

EUROPEAN PHARMACOPOEIA COMMISSION

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Strasbourg, December 2012

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(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 144th Session

Résumé des Décisions prises lors de la 144e Session

Strasbourg, 27-28 novembre 2012

Strasbourg, 27-28 November 2012

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOEPEE**

**Summary of Decisions of the 144th Session
27-28 November 2012**

**Résumé des décisions de la 144^e Session
27-28 novembre 2012**

Deadline for confirmation / Date de confirmation 19 December 2012

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
24.3.4	Capsicum / Piment de Cayenne (1859)	
24.3.3	Capsicum oleoresin, refined and standardised Piment de Cayenne (oléorésine raffinée et titrée de) (2336)	
24.3.6	Capsicum soft extract, standardised Piment de Cayenne (extrait mou titré de) (2529)	
24.3.5	Capsicum tincture, standardised Piment de Cayenne (teinture titrée de) (2337)	
15.3.2	Cefradine (814)	
18.3.1	Dexamethasone / Dexaméthasone (0388)	
19.3.1	Dipyridamole (1199)	
21.3.3	Doxapram hydrochloride (1201)	
35.3.1	Ethylcellulose (822)	
17.3.1	Fenbendazole for veterinary use / Fenbendazole pour usage vétérinaire (1208)	
26.3.1	Fludeoxyglucose (18F) injection / Fludésoxyglucose (18F) (solution injectable de) (1325)	
17.3.2	Glipizide / Glipizide (0906)	
14.3.1	Human plasma for fractionation Plasma humain pour fractionnement (853)	
18.3.2	Hydrocortisone acetate / Hydrocortisone (acétate d') (0334)	
67.2.1	Insulin glargine / Insuline glargine (2571)	All
38.3.1	Maize starch (344)	
18.3.3	Megestrol acetate / Mégestrol (acétate de) (1593)	
18.3.4	Metoprolol succinate / Métoprolol (succinate de) (1448)	
18.3.5	Metoprolol tartrate / Métoprolol (tartrate de) (1028)	
24.3.1	Milk thistle dry extract, refined and standardised / Chardon marie (extrait sec purifié et titré de) (2071)	
24.3.2	Milk-thistle fruit / Chardon marie (1860)	
21.3.2	Nicotine ditartrate dihydrate (2599)	

	I.1.1 Minor revisions / Révisions mineures	
17.3.3	Oxfendazole for veterinary use / Oxfendazole pour usage vétérinaire (1458)	
38.3.2	Potato starch (355)	
26.3.2	Radiopharmaceutical preparations / Préparations radiopharmaceutiques (125)	
15.3.1	Sulfadiazine (294)	
21.3.1	Timolol maleate (572)	
38.3.3	Wheat starch (359)	
	I.1.2 Revisions / Révisions	
19.2.1	Aciclovir (968)	
77.2.1	Alfacalcidol / Alfacalcidol (1286)	
28.2.1	Aujeszky's disease vaccine (live) for pigs for parenteral administration / Vaccin vivant de la maladie d'Aujeszky pour le porc pour administration parentérale (745)	
61.2.3	Belladonna leaf dry extract, standardised / Belladone (feuille de), extrait sec titré de (1294)	
76.2.1	Bistort rhizome / Bistorte (rhizome de) (2384)	
17.2.1	Brompheniramine maleate / Bromphéniramine (maléate de) (0977)	
20.2.2	Cysteine hydrochloride monohydrate (895)	
38.2.2	Dextranomer (2238)	
25.2.1	Ethylene oxide and dioxan (2.4.25.)	
18.2.1	Finasteride / Finastéride (1615)	
18.2.2	Flutamide / Flutamide (1423)	
61.2.4	Frangula bark dry extract, standardised / Bourdaine (extrait sec titré de) (1214)	
13.2.1	Heparins, low-molecular-mass / Héparines de basse masse moléculaire (828)	
14.2.1	Human alpha-1-proteinase inhibitor / Inhibiteur d'alpha-1-protéinase humain (2387)	
35.2.1	Hypromellose (348)	
18.2.3	Levonorgestrel / Lévonorgestrel (0926)	
19.2.3	Lomustine (928)	
38.2.1	Mannitol (559)	
17.2.2	Metformin hydrochloride / Metformine (chlorhydrate de) (0931)	
35.2.2	Methylcellulose (345)	
18.2.4	Methylprednisolone / Méthylprednisolone (0561)	

	I.1.2 Revisions / Révisions	
61.2.2	Microbiological examination of herbal medicinal products for oral use / Contrôle microbiologique des médicaments à base de plantes pour usage oral (2.6.31)	
61.2.1	Microbiological quality of herbal medicinal products for oral use / Qualité microbiologique des médicaments à base de plantes pour usage oral (5.1.8)	
12.1	Microbiological quality of non-sterile pharmaceutical preparations and substance/ Qualité microbiologique des préparations pharmaceutiques et des substances pour (50104)	
19.2.2	Minoxidil (937)	
68.2.1	Near-infrared spectrophotometry / Spectrophotométrie dans le proche infrarouge (2.2.40.)	
22.2.1	Parenteral preparations / Préparations parentérales (520)	
42.2.1	Peritoneal dialysis, solutions for Solutions pour dialyse péritonéale (862)	
11.4	Pharmacopoeial harmonisation (5.8.) / Harmonisation des pharmacopées (5.8.)	
77.2.2	Phytomenadione/Phytoménadione (1036)	
22.2.2	Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037)	
20.2.3	Proline (785)	
28.2.2	Rabies vaccine (live, oral) for foxes / Vaccin vivant oral de la rage pour renards (746)	
28.2.1	Rubber closures for containers for aqueous parenteral preparations, for powders Fermetures en caoutchouc pour récipients destinés aux préparations parentérales (30209)	
61.2.5	Senna leaf dry extract, standardised / Séné (feuille de), extrait sec titré de (1261)	
20.2.4	Serine (788)	
22.2.3	Tablets/ Comprimés (478)	
20.2.5	Threonine (1049)	
20.2.1	Valine (796)	
	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
17.1.1	Alimemazine hemitartrate / Alimémazine (hémitartrate d') (2650)	
26.1.2	Alovudine (18F) injection / Alovudine (18F) (solution injectable d') (2460)	
30.1.1	Atomoxetine hydrochloride / Atomoxétine (chlorhydrate d') (2640)	

	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
76.1.6	Belamcanda chinensis rhizome / Belamcanda chinensis (rhizome de) (2561)	
17.1.2	Desloratadine / Desloratadine (2570)	
26.1.1	Detection and measurement of radioactivity / Détection et mesure de la radioactivité (2.2.66.)	
21.1.1	Diacerein (2409)	
30.1.2	Dutasteride / Dutastéride (2641)	
76.1.2	Eclipta prostrata herb / Eclipta prostrata (partie aérienne d') (2564)	
76.1.3	Eucommia bark / Eucommia (écorce d') (2412)	
76.1.5	Fleeceflower root / Polygonum multiflorum (racine de) (2433)	
26.1.3	Fluoromisonidazole (18F) injection / Fluoromisonidazole (18F) (solution injectable de) (2459)	
13.1.1	Follitropin / Follitropine (2285)	
13.1.2	Follitropin concentrated solution / Follitropine (solution concentrée de) (2286)	
76.1.1	Fraxinus rhynchophylla bark / Fraxinus rhynchophylla (écorce de) (2452)	
67.1.1	Human coagulation factor VIIa (rDNA) Facteur VIIa de coagulation humain (ADNr) 2534	
76.1.4	Mandarin epicarp and mesocarp / Mandarine (épicarpe et mésocarpe de) (2430)	
23.1.1	Saw palmetto extract / Sabal (extrait de) (2579)	
22.1.1	Veterinary semi-solid preparations for oral use / Préparations vétérinaires semi-solides pour usage oral (2638)	
	I-2 CRS/BRP SCR/PBR	
	New substances / Nouvelles substances	
	2-(dimethylamino)ethyl methacrylate CRS 1	
	3-trimethylsilyl-1-propanesulfonic acid sodium salt CRS 1	
	Abacavir for peak identification CRS 1	
	Abacavir for system suitability CRS 1	
	Abacavir sulfate CRS 1	
	Amisulpride for system suitability CRS 1	
	Anastrozole CRS 1	
	Anastrozole Impurity E CRS 1	
	Basic butylated methacrylate copolymer CRS 1	
	Buflomedil for peak identification CRS 1	
	Butyl methacrylate CRS 1	

	New substances / Nouvelles substances	
	Cefoxitin for peak identification CRS 1	
	Ciclesonide containing impurity A CRS 1	
	Ciclesonide CRS 1	
	Ciclesonide impurity B CRS 1	
	Ciclesonide impurity C CRS 1	
	Coix seed HRS 1	
	Docusate sodium CRS 1	
	Doxylamine for system suitability CRS 1	
	Doxylamine hydrogen succinate CRS 1	
	Ginseng dry extract HRS 1	
	Ginsenoside Rb1 CRS 1	
	Glibenclamide for peak identification CRS 1	
	Long pepper for system suitability HRS 1	
	Lopinavir CRS 1	
	Lopinavir for peak identification CRS 1	
	Megestrol acetate CRS 1	
	Mesalazine for system suitability CRS 1	
	Mesalazine impurity A CRS 1	
	Mesalazine Impurity C CRS 1	
	Methyl methacrylate CRS 1	
	Methylphenidate Impurity C CRS 1	
	Norethisterone acetate for system suitability CRS 1	
	Oleanolic acid CRS 1	
	Orienvine stem HRS 1	
	Pemetrexed for system suitability CRS 1	
	Pemetrexed impurity mixture CRS 1	
	Picrotin CRS 1	
	Picrotoxinin CRS 1	
	Piperine CRS 1	
	Quinapril for system suitability CRS 1	
	Quinapril hydrochloride CRS 1	
	Rivastigmine hydrogen tartrate CRS 1	
	Rivastigmine impurity D CRS 1	
	Rocuronium bromide CRS 1	
	Sildenafil citrate CRS 1	

	New substances / Nouvelles substances	
	Sildenafil Impurity A CRS 1	
	Sinomenine CRS 1	
	Sulfadimidine for peak identification CRS 1	
	Triolein CRS 1	
	Ursolic acid CRS 1	
	Replacement batches / Lots de remplacement	
	1,1'-Ethylidenebistryptophan CRS 5	
	1,4-Sorbitan CRS 2	
	1-N-ethylgaramine sulfate CRS 3	
	Acarbose for peak identification CRS 2	
	Alfacalcidol CRS 8	
	Allopurinol Impurity C CRS 3	
	Alprostadil CRS 2	
	Amikacin CRS 3	
	Amiloride Impurity A CRS 3	
	Amlodipine for peak identification CRS 2	
	Amlodipine Impurity A CRS 2	
	Amlodipine impurity B CRS 2	
	Amlodipine impurity G CRS 2	
	Amphotericin B for peak identification CRS 2	
	Atorvastatin Impurity A CRS 2	
	Atorvastatin Impurity B CRS 2	
	Atorvastatin Impurity D CRS 2	
	Beclometasone dipropionate anhydrous CRS 4	
	Bupivacaine impurity F CRS 2	
	Calcifediol CRS 4	
	Calcipotriol monohydrate CRS 2	
	Calcitonin CRS 9 & 10	
	Captopril for system suitability CRS 2	
	Carbamazepine CRS 5	
	Cefadroxil CRS 3	
	Chondroitin sulfate sodium CRS 2	
	Ciprofloxacin HCl for peak identification CRS 2	
	Codergocrine mesilate CRS 2	

	Replacement batches / Lots de remplacement	
	Desmopressin CRS batch 8	
	Diclofenac Impurity A CRS 8	
	Digoxigenin CRS 2	
	Enalapril Impurity mixture CRS 2	
	Estriol Impurity A CRS 2	
	Fenbendazole CRS 3	
	Finasteride for system suitability CRS 3	
	Flecainide impurity A CRS 3	
	Gammacyclodextrin CRS 2	
	Gentamicin sulfate CRS 8	
	Glycerol mono-oleate CRS 2	
	Hydrochlorothiazide CRS 7	
	Ibuprofen impurity B CRS 7	
	Insulin lispro CRS 2	
	Irbesartan impurity A CRS 2	
	Isomalt CRS 5	
	Isosorbide dinitrate CRS 3	
	Labetalol hydrochloride CRS 2	
	Lorazepam for system suitability CRS 2	
	Lysine hydrochloride CRS 3	
	Meclozine dihydrochloride CRS 2	
	Methionine CRS 2	
	Methotrexate CRS 6	
	Metoprolol impurity A CRS 3	
	Minocycline hydrochloride CRS 3	
	Naproxen CRS 2	
	Nicotine ditartrate CRS 4	
	Nimodipine impurity A CRS 4	
	Nomegestrol acetate CRS 2	
	Nystatin CRS 7	
	Ondansetron hydrochloride dihydrate CRS 4	
	Orphenadrine Impurity E CRS 2	
	Oxaliplatin CRS 4	
	Oxaliplatin impurity B CRS 8	
	Paclitaxel semi-synthetic for system suitability CRS 2	

	Replacement batches / Lots de remplacement	
	Pantoprazole for system suitability CRS 5	
	Perindopril for stereochemical purity CRS 2	
	Perindopril impurity A CRS 2	
	Prednisolone acetate CRS 4	
	Propofol CRS 5	
	Risperidone impurity K CRS 2	
	Rosmarinic acid CRS 2	
	Salbutamol Impurity B CRS 5	
	Salbutamol impurity D CRS 5	
	Silicon oil CRS 2	
	Sulfaguanidine CRS 2	
	Sumatriptan for system suitability CRS 5	
	Terbutaline sulfate CRS 2	
	Tribenoside impurity A CRS 4	
	Ursodeoxycholic acid for system suitability CRS 2	
	II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTEES – A INSCRIRE A LA PROCHAINE SESSION	
6.3	Deferasirox	
6.3	Menotrophin (0508)	
53.3.1	New titles for already published monographs on stocks for homoeopathic preparations	
Item	III. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	III.1 Approved by the Commission	
24.4.1	Acacia / Gomme arabique (307) -> Group 13B	
25.4.1	Arachis oil, refined / Arachide (huile d') raffinée (263) -> Group 13H	
27.4.1	Assay of hepatitis A vaccine / Titrage de l'activité du vaccin de l'hépatite A (2.7.14) -> Group 15	
18.4.1	Atenolol / Aténolol (0703) -> Group 10B	
28.4.2	Avian live virus vaccines: tests for extraneous agents in batches of finished product / Vaccins viraux vivants aviaires : recherche des agents étrangers dans les lots de produit final (20625) -> Group 15V	
28.4.1	Avian viral vaccines: tests for extraneous agents in seed lots (2.6.24.) / Vaccins viraux aviaires : recherche des agents étrangers dans les lots de semence (20624) -> Group 15V	

	III.1 Approved by the Commission	
34.4.1	Capillary electrophoresis (2.2.47) -> CE Working Party	
18.4.6	Carbimazole / Carbimazol (0884) -> Group 10B	
23.4.3	Clary sage oil / Saugé sclarée (huile essentielle de) (1850)	
20.4.1	D-Camphor (1400) -> Group 10D	
17.4.1	Desloratadine / Desloratadine (2570) -> Group 10A	
17.4.2	Doxazosin mesilate / Doxazosine (mésilate de) (2125) -> Group 10A	
19.4.1	Enalapril maleate (1420) -> Group 10C	
17.4.3	Ethosuximide / Éthosuximide (0764) -> Group 10A	
13.4.1	Filgrastim concentrated solution / Filgrastim (solution concentrée de) (2206) -> Group 6	
19.4.2	Fluticasone propionate (1750) -> Group 10C	
23.4.1	Fresh bilberry fruit dry extract, refined and standardised (2394)	
22.4.1	Friability of granules and spheroids / Friabilité des granulés et des sphéroïdes (2.9.41.) -> Group 12	
16.5.1	Helium -> Group 9G	
27.4.2	Hepatitis A vaccine (inactivated, adsorbed) / Vaccin inactivé de l'hépatite A adsorbé (1107) -> Group 15	
27.4.3	Immunochemical methods / Méthodes immunochimiques (2.7.1) -> Group 15	
18.4.2	Levetiracetam / Lévétiracétam (2535) -> Group 10B	
55.4.1	Magnesium stearate (229) -> INC Working Party	
24.4.3	Milk thistle dry extract, refined and standardised (2071) -> Group 13B	
24.4.3	Milk-thistle fruit / Chardon marie (1860) -> Group 13B	
24.4.2	Myrrh / Myrrhe (1349) -> Group 13B	
24.4.2	Myrrh tincture / Myrrhe (teinture de) (1877) -> Group 13B	
16.5.1	Nitrogen -> Group 9G	
14.4.1	Nucleic acid amplification techniques / Techniques d'amplification des acides nucléiques (20621) – Group 6B	
25.4.2	Olive oil, virgin (0518) -> Group 13H	
25.4.2	Olive oil, refined / Olive (huile d') raffinée (1456) -> Group 13H	
16.5.1	Oxygen/Oxygène (417) -> Group 9G	
23.4.2	Peppermint leaf (406)	
29.4.1	Plastic additives (3.1.13.) -> Group 16	
11.3	Potentiometric determination of pH / Détermination potentiométrique du pH (2.2.3.) -> PCM in collaboration with OMCL network	

	III.1 Approved by the Commission	
18.4.3	Proguanil hydrochloride / Proguanil (chlorhydrate de) (2002) -> Group 10B	
59.4.1	Pyrogens / Pyrogènes (2.6.8) -> MAT Working Party	
11.2	Relationship between reaction of solution, approximate pH and colour of certain indicators / Correspondance entre la réaction du milieu, le pH approximatif et la coloration de quelques indicateurs (2.2.4) -> PCM	
75.1	Statistical analysis of results of biological assays and tests (5.3.) / Analyse statistique des résultats des dosages et essais biologiques (5.3.) -> STA Working Party	
18.4.4	Triamcinolone hexacetonide / Triamcinolone (hexacétonide de) (0867) -> Group 10B	
80.1	Viscose Wadding, Absorbent / Ouate Viscose Hydrophile(34): request for revision	
11.1	Water: micro determination / Microdosage de l'eau (2.5.32.) -> PCM	
18.4.5	Ziprasidone hydrochloride monohydrate / Ziprasidone (chlorhydrate de) monohydraté (2421) -> Group 10B	
	III.2 Referred to Group for further consideration	
42.4.2	Peritoneal dialysis, solutions for / Solutions pour dialyse péritonéale (862) -> DIA Working Party	
15.4.2	Products of fermentation / Produits de fermentation (1468) -> Group 7	
68.5.1	Proposal to elaborate new general chapters on new advanced analytical methods -> PAT Working Party	
15.4.1	Tobramycin (645) – Group 7	
	IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
6.3	Achillea millefolium ferm 33d (Achillea ex herba ferm 33d) (HOM WP)	
6.3	Acidum benzoicum e resina (HOM WP)	
6.3	Adonis vernalis (HOM WP)	
6.3	Apisinum (HOM WP)	
6.3	Arsenum iodatum (Arsenum iodatum) (HOM WP)	
6.3	Asa foetida (HOM WP)	
6.3	Atropa-bella-donna Rh (Belladonna Rh) (HOM WP)	
6.3	Bacopa Monnieri (Group 13A)	
6.3	Berberis Aristata (Group 13B)	

	IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
6.3	Disci intervertebrales bovis <i>GI</i> (HOM WP)	
6.3	Eclipta Prostrata Whole plant (TCM Working Party)	
8.1	Ephedra distachya ad preparations homoeopathicas siccum (HOM Working Party)	
6.3	Ethanolamine (Group 10D)	
13.5.1	Filgrastim FP (Group 6)	
6.3	Hydroxychloroquine sulphate (Group 11)	
6.3	Iberis amara (HOM WP)	
6.3	Lilium lancifolium (Limium tigrinum) (HOM WP)	
6.3	Liquorice liquid extract (Group 13A)	
6.3	Liquorice root for use in TCM (TCM Working Party)	
8.1	Magnesium Aluminometasilicate (INC Working Party)	
6.3	Mandragora e radice siccata (HOM WP)	
6.3	Mandragora, ethanol. Decoctum (HOM WP)	
8.1	Mepifiline (Group 10A)	
8.1	Mometasone furoate monohydrate (Group 10B)	
6.3	Nicorandil (Group 10C)	
6.3	Okoubaka aubrevillei (Okoubaka) (HOM WP)	
8.1	Pirfenidone (Group P4)	
6.3	Processed liquorice root for use in TCM (TCM Working Party)	
6.3	Punica granatum (Granatum) (HOM WP)	
6.3	Pyrogenium-Nosode (Pyrogenium) (HOM WP)	
6.3	Salviae aetheroleum (Group 13A)	
6.3	Sanguinaria canadensis, ethanol. Decoctum (Sanguinaria, ethanol. Decoctum) (HOM WP)	
6.3	Selenium (HOM WP)	
6.3	Trazodone hydrochloride (Group 10B)	
6.3	Ustilago maydis (HOM WP)	
6.3	Veronica officinalis, ethanol. Decoctum (HOM WP)	
	V DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)	
8.3	Acetonum for homoeopathic preparations (2694)	
8.3	Acidum aceticum for homoeopathic preparations (2693)	

	V. Deletions from the work programme	
8.3	Chloralum for homoeopathic preparations (2701)	
8.3	D-Camphora for homoeopathic preparations (2704)	
8.3	Ferrum sulfuricum for homoeopathic preparations (2707)	
8.3	Opium for homoeopathic preparations (2682)	
8.3	Phenolum for homoeopathic preparations (2685)	
8.3	Tablets (0478)	
26.5.1	Technetium (99mTc) human albumin injection (640)	
26.5.1	Technetium (99mTc) succimer injection (643)	
26.5.1	Technetium (99mTc) gluconate injection / Technétium (99mTc) (gluconate-), solution injectable de (1047)	
8.3	Vincamine (1800)	
Agenda Item No.	VI. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
7.2	FP monographs pilot phase: Terms of Reference	
10.2	Good Pharmacopoeial Practices:	
80.1	Sutures Working Party to be reconvened following addition of Viscose Wadding, Absorbent / Ouate Viscose Hydrophile(34) to the work programme: request for revision	
22	General chapters 2.9.5 and 2.9.6: no phasing out and withdrawal from the Ph. Eur.	DE
	VII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	- 19-20 March 2013 - 18-19 June 2013 - 26-27 November 2013	

Annex 1
144th Session Nominations
November 2012 SESSION
ITEM 7.1

GROUPS OF EXPERTS

Group 1

Germany	Dr HANSCHMANN (Statistical evaluation methods)
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Group 7

Denmark	Mr KLASSON
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Group 11

France	Mr ROTGER as an expert – he is currently a specialist (replacing Mrs Troubat)
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Group 12

Observer from Ukraine	Dr ASMOLOVA
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Group 15

Germany	Dr CUSSLER (Vaccine safety)
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Group 15V

Belgium	Dr TRUYENS (replacing Dr Goosens)
Germany	Dr KRAEMER (Rabies vaccines)

Group 16

Luxembourg	Dr TRIERWEILER (replacing Mr Wagner)
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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)

Switzerland	Prof BORCHARD
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WORKING PARTIES

Capillary Electrophoresis (CE)

Norway	Dr SOLSTAD SAUNDERS
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Cell Therapy Products (CTP): **Request for additional specialists following extension of the Terms of Reference**

No nominations yet received	
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Cell Therapy Products (CTP)

Germany	Dr KARO (Microbiology, microbiological quality of ATMPs and tissue preparations (replacing Dr Montag-Lessing) Dr SCHURIG (Microbiology especially bacteriology and assessment of microbial quality aspects of ATMP and tissue preparations)
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Host Cell Protein (HCP)

United Kingdom	Dr KIPPEN
France	Dr HO

Homoeopathic Manufacturing Methods (HMM)

Belgium	Mrs MOUYART
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Non-biological complexes (NBC)

Germany	Dr BUNJES
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Raw Materials for the production of cellular and gene transfer products (RCG)

The Netherlands	Dr JORRITSMA-SMIT (replacing Dr Oostendorp)
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Traditional Chinese Medicines

Switzerland	Dr BRUENTRUP
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NEW WORKING PARTIES

Finished Product Monograph (FP)

Sweden	<u>Chair nomination:</u> Dr EK
Sweden	Dr WALLINDER MARKLUND (Assessor)
United Kingdom	Dr ATKINSON (Pharmacopoeia)
Serbia	Dr JOVIC (OMCL)
Slovenia	Dr PIRNAT (OMCL / Pharmacopoeia)
Finland	Dr KANKKUNEN (Assessor)
Croatia	Mr BENKOVIC (HPLC analysis of finished medicinal products) (OMCL / Pharmacopoeia)
France	Mr GRANGE (Analytical methods for market surveillance) (OMCL) Ms LEFEBVRE (Inspector)
Austria	Dr MAYRHOFER (OMCL)
Swiss	Ms SCOGNAMIGLIO (development of the analytical part of preparation monographs) (Pharmacopoeia)
Germany	Dr HORN (OMCL) Dr NORWIG (Pharmacopoeia / OMCL) Ms GIESE (Assessor)
Norway	Dr HATLELID (Assessor)
Spain	Dr RODRIGUEZ PACHON (Assessor)
Belgium	Mrs DELNEUVILLE (Assessor)
The Netherlands	Dr LAMME (OMCL)
Portugal	Mrs PORTELA (OMCL)

Second Identification Test (SIT)

	<u>No proposal for Chair yet received</u>
Germany	Dr GUMZ Dr HOERNIG
Switzerland	Dr SCHMID (analytical methods commonly available in pharmacies) (updated CV received) Dr HUBER Ms GOLAZ (extemporaneous or stock preparation of medicinal products in community pharmacies as well as analysis of the pharmaceutical substances used)
Austria	Dr KIRCHDORFER