

PSI Public Consultation Report on Draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses

March 2016

1. Introduction

The Pharmaceutical Society of Ireland (PSI) has prepared Guidance for Pharmacists on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses. The guidance is a revised version of the Guidance on the Provision of Seasonal Influenza Vaccination Service by Pharmacists in Retail Pharmacy Businesses originally published in 2011.

The purpose of the guidance is to support and assist pharmacists in delivering a vaccination service to patients in pharmacies. The guidance sets out the legal and professional requirements which need to be fulfilled in order to safely provide the service. It details the general requirements applicable to the provision of a vaccination service in a pharmacy and additional considerations specific to the provision of each vaccination service, i.e. seasonal influenza, pneumococcal polysaccharide and herpes zoster vaccines.

1.1. About the Consultation

A public consultation on the Draft Guidance for Pharmacists on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses was held in February 2016 for pharmacists and stakeholders. The draft guidance document was published on the PSI website along with a link to a questionnaire to be completed with comments. The option of sending comments in writing was also provided. A number of relevant stakeholders, including the National Immunisation Office and Chair of the National Immunisation Advisory Committee, were contacted directly to encourage engagement with the process.

1.2. Response to the Consultation

A total of 56 respondents accessed the online survey and answered question 1. Of these 56 respondents who answered question 1, between 28 and 30 respondents went on to answer the questions 4 to 15 that followed regarding the contents of the guidance document. In addition, 4 responses were received via email. The PSI would like to thank all who took the time to provide submissions to the consultation.

This report summarises the comments received from the online survey questions and email submissions. Responses have been analysed and presented in table/graph format throughout and a summary of the submissions received via emails and responses to the final question of the survey has been included in the 'General Comments/Submissions' section of the report.

A profile of the respondents is presented below in Section 2.1 'Respondents' Profile'. These figures include those respondents who accessed the online survey and those who submitted comments via email. Respondents who provided their names/organisation name or PSI registration numbers are listed in Appendix A.

2. Results

2.1 Respondents' Profile

This section details the profile of the respondents. It includes information gathered via the online survey and profile information indicated in email submissions.

Question 1:

Table 1: Respondents Profession (I am a ...)

Pharmacist	46
Pharmaceutical Assistant	5
Pharmacy Technician	1
Pharmacy Manager	0
Other Healthcare Professional	6
Member of the Public	2
Other	0
Total	60

Question 2:

Table 2: Respondents Practice Area...

Community	44
Hospital	1
Industry	2
Academia	0
Other	8
Total	55

Other areas of practice listed were 1) community and provider of outpatient services, 2) training and research, 3) regulation, 4) HSE and 5) immunisation organisations/ support (NIO/ NIAC).

Question 3:

Respondents Response Capacity (I am responding in a ...)

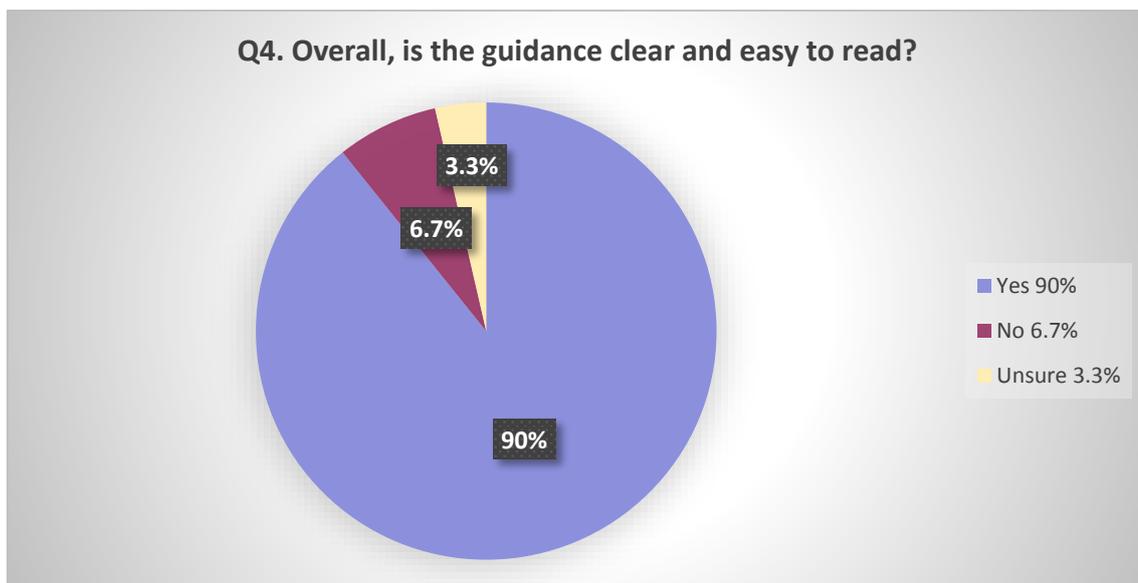
In personal capacity	50
As the authorised person on behalf of an organisation or group	10
Total	60

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

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

Question 4:

Figure 1: Is the guidance clear and easy to read?



The majority of respondents (90%) responded that the guidance was clear and easy to read.

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

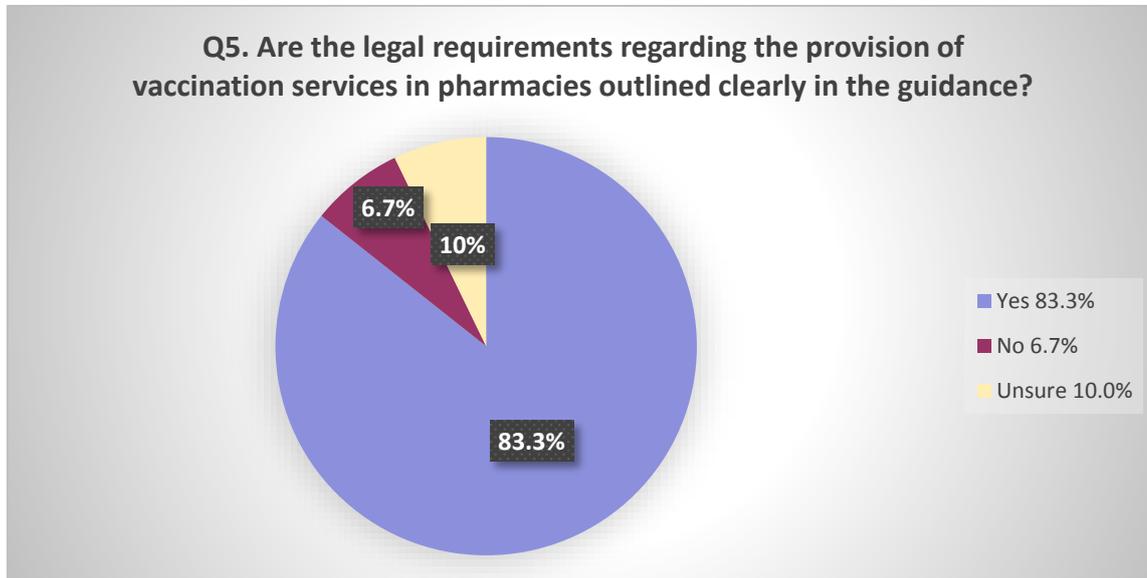
Two comments were received in response to this question. The record keeping requirements were compared to those of other healthcare professionals administering vaccines and the requirements queried. It was suggested to replace the term pneumonia in the guidance by the term pneumococcal.

PSI Response

The PSI has noted the responses with thanks and reviewed the guidance in light of the comments received. Most of the vaccination record keeping requirements are set out in legislation and the guidance reflects these requirements. The terms used to describe vaccines throughout the document were reviewed and where appropriate updated.

Question 5:

Figure 2: Are the legal requirements regarding the provision of vaccination services in pharmacies outlined clearly in the guidance?



83.3% of respondents stated that the guidance assisted them in the legal requirements regarding the provision of vaccination services in pharmacies.

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

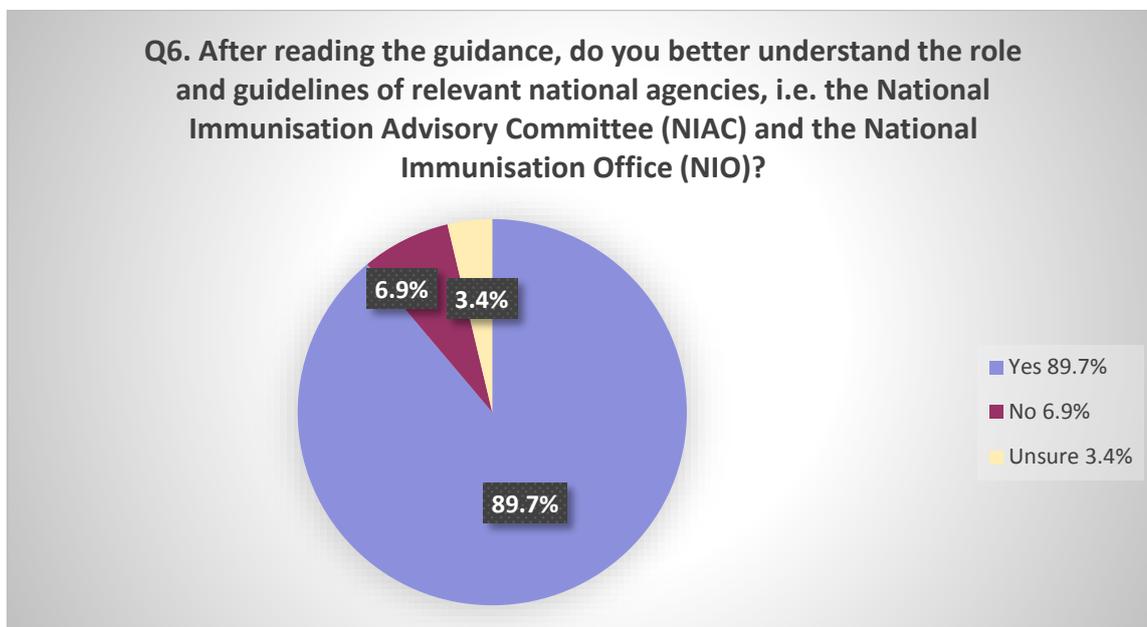
Two comments were received in response to this question. The complexity of deciphering legal information was highlighted as an issue for those who don't routinely engage with legislation.

PSI Response

The PSI has noted all responses with thanks and reviewed the guidance in light of the comments received. The PSI intends that this guidance will clarify for pharmacists the requirements outlined in the legislation and will facilitate pharmacists meeting those requirements.

Question 6:

Figure 3: After reading the guidance, do you better understand the role and guidelines of relevant national agencies, i.e. the National Immunisation Advisory Committee (NIAC) and the National Immunisation Office (NIO)?



89.7% of respondents stated that the guidance gave them a better understating of the role and guidelines of relevant national agencies.

Question: If not, please explain which part of the guideline is unclear? No comments were received in response to this question.

Question 7:

Figure 4: Is it clear from the guidance what the roles and responsibilities of pharmacy owners and superintendent pharmacists are, in providing a vaccination service?



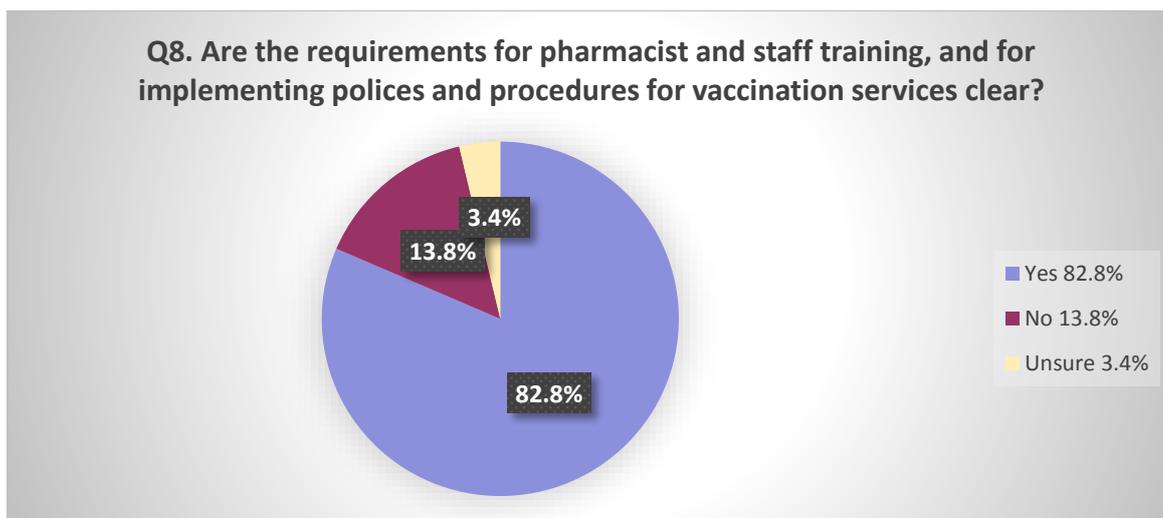
The majority of respondents (96.6%) responded that the guidance was clear as to the roles and responsibilities of pharmacy owners and superintendent pharmacists, in providing a vaccination service.

If not, please explain how this can be improved. One comment was received in response to this question. The respondent requested an explanation of the meaning of practice runs as set out in the guidance and suggested it was unclear if the practice runs completed as part of the training programmes met the criteria for practice runs.

PSI Response The PSI has noted the response and reviewed the guidance in light of the comments received. Supervised practice runs in the pharmacy should be carried out regularly as part of an internal sign-off process to assure that pharmacists are familiar with all aspects of the delivering the service in the specific pharmacy environment. As training does not occur in the specific pharmacy environment under the responsibility of the superintendent pharmacist, the practice runs referred to in the guidance are in addition to any practice runs undertaken as part of vaccination training.

Question 8:

Figure 5: Are the requirements for pharmacist and staff training, and for implementing policies and procedures for vaccination services clear?



The majority of respondents (82.8%) responded that the guidance was clear as to the requirements for pharmacist and staff training and for implementing policies and procedures for vaccination services.

If not, please explain which of the steps are not useful. Five comments were received in response to this question. Suggestions were received on the content, frequency and details of pharmacist's vaccination training, e.g. refresher training should be provided online, more CPR training courses should be recognised. It was also suggested that vaccination skills be included in pharmacist undergraduate and intern training.

It was suggested that the guidance be reviewed to increase clarity around non-pharmacist staff training particularly the ability of staff to support the pharmacist if responding to an emergency and the advantage of ensuring emergency protocols are subject to practice runs involving relevant staff.

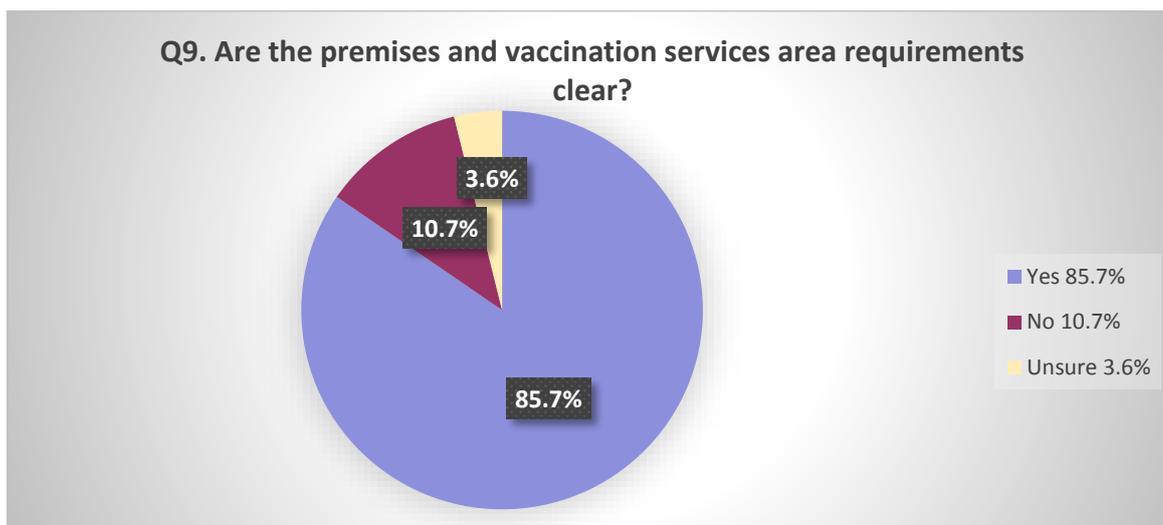
PSI Response The PSI has noted all responses with thanks and the section was reviewed and updated in line with the comments received. The training requirements are outside the scope of the vaccination guidance

and the details included in the guidance document on training are for information. The comments were noted for feedback on vaccination training.

The guidance was updated to reflect that the pharmacy's emergency protocols should be subject to practice runs involving all relevant staff to ensure the optimal response to a serious adverse event.

Question 9:

Figure 6: Are the premises and vaccination services area requirements clear?



The majority of respondents (85.7%) responded that the guidance was clear as to the premises and vaccination services area requirements.

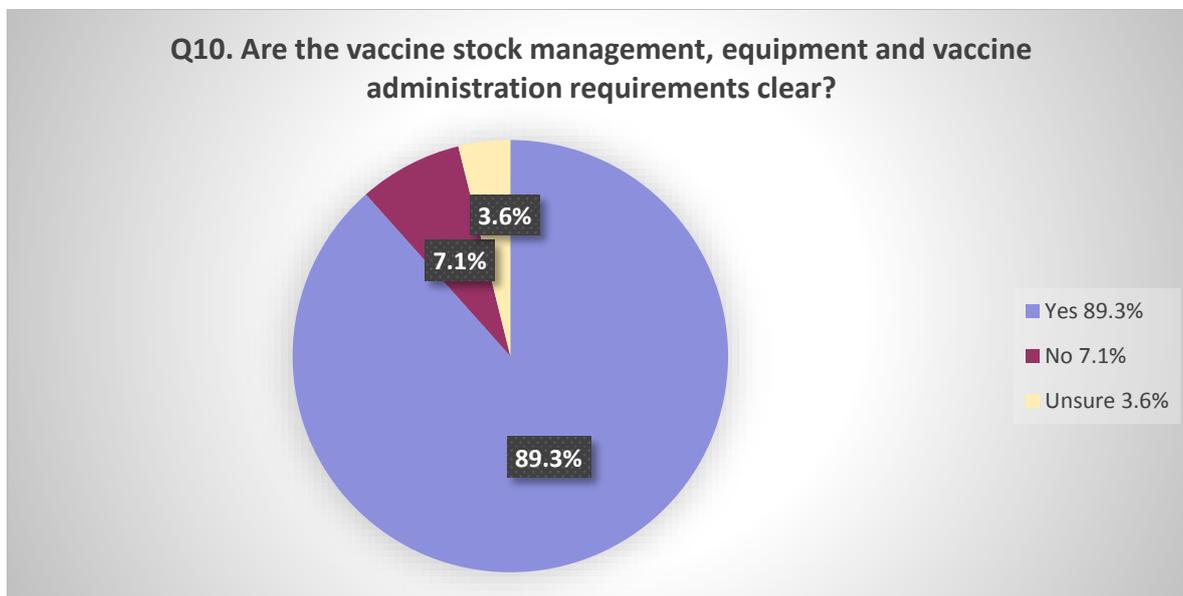
If not, please explain which of the steps are not useful. Five comments were received in response to this question.

It was suggested that further information on the accessibility of the vaccination services area be provided in the guidance and that minimum size requirements be specified. One respondent was unclear if there should be separate areas for vaccination and consultation or if one area was sufficient. The requirements for storing sharps bins and records were also queried.

PSI Response The PSI has noted all responses with thanks. Further information on the accessibility requirements for vaccination service areas was included in the guidance. As per the patient consultation area guidelines, it was decided to provide information on the requirements a vaccine services area must meet and not specify minimum dimensions for the area. The guidance was reviewed and outlines when one consultation/ vaccination services area is sufficient and when two areas must be provided to fulfil the requirements. The requirements for storing sharps bins and confidential records were also reviewed.

Question 10:

Figure 7: Are the vaccine stock management, equipment and vaccine administration requirements clear?



The majority of respondents (89.3%) responded that the guidance was clear as to the vaccine stock management, equipment and vaccine administration requirements.

If not, please explain which of the steps are not useful. Three comments were received in response to this question.

Submissions received suggest including greater emphasis on cold chain management in the guidance and addressing the longevity of vaccines when drawn up. The requirement to keep separate adrenaline for vaccinations/ emergencies and dispensing was queried and it was suggested that pharmacists should be permitted to stock adrenaline vials instead of just autoinjecters for emergency use.

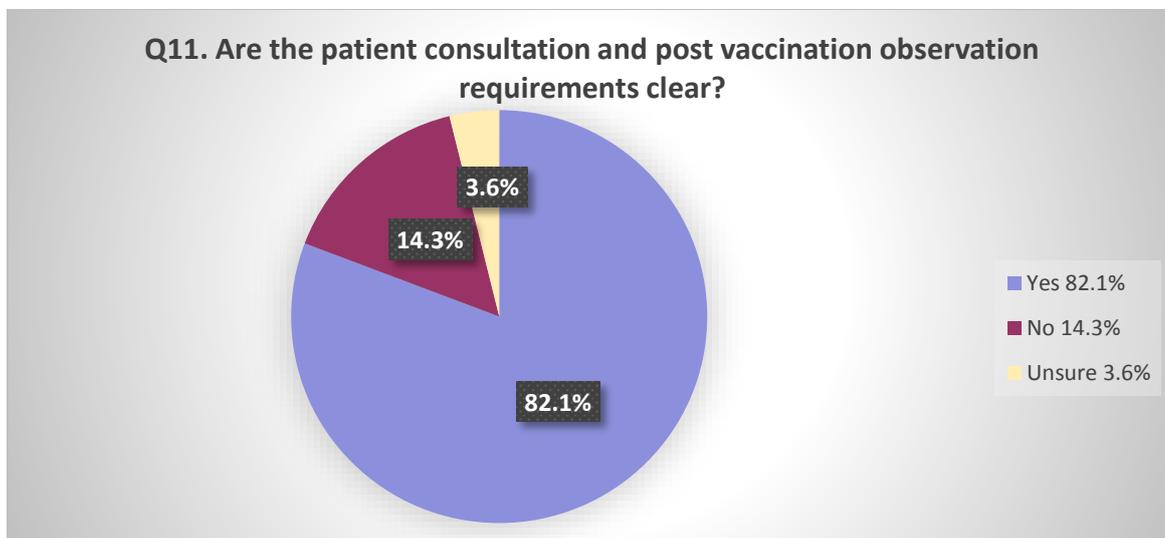
PSI Response

The PSI has noted all responses with thanks. Greater emphasis has been placed in the guidance on cold chain management. It should also be noted that the guidance states that vaccines must be managed in accordance with PSI *Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business* and the storage guideline includes sections on the management of products requiring refrigeration. The guidance has also been updated to state that once a vaccine has been drawn up it must be used within any timeframe specified in the SmPC.

The adrenaline requirements were reviewed. It is important that adequate adrenaline is designated for emergency use only to ensure adrenaline is always available when a vaccine is administered. Legislation states that the adrenaline stocked for the emergency treatment of anaphylaxis may be in the form of a pre-filled syringe or ampoule and additional information has been included in the guidance to clarify this requirement.

Question 11:

Figure 8: Are the patient consultation and post vaccination observation requirements clear?



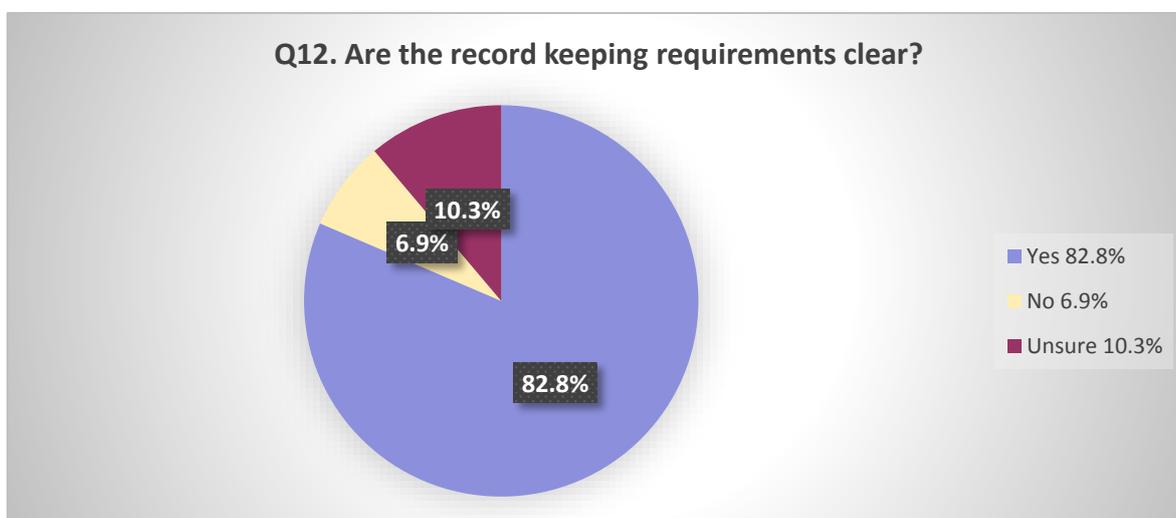
The majority of respondents (82.1%) stated that the patient consultation and post vaccination observation requirements were clear.

If not, please explain which of the steps are not useful. Two comments were received in response to this question. Submissions highlighted the potential confusion regarding the written information requirements relating to counselling patients referred to in the post vaccination section of the guidance and the checklist.

PSI Response The PSI has noted all comments with thanks. The post vaccination section of the guidance and checklist have been updated to clarify that written information refers to the package leaflet and any other relevant written information, e.g. HSE leaflets.

Question 12:

Figure 9: Are the record keeping requirements clear?



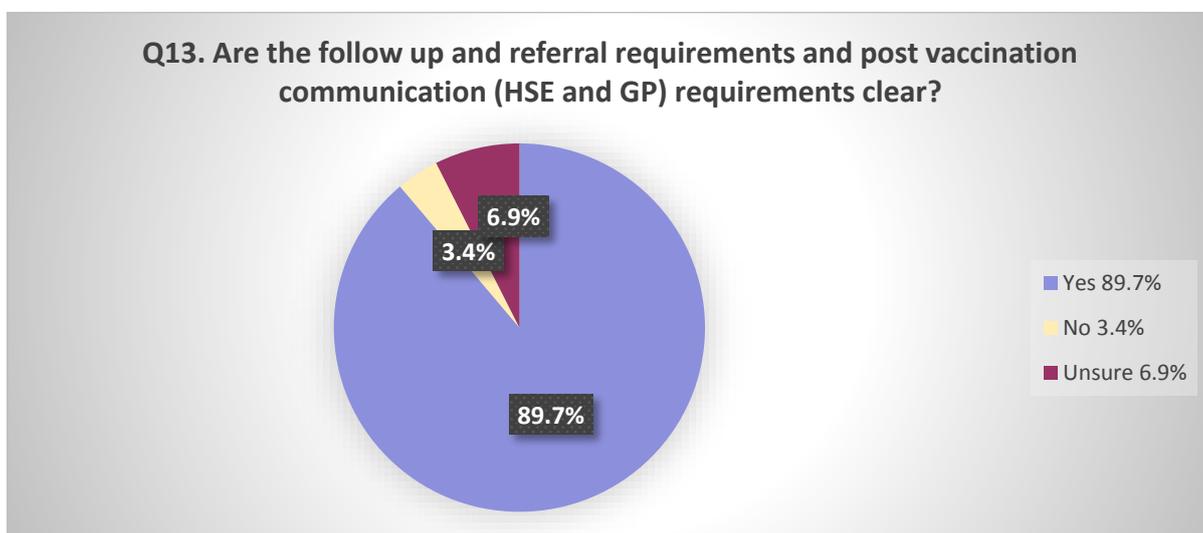
The majority of respondents (82.8%) responded that the record keeping requirements in the guidance were clear.

If not, please explain which of the steps are not useful. Three comments were received in response to this question. The two year and eight year retention requirements for vaccination records and the difference in the vaccination register and prescription register requirements were queried.

PSI Response The PSI has noted all comments with thanks. The comments in relation to vaccination records are noted, however the two and eight year retention requirements and the vaccination register requirements are both specified in legislation.

Question 13:

Figure 10: Are the follow up and referral requirements and post vaccination communication (HSE and GP) requirements clear?



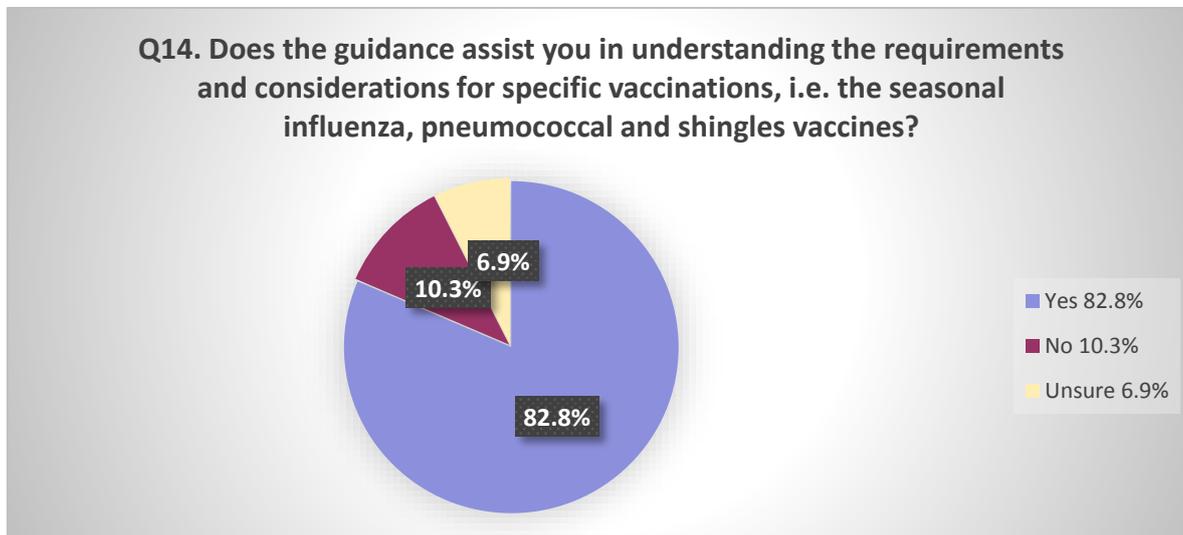
The majority of respondents (89.7%) responded that the guidance was clear as to the follow up and referral requirements and post vaccination communication (HSE and GP) requirements.

If not, please explain which of the steps are not useful. Two comments were received in response to this question. The requirements to communicate vaccination records to GPs were queried.

PSI Response The PSI noted all comments with thanks. The requirement to communicate vaccination records to GPs is set out in the vaccination legislation and sharing of this information is important to ensure consistent patient care.

Question 14:

Figure 11: Does the guidance assist you in understanding the requirements and considerations for specific vaccinations, i.e. the seasonal influenza, pneumococcal and shingles vaccines?



82.8% of respondents stated that the guidance assisted in understanding the requirements and considerations for specific vaccinations, i.e. the seasonal influenza, pneumococcal and shingles vaccines.

If not, please explain which of the steps are not useful. Two comments were received in response to this question. It was suggested that the guidance include an explanation of each licensed vaccine and details of their indication.

PSI Response: The PSI has noted the comments with thanks and reviewed the guidance in line with the comments received. The guidance does not provide clinical advice and pharmacists should refer to NIAC and NIO guidelines, the vaccine's SmPCs and vaccination training materials for the relevant vaccine for clinical information on supplying and administering each vaccine. Information on vaccine indications has been provided.

Question 15:

Please let us know if you have any further queries or comments regarding the provision of a vaccination service in a pharmacy. Responses to Question 15 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:

Responses included:

- Expanding the pharmacy vaccination service is a welcome development which will enhance public access.
- Pharmacies should be included in the national immunisation programme for all vaccines to increase the overall uptake by the public.

- The national data collection process, and a requirement for communication with GPs, are very important aspects of the new services.
- A recommendation that the HSE advertise the availability of these new services more extensively.
- The notification of vaccine provision to an increasing number of GPs through various different media is cumbersome. The respondent recommended that as all vaccinations are notified to the HSE online and that this form part of the GP notification requirements.
- The complexities associated with patient's crossing the border to request a vaccination.
- A number of comments related to vaccination training were also provided.

The National Immunisation Office (NIO) and the Chair of National Immunisation Advisory Committee (NIAC) provided feedback on the guidance. Use of the medicinal product and adverse reaction terms used in NIAC's Immunisation Guidelines for Ireland was encouraged. Comment was provided on the population cohort the NIO provide the seasonal influenza vaccination to as part of the national immunisation strategy. Recommendations were made on some elements of the specific vaccinations sections, including increasing clarity around the age recommendations. They also highlighted a number of areas where the vaccines SmPCs differ from the immunisation guidelines, e.g. minimum times between the administration of the pneumococcal and herpes zoster vaccines.

The Health Products Regulatory Authority (HPRA) made a number of recommendations relating to reporting adverse effects to the HPRA and the adrenaline products pharmacies should stock for the emergency treatment of anaphylaxis.

PSI Response

The PSI has noted all responses with thanks and has amended the content of the guidelines to reflect the concerns raised. Responses in relation to the national immunisation programme or HSE are noted but do not fall under the remit of the PSI. The content of vaccination training is not within the scope of the vaccination guidance document, however, all comments on training has been communicated to the relevant PSI staff.

The feedback provided by the NIO, the Chair of NIAC and the HPRA was incorporated in the guidance.

3. Conclusion

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

The intention of the PSI Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses is to support and assist pharmacists in delivering a vaccination service to patients in pharmacies. The guidance sets out the legal and professional requirements which need to be fulfilled in order to safely provide the service. It details the general requirements applicable to the provision of a vaccination service in a pharmacy and additional considerations specific to the provision of each vaccination service, i.e. seasonal influenza, pneumococcal polysaccharide and herpes zoster vaccines.

Appendix A

NAME/ORGANISATION		REGISTRATION NO. (if applicable)
Paula	Murphy	9618
Colette	Loughman	4397
Pamela	Logan	5944
Tim	Delaney	4894
Mary	McBride	8103

NAME/ORGANISATION
IPU Academy
Irish Cancer Society
Hilton Pharmacy
Boots
National Immunisation Office
Chair of the National Immunisation Advisory Committee
Primary Care Reimbursement Service, Health Service Executive
Health Products Regulatory Authority