



Notification Number: 2017/410/UK

## British Pharmacopoeia 2018

Date received : 29/08/2017

End of Standstill : 01/12/2017

### Message

Message 001

Communication from the Commission - TRIS/(2017) 02294

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 : 2017/0410/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: 201702294.EN)

#### 1. Structured Information Line

MSG 001 IND 2017 0410 UK EN 29-08-2017 UK NOTIF

#### 2. Member State

UK

#### 3. Department Responsible

Department for Business, Energy and Industrial Strategy  
European Reform 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  
151 Buckingham Palace Road



London  
SW1W 9SZ

**4. Notification Number**

2017/0410/UK - C30P

**5. Title**

British Pharmacopoeia 2018

**6. Products Concerned**

Various pharmaceutical products

**7. Notification Under Another Act**

-

**8. Main Content**

New and revised national standards for the British Pharmacopoeia 2018 and changes to implement the 9th Edition and Supplements of the European Pharmacopoeia

The following monographs are new additions to the British Pharmacopoeia 2018

Medicinal and Pharmaceutical Substances

Hydroquinone

Tobramycin Sulfate

Formulated Preparations: Specific Monographs

Azithromycin Capsules

Azithromycin for Infusion

Azithromycin Oral Suspension

Azithromycin Tablets

Benzoyl Peroxide and Clindamycin Gel

Ceftazidime Injection

Ciclosporin Capsules

Sterile Doxorubicin Concentrate

Doxorubicin for Infusion

Heparin Flush Solution

Loperamide Oral Suspension

Methylphenidate Tablets

Morphine Capsules

Prolonged-release Morphine Capsules

Morphine Granules for Oral Suspension

Morphine Oral Solution

Pantoprazole for Injection

Gastro-resistant Pantoprazole Tablets

Pramipexole Tablets



Prolonged-release Pramipexole Tablets

Orodispersible Sildenafil Films

Sildenafil Injection

Sildenafil Powder for Oral Suspension

Sildenafil Tablets

Chewable Sildenafil Tablets

Orodispersible Sildenafil Tablets

Telmisartan Tablets

Tobramycin Oral Solution

Tretinoin, Hydrocortisone and Hydroquinone Cream

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Standardised Capsicum Oleoresin

Capsicum Tincture

Liquorice Liquid Extract

Tribulus Terrestris Fruit

Revised monographs

Medicinal and Pharmaceutical Substances

Melatonin

Menotrophin

Pancreatin

Papaveretum

Ritodrine Hydrochloride

Trazodone Hydrochloride

Formulated Preparations: Specific Monographs

Abacavir and Lamivudine Tablets

Acitretin Capsules

Adrenaline Injection

Dilute Adrenaline Injection 1 in 10,000

Aminophylline Injection

Alverine Capsules

Aspirin Tablets

Dispersible Aspirin Tablets

Gastro-resistant Aspirin Tablets

Bendroflumethiazide Oral Suspension

Betamethasone Valerate Lotion

Gastro-resistant Bisacodyl Tablets

Bisoprolol Tablets

Calcipotriol Ointment

Caffeine Citrate Injection

Caffeine Citrate Oral Solution

Chewable Carbamazepine Tablets

Ceftazidime for Injection

Ceftriaxone Injection

Cefuroxime Intracameral Injection

Cetirizine Capsules



Cetrimide Cream  
Chlorhexidine Gluconate Eye Drops  
Chlorhexidine Gluconate Gel  
Chlorhexidine Mouthwash  
Ciclosporin Oral Solution  
Cisplatin Injection  
Clonidine Injection  
Co-beneldopa Capsules  
Dispersible Co-beneldopa Tablets  
Dalteparin Sodium Injection  
Prolonged-release Diltiazem Tablets  
Dobutamine Infusion  
Doxepin Capsules  
Enalapril Tablets  
Enoxaparin Sodium Injection  
Ergocalciferol Tablets  
Ferrous Fumarate and Folic Acid Tablets  
Flupentixol Tablets  
Fluorescein Eye Drops  
Fluorescein Injection  
Fluticasone and Salmeterol Pressurised Inhalation Suspension  
Fluvastatin Capsules  
Prolonged-release Fluvastatin Tablets  
Folic Acid Injection  
Gabapentin Oral Solution  
Goserelin Implants  
Glycopyrronium Bromide Oral Solution  
Heparin Injection  
Hydroxyzine Oral Solution  
Hyoscine Butylbromide Injection  
Hyoscine Butylbromide Tablets  
Prolonged-release Indapamide Tablets  
Insulin Lispro Injection  
Ketoconazole Cream  
Ketoprofen Capsules  
Ketoprofen Gel  
Lidocaine and Chlorhexidine Gel  
Magnesium Hydroxide Mixture  
Methotrexate Injection  
Methotrexate Oral Solution  
Methotrexate Tablets  
Methylthioninium Injection  
Morphine Sulfate Injection  
Morphine Suppositories  
Morphine Tablets  
Prolonged-release Morphine Tablets  
Mupirocin Ointment  
Naloxone Injection  
Nitrazepam Tablets  
Olanzapine Tablets  
Orodispersible Olanzapine Tablets  
Olmesartan Tablets



Pancreatin Granules  
Gastro-resistant Pancreatin Tablets  
Papaveretum Injection  
Paracetamol Capsules  
Phenindione Tablets  
Paediatric Phenobarbital Oral Solution  
Phenylephrine Eye Drops  
Phenylephrine Injection  
Phenylephrine Intracameral Injection  
Prednisolone Sodium Phosphate Oral Solution  
Soluble Prednisolone Tablets  
Ranitidine Tablets  
Effervescent Ranitidine Tablets  
Ritodrine Injection  
Ritodrine Tablets  
Orodispersible Rizatriptan Tablets  
Sodium Chloride Oral Solution  
Tinzaparin Sodium Injection  
Trazodone Capsules  
Trazodone Tablets  
Vinblastine Injection  
Warfarin Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Tolu-flavour Solution

Changes in Title

Pholcodine  
Beclometasone Inhalation Powder, pre-dispensed  
Budesonide Inhalation Powder, pre-dispensed  
Ceftazidime Injection  
Fluticasone Inhalation Powder, pre-dispensed  
Fluticasone and Salmeterol Inhalation Powder, pre-dispensed  
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: 2016/446/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**

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**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

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European Commission

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