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 Record Keeping f Medicinal Products in a Retail Pharmacy Business

December 2016

1. Introduction

The Pharmaceutical Society of Ireland has prepared Guidelines on Record Keeping for Medicinal Products in a Retail Pharmacy Business (i.e. a pharmacy). The purpose of these guidelines is primarily to facilitate compliance with Regulation 12 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. 488 of 2008) which details the records that must be kept in respect of medicinal products when conducting a pharmacy. The requirements for some other important records that ensure safe pharmacy practice are also included in these guidelines.

1.1. About the Consultation

A public consultation was held from 14 March to 6 April 2016. The draft document was published on the PSI website along with a link to an online questionnaire about the contents of the guidelines. The option of sending comments in writing or by email was also provided. An email highlighting the consultation was sent to all registrants and relevant stakeholders.

1.2. Response to the Consultation

A total of 24 responses were received to the online questionnaire and one response was received by email. Of the 25 responses received, 21 were from individuals and 4 were from persons responding on behalf of the following organisations, the Health Products Regulatory Authority (HPRA), the Irish Pharmacy Union (IPU), the Hospital Pharmacists Association of Ireland (HPAI) and the Mater Misericordiae University Hospital.

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

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 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 one email submission. Respondents who provided their names, organisation name, and/or PSI registration number are listed in Appendix A.

2. Results

2.1 Respondents' Profile

Tables 1-3 show the profile of those that responded to the consultation.

Question 1:

Table 1: Respondents Profession

Pharmacist	22
Pharmaceutical Assistant	1
Other Pharmacy Staff Member	2
Total	**25**

Question 2:

Table 2: Respondents Practice Area

Community	15
Hospital	5
Academia	1
Regulation	1
Not Provided	3
Total	**25**

Question 3:

Respondents Response Capacity (I am responding …)

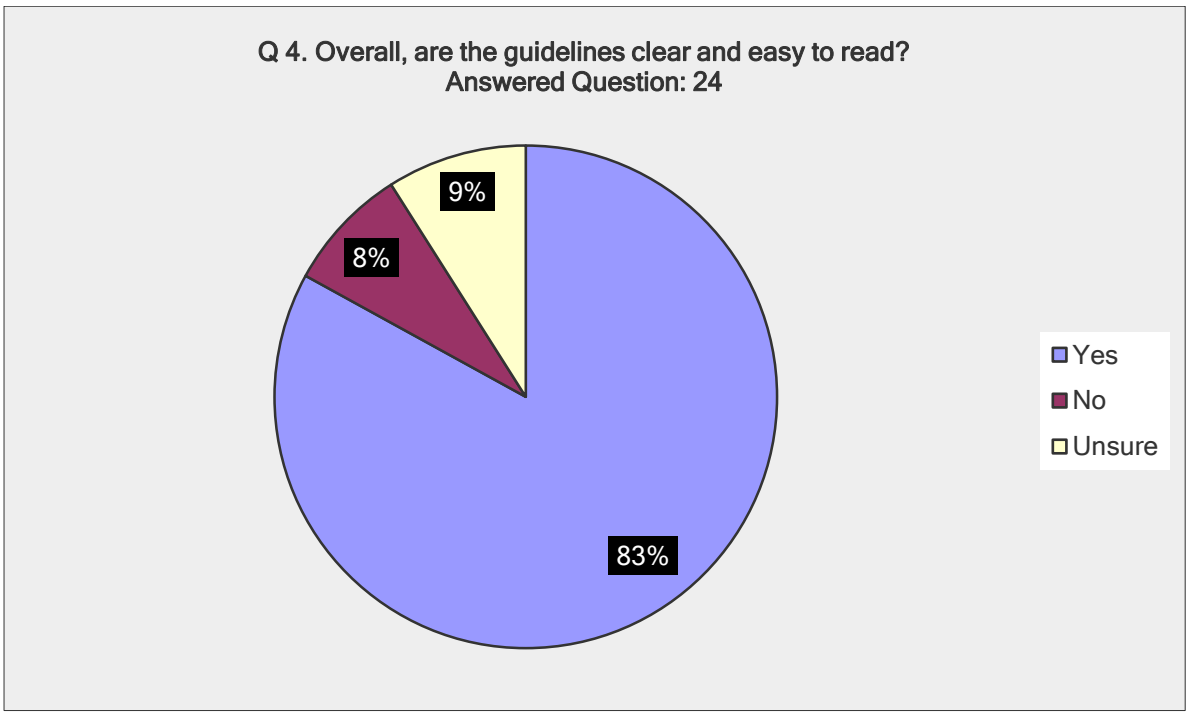
In personal capacity	21
As the authorised person on behalf of an organisation or group	4
Total	**25**

Details of the respondents, where provided, are listed in Appendix A.

2.2. Summary of the Responses to the Online Questionnaire

Question 4:

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



83% of respondents stated that the guidelines are clear and easy to read.

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

Three comments were received in response to this question.

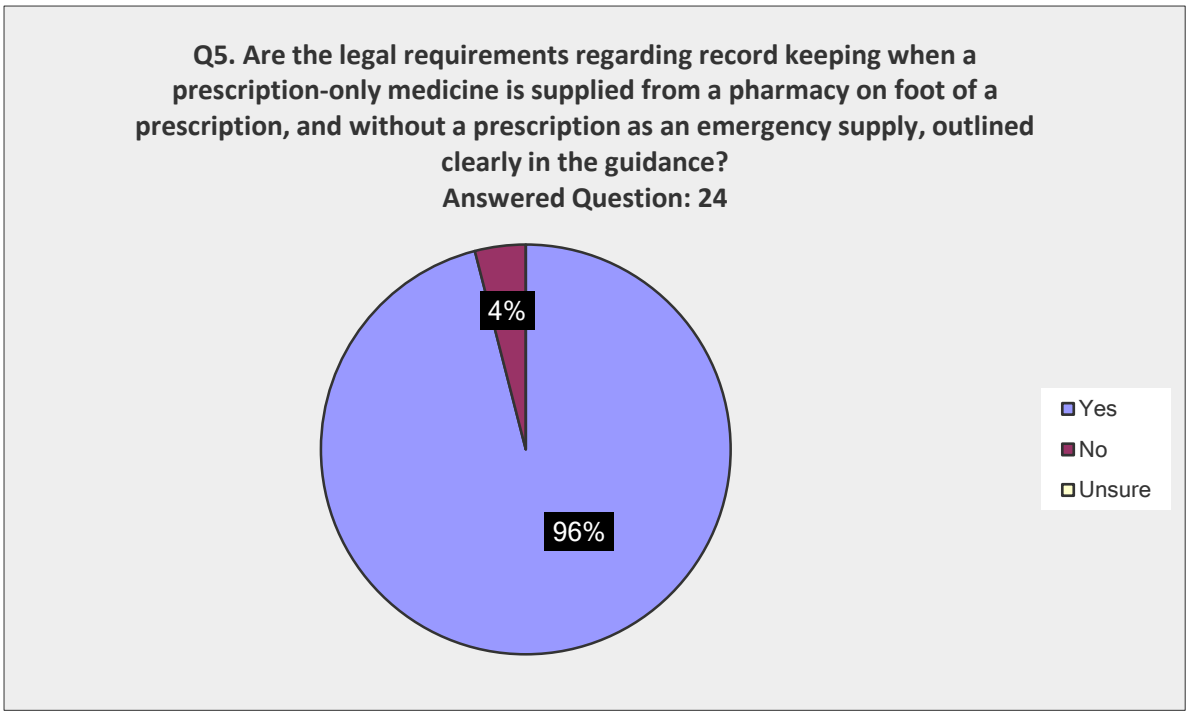
It was questioned whether the record keeping requirements for supplying an exempt medicinal product are fulfilled by recording information in the Patient Medication Record (PMR) and keeping invoices, or does a separate register need to be kept. It was also suggested that a brief summary of how long to keep each record outlined in the guideline would be helpful.

PSI Response

The PSI has noted all responses with thanks. The record keeping requirements for supply of an exempt medicinal product from a pharmacy are detailed in the Medicinal Products (Control of Placing on the Market) Regulations 2007 (as amended); the format (i.e. electronic or hard copy) for this record is not specified. To facilitate the efficient recall of any defective exempt medicinal products, it is important that all the details listed are recorded in such a way that the record can be easily searched to identify those patients who have been supplied with a particular batch of an exempt medicinal product, where necessary. In light of the comments this section in the guidelines has been reviewed and clarified.

Question 5:

Figure 2: Are the legal requirements regarding record keeping when a prescription-only medicine is supplied from a pharmacy on foot of a prescription, and without a prescription as an emergency supply, outlined clearly in the guidance?



96% of respondents stated that the legal requirements are outlined clearly in this regard.

Question: Please provide any comments.

Four comments were received in response to this question.

The practicality of recording the name and address of the previous supplying pharmacy, which is stated as a requirement under section 3.1.2 'Supply of a Prescription-Only Medicine on foot of a Repeat Prescription' and 3.1.3 'Emergency Supply of a Prescription-Only Medicine', was questioned. It was suggested that the record keeping requirements for emergency supply of a medicine at the request of a doctor, dentist or nurse prescriber in Section 3.1.3, be divided out into what is recorded when the supply is made and what is recorded when the prescription has been received by the pharmacy.

In relation to the daily dispensing report, one respondent highlighted that some pharmacies have two pharmacists on duty at the same time or sequentially and that in signing the 'daily record' it would not be clear which pharmacist was responsible for each entry.

PSI Response

The PSI has noted all responses with thanks. The requirement to record the name and address of the previous supplying pharmacy is specified in legislation.

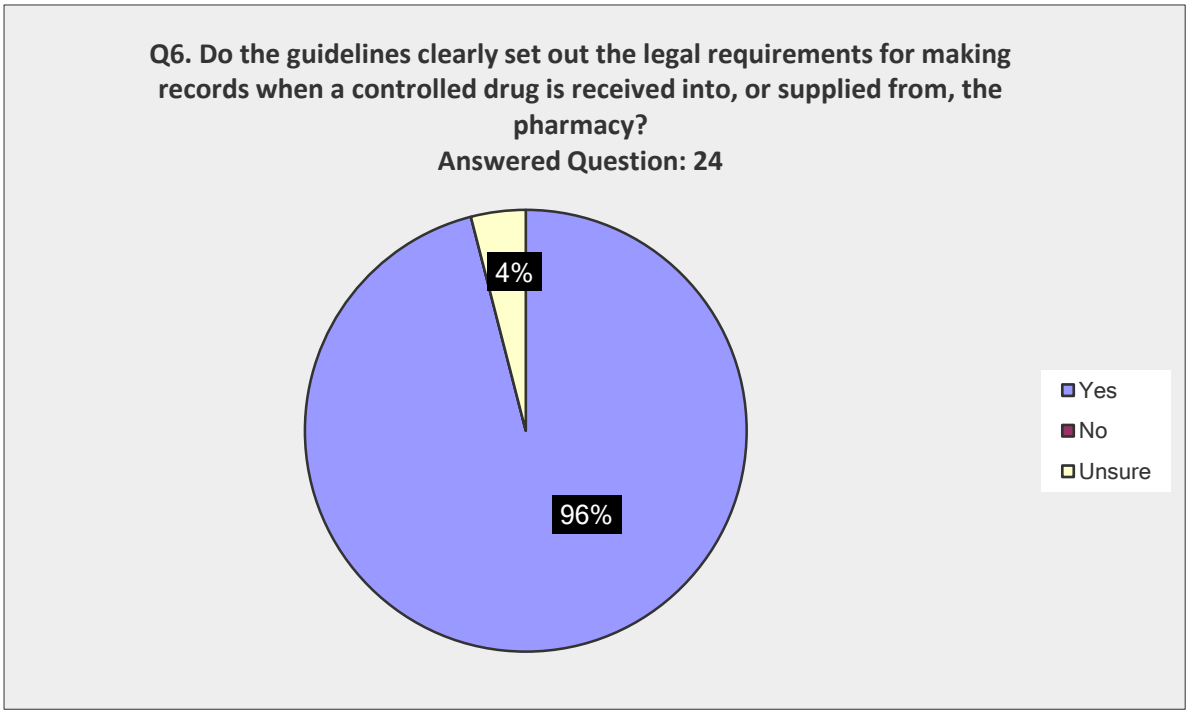
The suggestion to separate the record keeping requirements for an emergency supply of a prescription-only medicine at the request of a doctor, dentist or nurse, into what is recorded when the supply is made and

what is recorded when the prescription has been received by the pharmacy, is accepted and the guidance has been updated to reflect this.

With regard to the requirement for the daily dispensing report, legislation states 'Such print-out shall be dated and certified, on the day to which the print-out relates or within the period of twenty four hours thereafter, by the authorised person (i.e. a registered pharmacist) by whom the shop is managed'.

Question 6:

Figure 3: Do the guidelines clearly set out the legal requirements for making records when a controlled drug is received into, or supplied from, the pharmacy?



96% of respondents stated that the guidelines clearly set out the the legal requirements for making records when a controlled drug is received into, or supplied from, the pharmacy.

Question: Please provide any comments.

There was one comment to this question.

The submission stated that the list of requirements for completing the controlled drug register in Section 3.6.1 is confusing, in particular clarification was requested on the terms 'drug class', 'drug name' and 'drug product'. The respondent also questioned whether it is appropriate to put a line through an error in the controlled drugs register so that it is easier to see the mistake. With regard to Section 3.7 'Supply of Exempt Medicinal Products', it was queried why there is a requirement for the pharmacist to document suspected adverse reactions.

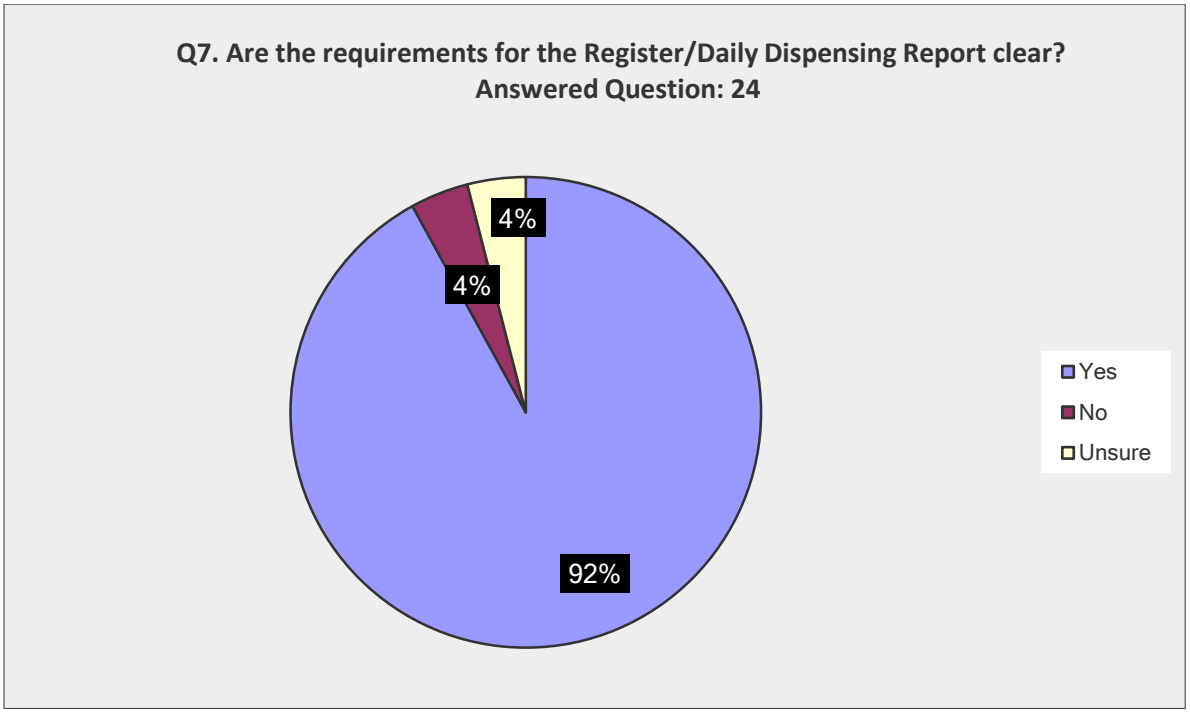
PSI Response

The PSI has noted the response with thanks. The legislation sets out the way in which the controlled drugs register must be completed. This section in the guidelines has been reviewed and now mirrors the information provided in the front of the PSI Register of Controlled Drugs which reflects the requirements of the legislation.

With regard to recording suspected adverse reactions for exempt medicinal products, due to the nature of these medicines pharmacovigilance is of particular importance. Paragraph 7 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) (as amended), which governs the supply of exempt medicinal products requires the pharmacist to keep a record of suspected adverse reactions in the pharmacy, and available for inspection. Pharmacists, as healthcare professionals, are responsible for reporting any adverse drug reaction they become aware of to the HPRA.

Question 7:

Figure 4: Are the requirements for the Register/Daily Dispensing Report clear?



92% of respondents stated that the requirements for the Register/Daily Dispensing Report are clear.

Question: Please provide any comments.

There were four comments received in response to this question.

It was raised that within the hospital, medicines are supplied as stock on foot of a requisition to the wards for the nursing staff to administer to patients and record on the patient's *'kardex'*. As such the pharmacist has no way of generating a daily dispensing report for every medicine administered to patients.

One respondent questioned the need for a print out of the daily dispensing report, when this is available on the computer which is backed up.

It was questioned how to ensure that 'It is clear when an amendment has been made to a pharmacy record' as stated in Section 3.9 'Ensuring Accuracy of Pharmacy Records'.

Clarification was requested with regard to the recommendation to include medicines dispensed against a health prescription e.g. GMS prescriptions, in the daily dispensing report, when carbon copies of these prescriptions are retained.

PSI Response

The PSI has noted all responses with thanks. The requirements of the Regulation of Retail of Pharmacy Businesses Regulations 2008 apply to retail pharmacy businesses. The requirements of Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) apply to retail pharmacy businesses and to supplies of prescription-only medicines which can only be made on foot of a prescription. Hospital pharmacies should have their own procedures in place for recording the supply of medicines internally, within the hospital.

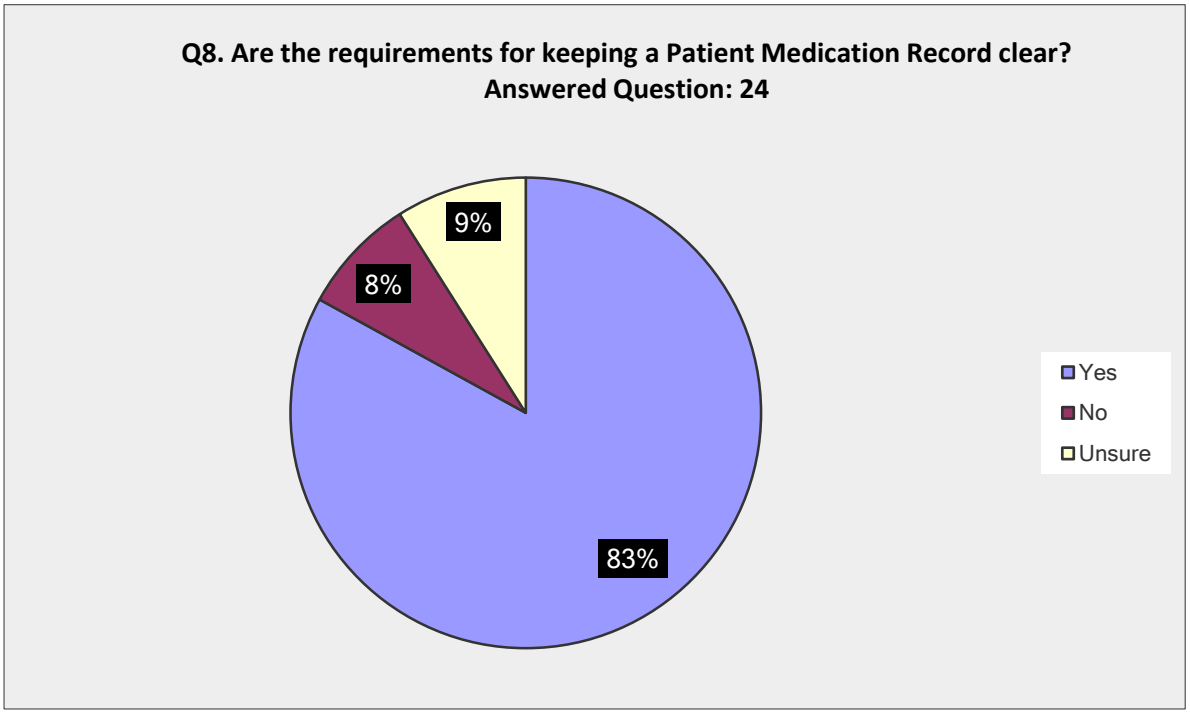
Regulation 12(2) of the Regulation of Retail of Pharmacy Businesses Regulations 2008, allows the prescription register to be kept solely in electronic format if the computer software has been independently validated by a body approved by the Minister for Health and certified as suitable for the retention of such records. However, to date the Minister for Health has not approved a body to carry out this function. Therefore, a hard copy print-out of these records is currently the only validated manner that meets the requirements of the legislation.

With regard to showing when an amendment has been made to a pharmacy record, it is up to the professional judgement of the pharmacist how this is done, for example by providing details of the amendment in the notes section of the PMR. The guidelines have been amended to include this example.

The legislation provides an exception to the requirements to keep the records detailed in sections 3.1 and 3.2, where the medicinal product is supplied in accordance with a health prescription, as the duplicate part of the prescription is retained. However, in order to maintain a complete and accurate record of all medicines dispensed on a given day the PSI recommends that these supplies are also included in the prescription register/daily dispensing report.

Question 8:

Figure 5: Are the requirements for keeping a Patient Medication Record clear?



83% of respondents stated that the requirements for keeping a patient medication record are clear.

Question: Please provide any comments.

Four comments were received in response to this question.

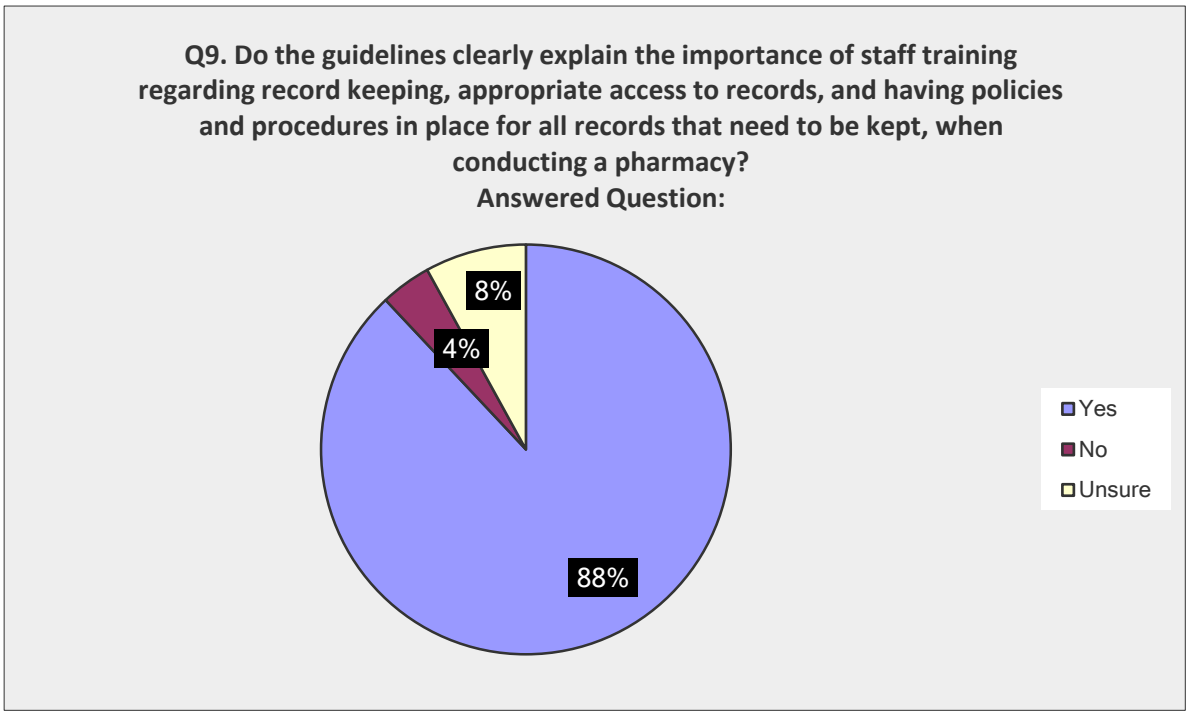
It was commented that documenting issues relating to patients is good, but in practice the notes can become very long and these should be allowed to be tidied up occasionally. It was questioned whether the sale of non-prescription medicines should be included in the PMR and who can enter conversations or counselling in the PMR.

PSI Response

The PSI has noted all responses with thanks. Pharmacists should use their professional judgement with regard to what information is recorded in the PMR, and by who, to support them in providing care to patients. The written procedures in the pharmacy should reflect this.

Question 9:

Figure 6: Do the guidelines clearly explain the importance of staff training regarding record keeping, appropriate access to records, and having policies and procedures in place for all records that need to be kept, when conducting a pharmacy?



88% responded that the guidelines clearly explain the importance of staff training regarding record keeping, appropriate access to records, and having policies and procedures in place for all records that need to be kept, when conducting a pharmacy.

Question: Please provide any comments.

Four comments were received in response to this question.

One respondent questioned if the staff training records need to be kept on the pharmacy premises or whether these can be kept at the pharmacy's support office. It was suggested by another respondent that it would be useful to have minimum training standards for pharmacy staff members who have access to patient records.

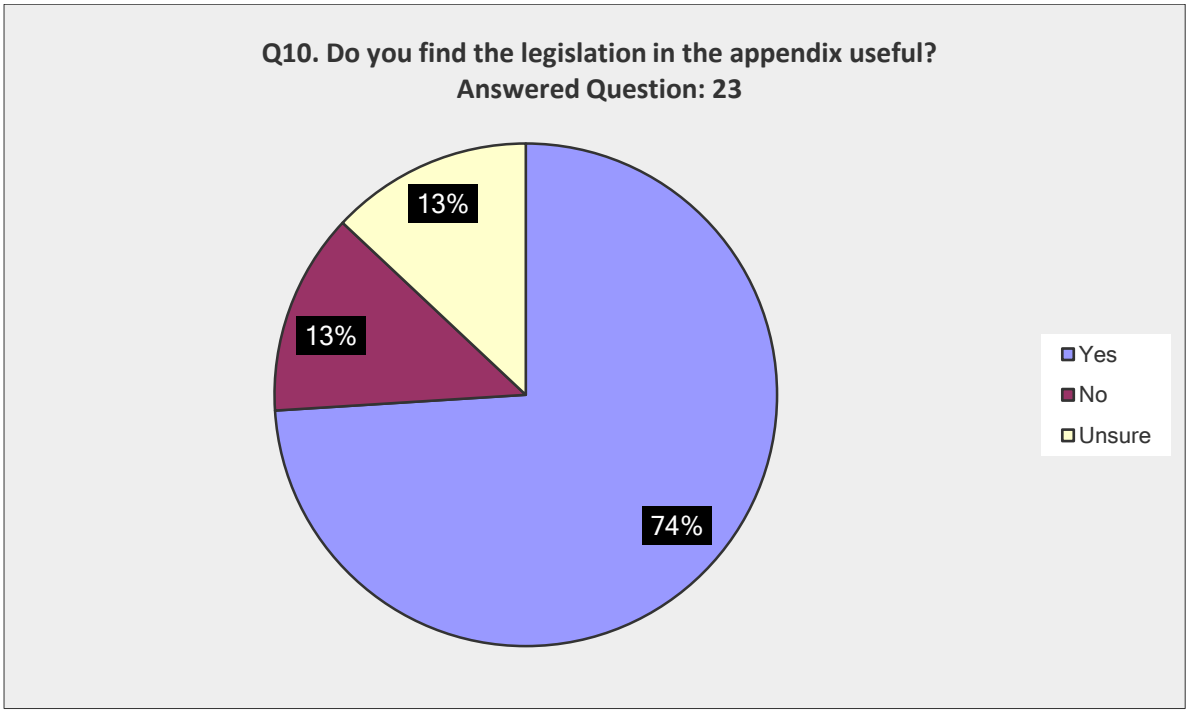
The length of time that a pharmacy should keep data on a PMR was questioned, in the context of Data Protection legislation. The submission highlighted that Data Protection legislation suggests that personal data is kept for a defined period, however there could be patient safety issues if a pharmacist did not have access to a patient's full medical history.

PSI Response

The PSI has noted all responses with thanks. Legislation does not specify where training records are kept, but these should be easily retrievable on request. The pharmacy's policies and procedures should detail the required retention period for each record. This can be longer than that required in legislation provided it is documented and justified, for example in the interest of providing a safe service to patients.

Question 10:

Figure 7: Do you find the legislation in the appendix useful?



74% of respondents stated that it is useful to have the legislation in the appendix.

Question: Please provide any comments.

Two comments were received in response to this question.

It was highlighted that the law language can be difficult to read. It was suggested that the inclusion of links to legislation in the footnotes, when not already provided as an appendix, would also be useful.

PSI Response

The PSI has noted all responses with thanks. The PSI maintains an up to date list of relevant pharmacy and medicines legislation in the Inspection & Enforcement section of the PSI website.

Question 11:

Please let us know if you have any further comments about the guidelines.

Eleven comments were received in response to this question.

Comments included:

- Guidelines more pertinent to the hospital setting would be useful.
- The need for records to be a paper copy was questioned.
- A shorter on-site storage duration for records should be considered, the remainder of the 2 year time frame (as required for many of the records) could then be accommodated with secure off-site storage, with records accessible within 24 hours.
- PSI should engage with the computer software vendors to ensure all the required information for supply of an exempt medicinal product can be recorded in the electronic PMR at the point of dispensing.
- The supply of 'codeine OTC products' should be recorded so that different pharmacists would know if a customer is overusing them.
- Very legalistic, could be laid out in a more readable manner
- Records for the supply of exempt medicinal products must be kept for five years, yet the daily audit is only 2 years, clarification was requested on what exactly must be kept for 5 years.

A response was also received from the Hospital Pharmacists Association of Ireland (HPAI) which refers to the record keeping requirements, supply chain management and operations within a hospital pharmacy and the broader hospital structure. These comments have been noted, however many comments refer to areas outside of the scope of this guidance document. As previously stated the requirements of the Regulation of Retail of Pharmacy Businesses Regulations 2008 and Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations apply to retail pharmacy businesses. The PSI are committed to looking at the area of hospital pharmacy specifically as a separate project.

PSI Response

The PSI has noted all responses with thanks. When an exempt medicinal product is supplied, the details specified in Section 3.7 must be recorded and retained for 5 years. It is noted that this is longer than the required retention time for the daily dispensing report and therefore it may be more practical to record this information electronically on the PMR or in hard copy with the invoice. Pharmacists are encouraged to engage with their own computer software vendor if needed to facilitate the recording of the required information.

Question 12:

Please let us know if there is any other information that you think the guidelines should include.

Six comments were received in response to this question.

Comments included:

- Guidance on record keeping for veterinary medicines.
- Interlinking pharmacies to monitor the supply of potentially abusive drugs e.g. medicines containing codeine.
- Recording and documentation of patient counselling and interventions.
- Requirements under the upcoming falsified medicines directive.
- A list of additional record keeping requirements that are required by PSI or recommended in PSI guidance documents to show the safe operation of a pharmacy.

PSI Response

The PSI has noted all comments with thanks. The purpose of these guidelines is to address the record keeping requirements under Regulation 12 of the Regulation of Retail Pharmacy Businesses Regulations 2008. Therefore, some of the suggestions do not fall within the scope of this guideline. All comments will be reviewed and given due consideration as to whether guidance on these topics is required in the future.

3. Conclusion

The PSI welcomed the submissions to this public consultation and would like to thank all contributors for the information provided. The comments received proved invaluable in updating and refining the guidance.

Appendix A

Organisational Responses
Health Products Regulatory Authority (HPRA)
Hospital Pharmacists Association of Ireland (HPAI)
Irish Pharmacy Union (IPU)
Mater Misericordiae University Hospital (MMUH)

Individuals	Registration no. (where provided)
Jacinta McGowan	2419a
Niamh Kilcullen	6715
Ryan Alam	11319
Eilish Costello	10740
Joanne Kissane	6960
Siobhan Anne Cuddy	4759
Anne Marie Cafferkey	-
Bridget Cullen	-
Kieran Lynch	6324