THE PHARMACEUTICAL SOCIETY OF IRELAND

Guidance for Pharmacists on Extemporaneous Dispensing

Consultation Report March 2015

PSI Report on the Public Consultation on Draft Guidance for Pharmacists on Extemporaneous Dispensing

1. Introduction

The Pharmaceutical Society of Ireland has prepared Guidance for Pharmacists on Extemporaneous Dispensing to assist pharmacists in discharging their legal and professional obligations to patients in the area of extemporaneous dispensing, and to help to assure the safe and appropriate preparation and supply of these products.

1.1. About the Consultation

A public consultation on the draft Guidance for Pharmacists on Extemporaneous Dispensing was held from Monday 2nd of February 2015 until Friday 27th February 2015. The draft guidance was available to view on the PSI website along with a link to a short online questionnaire to be completed with comments.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.

An email was sent to all pharmacists and pharmaceutical assistants inviting comments to the consultation and a reminder about the consultation was included in the PSI e-newsletter Issue 1, 2015. An email was also sent to stakeholders including other regulators and patient groups inviting comments to this consultation.

1.2. Response to the Consultation

A total of 289 respondents accessed the online survey. Of these 289 individuals, on average 99 respondents went on to complete each of the quantitative questions that followed regarding the contents of the guidance. Responses to the quantitative questions in the online survey have been analysed and presented in table format throughout the proceeding document. Comments and feedback received from questions 8 and 9 in the online survey were very similar, and so it was decided to group these into one section entitled 'General Comments/Submissions'.

A total of 7 responses were received via email. A summary of the comments and feedback received in the emails have 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 7 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 responses. It was not possible to include all responses in this report, however all comments have been taken into account and the guidance has 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 (including information gathered in questions 1-3 of the online survey and as indicated in email submissions)

Respondents	
Pharmacist	271
Pharmaceutical Assistant	9
Pharmacy Manager	9
Other Healthcare Professional	1
Member of the Public	5
other	1
Total	**296**

Area of Practice	
Community	219
Hospital	31
Industry	8
Academia	9
Other	12
Total	**279**

Responding in	
Personal Capacity	98
As the authorised person on behalf of an organisation or group	13
Total	**111**

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

Question 4: Is the guidance clear and easy to read?		
Yes	78	79%
No	15	15%
Unsure	6	6%
Total	**99**	

The majority of respondents (79%) responded that the guidance is clear and easy to read.

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

It was commented that it was unclear from the guidance what an 'extemporaneously dispensed' medicine is, and how this differs, for example, from a product not licensed in Ireland, but licensed in

another EEA country. The use of the term 'unauthorised' was also questioned along with a request for a clear definition. It was also commented that the section about the use of the Ph. Eur. Pharmaceutical Preparations Monograph was unclear.

PSI Response

The PSI has noted all responses with thanks and amended the guidance in light of the comments and feedback received.

Question 5: After reading this guidance do you understand the limited circumstances, as laid out in the legislation, whereby a pharmacist may supply an extemporaneously prepared medicinal product to a patient?		
Yes	84	84%
No	9	9%
Unsure	7	7%
Total	**100**	

84% of respondents felt that after reading the guidance they understood the limited circumstances, as laid down in the legislation, whereby a pharmacist may supply an extemporaneously prepared medicine to a patient.

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

It was felt that this is an interpretation of legislation and discounts the pharmacist's ability to prepare a safe product if necessary, for example for practical purposes and in the interest of the patient. With regards to the section on 'Risk Assessment' in the guidance document, it was highlighted that the guidance does not provide suitable references or approaches to classify risk, or what risks are considered acceptable and what are not. It was questioned as to how a pharmacist can source a product through an authorised wholesaler or manufacturer in another EEA country.

PSI Response

The PSI has noted all responses with thanks and amended the guidance in light of the comments and feedback received.

6. Question: Is the Decision Tree useful to help decide whether it is necessary, and in the patient's best interest, to extemporaneously prepare a medicinal product for a patient?		
Yes	76	77%
No	14	14%
Unsure	9	9%
Total	**99**	

The majority of respondents (77%) felt that the Decision Tree is useful to help decide whether it is necessary, and in the patient's best interest, to extemporaneously prepare a medicinal product for a patient.

Question: If not, please explain which of the steps in the Decision Tree or decision process are unclear.

Respondents commented that the Decision Tree was very useful and easy to follow.

However, it was felt that the Decision Tree does not reflect the short time line often involved in the decision making and/or procurement process for these types of medicines. An example was given of where the product is required the same day for the patient, highlighting that some steps would be ruled out by the lead time involved. It was emphasised that excessive cost or delay might justify the preparation of the product in the pharmacy even when it is available from a specials manufacturer. The premise that all other suppliers provide a superior option for patients, especially taking cost and time of supply into account, was also refuted.

It was commented that there could be some confusion where the guidance states that products can be sourced from Canada and Australia from an authorised wholesaler within the EEA, and the facility to source products outside the EEA, other than through a specialist manufacturing company was questioned. It was suggested that the Decision Tree could be simplified in this regard. It was also suggested that an example of a risk assessment should be provided to help pharmacists with this process, and that risk-benefit analyses should be carried out by pharmacists at the beginning of the decision process when they were evaluating the need for extemporaneous dispensing.

PSI Response

The PSI has noted all responses with thanks and amended the guidance in light of the comments and feedback received.

7. Question: Are the labelling and record keeping requirements for extemporaneously prepared products clear?		
Yes	84	85%
No	15	15%
Unsure	0	0%
Total	**99**	

85% of respondents felt that the labelling and record keeping requirements for extemporaneously prepared products are clear.

If not, please explain what is unclear.

Respondents commented that all the information required will not fit onto one label. It was suggested that in order to increase compliance, a template for the records that need to be kept be appended to the guidance document.

It was highlighted that a record sheet for recording each preparation is also commonly known as a 'worksheet' and that this term should be included. Clarity was sought as to whether the last sentence in Section 3.5 where it states 'This audit should facilitate a checking mechanism at each stage of the procedure', refers to the record/work sheet acting as an audit check to ensure all steps in the method have been adhered to.

It was commented that established formulae, appropriately prescribed by a practitioner may not be included in the pharmacopoeia and that there was an inference in the guidance that these would be inappropriate, it was emphasised that there should be allowances for the exercise of professional judgement by the pharmacist.

It was also suggested that a reference source for expiry dates be included in the guidance.

PSI Response

The PSI has noted all responses with thanks and amended the guidance in light of the comments and feedback received.

Question 8: Have you further queries on extemporaneous dispensing that you would like the guidance document to address?

Question 9: Do you have any further comments about the contents of this guidance?

(Please note that responses to Question 8 and 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:

The most common concern amongst respondents was that the guidance does not take account of the time it takes to procure an exempt medicinal product from a wholesaler or manufacturer outside Ireland or from a specials manufacturer, and that often these products are needed as a matter of urgency. The increased cost of procuring these products from a specials manufacturer compared to preparing them in the pharmacy was also emphasised. It was highlighted that if products are sourced from a specials manufacturer rather than being prepared in the pharmacy this will increase the cost to the government and the patient. It was commented that the Primary Care Reimbursement Service (PCRS), which is the part of the HSE responsible for making payments to pharmacies for dispensed medicines, will not pay the full cost of a product being ordered from a specials manufacturer for a patient under a government scheme, and often the patient cannot afford to pay for the medicine privately. It was emphasised that both these factors can have a negative impact on patient care, and in these circumstances the pharmacist extemporaneously preparing the product may be in the best interest of the patient.

It was also highlighted that a large proportion of medicines extemporaneously prepared in pharmacies involve the dilution of a steroid cream/ointment or the combination of a steroid cream/ointment with an antibiotic cream/ointment, which was felt could be safely done by a pharmacist. Some pharmacists suggested that feedback on the guidance should be sought from the HSE and PCRS so that they are fully aware of dispensing practice currently taking place in Irish pharmacies.

Respondents also expressed concern regarding the fact that the pharmacist should only extemporaneously prepare a product when they had exhausted all the other routes of procurement including sourcing from a different country or a specials manufacturer. It was emphasised that pharmacists are highly skilled and have received robust training during their undergraduate career on the accurate production of extemporaneous products and therefore the extemporaneous preparation of medicines in the pharmacy should be a viable option for supply, provided the pharmacist is satisfied that they have the appropriate knowledge and equipment to do so.

A number of respondents commented that the guidance should specify requirements for the area of the pharmacy used for extemporaneously preparing medicines as well as for weighing and

measuring equipment. For example, to emphasise the need to ensure that weights and measures are tested and calibrated on a regular basis to reduce the risk of error.

It was also commented that facilities for extemporaneous preparation of medicines in pharmacies are not adequate to ensure the products' quality. Facilities in Ireland were compared to the standards in other European countries (e.g. Germany) where the pharmacy must contain a specific laboratory area where extemporaneous products can be made, tested and packaged according to authorised and validated procedures.

Respondents stated that it would be useful to have access to an appropriate formulary or resource for extemporaneously prepared products, with a number of respondents giving examples of websites which provide formulae online. It was highlighted that it can be difficult to obtain robust formulae for a preparation prescribed by a doctor and sources of information, e.g. hospitals, can vary.

It was commented that it would be useful for the guidance to provide further information for Superintendent Pharmacists on the education and training requirements for pharmacists to remain competent in this area of practice, and the resources or courses available to pharmacists to update their knowledge if needed. It was highlighted that there is a lack of recognition of competence for those who have studied extemporaneous pharmacy more extensively, and a lack of practice standards with regards to community pharmacy extemporaneous practice.

It was suggested that the availability of an extemporaneous dispensing service in all pharmacies should not be compulsory and only those pharmacies opting to engage in extemporaneous dispensing should be required to maintain the range of equipment needed for this activity.

It was also highlighted that the guidance does not specifically take into account the particular environment of a hospital and that it would be beneficial to provide additional content for hospital practice.

PSI Response

The PSI has noted all responses with thanks and amended the guidance in light of the comments and feedback received.

3. Next Steps

The PSI welcomed the number of responses received to this consultation, and that the majority of respondents felt that the guidance was clear and easy to read. The PSI acknowledges the training undertaken by pharmacists during their undergraduate study in this area of practice, and the skills and expertise that pharmacists hold to extemporaneously prepare medicines. The intention of this guidance is not to prevent pharmacists from carrying out this practice but rather to ensure pharmacists are practising in line with the legislation and that they have considered the risks and benefits of extemporaneously preparing a product for their patient.

It is recognised that there are other resources and guidance available to pharmacists on the extemporaneous preparation of medicines. These may be more relevant to those preparing

specialised medicines on a regular basis, for example in a hospital. The pharmacist preparing the medicine should be satisfied that they are operating to good practice standards, as available.

A number of respondents suggested that the PSI provide access to pharmaceutical monographs or provide a resource for recognised formulae for compounding extemporaneous medicines. However, as the pharmacy regulator, it would be outside the PSI's remit to provide this type of resource and it is not possible to recommend a national online resource which has not been appropriately verified at this time.

A number of respondents requested that further training and resources be made available to those pharmacists that wanted to update their knowledge on extemporaneous dispensing. The PSI intends to consider this request in light of the future work programmes of the Irish Institute of Pharmacy (the body established by the PSI to manage Pharmacists' Continued Professional Development in Ireland).

Appendix A

NAME	REGISTRATION NO./ORGANISATION
Anna Bradley	6345
Barry O'Sullivan	9229
Bart Van Oyen	7106
Brendan Griffin	6147
Brendan Quinn	5172
Dr Caitríona M Fisher	Healthcare Products Regulatory Authority
Caitriona Gowing	6578
Caroline Gallagher	6543
Catherine Halpin	9915
Ciara McGee	6513
Colm Kennelly	5607
D Conaty	5444
Daragh Quinn	5335
Darragh Garrahy	Meaghers Pharmacy Group
David Jordan	4850
David McMahon	Irish Skin Foundation
Denis O'Driscoll	5673
Eimear McGowan	6181
Emmeline Landers	5645
Fearghal Ó Nia	Dargans Pharmacy, Dublin 7
Francis Bonner	5245
Gavin O'Kane	7829
Jack Shanahan	4933
James Hamilton	6302
Jan McAuliffe	9037
Joanna Sugrue	2548a
Joanne Kissane	6960
John Michael Morris	5088
John Murphy	10330
Kathleen Walsh	Professional Officer – Nursing and Midwifery Board of Ireland
Kieran Gallagher	9874
Kieran Lynch	6324
Li Wah Kyaw Tun	9048
Margaret Doherty	4943
Maria Creed	Pharmacy Dept. at the Mater Misericordiae University Hospital
Marie Louisa Power	9409
Mary Boissieux	6700
Maureen Reidy	4578
Miriam Moffitt	4821
Pamela Logan	5944
Patricia Heckmann	5144

Paul Mc Neill	5529
Rachel Gubbins	5458
Shane Diamond	10022
Sinead Buckley	10178
Thomas Doody	9661
Tom Holly	4405
Veronica Larkin	Member of the Public