Public consultation MLX 375: Consolidation and review of UK medicines legislation

The MHRA's response

July 2012

Contents

1 Introduction

1.1 The consolidation and review of UK medicines legislation will replace around 200 statutory instruments and much of the Medicines Act 1968 with one set of regulations – the Human Medicines Regulations 2012. The Regulations result in shorter, simplified law that is easier to understand and apply. This will save time and costs for business, civil society organisations and the public sector in understanding and applying the law, and reduce the likelihood of costly legal cases arising from different interpretations of the law.

1.2 We have also taken the opportunity to introduce some small policy changes through the Regulations to help ensure that medicines legislation is modern, as user-friendly as it can be and does not introduce unnecessary burdens. The approach we have taken echoes the work we have done to simplify regulatory requirements and adds momentum to a regulatory programme the Agency is developing to explore how we could streamline without introducing risk. This is a much easier task to undertake with simplified medicines legislation as the framework.

1.3 We could not have developed the Regulations without the input of interested parties. We engaged with them throughout the exercise to test ideas and from 25 October 2011 to 17 January 2012 we ran a public consultation, *MLX 375: Consolidation and review of UK medicines legislation*. This aimed to:

- present a draft of the Regulations and explain our approach to producing them
- test that the Regulations were a full, accurate and workable legislative text
- ensure that the Regulations did not introduce any unintended changes
- seek views on policy changes that we proposed to introduce in the Regulations

- seek further evidence of the impact of the Regulations and proposed policy changes.

Consultation process

1.4 We encouraged responses from all interested parties. MLX 375 was published on our website and we alerted a wide range of over 700 organisations and individuals by email. It was also publicised through our regular news alert emails.

1.5 At the start and end of the consultation period, and subsequently in April 2012, we met with pharmaceutical industry bodies and pharmacy professional, trade and negotiating bodies. These represent those most likely to be most effected by the Regulations.

1.6 MLX 375 was also informed by a number of prior informal consultations:

Jan 2009	Publication of a concept paper that described the project and solicited topics for review
July 2010	Meeting with pharmaceutical industry bodies
Aug 2010	Publication of an informal consultation on the first complete draft of the consolidated Regulations
Sept 2010	Meeting with pharmacy professional, trade and negotiating bodies
Oct 2010	Publication of an informal consultation on exemptions related to the sale, supply, and administration of medicines

Oct 2010	Publication of an informal consultation on patient group directions (PGDs)
Nov 2010	Publication of an informal consultation that set out possible proposals to reduce regulatory burdens and sought further suggestions to that end
Jan 2011	Publication of an informal consultation on issues relating to the PLR regime and homeopathy

The purpose of this document

1.7 This document presents a summary of responses we received to MLX 375 and a commentary on key issues raised. It highlights significant changes we have made in response and outlines why we have not been able to take on some of the suggestions we received.

1.8 We received over 200 responses to MLX 375. These provided a large number of comments and often raised detailed drafting points. This document is not intended to cover every individual comment we received or drafting change we have made as a result. Rather, it is intended to support an understanding of how feedback has been used to improve the Regulations. The responses we received have played an important role in shaping and refining the Regulations.

1.9 The rest of this document is structured as follows:

- **Chapter 2** summarises the key findings from consultation responses and sets out next steps.
- **Chapter 3** covers responses to questions on the impact of consolidation and the accuracy and clarity of the Regulations.

- **Chapter 4** covers responses to questions we asked on key drafting changes made by the Regulations.
- **Chapter 5** covers responses to policy proposals we made.
- **Chapter 6** covers other comments made in responses.

1.10 References to regulation numbers in this document are to those in the consultation draft of the Regulations.

1.11 The Regulations also implement European Directive 2010/84/EU, which introduces substantial changes to pharmacovigilance requirements.[1] For clarity, we published a separate consultation on this initiative (MLX 374) and have also published a separate response. This is available on our website.[2]

Next steps

1.12 We are grateful to everyone who took the time to respond to MLX 375. Given the broad support in responses, we intend to lay the Regulations (including the amendments outlined in this document) before Parliament as soon as possible.

1.13 As set out in chapter 3, we will publish a briefing document to accompany the Regulations and update our existing guidance where appropriate; and in order to maintain the benefits of the Regulations, we also intend to periodically remake them in both informal and formal versions.

1.14 We will also build on this legislative simplification by delivering a suite of better regulation initiatives through our Regulatory Excellence programme. In particular this will take forward the findings from our participation in the

[1] Pharmacovigilance is the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk.
[2] www.mhra.gov.uk

Government's Red Tape Challenge[3], on which we will report publicly in the Autumn this year.

[3] More information on the Red Tape Challenge is available at www.redtapechallenge.cabinetoffice.gov.uk.

2 Summary

2.1 In total we received 204 responses to MLX 375. These came from a wide spectrum of organisations and individuals, including pharmaceutical industry bodies; professional, trade and negotiating pharmacy bodies; pharmaceutical and pharmacy companies; NHS bodies; Royal Colleges; charities; and individuals responding in a personal capacity. A list of the respondents is annexed to this document.

2.2 The scope of the legislation being consolidated led to a great range and depth of comments in responses. There was widespread support for the aim of simplifying medicines legislation and for the approach that we have taken, and agreement that consolidation would bring significant benefits. Many respondents suggested drafting amendments to ensure that the Regulations were clear and accurately consolidated existing legislation. We have amended the Regulations to take account of these comments where appropriate.

2.3 There was also general support for our proposed policy changes. The most notable change we have made to proposals as a result of the consultation is to retain statutory warnings for paracetamol. This is due to the specific dangers it poses in relation to overdose. The other changes are some small adjustments to the proposals on sale, supply and administration exemptions and patient group directions. We made these so that the Regulations reflect current healthcare delivery arrangements where possible and do not inadvertently introduce unhelpful restrictions.

2.4 Some respondents questioned whether the Regulations were introducing certain policy changes that were not outlined in MLX 375. All our intended policy changes were outlined in MLX 375, and we have reviewed the Regulations to ensure that they do not introduce any other changes unintentionally.

2.5 In addition, a number of respondents themselves suggested policy changes on areas that were not specifically covered in our questions. These are covered in more detail in chapter 6, but issues of particular note included the following:

- The homeopathy sector were concerned that consolidation would change the legal provisions regulating homeopathy and suggested changes to the legislation. The consolidation does not, and is not intended to, change either the current regulatory status of regulations governing homeopathic medicinal products or their sale and supply. There would need to be detailed consideration of the policy and legal implications of any reforms to homeopathy provisions, including full consultation with interested parties.
- The pharmacy sector were concerned about the impact on the supply of medicines of the repeal of the pharmacy wholesale dealing exemption under section 10(7) of the Medicines Act 1968. Section 10(7) is being repealed because it is incompatible with EU law. We have since worked extensively with pharmacy representative bodies and published a note on our website setting out how we propose to address these concerns and ensure that supply of medicines within the healthcare system is not adversely affected.
- The pharmacy sector also expressed concerns that the Regulations did not address the risk of prosecution for dispensing errors where a simple mistake has been made without other aggravating circumstances. We do not have the legal powers to consolidate, or include an amendment to, section 64 of the Medicines Act 1968 in the Regulations to respond to these concerns. However, Ministers have undertaken that we will be considering dispensing errors as part of our forthcoming wider review of sanctions and penalties in medicines legislation.

3 Ensuring that we meet the aims of consolidation

3.1 In MLX 375 we asked questions to strengthen our understanding of the impact of the consolidation. We then asked questions to ensure that the Regulations accurately consolidated existing legislation and were as clear as possible.

Question 1
Are there any benefits and costs of consolidation other than those outlined in the impact assessment? If so, what are they?

Question 2
What other evidence is there of the benefits and costs of consolidation for you or your organisation?

Question 3
Please review the sections relevant to your industry and/or body and provide comments on the accuracy of our assumptions. In particular, we would like to know the following:

3a. Approximately how much time does your firm or body currently spend every year understanding the Regulations as they are currently drafted?
3b. What change in this annual amount of time would you expect a result of the consolidated Regulations?
3c. Roughly how much time do you think your firm or body will take in familiarising itself with them?
3d. Where relevant, how much time do you estimate your firm or body will require to alter your own guidance material in response to the consolidated Regulations?

3e. What is the approximate wage rate of the staff who will engage in understanding Regulations and revising guidance?

3f. Is our assumption that small and micro businesses generally rely on their trade and professional bodies for regulatory information correct?

3.2 Over a quarter of responses provided substantive answers to these questions. We followed up by contacting other organisations to fill in gaps in our evidence base. The consultation responses and our further investigations helped us significantly in refining our impact assessment. They supported our analysis that consolidation will reduce private and public sector costs of understanding and applying the law; reduce litigation costs to the private and public sectors; and facilitate future better regulation initiatives, including reviews of policies embodied in the law. We have updated our impact assessment to take account of our findings. This will be made available online alongside the Regulations.

Question 4

Do you agree with the structure of the draft Regulations? Why, or why not?

3.3 Respondents were broadly positive about the structure and indicated that it was logical and clear, bearing in mind that legislation can be inherently complicated and detailed. This supports our belief that the consolidation process will make medicines legislation more accessible and easier to use, reducing the burdens associated with understanding and complying with the requirements of the legislation. Key points raised in responses are set out in the following paragraphs.

3.4 Terms are generally defined at the start of the Regulations, but where they have a specific meaning for an individual Part, the definition is provided at the start of that Part. Some respondents suggested that it would be helpful in those cases if the terms could be cross-referenced at the start of the Regulations. However, as the terms might have a different meaning elsewhere in the Regulations, we think that this could create unnecessary confusion.

3.5 Existing medicines legislation often just cross-refers to Directive 2001/83/EC. The Regulations instead generally transpose Directive text, so that users are not required to refer to it so often. The Regulations continue to cross-refer to European Regulations, other directives that are implemented elsewhere in UK law and the detailed annexes of Directive 2001/83/EC. Some responses suggested that this text should also be included in the Regulations. However, we do not feel this would be appropriate. Regulations have direct effect in the UK so cannot be duplicated in UK legislation, and it is not practical to provide the text to which we make cross-reference given the volume of material involved.

3.6 Some responses was asked whether the link between Part 10 (exceptions to requirement for marketing authorisations etc.) and schedule 4 [j004s] (standard provisions of licences under Part 3) could be made clearer. These provisions relate to a notification scheme under a manufacture's and wholesale dealer's licence. We have reconsidered the Regulations and believe that the current drafting is sufficiently clear. We might however be able to consider this issue further in our ongoing review of unlicensed medicines.

3.7 There were some suggestions that the Regulations could be reordered. For example, having separate Parts for wholesale dealing and manufacturing; placing Part 13 after Part 10 because products cannot be marketed and thus available for sale or supply until the packaging and leaflet have been approved; moving Part 10 closer to Part 4. However, given that responses were generally content with the structure, and that there was no clear support for any particular alternatives, we have concluded that it should not change.

3.8 Some respondents were disappointed that legislation was excluded from the consolidation, although it was not clear what legislation they meant. As we set out in MLX 375, some medicines legislation is excluded from the consolidation for technical reasons or because of parallel projects in those areas, but we will

consider consolidating these in the future where possible.[4] The consolidation is concerned with legislation that relates primarily to medicines, so some pharmacy legislation is out of scope.

Question 5

Do the draft Regulations introduce any changes other than those outlined in this document?

Question 6

Are there any drafting errors in the draft Regulations?

Question 7

Are there any provisions in the draft Regulations that could be made clearer?

3.9 Over 20 respondents suggested a range of changes to ensure that the legislation did not make unintended policy changes, to address drafting mistakes or to make the Regulations clearer.

3.10 In a number of cases where amendments have been suggested, we have not felt it is appropriate to amend the Regulations – for example, where we can see no obvious way to make improvements without compromising clarity or meaning, or where respondents seem to have misread the draft. Given the need to retain legal accuracy and avoid introducing unintentional changes in effect, it also was not always possible or desirable to provide the degree of simplicity or 'plain English' asked for. We have however made a number of changes in the Regulations and will provide further clarification in guidance. Notable changes are set out in the following paragraphs.

[4] Legislation concerning clinical trials, the administration of radioactive medicinal products and fees charged by the MHRA for the administration of procedures under the provisions being consolidated are left in place. They have been, or will be, subject to changes as part of separate policy initiatives, so it would have been unhelpful to consolidate them at this point. Various orders made under section 62 of the Medicines Act 1968 to prohibit the sale, supply and importation of products containing particular substances will also remain in force along with section 62, because they are outside the scope of EU provisions we are consolidating.

3.11 Some responses asked us to clarify the meaning of the term 'healthcare professional'. We have now defined this term under regulation 8 [j002] (general interpretation). In addition, it was pointed out that regulation 245 [j915] (supply to the public for promotional purposes) goes beyond existing law, as in effect it prohibits the supply of medicines to retailers of general sale list medicines for promotional purposes. We have addressed this point by replacing the term ‘person who is not a healthcare professional’ with ‘person who is not qualified to prescribe medicines’ in that regulation.

3.12 Regulation 21 [j203A] (exemption for certain radiopharmaceuticals) provided an exemption from the requirement for a manufacturer’s licence where a radiopharmaceutical is prepared in a hospital under certain conditions. A number of responses pointed out that the regulation included the term ‘prepared’ when we had separately proposed to replace that term with ‘manufactured’ (see chapter four). It was also suggested that the Regulations seemed to have extended the exemption to nurses, where in existing law it applies only to pharmacists. It was not our intention to extend the exemption to nurses, and we have in fact removed regulation 21. This is because we have established that the manufacturing activity for which it provides an exemption is already exempted under section 10(1)(a) of the Medicines Act 1968.

3.13 There were concerns that the definition of ‘persons qualified to prescribe or supply medicinal products’ in regulation 8 [j002] (general interpretation) was very broad and could apply to a wide range of employees not directly connected to the sale or supply of medicines, for example cleaning staff. The definition was intended only to apply to Part 14 on advertising, and has been moved to that Part for clarity.

3.14 In answer to questions 5 and 6 and elsewhere in responses, some respondents suggested that the Regulations be amended to ensure that they accurately reflect the wording of Directive 2001/83/EC. We have amended the Regulations

in a number of instances in order to ensure that they accurately consolidate corresponding provisions in existing legislation. In all other instances, we are content that they do not change the meaning of the UK legislation being consolidated. Notable changes we have made include the following:

- We have amended the definition of medicinal product in regulation 2 [j002A] (medicinal products) to ensure that it aligns with Directive 2001/83/EC by taking account of proprietary, industrially-prepared medicinal products derived from human blood or plasma as included in that Directive.
- We have redrafted regulations 51 [j102A] (accompanying material) to 58 [j105C] (application relating to new combinations of active substances) to make it clearer that they accurately implement article 10 of Directive 2010/83/EC.
- We have amended regulations 53(6) [j192] (application relating to generic medicinal products: further provisions) and 57(5) [j105B] (application relating to products in well-established medicinal use) to be clear that those Regulations are without prejudice to the law relating to the protection of industrial and commercial property.
- We have deleted regulation 54 [j105A] (meaning of “generic medicinal product”) and instead defined ‘generic medicinal product’ in regulation 49 [j101] (application of this Part) as having the meaning given in Article 10(2)(b) of Directive 2001/83/EC.
- In regulation 61(6) [j106A] (conditions of UK marketing authorisation), we have replaced the term ‘incident’ with ‘serious adverse reaction’.
- We have removed the requirement under Schedule 3 [J003s] (applications for licences under Part 3) for a manufacturer’s licence to contain the name of the medicinal product to be manufactured or assembled in addition to the form.
- We have removed the requirement in Schedule 30 [917s] (particulars for advertisements to persons qualified to prescribe or supply) that the cost of

the product must be printed clearly and placed in a certain position on an advertisement.

Question 8

What should we do to help users prepare for the entry into force of the consolidated Regulations?

3.15 There was general agreement that guidance would be necessary to support the regulations. Some responses suggested that seminars or similar events should be held to explain the Regulations. However, given that the consolidation will on the whole not change the meaning of the law, we feel that supporting guidance should be adequate. We will, however, keep this under review.

3.16 To assist interested parties with the transition from the old legislation, we will publish on our website a briefing document to introduce the Regulations and explain the changes that are being introduced. We will also update existing guidance to reflect the new legislative references and provide clarity on specific points as outlined above. In addition, we will monitor any issues interested parties raise with the new legislation, and consider whether any additional support can be provided.

Question 28

Do you agree with our proposal for keeping the consolidated Regulations up to date? Why, or why not?

3.17 There was broad support for our proposal to periodically remake the Regulations to incorporate amendments that will inevitably need to be made, and to publish on our website an informal consolidated version of the Regulations each time they are amended.

3.18 A number of respondents highlighted the need to ensure that the Regulations kept pace with changes in the NHS. The parallel timetables for the

consolidation and the Health and Social Care Act 2012 will require further updates to the Regulations to ensure that they continue to operate when the Act comes into force. Necessary changes will in the main relate to patient group directions.

4 Questions on material drafting changes

4.1 In the questions in this chapter we sought views on significant drafting changes made in the consolidation.

Question 9a
Should we add more requirements to regulation 3 [j002B] for medicinal products that fall outside the scope of the consolidated Regulations? If so, what?

4.2 Regulation 3 [j002B] (scope of these regulations) consolidates sections 9, 11 and 12 of the Medicines Act 1968. These sections contain provisions permitting doctors, dentists, herbal practitioners, nurses and midwives to conduct certain activities without obtaining the required licences, and reflect the fact that these practitioners use their professional skill and judgment in treating patients. In regulation 3 we drafted these provisions in more simple terms and presented them differently, but without aiming to appreciably change their practical effect. Questions 9a to 9c asked specific questions on regulation 3.

What respondents said

4.3 The majority were content with the requirements as drafted. The only clear theme was that it was felt that no further additions were necessary.

Our conclusion

4.4 Given the responses, we do not intend to add any more requirements.

Question 9b

We have replaced the term "prepared" that was used in a few of the exemptions in the Medicines Act 1968 with "manufactured", as we believe that term covers the making of any product. Do you see any difficulties with this?

What respondents said

4.5 We received a mixed reaction to this question. Just under half of those who responded felt that the suggested change would not be a problem, provided sufficient guidance and explanation is provided. However, others voiced concerns, including the following:

- Current practitioners understand the relevance of 'prepare' to those activities carried out under section 9 or 10 exemptions, while they will not understand the new drafting. For example there is a perceived difference between 'prepare', which is viewed as being done under section 10 exemptions, as opposed to 'manufacturing', which is undertaken under a 'specials' manufacturing licence. The changes risk confusion for professionals and the public.
- 'Prepared' and 'manufactured' are currently understood to be different scales of production. The change risks blurring understanding about volumes of production.
- The change risks blurring the boundary between the quality of products prepared under Good Manufacturing Practice standards and extemporaneous dispensing, or suggests that additional standards and requirements will be placed on extemporaneous dispensing as a result.

Our conclusion

4.6 Given the extent of the concerns that the proposed change would create unnecessary confusion, we have reverted to the use of 'prepared'.

Question 9c

Is the provision too narrow or too broad in any respect?

Summary of responses

4.7 Comments fell into a few broad areas. Some respondents were content with the provision. Some felt that it seemed to be sufficient other than definitions for terms used should be provided. A few requested more clarity on the position of dispensing doctors, and a few others suggested the provision capture homeopathic practitioners but provided no further detail.

Our conclusion

4.8 The scope provision now has been redrafted and aligns UK medicines legislation with the Directive 2001/83/EC while retaining existing exemptions from certain healthcare professionals currently covered by the Medicines Act 1968 and its supporting legislation.

Question 10

Is the new definition of advertisement sufficient to cover all relevant forms of advertising?

4.9 The Regulations update the definition of ‘advertisement’. The definition in Part 1 is based on that of ‘advertising’ in Article 86 of Directive 2001/83/EC, instead of the definition from the Medicines Act 1968. The definition refers to an ‘advertisement’ as anything designed to promote the prescription, supply, sale or use’ of a medicinal product. It continues with a non-exhaustive list of particular activities that may constitute advertising.

Summary of responses

4.10 There were over 30 responses to this question. The vast majority were in agreement. Several respondents emphasised the need to ensure current forms of electronic communication were all included and that the definition should be sufficiently broad to encompass any new developments in this area.

Our conclusion

4.11 We do not intend to make further changes to the definition of advertising, as the reference to 'anything designed to promote …', in conjunction with the definition of 'publication', is sufficiently wide to capture innovative forms of communication. We will provide clarity on electronic communications through updated guidance.

Question 11

Do you agree with the proposals for the two simplifications in relation to herbal medicines? Why, or why not?

4.12 We proposed to make the following two simplifications:

- Transpose the definition in article 1 of Directive 2001/83/EC of a 'herbal medicinal product' for all relevant medicines legislation affecting herbal medicines. Currently, the differently expressed definition of a "herbal remedy" contained in section 132 of the Medicines Act 1968 applies to some legislative provisions that are not covered by European requirements. Use of the European definition in relation to all the herbal provisions will lead to a more consistent approach.
- Simplify the sale and supply provisions relating to herbal medicines that are currently contained in sections 52 and 53 of the Medicines Act 1968 and exemptions in the Medicines (Retail Sale or Supply of Herbal Remedies)

Order 1977 (SI 1977/2130). The changes entail removing redundant provisions, the most significant of which relate to the requirement to notify the enforcement authority that a person is selling or supplying the potent herbs listed in the 1977 Order. These provisions have never been applied in practice and in our view would not add meaningfully to public health protection if they were now to be applied. Their removal represents a useful simplification of the current provisions.

Summary of responses

4.13 We received 28 responses directly addressing these proposals. Of these, 27 supported the proposals as helpful simplifications.

4.14 The one response not in support was in relation to simplification of the sale and supply provisions. This stated that the requirement was presumably to notify the regulatory authorities of person supplying potent herbs was originally established for a good reason, and the fact that it is not being adhered to is not reason enough to withdraw it.

Our conclusion

4.15 The concern raised suggests a misunderstanding of our reasons for making the proposal. As we set out in MLX 375, our view is that these provisions would not bring meaningful public health protection even if applied.

4.16 Given the otherwise overwhelming support for them, we intend to introduce the proposals.

Question 12

Do you agree with the proposal to remove the requirement to dispense certain medicinal products in fluted bottles? Why, or why not?

4.17 Existing legislation requires that certain medicines for external application be dispensed in a fluted bottle. This is for the benefit of blind and partially sighted persons in relation to medicines that are potentially toxic if used incorrectly. This practice has however fallen into disuse, and fluted bottles are no longer readily available. We therefore proposed that it should be left to the professional discretion of pharmacists to ensure that people with sight loss will use these medicines safely.

Summary of responses

4.18 Forty responses were received to this question. The vast majority supported the proposal, recognising that fluted bottles were no longer available and that alternative safeguards could be employed by pharmacists dispensing for vulnerable patients. Four respondents did not agree and were concerned that alternative tactile methods should be available to ensure that the safety of blind and partially sighted people were not compromised.

Our conclusion

4.19 Given the level of support for removal of the requirement to dispense certain medicinal products in fluted bottles, we intend to introduce the proposal.

5 Questions on review changes

5.1 In the questions in this chapter we sought views on policy changes we proposed to introduce through the Regulations.

Question 13
Do you agree with the proposal to remove statutory warnings, including for paracetamol? Why, or why not?

5.2 Existing legislation requires that standardised warnings in prescribed form, known as 'statutory warnings', are included on labelling and in patient information leaflets for certain over the counter medicines to ensure patients receive clear warnings, and that these warnings are consistent across products with the same active ingredient. We proposed to remove statutory warnings and instead rely on the use of warnings specific to products or classes of medicinal products in marketing authorisations. This was intended to allow warnings to reflect the results of user testing and be changed without the need for legislative action, and to avoid the burden of recalling medicines from the supply chain when warning requirements in legislation are changed. In particular we asked whether this was appropriate for paracetamol, which poses particular dangers in relation to overdose.

Summary of responses

5.3 In summary, most responses (28 of 34) agreed with the proposal to remove all warnings. The need for clear guidance and robust means of ensuring consistency were regular themes, in particular in relation to paracetamol.

5.4 Six respondents, including the Pharmaceutical Society of Northern Ireland and three NHS bodies, supported retaining the statutory warning for paracetamol to ensure that every paracetamol product carries the same messages based in

legislation. A number of other respondents also expressed reservations about the removal of paracetamol warnings from statute, particularly highlighting the need for extra reassurance that the safety benefits of these important warnings were not lost for any reason.

Our conclusion

5.5 We intend to remove statutory warnings for products other than paracetamol. We will ensure that guidance for companies and a means of enforcement is available if a consistent approach cannot be achieved and results in significant risks to public health or patient safety.

5.6 We intend to retain statutory warnings for paracetamol due to the concerns specific to the product. In addition, we have used this opportunity to update the existing warnings for paracetamol to take account of user-testing.

Question 14
Do you agree with the proposals to change the persons appointed process? Why, or why not?

5.7 The Regulations consolidate provisions requiring the licensing authority to appoint a panel to review their licensing decisions at the request of applicants in certain circumstances. Existing legislation excludes former members of the medicines advisory bodies from the membership of this panel. This restriction was intended to address the risk of members having a conflict of interest. In MLX 375, we proposed to revise the restriction so that former members of medicines advisory bodies can be appointed providing that one year has elapsed since their term of office on any such body has expired.

Summary of responses

5.8 Eighteen respondents answered this question, of which 17 gave their support. One respondent (the Proprietary Association of Great Britain) questioned whether one year is a sufficiently long period, as recent members might be familiar with the cases even if they were not party to formal discussions about them. They suggested that, in order to ensure balance, the panel should not be comprised solely of ex-members of advisory bodies or expert advisory groups.

Our conclusion

5.9 Given the clear support among respondents, we intend to introduce this change. We should point out that the Chair is a lawyer and will be independent of ex-advisory body members; also, each panel is chosen for its expertise depending on the case. However, we will seek to ensure that there is a balance of panel members.

Question 15
Do you agree with our proposals to remove exemptions that are obsolete or no longer relevant? If not, why?

5.10 Existing medicines legislation allows health professionals and others to sell, supply and/or administer medicines by way of exemptions from the usual restrictions. We made a number of proposals to remove exemptions that are obsolete or no longer relevant. This was intended to introduce small but beneficial changes to reflect modern clinical practice.

Summary of responses

5.11 The responses supported the removal of the following obsolete/irrelevant provisions relating to:

- persons providing poultry vaccination services or selling and supplying poultry vaccines
- people selling or supplying medicines to the British Standards Institution
- sale or supply of Amyl Nitrite by pharmacists
- a provision allowing people to administer parenteral (injectable) medicines if they are, and were at 11 February 1982, doing so in the course of a business in the field of osteopathy, naturopathy or other similar field except chiropody.

5.12 Several replies disagreed with the proposal to remove a provision allowing sale or supply of medicines to people employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977 and their equivalents in Scotland and Northern Ireland. This was because they thought it was still relied upon and not obsolete. There was otherwise broad support for these changes.

Our conclusion

5.13 We intend to remove all the exemptions as proposed, with the exception of the provision allowing sale or supply of medicines to people employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977 and their equivalents in Scotland and Northern Ireland.

Question 16a

Do you agree with our proposal to extend to other organisations concerned with research the provisions allowing sale or supply of medicines to universities and institutions concerned with research or higher education. Why, or why not?

Question 16b

If such a change were introduced, should it be subject to the exclusion of any classes of medicines in addition to controlled drugs? Why, or why not?

5.14 The proposal was supported by the great majority of replies with various caveats, for example relating to provision of guidance, identifying who should be eligible and legally identifying persons who receive supplies to ensure a safe supply chain.

5.15 Several responses from pharmacy interests questioned the proposal on the grounds that the supply would be made under section 10(7) of the Medicines Act 1968, which we intend to repeal. Section 10(7) does not apply in these circumstances, as it covers wholesale transactions.

5.16 In relation to possible exclusions, several replies suggested that cytotoxic and teratogenic medicines should be included in this category because of the risks to the persons handling them. The British Oncology Pharmacy Association would be concerned over the governance for handling of cytotoxics but they were aware that cytotoxic drugs are obtained in this way for research. The Royal Pharmaceutical Society felt unable to comment on the classes of drugs that should be available prior to knowing the details of the intended use and the other organisations referred to. Balanced against this, other responses (for example the Association of the British Pharmaceutical Industry) took the view that there should be no additional restrictions.

5.17 Alliance Boots said the supplier (normally a pharmacist) would be expected to use his or her professional judgment before making a supply of a medicine that was potentially dangerous or liable to misuse. If necessary, the institution making the request could be asked to set out the nature of the need, possibly as part of the signed order.

Our conclusion

5.18 Given the significant level of support, we intend to extend the provision in question to other organisations concerned with research. We note the suggestions by some respondents in relation to cytotoxic and teratogenic medicines. On balance, however, we take the view that the existing safeguards are sufficient and that these classes of medicines should not be excluded.

Question 17
Should the limit on the size of ampoule in which water for injection can be supplied be extended to 5ml? Why, or why not?

5.19 Water for injection can be supplied in ampoules containing a maximum of 2ml of water by people engaged in the provision of lawful drug treatment services. We sought views on increasing the limit to 5ml. The aim was to facilitate the provision of lawful drug treatment involving water for injection, providing flexibility for providers of drug treatment services.

Summary of responses

5.20 The proposal was generally supported. The Royal Pharmaceutical Society said introduction of the 5ml ampoule will allow flexibility of supply, ease of administration and improved patient safety with the use of plastic rather than glass ampoules or containers. These views were reflected in other responses. For example, the Secure Environment Pharmacists Group thought that the proposal would facilitate continuity of care during periods where smaller sizes were unavailable. They also thought there should be guidance by professional bodies that the most appropriate size should be usually provided, given that providing a larger volume constitutes a risk.

5.21 A few respondents thought that the larger size should only be supplied if the smaller ampoules were unavailable. Only one reply disagreed with the

proposal. This was because of the theoretical risk arising from sharing the 5ml ampoule. In contrast, another response expressed the view that the benefits of sterile water outweighed the theoretical risks of sharing.

5.22 Balanced against the generally positive response above, further informal consultation with drug treatment interests showed a more cautious approach. The National Needle Exchange Forum said that none of their members saw any need or benefit from making amounts larger than 5ml available. Exchange Supplies said they chose not to sell 5ml ampoules because of the risk of blood borne virus transmissions. Daniels thought the problem was due to the smaller size being only available in glass so some services preferred to supply plastic ampoules.

Our conclusion

5.23 We do not intend to introduce the change. Given the mixed views, the Department of Health has advised us that they require further assurance of the balance of health harms related to the expansion of the current limit.

Question 18a
Should the existing exemption allowing the administration of adrenaline by injection by any person for the purpose of saving life in an emergency be amended to allow injection up to and including 1 in 1000?

Question 18b
Should an increased range of adrenaline preparations be subject to any limitations on the route of administration. Why, or why not?

5.24 In Article 7 of the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830), there is a list of parenteral medicines that can be administered by any person for the purpose of saving life in an emergency. The list includes adrenaline injection of 1 in 1000 (1mg in 1ml). We proposed to amend this

provision to allow for the use of preparations *up to and including* 1 in 1000 (1mg in 1ml). This was because other preparations are now available which are more suitable for administration to a child.

Summary of responses

5.25 There were no objections to amending the existing exemption. A number of responses noted that this would make it easier to give children an appropriate dose. However, the Resuscitation Council questioned the proposed wording and suggested that it needed to be made clearer.

5.26 On the question of limiting the route of administration, several replies thought that adrenaline for emergency use by anyone should be restricted to intramuscular use only. Others thought that there was no need for restrictions if Adrenaline was administered by trained professionals and/or there was robust guidance in place to cover the various routes of administration.

Our conclusion

5.27 We intend to introduce the change. We agree with the Resuscitation Council that the wording should be made clearer and have amended the entry for adrenaline in the draft consolidated legislation to ‘Adrenaline 1:1000 up to 1 mg for intramuscular use to treat anaphylaxis’.

5.28 With regard to limitations on the route of administration, our view is that this exemption applies to anyone administering in a life-threatening situation. There are currently no restrictions on the route of administration, but we will specify intramuscular administration only in order to clarify the law.

Question 19

Should paracetamol and ondansetron be added to the list of medicines that can be administered parentally by registered ambulance paramedics on their own initiative? Why, or why not?

5.29 The Joint Royal Colleges Ambulance Liaison Committee (JRCALC), the expert national body on ambulance issues, had requested that intravenous paracetamol and ondansetron be added to the list of parenteral medicines which can be administered by registered ambulance paramedics on their own initiative. We asked whether this would be appropriate.

Summary of responses

5.30 This proposal was generally supported, although a number of concerns were raised regarding the individual medicines. The Scottish Ambulance Service thought the proposals represented a positive change. The Resuscitation Council noted that both were effective drugs and in the case of paracetamol, would reduce the amount and times it was used.

5.31 Two responses opposed the addition of paracetamol. NHS Glasgow and Clyde thought there was no clear indication as to which clinical situations paramedics would wish to administer IV paracetamol. If the oral or rectal routes are compromised then other analgesics could be used. As paracetamol must be dosed on weight, with the dose reduced for patients <50kg or with liver impairment, there is the potential for patients to be given the wrong dose, assuming that more paramedics will not have facilities to weigh patients. One response objected to the addition of ondansetron on the grounds that there are now available oral melt or dispersible versions of ondansetron, which act rapidly and would be relatively safer to use by ambulance paramedics than having to prepare and give an injection in an emergency situation. Another thought it was unnecessary. While supporting the proposal for ondansetron, the

Royal Pharmaceutical Society noted, as did some other replies, that it was for an off-label use.

5.32 The concerns raised tended to be around paracetamol. For example, the Royal Pharmaceutical Society said that patient safety could be compromised for quicker drug access. Many patients take paracetamol routinely for pain and may have ingested their daily dose prior to the ambulance arrival, in a confused or vulnerable patient this information may not be conveyed to the ambulance paramedic and additional paracetamol be given leading to a potential overdose. Other responses shared these concerns and also noted potential difficulties for use in children due to the more complex dosing system as well as those weighing under 50kg.

5.33 The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) have advised us that that they have carefully considered the adverse incidents relating to IV paracetamol. These incidents tended to relate to repeat dosing of paracetamol and also to patients with rare genetic errors of drug metabolism.

5.34 On a separate issue, the Resuscitation Council (UK) commented that there were several medicines on the paramedics' list which were no longer available or indicated for paramedic use. These were Bretylium, nalbuphine, Polygeline and sodium bicarbonate. The Council also suggested that tramadol should replace nalbuphine. JRCALC have agreed with these comments. In the case of tramadol, they note it is a useful alternative as an analgesic which is not a controlled drug. They thought that if IV paracetamol were to be made available, this may mean the inclusion of tramadol was less important.

Our conclusion

5.35 We intend to introduce the proposal. We note the concerns about paracetamol. However, given the advice of the JRCAL, and the context in which a single dose of IV paracetamol will be administered by paramedics, we consider that

the risk of adverse incidents will be extremely low. The dosage regime is clearly laid out and does not require any mathematical calculations to be made in the emergency situation.

5.36 In line with the response from the Resuscitation Council (UK), we intend to remove from the paramedics' list Bretylium, nalbuphine, Polygeline and sodium bicarbonate. As IV paracetamol will be available, we do not intend to add tramadol to the list.

Question 20

Should people be allowed to obtain water for injection for purposes other than parenteral administration without a prescription? Why, or why not?

5.37 Water for injection is classed as a Prescription Only Medicine because it is for parenteral administration. We proposed to allow persons who require water for injection (WFI) for purposes other than parenteral administration to obtain it without a prescription. This proposal was intended to address situations where the product is required, for example, to inflate balloons in catheters but there are no lawful means of obtaining stocks, due to its prescription only status.

Summary of responses

5.38 There was wide support for this proposal. Several respondents stated that it would improve patient care, for example if a nurse could purchase the water for injection required for a catheter instillation, rather than travel miles to a base to obtain it.

5.39 The Association of the British Pharmaceutical Industry was one of a few respondents who were concerned about the risk of potential misuse by drug addicts. They thought it appeared from the document that the proposal is to allow the water for injection to be available without pharmacist supervision

(general sale list status). However they believed that pharmacy only status was a more appropriate option.

Our conclusion

5.40 We intend to introduce the proposal. With regard to the Association of the British Pharmaceutical Industry's concern, it is intended that the pharmacist would make the sale. We will liaise with the Royal Pharmaceutical Society about producing guidance in this area.

Question 21

Should pharmacists be allowed to sell or supply water for injection without a prescription for purposes other than parenteral administration or for use as a dilutant where no dilutant has been specified by the prescriber? Why, or why not?

5.41 We proposed to allow pharmacists to sell or supply WFI as a dilutant where no dilutant has been specified by the prescriber. This was intended to avoid unnecessary delay in administering medicines when a dry powder for injection has been prescribed without the necessary dilutant.

Summary of responses

5.42 This proposal was widely supported. The only significant issues raised related to extending the proposal to cover Sodium Chloride 0.9% and requests to allow diluents to be supplied at NHS expense where appropriate.

Our conclusion

5.43 We intend to introduce the proposed change. We plan to raise the issues of Sodium Chloride and supply of dilutants at NHS expense with the Department of Health.

Question 22

Should holders of the Council's Advanced Life Support (ALS) certificate be allowed to administer adrenaline and amiodorone in emergencies involving cardiac arrest? Why, or why not?

5.44 Following discussions with the Resuscitation Council (UK), we proposed to allow holders of the Council's Advanced Life Support (ALS) certificate to administer adrenaline and amiodorone in emergencies involving cardiac arrest. Treatment of cardiac arrest is very time-sensitive, and there are a large number of potential rescuers (doctors, nurses and paramedics are the main groups) not all of whom can prescribe. It is also becoming more common for resuscitation teams to be made up of non-doctors. The ALS course specifically covers the use of adrenaline and amiodorone in cases of cardiac arrest.

Summary or responses

5.45 This proposal was well supported and there were no objections. Several respondents, including the NHS Scotland Directors of Pharmacy, referred to the fact that adrenaline is already covered under the Article 7 list of medicines that anyone can administer in an emergency. Other issues raised included requests for clarification around whether ALS providers would seek personal supplies of the medicines, the need for clear national guidance and a request from the Neonatal and Paediatric Pharmacist group to include holders of the paediatric ALS qualification.

Our conclusion

5.46 We intend to introduce the proposed change. Although adrenaline is already covered under the Article 7 list, this is primarily for treatment of analphylaxis. Adrenaline for treatment of cardiac arrest is administered intravenously and requires specific training. This is why the Agency is proposing a specific

exemption for ALS providers and, at the same time, clarifying that the Article 7 exemption applies to intramuscular administration of adrenaline. This is in line with advice from the Resuscitation Council.

Question 23

Do you agree with the proposal to retain the general structure and requirements of Patient Group Directions (PGDs) in their current form, and to retain the principle that only registered health professionals should be able to use PGDs?

5.47 We proposed to retain the general structure and requirements of PGDs on the basis of the results of earlier informal consultation.

Summary of responses

5.48 Nearly all of those who specifically commented agreed with the proposal to retain the structure and requirements for PGDs, although the Resuscitation Council observed that they were often used in circumstances where they were not needed and often where there were already exemptions.

5.49 A majority also supported the principle that use of PGDs should be restricted to registered health professionals. The Pharmacy and Medicines Directorate Grampian thought that physician's assistants should be able to use PGDs, as did one other reply. A few replies thought that there were other support staff who could benefit from access to PGDs.

5.50 Several replies, including the Association of Teaching Hospital Pharmacists, thought that in a few legitimate circumstances there could be grounds for including unlicensed medicines. The Mantoux test was cited as an example. It is a standard diagnostic test which is well-established and commonly used but not available as a licensed medicine. Clindamycin oral suspension was another. One response asked that if such products are never to be available in UK as licensed products, should they be allowed under PGDs. The Association

of the British Pharmaceutical Industry, on the other hand, took the view that unlicensed products should not be allowed.

Our conclusion

5.51 We intend to retain the existing structure for PGDs.

5.52 We considered the issue of extending PGDs to a limited list of unlicensed medicines when we consulted informally on PGDs in 2010. We concluded that even if extending PGDs to a limited list of unlicensed medicines was justified, medicines legislation would not support it. This is because current provisions for the supply of unlicensed medicines are based around a prescriber ordering an unlicensed medicine to meet the special clinical needs of an individual patient, whereas PGDs are aimed at groups of patients who may not have been identified beforehand.

Question 24
Should NHS bodies be able to supply medicines in accordance with the written directions of an independent nurse, pharmacist or optometrist prescriber? Why, or why not?

5.53 Under existing legislation, NHS bodies can supply medicines in accordance with the written directions of a doctor or dentist without needing to do so from registered pharmacy premises. We proposed to enable these bodies to supply medicines similarly where the directions are written by other independent prescribers.

Summary of responses

5.54 This proposal was aimed at extending an existing provision which applied to doctors and dentists. Effectively, it would allow prescribers to prescribe medicines without meeting the usual prescription requirements in certain

settings. The majority of replies supported it. No major themes or issues emerged.

Our conclusion

5.55 Given the general support, we intend to introduce the proposal.

Question 25

Should independent hospitals, clinics etc. in England continue to be allowed to use PGDs but by reference to them being registered for the following regulated activities in England?

- **treatment of disease, disorder or injury**
- **assessment of persons under the Mental Health Act 1983**
- **surgical procedures**
- **diagnostic and screening procedures**
- **midwifery services.**

Why, or why not?

5.56 In England, independent hospitals, clinics and medical agencies can sell, supply and administer medicines under a PGD by way of exemptions from the usual restrictions. body. In England, they have to be registered with the Care Quality Commission (CQC). We proposed the changes in question 25 in order to reflect changes made by the CQC to the way in which private healthcare providers are registered in England – namely, that independent hospitals, clinics and agencies are no longer required to register, and that registration is now by reference to regulated activities

Summary of responses

5.57 There were few substantive comments on this proposal, but it was generally supported. The Royal Pharmaceutical Society said it was vital that the Medicines Act 1968 is not amended piecemeal to correspond to individual

countries' policy intent. The Care Standards Act 2000 is still applicable in Wales, and as many companies work across borders it is difficult to work within and especially uphold compliance with the differing legislation. As the Medicines Act 1968 is intended to be UK-wide they would request that the MHRA consults with the appropriate organisation in the devolved countries – Healthcare Inspector Wales, and Health Improvement Scotland – to gain UK agreement with such specific legislation.

Our conclusion

5.58 With regard to the suggestion that services eligible to register with the CQC are suitable for inclusion in any exemption that allows the development of PGDs, we were conscious when drawing up the list of regulated activities that the CQC regulate a wide range of services. Our intention was to capture those independent providers who are currently able to develop their own PGDs and look at other providers as part of other work we intend to take forward after consolidation.

5.59 The Royal Pharmaceutical Society's comments about piecemeal amendment of the Medicines Act 1968 relate to a long standing issue about the ability of healthcare providers in one country to operate services in another. These will be addressed in the context of further work we are undertaking in relation to PGDs.

Question 26

Should dental practices and dental clinics registered with the CQC or private dentists registered with its equivalent in Wales be able to sell, supply or administer medicines under PGDs? Why, or why not?

5.60 PGDs can already be used in dental practices and clinics registered with the CQC, or private dentists registered with its equivalent in Wales, where NHS-funded services are being provided. We made the proposal under question 26

because most primary dental care providers treat NHS and private-sector patients in the same setting, and in these circumstances it makes little sense to differentiate between the two. We also understood that the existing legal situation had caused confusion, since dental therapists and hygienists were in 2010 added to the list of health professionals who are able to use PGDs.

Summary of responses

5.61 There were few substantive replies to this the proposal, but it was generally supported. Several respondents thought medicines used under the PGDs ought to be restricted to those that were within a dentist's competency. Rowlands Pharmacy was opposed to the proposal on the grounds that there would be no separation of prescribing and supply. Community Pharmacy Scotland believed that the pharmacy is the most appropriate place for the sale and supply of medicines not used for immediate treatment for example painkillers. They thought that the use of PGDs in isolation of an accurate picture of medicines taken by a patient may lead to unacceptable risks and they would therefore not support the use of PGDs for non-immediate treatment.

Our conclusion

5.62 Given the general support, we intend to introduce the proposal.

Question 27
Do you agree with the proposal to facilitate the optimisation of medicines use? Why, or why not?

5.63 Existing legislation provides that if, in the exercise of professional skill and judgement they believe it is appropriate to do so, a pharmacist may make changes to a prescription relating to the name of the product or its common name; directions for use of the product; and precautions relating to the use of the product. This enables pharmacists to change a prescriptions in order to

'optimise' patients' use of medicines, for example by changing the dose or duration for which the medicines is taken, but keeping within the overall ceiling of the dosage or timeframe originally prescribed.

5.64 The legislation currently states that the pharmacist can only make such changes if they have attempted to contact the prescriber but have been unable to do so. It was proposed to remove this requirement, with the aim of enabling pharmacists to use their expertise and professional judgement to make such changes in a more timely way.

Summary of responses

5.65 We received 31 responses to this proposal. The pharmacy sector – including the GPhC, RPS and PSNI, and various other representative bodies and NHS pharmacy groups – supported it as a positive development for pharmacists and patients. A number of responses stressed the need for professional guidance to support the change if introduced – for example, to give criteria for pharmacists decisions, clarify lines of accountability when changes are made to prescriptions and ensure that patient records are updated as necessary.

5.66 Conversely, some concerns were raised by the pharmaceutical industry that (a) the proposal would facilitate generic substitution, albeit with pharmacists still needing an incentive to undertake substitution; and (b) there would be safety risks if pharmacists made substantive changes to the prescription without consulting the prescriber.

Our conclusion

5.67 With regard to the first concern raised by the pharmaceutical industry, there is no intention behind the proposal to facilitate generic substitution at the discretion of a pharmacist without the agreement of the prescriber under medicines legislation. The Government's position on generic substitution has

not changed since its response to its 2009 consultation on this issue. Having reviewed the relevant legislation, we are also comfortable that the change does not inadvertently facilitate generic substitution. The amendment is to the packaging requirement provisions. As such, it permits the pharmacist to make changes to the dispensing label as outlined above, but not to dispense a medicine other than that specified on the prescription.

5.68 With regard to the second concern, the proposal is in keeping with the direction of travel of health services towards an increased clinical role for pharmacists in supporting people to get the most from their medicines, encouraging the use of pharmacist's skills and professional judgement. The Department of Health – who proposed the change – will be working with the regulatory and professional bodies to ensure that robust guidance is in place that would support the decisions made by pharmacists in this area. This is in line with the Government's approach of relying on professional judgement where appropriate.

5.69 Given this, and the otherwise clear support from interested parties, we intend to introduce the proposed change.

6 Further comments received

6.1 We received a large number of comments on areas other than those on which we asked specific questions. Notable issues are outlined below.

Repeal of section 10(7) of the Medicines Act 1968

6.2 Section 10(7) of the Medicines Act 1968 provides an exemption which permits pharmacists to trade in small quantities of medicines without a wholesale dealer's licence. MLX 375 set out our intention to repeal section 10(7) because it is not compatible with EU law. This followed earlier consultations on this issue as part of our review of the medicines supply chain.

6.3 We received a number of comments on this issue. A number of pharmacy trade, NHS and professional bodies expressed concern about the impact of removing the exemption on pharmacy supply of medicines to other bodies for public health needs. There was some support, mostly from the pharmaceutical industry, for the change on the condition that it did not prevent supply where there is a clear public health need.

6.4 Since MLX 375 was published we have had substantial discussions with pharmacy bodies. We recently published on our website a note setting out how, as the regulator responsible for the enforcement of medicines legislation, we propose to address the implications of the necessary repeal of the exemption to ensure that there will be no adverse impact on the supply of medicines within the UK healthcare system.

Homeopathy

6.5 The homeopathic medicines sector expressed concerns that the consolidation should allow the continuation of pharmacy supply of unlicensed homeopathic

medicines by present routes. Points made by respondents include the following:

- Section 10 of the Medicines Act 1968 should be consolidated and reviewed in order to ensure the continuation of the present routes of supply of unlicensed homeopathic medicines. In particular, enforcement of section 10(4)(a) would restrict the supply of unlicensed homeopathic medicines to 'face to face' supply only.
- Since the abolition of the non-orthodox practitioner assembly licence, regulation 281[j706] (powers of inspection, sampling and seizure) makes non-statutory regulated homeopaths vulnerable to possible inspectorate visits concerning their long term practice of using unlicensed medicines for their patients. This could be used by anti-homeopathy complainants to force an issue knowing that the MHRA have to respond to all complaints.
- Enforcement of regulation 195 [j512] (exemptions for medicinal products at high dilution) could imply that no member of the public or 'healthcare provider' could advise the use of an unlicensed homeopathic medicine as a result of a phone call or internet conversation, where this has been routine practice for many years. Regulation 195 mentions 'in that person's presence'. As for pharmacies, this would also restrict homeopathic practitioners from being able to prescribe over the phone or internet. Telephone support is an important part of their practice.
- The requirement in section 10(4)(a) of the Act that a person is 'present in the pharmacy at the time of the request' for a product should be removed. Alternatively, homeopathic medicines prepared at a dilution of one part in a million (6X) or greater should be exempted from several provisions, in particular section 10 and regulation 195. In response to question 6 on drafting errors, nearly all the response suggested in relation to regulation 195 that one part per million is a 6x dilution, not 6c.

- Parts 1,2,3,4 of schedule 21 [j512s] (medicinal products at high dilutions) are historic lists and need to be reviewed in consultation with homeopathic pharmacies and homeopathic regulatory bodies.
- The consultation should only be open to those affected, i.e. those who fall into one of the categories listed in paragraph 3.16 of MLX 375.

6.6 In summary, the consolidation does not, and is not intended to, change either the current regulatory status of regulations governing homeopathic medicinal products or their sale and supply. Nor do we intend to change our current approach to enforcement of these provisions. There would need to be detailed consideration of the policy and legal implications of any reforms to homeopathy provisions, including full consultation with interested parties.

6.7 Section 10 of the Medicines Act 1968 exempts pharmacists from the requirement for a marketing authorisation and/or manufacturer's and wholesale dealer's licence in certain circumstances. As we were considering whether we could consolidate them without compromising their legal effect, section 10 and section 15 (which provides the powers to modify the exemptions in section 10) were not consolidated in the version of the Regulations on which we consulted. We have since concluded that we cannot safely consolidate sections 10 and 15 without compromising their legal effect. These sections will therefore be retained, with section 10 amended so that it provides exemptions from the Regulations rather than existing medicines legislation.

6.8 Separately, regulations 195 and 281 accurately consolidate corresponding provisions in existing medicines legislation. Responses suggesting that regulation 195 made an error in referring to dilutions were incorrect: the regulation correctly states that one part in a million is a 6x dilution, and that one part in a *million million* is a 6c dilution. Similarly, as set out below, the non-orthodox practitioner scheme has not been abolished.

6.9 Finally, with regard to views about whom the consultation should have been open to, MLX 375 was a public consultation and as such any interested parties could provide a response. We welcome consultation responses from all interested parties and take each response on its own merits.

Product licences of right and non-orthodox practitioners

6.10 Due to ongoing policy considerations, provisions for the product licence of right (PLR) regime[5] and non-orthodox practitioner (NOP) scheme[6] were not included in the draft Regulations accompanying MLX 375. A number of responses stated that the PLR regime needs to be retained in order that products within it still have a regulatory home.

6.11 We have subsequently concluded that we will save the existing legal basis for PLRs and NOPs so that they remain in force when the Regulations come into force. We have inserted provisions in Schedule 32 [j992s] (transitional provisions and savings) of the Regulations to this effect. Our intention remains to complete a review of PLR and NOP provisions with a view to the regulation of, respectively, products and practitioners under these schemes being more appropriately delivered through other means.

Advisory bodies

6.12 In MLX 375, we stated that provisions for the following bodies would be removed from medicines legislation through the consolidation, as part of the Government's review of advisory non-departmental public bodies:

[5] PLRs were issued to all medicinal products on the market at the time that the Medicines Act 1968 was implemented (1971). Most categories of medicine were subsequently reviewed by the early 1990s and products were granted a full product licence or the PLR was revoked.
[6] A NOP may be anyone other than a registered doctor, dentist or pharmacist. The exemption permits the NOP, subject to a number of conditions, to mix and assemble certain medicines without the need for a product licence.

- Herbal Medicines Advisory Committee (HMAC)
- Advisory Board on the Registration of Homeopathic Products (ABRHP)
- Independent Review Panel for Advertising
- Independent Review Panel for the Classification of Borderline Products.

6.13 All four bodies would, though, continue to operate with the same functions, as appointees of the MHRA as the licensing authority.

6.14 The following concerns were raised by some respondents:

- The independence and expertise of the panels and members were fundamental to the functioning of these panels.
- The removal of the protection afforded to companies by the statutory basis of the Borderline and Advertising Panels would be unacceptable (Proprietary Association of Great Britain).
- Some clarification on the appointments process to the panels was felt necessary.

6.15 The changes made will not alter the functions of these panels in practice. We fully support the need to safeguard their independence, and of being able to draw on the relevant expertise for each case. With regard to the Proprietary Association of Great Britain's concern, a legal basis for review of borderline decisions will be retained and the legislative requirement providing for a review of an advertising case is unchanged. While the Regulations do not provide specifically for an Independent Review Panel on the Classification of Borderline Products, they do consolidate provisions in existing legislation that require the appointment of a review panel to advise on provisional determinations.

NHS/health/pharmacy developments

6.16 We received a number of comments on wider issues of NHS and pharmacy developments which are outside the scope of the consolidation.

6.17 As set out above, the consolidated Regulations will be amended in due course in order to ensure that they reflect changes introduced by the Health and Social Care Act 2012. The broader comments have been noted and will be kept under review in future work.

Dispensing errors

6.18 We explained in MLX 375 that we do not have the legal powers to consolidate, or include an amendment to, section 64 of the Medicines Act 1968 in the consolidated Regulations to respond to concerns of pharmacy interests about the risk of prosecution for dispensing errors where a simple mistake has been made without other aggravating circumstances. A number of responses expressed concerns and urged us to introduce legislative changes as soon as possible.

6.19 A possible amendment to the Medicines Act 1968, extending the possibility for someone facing prosecution for breach of section 64 to mount the defence that they had exercised all due diligence to avoid committing the offence, was tabled by Lord Clement-Jones and debated during the passage of the Health and Social Care Act 2012. However, Lord Clement-Jones indicated that, notwithstanding the extensive dialogue that had taken place with pharmacy bodies, there had not been a sufficient measure of agreement to proceed and the amendment was withdrawn. Ministers have undertaken that MHRA will be considering dispensing errors as part of the forthcoming wider review of sanctions and penalties in medicines legislation. In the meantime, Crown Prosecution Service guidance for Government prosecutors in England and

Wales aims to enhance prosecutors' understanding of the issue and promotes liaison with MHRA where a prosecution is under consideration.

Labelling, leafleting and packaging

6.20 A few responses suggested a more flexible approach to the requirement for patient information leaflets with monitored dosage systems (MDS) or multi-compartmental compliance aids (MCA), on the basis that this is not always practical for pharmacists or necessary to ensure patient safety. In addition, it was suggested that there should be a more flexible labelling requirements for MDS and MCA, because it could be difficult to attach full labels given the limited space available. Responses suggested that, instead, basic information could be provided on the labels and then additional information and cautions provided on an accompanying card.

6.21 We have concluded that the legislative requirements should remain and that how the pharmacist achieves compliance with the requirements should be addressed in guidance, as has previously been issued by the Royal Pharmaceutical Society and the National Pharmacy Association.

Child resistant containers

6.22 The Regulations consolidate the requirement in existing legislation that – with some exceptions – medicinal products in certain forms must be sold in child resistant containers if they contain asprin, paracetamol or more than 24mg of elemental iron.

6.23 Some responses suggested that this requirement should be extended to all medicines or, in one case, all liquid preparations. We feel this would be disproportionate and create an unnecessary burden. Child resistant containers are a last resort and should only be applied to medicines that will cause serious harm if ingested by a child.

Obligation to ensure continued and appropriate supply of medicinal products

6.24 The Regulations consolidate the existing requirement for marketing authorisation holders to take all reasonable steps to ensure appropriate and continued supplies of the product to which the authorisation relates to pharmacies and persons authorised to supply the product, so that the needs of patients in the UK are met.

6.25 Some responses suggested that this obligation should be extended to require manufacturers to inform the Department of Health of any planned withdrawals of a product from the market, in order to help address problems with the medicines supply chain. In addition, one respondent suggested that we should define 'all reasonable steps'.

6.26 We do not believe that it is appropriate at this point to add the suggested obligations in this area. There are already legal obligations on manufacturer's licence holders to help ensure continuous supply, and introducing the suggested obligation in the consultation responses would go beyond the requirements of Directive 2001/83/EC. We recognise the ongoing difficulties with the supply chain, and we are working with the Department of Health and organisations representing the supply chain to better understand and mitigate the impact of these difficulties to ensure that patients receive the medicines they need. In February 2011, this group published joint guidance on this issue.[7] We will continue to monitor this area and will take account of ongoing work by the European Medicines Agency to explore what more can be done to further assure supply.

6.27 We also do not consider that it would be possible to define 'all reasonable steps' in a helpful way in legislation. The Association of the British

[7] This guidance is titled *Best practice for ensuring the efficient supply and distribution of medicines to patients* and is available on the Department of Health website.

Pharmaceutical Industry does, though, provide best practice guidance on this term.

‘Specials’ and unlicensed medicines

6.28 Separately from consolidation, we have been undertaking a review of the ‘specials’ scheme that allows the manufacture or import of unlicensed medicines commission by doctors or other authorised healthcare professionals to meet the special clinical needs of their individual patients.

6.29 There was a suggestion that specials provisions should be removed from the consolidation, as it was difficult to review them while the MHRA is undertaking its separate ongoing review of unlicensed medicines. However, we feel that this would be unhelpful and detract from the consolidation, as users would need to cross-refer between the existing specials legislation and the Regulations.

6.30 In addition, a change was requested to prevent the importation and supply to NHS organisations of unlicensed medicines for reasons of cost rather than clinical need. Similarly, another response suggested the creation of an offence of supply of information by a doctor or pharmacist that is misleading about the existence of a special need of a patient, in order to address the use of unlicensed medicines as cheaper alternatives to licensed versions.

6.31 It would not be appropriate to introduce any policy changes to the specials regime without further detailed consideration and full consultation with interested parties. However, we will take account of these views in our review of unlicensed medicines.

Mock-up requirements

6.32 There were a number of calls for a more flexible approach to the requirement for mock-ups for new authorisation applications and complex or extended procedure variations.

6.33 In April 2012 we published guidance for new marketing authorisation applications, including extension applications and Type 1B and Type II variation applications requiring changes to labelling and patient leaflets. This is designed to ensure proportionate requirements in this area and reduce unnecessary burdens on industry.

Annex – Respondents to MLX 375

Thirteen respondents wished to remain anonymous and so are not listed below.

Organisations/companies

Advertising Standards Authority
Ainsworths
Alcon
Alliance Boots
Anthroposophic Medical Association
APPLET Network
Association of Pharmaceutical Specials Manufacturers Limited
Association of Teaching Hospital Pharmacists
Association of the British Pharmaceutical Industry
Association of Traditional Chinese Medicine and Acupuncture UK
Asthma UK
Ayurvedic Trade Association
Berkshire Local Pharmaceutical Committee
BioIndustry Association
British Association of Anthroposophic Pharmacists
British Association of Homoeopathic Manufacturers
British Association of Pharmaceutical Wholesalers
British Generic Manufacturers Association
British Homeopathic Association
British Medical Association
British Oncology Pharmacy Association.
Brook
Children's Allergy Clinic
Colchester Hospital University NHS Foundation Trust
College of Optometrists & Optical Confederation

Community Pharmacy Scotland
Council for Anthroposophic Health and Social Care
Daiichi Sankyo UK Ltd
East & South East England Specialist Pharmacy Services
Epilepsy Action
European Herbal and Traditional Medicine Practitioners Association
European Medicines Group
Faculty of Homeopathy
FRIENDS of the Royal London Hospital for Integrated Medicine
General Pharmaceutical Council
Grünenthal Ltd
Guild of Healthcare Pharmacists
Hampshire and IOW Local Pharmaceutical Committee
Hampshire Hospitals NHS Foundation Trust
Health Food Manufacturers Association
Health Protection Agency
Herbal Forum
Idis
Independent Pharmacy Federation
Kidney Alliance
LEO Pharma
Lilly
Lloydspharmacy
London School of Medicine and Dentistry
Lothian Area Pharmaceutical Committee
Maritime & Coastguard Agency
Neonatal and Paediatric Pharmacists Group
NHS Greater Glasgow and Clyde
NHS Kent and Medway
NHS Pharmaceutical Quality Assurance Committee
NHS Scotland Directors of Pharmacy
NHS SHA Leads Group (England)

NHS Sheffield
NHS South Central Chief Pharmacists Network
Norgine Pharmaceuticals Ltd
Novo Nordisk Ltd
Proprietary Association of Great Britain
Parkinsons UK
Patients and Friends of Anthroposophic Medicine
Penlan Healthcare Limited
Pharmaceutical Society of Northern Ireland
Pharmacy and Medicines Directorate, NHS Grampian
Pharmacy Professional Forum
Pharmacy Voice, Pharmaceutical Services Negotiating Committee and Community
Pharmacy Wales
PharmaTrust UK
Prescription Medicines Code of Practice Authority
Primary & Community Care Pharmacy Network
Reckitt Benckiser UK
Regulations of Medicines Review Panel (RMRP)
Resuscitation Council
Roche Products Limited
Rowlands Pharmacy
Royal College of General Practitioners
Royal College of Physicians and Surgeons of Glasgow
Royal College of Physicians
Royal College of Radiologists
Royal Pharmaceutical Society
Salisbury NHS Foundation Trust
Scottish Ambulance Service
Secure Environment Pharmacists Group
Shire
Society of Homeopaths
University of Leeds and Luto Research

Warner Chilcott
WELEDA

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Emma Wright
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Gill Upham
Giovanna Gfraud-Saunder
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Hazel Rank-Broadley
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