General Pharmaceutical Council

Draft guidance for registered pharmacies preparing unlicensed medicines

A consultation report

About this consultation

Between the dates of 28 January and 14 March 2014 we consulted on the GPhC's *Draft guidance for registered pharmacies preparing unlicensed medicines*.

The draft guidance describes the factors that should be considered when preparing unlicensed medicines in a registered pharmacy, to ensure that patients receive their medicines safely and effectively. This guidance applies to all registered pharmacies where unlicensed medicines are prepared by or under the supervision of a pharmacist. The document should be read alongside the standards for registered pharmacies[1], which aim to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy. Following this guidance will help the pharmacy to:

- meet our standards, and
- provide assurances that the health, safety and wellbeing of patients and the public are safeguarded.

How we consulted

The consultation was designed in the form of a questionnaire and was based on the Survey Monkey web platform[2]. The questionnaire was distributed in an electronic format only and consisted of questions divided in two parts:

- Background information on the respondents;
- Views on the *Draft guidance for registered pharmacies preparing unlicensed medicines.*

Using this report

This report summarises what we heard during the consultation process, by presenting some key statistics and drawing out some key themes that have been identified. It also includes our response to the issues raised and outlines the next steps in the development and implementation of the draft guidance for registered pharmacies preparing unlicensed medicines.

[1] **http://pharmacyregulation.org/standards/standards-registered-pharmacies**

[2] A copy of the questionnaire is included as part of the Appendix 1 to this report.

We have taken a systematic approach to capturing feedback and ensuring we take full account of all responses. Responses to the quantitative (multiple choice) questions have been analysed and are presented throughout the report. All responses to the qualitative (open-ended) questions were considered and coded in order to identify themes. We followed the same coding approach with regard to responses submitted by email which tended to provide more general feedback on the issues, rather than addressing the specific consultation questions.

A list of the organisations that responded to this consultation is set out in the Appendix 2 of the report.

As a result of the feedback received through the consultation process, we have made a number of changes to our guidance. These have been reflected in the 'our response' sections throughout this report, while the updated guidance was published in May 2014.

Who we heard from

We received a total of 60 responses via Survey Monkey and 12 more responses via email. All responses that answered at least one of the core consultation questions (i.e. the questions asking for views on the guidance) were included in the analysis. Duplicate responses submitted through both channels and incomplete responses submitted via Survey Monkey were excluded, resulting in the total number of responses counted as valid was 40.

Please note that the total number of responses is very small and, where included, percentages are best read in conjunction with the total numbers.

Total number of responses	**40**

Background information

Responding as an individual

Individual respondents		
Pharmacy professionals		18
Of whom		
Pharmacists		17
Pharmacy technicians		1
Members of the public		0
Other*		4
Total individual respondents		**22**

*The 'other' respondents included a pharmacy student, a research fellow and a respondent working in the pharmaceutical industry.

Individual respondents – countries of residence	
England	16
Scotland	3
Wales	1
NI	0
Other / not specified	2
Total individual respondents	**22**

Pharmacy professionals – settings	
Community pharmacy	5
Hospital pharmacy	6
Primary care organisation / provider	3
Pharmacy education, training and research	0
Pharmaceutical industry	1
Other / not specified	3
Total pharmacy professionals	**18**

Community pharmacists – roles	
Superintendent	1
Pharmacy owner	0
Employee / locum	3
Other / not specified	1
Total working in community pharmacy	**5**

Responding on behalf of an organisation

Pharmacy / non pharmacy organisation	
Responding on behalf of	
A pharmacy organisation	11
A non-pharmacy organisation	7
Total respondents (org.)	**18**

Organisations – countries of operation	
England	15
Wales	6
Scotland	7
NI	3
Other / not specified	0
Total respondents (org.)	**18**[3]

Organisations - sectors	
Body/ organisation representing patients / the public	0
Body/ organisation representing professionals / practitioners	2
Body/ organisation representing trade/ industry	2
Community pharmacy –	1

[3] Inconsistencies in the sum of responses are due to the fact that some organisations operated in the whole of Great Britain or the whole of the UK. The multiple choice question allowed for selection of multiple answers.

Corporate	
Community pharmacy – Independent	3
Government department/ organisation	2
NHS organisation/ group	3
Pharmaceutical manufacturer	3
Regulatory body	1
Research, education and/ or training organisation	0
Other / not specified	1
Total respondents (org.)	**18**

Views on the guidance

What we heard

Q. Do you think that the guidance is written in a clear and understandable way?		
Yes	23	(88%)
No	3	(12%)
Total N of responses	**26**	**100%**

The majority of respondents thought that the guidance was written in a clear and understandable way.

Q. Do you have any comments about whether the guidance is written in a clear and understandable way?

Some respondents thought that the guidance was too generic in parts and consequently, could be difficult to apply in practice.

Some respondents commented in this section and also the section on how the guidance can be improved, on how the levels of risk vary when making different types of unlicensed preparations. For completeness we have covered those comments under this section.

Respondents thought that the guidance did not make enough of a distinction between the different types of preparations and acknowledge how these, ranging from the simple to the more complex, each carried different levels of inherent risk. As a result, they thought the process proposed, was 'one size fits all' and disproportionately complex, particularly in relation to some of the lower risk preparations. It was suggested that the processes proposed should reflect the appropriate level of risk in different preparations. Some believed that if the process for community pharmacies preparing the lower level of risk preparations was too onerous or too complicated to implement, they would stop preparing unlicensed medicines altogether. Some respondents commented that, in their experience, a very limited number of pharmacies prepare and dispense unlicensed medicines themselves.

There were also suggestions that some more high risk preparations, such as preparing aseptics and cytotoxics, should be covered by separate guidance.

It was pointed out that there is national guidance for the higher risk preparations, which are also covered by hospital governance processes. Some respondents were of the view that the draft guidance mainly focused on community pharmacy and that high risk preparations should not be covered in this guidance as it was thought to be less relevant to the community setting.

A clearer, more limited focus for the guidance, reflecting the different levels of risk, was suggested.

Our response

We are aware that the preparation of unlicensed medicines can range from a simple process to one that is very complex. It is the difference in the type of preparation and process that affects the level of risk involved. Our view is that the guidance applies to all preparations made within a registered pharmacy to ensure that patients and the public are safeguarded.

We clarified areas that respondents said were unclear and needed further detail or alteration. We also added footnotes to explain certain terms used (such as certificates of conformity and analysis).

What we heard

Q. Do you think that there any areas where you think this guidance could be improved?		
Yes	15	(54%)
No	12	(43%)
Total N of responses	**27**	**100%**

Just over a half of respondents thought that there were areas where the guidance could be improved.

Q. Do you have any comments about whether there any areas where you think this guidance could be improved?

Some respondents commented in this section and also the section on whether the guidance was clear, on how the different levels of risk vary in making different types of unlicensed preparations. For completeness we have covered those comments in the section above.

We also received comments regarding the labelling of unlicensed medicines and the information given to patients about their unlicensed medicines.

Our response

We have made a number of the changes suggested by respondents to improve our guidance. For example, in section 4.3 Patient Information, on page 23 of the guidance, we have added that there are labelling requirements if a medicine is prepared in line with a British Pharmacopoeia (BP) formula or general monograph in the BP. We have also highlighted that information should be given to patients when there is limited or no direct contact with the patient when the unlicensed medicine is supplied.

Following suggestions by respondents, we have also included additional references in the useful information section, (for example we have included the *Handbook of Extemporaneous Preparation* and the *Quality Assurance of Aseptic Preparation Services* publications) on page 25 of the guidance.

What we heard

Q. Please give any other comments you have on the guidance.

Finally, respondents were asked to provide any other comments they had on the guidance.

All respondents agreed that patient safety is the most important consideration when preparing unlicensed medicines.

Respondents suggested two areas where more guidance and advice would be helpful:

- Ensuring the appropriateness / establishing the clinical need for an unlicensed medicine with the prescriber; and
- Quality assurance of unlicensed medicines purchased.

Our response

The aim of this guidance was to provide advice to pharmacy owners and superintendent pharmacists considering preparing unlicensed medicines in their registered pharmacies, and to assist them in demonstrating how they meet the standards for registered pharmacies and safeguard the health, safety and wellbeing of patients and the public.

It was not the intention of this guidance to cover the prescribing and purchasing of unlicensed medicines. This guidance covers the process of preparing the medicine and considering whether the registered pharmacy is suitable for carrying out this activity.

The prescribing of an unlicensed medicine is covered in the General Medical Council's (GMC's) *Good practice in prescribing and managing medicines and devices*. Establishing the clinical need and appropriateness of prescribing an unlicensed medicine is covered in the GMC's guidance and elsewhere, such as the MHRA's guidance note.

There is guidance available on the purchasing of unlicensed medicines from other pharmacy support organisations (such as the Royal Pharmaceutical Society [RPS] and the Pharmaceutical Services Negotiating Committee [PSNC]). The Medicines and Healthcare products Regulatory Agency (MHRA) has produced a guidance note on the requirements concerned with commercially available (manufactured) unlicensed medicines (specials), which is available on their website.

What next?

Thank you for responding to our consultation. Your responses have informed the changes we have made to the guidance. We value your comments and have tried to address as many of your points as we could. We will continue to monitor how this pharmacy service is provided and ensure that our guidance is regularly reviewed to take account of this.

Appendix 1: Consultation questionnaire

Part 1: Background information

Q1. In what capacity are you responding?

☐ As an individual - **Section A**

☐ On behalf of an organisation - **Section B**

Section A – Responding as an individual

Q2. Please provide your contact details:

Your name:

Job Title:

Address:

Email :

Contact tel:

Q3. What is your country of residence?

☐ England

☐ Scotland

☐ Wales

☐ Northern Ireland

☐ Other (please give details)

Q4. Are you responding as:

☐ A pharmacy professional – **Section A1**

☐ A member of the public – **Part 2**

☐ Other (Please give details) – **Part 2**

Section A1 - Pharmacy professionals

Q5. Are you:

☐ A pharmacist

☐ A pharmacy technician

☐ Other (please give details)

Q6. Please select the option below which best describes the area which you primarily work in:

☐ Community pharmacy – **Section A2**

☐ Hospital pharmacy

☐ Primary care organisation / provider

☐ Pharmacy education, training and research

☐ Pharmaceutical industry

☐ Other (please give details)

Section A2 – Community pharmacy

Q7. Which of the options below best describes your role in the pharmacy:

☐ Superintendent

☐ Pharmacy owner

☐ Employee/ locum

☐ Other, (please give details):

Section B – Responding on behalf of an organisation

Q8. Please provide your contact details:

Your name:

Job Title:

Organisation:

Address:

Email :

Contact tel:

Q9. Is your organisation a

☐ Pharmacy organisation

☐ Non-pharmacy organisation

Q10. Please select the country / countries in which your organisation operates:

☐ England

☐ Scotland

☐ Wales

☐ Northern Ireland

☐ Other (please give details)

Q11. Please choose an option below which best describes your organisation

☐ Body / organisation representing patients / the public

☐ Body / organisation representing professionals / practitioners

☐ Body / organisation representing trade / industry

☐ Pharmaceutical manufacturer

☐ Community pharmacy – corporate

☐ Community pharmacy – independent

☐ NHS organisation / group

☐ Government department / organisation

☐ Regulatory body

☐ Research education and / or training organisation

☐ Other (please give details)

Part 2: Draft guidance for registered pharmacies preparing unlicensed medicines

Q12. Do you think that the guidance is written in a clear and understandable way?

☐ Yes

☐ No

Q13. Do you have any comments about whether the guidance is written in a clear and understandable way?

Q14. Do you think that there any areas where you think this guidance could be improved?

☐ Yes

☐ No

Q15. Do you have any comments about whether there any areas where you think this guidance could be improved?

Q16. Please give any other comments you have on the guidance.

Appendix 2: Organisations responding to the draft guidance consultation:

Accountable Officers Network

Airedale NHS Trust

Associated Chemists (Wicker) Ltd

Association of the British Pharmaceutical Industry

Bayer Healthcare

Care Meds UK Ltd

Guild of Healthcare Pharmacists

JAJR investments UK Ltd

Medicines and Healthcare products Regulatory Agency

NHS Pharmaceutical Quality Assurance Committee

Pharmacy Voice

Rosemont Pharmaceuticals Ltd

Royal Pharmaceutical Society

Scottish Government Health Department

St Christopher's Hospice

Welsh Government

WR Evans (Chemist) Ltd