



Notification Number: 2009/396/UK

British Pharmacopoeia 2010

Date received : 16/07/2009

End of Standstill : 19/10/2009

Message

Message 001

Communication from the Commission - SG(2009) D/51668

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 : 2009/0396/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: 200901668.EN)

1. Structured Information Line

MSG 001 IND 2009 0396 UK EN 19-10-2009 16-07-2009 UK NOTIF 19-10-2009

2. Member State

United Kingdom

3. Department Responsible

Department for Business, Innovation and Skills
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3. Originating Department

Medicines and Healthcare products Regulatory Agency

4. Notification Number

2009/396/UK - C30P



5. Title

British Pharmacopoeia 2010

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 2010 and changes to implement the 6th Edition and Supplements 6.3, 6.4 and 6.5 of the European Pharmacopoeia.

New

Allopurinol Oral Suspension
Budesonide Aqueous Nasal Spray
Budesonide Nebuliser Suspension
Budesonide Powder for Inhalation
Budesonide Pressurised Inhalation
Bupivacaine and Fentanyl Injection
Chewable Calcium Carbonate and Heavy Magnesium Carbonate Tablets
Ceftazidime Injection
Chloral Hydrate Oral Solution
Clonazepam Tablets
Co-amoxiclav Oral Suspension
Dispersible Co-amoxiclav Tablets
Ephedrine Injection
Gastro-resistant Erythromycin Capsules
Erythropoietin Injection
Goserelin Implants
Prolonged-release Ibuprofen Capsules
Prolonged-release Ibuprofen Tablets
Gastro-resistant Lansoprazole Capsules
Gastro-resistant Lansoprazole Tablets
Loratadine Tablets
Magnesium Glycerophosphate Oral Solution
Chewable Magnesium Glycerophosphate Tablets
Prolonged-release Metoprolol Tartrate Tablets
Midazolam Oral Solution
Mirtazapine Tablets
Orodispersible Mirtazapine Tablets
Paediatric Paracetamol Oral Suspension
Phosphate Oral Solution
Propylene Glycol Solution
Prolonged-release Salbutamol Capsules
Prolonged-release Salbutamol Tablets
Prolonged-release Tamsulosin Capsules
Tibolone Tablets



Trazodone Capsules
Trazodone Tablets
Warfarin Oral Suspension
New Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products
Processed Herbal Drugs
Phyllanthus Emblica Pericarp for use in THMP
New Materials for use in the Manufacture of Homoeopathic Preparations
Cineraria Maritima for Homoeopathic Preparations
Cydonia Oblonga for Homoeopathic Preparations

Revised
Medicinal and Pharmaceutical Substances
Fluocinolone Acetonide Dihydrate
Menotrophin
Sumatriptan
Tioguanine
Trazodone Hydrochloride
Formulated Preparations: Specific Monographs
Amikacin Injection
Amiodarone Intravenous Infusion
Betahistine Dihydrochloride Tablets
Benzylpenicillin Injection
Caffeine Citrate Injection
Caffeine Citrate Oral Solution
Chloramphenicol Sodium Succinate Injection
Co-amoxiclav Tablets
Colistin Tablets
Dacarbazine Injection
Desmopressin Intranasal Solution
Doxepin Capsules
Erythromycin Estolate Capsules
Erythromycin Ethyl Succinate Tablets
Estradiol and Norethisterone Acetate Tablets
Glibenclamide Tablets
Heparin Injection
Hypromellose Eye Drops
Isotretinoin Gel
Levobunolol Eye Drops
Levomepromazine Tablets
Lisinopril Tablets
Menotrophin Injection
Methotrexate Injection
Methotrexate Tablets
Metoprolol Injection
Metoprolol Tartrate Tablets
Paroxetine Tablets
Sodium Valproate Oral Solution
Sodium Valproate Tablets
Gastro-resistant Sodium Valproate Tablets
Sulpiride Tablets
Tioguanine Tablets
Vincristine Injection



Materials for use in the Manufacture of Homoeopathic Preparations
Artemisia Cina for Homoeopathic Preparations
Toxicodendron Quercifolium for Homoeopathic Preparations
Urtica Urens Herb for Homoeopathic Preparations

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 2008/0305/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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