Consolidation and review of UK medicines legislation

Public consultation MLX 375

25 October 2011
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Executive summary

In this consultation document we are seeking views on the MHRA’s exercise to consolidate and review UK medicines legislation. This exercise entails bringing together the existing fragmented and complex medicines legislation, and taking the opportunity to rationalise and simplify the legislation to improve the coherence of the regulatory framework.

What we are consulting on

We ask questions throughout the consultation document, and these are collated at Annex G. In summary, this document aims to:

- present draft consolidated medicines regulations and explain our approach to producing them
- test that the draft consolidated regulations are a full, accurate and user-friendly legislative text
- ensure that the draft consolidated regulations do not introduce any unintended changes
- seek views on policy changes that we propose to introduce in the consolidated regulations
- seek further evidence on the impact of the consolidated regulations and proposed policy changes.

This document builds on a number of previous consultations (outlined in chapter 5). We are not consulting on whether to consolidate medicines legislation. We have already consulted on this question and received widespread support.

The consolidation

The consolidation will bring significant benefits. We will replace around 200 statutory instruments and much of the Medicines Act 1968 with one set of
regulations, in the process removing much obsolete law. This will result in shorter, simplified law that is easier to understand and apply. This will in turn reduce net burdens for users: it 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. In addition, it will provide a platform for further better regulation initiatives by the MHRA, including reviewing the policies underlying the law and improving the guidance on the law. These initiatives would be much more difficult to carry out under the current legislative framework.

The draft consolidated regulations are provided at Annex A, and in chapter 6 we explain and seek views on our approach to developing them. Chapter 3, in conjunction with the impact assessment at Annex B, sets out our analysis of the costs and benefits of the consolidation, and seeks further evidence.

Policy changes

In chapters 7 to 11 we present proposals to introduce some policy changes in the consolidated regulations. The proposed changes relate to the removal of statutory warnings on packaging; improvements to the process for review hearings; sale, supply and administration exemptions; Patient Group Directions; and optimisation of medicines use.

These proposed changes build on responses to a concept paper that we published in 2009 and subsequent informal consultation. They are intended to help ensure that medicines legislation takes a modern approach to regulation, while ensuring that we do not impose regulatory burdens unless there is no alternative. In an informal consultation published in November last year we outlined some other potential proposals. We are still considering these, so they are not included in this consultation. Chapter 4 provides more information on this.
Parallel and forthcoming consultations

We will shortly be publishing a separate, but closely related, consultation document on the implementation of European Directive 2010/84/EU, which introduces substantial changes to pharmacovigilance requirements. Having two separate but linked consultation processes is intended to make both exercises clearer. We intend to bring the two projects together in the future, and to implement the Directive in July 2012 as part of the consolidated regulations.

We will be undertaking a number of other initiatives that would result in changes to medicines legislation. Our timetables vary: some of these changes may be made by amending existing law before the consolidation, some through the consolidated regulations next year and some after the consolidated regulations have come into force. We are not consulting on these projects in this document, but in chapter 4 we set out our plans for taking them forward and explain how they relate to consolidation.

We will be participating in the Government’s Red Tape Challenge. We intend to use the suggestions received during that exercise, together with ideas generated within the MHRA and others already received from trade associations, in deciding which areas of regulation should be prioritised for review. Changes flowing from this would be introduced as amendments to the consolidated regulations after they come into force.

1 Pharmacovigilance is the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk.
2 www.redtapechallenge.cabinetoffice.gov.uk/home/index
Next steps

The deadline for responses to this consultation is **Tuesday 17 January 2012**. Thereafter, we will consider the responses and publish our conclusions. Our intention is to lay the consolidated regulations before Parliament in spring 2012, and that they come into force in July that year.

The consolidated regulations will inevitably require periodic amendments once they are in force, not least to implement EU legislation such as Directive 2011/62/EU on falsified medicines (which will require implementation by 2 January 2013). As explained in chapter 12, we propose to maintain on our website an informal up to date version of the consolidated regulations showing all amendments made to them, and to formally remake the whole regulations at appropriate intervals. This will ensure that the considerable benefits of the consolidation are maintained.
1 Introduction

1.1 We intend to consolidate UK medicines legislation. We are aiming to lay the consolidated regulations before Parliament next year, as the Human Medicines Regulations 2012, and to bring them into force in July 2012.

1.2 We are consolidating most UK medicines legislation, including rules relating to manufacture and wholesale dealing, the requirements for an authorisation (marketing authorisations, homeopathic certificates of registration, traditional herbal registrations, and Article 126a authorisations), product information, advertising, expert advisory bodies and the British Pharmacopoeia.

1.3 We are keen to hear the views of interested parties, and this document aims to:

- present draft consolidated medicines regulations and explain our approach to producing them
- test that the draft consolidated regulations are a full, accurate and workable legislative text
- ensure that the draft consolidated regulations do not introduce any unintended changes
- seek views on policy changes that we propose to introduce in the consolidated regulations
- seek further evidence on the impact of the consolidated regulations and proposed policy changes.

1.4 We are not consulting on whether to consolidate medicines legislation. We have already consulted on this question and received widespread support.
1.5 This consultation is open for 12 weeks, and the deadline for responses is Tuesday 17 January 2012. Chapter 13 explains how to respond.

Context of related reform

Parallel consultation on pharmacovigilance

1.6 European Directive 2010/84/EU introduces substantial changes to existing pharmacovigilance requirements contained in Directive 2001/83/EC on medicines for human use. The UK Government is required to implement these changes by July 2012, and the MHRA intends to do so as part of the consolidated regulations. Most, but not all, of the changes will appear in the pharmacovigilance part of the consolidated regulations (Part 11).

1.7 This consultation document therefore does not cover pharmacovigilance, and the accompanying draft consolidated regulations contain no text under Part 11. Instead, we are consulting on the changes to pharmacovigilance in parallel and will publish a separate consultation document (MLX 374). This parallel document will contain a draft of Part 11 and explain in policy terms proposed changes to provisions elsewhere in the consolidated regulations.

NHS Reform

1.8 The consolidation is also being undertaken in the context of proposed significant structural changes to the NHS. The consolidation is not part of proposed NHS reforms, but we will aim to ensure that the consolidated regulations reflect any changes to NHS legislation as necessary. As noted in chapter 10 below, this will include working with the Department of Health to ensure that the consolidated regulations...
regulations accommodate any changes concerning Patient Group Directions.

Other MHRA legislative projects
1.9 We are undertaking the consolidation in the context of a number of other legislative projects. This is explained in more detail in chapter 4 below.

Structure of this document

1.10 The rest of this document is structured as follows:

• Chapter 2 explains how the consolidation supports the Government’s aim to minimise regulatory burdens, and how it fits with Government policies designed to meet this aim.
• Chapter 3 explains why we are undertaking the consolidation and sets out our views on the benefits it will bring and who it will affect.
• Chapter 4 explains which existing legislation the consolidation does and does not encompass, and how it relates to other initiatives concerning medicines regulation.
• Chapter 5 outlines previous consultation we have undertaken on the consolidation.
• Chapter 6 summarises existing medicines legislation, explains how we have approached consolidating it and outlines some key drafting changes we have made in the process.
• Chapters 7 to 11 outline proposals for policy changes stemming from our review of the existing medicines legislation. The draft consolidated regulations include provision for these proposals, to help explain how they would work.
• Chapter 12 sets out a proposal for keeping the consolidated regulations up to date once they have come into force.
• Chapter 13 explains how to respond to the consultation.
UK medicines legislation

Pre-consolidation

Medicines Act 1968

Post-consolidation

Medicines Act 1968
(Much reduced in length)

Human Medicines Regulations 2012

Fees
Clinical trials
Prohibition orders
2 Reducing regulatory burdens

2.1 The Government has made it a priority to minimise regulatory burdens in order to boost enterprise and drive growth, and has published principles of regulation to support this. We believe that the consolidation is consistent with these principles. It will be a major simplification of an extremely complex area of regulation, which will reduce burdens on business and civil society organisations and underpin our core mandate of protecting public health.

2.2 Crucially, the consolidation will also provide a platform for us to undertake over the coming years a programme of better regulation measures, known as the Regulatory Excellence programme. We intend to ensure that we impose obligations only where there is no alternative self-regulatory or non-regulatory approach; that any obligations are supported by a robust analysis of the costs and benefits; and that the regulation and the enforcement framework can operate in a fashion which meets our EU obligations while being demonstrably proportionate, accountable, consistent, transparent and targeted.

2.3 By bringing most of medicines law into one rationalised document, the consolidation will greatly assist the Regulatory Excellence programme. For example, it should be easier to produce improved guidance; to identify inconsistencies or logical errors in the rules; to review whether a particular regulatory policy has worked as intended, without unintended consequences; and to carry out a future review of criminal penalties and civil sanctions.

5 See, for example, The Coalition Programme for Government (May 2010), section 2; The Plan for Growth (March 2011), pp 20-27 and 51-56.

6 http://www.bis.gov.uk/policies/better-regulation/better-regulation-executive/reducing-regulation-made-simple/regulatory-decision-making/general-principles
2.4 The Government has introduced a number of policies to ensure that new regulation minimises burdens. We set out below how these relate in general to the consolidation and the specific policy proposals we are making.

One-in, One-out

2.5 The ‘One-in, One-out’ rule means that no new primary or secondary UK legislation which imposes costs on business or civil society organisations can be brought in without the identification of existing regulations with an equivalent value that can be removed. Regulation which is required to implement EU obligations is not within the scope of One-in, One-out at this time.

2.6 The independent Regulatory Policy Committee has confirmed that the consolidation is an ‘OUT’, because it reduces costs for business and civil society organisations of understanding and applying the law. These benefits are explained below in chapter 3 and analysed in more detail in the impact assessment at annex B.

2.7 The policy proposals in this document that go beyond the pure simplification objectives of consolidation (see chapters 7 to 11) would produce a net benefit, but the economic effects would be insignificant. Therefore, we have not produced an impact assessment for the proposals and they count as neither an ‘IN’ nor an ‘OUT’. The proposed repeal of section 10(7) of the Medicines Act 1968 (see paragraphs 4.21 to 4.22 below) has been the subject of a separate impact assessment (at annex C) and, as an EU implementing measure, is exempt from the ‘One-in, One-out’ policy.
Sunsetting and review

2.8 The Government has introduced a policy of sunsetting new regulations that impose a net burden on business. Broadly speaking:

- new regulation implementing EU law is to contain a duty to review the legislation within 5 years
- new domestic regulation is to contain a sunset clause that provides for automatic expiry after 7 years, together with a duty to review.

2.9 As the consolidated regulations do not introduce new regulation, we do not intend to subject them to a sunsetting or duty to review clause. We will, though, aim to meet the objectives of the sunsetting and review policy through seeking to introduce further simplification when amending the consolidated regulations once they are in force and when periodically ‘re-consolidating’ them (see chapter 12); and by introducing better regulation measures through our Regulatory Excellence programme.

Micro-business and start-up exemption

2.10 The Government has introduced a three-year moratorium on new domestic regulation affecting start-up businesses or those with fewer than 10 employees (micro-businesses).

2.11 We do not intend to subject the consolidated regulations to the moratorium, as the consolidation is a de-regulatory initiative. All businesses, including micro-businesses and start-ups, will gain direct

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7 Sunsetting Regulations: Guidance, BIS, April 2011.
8 The Plan for Growth, March 2011, at page 23.
benefits from the consolidation. Therefore, an exemption would disadvantage them.

The Red Tape Challenge

2.12 We are participating in the Healthy Living and Social Care theme of the Red Tape Challenge; this is anticipated to take place in 2012. We intend to use suggestions received during that exercise, together with ideas generated within the MHRA and others received from trade associations, in deciding which areas of regulation should be prioritised for review.
3 Purpose of the consolidation

3.1 Medicines legislation creates a comprehensive regime for the licensing of medicines for human use and their manufacture, importation, distribution, sale and supply in the UK. It is the cornerstone of the regulatory system for medicines in the UK and underpins the protection of public health from unsafe medicines. However, the legislation has become very complex and confusing, and can seem impenetrable to users. It comprises the Medicines Act 1968, around 60 principal statutory instruments and around 150 amending statutory instruments, which reflect developments in pharmaceuticals, wholesale trade, regulatory practice and European harmonisation. Even excluding the amending statutory instruments, this amounts to about 850 pages of legislation.

The weaknesses of medicines legislation

3.2 The legislation suffers from a number of weaknesses.

3.3 Fragmentation. In order for people to ascertain legal requirements, they have to consult many pieces of legislation. Once they have identified the relevant provisions (which are often spread across the Medicines Act 1968 and a number of statutory instruments, and often implement provisions of EU law merely by cross-reference rather than by transposing them as is the more usual practice in the United Kingdom) they must then take considerable time to understand the relationship between them.

3.4 Complexity. Many provisions are complex and difficult to follow. This situation has arisen for a variety of reasons: the legislation has been drafted at different times over many years, leading to inconsistencies in language and drafting approach; it has been
amended many times; and it includes detailed transitional provisions, many of which are no longer necessary.

3.5 **Obsolete provisions.** The legislation includes a great deal of obsolete material. In some cases, this material has become outdated as a result of scientific developments or new approaches to interpreting certain words and phrases. In other cases, it has been superseded by subsequent UK legislation that relates to other areas of regulation (such as medical devices or veterinary medicines) or implements European law – for example, much of the obsolete legislation relates to the national product licensing scheme that was in place prior to the introduction of marketing authorisations (see paragraph 6.5 below). Although this national legislation now has little or no application, it nevertheless litters the legislative landscape and makes it harder for users to understand the law that is in force.

3.6 **Poor structure.** Provisions that cover similar ground or apply broadly across the framework are repeated across the legislation. Examples include definitions, enforcement provisions and appeals mechanisms. This results in there being numerous provisions covering much the same ground, sometimes in different language.

The problems the weaknesses cause

3.7 These weaknesses have created the following principal problems, which are becoming more acute over time as the stock of medicines legislation grows.

3.8 **Difficulties for the MHRA in identifying areas for deregulation.** The legislative structure hampers MHRA’s efforts to ensure that its regulation is proportionate and reflects best practice. It makes it

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9 Many medicinal products retain a ‘PL’ number, but under existing legislation they are regulated by the marketing authorisation scheme. For more on the product licence of right scheme see chapter 4 below.
harder to identify opportunities for deregulation and ensure that regulation is consistent.

3.9 **Difficulties for business, civil society organisations and the public sector in understanding and applying the law.** It can take significantly more time and money to understand and apply medicines legislation than necessary. Practitioners in pharmaceutical law estimate that giving legal advice can take several times longer – and therefore cost several times more – than it would do if there were a single, coherent set of regulations.\(^\text{10}\)

3.10 **Potential for wasteful legal proceedings.** Unclear law can lead to uncertainty about its meaning and the obligations it creates and could, in the extreme, render it unenforceable.

**The objectives of the consolidation**

3.11 The MHRA intends to consolidate 200 or so legislative instruments into one statutory instrument that sets out for the first time almost all of the regulatory requirements for medicines in a single text. The scope of the consolidation is outlined in chapter 4 below.

3.12 Most importantly, improving the accessibility of the law will contribute to transparency, to legal certainty and to the effectiveness of the law. Moreover, it is a simplifying measure which, by making it easier for business, civil society organisations and public sector to understand and comply with the law, is intended to reduce net burdens.

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\(^{10}\) A pharmacy lawyer has given an example where drafting a letter of advice supported by reference to the legislation took 8 hours. If there had been a single set of regulations, the work might have been completed in about 2 hours.
3.13 Legislative simplification is an established form of better regulation.\textsuperscript{11} As outlined in chapter 2 above, the consolidated regulations will form the foundation for the MHRA programme of better regulation measures, known as the Regulatory Excellence programme.

3.14 In short, the objectives of the consolidation are to:

- provide a platform for future better regulation initiatives, including reviews of the policies embodied in the legislation
- reduce the difficulties and associated costs for business, civil society organisations and public sector of understanding and applying the law
- reduce the risk of time-consuming and costly litigation stemming from lack of clarity in the law.

3.15 The intended effects of these objectives are to:

- safeguard public health in the most cost-effective and transparent manner
- reduce burdens, and contribute to productivity and growth in business and civil society organisations.

Who will be affected by consolidation

3.16 Those affected by the consolidation will include:

- holders of an authorisation to manufacture, wholesale deal or import medicines
- marketing authorisation holders
- herbal and homeopathic registration holders
- the NHS

\textsuperscript{11} The European Commission, for example, frequently uses recasts/consolidations as part of its rolling simplification programme: http://ec.europa.eu/governance/better_regulation/codif_recast_en.htm
• pharmacies
• pharmacy industry bodies
• business regulatory bodies
• pharmacy schools
• healthcare professionals
• certain healthcare providers
• private/independent hospitals, clinics etc.
• other higher education institutions that teach future health professionals.

3.17 We do not expect the consolidation to have a significant direct impact on patients or consumers of medicines, or non-pharmacy retailers of medicines, since they typically do not need to consult medicines legislation (as opposed to other information or guidance).

3.18 We will undertake a structured consultation, meeting pharmacy and pharmaceutical industry interests early in the process and holding further meetings if necessary.

3.19 The draft impact assessment for consolidation at annex B sets out in more detail the material impact of consolidation on these groups.

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:

a. Approximately how much time does your firm or body currently spend every year understanding the regulations as they are currently drafted?

b. What change in this annual amount of time would you expect as a result of the consolidated regulations?

c. Roughly how much time do you think your firm or body will take in familiarising itself with them?

d. 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?

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

f. Is our assumption that small and micro businesses generally rely on their trade and professional bodies for regulatory information correct?
4 Scope of the consolidation

4.1 The consolidation is concerned with legislation that relates primarily to medicines for human use. At annex D is a list of the legislation (excluding purely amending legislation) that is within scope of the consolidation and will be repealed. Some of this legislation, notably the Medicines Act 1968 and the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830) (“the POM Order”), is not being consolidated and repealed in its entirety. The extent of repeals are set out under schedule 34 to the draft regulations.

4.2 The consolidated regulations aim, so far as possible, to replace all UK legislation relating primarily to medicinal products for human use, with some exceptions outlined from paragraph 4.7 below.

4.3 The consolidation does not encompass:

- legislation primarily relating to other areas that the MHRA regulates, including medical devices, the safety and quality of blood and blood components, and good laboratory practice
- veterinary medicinal products. The Medicines Act 1968 and related secondary legislation covered both human and veterinary medicines until 2005, when the Veterinary Medicines Regulations were introduced. Those regulations are administered by the Veterinary Medicines Directorate, an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra).

Pharmacy

4.4 We are consolidating most of the legislation that the MHRA is responsible for and relates to pharmacy professional practice. This includes the following:
• Part III of the Medicines Act 1968 (relating to dealing in medicinal products, including classification) and associated offences. This is consolidated in Part 12 and associated schedules 16 [j507s] to 23 to [j546As] as regards dealings. Regulations 5 [j500A], 62 [j110], 99 [j305] and 121 [j416A] of the consolidated regulations deal with classification.

• The Prescription Only Medicines (Human Use) Order 1997 (1997/1830). With the exception of articles 5 and 10 and Schedules 1 and 2, which will remain in force for the time being, this is largely consolidated in Part 12 of the consolidated regulations. Schedule 1 [j500As] of the consolidated regulations relies on the excepted provisions to provide Prescription Only status for a number of medicines that may be lawfully supplied without a marketing authorisation.

• Enforcement functions of the General Pharmaceutical Council (GPhC) in relation to Great Britain in sections 108 and 109 of the Medicines Act 1968. These are consolidated in regulations 275 [j701] to 278 [j703] of the consolidated regulations, with the exception of sections needed to enforce provisions remaining in the Medicines Act 1968.

• Pharmacy qualifications for qualified persons in relation to a manufacturer's licence. These are currently in regulation 4 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789) and are consolidated in Regulation 42 [j221] of the draft consolidated regulations.

4.5 In our November 2010 informal consultation on the consolidation exercise we explained that we would generally review section 10 of the Medicines Act 1968 (exemptions for pharmacists). As the consolidated regulations are currently drafted, section 10 is not consolidated and will be retained in the Medicines Act 1968, amended to refer to the consolidated regulations. This is with the
exception of subsection (7), which is to be repealed (see paragraphs 4.21 to 4.22 below for more on this issue). Section 15 of the Medicines Act 1968, which provides the power to modify the exemptions in section 10, will also be retained insofar as it relates to section 10. We have retained these aspects of sections 10 and 15 because we are considering whether we can consolidate them without compromising their legal effect. In the draft consolidated regulations, regulation 4 [j002C] links to section 10.

4.6 We are not consolidating pharmacies legislation administered by the Department of Health and, in Northern Ireland, the Department for Health Social Services and Public Safety. This includes Part IV of the Medicines Act 1968 (Pharmacies) and some enforcement powers of the GPhC and Pharmaceutical Society of Northern Ireland which will not be repealed and will still need to be read in conjunction with other pharmacies legislation, including the Pharmacy Order 2010. For reasons set out in paragraph 4.34 below, we are not consolidating section 64 of the Medicines Act 1968 (‘Protection of purchasers of medicinal products’).

Legislation relating to medicinal products for human use that is not in scope of the consolidation

4.7 The consolidated regulations aim, so far as possible, to replace all UK legislation relating primarily to medicinal products for human use, with the exception of legislation in the following areas:

Fees

4.8 This is a discrete and complex area of legislation, which the MHRA intends to simplify and rationalise by April 2012. We believe it would be too complicated to consolidate fees legislation before this work has been carried out.
Accordingly, part 3 and schedules 2 and 3 of the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994 (SI 1994/105) are not being consolidated, as they concern fees. They will instead be brought into the new fees legislation in April 2012.

Clinical trials

There are ongoing negotiations at a European level about the introduction of a Directive that would require substantial changes to the regulation of clinical trials. In addition, on 23 March the Chancellor of the Exchequer announced that the Government will review the UK’s implementation of the Clinical Trials Directive in order to reduce perceived gold-plating and to increase the proportionality of the system. We intend to leave the existing UK legislation regulating clinical trials as it is for the moment, rather than consolidate it now and then amend it substantially not long afterwards.


These Regulations (‘the MARS regulations’) are made under Section 60 (Restricted sale, supply and administration of certain medicinal products) of the Medicines Act 1968 and are one of several pieces of legislation regulating administration of radioactive medicinal products (RMPs). RMPs are classed as Prescription Only Medicines. The MARS regulations implement a Euratom Directive Requirement for a system of prior authorisation of persons responsible for the administration of radioactive substances. Specifically, the regulations place the primary responsibility for administration of RMPs on doctors and dentists holding a certificate issued by the Administration of Radioactive Substances Advisory Committee. Later legislation, namely the Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000/1059) (‘the IR(ME) Regulations’), lays down measures on health protection of individuals against the dangers of ionising

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12 The Plan for Growth, HM Treasury and BIS, at page 93.
radiation in relation to medical exposure. Under those regulations, a suitably trained operator may also undertake practical aspects of medical exposures, and may authorise the decision to undertake an exposure to ionising radiation in accordance with written guidelines issued by a medical professional entitled to do so. The latter regulations are not made under the Medicines Act 1968.

4.12 As part of the implementation of the Basic Safety Standards (BSS) Directive, which will supersede a number of Directives relating to radiation protection, the Department of Health plan to review current legislation in this area with a view to improving the regulation of administration of radioactive substances. In particular, they will be considering streamlining the MARS and IR(ME)R provisions to reflect current approaches to delivery of nuclear medicines services. For this reason, we are not including the MARS regulations in the consolidation. Medicines legislation will continue to regulate RMPs as Prescription Only Medicines.

4.13 When legislation in the three areas above is more settled, we will explore consolidating it through amending the consolidated regulations after they are in force.

**Prohibition orders**

4.14 The following orders made under section 62 (Prohibition of sale or supply, or importation, of medicinal products of specified description) of the Medicines Act 1968 prohibit, with some exemptions, the sale, supply and importation of certain products or medicinal products containing certain substances:

- the Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977 (1977/670)
- the Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977 (1977/2131)
• the Medicines (Chloroform Prohibition) Order 1979 (SI 1979/382)
• the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001 (SI 2001/1841)
• the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 (SI 2002/3170)
• the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 (SI 2008/548).

4.15 This legislation will remain in force along with section 62 of the Medicines Act 1968. This is because the consolidated regulations will mainly be made using the powers in section 2(2) of the European Communities Act 1972, and prohibitions of this sort are not clearly within the scope of the European enactments being implemented.

Relationship with other initiatives relating to medicines regulation

4.16 The MHRA is undertaking a number of other initiatives relating to medicines regulation, some of which have been addressed in previous consultation on the consolidation. This consultation is not seeking views on these issues; they have, or will be, addressed in separate consultations. However, for clarity this section summarises these initiatives and describes their relationship with the consolidation, and the diagram at page 35 shows a planned schedule for forthcoming consultations).

Review of unlicensed medicines

4.17 We have been undertaking a review of the scheme that allows the manufacture or import of unlicensed medicines ("specials") commissioned by doctors or other authorised healthcare professionals to meet the special clinical needs of their individual patients. This is a UK scheme set up under a derogation in European
medicines legislation which permits such national arrangements. We will be consulting in due course on proposals to update and reform these arrangements. Subject to the timelines and outcome of that consultation, we would seek to introduce these changes by amending the consolidated regulations later in 2012 or 2013.

Review of the medicines supply chain

4.18 We have for a number of years been undertaking a review of the UK medicines supply chain to better protect patients from the threat of counterfeit medicines. We have published two public consultations on this review\textsuperscript{13}, encompassing the following changes.

\textit{New requirements on wholesale dealers and responsible persons}

4.19 We are considering placing certain new obligations on wholesale dealers and responsible persons. These changes have not been included in the draft consolidated regulations. If we were to decide to introduce them, we would aim to bring them into law by amending the existing legislation ahead of consolidation. The changes would be incorporated in the consolidated regulations when they are laid before Parliament in 2012.

\textit{Import for export exemptions}

4.20 Proposals to tighten regulatory controls on medicines imported into the UK solely with the intention of exporting them to third countries have been superseded by the EU Falsified Medicines Directive (Directive 2011/62/EU) which requires implementation by 2 January 2013. Implementing this Directive will require repeal of sections 14 (Exemptions for re-exports) and 48 (Postponement of restrictions in relation to exports) of the Medicines Act 1968. Until then, these provisions remain and are consolidated in the draft regulations.

\textsuperscript{13} MLX 357: \url{http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON033660}
MLX 365: \url{http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065685}
Removal of the Section 10(7) Medicines Act 1968 exemption for pharmacy wholesale dealing

4.21 An exemption currently exists in section 10(7) of the Medicines Act 1968 which permits pharmacists to trade in small quantities of medicines without a wholesale dealer’s licence. We are removing this exemption because it is not compatible with EU law. Once the consolidated regulations come into force, pharmacists who wish to trade commercially in medicines will be required to hold a wholesale dealer’s licence and meet all the regulatory obligations associated with that licence. Pharmacists will not be required to hold a wholesale dealer’s licence if they provide medicines to healthcare professionals and others who need to hold them to pass on to their patients. Pharmacists will also be allowed to supply other pharmacists with small quantities of medicines without holding a wholesale dealer's licence as long as this is on an occasional and not for profit basis and to meet the individual needs of patients (for example, if a pharmacy cannot otherwise obtain supplies to dispense a prescription for a patient).

4.22 The MHRA will be developing advice for pharmacy on how these changes will impact on current practice. The impact assessment for the removal of section 10(7) is provided at annex C for information. As the removal of section 10(7) is an implementation measure to bring the UK into compliance with EU law, it is in scope of the Government’s sunsetting and review policy and will accordingly be subject to a duty to review clause.

Fees

4.23 We are considering various changes in legislation to introduce a more rigorous approach to payment of fees associated with wholesale dealing, so that when applying for a licence, applicants must pay a fee in advance, together with a fee to cover the costs of an MHRA inspection. We are also considering introducing a provision that
allows the MHRA to suspend or revoke a wholesale dealer’s licence if fees are not paid, and to remove some current concessions for wholesales dealers and pharmacists. Any changes in this area would be made in fees legislation, which, as outlined above, is outside the scope of the consolidation.

Introduction of a training and examination scheme for Responsible Persons.\(^{14}\)

4.24 This would be a non-legislative change.

Issues relating to the product licence of right (PLR) regime, homeopathy and non-orthodox practitioners (NOPs)

4.25 In January this year we published an informal consultation on proposals to amend (a) the PLR regime\(^{15}\); (b) information requirements for marketing authorisation of homeopathic medicinal products under national rules, implementing Article 16(2) of Directive 2001/83; and (c) the NOP scheme.\(^{16}\) We are still developing proposals in this area.

4.26 As they are still being considered, the provisions for the PLR regime and NOP scheme are not included in the draft regulations accompanying this consultation. The lack of provisions for PLRs and NOPs in the draft accompanying this consultation is not an indication of our policy in these areas and does not affect their current status.

Herbal medicine reforms

4.27 In February 2011 Ministers announced proposals to introduce a requirement for practitioners wishing to prepare or commission an

\(^{14}\) Wholesale dealers’ licences require that there be a named person responsible for ensuring compliance with the licence and maintaining the quality of products.

\(^{15}\) 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.

\(^{16}\) 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. The exemption stems primarily from the Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971 (SI 1971/1450).
unlicensed herbal medicine for use in their consultations with individual patients to be registered with the Health Professions Council. The intention is to link the introduction of this requirement to reforms of related medicines legislation, with the aim of ensuring that the public has continuing access to unlicensed herbal medicines supplied by practitioners but strengthening the current limited safeguards for the public. There will be separate consultation on these reforms, expected to be later this year.

4.28 In the meantime we are proposing two minor simplification measures which can usefully be made in advance of these wider reforms of herbal medicines legislation. These are outlined in chapter 6 below.

**Falsified medicines directive**

4.29 The European Parliament and Council have adopted a new directive on falsified medicines\(^{17}\), in order to combat the entry of counterfeit medicines into the regulated supply chain. This was part of the pharmaceutical package published by the European Commission in December 2008. The UK will be required to implement parts of this Directive by 2 January 2013. The MHRA will consult separately on this implementation and will implement the Directive by amending the consolidated regulations after they are in force.

**European Commission proposals on information to patients**

4.30 This was the third part of the European Commission’s 2008 pharmaceutical package. MHRA published MLX 358 in 2009 on the first proposal and will publish a further consultation in due course on the next proposal, when available.

**Manufacturing & wholesale dealing review proposals**

4.31 In our November 2010 informal consultation on the consolidation exercise we said we were considering changes to the process of

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\(^{17}\) Directive 2011/62/EU, which amends Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products
applying for a manufacturing and wholesale dealing licence, procedure for appointing responsible persons and variations to wholesale dealing and manufacturing licences that could be made without full MHRA consideration. These issues are still being considered, and if they are to be taken forward they will be introduced in January 2013 with the implementation of the falsified medicines directive referred to in 4.29 above.

Enforcement review proposals on offences
4.32 We are considering legal options for the following:

- In relation to inspections, extension of the power to inspect to include powers to search.
- Introducing a power to destroy unlicensed and potentially dangerous medicinal products in cases where no criminal prosecution is brought.
- Introducing an offence of possession of a pharmacy medicine with intent to supply otherwise than in accordance with pharmacy requirements. This would be analogous to the existing offence in relation to Prescription Only medicines.

Paediatrics Strategy
4.33 The MHRA is proposing to consult on a revised Strategy for Paediatric Medicine later in 2011. This will build on our previous 2004 strategy, taking account of changes introduced by the EU Paediatric Regulation in 2006. The proposals under consideration for the consultation are aimed at increasing the number and quality of paediatric formulations currently on the UK market.

Amendment of section 64 (Protection of purchasers of medicinal products) of the Medicines Act 1968 to ensure a proportionate regulatory approach to dispensing errors
4.34 We have established that we do not have the legal powers under the European Communities Act 1972 to consolidate or include an amendment to section 64 of the Medicines Act 1968 in the consolidated regulations responding to concerns of pharmacy interests about the risk of prosecution for dispensing errors where a simple mistake has been made without other aggravating circumstances. Regulation 243 [j546] from the draft of the consolidated regulations we published in August 2010, which consolidated section 64, does not appear in the draft accompanying this consultation, and section 64 will remain in force at present. While interim improvements have been made by way of guidance, the intention has always been to amend legislation to secure a more proportionate regulatory approach to dispensing errors at the earliest opportunity. We intend during Autumn 2011 to discuss the way forward with interested parties.

The Medicines (Miscellaneous Amendments) Order 2011 (SI 2011/1327)

4.35 This Order updates the chiropodist exemptions in the Medicines (Pharmacy and General Sale Exemption) Order 1980 (SI 1980/1924) and ensures that those exemptions apply to podiatrists also. It makes similar amendments to the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830) (“the POM Order”) in relation to medicines that may be sold, supplied or administered by chiropodists and podiatrists; it also amends that Order to allow student midwives to administer certain parenteral (injectable) medicines under the supervision of a registered midwife.

4.36 The Medicines (Miscellaneous Amendments) Order 2011 came into force on 1 July 2011, and the provisions are included in the draft consolidated regulations at Annex A.

Extending independent prescribing for podiatrists and physiotherapists

4.37 The Department of Health is taking forward proposals to extend independent prescribing to registered podiatrists and
physiotherapists. This work is outside the scope of this consultation although it is expected that any changes to legislation will be introduced in the consolidated regulations in July 2012.

**Criteria for deciding whether unlicensed medicines are Prescription Only Medicines (POMs)**

4.38 We have identified a need to review the circumstances in which unlicensed medicines are classified as Prescription Only Medicines (POM). Since 2002 decisions on the legal status of authorised products (that is, whether they are categorised as POM, pharmacy only or subject to general sale) have been taken as part of the licensing decision and this classification has been specified in the individual marketing authorisation. As a consequence of this approach, the statutory list of substances subject to POM status in Schedule 1 of the POM order has not been updated since 2002. A number of unlicensed medicines continue to attract POM status by virtue of the POM Order, either because they consist of or contain a relevant substance listed in Schedule 1 to the POM Order, or because they are covered by generic POM classification criteria elsewhere in the Order (for example, medicines for parenteral administration).

4.39 The current situation has not so far caused significant problems in relation to unlicensed medicines for the MHRA or, as far as we are aware, healthcare professionals or others in the field. There are in any case other underlying safeguards for the public depending on the situation. For example, unless there is a relevant exception in medicines legislation the default position is that supply of a medicine without a suitable product licence is illegal. In addition, regulated healthcare professionals have an obligation to act in a professional manner at all times and are accountable for their actions.

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18 The Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830)
4.40 It is nonetheless undesirable that, by default, the statutory list of POM substances in Schedule 1 of the POM Order is becoming progressively less systematic in relation to medicines and substances actually on the market. We propose to review the criteria and circumstances in which unlicensed medicines are classified as POM with a view to reaching a regulatory position which effectively responds to the changing pattern of medicines that may be found on the market; reflects safe, modern clinical practice by health care professionals; acknowledges other regulatory safeguards that exist; and provides appropriate and proportionate public health protection. We do not repeal articles 5 and 10 and Schedules 1 and 2 of the POM Order in the draft consolidated regulations at Annex A. There will be a further consultation on this issue.
**Likely MHRA engagement with interested parties about medicines – Oct 2011 onwards**

**Autumn 2011**

- Draft Human Medicines Regulations 2012 (minus Part 11)
- Consolidation of medicines legislation, and some policy changes relating to:
  - removal of statutory warnings
  - review process for licensing decisions (change to membership criteria)
  - sale, supply and administration exemptions
  - patient group directions
  - optimisation of medicines use

**2011/12**

- Dispensing errors
- 64 Medicines Act 1968
- Enforcement review proposals on offences
- Paediatrics strategy
- Herbal regulation reforms
- POM classification of unlicensed medicines
- Product Licences of Right (PLRs), Non-Orthodox Practitioners (NOPs) and homeopathic labelling
- Review of unlicensed medicines (RUM)
- 2012 fees and fees simplification

**2012**

- Implementation of Directive 2011/62/EU
  - Falsified medicines
- Manufacturing and wholesale dealing review proposals
- European Commission proposals on information to patients
- Red Tape Challenge

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*The current intention is for all the policy changes with a dotted background to come into force together in July 2012.*

*The current intention is for all the policy changes with a shaded background to come into force together in Jan 2013.*
MHRA legislation currently in force

**Medicines**
- Medicines legislation in consolidation exercise
  - Medicines Act 1968
    - (and around 200 SIs)
- Fees
  - Medicines Act 1971
  - Medicines Products for Human Use (Fee) Regulations 2010
  - SI 2010/5551
  - MHRA Trading Fund Amendment Order 2005
    - SI 2005/2001
- Clinical Trials
  - The Medicines for Human Use (Clinical Trials) Regulations 2004
    - SI 2004/931
    - Amended by:
      - SI 2009/328
      - SI 2009/84
      - SI 2009/941
- Prohibition Orders
  - SI 1978/870
  - SI 1978/131
  - SI 1978/852
  - SI 2001/984
  - SI 2002/170
  - SI 2009/848

**Devices**
- Devices
  - Medical Devices Regulations 2002
    - SI 2002/619
    - Amended by:
      - SI 2003/657
      - SI 2003/908
      - SI 2009/220
      - SI 2009/236
- Fees
  - Medical Devices Consultation Requirements Fee Regulations 1995
    - SI 1995/649
    - Amended by:
      - SI 2002/950
      - SI 2003/920
      - SI 2009/537

**Other**
- Good Laboratory Practice
  - Good Laboratory Practice Regulations 1999
    - SI 1999/3106
    - Amended by:
      - SI 2004/664
- Blood
  - Blood Safety and Quality Regulations 2005
    - SI 2005/820
    - Amended by:
      - SI 2009/208
      - SI 2009/295
      - SI 2009/924
  - Anticipated Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003
    - SI 2003/1680

**Directly applicable EU regulations**
- Centrally authorised products
  - 7292004
- Variations Regulation
  - 12340006
- ATMP Regulation
  - 13940007
- Paediatric Regulation
  - 13942008
  - 19200916
- Orphan Drugs
  - 14220001
  - 84220000

* SI 2009/941 amends blood and clinical trials
5 Consultation on the consolidation to date

5.1 Although this is the first formal consultation on the consolidation, we have already consulted informally on a number of occasions. This includes the following:\textsuperscript{19}:

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2009:</td>
<td>publication of a “concept paper” that described the project and solicited topics for review</td>
</tr>
<tr>
<td>July 2010:</td>
<td>meeting with pharmaceutical industry bodies</td>
</tr>
<tr>
<td>Aug 2010:</td>
<td>publication of the first complete draft of the consolidated regulations</td>
</tr>
<tr>
<td>Sept 2010:</td>
<td>meeting with pharmacy professional, trade and negotiating bodies</td>
</tr>
<tr>
<td>Oct 2010:</td>
<td>publication of an informal consultation on exemptions related to the sale, supply, and administration of medicines</td>
</tr>
<tr>
<td>Oct 2010:</td>
<td>publication of an informal consultation on patient group directions (PGDs)</td>
</tr>
<tr>
<td>Nov 2010:</td>
<td>publication of an informal consultation that set out possible proposals to reduce regulatory burdens and sought further suggestions to that end</td>
</tr>
<tr>
<td>Jan 2011:</td>
<td>issues relating to the PLR regime and homeopathy</td>
</tr>
</tbody>
</table>

\textsuperscript{19} All the published informal consultations are available here: http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/ProjecttoconsolidateandreviewUKmedicineslegislation/index.htm
5.2 The MHRA has also discussed the consolidation in meetings with interested parties including the following:

- Association of the British Pharmaceutical Industry
- Proprietary Association of Great Britain
- British Generic Manufacturers Association
- General Medical Council
- Royal Pharmaceutical Society of Great Britain (now General Pharmaceutical Council and Royal Pharmaceutical Society)
- The Pharmaceutical Society of Northern Ireland
- the four Chief Pharmaceutical Officers for the UK
- the MHRA’s Medicines Advertising Liaison Group (MALG)
- the MHRA’s GMP-GDP Consultative Committee
- Dispensing Doctors Association
- National Pharmacy Association
- Company Chemists’ Association
- Interest groups in the homeopathy and anthroposophy sectors.

5.3 The MHRA has also liaised with other government Departments that have an interest, or might be affected by, medicines legislation. These include the Veterinary Medicines Directorate (Defra), Home Office, Ministry of Justice, Cabinet Office and BIS.

5.4 We have liaised with the Wales Office, Scotland Office, Northern Ireland Office, devolved administrations for each part of the UK, crown dependencies and Gibraltar.

5.5 The MHRA has also consulted its own statutory expert advisory bodies: the Commission on Human Medicines, British Pharmacopoeia Commission, Herbal Medicines Advisory Committee and Advisory Board on Registration of Homeopathic Products. Each of these bodies nominated members to sit on a working group that
met twice in 2010. Each advisory body endorsed the policy proposals at chapters 7 to 11 that fell within its scientific remit.

5.6 As a result of these consultations, we have found widespread support for the principle and objectives of the consolidation. We have therefore decided to proceed with the consolidation. This document is not consulting on whether to undertake the consolidation; it is primarily seeking views on whether the draft text is fit for purpose.
6 The consolidation

6.1 This section explains and seeks views on how we have undertaken the consolidation. References to existing legislation should be read to include any subsequent amendments to that legislation.

Existing UK medicines legislation

6.2 The legal framework for medicinal products for human use is made up of the following enactments:

a. the Medicines Act 1968
b. statutory instruments (regulations and orders) made under the Act
c. regulations that implement European Directive 2001/83/EC and its amending instruments, and make provision in national legislation for the enforcement of EU regulations
d. regulations that implement European Directive 2001/20/EC (this regulates clinical trials, which are out of scope of the consolidation).

6.3 The Medicines Act 1968 was the UK’s first comprehensive legislation relating to medicinal products. The Act, which was in part a response to the thalidomide tragedy in the late 1950s and early 1960s, formed the basis of a domestic licensing scheme for medicinal products. Over several decades many statutory instruments have been made under powers contained in the Act.

6.4 The legal framework began to change with the introduction of European directives related to medicinal products. The first of these was Directive 65/65/EEC, which required Member States to ensure that no medicinal product is placed on the market unless a marketing authorisation had been issued. Subsequent European legislation
introduced further measures in particular subject areas. Eventually, the Directives were consolidated into Directive 2001/83/EC, which is currently the central piece of European legislation relating to medicinal products for human use. Directive 2001/83/EC has been subject to a number of amending directives.

6.5 The development of the European directives meant that the domestic regime had to be changed substantially. The requirements were implemented by way of new statutory instruments, amendments to existing statutory instruments and amendments to the Medicines Act 1968. The previous domestic product licensing scheme has remained in force, and been updated, to allow for the possibility that certain products regulated in national law might fall outside the scope of Directive 2001/83/EC and therefore the scope of our implementing legislation in the UK. In fact there are few if any such products, and in the consolidated regulations we intend to make it clearer what products are within, and what outside, the terms of a unified system for authorisation and registration of medicinal products. This system is based on EU provision, but extended as necessary to ensure that existing or new products hitherto subject only to national requirements will be subject to the new scheme also.

6.6 The regulatory regime for medicines covers a number of areas, including:

a. clinical trials (outside the scope of the consolidation)
b. rules relating to manufacturing and wholesale dealing
c. the requirement that medicinal products be authorised and the rules for applying for authorisation
d. the specific requirements for the manufacture and supply of medicinal products exempt from the requirement to be authorised
e. specific provisions for homeopathic and herbal medicinal products
f. the classification of medicinal products as prescription only medicines, pharmacy only, and subject to general sale, and related rules pertaining to supply
g. packaging, labelling, and advertising
h. pharmacovigilance.

The consolidated regulations

6.7 The draft consolidated regulations are entitled the Human Medicines Regulations 2012 and are in 17 Parts and 34 schedules; they are at Annex A. A broad description of each part of the draft consolidated regulations is at Annex E, and a table of origins mapping how they consolidate existing legislation is at annex F.

6.8 The draft contains “j-numbers”. For example, the explanatory heading that precedes regulation 47 says “Requirement for authorisation [j005A]”. J-numbers are unique identifiers for each draft regulation and will not appear in the final legislation. To assist us in any further drafting, we ask that you include the j-number for any regulation you refer to in your response.

Question 4
Do you agree with the structure of the draft regulations? Why, or why not?

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?
**The Medicines Act 1968**

6.9 The consolidated regulations will repeal large parts of the Medicines Act 1968. Power to amend or repeal legislation, including statute, for the purposes of implementing EU law is granted to Ministers by section 2(2) of the European Communities Act 1972. It is this power that will be exercised to repeal those sections of the Medicines Act 1968 that will be replaced by the consolidated regulations.

6.10 An amended, and much smaller, Medicines Act 1968 will remain. It will relate primarily to the regulation of pharmacies, an area that is currently covered by Part IV of the Act. Part IV will remain for the most part unaltered. Those changes that are made to it will be of a consequential nature and will not have a substantive effect. Provisions elsewhere in the Act that support Part IV will also be retained, including enforcement provisions. Certain other provisions may also be left in place, particularly where we want to maintain national provisions that are arguably outside the strict scope of the European Communities Act 1972. Consequential amendments are in Schedule 33 [j990s] of the draft regulations.

6.11 All other provisions in the Medicines Act 1968 that are being consolidated or have been deemed to be unnecessary will be repealed as outlined in Schedule 34 [j991s] of the draft regulations.
Powers

6.12 Secondary legislation is made under powers found in statute, or primary legislation. As the consolidated regulations will primarily implement Directive 2001/83/EC, they will be made largely under section 2(2) of the European Communities Act 1972. It is likely that we shall continue to rely on Medicines Act 1968 powers in areas where we wish to consolidate provisions that may fall outside the scope of our European obligations – an example of where this may be the case is child-proof packaging for certain products. The powers to make regulations in this area in the Medicines Act 1968 will be maintained. Other powers, in areas where section 2(2) will clearly provide powers for present consolidation and future amendment, will be repealed.

Material drafting changes

6.13 In consolidating the law we have made drafting changes to some areas. For the most part these changes have no substantive effect. Significant material drafting changes are set out in this chapter below. We are also proposing to make some policy changes, and these are set out in sections 7 to 11.

Practitioner exemptions

6.14 Sections 9 to 12 of the Medicines Act currently contain exemptions from licensing requirements. These permit doctors, dentists, pharmacists, 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. With the exception of herbal practitioners, these professions are also statutorily regulated by a supervisory body.
6.15 As explained in paragraph 4.5 above, section 10 of the Medicines Act 1968 (exemptions for pharmacists) is not consolidated and will be retained in the Medicines Act 1968 for now. We have however reviewed sections 9, 11 and 12 to ensure that they are compliant with the relevant provisions in Directive 2001/83/EC, including Articles 2(1), 3(1), 3(2), and 40(2). Their subject matter is now dealt with in the scope provision at regulation 3 [j002B]. Our objective however is to emphasise how our provisions implement the scope provision of the Directive and not to make changes of substance to the practice of those operating under the current exemptions. Section 12(2) of the Medicines Act 1968 has not been consolidated, as it was repealed on 30 April 2011.  

6.16 While the scope provisions are drafted in more simple terms and presented differently, we believe that their practical effect has not changed appreciably, and we think that practitioners will be able to continue to conduct the professional activities currently covered by the Medicines Act 1968 exemptions in sections 9, 11 and, subject to the repeal of section 12(2), section 12. We have tried to make the provisions as broad as possible while keeping in mind consumer safety and the constraints imposed by Directive 2001/83/EC. For example, consistent with Article 2(1), we have limited the out of scope provisions where necessary to products that are supplied in a therapeutic rather than a commercial context and are not industrially produced.

6.17 The Medicines Act 1968 provisions that currently operate provide exemptions from specified requirements only, mainly the requirement for a product licence or manufacturer’s/wholesale dealer’s licence.

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20 Section 12(2) provided an exemption (from the requirement to comply with the restrictions set out in sections 7 and 8 of the Medicines Act 1968) for the manufacture, sale or supply of herbal remedies, where the process to which the plant or plants are subjected consists only of drying, crushing or comminuting and certain other specified conditions are met. The Medicinal Products (Herbal Remedies) (Amendment) Regulations 2011 (SI 2011/915) repealed section 12(2), as it did not comply with Directive 2001/83/EC or Directive 2004/24/EC.
For instance, section 9 of the Act says that 'sections 7 and 8 of the Act do not apply to anything done by a doctor or dentist…'.

6.18 The new scope provision takes a different approach. It provides, at paragraph (1), that none of the consolidated regulations apply in circumstances described in the subsequent paragraphs. Essential safeguards are provided for. So the exception in paragraph (8) provides that the essential restrictions relating to prescription only medicines and the prohibition on advertising medicinal products without a marketing authorisation still apply even to out of scope products. Paragraphs (9) and (10) moreover consolidate essential labelling requirements for products that are out of scope. It should also be noted that enforcement provisions consolidated from the Medicines Act 1968 will continue to apply, as do the rights of entry in now in Part 16. So, regulation 279 [j704] permits an inspector to enter premises “in order to determine whether there has been a contravention of a provision of these regulations” and will be available if an inspector has grounds to believe unlicensed medicinal products are being manufactured and that they are within the scope of the regulations.

6.19 The MHRA will issue guidance that explains this new provision in detail.

6.20 This is an extremely important provision; we would ask practitioners who benefit from the existing exemption provisions to review it with particular care.

Question 9:

a. Should we add more requirements to Reg 3 [j002B] for medicinal products that fall outside the scope of the consolidated regulations? If so, what?

b. 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?
c. Is the provision too narrow or too broad in any respect?

Streamlining panels for reviewing licensing decisions

6.21 The Government’s review of advisory non-departmental public bodies (ANDPBs) in 2010 announced a reduction in the number of medicines ANDPBs, including the following bodies:

- **The Herbal Medicines Advisory Committee (HMAC)**, which advises the MHRA on homeopathic medicinal products and is currently provided for in regulations made under section 4 of the Medicines Act 1968.
- **Advisory Board on the Registration of Homeopathic Products (ABRH)**, which advises the MHRA on homeopathic medicinal products and is also currently provided for in regulations under section 4 of the Medicines Act 1968.
- **Independent Review Panel for Advertising**, which considers written representations from recipients in relation to notices that the Minister is minded to determine that an advertisement, if published, would be in breach of advertising regulations (known as ‘minded to’ notices).
- **Independent Review Panel on the Classification of Borderline Products**, which considers representations from recipients against a provisional determination notice that a product is a medicinal product (and as such requires a marketing authorisation).

6.22 Accordingly, there is no provision for the continued establishment of HMAC or the ABRHP in the draft consolidated regulations. However, the MHRA has concluded that the functions carried out by these bodies are still necessary, and that they should continue as expert committees appointed by the licensing authority. They will continue to

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perform the functions currently identified on the MHRA's website. Similarly, while there are no provisions establishing bodies for the consideration of written representations in relation to ‘minded to’ notices on advertising\textsuperscript{21}, or relating to the requirement that the licensing authority must appoint a panel to review written or oral representations in relation to borderline decisions\textsuperscript{22}, the borderline or advertising review panels operate as appointees of the licensing authority.

**Person appointed process**

6.23 The licensing authority is required under current legislation\textsuperscript{23} to appoint an individual to hear from an applicant who disagrees with a decision of the licensing authority about the grant, renewal, suspension, revocation or variation of a marketing authorisation, clinical trials authorisation, herbal registration, homeopathic certificate of registration, or manufacture’s and wholesale dealer’s licence. This is known as the ‘person appointed’ function, and it is fulfilled on an ongoing basis by members of the Regulation of Medicines Review Panel.

6.24 The draft consolidated regulations do not refer to a ‘person appointed’. Instead, they provide that a person may notify the licensing authority in writing that they wish the licensing authority to submit the decision to review upon oral representations, and that the licensing authority must appoint a panel of at least two people (‘the reviewers’). This would not affect the operation of the Regulation of Medicines Review Panel, which would continue to exist and function as it does now.

\textsuperscript{21} Under regulations 257 \[j932\] and 258 \[j933\] of the consolidated regulations
\textsuperscript{22} Under regulations 150 \[j151\] and 151 \[j152\] of the consolidated regulations
\textsuperscript{23} Under the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (SI 1994/3144); Medicines for Human Use (Clinical trials) Regulations 2004 (SI 2004/1031); Medicines (Traditional Herbal Product for Human Use) Regulations 2005 (SI 2005/2750); Medicines (Homoeopathic Medicinal product for Human Use) Regulations 1994 (SI 1994/105); and Medicines Act 1968.
6.25 In addition, in order to address uncertainty that the existing legislation sometimes creates for applicants, we have made the following clarifications in the draft consolidated regulations to reflect existing policy:

- By using the word ‘review’ and stating that the licensing authority must take the report of the reviewer into account\(^\text{24}\), we have clarified that the remit of the licensing decision review process is to review licensing decisions and provide advice on those decisions, rather than provide an appeal process – i.e. the reviewers cannot overturn a decision.
- We have explicitly stated\(^\text{25}\) that the reviewers may refuse to take into account any documents or other evidence, and any representations based on such documents or evidence, in the conduct of the hearing if they think that the documents or evidence were not available to the licensing authority at the time when the decision in question was made.

6.26 The changes to the person appointed process will not apply to clinical trials authorisations, since clinical trials legislation is not being consolidated. Accordingly, the references to the person appointed process in the Medicines for Human Use (Clinical trials) Regulations 2004 (SI 2004/1031) will remain unchanged.

6.27 A proposal for a policy change in relation to the eligibility of persons to act as reviewers under the consolidated regulations is made in chapter 8 below.

Implementing Directive 2001/83/EC

6.28 In consolidating the legislation implementing the Directive 2001/83/EC (“the Directive”) we have made several changes to the approach taken in the existing legislation. First, where necessary we

\(^{24}\) Under Schedule 5 [211s] of the draft consolidated regulations.
\(^{25}\) Under Schedule 5, paragraph 3(e) [211s] of the consolidated regulations.
have re-drafted provisions so that they reflect the relevant Article as clearly as possible. Second, so that users are no longer required to consult the Directive as well as the domestic legislation, we have generally replaced cross-references to Directive provisions with provisions transposing them into national law. For example, regulation 117 [j400] of the draft consolidated regulations defines “traditional herbal medicinal product” in terms, while the equivalent regulation in the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789) says that ‘traditional herbal medicinal product’ has the meaning given by Article 1(29) of the Directive”.

Definition of ‘advertisement’

6.29 We have taken the opportunity of the consolidation to update the definition of ‘advertisement’. Instead of the definition from the Medicines Act 1968, the definition in Part 1 of the draft consolidated regulations is based on that of ‘advertising’ in Article 86 of Directive 2001/83/EC. 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. This change is not intended to have any practical consequences in terms of what is or is not covered by the legislation.

Question 10

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

Offence provisions

Simplification of existing provisions

6.30 The existing medicines legislation employs a variety of drafting techniques to create offences. The draft consolidated regulations
present the offence provisions in a more convenient way. In particular, we have where possible established a single offence in each Part to cover breach of requirements.

6.31 These amendments are stylistic changes that improve the structure and clarity of the offence provisions; they are not intended to introduce any substantive change in meaning or effect.

Civil sanctions

6.32 In our November 2010 informal consultation on the consolidation\(^{26}\), we stated that we were considering introducing powers to use civil sanctions to address breaches of advertising and borderline requirements. Civil sanctions could provide a proportionate and flexible alternative to criminal prosecution, and responses to the consultation showed general support for them in principle. On further reflection we believe that, to ensure a consistent and efficient approach, any introduction of civil sanctions should be explored as part of a broader review of offences and penalties across medicines legislation. We would not be able to undertake this work within the timescales of the consolidation. We will, though, consider conducting a review separately as part of our ‘Regulatory Excellence’ programme. We would introduce any resulting changes by amending the consolidated regulations once in force.

Due diligence defence

6.33 A due diligence defence provides a defence for an accused person who can demonstrate that he or she took all reasonable steps and exercised all due diligence to avoid committing the offence. Due diligence defences in various forms are attached to a number of offences in existing medicines legislation, but by no means all of them. The draft consolidated regulations consolidate the existing

\(^{26}\) Available here:
http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/ProjecttoconsolidateandreviewUKmedicineslegislation/index.htm
provisions in this respect, and we are not at this time proposing to makes changes in this area. We do, though, intend to consider this issue in any future review of offences and penalties.

Herbal medicines

6.34 As mentioned in chapter 4 above, we are proposing two minor simplification measures in advance of any wider reforms relating to the registration of herbal practitioners:

- First, we propose to 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.

- Second, we are proposing to 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. 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.

Question 11
Do you agree with the proposals for the two simplifications in relation to herbal medicines? Why, or why not?
Paragraph 4 of Schedule 1 of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI 1994/3144) permits the supply of an unlicensed medicinal product to a person, exclusively for administration during the course of their business to a patient under their care. The unlicensed product may not be a Prescription Only Medicine. The unlicensed medicine may be manufactured by or under the supervision of a pharmacist, or by the holder of an appropriate Manufacturer (Specials) licence.

The basis for this exemption is the derogation in Article 5(1) of Directive 2001/83/EC, which permits Member States to provide national legislation for the supply of an unlicensed medicinal product to authorised healthcare professionals under certain circumstances.

It has been the MHRA's policy to view the exemption in paragraph 4 of Schedule 1 as applicable to regulated healthcare professionals who cannot commission unlicensed medicinal products by other means. For example, doctors and dentists can claim an exemption described under paragraph 1 of Schedule 1 and so are unlikely to use the exemption in paragraph 4, whereas a chiropodist could use the exemption in paragraph 4 to obtain a suitable unlicensed product (such as a concentrated Salicylic acid solution for the treatment of corns), where an equivalent licensed product was not available.

The consolidation provides an opportunity to clarify the policy intention of this particular exemption, and to ensure the exemption more clearly reflects the derogation in Article 5(1). In particular, the consolidated provision in draft regulation 158 [j125] (use of non-prescription medicines in the course of a business) defines authorised healthcare professionals by reference to regulation 229
Removal of requirement for fluted bottles for dispensing of certain medicinal products

6.39 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 propose that it should be left to the professional discretion of pharmacists to ensure that people with sight loss will use these medicines safely.

Question 12
Do you agree with the proposal to remove the requirement to dispense certain medicinal products in fluted bottles? Why, or why not?

27 The Medicines (Fluted Bottles) Regulations 1978 (SI 1978/40)
7 Removal of statutory warnings

7.1 This section, and the five that follow, set out proposed policy changes. The proposed changes are incorporated in the draft consolidated regulations in order to help illustrate how the changes would work. Legislative references are provided with each proposal.

7.2 Legislation currently requires marketing authorisation holders to include prescribed warnings, known as ‘statutory warnings’, on labelling and/or in the patient information leaflet for certain over-the-counter medicines. The policy intention behind this is to ensure that (a) patients receive clear warnings about important safety issues; and (b) these warnings are consistent across products with the same active ingredient.

7.3 Statutory warnings in the past been introduced following the advice of the Commission on Human Medicines (or its predecessors) on specific safety issues. We have a long-standing commitment to review the content of statutory warnings, as feedback suggests they are not well understood by patients and do not reflect what we have learned from user testing of patient information leaflets.

7.4 We now consider that placing labelling requirements in legislation is not necessary to meet the policy objective and that, owing to the time it takes to introduce legislative change, it lacks flexibility. Therefore, we propose to remove statutory warnings through the consolidated regulations, and instead to place product-specific or class warnings in the marketing authorisation for each product concerned, following negotiation with the relevant companies. The key benefits would be that:

28 Schedule 5 of the Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 (SI 1944/3144)
• warnings could be kept up to date with good practice as more evidence about the most effective forms of information becomes available from user testing, and changes implemented in a flexible way without legislative deadlines for compliance. This would help to ensure that recall of existing stock in the supply chain is not required
• time would be saved when making changes, as the MHRA would not need to undertake a formal legislative consultation and lay amending legislation before Parliament.

7.5 We have considered the case for making an exception for the warnings relating to paracetamol. Paracetamol poses a particular danger in overdose, and it is important to continue to ensure that consistent warnings are employed across the wide range of paracetamol-containing products. There are currently requirements for boxed warnings to advise that the product contains paracetamol; that the product should not be taken with other paracetamol-containing medicines; that the dose must not be exceeded; and that, in the event of an overdose, medical advice should be sought, even if you feel well. There is a risk that the lack of a statutory warning would make it more difficult to achieve a consistent approach. On balance, however, we propose to remove the warning from statute and rely on a requirement for consistent warnings in the marketing authorisation, underpinned by guidance to the industry. We would, though, welcome views on this proposal.

7.6 We have already had success with a non-statutory approach to labelling for codeine. Following CHM advice on the need for a warning about the risk of addiction and the short term nature of treatment, marketing authorisation holders agreed to a common approach to the introduction of warning statements on the front of over-the-counter packs.
Question 13
Do you agree with the proposal to remove statutory warnings, including for paracetamol? Why, or why not?
8 Review process for licensing decisions – change to membership criteria

8.1 In addition to the clarifications of existing policy relating to the person appointed process outlined in chapter 6 above, we are proposing to make a policy change in relation to the review hearing. There is a significant amount of work involved in conducting a person appointed hearing. Members of the Regulation of Medicines Review Panel must have the appropriate technical/scientific or legal skills required to consider these applications; they must be independent of the licensing authority; and, as with CHM members, must have no interests in pharmaceutical companies.

8.2 Current legislation specifically excludes former members of the medicines advisory bodies from acting as persons appointed. This exclusion is intended to address the risk of a conflict of interest. However, we believe that it goes beyond what is necessary to address that risk. We therefore propose to permit former members of medicines advisory bodies to be appointed as reviewers, providing that one year has elapsed since their term of office on any such body has expired. We believe that the risk of any conflict of interest would be addressed sufficiently by good practice in the appointment process and declaration of conflict of interests by members.

Question 14
Do you agree with the proposals to change the persons appointed process? Why, or why not?
9 Sale, supply and administration exemptions

9.1 Current medicines legislation allows health professionals and others to sell, supply and/or administer medicines by way of exemptions from the usual Medicines Act restrictions. We believe that:

- some exemptions are obsolete or no longer relevant and should be removed;
- others require extensions; and
- there should be several new exemptions.

9.2 This section will deal with each of these proposed changes in turn.

9.3 The proposals set out below are intended to introduce small but beneficial changes and are designed to reflect modern clinical practice. We do not believe that any of these proposals would create risks to public health.

Removal of exemptions that are obsolete or no longer relevant

9.4 The MHRA proposes to remove the provisions which relax restrictions on the sale or supply of medicines to:

- people who are employed or engaged in connection with schemes for testing the quality and quantity of medicines supplied in the NHS.

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29 The exemptions are set out in the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/183) ("the POM Order"), and the Medicines (Pharmacy and General Sale - Exemption Order) 1980 (1980/1924) ("the P and GSL Order"). In the draft consolidated regulations, they are set out in Part 12 and the associated schedules.

30 Currently in Paragraph 3, Part I of Schedule 5 of the POM Order, and Paragraph 6, Part 1 of Schedule 1 of the P and GSL Order.
• persons providing poultry vaccination services or selling and supplying poultry vaccines\textsuperscript{31}
• people selling or supplying medicines to the British Standards Institution.\textsuperscript{32}

9.5 This is because these provisions are obsolete or no longer relevant. For example, the British Standards Institution have informed us that they no longer require their exemption.

9.6 We also propose to remove a provision which allows pharmacists to sell or supply Amyl Nitrite\textsuperscript{33}. Amyl Nitrite used to be administered in cases of Cyanide poisoning, but it is no longer recommended by the Health and Safety Executive as an antidote. The Royal Pharmaceutical Society believes that a supply of Amyl Nitrite from a pharmacy would be a rare occurrence, since Cymag pesticides were banned for use, storage or supply on 31 December 2001. We therefore take the view that this provision is obsolete.

9.7 Finally, we propose to remove a provision allowing people to administer parenteral (injectable) medicines that are prescription only by virtue only of their being parenteral medicines if they are, and were at 11 February 1982, doing so in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.\textsuperscript{34} There is no evidence that the provision has any benefit or is used to any significant extent.

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

\textsuperscript{31} Currently in Paragraph 7, Part 1 of Schedule 1 of the P and GSL Order.
\textsuperscript{32} Currently in Paragraph 7, Part I of Schedule 5 of the POM Order, and Paragraph 10, Part 1 of Schedule 1 of the P and GSL Order.
\textsuperscript{33} Currently in Paragraph 9, Part I of Schedule 5 of the POM Order
\textsuperscript{34} Currently in Paragraph 7, Part III of Schedule 5 of the POM Order.
Extension of existing exemptions

9.8 We believe that the following extensions should be made to existing exemptions.

Sale or supply of medicines to organisations concerned with research

Extension of existing exemption

9.9 We propose 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. This extension would permit sale or supply of medicine for legitimate purposes outside an educational setting – for example where a company wishes to use a medicine to test a piece of machinery – in certain circumstances where those medicines are not for administration to human beings and there is no onward sale or supply. As with sale or supply to research institutes, sale or supply would require a signed order stating who wants the medicine and why, the quantity and the research purpose.

9.10 Provisions for this proposed change are in paragraph 7 of Part 4 of Schedule 17 [j511s, j529s] to the draft consolidated regulations.

9.11 The existing provisions allowing sale or supply of medicines to universities and institutions concerned with research or higher education do not exclude any class of medicines other than controlled drugs. We would welcome views on whether any extension of the provisions to other organisations concerned with research should be subject to the exclusion of any other classes of medicines – for example, cytotoxic and teratogenic drugs.
Question 16
a. 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?

b. 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?

Increasing the 2ml ampoule size limit for water for injection

9.12 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. However, we understand that there are occasional problems with availability of ampoules of this size. The Advisory Council on the Misuse of Drugs (an independent advisory body to the Government on drug-related issues) support a more flexible approach, although they could see a theoretical risk from sharing water if large ampoules of water were made available. Therefore, we are seeking views on increasing the limit to 5ml. This would facilitate the provision of lawful drug treatment involving water for injection, providing flexibility for providers of drug treatment services.

9.13 Provisions introducing this proposed change are in Part 2 of Schedule 17 [j511s and j529s] of the draft consolidated regulations.

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?
Removal of restriction on parenteral administration of adrenaline

9.14 In Article 7 of the POM Order, there is a list of parenteral medicines\(^{35}\) 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 propose to amend this provision to allow for the use of preparations \textbf{up to and including} 1 in 1000 (1mg in 1ml). This is because other preparations are now available which are more suitable for administration to a child.

9.15 Provision for this proposed change is in schedule 19 [\(\text{j523s}\)] to the draft consolidation regulations.

Question 18
a. 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 \textit{up to and including} 1 in 1000?

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

Additions to medicines that can be administered by registered ambulance paramedics on their own initiative

9.16 The Joint Royal Colleges Ambulance Liaison Committee (JRCALC), which is the expert national body on ambulance issues, has 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.\(^{36}\)

9.17 Intravenous Paracetamol, which is routinely used in hospitals, would be used by paramedics as part of balanced pain management. JRCALC consider that it is effective in easing pain and has also been

\(^{35}\)“Parenteral” is defined in the POM Order as “administration by breach of the skin or mucous membrane”.

\(^{36}\)Currently in Paragraph 9, Part III of Schedule 5 of the POM Order.
shown to reduce the dose of Morphine required to achieve adequate pain relief.

9.18 Ondansetron would be used for the treatment of nausea and vomiting when indicated. Only Metoclopramide is currently available for paramedic use, and it is restricted to patients aged 20 years and older. In the pre-hospital field vomiting and aspiration into the lungs presents a risk to patients, especially when they are immobilised on their back during transport to hospital. Ondansetron is very effective in treating nausea and vomiting and would be available to all age groups to reduce suffering and the risks of aspiration pneumonia.

9.19 Provisions for these proposed changes are in Part 3 of schedule 17 [j511s, j529] of the draft consolidated regulations.

<table>
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<th>Question 19</th>
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<td>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?</td>
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New exemptions

9.20 We propose to introduce the following new exemptions.

**Water for injection**

9.21 Water for injection is classed as a Prescription Only Medicine because it is for parenteral administration. We propose to allow persons who require water for injection for purposes other than parenteral administration to obtain it without a prescription. This proposal is 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.
9.22 The MHRA also proposes to allow pharmacists to sell or supply water for injection as a dilutant where no dilutant has been specified by the prescriber. This is intended to avoid unnecessary delay in administering medicines when a dry powder for injection has been prescribed without the necessary dilutant.

9.23 Provision for these proposed changes is in Part 1 of Schedule 17 [j511s and j529s] of the draft consolidated regulations.

Question 20
Should people be allowed to obtain water for injection for purposes other than parenteral administration without a prescription? Why, or why not?

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?

Administration of Adrenaline and Amiodorone
9.24 Following discussions with the Resuscitation Council (UK), we propose to allow holders of the Council’s Advanced Life Support (ALS) certificate to administer Adrenaline and Amiodorone in emergencies involving cardiac arrest. The article 7 list (see 9.14 above) does not currently allow for either. 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.
9.25 Provision for this proposed change is at Part 3 of Schedule 17 [j511s and j529s] of the draft consolidated regulations.

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?

Issues that are not included in this consultation

9.26 There are two proposals from our November 2010 informal consultation on sale, supply and administration issues that are not included in this consultation document.

Lists of medicines that can be accessed by health professionals

9.27 We consulted informally on a proposal to depart from the current system whereby medicines that may be accessed by different groups of health professional are specified in lists contained in a statutory instrument. The proposal would allow the relevant professional regulatory body to determine the medicines that should be available to registrants and maintain the list of these itself. This would be consistent with the Government’s approach to regulation, which is to rely on professional judgement where it is appropriate to do so. However, this issue requires more detailed consideration and further discussion with interested parties, including the regulatory bodies concerned, to ensure there would be appropriate and proportionate safeguards for the public. This work cannot be completed within the timescales for the consolidation, so the MHRA will progress it separately.
Sale of medicines on aircraft

9.28 Secondly, the exemptions include arrangements for medicines to be supplied to sick or injured persons on aircraft. We have received a request to extend the exemption to allow medicines to be sold on aircraft as well. We consulted informally on the proposal and responses were equally balanced. Responses in favour suggested that there should be a specific exemption to allow the sale of nicotine replacement products. The Medicines Advisory Bodies Working Group\textsuperscript{37} for the consolidation on the other hand took the view in 2010 that there is no case for allowing the sale of GSL medicines on an aircraft, as they can be supplied (free of charge) when needed. We do not, therefore, consider that a sufficient case has been made to change the law.

\textsuperscript{37} The joint working group mentioned in chapter 5 above.
10 Patient Group Directions

10.1 Patient Group Direction (PGDs) are written directions relating to the sale, supply or administration of a description or class of medicines to persons generally. A PGD must be signed by a doctor or dentist and a pharmacist. A PGD will be applicable in a defined clinical situation, and relate to sale, supply or administration by a particular body or person. When a product is to be supplied under it, there will be a legislative requirement that it be signed by or on behalf of that person or body. PGDs can be used in NHS settings and independent hospitals, clinics and medical agencies registered with the Care Quality Commission or its equivalents in Wales, Northern Ireland and Scotland. The individuals who are responsible for the sale, supply or administration of products to patients under the PGD are required by legislation to be members of certain groups of registered health professionals.  

10.2 Informal consultation has showed that PGDs were generally viewed as a positive development. There were, however, concerns about the bureaucracy involved in developing them. For example, different organisations preparing PGDs relating to the same medicine may duplicate effort. We intend to raise awareness of the PGD website hosted by the National electronic Library for Medicines, which contains local examples and tools to help decide whether a PGD is appropriate, as well as a range of frequently asked questions.

10.3 Overall, we propose to retain the general structure and requirements for PGDs in their current form, since we have not seen any evidence to suggest that they are no longer fit for purpose. We are also retaining the principle that only named registered and regulated

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38 The relevant existing legislation for PGDs is Articles 12A to E and Schedule 7 of the POM Order 1997, Articles 4A to D and Schedule 3 of the P and GSL Order 1980 and Regulation 5 and Schedule 1 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980.
health professionals should be able to use PGDs. In the interests of patient safety and governance, we need to be specific in law about which particular groups of health professional can access medicines. Therefore, they need to be identifiable and to have reached certain standards of competence consistent across the profession which can be confirmed by virtue of registration with the relevant professional body.

**Question 23**

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

10.4 We do, though, propose to make some minor changes. These are set out below.

Amendments to existing PGD provisions

10.5 We believe that the following amendments should be made to existing PGD provisions.

**Enabling an NHS body to supply in accordance with written directions by an independent nurse, pharmacist or optometrist independent prescriber.**

10.6 NHS bodies\(^{39}\) can supply medicines in accordance with the written directions of a doctor or dentist without needing to do so from registered pharmacy premises.\(^{40}\) We see no reason why NHS bodies should not be able to supply medicines similarly where the directions are written by other independent prescribers. We therefore propose to amend these provisions so that NHS bodies can also supply

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\(^{39}\) Defined in the draft consolidated regulations as the Common Services Agency, a health authority, a special health authority, a Primary Care Trust, an NHS trust, or an NHS foundation trust.

\(^{40}\) Article 12A of the POM Order and Article 4A of the P and GSL Order.
medicines in accordance with the written directions of an independent nurse, pharmacist or optometrist prescriber.

10.7 Provision for this proposed change is in regulation 182 [j507 and j531] of the draft consolidation regulations.

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?

Reflecting change in the Care Quality Commission registration process
10.8 Independent hospitals, clinics, medical agencies – and, in Northern Ireland, nursing homes – can sell, supply and administer medicines under a PGD by way of exemptions from the usual Medicines Act 1968 restrictions.\(^{41}\) In England, these bodies all have to be registered with the appropriate regulatory body. In England this body is the Care Quality Commission (CQC), which has changed the way in which private healthcare providers are registered in England: independent hospitals, clinics and agencies are no longer required to register, and registration is now by reference to regulated activities.\(^{42}\) To reflect this change, we therefore propose to continue to allow independent hospitals, clinics etc to use PGDs but to do so 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.

\(^{41}\) Article 12D of the POM Order and Article 4C of the P and GSL Order.
10.9 No change is required in relation to arrangements in Wales, Scotland or Northern Ireland.

10.10 The requirement that PGDs must be signed by the registered provider and the registered manager (if there is one), including sign off by the Clinical Governance Lead and the pharmacists, will remain.

10.11 Provision for this proposed change is in Regulation 184 [j509] [j534] of the draft consolidated regulation.

**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?

**New provision**

10.12 We propose to introduce the following new provision for PGDs.

Allowing dental practices and dental clinics registered with the CQC or its equivalents to sell, supply or administer medicines under PGDs.

10.13 We propose to allow dental practices and dental clinics registered with the CQC and private dentists registered with its equivalent in Wales⁴³ to sell, supply or administer medicines under PGDs. PGDs can already be used in these settings if NHS-funded services are

⁴³ Healthcare Inspectorate Wales
being provided. However, 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 understand that the current legal situation has caused confusion since dental therapists and hygienists were last year added to the list of health professionals who are able to use PGDs. We propose that PGDs developed in dental practices and clinics should be subject to the same authorisation requirements as those that apply to independent hospitals, clinics and medical agencies. In Wales, it is individual private dentists who are required to register, which explains the difference in references relating to Wales.

10.14 This provision does not extend to Northern Ireland or Scotland. This is because the current legal arrangements for the use of PGDs in independent hospitals and clinics cover dental practices and clinics registered by the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland. The position will be the same in Scotland once there is a commencement date for registration of these services by Health Improvement Scotland.

10.15 Provision for this proposed change is at regulation 185 [j534A] of the consolidation regulation accompanying this consultation.

**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?
PGD issues in relation to which we are not making proposals at this time

Accommodating structural changes in the NHS

10.16 Certain proposed NHS reforms, such as the establishment of social enterprises and the abolition of Primary Care Trusts, may have implications for the PGD regime. We will work with the Department of Health to ensure that the consolidated regulations will accommodate these changes as necessary.

Pharmacy

10.17 In the course of the informal consultation, some pharmacy-related issues were raised:

- allowing pharmacists registered with the General Pharmaceutical Council to develop their own PGDs
- adding pharmacy technicians to the list of health professionals who can use PGDs.

10.18 These issues require more detailed consideration which cannot be completed within the timescales for the consolidation. We will therefore progress them separately.

Use of unlicensed medicines in PGDs

10.19 Unlicensed medicines are currently excluded from the scope of PGDs. The informal consultation asked for views on including medicines in this category where there was a nationally identified need and no licensed alternative.

10.20 The legislation around unlicensed medicines is based on a doctor or dentist, an independent prescriber or a supplementary prescriber (acting in accordance with a clinical management plan) ordering a medicine on his/her own responsibility to meet the needs of a
particular patient. The use of PGDs, which are aimed at groups of patient who may not have been identified beforehand, would be inconsistent with these arrangements. On balance, we have decided that while there could be some advantages in allowing unlicensed medicines to be included in PGDs, we should continue to exclude them. We are therefore not proposing a change to the current exclusion.

Signatures required for PGDs in prisons

10.21 The informal consultation on PGDs included a proposal to make an amendment to the provisions which are currently in place for the use of PGDs in the prison service. At the time, we understood that where healthcare in a prison was provided by the NHS under a PGD authorised by an NHS body, the prison governor in England and Wales or the appropriate Prison Service Management Board in Scotland and Northern Ireland was also required to sign it. We have now received legal advice to the effect that the additional signature of the governor or Board is not necessary in these circumstances.
11 Optimisation of medicines use

11.1 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 (a) the name of the product or its common name; (b) directions for use of the product; and (c) precautions relating to the use of the product. Importantly, the existing legislation also states that the pharmacist can only make such changes if they have attempted to contact the prescriber but have been unable to do. This provision has been commonly interpreted as enabling pharmacists to ‘optimise’ the use of medicines – for example, by changing the dose or duration for which the medicine is taken, so long as the changes remain within the overall ceiling of the dosage and the timeframe specified in the prescription.

11.2 The direction of travel of health services has been to provide 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. Pharmacists are well-placed to support patients in making better use of their medicines and provide increased clinical support to patients, including optimising the use of medicines, which in turn better supports patients in a timely and effective way.

11.3 With this in mind, the Department of Health has proposed the removal of the requirement that pharmacists can only make the changes in question if they have attempted to contact the prescriber but have been unable to do so. In effect, this would remove the requirement for a pharmacist to attempt to seek the prescriber’s permission before making a change. This proposal is not seeking to

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44 The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI 1994/3144)
interfere with the clinical reason for prescribing a specific medicine. The proposed change is that the pharmacist, acting within their competence, uses in-depth knowledge of medicines and clinical judgement to help the patient obtain the most from the medicines prescribed but within the overall prescription. For example, this would enable a pharmacist to take action if a patient is prescribed an antibiotic three times a day for a condition which requires a single, combined daily dose. At the end of the period of the prescription the patient would have taken the total amount of the medicine prescribed thus achieving the intention of the prescriber.

11.4 The Devolved Administrations, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) have been approached and are content that this proposed change to support the optimisation of medicines use be included in the consultation. There would still be a need to ensure that prescriber and patient records are updated, and this could more appropriately be prescribed in guidance by the pharmacy independent professional regulators (GPhC and PSNI).

11.5 Provision for this proposed change is in Schedule 25 [j610s] Part 1 of the consolidation regulation accompanying this consultation.

Question 27
Do you agree with the proposal to facilitate the optimisation of medicines use? Why, or why not?
12 Keeping the consolidated regulations up to date

12.1 The UK’s medicines legislation has been amended frequently over the years. We expect this trend to continue, as a result of scientific developments, efforts to streamline processes and the development of EU law. We propose to amend the consolidated regulations as necessary, and periodically re-make them so that we incorporate all the changes and ensure that they remain easy to access and understand. This periodic consolidation exercise might take place every few years, depending on the nature of changes and the views of interested parties, and potentially to coincide with transposition of European Directives.

12.2 We plan to undertake a ‘Regulatory Excellence’ programme, which will have a particular focus on how we lift burdens on business and will report to the MHRA Executive Board from 2011. This programme will build on the benefits of consolidation and feedback from our participation in the Red Tape Challenge. It is likely to include reviews of sanctions and penalties in medicines legislation and our guidance that supplements medicines legislation.

12.3 We also propose to publish on our website an informal consolidated version of the regulations each time they are amended. This version would assist users by incorporating the amendments in a clean text. It would not be laid before Parliament, so would have no legal force.

Question 28
Do you agree with our proposal for keeping the consolidated regulations up to date? Why, or why not?
13  How to respond

13.1  We are consulting for 12 weeks. Responses must be received by Tuesday 17 January 2012.

13.2  To respond, please complete the response sheet at annex G together with the confidentiality template at annex H, providing a clear justification for treating your reply as confidential where you wish this to be the case. In order to help us analyse responses, we would strongly encourage you to use the response sheet at annex G and to reply by email if possible.

13.3  To help informed debate on the issues raised by this consultation exercise, the Agency intends to make copies of comments received proactively and publicly available on our website. Unless you state otherwise we will assume that you have no objections to your comments being made available in this way. Any consultation replies withheld, will still be subject to consideration under the FOIA if we receive a request, although we will then consider whether any exemptions against disclosure apply

13.4  If possible, responses should be sent by email to:

medicines.consolidation@mhra.gsi.gov.uk

Alternatively, they can be sent to:

Stephen Fawbert
Medicines and Healthcare products Regulatory Agency (MHRA)
Area 5-M, 5th Floor
151 Buckingham Palace Road, London
SW1W 9SZ
13.5 A summary of the responses will be published on the MHRA’s website, together with an update on next steps.

13.6 The interested parties listed at annex I are being alerted to this consultation by email. The consultation is available from our website (www.mhra.gov.uk) and replies are welcomed from all interested parties.

Confidentiality
13.7 We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

13.8 If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department. The MHRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.
Code of Practice on conducting consultations

13.9 This consultation follows the ‘Government Code of Practice’. In particular, we have aimed to:

- consult at a stage when there is scope to influence the policy outcome
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible
- ensure the consultation documents are clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals
- ensure the consultation exercise is accessible to, and clearly targeted at, those people the exercise is intended to reach
- keep the burden of consultation to a minimum so that consultations are effective and consultees’ buy-in is obtained
- carefully analyse responses and give clear feedback to participants following the consultation
- provide guidance to officials in how to run an effective consultation and share what they have learned from the experience.

13.10 Further information on Government policy on better regulation is provided by the Better Regulation Executive (http://www.bis.gov.uk/bre).

Comments on the consultation process itself

13.11 If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please contact:

Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds, LS2 7UE

Email: consultations.co-ordinator@dh.gsi.gov.uk