



Notification Number: 2013/450/UK

British Pharmacopoeia 2014

Date received : 08/08/2013

End of Standstill : 11/11/2013

Message

Message 001

Communication from the Commission - TRIS/(2013) 02061

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 : 2013/0450/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: 201302061.EN)

1. Structured Information Line

MSG 001 IND 2013 0450 UK EN 08-08-2013 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
151 Buckingham Palace Road
London



SW1W 9SZ

4. Notification Number

2013/0450/UK - C30P

5. Title

British Pharmacopoeia 2014

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 2014 and changes to implement the 7th Edition and Supplements of the European Pharmacopoeia.

The following monographs are new additions to the British Pharmacopoeia 2014.

Medicinal and Pharmaceutical Substances:

Diflunisal

Trifluridine

Formulated Preparations: Specific Monographs:

Abacavir Oral Solution

Abacavir Tablets

Adapalene Cream

Adapalene Gel

Amisulpride Oral Solution

Amisulpride Tablets

Amphotericin for Infusion

Bicalutamide Tablets

Bisoprolol Tablets

Prolonged-release Clomipramine Tablets

Prolonged-release Co-beneldopa Capsules

Dithranol and Salicylic Acid Ointment

Glimepiride Tablets

Glyceryl Trinitrate Ointment

Human Glucagon for Injection

Prolonged-release Indapamide Tablets

Irbesartan Tablets

Prolonged-release Isosorbide Mononitrate Capsules

Dispersible Lamotrigine Tablets

Levothyroxine Oral Solution

Midazolam Oromucosal Solution

Mirtazapine Oral Solution



Polymyxin and Bacitracin Ointment
Prednisolone Acetate Injection
Spironolactone Oral Suspension
Prolonged-release Tramadol Capsules
Prolonged-release Tramadol Tablets
Trandolapril Capsules
Trifluridine Eye Drops

In addition to the above new monographs, the following monographs have been included as a consequence of splitting monographs that previously referred to two pharmaceutical forms into separate monographs.

Chewable Ascorbic Acid Tablets
Chewable Calcium and Colecalciferol Tablets
Chewable Calcium and Ergocalciferol Tablets
Chewable Calcium Gluconate Tablets
Effervescent Paracetamol Tablets
Chewable Piperazine Phosphate Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products:
Anethum Graveolens Sowa Fruit
Trachyspermum Ammi

Materials for use in the Manufacture of Homoeopathic Preparations
Medicago Sativa for Homoeopathic Preparations

The following monographs are technical revisions.

Medicinal and Pharmaceutical Substances:
Cyclizine

Formulated Preparations: Specific Monographs:

Aciclovir Cream
Aciclovir Eye Ointment
Aciclovir Infusion
Aciclovir Oral Suspension I
Aciclovir Tablets
Dispersible Aciclovir Tablets
Ampicillin Injection
Carbamazepine Tablets
Cefradine Capsules
Cefradine Injection
Cefradine Oral Suspension
Ciprofloxacin Tablets
Co-amoxiclav Injection
Cyclizine Injection
Cyclizine Tablets
Diclofenac Gel
Prolonged-release Diltiazem Tablets
Fluoxetine Oral Solution
Gentamicin Ear Drops
Gentamicin Eye Drops
Gentamicin Injection
Hydrocortisone Acetate Oral Suspension



Ipratropium Inhalation Powder, hard capsule
Isoniazid Oral Solution
Ketamine Injection
Levothyroxine Tablets
Lisinopril Oral Solution
Loperamide Capsules
Meloxicam Tablets
Methotrexate Tablets
Norfloxacin Eye Drops
Ondansetron Injection
Ondansetron Tablets
Paediatric Oseltamivir Oral Solution
Pilocarpine Nitrate Eye Drops
Sulfasalazine Tablets
Tramadol Capsules

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products:
Eclipta Prostrata Whole Plant

Homoeopathic Preparations
Artemisia Cina for Homoeopathic Preparations
Toxicodendron Quercifolium for Homoeopathic Preparations
In addition to the above changes, the following monographs of the British Pharmacopoeia 2013 that have been retained in the British Pharmacopoeia 2014 have been amended as a consequence of the review of monographs for Inhaled Products.

BRITISH PHARMACOPOEIA 2014
Formulated Preparations: Specific Monographs
Beclometasone Powder for Inhalation
Replaced by:
Beclometasone Inhalation Powder and
Beclometasone Inhalation Powder, pre-dispensed
Budesonide Powder for Inhalation Replaced by:
Budesonide Inhalation Powder and Budesonide Inhalation Powder, pre-dispensed
Colistimethate Nebuliser Solution Replaced by:
Colistimethate Sodium Powder for Nebuliser Solution
Fluticasone Powder for Inhalation Replaced by:
Fluticasone Inhalation Powder and Fluticasone Inhalation Powder, pre-dispensed
Ribavirin Nebuliser Solution Replaced by:
Ribavirin Powder for Nebuliser Solution
Salbutamol Powder for Inhalation Replaced by:
Salbutamol Inhalation Powder and Salbutamol Inhalation Powder, pre-dispensed

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: 2012/0427/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

European Commission

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