



Notification Number: 2018/463/UK

## British Pharmacopoeia 2019

Date received : 17/09/2018

End of Standstill : 18/12/2018

### Message

Message 001

Communication from the Commission - TRIS/(2018) 02487

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 : 2018/0463/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: 201802487.EN)

#### 1. Structured Information Line

MSG 001 IND 2018 0463 UK EN 17-09-2018 UK NOTIF

#### 2. Member State

UK

#### 3. Department Responsible

Department for Business, Energy and Industrial Strategy

Europe Directorate

1 Victoria Street

London, SW1H 0ET

Email: [technicalregulations@beis.gov.uk](mailto:technicalregulations@beis.gov.uk)

#### 3. Originating Department

Medicines and Healthcare Products Regulatory Agency (MHRA)

British Pharmacopoeia Commission

10 South Colonnade



Canary Wharf  
London  
E14 4PU

**4. Notification Number**

2018/0463/UK - C30P

**5. Title**

British Pharmacopoeia 2019

**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 2019 and changes to implement the 9th Edition and Supplements of the European Pharmacopoeia

The following monographs are new additions to the British Pharmacopoeia 2019

Formulated Preparations: Specific Monographs

Amlodipine Oral Solution  
Amlodipine Besilate Tablets  
Anastrozole Tablets  
Candesartan Tablets  
Cinnarizine Tablets  
Dihydrocodeine Prolonged-release Tablets  
Doxycycline Prolonged-release Capsules  
Doxycycline Tablets  
Ethambutol Oral Solution  
Biphasic Insulin Aspart Injection  
Biphasic Insulin Lispro Injection  
Itraconazole Capsules  
Itraconazole Oral Solution  
Itraconazole Sterile Concentrate  
Ketamine Nasal Spray  
Lorazepam Oral Suspension  
Moxifloxacin Tablets  
Potassium Acetate Sterile Concentrate  
Quetiapine Tablets  
Quetiapine Prolonged-release Tablets  
Tigecycline for Infusion  
Tolterodine Prolonged-release Capsules  
Tolterodine Tablets



Vardenafil Tablets

Vardenafil Orodispersible Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Glehnia Littoralis Root

Nutmeg

Revised monographs

Medicinal and Pharmaceutical Substances

Benzydamine Hydrochloride

Hydroquinone

Isometheptene Mucate

Melatonin

Oxytetracycline Calcium

Phenindione

Procyclidine Hydrochloride

Quinine Dihydrochloride

Formulated Preparations: Specific Monographs

Amikacin Injection

Benzoyl Peroxide and Clindamycin Gel

Bupivacaine Heavy Injection

Carbimazole Tablets

Carboplatin Injection

Cefoxitin Injection

Chloral Hydrate Oral Solution

Ciclosporin Eye Drops

Co-codamol Tablets

Co-dydramol Tablets

Clobazam Oral Suspension

Colistimethate Injection

Colistimethate Powder for Nebuliser Solution

Dalteparin Sodium Injection

Diclofenac Gel

Dihydrocodeine Injection

Dihydrocodeine Oral Solution

Dihydrocodeine Tablets

Doxepin Capsules

Doxorubicin Sterile Concentrate

Doxorubicin for Infusion

Doxycycline Capsules

Doxycycline Dispersible Tablets

Enalapril Tablets

Ferrous Fumarate Capsules

Fluticasone and Salmeterol Inhalation Powder, pre-metered

Fluticasone and Salmeterol Pressurised Inhalation, Suspension

Fluvoxamine Tablets

Glimepiride Tablets



Heparin Flush Solution  
Hydroxyzine Oral Solution  
Hydroxyzine Tablets  
Interferon Alfa-2a Injection  
Interferon Alfa-2b Injection  
Interferon Beta-1a Injection  
Levothyroxine Oral Solution  
Lorazepam Injection  
Lorazepam Tablets  
Magnesium Sulfate Injection  
Mercaptopurine Tablets  
Methylphenidate Tablets  
Mesalazine Enema  
Mesalazine Foam Enema  
Mesalazine Prolonged-release Granules  
Mesalazine Suppositories  
Mesalazine Gastro-resistant Tablets  
Mesalazine Prolonged-release Tablets  
Morphine Granules for Oral Suspension  
Moxifloxacin Intracameral Injection  
Naloxone Injection  
Nimodipine Infusion  
Nimodipine Tablets  
Omeprazole Gastro-resistant Capsules  
Omeprazole Gastro-resistant Tablets  
Oxycodone Prolonged-release Tablets  
Oxytetracycline Capsules  
Oxytetracycline Tablets  
Pantoprazole for Injection  
Prednisolone Tablets  
Prednisolone Gastro-resistant Tablets  
Prednisolone Soluble Tablets  
Propofol Injection  
Propranolol Tablets  
Rizatriptan Orodispersible Tablets  
Salbutamol Oral Solution  
Sertraline Tablets  
Sodium Valproate Gastro-resistant Tablets  
Sumatriptan Injection  
Sumatriptan Nasal Spray  
Telmisartan Tablets  
Tetracaine Eye Drops  
Tobramycin Injection  
Tobramycin Nebuliser Solution

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Liquorice Liquid Extract

Changes in Title

Codeine Monohydrate



Folic Acid Hydrate  
Metoclopramide Hydrochloride Monohydrate  
Colistimethate Powder for Nebuliser Solution  
Doxorubicin Sterile Concentrate  
Doxycycline Dispersible Tablets  
Mesalazine Prolonged-release Granules  
Mesalazine Gastro-resistant Tablets  
Mesalazine Prolonged-release Tablets  
Omeprazole Gastro-resistant Capsules  
Omeprazole Gastro-resistant Tablets  
Oxycodone Prolonged-release Tablets  
Pancreatin Gastro-resistant Capsules  
Pantoprazole Gastro-resistant Tablets  
Prednisolone Gastro-resistant Tablets  
Prednisolone Soluble Tablets  
Rizatriptan Orodispersible Tablets  
Sodium Valproate Gastro-resistant 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: 2017/0410/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



EUROPEAN COMMISSION  
GROWTH DIRECTORATE-GENERAL

Single Market for goods  
Prevention of Technical Barriers

SPS aspect

No - The draft has no significant impact on international trade

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European Commission

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