



Notification Number: 2008/305/UK

British Pharmacopoeia 2009

Date received : 17/07/2008

End of Standstill : 20/10/2008

Message

Message 001

Communication from the Commission - SG(2008) D/51387

Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2008/0305/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: 200801387.EN)

1. Structured Information Line

MSG 001 IND 2008 0305 UK EN 20-10-2008 17-07-2008 UK NOTIF 20-10-2008

2. Member State

UK

3. Department Responsible

Department for Innovation, Universities and Skills
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3. Originating Department

Medicines and Healthcare products Regulatory Agency

4. Notification Number

2008/305/UK – C30P



5. Title

British Pharmacopoeia 2009

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 2009 and changes to implement the 6th Edition and Supplements 6.1 and 6.2 of the European Pharmacopoeia.

New

Adrenaline and Cocaine Intranasal Solution
Prolonged-release Aminophylline Tablets
Prolonged-release Bezafibrate Tablets
Bupivacaine Heavy Injection
Captopril Oral Solution
Chlorhexidine Gluconate Gel
Clarithromycin Tablets
Prolonged-release Clarithromycin Tablets
Cocaine Paste
Desmopressin Tablets
Desogestrel Tablets
Dexamethasone Eye Drops, Suspension
Dexamethasone Sodium Phosphate Eye Drops, Solution
Prolonged-release Felodipine Tablets
Fluticasone Nasal Drops
Compound Glucose, Sodium Chloride and Sodium Citrate Oral Solution
Hydrocortisone Sodium Phosphate Oral Solution
Iron Sucrose Injection
Ifosfamide Injection
Mupirocin Cream
Mupirocin Nasal Ointment
Ondansetron Injection
Ondansetron Tablets
Paracetamol, Codeine Phosphate and Caffeine Capsules
Paracetamol, Codeine Phosphate and Caffeine Tablets
Potassium Dihydrogen Phosphate Oral Solution
Prednisolone Sodium Phosphate Ear Drops
Pseudoephedrine Oral Solution
Gastro-resistant Sulfasalazine Tablets
Vancomycin Oral Solution
Zopiclone Tablets

New Immunological Products

Haemophilus Type b and Meningococcal Group C Conjugate Vaccine



New Herbal Drugs and Herbal Drug Preparations

Salvia Miltiorrhiza Rhizome and Root for use in THM
Processed Salvia Miltiorrhiza Rhizome and Root for use in THMP
Terminalia Arjuna Stem Bark for use in THMP
Terminalia Belerica Fruit for use in THMP
Terminalia Chebula Fruit for use in THMP
Withania Somnifera Root for use in THMP

New Materials for use in the Manufacture of Homoeopathic Preparations

Apomorphine Hydrochloride for Homoeopathic Preparations
Calcium Phosphate for Homoeopathic Preparations
Hydrated Iron (III) Phosphate for Homoeopathic Preparations
Hydrated Iron (II) and Iron (III) Phosphate for Homoeopathic Preparations

Revised

Amikacin Injection
Amoxicillin Injection
Beclometasone Pressurised Inhalation
Caffeine Citrate Oral Solution
Calamine Lotion
Camphorated Opium Tincture
Cefotaxime Injection
Compound Orange Spirit
Concentrated Anise Water
Concentrated Camphorated Opium Tincture
Co-proxamol Tablets
Dantrolene Oral Suspension
Desmopressin Intranasal Solution
Desmopressin Injection
Diphenylpyraline Hydrochloride
Erythromycin Lactobionate Intravenous Infusion
Gastro-resistant Bisacodyl Tablets
Hydrogenated Vegetable Oil
Hydroxychloroquine Sulphate
Meloxicam Tablets
Mercaptopurine Tablets
Methotrexate Injection
Methotrexate Tablets
Pancuronium Injection
Phenindamine Tartrate
Piperacillin Intravenous Infusion
Pyridostigmine Tablets
Quillaia
Senna Tablets
Squill

Revised Herbal Drugs and Herbal Drug Preparations

Angelica Sinensis Root for use in THM
Processed Angelica Sinensis Root for use in THMP
Astragalus Root for use in THM



Processed Astragalus Root for use in THMP
White Peony Root for use in THM
Processed White Peony Root for use in THMP

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 2007/0326/UK

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 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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