Notification Number: 2010/72/UK

# The Medicines for Human Use (Advanced Therapy and Miscellaneous Amendments) Regulations 2010

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| Date received | : | 28/01/2010 |
| End of Standstill | : | 29/04/2010 |
| Issue of comments by | : | Commission |

## Message

Message 001

Communication from the Commission - SG(2010) D/5267
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 : 2010/0072/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: 201000267.EN)

**1. Structured Information Line**
MSG 001 IND 2010 0072 UK EN 28-01-2010 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

**4. Notification Number**
2010/0072/UK - C10P

**5. Title**
The Medicines for Human Use (Advanced Therapy and Miscellaneous Amendments) Regulations 2010

**6. Products Concerned**
The Regulations will apply to any advanced therapy medicinal product (ATMP) as defined in Regulation (EC) No 1394/2007, which is prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.

**7. Notification Under Another Act**
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**8. Main Content**
Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products (the ATMP Regulation) entered into force on 30 December 2007 and applied from 30 December 2008. Under the Regulation, there is an exemption for ATMPs that are made and used in a hospital in the same Member States (as outlined in paragraph 6 of this notification). The Regulation stipulates that manufacture of ATMPs under the hospital exemption must be authorised by the Member State. Traceability, quality and pharmacovigilance standards for ATMPs made and used under the exemption must be equivalent to ATMPs for which a centralised authorisation would be granted under the Regulation. The requirements that would apply under the UK's national exemption scheme are laid down in the draft Regulation. Those requirements cover quality, manufacturing, pharmacovigilance and traceability along with additional patient information and advertising requirements that the UK considers to be necessary under the exemption. The specific requirements that would apply under the UK's exemption scheme including patient information and advertising requirements are laid down in the draft Regulations which accompany this notification form. The specific provisions are in Schedules 1, 2 and 3.

**9. Brief Statement of Grounds**
The specific parameters that are laid down in the Regulation are intended to ensure minimum standards and Member States may introduce additional requirements under their national exemption schemes. The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for the Regulation in the UK. The MHRA considered whether additional provisions would be necessary under the UK's exemption scheme and on public health grounds is proposing specific patient information and advertising requirements. Those requirements are included in the draft Regulations.

**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**
Yes

**16. TBT and SPS aspects**
TBT aspect

No - The draft has no significant impact on international trade

SPS aspect

No - The draft has no significant impact on international trade

Catherine Day
General Secretary
European Commission

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