PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

PSI Report on the Public Consultation on Draft Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business

Version 1 August 2015

1. Introduction

The Pharmaceutical Society of Ireland has prepared Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business. The purpose of these guidelines is to facilitate compliance with the personal supervision requirements of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), in particular, Regulation 9. Regulation 9 provides a legislative basis for the therapeutic and pharmaceutical review that must be undertaken by a registered pharmacist upon receipt of a prescription. As a recognised expert in the use of medicines, the pharmacist has a unique opportunity and duty to discharge that responsibility in the course of his or her interaction with patients.

1.1. About the Consultation

A public consultation on the Draft Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business was held from Friday 26th June 2015 until Friday 24th July 2015. The draft guidelines were available to view on the PSI website along with a link to a short online questionnaire to be completed with comments. The option of sending comments in writing, via letter or email, was also provided.

Issue 4, 2015 of the PSI Newsletter invited comments to this consultation. The newsletter was sent to all registrants as well as all stakeholders including other regulators and patient representative groups. In addition, a reminder email was subsequently sent out to all registrants and stakeholders on 20th July, reminding them to provide comment.

1.2. Response to the Consultation

A total of 122 respondents accessed the online survey and answered question 1. Of these 122 respondents who answered question 1, between 41 and 45 respondents went on to answer the questions 3 to 9 that followed regarding the contents of the guidelines. Responses to the quantitative questions in the online survey have been analysed and presented in table and graph format throughout this report. Comments and feedback received from question 9 in the online survey encompassed a variety of opinions, and as such it was decided to group these comments into relevant themes in one section entitled 'General Comments/Submissions'.

A total of 3 responses were received via email. A summary of the comments and feedback received in the emails has also been included in the section entitled 'General Comments/Submissions'.

A profile of the respondents is presented below in Section 2.1 'Respondents' Profile'. These figures include those respondents who accessed the online survey, as well as the further 3 respondents who submitted comments via email.

Respondents who provided their names or PSI registration numbers are listed in Appendix A.

1.3. About this Report

This report summarises the comments received from the online survey questions and email submissions. It was not possible to include all responses in this report, however all comments have been taken into account and the guidelines have been revised and amended as appropriate.

The PSI would like to thank all who took the time to provide submissions to the consultation.

2. Results

2.1 Respondents' Profile

This section includes information gathered in questions 1-3 of the online survey and as indicated in email submissions.

Question 1: I am a…	
Pharmacist	102
Pharmaceutical Assistant	17
Pharmacy Manager	5
Pharmacy Technician	1
Other Healthcare Professional	0
Member of the Public	0
Other	0
Total	**126**

Four respondents selected more than one response when answering this question; responding positively to two of the options given. When this irregularity is accounted for, the total number of respondents was found to be 122.

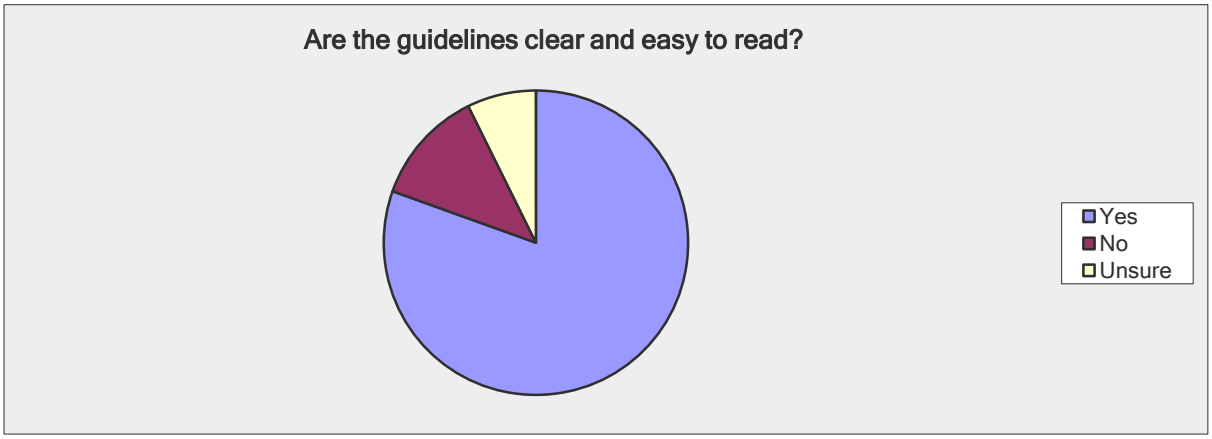
Question 2: If you are responding as a pharmacist /technician/assistant please indicate your main area of practice at present	
Community	107
Hospital	7
Industry	3
Academia	2
Other	1
Total	**120**

Question 3: I am responding in a…	
Personal Capacity	40
As the authorised person on behalf of an organisation or group	5
Total	**45**

2.2. Summary of the Response to the Online Survey Consultation Questions and Email Submissions

Question 4: Are the guidelines clear and easy to read?		
Yes	33	80.5%
No	5	12.2%
Unsure	3	7.3%
Total	**41**	

The majority of respondents (80.5%) responded that the guidelines are clear and easy to read.



Question: If not, please explain which part and why.

It was commented that it was unclear from the guidelines what the term 'carer' referred to, with clarification being sought on the interchangeability between the terms 'carer' 'patient representative' and 'care-giver'. Also concern was raised about the apparent representation of 'dispensing' as one step in the supply process, rather than the multistep processes that dispensing, in the opinion of the respondent, encompasses. Additionally, it was commented that it would be useful to specify the maximum period of validity of a CD prescription. When endorsing a prescription in situations where generics are supplied, it was felt that the manufacturer/brand which was dispensed should only be recorded in situations where a narrow therapeutic index exists or there is a variance in product bioavailability. Also it was suggested that the guideline should state that the manufacturer's original blister packaging should suffice as a suitable Child Resistant Container (CRC).

PSI Response

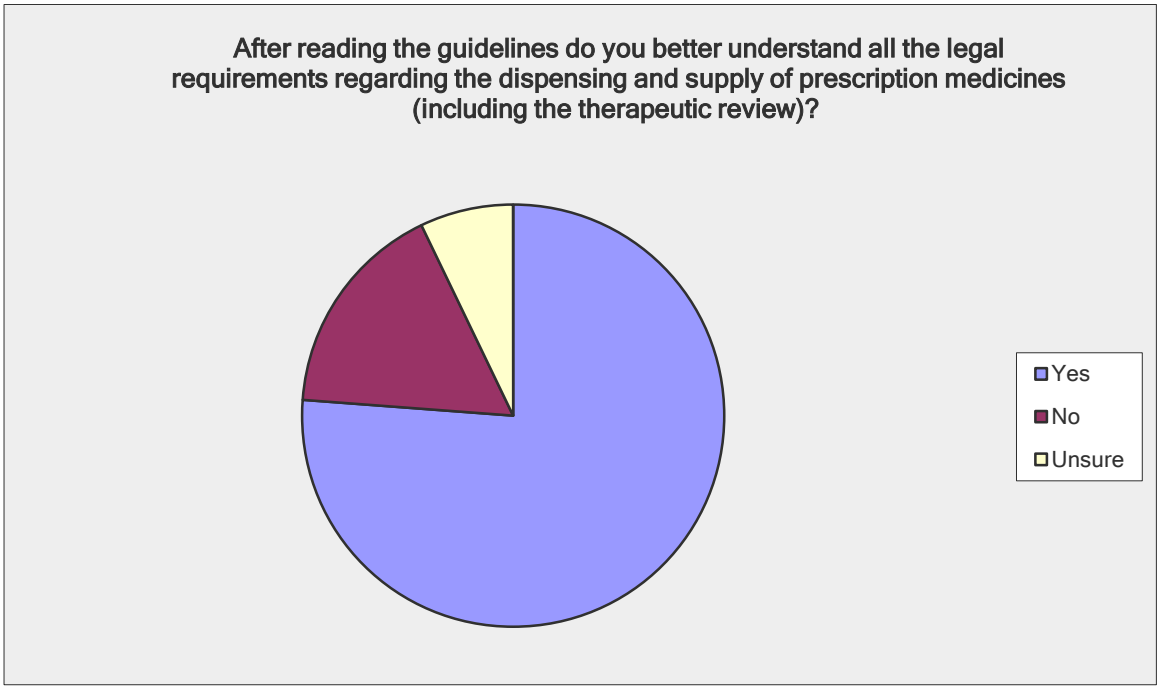
The PSI has noted all responses with thanks and amended the guidelines as follows in light of the comments and feedback received. The term 'carer' was defined in the opening paragraph of the guidelines to address any concerns regarding the meaning of the term. The concerns raised about dispensing were noted but it was felt that within the scope of the current guidelines, as dispensing is an outcome driven process, the step by step machinations of the process may vary between practice settings and discussing this process in detail would cloud the clarity of the guidelines. The overall tenets to ensure best practice and patient safety

during the dispensing process were addressed in the guidelines. The scope of the guidelines has been further clarified through amendments to the title and introductory sections of the guidelines.

The guidelines were amended to give clear instruction on the maximum period of validity of CD 2 and CD 3 prescriptions in those cases where such medicinal products have been dispensed in instalments. It was decided that the endorsement of the prescription with the name of the generic supplied aided the pharmacist identifying the brand/name of the product previously supplied to the patient on previous occasions and thus empowered the pharmacist to offer better counselling to the patient upon potentially issuing a new generic medicinal product.

Question 5: After reading the guidelines do you better understand all the legal requirements regarding the dispensing and supply of prescription medicines (including the therapeutic review)?		
Yes	32	76.2%
No	7	16.7%
Unsure	3	7.1%
Total	**42**	

76.2% of respondents felt that after reading the guidelines they understood all the legal requirements regarding the dispensing and supply of prescription medicines (including the therapeutic review) needed to be adhered to when supplying a prescribed medicinal product.



Question: If not, please explain which part is unclear.

It was felt that the issues surrounding the supply to children under 12 years of age needs to be clarified, and clearer instructions given on when a pharmacist can annotate a prescription in those situations where information has been omitted by the prescriber. In addition, greater clarity was sought on the situations where a pharmacist is permitted to dispense a prescription to a child aged under 12 years if certain pertinent pieces of information are not included on the original prescriber's prescription. Also, it was

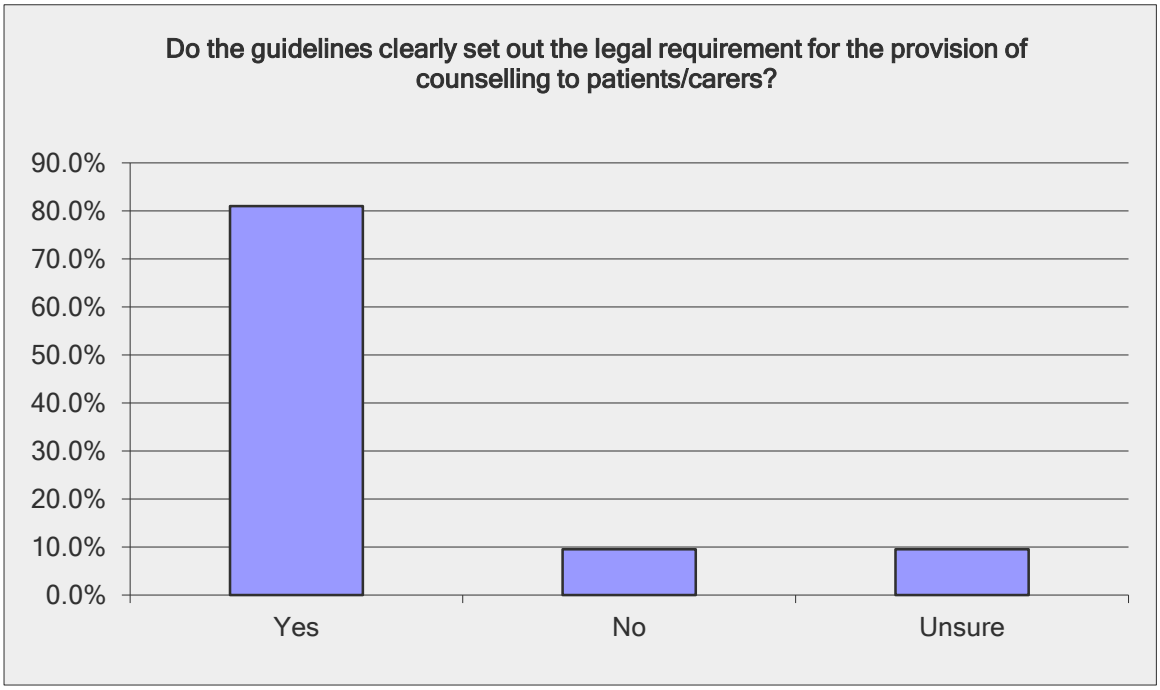
suggested that the information which is required to be recorded for repeat prescriptions, as outlined in regulation 10 (1) (b) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2011, be included.

PSI Response

The PSI has noted all responses with thanks and amended the guidelines to address any potential issues that may arise where a prescriber omits vital, legally required information. The guidelines were amended to better clarify this matter, specifically highlighting the legislative instruction in place in this regard (e.g. Regulation 7(7) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2011). In light of the comment regarding the recording of information when dispensing repeat prescriptions, the guidelines were updated accordingly.

6. Question: Do the guidelines clearly set out the legal requirement for the provision of counselling to patients/carers?		
Yes	34	80.95%
No	4	9.52%
Unsure	4	9.52%
Total	**42**	

The majority of respondents (80.95%) felt that the guidelines clearly set out the legal requirement for the provision of counselling to patients/carers.



Question: If not, please explain which part of the guideline is unclear?

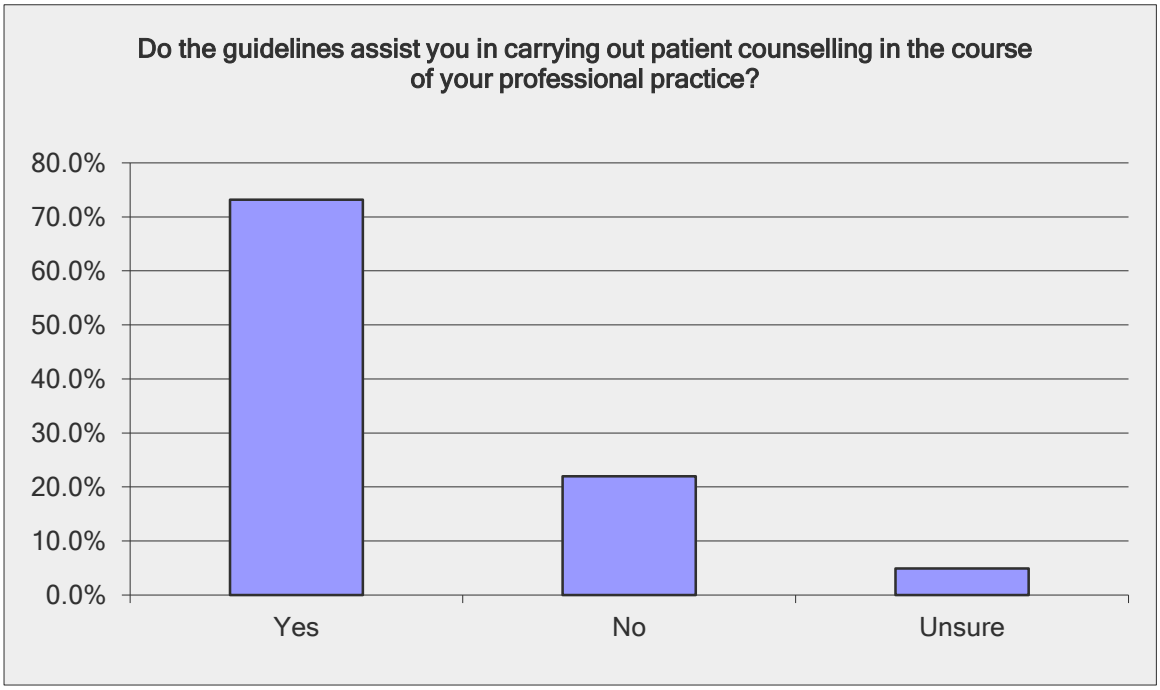
One respondent sought clarification on whether the guidelines accommodated those patients who do not personally attend at the pharmacy to collect their prescribed medicinal products. Again it was felt that the meaning of the term 'carer' needed to be defined. Additionally it was commented that current guidelines did not make reference to those pharmacy practices, where medicinal products were delivered to patients from the pharmacy. Also it was noted that the same pharmacist may not be involved from start to finish in the supply process.

PSI Response

The PSI has noted all responses with thanks. The guidelines were amended to take account of the possibility that more than one pharmacist may be involved in the dispensing and supply of the medicinal products to the patient. Specific practice settings were deemed to be outside of the scope of the guidelines.

7. Question: Do the guidelines assist you in carrying out patient counselling in the course of your professional practice?		
Yes	30	73.17%
No	9	21.95%
Unsure	2	4.88%
Total	**41**	

73.17% of respondents felt that the guidelines assisted them in carrying out patient counselling in the course of their professional practice.



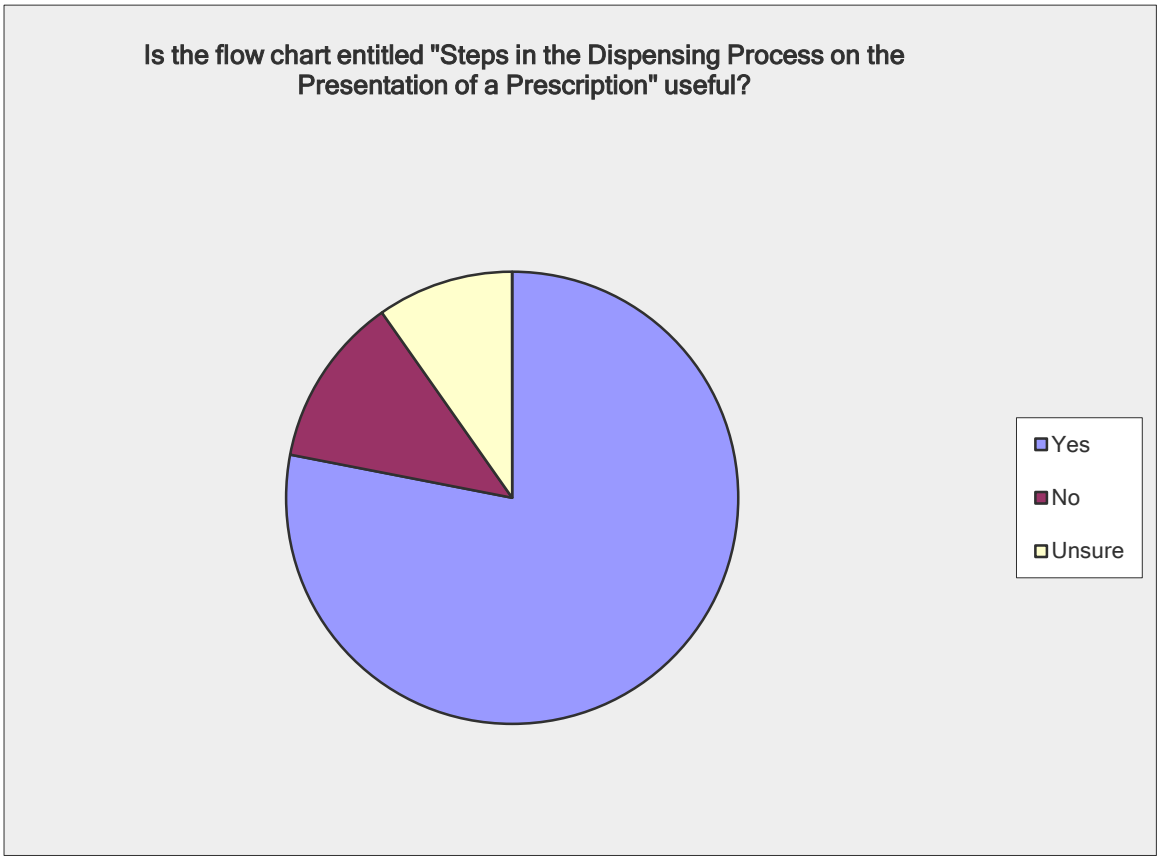
If not, please explain how this can be improved.

It was suggested that the guidelines should emphasise the potential intellectual or physical impairments of some patients and that others may be incapable of understanding all the information given to them during the counselling session with the pharmacist. It was also advised that the draft guidelines be amended to give more prominence to the use of the pharmacy consultation area. It was noted that there was no emphasis on the importance of ensuring patient confidentiality in those cases where patients are unable to attend the pharmacy themselves. It was suggested that the guidelines should address how best pharmacy staff should establish that the person presenting/collecting the prescription has the authority to do so and that they, in the absence of the patient, can receive any information on behalf of the patient. Such situations could result in a real risk of unintentional breaches of confidentiality. It was also suggested that the guidelines would be improved by acknowledging that large numbers of patients 'choose' to avoid presenting at the pharmacy to collect their prescribed medicinal products and avoid the interaction with the pharmacist.

PSI Response

The PSI amended the guidelines to ensure that the pharmacist exercised their professional judgement and due diligence in determining the level of understanding of the patient/carer to whom they were counselling and issuing advice. The potential use of the patient consultation area in carrying out this counselling process was also highlighted. In light of the concerns raised concerning patient confidentiality, the guidelines were amended to read: "Pharmacists should do their utmost to ensure that the person they are providing counselling to is in fact the patient themselves, or an approved representative of the patient to avoid any unintentional breaches of patient confidentiality."

8. Question: Is the flow chart entitled "Steps in the Dispensing Process on the Presentation of a Prescription" useful?		
Yes	32	78.05%
No	5	12.2%
Unsure	4	9.75%
Total	**41**	



If not, please explain which of the steps are not useful.

It was noted that the flow chart does not seem to accommodate those patients who do not physically wait in the pharmacy each time to collect their prescribed medicines. It was felt that the flow chart should accommodate those patients who collect their medicines at a later date following final check by the pharmacist. It was also commented that the flow chart does not make allowances for those tasks in the dispensing and supply process, which can be delegated to other members of the pharmacy staff.

PSI Response

The PSI has noted all responses with thanks and amended the guidelines in light of the comments and feedback received to reflect that many steps of the dispensing process can be delegated to other appropriately trained members of staff and to accommodate patients who return to the pharmacy at a later date to collect their medicines.

Question 9: Have you further queries or comments regarding the sale and supply of prescribed medicinal products that you would like the guidelines to address?

(Please note that responses to Question 9 from the online survey have been considered together with submissions received via email, and a summary of the comments and feedback received have been included in the 'General Comments/submissions' section below.)

General Comments/Submissions:

Prescription Requirements:

It was felt that the guidelines didn't adequately address the practical problems faced by pharmacists when dispensing prescriptions (e.g. illegally written, incomplete or unsafe prescriptions). Additionally it was felt that the consequences prescribers may face if a prescription is not written correctly should be outlined.

More broadly speaking, it was felt that the current prescription writing requirements as laid down in legislation needed to be amended to better deal with controlled drug supply and, as a separate issue, that the period of validity of some prescriptions should be increased beyond the current 6 months. It was also felt that the guidelines should accommodate the use of professional judgement by pharmacists in situations where he/she deems it appropriate to dispense a medicinal product using a prescription that is not legally compliant in every aspect.

Packaging and Labelling of Medicinal Products:

It was suggested that under the section "Packaging of Medicinal Products", the provision of further information on the selection of an appropriate container for dispensing medicinal products otherwise than in the manufacturer's original packaging may prove useful (e.g. containers which allow protection from light / heat etc.) as required by the SmPC of the individual product.

Furthermore, regarding the packaging of medicinal products, it was suggested that PSI guidelines be stricter on the issue of "broken bulk" dispensing, proposing that this practice be more stringently regulated. It was also pointed out that at times, supplying the SmPC or PL to a patient is deemed impractical particularly for those patients on weekly dispensing(s) and those receiving methadone. The issue of how best to label medicinal products was raised, with one respondent suggesting that the guidelines should acknowledge that

it may not be possible to appropriately affix labels to certain medicinal product packaging (e.g. small size or unconventional shape of container).

Therapeutic Review and Counselling:

It was highlighted that in practice, it is often very difficult for pharmacists to clinically review the original prescription before each dispensing to ensure the medicine is safe and appropriate for the patient to take and to make a clinical assessment as to the appropriateness of the prescribed medicine therapy for the individual concerned. It was felt that this was outside the remit of the pharmacy profession and an unfair burden to put on practising pharmacists. It was suggested that the "dispensing process" needs to be re-examined, with the guidelines clarifying that the dispensing process only finishes when the medicines have been physically handed over to the patient/carer.

Additionally, with specific reference to the flowchart, it was felt that the chart as currently drafted did not accommodate prescriptions that are prepared one day and collected another day (and in some situations when a different pharmacist is on duty).

The use of Skype and video conferencing was raised, with two respondents suggesting that this form of communication and counselling needs to be acknowledged in the guidelines. Furthermore the issue of online prescriptions was also raised, with one respondent highlighting the prevalence of this practice in the United Kingdom. It was suggested, that the PSI should pre-empt such evolutions of practice, and issue guidance to the profession on the issue of online doctors, online prescribing and online prescriptions.

One respondent queried why Pharmaceutical Assistants were not mentioned in the guidelines.

Supply to Ships

It was suggested that further guidance should be given on the subject of supplying medicines on foot of a requisition to ships which pass in port. Also it was highlighted that the guidelines remain mute on the subject of pharmacist-conducted inspections of medical lockers on ships/marine vessels.

HSE Drug Schemes

It was commented that since the introduction of the GMS prescription levy many patients do not take certain medications in order to reduce the monthly cost incurred by them. In light of this it was felt that the guidelines should make allowances for these types of situations. The number of tablets dispensed per calendar month for each medicinal product was raised in light of the Drug Payments Scheme (DPS) and reimbursement from the PCRS. It was suggested that the effective "13th" month allowed to be supplied to those patients receiving a 28 day supply per calendar month needs to be reviewed.

PSI Response

The PSI has noted all responses with thanks and has amended the content of the guidelines to reflect the concerns raised.

The concerns raised over the DPS and GMS schemes fall outside of the remit of the PSI, as too do the suggestions concerning possible amendments to the prescription writing regulations and period(s) of validity of prescriptions. The HSE/PCRS and Department of Health, respectively, have oversight of these issues. It was also felt that the issues raised concerning supply to merchant vessels/ships was too prescriptive and

rested more suitably outside of the guidelines as a separate issue. Such an issue is, and can be, addressed by the PSI through its query management service (info@psi.ie).

In those situations where a prescriber has incorrectly written a prescription, if the directions on a prescription are not clear, or do not meet the requirements for a legally valid prescription, the guidelines were amended to provide advice to pharmacists on how best to resolve or deal with these issues.

In light of the comments made about the re-packaging of medicinal products into appropriate containers, the guidelines were amended to reflect that due regard should be paid to the suitability of that container for the medicinal product concerned (e.g. adequate protection from light and heat) as required by the product's SmPC. The inclusion of PLs when supplying a prescribed medicinal product was deemed to be an appropriate patient safety issue and a step in the dispensing process that should be adhered to, notwithstanding that this may not be practicable in all situations encountered in the pharmacy. As the labelling of a prescribed medicinal product is enshrined in the legislation, it was considered that this was an issue that would be best directed towards the Department of Health who oversee the implementation of this specific legislation.

The guidelines were amended to address concerns raised that the guidelines remained silent on the potential for more than one pharmacist to be involved in the supply of a prescribed medicinal product. The guidelines and flow chart were changed to clarify that the therapeutic review and counselling requirements cannot be fully fulfilled until the prescribed medicinal product is physically handed over to the patient/their carer. Concerns about communication technology and advances therein, were addressed in the guidelines, in an effort to provide additional guidance to pharmacists on this matter. The guidelines were amended, and it was noted that, any method of communication engaged with in the provision of counselling to patients must be in compliance with the Data Protection Acts 1988 (as amended).

3. Next Steps

The PSI welcomed the number of responses received to this consultation, and noted that the majority of respondents felt that the guidelines were clear and easy to read. The PSI acknowledges the training undertaken by pharmacists during their undergraduate study, and the skills and expertise that pharmacists hold and have acquired in the years of practise. The intention of these guidelines is to support pharmacists in their legislative duty to effectively and safely counsel patients, conduct therapeutic reviews and assist them in providing a clinically robust service to patients in receipt of prescribed medicinal products.

It is recognised that there are other resources and guidelines available to pharmacists on the issue of conducting therapeutic and clinical reviews, and also in how best to counsel patients. The techniques used, and the level to which the processes are followed are practice dependent, but the PSI reminds all pharmacists of their legal obligations as enshrined in Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008. The PSI also encourages registrants to actively engage with the IIoP who may offer additional support to pharmacists in the area of effective communication.

Appendix A

NAME/ORGANISATION	REGISTRATION NO. (if applicable)
Anne Gaughan	2377A
Boots Retail Ireland Ltd	-
Carol Mahon	7044
Cicely Roche	4906
Daire Scanlan	6053
Daniel Fallon	5958
Emmeline Landers	5645
Eugene Daly	11342
Irish Pharmacy Union	-
Joe Britton	5640
Johanna Sugrue	2548A
Kevin McCormack	5681
Mark Beddis	7315
Maurice O'Connell	4598
Michelle Concannon	5783
Pat McGee	Not provided/ n/a
Siobhan Knightly	7369
Sonja Bliessen	11025