CONSULTATION LETTER: MLX 317

IMPLEMENTATION OF REVISED EU MEDICINES LEGISLATION: IMPLEMENTING THE “2001 REVIEW”

1. Summary


1.2 This consultation also seeks comments on proposals to make various amendments to the existing legislation (the Medicines Act 1968 and regulations/orders made under that Act) which implements the provisions of Directive 2001/83/EC and Commission Directive 2003/94/EC relating to manufacture and wholesale distribution.

1.3 The consultation is being conducted by the MHRA on behalf of the Secretary of State for Health. The closing date for receipt of replies is 16 June 2005.

1.4 The consultation documents, which can be found on the MHRA’s website (www.mhra.gsi.gov.uk) contain the following:

\[\text{Annex A} \quad \text{- Proposals for implementation of the remaining provisions in Directive 2004/27/EC}\]
\[\text{Annex B} \quad \text{- Proposals to introduce sanctions for non-compliance with the obligations of Regulation 726/2004 and amending Directive 2004/27/EC}\]
\[\text{Annex C} \quad \text{- A Partial Regulatory Impact Assessment on the implementation of Directive 2004/27/EC}\]
Annex D - Other changes to legislation  
Annex E - A Partial Regulatory Impact Assessment of the changes outlined in Annex D  
Annex F - Glossary of Terms  
Annex G - Reply proforma  
Annex H - Consultation list

1.5 However, if you wish to receive a paper copy of the consultation, please contact:

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1.6 You are invited to comment and a form is attached for your reply at Annex G. Responses received after the closing date cannot be included in the exercise.

2. Background

2.1 In October 2001, the Commission published its proposals to amend the body of legislation covering the EU medicines regulatory regime (Regulation 2309/93 and Directives 2001/82/EC and 2001/83/EC). Regulation 2309/93 established a centralised authorisation procedure for human and veterinary medicinal products and established the European Agency for the Evaluation of Medicinal Products (EMEA). Directives 2001/82/EC and Directive 2001/83/EC set out the Community codes for medicinal products for veterinary and human use. The Directives lay down provisions governing the marketing authorisation, manufacture and distribution of such products. Following detailed negotiations between the Council of the European Union and the European Parliament, agreement on the proposed legislative amendments was reached in early 2004.

2.2 The agreed texts were adopted by the Council and the European Parliament on 31 March 2004 as–

- Regulation (EC) No. 726/2004 (replacing Regulation 2309/93)  

2.3 The legislation was published in the Official Journal on 30 April 2004 - OJ L 136, 30.4.2004, p.1 to 84. Copies of the agreed texts are available at:
2.4 The agreed package of measures meets the Government’s objectives of strengthening the protection of public health of EU citizens, whilst improving the competitiveness of the EU pharmaceutical industry. The agreed legislation also prepares the EU regulatory regime for the participation of 10 new Member States (from 1 May 2004).

2.5 The Veterinary Medicines Directorate (VMD) are consulting separately on Directive 2004/28/EC and other provisions that amend the legislation as it applies to veterinary medicines. Their consultation can be found at [www.vmd.gov.uk](http://www.vmd.gov.uk). Please note, however, that we are seeking views on a proposal to amend the Patents Act 1977 to implement the “Bolar” provisions from both the veterinary and the medicines directives – see the paragraphs below on Article 10(6) of Directive 2001/83/EC.

3. Implementation

Timetable

3.1 The UK is obliged to implement the new EU legislation. Regulation 726/2004 is directly applicable in national law and its main provisions will apply in the UK from 20 November 2005. The provisions of Directive 2004/27/EC must be transposed into national law; the Member States have until 30 October 2005 to adopt the legislation necessary to transpose the directives. We propose that the provisions would be implemented primarily by regulations made by the Secretary of State for Health under section 2(2) of the European Communities Act 1972, amending the relevant UK legislation.

3.2 Consultation MLX 309 sought views on the possibility of implementing early three provisions in Directive 2004/27/EC that were identified by the Government as offering clear public health benefits. In view of the number of positive responses, the Government has decided to implement the three provisions early and those parts of the Directive (Articles 1(21), (44), (45) and (54)) are therefore excluded from this exercise (ie Articles 23, 59(3), and 61(1) of Directive 2001/83/EC as amended). These provisions were implemented by the Medicines Use (Marketing Authorisation and Miscellaneous Amendments) Regulations 2004 (SI 2004/3224).

Scope of this exercise

3.3 This consultation letter seeks your views on proposals to implement the remaining provisions of amending Directive 2004/27/EC. Although Member States are required to transpose the provisions into domestic law, there is some flexibility in relation to the way in which individual Member States choose to implement the agreed legislation. **This consultation does not seek your views on the Directive itself but our proposals for implementation.**

3.4 The key issues are summarised in [Annex A](#), although we welcome comments on any aspect of implementing or applying the new legislation. **Annex A** also includes an explanation of how the provisions change existing arrangements and the implications of those changes. The provisions in **Annex A** have been grouped...
according to the life cycle of a product, although the new Article numbers have also been provided for ease of reference.

3.5 Proposals to revise the MHRA’s current schedule of fees to take account of the new provisions will be included in a separate public consultation due to begin in April/May 2005. Although this consultation does not include fees proposals, the RIA at Annex C does contain the estimated costs to industry in complying with the new provisions.


4.1 A Partial Regulatory Impact Assessment is attached at Annex C. Views on the impact of the proposals – particularly in cost terms – are invited. Copies of the final RIA will be made available to Ministers, Parliament and the public.

5. Stakeholders

5.1 The regulation of medicines impacts on a wide range of stakeholders. They include patients and patient groups, healthcare professionals, the pharmaceutical industry, the herbal and homoeopathic sectors, and non-governmental organisations. MHRA is committed to involving views from as many interested parties as possible. If you know of other organisations that might have views that have been omitted from this consultation (list at Annex H), please forward this letter or contact us so that we can send a consultation pack.

5.2 Whilst responsibility for human medicines legislation is not a devolved matter, we are also consulting the devolved administrations in Scotland, Wales and Northern Ireland.

6. Format of response

6.1 We invite your views and comments on the proposals for implementation. In particular you may like to consider, in relation to each of the provisions set out in Annexes A – E whether the proposals for implementation of the provisions would (or would not) make a significant contribution to any of the following:

- Public health protection
- Patient safety
- The competitiveness of the UK/EU pharmaceutical industry
- The development of innovative medicines
- Improving information to patients and health care professionals
- Drug safety monitoring (pharmacovigilance).

6.2 In preparing this consultation document we have examined a number of issues on which you may like to reflect when preparing your response. In particular, you may wish to consider the effects of implementation on the herbal, parallel import, and homoeopathic sectors, where you feel the costs of compliance may be disproportionate to the increased levels of public health protection achieved. In addition, you may wish to consider our proposed transitional arrangements and
sanctions for non-compliance. The need to ensure EU harmonisation in the operation of certain procedures should also be considered.

6.3 Where possible, we would be grateful for responses expressed in terms of the costs and benefits (including financial) associated with the new provisions. In order to inform discussion on these issues, the annexes (including the Partial RIA) also include our initial analysis of the relative benefits and costs associated with implementation of the measures.

Transitional arrangements

6.4 Where appropriate, we have included the proposed transitional arrangements that we intend to introduce for each provision. Where the provision offers significant public health benefits compared with existing requirements, a three year transitional period is proposed, during which time products for which an application was submitted before 30th October 2005 will not be required to comply with the new requirements. However, where we propose to take a different approach, explanatory text is included in relation to the relevant provision in Annex A. For example, in relation to the Braille provision, we are proposing to introduce a five year transitional period, at which point all existing products would have to comply. We have taken a different approach on this provision to reflect concerns about the cost of compliance balanced against the proportionate public health gain. Further information on proposed transitional arrangements is provided in relation to relevant provisions in Annex A.

Enforcement and sanctions

6.5 Member States are responsible for determining the penalties to be applied in respect of infringements of the obligations in Regulation 726/2004. MHRA has identified four obligations for which sanctions for non-compliance may need to be applied. These are at Annex B. This annex also contains the sanctions that we are proposing to introduce in relation to the new obligations set out in the amending Directive.

EU Harmonisation

6.6 The Directive is intended to harmonise the rules of Member States relating to the authorisation of medicinal products. Member States must determine how the provisions are implemented in their territory, but a number of the agreed provisions require a level of EU conformity to ensure compatibility between Member States (particularly those relating to mutual recognition). Member States have therefore discussed proposals for implementation of certain provisions to ensure consistency in approach on certain regulatory activities.

6.7 Where relevant we have included text outlining the current interpretation of the measure at an EU level or the state of progress on matters such as Commission guidance. A further section describes the proposals for implementation and, where necessary, the UK’s interpretation of the provision, taking into account the EU position where appropriate. However, in many cases EU discussions are ongoing, and final decisions taken by the UK with regard to implementation will need to take
account of guidance yet to be produced by the Commission and the position adopted by other Member States in the coming months. Where the positions favoured at EU level are published for public consultation, we will include details and any relevant documentation on our web-site.

7. Making copies of replies available to the public

7.1 To help informed debate on the issues raised by this consultation exercise, and within the terms of the Freedom of Information Act 2000, the MHRA intends to make copies of comments received publicly available. Copies will be available shortly after the public consultation has ended.

7.2 The MHRA’s Information Centre at Market Towers will supply these copies on request. Copies may be further reproduced. Alternatively, personal callers can inspect the replies at the Information Centre by appointment. To make an appointment, please telephone 020 7084 2351.

8. Confidentiality

8.1 It will be assumed that your comments can be made publicly available unless you indicate that you wish all or part of them to be treated as confidential and excluded from this arrangement. Under the Freedom of Information Act, the MHRA will not release confidential replies or replies containing personal confidential information.

8.2 Should you have any questions regarding the proposals outlined in this consultation, or the conduct of the consultation exercise, please contact Michael Darbyshire at the postal or e-mail address provided.

8.3 This consultation is designed to meet the Government’s Code of Practice on written consultation, which states that the Government will:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department’s effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

Yours faithfully,

Margaret Jackman
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