PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

PSI Report on the Public Consultation of the Draft Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy

March 2018

1. Introduction

The Pharmaceutical Society of Ireland (PSI) prepared a guideline on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business. The purpose of this guideline is to facilitate compliance with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), and in addition with Regulation 5(1)(d) and 5(1)(h) insofar as they relate to the sale or supply of non-prescription medicinal products from a retail pharmacy business.

Regulation 10 provides a legislative basis for all pharmacists to ensure that the medical needs of the patient are established and that appropriate counselling is provided to the patient prior to the sale or supply of non-prescription medicinal products. Regulation 5(1)(d) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended) confers obligations on pharmacy owners, superintendent pharmacists and supervising pharmacists, to ensure the personal supervision of the sale or supply of medicinal products (including non-prescription medicinal products), by a registered pharmacist is met. Regulation 5(1)(h) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended) stipulates the requirement for pharmacists and other staff employed in the retail pharmacy business to have the requisite knowledge and skills necessary to effectively carry out their roles.

1.1. About the Consultation

A public consultation on the 'Draft Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business' was held from Wednesday 25 October 2017 until Wednesday 22 November 2017. The draft guideline was available to view on the PSI website along with a link to a short online questionnaire. The option of sending additional comments in writing, via letter or email, was also included. Issue 6, 2017 of the PSI Newsletter invited pharmacists to participate in this consultation. The newsletter was sent to all registrants as well as all stakeholders including other regulators and patient representative groups. The consultation was also highlighted on various PSI social media accounts.

1.2. Response to the Consultation

A total of 108 respondents accessed the online survey. Of the 108 respondents who answered question 1, between 42 and 45 respondents went on to answer questions 4 to 11 regarding the contents of the guidelines. Two responses were received via e-mail. Responses to the quantitative questions in the online survey have been analysed and presented in a table and graph format throughout this report.

Comments and feedback received from question 11 of the online survey encompassed a variety of opinion. These comments were grouped into relevant themes in the 'General Comments/Submissions' section of this document. In addition, a summary of the comments and feedback received via email has also been included in the 'General Comments/Submissions' section.

A profile of the respondents is presented below in Section 2.1 'Respondents' Profile'. These figures include respondents who accessed the online survey, as well as two 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 questionnaire and email submissions. It was not possible to include all responses in this report, however all comments have been taken into account and the draft guideline has been revised and amended as appropriate.

Please note that when all responses were analysed it became evident that a significant number of responses were received from a group of pharmacy technician students. Due to the large number of responses received from this respondent group (as a proportion of the responses received in total), it was decided to collate feedback from this respondent group into one section of the report (see general comments/submissions). Further commentary and the response of the PSI on the issues raised by this student group can also be found in this section of the report.

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

2. Results

2.1 Respondents' Profile

Questions 1-3 relate to the respondents' profile. Results from the submissions received via email have also been included in these figures.

Question 1:

Table 1 – Profession of Respondents

Pharmacist	86
Pharmaceutical Assistant	3
Pharmacy Owner	4
Member of the Public	5
Other	10
Total	**108**

Question 2:

Table 2: Respondents' Practice Area

Community	87
Hospital	9
Industry	3
Academia	3
Other	2
Total	**104**

Question 3:

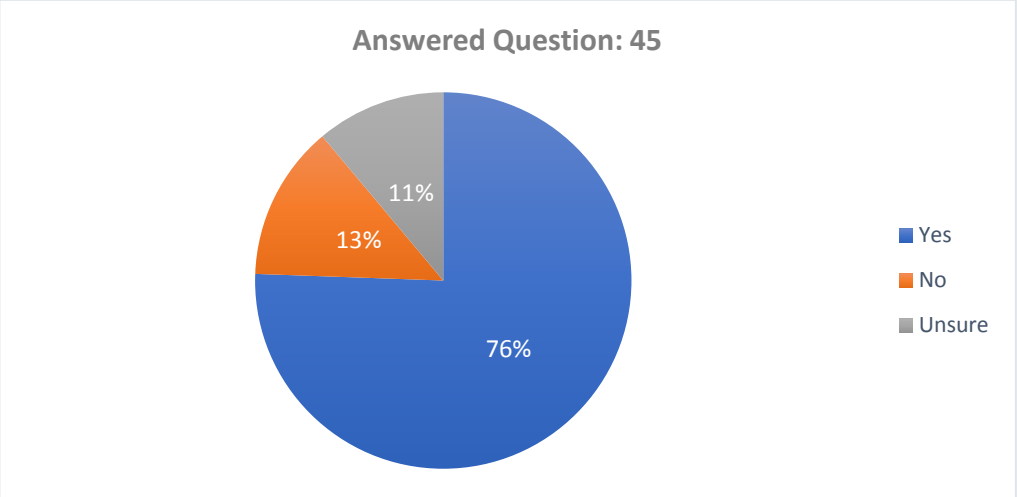
Table 3: Respondents Response Capacity (I am responding …)

In a personal capacity	102
As the authorised person on behalf of an organisation or group	6
Total	**108**

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

Question 4:

Figure 1: Overall, are the guidelines clear and easy to read?



The majority of respondents (76%) responded that the guideline was clear and easy to read.

Question: If not, please explain which part and why

18% of responses received for this question were from a group of pharmacy technician students who highlighted the role pharmacy technicians could play in the sale or supply of non-prescription medicinal products from a pharmacy.

Concern was raised by a few respondents who queried how the pharmacist could personally supervise the sale or supply of all non-prescription medicinal products.

Regarding the self-assessment checklist at the end of the guideline document, one respondent enquired about the necessity to maintain relevant records of the sale or supply of non-prescription medicinal products.

PSI Response

The PSI has noted all responses with thanks.

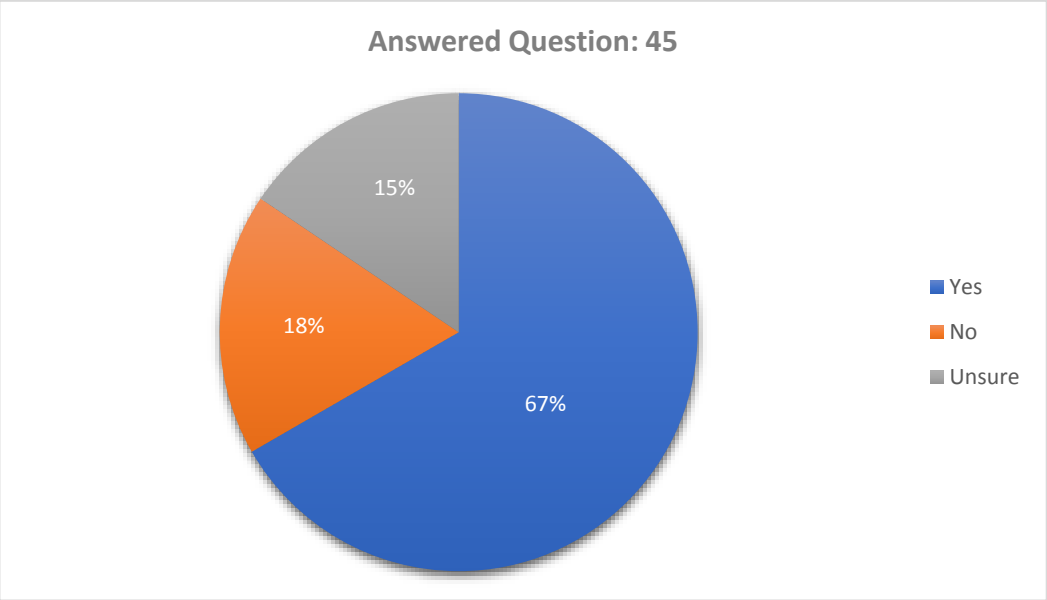
The PSI welcomes the feedback received regarding the personal supervision by the pharmacist of each sale or supply of medicinal products. This issue is discussed in further detail in the general comments/submission section of this document.

In response to the comment received expressing concern regarding the necessity for record keeping in the sale or supply of non-prescription medicinal products, the term 'as appropriate' has been inserted for clarification. The PSI wishes to remind all pharmacists that in line with good pharmacy practice, it is recommended that the supply of certain medicinal products, for example Levonorgestrel 1500mcg, be appropriately recorded. Records could be kept for example in a patient consultation record or a Patient Medication Record (PMR), as detailed in the PSI Guidance for Pharmacists on the Safe Supply of Non-Prescription Levonorgestrel 1500mcg for Emergency Hormonal Contraception.

Please see the general comments/submissions section at the end of this report for response on the role of pharmacy technicians.

Question 5:

Figure 2: After reading the guidelines, do you have a clear understanding of the legal requirements of Pharmacists to supervise the sale or supply of all non-prescription medicinal products?



67% of respondents felt that after reading the guideline, they clearly understood the legal responsibilities of a pharmacist to personally supervise the sale or supply of non-prescription medicinal products from a Retail Pharmacy Business.

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

18% of responses received for this question were from a group of pharmacy technician students who highlighted the role pharmacy technicians could play in the sale or supply of non-prescription medicinal products from a pharmacy.

Feedback was received that the need for the 'active involvement' of the pharmacist at all times, as described in the guideline, was not required by legislation. Additionally, it was suggested that describing the professional input that a pharmacist provides as 'essential' was not reflective of the legislation and that wording should be adjusted to reflect this.

One respondent commented that the requirement for pharmacists to supervise the sale of every non-prescription medicinal product is not feasible and suggested that regulations be updated to reflect this issue.

Concern was raised on the subject of internet supply. Some respondents stated that they fundamentally disagree with the supply of non-prescription medicinal products over the internet. It was queried how the requirement for personal supervision by a pharmacist could be applied practically or safely to an online sale of a non-prescription medicinal product.

PSI Response

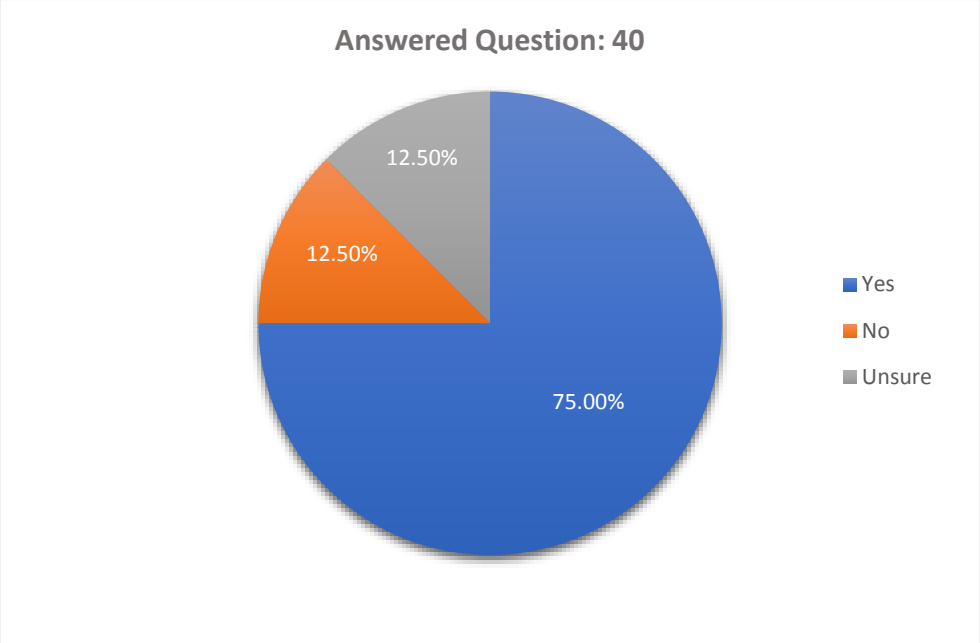
The PSI has noted all responses with thanks. The feedback received regarding the pharmacists "active" involvement and "essential" professional input were duly noted and the guideline was amended to incorporate this advice.

In relation to the issue of internet supply of non-prescription medicinal products, the supply of these medicinal products via the internet is allowed for under EU and Irish law, as shall be detailed in the general comments/submissions section of this report. Furthermore, the issue of personal supervision by the pharmacist when supplying non-prescription medicinal products via this route is addressed in the General Comments/Submission section at the end of this document.

Please see the general comments/submissions section at the end of this report for response on the role of pharmacy technicians.

Question 6:

Figure 3: Do these guidelines clearly set out the legal requirement for the provision of counselling to patients/carers?



The majority of respondents (75%) believed that the guideline 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?

20% of responses received for this question were from a group of pharmacy technician students who highlighted the role pharmacy technicians could play in the sale or supply of non-prescription medicinal products from a pharmacy.

It was put forward by one respondent that preventing self-selection of pharmacy-only medicinal products would prevent patients from having access to product information, which is printed on product packaging, and it was alleged that this would lead to less information being available to the patient.

PSI Response

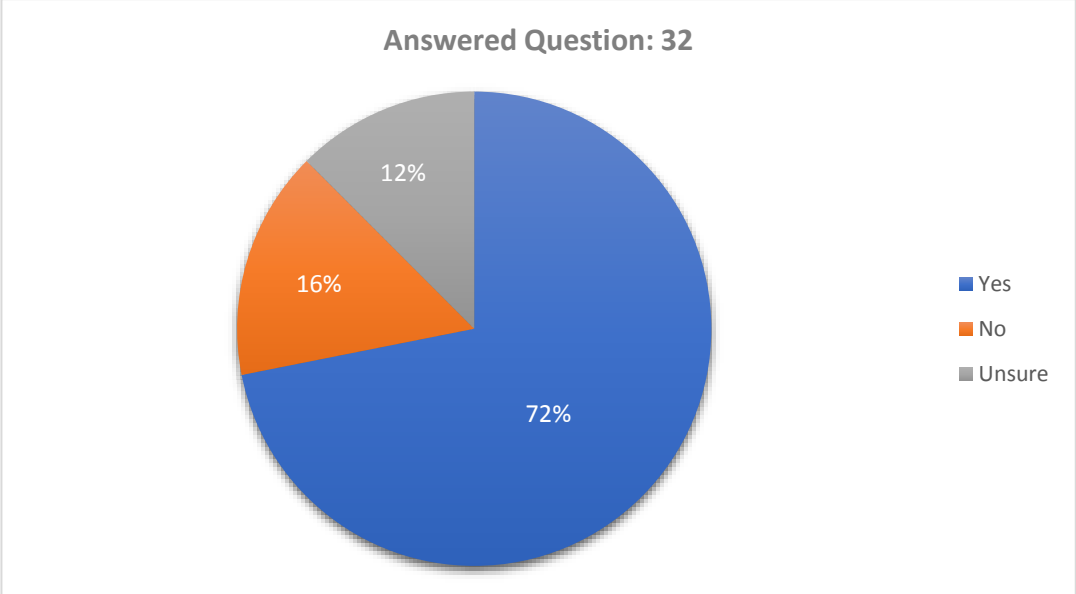
The PSI has noted all responses with thanks. Regarding the issue of self-selection of pharmacy-only medicinal products, as stipulated in Regulation 5(1) (ea) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (amendment S.I. 80 of 2016), pharmacy–only medicinal products must be stored in an area of the pharmacy to which the public does not have access.

The suggestion that preventing self-selection of non-prescription medicinal products leads to less information being available to the patient has been duly noted. The PSI reminds all pharmacists that they have a professional role and statutory duty to carry out, or personally supervise, the sale or supply of all non-prescription medicinal products from a retail pharmacy business and to ensure that the patient/purchaser is made aware of the safe and appropriate use of the non-prescription medicinal product and that it is not intended for misuse or abuse. As experts in medicines, pharmacists have a duty to discharge their responsibilities professionally in the course of their interaction with patients and discharging all necessary information regarding non-prescription medicinal products with them. The pharmacist's role involves the responsible supply of medication for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include managing an illness, slowing of a disease process, preventing a disease from occurring or the relief of a patient's symptoms.

Please see the general comments/submissions section at the end of this report for response on the role of pharmacy technicians.

Question 7:

Figure 4: Do these guidelines assist you in carrying out a patient consultation in the course of your professional practice?



72% 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.

25% of responses received for this question were from a group of pharmacy technician students who highlighted the role pharmacy technicians could play in the sale or supply of non-prescription medicinal products from a pharmacy.

Comments were received regarding the use of the Patient Consultation Area. In addition, one respondent commented that pharmacists can often encounter difficulty when trying to elicit all necessary information from the patient, presenting at the pharmacy prior to the sale or supply of certain non-prescription medicinal products. The sale or supply of domperidone was cited as an example.

PSI Response

The PSI have noted all responses with thanks**.** With regards to the concerns expressed over the use of the Patient Consultation Area (PCA), the guideline state that the PCA should be used 'as appropriate'. Further information on the PCA can be found in PSI Guidelines on the Patient Consultation Area in a Retail Pharmacy Business.

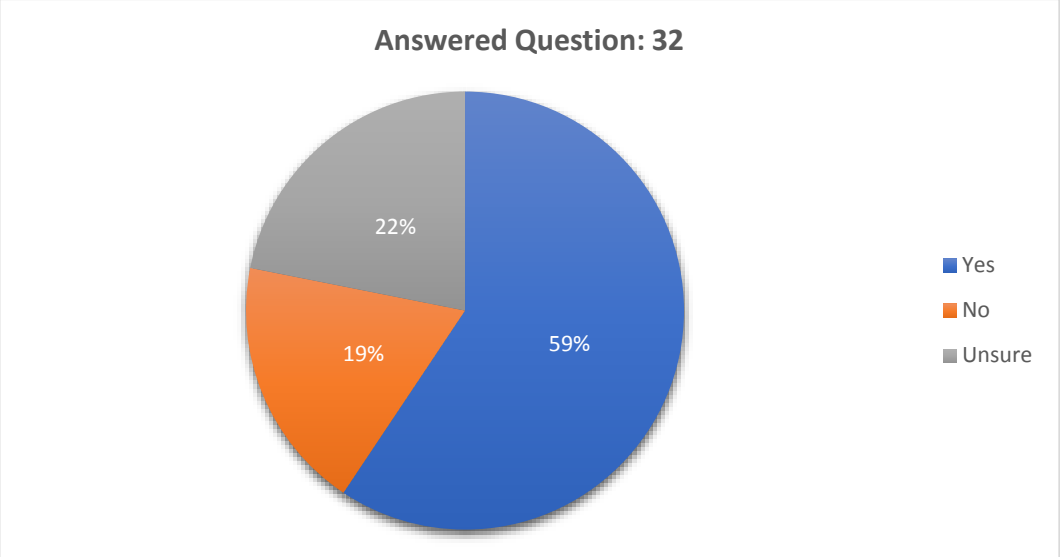
With reference to potential barriers to communicating with patients during the course of the sale or supply of certain non-prescription medicinal products, the PSI would like to highlight a suite of published guidance material in this regard. In addition, due to the potential patient safety concerns

with the use of domperidone, the PSI reminds all registrants that the supply of this medicinal product should only be carried out by a pharmacist who should conduct a thorough consultation with the patient requesting domperidone or presenting with symptoms, in order to determine whether or not the sale or supply of domperidone to the patient is safe and appropriate. During the course of such a consultation, it may be appropriate in certain circumstances to conduct the consultation in the PCA for privacy.

Please see the general comments/submissions section at the end of this report for response on the role of the pharmacy technician.

Question 8:

Figure 5: Do the guidelines clearly set out the requirements for staff training in the sale or supply of non-prescription medicinal products?



59% of respondents felt that the guidelines clearly set out the requirements for staff training in the sale or supply of non-prescription medicinal products.

If not, please explain how this can be improved.

25% of responses received for this question was from a group of pharmacy technician students who highlighted the role pharmacy technicians could play in the sale or supply of non-prescription medicinal products from a pharmacy.

Concern was raised that staff training levels in a retail pharmacy business are left to the individual interpretation of the pharmacist and that neither legislation nor PSI guidelines set out any standards of training for non-pharmacist members of staff. Furthermore, it was stressed that there are no officially recognised non-pharmacist staff training courses approved by the PSI.

PSI Response

The PSI has noted all responses with thanks. With regards to the staff training, the issue of specific training modules and courses was raised by a number of respondents. Comments were made that training of non-pharmacist staff should be carried out in a structured manner with official courses and qualifications to be approved by the PSI as well as a clear timeline of training. Currently the training of

non-pharmacists is beyond the legislative remit of the PSI, therefore the PSI is not in a position to provide further comments on this subject.

Please see the general comments/submissions section at the end of this report for response on the role of the pharmacy technician.

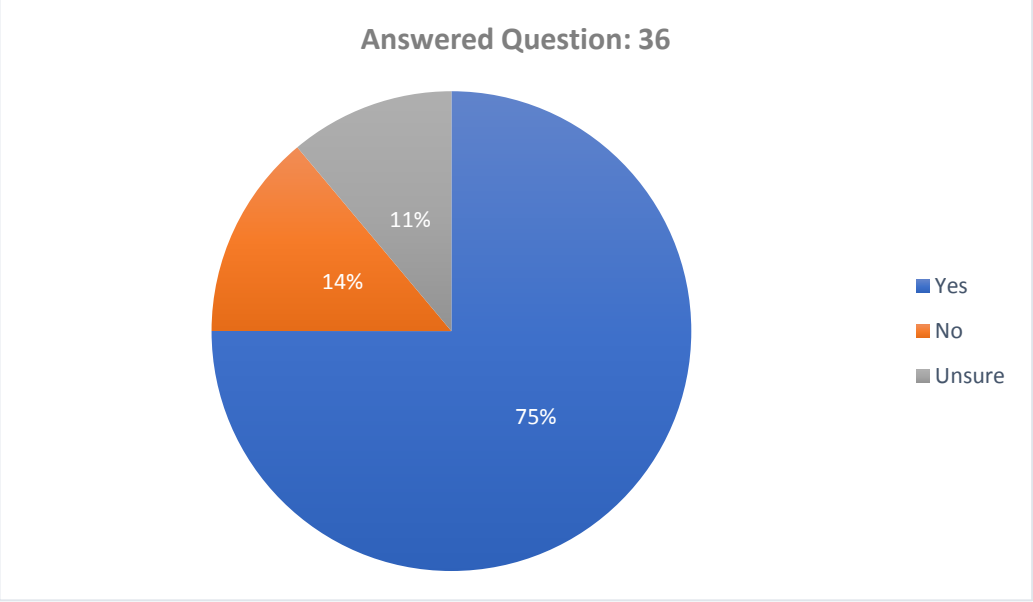
Question 9:

Figure 6: Do the guidelines clearly outline the additional counselling requirements for the sale or supply of medicinal products for children?

75% of respondents felt that the guidelines clearly outline the additional counselling requirements for the sale or supply of non-prescription medicinal products for children.

If not, please explain how this can be improved.

22% of responses to this question were received from a cohort of pharmacy technician students who queried the role of the pharmacy technician.



Regarding internet supply, it was suggested that children would potentially be able to order non-prescription medicinal products via the internet and that there was the potential that a pharmacist would not be aware that the supply was being requested by a child. It was also suggested that guidance be provided surrounding the issue of the sale or supply of non-prescription medicinal products directly to a child.

PSI Response

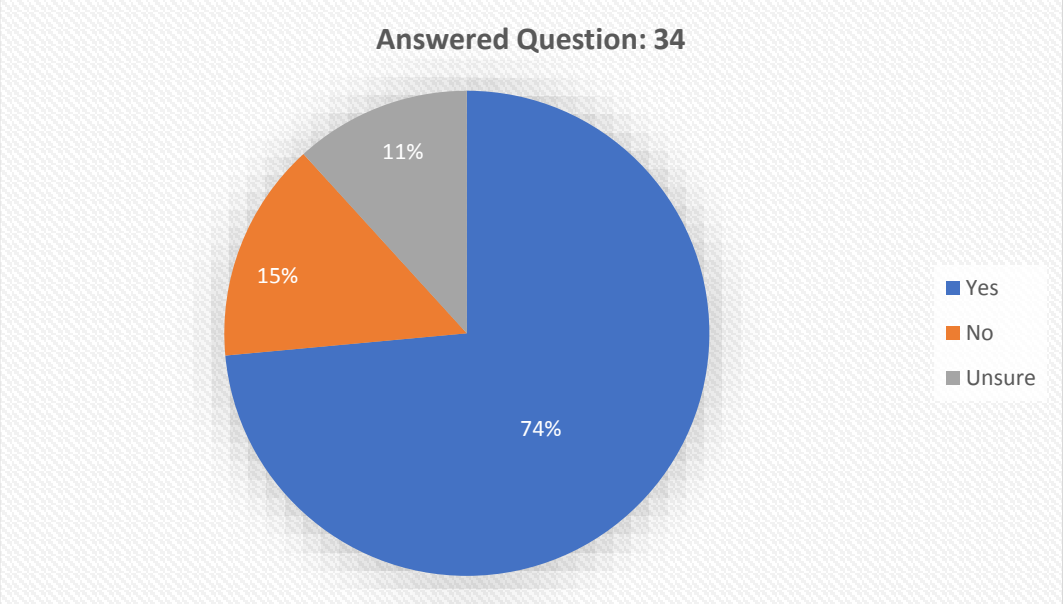
The PSI have noted all responses with thanks**.** With regards the comments concerning the Package Leaflets (PLs) the PSI would like to clarify that all non-prescription medicinal products should be sold or supplied in their original pack and therefore contain PLs. The PSI expects that prior to the sale or supply of any non-prescription medicinal product, an effective consultation is carried out by a pharmacist or non-pharmacist member of staff acting under their personal supervision. Following such a consultation, the pharmacist should be satisfied that the patient has received all the necessary information pertaining to the use of the medicinal product.

The issue of supply directly to children was raised. The PSI acknowledges the inherent intricacies surrounding the supply of medicinal products to children. Pharmacists need to be aware of all legislation governing their practice and any relevant guidelines and guidance that has been published. The PSI reminds all pharmacists to exercise their professional responsibilities, as per pharmacy legislation and the Code of Conduct for Pharmacists, to ensure the safe supply of all medicinal products.

Please see the general comments/submissions section at the end of this report for response on the role of the pharmacy technician.

Question 10:

Figure 7: Do the guidelines clearly set out the regulations governing the supply of non-prescription medicinal products over the internet, including the requirement for pharmacists to personally review all such sales?



74% of respondents felt that the guidelines clearly outline the regulations governing the sale or supply of non-prescription medicinal products over the internet including the requirement for the pharmacist to personally review all such sales.

If not, please explain how this can be improved.

Concerns were raised over the issue of internet supply of non-prescription medicinal products, with some respondents commenting that they did not agree with supply of non-prescription medicinal products via this route. Questions were posed as to how internet supply could be carried out practically or safely.

PSI Response

The PSI have noted all responses with thanks and welcomes feedback in this regard. The legal framework governing internet supply of medicines was transposed into Irish legislation following the publication of the EU Directive (Falsified Medicines Directive, 2011). This Directive facilitates the safe supply of medicines via the internet, through the introduction of regulatory controls, in order to reduce potential risks associated with the supply of counterfeit medicines. Following from this Directive, the European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S.I. No. 86 of

2015) made it a principal function of the PSI to establish and maintain a list of persons entitled to supply non-prescription medicinal products via internet supply. The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015) require all pharmacies and other entities engaged in the supply of non-prescription medicinal products via the internet, to notify the PSI of their internet activities. The PSI Guidance on Internet Supply of Non-Prescription Medicines is also available on the PSI website. The PSI will continue to monitor this situation and provide updates to the profession accordingly.

Question 11:

Do you have any further queries or comments regarding the sale or supply of non-prescription medicinal products that you would like the guidelines to address?

Answered	17
Skipped	91

General Comments/Submissions:

Role of the pharmacy technician and other non-pharmacists members of staff:

The PSI welcomes feedback received from the group of pharmacy technician students. While the PSI acknowledges the valuable role that other appropriately trained members of the pharmacy team can play in the sale or supply of non-prescription medicinal products, as per the Pharmacy Act 2007 and the Regulations of Retail Pharmacy Businesses Regulations 2008 (as amended), it remains solely the responsibility of the pharmacist to personally supervise the sale or supply of all medicinal products in a retail pharmacy business. The aim of this guideline is to facilitate compliance by pharmacists, with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended) and also with Regulations 5(1)(d), 5(1)(h) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (as amended) insofar as they relate to the sale or supply of non-prescription medicinal products. These regulations confer obligations on pharmacy owners, superintendent pharmacists, supervising pharmacists and all other pharmacists. The PSI recognises the important role pharmacy technicians and other non-pharmacist members of staff play in the sale or supply of non-prescription medicinal products from a Retail Pharmacy Business. However an expanded description of the role of pharmacy technicians is outside the scope of this guideline and it was felt that further commentary on the training and role of pharmacy technicians and other pharmacy staff would result in the obfuscation of the intent of the guideline.

Personal supervision:

It was highlighted that it is often difficult or not feasible for pharmacists to personally supervise the sale or supply of all non-prescription medicinal products in the pharmacy. One respondent advocated that the Regulations be updated to allow trained members of staff to carry out non-prescription medicinal sales following appropriate policies and procedures. It was also suggested that the pharmacist's prior knowledge of the customer or patient be used in deciding the extent of each intervention by a pharmacist. The PSI recognises the valuable role that non-pharmacist members of staff play in the sale or supply of non-prescription medicinal products from a Retail Pharmacy Business, nonetheless, the legislation that governs the sale or supply of non-prescription medicinal products stipulates that pharmacists must personally supervise the sale or supply of all non-prescription medicinal products from a retail pharmacy business.

Roles and responsibilities of pharmacy staff:

The guidelines state that "all staff members must operate within the limit of their authority and be clear of their roles and responsibilities." It was commented that the guidelines should define the roles of each member of staff in the pharmacy. Whilst the PSI acknowledges this issue, defining the roles and responsibilities of various members of the pharmacy team goes beyond the scope of this guideline. The issue of staffing and roles may be addressed in a separate guideline at a future date.

A large proportion of the feedback received during the course of this public consultation was from a cohort of student technicians who queried their role in the sale or supply of non-prescription medicinal products. Whilst the PSI acknowledges the valuable role that pharmacy technicians and other non-pharmacist members of staff play in the running of a retail pharmacy business, legislation clearly states that it is the responsibility of the pharmacist to personally supervise the sale or supply of non-prescription medicinal products from a retail pharmacy business and when the sale or supply is carried out by a non-pharmacist member of staff this must be done under the personal supervision of a pharmacist. Therefore the sale or supply of non-prescription medicinal products cannot be carried out by non-pharmacist members of the pharmacy team without the required pharmacist supervision.

Sale or supply of general sales medicines:

Comments were made that the guideline does not distinguish between levels of pharmacist intervention required for the sale of general sales list (GSL) medicinal products compared to pharmacy-only medicinal products in a retail pharmacy business. To clarify, GSL medicinal products can be sold from non-pharmacy outlets without the supervision of a pharmacist. However, when conducting a retail pharmacy business, the sale or supply of all medicinal products, including GSL medicinal products, must be carried out in accordance with the Pharmacy Act 2007. The Act and supporting legislation states that sale or supply of all medicinal products must be carried out under the personal supervision of a pharmacist.

Reclassification of prescription-only medicinal products:

Examples were provided in the guideline of prescription-only medicinal products that had been reclassified from prescription-only to supply by the pharmacist. In relation to this, it was commented that since the list of reclassified medicines is non-exhaustive, this should be indicated in the guideline. The guideline was therefore updated to include the statement "this is a non-exhaustive list".

One respondent requested that a full list of reclassified medicinal products be provided in the guideline. As such a list would be non-exhaustive, the PSI considered it more appropriate to direct readers to the regulator of medicinal products in Ireland; the Health Products Regulatory Authority (HPRA), where further information on this subject can be sought, and where such information is monitored and updated as appropriate.

Substances of 'abuse':

Feedback was received regarding the wording included in the guideline describing medicinal products with the potential for 'abuse'. It was commented that the description of non-prescription medicinal products as having a "high potential for abuse and/or misuse', was potentially misleading, as by definition these products would be unsuitable for non-prescription status. This comment was duly noted and the guidelines were amended accordingly.

One respondent requested that a full list of active ingredients of substance of abuse be provided in the guideline. In response to this request, it is the option of the PSI that pharmacists should use their knowledge and expertise in this area to determine which non-prescription medicinal products could potentially be abused or misused, particularly in light of the fact that non-prescription medicinal products that may be likely to be abused could potentially change over time. The guideline has also been updated to specify that policies and procedures governing the sale or supply of particular non-prescription medicinal products (e.g. those with a potential for abuse/misuse), as deemed appropriate by the superintendent and/or supervising pharmacist, should be in place in pharmacies.

Original packs:

Regarding the statement in the guideline that "medicinal products should, where feasible, be provided in their original pack", it was recommended that the guidelines be unequivocal about the need to supply non-prescription medicinal products in their original pack, with the PL in all cases. This feedback has been duly noted and the term "where feasible" has been removed from the aforementioned statement.

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. All comments made were taken into account and many of the suggestions received were incorporated into the revised guideline document.

The PSI acknowledges the training undertaken by pharmacists during their undergraduate study, and the skills and expertise that pharmacists hold and have acquired during their years of practice. 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 non-prescription medicinal products.

The PSI would further like to remind all pharmacists and non-pharmacist members of staff that there are a range of resources and guidelines available to them on the PSI website, covering issues such as how best to counsel patients.

Again, the PSI would like to thank everyone who participated in this public consultation and provided feedback.

Appendix A:

Individual:	**Registration no. (where provided)**
Emer Sheehan	
Diane Patterson	6747
Danielle Harkin	
Katherine Bergin	
Michelle Green	
Fiona Dempsey	
Pamela Logan	5944
Eamon Hayes	9708
Luigi Barlassina	7735
Jason Kiernan	10285
Patrick Lannen	6380
Sonja Bliessen	11025
Anne Egan	5588
Patrick Lehane	9974
Fabian Sweeney	9386

Organisational Responses
Irish Pharmaceutical Healthcare Association (IPHA)
Health Products Regulatory Authority (HPRA)
Athlone Institute of Technology
Irish Pharmacy Union (IPU)
Hicktron Limited