

EUROPEAN PHARMACOPOEIA COMMISSION

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Strasbourg, July 2013

GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION)

Summary of Decisions taken at the 146th Session

Strasbourg, 18-19 June 2013

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPÉE**

**Summary of Decisions of the 146th Session
18-19 June 2013**

**Résumé des décisions de la 146^e Session
18-19 juin 2013**

Deadline for confirmation / Date de confirmation : 10 July 2013

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	Allergen products / Produits allergènes (1063)	
15.3.1	Amikacin / Amikacine (1289)	
15.3.2	Amikacin sulfate/Amikacine (sulfate d') (1290)	
14.3.3	Assay of human coagulation factor VIII / Dosage du facteur VIII de coagulation humain (2.7.4.)	
14.3.2	Assay of human coagulation factor XI / Dosage du facteur XI de coagulation humain (2.7.22.)	
83.3.2	Cholesterol / Cholestérol (0993)	
83.3.1	Cyanocobalamin / Cyanocobalamine (0547)	
21.3.1	Fenticonazole nitrate / Fenticonazole (nitrate de) (1211)	
14.3.4	Fibrin sealant kit / Colle-fibrine (nécessaire de) (903)	
30.3.1	Fulvestrant / Fulvestrant (2443)	
14.3.1	Human plasma (pooled and treated for virus inactivation) / Plasma humain (mélange de) traité pour viro-inactivation (1646)	
13.3.2	Interféron gamma-1b concentrated solution / Interféron gamma 1- (solution concentrée de) (1440)	
25.3.2	Linseed oil, virgin; Lin (huile de) vierge (1908)	
25.3.1	Macrogol stearate / Macrogol (stéarate de) (1234)	
57.3.2	Magnesium gluconate / Magnésium (gluconate de) (2161)	
57.3.1	Manganese gluconate / Manganèse (gluconate de) (2162)	
55.3.1	New titles / Changements de titres	
14.3.5	Nucleic acid amplification techniques / Techniques d'amplification des acides nucléiques (2.6.21.)	
13.3.1	Pancreas powder / Poudre de pancréas (350)	
74.3.1	Pesticide residues / Résidus de pesticides (2.8.13.)	
15.3.3	Rifamycin sodium/Rifamycine sodique (432)	
19.3.1	Selegiline hydrochloride / Sélégiline (chlorhydrate de) (1260)	
	I.1.2 Revisions / Révisions	
20.2.3	Alanine / Alanine (752)	

	I.1.2 Revisions / Révisions	
20.2.4	Arginine / Arginine (806)	
20.2.5	Arginine hydrochloride/Arginine (chlorhydrate d') (805)	
19.2.1.	Cilastatin sodium / Cilastatine sodique (1408)	
55.2.1	Cocculus for homoeopathic preparations/Cocculus indicus pour préparations homéopathiques (2486)	
23.2.2	Coriander / Coriandre (1304)	
23.2.1	Coriander oil / Coriandre (huile essentielle de) (1820)	
20.2.9	Diclofenac potassium / Diclofénac potassique (1508)	
20.2.8	Diclofenac sodium / Diclofénac sodique (1002)	
19.2.2	Esomeprazole magnesium trihydrate / Ésoméprazole magnésique trihydraté (2372)	
23.2.3	Eucalyptus leaf / Eucalyptus (feuille d') (1320)	
11.3	General notices / Prescriptions générales (1.)	
24.2.3	Heavy metals in herbal drugs and fatty oils/ Métaux lourds dans les drogues végétales et dans les huiles grasses (2.4.27.)	
20.2.7	Histidine / Histidine (911)	
20.2.6	Histidine hydrochloride monohydrate / Histidine (chlorhydrate d') monohydraté (910)	
17.2.3	Indometacin / Indométacine (0092)	
18.2.1	Levocabastine hydrochloride / Lévocabastine (chlorhydrate de) (1484)	
23.2.6	Long pepper / Poivre long (2453)	
11.2	Loss on drying / Perte à la dessiccation (2.2.32.)	
17.2.1	Neostigmine bromide / Néostigmine (bromure de) (0046)	
17.2.2	Neostigmine metilsulfate / Néostigmine (métilsulfate de) (0626)	
20.2.1	Phenylalanine / Phénylalanine (782)	
27.2.1	Rabies vaccine for human use prepared in cell cultures / Vaccin rabique pour usage humain préparé sur cultures cellulaires (216)	
24.2.1	Restharrow root / Bugrane (racine de) (1879)	
82.2.1	Safflower flower / Carthame (fleur de) (2386)	
23.2.7	Sage leaf, three-lobed / Sauge trilobée (feuille de) (1561)	
23.2.5	Thyme / Thym (865)	
23.2.8	Turpentine oil, Pinus pinaster type / Térébenthine type Pinus pinaster (huile essentielle de) (1627)	
20.2.2	Tyrosine / tyrosine (1161)	
24.2.2	Valerian dry hydroalcoholic extract / Valériane (extrait hydroalcoolique sec de) (1898)	

	I.1.2 Revisions / Révisions	
11.1	Water: semi-micro determination / Semi-microdosage de l'eau (2.5.12.)	
23.2.4	Wild thyme / Serpolet (1891)	
23.2.9	Yarrow / Achillée millefeuille (1382)	
19.2.3	Zidovudine / Zidovudine (1059)	
	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
19.1.1	Brimonidine tartrate / Brimonidine (tartrate de) (2760)	
18.1.1	Chlormadinone acetate / Chlormadinone (acétate de) (2702)	
27.1.1	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, redu / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé), adsorbé (2764)	
19.1.2	Esomeprazole magnesium dihydrate / Ésoméprazole magnésique dihydraté (2787)	
69.1.1	Human coagulation factor IX (rDNA) / Facteur IX de coagulation humain (ADNr) (2522)	All delegations
55.1.1	Magnesium phosphoricum for homoeopathic preparations/Magnésium phosphorica pour préparations homéopathiques (2505)	
82.1.1	Names of herbal drugs used in traditional Chinese medicine / Noms des drogues végétales utilisées en médecine traditionnelle chinoise (5.22.)	
18.1.2	Quetiapine fumarate / Quétiapine (fumarate de) (2541)	
19.1.3	Valaciclovir hydrochloride, hydrated / Valaciclovir (chlorhydrate de) hydraté (2751)	SE
30.1.1	Vardenafil hydrochloride trihydrate / Vardénafil (chlorhydrate de) trihydraté (2782)	
	I.1.4 Texts not adopted/ Textes non-adoptés	
22.3.1	Capsules / Capsules (0016)	
22.3.2	Chewing gums, medicated / Gommages à mâcher médicamenteuses (1239)	
22.3.3	Ear preparations / Préparations auriculaires (0652)	
22.3.4	Eye preparations / Préparations ophtalmiques (1163)	
22.3.5	Foams, medicated / Mousses médicamenteuses (1105)	
22.3.6	Granules / Granulés (0499)	
22.3.7	Intramammary preparations for veterinary use / Préparations intramammaires pour usage vétérinaire (0945)	
22.3.8	Intraruminal devices / Dispositifs intraruminaux (1228)	

	I.1.4 Texts not adopted/ Textes non-adoptés	
22.3.9	Intrauterine preparations for veterinary use / Préparations intra-utérines pour usage vétérinaire (1806)	
22.3.10	Liquid preparations for cutaneous application / Préparations liquides pour application cutanée (0927)	
22.3.11	Liquid preparations for oral use / Préparations liquides pour usage oral (0672)	
22.3.12	Nasal preparations / Préparations nasales (0676)	
22.3.13	Oromucosal preparations / Préparations buccales (1807)	
22.3.14	Parenteral preparations / Préparations parentérales (0520)	
22.3.15	Patches, transdermal / Dispositifs transdermiques (1011)	
22.3.16	Powders for cutaneous application / Poudres pour application cutanée (1166)	
22.3.17	Powders, oral / Poudres orales (1165)	
22.3.18	Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037)	
22.3.19	Preparations for inhalation / Préparations pour inhalation (0671)	
22.3.20	Preparations for irrigation / Préparations pour irrigation (1116)	
22.3.21	Pressurised Pharmaceutical Preparations / Préparations Pharmaceutiques Pressurisées (0523)	
22.3.22	Rectal preparations / Préparations rectales (1145)	
22.3.23	Semi-solid preparations for cutaneous application / Préparations semi- solides pour application cutanée (0132)	
22.3.24	Sticks / Bâtons (1154)	
22.3.25	Tablets / Comprimés (0478)	
22.3.26	Tampons, medicated / Tampons médicamenteux (1155)	
22.3.27	Vaginal preparations / Préparations vaginales (1164)	
22.3.28	Veterinary liquid preparations for cutaneous application / Préparations vétérinaires liquides pour application cutanée (1808)	
	<i>I-2 CRS/BRP SCR/PBR</i>	
	New substances / Nouvelles substances	
87	Esculetin CRS 1	
87	Esculin CRS 1	
87	Ethylcellulose CRS 1	
87	Ivy leaf dry extract HRS 1	
87	Levonorgestrel for system suitability 2 CRS 1	

	New substances / Nouvelles substances	
87	Megestrol acetate for impurity K identification CRS 1	
87	Metformin impurity A CRS 1	
87	Prednicarbate for system suitability A CRS 1	
88.4	Hepatitis B Immunoglobulin BRP batches 1, 2 & 3	
	Replacement batches / Lots de remplacement	
87	Acesulfame potassium impurity B CRS 4	
87	Alpha Tocopherol CRS 7	
87	Alpha-Tocopheryl acetate CRS 9	
87	Amiloride hydrochloride CRS 2	
87	Ampicillin anhydrous CRS 5	
87	Azithromycin CRS 4	
87	Azithromycin for system suitability CRS 6	
87	Calcitonin CRS 9 and 10	
87	Calcium gluconate CRS 2	
87	Chlortalidone for peak identification CRS 3	
87	Cinchocaine hydrochloride CRS 2	
87	Ciprofloxacin hydrochloride CRS 5	
87	Cyclopentolate for system suitability CRS 2	
87	Delta-3-Cefaclor CRS 4	
87	Desogestrel for system suitability CRS 2	
87	Dosulepin impurity A CRS 2	
87	Enoxaparin sodium CRS 5	
87	Etilefrine hydrochloride CRS 2	
87	Fenticonazole impurity D CRS 2	
87	Flecainide acetate CRS 2	
87	Fluphenazine octanoate CRS 4	
87	Flutamide CRS 2	
87	Guaiacol CRS 2	
87	Heparin for physico-chemical analysis CRS 2	
87	Histidine hydrochloride monohydrate CRS2	
87	Interferon gamma-1b validation solution CRS 3	
87	Isoprenaline sulfate CRS 3	
87	Lamotrigine for system suitability CRS 2	
87	Levamisole HCL for system suitability CRS 4	
87	Levetiracetam impurity B CRS 2	
87	Levetiracetam impurity C CRS 2	

	Replacement batches / Lots de remplacement	
87	Levetiracetam impurity D CRS 2	
87	Levodropropizine impurity A CRS 3	
87	Lisinopril for system suitability CRS 2	
87	Mesalazine for SST CRS 2	
87	Metamizole sodium CRS 4	
87	Methylprednisolone CRS 3	
87	Metoprolol tartrate CRS 2	
87	N-acetyl cys1 calcitonin validation solution CRS 5	
87	Nadroparin calcium CRS 2	
87	Oxaliplatin impurity B CRS 9	
87	Oxycodone impurity D CRS 3	
87	Oxytocin / Desmopressin validation mixture CRS 4	
87	Phytomenadione CRS 4	
87	Prednisolone pivalate CRS 2	
87	Primaquine diphosphate CRS 3	
87	Promethazine for peak identification CRS 2	
87	Promethazine impurity D CRS 2	
87	Ranitidine impurity J CRS 6	
87	Salicylic acid impurity B CRS 2	
87	Sorbitol CRS 4	
87	Spironolactone for system suitability CRS 2	
87	Sulfanilamide CRS 2	
87	Tetracycline hydrochloride CRS 3	
87	Ticarcillin impurity A CRS 2	
87	Xylitol CRS 2	
88.2	Oral Poliomyelitis Vaccine (OPV) BRP batch 4	
88.3	Heparin Sodium BRP batch 3 for chromogenic potency assays	
	II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTEES – A INSCRIRE A LA PROCHAINE SESSION	
15.2.1	Demeclocycline hydrochloride / Déméclocycline (chlorhydrate de) (176)	
Item	III. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	III.1 Approved by the Commission	
14.4.7	Anti-A and anti-B haemagglutinins (2.6.20.) / Titre en hémagglutinines anti-A et anti-B (2.6.20.) -> Group 6B	

	III.1 Approved by the Commission	
14.4.6	Anti-T lymphocyte immunoglobulin for human use, animal / Immunoglobuline animale anti-lymphocytes T pour usage humain (1928) -> Group 6B	
14.4.9	Assay of human coagulation factor II / Dosage du facteur II de coagulation humain (2.7.18.) -> Group 6B	
27.1.1	Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) / Vaccine diphtérique et tétanique adsorbé, à teneur réduite en antigène(s) (0647) -> Group 15	
27.1.1	Diphtheria vaccine (adsorbed, reduced antigen content) / Vaccin diphtérique adsorbé, à teneur réduite en antigène (646) -> Group 15	
27.1.1	Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique et de l'hépatite B (ADNr), adsorbé (2062) -> Group 15	
27.1.1	Diphtheria, tetanus and pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), et de l'hépatite B (ADNr), adsorbé (1933) -> Group 15	
27.1.1	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé), adsorbé, à teneur réduite en antigène(s) (2764) -> Group 15	
27.1.1	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé), adsorbé (1931) -> Group 15	
27.1.1	Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed), reduced antigen(s) content / Vaccin diphtérique, tétanique et poliomyélitique (inactivé), adsorbé, à teneur réduite en antigène(s) (2328) -> Group 15	
27.1.1	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	
27.1.1	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)/Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyélitique (inactivé), adsorbé (1934) -> Group 15	
27.1.1	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) -> Group 15	

	III.1 Approved by the Commission	
27.1.1	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) -> Group 15	
27.1.1	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) -> Group 15	
14.4.1	Human albumin solution / Albumine humaine (solution d') (255) -> Group 6B	
69	Human coagulation factor VIIa (rDNA) concentrated solution / Facteur VIIa de coagulation humain (ADNr), solution concentrée de (2534) -> P4BIO Working Party	
14.4.5	Human coagulation factor VIII / Facteur VIII de coagulation humain (0275) -> Group 6B	
14.4.2	Human coagulation factor XI Facteur XI de coagulation humain (1644) -> Group 6B	
14.4.4	Human plasma (pooled and treated for virus inactivation) / Plasma humain (mélange de) traité pour viro-inactivation (1646) -> Group 6B	
14.4.8	Human von Willebrand factor / Facteur Willebrand humain (2298) -> Group 6B	
21.4.1	Hyoscine butylbromide / Scopolamine (butylbromure de) (737) -> Group 11	
15.4.2	Lymecycline / Lymécycline (1654) -> Group 7	
57.4.1	Magnesium hydroxide/ Magnésium (hydroxyde de) (39) -> INC Working Party	
22.4.1	Parenteral preparations / Préparations parentérales (0520) -> Group 12	
71	Pharmaceutical preparations / Préparations pharmaceutiques (2619) -> PHP Working Party	
15.4.1	Piperacillin / Pipéracilline (1169) -> Group 7	
57.4.2	Potassium hydroxide / Potassium (hydroxyde de) (840) -> INC Working Party	
14.4.3	Prekallikrein activator / Activateur de prékallikréine (2.6.15.) -> Group 6B	
18.4.1	Rivastigmine hydrogen tartrate / Rivastigmine (hydrogénotartrate de) (2630) -> Group 10B	

	III.1 Approved by the Commission	
57.4.3	Sodium hydroxide / Sodium (hydroxyde de) (677) -> INC Working Party	
26.4.1	Sodium pertechnetate (99mTc) injection (fission) / Sodium (pertechnétate (99mTc) de, obtenu par fission), solution injectable de (124) -> Group 14	
26.4.1	Sodium pertechnetate (99mTc) injection (non-fission) / Sodium (pertechnétate (99mTc) de, non obtenu par fission), solution injectable de (283) -> Group 14	
25.4.1	Sorbitan laurate / Sorbitan (laurate de) (1040) -> Group 13H	
25.4.1	Sorbitan oleate / Sorbitan (oléate de) (1041) -> Group 13H	
25.4.1	Sorbitan palmitate / Sorbitan (palmitate de) (1042) -> Group 13H	
25.4.1	Sorbitan sesquioleate / Sorbitan (sesquioléate de) (1916) -> Group 13H	
25.4.1	Sorbitan stearate / Sorbitan (stéarate de) (1043) -> Group 13H	
25.4.1	Sorbitan trioleate / Sorbitan (trioléate de) (1044) -> Group 13H	
15.4.3	Teicoplanin / Téricoplanine (2358) -> Group 7	
84.4.1	Water for injections / Eau pour préparations injectables (0169) -> WAT Working Party	
	III.2 Referred to Group for further consideration	
12.5.1	Biological Indicators of sterilisation (5.1.2): Secretariat to establish a time plan	ALL
8.1	Meningococcal B (rDNA vaccine (adsorbed): for discussion within Group 15 and report back to the Commission in November	
	III.3 Rejected by the Commission	
	IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
8.1	[18F]Fluoro-L-Dopa (prepared by nucleophilic substitution) (Group 14)	
6.6	Alchemilla vulgaris (HOM WP)	
6.6	Apisinum (HOM WP)	
8.1	Assay for human C 1-esterase inhibitor (Group 6B)	
6.6	Betula pendula e foliis(HOM WP)	
6.6	Candle Bush leaflet (Group 13A)	
6.6	Cuprum aceticum (HOM WP)	
8.1	Dioscoreae Nipponicae Rhizoma (TCM WP)	

	Additions to the work programme	
8.1	Fipronil (Group 10C)	
8.1	Fluciclovine (Group 14)	
6.6	Fluorit (HOM WP)	
6.6	Galipea officinalis (HOM WP)	
6.6	Gentiana lutea (HOM WP)	
6.6	Gentiana lutea, ethanol. Decoctum (HOM WP)	
6.6	Graphite for homoeopathic preparations (HOM WP)	
6.6	Hekla lava e lava (HOM WP)	
6.6	Hepar sulfuris (HOM WP)	
6.6	Iris versicolor (HOM WP)	
6.6	Justicia adhatoda (HOM WP)	
6.6	Kalium stibyltartaricum (HOM WP)	
6.6	Kieserit (HOM WP)	
8.1	Live biotherapeutic products (creation of a new working party might be needed)	
6.6	Lophophytum leandri (HOM WP)	
6.6	Lytta vesicatoria (HOM WP)	
69.5.1	Pegfilgrastim (P4Bio WP)	
6.6	Phytolacca Americana (HOM WP)	
27.4.1	Position paper of Group 15: Request for elaborating guidance to facilitate the introduction of 3Rs compliant assays: to be draft by Group 15 in collaboration with the OMCLs and EMA working parties	
6.6	Prunus spinosa e summitatibus Rh (HOM WP)	
8.1	Raltegravir potassium (Group P4)	
8.1	Rhodiola rosea L (Group 13B)	
8.1	Rupatadine fumarate (Group P4)	
6.6	Sedum acre (HOM WP)	
6.6	Senecio cineraria (HOM WP)	
6.6	Siderit (HOM WP)	
8.1	Sodium pertechnetate sodium (99mTC) injection (cyclotron produced) (Group 14)	
6.6	Witherit (HOM WP)	

	V DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)	
8.1	Aluminium chloride anhydrous (2789)	
8.1	Liquorice root, processed (2861)	
8.1	Liquorice root for use in TCM (2862)	
13.5.1	Aprotinin (580) (2009 report B)	
13.5.1	Aprotinin concentrated solution (570) (2009 report B)	
25.5.1	Olive oil, refined, Olive (huile d') raffinée (1456)	
25.5.1	Olive oil, virgin (0518)	
8.1	Test for bacterial endotoxins using recombinant factor C (2.6.32)	
Agenda Item No.	VI. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
7.1	Election of the two new Vice-Chairs / Election de deux nouveaux Vice-Présidents: 1 st Vice-Chair: Dr Tobias GOSDSCHAN 2 nd Vice-Chair: Mr Erik WOLTERS	
7.4	Request for Observer Status from the South Africa / Demande de statut d'observateur de l'Afrique du Sud : <i>EU confirmation pending</i>	CH
8.2	Standardised vehicles for the oral administration of medicinal products: further consideration within the context of the European Formulary	
	VII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	- 26-27 November 2013 Proposed dates for 2014 : 25 & 26 March 17 & 18 June 25 & 26 November	

146th Session Nominations
JUNE 2013
ITEM 7.2

GROUPS OF EXPERTS

Group 7

Switzerland	Dr Alexandra JAUS (replacing Dr Adrian HAEBERLI after Group 7 meeting on 25 June)
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Group 11

Switzerland	Dr Eric FISCHER (replacing Dr Wolfgang Beck)
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Group 12

Denmark	Prof. Dr. Annette BAUER-BRANDL (replacing Dr Poul Bertelsen)
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Group 13H

Spain	Dr Juan FERREIRA
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WORKING PARTIES

Finished Product Monograph Working Party (FPM)

QWP Observer	DI Susanne STOTTER
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Precursors for Radiopharmaceutical Preparations Working Party (PRP)

Germany	Ms Dinka COLDITZ
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Inhalanda Working Party (INH)

The Netherlands	Mr Peter CASPERS (replacing Dr Marjolein Weda)
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Vibrational Spectroscopy and Analytical Data Modelling Working Party (VSADM)

Spain	Dr Manuel ALCALA BERNARDEZ (replacing Dr Marcel Blanco)
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Newly re-instated Working Party on Sutures (SUT)

Germany	<u>Chair of the WP:</u> Dr Hugo PEETERS
Germany	Dr Claus FUCHS
Austria	Dr Peter DOBSON
Turkey	Dr Umut BESKAN Dr Meral ELCAN