Notification Number: 2002/348/UK

The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2002. [S.I. 2002 No. -----]

Date received : 06/09/2002

End of Standstill : 09/12/2002

Message

Message 001

Communication from the Commission - SG(2002) D/51773
Directive 98/34/EC
Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notification - Notifica - Kennisgeving - Notificacão - Ilmoitus - Anmälan : 2002/348/UK.

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200201773.EN)

1. Structured Information Line
MSG 001 IND 2002 0348 UK EN 09-12-2002 06-09-2002 UK NOTIF 09-12-2002

2. Member State
United Kingdom.

3. Department Responsible
Department of Trade and Industry: Standards and Technical Regulations
Directorate

3. Originating Department
The Department of Health.

4. Notification Number
2002/348/UK – C00P

5. Title

The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2002. [S.I. 2002 No. -----]

6. Products Concerned
The regulations apply to medicinal products for human use which are supplied under UK law other than in accordance with a marketing authorisation under Directive 2001/83/EC nor a product licence under the UK national scheme for regulating medicines not covered by the Community scheme, the Medicines Act 1968.

The two main categories of unlicensed medicines to which the Regulations will apply are:

(a) medicines (commonly known as “specials”) which are exempt from licensing because they are supplied in response to the unsolicited order of a doctor or dentist to meet the special needs of an individual patient on his direct personal responsibility;

(b) medicines (excluding herbal remedies) mixed, assembled and supplied by someone who is not a doctor or dentist, (known as a “non-orthodox practitioner”), to a patient who has consulted him about his health and

In addition, the Regulations will apply to any substance which, although not requiring a marketing authorisation under Directive 2001/83/EC or a product licence under the Medicines Act 1968, is classified as a “medicinal product” within the United Kingdom, and is regulated accordingly.

The Regulations will not apply to:

(a) investigational medicinal products which are dealt with under the clinical trials scheme

(b) products prepared under the supervision of a pharmacist in a pharmacy which will be dealt with under the existing professional arrangements and

(c) unlicensed herbal remedies.

7. Notification Under Another Act
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8. Main Content
The Regulations contain measures that prohibit the importation or marketing of unlicensed medicinal products for human use, unless they have been manufactured in accordance with the “Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products” as published and updated by the European Commission, in order to minimise the risk of the transmission of Transmissible Spongiform Encephalopathies via those products.

There is a procedure for enabling the appropriate Minister (the Secretary of State of Health or the Minister of Health, Social Services and Public Safety) to determine compliance with this Note for Guidance, and a notice procedure enabling the appropriate Minister to take action against non-compliant products.

In cases where non-compliance has been determined, there is a procedure for revisiting the determination where the appropriate Minister is satisfied that there is new evidence of compliance.

If products are manufactured using materials to which the Note for Guidance applies, designated record-keepers for the products have to keep records of evidence of compliance for five years, or for one year

after the expiry date of the product, which ever is the longer.

9. Brief Statement of Grounds
The Commission Directive 1999/82/EC requires all licensed medicines to comply with the European Commission's "Notes for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" and future updates. The amendments to Directive 75/318/EEC in this Directive have now been consolidated in to Directive 2001/83/EC. All licensed medicines in the UK are now required to comply with these guidelines. UK Ministers now want to protect patients from the same risk arising from unlicensed medicines. As the Commission's TSE Guideline states: "...due prudence continues to be warranted if biological materials from species affected by... [Transmissible Spongiform Encephalopathy] diseases other than by experimental challenge, especially bovine species, are used for the manufacture of medicinal products. " 10 (The draft measure must be forwarded with the notification, this part relates to other documents necessary for an understanding of the measure.)

10. Reference Documents - Basic Texts
a) Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human medicinal products.

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
b) The impact assessment is attached.

16. TBT and SPS aspects
Considering whether notification is appropriate.

David O'Sullivan
General Secretary
European Commission

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sent to :

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