

EUROPEAN PHARMACOPOEIA COMMISSION

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(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 143rd Session of the Commission

Résumé des Décisions prises lors de la 143e Session de la Commission

Strasbourg, 19-20 juin 2012

Strasbourg, 19-20 June 2012

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPÉE**

**Summary of Decisions of the 143rd Session
19-20 June 2012**

**Résumé des décisions de la 143^e Session
19-20 juin 2012**

Deadline for confirmation / Date de confirmation 13 July 2012

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
14.3.3	Anti-T lymphocyte immunoglobulin for human use, animal / Immunoglobuline animale anti-lymphocytes T pour usage humain (1928)	
34.3.1	Cellulose acetate butyrate / Cellulose (acétate butyrate de) (1406)	
24.3.1	Digitalis leaf / Digitale pourprée (feuille de) (117)	
14.3.1	Human coagulation factor VIII /Facteur VIII de coagulation humain (275)	
14.3.4	Human coagulation factor XI / Facteur XI de coagulation humain (1644)	
14.3.2	Human von Willebrand factor / Facteur Willebrand humain (2298)	
17.3.1	Isoprenaline hydrochloride / Isoprénaline (chlorhydrate d') (1332)	
23.3.1	Juniper / Genièvre (1532)	
23.3.2	Juniper oil / Genièvre (huile essentielle de) (1832)	
20.3.1	Magaldrate (1539)	
17.3.2	Molsidomine (1701)	
19.3.1	Nimesulide (1548)	
19.3.2	Vecuronium bromide / Vécuronium (bromure de) (1769)	
	I.1.2 Revisions / Révisions	
14.2.1	Alteplase for injection /Altéplase pour solution injectable (1170)	
24.2.1	Bearberry leaf / Busserole (feuille de) (1054)	
61.6.1	Betahistine mesilate (1071)	
61.6.2	Bromocriptine mesilate (0596)	
24.2.2	Buckwheat herb / Sarrasin (2184)	
18.2.1	Chlorhexidine digluconate solution / Chlorhexidine (digluconate de), solution de (658)	
61.6.3	Codergocrime mesilate (2060)	
61.6.4	Deferoxamine mesilate (0896)	
61.6.5	Dihydroergocristine mesilate (1416)	

61.6.6	Dihydroergotamine mesilate (0551)	
28.2.1	Dimeticone / Diméticone (138)	
27.2.3	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed)/Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé), adsorbé (1931)	
27.4.5	Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et de l'hépatite B (ADNr), adsorbé (1933)	
27.4.6	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyélitique (inactivé), adsorbé (1934)	
27.4.9	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)/Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyélitique (inactivé), adsorbé, à teneur réduite en antigène(s) (2329)	
27.2.4	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)	
27.4.8	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2067)	
27.4.7	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2065)	
18.2.2	Docusate sodium / Docusate sodique (1418)	
61.6.7	Doxazosin mesilate (2125)	
44.2.1	Gelatin / Gélatine (330)	
41.2.1	Haemofiltration and haemodiafiltration, solutions for / Solutions pour hémofiltration et pour hémodiafiltration (861)	
13.2.1	Human glucagon / Glucagon humain (1635)	
14.2.2	Human plasma (pooled and treated for virus inactivation) / Plasma humain mélange de traité pour viro-inactivation (1646)	
37.2.1	Hydroxypropylbetadex (1804)	
20.2.1	Isoleucine (770)	
24.2.3	Knotgrass / Renouée des oiseaux (1885)	

20.2.2	Leucine (771)	
20.2.3	Lysine hydrochloride / Lysine (chlorhydrate de) (930)	
61.6.8	Pefloxacin mesilate dihydrate (1460)	
61.6.9	Pergolide mesilate (1555)	
27.2.1	Pertussis vaccine (acellular, component, adsorbed)/Vaccin coquelucheux (adsorbé, multicomposé, acellulaire) (1356)	
27.2.2	Pertussis vaccine (acellular, co-purified, adsorbed)/Vaccin coquelucheux (adsorbé, copurifié, acellulaire) (1595)	
61.6.10	Phentolamine mesilate (1138)	
28.2.3	Poly(vinyl acetate) / Poly(acétate de vinyle) (1962)	
28.2.2	Poly(vinyl alcohol) / Poly(alcool vinylique) (1961)	
11.1	Potentiometric titration / Titrage potentiométrique (2.2.20.)	
19.2.1	Rocuronium bromide / Rocuronium (bromure de) (1764)	
61.6.11	Saquinavir mesilate (2267)	
24.2.4	St. John's wort / Millepertuis (1438)	
18.2.3	Tamoxifen citrate / Tamoxifène (citrate de) (1046)	
	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
27.1.1	Absence of residual pertussis toxin and irreversibility of pertussis toxoid / Absence de toxine coquelucheuse résiduelle et irréversibilité de l'anatoxin coquelucheuse (2.6.33)	
19.1.1	Atovaquone (2192)	
24.1.1	Blackcurrant leaf / Cassis (feuille de) (2528)	
26.1.1	Gallium (⁶⁸ Ga) chloride solution for radiolabelling / Gallium (⁶⁸ Ga) (chlorure de) pour radiomarquage, solution de (2464)	
19.1.2	Oxcarbazepine (2577)	
37.1.1	Starch, hydroxypropyl, pregelatinised / Amidon hydroxypropylé prégélatinisé (2645)	
	I.1.4 Approved texts	
52.6.1	Guide for the elaboration of monographs on homoeopathic preparations / Guide pour l'élaboration de monographies pour préparations homéopathiques	CH, DE, IT
78	I-2 CRS/BRP SCR/PBR	
78.1	New substances / Nouvelles substances	
78.1	Acetylsulfadiazine CRS 1	
78.1	Amidotrizoic acid for system suitability CRS 1	
78.1	Amikacin impurity I CRS 1	

78.1	Apomorphine hydrochloride hemihydrate CRS 1	
78.1	Apomorphine impurity B CRS 1	
78.1	Benzoic acid CRS 1	
78.1	Goserelin for NMR identification CRS 1	
78.1	Honokiol CRS 1	
78.1	Labetalol impurity A CRS 1	
78.1	Lopinavir for system suitability CRS 1	
78.1	Magnolol CRS 1	
78.1	Melphalan hydrochloride CRS 1	
78.1	Metamizole impurity E CRS 1	
78.1	Nevirapine hemihydrate CRS 1	
78.1	Pioglitazone for system suitability CRS 1	
78.1	Pioglitazone hydrochloride CRS 1	
78.1	Pipemidic acid trihydrate CRS 1	
78.1	Praziquantel for system suitability CRS 1	
78.1	Purified quillaia saponins HRS 1	
78.1	Pyridostigmine impurity B CRS 1	
78.1	Rivastigmine for system suitability CRS 1	
78.1	Sulfadiazine for impurity F identification CRS 1	
78.1	Sulfadiazine impurity A CRS 1	
78.1	Replacement batches / Lots de remplacement	
78.1	Amikacin for system suitability CRS 2	
78.1	Atropine for peak identification CRS 2	
78.1	Capsaicin CRS 2	
78.1	Chlortetracycline hydrochloride CRS 5	
78.1	Dextromethorphan hydrobromide CRS 4	
78.1	Dextromethorphan Impurity A CRS 2	
78.1	Dithranol CRS 2	
78.1	Docetaxel for system suitability CRS 2	
78.1	Docosahexaenoic acid ethyl ester CRS 4	
78.1	Flurbiprofen impurity A CRS 2	
78.1	Isosorbide mononitrate CRS 4	
78.1	Itraconazole for system suitability CRS 2	
78.1	Levetiracetam impurity A CRS 2	
78.1	Medroxyprogesterone acetate CRS 3	
78.1	Metoclopramide Impurity A CRS 2	

78.1	Milk thistle standardised dry extract CRS 3	
78.1	Mitomycin CRS 2	
78.1	Nabumetone Impurity F CRS 4	
78.1	Naftidrofuryl impurity B CRS 2	
78.1	Oxazepam for peak identification CRS 2	
78.1	Oxytetracycline CRS 7	
78.1	Paracetamol CRS 4	
78.1	Pipemidic acid trihydrate CRS 2	
78.1	Piroxicam for system suitability CRS 4	
78.1	Proline CRS 3	
78.1	Sulfasalazine CRS 4	
78.1	Tamsulosin impurity D proposed CRS 2	
78.1	Tamsulosin impurity H CRS 2	
78.1	Telmisartan for peak identification CRS 2	
78.1	Telmisartan for system suitability CRS 3	
78.1	Trolamine CRS 3	
78.1	Tyrosine CRS 2	
78.1	Ubidecarenone CRS 2	
78.1	Venlafaxine for system suitability CRS 3	
78.1	Zopiclone oxide CRS 3	
	II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTEES – A INSCRIRE A LA PROCHAINE SESSION	
Item	III. WORK PROGRAMME/PROGRAMME DE TRAVAIL	
	III.1 Requests for revision / Demandes de révision	
31.4.1	Allergen products / Produits allergènes (1063) -> ALG Working Party	
18.4.3	Amiloride hydrochloride / Amiloride (chlorhydrate d') (0651)	
20.4.2	Arginine (806) -> Group 10D	
24.4.1	Artichoke leaf / Artichaut (feuille d') (1866) -> Group 13B	
13.4.1	Buserelin / Busérelina (1077) -> Group 6	
28.1.1	Clostridium botulinum vaccine for veterinary use / Vaccin botulinique pour usage vétérinaire (360) -> Group 15V	
19.4.1	Detomidine hydrochloride for veterinary use / Détomidine (chlorhydrate de) pour usage vétérinaire (1414) -> Group 10C	
28.2.1	Dimeticone / Diméticone (138) -> FRC Working Party	

18.4.2	Docosate sodium / Docosate sodique (1418)	
23.4.1	Fennel, bitter / Fenouil amer (fruit de) (824) -> Group 13A	
14.4.1	Fibrin sealant kit/Colle-fibrine (nécessaire de) (903) – Group 6B	
28.1.3 / 79.2	General Notices -> various groups	
71.1.1	Guide for Work / Guide des Travaux -> ROP Working Party	
41.4.1	Haemodialysis solutions, concentration, water for diluting / Solutions concentrées pour hémodialyse (eau pour dilution des) (1167) -> DIA Working Party	
41.4.1	Haemodialysis, solutions for Solutions pour hémodialyse (128) -> DIA Working Party	
27.4.1	Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219) -> Group 15	
37.4.1	Lactulose (1230) -> CRB Working Party	
23.4.2	Meadowsweet / Reine des prés (sommité fleurie de) (1868) -> Group 13A	
17.4.1	Mepivacaine hydrochloride / Mèpivacaïne (chlorhydrate de) (1242) -> Group 10A	
21.4.1	Nicotine ditartrate dihydrate / Nicotine (ditartrate de) dihydraté (2599) -> Group 11	
25.4.2	Paraffin, hard / Paraffine solide (1034) -> Group 13H	
28.2.3	Poly(vinyl acetate) / Poly(acétate de vinyle) (1962) -> FRC Working Party	
43.4.2	Poly(vinyl acetate) / Poly(acétate de vinyle) (1962) -> FRC Working Party	
43.4.1	Poly(vinyl alcohol) / Poly (alcool vinylique) (1961) ->FRC Working Party	
28.2.2	Poly(vinyl alcohol) / Poly(alcool vinylique) (1961) -> FRC Working Party	
28.4.1	Polyolefines / Polyoléfines (3.1.3.) -> Group 16	
71.1.2	Procedure for the Notification of National Monographs / Procédure de Notification des Monographies Nationales -> ROP Working Party	
25.4.1	Propylene glycol dicaprylocaprates / Propylèneglycol (dicaprylocaprates de) (2122) -> Group 13H	
79.1	Reference standards / Etalons de reference (5.12): Request for revision	
25.4.3	Stearoyl macrogolglycerides / Macrogolglycérides stéariques (1268) -> Group 13H	
18.4.1	Tamoxifen citrate / Tamoxifène (citrate de) (1046)	
28.1.2	Vaccines for veterinary use / Vaccins pour usage vétérinaire (62)	

20.4.1	Zopiclone (1060) -> Group 10D	
	III.2 Additions to the work programme	
8.1	Abelmosichi corolla -> TCM Working Party	IT
6.3	Drosera for homoeopathic preparations, <i>Drosera</i> PPH (rev)	
8.1	Entecavir -> Group of Experts P4	
6.3	Fumitory for homoeopathic preparations, <i>Fumaria officinalis</i> PPH (rev)	
6.3	Herbal teas (rev)	
8.1	Human C1-Esterase Inhibitor -> Group of Experts 6B	
6.3	Lungwort for homoeopathic preparations, <i>Sticta pulmonaria</i> PPH (rev)	
6.3	Marjoram for homoeopathic preparations, <i>Origanum majorana</i> PPH (rev)	
6.3	Mixture for herbal teas for officinal preparations	
6.3	Mouse-ear hawkweed (rev)	
6.3	Myrtle oil	
6.3	Succinic acid for homoeopathic preparations, <i>Succinicum acidum</i> PPH	
6.3	Thiocolchicoside (rev)	
8.1	Tigecycline -> Group of Experts P4	
6.3	Umbellate wintergreen for homoeopathic preparations, <i>Chimaphila umbellata</i> PPH (rev)	
Agenda Item No.	IV. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
8.2	FP monographs pilot phase	DE
7.2	Request for extension of the terms of reference of the Cell Therapy Products Working Party to draft a general text on the microbial safety of tissues for human use / Demande d'extension du mandat du Groupe de Travail Produits de Thérapie Cellulaire pour l'élaboration d'un texte général relatif à la sécurité microbienne des tissus pour usage humain	
7.3	Terms of Reference for the Second Identification Test Working Party (SIT)	

	V. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	- 27-28 November 2012 - 19-20 March 2013 - 18-19 June 2013 - 26-27 November 2013	

Annex 1
143rd Session Nominations
June 2012 SESSION
ITEM 7.1

GROUPS OF EXPERTS

Group 1

Portugal	Dr MIRANDA (replacing Dr Meirinhos Soares)
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Group 6B

Portugal	Dr MEIRINHOS SOARES (replacing Dr Figueiredo)
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Group 9G

Austria	Dr SCHOEFNAGL
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Group 10B

Germany	Dr AGUILAR-PARRILLA (replacing Dr Schulze)
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Group 13A

Ukraine: Observer	Dr KOTOV
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Group 13B

Ukraine: Observer	Dr KOTOV
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Group 14

Spain	Dr RAMIREZ DE ARELLANO SERNA (specialist: radiopharmacist)
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Group P4

Finland	Dr SALO (replacing Mrs Sinivuo)
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Chair of the Conductivity Working Party (CND)

No nominations yet received	
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Chair of the Non-Biological Complexes Working Party (NBC)

No nominations yet received	
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WORKING PARTIES

Production and Compounding of radiopharmaceutical preparations (CRP)

Spain	Dr RAMIREZ DE ARELLANO SERNA (specialist: radiopharmacist)
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Chromatographic Separation Techniques (CST)

Germany	Dr LAMOTTE (replacing Dr Fendt)
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Homoeopathic Manufacturing Methods (HMM)

United Kingdom	Mr Jasbinder SUMAL
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Homoeopathic Raw Materials and Stocks (HOM)

United Kingdom	Mr Jasbinder SUMAL
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Modern Microbiological Methods (MMM)

Portugal	Dr MIRANDA (replacing Dr Meirinhos Soares)
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Mycoplasmas (MYC)

Germany	Dr ZOLLER
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P4 BIO

Portugal	Dr URMAL (replacing Dr Meirinhos Soares)
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Process Analytical Technology (PAT)

United Kingdom	Mr LYNCH (Specialist: Raman Spectroscopy)
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Raw Materials for the Production of Cellular and Gene Transfer Products (RCG)

Portugal	Dr MENEZES FERREIRA
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Traditional Chinese Medicines

Switzerland	Dr WANG-TSCHEN
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