

# CONTENTS OF SUPPLEMENT 7.7

*A vertical line in the margin indicates where part of a text has been revised or corrected. A horizontal line in the margin indicates where part of a text has been deleted. However, these indications, which are not necessarily exhaustive, are given for information and do not form an official part of the texts. Editorial changes are not indicated.*

*Individual copies of texts will not be supplied.*

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## NEW TEXTS

*The texts below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 April 2013 at the latest.*

### GENERAL CHAPTERS

- 2.4.20. Determination of metal catalyst or metal reagent residues
- 2.9.47. Demonstration of uniformity of dosage units using large sample sizes
- 5.20. Metal catalyst or metal reagent residues

### MONOGRAPHS

#### General monographs

Pharmaceutical preparations (2619)

#### Vaccines for veterinary use

- Bordetella bronchiseptica vaccine (live) for dogs (2525)
- Salmonella Enteritidis vaccine (live, oral) for chickens (2520)
- Salmonella Typhimurium vaccine (live, oral) for chickens (2521)
- Turkey infectious rhinotracheitis vaccine (live) (2461)
- Yersiniosis vaccine (inactivated) for salmonids (1950)

### Herbal drugs and herbal drug preparations

- Capsicum soft extract, standardised (2529)
- Clematis armandii stem (2463)
- Magnolia officinalis flower (2568)
- Quillaia bark (1843)
- Salvia miltiorrhiza root and rhizome (2663)
- Sophora flower (2639)
- Turmeric rhizome (2543)

### Monographs

- Abacavir sulfate (2589)
- Anastrozole (2406)
- Ciclesonide (2703)
- Norflurane (2257)
- Pemetrexed disodium heptahydrate (2637)
- Risedronate sodium 2.5-hydrate (2572)
- Rivastigmine hydrogen tartrate (2630)

## REVISED TEXTS

*The texts below have been technically revised since their last publication. They will be implemented on 1 April 2013.*

### GENERAL CHAPTERS

- 2.5.39. Methanesulfonyl chloride in methanesulfonic acid
- 2.9.10. Ethanol content
- 2.9.11. Test for methanol and 2-propanol
- 4. Reagents
- 5.2.6. Evaluation of safety of veterinary vaccines and immunosera
- 5.2.9. Evaluation of safety of each batch of immunosera for veterinary use
- 5.15. Functionality-related characteristics of excipients

### MONOGRAPHS

#### General monographs

- Substances for pharmaceutical use (2034)
- Vaccines for veterinary use (0062)

#### Vaccines for veterinary use

- Anthrax spore vaccine (live) for veterinary use (0441)
- Aujeszky's disease vaccine (inactivated) for pigs (0744)
- Avian infectious bronchitis vaccine (inactivated) (0959)
- Avian infectious bronchitis vaccine (live) (0442)
- Avian infectious bursal disease vaccine (inactivated) (0960)
- Avian infectious bursal disease vaccine (live) (0587)
- Avian infectious encephalomyelitis vaccine (live) (0588)

- Avian infectious laryngotracheitis vaccine (live) (1068)
- Avian paramyxovirus 3 vaccine (inactivated) for turkeys (1392)
- Avian viral tenosynovitis vaccine (live) (1956)
- Bovine leptospirosis vaccine (inactivated) (1939)
- Bovine parainfluenza virus vaccine (live) (1176)
- Bovine respiratory syncytial virus vaccine (live) (1177)
- Bovine viral diarrhoea vaccine (inactivated) (1952)
- Brucellosis vaccine (live) (Brucella melitensis Rev. 1 strain) for veterinary use (0793)
- Calf coronavirus diarrhoea vaccine (inactivated) (1953)
- Calf rotavirus diarrhoea vaccine (inactivated) (1954)
- Canine adenovirus vaccine (inactivated) (1298)
- Canine adenovirus vaccine (live) (1951)
- Canine distemper vaccine (live) (0448)
- Canine leptospirosis vaccine (inactivated) (0447)
- Canine parainfluenza virus vaccine (live) (1955)
- Canine parvovirus vaccine (inactivated) (0795)
- Canine parvovirus vaccine (live) (0964)
- Clostridium botulinum vaccine for veterinary use (0360)
- Clostridium chauvoei vaccine for veterinary use (0361)
- Clostridium novyi (type B) vaccine for veterinary use (0362)
- Clostridium perfringens vaccine for veterinary use (0363)
- Clostridium septicum vaccine for veterinary use (0364)
- Coccidiosis vaccine (live) for chickens (2326)

Distemper vaccine (live) for mustelids (0449)  
 Duck plague vaccine (live) (1938)  
 Duck viral hepatitis type I vaccine (live) (1315)  
 Egg drop syndrome '76 vaccine (inactivated) (1202)  
 Equine herpesvirus vaccine (inactivated) (1613)  
 Equine influenza vaccine (inactivated) (0249)  
 Feline calicivirolosis vaccine (inactivated) (1101)  
 Feline calicivirolosis vaccine (live) (1102)  
 Feline chlamydiosis vaccine (inactivated) (2324)  
 Feline infectious enteritis (feline panleucopenia) vaccine (inactivated) (0794)  
 Feline infectious enteritis (feline panleucopenia) vaccine (live) (0251)  
 Feline leukaemia vaccine (inactivated) (1321)  
 Feline viral rhinotracheitis vaccine (inactivated) (1207)  
 Feline viral rhinotracheitis vaccine (live) (1206)  
 Fowl cholera vaccine (inactivated) (1945)  
 Fowl-pox vaccine (live) (0649)  
 Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521)  
 Infectious bovine rhinotracheitis vaccine (live) (0696)  
 Infectious chicken anaemia vaccine (live) (2038)  
 Mannheimia vaccine (inactivated) for cattle (1944)  
 Mannheimia vaccine (inactivated) for sheep (1946)  
 Marek's disease vaccine (live) (0589)  
 Mycoplasma gallisepticum vaccine (inactivated) (1942)  
 Myxomatosis vaccine (live) for rabbits (1943)  
 Neonatal piglet colibacillosis vaccine (inactivated) (0962)  
 Neonatal ruminant colibacillosis vaccine (inactivated) (0961)  
 Newcastle disease vaccine (inactivated) (0870)  
 Newcastle disease vaccine (live) (0450)  
 Pasteurella vaccine (inactivated) for sheep (2072)  
 Porcine actinobacillosis vaccine (inactivated) (1360)  
 Porcine enzootic pneumonia vaccine (inactivated) (2448)  
 Porcine influenza vaccine (inactivated) (0963)  
 Porcine parvovirus vaccine (inactivated) (0965)  
 Porcine progressive atrophic rhinitis vaccine (inactivated) (1361)  
 Rabbit haemorrhagic disease vaccine (inactivated) (2325)  
 Rabies vaccine (inactivated) for veterinary use (0451)  
 Salmonella Enteritidis vaccine (inactivated) for chickens (1947)  
 Salmonella Typhimurium vaccine (inactivated) for chickens (2361)  
 Swine erysipelas vaccine (inactivated) (0064)  
 Swine-fever vaccine (live, prepared in cell cultures), classical (0065)  
 Tetanus vaccine for veterinary use (0697)  
 Vibriosis (cold-water) vaccine (inactivated) for salmonids (1580)  
 Vibriosis vaccine (inactivated) for salmonids (1581)

### Herbal drugs and herbal drug preparations

Birch leaf (1174)  
 Capsicum oleoresin, refined and standardised (2336)  
 Fennel, bitter (0824)  
 Hawthorn berries (1220)  
 Loosestrife (1537)  
 Meadowsweet (1868)  
 Primula root (1364)  
 Sophora flower-bud (2427)

### Monographs

Amisulpride (1490)  
 Ascorbyl palmitate (0807)  
 Atracurium besilate (1970)  
 Bufloxedil hydrochloride (1398)  
 Bupivacaine hydrochloride (0541)  
 Calcipotriol, anhydrous (2011)  
 Calcipotriol monohydrate (2284)  
 Carmellose (2360)  
 Cefalotin sodium (0987)  
 Cefazolin sodium (0988)  
 Cetirizine dihydrochloride (1084)  
 Difloxacin hydrochloride trihydrate for veterinary use (2239)  
 Diltiazem hydrochloride (1004)  
 Famotidine (1012)  
 Fludarabine phosphate (1781)  
 Fluvastatin sodium (2333)  
 Imipenem monohydrate (1226)  
 Labetalol hydrochloride (0923)  
 Lactulose, liquid (0924)  
 Levodopa (0038)  
 Lincomycin hydrochloride (0583)  
 Macrogols (1444)  
 Mebendazole (0845)  
 Mesalazine (1699)  
 Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)  
 Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (1129)  
 Naloxone hydrochloride dihydrate (0729)  
 Naproxen (0731)  
 Nitrofurantoin (1135)  
 Norethisterone acetate (0850)  
 Omeprazole (0942)  
 Oxacillin sodium monohydrate (2260)  
 Pilocarpine hydrochloride (0633)  
 Pilocarpine nitrate (0104)  
 Praziquantel (0855)  
 Selegiline hydrochloride (1260)  
*RRR*- $\alpha$ -Tocopherol (1256)  
*RRR*- $\alpha$ -Tocopheryl acetate (1257)

## CORRECTED TEXTS

*The texts below have been corrected and are republished in their entirety. These corrections are to be taken into account from the publication date of Supplement 7.7 (1 October 2012).*

### GENERAL CHAPTERS

2.6.1. Sterility

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

Common selfheal fruit-spike (2439)

### Monographs

Aceclofenac (1281)  
 Heparin calcium (0332)  
 Heparin sodium (0333)  
 Metamizole sodium monohydrate (1346)  
 Sertraline hydrochloride (1705)

## TEXTS WHOSE TITLE HAS CHANGED

*The titles of the following texts have been changed in Supplement 7.7.*

### GENERAL CHAPTERS

- 5.2.9. Evaluation of safety of each batch of immunosera for veterinary use (*previously Evaluation of safety of each batch of veterinary vaccines and immunosera*)

### MONOGRAPHS

#### Vaccines for veterinary use

Avian paramyxovirus 3 vaccine (inactivated) for turkeys (1392) (*previously Avian paramyxovirus 3 vaccine (inactivated)*)

#### Herbal drugs and herbal drug preparations

Capsicum oleoresin, refined and standardised (2336) (*previously Capsicum oleoresin, refined and quantified*)

#### Monographs

Imipenem monohydrate (1226) (*previously Imipenem*)

## DELETED TEXTS

*The following text is deleted as of 1 April 2013.*

### MONOGRAPHS

#### Monographs

Diflunisal (0818)

*The following text is deleted as of 1 January 2013.*

### MONOGRAPHS

#### Monographs

Protamine hydrochloride (0686)

*The following texts are deleted as of 1 July 2012.*

### MONOGRAPHS

#### Monographs

Chlorothiazide (0385)

Dienestrol (0483)

Emetine hydrochloride heptahydrate (0080)

Etofylline (0492)

Hexobarbital (0183)

Histamine phosphate (0144)

Iotalamic acid (0751)

Methaqualone (0510)

Methylatropine bromide (0511)

Methylatropine nitrate (0512)

Physostigmine sulfate (0684)

Succinylsulfathiazole (0357)

Sulfisomidine (0639)

Tubocurarine chloride (0305)

*The following text is deleted as of 1 April 2012.*

### MONOGRAPHS

#### Monographs

Benfluorex hydrochloride (1601)