Report on the responses to the Draft Indicative Sanctions Guidance Consultation 30 August 2018 – 26 October 2018

This report was considered by the Council of the Pharmaceutical Society NI on 13 November 2018. Council accepted the 12 recommendations included in the report.

Contents

1. About the Pharmaceutical Society of Northern Ireland

1.1 The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists 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 the organisation's 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;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; 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 (the Council) consulted upon revised Indicative Sanctions Guidance. Indicative Sanctions Guidance is used by the Statutory Committee of the Pharmaceutical Society NI when considering what is an appropriate sanction when a pharmacist's Fitness to Practise has been found to be impaired. The Consultation ran for eight weeks from 30 August 2018 – 26 October 2018.

2.2 The Statutory Committee considers and adjudicates on serious Fitness to Practise allegations made against pharmacists in Northern Ireland. Indicative Sanctions Guidance is used by the Statutory Committee as a reference point when it is deciding on an appropriate sanction to impose in a situation where a pharmacist's Fitness to Practise has been found to be impaired.

2.3 The Statutory Committee is independent of Council and its decisions are made on the merits of the case in front of it[1]. The Statutory Committee is tasked to make decisions on sanctions in the public interest and they are not intended to be punitive against a pharmacist. The Indicative Sanctions Guidance seeks to support consistent, proportionate and fair decision making which reflects current case law and best regulatory practice.

[1] CHRP v (1) GMC (2) Leeper [2004] EWHC 1850 (Admin)

2.4 The Statutory Committee must pay proper regard to the Pharmaceutical Society NI's Indicative Sanctions Guidance when deciding upon sanctions and must provide sound reasons if it chooses to depart from the Guidance[2].

2.5 The current Indicative Sanctions Guidance was published in 2012 and the Council of the Pharmaceutical Society NI has carried out a comprehensive review of the document, engaging in pre-Consultation and receiving feedback from a number of stakeholders.

3. Consultation Engagement

Pre-public Consultation Engagement:

3.1 The current Indicative Sanctions Guidance was published in 2012 and the Council of the Pharmaceutical Society NI carried out a comprehensive review of the document, engaging in pre-Consultation and receiving feedback from a number of stakeholders. In carrying out the review, the following objectives were set:

1. *To make the revised Indicative Sanctions Guidance clear and understandable within the context of wider Fitness to Practise processes;*
2. *To ensure the document is up to date and proportionate, providing:*

    a. *suitable focus on the public interest;*
    b. *clear advice on insight and remediation, aggravating and mitigating circumstances and testimonials; and*
    c. *appropriate additional guidance in the areas of dishonesty, duty of candour, raising concerns, sexual misconduct and violent conduct.*

The review resulted in the proposed Draft Indicative Sanctions document which is the subject of this consultation report.

3.2 **Correspondence with key stakeholders**: All registrants and key stakeholders were emailed along with details of the consultation and instructions on how to respond.

3.3 **Website:** The consultation document and the draft Indicative Standards Guidance were available to download from the website along with a response form between 30 August 2018 – 26 October 2018.

[2] PSA v HCPC + Doree [2017] EWCA Civ 319

3.4 **Facebook and other media**: the consultation document was advertised on our Facebook page over the consultation period and a reminder of the consultation was placed in the October edition of our regulatory Newsletter.

4. Purpose of Report – approach and analysis

4.1 This report provides a summary of the responses to the consultation on the Draft Indicative Sanctions Guidance held from 30 August 2018 – 26 October 2018.

4.2 The consultation document was based on fourteen questions relating to the Draft Indicative Sanctions Guidance, with space provided for respondents to make further comments in relation to the relevant question. The analysis primarily summarises general qualitative themes, responses and issues – highlighted areas of agreement and diversity of opinion.

4.5 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.

4.6 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.

4.7 The report provides comments on the feedback received and makes a number of recommendations to Council regarding amendments to the draft Indicative Sanctions Guidance.

5. Consultation Document

5.1 The Consultation document outlined how to respond to the consultation; outlined and explained the fourteen consultation questions; and provided a rationale for the proposed Draft Indicative Sanctions Guidance.

5.2 Consultees were asked the following questions and were provided with space to make further comments on each question and in general.

1. Does the document clearly set out the processes of the Statutory Committee?

Yes, No, Unsure

2. Does the document clearly set out the purpose of Indicative Sanctions Guidance?

Yes, No, Unsure

3. Is the Guidance on the public interest and proportionality (Pg.8) appropriate?

Yes, No, Unsure

4. Is the Guidance on when a particular sanction might be appropriate (Pg.9) clear?

Yes, No, Unsure

5. Is the Guidance on when a particular sanction might be appropriate proportionate?

Yes, No, Unsure

6. Is the Guidance on mitigating and aggravating circumstances (Pg.12) appropriate?

Yes, No, Unsure

7. Is the Guidance on insight and remedial actions (Pg.13) appropriate?

Yes, No, Unsure

8. Is the Guidance on testimonials (Pg.14) appropriate?

Yes, No, Unsure

9. Is the Guidance on how the Statutory Committee should consider an Interim Suspension Order proportionate (Pg.14)?

Yes, No, Unsure

10. Is the section on additional issues identified for requiring further Guidance (Pgs. 14-16) clear?

Yes, No, Unsure

11. Is the content of the section on additional issues identified for requiring further guidance appropriate?

Yes, No, Unsure

12. Is the Guidance on actions when a sanction has been decided upon (Pgs. 18-20) clear?

Yes, No, Unsure

13. Are any aspects of our proposals that could result in equality and diversity implications for groups or individuals based on one or more of the following protected characteristics? If yes, please explain what could be done to change this.

- Age
- Gender reassignment
- Disability
- Pregnancy and maternity
- Race
- Religion or belief
- Political Opinion
- Sex
- Sexual orientation

Yes, No, Unsure

14. Do you have any other comments about the Draft Indicative Sanctions Guidance?

Yes, No, Unsure

6. Respondents

6.1 The Pharmaceutical Society NI received 8 responses. One response was made in an individual capacity and seven were made on behalf of an organisation. Of the responses made on behalf of organisations, five were made by Pharmacy Representative Bodies, one was made on behalf of a Health and Social Care Organisation, and one was made by a regulatory oversight body. The one individual response was made by a pharmacist. A full list of respondents can be found at Appendix 1.

7. Overview of Main Findings

Question 1: Does the document clearly set out the processes of the Statutory Committee?			
Yes	**No**	**Unsure**	**Did not answer**
5 (83.3%)	**1 (16.7%)**	**0 (0%)**	**2**
Question 2: Does the document clearly set out the purpose of Indicative Sanctions Guidance			
Yes	**No**	**Unsure**	**Did not answer**

5 (100%)	0 (0%)	0 (0%)	3
Question 3: Is the Guidance on the public interest and proportionality (Pg.8) appropriate?			
Yes	No	Unsure	Did not answer
6 (85.7%)	0 (0%)	1 (14.3%)	1

Question 4: Is the Guidance on when a particular sanction might be appropriate (Pg.9) clear?			
Yes	No	Unsure	Did not answer
6 (100%)	0 (0%)	0 (0%)	2
Question 5: Is the Guidance on when a particular sanction might be appropriate proportionate?			
Yes	No	Unsure	Did not answer
5 (83.3%)	0 (0%)	1(16.7%)	2
Question 6: Is the Guidance on mitigating and aggravating circumstances (Pg.12) appropriate?			
Yes	No	Unsure	Did not answer
6 (85.7%)	1 (14.3%)	0	1
Question 7: Is the Guidance on insight and remedial actions (Pg.13) appropriate?			
Yes	No	Unsure	Did not answer
6 (100%)	0 (0%)	0 (0%)	2

Question 8: Is the Guidance on testimonials (Pg.14) appropriate?			
Yes	No	Unsure	Did not answer
6 (85.7%)	0 (0%)	1 (16.7%)	1
Question 9: Is the Guidance on how the Statutory Committee should consider an Interim Suspension Order proportionate (Pg.14)?			
Yes	No	Unsure	Did not answer
4 (66.7%)	0 (0%)	2 (33.3%)	2
Question 10: Is the section on additional issues identified for requiring further Guidance (Pgs. 14-16) clear?			
Yes	No	Unsure	Did not answer
6 (85.7%)	1 (14.3%)	0 (0%)	1

Question 11: Is the content of the section on additional issues identified for requiring further guidance appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
3 (60%)	**2 (40%)**	**0 (0%)**	**3**

Question 12: Is the Guidance on actions when a sanction has been decided upon (Pgs. 18-20) clear?			
Yes	**No**	**Unsure**	**Did not answer**
5 (71.4%)	**0 (0%)**	**2 (28.6%)**	**1**

Question 13: Are any aspects of our proposals that could result in equality and diversity implications for groups or individuals based on one or more of the following protected characteristics? If yes, please explain what could be done to change this. • **Age** • **Gender reassignment** • **Disability** • **Pregnancy and maternity** • **Race** • **Religion or belief** • **Political Opinion** • **Sex** • **Sexual orientation**			
Yes	**No**	**Unsure**	**Did not answer**
0 (0%)	**3 (60%)**	**2 (40%)**	**3**

Question 14: Do you have any other comments about the Draft Indicative Sanctions Guidance?			
Yes	**No**	**Unsure**	**Did not answer**
2 (40%)	**3 (60%)**	**0**	**3**

It should be noted that the Guild for Healthcare Pharmacists responded to the consultation via email, not answering the consultation questions but stating the following:

> *Thank you for the opportunity to respond to the PSNI Indicative Sanctions Guidance Consultation.*
>
> *After reviewing the guidance and circulating the consultation to our membership; we are satisfied with the level of clarity in the consultation document and with the appropriateness of the proposals. We have no further comments to make about the draft Indicative Sanctions Guidance.*

Please accept this response on behalf of the Northern Ireland Group of Guild of Healthcare Pharmacists (GHPNI).

8. Responses to Question 1

Question 1: Does the document clearly set out the processes of the Statutory Committee?			
Yes	**No**	**Unsure**	**Did not answer**
5 (83.3%)	**1 (16.7%)**	**0 (0%)**	**2**

8.1 Of the five respondents that answered 'Yes' to Question 1, one provided an additional comment. The Pharmacy Forum NI stated:

> *Yes, at a very high level the processes of the Statutory Committee are outlined however clarity would be sought on the following:*
>
> *- General governance processes / quality assurance activities undertaken to maintain the consistency of approach to be used by the Statutory Committee.*
>
> *- Who is responsible for the selection of the Statutory Committee Panel of three. Is this a random selection from the list or is a selection methodology rolled out by the Registrar?*

8.2 The one respondent that answered 'No' to Question 1, provided an additional response. The Health and Social Care Board stated:

> *The title of this document is "Indicative Sanctions Guidance" but Part 1 of the document provides an overview of the whole fitness to practice process, however not in any detail. It requires a lot of trawling through the PSNI website to find all the other relevant documents that you need to read and link to get a complete overview of the process. Some of these are hyperlinked in the guidance (e.g. threshold criteria) but not all. It would be useful to have a summary document or flowchart that includes all hyperlinks so that readers can get a quick overview of the entire process.*
>
> *It would be useful to include a summary of the threshold and referral criteria referenced on page 3 of the guidance as appendices to the guidance.*

Not all the processes of the Statutory Committee are set out in this guidance in detail. There is another more detailed document included on the PSNI website ("procedures of fitness to practice committees") which provides more details around the actual process but isn't referenced in the guidance document. It would be helpful to include this as a hyperlink in the guidance document so that readers can refer to the details if they wish.

Comment and Recommendation to Council
In relation to the Pharmacy Forum NI's queries on governance and quality assurance issues, and the selection of Panel members, Council should note that these issues are largely laid out Legislation, with oversight being provided by the Registrant's and the PSA's right to appeal Statutory Committee decisions to the High Court. Please also see comments provided in relation to Question 4.
In relation to the issues raised by the HSCB, whilst we note that the majority of respondents consider the document to clearly set out the processes of the Statutory Committee, Council should note that a review of the Threshold Criteria is ongoing, with a potential future review of Scrutiny Committee's Referral Criteria. Upon reviewing these documents, and in line with plans under the Communications Strategy to review website content etc., FtP Guidance and information will be appropriately assessed. In the short-term the following recommendation is made.
Recommendation 1: The *Procedures of fitness to practice committees* document should be hyperlinked into the Indicative Sanctions Guidance document as suggested by the HSCB.

9. Responses to Question 2

Question 2: Does the document clearly set out the purpose of Indicative Sanctions Guidance			
Yes	**No**	**Unsure**	**Did not answer**
5 (100%)	**0 (0%)**	**0 (0%)**	**3**

9.1 Of the 5 respondents that answered 'Yes' to Question 2, three provided additional comments.

9.2 The Pharmacy Forum NI stated:

The document clearly defines its purpose to be that of providing guidance from the Council of the Pharmaceutical Society of Northern Ireland to the Statutory Committee (same organisation) when the Committee are deciding upon what sanctions are appropriate in any given case.

9.3 The National Pharmacy Association (NPA) stated:

We welcome the opportunity to comment on the Society's Draft Indicative Sanction's guidance, and are broadly supportive of the way in which the document has been developed. We believe it provides a clear articulation of the guidance to people involved, or with an interest, in a fitness to practise hearings.

Purpose of ISG

9.4 The Professional Standards Authority (PSA) did not directly answer the question, however, feedback was provided in relation to purpose of Indicative Sanctions Guidance with the PSA stating:

"*We suggest that the ISG could be clearer on a panel's relationship to the ISG as the word 'reference' is vague. It would be useful for determinations to explain more about how an ISG was used rather than just saying it had been considered. It might be helpful if the ISG clarifies that it exists in order to enable panels' decisions to be transparent, fair and consistent".*

9.5 The PSA cited a number of legal cases to illustrate this point, suggesting the purpose of the Guidance needs to be strengthened to ensure that it is understood to be a framework for how panels can arrive at a sanction and also ensure consistent approach to decision making. The PSA concluded by stating:

"[W]e consider that the PSNI could expand on the purpose of an ISG by confirming the importance of having an ISG, for amongst other reasons, to create a consistent approach to cases and the provision of a framework to focus on the relevant issues to consider before a sanction".

Premises Standards

The Pharmacy Defence Association did not directly answer the question but made the following recommendations.

Recommendation *Whilst the document does set out its stated purpose clearly, it should be revised to include an equal amount of information about the approach to be taken to pharmacy owners for breaches of pharmacy premises standards as it contains about individual pharmacist registrants. This should include details of the investigation process, the*

available sanction(s), the factors for Statutory Committees to take in to account when considering applying them and the process to be followed.

Recommendation *The guidance should include a requirement that the PSNI must ensure it has the resources to ensure cases are dealt with both thoroughly and expediently. Expediency is important both to complainants and pharmacists; it limits the potential for adverse effects of being subjected to protracted proceedings with uncertainty of outcome.*

Comment and Recommendation to Council

In relation to the PDA's recommendation that the draft ISG should reflect the FtP process and sanctions for pharmacy owners who breach the premises standards, Council should note that the section of the ISG relating to Corporate Bodies is contained in Part 1 of the document, which outlines the Fitness to Practise process and is included to provide a wholistic picture of the Fitness to Practise process. The section on deciding on Sanction does not relate to Corporate Bodies or Owners.

Council should further note that the powers related to Corporate Bodies are limited, as outlined in legislation and that until the new Premises Standards come into effect under The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, we do not have enforcement powers directly related to the current premises Standards. In this regard we consider that the current section on Corporate Bodies within the draft ISG is appropriate.

Considering the agreed Premises Standards developed under The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, and the fact that the organisation is currently working with the Department of Health and its Inspectorate to develop an inspection regime, Council should consider what, if any additional Guidance is needed for the Statutory Committee in relation to processing allegations regarding Premises Standards and Pharmacy Owners.

Recommendation 2: As part of its development work in implementing new Premises Standards, Council should consider what additional Guidance is needed, if any to the Statutory Committee when considering allegations related to breaches of the Premises Standards and in relation to Pharmacy Owners.

In relation to the PDA's second recommendation, we do not consider it directly relevant to the purpose of the ISG.

Reflecting upon the PSA's comments and the legal cases cited, it is considered that understanding of the purpose of the document can be improved upon. The following recommendation is therefore made to Council

<u>Recommendation 3</u>: The introductory paragraph under the *heading What is this document for?* Should be amended to read as follows:

This document provides Guidance from the Council of the Pharmaceutical Society NI to the Statutory Committee of the Pharmaceutical Society NI to use when deciding upon what sanction is appropriate in any given case. The document is designed to provide a decision-making framework to assist with the delivery of consistent, proportionate and reasonable decisions on sanction and should be considered by the Statutory Committee when coming to a decision on sanction.

10. Responses to Question 3

<u>Question 3:</u> Is the Guidance on the public interest and proportionality (Pg.8) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
6 (85.7%)	**0 (0%)**	**1 (14.3%)**	**1**

10.1 Of the six respondents that answered 'Yes' to Question 3, four provided additional comments.

The Public Interest

10.2 The NPA made the following comment:

> *The NPA is keen to ensure that the guidance strikes the right balance between the public interest, which includes the health, safety and wellbeing of the public, and the rights and freedoms of the pharmacy professional. We encourage the Society to continue to maintain the dignity of the individuals involved throughout the whole Fitness to Practise process.*

10.3 The HSCB stated:

> *We would note the importance of not bowing to public pressure and to ensure that there is a clear boundary between this and maintaining public confidence in the profession. The greatest emphasis should be on protecting the public and maintaining standards of behaviour.*

10.4 Whilst the PDA made the following recommendation:

> ***Recommendation*** *Consideration of the public interest must also include the effects of depriving the public of a pharmacist and the wider consequences of the decision. For example, issuing a harsher sanction simply because of media coverage of a particular case may be unfair, and lead to detriment to the public interest if an unfair process was applied. This ought to be reflected in the indicative sanctions guidance.*

Structure of Section

10.5 The Professional Standards Authority made the following comment in relation to the structure of this section:

> *Yes. However, we suggest that the section could be clearer for panel members if paragraph 2.4 is moved towards the end of the section. This is because this section needs to clarify that proportionality requires the panel to weigh the interests of the public against the interests of the registrant, paragraph 2.7 is better suited particularly to being earlier in the section.*

In relation to the comments on the Public Interest, and specifically the Panel's entitlement to give greater weight to the public interest, and the need to maintain public confidence in the profession, than to the consequences to the registrant of the imposition of the sanction, Council should note that the requirement of the Statutory Committee to consider the three aspects of the Public Interest is established in case law, see: *CHRE v NMC and P Grant [2011] EWHC 927 (Admin)*. The principle of the statutory Committee being entitled to give more weight to the public interest is also established in case law, see: *Marinovich v General Medical Council [2002] UKPC36*

The Statutory Committee is required to make decisions based on the specific facts relating to the case under consideration. Consideration concerning the public interest is not reduced to public pressure or the interest of the media. Council should note that in this section the Panel is required to be proportionate, and that the Statutory Committee is required to give reasons for its decisions in relation to sanction, which should include reasons related to the public interest test. In this regard we consider that the current wording of this section is appropriate and in line with current best-regulatory practice.

Council should, however, be aware that the PSA has carried out research on what the 'public interest' means and this is an area of ongoing discussion within regulation. The organisation will continue to keep this under review and will assess the ISG document accordingly going forward.

In relation to the PSA's comments on the structure of this section, we consider this to be reasonable and making the changes recommended will improve the Panel's understanding of this section.

Recommendation 4: move paragraph 2.4 to end of section and move paragraph 2.7 to earlier in the section.

11. Responses to Question 4

Question 4: Is the Guidance on when a particular sanction might be appropriate (Pg.9) clear?			
Yes	**No**	**Unsure**	**Did not answer**
6 (100%)	**0 (0%)**	**0 (0%)**	**2**

11.1 Of the six respondents that answered 'Yes' to Question 4, three provided additional comments.

Consistent Application

11.2 The Pharmacy Forum NI stated:

> *Yes, the guidance is clear on when a particular sanction might be appropriate, however we would seek clarity on how the consistent application of the guidance is to be monitored and assessed.*

11.3 The HSCB raised a similar point when it stated:

> *These look fine but to ensure they cover all cases in the most appropriate way, there would need to be an exercise undertaken to review them against previous referrals to stat com.*

Publication Policy

11.4 The NPA made the following statement in relation to our publication policy concerning sanctions:

> *The NPA is broadly supportive of the proposals outlined in this consultation on when a particular sanction might be imposed. However, we would welcome further clarification on "Impact on Registration" in relation to the period of warnings, conditions and suspensions remaining*

on the online register, and that this time limit is fair and proportionate and consistent with the sanction imposed.

11.5 Although the PSA did not directly answer Question 4 the provided the following comment:

With regard to warnings, we note that if a panel has found impairment on public protection grounds, then they need to provide very clear reasons as to why a restrictive sanction is not being imposed.

Comment and Recommendations

Consistent Application

In relation to the consistent application of the guidance on when a particular sanction is appropriate, Council is reminded that the Statutory Committee acts independently of Council and is tasked with making decisions based on the specific case in front of it and the facts established. All panel Chairs are legally qualified and tasked with ensuring the panel adheres to its legislative requirements and appropriately reflects on case law and guidance provided. All Statutory Committee Determinations, apart from those cases heard in private, are published on our website. The registrant has the power to appeal Statutory Committee decisions to the High Court, as does the PSA on public protection grounds. The PSA can also write learnings on Statutory Committee Determinations, which they have concerns about, but which do not meet their threshold for an appeal to the Hight Court. Statutory Committee members are all provided with training by the Regulator, which includes applying Guidance and what makes a good determination. All statutory Committee members are subject to an appraisal process and we have an internal process for reviewing Statutory Committee Determinations and identifying issues around consistency of approach.

Publication Policy

Council should note that publication of sanction information is subject to the following policy: Policy on the disclosure and publication of fitness to practise information, which is published on our website. It is recommended that a link to this document should be placed in this section of the ISG document. We will seek stakeholder feedback on the content of this policy to provide assurance that it remains appropriate and proportionate.

Recommendation 5: The Policy on the disclosure and publication of fitness to practise information should be clearly referenced within the final ISG document.

12. Responses to Question 5

Question 5: Is the Guidance on when a particular sanction might be appropriate proportionate?			
Yes	**No**	**Unsure**	**Did not answer**
5 (83.3%)	**0 (0%)**	**1(16.7%)**	**2**

12.1 Of the five respondents that answered 'Yes' to Question 5, two provided additional comments.

Consistency of Application

12.3 The Pharmacy Forum NI repeated their concerns outlined in answer to Question 4, concerning consistency of application.

12.4 The NPA raised similar issues, making the following comment:

> *We welcome the emphasis in the guidance on ensuring that a Panel of the Statutory Committee provide adequate explanations for their determinations so that it is clear why a particular decision about a sanction has been made. We would like to further highlight the importance of consistency in the application of the guidance by the Statutory Committee to assure credibility and trust with the public and the profession. To support this, we believe it would be beneficial if the Society could share with registrants, and the public, how the Statutory (and Scrutiny) committees are regulated and reviewed*.

12.5 The one respondent that stated they were unsure provided an additional comment with the HSCB stating:

> *The guidance is clear but, like Q3 it is difficult to comment if a particular sanction is proportionate – although this is probably not possible and example would be useful. More use of plain language would be helpful as it can be difficult to interpret due to complex nature of the subject matter.*

12.6 Although the PSA did not directly answer Question 5, they provided the following comment:

> *In dealing with suspension, the ISG accurately confirms the position of Fleischmann regarding the need for panels to be mindful of the general, but not complete, prohibition of registrants returning to practice before*

completing a sentence. It also emphasises the need for a panel to explain why it departed from the Fleischmann principle.

Comments
In relation to comments on consistent application of the Guidance, Council is referred to comments outlined in response to Question 4.
Reflecting on the responses to Question 4, we consider that the Guidance on when a particular sanction might be appropriate is adequately clear.

13. Responses to Question 6

Question 6: Is the Guidance on mitigating and aggravating circumstances (Pg.12) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
6 (85.7%)	**1 (14.3%)**	**0**	**1**

13.1 Of those respondents that answered 'Yes', two provided an additional comment.

13.2 The HSCB stated:

This is clear and easy to read.

Weight given to Mitigating and Aggravating Circumstances

13.3 The PSA made the following comments:

Yes, Although we suggest that it should be made clear in the ISG that when weighing up mitigating and aggravating factors, the reasons should allow the reader to understand what weight the panel has given these features.

Additionally, we note that personal mitigation carries less weight in public protection matters as compared to the criminal context.

Working environments

13.4 The one respondent that answered 'No' to Question 6, provided an additional comment, with the PDA making the following recommendation:

Recommendation The list of potential mitigating factors at paragraph 2.16 must include poor working environments or poor premises standards in the pharmacy as a result of the actions of an employer, and other factors that are outside the control of the pharmacist.

Comments and Recommendation

The PSA's comment on the reader being able to understand the weight given to a mitigating or aggravating circumstance is helpful and resonates with comments made by other respondents regarding consistency of approach. It is therefore recommended that a new paragraph be added to provide guidance to the Panels that they should provide reasons to allow the reader to understand what weight the panel has given a cited mitigating or aggravating factor.

<u>Recommendation 6:</u> An additional paragraph should be included in the Mitigating and Aggravating Circumstances section to provide guidance to the Panels that they should provide reasons to allow the reader to understand what weight the panel has given a cited mitigating or aggravating factor.

In relation to the comment made by the PDA, that mitigating factors must include poor working environments or poor premises standards in the pharmacy as a result of the actions of an employer and other factors that are outside the control of the pharmacist, the comments are considered helpful and Council is reminded that this is an issue that has gained considerable focus in regulation, in light of external inquiries and investigations. At this stage we are content that this type of information can be captured within the broad scope of the first bullet point for both Mitigating and Aggravating circumstances, which are: '*The circumstances leading to the incident/s in question'*. We would expect the parties to the proceedings to raise the specific set of circumstances raised by the PDA, with the Panel if deemed appropriate, under these headings.

14. Responses to Question 7

Question 7: Is the Guidance on insight and remedial actions (Pg.13) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
6 (100%)	**0 (0%)**	**0 (0%)**	**2**

14.1 Of the six respondents that answered 'Yes' to Question 7, none provided an additional comment.

14.2 Although the PSA did not directly answer Question 7, it provided the following comment:

Weight of remediation in cases relating to public confidence

> *We suggest that the ISG refers to the general point that remediation carries less weight if there are serious public confidence issues involved. In the case of Yeong, it was confirmed:*
>
> *'Where a FTPP [fitness to practise panel] considers that the case is one where the misconduct consists of violating such a fundamental rule of the professional relationship between medical practitioner and patient and thereby undermining public confidence in the medical profession, a finding of impairment of fitness to practise may be justified on the grounds that it is necessary to reaffirm clear standards of professional conduct so as to maintain public confidence in the practitioner and in the profession. In such as case, the efforts made by the medical practitioner in question to address his behaviour for the future may carry very less weight than in case where the misconduct consists of clinical errors or incompetence'. (Dr Cheng Toh Yeong v The General Medical Council [2009] EWCH 1923 (Admin))*

Wishful Thinking

> *We also point out that panels ought to be aware that they should not impose a sanction based on 'wishful thinking' that a registrant may develop insight at a later stage when there is not likely to be any*. (Citing PSA v NMC & Judge [2017] EWHC 817 (Admin))

Confirmation of remediation

> *Additionally, the ISG states at paragraph 2.19 that: 'The Panel should consider whether there is evidence that the registrant has assessed and understood the reasons for their Fitness to Practise being impaired and whether they have displayed genuine regret and/or apologised for their actions, if appropriate.' We suggest that panels should state how the actions of a registrant have*

remediated their conduct because it is not enough for panels to simply say that there is remediation. They should list, for example, in a record-keeping case that the registrant has remediated the concerns by undertaking a record keeping course.

Additionally, we point out that panels need to interrogate registrants in relation to any online courses they have taken to ensure that these have been of some value and panels should have in mind the timing of insight and remediation.

Comments and Recommendations

The PSA's comments are considered helpful and it is recommended that a new paragraph be included reflect the general position of the Case Law cited: *Dr Cheng Toh Yeong v The General Medical Council [2009] EWCH 1923 (Admin).*

Recommendation 7: A new paragraph should be added in the section on Insight and Remediation, which states the following: *Panels should consider that in cases related to a serious public confidence issues compared to clinical errors and incompetence, insight and remediation may carry less weight.*

In relation to the comment on 'wishful thinking', we are content that the current wording of paragraph 2.18, requires the panel to consider 'the extent to which the registrant has shown insight' which requires evidential proof of current insight not potential insight.

In relation to the comment relating to the confirmation of remediation, this is considered a helpful comment. It is recommended that an additional sentence be added at the end of Paragraph 2.19, which states: 'The Panel should seek to verify remedial activity as far as is possible and provide clear reasons as to why any activities undertaken amount to or do not amount to remediation of the issues at hand.

Recommendation 8: A new sentence should be added to the end of Paragraph 2.19 which states: '*The Panel should seek to verify remedial activity as far as is possible and provide clear reasons as to why any activities undertaken amount to or do not amount to remediation of the issues at hand*.'

15. Responses to Question 8

Question 8: Is the Guidance on testimonials (Pg.14) appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
6 (85.7%)	**0 (0%)**	**1 (16.7%)**	**1**

15.1 Of the six respondents that answered 'Yes' to Question 8, one provided an additional comment.

Weight given to Testimonials

15.2 The HSCB stated:

> *Is there any guidance for the panel on how to weight these? Useful to include this.*

15.3 The one respondent that answered 'Unsure' provided an additional comment, with the Pharmacy Forum NI stating:

> *To ensure a consistent approach on the use of testimonials we would like more clarity on*
>
> *- the process by which testimonials are evaluated e.g. based on relevance to the case etc the grounds on which a testimonial may not be used or considered*
>
> *- What gives a testimonial more weight?*
>
> *It may be helpful to give some illustration of how a testimonial may be used and at what point in the process they can be submitted as evidence of character.*

Comments
The contents of the Testimonials and Character References section of the draft ISG is considered to be clear. As each case is unique to the facts established and the circumstances of the case, the Guidance clearly states that the weight to be given to testimonials is a decision for the panel.
The Guidance further states that the Panel will decide upon the appropriate stage of the hearing for testimonials to be considered and if testimonials have been considered in the context of a decision on impairment, it should review them in the context of a decision on sanction.

16. Responses to Question 9

Question 9: Is the Guidance on how the Statutory Committee should consider an Interim Suspension Order proportionate (Pg.14)?			
Yes	**No**	**Unsure**	**Did not answer**
4 (66.7%)	**0 (0%)**	**2 (33.3%)**	**2**

16.1 Of the two respondents that answered 'Unsure' to Question 9, both provided additional comments.

Clarity of meaning

16.2 The HSCB stated:

> *Not entirely clear what this means. Could it be re-expressed in clearer terms?*

16.3 Whilst the individual respondent stated:

> *Didn't really understand how an interim suspension order could impact on an appropriate sanction being imposed*

Comments
Although it is acknowledged that two respondents found this section difficult to understand, it is considered that it is suitably clear for its purposes in advising the Statutory Committee. As Interim Order proceedings should not be considered by a Panel when deciding upon the facts of a case or determining whether a registrant's FtP is impaired, to provide additional information on Interim Order proceedings within the ISG may cause more uncertainty.

17. Responses to Question 10

Question 10: Is the section on additional issues identified for requiring further Guidance (Pgs. 14-16) clear?			
Yes	**No**	**Unsure**	**Did not answer**
6 (85.7%)	**1 (14.3%)**	**0 (0%)**	**1**

17.1 The one respondent that answered 'No' to Question 10, provided an additional comment, with the individual pharmacist stating:

> *More clarity given as to what constitutes 'dishonesty' – this is very subjective and dishonesty can take many different forms to v minor to significant.*

Comment
See comment related to Question 11.

18. Responses to Question 11

Question 11: Is the content of the section on additional issues identified for requiring further guidance appropriate?			
Yes	**No**	**Unsure**	**Did not answer**
3 (60%)	**2 (40%)**	**0 (0%)**	**3**

18.1 Of the three respondents that answered 'Yes' to Question 11 one provided an additional response.

Premises

18.1 The PDA provided the following recommendation:

> ***Recommendation*** *The guidance must state that where, during the course of investigation by the PSNI or statutory committee processes it becomes apparent that the standards within a registered pharmacy are inappropriate, the PSNI must investigate this.*

18.2 Of the two respondents that answered 'Unsure' to Question 11, one provided an additional response, with the HSCB stating:

> *Are there other specific types of issues that have come before stat com and should be included e.g. driving offences, health related issues such as drug taking or behavioural issues*

18.3 Although the PSA did not directly answer Question 11, they provided the following comment:

> **Most serious misconduct**

We suggest that it needs to be made clearer in the document that these additional issues are the most serious types of misconduct and as such indicate that more serious action is likely to be required

Erasure

In relation to paragraph 2.30 and 2.43, the impression might be given that erasure should be an automatic sanction. It might be preferable to say that dishonesty and sexual misconduct are very serious and may well merit erasure and, in all cases panels should give consideration as to whether erasure is an appropriate sanction and give reasons if they consider that it is not.

Dishonesty

We find the guidance to be helpful on dishonesty, in that it confirms at paragraph 2.25 that: 'allegations of dishonesty may relate to a registrant's professional or personal life.' That is confirmed in the case of Lawrance in which it was stated that 'dishonesty by doctors will usually be misconduct even if it has nothing to do with professional competence'.7

We find the ISG's emphasis of dishonesty impacting public confidence and trust in the profession is helpful. Similarly, we commend the ISG's emphasis that if a panel imposes a less severe sanction for dishonesty, it should explain why.

Spectrum of Dishonesty

Given the scope of potential fraud in the pharmacy profession we suggest that the PSNI expand the section on dishonesty to suggest that there is further information provided in relation to the spectrum of dishonesty. For example, in the case of Lusinga the Court raised concerns about the failure to distinguish different types of dishonesty:

'I hope the Indicative Sanctions Guidance will be looked at again in the light of this judgment. The guidance does not differentiate between different forms of dishonesty and takes one of the most serious forms of dishonesty (fraudulent financial gain) as the paradigm, without alluding to the possibility that dishonest conduct can take various forms; some criminal, some not; some destroying trust instantly, others merely undermining it to a greater or lesser extent.' (Lusinga v Nursing and Midwifery Council [2017] EWHC 1879 (Admin))

Comments and Recommendations

In relation to the recommendation made by the PDA that the guidance must state that where, during the course of investigation by the PSNI or statutory committee processes it becomes apparent that the standards within a registered pharmacy are inappropriate, the PSNI must investigate this. This is a legitimate issue. Council is reminded that under the provision of the Pharmacy (Northern Ireland) Order 1976, the power to inspect premises lies with the Department of Health NI. Council should note the comments in relation to Question 2, which outline the fact that the organisation is currently working with the Department of Health and its Inspectorate to develop an inspection regime related to the new Premises Standards. The issue raised by the PDA concerning the sharing of information with the inspectorate uncovered during an investigation into an individual pharmacist should be considered in this context. Council is also reminded that we participate in the Pharmacy Network Group which assesses concerns and complaints with branches of the Department of Health, including the Inspectorate, to ensure the appropriate body is carrying out an investigation. It is considered that the Indicative Sanctions Guidance is not the most appropriate place to address this issue but the need for further Guidance for the Statutory Committee and the Registrar will be explored in the context of new premises standards and discussions with the Inspectorate.

In relation to the PSA's comments on identifying that the section on Guidance for specific issues should be clearer that it is related to the most serious types of misconduct, this is considered a helpful comment, which if addressed, should resolve the issue identified by the HSCB, as to why Guidance is not provided for other areas.

Recommendation 9: Introduce a new paragraph in the Guidance on Specific Issues, which clearly states that this section relates to the most serious types of misconduct.

In relation to the PSA's comment that in paragraph 2.30 and 2.43, the impression might be given that erasure should be an automatic sanction, this is considered a helpful comment, and it is recommended that paragraphs 2.30 and 2.43 are reworded to ensure that Panels do not consider that erasure should be an automatic sanction.

Recommendation 10: Reword paragraphs 2.30 and 2.43 to ensure that Panels do not consider that erasure should be an automatic sanction.

In relation to the PSA's comments on the spectrum of dishonesty, these are considered helpful. It is suggested that a new paragraph be added after paragraph 2.28 which states the following: *Dishonesty can take various forms, some acts of dishonesty are criminal, some are not; some acts of dishonesty can destroy trust instantly whilst others will undermine trust to a greater or lesser extent. The Panel should take into consideration the type of dishonesty they are dealing with in a given case and asses its impact on the public's trust in the profession and public safety.*

Recommendation 11: A new paragraph should be added after Paragraph 2.28 which states: *Dishonesty can, however, take various forms, some acts of dishonesty are criminal, some are not; some acts of dishonesty can destroy trust instantly whilst others will undermine trust to a greater or lesser extent. The Panel should take into consideration the type of dishonesty they are dealing with in a given case and assess its impact on the public's trust in the profession and any public safety implications.*

19. Responses to Question 12

Question 12: Is the Guidance on actions when a sanction has been decided upon (Pgs. 18-20) clear?			
Yes	**No**	**Unsure**	**Did not answer**
5 (71.4%)	**0 (0%)**	**2 (28.6%)**	**1**

19.1 Of the five respondents that answered 'Yes' to Question 12, one provided an additional comment.

Timings of reviews

19.2 The PSA stated:

> *We point out the need for reviewing panels not to hold review after review for conditions, and that instead time scales should be put in place for the completion of specific requirements to return to the register. This is affirmed in the case of Annon in which the court confirmed 'It is entirely a matter for the NMC but it may be that a repetition of this appeal could be avoided if consideration is given by panels dealing with this sort of case to a realistic time limit by which a course must be* completed.**'** *(Annon v The NMC [2017] EWHC 1879 (Admin))*

19.3 Of the two respondents that answered 'Unsure' to Question 12, both provided an additional response:

Suspended indefinitely

19.4 The Pharmacy Forum NI Stated:

> *Section 3.9 of the Guidance - Review of suspension – 'If a suspension has been in place for 2 years on review and the registrant's fitness to practice remains impaired the panel may give the direction that "the entry be suspended indefinitely".*
>
> *We do not think the guidance goes far enough to explain how 'suspended indefinitely' differs from being stuck off (apart from the 5-year veto). We suggest that it would be helpful to give some illustration on how this provision may be used. For example, we are aware that this could be used in the circumstance of someone not being struck of due to ongoing health issues and yet has an outstanding issue of fitness to practice to be addressed. We appreciate every circumstance cannot be covered but illustration might help to increase understanding on the use of 'suspended indefinitely' as a panel decision which on first inspection seems to be overly punitive.*

19.5 The HSCB stated:

> *The guidance is clear but the title of this section is misleading – the section is more focused on the process to be followed after a sanction has been decided upon and follow-up steps. Consider a different title.*

Comments and Recommendations

In relation to the PSA's comment on reviewing conditions order we consider this to be a helpful comment. We consider the most appropriate place to address this issue is within Figure 1. In the section on 'Conditions, Actions to be considered by the Panel', it is recommended that the following additional sentence be added: *The Panel should give consideration to a realistic timetable for completing Conditions and subsequently what is the most appropriate point at which to Review any Conditions Order.*

<u>Recommendation 12</u>: Include an additional sentence in Figure 1, Conditions, Actions to be considered by the Panel as follows: *The Panel should give consideration to what is a realistic timetable for completing any Conditions imposed and subsequently what is the most appropriate point at which to Review a Conditions Order.*

Comments
In relation to the issues raised by the Pharmacy Forum NI, Council should note that the power to impose an indefinite suspension is provided for in Schedule 3 of the Pharmacy (Northern Ireland) Order 1976 and can only be used after a suspension order has been extended by a further 12 months after an original 12 months suspension. (24 months in total). This power would normally be used in relation to a health case where a registrant cannot be struck off the register, however, their condition may be of such a nature that they are unable to return to the register for public safety reasons. Council should further note that If the Statutory Committee gives a direction of indefinite suspension the Statutory Committee must review the direction if— (a) the person concerned asks it to do so; and (b) at least 2 years have elapsed— (i) since the direction took effect, or (ii) if the direction has already been reviewed by the Statutory Committee, since the conclusion of the last review by the Statutory Committee.
This power should be considered along with Regulation 7(6)(b) of the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012, which allows the Registrar to grant an application for voluntary removal from the register, even if a registrant is subject to Fitness to Practise proceedings, if it is considered in the public interest.
Although to our knowledge the power of indefinite suspension has not been used by a Statutory Committee to date, we would like to consult with legal in more detail and make a decision on whether additional guidance is required for the Statutory Committee in this area. If this is the case, we propose updating the ISG at a later date.

20. Responses to Question 13

Question 13: Are any aspects of our proposals that could result in equality and diversity implications for groups or individuals based on one or more of the following protected characteristics? If yes, please explain what could be done to change this.

- **Age**
- **Gender reassignment**
- **Disability**
- **Pregnancy and maternity**
- **Race**
- **Religion or belief**
- **Political Opinion**
- **Sex**
- **Sexual orientation**

Yes	No	Unsure	Did not answer
0 (0%)	3 (60%)	2 (40%)	3

21. Responses to Question 14

Question 14: Do you have any other comments about the Draft Indicative Sanctions Guidance?			
Yes	**No**	**Unsure**	**Did not answer**
2 (40%)	**3 (60%)**	**0**	**3**

21. 1 Of the respondents that answered 'Yes' to Question 14, both provided an additional comment:

Indemnity Insurance

21.2 The PSA stated:

We note that there is no reference to the issue of practising without indemnity insurance. Given the nature of pharmacy, we suggest this could be a useful addition to the 'Guidance on specific issues' section.

It may also be helpful to expand the section 'Health Cases' within the ISG so as to provide some guidance in relation to testing and monitoring through conditions.

Pharmacy Owners and Premises Standards

21.2 Two respondents did not directly answer the question but provide the following comments.

21.3 The PDA stated:

The PSNI's consultation document states "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." It then lists four bullet points about how the PSNI protects and maintains public safety, which do not include the regulation of registered pharmacies. We were disappointed that the PSNI approaches its role in this way, since it is an important part of the PSNI's role to regulate pharmacy premises, as a foundation to patient safety in pharmacy. This function is given scant mention in the document.

Broadly speaking, the PSNI protects the public in two ways – through the regulation of:

- *registered pharmacists*
- *registered pharmacy premises*

Overall the PDA is generally supportive of this document as we feel it takes a generally balanced approach insofar as it relates to indicative sanctions for individual registered pharmacists. However, it contains very little detail about the indicative sanctions applicable to pharmacy owners for a breach of premises standards and must be revised to include an equal amount of information on this matter (see our recommendation in response to question 2).

The section on corporate bodies is brief and starts immediately with how the Statutory Committee panel may dispose of disqualification proceedings, rather than how it should approach them and the factors it should consider. The remainder of the document is focused on the regulation of pharmacists and is not written to be applicable to the regulation of pharmacy owners or pharmacy premises. It contains very little detail about the considerations which may lead to action being taken against a pharmacy owner or the disqualification of premises.

The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 made changes to the PSNI's statutory powers. The explanatory note to the order states, inter alia: "The sanctions regime that the FTPC and the PSNI's Statutory Committee (SC) operate in relation to pharmacy owners is altered in a number of respects. Firstly, the procedure in section 80 of the Medicines Act 1968 (which enables the FTPC and the SC to remove entries from the premises part of the GPhC's register or from the PSNI premises register – or to disqualify a pharmacy owner) now applies in relation to breaches of PSNI premises standards as well as to breaches of GPhC premises standards.

Secondly, the section 80 procedures are changed so that they apply not just to pharmacy owners that are bodies corporate, but also to pharmacy owners that are partnerships or individual pharmacists. Thirdly, provision is made so that sanctions may only be applied in relation to breaches of premises standards where the FTPC or SC is satisfied that the pharmacy owner is unfit to carry on the relevant business safely and effectively (articles 9, 10, 16 and 26)." [1] In light of these new powers the public might have expected that the PSNI would elaborate on the circumstances in which it might use them, within its guidance to Statutory Committees on issuing sanctions.

21.4 The Pharmacy Forum NI stated:

We would like further illustration of the types of sanctions and conditions that are available to the Regulator/ Statutory Committee impose on Corporate Bodies.

Comments

Council is directed to the comments related to Question 2 and Recommendation 2, as a means of addressing the issues raised.

Appendix 1

Respondents	
Name	**Organisation/Job Type**
Guild of Healthcare Pharmacists	Pharmacist Representative Body
Pharmacist Defence Association	Pharmacist Representative Body
Pharmacy Forum NI	Pharmacist Representative Body
Community Pharmacy NI	Pharmacist Representative Body
National Pharmacy Association	Pharmacist Representative Body
Health and Social Care Board	Health and Social Care
Individual*	Pharmacist

*Note we received one response from an individual pharmacist who requested that their name not be listed.