Notification Number: 2012/45/UK

The Human Medicines Regulations 2012

Date received : 23/01/2012

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Message

Message 001

Communication from the Commission - SG(2012) D/5155
Directive 98/34/EC
Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificacão - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2012/0045/UK - Notificare.

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201200155.EN)

1. Structured Information Line
MSG 001 IND 2012 0045 UK EN 23-01-2012 UK NOTIF

2. Member State
UK

3. Department Responsible
Department for Business, Innovation and Skills
Innovation & Enterprise Group
1 Victoria Street, London, SW1H 0ET.

Email: 9834@bis.gsi.gov.uk.

3. Originating Department
Department of Health/Medicines and Healthcare products Regulatory Agency (MHRA)

4. Notification Number

2012/0045/UK - C00P

5. Title
The Human Medicines Regulations 2012

6. Products Concerned
The draft regulations apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, as amended.

7. Notification Under Another Act
- Provisions for national homeopathic products, primarily in Part 5 of the draft regulations, are being notified under Article 16(2) of Directive 2001/83/EC, as amended.

8. Main Content
The draft regulations are made under section 2(2) of the European Communities Act 1972 and various sections of the UK's Medicines Act 1968. They consolidate most of the existing United Kingdom legislation relating to the regulation of medicinal products for human use – comprising an Act and around 200 statutory instruments – and seek to introduce simpler and more consistent drafting. The legislation being consolidated mainly implements Directive 2001/83/EC as amended.

The draft regulations implement Directive 2010/84/EU of the European parliament and of the Council of 15 December 2010, amending Directive 2001/83/EC. Provisions implementing Directive 2010/84/EU are primarily in Part 11 of the draft regulations, but also in Parts 1, 5, 7, 13, 16 and 17.

The draft regulations do not implement Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, amending Directive 2001/83/EC.

The broad effect of the draft regulations is as follows:

• Part 1 contains definitions that apply to the rest of the draft regulations and deals with the scope of the Regulations. There are further definitions in other parts of the draft consolidated regulations, for terms that are only used in those particular parts.
• Part 2 allows for the continuing functioning of a number of bodies established to advise the licensing authority, which is the United Kingdom competent authority for the purposes of Directive 2001/83/EC. It also provides rules for the appointment and role of expert advisory groups.
• Part 3, with several associated schedules, sets out the rules for manufacturing, importing and wholesale dealing. It requires that these activities be the subject of a licence and establishes what the licensing authority must consider when assessing an application for a licence. It also provides rules concerning the suspension, revocation, and varying of licences and sets out requirements for manufacturers to have the services of qualified persons to oversee compliance with the Regulations and the terms of the marketing authorisation or registration of the products manufactured, and for wholesale dealers to have the services of responsible persons to oversee compliance with their licences and the maintenance of the quality of products handled. This Part implements Titles 4 and 7 of Directive 2001/83/EC.
• Part 4 sets out the overall requirement that medicinal products be the subject of whichever is appropriate of a marketing authorisation, homeopathic certificate of registration, traditional herbal registration or Article 126a authorisation. For clarity, the requirements relating to each of these forms of licensing are set out separately in Parts 5 to 7.

• Part 5 contains the requirements regarding standard marketing authorisations, implementing Chapter 1 of Title III of Directive 2001/83/EC. It also implements Chapter 2 of Title III of the Directive in respect of homeopathic products described in Article 16 of the Directive, called in the United Kingdom “national homoeopathic products”. It sets out the material that needs to accompany applications for authorisations and makes specific provision for generic medicinal products, certain biological medicinal products, products in well-established medicinal use, and new combinations of active substances. It also establishes the criteria that are considered in determining whether a product needs to be subject to prescription requirements. The Part imposes obligations on authorisation-holders, such as a requirement to take into account scientific and technical progress, and contains rules relating to renewal, revocation, variation, suspension, withdrawal of authorisations. It contains enforcement provisions for requirements under this Part, and also for a number of parallel requirements for EU marketing authorisations granted under Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Finally, it contains enforcement provision for medicinal products that are subject to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.
• Part 6 implements Chapter 2 of Part III of Directive 2001/83/EC in respect of the simplified registration scheme for homoepathic medicinal products defined in Article 14(1) of the Directive, which results in the United Kingdom in the issue of a “certificate of registration”. It describes the products to which it applies and sets out information that must be supplied with an application for a certificate of registration. As with marketing authorisations, it imposes certain obligations on registration holders and sets out rules regarding revocation, variation, withdrawals, and suspensions.
• Part 7 implements Chapter 2a, Title 3 of Directive 2001/83/EC on traditional-use registration for herbal medicinal products, which results in the United Kingdom in the issue of a “traditional herbal registration”. It describes the traditional herbal medicinal products that are subject to the Part and sets out the information that must accompany an application for a traditional herbal registration. It imposes certain obligations on registration-holders and sets out rules regarding revocation, variation, withdrawals, and suspensions.
• Part 8 implements Article 126a of Directive 2001/83/EC. This article permits Member States, for justified public health reasons, to authorise the placing on the market of medicinal products authorised in another EEA state in the absence of a UK marketing authorisation.
• Part 9 establishes a process that may be followed when the licensing authority determines provisionally that an unlicensed product is a medicinal product and therefore subject to regulation as such. It permits persons supplying the product to make written and oral representations to the contrary, and for final determination.
• Part 10 brings together exceptions from marketing authorisation requirements that are found in several different statutory instruments. In accordance with the derogation found in Article 5(1) of Directive 2001/83/EC, this includes provision for unlicensed medicinal products that can be supplied to meet special patient needs. The Part also makes provision for parallel import licences, exempt advance therapy medicinal products, assembly of radiopharmaceuticals from authorised components and the supply of unlicensed medicines in response to the spread of toxic substances or nuclear radiation.
• Part 11 comprises all the rules governing pharmacovigilance, including those introduced by Directive 2010/84/EU. Pharmacovigilance is the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk. The text of Part 11 is currently the subject of a separate public consultation in the United Kingdom and has been included here for completeness. Any minor changes arising from that consultation will be incorporated into Part 11 before its amalgamation with the draft regulations, to come into force - as required - by July 2012.
• Part 12 establish rules relating to the sale supply and administration of medicinal products related to their classification as general sale list, pharmacy, and prescription only. It also creates a number of exemptions from the basic rules for hospitals, certain professionals and supply under patient group directions. These provisions are related to obligations under Directive 2001/83/EC rather than implementing Directive provisions directly, but we do not believe that they establish any technical requirements or standards that required notification.
• Part 13 Chapter 1 implements obligations found in Title 5 of Directive 2001/83/EC. It sets out the information that must appear on packaging and in leaflets, and contains specific rules for Braille, radionuclides, and homeopathic and herbal medicinal products. Chapter 2 carries forward certain requirements relating to child

safety that are national in origin.
• Part 14 implements Title 8 of Directive 2001/83/EC and contains a variety of prohibitions on advertising including those relating to unlicensed medicines, prescription medicines, recommendations by scientists, and advertisements aimed at children. In addition, it sets out the information that needs to be included in advertisements and establishes rules for the provision of samples, the promotion of medicinal products by medical sale representatives, and inducements and hospitality. It also creates a process by which Ministers can take action when they think an advertisement is likely to breach, or has breached these requirements, including suspension of publication and requiring corrective action to be taken. Finally, it requires Ministers and the regulation OFCOM to consider complaints about advertisements and permits Ministers to apply to a court for an injunction prohibiting a particular advertisement.
• Part 15 provides for the publication of the British Pharmacopoeia and related documents.
• Part 16 sets out how the draft consolidated regulations are to be enforced in England, Wales, Scotland, and Northern Ireland. It also provides inspectors with powers to enter premises and inspect and seize medicinal products. Where the premises in question are private dwellings, it requires that 24 hours' notice be given to the occupier.
• Part 17 contains a variety of technical provisions, including defences available in prosecutions, time limits for prosecution, notification of decisions made under the regulations, and liability of corporations and partnerships.. It also introduces Schedules that contain transitional provisions, consequential amendments, and repeals and revocations.

9. Brief Statement of Grounds
The draft regulations will introduce consolidated, shorter, rationalised legislation that is easier to interpret and provides a platform for further simplification of the regulatory regime for human medicinal products in the UK.

10. Reference Documents - Basic Texts
No Basic Text exists

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
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13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
Impact Assessment not available

16. TBT and SPS aspects
TBT aspect

No - The draft is not a technical regulation nor a conformity assessment

No - The draft is in conformity with an international standard

No - The draft has no significant impact on international trade

SPS aspect

No - The draft is not a sanitary or phytosanitary measure

No - The draft has no significant impact on international trade

Catherine Day
General Secretary
European Commission

Contact point Directive 98/34
Fax: (32-2) 296 76 60
email: dir83-189-central@ec.europa.eu