Notification Number: 2000/173/UK

The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000

Date received : 26/04/2000

End of Standstill : 26/07/2000

Message

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Message 001

Communication from the Commission - SG(2000) D/50880
Directive 98/34/EC
Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notification - Notifica - Kennisgeving - Notificacão - Ilmoitus - Anmälan : 2000/173/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: 200000880.EN)

1. Structured Information Line
MSG 001 IND 2000 0173 UK EN 26-07-2000 26-04-2000 UK NOTIF 26-07-2000

2. Member State
United Kingdom.

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

3. Originating Department
Ministry of Agriculture, Fisheries and Food (Veterinary Medicines Directorate)

4. Notification Number
2000/0173/UK

5. Title
The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000

6. Products Concerned
Veterinary medicinal products

7. Notification Under Another Act
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8. Main Content
As part of the controls on advertising veterinary medicinal products in the UK, section 96 of the Medicines Act 1968 requires companies marketing such products to produce for each product a data sheet and to distribute copies to veterinary practices with or before any promotional material. The data sheet provides objective factual information about the product and its recommended use and is widely used for reference by veterinarians. The content and format of data sheets is set out in the Medicines (Data Sheet) Regulations 1972 (SI 1972/2076) as amended by SIs 1981/1633 and 1989/1183. The draft Regulations would revoke and replace existing Regulations laying down the content and format of data sheets.

9. Brief Statement of Grounds
Point 11 of the third paragraph of Article 5 of Council Directive 81/851/EEC (as amended) requires an applicant for an authorisation to market a veterinary medicinal product to prepare a summary of the product characteristics (SPC) as part of the data submitted in support of an application. The information required in SPCs is set out in Article 5a of the Directive and is almost identical to that required in data sheets. Current legislation requires companies to produce both an SPC and a data sheet for each product. The draft Regulations would allow companies marketing veterinary medicinal products to use SPCs to fulfil the requirements of data sheets if they so choose. Companies taking advantage of this option would not have to prepare a separate data sheet. In addition the draft Regulations provide for data sheets to be produced in electronic format and remove some of the prescriptive provisions controlling format that are no longer considered necessary.

10. Reference Documents - Basic Texts
Draft Regulations : The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000 (included)

Sent by post:
The Medicines (Data Sheet) Regulations 1972 (SI 1972/2076)

The Medicines (Data Sheet) Amendment Regulations 1981 (SI 1981/1633)

The Medicines (Data Sheet and Labelling) Amendment Regulations 1989 (SI 1989/1183)

Schedule 5 of The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (1994/3142)

Section 96 of The Medicines Act 1968

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
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13. Confidentiality
No

14. Fiscal measures
No

Carlo Trojan
General Secretary
European Commission