



Notification Number: 2014/404/UK

## British Pharmacopoeia 2015

Date received : 18/08/2014

End of Standstill : 19/11/2014

### Message

Message 001

Communication from the Commission - TRIS/(2014) 02403

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 : 2014/0404/UK - Notificare.

No abre el plazo - Nezhajuje 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: 201402403.EN)

#### 1. Structured Information Line

MSG 001 IND 2014 0404 UK EN 18-08-2014 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**

2014/0404/UK - C30P

**5. Title**

British Pharmacopoeia 2015

**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 2015 and changes to implement the 8th Edition and Supplements of the European Pharmacopoeia

The following monographs are new additions to the British Pharmacopoeia 2015

Formulated Preparations: Specific Monographs:

Sterile Arginine Hydrochloride Concentrate  
Calcipotriol Scalp Application  
Calcipotriol Cream  
Calcipotriol Ointment  
Cetirizine Capsules  
Sterile Ciclosporin Concentrate  
Ciclosporin Oral Solution  
Ciprofloxacin Eye Drops  
Citalopram Oral Drops  
Citalopram Tablets  
Clobetasol Scalp Application  
Clobetasol Cutaneous Foam  
Clobetasol Shampoo  
Clotrimazole and Hydrocortisone Acetate Cream  
Cyanocobalamin Oral Solution  
Fosinopril Tablets  
Insulin Glargine Injection  
Lidocaine Intraocular Injection  
Methotrexate Oral Solution  
Montelukast Granules  
Montelukast Tablets  
Chewable Montelukast Tablets  
Moxifloxacin Intracameral Injection  
Sterile Phenoxybenzamine Concentrate  
Phenylephrine Intracameral Injection  
Prednisolone Sodium Phosphate Oral Solution  
Effervescent Ranitidine Tablets  
Risperidone Oral Solution



Risperidone Tablets  
Dispersible Risperidone Tablets  
Simvastatin Oral Suspension  
Sterile Sodium Acetate Concentrate  
Prolonged-release Trosium Chloride Capsules  
Trosium Chloride Tablets  
Ursodeoxycholic Acid Oral Suspension  
Valsartan Capsules  
Valsartan Tablets  
Vancomycin Eye Drops  
Zolpidem Tablets

Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products  
Sesame Seed

Technical Changes: Medicinal and Pharmaceutical Substances

Chloroxylenol  
Domiphen  
Pancreatin  
Phenelzine Sulfate I  
Phenoxybenzamine Hydrochloride  
Procyclidine Hydrochloride  
Sodium Feredetate

Formulated Preparations: Specific Monographs

Abacavir Oral Solution  
Abacavir Tablets  
Aciclovir Infusion  
Aciclovir Tablets  
Dispersible Aciclovir Tablets  
Amiodarone Infusion  
Amisulpride Oral Solution  
Amisulpride Tablets  
Aspirin Tablets  
Dispersible Aspirin Tablets  
Effervescent Soluble Aspirin Tablets  
Aspirin and Caffeine Tablets  
Beclometasone Aqueous Nasal Spray  
Benzoyl Peroxide Cream  
Benzoyl Peroxide Gel  
Benzoyl Peroxide Lotion  
Budesonide Aqueous Nasal Spray  
Budesonide Nebuliser Suspension  
Budesonide Inhalation Powder  
Budesonide Inhalation Powder, pre-dispensed  
Budesonide Pressurised Inhalation  
Carbimazole Tablets  
Cefotaxime Injection  
Cetirizine Oral Solution  
Cetirizine Tablets  
Chloral Hydrate Oral Solution



Clotrimazole Cream  
Co-codaprin Tablets  
Dispersible Co-codaprin Tablets  
Colchicine Tablets  
Cyproterone Tablets  
Dantrolene Oral Suspension  
Dexamethasone and Neomycin Ear Spray  
Dexamethasone Sodium Phosphate Oral Solution  
Gastro-resistant Diclofenac Tablets  
Prolonged-release Diclofenac Tablets  
Domperidone Tablets  
Doxepin Capsules  
Enoxaparin Sodium Injection  
Fentanyl Injecton  
Fusidic Acid Cream  
Fusidic Acid Eye Drops  
Fusidic Acid Oral Suspension  
Glycopyrronium Bromide Oral Solution  
Goserelin Implants  
Hydrocortisone and Neomycin Cream  
Hydroxycarbamide Capsules  
Insulin Aspart Injection  
Iron Sucrose Injection  
Levonorgestrel Tablets  
Mianserin Tablets  
Minoxidil Scalp Application  
Neomycin Eye Drops  
Neomycin Eye Ointment  
Neomycin Tablets  
Gastro-resistant Omeprazole Capsules  
Ondansetron Injection  
Ondansetron Tablets  
Paediatric Oseltamivir Oral Solution  
Pancreatin Granules  
Gastro-resistant Pancreatin Tablets  
Phenoxybenzamine Capsules  
Phenytoin Capsules  
Phenytoin Tablets  
Potassium Hydroxyquinoline Sulfate and Benzoyl Peroxide Cream  
Prednisolone Tablets  
Ranitidine Oral Solution  
Ritodrine Tablets  
Sertraline Tablets  
Sodium Fusidate Ointment  
Sotalol Injection  
Sotalol Tablets  
Streptomycin Injection  
Tobramycin Injection  
Trihexyphenidyl Tablets  
Ursodeoxycholic Acid Capsules  
Ursodeoxycholic Acid Tablets



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

**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: 2013/0450/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

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European Commission

Contact point Directive 98/34

Fax: +32 229 98043

email: [dir83-189-central@ec.europa.eu](mailto:dir83-189-central@ec.europa.eu)