

EUROPEAN PHARMACOPOEIA COMMISSION

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GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 155th Session of the Commission

Résumé des Décisions prises lors de la 155^e Session de la Commission

Strasbourg 21-22 juin 2016
Strasbourg 21-22 June 2016

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPÉE**

**Summary of Decisions of the 155th Session
21-22 June 2016**

**Résumé des décisions de la 155^e Session
21-22 juin 2016**

Deadline for confirmation / Date de confirmation: 17 July 2016

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
19.3.1	Amiloride hydrochloride dihydrate / Amiloride (chlorhydrate d') dihydraté (0651)	
11.3	Cellulose acetate (0887)	
72.3.1	Cholesterol for parenteral use / Cholestérol pour usage parentéral (2397)	
29.3.1	Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521)	
14.3.1	Human plasma (pooled and treated for virus inactivation) / Plasma humain (mélange de) traité pour viro-inactivation (1646)	
31.3.1	Imatinib mesilate/ Imatinib (mésilate d') (2736)	
16.3.1	Manganese sulfate monohydrate / Manganèse (sulfate de) monohydraté (1543)	
71.3.1	Names of herbal drugs used in traditional Chinese medicine / Noms des drogues végétales utilisées en médecine traditionnelle chinoise (52200)	
11.1	Pharmacopoeial harmonisation (5.8)	
26.3.1	Polysorbate 80 / Polysorbate 80 (0428) -> published as a correction to take account of the change by publication date	
11.2	Povidone (0685)	
20.3.1	Pregabalin / Prégabaline (2777)	
31.3.2	Sucralose / Sucralose (2368)	
27.3.2	Technetium (^{99m} Tc) bicsate injection / Technétium (^{99m} Tc) (bicsate), solution de (2123)	
27.3.1	Technetium (^{99m} Tc) mebprofenin injection / Technétium (^{99m} Tc) (mébrofénine-), solution injectable de (2393)	
29.3.2	Vibriosis (cold-water) vaccine (inactivated) for salmonids (1580)	
29.3.3	Vibriosis vaccine (inactivated) for salmonids (1581)	
29.3.4	Yersiniosis vaccine (inactivated) for salmonids (1950)	

	I.1.2 Revisions / Révisions	
71.2.1	Acanthopanax bark / Acanthopanax (écorce d') (2432)	
12.2.3	Alternative methods for control of microbiological quality / Méthodes alternatives pour le contrôle de la qualité microbiologique (50106)	
24.2.3	Aniseed / Anis (fruit d') (0262)	
71.2.2	Astragalus mongholicus root / Astragalus mongholicus (racine d') (2435)	
71.2.3	Aucklandia root / Aucklandia (racine d') (1797)	
15.2.2	Benzylpenicillin potassium / Benzylpénicilline potassique (0113)	
15.2.3	Benzylpenicillin sodium / Benzylpénicilline sodique (0114)	
12.2.2	Biological indicators of sterilisation / Indicateurs biologiques de stérilisation (50102)	ALL
36.2.1	Clarity and degree of opalescence of liquids / Limpidité et degré d'opalescence des liquides (2.2.1.)	
71.2.4	Coix seed / Larme de Job (graine de) (2454)	
15.2.4	Colistimethate sodium / Colistiméthate sodique (0319)	
62.2.3	Copper tetramibi tetrafluoroborate for radiopharmaceutical preparations / Cuivre (tétrafluoroborate de tétramibi-) pour préparations radiopharmaceutiques (2547)	
71.2.5	Drynaria rhizome / Drynaria (rhizome de) (2563)	
71.2.6	Eclipta herb / Eclipta (partie aérienne d') (2564)	
11.4	Ethylcellulose (0822)	
71.2.7	Eucommia bark / Eucommia (écorce d') (2412)	
45.2.2	Functionality-related characteristics of excipients / Caractéristiques liées à la fonctionnalité des excipients (5.15.)	
23.2.1	Glossary / Glossaire (1502)	
45.2.1	Glycerol monostearate 40-55 / Glycérol (monostéarate de) 40-55 (0495)	
25.2.3	Herbal drugs / Drogues végétales (1433)	
62.2.4	Iobenguane sulfate for radiopharmaceutical preparations / Iobenguane (sulfate d') pour préparations radiopharmaceutiques (2351)	
62.2.5	Medronic acid for radiopharmaceutical preparations / Médronique (acide) pour préparations radiopharmaceutiques (2350)	
12.2.1	Methods of preparation of sterile products / Méthodes de préparation des produits stériles (50101)	
42.2.1	Microbiological control of cellular products / Contrôle microbiologique des produits cellulaires (20627)	

	I.1.2 Revisions / Révisions	
15.2.1	Minocycline hydrochloride dihydrate / Minocycline (chlorhydrate de) dihydraté (1030)	
33.2.1	Monocyte-activation test / Essai d'activation des monocytes (2.6.30.)	
25.2.1	Myrrh / Myrrhe (1349)	
25.2.2	Myrrh tincture / Myrrhe (teinture de) (1877)	
15.2.5	Netilmicin sulfate / Nétilmicine (sulfate de) (1351)	
26.2.1	Omega-3-acid ethyl esters 90 / Oméga-3 (esters éthyliques 90 d'acides) (1250)	
24.2.1	Peppermint leaf / Menthe poivrée (feuille de) (0406)	
24.2.2	Peppermint leaf dry extract / Menthe poivrée (feuille de), extrait sec de (2382)	
30.2.5	Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations / Poly(éthylène - acétate de vinyle) pour récipients et tubulures destinés aux préparations pour l'alimentation parentérale totale (30107)	
30.2.3	Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations / Polyéthylène avec additifs pour récipients destinés aux préparations parentérales et aux préparations ophtalmiques (30105)	
30.2.2	Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations / Polyéthylène sans additif pour récipients destinés aux préparations parentérales et aux préparations ophtalmiques (30104)	
30.2.1	Polyolefins / Polyoléfines (30103)	
30.2.4	Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations / Polypropylène pour récipients et fermetures destinés aux préparations parentérales et aux préparations ophtalmiques (30106)	
11.5.1	Primary standards for volumetric solutions (4.2.1.) / Substances étalons pour volumétrie (4.2.1.)	
19.2.1	Proguanil hydrochloride / Proguanil (chlorhydrate de)	
26.2.2	Propylene glycol dilaurate / Propylèneglycol (dilaurate de) (2087)	
20.2.1	Ranitidine hydrochloride/ Ranitidine (chlorhydrate de) (0946)	
19.2.2	Sildenafil citrate / Sildénafil (citrate de) (2270)	
62.2.2	Sodium iodohippurate dihydrate for radiopharmaceutical preparations / Sodium (iodohippurate de) dihydraté pour préparations radiopharmaceutiques (2352)	

	I.1.2 Revisions / Révisions	
62.2.1	Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations / Tétracétylmannose (triflate de) pour préparations radiopharmaceutiques (2294)	
11.5.2	Volumetric solutions (4.2.2.) / Solutions titrées (4.2.2.)	
39.1.1	Xanthan gum / Gomme xanthane (1277)	
	I.1.2 New texts adopted / Nouveaux textes adoptés	
12.1.1	Determination of bactericidal, fungicidal or yeasticidal activity of antiseptic medicinal products / Détermination de l'activité bactéricide, fongicide ou levuricide des médicaments à visée antiseptique (50111)	ALL
52.1.1	Egg phospholipids for injection / Phospholipides d'œuf pour préparations injectables (2315)	
71.1.1	Evodia fruit / Evodia (fruit d') (2718)	
26.1.2	Isopropyl isostearate / Isopropyle (isostéarate d') (2867)	
27.1.1	Lutetium (¹⁷⁷ Lu) solution for radiolabelling / Lutécium (¹⁷⁷ Lu) pour radiomarquage, solution de (2798)	
15.1.1	Milbemycin oxime for veterinary use / Milbémycine oxime pour usage vétérinaire (2536)	
19.1.1	Remifentanil hydrochloride/ Rémifentanil (chlorhydrate de) (2644)	
49.1.1	Selenium for homoeopathic preparations / Sélénium pour préparations homéopathiques (2844)	
62.1.1	Sodium pyrophosphate for radiopharmaceutical preparations / Sodium pyrophosphate for radiopharmaceutical preparations (2552)	
13.1.1	Terlipressin / Terlipressine (2646)	
	I-2 CRS/BRP SCR/PBR	
	New substances	
	Dexamethasone acetate for peak identification CRS 1	
	Enalapril impurity G CRS 1	
	Enalapril impurity mixture A CRS 1	
	Temozolomide CRS 1	
	Teriparatide for system suitability CRS 1	
	Replacement batches	
	Acamprosate impurity A CRS 2	
	Acetylcysteine impurity C CRS 11	

	Acetylsalicylic acid for peak identification CRS 3	
	Atropine impurity B CRS 2	
	Carbamazepine impurity A CRS 6	
	Cefapirin sodium CRS 2	
	Cefepime dihydrochloride monohydrate CRS 3	
	Ceftazidime for peak identification CRS 2	
	Ciprofloxacin impurity A CRS 5	
	Clobetasol propionate CRS 2	
	Cyproterone impurity mixture CRS 2	
	Diclofenac impurity A CRS 9	
	Domperidone maleate CRS 2	
	Doxazosin impurity F CRS 3	
	Doxorubicin hydrochloride CRS 7	
	Ergosterol CRS 6	
	Erythromycin for microbiological assay CRS 5	
	Fexofenadine impurity A CRS 2	
	Flucytosine CRS 2	
	Fluorouracil CRS 3	
	Fluorouracil impurity mixture CRS 2	
	Gabapentin CRS 2	
	Glibenclamide for peak identification CRS 2	
	Glimepiride for system suitability CRS 4	
	Heptaminol hydrochloride CRS 2	
	Indometacin CRS 3	
	Ketamine impurity A CRS 3	
	Loratadine for system suitability CRS 2	
	Loratadine impurity F CRS 2	
	Loratadine impurity H CRS 2	
	Melphalan hydrochloride CRS 2	
	Nicotine ditartrate CRS 5	
	Nicotine for system suitability CRS 4	
	Norethisterone acetate CRS 2	
	Paclitaxel CRS 3	
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	Picosulfate for system suitability CRS 2	
	Progesterone for impurity H identification CRS 2	

	Retinol acetate CRS 7	
	Ropivacaine impurity G CRS 2	
	Salbutamol impurity D CRS 6	
	Salbutamol impurity G CRS 4	
	Serine CRS 2	
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	Tramadol impurity E CRS 4	
	Tricaprin CRS 2	
	Trimethoprim for system suitability CRS 4	
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	Ursodeoxycholic acid for system suitability CRS 3	
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	III. ITEMS DEFERRED – SCHEDULED FOR A FUTURE SESSION/ SUJETS REPORTES – A INSCRIRE A UNE PROCHAINE SESSION	
	IV. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	IV.1 Approved by the Commission	
12.4.1	Application of the F0 concept to steam sterilisation of aqueous preparations / Application du concept F0 à la stérilisation par la vapeur des préparations aque (50105) – Group 1	
26.4.2	Beeswax, white / Cire d'abeille blanche (0069) - Group 13H	
26.4.2	Beeswax, yellow / Cire d'abeille jaune (0070) - Group 13H	
28.4.1	Botulinum toxin type A for injection / Toxine botulinique type A pour préparation injectable (2113) – Group 15	
28.4.1	Botulinum toxin type B for injection / Toxine botulinique type B pour préparation injectable (2581) – Group 15	
18.4.1	Butylhydroxyanisole / Butylhydroxyanisole (0880) - Group 10A	
18.4.2	Butylhydroxytoluene / Butylhydroxytoluène (0581) - Group 10A	
26.4.1	Cod-liver oil (type A) / Foie de morue (huile de) (type A) (1192) - Group 13H	
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13.4.2	Danaparoid sodium / Danaparoïde sodique (2090) - Group 6	
	IV.1 Approved by the Commission	
12.4.2	Determination of bactericidal, fungicidal or yeasticidal activity of antiseptic medicinal products / Détermination de l'activité bactéricide, fongicide ou levuricide des médicaments à visée antiseptique (50111) – Group 1	
15.4.3	Dihydrostreptomycin sulfate for veterinary use / Dihydrostreptomycine (sulfate de) pour usage vétérinaire (0485) - Group 7	
28.4.1	Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et conjugué de l'haemophilus type b, adsorbé (1932) – Group 15	
45.4.1	Ethylcellulose / Éthylcellulose (0822) – CEL Working Party	
27.4.1	Gallium (⁶⁸ Ga) chloride solution for radiolabelling / Gallium (68Ga) (chlorure de) pour radiomarquage, solution de (2464) - Group 14	
27.4.2	Gallium (⁶⁸ Ga) edotreotide injection (2482) - Group 14	
13.4.1	Gonadotrophin, chorionic / Gonadotropine chorionique (498) - Group 6	
28.4.1	Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219) – Group 15	
28.4.1	Hepatitis A (inactivated, adsorbed) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin de l'hépatite A (inactivé) et de l'hépatite B (ADNr), adsorbé (1526) – Group 15	
28.4.1	Hepatitis A (inactivated, adsorbed) and typhoid polysaccharide vaccine/Vaccin de l'hépatite A (inactivé, adsorbé) et typhoïdique polyosidique (2597) – Group 15	
28.4.1	Hepatitis A (inactivated, virosome) / Vaccin de l'hépatite A (inactivé, virosomal) (1935) – Group 15	
28.4.1	Hepatitis A vaccine (inactivated, adsorbed) / Vaccin de l'hépatite A (inactivé) adsorbé (1107) – Group 15	
28.4.1	Hepatitis B (rDNA) vaccine / Vaccin de l'hépatite B (ADNr) (1056) – Group 15	
60.4.1	Homoeopathic preparations / Préparations homéopathiques (2619) – PHP Working Party	
14.4.1	Human coagulation factor VIII (rDNA) / Facteur VIII de coagulation humain (ADNr) (1643) - Group 6B	
28.4.1	Human papillomavirus vaccine (rDNA) / Vaccin du papillomavirus humain (ADNr) (2441) – Group 15	
49.4.1	Hyoscyamus for homoeopathic preparations / Hyoscyamus niger pour préparations homéopathiques (2091) – HOM Working Party	

18.4.3	Indometacin / Indométacine (0092) - Group 10A	
	IV.1 Approved by the Commission	
28.4.1	Influenza vaccine (split virion inactivated) / Vaccin grippal inactivé à virion fragmenté (0158) – Group 15	
28.4.1	Influenza vaccine (surface antigen inactivated prepared in cell cultures) / Vaccin grippal inactivé (antigène de surface préparé sur cultures cellulaires) (2149) – Group 15	
28.4.1	Influenza vaccine (surface antigen inactivated) / Vaccin grippal inactivé (antigène de surface) (0869) – Group 15	
28.4.1	Influenza vaccine (surface antigen inactivated, virosome) / Vaccin grippal inactivé (antigène de surface, virosomal) (2053) – Group 15	
28.4.1	Influenza vaccine (whole virion inactivated prepared in cell cultures) / Vaccin grippal inactivé à virion entier préparé sur cultures cellulaires (2308) – Group 15	
28.4.1	Influenza vaccine (whole virion, inactivated) / Vaccin grippal inactivé à virion entier (0159) – Group 15	
72.4.1	Isotretinoin / Isotrétinoïne (1019) – VIT Working Party	
15.4.3	Kanamycin acid sulfate / Kanamycine (sulfate acide de) (0033) - Group 7	
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28.4.1	Measles vaccine (live) / Vaccin rougeoleux vivant (0213) – Group 15	
28.4.1	Measles, mumps and rubella vaccine (live) / Vaccin rougeoleux des oreillons et rubéoleux vivant (1057) – Group 15	
28.4.1	Measles, mumps, rubella and varicella vaccine (live) / Vaccin rougeoleux des oreillons, rubéoleux et varicelleux vivant (2442) – Group 15	
28.4.1	Meningococcal group C conjugate vaccine / Vaccin conjugué méningococcique groupe C (2112) – Group 15	
28.4.1	Meningococcal polysaccharide vaccine / Vaccin méningococcique polysidique (0250) – Group 15	
55.4.1	Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation / Qualité microbiologique des médicaments à base de plantes pour usage oral et des (50108) – LBP Working Party with Groups 13A and 13B	
28.4.1	Mumps vaccine (live) / Vaccin vivant des oreillons (0538) – Group 15	
28.4.1	Pneumococcal polysaccharide conjugate vaccine (adsorbed) / Vaccin pneumococcique polysidique conjugué adsorbé (2150) – Group 15	
28.4.1	Pneumococcal polysaccharide vaccine / Vaccin pneumococcique polysidique (0966) – Group 15	

	IV.1 Approved by the Commission	
28.4.1	Poliomyelitis vaccine (inactivated) / Vaccin poliomyélitique inactivé (0214) – Group 15	
18.4.4	Propyl gallate / Propyle (gallate de) (1039) - Group 10A	
28.4.1	Rabies vaccine for human use prepared in cell cultures / Vaccin rabique pour usage humain préparé sur cultures cellulaires (0216) – Group 15	
15.4.3	Rifamycin sodium / Rifamycine sodique (0432) - Group 7	
21.4.1	Ropinirole hydrochloride / Ropinirole (chlorhydrate de) (2604) - Group 10D	
28.4.1	Rubella vaccine (live) / Vaccin rubéoleux vivant (0162) – Group 15	
28.4.1	Shingles (herpes zoster) vaccine (live) / Vaccin vivant du zona (2418) – Group 15	
28.4.1	Smallpox vaccine (live) / Vaccin vivant de la variole (0164) – Group 15	
15.4.3	Streptomycin sulfate / Streptomycine (sulfate de) (0053) - Group 7	
22.4.1	Sucralfate / Sucralfate (1796) - Group 11	
28.4.1	Tick-born encephalitis vaccine (inactivated) / Vaccin inactivé de l'encéphalite verno-estivale (1375) – Group 15	
28.4.1	Typhoid polysaccharide vaccine / Vaccin typhoïdique polysodique (1160) – Group 15	
13.4.1	Urofollitropin / Urofollitropine (958) - Group 6	
13.4.1	Urokinase / Urokinase (695) - Group 6	
28.4.1	Varicella vaccine (live) / Vaccin varicelleux vivant (0648) – Group 15	
28.4.1	Yellow fever vaccine (live) / Vaccin vivant de la fièvre jaune (0537) – Group 15	
8.4	V ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
8.4	Acetylene / Acétylène (3048) – Group 9G	
8.4	Depyrogenation processes and related indicators (50112) – Group 1	
8.4	Etonogestrel / Etonogestrel (0349) – Group 10B	
8.4	Gallium (⁶⁸ Ga) DOTA – NOC injection / gallium (⁶⁸ Ga) DOTA – NOC (solution injectable de) (3051) – Group 14	
8.4	Gallium (⁶⁸ Ga) DOTA-TATE injection / gallium (⁶⁸ Ga) DOTA-TATE (solution injectable de) (3050) – Group 14	
8.4	Lercanidipine hydrochloride / Lercanidipine (chlorhydrate de) (3052) – Group 10B	

	V ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
8.4	Microbiological examination of Live Biotherapeutic Products (LBPs): microbial contamination enumeration tests (2.6.36) - LBP WP	
8.4	Microbiological examination of Live Biotherapeutic Products (LBPs): specified micro-organisms (2.6.38) - LBP WP	
8.4	Principles for the detection of extraneous viruses in IVMPs by using culture methods (20637) – Group 15V	
8.4	Process analytical technology (52500) – PAT WP	
8.4	Scanning electron microscopy (20952) – VSADM WP	
	VI. SUPPRESSIONS FROM THE PH. EUR. / SUPPRESSIONS DE LA PH. EUR.	
	VII.1 Approved by the Commission	
8.4	Suppression: Test for neurovirulence of poliomyelitis vaccine (oral) / Essai de neurovirulence du vaccin poliomyélitique oral (2.6.19.) (2.6.19)	
	VII.1 PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
8.1	Election of the Vice-Chairs of the Commission: First Vice-Chair - Prof Arvidsson Second Vice-Chair - Dr Koszegine-Szalai	
8.2	Terms of Reference and Profile for Experts – Approved A revised version would be sent to delegations to incorporate changes in the ST Working Party	ALL
8.3	Nominations (see Annex)	
52.5.1	MAB WP: Monograph on Infliximab: publication of draft monograph in Pharmeuropa for public consultation	
65.1	Code of Practice: proposals made by UK, Switzerland and Presidium referred to ROP WP for further reflection and to make a recommendation to the Commission	
	VIII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	Dates for 2016 - 22-23 November 2016 Dates for 2017 - 21-22 March - 20-21 June - 21-22 November	

155th Session Nominations – Item 8.3
GROUPS OF EXPERTS

Group 11

Turkey	Prof. Dr. Erhan PALASKA	University
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Group 13A

Switzerland	Dr Leo ZÄNGERLE (replacing Dr PESHCKE)	Industry
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Group 15V

Spain	Dr Beatriz HERNANDEZ BLANCO	Licensing authority
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Group 16

Luxembourg	Mrs Elke DAVID - CLOS (replacing Dr H.P TRIERWEILER)	NF&DoI mail 03/06/2016
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WORKING PARTIES

P4Bio (Biologicals Substances biologiques)

Denmark	Dr Leif KONGSKOV LARSEN	NPA / OMCL
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PaedF (Paediatric Formulary)

France	Mrs Laurence MALEC	NPA
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ST (Standard Terms)

Italy	Dr Paola QUARANTA	Licensing Authority
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