

## EUROPEAN PHARMACOPOEIA COMMISSION

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# BILINGUE

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GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

### **Summary of Decisions taken at the 147th Session of the Commission**

Résumé des Décisions prises lors de la 147<sup>e</sup> Session de la Commission

Strasbourg, 26-27 novembre 2013

Strasbourg, 26-27 November 2013

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**EUROPEAN PHARMACOPOEIA COMMISSION  
COMMISSION EUROPEENNE DE PHARMACOEPE**

**Summary of Decisions of the 147<sup>th</sup> Session  
26-27 November 2013**

**Résumé des décisions de la 147<sup>e</sup> Session  
26-27 novembre 2013**

**Deadline for confirmation / Date de confirmation: 20 December 2013**

<b>Item</b>	<b>I. ADOPTED TEXTS</b>	<b>Subject to Confirmation</b>
	<b>I.1 Monographs and chapters/Monographies et chapitres</b>	
	<b>I.1.1 Minor revisions / Révisions mineures</b>	
16.3.2	Acetic acid, glacial / Acétique glacial (acide) (0590)	
26.3.5	Almond oil, virgin / Amande (huile d') vierge (0261)	
26.3.3	Castor oil, refined / Ricin (huile de) raffinée (2367)	
26.3.2	Castor oil, virgin / Ricin (huile de) vierge (0051)	
18.3.7	Chlorprothixene hydrochloride / Chlorprothixène (chlorhydrate de) (0815)	
26.3.4	Coconut oil, refined / Coco (huile de) raffinée (1410)	
26.3.1	Composition of fatty acids by gas chromatography / Composition en acides gras par chromatographie en phase gazeuse (2.4.22.)	
21.3.1	D-Camphor / D-camphre (1400)	
28.3.2	Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) / Vaccin diphtérique et tétanique adsorbé, à teneur réduite en antigène(s) (0647)	
28.3.1	Diphtheria vaccine (adsorbed, reduced antigen content) / Vaccin diphtérique adsorbé, à teneur réduite en antigène (0646)	
21.3.4	Ethanol (96 per cent)/Ethanol à 96 per cent (1317)	
21.3.3	Ethanol anhydrous/ethanol anhydre (1318)	
20.3.1	Etoposide / Etoposide (0823)	
13.3.1	Follitropin / Follitropine (2285)	
13.3.2	Follitropin concentrated solution / Follitropine (solution concentrée de) (2286)	
77.3.1	Fraxinus rhynchophylla bark / Fraxinus rhynchophylla (écorce de) (2452)	
14.3.1	Human anti-D immunoglobulin / Immunoglobuline humaine anti-D (0557)	
64.3.1	Human coagulation factor VIIa (rDNA) concentrated solution / Facteur VIIa de coagulation humain (ADNr), solution concentrée de (2534)	
14.3.2	Human hepatitis A immunoglobulin / Immunoglobuline humaine de l'hépatite A (0769)	

	<b>I.1.1 Minor revisions / Révisions mineures</b>	
14.3.3	Human hepatitis B immunoglobulin / Immunoglobuline humaine de l'hépatite B (0722)	
14.3.8	Human hepatitis B immunoglobulin for intravenous administration / Immunoglobuline humaine de l'hépatite B pour administration par voie intraveineuse (1016)	
14.3.4a	Human measles immunoglobulin / Immunoglobuline humaine rougeoleuse (0397)	
14.3.4b	Human rabies immunoglobulin / Immunoglobuline humaine rabique (0723)	
14.3.5	Human rubella immunoglobulin / Immunoglobuline humaine rubéoleuse (0617)	
14.3.6	Human tetanus immunoglobulin / Immunoglobuline humaine tétanique (0398)	
14.3.7	Human varicella immunoglobulin / Immunoglobuline humaine de la varicelle (0724)	
31.4.1	Lamivudine, anhydrous / Lamivudine, anhydre (2217) : <b>title change (addition of anhydrous)</b>	All
16.3.1	Magnesium Hydroxide / Magnésium (Hydroxyde De) (0039)	
18.3.1	Methotrexate / Méthotrexate (0560)	
21.3.2	Methylene chloride / Méthylène (chlorure de) (0932)	
18.3.5	Neostigmine bromide / Néostigmine (bromure de) (0046)	
18.3.6	Neostigmine metilsulfate / Néostigmine (métilsulfate de) (0626)	
78.3.1	Phytomenadione / Phytoménadione (1036)	
15.3.1	Piperacillin / Pipéracilline (1169)	
18.3.2	Prilocaine / Prilocaine (1362)	
18.3.3	Prilocaine hydrochloride / Prilocaine (chlorhydrate de) (1363)	
16.3.3	Silica, colloidal hydrated/ silica colloïdale hydratée (0738)	
24.3.1	Sophora flower / Sophora (fleur de) (2639)	
24.3.2	Sophora flower-bud / Sophora (bouton floral de) (2427)	
18.3.4	Xylazine hydrochloride for veterinary use / Xylazine (chlorhydrate de) pour usage vétérinaire (1481)	
39.3.1	Xylitol / Xylitol (1381)	
19.3.1	Ziprasidone hydrochloride monohydrate / Ziprasidone (chlorhydrate de) monohydraté (2421)	
	<b>I.1.2 Revisions / Révisions</b>	
25.2.1	Agnus castus fruit / Gattilier (fruit de) (2147)	
24.2.4	Aloe barbadensis / Aloès des Barbades (257)	
24.2.5	Aloe extractum siccum normatum / Aloès (extrait sec titre d') (259)	

	<b>I.1.2 Revisions / Révisions</b>	
13.2.3	Assay of heparin / Titrage de l'héparine (2.7.5.)	
19.2.1	Chlorhexidine diacetate / Chlorhexidine (diacétate de) (0657)	
15.2.2	Clindamycin phosphate / Clindamycine (phosphate de) (0996)	
19.2.2	Diosmin / Diosmine (1611)	
18.2.1	Ethionamide / Éthionamide (0141)	
14.2.1	Fibrin sealant kit / Colle-fibrine (nécessaire de) (0903)	
29.2.1	Foot-and-mouth disease (ruminants) vaccine (inactivated) / Vaccin inactivé de la fièvre aphteuse pour ruminants (0063)	
19.2.3	Furosemide / Furosémide (0391)	
29.2.2	Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids / Vaccin inactivé, injectable, à adjuvant huileux, de la furonculose pour salmonid (1521)	
11.11	Gelatine (0330)	
22.2.2	Gemcitabine hydrochloride / Gemcitabine (chlorhydrate de) (2306)	
48.2.1	Glass containers for pharmaceutical use / Récipients de verre pour usage pharmaceutique (3.2.1.)	
28.2.1	Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219)	
13.2.2	Heparin calcium / Héparine calcique (0332)	
13.2.1	Heparin sodium / Héparine sodique (0333)	
53.2.2	Homoeopathic preparations / Préparations homéopathiques (1038)	
14.2.2	Human normal immunoglobulin / Immunoglobuline humaine normale (0338)	
14.2.3	Human plasma (pooled and treated for virus inactivation) / Plasma humain (mélange de) traité pour viro-inactivation (1646)	
11.5	Hydroxypropylcellulose (0337)	
11.4	Isomalt (1531)	
39.2.1	Lactulose / Lactulose (1230)	
41.2.1	Liquid chromatography / Chromatographie liquide (2.2.29.)	
11.3	Magnesium stearate (0229)	
28.2.2	Meningococcal group C conjugate vaccine / Vaccin conjugué méningococcique groupe C (2112)	
22.2.1	Nicotine resinate / Nicotine (résinate de) (1792)	
25.2.5	Opium dry extract, standardised / Opium (extrait sec titré d') (1839)	
25.2.7	Opium tincture, standardised / Opium (teinture titrée d') (1841)	
25.2.6	Opium, prepared / Opium (poudre titrée d') (1840)	
25.2.4	Opium, raw / Opium brut (0777)	
11.2	Pharmacopoeial harmonisation (5.8)	

	<b>I.1.2 Revisions / Révisions</b>	
28.2.3	Pneumococcal polysaccharide conjugate vaccine (adsorbed) / Vaccin pneumococcique polysidique conjugué adsorbé (2150)	
18.2.2	Probenecid / Probénécide (0243)	
19.2.4	Progesterone / Progestérone (0429)	
25.2.8	Pygeum africanum bark / Prunier d'Afrique (écorce de) (1886)	
25.2.10	Rhatany root / Ratanhia (racine de) (0289)	
25.2.11	Rhatany tincture / Ratanhia (teinture de) (1888)	
11.6	Saccharin (0947)	
25.2.9	Sage leaf (Salvia officinalis) / Saugue officinale (feuille de) (1370)	
24.2.1	Senna leaf / Séné (feuille de) (206)	
24.2.2	Senna pods, Alexandrian / Séné de Khartoum ou d'Alexandrie (fruit de) (207)	
24.2.3	Senna pods, Tinnevelly / Séné de l'Inde ou de Tinnevelly (fruit de) (208)	
22.2.3	Sodium alendronate / Sodium (alendronate de) (1564)	
18.2.3	Sodium aminosalicylate dihydrate / Sodium (aminosalicylate de) dihydraté (1993)	
11.7	Sodium starch glycolate (type A) (0983)	
11.8	Sodium starch glycolate (type B) (0984)	
11.9	Sodium starch glycolate (type C) (1566)	
20.2.1	Stavudine / Stavudine (2130)	
11.10	Sucrose (0204)	
21.2.1	Tryptophan/Tryptophane (1272)	
25.2.2	Turmeric rhizome / Curcuma (rhizome de) (2543)	
25.2.3	Turmeric, Javanese / Temoe lawacq (1441)	
	<b>I.1.3 New texts for adoption / Nouveaux textes pour adoption</b>	
54.1.1	Agaricus phalloides for homoeopathic preparations/Agaricus bulbosus pour préparations homéopathiques (2290)	
25.1.1	Agnus castus fruit dry extract / Gattilier (fruit de), extrait sec de (2309)	
28.1.1	Carrier proteins for the production of conjugated polysaccharide vaccines for human use / Protéines vectrices pour la production de vaccins polysidiques conjugués pour usage humain (50211)	
22.1.1	Glucosamine sulfate potassium chloride / Glucosamine (sulfate de) -chlorure de potassium (2708)	
53.1.1	Homoeopathic pillules, coated / Granules homéopathiques enrobés (2786)	

	<b>I.1.3 New texts for adoption / Nouveaux textes pour adoption</b>	
14.1.1	Human normal immunoglobulin for subcutaneous administration / Immunoglobuline humaine normale pour administration par voie sous-cutanée (2788)	
54.1.2	Ignatia for homoeopathic preparations/Ignatia amara pour préparations homéopathiques (2513)	
31.1.1	Imatinib mesilate / Imatinib (mésilate d') (2736) : info from CHMP/SWP awaited before confirmation of adoption of the monograph	All
26.1.1	Macrogols, high-molecular-mass / Macrogols de masse moléculaire élevée (2444)	
18.1.1	Meldonium dihydrate / Meldonium dihydraté (2624)	
17.1.1	Methane / Méthane (2413)	
25.1.2	Nettle root / Ortie (racine d') (2538)	
54.1.3	Nux-vomica for homoeopathic preparations/Nux-vomica pour préparations homéopathiques (2514)	
39.1.1	Pullulan / Pullulan (2603)	
15.1.1	Sulfadimethoxine / Sulfadiméthoxine (2741)	
15.1.2	Sulfadimethoxine sodium for veterinary use / Sulfadiméthoxine sodique pour usage vétérinaire (2745)	
83	<b><i>I-2 CRS/BRP SCR/PBR</i></b>	
	<b>New substances / Nouvelles substances</b>	
83	2,4-dichlorobenzyl alcohol CRS 1	
83	2,4-dichlorobenzyl alcohol impurity A CRS 1	
83	2,4-dichlorobenzyl alcohol impurity C CRS 1	
83	Amoxicillin trihydrate for performance verification CRS 1	
83	Aripiprazole CRS 1	
83	Aripiprazole impurity F CRS 1	
83	Atomoxetine for impurity A identification CRS 1	
83	Atomoxetine hydrochloride CRS 1	
83	Atomoxetine impurity B CRS 1	
83	Atomoxetine impurity D CRS 1	
83	Belamcanda chinensis rhizome HRS 1	
83	Beta-sitosterol CRS 1	
83	Brimonidine for system suitability CRS 1	
83	Brimonidine tartrate CRS 1	
83	Capecitabine CRS 1	
83	Capecitabine imp A CRS 1	

	<b>New substances / Nouvelles substances</b>	
83	Capecitabine imp C CRS 1	
83	Capecitabine imp D CRS 1	
83	Chlormadinone acetate CRS 1	
83	Chlormadinone acetate for SST CRS 1 B61	
83	Chlormadinone acetate Impurity G CRS 1	
83	Cilastatin for system suitability 1 CRS 1	
83	Cilastatin for system suitability 2 CRS 1	
83	Clemastine for system suitability CRS 1	
83	Diacerein CRS 1	
83	Diacerein impurity B CRS 1	
83	Diacerein impurity mixture CRS 1	
83	Diclofenac for system suitability CRS 1	
83	Dutasteride CRS 1	
83	Dutasteride for SST CRS 1	
83	Esculin CRS 1	
83	Esomeprazole magnesium dihydrate CRS 1	
83	Eucommia bark HRS 1	
83	Fleeceflower root HRS 1	
83	Hesperidin CRS 1	
83	Human coagulation factor VIIa (rDNA) concentrated solution CRS 1	
83	Indometacin impurity mixture CRS 1	
83	Irisfloreantin CRS 1	
83	Ketotifen for peak identification CRS 1	
83	Ketotifen hydrogen fumarate CRS 1	
83	Levocabastine for system suitability 1 CRS 1	
83	Levocabastine for system suitability 2 CRS 1	
83	Quetiapine fumarate CRS 1	
83	Resveratrol CRS 1	
83	Salmeterol xinafoate FPI CRS 1	
83	Tribenoside impurity D CRS 1	
83	Valaciclovir impurity P CRS 1	
83	Wedelolactone CRS 1	
83	Zidovudine for system suitability CRS 1	
83	Ziprasidone mesilate trihydrate CRS 1	

83	<b>Replacement batches / Lots de remplacement</b>	
83	Aceclofenac impurity F CRS 2	
83	Adapalene impurity C CRS 3	
83	Alverine for peak identification CRS 2	
83	Arginine hydrochloride CRS 3	
83	Articaine Impurity E CRS 2	
83	Atorvastatin impurity C CRS 2	
83	Beclometasone dipropionate imp F&N CRS 2	
83	Benazepril impurity A CRS 2	
83	Bleomycin sulfate CRS 2	
83	Bromazepam for system suitability CRS 2	
83	Buspirone for system suitability CRS 2	
83	Calcium folinate CRS 6	
83	Cefalotin sodium CRS 3	
83	Cefepime dihydrochloride monohydrate for system suitability CRS 2	
83	Cetirizine for peak identification CRS 2	
83	Chloramphenicol sodium succinate CRS 2	
83	Chlorogenic acid CRS 2	
83	Class 1 Residual Solvent Solution CRS 5	
83	Class 1 Residual Solvent Solution CRS 6	
83	Class 1 Residual Solvent Solution CRS 7	
83	Clobetasol for peak identification CRS 2	
83	Colistin sulfate CRS 4	
83	Dexamethasone sodium phosphate CRS 6	
83	Dibenzosuberone CRS 2	
83	Dihydroergocristine mesilate CRS 3	
83	Diphenhydramine impurity A CRS 4	
83	Dopamine hydrochloride CRS 2	
83	Dorzolamide impurity A CRS 2	
83	Doxazosin impurity F CRS 2	
83	Doxylamine for SST CRS 2	
83	Duloxetine impurity A CRS 2	
83	Eicosapentaenoic acid ethyl ester CRS 4	
83	Erythromycin C CRS 5	
83	Esomeprazole magnesium trihydrate CRS 2	



	<b>Replacement batches / Lots de remplacement</b>	
83	Etoposide CRS 6	
83	Fenofibrate Impurity A CRS 4	
83	Fluconazole Impurity B CRS 3	
83	Fluocinolone acetonide CRS 4	
83	Fluoxetine hydrochloride CRS 5	
83	Fluoxetine impurity B CRS 6	
83	Fluticasone impurity D CRS 3	
83	Fluxinin impurity C CRS 2	
83	Fosfomycin trometamol CRS 3	
83	Framycetin sulfate CRS 6	
83	Framycetin sulfate CRS 7	
83	Galantamine synthetic for SST CRS 2	
83	Gemfibrozil SST CRS 2	
83	Gentamicin sulfate CRS 9	
83	Gestodene CRS 2	
83	Granisetron hydrochloride CRS 2	
83	Hydrochlorothiazide FPI CRS 2	
83	Hydroxycarbamide CRS 2	
83	Ibuprofen for peak identification CRS 5	
83	Ifosfamide impurity A CRS 4	
83	Indapamide impurity B CRS 4	
83	Interferon alfa-2b CRS 6	
83	Lactulose for system suitability CRS 4	
83	Lisinopril impurity F CRS 2	
83	Methylcarbidopa CRS 5	
83	Midazolam impurity C CRS 3	
83	Noscapine CRS 2	
83	Ofloxacin impurity E CRS 4	
83	Olmесartan medoxomil for SST CRS 2	
83	Ondansetron impurity D CRS 3	
83	Oxfendazole impurity B CRS 2	
83	Oxybutynin hydrochloride CRS 2	
83	Pancreas powder (amylase) BRP batch 4	
83	Pancreas powder (lipase) BRP batch 4	
83	Pancreas powder (protease) BRP batch 4	

	<b>Replacement batches / Lots de remplacement</b>	
83	Parnaparin sodium CRS 2	
83	Pentamidine diisetonate CRS 2	
83	Pidolate Impurity B CRS 3	
83	Piperacillin CRS 4	
83	Plastic additive 23 CRS 2	
83	Prednisolone for system suitability CRS 2	
83	Pyrantel impurity A CRS 2	
83	Pyridoxine Impurity A CRS 3	
83	Quetiapine for system suitability CRS 2	
83	Racemic camphor CRS 2	
83	Rifamycin CRS 2	
83	Rifamycin S CRS 3	
83	Salbutamol sulfate for system suitability CRS 2	
83	Salmeterol xinafoate SST CRS 2	
83	Sestamibi labelling kit CRS 3	
83	Sodium valproate CRS 5	
83	Temazepam impurity F CRS 2	
83	Theobromine CRS 2	
83	Tiotropium impurity F CRS 2	
83	Trans-epoxyphytomenadione CRS 3	
83	Trimetazidine for system suitability CRS 3	
83	Trospium impurity C CRS 3	
83	Zolpidem impurity A CRS 4	
84.2	Human Immunoglobulin for Electrophoresis BRP batch 3 (adopted by correspondence, for information only)	
84.3	Prekallikrein Activator in albumin BRP batches 4, 5 & 6	
	<b>II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTEES – A INSCRIRE A LA PROCHAINE SESSION</b>	
12.5.1	Biological indicators of sterilisation / Indicateurs biologiques de stérilisation (50102)	
31.1.1	Imatinib mesilate / Imatinib (mésilate d') (2736) : if confirmation from CHMP/SWP received too late	
28.1.2	Influenza vaccine (live, nasal) / Vaccin grippal nasal vivant (2772)	
26.2.1	Omega-3-acid ethyl esters 90 / Oméga-3 (esters éthyliques 90 d'acides) (1250)	

Item	III. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	<b>III.1 Approved by the Commission</b>	
32.4.1	Allergen products / Produits allergènes (1063) -> ALG WP	
77.4.1	Angelica dahurica root / Angelica dahurica (racine d') (2556) -> TCM WP	
25.4.1	Black cohosh / Actée à grappes (2069) -> Group 13B	
18.3.7	Chlorprothixene hydrochloride / Chlorprothixène (chlorhydrate de) (0815)	
27.4.1	Gallium (68Ga) chloride solution for radiolabelling / Gallium (68Ga) (chlorure de) pour radiomarquage, solution de (2464) -> Group 14	
18.4.1	Gemfibrozil / Gemfibrozil (1694) -> Group 10A	
21.4.1	Glutathione / Glutathion (1670) -> Group 10D	
18.4.6	Hydralazine hydrochloride / Hydralazine (chlorhydrate d') (0829) -> Group 10A	
31.4.1	Lamivudine / Lamivudine (2217)	
53.4.1	Methods of preparation of homoeopathic stocks and potentisation / Méthodes de préparation des souches homéopathiques et déconcentration (2371) -> HMM WP	
18.4.2	Phenazone / Phénazone (0421) -> Group 10A	
18.4.4	Phenylbutazone / Phénylbutazone (0422) -> Group 10A	
76.4.1	Polyamide 6 6 suture sterile in distributor for veterinary use (0610) -> SUT WP	
76.4.1	Polyamide 6 suture sterile in distributor for veterinary use (0609) -> SUT WP	
76.4.1	Polyethylene terephthalate suture sterile in distributor for veterinary use (0607) -> SUT WP	
41.4.1	Reagents / Réactifs (4.1.1.) (Acetonitrile R) -> CST WP	
11.12	Recombinant DNA technology, products of / ADN recombinant (produits obtenus par la méthode dite de l') (0784) -> drafting group with participation of Experts from current Ph. Eur. Biological Groups (appointment via their Chairs) and from BWP.	
22.4.1	Risedronate sodium 2.5-hydrate / Risédronate sodique 2,5-hydraté (2572) -> Group 11	
18.4.3	Sodium aminosalicylate dihydrate / Sodium (aminosalicylate de) dihydraté (1993) -> Group 10A	
18.4.5	Sodium aminosalicylate dihydrate / Sodium (aminosalicylate de) dihydraté (1993) -> Group 10A	
16.4.1	Sodium carbonate, anhydrous / Sodium (carbonate de) anhydre (0773) -> Group 9	
22.4.2	Sodium citrate / Sodium (citrate de) (0412) -> Group 11	

	<b>III.1 Approved by the Commission</b>	
16.4.2	Sodium hydrogen carbonate / Sodium (bicarbonate de) (0195) -> Group 9	
11.13	Substances for pharmaceutical use / Substances pour usage pharmaceutique (2034) -> Group PCM	
29.4.1	Substances of animal origin for the production of immunological veterinary medic / Substances d'origine animale utilisées pour la préparation de médicaments immuno (50205) -> Group 15V	
76.4.1	Sutures, sterile non-absorbable / Fils chirurgicaux, fils non résorbables stériles (0324) -> SUT WP	
28.4.1	Test for neurovirulence of poliomyelitis vaccine oral / Essai de neurovirulence du vaccin poliomyélitique oral (2.6.19) -> Group 15	
26.4.1	Total cholesterol in oils rich in omega-3 acids / Cholestérol total dans les huiles riches en acides oméga-3 (2.4.32.) -> Group 13H	
85.1	Use of Mercury thermometers - request for revision -> PCM WP	
20.4.1	Vecuronium bromide / Vécuronium (bromure de) (1769) -> Group 10C	
	<b>III.2 Rejected by the Commission</b>	
21.4.2	Pemetrexed disodium heptahydrate / Pémétrexed disodique heptahydraté (2637)	
	<b>III.3 On hold</b>	
14.4.1	Human plasma (pooled and treated for virus inactivation) / Plasma humain (mélange de) traité pour viro-inactivation (1646) : until feedback received from EMA	
	<b>IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
8.1	Acetylene / Nitrogen Intermix -> Group 9G	
6.3	Ammonium carbonate for homoeopathic preparations, <i>Ammonii carbonas</i> for homoeopathic preparations -> HOM WP	
6.3	Anethum Graveolens Sowa Fruit ( <i>elaboration based on traditional use in Ayurveda</i> )	ALL
6.3	Apramycin sulphate -> Group 7	
6.3	Ash for homoeopathic preparations, <i>Fraxinus excelsior</i> for homoeopathic preparations -> HOM WP	
8.1	Atazanavir sulphate -> Group P4	
8.1	Borreliosis vaccine (inactivated) for dogs -> Group 15V	

	<b>ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
8.1	Carbon Monoxide / Nitrogen Intermix -> Group 9G	
8.1	Cetostearyl alcohol, emulsifying (Type C) -> Group 13H	
79.5.1	Chemical Imaging -> VSADM WP	
64.1	Etanercept -> P4Bio WP	
6.3	Giant puffball for homoeopathic preparations, <i>Bovista gigantea</i> for homoeopathic preparations -> HOM WP	
8.1	Immunonephelometry for vaccine component assay -> Group 15 and at a later stage with Group 6 and Working Parties P4BIO and HCP	
6.3	Medicago Sativa for Homoeopathic Preparations -> HOM WP	
8.1	Methane / Nitrogen Intermix -> Group 9G	
8.1	Methods used for detection and assessment of residual substrate cell-DANN -> Group 15 in collaboration with Groups 6 and 6B	
6.3	Mullein for homoeopathic preparations, <i>Verbascum thapsus</i> for homoeopathic preparations -> HOM WP	
8.1	Tetracain base -> Group 10A	
6.3	Trachyspermum Ammi ( <i>elaboration based on traditional use in Ayurveda</i> ) -> information from BP expected before decision	ALL
6.3	Trifluridine-> Group 11	
6.3	Walnut for homoeopathic preparations, <i>Juglans regia</i> for homoeopathic preparations -> HOM WP	
	<b>V DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)</b>	
14.5.1	Anti-T lymphocyte immunoglobulin for human use, animal (1928)	
29.5.1	Bluetongue Vaccine/Vaccin de la fièvre catarrhale	
76.5	Catgut, sterile / Fils chirurgicaux, catgut stérile (0317)	
76.5	Catgut, sterile, in distributor for veterinary use / Fils chirurgicaux, catgut stérile en distributeur pour usage vétérinaire (0660)	
24.5.1	Hamamelis water / Hamamélis (eau d') (2533)	
25.5.1	herbal tea preparations (1435)	
14.5.1	Human coagulation factor VIII (0275)	
14.5.1	Human coagulation factor XI (1644)	
14.5.1	Human plasma (pooled and treated for virus inactivation) (1646)	
14.5.1	Human von Willebrand factor (2298)	
28.5.4	Immunochemical methods (2.7.1) / Méthodes immunochimiques	

	<b>DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)</b>	
28.5.1	Meningococcal group B (rDNA) vaccine	
25.5.1	mixture for herbal teas for officinal preparations (2821)	
28.5.3	Terminology used in monographs on biological products (5.2.10)	
28.5.2	Vaccines for human use (0153)	
<b>Agenda Item No.</b>	<b>VI. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE</b>	
7.1	Terms of Reference and Profile for Experts: Live Biotherapeutic Products WP -> Secretariat to send out a request for nominations	
7.2	Nominations to Groups of Experts and Working Parties / Nominations pour Groupes d'Experts et Groupes de Travail -> delegations to send all missing information to the Secretariat	
7.3	Request for observership from the Taiwan Food and Drug Administration (TFDA), the Ministry of Health and Welfare (MOHW) -> EU gave positive reply; non EU-member states also in favour	
	<b>VII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION</b>	
	25 & 26 March 17 & 18 June 25 & 26 November	