



Notification Number: 2010/503/UK

British Pharmacopoeia 2011

Date received : 19/07/2010

End of Standstill : 20/10/2010

Message

Message 001

Communication from the Commission - SG(2010) D/51875

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 : 2010/0503/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: 201001875.EN)

1. Structured Information Line

MSG 001 IND 2010 0503 UK EN 19-07-2010 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
Market Towers
1 Nine Elms Lane



London SW8 5NQ

4. Notification Number

2010/0503/UK - C30P

5. Title

British Pharmacopoeia 2011

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 2011 and changes to implement the 6th Edition and Supplements 6.6, 6.7 and 6.8 of the European Pharmacopoeia.

NEW MONOGRAPHS

Acetazolamide Oral Suspension
Acetylcysteine Eye Drops
Alendronic Acid Tablets
Alfuzosin Tablets
Prolonged-release Alfuzosin Tablets
Azathioprine Oral Suspension
Bupivacaine and Diamorphine Injection
Cefuroxime Eye Drops
Chlorhexidine Gluconate Eye Drops
Ciclosporin Eye Drops
Clozapine Oral Suspension
Colistimethate Nebuliser Solution
Dalteparin Sodium Injection
Dexamethasone Sodium Phosphate Oral Solution
Prolonged-release Diltiazem Tablets
Dinoprostone Oral Solution
Disodium Edetate Eye Drops
Enoxaparin Sodium Injection
Etidronate Tablets
Hydroxyzine Oral Solution
Hydroxyzine Tablets
Interferon Alfa-2a Injection
Iopamidol Injection
Iopamidol Oral Solution
Metformin Oral Solution
Oxybutynin Oral Solution
Prolonged-release Oxybutynin Tablets
Paracetamol and Caffeine Tablets



Soluble Paracetamol and Caffeine Tablets

Povidone-Iodine Eye Drops

Pyrazinamide Oral Suspension

Salicylic Acid Cream

Sertraline Tablets

Silver Nitrate Solution

Sodium Chloride Nebuliser Solution

Tinzaparin Sodium Injection

Tranexamic Acid Mouthwash

Prolonged-release Venlafaxine Capsules

Venlafaxine Tablets

Zidovudine Capsules

Zidovudine Tablets

Zidovudine and Lamivudine Tablets

Zinc Sulphate Capsules

Zinc Sulphate Injection

Zinc Sulphate Tablets

Azadirachta Indica Leaf for use in THMP

Bacopa Monnieri for use in THMP

Phellodendron Chinense Bark for use in THM

Processed Phellodendron Chinense Bark for use in THMP

Citrullus Colocynthis Fruit for Homoeopathic Preparations

Prunus Spinosa Fruit for Homoeopathic Preparations

REVISED MONOGRAPHS -TECHNICAL CHANGES

Dextropropoxyphene Napsilate

Menotrophin

Liquefied Phenol

Tioguanine

Acetylcysteine Injection

Amiodarone Tablets

Beclometasone Powder for Inhalation

Budesonide Aqueous Nasal Spray

Budesonide Nebuliser Suspension

Budesonide Powder for Inhalation

Bupivacaine and Fentanyl Injection

Captopril Oral Solution

Ceftriaxone Injection

Clonazepam Injection

Clotrimazole Cream

Clotrimazole Pessaries

Colistimethate Injection

Co-proxamol Tablets

Dithranol Paste

Fluticasone Cream

Fructose Intravenous Infusion

Isoniazid Tablets

Gastro-resistant Lansoprazole Capsules

Gastro-resistant Lansoprazole Tablets



Levomenthol Cream
Levonorgestrel Tablets
Levothyroxine Tablets
Lisinopril Tablets
Loratadine Tablets
Lymecycline Capsules
Meglumine Amidotrizoate Injection
Meglumine Iodipamide Injection
Menotrophin Injection
Metoclopramide Injection
Miconazole Oromucosal Gel
Gastro-resistant Omeprazole Capsules
Gastro-resistant Omeprazole Tablets
Oxybutynin Tablets
Paediatric Phenobarbital Oral Solution
Polymyxin and Bacitracin Eye Ointment
Salicylic Acid Ointment
Sterile Silver Nitrate Solution
Simeticone Suspension for Infants
Sodium Bicarbonate Intravenous Infusion
Sodium Bicarbonate Oral Solution
Sodium Calcium Edetate Intravenous Infusion
Sodium Ferredate Oral Solution
Tibolone Tablets
Tioguanine Tablets
Tranexamic Acid Injection
Tranexamic Acid Tablets
Trisodium Edetate Intravenous Infusion
Warfarin Oral Suspension
Cascara Tablets
Senna Tablets

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: 2009/0396/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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