



Notification Number: 2011/419/UK

British Pharmacopoeia 2012

Date received : 08/08/2011

End of Standstill : 09/11/2011

Message

Message 001

Communication from the Commission - SG(2011) D/51908

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 : 2011/0419/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: 201101908.EN)

1. Structured Information Line

MSG 001 IND 2011 0419 UK EN 08-08-2011 UK NOTIF

2. Member State

UK

3. Department Responsible

Department for Business, Innovation and Skills
Knowledge and Innovation 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,
5th Floor (Yellow)
151 Buckingham Palace Road,



London SW1W 9SZ

4. Notification Number

2011/0419/UK - C30P

5. Title

British Pharmacopoeia 2012

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 2012 and changes to implement the 7th Edition and Supplements 7.1 and 7.2 of the European Pharmacopoeia.

NEW MONOGRAPHS

Melatonin

Acitretin Capsules

Amiodarone Oral Suspension

Arginine Hydrochloride Oral Solution

Cefradine Injection

Cetirizine Oral Solution

Cetirizine Tablets

Clobazam Oral Suspension

Clobazam Tablets

Fluticasone Powder for Inhalation

Fluticasone Pressurised Inhalation

Folic Acid Injection

Isoniazid Oral Solution

Lamivudine Tablets



Leuprorelin Injection

Losartan Potassium Tablets

Melatonin Capsules

Mesalazine Enema

Prolonged-release Mesalazine Granules

Mesalazine Suppositories

Gastro-resistant Mesalazine Tablets

Prolonged-release Mesalazine Tablets

Nicotine Inhalation Cartridges

Nicotine Nasal Spray

Nicotine Resinate Medicated Chewing Gum

Nicotine Transdermal Patches

Nicotine Sublingual Tablets

Prolonged-release Nifedipine Capsules

Omeprazole Oral Suspension

Paediatric Oseltamivir Oral Solution

Perindopril Erbumine Tablets

Testosterone Enantate Injection

Ticarcillin and Clavulanic Acid Intravenous Infusion

Trichloroacetic Acid Solution

Prolonged-release Verapamil Capsules

REVISED MONOGRAPHS -TECHNICAL CHANGES

Flupentixol Decanoate

Liquefied Phenol

Tioguanine



Trazodone Hydrochloride

Unlicensed Medicines Formulated preparations

Oral Liquids

Alendronic Acid Tablets

Aqueous Cream

Azathioprine Oral Suspension

Beclometasone Aqueous Nasal Spray

Budesonide Aqueous Nasal Spray

Budesonide Nebuliser Suspension

Budesonide Powder for Inhalation

Budesonide Pressurised Inhalation

Calcium Folate Injection

Calcium Folate Tablets

Cefuroxime Axetil Tablets

Chloramphenicol Capsules

Chloramphenicol Ear Drops

Chloramphenicol Eye Drops

Chloramphenicol Eye Ointment

Clozapine Oral Suspension

Cocaine Paste

Colchicine Tablets

Prolonged-release Diclofenac Tablets

Fluticasone Cream

Gentamicin Injection

Goserelin Implants

Heparin Injection



Isoniazid Tablets

Meloxicam Tablets

Mupirocin Ointment

Nitrofurantoin Oral Suspension

Paracetamol Suppositories

Penicillamine Tablets

Simeticone Suspension for Infants

Sodium Chloride Oral Solution

Tioguanine Tablets

Tranexamic Acid Mouthwash

Trazodone Capsules

Trazodone Tablets

Warfarin Oral Suspension

Withania Somnifera Root for Use in THMP

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: 2010/503/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

Catherine Day
General Secretary
European Commission

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