



Notification Number: 2016/446/UK

British Pharmacopoeia 2017

Date received : 22/08/2016

End of Standstill : 23/11/2016

Message

Message 001

Communication from the Commission - TRIS/(2016) 02601

Directive (EU) 2015/1535

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2016/0446/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 - Não 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: 201602601.EN)

1. Structured Information Line

MSG 001 IND 2016 0446 UK EN 22-08-2016 UK NOTIF

2. Member State

UK

3. Department Responsible

Department for Business, Energy & Industrial Strategy
Europe Directorate
1 Victoria Street
London, SW1H 0ET

Email: technicalregulations@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

2016/0446/UK - C30P

5. Title

British Pharmacopoeia 2017

6. Products Concerned

Various pharmaceutical products

7. Notification Under Another Act

-

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 2017

Formulated Preparations: Specific Monographs

Aprepitant Capsules
Betamethasone Valerate and Coal Tar Paste
Carbamazepine Oral Suspension
Chewable Carbamazepine Tablets
Prolonged-release Carbamazepine Tablets
Clarithromycin Granules for Oral Suspension
Co-cyprindiol Tablets
Desmopressin Oral Lyophilisate
Desmopressin Nasal Spray
Dydrogesterone Tablets¹
Ferrous Fumarate and Folic Acid Capsules
Fluvastatin Capsules
Prolonged-release Fluvastatin Tablets
Gabapentin Capsules
Gabapentin Oral Solution
Gabapentin Tablets
Interferon Alfa-2b Injection
Loperamide Oral Solution
Loperamide Tablets
Orodispersible Loperamide Tablets
Prolonged-release Metformin Tablets
Pancreatin Capsules
Propranolol Oral Solution
Quinapril Tablets
Sterile Sodium Benzoate Concentrate



Tobramycin Nebuliser Solution

Valaciclovir Tablets

Verapamil Oral Solution

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Vitex Negundo Leaf

Revised monographs

Medicinal and Pharmaceutical Substances

Dispersible Cellulose

Clomethiazole

Clomethiazole Edisilate

Diclofenac Diethylamine

Phenelzine Sulfate

Sodium Dihydrogen Phosphate

Sodium Dihydrogen Phosphate Monohydrate

Formulated Preparations: Specific Monographs

Adapalene Cream

Adapalene Gel

Aminophylline Injection

Aminophylline Tablets

Prolonged-release Aminophylline Tablets

Azathioprine Oral Suspension

Baclofen Tablets

Gastro-resistant Bisacodyl Tablets

Buprenorphine Transdermal Patches

Caffeine Citrate Injection

Carmellose Sodium Eye Drops

Cetirizine Tablets

Chlordiazepoxide Capsules

Chlordiazepoxide Tablets

Chlorhexidine Gluconate Eye Drops

Chlorhexidine Irrigation Solution

Chlortetracycline Eye Ointment

Chlortetracycline Ointment

Clomethiazole Capsules

Clomethiazole Oral Solution

Clonazepam Oral Suspension

Colecalciferol Tablets

Cyclizine Injection

Cyclophosphamide Injection

Dalteparin Sodium Injection

Desferrioxamine Injection

Desmopressin Injection

Desmopressin Intranasal Solution

Desmopressin Tablets



Dexamethasone Sodium Phosphate Injection
Diamorphine Injection
Gastro-resistant Diclofenac Tablets
Digoxin Injection
Paediatric Digoxin Injection
Dimercaprol Injection
Dipyridamole Oral Suspension
Dithranol Ointment
Dithranol and Salicylic Acid Ointment
Enoxaparin Sodium Injection
Ferrous Fumarate and Folic Acid Tablets
Finasteride Tablets
Fluticasone Nasal Spray
Fluvoxamine Tablets
Goserelin Implants
Heparin Injection
Indapamide Tablets
Prolonged-release Indapamide Tablets
Lisinopril Oral Solution
Loperamide Capsules
Melphalan Injection

Methyl Salicylate Ointment
Mesalazine Enema
Mesalazine Foam Enema
Mesalazine Suppositories
Gastro-resistant Mesalazine Tablets
Prolonged-release Mesalazine Granules
Prolonged-release Mesalazine Tablets
Methylthioninium Injection
Metoclopramide Oral Solution
Montelukast Granules
Montelukast Tablets
Chewable Montelukast Tablets
Nicorandil Tablets
Nicotine Resinate Medicated Chewing Gum
Nitrazepam Oral Suspension
Nitrazepam Tablets
Omeprazole Oral Suspension
Phenobarbital Elixir
Phenobarbital Injection
Phenobarbital Tablets
Progesterone Injection
Prolonged-release Propranolol Capsules
Propranolol Injection
Propranolol Tablets
Sodium Bicarbonate Oral Solution
Sodium Chloride Nebuliser Solution
Prolonged-release Tamsulosin Tablets
Tinzaparin Sodium Injection
Tobramycin Injection
Vinblastine Injection



Warfarin Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Berberis Aristata

Gastro-resistant Peppermint Oil Capsules

Materials for use in the Manufacture of Homoeopathic Preparations

Medicago Sativa for Homoeopathic Preparations

Changes in Title

Sodium Dihydrogen Phosphate

Chlordiazepoxide 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: 2015/495/UK

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

-

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



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

No - The draft has no significant impact on international trade

European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: grow-dir83-189-central@ec.europa.eu