



Notification Number: 2015/495/UK

British Pharmacopoeia 2016

Date received : 24/08/2015

End of Standstill : 25/11/2015

Message

Message 001

Communication from the Commission - TRIS/(2015) 02699

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 : 2015/0495/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: 201502699.EN)

1. Structured Information Line

MSG 001 IND 2015 0495 UK EN 24-08-2015 UK NOTIF

2. Member State

UK

3. Department Responsible

Department for Business, Innovation and Skills
European Reform Directorate
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

2015/0495/UK - C30P

5. Title

British Pharmacopoeia 2016

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 2016 and changes to implement the 8th Edition and Supplements of the European Pharmacopoeia

The following monographs are new additions to the British Pharmacopoeia 2016

Formulated Preparations: Specific Monographs

Abacavir and Lamivudine Tablets

Abacavir, Zidovudine and Lamivudine Tablets

Gastro-resistant Acamprosate Tablets

Bendroflumethiazide Oral Suspension

Carvedilol Tablets

Ceftazidime Eye Drops

Clotrimazole Eye Drops

Clotrimazole Vaginal Tablets

Diamorphine Tablets

Estradiol Vaginal Tablets

Etinodiol Tablets

Fluconazole Capsules

Fluconazole Infusion

Fluconazole Oral Suspension

Flumetasone and Clioquinol Ear Drops

Flupentixol Tablets

Fluticasone and Salmeterol Pressurised Inhalation Powder, pre-dispensed

Fluticasone and Salmeterol Pressurised Inhalation, Suspension

Interferon Beta-1a Injection

Ketoconazole Cream

Ketoconazole Shampoo

Lorazepam Oral Solution

Miconazole Eye Drops

Olanzapine Tablets

Orodispersible Olanzapine Tablets

Olmesartan Tablets

Soluble Prednisolone Tablets



Rizatriptan Tablets
Orodispersible Rizatriptan Tablets
Prolonged-release Sodium Valproate Capsules
Prolonged-release Sodium Valproate Tablets
Terbinafine Tablets
Vecuronium Bromide for Injection
Zidovudine Infusion

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Holy Basil Leaf
Phellodendron Amurense Bark
Phellodendron Chinense Bark

Technical Changes

Medicinal and Pharmaceutical Substances

Nicorandil
Phenelzine Sulfate

Formulated Preparations: Specific Monographs

Abacavir Tablets
Adapalene Cream
Adapalene Gel
Alendronic Acid Tablets
Alfuzosin Tablets
Prolonged-release Alfuzosin Tablets
Aminophylline Injection
Aminophylline Tablets
Prolonged-release Aminophylline Tablets
Carbimazole Tablets
Chloral Hydrate Oral Solution
Clobazam Oral Suspension
Clobazam Tablets
Clonazepam Tablets
Clonidine Tablets
Clotrimazole Pessaries
Codeine Phosphate Oral Solution
Desmopressin Tablets
Dexamethasone Sodium Phosphate Injection
Prolonged-release Dipyridamole Capsules
Dipyridamole Infusion
Doxorubicin Injection
Econazole Pessaries
Enoxaparin Sodium Injection
Ergocalciferol Injection
Ethinylestradiol Tablets
Paediatric Ferrous Sulfate Oral Solution
Glimepiride Tablets
Goserelin Implants



Heparin Injection
Hydroxychloroquine Tablets
Hydroxyzine Oral Solution
Kaolin Mixture
Kaolin and Morphine Mixture
Lamotrigine Tablets
Dispersible Lamotrigine Tablets
Levonorgestrel Tablets
Lisinopril Oral Solution
Lymecycline Capsules
Aromatic Magnesium Carbonate Mixture
Magnesium Hydroxide Mixture
Magnesium Sulfate Mixture
Magnesium Trisilicate Mixture
Melphalan Injection
Methotrexate Injection
Methotrexate Oral Solution
Morphine Sulfate Injection
Naloxone Injection
Omeprazole Oral Suspension
Oxymetholone Tablets
Liquid Paraffin Oral Emulsion
Liquid Paraffin and Magnesium Hydroxide Oral Emulsion
Paroxetine Tablets
Phenobarbital Elixir
Paediatric Phenobarbital Oral Solution
Phenobarbital Tablets
Phenobarbital Sodium Tablets
Phentolamine Injection
Phenytoin Capsules
Phenytoin Oral Suspension
Phenytoin Tablets
Potassium Citrate Mixture
Prednisolone Oral Solution
Primidone Oral Suspension
Primidone Tablets
Ramipril Capsules
Ramipril Tablets
Simvastatin Oral Suspension
Sodium Bicarbonate Oral Solution
Compound Sodium Chloride Mouthwash
Sodium Chloride Oral Solution
Sodium Valproate Oral Solution
Sodium Valproate Tablets
Gastro-resistant Sodium Valproate Tablets
Sumatriptan Injection
Sumatriptan Nasal Spray
Sumatriptan Tablets
Vinblastine Injection
Vincristine Injection
Zidovudine Capsules
Zidovudine Tablets



Zidovudine and Lamivudine Tablets
Zuclopenthixol Decanoate Injection

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: 2014/404/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

-

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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