European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Decisions Ph. Eur. Com.
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Report of the 136th Session of the European Pharmacopoeia Commission 23-24 March 2010

Participants:
Member States: 32 delegations were present
Observer States: 2 delegations participated in the session

Election of the Chair: Dr Marianne EK, Sweden was elected for a mandate of 3 years.

I. TEXTS AND REFERENCE STANDARDS ADOPTED LIST OF TEXTS ADOPTED FOR PUBLICATION IN THE 7TH EDITION (SUPPLEMENT 7.1) AND DATE OF IMPLEMENTATION: 01/04/2011

10 NEW MONOGRAPHS ADOPTED

Atorvastatin calcium / Atorvastatine calcique (2191)
Baical skullcap root / Scutellaria baicalensis (racine de) (2438)
Clopidogrel hydrogen sulphate / Clopidogrel (hydrogénosulfate de) (2531)
Dextropropoxyphene (2365)**
Glycopyrronium bromide / Glycopyrronium (bromure de) (1783)
Oseltamivir phosphate / Oseltamivir (phosphate d') (2422)*
Oxygen (93 per cent) / Oxygène à 93 pour cent (2455)*
Potassium dichromate for homoeopathic preparations / Potassium (dichromate de) pour préparations homéopathiques (2501)
Sodium tetrachloroaurate dihydrate for homoeopathic preparations / Sodium (tétrachloroaurate de) dihydraté pour préparations homéopathiques
Sulphur for homoeopathic preparations / Soufre pour préparations homéopathiques (2515)

2 NEW GENERAL TEXTS AND GENERAL METHODS OF ANALYSIS

Determination of methyl, ethyl and isopropyl methanesulphonate in methanesulphonic acid / Détermination du méthanesulfonate de méthyle, d'éthyle et d'isopropyle dans l'acide méthanesulfonique (20537)
Water-solid interactions: determination of sorption-desorption isotherms / Interactions eau-solide : détermination des isothermes de sorption-désorption (20939)

18 REVISED MONOGRAPHS

Cetostearyl alcohol (type A), emulsifying / Cétostéarylique (alcool) émulsifiant (type A) (801)
Cetostearyl alcohol (type B), emulsifying / Cétostéarylique (alcool) émulsifiant (type B) (802)
Chlorambucil (137)*
Ear preparations / Préparations auriculaires (652)
Etoposide / Étoposide (823)
Gentamicin sulphate / Gentamicine (sulfate de) (331)
Heparin calcium / Héparine calcique (332) Rapid implementation: 1 August 2010 / Mise en application rapide : 1er août 2010
Heparin sodium / Héparine sodique (333): Rapid implementation: 1 August 2010 / Mise en application rapide : 1er août 2010
Herbal drugs for homoeopathic preparations / Drogues végétales pour préparations homéopathiques (2045)*
Lavender flower / Lavande (fleur de) (1534)
Nadolol (1789)

Oleyl alcohol / Oléique (alcool) (2073)
Pharmacopoeial harmonisation / Harmonisation des pharmacopées (5.8.)
Phenytoin sodium / Phénytoïne sodique (521)
Sodium cetostearyl sulphate / Cétostéaryle (sulfate de) sodique (847)
Sodium cromoglicate / Sodium (cromoglicate de) (562)
Testosterone enantate / Testostérone (énantate de) (1048)
Valerian dry hydroalcoholic extract / Valériane (extrait hydroalcoolique sec de) (1898)

3 REVISED GENERAL TEXTS AND GENERAL METHODS

Disintegration of tablets and capsules / Désagrégation des comprimés et des capsules (2.9.1.)
Particulate contamination: sub-visible particles / Contamination particulaire: particules non visibles (2.9.19.)
Sterility / Stérilité (2.6.1.)

19 MINOR REVISION OF MONOGRAPHS AND GENERAL TEXTS

Bearberry leaf / Busserole (feuille de) (1054)
Cascara / Cascara (105)
Cinnamon / Cannelle dite de Ceylan (387)
Cinnamon bark oil, Ceylon / Cannelle dite de Ceylan (huile essentielle de) (1501)
Ciprofloxacin hydrochloride / Ciprofloxacine (chlorhydrate de) (888)
Citalopram hydrobromide / Citalopram (bromhydrate de) (2288)
Couch grass rhizome / Chiendent (rhizome de) (1306)
Fennel, sweet / Fenouil doux (fruit de) (825)
Flecainide acetate / Flécaïnide (acétate de) (1324)
Frangula bark / Bourdaine (25)
Linseed / Lin (graine de) (95)
Lovastatin / Lovastatine (1538)
Norfloxacin / Norfloxacine (1248)
Noscapine (516)
Noscapine hydrochloride / Noscapine (chlorhydrate de) (515)
Rifaximin / Rifaximine (2362)
Tolnaftate / Tolnaftate (1158)
Verapamil hydrochloride / Vérapamil (chlorhydrate de) (573)
Wormwood / Absinthe (1380)

NEW REFERENCE STANDARDS ADOPTED/ REPLACEMENT BATCHES ADOPTED

A list of new reference standards and new batches with the date of release is now available in the Reference Standards database. Click on the database button and then choose ‘News’.
The database is available online, click on the following link: http://www.edqm.eu/en/Databases-10.html.

II. EUROPEAN PHARMACOPOEIA WORK PROGRAMME

ADDITIONS TO THE WORK PROGRAMME

The European Pharmacopoeia invites contributions to the following items of the work programme:
Alimemazine tartrate
Atomoxetine hydrochloride
Atovaquone
Black mercuric sulphide for homoeopathic use - Aethiops mercuralis mineralis PPH
Dutasteride
Iron III phosphate for homoeopathic use - Ferrum phosphoricum A PPH
Meadowsweet for homoeopathic use - Spiraea ulmaria PPH
Modified Wool Fat
Naratriptan hydrochloride
Nelarabine
Oleander for homoeopathic use - Nerium Oleander PPH
Pemetrexed disodium heptahydrate
Potassium dichromate for homoeopathic use - Kalium bichromatum PPH

Remifentanil hydrochloride
Sage for homoeopathic use - Salvia officinalis PPH
Sodium chloride for homoeopathic use - Natrium muriaticum PPH
Starch, hydroxypropyl, pregelatinised
Terlipressin
Valaciclovir hydrochloride dehydrate
Valaciclovir hydrochloride monohydrate
Ziprasidone mesilate trihydrate

(Please note that the accumulative work programme is available in the Knowledge Database: http://www.edqm.eu/site/Databases-10.html)

REVISIONS OF MONOGRAPHS AND GENERAL CHAPTERS

Amisulpride (1490)
Bearberry leaf / Busserole (feuille de) (1054)
Bitter-orange epicarp and mesocarp / Orange amère (épicarpe et mésocarpe d') (1603)
Cod-liver oil (type A) / Foie de morue (huile de) (type A) (1192)
Cod-liver oil (type B) / Foie de morue (huile de) (type B) (1193)
Cod-liver oil, farmed / Foie de morue d'élevage (huile de) (2398)
Cyproterone acetate / Cyprotérone (acétate de) (1094)
Distemper vaccine (live) for mustelids / Vaccin vivant de la maladie de Carré pour mustélidés (0449)
Fish oil, rich in omega-3 acids / Poisson (huile de) riche en acides oméga-3 (1912)
Glucagon, human / Glucagon humain (1635)
Guaifenesin / Guaifénésine (615)
All inactivated and live vaccines (all) / Vaccins inactivés et vivants (tous)
Influenza vaccine (split virion, inactivated) / Vaccin grippal inactivé à virion fragmenté (158)
Lemon oil / Citron (huile essentielle de) (620)
Lime flower / Tilleul (fleur de) (957)
Omega-3 acid ethyl esters 60 / Oméga-3 (esters éthyliques 60 d'acides) (2063)
Omega-3 acid ethyl esters 90 / Oméga-3 (esters éthyliques 90 d'acides) (1250)
Omega-3 acid ethyl esters triglycerides / Oméga-3 (triglycérides d'acides) (1352)
Polyolefines / Polyoléfines (3.1.3)
Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037)
Preparations for inhalation / Préparations pour inhalation (671)
Rabies vaccine (live, oral) for foxes / Vaccin vivant oral de la rage pour renards (0746)
Repaglinide / Répaglinide (2135)
Salmon oil, farmed / Saumon d'élevage (huile de) (1910)
Simeticone / Siméticone (1470)
Sodium hyaluronate / Sodium (hyaluronate de) (1472)
Sodium hydroxide / Sodium (hydroxyde de) (677)
Squalane (1630)
Standard method for the quantification of flavonoids / Méthode standard pour la quantification des flavonoïdes
Sulfadiazine (294)
TLC/HPTLC identification of flavonoids / Identification CCM/CCMHP des flavonoïdes
Vaccines intended for species out of the VICH GL 41 and 44 scope (fish, duck, foxes, rabbit, ferret, etc.) / Vaccins destinés à des espèces hors du champs d'application des Guidelines VICH 41 et 44 (poisson, canard, renard, lapin, furet, etc.)
Wool alcohols / Alcools de graisse de laine (593)
Wool fat / Graisse de laine (134)
Wool fat, hydrogenated / Graisse de laine hydrogénée (969)
Wool fat, hydrous / Graisse de laine hydratée (135)

* subject to confirmation

** not to be published