guidance provided in Section 3 (Religion and Beliefs) clear?

Yes	No	Unsure	Did not answer
8 (47.1%)	8 (47.1%)	1 (5.9%)	6

Question 6: Is the Guidance provided in section 3 (Religion and Beliefs) appropriate?

Yes	No	Unsure	Did not answer
5 (25%)	14 (70%)	1 (5%)	3

Question 7: Is the Guidance in Section 4 (A patient or service user is violent, threatens violence or is verbally abusive) clear?

Yes	No	Unsure	Did not answer
9 (65.3%)	5 (31.3%)	2 (12.5%)	7

Question 8: **Is the Guidance in Section 4 (A patient or service user is violent, threatens violence or is verbally abusive) appropriate?**

Yes	No	Unsure	Did not answer
5 (31.3%)	6 (37.5%)	5 31.3%)	7

Question 9: **Is the Guidance in Section 5 (The medicine, service or medicinal device is not currently in stock or available) clear?**

Yes	No	Unsure	Did not answer
10 (58.8%)	4 (23.5%)	3 (17.6%)	6

Question 10: **Is the Guidance in Section 5 (The medicine, service or medicinal device is not currently in stock or available) appropriate?**

Yes	No	Unsure	Did not answer
9 (52.9%)	5 (29.4%)	3 (17.6%)	6

Question 11: **Do Sections 6 (Help and Advice) and 7 (Useful Contacts) contain the appropriate information?**

Yes	No	Unsure	Did not answer
10 (58.8%)	2 (11.8%)	5 (29.4%)	6

Question 12: **Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories? If yes, please explain what could be done to change this. We would welcome any research/sources you may have to evidence your response.**

- **Age**
- **Gender**
- **Disability**
- **Pregnancy and maternity**
- **Race /ethnicity**
- **Religion or belief**
- **Political Opinion**
- **People with dependants**
- **Sexual orientation**
- **Marital Status**

Yes	No	Unsure	Did not answer
4 (25%)	7 (43.8%)	5 (31.3%)	7

Question 13: Do you have any other comments about the proposed Guidance on the Provision of Services?			
Yes	**No**	**Unsure**	**Did not answer**
7 (41.2%)	**10 (58.8%)**	**0**	**6**

8. Responses to Question 1

Question 1: Does Section 1 (Introduction) of the draft Guidance clearly set out the purpose of the document?			
Yes	**No**	**Unsure**	**Did not answer**
14 (82.4%)	**1 (5.9%)**	**2 (11.8%)**	**6**

8.1 Of the 14 respondents that answered 'Yes' to Question1, 2 provided additional comments.

8.2 CPNI noted that '*the three areas covered by this guidance…. are areas with which pharmacy teams have been dealt with successfully and professionally over many years*'.

8.3 CPNI further welcomed '*the overarching caveat (page4) that pharmacist should use their professional judgement when applying this guidance and be able to justify their decisions*'.

8.4 The 1 respondent that answered 'No' to Question 1 provided an additional .

8.5 The Pharmacists Defence Association (PDA) outlined in its response its concern that the reasons for additional guidance were unclear, suggesting there was not clear or transparent evidence as to what prompted the development of the additional guidance, suggesting that the reason for its development was '*to satisfy the PSA which seems intent on foisting the revised GPhC standards on the PSNI'*.

8.6 The PDA went on to recommend:

"*Any proposed Guidance or changes or adjunct documents relating to already published Guidance should always be proposed with full transparency and the discussion by Council must always be in the Public Domain. The PSNI should not be forced to follow political dictat and it should be more robust in defending*

its independence". The PDA also went on to cite the Nolan Principles of Public Life in particular that relating to openness.

8.7 Analysis – Question 1 - openness

8.7.1 when considering rationale for the proposed guidance Council is reminded that at its public Council meeting in July 2018 it considered an initial review, which assessed whether there is evidence of a need to develop and publish additional guidance for pharmacists as to when they are unable to provide a service to a patient/service user and what they should take into consideration when making decisions in this regard. The review consisted of an extensive survey of registrants to better understand the issues and a literature and practice review of how other regulators approach this issue. Based on this review Council decided to develop additional guidance in this area, at its public meeting.

8.7.2 Further, Council is asked to note that as part of the policy development of this project, pharmacy representative groups were invited to attend a roundtable discussion on initial policy proposals. At this roundtable discussion the findings of the initial review and survey results were presented to attendees for their consideration and feedback.

9. Responses to Question 2

Question 2: Does Section 2 (Legal Framework) of the document clearly set out the basic legal framework within which this Guidance sits?			
Yes	**No**	**Unsure**	**Did not answer**
13 (76.5%)	**0 (0%)**	**4 (23.5%)**	**6**

9.1 Of the 13 respondents that answered 'Yes' to Question 2, 2 provided additional comments.

9.2 General Support for balanced position as set out in legal framework section

9.2.1 The PDA stated that the framework set now '*could have profound implications as what were previously classified illegal acts become legalised',* such as assisted suicide and euthanasia and this might have 'profound implications' for pharmacists who might consider such acts immoral.

9.2.3 The PDA stated that in light of these issue they 'support the *'clear and explicit reference in this Guidance of a balance between the expectation of a service that may be provided (and the requisite need to signpost if not provided) and the right of the practitioner who may have a conscientious objection to providing the service'.*

'The PSNI clearly achieved the right balance without alienating any of the competing viewpoints and this is especially important when dealing with such complex and sensitive matters.'

9.3.4 The PDA also outlined its support for our decision to retain Standard 1.1.5 of the Code, which requires a pharmacist to refer to an alternative provider if for any reason they are unable to provide a service.

9.4 Concern over monitoring non-discrimination of pharmacists by employers

9.4.1 The PDA welcomed paragraph 2.6 of the Guidance, which makes it clear that employers must not discriminate against pharmacists and employees, however, went on to say:

'… *in practice how will the PSNI monitor or enforce that pharmacists who hold certain beliefs are not discriminated against? The PDA is aware of cases whereby employers have exerted undue pressure onto their employee to offer services, notwithstanding the conscientious objection held by the pharmacist*'.

'We would welcome specific information on how the PSNI will ensure that employees do not misuse this Guidance to discriminate against pharmacists who hold genuine legitimate beliefs.'

9.5 Contractual Requirements

9.5.1 Boots stated that it '*would be helpful for community pharmacists and employers if the guidance also made reference to the need to take account of Terms of Service that are part of the HSC pharmacy contractual requirements*.'

9.6 Analysis - Question 2

Monitoring non-discrimination of pharmacists by employers

9.6.1 As the PDA has noted, paragraph 2.6 of the draft guidance makes it clear that employers must also keep to the relevant employment, human rights and equalities law in Northern Ireland and must not discriminate against pharmacists because of their stated or perceived religion and/or beliefs. Council should also note that Section 3.9 of the draft, provides specific guidance for employers, which outlines employers' responsibilities to

patients and service users; reiterates their responsibilities to pharmacists, and that they must abide by equality and discrimination laws in relation to employees. it states that employers should consider maintaining a policy on this issue to help ensure good communication between pharmacists, other pharmacy staff and employers.

9.6.2 We recommend, however, to include a link to the Equality Commission's website in Section 3.9, to facilitate employers' sourcing further information in relation to meeting their legal requirements in this area.

<u>Recommendation 1</u>: Include a link to the Equality Commission for Northern Ireland's website in section 3.9 of the Guidance.

Monitoring non-discrimination

9.6.3 In relation to monitoring non-discrimination of pharmacists by employers, it should initially be noted that discriminating against a pharmacist is against the law and we would expect that a pharmacist who considers that they have been discriminated against to seek legal advice and report this to the relevant authorities, as they should for any form of discrimination.

9.6.4 We do not hold a specific monitoring role in relation to our regulatory work, however, it should be noted that the implementation of new premises standards would afford the regulator a greater opportunity to influence overall governance arrangements in premises, working in conjunction with DoH's pharmacy inspectorate.

9.6.5 Council should also note that we will investigate any Fitness to Practise complaints raised with us, which meets our jurisdictional test, about a pharmacist. Likewise, concerns which call into question the suitability of a corporate body (i.e. a company) from operating a registered pharmacy may be investigated.

Contractual Requirements

9.6.6 Council should note that paragraph 2.3 states that pharmacists must make sure that they keep up to date and comply with the law, with any Health and Social Care or employment policies and contractual responsibilities of their employer, that apply to their particular area of work.

10. Responses to Question 3

Question 3: 1. Is the information provided in Section 2 (Legal Framework) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
12 (70.6%)	**0 (0%)**	**5 (29.4%)**	**6**

10.1 Of the 12 respondents that answered 'Yes' 4 provided additional comments. – 4 additional comments.

10.2 Balanced Approach

10.2.1 An individual Pharmacist stated that '*Conscientious objection is available to both employer and employee. Employee protection*.'

10.2.2 The PDA stated that it recognises **'***that this is a complex and sensitive matter and it is not possible to cover every situation that a pharmacist may face. In that context and taking an overarching view, we acknowledge that the balance struck in the consultation document, with respect to the conscience clause and the obligation not to discriminate is reasonable*.'

10.3 Supreme Court Ruling

10.3.1 Boots suggested that it **'***It might be useful for pharmacists if there was a further paragraph explaining the Supreme Court ruling on conscientious objection and its implications for any actions that they might take (or refrain from taking) [para 2.4].*'

10.4 Limits of conscientious objection

10.4.1 HereNI suggested that 'Some further explanations on the limits of conscientious objection would be useful'

10.5 Analysis - Question 3

Supreme Court Ruling

10.5.1 As is clearly outlined in paragraph 2.5 of the draft Guidance, it is not for our Standards or Guidance to set out the law in detail or provide legal advice. Pharmacists need to understand how the law applies to them

and get legal advice when they need it. We would consider that providing an explanation of of the Supreme Court Ruling into the Greater Glasgow Health Board v Doogan and another [2014] UKSC 68, may stray into an interpretation of the law and be inappropriate for this Guidance. A link to the Ruling is provided in the Guidance.

Limits of conscientious objection

10.5.2 It is noted that paragraph 2.4 states that Article 9 rights on freedom of thought, religion, and belief, are qualified rights. In that the right to manifest one's religion and belief in public can require a balance to be struck between the needs of the individual and the competing considerations of other individuals/groups, organisations, the wider community or society as a whole. It is suggested that our document as a whole provides a regulatory framework on what we, as a regulator, consider to be appropriate limitations in relation to providing patient care and safety and balancing obligations under the Code.

11. Responses to Question 4

Question 4: Should any further information be included in Section 2 (Legal Framework)?		
No	**Unsure**	**Did not answer**
7 (41.2%)	**6 (35.3%)**	**6**

11.1 Of the 4 respondents that answered 'Yes' 4 provided additional responses.

11.2 Explicit reference to non-discrimination for exercising conscientious objection

11.2.1 The PDA stated that it '*needs to be explicit that a pharmacist should not be discriminated against just because they may wish to exercise their legal right to the 'conscience clause'. It is manifestly unfair that pharmacists who entered the register many years ago could now suddenly find themselves being called upon by their regulator to explain why they are unwilling to provide a service which conflicts with their closely held beliefs*'

11.2.2 In relation to paragraphs 2.3 and 2.6 of the draft guidance, the National Pharmacy Association (NPA) stated that '*pharmacists should*

understand the services they are not prepared to provide and inform their employer. We would welcome clarification on steps a pharmacist should take if they find that an employer's policies are in breach of legislation. The pharmacist should have a clear procedure to raise concerns in this instance.'

11.2.3 The Pharmacy Forum NI made a similar point by asking '*If an employer's policy/policies are flawed e.g. in breach of legislation, how is this dealt with? What is the procedure for pharmacists to raise concerns?'*

11.3 Racism

11.3.1 In relation to paragraph 2.4 the Pharmacy Forum NI stated that '*In light of news coverage in June 2020, which highlighted the experience of racism in Northern Ireland pharmacies – including from patients – thus impacting service delivery, we would suggest to include reference to legislation against racism and intolerance'*.

11.3.2 HereNI stated that '*links to case law and best practice would be helpful'*

11.4 Analysis - Question 4

Explicit reference to non-discrimination for exercising conscientious objection

11.4.1 The feedback from the PDA is noted and the sensitivities of the position are acknowledged. Council should note that paragraph 2.6 clearly states that 'employers must also keep to the relevant employment, human rights and equalities law in Northern Ireland and must not discriminate against pharmacists because of their stated or perceived religion and beliefs. In this regard employers in no way can discriminate against individual pharmacists for their religion and/or the beliefs they hold.

11.4.2 The issue of manifesting a conscientious objection is complicated and it is to this which we consider the PDA to be referring. As noted in paragraph 2.4, Under Article 9 of the ECHR, manifesting one's religion and belief in public is a qualified right and can require a balance between competing considerations of other individuals/groups. Paragraph 2.3 of the guidance also reminds pharmacists that they also have to comply with their contractual obligations. This is why we recommend that pharmacists and employers work collaboratively together and communicate effectively to ensure an appropriate balance between pharmacist's rights, patients' rights and employers' obligations. However, this guidance cannot be a definitive reference for what position each actor must take in this balance. Council should note this complexity is reflected in other regulators' guidance in this area, for example, the GMC notes in its guidance on personal beliefs in medical practice that except where employer requirements are inconsistent with legislation or where the law provides protection on grounds of conscience, '*employing*

and contractual bodies are entitled to require doctors to fulfil contractual requirements that may restrict doctors' freedom to work in accordance with their conscience. This is a matter between doctors and their employing or contracting bodies[2]'. In this regard we consider the current balance in the draft guidance is appropriate.

11.4.3 In relation to the points raised by the NPA and the Pharmacy Forum NI, if a pharmacist has reason to believe that an employer is in breach of the law or they consider employer requirements are inconsistent with legislation, or it is in an area where the law provides protection on grounds of conscience, they should consider seeking legal advice and reporting their concerns to the relevant authorities.

11.4.4 As outlined above, we will investigate any referral made to us which meets our Fitness to Practise jurisdictional test in relation to individual pharmacists and concerns which call into question the suitability of a corporate body (i.e. a company) from operating a registered pharmacy may be investigated.

Racism

11.4.5 Council should note that paragraph 3.2 makes it clear that pharmacists cannot discriminate against patients and service users based on a protected characteristic including race. Whilst it is acknowledged that the issue of racism experienced by pharmacists is a serious issue, it is considered outside the purpose of this section of the guidance to address this aspect of patient to pharmacist racism.

12. Responses to Question 5

Question 5: Is the Guidance provided in Section 3 (Religion and Beliefs) clear?			
Yes	**No**	**Unsure**	**Did not answer**
8 (47.1%)	**8 (47.1%)**	**1 (5.9%)**	**6**

12.1 Of the 8 respondents that answered 'No' to Question 5, 8 provided additional comments.

[2] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/personal-beliefs-and-medical-practice/personal-beliefs-and-medical-practice

12.2 2 individual pharmacists provided the same answer, which outlined specific issues with the text in this section.

12.3 Misquote of Code

12.3.1 *Section 3.3 of the draft guidance seems to misquote 'the Code', stating "they have a professional responsibility to take <u>all</u> reasonable steps to refer the patient…" where Standard 1.1.5 of 'the Code' does not include the word "all". This could be said to put more weight than the Code warrants on the responsibility of an objecting pharmacist to assist someone attaining the service. This should be rectified.*

12.4 Requirement to provide reasons for refusal to provide services

12.4.1 The individual pharmacists noted that, *Section 3.8.1 of the draft guidance requires that pharmacists "answer any questions the patient may have in relation to their treatment". This could lead to pharmacists being compelled to advise on services contrary to their beliefs*.

12.4.2 The Pharmacy Forum NI and the NPA took similar issues with this section. The Pharmacy Forum NI stated: "*We do not agree with the requirement to provide reasons for the refusal to provide the service. This requirement puts the pharmacist's Fitness to Practise and reputation at risk both within the profession and more broadly should a discrimination case be filed by the patient/service user"*.

12.4.3 This position was countered by the PSA in its response, which whilst not directly answering Question 5, stated: "*We acknowledge that this is a complex and sensitive area but are of the view that ultimately the patients' rights to access safe, legal care must come first*". Going on to say that the PSA specifically welcomed a number of inclusions in the guidance, including: "*Guidance that pharmacists should explain to the patient that they will not provide the service and give reasons for this*".

12.5 Additional Guidance for Employers

12.5.1 A number of respondents suggested that additional guidance for employers would be helpful in relation to when a pharmacist should inform their employer that there are services they are unable to provide.

12.5.2 The NPA stated: "*employers would welcome more explicit guidance on when they should seek to establish if an employee or potential employee's religion and/or beliefs will impact on the delivery of services*."

12.5.3 The Pharmacy Forum NI asked in relation to paragraph 3.5.2 of the draft guidance, "*at what stage should [a] pharmacist tell their employer – potential ramifications – Guidance needed on this item"*.

12.6 Objection to requirement to refer, in Standard 1.1.5 of the Code

12.6.1 Two members of the public that responded 'No' to Question 5, outlined their objection to the professional responsibility of a pharmacist to take reasonable steps to refer the patient or service user to an appropriate provider for the service they require.

12.6.2 One respondent stated that '*in relation to requirement to refer in Code – 'To refer someone for something immoral is itself immoral. Doing something immoral is unreasonable. Therefor the Code of Practice (since it requires only reasonable actions) does not require a pharmacist to refer someone for abortion or contraception'.*

12.6.3 Another member of the public stated: *If this is indeed the case, then not only should a pharmacist be free to not dispense an abortifacient drug, but should be free to not refer a woman seeking an abortion to a colleague who would be free to supply the drug. A pharmacist so exercising his/her conscience, should be free from discipline or threat of discipline*.'

12.7 Conditions placed on decision to refer too onerous

12.7.1 The PDA, whilst initially supporting the balanced approach set out in the Section 2, outlined its concerns that the draft guidance '*purports to support the right of the practitioner to decline providing a service but signpost appropriately, however, it places such onerous conditions that were any practitioner to do so would potentially lead to conflicts with employers and others*'

12.7.2 The PDA went on to say that *Striking the balance between practitioners being placed in a position of compromising their genuine beliefs or providing a service for those that have, for whatever reason been placed in a situation to seek that service is fortunately a rare occurrence…. Given this fact, it seems that the huge detail in this section of the proposed Guidance is not necessary and that pharmacists have provided services or referred in the manner expected of any professional. We would contend that such detailed guidance will be counterproductive. Section 3.4 to 3.8 (inclusive) are unnecessary and should be removed*'.

12.8 Standardisation of Language

12.8.1 The CPNI stated that some language needed to be standardised throughout the document:

We recognise that this document draws on similar issued by GPhC, but as a general comment, throughout the guidance the language needs to be standardised. Some phraseology indicates that the "pharmacist should" while it

is also stated that "pharmacist should consider" (sometimes within the same section). There would appear to be a difference in these two directions and CPNI feels that the latter is more appropriate. Additionally, there should be a caveat running through the document that the actions should be considered "where possible, reasonable and appropriate…

12.9 Not as applicable for Hospital Pharmacists

12.9.1 The one respondent that answered 'Unsure' to Question 5 suggested that the Guidance is written in a way that is most applicable to community pharmacists, where a pharmacist can refer an individual patient to another healthcare professional directly. Stating that:

12.9.2 In hospital sector pharmacists (and potentially pharmacy technicians and assistants) are often supplying medication to clinics in bulk orders for use in clinic rather than to individual patients. This is currently specifically the case in relation to abortion drugs. It would be helpful to specifically reference this type of scenario and give guidance in the document. For example where a hospital pharmacy supplying a clinic with abortion drugs is small they may only have 1 or 2 pharmacists working there – if both these pharmacists are unwilling to supply specific medicines due to religious beliefs, how can this be addressed as the supply is not being made directly to a named patient?'

12.10 Analysis - Question 5

Misquote of Code

12.10.1 It is acknowledged that paragraph 3.3 may suggest that the Code requires pharmacists to take 'all' reasonable steps to refer the patient or service user to an appropriate alternative provider for the service they require, which is not the case. It is therefore recommended that paragraph 3.3 be amended to remove the word 'all'.

<u>Recommendation 2:</u> Remove the word 'all' from the opening sentence of paragraph 3.3.

Requirement to provide reasons for refusal to provide services

12.10.2 We acknowledge that referring a patient to an alternative provider for a specific service, because of a pharmacist's religion and/or beliefs is a sensitive matter for pharmacists.

12.10.3 We do not, however, agree with the Pharmacy Forum NI or the NPA that a pharmacist should not have to explain to a patient/service user the

reasons why they are being referred to an alternative provider for a service they may expect to receive.

12.10.4 We note that the PSA welcomed the inclusion of this aspect of our guidance and the feedback they provided to the GPhC, in response to its consultation on a similar piece of Guidance in Great Britain. The PSA stated:

If a patient is refused a service which they would ordinarily expect to receive they have a right to know why the professional is withholding treatment. It is generally accepted that patients are entitled to an open culture in healthcare which allows them to be as fully informed as possible about their treatment[3].

12.10.5 Council should note that being open, honest and communicating clearly with patients and service users is very important and in line with obligations under the Code, in particular Council should note Standard 3.1.3: *When providing information or advice, in whatever format, do so accurately, clearly and unambiguously'.*

12.10.6 Reflecting, on the comments and concerns raised, we do, however, consider that the way the guidance is currently written at paragraph 3.8.1, may suggest that a pharmacist must provide extensive reasons for their decision. Providing extensive reasons may encroach on privacy issues and may complicate an interaction with a patient/service user. It is therefore recommended that the second bullet point in paragraph 3.8.1 be amended to read as follows:

- '*Explain to the patient why they will not provide the service'*.

<u>Recommendation 3:</u> Amend the second bullet point in paragraph 3.8.1 to read:

'Explain to the patient why they will not provide the service'.

Additional Guidance for Employers

12.10.7 These are valid questions that touch upon sensitive issues. Council should note that the overriding purpose of this section of the guidance is the fostering of collaborative working environment to ensure that patients receive the care they need, employers are able to meet their contractual obligations and pharmacists' rights are respected. It is important that an open and honest working environment is promoted, which respects the rights and obligations of patients, pharmacists and employers. It is for

[3] https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2017/response-to-gphc-religion-personal-values-and-beliefs-consultation-final.pdf?sfvrsn=97a97020_14

this reason that the guidance recommends employers develop a policy in relation to these issues.

12.11.8 It is also noted that the juncture at which an employer seeks potential information on services a pharmacist is unwilling to provide, or the juncture at which a pharmacist should inform an employer, may vary according to the circumstances. For example, it may be appropriate for a locum pharmacist to inform a potential employer of the services they are not willing to provide, prior to their engagement. Whilst a permanently employed pharmacist may only seek to inform an employer when they are planning to introduce a new service, which they are unwilling to provide due to their religion and/or beliefs.

12.10.9 Taking the two points outlined above into consideration, the following recommendations are made:

Recommendation 4: Amend paragraph 3.5.2 to read as follows (additions underlined): '*Pharmacists should understand the services they are not prepared to provide and inform their employer at the earliest appropriate opportunity*'.

Recommendation 5: Amend paragraph 3.9.1 to read as follows (additions underlined): *Employers have a responsibility to patients and service users. Employers should work to foster an open, honest and collaborative working environment. Employers should work collaboratively with pharmacists to understand when and why their religion and/or beliefs may impact upon their willingness to provide a service. Employers should work collaboratively with pharmacists to ensure continuity of services, wherever possible.*

Objection to requirement to refer

12.10.11 A number of respondents outlined their objection to the professional obligation placed on a pharmacist in the Code, to take reasonable steps to refer a patient or service user to an appropriate alternative provider for the service they require. Stating that conscientious objection rights should extend to being able to refuse to refer certain services, as referral may also be immoral under certain circumstances.

12.10.12 Council should note that whilst it is acknowledged that these are sensitive issues, which individuals hold strong views on, Standard 1.1.5 of the Code is not under consultation and is not being considered for amendment. These comments are therefore out with the remit of this consultation.

Conditions placed on decision to refer too onerous

12.10.13 As stated in the introduction to the Guidance, its purpose is to assist pharmacists in Northern Ireland when considering their obligations under the Code, to put the patient first and their duty to refer should they be unable to provide a service for any reason, including they are unwilling

to because of their religion and/or beliefs. Neither of these obligations can be considered in isolation and there are potential circumstances where a patient's care may be compromised if a pharmacist does not provide a service, or where they refer without ensuring the patient has all the information they need to access the service with an alternative provider in a timely and safe manner.

12.10.14 As a counterbalance to the PDA's position in relation to this section of the Guidance, Council should reference the response by the PSA (Section 13.9), when it states: '*In the event that there is no straightforward alternative route to get the treatment that they require, it is difficult to see how a professional can justify refusal of service on religious grounds and remain in compliance with their professional responsibilities and the law'*.

12.10.15 We consider that the Guidance in section 3.4 – 3.8 to be appropriate and balanced in relation to the above and reflective of the balanced and thoughtful approach which should be adopted by pharmacists when considering these complex issues.

12.10.16 Council should also note that a primary purpose of the guidance is to ensure patients have access to their care in a timely and safe manner, the guidance, however, also provides pharmacists with an understanding of what is expected of them by their regulator when faced with certain scenarios. It should therefore provide them with some assurance that should they be cognisant of the guidance in their professional decision making, they are much less likely to face fitness to practise concerns, should a complaint be made against them by a member of the public in relation to the issues covered.

Standardisation of Language

12.10.17 We have reviewed the document in relation to CPNI's comment that about the different phraseology of 'a pharmacist should' and 'a pharmacist should consider'. Based on this review, we consider that the current phraseology in the document is appropriate. The guidance gives clear instructions of 'a pharmacist should' when there is a linear and singular action required. The guidance gives the instruction, a pharmacist should consider' when they are being asked to use their professional judgement based on a number of potential options. For example, at paragraph 4.3.3 the guidance states: 'Upon refusing a service to a patient or service user, a pharmacist should consider the following:…'

12.10.18 In relation to the CPNI's further comment that actions outlined in the guidance should only be considered "where appropriate, reasonable and appropriate…' we consider that this would cause more confusion in relation to the standardisation of the application of the guidance. The guidance already states that pharmacists should use their professional

judgement when applying the guidance and take notes in relation to the decisions they make.

Not as applicable for Hospital Pharmacists.

12.10.19 It is recognised that the guidance's main focus is on pharmacist/patient interactions in relation to service provision. This is by design. It is further noted that a number of pharmacy roles, including some hospital pharmacy roles, are not as patient facing, if at all. It is considered that it is important to retain the focus on patient/pharmacist interaction as this is where the majority of issues relating to refusal of service will emerge. It is also considered that the principles outlined in the guidance, such as informing your employer of the services you are not prepared to provide and working with your employer with regards continuity of service, are appropriate to hospital pharmacists with a non-patient facing role and can be used by hospital pharmacists and employers to navigate issues relating to conscientious objection.

13. Responses to Question 6

Question 6: Is the Guidance provided in section 3 (Religion and Beliefs) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
5 (25%)	**14 (70%)**	**1 (5%)**	**3**

13.1 Of the 14 respondents that answered 'No' to Question 6, 14 provided additional comments.

13.2 Objection to requirement to refer, in Standard 1.1.5 of the Code

13.2.1 Eight respondents that answered 'No' to Question 6, made objections to the requirement in Standard 1.1.5 regarding the professional responsibility of a pharmacist to take reasonable steps to refer the patient or service user to an appropriate provider for the service they require. The breakdown of those that provided comments in relation to this was 7 members of the public and 1 pharmacist.

13.2.2 For example, a member of the public stated that: "*Abortion and contraception are immoral. To refer someone for something is immoral itself. Doing something immoral is unreasonable. Therefore , the Code of Practice (since it requires only reasonable actions) does not require a pharmacist to refer someone for abortion or contraception*."

13.3 Requirement to provide information on options

13.3.1 HereNI stated that: *There should be an obligation to refer on to another healthcare practitioner, should the patient want that. The guidance sets out the importance of putting the patient first and timely care. Without an obligation to refer on some pharmacists may decide not to, and not provide any information for alternative care. In some situations, for example emergency contraception, timely care is very important. The measure contained in Section 5 such as providing information on options and taking reasonable steps to refer should apply in section 3.*

13.4 More Guidance for Employers

13.4.1 An individual pharmacist repeated the points made in response to Question 5, responding that more guidance needs to be added at 3.5 and 3.9 about how employers should discuss pharmacists "*not being prepared to provide services. When should it be discussed? Before contracts signed. An interview? Could it lead to potential unintended discrimination in the selection process*".

13.5 Hospital Pharmacists

13.5.1 One individual pharmacist that answered 'Unsure' to Question 6, repeated their concerns relating to the Guidance being less applicable to Hospital Pharmacists.

13.6 Clarity on Language

13.6.1 The HSCB answered 'Yes' to Question 6 and provided feedback in relation to the language used in section 3.9.1, which stated that 'employers should work with pharmacists to understand when and why their religion and/or beliefs may impact upon their willingness to provide a service". The HSCB asked, should this read 'when and how'? The use of 'why' suggests the belief may be questioned.

13.7 Professional Standards Authority

13.7.1 The PSA provided a general written response and did not specifically answer the questions provided. However, the PSA focused their response on Section 3 of the Guidance and it is considered most appropriate that its response is considered against Question 6.

13.8 Welcome inclusions

13.8.1 The PSA stated:

We acknowledge that it is a complex and sensitive area but are of the view that ultimately the patients' right to access safe, legal care must come first. The primary duty of healthcare professionals is to meet the health and care needs of patients, to the best of their ability. 3.2 We welcome the fact that the PSNI has, in this guidance, addressed some of the areas that we had previously commented on in our response to the draft GPhC guidance.

This includes:

- *Provision of an initial equality assessment alongside the consultation*
- *Providing clarity that the Abortion (Northern Ireland) (No. 2) Regulations 2020 put in place a statutory protection for conscientious objection in Northern Ireland specifically in relation to abortion*
- *Guidance that pharmacists should explain to the patient that they will not provide the service and give reasons for this*
- *Guidance that pharmacists must not discriminate against patients and service users based on their sex (including gender reassignment and pregnancy/maternity), disability, race, religious belief or political opinion, or sexual orientation.*

13.9 Putting patient first

13.9.1 The PSA went on to say:

In the event that there is no straight forward alternative route to get the treatment that they require, it is difficult to see how a professional can justify refusal of service on religious grounds and remain in compliance with their professional responsibilities and the law.

We therefore suggest that the guidance could be stronger on outlining how pharmacists should respond when it is clear that declining to provide a service will have a detrimental impact on the patient or service user.

We note that the introduction lists Standard 2.1.6 of the PSNI Code as being relevant ('Ensure that you do not, whether by your actions or omissions, create a risk to patient care or public safety') however, there is no explicit mention of risk in the later sections of the guidance document. The guidance would be strengthened if para 3.6.3 were to include 'potential risks to the patient resulting from a delay in the service being provided' as a factor to be assessed to inform the pharmacist's decision on providing services.

13.10 Analysis - Question 6

Overview

13.10.1 Council should note that of the 14 respondents that answered 'No' to Question 6, 8 provided reasons for their objection which were out-with the remit of this consultation, namely the requirement of Standard 1.1.5, of the Code for a pharmacist to refer to an alternative healthcare provider in general. As noted above, standard 1.1.5 of the Code is not under consultation and is not being considered for change. Whilst this does not change the headline figures in relation to those respondents that consider the guidance in this area to be inappropriate, Council should reflect on the fact that over half of the respondents who answered 'No' to Questions 6 primarily objected to an overarching principle of the Code. This, it can be argued, somewhat skews the headline figures.

Objection to requirement to refer.

10.10.2 Please see analysis outlined in paragraph 12.10.11 above.

Requirement to provide information on options (HereNI)

10.10.3 It is considered that this comment is not reflective of the actual guidance and sections 3.6 to 3.8 adequately cover the issues raised in this comment.

More Guidance for Employers

10.10.4 Please see analysis outlined in paragraph 12.10.7 above.

Hospital Pharmacists

10.10.5 Please see analysis outlined in paragraph 12.10.19 above.

Clarity on Language

10.10.6 We agree with the HSCB's comment in relation to paragraph 3.9.1 and recommend amending the guidance accordingly.

<u>Recommendation 6:</u> Amend paragraph 3.9.1 to read: '*Employers should work with pharmacists to understand when and <u>how</u> their religion and/or beliefs may impact upon their willingness to provide a service*.'

PSA – inclusion of reference to risk to patients.

10.10.7 We note the PSA's response to the consultation and have reflected upon certain aspects of their feedback above. In relation to the substantive recommendation by the PSA, that paragraph 3.6.3 '*would benefit from a direct reference to potential risks to patients, resulting from a delay in the*

service being provided'. It should be noted that paragraph 3.6.2 of the guidance states that patients' individual needs should be at the centre of decision making so they can access the service they need in a timely manner without difficulty. Likewise, paragraph 3.6.3 requires a pharmacist to assess the acuteness of the patient's need, prior to making a decision to refer. However, it is considered that making a direct reference to the risk to a patient or service user would be helpful in focusing a pharmacist's decision making and is in line with the guidance and the Code at Standard 2.1.6.

10.10.8 It is therefore recommended that paragraph 3.6.3 be amended to include an additional bullet point which would require a pharmacist to consider the 'potential risks to the patient or service user resulting from a delay in the service being provided', before they make their decision to refer.

Recommendation 7: Amend paragraph 3.6.3 to include the following bullet point:

- **'potential risks to the patient or service user resulting from a delay in the service being provided'**

11. Responses to Question 7

Question 7: Is the Guidance in Section 4 (A patient or service user is violent, threatens violence or is verbally abusive) clear?			
Yes	**No**	**Unsure**	**Did not answer**
9 (65.3%)	**5 (31.3%)**	**2 (12.5%)**	**7**

11.1 Of the 9 respondents that Answered 'Yes' to Question 7, 1 provided an additional response.

11.2 Clarity on the right to refuse a service

11.2.1 The NPA stated that they '*welcome that the Guidance supports the Health and Social Care Board's (HSCB) Zero Tolerance campaign and would call for a clear position on the right to refuse a service and guidance for the pharmacist on seeking provision of an alternative service (4.3.2)'*.

11.2.2 Of the 5 respondents that answered 'No' to Question 7, 3 provided additional responses.

11.3 Opposition to the section in general/pharmacist safety

11.3.1 The PDA outlined its opposition to the Section 4 in general, outlining that they consider it may place pharmacists at risk if followed and applied.

11.3.2 Citing the rise of violence against and abuse directed towards pharmacists, particularly during the Covid-19 pandemic, the PDA iterated that a 'Zero Tolerance Approach' must mean a zero-tolerance approach. Stating that: "*The PSNI Guidance is particularly unhelpful in that it seems to obligate pharmacists to consider a variety of "assessments" to determine why a patient may be aggressive or abusive. It is the patient facing pharmacist who will (on occasions) be encountering patients who may be aggressive or violent who should be at the forefront of any development of guidance*".

"*This guidance suggests exploring why the patient may be exhibiting such a behaviour. This is not acceptable and downright dangerous. It may not be possible for a pharmacist to engage with a patient who is shouting and making threats*".

11.3.3 Community Pharmacy NI stated that "*in respect of the three questions posed it would be extremely difficult in all cases for a pharmacist to accurately decided the reason for the behaviour of the patient, particularly if facing a violent and abusive patient".*

11.4 Analysis - Question 7

11.4.1 Analysis has been carried out in relation to questions 7 and 8 together, see paragraphs 12.6.1 to 12.6.20 below.

12. Responses to Question 8

Question 8: Is the Guidance in Section 4 (A patient or service user is violent, threatens violence or is verbally abusive) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
5 (31.3%)	**6 (37.5%)**	**5 31.3%)**	**7**

12.1 Of the 6 respondents that answered 'No' to Question 8, 5 provided additional comments.

12.2 Need for a clear Zero Tolerance Approach

12.2.1 The PDA cites that '*over 72% of pharmacists in Northern Ireland are female. Over 40% of PSNI are under 35.* Stating that *'we must*

understand the context that abusive, threatening behaviour may have on all these younger pharmacists.'

12.2.2 Going on to say that '*Violence in pharmacies is getting worse year on year*.'

12.2.3 The PDA restated arguments against this section of the Guidance, comparing the concise advice provided by the BMA to doctors in relation to zero tolerance and the fact that violent or aggressive patients can be immediately removed from the GP practice list and the special allocation system can provide GP services in a secure environment. With Designated GP practices providing services to patients by appointment at specific locations and times as detailed in individually agreed contracts.

12.2.4 The PDA considers the Guidance provided by the BMA '*is clear concise and does not require the GP to "consider" this, that or the other. The safety of the GP, practice staff and other patients is considered to be paramount*'.

12.2.5 The PDA then compares this clarity with section 4.3.5 of the draft Guidance which outlines that pharmacists working in community pharmacy should be aware that the HSCB can assist with delivering professional services to difficult and threatening and potentially violent patients and service users.

12.2.6 The PDA cites DoH's consultation in 2016 which proposed amending the Provision of Services Regulations (1997) to allow pharmacists to refuse the supply of drugs or appliances to abusive patients. The PDA outlined its support for the proposed changes, which have not been brought forward. The PDA stated the '*Irrespective of the fact that this regulation has not come into effect, the PSNI can show clear leadership by supporting the ethos of the proposed regulation by including it in this Guidance.*'

12.2.7 The PDA states that the draft guidance '*does little to inspire confidence hat pharmacists feel valued and that their health and mental well being is important'*.

12.3 Guidance needs to focus more on patients with ongoing pattern of violence or abuse

12.3.1 Boots outlined its concern that the guidance is '*too theoretical to be of real use in a sudden crisis situation*', going on to say, '*it does not seem reasonable to expect that pharmacists will start thinking 'Is the patient's behaviour a feature/symptom of a medical condition or disability' if they are unexpectedly confronted by an angry, distressed or violent person.*

Decisions to protect themselves and others will be natural and instinctive and must be acknowledged'.

12.3.2 Boots suggested that the guidance '*should have stronger distinction between the actions to be taken in a one-off incidence of violence and abuse and those that might arise form an ongoing pattern or harassment of staff.*

12.3.3 The guidance should cover the need for having a process around the decision to suspend the provision of services to violent or abusive customers on either a temporary or permanent basis. Such decisions would have to be taken in response to local circumstances, but with the support and guidance of employers/owners and their representatives (eg area managers).

12.3.4 Such decisions should be documented. There may need to be a requirement to liaise with HSCB or other local bodies, depending on the circumstances.

12.3.5 While healthcare professionals, including pharmacists, have a duty to put the patient first, they also owe a duty of care to themselves and those working with them, especially in urgent situations where there is a real possibility of violence or harm occurring".

12.3.6 Similar issues were raised by the Pharmacy Forum NI. Referring to Paragraph 4.3.1 of the draft guidance the Pharmacy Forum NI pointed out that '*there could be cases where the pharmacists are unable to evaluate the psychological sate/medical condition of a service user/patient. It is therefore important that proper policies/procedures are in that empower the pharmacist and allow them to protect themselves, the team and other service users/patients on site, should an incident of challenging behaviour occur*".

12.3.7 The Pharmacy Forum NI goes on to query paragraph 4.3.2, which outlines that if a pharmacist considers that it is not safe to provide a professional service to a patient or service user, they still have obligations under the Code, including to always consider and act in the best interests of the patient or service user.

12.3.8 The Pharmacy Forum NI asks *'is this statement contradictory to the essence of the document – that pharmacists can refuse service to a patient if it is unsafe to do so? Does the interests of the patient accessing their medications in a timely manner override the safety of the pharmacist and staff?*"

12.3.9 The Pharmacy Forum NI, also cites the BMA's guidance the fact that GPs have access to specially commissioned secure sites.

12.4 Racism

12.4.1 Both the NPA and the Pharmacy Forum NI suggested that the issue of racist abuse towards pharmacists be specifically addressed in this section and considered as a ground for refusing service.

12.4.2 Of those respondents that answered 'Unsure' to Question 8, 2 provided additional responses.

12.5 Community Pharmacy Terms of Service

12.5.1 The Health and Social Care Board, referring to paragraph 4.3.1, which outlines that if a pharmacist considers the service cannot be provided safely, they should consider refusing the service and assessing what steps need to be taken, if any upon that refusal, states that the "*existing Community Pharmacy Terms of Service do not allow community pharmacists to refuse to provide a service. Currently the HSCB recommendation under such circumstances is that the community pharmacy service is altered to protect staff and patients. DH is aware of the need to review the Terms of Service.*

HSCB is supportive of the PSNI recommendation but amendments are needed as above to align the Terms of Service before it can be actioned".

12.6 Analysis Questions 7 and 8

12.6.1 When considering the feedback to this section of the Guidance it is worth reflecting on what originally prompted its development and its purpose.

12.6.2 In 2016 the Department of Health carried out a public consultation on revising the Pharmaceutical Services Regulations (NI) 1997 (the Regulations). The Regulations set out the terms of service for pharmacy contractors which outline the framework for the delivery of community pharmacy services.

12.6.3 The Department proposed to amend these terms of service to clarify that community pharmacy contractors will not be in breach of the terms of service if they (or their staff) refuse to provide pharmaceutical services to a person who is violent, threatens violence, commits or threatens to commit a criminal offence. Similarly, it proposed that they can also refuse to provide pharmaceutical services if anyone accompanying the person seeking pharmaceutical service behaves in this manner.

12.6.4 The proposed amendment was considered in line with a wider policy position across the HSC that attacks on health professionals are not acceptable.

12.6.5 Developing this guidance, it was our understanding that changes to the Regulations would be progressed by the Department of Health. To date this has not happened.

12.6.6 When considering the changes to the Regulations, and reflecting on our regulatory obligations to the public, it was considered appropriate that pharmacists should be provided with guidance which reflected their obligations under the Code in relation to patient care and access to medicines, when making decisions regarding the refusal of services, which would no longer break contractual agreement of contractors.

12.6.7 For example, when we consider the feedback of the PDA to this section, they compare the approach in pharmacy to how GP surgeries protect GPs and staff by reference to the special allocation system, which refer abusive patients to designated and specially equipped GP practices. However, the PDA's response, does not acknowledge the fact that the purpose of this system is two-fold. Firstly, it is to protect GPs and their staff, but also it is to ensure that 'difficult' patients can gain access to the care they need in designated practices.

12.6.8 The purpose of this section of our Guidance is to provide balance between protection of pharmacists and their staff and difficult patients' access to care. It was for this reason that we also worked with the HSCB on the development of the guidance in this section and provided contact information for HSCB, in relation to how they can assist pharmacies facing difficult patients/service users.

12.6.9 There are, however, a few aspects to the feedback to this consultation that has given reason to give circumspect consideration to this section of the guidance.

Clarification on the right to refuse a service

12.6.10 The NPA welcomed the guidance's support for the HSCB's Zero Tolerance approach but called for a clear position on the right to refuse to provide a service in relation to abusive patient/service users. This point was echoed in some of the feedback from the PDA.

12.6.11 The HSCB, responded by reflecting on the fact that the existing Community Pharmacy Terms of Service do not allow community pharmacists to refuse to provide a service. And that DH is aware of the need to review the Terms of Service. HSCB stated that amendments are needed to the Guidance to align it with the Terms of Service before it

can be actioned. It should be noted that this issue was not raised by HSCB in the policy development phase.

12.6.12 As the regulator we do not have any direct influence over the HSCB's Zero Tolerance campaign, nor the Terms of Service Regulations, held by the Department. However, until the Terms of Service Regulations are amended, there appears to be an inconsistency between the two positions, which our guidance, focused on the actions of pharmacists, is unable to resolve.

More focus on managing continuously 'difficult' patients/service users

12.6.13 A number of respondents outlined their concerns that the approach the guidance takes may not be applicable in one-off scenarios, where pharmacists are faced with a potentially violent and abusive patient/service user.

12.6.14 Boots suggested that the guidance needed to focus more on those patients/service users that are continuously difficult and how to manage these individuals in a way that both protects staff and allows them to provide a service to the patient. They suggested greater emphasis on working with HSCB, other agencies and within employer organisations.

12.6.15 These comments are noted and reflected upon in light of comments above in relation to clarity on the ability to refuse a service.

Current high levels of abusive behaviour/aggression against pharmacists

12.6.16 When considering this section of the guidance Council may wish to reflect on the reported high levels of abuse against pharmacist that have been described during the Covid-19 pandemic.

Recommendation.

12.6.17 Based on the feedback above we have engaged with the Department of Health and HSCB on the issues raised in relation to the Terms of Service Regulations and the HSCB's suggestion that the guidance should not be actioned until aligned with the Terms of Service. When these are considered in line with the Zero Tolerance message and the request for clarity on rights to refuse service, it is considered that to proceed to publish this section of the guidance, at this stage, may prove counterproductive and not provide adequate clarity to pharmacists on the ground.

12.6.18 We consider that the most appropriate approach, at this stage, is to pause this section of the guidance and consult further with the Department of Health on its plans to amend the terms of service

regulations and then work with the Department and HSCB to provide the most appropriate guidance that provides a robust message on the balance between refusal of service and patient care, but which better explores the options available to pharmacies in accessing HSCB, and any other, support to manage these situations.

12.6.19 In short, resolving the issues relating to the refusal of services are not within the gift of this section of the guidance and to proceed ahead of the changes to the Terms of Service Regulations may not assist the pharmacy profession. It is therefore recommended that Council pauses Section 4 of the guidance, amends the remaining sections to accommodate its removal and commits to working with the Department of Health on its approach to amending the Terms of Service Regulations and based on this, work with the HSCB and other stakeholders to refine the guidance to offer the appropriate messages and support to pharmacists.

12.6.20 Council should reflect on the fact that this consultation has crystalised a number of issues and there is an opportunity to work with our stakeholders, the Department of Health and HSCB, on refining this guidance in line with changes to the Terms of Service Regulations and support offered by the HSCB.

Recommendation 8:

- **Do not publish Section 4 of the Guidance at this stage.**
- **Amend the remainder of the document to accommodate this change**
- **Work with DoH, HSCB and other stakeholders to develop revised guidance to be introduced at an appropriate time in line with changes to the Pharmaceutical Services Regulations (NI) 1997 (the Regulations).**

13. Responses to Question 9

Question 9: Is the Guidance in Section 5 (The medicine, service or medicinal device is not currently in stock or available) clear?			
Yes	**No**	**Unsure**	**Did not answer**
10 (58.8%)	**4 (23.5%)**	**3 (17.6%)**	**6**

13.1 Of the 10 respondents that answered 'Yes' to Question 9, 1 provided an additional response.

13.2 Medicine Shortages

13.2.1 CPNI stated that '*the shortage of medicines continues to create significant challenges for CP teams who are dealing with this daily occurrence in a highly professional manner, safeguarding patient interests at all times. Unfortunately, these issues increased in frequency and severity over the Covid period and it is anticipated that the problem of interrupted medicines supplies will be exacerbated by the EU-exit period.*

CPNI is of the view that it is very evident that contractors and their teams do, in circumstances where shortages are imposed upon them, act in the best interests of the patient and do take all reasonable steps to ensure safe and timely access to medicines and pharmaceutical care'.

13.2.2 Of the 4 respondents that answered 'No' to Question 9, 3 provided additional comments.

13.3 Guidance unnecessary and should be withdrawn

13.3.1 The PDA states that it is 'unclear as to why further 'Guidance' is needed for such an issue. We appreciate that shortages do occur from time to time and pharmacists routinely speak to prescribers and others to ensure that issues surrounding difficult to obtain medicines are addressed to reduce potential harm to patients.

13.3.2 Going on to say that the PDA feels 'that Guidance on this matter is demeaning to pharmacists and we recommend that it be withdrawn".

13.3.3 The PDA does, however, go on to say that it is '*aware of cases whereby multiples have attempted to stockpile items which are going out of stock and moving it around their stores, to the detriment of smaller contractors. There are also incidences of wholesalers showing preferential treatment for one chain of contractor over another. This behaviour requires regulation however, it has no place in a guidance document for pharmacists*.'

13.4 Supply of Medicines

13.4.1 The NPA also cites 'unprecedented difficulties in securing supplies of medicines, going on to say that the guidance "*calls for pharmacists to take reasonable steps to refer the patient to an alternative provider. However, urgent action is also needed throughout the supply chain to reduce the risk of harm and to allow pharmacists to effectively spend more time with patients instead of sourcing stock*".

13.5 Analysis – Question 9

13.5.1 Analysis for responses to Questions 9 and 10 have been carried out together. Please see response to Question 10 outlined below.

14. Responses to Question 10

Question 10: Is the Guidance in Section 5 (The medicine, service or medicinal device is not currently in stock or available) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
9 (52.9%)	**5 (29.4%)**	**3 (17.6%)**	**6**

14.1 Of the 9 respondents that answered 'Yes' to Question 10, 1 provided an additional response.

14.2 Timely intervention

14.2.1 The HSCB suggested that we '*consider adding a few words to section 5.3 about the need to let the patient know in a timely way, as soon as possible after the patient presents the prescription.*

14.2.2 Also consider adding in the need to provide written information to the patient on occasion e.g. in the case of "owings" and additionally the need for community pharmacy to "code" prescriptions in line with what was dispensed rather than prescribed where medicines are not available'.

14.2.3 Of the 5 respondents that answered 'No' 3 provided additional responses.

14.3 Greater clarity on different types and levels of shortages

14.3.1 Boots stated that the "*Guidance needs to be clearer on the different types or levels of shortages or unavailability that might occur*".

For example, there is considerable difference between "You'll have to come back tomorrow for the rest of this" and "we don't know when this will be available again".

Pharmacists should also help patients and prescribers understand the underlying nature of the shortage. Is it temporary or longer term? Is it something that is outside the control of the pharmacy or wholesaler? Will the patient need to be prescribed a different product?

The guidance suggests referring the provider to an alternative provider, but this is unlikely to be helpful or reasonable of the product in question is going to be out-of-stock for all the providers for a long time (manufacturer cannot supply).

Again, the guidance appears to be more theoretical than practical".

14.4 Referral to healthcare provider/prescriber or healthcare practitioner.

14.4.1 The Pharmacy Forum NI suggested that at section 5.3 an addition is made to the Guidance that pharmacists 'refer the patient also to their healthcare provider /prescriber or healthcare practitioner.

14.4.2 The Pharmacy Forum NI also suggests adding examples/vignettes to be included for illustrative purposes as to what qualify as 'reasonable' and 'reasonable steps'.

14.4.3 They also suggest that the guidance be expanded to advise pharmacists to take contemporaneous notes of actions taken should a service not be available.

14.5 Shortages and proportion

14.5.1 The CPNI again cited the increase in shortages caused by Covid-19 and the EU-exit period. CPNI stated that it is of the view that '*it is very evident that contractors and their teams do, in circumstances where such shortages are imposed upon them, act in the best interests of the patient and do take all reasonable steps to ensure safe and timely access to medicines and pharmaceutical care'*.

14.5.2 CPNI welcomes the guidance offered in sections 5.3 and 5.4, however, stated that this '*must be caveated in the opening paragraph with the phrase "they should, where possible, reasonable and appropriate…"*'

14.5.3 Going on to say*: "It may not for instance, in the midst of a large volume of shortages and mounting external and internal pressures, be possible or reasonable for a contractor's team to consider the availability of the service elsewhere. It certainly would not always be possible, reasonable or appropriate for the contractor's team to take notes to document decisions and reasons for them, and their interactions with patients, nor to provide answers to 'any questions that the patient may have'.*

14.6 Analysis – Questions 9 and 10

Medicine Shortages/Supply Issues

14.6.1 The responses which outline ongoing and potentially increasing medicine shortages and supply issues are noted. Such shortages and

supply issues add weight to position that guidance from the Regulator, which outlines the requirement to ensure that patients and service users are provided with the correct information and where appropriate are referred to an alternative provider, is needed and potentially beneficial to patients and pharmacists alike. Council should also note that Guidance also outlines what patients can expect from their pharmacist/pharmacy.

Greater clarity on different types and levels of shortages

14.6.2 The feedback from Boots, which suggests that the guidance could be clearer on the different types or levels of shortages or unavailability that might occur is noted. It is important that patients and services users are provided with the most accurate and appropriate information.

Referral to healthcare provider/prescriber or healthcare practitioner.

14.6.3 In addition, the feedback which highlighted that direct referral to an alternative provider may not be the most appropriate course of action, is also noted. If the shortage is considered a long-term supply shortage, which is impacting regionally, working with the patient's general practitioner or designated prescriber on alternative options, may be the most appropriate action.

Timely Interventions

14.6.4 The HSCB suggested that we consider adding a sentence to the guidance to ensure that the patient is informed in a timely way after the patient presents the prescription. We consider this to be a reasonable recommendation, which complements the thrust of the guidance, which is about ensuring patients are fully informed of the issues and are able to access their healthcare in a timely manner.

14.6.5 The HSCB makes a further suggestion that a further sentence be added on the need to provide written information to the patient on occasion and the need for community pharmacy to "code" prescriptions in line with what was dispensed rather than prescribed where medicines are not available.

14.6.7 It is not considered appropriate to accommodate these suggestions in the guidance as they are deemed overly prescriptive. The first issue is captured by the requirement at 5.3 "*to provide the patient with all the options available to them in a clear and unambiguous manner*". Whilst it is considered that the second suggestion is beyond the scope of regulatory guidance, whose purpose is to provide a framework for professional decision making. Based on the analysis above the following recommendations are made:

Recommendation 9: Amend paragraph 5.3 Bullet point 1 to read as follows (Additions underlined):

- **Explain to the patient in a timely manner, that they cannot provide the service and the reasons for this. This explanation should include information about the underlying nature of the shortage, for example is it considered to be a short-term or long-term issue.**

Recommendation 11: Add in an additional bullet point at 5.3, which reads:

- **When appropriate, work with the patient's General Practitioner or the prescribing healthcare professional, to ensure safe and timely access to medicines and pharmaceutical care.**

15. Responses to Question 11

Question 11: Do Sections 6 (Help and Advice) and 7 (Useful Contacts) contain the appropriate information?			
Yes	**No**	**Unsure**	**Did not answer**
10 (58.8%)	**2 (11.8%)**	**5 (29.4%)**	**6**

15.1 Of the 10 respondents that answered 'Yes', 2 provided additional responses.

15.2 Boots suggested, "*It would also be helpful to make reference to contacting any helplines or support services offered by their employers in relation to pharmacy or HR topics, as well as seeking advice from more senior pharmacists within their own organisations*".

15.3 CPNI outlined that it felt their contact details should be included in this section.

15.4 Of those that answered 'No' to Question 11, 1 provided an additional comment.

15.5 The Pharmacy Forum NI stated that CPNI and UCA Ltd should be included as contacts in this section.

15.6 Of those that answered 'Unsure' to Question 11, 2 provided additional responses.

15.7 The HSCB suggested "*rewording 'to then ask to speak to someone in the Pharmacy Team in your local integrated care office*".

15.8 Analysis -Question 11

<u>Recommendation 11:</u> Include the contact details of CPNI in Section 6.

16. Responses to Question 12

<u>Question 12:</u> Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories? If yes, please explain what could be done to change this. We would welcome any research/sources you may have to evidence your response.

- **Age**
- **Gender**
- **Disability**
- **Pregnancy and maternity**
- **Race /ethnicity**
- **Religion or belief**
- **Political Opinion**
- **People with dependants**
- **Sexual orientation**
- **Marital Status**

Yes	No	Unsure	Did not answer
4 (25%)	**7 (43.8%)**	**5 (31.3%)**	**7**

16.1 Of the 4 respondents that answered 'Yes' to Question 12, 4 provided additional comments.

16.2 CPNI stated that **"***There may be equality implications cited by pharmacists who may fall into one or more of the above categories and who would have concerns in regards to, for example, directing patients to other pharmacies to have certain medicines dispensed. However, the guidance is in clear alignment with Principal 1 of the Code and this is fully endorsed by CPNI*".

16.3 Women and LGB+ and Transgender People

16.3.1 HerenNI stated "*the majority of the issues in section 3.2 disproportionately impact women and LGBT+ people.*

It must be made clear that a pharmacist cannot differentiate the service they provide because if a protected characteristic, for example providing fertility medicines to a heterosexual couple and not a lesbian couple, or providing medicines to married couples; as opposed to not offering the medicine to anyone because of a conscientious objection.

The limits of conscientious objection should be set out more clearly. A blanket refusal of services to LGBT+ people would be unlawful. While this is mentioned in terms of protected characteristics making it explicitly clear in section 3 that choosing to refuse service on the basis of a protected characteristic, regardless of the treatment, would be unlawful and would not qualify for conscientious objection would be good for the avoidance of doubt.

16.4 Requirement to Refer

16.4.1 An individual member of the public stated: "*Not only should a pharmacist be free to not dispense an abortifacient drug, but should be free not to refer a woman seeking an abortion to a colleague who would be free to supply the drug. A pharmacist, so exercising his/her conscience, should be free from discipline or threat of discipline*".

16.4.2 Whilst an individual pharmacist stated: *"The patient is out first and therefore may need to either wait or go to another pharmacy. The service is delivered.*

16.4.3 The pharmacist can have a conscientious objection or another reason and not be forced to provide a service which denies their equality rights.

16.4.5 This document provides both good information, support and some degree of pharmacist protection".

16.4.6 Of those that 5 respondents that answered, 'Unsure' to Question 12, 2 provided additional comments:

16.4.7 The HSCB stated: *the issues outlined are more likely to cause difficulties or issues for some pharmacists with particular religious beliefs*.

16.5 Analysis – Question 12

Women and LGB+ and Transgender People

16.5.1 The comments from HereNI that the guidance needs to be clearer on the distinction between discriminatory refusal to provide a service to a patient/service user because of a 'protected characteristic' and the refusal to provide a 'service' because of a pharmacist's religion values and beliefs are noted. It is acknowledged that the guidance should be as clear as possible on this issue to avoid any discriminatory actions. We consider that the guidance is clear in relation to this issue. For example, paragraph 2.1 states that equality legislation in Northern Ireland protects individuals from direct and indirect discrimination in the provision of goods, facilities and services against certain characteristics. Paragraph 3.2 states that pharmacists must not discriminate against patients and

service users based on any of the 'protected characteristics' and that they must respect diversity and cultural difference, beliefs and value systems of others and always act with sensitivity and understanding when engaging with patients and service users.

16.5.2 Section 2.4 outlines the limitations of manifesting Article 9 rights and section 3.2 outlines the services that may be impacted upon by a pharmacist's religion and/or beliefs.

16.5.3 However, it is considered prudent to provide additional clarity and it is suggested that the following the following addition is made.

<u>Recommendation 12:</u> Add an additional footnote to paragraph 3.2 as follows:

Referring a patient or service user to an alternative provider because the patient or service user holds a certain characteristic (e.g., their gender), would be considered as direct discrimination. This guidance deals with circumstances where a pharmacist is considering referring a patient or service user to an alternative provider because the pharmacist conscientiously objects to the <u>professional service</u> being offered<u>,</u> based on their religion and/or beliefs.

Requirement to Refer

16.5.4 Council should note that whilst it is acknowledged that these are sensitive issues, which individuals hold strong views on, Standard 1.1.5 of the Code is not under consultation and is not being considered for amendment. These comments are therefore out with the remit of this consultation.

17. Responses to Question 13

<u>Question 13:</u> Do you have any other comments about the proposed Guidance on the Provision of Services?			
Yes	**No**	**Unsure**	**Did not answer**
7 (41.2%)	**10 (58.8%)**	**0**	**6**

17.1 Of the 7 respondents that answered 'Yes' to Question 13', 7 provided additional responses.

17.2 Shortage Issues

17.2.1 The Pharmacy Forum NI Stated:

Based on the experience of working through Covid-19, we would suggest a reference be added in relation to the impact on service delivery as a result of a pandemic e.g., services being unavailable, medicine shortage/out of stock, related to changes in legislation. There may also be cases where the service commissioner could take down a service.

We would seek clarity in cases where an employer takes a decision pertaining to service provision that impacts the group at large and how pharmacists should respond.

17.3 Protected Characteristics

17.3.1 HereNI stated:

It is welcome that the guidance clearly sets out the protected characteristics and mentions the limits of conscientious objection.

It may be useful for pharmacists to have a notice stating what services they have a conscientious objection to providing, to avoid embarrassment and time being wasted.

Perhaps a register of conscientious objectors would also be useful? Both for patients and for pharmacists who would have the burden of proof to show they have a conscientious objection.

17.4 Highlight Guidance

17.4.1 A pharmacist stated: *The pandemic and Brexit have probably increased the potential risk of situations arising with regards to violence and unavailable stock. Due process obviously needs to occur with this consultation process but need to highlight the guidance further (even in draft form) in a timely manner to support the staff.*

17.5 Conscientious objection under attack

17.5.1 A member of the public stated: *It is obvious that the concept of conscience and personal conviction about spiritual and moral issues is under serious attack in today's society. I understand that any crank can raise objections and claim exemption from any rule or provision on a whim and claim conscience as the basis of the objection. The issue of abortion however, cannot by any stretch of the imagination fall into that category. Objection to it on the grounds of protecting the life in the womb is well established and accepted position held by large numbers of law*

abiding citizens whose conscience should not be overridden lightly. The wishes of a zealous majority should not trample underfoot the deeply held moral convictions of an honourable minority.

17.6 Document is needed

17.6.1 A pharmacist stated: *The document is needed to provide some degree of support to Pharmacists in NI, where the legislation of Abortion may have an psychological impact of them because of personal beliefs.*

17.7 Analysis – Question 13

17.7.1 The additional comments are noted and it is considered that all issues have been appropriately dealt with or considered in previous analysis.

Appendix 1

Respondents*	
Name	**Organisation/Job Type**
1. Mr David Kean	Individual Pharmacist
2. Mr Andrew Currie	Individual Pharmacist
3. The HSCB Pharmacy and Medicines Management Team	HSC Organization
4. Mr Michael Harper	Member of the Public
5. Pharmacy Defence Association	Trade Union Body
6. Boots Ltd	Pharmacy Business
7. Mr Andrew Dawson	Individual Pharmacist
8. Mr Terence Clarke	Member of the Public
9. Mr Ross McAdam	Member of the Public
10. HereNI	Charity
11. Ms Shona Dawson	Member of the Public
12. Mr Joel Dawson	Member of the Public
13. Community Pharmacy NI	Pharmacy Representative Group
14. National Pharmacy Association	Pharmacy Representative Group
15. Pharmacy Forum NI	Pharmacy Representative Group
16. Mr John Dawson	Member of the Public
17. Professional Standards Authority	Regulator
18. Ms Deborah Currie	Individual Pharmacist
19. Mr David Hawthorne	Member of the Public

*Four respondents stipulated that their name should not be listed or did not adequately clarify their intent.