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PA/PH/SG (12) 26

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Strasbourg, April 2012

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(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPÉE)

Summary of Decisions taken at the 142nd Session of the Commission

Résumé des Décisions prises lors de la 142e Session de la Commission

Strasbourg, 3-4 avril 2012

Strasbourg, 3-4 April 2012

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 142nd Session
3-4 April 2012**

**Résumé des décisions de la 142^e Session
3-4 April 2012**

Deadline for confirmation / Date de confirmation 9 May 2012

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28.2.25	Aujeszky's disease vaccine (inactivated) for pigs / Vaccin inactivé de la maladie d'Aujeszky pour le porc (744)	
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28.2.3	Evaluation of safety of each batch of veterinary vaccines and immunosera / Évaluation de l'innocuité de chaque lot des vaccins et immunosérums vétérinaires (5.2.9)	
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	I.1.2 Revisions / Révisions	
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78.1	Dichlorodiaminocyclohexaneplatinum CRS 5	
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78.1	Diosmin CRS 3	
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73.3.3	Calcipotriol monohydrate / Calcipotriol monohydraté (2284) -> VIT Working Party	
73.3.2	Calcipotriol, anhydrous / Calcipotriol anhydre (2011) -> VIT Working Party	
28.4.1	Cell cultures for the production of veterinary vaccines / Cultures cellulaires utilisées pour la préparation de vaccins pour usage vétérin (5.2.4.) -> Group 15V	
15.4.1	Chloramphenicol / Chloramphénicol (71) -> Group 7	
19.4.1	Diltiazem hydrochloride / Diltiazem (chlorhydrate de) (1004) -> Group 10C	
15.4.3	Epirubicin hydrochloride / Épirubicine (chlorhydrate d') (1590) -> Group 7	
41*.4.1	Extracts / Extraits (765) -> EXT Working Party	
18.4.2	Fosfomicin trometamol / Fosfomycine trométamol (1425) -> Group 10B	
21.4.2	Gemcitabine hydrochloride / Gemcitabine (chlorhydrate de) (2306) -> Group 11	
45.4.1	Glass containers for pharmaceutical use / Récipients de verre pour usage pharmaceutique (3.2.1.) -> GLS Working Party	
22.4.2	Ipecacuanha liquid extract, standardised / Ipécacuanha (extrait fluide titré d') (1875) -> Group 13B	
24.4.2	Ipecacuanha root / Ipécacuanha (racine d') (94) -> Group 13B	
22.4.2	Ipecacuanha tincture, standardised / Ipécacuanha (teinture titrée d') (1530) -> Group 13B	
22.4.2	Ipecacuanha, prepared / Ipécacuanha (poudre titrée d') (93) -> Group 13B	

15.4.2	Kanamycin acid sulfate / Kanamycine (sulfate acide de) (33) -> Group 7	
15.4.2	Kanamycin monosulphate / Kanamycine (monosulfate de) (32) -> Group 7	
19.4.2	Ketotifen hydrogen fumarate / Kétotifène (hydrogénofumarate de) (1592) -> Group 10C	
17.4.6	Metformin hydrochloride / Metformine (chlorhydrate de) (0931) -> Group 10A	
22.4.3	Microbiological quality of pharmaceutical preparations / Qualité microbiologique des préparations pharmaceutiques (5.1.4) -> Group 12	
15.4.6	Mupirocin (1450) -> Group 7	
15.4.6	Mupirocin calcium (1451) -> Group 7	
21.2.1	Naloxone hydrochloride dihydrate / Naloxone (chlorhydrate de) dihydraté (729) -> Group 11	
21.2.1	Naloxone hydrochloride dihydrate / Naloxone (chlorhydrate de) dihydraté (0729) -> Group 11	
53.4.1	Nasal preparations (676) INH Working Party	
18.4.1	Norethisterone acetate/Noréthistérone (acétate de) (0850) -> Group 10B	
21.4.3	Noscapine hydrochloride / Noscapine (chlorhydrate de) (515) -> Group 11	
22.4.3	Oromucosal preparations / Préparations buccales (1807) -> Group 12	
17.4.2	Paracetamol / Paracétamol (0049) -> Group 10A	
17.4.4	Pentobarbital (0200) -> Group 10A	
17.4.3	Pentobarbital sodium/Pentobarbital sodique (0419) -> Group 10A	
19.4.3	Prazepam / Prazépam (1466) -> Group 10C	
53.4.1	Preparations for inhalation (671) INH Working Party	
20.4.1	Pyrantel embonate / Pyrantel (embonate de) (1680) -> Group 10D	
23.4.1	Rosemary leaf / Romarin (1560) -> Group 13A	
19.4.4	Salmeterol xinafoate / Salmétérol (xinafoate de) (1765) -> Group 10C	
19.4.5	Sulpiride (1045) -> Group 10C	
22.4.1 + 2 + 3	Tablets / Comprimés (478) -> Group 12	
28.2.1	Vaccines for veterinary use / Vaccins pour usage vétérinaire (62) -> Group 15V	
19.4.6	Vecuronium bromide / Vécuronium (bromure de) (1769) -> Group 10C	

	III.2 Additions to the work programme	
8.1	Fir needle oil -> Group 13A	
63.5.1	Human coagulation factor IX (rDNA) / Facteur IX de coagulation humain (ADNr) (2522) -> P4 BIO Working Party	
8.1	Intravesical solutions – Group 12	
8.1	Lysine acetylsalicylate -> Group 10D	
8.1	Mycophenolate sodium -> Group P4	
8.1	Thiocolchicoside -> Group 11	
	III.3 Suppression from the work programme	
8.1	Apaflurane (2189)	
18.5.1	Cetylpyridinium chloride / Cétylpyridinium (chlorure de) (0379)	
8.1	Hydralazine (0829)	
8.1	Hyssop oil for homoeopathic preparations (2673)	
8.1	Medicinal oils for homoeopathic preparations (2679)	
18.5.2	Metoprolol succinate / Métoprolol (succinate de) (1448)	
8.1	Natrium chloratum for homoeopathic preparations (2507)	
8.1	Natrium sulfuricum for homoeopathic preparations (2508)	
	III.4 Suppression from the Ph. Eur.	
8.1	Diflunisal (0818)	
Agenda Item No.	IV. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
7.3	Request for Observer Status from the Republic of Guinea -> Approved	
59.6.1	Revision of the Production statement in the monographs for mesilate salts / Révision de la déclaration relative à la production dans les monographies de sels de mésilate	
	V. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	- 19-20 June 2012 - 27-28 November 2012	

Annex 1

142nd Session Nominations
April 2012 SESSION
ITEM 7.1

GROUPS OF EXPERTSGroup 6

Germany	Dr Wilfried ARZ (replacing Dr DOLL)
Italy	Dr Lino LIVERANI (Specialist: Heparins)

Group 10B

Germany	Dr Wilhelm TRENTMANN (Specialist: Steroids)
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Group 10C

Switzerland	Dr Darragh NORTON (replacing Dr SCHLEGEL)
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Group 13B

Swedish	Dr Robert BURMAN
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Group 15

Switzerland	Dr Elke JAECKLE (Specialist: Industrial production of Vaccines) (replacing Dr PITTERTSCHATSCHER)
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Group 15V

Germany	Dr Carmen JUNGBACK (replacing Dr MOOS)
Spain	Dr Lourdes MACUA PEQUENO Dr Rosario BULLIDO GOMEZ-HERAS (Specialist: Equine, ruminants (bovine, ovine, caprine), pig, avian, rabbit and fish vaccines)

Group P4

Bosnia and Herzegovina	Dr Alija UZUNOVIC (replacing Dr A KISO)
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WORKING PARTIES

Cellulose Ethers (CEL)

The Netherlands	Mr Evert IZEBLOUD (replacing Mr Mansfeld)
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Cell Therapy Products (CTP)

The Netherlands	Dr Inge SLAPER-CORTENBACH
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Extracts (EXT)

Italy	Dr Francesco VILLA
United Kingdom	Dr Linda ANDERSON Dr Melanie PIRES

Glass Containers (GLS)

Germany	Dr Michael ROESSLER
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Gene Therapy Products (GTP)

United Kingdom	Dr Elizabeth POLLITT (replacing Dr Sharon LONGHURST)
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Propellants (HFA)

Germany	Ms Cornelia HIPPCHEN
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Homoeopathic raw materials and stocks (HOM)

Germany	Dr Christina VON DER HEIDT (replacing Dr BELZ)
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Inhalanda (INH)

Germany	Ms Cornelia HIPPCHEN
Spain	Mrs Margarita BERROCAL NAVAS

P4 BIO

Germany	Dr Stefan CHRISTIANS (Specialist: Physico-Chemical Characterisation) Dr Tilmann ROOS (Specialist: Bioactivity of MAB's)
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Process Analytical Technology (PAT)

Spain	Dr José Maria RODRIGUEZ PACHON
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Pharmaceutical Preparations (PHP)

Slovak Republic	Dr Tomas TESAR
Turkey	Dr Canan ISKENDEROGLU

Water for Pharmaceutical Use (WAT)

Slovenia	Dr Mateja KRAMER
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Chair of the Bacterial Endotoxins Working Party (BET)

Germany	Dr Ingo SPREITZER
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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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NEWLY APPOINTED WORKING PARTIES**Host-Cell Proteins Working Party (HCP)****Proposals for Chair:**

France	Mr Alain BAYOL
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Proposals for Members:

Sweden	Dr Karin SEWERIN
Germany	Dr Michael WIEDMANN Dr Jürg ENGELSBERGS Dr Erika FRIEDL
Switzerland	Dr Oliver ANDERKA Dr René GYSIN Dr Steffen PAHLICH
Austria	Dr Martin SCHIESTL
France	Saliha MOUSSAOUI

Raw Materials for the Production of Cellular and Gene Transfer Products Working Party (RCG)

Chair:

Finland	Dr Jaana VESTERINEN
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Proposals for Members:

United Kingdom	Dr Louise BISSET
EMA Representative	Dr Caroline VOLTZ-GIROLT
Czech Republic	Dr Ivana HAUNEROVA
Sweden	Dr Lennart AKERBLOM
Finland	Dr Marjatta HIRVONEN Dr Paula SALMIKANGAS Dr Sirkku SAARELA
Switzerland	Dr Ottmar HORN-LOHRENS
Spain	Dr Sol RUIZ ANTUNEZ
Germany	Dr Thomas HINZ
France	Prof. Jean-Hugues TROUVIN
The Netherlands	Dr Jaap OOSTENDORP