

Council, 6 July 2016

Outcomes of the consultation on renaming the 'Local anaesthetics' and 'Prescription only medicines' annotations for chiropodist / podiatrists

Executive summary and recommendations

### **Introduction**

Chiropodists / podiatrists who have undertaken approved training are annotated on the Register to indicate their ability to sell or supply (the 'prescription only medicines' annotation) and/or administer (the 'local anaesthetics' annotation) certain medicines from exemption lists in medicines legislation.

The Executive ran a public consultation between 8 March and 3 May 2016 on renaming these annotations, in order to ensure that they reflect the respective exemption lists to which they refer, and also that they are easily understood by professionals and members of the public who use our online Register.

We have analysed the 132 responses we received to the consultation. As a result of these responses, we are proposing to proceed with renaming the annotations, but with a slight modification to our original proposal, as follows:

- 'Local anaesthetics' to become 'Prescription only medicines – administration'; and
- 'Prescription only medicines' to become 'Prescription only medicines – sale / supply'.

The attached document provides a summary of the consultation responses and key themes emerging from them, as well as the decisions we are proposing as a result. At its meeting in June 2016, the Education and Training Committee agreed these and recommended them to the Council.

### **Decision**

The Council is invited to discuss and agree the renaming of the annotations and the text of the consultation analysis document, subject to minor editing amendments and formal legal scrutiny.

### **Background information**

See paper.

### **Resource implications**

Work to implement the renaming of the annotations will be incorporated in a major project which covers a number of other changes to the registration system and online Register. Resource implications have been accounted for in departmental and project planning for 2016/17.

### **Financial implications**

The financial implications, including the costs associated with changes to the online Register (part of the major project), have been accounted for in 2016/17 budgets.

### **Appendices**

None

### **Date of paper**

21 June 2016

## **Outcomes of the consultation on renaming the ‘Local anaesthetics’ and ‘Prescription only medicines’ annotations for chiropodist / podiatrists**

Analysis of responses to the consultation, and our decisions as a result

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## **1. Introduction**

### **About the consultation**

- 1.1 We consulted between 8 March and 3 May 2016 on a proposal to rename the 'local anaesthetics' and 'prescription only medicines' annotations which appear on our Register for chiropodists / podiatrists who have undertaken appropriate training.
- 1.2 This work is aimed at ensuring that the way these annotations are described on the Register is up to date and clear for professionals, service users and the public.

### **About us**

- 1.3 We are a regulator and were set up to protect the public. To do this, we keep a Register of health and care professionals who meet our standards for their professional skills and behaviour. Individuals on our Register are called 'registrants'.
- 1.4 We currently regulate 16 professions:
  - Arts therapists
  - Biomedical scientists
  - Chiropodists / podiatrists
  - Clinical scientists
  - Dietitians
  - Hearing aid dispensers
  - Occupational therapists
  - Operating department practitioners
  - Orthoptists
  - Paramedics
  - Physiotherapists
  - Practitioner psychologists
  - Prosthetists / orthotists
  - Radiographers
  - Social workers in England
  - Speech and language therapists

### **Renaming the annotations**

- 1.5 There are two exemptions in medicines legislation which allow registered chiropodists / podiatrists to sell, supply and administer certain listed prescription only medicines (POMs) to patients, without the need for a prescription from a doctor or other independent prescriber. In order to use the

exemptions, a chiropodist / podiatrist must be appropriately trained and have a relevant annotation on the HCPC Register.<sup>1</sup>

- 1.6 These exemptions are currently annotated on the Register as follows:
- ‘Local anaesthetics’: This annotation enables chiropodists / podiatrists who have completed appropriate training to administer by injection (parenterally) medicines in the relevant exemption list.
  - ‘Prescription only medicines’: This annotation enables chiropodists / podiatrists who have completed appropriate training to legally sell or supply medicines in the relevant exemption list.
- 1.7 We have received feedback from stakeholders, including the Society of Chiropodists and Podiatrists, that the way the annotations are currently named is out of date and unclear. For example, the exemption list related to the ‘local anaesthetics’ annotation now includes other types of medicines, including some steroids. In addition, the ‘prescription only medicines’ annotation may be confusing because all of the medicines on both exemption lists are POMs.
- 1.8 Therefore we proposed to rename the annotations to make sure that they reflect the exemption lists they refer to, and also that they are easily understood by members of the public who use our online Register. We proposed the following:
- the ‘local anaesthetics’ annotation to be renamed ‘Medicines – administration’; and
  - the ‘prescription only medicines’ annotation to be renamed ‘Medicines – sale / supply’.

### **About this document**

- 1.9 This document summarises the responses we received to the consultation and our decisions taken as a result.
- 1.10 The remainder of this document is divided into the following sections.
- **Section 2** explains how we handled and analysed the responses we received, providing some overall statistics from the responses.
  - **Section 3** summarises the general comments we received in response to the consultation.
  - **Section 4** outlines the comments we received in relation to specific questions within the consultation.
  - **Section 5** outlines our responses to the comments we received and the decisions we have taken as a result.
  - **Section 6** lists the organisations which responded to the consultation.

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<sup>1</sup> The exemptions for chiropodists / podiatrists are set out in Schedule 17 to the Human Medicines Regulations 2012.

## **2. Analysing your responses**

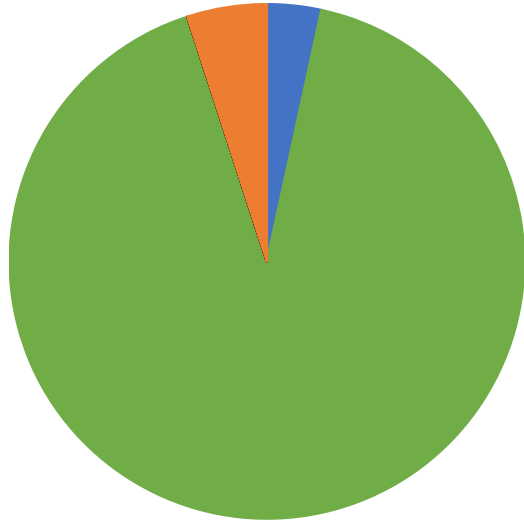
- 2.1 Now that the consultation has ended, we have analysed all the responses we received. Whilst we cannot include all of the responses in this document, a summary of responses can be found in sections 3 and 4.

### **Method of recording and analysis**

- 2.2 The majority of respondents used our online survey tool to respond to the consultation. They self-selected whether they were responding as an individual or representing an organisation, and selected their response to each consultation question (e.g. 'yes', 'no', 'partly', or 'don't know'). Where we received responses by email or by letter, we recorded each of those in a similar manner.
- 2.3 When deciding what information to include in this document, we assessed the frequency of the comments made and identified themes. This document summarises the common themes across all responses, and indicates the frequency of arguments and comments made by respondents.

### **Statistics**

- 2.4 We received 132 responses to the consultation. 119 (90.2%) of responses were received from individuals and 13 (9.8%) from organisations. Of the 119 individual responses, 109 (91.6%) were from HCPC registered professionals.
- 2.5 The breakdown of respondents and of responses to each question is shown in the graphs and tables which follow.



- Educator
- HCPC registered professional
- Other (please specify)

### Graph 1 – Breakdown of individual responses

Respondents were asked to select the category that best described themselves.

Those who selected 'Other' included students and a podiatrist practising outside of the UK.



- Employer
- Professional body
- Public body
- Other (please specify)

### Graph 2 – Breakdown of organisation responses

Respondents were asked to select the category that best described their organisation.

Those who selected 'Other' included private chiropody / podiatry practices.

**Table 1 – Breakdown of responses to each question**

Question	Yes	No	Partly	Don't know
Q1: Do you agree with our proposal to rename the 'local anaesthetics' annotation to read: 'Medicines – administration'?	61 (46.2%)	54 (40.9%)	16 (12.1%)	1 (0.8%)
Q2: Do you agree with our proposal to rename the 'prescription only medicines' annotation to read: 'Medicines – sale / supply'?	65 (49.2%)	48 (36.4%)	18 (13.6%)	1 (0.8%)

**Table 2 – Breakdown of responses by respondent type**

	Individuals				Organisations			
	Yes	No	Partly	Don't know	Yes	No	Partly	Don't know
Q1	51 (42.9%)	53 (44.5%)	15 (12.6%)	0 (0.0%)	10 (76.9%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
Q2	53 (44.5%)	48 (40.3%)	17 (14.3%)	1 (0.8%)	12 (92.3%)	0 (0.0%)	1 (7.7%)	0 (0.0%)

**NB:**

- Percentages in the tables above have been rounded to the nearest whole number and therefore may not add up to 100% in every instance.



### **3. General themes**

- 3.1 We received a large number of free text comments in response to the consultation questions. The main themes emerging from those comments are summarised below.

#### **Clarity and currency**

- 3.2 Many respondents highlighted the importance of making sure that the annotations are labelled clearly and that they reflect the exemption lists to which they refer. Those who agreed with the proposed changes considered them to be more up to date and to provide additional clarity to professionals and members of the public.
- 3.3 On the other hand, many of those who did not agree with the changes said that they would actually cause more confusion, especially for members of the public who may use the Register to check a professional's qualification. Concerns were also raised about a lack of clarity around the terms 'medicines', 'administration' and 'sale'.

#### **Access to medicines**

- 3.4 We received a number of comments about problems encountered by chiropodists / podiatrists when trying to access the medicines included in the exemption lists, due to a lack of understanding about the entitlements on the part of pharmacists. A few respondents suggested that the word 'access' should be included in both annotations to address this issue.

#### **Devaluing the profession**

- 3.5 A number of the responses we received from registrants raised concerns that, by making the annotations sound less specific, the proposed changes would 'downplay' or 'devalue' the associated qualifications and/or the chiropody / podiatry profession as a whole.
- 3.6 A related concern raised by some respondents was about the risk of obscuring the differences between chiropodists / podiatrists and unregulated practitioners, such as foot health practitioners.

#### **Suggested alternatives**

- 3.7 There were a number of suggested alternatives to the names we proposed. These are detailed in section 4 below.

## 4. Comments in response to specific questions

4.1 This section summarises comments made in response to the specific questions set out in the consultation document.

### **Question 1: Do you agree with our proposal to rename the ‘Local anaesthetics’ annotation to read: ‘Medicines – administration’. If not, why not?**

- 4.2 Nearly half (46.2%) of all respondents agreed with this proposal. A much higher proportion of organisational responses agreed (76.9%); whereas individual responses were more evenly split.
- 4.3 Most of those who agreed did not provide additional comments, although a small number did. Some who responded ‘yes’ to this question also commented that the proposed change was clearer for members of the public, as well as for chiropodists / podiatrists and pharmacists; and was a sensible and appropriate change to clarify that the annotation related to the administration of medicines.
- 4.4 A small number of respondents also stated that the current label of ‘Local anaesthetics’ was out of date. One respondent, representing a chiropody / podiatry professional body, highlighted the fact that the ‘local anaesthetics’ annotation was named at a time when all of the medicines on the relevant exemption list were local anaesthetics, which is no longer the case. This respondent also noted that the proposed change could be used to establish a template to apply to other professions’ annotations in future.
- 4.5 Another respondent, representing a pharmacist professional body, commented that reducing any confusion caused by the way the annotations are currently described would ensure that patients are able to receive the medicines they need in a timely manner.
- 4.6 A small number of respondents said that, whilst they agreed with the proposed change, it was on the understanding that the accompanying explanatory information on the online Register would be sufficiently clear. For example, one respondent, representing a pharmacists’ professional body, suggested that the annotation should make specific reference to the legislation which sets out the exemption list in order to eliminate confusion for registrants and pharmacists (i.e. Part 3 of Schedule 17 to the Human Medicines Regulations 2012).
- 4.7 On the other hand, 40.9% of respondents did not agree with the proposed change, and 12.1% only partly agreed.
- 4.8 A significant number of respondents who said that they did not agree with the proposal maintained that the label ‘Medicines – administration’ was too vague or general and would actually reduce clarity for members of the public. Several stated that the proposed label could be taken to mean that the exemption applied to a whole range of medicines, rather than only those listed in legislation. A few respondents noted that the term ‘medicines’ does not

distinguish between POMs, pharmacy (P) and general sales list (GSL) medicines.

- 4.9 Some commented that the term 'local anaesthetics' was well understood by patients and members of the public and that it was already a straightforward description of what the annotation refers to. These respondents said it was important to retain the existing name in order to keep clear what kind of medicines may be administered. One respondent stated that, whilst the exemption list included other medicines besides local anaesthetics, patients would not want to have to consult a full list, but would want to quickly gain an understanding of what the chiropodist / podiatrist was qualified to do. The change may lead to patients believing that the chiropodist / podiatrist was not actually qualified to administer local anaesthetics.
- 4.10 Moreover, a few respondents stated that some patients would not understand the term 'medicines' to cover things like local anaesthetics; they would think rather of medicines given to 'make them better', such as antibiotics, or medicines taken orally.
- 4.11 Two respondents questioned whether, with the proposed change, if a chiropodist / podiatrist was qualified to administer local anaesthetics but not steroids, the annotation would still be accurate and applicable. Similarly, one respondent who was qualified to administer local anaesthetics worried that the proposed wording would imply that they were qualified to administer other types of medicines as well.
- 4.12 Apart from issues around the clarity of the annotation, a number of respondents raised concerns that the proposed change was an attempt to 'devalue' the qualification that leads to the entitlement and/or the chiropody / podiatry profession itself. A small number stated that the proposed change would disregard the hard work required to obtain a qualification leading to the entitlement.
- 4.13 Some respondents were worried that this perceived 'downgrading' of the profession would allow unregulated practitioners, such as foot health practitioners, to replace chiropodists / podiatrists. One respondent commented that the proposed change would place chiropodists / podiatrists 'on par' in patients' minds with care workers who are trained to administer some medicines according to a prescription.
- 4.14 A small number of respondents pointed out that the term 'administration' was confusing as it could also mean office work or doing paperwork.
- 4.15 A few respondents who either did not agree or partly agreed with the change suggested alternative names for the annotation. These included the following:
- 'Access and administration';
  - 'Medicines – access and administration';
  - 'Medicines, local analgesic administration';

- ‘Medicines – administration by injection’; and
- ‘Local anaesthetics – administration’.

Among the reasons given for these suggestions was to make clear to pharmacists who may not understand a chiropodist / podiatrist’s entitlement and may be resistant to selling the medicines to a chiropodist / podiatrist.

- 4.16 One respondent, representing a chiropody / podiatry professional body, who partly agreed with the proposed change also suggested that it was ambiguous in that it would not explain the scope of the exemptions fully to members of the public and other non-professionals who are unfamiliar with medicines legislation. This respondent also said that the proposed wording was not clear that the exemptions related specifically to parenteral administration.
- 4.17 Another respondent, representing a medical professional body, who agreed partly with the change, thought that the annotation should differentiate between administration of small doses of local anaesthetics and higher doses (such as a regional block), which carry higher risks of tissue injury or overdose. This respondent asserted that chiropodists / podiatrists who administer high doses of local anaesthetics should receive specific training in techniques of regional anaesthesia, including dealing with complications. Furthermore it would be in the interests of patient safety to also expect them to have qualified as independent prescribers.

**Question 2: Do you agree with our proposal to rename the ‘Prescription only medicines’ annotation to read: ‘Medicines – sale / supply’. If not, why not?**

- 4.18 About half (49.2%) of the respondents agreed with the proposal to rename the annotation as ‘Medicines – sale / supply’. A much higher proportion of organisational responses agreed (92.3%); whereas individual responses were more evenly split.
- 4.19 Most of these did not provide additional comments, but those who did supported the change because it was clearer and more accurate than the current annotation and specified what the role of the chiropodist / podiatrist was.
- 4.20 A few respondents agreed that the way the annotation is currently labelled is outdated, confusing and misleading. One respondent, representing a podiatry professional body, highlighted the fact that both exemption lists available to chiropodists / podiatrists included POMs, so both changes together would eliminate any potential confusion and provide a clearer link to legislation. This respondent also noted that the proposed labels could be used to establish a template for annotations which could apply to other professions as well.
- 4.21 Another respondent, representing a pharmacist professional body, commented that reducing any confusion caused by the way the annotations are currently described would ensure that patients are able to receive the medicines they need in a timely manner.

- 4.22 A small number of respondents who agreed with the proposal also commented that the accompanying information on the online Register needed to adequately explain the annotation. One, representing a pharmacists' professional body, suggested that the annotation should explicitly refer to the relevant legislation, i.e. the medicines listed in Schedule 17, part 2, column 2, of the Human Medicines Regulations 2012. This would eliminate confusion for registrants as well as pharmacists who supply those medicines.
- 4.23 On the other hand, 36.4% of respondents did not agree with the proposal, and 13.6% only partly agreed.
- 4.24 Many of the objections expressed in response to this question were similar to those for the previous question. A number of respondents said that they did not understand the need for the change, stating that the current annotation is clearer than the proposed new one. For example, the term 'Prescription only medicine' was considered to be well understood by patients and members of the public.
- 4.25 A related objection was that 'Medicines – sale / supply' was seen as too generic, vague and ambiguous. Some respondents pointed out that the proposed wording does not differentiate between POMs and P or GSL medicines. One respondent raised concerns that this might be open to misinterpretation or even abuse by unqualified persons.
- 4.26 A few respondents thought that 'Medicines – sale / supply' could be taken to refer to a company selling a product, rather than a healthcare professional carrying out an intervention. One respondent asserted that the proposed label sounded like 'dealing in unwanted drugs'. In addition, there were a small number of objections to use of the word 'sale' in the annotation, as it would not reflect how medicines are supplied by a chiropodist / podiatrist working in the NHS.
- 4.27 As above, a small number of respondents expressed concerns that the proposed change would 'devalue' or 'downgrade' the chiropody / podiatry profession by making the use of medicines by chiropodists / podiatrists seem less professional. One registrant highlighted the fact that removing the term 'prescription only medicine' would obscure the fact that use of these medicines requires special knowledge and training, for example an understanding of pharmacokinetics and pharmacodynamics and patient management.
- 4.28 A few respondents who either did not agree or partly agreed with the change suggested alternative names for the annotation. These included the following:
- 'Access, sale and supply';
  - 'Prescription only medicine to sell/supply';
  - 'Prescription medicines – sale / supply';
  - 'Exemptions from prescription only medicines';

- ‘Medicines from the current podiatry list – sale / supply’; and
- ‘Sale / supply of prescription only medicines’.

One respondent commented that the annotation needed to include the word ‘access’ because some pharmacists were still resistant to allowing qualified chiropodists / podiatrists to have access to the medicines on the exemption list.

- 4.29 Another respondent, representing a chiropody / podiatry professional body who partly agreed with the proposed change, also suggested that it was ambiguous in that it would not explain the scope of the exemptions fully to members of the public and other non-professionals who are unfamiliar with medicines legislation.

## 5. Our decisions

- 5.1 We have carefully considered all of the responses we received to this consultation. In conclusion we have decided to proceed with changing the way the 'Local anaesthetics' and 'Prescription only medicines' annotations are displayed on the Register, but with some modification of our original proposals, as follows:
- 'Local anaesthetics' will become '**Prescription only medicines – administration**'.
  - 'Prescription only medicines' will become '**Prescription only medicines – sale / supply**'.
- 5.2 In this section we have set out our responses to issues raised in respondents' comments, as well as how some of them have influenced our decisions regarding whether and how to implement the proposed changes.

### Clarity

- 5.3 Many of the comments we received, both from those who supported the proposed changes and those who did not, stressed the importance of clarity for professionals, patients and members of the public. We agree that clarity is extremely important, and increasing clarity was our primary motive in consulting on these proposals.
- 5.4 We do not agree with the assessment of some respondents that the names 'Local anaesthetics' and 'Prescription only medicines' provide sufficient clarity as they are. As many of our stakeholders have pointed out, both before and during the consultation, these labels do not reflect the current exemption lists to which they refer; or the distinction, set out in legislation, between the ability to administer and to sell or supply certain medicines.
- 5.5 However, we have taken on board comments that the word 'medicines' is too generic and does not provide any clarity about which types of medicines are included in the exemptions. It would be impractical to have an annotation which lists every medicine included in the exemption, not least because the lists can be and are amended overtime. But, we do recognise that the distinction between POMs and other types of medicines (including P and GSL) is an important one. We have therefore decided to change 'medicines' to 'prescription only medicines' in the new names.
- 5.6 In addition, we will update the explanatory information on the online Register in order to ensure that it provides the necessary clarity about the relevant exemptions and signposts to the legislation.

### Use of the terms 'sale' and 'administration'

- 5.7 We recognise that some respondents were concerned that use of the term 'sale' in the annotation would be misleading, particularly in relation to chiropodists / podiatrists who work in the NHS and would not sell a medicine

to a patient. Likewise, a small number of respondents highlighted the fact that 'administration' could also refer to office work or paperwork, as well as administration of a medicine.

- 5.8 However, we have decided to retain the terms 'administration', 'sale' and 'supply', as these are used in the Human Medicines Regulations 2012, which sets out the exemptions. We will explore whether the explanatory information on the online Register could be used to minimise any confusion that might arise about the use of these terms.

### **Risk of 'devaluing' the qualification or profession**

- 5.9 A significant number of responses to the consultation expressed concerns that the proposed changes would result in devaluing of the exemptions, the training or qualifications required to access the exemptions, or even of the profession as a whole. We hope that this document will help to allay some of those concerns.
- 5.10 It is important to state outright that the way the annotations appear on the Register does not and cannot have any impact on the content of relevant training, the legal status of the exemptions, or on the medicines which are included in the respective exemption lists. Changing the name of an annotation certainly would not enable unregistered practitioners to access medicines in a way that is contrary to current legislation.
- 5.11 It was definitely not our intention in proposing these changes to negatively affect the public's perception of the professionalism or qualification of chiropodists / podiatrists. On the contrary, as stated above, we hope that the renamed annotations will contribute to a better understanding among members of the public (as well as other professionals) about how certain chiropodists / podiatrists are qualified to use medicines. We believe that the modifications we have made as a result of the consultation – i.e. to refer to 'prescription only medicines' rather than simply 'medicines' in the annotations – will assist in this.

### **Next steps**

- 5.12 Whilst we believe that these changes will increase clarity for professionals and members of the public, we do acknowledge that the current names of the annotations have been in use for a long time and are therefore engrained to some extent in the language of the profession and relevant education and training. We will therefore ensure that the changes and the reasons behind them are communicated thoroughly to our stakeholders, including registered chiropodist / podiatrists, education providers, professional bodies and the wider public.
- 5.13 We expect that the renamed annotations, along with explanatory information on the online Register, will be in place from autumn 2016.



## 6. List of respondents

6.1 The organisations which responded to the consultation are listed below:

Biped Podiatry  
British and Irish Orthoptic Society  
British Orthopaedic Association  
College of Podiatry  
Foot Care  
Guild of Healthcare Pharmacists  
Institute of Chiropodists and Podiatrists  
NHS [no specific organisation provided]  
NHS Greater Glasgow and Clyde [3 responses]  
Royal College of Anaesthetists, Faculty of Pain Medicine  
Royal Pharmaceutical Society