



AN RIALTÓIR CÓGAIŚÍOCHTA
THE PHARMACY REGULATOR

PSI Report on the Public Consultation on the Draft Revised Code of Conduct for Pharmacists

Version 1

November 2018

1. Introduction

The Pharmacy Act 2007 requires the PSI to publish a Code of Conduct for Pharmacists ('the Code'). This is a public declaration of the principles and ethical standards which govern pharmacists in the practice of their profession and which the public, patients, other healthcare professionals and society require and expect from pharmacists as frontline health professionals.

Following approval by the Minister for Health and Children in November 2008, the present Code was laid before the Houses of the Oireachtas in February 2009. The Council of the PSI undertook to review the Code every 5 years.

Section 12 of the Pharmacy Act obliges the Council of the PSI to submit a draft of the Code to the Competition Authority (now the Competition and Consumer Protection Commission) for its opinion as to whether any provision of the draft Code would, if given effect, be likely to result in competition being prevented, restricted or distorted. The Code is also subject to the consent of the Minister under the Act.

1.1. About the Consultation

A public consultation on the Code of Conduct ("the Code") was held in August 2018. The draft Code was available to view on the PSI website along with a link to an online questionnaire. The option of sending additional comments in writing, via letter or email, was also provided. An email was sent to all pharmacists and a large number of stakeholders including other regulators and patient groups, inviting comments on the draft revised Code. The consultation was also highlighted on various social media accounts.

1.2. Response to the Consultation

A total of 454 respondents accessed the online survey and 20 responses were received by email.

Of the 454 respondents who answered Question 1 in the survey, between 223 and 232 respondents went on to answer Questions 2 to 9 and between 72 and 86 respondents went on to answer Questions 10 – 11. Of the 239 survey respondents and 20 email respondents, 163 were Pharmacists, 27 was a Patient/or member of the public, 23 were Pharmacy owners, 15 were a Healthcare Professional (non-pharmacist), 12 were from Members of a pharmacy team (non-pharmacist), 4 were involved in healthcare education or training, 3 were from a Regulator, 2 were from Industry and 10 other/not specified. Respondents from Organisations included the Irish Pharmacy Union (IPU), Pharmacists in Industry, Education and Regulatory (PIER), Pharmacy Council of NSW Health Professional Councils Authority Australia, Care Alliance Ireland and the Health Products Regulatory Authority (HPRA).

All comments were considered when revising and updating the Code. The PSI would like to thank all who took part and gave their time to provide submissions.

1.3. About this Report

This report summarises the comments received to the consultation. Responses have been analysed and presented in table/chart format throughout, along with a summary of the responses to each question in the online questionnaire. A section is included summarising the qualitative responses from Question 10, 11 and General Comments/Submissions received (Section 2.3)

A profile of the respondents is presented below in Section 2.1 'Respondents' Profile'. These figures include those respondents who answered the online questionnaire and the 20 email submissions.

2. Results

2.1 Respondents' Profile

This section includes information gathered in questions 2-3 of the online survey and as indicated in email submissions.

Question 2:

Which category best describes you?

Answered		259
-----------------	--	------------

Table 1: Which category best describes you?

Patient and/or member of the public (including representative groups)	27
Healthcare professional (non-pharmacist)	15
Pharmacy Owner	23
Pharmacist	163
Member of a pharmacy team (non pharmacist)	12
Involved in healthcare education or training	4
Regulator	3
Industry	2
Other/Not Specified	10
Total	259

Question 3:

Are you responding on your own behalf or on behalf of an organisation?

Table 2: Respondents Response Capacity (I am responding ...)

In a personal capacity	224
On behalf of an organisation	4
Total	228

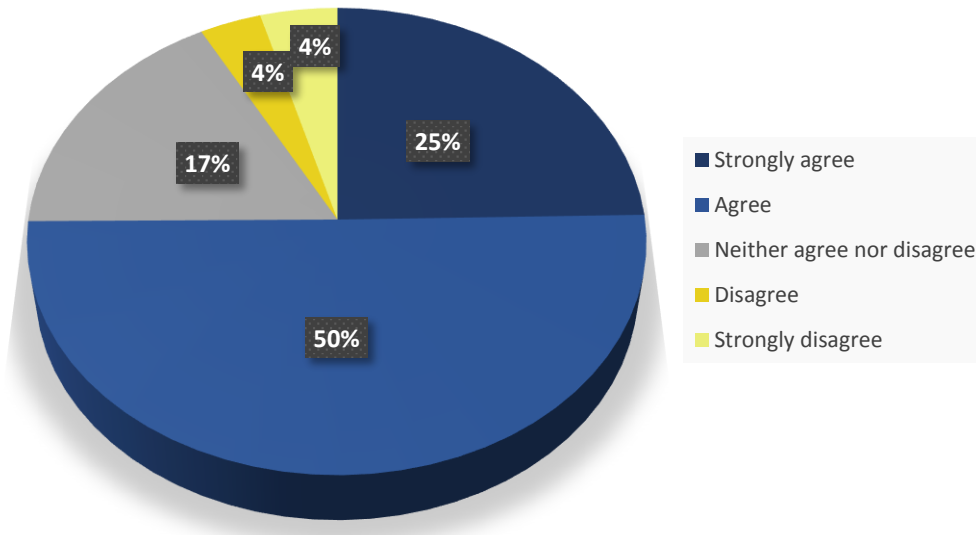
2.2. Summary of the Response to the Online Survey Consultation Questions
(completed questions 5 to 11)

Question 5:

How strongly do you agree that the opening section ('Why does the code matter?') is clear?

Answered	227
-----------------	------------

Figure 1: How strongly do you agree that the opening section ('Why does the code matter?') is clear?



PSI Response

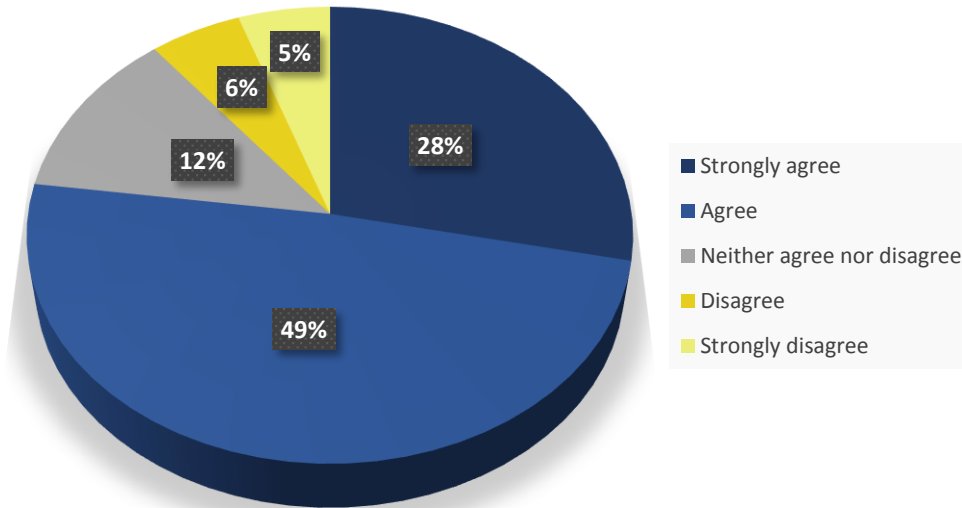
75% of respondents agreed (Agreed or Strongly Agreed) that the opening section of the revised Code is clear. 8% of respondents disagreed (Disagreed or Strongly Disagreed). General comments received regarding clarifications have been considered and incorporated as appropriate.

Question 6:

How strongly do you agree that the principles are easy to understand?

Answered	223
----------	-----

Figure 2: How strongly do you agree that the principles are easy to understand?



PSI Response

77% of respondents agreed (Agreed or Strongly Agreed) that the principles of the revised Code are easy to understand. 11% of respondents disagreed (Disagreed or Strongly Disagreed). General comments and suggestions received regarding wording and structure of the principles have been considered and incorporated as appropriate.

Question 7

How strongly do you agree that each principle reflects the professional role of the pharmacist?

Answered	228
----------	-----

(Summary of Responses included after Figure 9)

Figure 3: Principle 1 - Put the patient first

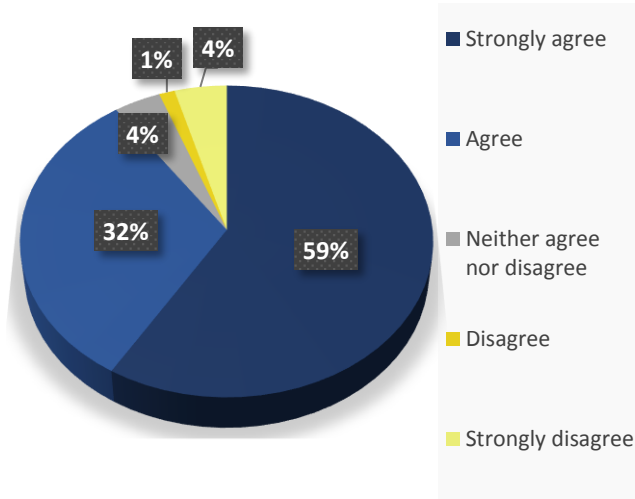


Figure 4: Principle 2 - Act professionally

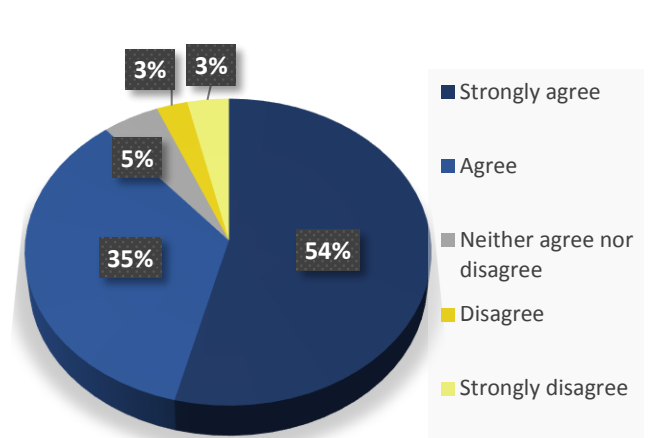


Figure 5: Principle 3 - Communicate effectively

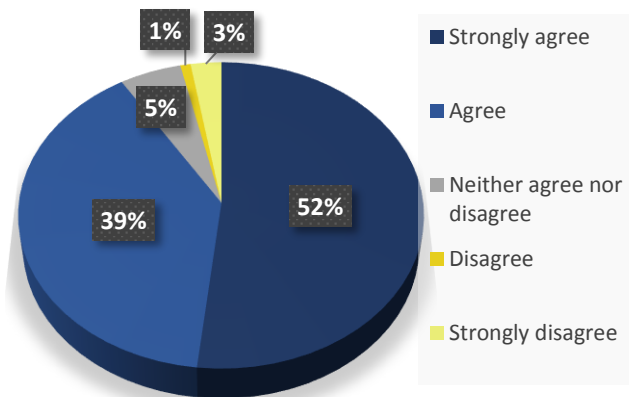


Figure 6: Principle 4 - Work with others

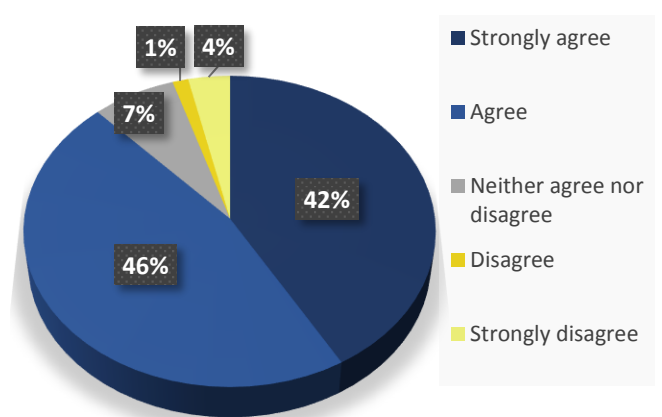


Figure 7: Principle 5 - Demonstrate leadership

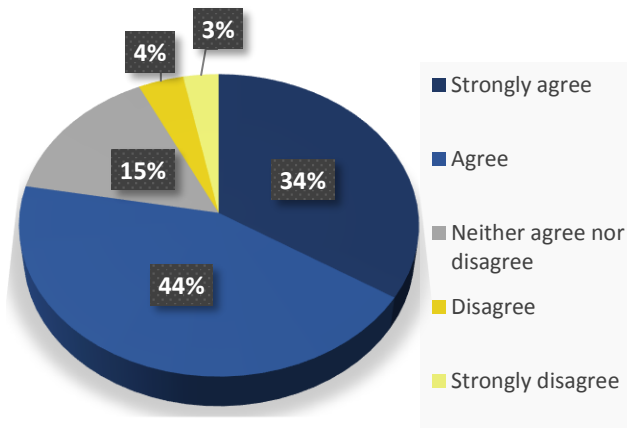


Figure 8: Principle 6 - Maintain competence

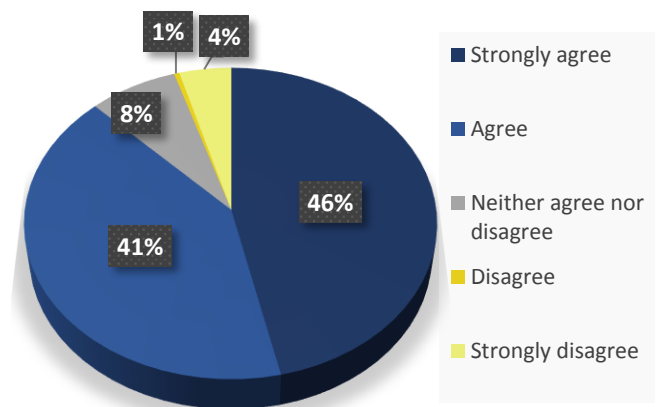
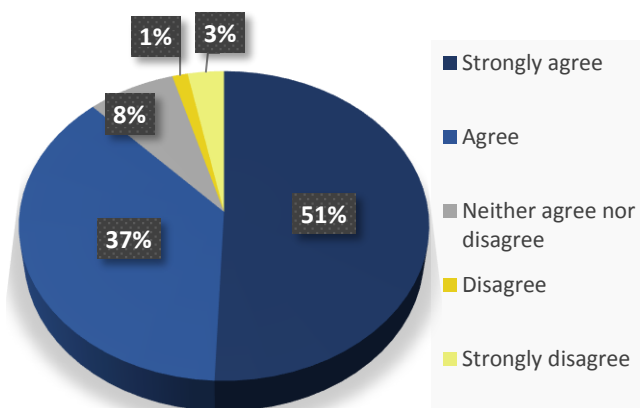


Figure 9: Principle 7 - Be open and honest



The majority of respondents agreed that each principle reflects the professional role of the pharmacist, the results of this question are summarised below:

How strongly do you agree that each principle reflects the professional role of the pharmacist?

PRINCIPLE	AGREE (Strongly Agree & Agree)	DISAGREE (Strongly Disagree & Disagree)
1 - Put the patient first	91%	5%
2 - Act professionally	89%	6%
3 - Communicate effectively	91%	4%
4 - Work with others	88%	5%
5 - Demonstrate leadership	78%	7%
6 - Maintain competence	87%	5%
7 - Be open and honest	88%	4%

PSI Response

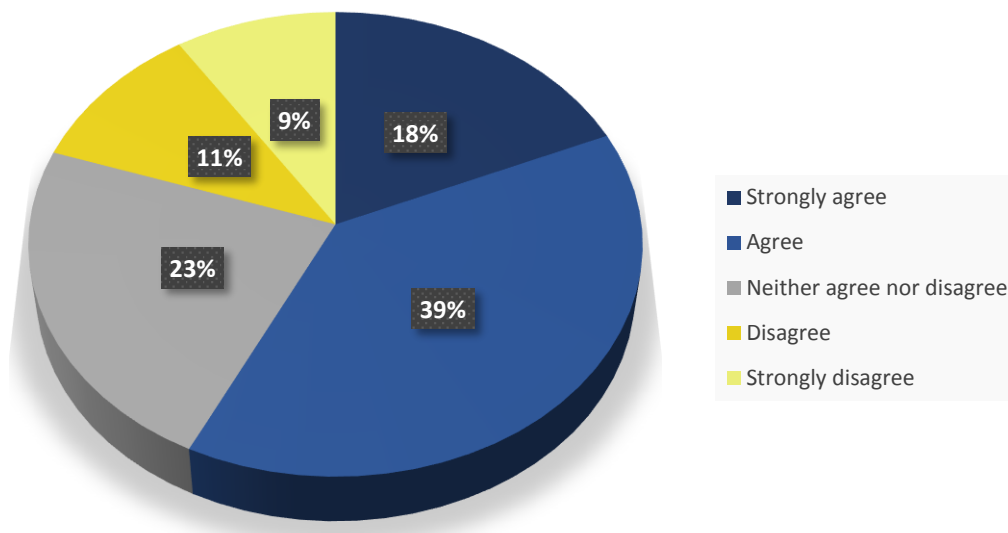
Comments and suggestions received regarding the individual principles, both content and wording, have been considered and incorporated as appropriate.

Question 8:

How strongly do you agree that the revised code will be useful to pharmacists in their day to day professional practice?

Answered	227
----------	-----

Figure 10: How strongly do you agree that the revised code will be useful to pharmacists in their day to day professional practice?



PSI Response

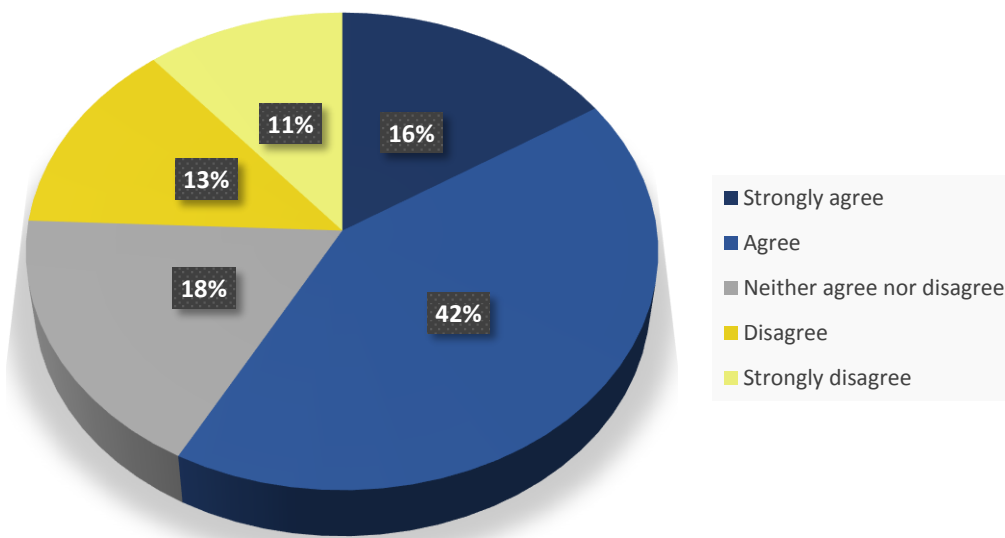
57% of respondents agreed (Agreed or Strongly Agreed) that the revised Code will be useful to pharmacists in their day to day professional practice. 20% of respondents disagreed (Disagreed or Strongly Disagreed). General responses received regarding clarification on the practical application of the Code have been considered and incorporated as appropriate. In particular additional guidance, resources and aids in implementing the revised Code will be considered in this regard.

Question 9:

Overall, do you agree that the revised Code is contemporary, comprehensive and appropriate for pharmacists?

Answered	226
----------	-----

Figure 11: Overall, do you agree that the revised Code is contemporary, comprehensive and appropriate for pharmacists?



PSI Response

58% of respondents agreed (Agreed or Strongly Agreed) that the revised Code is contemporary, comprehensive and appropriate for pharmacists. 24% of respondents disagreed (Disagreed or Strongly Disagreed). General comments and suggestions received regarding the Code have been considered and incorporated as appropriate.

2.3 General Comments/Submissions:

(Including responses to:

Question 10: Is there anything which is not considered or covered in the revised Code of Conduct?

Answered: 86

Question 11: Is there any supplementary guidance you think would help in your understanding of the information contained in the Code of Conduct, either as a registrant or a member of the public?

Answered: 72)

Other Comments and Submissions Received - 20

A substantial number of comments were received in response to Question 10, Question 11 and as general comments/submissions. Some of the responses received were related specifically to the questions posed (Questions 10 and 11) while others were broader submissions. For ease of reading and analysis, The responses received have been grouped into subject areas (Summary of Themes) and Suggested Additional Resources.

2.3.1 Summary of Themes

General Comments

Overall, comments received were very positive. Many respondents felt that in general, the revised Code has improved from the previous code particularly with regard to clarity of language and concise layout. Respondents were generally happy with the content. Feedback indicated the revised Code was clear, comprehensive and concise. The respondents commented on its simple language, which makes the revised Code easy to read and understand. One response, on behalf of an organisation, recognised the value of the detail provided under the Principles and the specific information given to highlight the types of attitudes and behaviours that should be demonstrated by pharmacists. In particular, it was acknowledged that the behaviours described may not apply in all situations but are intended to direct and guide pharmacists. There were also a number of comments around whether particular behaviours should be mandated or advised ('must' vs 'should'). A small number of respondents questioned the need for the review of the Code as the existing Code is fit for purpose. Feedback was also received concerning the applicability of the Code to pharmacy practice settings outside of community or hospital, such as industry and academia.

PSI Response

The Pharmacy Act 2007 requires PSI, the pharmacy regulator, to publish a statutory Code of Conduct for Pharmacists. As part of this requirement, PSI Council undertook to review the Code periodically. The purpose of this review process is to review if the current Code is fulfilling its required function and update it to support the evolving role of pharmacists in a changing health service.

The Code had been reviewed from a clarity of wording perspective as a result of the research and engagement carried out in 2017 ([link when reports published](#)) on the existing Code.

The PSI have reviewed each of the statements in the Code from a legal and professional perspective with regard to the behaviours mandated or advised.

Regarding the applicability of the Code to non-patient facing pharmacists, the PSI is of the view that the Code applies to all pharmacists whatever their area of practice. Although a pharmacist may not provide care directly to patients and the public, their practice can indirectly have an impact on the safe and effective care that patients and the public receive, and on the confidence of members of the public in pharmacy as a whole.

Conscientious Objection

Many comments received detailed concerns surrounding conscientious objection for pharmacists. Potentially as a result of the timing of the consultation, post the referendum on the 8th amendment, there was a particular focus in these comments on the role of pharmacists in termination of pregnancy services.

Comments in this area varied from those who expressed concerns around providing treatment to those who stated they would be morally and ethically unable to 'refer' a pregnant woman seeking termination of pregnancy services. There was substantial comment on this ability to facilitate transfer of care of the patient in the case of conscientious objection. Many of these respondents mentioned the importance of respecting the values, beliefs and diversity of pharmacists.

PSI Response

It is reasonable to acknowledge the timing of the consultation on the draft revised Code post referendum affected the volume of responses in this area. The area of conscientious objection has now been specifically acknowledged in the Code. This reference is in line with that in the Heads of Bill on the Termination of pregnancy legislation, notwithstanding that conscientious objection is a broader issue.

It would be important to emphasise the role of the PSI as the pharmacy regulator, regulating the profession of pharmacy in the public interest. The primary function of the PSI is to protect the health safety and wellbeing of the public. The revised Code, and the specific reference to conscientious objection, has been drafted in this context.

Legal Status of the Code

There were a number of comments from both individuals and organisations on the legal status of the Code. These related to the use of the Code from a Fitness to Practise perspective and the standing of the Code in the context of the Pharmacy Act 2007 and the interpretation of professional misconduct.

PSI Response

The Pharmacy Act 2007 ("**the Act**") defines professional misconduct as any act, omission or pattern of conduct which, amongst other things, is a breach of the Code of Conduct. Any breach of the Code of Conduct must be interpreted, in light of the case law, to mean a "serious breach" if it is to amount to professional misconduct. According to the case law, a "serious breach" is a breach whereby a pharmacist's conduct is considered to have fallen "*seriously short, by omission or commission, of the standard of conduct expected amongst practitioners.*"¹ The Act also provides that professional misconduct

¹ O'Laoire v. Medical Council, Unreported January 27th 1995.

does not include an act, omission or pattern of conduct that consists of a wrongly but honestly formed professional judgement.

The PSI have worked comprehensively internally and externally on this issue, seeking substantial legal expertise, cognisant of existing case law and the practical application of the Code. The Fitness to Practise systems of the PSI work through complaints on a case by case basis in the context of the current legislative background and relevant case law.

Evidence Base

Respondents commented on the use of the words “evidence base” in the revised Code. Many highlighted the existence of medicines which do not have an extensive evidence base particularly in the context of non – prescription medicines. Respondents also raised the issue of evidence base in relation to the appropriate use of unlicensed medicines.

PSI Response

It is acknowledged that in specific cases pharmacists may be recommending products or services which do not have a comprehensive evidence base, however in such cases the pharmacist must be satisfied that a thorough risk assessment has been undertaken and that the needs of the patients are best met by the approach taken. The revised Code will be amended to better reflect these aspects of pharmacy practice.

Open Disclosure and Raising Concerns

A substantial number of comments were received regarding requirements in the Code around raising concerns and responding to errors, including communication to other healthcare professionals and the public in this regard. Some of these respondents also made comments with respect to indemnity cover and confidentiality. A small number of respondents specifically referred to the subject of Open Disclosure.

PSI Response

The PSI is engaging with the HSE specifically on the area of Open Disclosure, in the context of the legislation recently implemented and that to be brought into force in the near future.

The revised Code has been reviewed by relevant experts in the area of Open Disclosure to ensure the Code is fit for purpose in the context of this legislation and the role of pharmacists.

The PSI currently provides a facility where pharmacists, other healthcare professionals and members of the public can raise a concern anonymously, regarding any aspect of pharmacy practice, which impacts on patient health or safety.

Role of Carers

Comments were made by an organisation suggesting the role of carers be further emphasised in the revised Code, as pharmacists are key communicators with family carers. The respondent highlighted that ‘The National Carers’ Strategy (2012) is the current policy and conduct for health & social care professionals with regards to Ireland’s family carers. The respondent mentioned some key objectives from this policy; “promoting a better recognition of the role and contribution of carers at a national level” and “Including carers in care planning and decision making for those that they care for”.

PSI Response

The revised Code has been amended to reflect these comments and to more accurately reflect the role of carers.

Societal Obligations

A number of responses made reference to the potential loss of emphasis on societal obligations in the revised Code. These comments were made in the context of the broad role pharmacists have in society notwithstanding responsibilities in the individual care of patients.

PSI Response

PSI have reviewed the revised Code in the context of these comments and made revisions as necessary to ensure this essential role of pharmacists continues to be acknowledged.

Professionalism outside Work and Pharmacists' Own Health/Wellbeing

Principle 2 of the revised Code makes reference to being professional both inside and outside the work environment and Principle 3 states that pharmacists should look after their own health and wellbeing.

Some comments received stated that professional and personal lives should be kept separate and that being a pharmacist should not dictate how pharmacists conduct themselves outside the work environment. There were mixed views on the use of social media and whether views expressed in a personal capacity affected a pharmacists' professional persona.

PSI Response

The current reference in the revised Code is reflective of international evidence in this area. It should be noted however that the application of such a requirement would be applied and interpreted from a common-sense perspective and only elements of a pharmacists' behaviour or actions outside the work environment, which impacted on the integrity of the profession would be of relevance.

Use of Digital and Social Media

Principle 2 makes reference to using social media and other forms of electronic communication appropriately and responsibly, both professionally and personally. Feedback was received questioning what is and what is not considered appropriate and if further guidance/clarification could be given. One respondent felt that personal social media use should be a matter of the private individual and not appropriate to be mentioned in the Code.

PSI Response

Similarly, to the issue of professionalism outside work, engagement on social media in a professional or personal capacity which would bring the profession into disrepute may be inappropriate.

Specific guidance on the use of digital and social media is already available on the PSI website, however, PSI acknowledges that additional information may be required in this area.

CPD, Student Learning and Culture of Learning

Feedback indicated some reluctance on the mandating of competency assessment and CPD and suggested that CPD should be separate to the Code.

A number of respondents felt that pharmacists should not be required to facilitate student learning and that this issue shouldn't be included in the Code. Suggestions around rewording of these references were made.

Another respondent indicated that a culture of learning should be woven with the principles of raising concerns and quality improvement.

PSI Response

These concerns have been noted and will be considered in the revision of the Code.

Other Issues Raised

A number of other issues were raised by smaller numbers of respondents and these are summarised below.

The issue of the responsibilities of Pharmacy Owners in the context of facilitating professional practice was raised on a number of occasions, with some suggestions that further supports in this area may be required. Associated with this area the issue of financial conflict in making professional decisions was also discussed. This matter is being examined by the PSI in the course of the ongoing project on the development of Standards for Governance and Accountability in a Retail Pharmacy Business. This project also links to comments received in the course of the consultation around transparency and accountability.

Respondents questioned the ability of pharmacists to communicate and build effective relationships with other Healthcare professionals, in all situations. The issue of mutual respect of skills was linked to this matter. PSI acknowledges that it may not always be possible to foster good relationships with other healthcare professionals, however, pharmacist should endeavour to cultivate effective professional relationships where possible.

A number of respondents highlighted issues around pharmacists' working hours and time management. While some of the matters underpinning this feedback are outside the remit of the PSI, the PSI will explore these matters further when developing Standards for Governance and Accountability in Retail Pharmacy Businesses.

Comments were received with regard to ensuring that the wording of the Code acknowledges pharmacists' ability to act in emergency situations, these observations were made in the context of requirements around seeking consent and pharmacist training. PSI would seek to enable pharmacists to act in the best interests of patients in such situations and these references in the Code have been considered in this light.

Questions were posed in the consultation around the General Data Protection Regulations (GDPR), specifically relating to raising concerns and patient confidentiality. The references in the Code to these matters have been reviewed in the context of current relevant statutory requirements in this area.

Some comments were made regarding effective communication with patients. These related to the ability of the pharmacist to assure patient understanding and to enable informed decision making by the patient. Related to this, comments were also received regarding the ability of the pharmacist to obtain informed consent. PSI have reviewed the relevant references in the Code from a statutory and professional perspective and made amendments as necessary.

In response to comments received, the reference to managing conflicts of interest has been strengthened to acknowledge declarations in this regard.

2.4 Suggestions for Supplementary Guidance/Resources

A substantial number of suggestions were provided on supplementary guidance/resources to facilitate implementation of the revised Code. This information will be carefully considered and utilised in the ongoing progress of this project and the future roll out of the Code.

The main suggestions for supplementary resources were;

➤ **Ethical Dilemmas/Scenarios/Examples/ Videos**

A large number of respondents suggested that ethical dilemmas or scenarios/examples would be very useful in the implementation of the revised Code. These resources and the format and delivery of such in the context of the roll out of the revised Code, is currently being considered by the PSI in the planning of roll out and implementation and roll out of the revised Code.

➤ **Links to Guidance/Legislation and Patient Charter**

Respondents suggested that links to other guidance and relevant legislation would be useful. It was also suggested that providing a link to patients on what they should expect from their pharmacist would be useful, potentially a link to the Patient Charter. These suggestions will feed into the launch and publishing of the revised Code.

➤ **Guidance on Conscientious Objection**

Suggestions were received that guidance was required acknowledging pharmacists' rights to conscientiously object where they were unable/unwilling to provide a medicine or service due to personal values or beliefs. The matter of referral or transfer of care was also highlighted in the consultation as requiring further clarification.

➤ **Open Disclosure Guidance**

It was suggested that specific guidance for pharmacists on the area of Open Disclosure may be required. PSI are engaging with relevant national experts in this area and guidance and training required for pharmacists is being considered.

➤ **Further Social Media Guidance**

A substantial number of requests for guidance in the area of digital and social media were made. PSI will consider additional supports required in the context of the implementation of the revised Code and the previously published PSI Guidance for Pharmacists on the use of Digital and Social Media (April 2013)

➤ **Guidance for Pharmacy Owners**

As previously discussed a number of respondents highlighted the impact of the role of pharmacy owners on the professional role of the pharmacist. As indicated, this area will be further examined in the course of the development of Standards for Governance and Accountability in a Retail Pharmacy Business.

➤ **App/ Concise Leaflet/Hardcopies**

With respect to roll out of the revised Code a number of suggestions were made around the availability of the Code as an 'app', as a concise leaflet and in hard copy form to be made available in pharmacies.

➤ **Legal Status of the Code and Interpretation of Breach**

It was suggested that further information may be required on the legal status of the Code, its role from a Fitness to Practise perspective and the interpretation of a breach of the Code. These matters will be further examined in the context of publishing and roll out.

3. Next Steps

The PSI welcomes the large number of responses received to this consultation and noted that the majority of respondents felt that the revised Code of Conduct for pharmacists was clear, concise and relevant to current pharmacy practice.

All comments made were taken into account and many of the suggestions received have been incorporated into the revised Code. The substantial number of useful suggestions around additional supports and resources in the roll out and implementation of the revised Code will be considered and incorporated in PSI work planning for the launch and roll out of this project.

The PSI would like to thank everyone who participated in this public consultation and provided feedback, your contributions are greatly appreciated.