

EUROPEAN PHARMACOPOEIA COMMISSION

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Strasbourg, July 2011

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 140th Session of the Commission

Résumé des Décisions prises lors de la 140e Session de la Commission

Strasbourg, 28-29 juin 2011

Strasbourg, 28-29 June 2011

Distribution

For action:

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 140th Session
28-29 June 2011**

**Résumé des décisions de la 140^e Session
28-29 juin 2011**

Deadline for confirmation / Date de confirmation : 15 August 2011

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
17.3.1	Acetylsalicylic acid/Acétysalicylique (acide) (309)	
15.3.1	Ciclosporin / Ciclosporine (994)	
23.3.1	Dandelion herb with root / Pissenlit (partie aérienne et racine de) (1851)	
27.3.2	Diphtheria, tetanus and pertussis (whole cell) vaccine (adsorbed) Vaccin diphtérique, tétanique et coquelucheux (à cellules entières), adsorbé (445)	
27.3.1	Diphtheria, tetanus, pertussis (whole cell) and poliomyelitis (inactivated) vacc Vaccin diphtérique, tétanique, coquelucheux (à cellules entières) et poliomyélit (2061)	
21.3.1	Docetaxel trihydrate / Docétaxel trihydraté (2449)	
18.3.1	Etofenamate/Étofénamate (1513)	
20.3.1	Fluorescein / Fluorescéine (2348)	
17.3.2	Fluphenazine dihydrochloride / Fluphénazine (dichlorhydrate de) (904)	
19.3.1	Fosinopril sodium / Fosinopril sodique (1751)	
15.3.2	Gentamicin sulfate / Gentamicine (sulfate de) (331)	
20.3.2	Magnesium aspartate dihydrate / Magnésium (aspartate de) dihydraté (1445)	
18.3.2	Midazolam/Midazolam (936)	
17.3.3	Piretanide / Pirétanide (1556)	
18.3.3	Torasemide, anhydrous/Torasémide anhydre (2132)	
	I.1.2 Revisions / Révisions	
17.2.1	Amantadine hydrochloride / Amantadine (chlorhydrate d') (463)	
21.2.1	Amidotrizoic acid dihydrate / Amidotrizoïque (acide) dihydraté (873)	
15.2.1	Amikacin / Amikacine (1289)	
15.2.2	Amikacin sulfate / Amikacine (sulfate d') (1290)	
52.2.1	Ammonium bromide / Ammonium (bromure d') (1389)	

	I.1.2 Revisions / Révisions	
21.2.2	Apomorphine hydrochloride / Apomorphine (chlorhydrate d') (136)	
24.2.1	Ash leaf / Frêne (feuille de) (1600)	
27.2.1	Assay of pertussis vaccine (acellular) (2.7.16.) / Titrage de l'activité du vaccin coquelucheux acellulaire (2.7.16.)	
18.2.1	Carbimazole/Carbimazol (0884)	
17.2.2	Chlorpromazine hydrochloride / Chlorpromazine (chlorhydrate de) (475)	
15.2.3	Chlortetracycline hydrochloride / Chlortétracycline (chlorhydrate de) (173)	
25.2.1	Cod-liver oil (type A) / Foie de morue (huile de) (type A) (1192)	
25.2.2	Cod-liver oil (type B) / Foie de morue (huile de) (type B) (1193)	
25.2.3	Cod-liver oil, farmed / Foie de morue d'élevage (huile de) (2398)	
23.2.1	Coriander / Coriandre (1304)	
18.2.2.	Dexamethasone sodium phosphate/Dexaméthasone (phosphate sodique de) (0549)	
27.2.7	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé) (1931)	
27.2.5	Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) (1932)	
27.2.8	Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) (1933)	
27.2.9	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactiv) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et polio (1934)	
27.2.10	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactiv) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et polio (2329)	
27.2.6	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), polio / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) (2067)	
27.2.4	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivate) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomy (2065)	
27.2.12	Diphtheria, tetanus, pertussis, poliomyelitis (inactivated) and haemophilus type / Vaccin diphtérique, tétanique, coquelucheux, poliomyélitique (inactivé) et conju (2066)	
23.2.2	Ethanol content and alcoholimetric tables / Teneur en éthanol et tableaux alcoométriques (20910)	

	I.1.2 Revisions / Révisions	
25.2.8	Fish oil, rich in omega-3 acids / Poisson (huile de) riche en acides oméga-3 (1912)	
11.1	General notices / Prescriptions générales (1.)	
24.2.2	Greater celandine / Chélidoine (1861)	
27.2.11	Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219)	
14.1.1	Human normal immunoglobulin for intravenous administration / Immunoglobuline humaine normale pour administration par voie intraveineuse (918)	All delegations
18.2.3	Hydrocortisone acetate/Hydrocortisone (acétate d') (0334)	
20.2.1	Magaldrate (1539)	
24.2.3	Melilot / Mélilot (2120)	
19.2.1	Metamizole sodium / Métamizole sodique (1346)	
18.2.4	Nitrendipine/Nitrendipine (1246)	
19.2.2	Nizatidine (1453)	
25.2.6	Omega-3-acid ethyl esters 60 / Oméga-3 (esters éthyliques 60 d'acides) (2063)	
25.2.5	Omega-3-acid ethyl esters 90 / Oméga-3 (esters éthyliques 90 d'acides) (1250)	
25.2.7	Omega-3-acid triglycerides / Oméga-3 (triglycérides d'acides) (1352)	
23.2.3	Peppermint oil / Menthe poivrée (huile essentielle de) (405)	
27.2.2	Pertussis vaccine (acellular, component, adsorbed) / Vaccin coquelucheux (adsorbé, multicomposé, acellulaire) (1356)	
27.2.3	Pertussis vaccine (acellular, co-purified, adsorbed) / Vaccin coquelucheux (adsorbé, copurifié, acellulaire) (1595)	
19.2.3	Pipemidic acid trihydrate / Pipémidique (acide) trihydraté (1743)	
19.2.4	Piroxicam (944)	
52.2.2	Potassium bromide / Potassium (bromure de) (184)	
52.2.3	Potassium chloride / Potassium (chlorure de) (185)	
17.2.3	Propyphenazone / Propyphénazone (636)	
25.2.4	Salmon oil, farmed / Saumon d'élevage (huile de) (1910)	
23.2.4	Saw palmetto fruit / Sabal (fruit de) (1848)	
52.2.4	Sodium bromide / Sodium (bromure de) (190)	
15.2.4	Sulfadiazine (294)	
23.2.5	Test for methanol and 2-propanol / Recherche du méthanol et du 2-propanol (20911)	
17.2.4	Thiopental sodium and sodium carbonate / Thiopental et carbonate sodiques (212)	
42.2.1	Titanium dioxide / Titane (dioxyde de) (150)	

	I.1.2 Revisions / Révisions	
18.2.5	Triamcinolone acetonide/Triamcinolone (acétonide de) (0533)	
23.2.6	Verbena herb / Verveine officinale (1854)	
27.2.13	Yellow fever vaccine (live) / Vaccin vivant de la fièvre jaune (537)	
	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
52.1.1	Aluminium monostearate / Aluminium (monostéarate de) (1663)	
71.1.1	Angelica sinensis root / Angelica sinensis (racine d') (2558)	
71.1.2	Atractylodes lancea rhizome / Atractylodes lancea (rhizome d') (2559)	
71.1.3	Atractylodes largehead rhizome / Atractylodes macrocephala (rhizome d') (2560)	
24.1.1	Black cohosh / Actée à grappes (2069)	
30.1.4	Celecoxib / Célécoxib 2591	
21.1.1	Docetaxel anhydrous / Docétaxel anhydre (2593)	
71.1.4	Drynaria rhizome / Drynaria (rhizome de) (2563)	
30.1.1	Duloxetine hydrochloride Duloxétine (chlorhydrate de) (2594)	
17.1.1	Melphalan (1698)	
23.1.1	Niaouli oil, cineole type / Niaouli type cinéole (huile essentielle de) (2468)	
71.1.5	Poria / Poria (2475)	
30.1.2	Rosiglitazone maleate Rosiglitazone (maléate de) (2605)	FR ¹
67.1.1	Sodium iodohippurate dihydrate for radiopharmaceutical preparations / Sodium (iodohippurate de) dihydraté pour préparations radiopharmaceutiques (2352)	
	I-2 CRS/BRP SCR/PBR	
Item	New substances / Nouvelles substances	
77.1	Betamethasone dipropionate for SST CRS 1	
77.1	Betamethasone for peak identification CRS 1	
77.1	Bifonazole for system suitability CRS 1	
77.1	Butyl parahydroxybenzoate Impurity E CRS 1	
	New substances / Nouvelles substances	
78.2	Calibration of the European Pharmacopoeia Biological Reference Preparation Batches 1 and 2 for Human Coagulation Factor V, VIII and XIII in Normal Human Plasma	
77.1	Candesartan cilexetil CRS 1	

¹ Even if adoption is confirmed, the monograph will not be published in the Ph. Eur

	New substances / Nouvelles substances	
77.1	Candesartan cilexetil for system suitability CRS 1	
77.1	Cefepime dihydrochloride monohydrate for system suitability CRS 1	
77.1	Cefepime Impurity E CRS 1	
77.1	Fluphenazine Impurity mixture CRS 1	
77.1	Fluphenazine Impurity mixture CRS 1	
77.1	Gabapentin CRS 1	
77.1	Kudzuvine root dry extract HRS 1	
77.1	Levonorgestrel for system suitability CRS 1	
77.1	Levonorgestrel Impurity B CRS 1	
77.1	Macrogol 30 dipolyhydroxystearate CRS 1	
77.1	Montelukast dicyclohexylamine CRS 1	
77.1	Montelukast for peak identification CRS 1	
77.1	Montelukast racemate CRS 1	
77.1	Montelukast sodium CRS 1	
77.1	Nicergoline CRS 1	
77.1	Nicergoline for peak identification CRS 1	
77.1	Nicergoline Impurity D CRS 1	
77.1	Nitrofural for peak identification CRS 1	
77.1	Olmесartan for system suitability CRS 1	
77.1	Ondansetron Impurity E CRS 1	
77.1	Ondansetron Impurity F CRS 1	
77.1	Prednicarbate for system suitability CRS 1	
77.1	Racemic methyldopa CRS 1	
77.1	Ribavirin CRS 1 (for information)	
77.1	Rizatriptan benzoate CRS 1	
77.1	Rizatriptan for system suitability CRS 1	
77.1	Stanozolol Impurity B CRS 1	
77.1	Sucralose CRS 1	
77.1	Sucralose Impurity B CRS 1	
77.1	Testosterone propionate for SST CRS 1	
77.1	Valproic acid for system suitability CRS 1	
77.1	Replacement batches / Lots de remplacement	
77.1	Boldine CRS 2	
77.1	Butyl parahydroxybenzoate CRS 3	
77.1	Cefoperazone dihydrate CRS 2	
77.1	Cholesterol CRS 3	
77.1	Ciclopirox olamine CRS 2	

77.1	Replacement batches / Lots de remplacement	
77.1	Clotrimazole impurity E CRS 2	
77.1	Estrone CRS 4	
77.1	Ethosuximide Impurity A CRS 4	
77.1	Fluoxetine Impurity B CRS 5	
77.1	Fluoxetine Impurity C CRS 4	
77.1	Folic acid impurity D CRS 2	
77.1	Glibenclamide Impurity B CRS 2	
77.1	Human insulin CRS 4	
77.1	Ibuprofen Impurity B CRS 6	
77.1	Leuprorelin CRS 5	
77.1	Mefloquine hydrochloride CRS 2	
77.1	Midazolam for system suitability CRS 2	
77.1	Oxycodone Impurity D CRS 2	
77.1	Phenylalanine CRS 4	
77.1	Plastic additive 09 CRS 3	
77.1	Prednisolone CRS 7	
77.1	Primidone CRS 2	
77.1	Pyridostigmine bromide CRS 3	
77.1	Ramipril Impurity D CRS 4	
77.1	Ribavirin CRS 2	
77.1	Riboflavin sodium phosphate CRS 2	
77.1	Rutoside trihydrate CRS 3	
77.1	Sertraline hydrochloride CRS 2	
77.1	Silicone elastomer CRS 2	
77.1	Stanozolol CRS 2	
77.1	Tribenoside Impurity A CRS 3	
77.1	Trimethoprim Impurity B CRS 4	
	II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTES – A INSCRIRE A LA PROCHAINE SESSION	
30.1.3	Pioglitazone hydrochloride Pioglitazone (chlorhydrate de) (2601)	

Item	III. WORK PROGRAMME/PROGRAMME DE TRAVAIL	
	III.1 Requests for revision / Demandes de révision	
28.4.1	Avian viral vaccines: tests for extraneous agents in seed lots/Vaccins viraux aviaires : recherche des agents étrangers dans les lots de semence (20624)	
52.4.1	Calcium hydrogen phosphate, anhydrous / Calcium (hydrogénophosphate de) anhydre (981)	
18.4.1	Dexamethasone sodium phosphate/Dexaméthasone (phosphate sodique de) (549)	
23.4.1	Essential oils / Huiles essentielles (2098)	
21.4.1	Glucosamine hydrochloride / Glucosamine (chlorhydrate de) (2446)	
21.4.1	Glucosamine sulfate sodium chloride / Glucosamine (sulfate de) - chlorure de (2447)	
68.4.2	Guide for Work of the European Pharmacopoeia	
14.4.1	Human alpha-1-proteinase inhibitor / Inhibiteur d'alpha-1-protéinase humain (2387)	
17.4.1	Hydralazine hydrochloride / Hydralazine (chlorhydrate d') (829)	
24.4.1	Indian frankincense / Encens indien (2310)	
23.4.2	Java tea / Orthosiphon (1229)	
17.4.3	Methylthioninium chloride / Méthylthioninium (chlorure de) (1132)	
16.4.1	Oxygen / Oxygène (417)	
68.4.1	Rules of Procedure of the European Pharmacopoeia	
17.4.2	Thiopental sodium and sodium carbonate / Thiopental et carbonate sodiques (212)	
28.4.2/ 28.4.3	Vaccines for veterinary use/Vaccins pour usage vétérinaire (0062)	
	III.2 Additions to the work programme	
8.1	Abbreviated Impactor Measurement and Efficient data Analysis (INH WP)	
8.2	Amorolfine hydrochloride (Gr 10B)	
8.1	Aprepitant (P4)	
8.2	Benzydamine HCl (Gr 10A)	
8.2	Brimonidine tartrate (Gr 10C)	
8.1	Bupivacaine free base (Gr 10A)	
8.2	Capecitabine (P4)	
42.5.1	Caprylocaproyl macrogolglycerides / Macrogolyglycérides caprylocarpiques (1184) (FRC WP)	
8.1	Cisatracurium besilate (Gr 10C)	

	III.2 Additions to the work programme	
6.3	Coptidis rhizoma / Huang Lian (TCM WP)	
8.1	Diphtheria, Tetanus, Pertussis (acellular) reduced antigen(s) vaccine (Gr 15)	
8.2	Eplerenone (Gr 10B)	
8.2	Exemestane (Gr 10B)	
8.1	Ezetimibe (P4)	
8.1	Fluticasone furoate (P4)	
6.3	Forsythiae fructus / Lao qiao (TCM WP)	
8.1	Gamma cyclodextrin (CRB WP)	
42.5.1	Glycerol distearate / Glycérol (distéarate de) (1428) (FRC WP)	
42.5.1	Glycerol mono-oleate / Glycérol (mono-oléate de) (1430) (FRC WP)	
42.5.1	Glycerol monostearate 40-55 / Glycérol (monostéarate de) 40-55 (495) (FRC WP)	
8.1	Haemofiltration and Haemodiafiltration, concentrated solutions (DIA WP)	
8.2	Ibandronate sodium (Gr 11)	
8.2	Latanoprost (Gr 10B)	
42.5.1	Lauroyl macroglycerides / Macroglyglycérides lauriques (1231) (FRC WP)	
6.3	Leonuri herba / Yi Mu Cao (TCM WP)	
42.5.1	Linoleoyl macroglycerides / Macroglyglycérides linoléiques (1232) (FRC WP)	
8.1	Live attenuated intranasal influenza vaccine (Gr 15)	
42.5.1	Macrogol 20 Glycerol monostearate / Macrogol 20 glycérol (monostéarate de) (2044) (FRC WP)	
42.5.1	Macroglycerol hydroxystearate / Macroglyglycérides (hydroxystéarate de) (1083) (FRC WP)	
42.5.1	Macroglycerol ricinoleate / Macroglyglycérides (ricinoléate de) (1082) (FRC WP)	
8.2	Memantine (Gr 10B)	
8.1	Mivacurium chloride (Gr 10C)	
8.2	Nebivolol (Gr 10A)	
8.1	Nicardipine hydrochloride (Gr 10D)	
42.5.1	Oleoyl macroglycerides / Macroglyglycérides oléiques (1249) (FRC WP)	
42.5.1	Poloxamers / Poloxamères (1464) (FRC WP)	
8.2	Pregabalin (P4)	
8.2	Rabeprazole (Gr 10C)	
8.1	Sitagliptin phosphate (P4)	

	III.2 Additions to the work programme	
8.2	Solifenacin (P4)	
42.5.1	Sorbitan laurate / Sorbitan (laurate de) (1040) (FRC WP)	
42.5.1	Sorbitan oleate / Sorbitan (oléate de) (1041) (FRC WP)	
42.5.1	Sorbitan palmitate / Sorbitan (palmitate de) (1042) (FRC WP)	
42.5.1	Sorbitan sesquioleate / Sorbitan (sesquioléate de) (1916) (FRC WP)	
42.5.1	Sorbitan stearate / Sorbitan (stéarate de) (1043) (FRC WP)	
42.5.1	Sorbitan trioleate / Sorbitan (trioléate de) (1044) (FRC WP)	
42.5.1	Stearoyl macrogolglycerides / Macrogolyglycérides stéariques (1268) (FRC WP)	
8.2	Temozolomide (Gr 10C)	
8.2	Tolterodine (Gr 10C)	
8.1	Vardenafil hydrochloride (P4)	
8.2	Varenicline Tartrate (P4)	
8.1	Water for dilution Haemofiltration and Haemodiafiltration, concentrated solutions (DIA WP)	
	III.3 Suppression from the Work Programme	
8.1	Necrotic enteritis vaccine (inactivated) for pigs (2681)	
31.5.1	Uniformity of dosage units for allergen products	
	III.4 Suppression from the Ph. Eur.	
8.3	Chlorothiazide	SI, HU, DE
8.3	Dienestrol	SI, HU, DE
8.3	Emetine hydrochloride heptahydrate	SI, HU, DE
8.3	Etofylline	SI, HU, DE
8.3	Hexobarbital	SI, HU, DE
8.3	Histamine phosphate	SI, HU, DE
8.3	Iotalamic acid	SI, HU, DE
8.3	Methaqualone	SI, HU, DE
8.3	Methylatropine bromide	SI, HU, DE
8.3	Methylatropine nitrate	SI, HU, DE
8.3	Physostigmine sulphate	SI, HU, DE
8.3	Succinylsulfathiazole	SI, HU, DE
8.3	Sulfafurazole	SI, HU, DE
8.3	Sulfisomidine	SI, HU, DE
8.3	Tubocurarine chloride	SI, HU, DE

Agenda Item No.	IV. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
7.1	Nominations to Groups of Experts and Working Parties / Nominations pour Groupes d'Experts et Groupes de Travail	See Annex I
7.2	Terms of Reference for the Extracts Working Party: Approved The Secretariat will send out a request for nominations	
7.3	Terms of Reference for the Non-Biological Complexes Working Party: Approved The Secretariat will send out a request for nominations for members and for Chair	
7.4	Revised Terms of Reference for the Rules of Procedure Working Party: Approved	
7.4	Terms of Reference for the Glass Containers Working Party: Approved The Secretariat will send out a request for nominations for additional specialists and for a Chair (to be approved by correspondence)	
	V. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	<ul style="list-style-type: none"> - 16-17 November 2011 - 3-4 April - 19-20 June - 27-28 November 	

**140th Session Nominations
June 2011 SESSION**

ITEM 7.1

GROUPS OF EXPERTS

Group 6

Croatia	Dr Marija KOZLOVIC
Slovenia	Dr Tomaz BRATKOVIC (replacing Dr B Strukelj)

Group 7

Sweden	Dr My MOBERG
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Group 10C

Poland	Dr Karina BOSZKO
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Group 10D

Turkey	Prof. Sibel SUZEN
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Group 11

Switzerland	Dr Wolfgang BECK
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Group 16

Belgium	Mr Renaud JANSSEN (Specialist: primary and secondary packaging components [mainly rubber and aluminium])
Sweden	Dr Anders LOFGREN

WORKING PARTIES

MSL

Germany	Dr Uwe WOLLEIN
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PAT

Germany	Dr Jobst LIMBERG (replacing Prof. Norwig)
Sweden	Prof. Bengt WITTGREN

TCM

United Kingdom	Mr Michael WHALEY
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CHAIR OF THE INHALANDA WORKING PARTY (INH)

Germany	Dr Stefan LEINER
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RE-APPOINTED WORKING PARTYRules of Procedure

Sweden	Dr Marianne EK (Chair)
Switzerland	Dr Tobias GOSDSCHAN
France	Dr An LE
Spain	Mme Carmen DE LA MORENA
Germany	Dr Hugo PEETERS
United Kingdom	Dr Ged LEE