



Notification Number: 2012/427/UK

British Pharmacopoeia 2013

Date received : 09/07/2012

End of Standstill : 10/10/2012

Message

Message 001

Communication from the Commission - SG(2012) D/51841

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 : 2012/0427/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: 201201841.EN)

1. Structured Information Line

MSG 001 IND 2012 0427 UK EN 09-07-2012 UK NOTIF

2. Member State

UK

3. Department Responsible

Department for Business, Innovation and Skills
Innovation & Enterprise Group
1 Victoria Street, London, SW1H 0ET.

Email: 9834@bis.gsi.gov.uk.

3. Originating Department

Medicines and Healthcare products Regulatory Agency (MHRA)
British Pharmacopoeia Commission
151 Buckingham Palace Road
London



SW1W 9SZ

4. Notification Number

2012/0427/UK - C30P

5. Title

British Pharmacopoeia 2013

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 2013 and changes to implement the 7th Edition Supplements 7.3, 7.4 and 7.5 of the European Pharmacopoeia.

The following monographs are new additions to the British Pharmacopoeia 2013.

Medicinal and Pharmaceutical Substances:

Nicorandil

Formulated Preparations: Specific Monographs:

Buprenorphine Injection
Buprenorphine Transdermal Patches
Buprenorphine Sublingual Tablets
Cefuroxime Axetil Oral Suspension
Cefuroxime Intracameral Injection
Clarithromycin for Infusion
Clonazepam Oral Suspension
Cyclophosphamide Oral Solution
Diphenhydramine Tablets
Prolonged-release Dipyridamole Capsules
Dipyridamole Infusion
Dipyridamole Oral Suspension
Dorzolamide Eye Drops
Dorzolamide and Timolol Eye Drops
Dosulepin Oral Solution
Epirubicin Injection
Fexofenadine Tablets
Glycopyrronium Bromide Oral Solution
Hydrocortisone Acetate Oral Suspension
Lamotrigine Tablets
Lisinopril Oral Solution



Malathion Lotion
Malathion Shampoo
Mesalazine Foam Enema
Nicorandil Tablets
Prolonged-release Nifedipine Tablets
Oxycodone Capsules
Oxycodone Injection
Oxycodone Oral Solution
Prolonged-release Oxycodone Tablets
Potassium Ascorbate Eye Drops
Sodium Chloride Eye Ointment
Prolonged-release Tamsulosin Tablets
Triamcinolone Acetonide Nasal Spray
Vancomycin Capsules
Prolonged-release Venlafaxine Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products:

Berberis Aristata
Eclipta Prostrata Whole Plant

The following monographs are technical revisions.

Medicinal and Pharmaceutical Substances:

Ethanolamine
Hydroxychloroquine Sulfate
Menotrophin
Trazodone Hydrochloride

Formulated Preparations: Specific Monographs:

Amiodarone Infusion
Amiodarone Oral Suspension
Amoxicillin Capsules
Azathioprine Oral Suspension
Betahistine Dihydrochloride Tablets
Gastro-resistant Bisacodyl Tablets
Cefotaxime Injection
Cefradine Capsules
Cefradine Injection
Cefradine Oral Suspension
Ceftazidime Injection
Cefuroxime Injection
Chloral Hydrate Oral Solution
Coal Tar Solution
Co-amoxiclav Injection
Co-amoxiclav Oral Suspension
Co-amoxiclav Tablets
Dispersible Co-amoxiclav Tablets
Colistin Tablets
Demeclocycline Capsules



Prolonged-release Diltiazem Tablets
Dipyridamole Tablets
Disopyramide Phosphate Capsules
Doxorubicin Injection
Goserelin Implants
Hydroxychloroquine Tablets
Leuporelin Injection
Loperamide Capsules
Prolonged-release Mesalazine Granules
Mesalazine Suppositories
Gastro-resistant Mesalazine Tablets
Prolonged-release Mesalazine Tablets
Phentolamine Injection
Polymyxin and Bacitracin Eye Ointment
Progesterone Injection
Pyrimethamine Tablets
Ranitidine Oral Solution
Prolonged-release Salbutamol Capsules
Salbutamol Injection
Salbutamol Nebuliser Solution
Salbutamol Powder for Inhalation
Salbutamol Pressurised Inhalation
Prolonged-release Salbutamol Tablets
Sertraline Tablets
Simvastatin Tablets
Sodium Feredetate Oral Solution
Streptokinase Injection
Prolonged-release Tamsulosin Capsules
Thiopental Injection
Ticarcillin and Clavulanic Acid Infusion
Tobramycin Injection
Trazodone Capsules
Trazodone Tablets
Triclofos Oral Solution
Prolonged-release Verapamil Capsules
Prolonged-release Verapamil Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products:

Bacopa Monnieri
Liquorice Liquid Extract
Liquorice Root for use in TCM
Processed Liquorice Root for use in TCM

9. Brief Statement of Grounds

Protection of health and welfare.

10. Reference Documents - Basic Texts

Basic Texts have been forwarded within the framework of a previous notification: 2011/0419/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

None available

16. TBT and SPS aspects

TBT aspect

No - The draft has no significant impact on international trade

SPS aspect

No - The draft has no significant impact on international trade

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European Commission

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