Notification Number: 2016/162/UK

The Human Medicines (Amendment) (No. 2) Regulations 2016

Date received : 07/04/2016

End of Standstill : 08/07/2016

Message

Message 001

Communication from the Commission - TRIS/(2016) 01062
Directive (EU) 2015/1535
Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2016/0162/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 - Não 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: 201601062.EN)

1. Structured Information Line
MSG 001 IND 2016 0162 UK EN 07-04-2016 UK NOTIF

2. Member State
UK

3. Department Responsible
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4. Notification Number
2016/0162/UK - C00P

5. Title
The Human Medicines (Amendment) (No. 2) Regulations 2016

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
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8. Main Content
The draft regulations are made under section 2(2) and (5) of the European Communities Act 1972 and amend the Human Medicines Regulations 2012 and Medicines Act 1968.

The draft regulations address four separate issues with the aim to:
1. Enable the use of ‘hub and spoke’ dispensing models by ‘spoke’ pharmacies that do not form part of the same retail pharmacy business as the ‘hub’ pharmacy;
2. Permit dispensing labels to include the indicative cost of a medicine and a statement about how that cost is met, should this be required under NHS terms of service for medicines dispensed as part of the NHS pharmaceutical services;
3. Clarify the dispensing label requirements of the Human Medicines Regulations 2012, in particular by updating the labelling requirements for monitored dosage systems to reflect current practice and by ensuring products supplied under patient group directions have a dispensing label in line with professional guidance; and
4. Redesign the ‘exemptions for pharmacists' in section 10 of the Medicines Act 1968 in respect of the preparation and assembly of medicines, using the clarification of the law provided by the Court of Justice of the European Union (CJEU) in its decision Abcur AB v Apoteket Farmaci AB (CJEU 17.07.2015 C-544/13), so that businesses can be confident that the uses they are making of the relevant exemptions are legally secure.

9. Brief Statement of Grounds
The draft regulations support the policy initiative to make it possible for pharmacies in separate legal entities to use 'hub and' spoke dispensing models which is currently restricted to pharmacies in the same legal entity. The draft regulations also support the policy initiative to publish prices of medicines as well as a statement about how the costs of medicines are met on dispensing labels.
Furthermore, the draft regulations clarify dispensing label requirements to reflect current practice and the exemptions for pharmacist following a recent judgment of the CJEU.

10. Reference Documents - Basic Texts

References of the Basic Texts: Human Medicines regulations 2012:
http://www.legislation.gov.uk/uksi/2012/1916/contents/made
Basic Texts have been forwarded within the framework of a previous notification: 2012/0045/UK

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
-

16. TBT and SPS aspects
TBT aspect

No - The draft has no significant impact on international trade

SPS aspect

No - The draft is not a sanitary or phytosanitary measure

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European Commission

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