



Notification Number: 2007/326/UK

British Pharmacopoeia 2008

Date received : 07/06/2007

End of Standstill : 10/09/2007

Issue of comments by : Italy

Message

Message 001

Communication from the Commission - SG(2007) D/51350

Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pietiekums - Pranešimas - Bejelerítés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2007/0326/UK - Notificare.

No abre el plazo - Nezahtuje 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 késések - Ma' jiftaħ 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: 200701350.EN)

1. Structured Information Line

MSG 001 IND 2007 0326 UK EN 10-09-2007 07-06-2007 UK NOTIF 10-09-2007

2. Member State

UK

3. Department Responsible

Department of Trade and Industry: Office of Science and Innovation

3. Originating Department

Medicines and Healthcare products Regulatory Agency

4. Notification Number

2007/0326/UK- C30P



5. Title

British Pharmacopoeia 2008

6. Products Concerned

Various pharmaceutical products

7. Notification Under Another Act

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8. Main Content

New and revised national standards for the British Pharmacopoeia 2008 and changes to implement Supplements 5.6, 5.7 and 5.8 of the European Pharmacopoeia.

New

Angelica Sinensis Root for use in THM

Processed Angelica Sinensis Root for use in THMP

Astralagus Root for use in THM

Processed Astralagus Root for use in THMP

Dantrolene Sodium

Processed Liquorice Root for use in THMP

White Peony Root for use in THM

Processed White Peony Root for use in THMP

Sumatriptan

General monograph for Formulated Preparations: Unlicensed Medicines

Bezafibrate Tablets

Caffeine Citrate Injection

Caffeine Citrate Oral Solution

Carmellose Sodium Eye Drops

Celiprolol Tablets

Co-codamol Capsules

Dantrolene Oral Suspension

Prolonged-release Diclofenac Capsules

Gentamicin Ear Drops

Gentamicin and Hydrocortisone Acetate Ear Drops

Insulin Aspart Injection

Insulin Lispro Injection

Ipratropium Powder for Inhalation

Ipratropium Nebuliser Solution

Levomethol Cream

Medroxyprogesterone Injection

Medroxyprogesterone Tablets

Mercaptopurine Oral Suspension

Prolonged-release Minocycline Capsules

Mometasone Scalp Application

Mometasone Cream

Mometasone Aqueous Nasal Spray

Mometasone Ointment

Gastro-resistant Omeprazole Capsules

Gastro-resistant Omeprazole Tablets



Paracetamol Capsules
Paediatric Phenobarbital Oral Solution
Potassium Chloride Oral Solution
Salbutamol Powder for Inhalation
Simvastatin Tablets
Sodium Bicarbonate Oral Solution
Sodium Chloride Oral Solution
Sodium Fluoride Oral Solution
Sumatriptan Nasal Spray
Artemisia Cina for Homoeopathic Preparations
Symphytum Officinale Root for Homoeopathic Preparations
Symphytum Officinale Root, Ethanol. decoctum for Homoeopathic Preparations
Toxicodendron Quercifolium for Homoeopathic Preparations
Urtica Urens Herb for Homoeopathic Preparations

Revised

Alimemazine Tartrate
Medical Air
Synthetic Air
Oxygen
Dispersible Aspirin Tablets
Effervescent Soluble Aspirin Tablets
Beclometasone Pressurised Inhalation
Captopril Tablets
Cefazolin Injection
Cisplatin Injection
Clobazam Capsules
Clotrimazole Cream
Clotrimazole Pessaries
Dispersible Co-codaprin Tablets
Fluticasone Nasal Spray
Glibenclamide Tablets
Hypromellose Eye Drops
Lorazepam Tablets
Minocycline Tablets
Mupirocin Ointment
Oral Rehydration Salts
Pancuronium Injection
Phenobarbital Elixir
Phenobarbital Tablets
Phenobarbital Sodium Tablets
Piperacillin Intravenous Infusion
Ramipril Capsules
Ramipril Tablets
Ranitidine Injection
Ranitidine Oral Solution
Ranitidine Tablets
Sulfadiazine Injection
Sumatriptan Injection
Sumatriptan Tablets
Tranexamic Acid Injection
Tranexamic Acid Tablets



Vancomycin Intravenous Infusion

9. Brief Statement of Grounds

Protection of health and welfare

10. Reference Documents - Basic Texts

b) The basic texts have already been transmitted in the framework of notification 2005/0239/UK.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

No

13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

Impact Assessment not available

16. TBT and SPS aspects

TBT Aspect

No

The draft does not have a significant effect on international trade.

SPS Aspect

No

The draft does not have a significant effect on international trade.

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European Commission

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