



Notification Number: 2002/477/UK

The Medicines (Child Safety) Regulations 2003

Date received : 11/12/2002

End of Standstill : 13/03/2003

Message

Message 001

Communication from the Commission - SG(2002) D/52409

Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notificación - Notification - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 2002/0477/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: 200202409.EN)

1. Structured Information Line

MSG 001 IND 2002 0477 UK EN 13-03-2003 11-12-2002 UK NOTIF 13-03-2003

2. Member State

United Kingdom.

3. Department Responsible

Department of Trade and Industry: Standards and Technical Regulations Directorate

3. Originating Department

Department of Health; Medicines Control Agency

4. Notification Number

2002/0477/UK – C00P

5. Title

The Medicines (Child Safety) Regulations 2003

6. Products Concerned



The following medicines for human use: Aspirin, Paracetamol and products containing more than 24mg of elemental iron.

7. Notification Under Another Act

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8. Main Content

The new Regulations require aspirin, paracetamol and medicines containing more than 24mg of elemental iron to be in child resistant containers. Non-reclosable containers will need to comply with a new British Standard, BS8404, on non reclosable packaging; and reclosable containers will need, as now, to comply with British Standard EN 28317 on reclosable packaging. Pack sizes for these products exclusively for children will be limited to 25. There are certain exemptions where doctors and dentists direct otherwise. Solid dosage forms of aspirin and paracetamol will, as now, need to be coloured white. There are transitional arrangements that allow products already on the market additional time to meet the new requirements.

The intention is to include recognition of equivalent standards and this will be incorporated into the UK Statutory Instrument. The draft Statutory Instrument on which public consultation in the UK has commenced does not include such a clause but this omission will be corrected.

9. Brief Statement of Grounds

The requirements relating to colouring, and the pack size requirements for aspirin and paracetamol in solid dosage form, have been in place since 1975. The requirements relating to reclosable containers have been in place, in their present form, since 1994. All have contributed to an important level of protection for children, who would otherwise be at greater risk of dangerous overdose from these very widely available medicines. As regards the requirements relating to non-reclosable packaging, the development of the new Standard BS8404 for non-reclosable packaging, with industry co-operation, has provided the opportunity to give children an equivalent level of protection from reclosable and non-reclosable packaging. Extending the packaging requirements to medicines containing more than 24mg of elemental iron is to reduce the level of overdose of these medicines in children, who are particularly vulnerable to comparatively low doses of these medicines, which are frequently prescribed to mothers of young children. Applying the provisions to liquid as well as oral formulations of paracetamol and elemental iron reflects the fact that these present the same safety risk as the solid dosage forms.

10. Reference Documents - Basic Texts

The Medicines (Child Safety) Regulations 2003.

a) BS8404 and The Medicines (Child Safety) Regulations 1975 (as amended). The other standards referred to in the Regulations, B are available on request, but as indicated, these have been applied in their present form since 1994.

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

The impact assessment is attached.

16. TBT and SPS aspects

TBT and SPS Aspects

TBT Aspect

a) YES

SPS Aspect

The draft is not a sanitary or phytosanitary measure in the sense of Annex A of the SPS Agreement.

David O'Sullivan
General Secretary
European Commission

sent to :

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