

EUROPEAN PHARMACOPOEIA COMMISSION

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Strasbourg, July 2014

GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION)

Summary of Decisions taken at the 149th Session of the Commission

Held in Strasbourg on 17-18 June 2014

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 149th Session
17-18 June 2014**

**Résumé des décisions de la 149^e Session
17-18 juin 2014**

Deadline for confirmation / Date de confirmation: 11 July 2014

| Item | I. ADOPTED TEXTS | Subject to Confirmation |
|-------------|---|--------------------------------|
| | I.1 Monographs and chapters/Monographies et chapitres | |
| | I.1.1 Minor revisions / Révisions mineures | |
| 31.3.1 | Acarbose / Acarbose (2089) | |
| 70.3.1 | Angelica dahurica root / Angelica dahurica (racine d') (2556) | |
| 18.3.1 | Articaine hydrochloride / Articaïne (chlorhydrate d') (1688) | |
| 11.3 | Boiling point (2.2.12.) / Point d'ébullition (2.2.12.) | |
| 11.4 | Distillation range (2.2.11.) / Intervalle de distillation (2.2.11.) | |
| 11.6 | Ethanol content / Teneur en éthanol (2.9.10.) | |
| 25.3.1 | Fumitory / Fumeterre (1869) | |
| 21.3.1 | Glutathione / Glutathion (1670) | |
| 13.3.1 | Interféron alfa-2 concentrated solution / Interféron alfa-2 (solution concentrée d') (1110) | |
| 11.1 | Loss on drying (2.2.32.) / Perte à la dessiccation (2.2.32.) | |
| 31.3.2 | Meloxicam / Méloxicam (2373) | |
| 11.5 | Melting point - instantaneous method (2.2.16.) / Point de fusion - méthode de la fusion instantanée (2.2.16.) | |
| 19.3.1 | Mianserin hydrochloride / Miansérine (chlorhydrate de) (0846) | |
| 19.3.2 | Miconazole / Miconazole (0935) | |
| 26.3.1 | Polysorbate 20 / Polysorbate 20 (0426) | |
| 26.3.2 | Polysorbate 40 / Polysorbate 40 (1914) | |
| 26.3.3 | Polysorbate 60 / Polysorbate 60 (0427) | |
| 19.3.3 | Progesterone / Progestérone (0429) | |
| 15.3.1 | Rifaximin / Rifaximine (2362) | |
| 15.3.2 | Selamectin for veterinary use / Sélamectine pour usage vétérinaire (2268) | |
| 11.2 | Water: semi-micro determination (2.5.12.) / Semi-microdosage de l'eau (2.5.12.) | |
| | | |
| | I.1.2 Revisions / Révisions | |
| 25.2.5 | Acacia / Gomme arabique (0307) | |

| | I.1.2 Revisions / Révisions | |
|--------------------|---|--|
| 25.2.6 | Artichoke leaf / Artichaut (feuille d')(1866) | |
| 28.2.1 | Assay of hepatitis A vaccine (2.7.14.) / Titration de l'activité du vaccin de l'hépatite A (20714) | |
| 14.2.1 | Assay of human coagulation factor II / Dosage du facteur II de coagulation humaine (2.7.18) | |
| 18.2.1 | Benzocaine / Benzocaïne (0011) | |
| 25.2.4 | Bitter-orange epicarp and mesocarp / Orange amère (épicarpe et mésocarpe d') (1603) | |
| 21.2.1 | Bufexamac / Bufexamac (1179) | |
| 60.2.1 | Bulk and tapped density of powders / Masse volumique vrac et masse volumique après tassement (2.9.34) | |
| 44.2.1 | Extracts / Extraits (0765) | |
| 25.2.1 | Gentian root / Gentiane (racine de) (0392) | |
| 21.2.4 | Glycine / Glycine (0614) | |
| 28.2.4 | Hepatitis A (inactivated) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin de l'hépatite A (inactivé) et de l'hépatite B (ADNr), adsorbé (1526) | |
| 28.2.5 | Hepatitis A (inactivated, adsorbed) and typhoid polysaccharide vaccine / Vaccin de l'hépatite A (inactivé, adsorbé) et typhoïdique polysaccharidique (2597) | |
| 28.2.2 | Hepatitis A vaccine (inactivated, adsorbed) / Vaccin inactivé de l'hépatite A adsorbé (1107) | |
| 28.2.3 | Hepatitis A vaccine (inactivated, virosome) / Vaccin de l'hépatite A (inactivé, virosomal) (1935) | |
| 21.2.2 | Isopropyl alcohol / Isopropylique (alcool) (0970) | |
| 21.2.3 | Methionine / Méthionine (1027) | |
| 22.2.1 | Noscapine hydrochloride / Noscapine (chlorhydrate de) (0515) | |
| 30.2.1 + 46.2.1 | Poly(vinyl acetate) / Poly(acétate de vinyle) (1962) | |
| 20.2.1 | Prazepam / Prazépam (1466) | |
| 15.2.1 | Sulbactam sodium / Salbactam sodique (2209) | |
| 28.2.6 | Typhoid vaccine (live, oral, strain Ty 21a) / Vaccin typhoïdique vivant, oral, souche Ty 21a (1055) | |
| 25.2.2 | Valerian root / Valériane (racine de) (0453) | |
| 25.2.3 | Valerian root, cut / Valériane (racine de) divisée (2526) | |
| | | |
| | I.1.3 New texts for adoption / Nouveaux textes pour adoption | |
| 27.1.1 | Fluoroethyl-L-tyrosine (18F) injection / Fluoroéthyl-L-tyrosine (18F) (solution injectable de) (2466) | |

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| | I.1.3 New texts for adoption / Nouveaux textes pour adoption | |
| 28.1.2 | Live attenuated intranasal influenza vaccine / Vaccin grippal vivant atténué intranasal (2772) | |
| 26.1.1 | Macrogol isotridecyl ether / Macrogol (éther isotridécyclique de) (2730) | |
| 44.1.1 | Monographs on herbal drug extracts (information chapter) / Monographies d'extraits à base de drogues végétales (chapitre informatif) (5.23.) | |
| 20.1.1 | Permethrin (25:75) / Perméthrine (25:75) (1762) | |
| 18.1.1 | Triclabendazole for veterinary use / Triclabendazole pour usage vétérinaire (2609) | |
| | | |
| | I.1.4 Corrections (to be published in Supplement 8.4) | |
| 13.4.1 | Erythropoietin concentrated solution / Érythropoïétine (solution concentrée d') (1316) | |
| | | |
| 75 | <i>I-2 CRS/BRP SCR/PBR</i> | |
| 75 | New substances / Nouvelles substances | |
| 76.2 | Erythropoietin for physicochemical tests CRS batch 1 | |
| 75 | Ethionamide for system suitability CRS 1 | |
| 75 | Gemcitabine Impurity C CRS 1 | |
| 75 | Insulin porcine for system suitability CRS 1 | |
| 75 | Progesterone for impurity H identification CRS 1 | |
| 75 | Sodium aminosalicylate dihydrate CRS 1 | |
| 75 | Sulfadimethoxine for peak identification CRS 1 | |
| 75 | Tizanidine Impurity B CRS 1 | |
| 75 | Tolterodine for system suitability CRS 1 | |
| 75 | Tolterodine Impurity E CRS 1 | |
| 75 | Tolterodine tartrate CRS 1 | |
| | | |
| | Replacement Batches / Lots de remplacement | |
| 75 | 4-Epidemecloxycline hydrochloride CRS 2 | |
| 75 | Acetylcysteine Impurity C CRS 10 | |
| 75 | Acetylcysteine Impurity C CRS 9 | |
| 75 | Acetylsalicylic acid for peak identification CRS 2 | |
| 75 | Adrenaline impurity mixture CRS 3 | |
| 75 | Articaine hydrochloride CRS 3 | |
| 75 | Calcifediol CRS 5 | |

| | Replacement Batches / Lots de remplacement | |
|------|---|--|
| 75 | Calcium pantothenate CRS 4 | |
| 75 | Chlorothiazide CRS 3 | |
| 75 | Chlorprothixene hydrochloride CRS 5 | |
| 75 | Cyanocobalamin CRS 5 | |
| 75 | Dexpanthenol CRS 5 | |
| 75 | Dithranol CRS 3 | |
| 75 | Enoxaparin sodium CRS 5 | |
| 75 | Ephedrine hydrochloride CRS 3 | |
| 75 | Haloperidol for peak identification CRS 2 | |
| 75 | Histidine CRS 3 | |
| 76.3 | Immunoglobulin panel for anti-D antibodies test BRP batch 2 | |
| 75 | Lactulose CRS 4 | |
| 75 | Levetiracetam CRS 2 | |
| 75 | Levonorgestrel for system suitability 1 CRS 2 | |
| 75 | Levonorgestrel impurity B CRS 2 | |
| 75 | Lithium clavulanate CRS 6 | |
| 75 | Metamizole impurity A CRS 4 | |
| 75 | Morphine for system suitability CRS 3 | |
| 75 | Moxidectin CRS 3 | |
| 75 | Moxifloxacin for peak identification CRS 2 | |
| 75 | Norethisterone CRS 3 | |
| 75 | Oxybuprocaine hydrochloride CRS 2 | |
| 75 | Phenylephrine hydrochloride FPI CRS 4 | |
| 75 | Procaine benzylpenicillin CRS 3 | |
| 75 | Progesterone CRS 3 | |
| 75 | Propofol CRS 6 | |
| 75 | Sertraline for peak identification CRS 4 | |
| 75 | Sodium picosulfate CRS 2 | |
| 75 | Sotalol impurity B CRS 2 | |
| 75 | Thioctic acid CRS 2 | |
| 75 | Thioctic acid for system suitability CRS 2 | |
| 75 | Tribenoside CRS 3 | |
| 75 | Trimyristin CRS 2 | |
| 75 | Xylometazoline hydrochloride CRS 3 | |
| 75 | Xylometazoline impurity A CRS 2 | |

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| | II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTES – A INSCRIRE A LA PROCHAINE SESSION | |
| | | |
| Item | III. REQUESTS FOR REVISION / DEMANDES DE REVISION | |
| | III.1 Approved by the Commission | |
| 23.4.3 | Ph.Eur. section 07 Dosage forms | |
| 23.4.3 | - Capsules / Capsules (0016) | |
| 23.4.3 | - Chewing gums, medicated / Gommages à mâcher médicamenteuses (1239) | |
| 23.4.3 | - Ear preparations / Préparations auriculaires (0652) | |
| 23.4.3 | - Foams, medicated / Mousse médicamenteuse(1105) | |
| 23.4.3 | - Granules / Granulés (0499) | |
| 23.4.3 | - Intramammary preparations for veterinary use / Préparations intramammaires pour usage vétérinaire (945) | |
| 23.4.3 | - Intraruminal devices / Dispositifs intraruminaux (1228) | |
| 23.4.3 | - Intrauterine preparations for veterinary use / Préparations intra-utérines pour usage vétérinaire (1806) | |
| 23.4.3 | - Liquid preparations for cutaneous application / Préparations liquides pour application cutanée (0927) | |
| 23.4.3 | - Liquid preparations for oral use / Préparations liquides pour usage oral (0672) | |
| 23.4.3 | - Oromucosal preparations / Préparations buccales (1807) | |
| 23.4.3 | - Parenteral preparations / Préparations parentérales (0520) | |
| 23.4.3 | - Patches, transdermal / Dispositifs transdermiques(1011) | |
| 23.4.3 | - Powders for cutaneous application / Poudres pour application cutanée (1166) | |
| 23.4.3 | - Powders, oral / Poudres orales (1165) | |
| 23.4.3 | - Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037) | |
| 23.4.3 | - Preparations for irrigation / Préparations pour irrigation (1116) | |
| 23.4.3 | - Pressurised pharmaceutical preparations / Préparations pharmaceutiques pressurisées (0523) | |
| 23.4.3 | - Rectal preparations / Préparations rectales (1145) | |
| 23.4.3 | - Semi-solid preparations for cutaneous application / Préparations semi-solides pour application cutanée (0132) | |
| 23.4.3 | - Sticks / Bâtons (1154) | |

| | III.1 Approved by the Commission | |
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| 23.4.3 | - Tablets / Comprimés (0478) | |
| 23.4.3 | - Tampons, medicated / Tampons médicamenteux (1155) | |
| 23.4.3 | - Vaginal preparations / Préparations vaginales(1164) | |
| 23.4.3 | - Veterinary liquid preparations for cutaneous application / Préparations vétérinaires liquides pour application cutanée (1808) | |
| 23.4.3 | - Veterinary semi-solid preparations for oral use / Préparations vétérinaires semi-solides pour usage oral (2638) | |
| 23.4.3 | - Preparations for inhalation / Préparations pour inhalation (0671) | |
| 27.4.1 | Alovudine (18F) injection / Alovudine (18F) (solution injectable d') (2460) | |
| 20.4.1 | Alverine citrate / Alvérine (citrate d') (2156) | |
| 24.4.1 | Aniseed / Anis (fruit d') (0262) | |
| 25.4.3 | Artichoke leaf / Artichaut (feuille d') (1866) | |
| 25.4.3 | Artichoke leaf dry extract / Artichaut (feuille d'), extrait sec de (2389) | |
| 29.4.1 | Avian infectious bronchitis vaccine (inactivated) / Vaccin inactivé de la bronchite infectieuse aviaire (0959) | |
| 29.4.1 | Avian infectious bursal disease vaccine (inactivated) / Vaccin inactif de la bursite infectieuse aviaire (0960) | |
| 29.4.1 | Avian paramyxovirus 3 vaccine (inactivated) for turkeys / vaccin inactif du paramyxovirus aviaire 3 pour la dinde (1392) | |
| 26.4.1 | Cetyl palmitate / Cétyle (palmitate de) (1906) | |
| 22.4.1 | Cocaine hydrochloride / Cocaïne (chlorhydrate de) (0073) | |
| 20.4.2 | Ebastine / Ébastine (2015) | |
| 29.4.1 | Egg drop syndrome '76 vaccine (inactivated) / Vaccin inactivé de la maladie des œufs hardés (1202) | |
| 29.4.1 | Equine influenza vaccine (inactivated) / Vaccin inactivé de la grippe équine (0249) | |
| 24.4.3 | Essential oils in herbal drugs / Huiles essentielles dans les drogues végétales (2.8.12.) | |
| 23.4.1 + 23.4.3 | Eye preparations / Préparations ophtalmiques (1163) | |
| 29.4.1 | Feline chlamydiosis vaccine (inactivated) / Vaccin inactivé de la chlamydie du chat (2324) | |
| 18.4.2 | Fenoterol hydrobromide / Fénotérol (bromhydrate de) (0901) | |
| 27.4.1 | Fludeoxyglucose (18F) injection / Fludeoxyglucose (18F) (solution injectable d') (1325) | |

| | III.1 Approved by the Commission | |
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| 27.4.1 | Fluoromisonidazole (18F) injection / Fluoromisonidazole (18F) (solution injectable d') (2459) | |
| 27.1.1 | Fluoroethyl-L-tyrosine (18F) injection / Fluoroéthyl-L-tyrosine (18F) (solution injectable de) (2466) | |
| 46.4.1 | Functionality-related characteristics of excipients / Caractéristiques liées à la fonctionnalité des excipients (5.15) | |
| 23.4.1 + 23.4.3 | Glossary / Glossaire (1502) | |
| 13.5.1 | Heparin calcium / Héparine calcique (0332) | |
| 13.5.1 | Heparin Sodium / Héparine sodique (0333) | |
| 77.3 | Identification reactions of ions and functional groups, Chlorides b) / Réactions d'identité des ions et des groupes fonctionnels (2.3.1.) | |
| 29.4.2 | Infectious chicken anaemia vaccine (live)/Vaccin vivant de l'anémie infectieuse du poulet (2038) | |
| 24.4.4 | Lavender oil / Lavande (huile essentielle de) (1338) | |
| 77.1 | Melting point - capillary method (2.2.14) | |
| 33.4.1 | Monocyte-activation test/Essai d'activation des monocytes (20630) | |
| 23.4.4 + 23.4.3 | Nasal preparations / Préparations nasales (0676) | |
| 29.4.1 | Newcastle disease vaccine (inactivated) / Vaccin inactivé de la pseudopeste aviaire (maladie de Newcastle) (0870) | |
| 19.4.1 | Olanzapine / Olanzapine (2258) | |
| 25.4.1 | Passion flower dry extract / Passiflore (extrait sec de) (1882) | |
| 29.4.1 | Porcine influenza vaccine (inactivated) / Vaccin inactivé de la grippe porcine (0963) | |
| 77.2 | Revision of all Ph. Eur. texts containing the term "overnight" | |
| 30.4.1 | Rubber closures for containers for aqueous parenteral preparations, for powders / Fermetures en caoutchouc pour récipients destinés aux préparations parentérales (30209) | |
| 26.4.2 | Sesame oil, refined / Sésame (huile de) raffinée (0433) | |
| 13.5.2 | Sodium hyaluronate / Sodium (hyaluronate de) (1472) | |
| 18.4.1 | Sumatriptan succinate / Sumatriptan (succinate de) -> to be published in Pharmeuropa | |
| 29.4.1 | Vaccines for veterinary use / Vaccins pour usage vétérinaire (0062) | |
| 25.4.2 | Valerian root / Valériane (racine de) (0453) | |
| 25.4.2 | Valerian root, cut / Valériane (racine de) divisée (2526) | |
| 24.4.2 | Wild pansy (flowering aerial parts) / Pensée sauvage (parties aériennes fleuries de) (1855) | |
| 39.4.1 | Xanthan gum / Gomme xanthane (1277) | |

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| | IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS) | |
| 6.6 | Amanita muscaria | |
| 8.1 | Arctii radix | |
| 8.1 | Armeniacae amarum semen (Xing ren) | |
| 8.1 | Bursae pastoris herba | |
| 8.1 | Cichorii intybi radix | |
| 8.1 | Common balm oil | |
| 8.1 | Cucurbitae semen | |
| 6.6 | <i>Cupressus sempervirens</i> L. | |
| 8.1 | Deferasirox dispersible tablets | |
| 8.1 | Deferasirox orphan drug | |
| 8.1 | Edotreotide (2544): re-introduction onto the work programme | |
| 6.6 | <i>Galium mollugo</i> L. | |
| 8.1 | Grindeliae herba | |
| 8.1 | Hippocastani cortex | |
| 6.6 | Humulus lupulus ferm 34d | |
| 8.1 | Juglandis folium | |
| 6.6 | <i>Leonurus cardiaca</i> L. | |
| 6.6 | Oxalic acid | |
| 8.1 | Particle size analysis by Image Analysis | |
| 8.1 | Phaseoli fructus (sine semine) | |
| 8.1 | Polypodii rhizome | |
| 8.1 | Psoraleae fructus (Bu gu zhi) | |
| 8.1 | Raltegravir chewable tablets | |
| 8.1 | Raltegravir tablets | |
| 8.1 | Ribaroxaban | |
| 6.6 | Ribwort plantain liquid extract | |
| 8.1 | Rosae flos | |
| 8.1 | Rubi idaei folium | |
| 8.1 | Shear cells | |
| 8.1 | Sisymbrii officinalis herba | |
| 8.1 | Solani dulcamarae stipites | |
| 8.1 | Sorafenib tosylate | |
| 8.1 | Syringes for aqueous solutions for injection | |
| 8.1 | Terpine | |

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| | IV Additions to the work programme | |
| 6.6 | Toadflax | |
| 8.1 | Typhae Pollen (Pu huang) | |
| 8.1 | Valganciclovir HCl | |
| | | |
| | V.1 DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision) | |
| 8.1 | Disodium oxidronate for radiopharmaceutical preparations (2549) | |
| 15.5.1 | Epirubicin hydrochloride / Épirubicine (chlorhydrate d') (1590) | |
| 23.5.1 | Non-preserved multi-dose preparations | |
| 8.1 | Rhenium sulphide (2550) | |
| 20.5.1 | Rocuronium bromide / Rocuronium (bromure de) (1764) | |
| 26.5.2 | Stearoyl macrogolglycerides / Macrogolglycérides stéariques (1268) | |
| | | |
| Agenda Item No. | VI.1 PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE | |
| 6.3 | Deadline for documents to be added to the Commission agenda = no later than 2 weeks before a session | |
| 6.3 | Deletion of reference to chapter 2.4.8 Heavy metals in individual monographs: Publication in Pharmeuropa of a list of monographs/chapters impacted | |
| 7.1 | Nominations (see Annex 1) | |
| 7.2 | Terms of Reference of the PaedForm Working Party (PDF) | |
| 7.3 | Terms of Reference of the General Methods Working Party (MG) | |
| 7.4 | Terms of Reference and Profile for members of groups of experts and working parties | |
| 7.5 | Request for Observer Status from <i>Kosovo Medicines Agency</i> -> refused | NO ¹ |
| 33.6 | Bacterial endotoxins Ph. Eur. Policy for Substances for Pharmaceutical Use | |
| | | |
| | VII. OPEN ITEMS | |
| 21.2.1 | Bufexamac / Bufexamac (1179): enquiry to see if there is still a need to keep this monograph in the Ph. Eur. | |
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¹ Answer received on 26 June 2014: in favour

| | VIII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION | |
|--|---|--|
| | 25-26 November Dates for 2015 - 17-18 March - 16-17 June - 17-18 November | |

ANNEX 1 - Nominations

149th Session Nominations - ITEM 7.1**GROUPS OF EXPERTS****Group 7**

| | | |
|--------|------------------------|---------------------|
| German | Dr Uwe Christian LIPKE | Licensing authority |
|--------|------------------------|---------------------|

Group 10C

| | | |
|----------------|----------------------|----------------------------------|
| United Kingdom | Dr John MCKENDRICK | University |
| Slovenia | Mrs Metka STOJICEVIC | Industry (Before NPA => COM Nov) |

Group 13A

| | | |
|-------|-------------------|----------|
| Spain | Dr Arantxa BORDAS | Industry |
|-------|-------------------|----------|

Group 13B

| | | |
|--------|----------------------------------|---------------------|
| German | Dr Klaus REH <u>Chair</u> | Licensing authority |
|--------|----------------------------------|---------------------|

WORKING PARTIES**Carbohydrates (CRB)**

| | | |
|---------|-------------------------|----------|
| Germany | Dr Eva-Maria LITTRINGER | Industry |
|---------|-------------------------|----------|

Dialysis Solutions (DIA)

| | | |
|---------|----------------------|----------|
| Germany | Dr Norbert GREIDZIAK | Industry |
|---------|----------------------|----------|

Host-cell proteins (HCP)

| | | |
|-------------|-----------------------------------|----------|
| Switzerland | Dr Kowid T HO <u>Chair</u> | Industry |
|-------------|-----------------------------------|----------|

Sutures (SUT)

| | | |
|-------|--------------|----------|
| Spain | Dr Lutz FUNK | Industry |
|-------|--------------|----------|