

## EUROPEAN PHARMACOPOEIA COMMISSION

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# BILINGUE

Strasbourg, April 2015

GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPÉE)

### Summary of Decisions taken at the 151st Session of the Commission

Résumé des décisions prises lors de la 151<sup>e</sup> Session de la Commission

Strasbourg, 17-18 mars 2015

Strasbourg, 17-18 March 2015

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**EUROPEAN PHARMACOPOEIA COMMISSION  
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 151<sup>st</sup> Session  
17-18 March 2015**

**Résumé des décisions de la 151<sup>e</sup> Session  
17-18 mars 2015**

**Deadline for confirmation / Date de confirmation: 20th April 2015**

<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>	
54.3.1	Amlodipine besilate / Amlodipine (bésilate d') (1491)	
54.3.2	Atracurium besilate / Atracurium (bésilate d') (1970)	
54.3.3	Betahistine mesilate / Bétahistine (mésilate de) (1071)	
54.3.4	Bromocriptine mesilate / Bromocriptine (mésilate de) (0596)	
31.3.1	Celecoxib / Célécoxib (2591)	
49.3.1	Cuprum metallicum for homoeopathic preparations / Cuprum metallicum pour préparations homéopathiques (1610)	
54.3.5	Dibrompropamide diisetonate / Dibrompropamide (diisétionate de) (2300)	
54.3.6	Dihydroergocristine mesilate / Dihydroergocristine (mésilate de) (1416)	
54.3.7	Dihydroergotamine mesilate / Dihydroergotamine (mésilate de) (0551)	
15.3.2	Doxycycline hyclate / Doxycycline (hyclate de) (0272)	
15.3.3	Doxycycline monohydrate / Doxycycline monohydratée (0820)	
19.3.1	Halothane / Halothane (0393)	
54.3.8	Hexamidine diisetonate / Hexamidine (diisétionate d') (1436)	
19.3.3	Hydrocortisone acetate / Hydrocortisone (acétate d') (0334)	
54.3.9	Imatinib mesilate / Imatinib (mésilate d') (2736)	
15.3.4	Ivermectin / Ivermectine (1336)	
54.3.10	Methyl, ethyl and isopropyl methanesulfonate in active substances / Méthanesulfonate de méthyle, d'éthyle et d'isopropyle dans les substances active (2.5.38)	
35.3.1	Microcrystalline cellulose and carmellose sodium / Cellulose microcristalline et carmellose sodique (2050)	
19.3.2	Midazolam / Midazolam (0936)	
15.3.1	Mitomycin / Mitomycine (1655)	

	<b>I.1.1 Minor revisions / Révisions mineures</b>	
69.3.1	Names of herbal drugs used in traditional Chinese medicine / Noms des drogues végétales utilisées en médecine traditionnelle chinoise (5.22.)	
54.3.11	Pefloxacin mesilate dihydrate / Péfloxacine (mésilate de) dihydraté (1460)	
54.3.12	Pentamidine diisetonate / Pentamidine (diisétionate de) (1137)	
54.3.13	Pergolide mesilate / Pergolide (mésilate de) (1555)	
11.1	Pharmacopoeial harmonisation / Harmonisation des pharmacopées (5.8.)	
54.3.14	Phentolamine mesilate / Phentolamine (mésilate de) (1138)	
64.3.1	Pilocarpine hydrochloride / Pilocarpine (chlorhydrate de) (0633)	
64.3.2	Pilocarpine nitrate / Pilocarpine (nitrate de) (0104)	
20.3.1	Ramipril / Ramipril (1368)	
20.3.2	Ranitidine hydrochloride / Ranitidine (chlorhydrate de) (0946)	
11.4	Saccharin sodium / Saccharine sodique (0787)	
54.3.15	Saquinavir mesilate / Saquinavir (mésilate de) (2267)	
31.3.2	Sevoflurane / Sévoflurane (2269)	
11.3	Sodium laurilsulfate / Sodium (laurilsulfate de) (0098)	
39.3.1	Sorbitol / Sorbitol (0435)	
54.3.16	Sultamicillin tosilate dihydrate / Sultamicilline (tosilate de) dihydraté (2212)	
54.3.17	Ziprasidone mesilate trihydrate / Ziprasidone (mésilate de) trihydraté (2649)	
	<b>I.1.2 Revisions / Révisions</b>	
20.2.1	Azelastine hydrochloride / Azélastine (chlorhydrate d') (1633)	
25.2.1	Boldo leaf / Boldo (feuille de) (1396)	
25.2.2	Boldo leaf dry extract / Boldo (feuille de), extrait sec de (1816)	
18.2.1	Clomipramine hydrochloride / Clomipramine (chlorhydrate de) (0889)	
13.2.1	Electrophoresis / Electrophorèse (2.2.31)	
19.2.6	Estradiol valerate / Estradiol (valérate d') (1614)	
19.2.2	Fentanyl / Fentanyl (1210)	
21.2.1	Glyceryl trinitrate solution / Glycéryle (trinitrate de), solution de (1331)	
28.2.1	Haemophilus type b conjugate vaccine/Vaccin conjugué de l'haemophilus type b (1219)	

	<b>I.1.2 Revisions / Révisions</b>	
14.2.1	Human coagulation factor XI / Facteur XI de coagulation humain (1644)	
25.2.6	Ipecacuanha liquid extract, standardised / Ipécacuanha (extrait fluide titré d') (1875)	
25.2.3	Ipecacuanha root / Ipécacuanha (racine d') (0094)	
25.2.4	Ipecacuanha tincture, standardised / Ipécacuanha (teinture titrée d') (1530)	
25.2.5	Ipecacuanha, prepared / Ipécacuanha (poudre titrée d') (0093)	
69.2.1	Mandarin epicarp and mesocarp / Mandarine (épicarpe et mésocarpe de) (2430)	
24.2.1	Matricaria flower / Matricaire (fleur de) (0404)	
28.2.2	Meningococcal group C conjugate vaccine/ Vaccin conjugué méningococcique groupe C (2112)	
28.2.4	Meningococcal polysaccharide vaccine/Vaccin méningococcique polysidique (0250)	
15.2.1	Meropenem trihydrate / Méropénem trihydraté (2234)	
19.2.3	Methylprednisolone / Méthylprednisolone (0561)	
19.2.4	Methyltestosterone / Méthyltestostérone (0410)	
18.2.2	Nalidixic acid / Nalidixique (acide) (0701)	
19.2.1	Nimodipine / Nimodipine (1245)	
28.2.3	Pneumococcal polysaccharide conjugate vaccine (adsorbed)/Vaccin pneumococcique polyo sidique conjugué adsorbé (2150)	
28.2.5	Pneumococcal polysaccharide vaccine/Vaccin pneumococcique polysidique (0966)	
45.2.1	Poly(vinyl alcohol) / Poly(alcool vinylique) (1961)	
14.2.2	Prekallikrein activator / Activateur de prékallikréine (20615)	
58.2.1	Raman spectrometry (2.2.48.) / Spectrométrie raman (2.2.48.)	
19.2.5	Tamoxifen citrate / Tamoxifène (citrate de) (1046)	
18.2.3	Trimipramine maleate / Trimipramine (maléate de) (0534)	
28.2.6	Typhoid polysaccharide vaccine/Vaccin typhoïdique polysidique (1160)	
	<b>I.1.3 New texts for adoption / Nouveaux textes pour adoption</b>	
49.1.2	Acidum picricum for homoeopathic preparations / Acidum picricum for homoeopathic preparations (2695)	
14.1.1	Assay of human C1-esterase inhibitor / Dosage de l'inhibiteur de C1-estérase humain (20734)	
69.1.1	Aucklandia root / Aucklandia (racine d') (1797)	

	<b>I.1.3 New texts for adoption / Nouveaux textes pour adoption</b>	
71.1.1	Chemometric methods applied to analytical data (5.21.) / Méthodes chimiométriques appliquées aux données analytiques (5.21.)	
20.1.1	Cisatracurium besilate / Cisatracurium (bésilate de) (2763)	
19.1.1	Dienogest / Diénogest (2732)	
31.1.1	Entecavir monohydrate / Entécavir monohydraté (2815)	
40.1.1	Extemporaneous preparation of radiopharmaceuticals (51900)	
31.1.2	Gadobutrol monohydrate / Gadobutrol monohydraté (2735)	
31.1.3	Gefitinib / Géfitinib (2866)	
28.1.1	Haemophilus type b and meningococcal group C conjugate vaccine/Vaccin haemophilus type b et méningococcique groupe C conjugué (2622)	
49.1.1	Histaminum for homoeopathic preparations / Histaminum pour préparations homéopathiques (2671)	
14.1.2	Human C1-esterase inhibitor / Inhibiteur de la C1-estérase humain (2818)	
11.2	Hydroxypropylcellulose, low-substituted / Hydroxypropylcellulose faiblement substituée (2083)	
54.1.1	Methyl, ethyl and isopropyl benzenesulfonate in active substances (2.5.41.) / Benzènesulfonate de méthyle, d'éthyle et d'isopropyle dans les substances active (20541)	
31.1.4	Pregabalin / Prégabaline (2777)	
20.1.2	Rabeprazole sodium / Rabéprazole sodique (2868)	
20.1.3	Rabeprazole sodium, hydrate / Rabéprazole sodique hydraté (2331)	
21.1.1	Ropinirole hydrochloride / Ropinirole (chlorhydrate de) (2604)	
31.1.5	Sitagliptin phosphate monohydrate / Sitagliptine (phosphate de) monohydraté (2778)	
31.1.6	Sitagliptin tablets / Sitagliptine (comprimés de) (2927)	
26.1.1	Sodium lauroyl sarcosinate / Sodium lauroyl sarcosinate (2542)	
27.1.1	Technetium (99mTc) oxidronate injection (2376)	
22.1.2	Thiocolchicoside crystallised from ethanol / thiocolchicoside cristallisé dans l'éthanol (2896)	
22.1.1	Thiocolchicoside hydrate / thiocolchicoside hydraté (2814)	
	I.1.4 Minor revisions enforced as corrections (Supplement 8.6)	
13.4.1	Insulin, bovine / Insuline bovine (1637)	
13.4.2	Insulin preparations, injectable / Insuline (préparations injectables d') (0854)	
13.4.3	Insulin, porcine / Insuline porcine (1638)	
13.4.4	Insulin, human / Insuline humaine (0838)	

13.4.5	Goserelin / Gos�er�line (1636)	
	<b><i>I-2 CRS/BRP SCR/PBR</i></b>	
	<b>New substances / Nouvelles substances</b>	
	Glimepiride for impurity A identification CRS 1	
	Lactose monohydrate CRS 1	
	Meldonium impurity A CRS 1	
	Meldonium impurity B CRS 1	
	Meldonium impurity C CRS 1	
	Meldonium impurity D CRS 1	
	Meldonium impurity E CRS 1	
	Meldonium impurity F CRS 1	
	Nicorandil CRS 1	
	Nicorandil impurity A CRS 1	
	Permethrin (25:75) CRS 1	
	Solifenacin succinate CRS 1	
	<b>Replacement Batches / Lots de remplacement</b>	
	Acarbose CRS 3	
	Adrenaline tartrate CRS 6	
	Albendazole CRS 2	
	Alfacalcidol CRS 9	
	Allopurinol CRS 3	
	Allopurinol impurity D CRS 4	
	Ammonium glycyrrhizate CRS 2	
	Amphotericin B CRS 5	
75.3	Anti-hepatitis A Virus Primary Detection Antibody BRR batch 3 and Conjugated Secondary Detection Antibody BRR batch 3	
	Benserazide impurity A CRS 2	
	Boldine CRS 3	
	Bupivacaine impurity B CRS 3	
	Cefalexin monohydrate CRS 4	
	Celecoxib CRS 2	
	Celecoxib impurity A CRS 2	
	Celecoxib impurity B CRS 2	
	Chlortetracycline for system suitability CRS 2	
	Chlortetracycline for system suitability CRS 3	

	Cholecalciferol CRS 9	
	Cholecalciferol for system suitability CRS 7	
	Cholesterol CRS 4	
	Cladribine CRS 2	
	Crotamiton CRS 3	
	Crotamiton impurity A CRS 5	
	Danaparoid sodium CRS 2	
	Desflurane impurity A CRS 2	
	Desloratadine CRS 2	
	D-His Buserelin CRS 2	
	Doxapram impurity B CRS 2	
	Doxycycline hyclate CRS 5	
	Etoposide CRS 7	
	Glibenclamide impurity B CRS 3	
	Glicazide impurity F CRS 5	
	Glimepiride CRS 2	
	Goserelin validation mixture CRS 2	
75.4	Human coagulation factor VIII concentrate BRP batch 5	
	Insuline porcine for system suitability CRS 2	
	Isotretinoin for peak id. CRS 2	
	Levamisole hydrochloride for system suitability CRS 5	
	Levocarnitine CRS 3	
	Levocarnitine impurity A CRS 3	
	Loperamide hydrochloride for system suitability CRS 2	
	Losartan impurity D CRS 3	
	Metamizole impurity E CRS 3	
	Metformin impurity F CRS 2	
	Metoprolol impurity A CRS 4	
	Metronidazole impurity A CRS 3	
	Mexiletine impurity C CRS 2	
	Montelukast dicyclohexylamine CRS 2	
	Nabumetone impurity F CRS 5	
	Naloxone impurity D CRS 2	
	Neohesperidine-dihydrochalcone CRS 2	
	Olanzapine CRS 2	
	Ondansetron for TLC system suitability CRS 2	
	Oxaliplatin impurity C CRS 6	

	Pemetrexed impurity mixture CRS 2	
	Permethrin for syst. suitability CRS 1	
	Permethrin for syst. suitability CRS 2	
	Phenytoin sodium CRS 2	
	Piroxicam for system suitability CRS 5	
	Propyl parahydroxybenzoate CRS 4	
	Quercetin dihydrate CRS 3	
75.2	Rabies Vaccine (Inactivated) for Veterinary Use BRP batch	
	Repaglinide for system suitability CRS 3	
	Rifamycin B CRS 3	
	Rifamycin sodium CRS 4	
	Rivastigmine hydrogen tartrate CRS 2	
	Rosmarinic acid CRS 3	
	Sulbactam CRS 2	
	Sulfathiazole CRS 2	
	Sumatriptan impurity mixture CRS 8	
	Tadalafil CRS 2	
	Ticarcillin monosodium CRS 2	
	Ticlopidine impurity F CRS 3	
	Tiotropium impurity mixture CRS 2	
	Trilaurin CRS 3	
	Trimebutine for syst. Suitability CRS 2	
	Trimethoprim impurity B CRS 5	
	Vinpocetine impurity C CRS 2	
	<b>II. ITEMS DEFERRED – SCHEDULED FOR A FUTURE SESSION/ SUJETS REPORTEES – A INSCRIRE A UNE PROCHAINE SESSION</b>	
<b>Item</b>	<b>III. REQUESTS FOR REVISION / DEMANDES DE REVISION</b>	
	<b>III.1 Approved by the Commission</b>	
71.4.1	Absorption spectrophotometry, infrared / Spectrophotométrie d'absorption dans l'infrarouge (2.2.24.) - VSADM WP	
47.4.1	Arsenic / Arsenic (2.4.2.) – PCM Group	



	<b>III.1 Approved by the Commission</b>	
24.4.2	Bilberry fruit, dried / Myrtille (fruit sec de) (1588) – Group 13A	
70.4.1	Calcifediol / Calcifédiol (1295) - VIT WP	
35.4.1	Capillary viscometer method / Viscosité - méthode au tube capillaire (2.2.9.) – CEL WP	
64.4.2	Chlorhexidine diacetate / Chlorhexidine (diacétate de) (0657)	
64.4.3	Chlorhexidine dihydrochloride / Chlorhexidine (dichlorhydrate de) (0659) - SIT WP	
22.4.1	Colchicine / Colchicine (0758) – Group 11	
11.5.1	Determination of metal catalyst or metal reagent residues / Dosage des résidus de catalyseurs ou de réactifs métalliques (2.4.20.) – HM WP	
21.4.1	Ether / Éther (0650) – Group 10D	
20.4.1	Etoposide (0823) – Group 10C	
64.4.1	Furosemide / Furosémide (0391) - SIT WP	
63.1	Guide for Work of the European Pharmacopoeia – ROP WP	
49.4.2	Ignatia for homoeopathic preparations / Ignatia amara pour préparations homéopathiques (2513) – HOM WP	
41.4.1	Liquid chromatography (2.2.29.) / Chromatographie liquide (2.2.29.) – CST WP	
16.4.1	Manganese sulfate monohydrate / Manganèse (sulfate de) monohydraté (1543) – Group 9	
11.5.2	Metal catalyst or metal reagent residues / Résidus de catalyseurs ou de réactifs métalliques (5.20.) – HM WP	
19.4.2	Methylprednisolone hydrogen succinate / Méthylprednisolone (hydrogénosuccinate de) (1131) – Group 10B	
35.4.2	Microcrystalline cellulose and carmellose sodium / Cellulose microcristalline et carmellose sodique (2050) – CEL WP	
49.4.1	Nux-vomica for homoeopathic preparations / Nux-vomica pour préparations homéopathiques (2514) – HOM WP	
23.4.1	Parenteral preparations / Préparations parentérales (0520) – Group 12	
24.4.1	Peppermint oil / Menthe poivrée (huile essentielle de) (0405) – Group 13A	
11.5	Pharmaceutical preparations / Préparations pharmaceutiques (2619) – HM WP	
16.4.2	Potassium sulfate / Potassium (sulfate de) (1622) – Group 9	
64.4.4	Prednicarbate / Prednicarbate (1467) - SIT WP	
31.4.2	Pregabalin / Prégabaline (2777) One of the 10A-D Groups	
63.2	Rules of Procedure of the European Pharmacopoeia – ROP WP	

	<b>III.1 Approved by the Commission</b>	
16.4.3	Sodium sulfate decahydrate / Sodium (sulfate de) décahydraté (100) – Group 9	
16.4.3	Sodium sulfate, anhydrous / Sodium (sulfate de) anhydre (0099) – Group 9	
13.5.1	Somatropin / Somatropine (0951) – Group 6	
13.5.1	Somatropin concentrated solution / Somatropine (solution concentrée de) (0950) – Group 6	
13.5.1	Somatropin for injection / Somatropine pour préparation injectable (0952) – Group 6	
13.5.1	Somatropin injection / Somatropine (solution injectable de) (2370) – Group 6	
31.4.1	Tiotropium bromide monohydrate / Tiotropium (bromure de) monohydraté (2420) P4 Group then transfer to one of the 10A-D Groups	
39.4.1	Wheat starch / Amidon de blé (0359) – CRB WP	
	<b>III.2 Rejected by the Commission</b>	
	<b>IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
8.1	Achyranthes bidentate BI (Radix) (2999) - TCM WP	
6.4	Bergamot oil (2995) – Group 13A	
8.1	Cajeputi aetheroleum ( <i>Melaleuca leucadendra L. var cajuputi</i> ) (3007) – Group 13A	
6.4	Calcium fluoride for homoeopathic preparations (2996) – HOM WP	
6.4	Carrageen (Irish moss) (2997) – Group 13B	
8.1	Cedri ligni aetheroleum ( <i>Cedrus atlantica</i> ) (3002) – Group 13A	
8.1	Cupressi aetheroleum ( <i>Cupressus sempervirens</i> ) (3003) – Group 13A	
8.1	Cyathula officinalis Kuan (Radix) (2998) - TCM WP	
56.5.1	Darbepoetin alfa (3009) - P4BIO WP	
8.1	Ganoderma Lucidum (Ley-ss ex Fr.) Karst (3001) - TCM WP	
8.1	Gaultheriae aetheroleum ( <i>Gaultheria procumbens</i> ) (3004) – Group 13A	
8.1	Geranii aetheroleum ( <i>Pelargonium graveolens/P. X asperum</i> ) (3005) – Group 13A	
8.1	Ophiopogon japonicas (Thunb) Ker-Gawl (Radix) (3000) - TCM WP	
8.1	Rosae aetheroleum ( <i>Rosa damascena/R. sp.</i> ) (3006) – Group 13A	

	<b>IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
8.1	Rosuvastatin calcium tablets (3008) – Group 10B	
	<b>V. DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)</b>	
49.5.3	Mercurius solubilis Hahnemanni for homoeopathic preparations (2506)	
8.1	Picrorhiza kurroa rhizome and root (2744)	
23.5.2	Test for extractable volume of parenteral preparations / Essai du volume extractible pour les préparations parentérales (2.9.17.)	
	<b>VI SUPPRESSION FROM THE PH. EUR. / SUPPRESSION DE LA PH. EUR.</b>	
8.1	Cinnamon tincture (1819)	
<b>Agenda Item No.</b>	<b>VI.1 PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE</b>	
54.5.1	MSL WP - continuation of activities: the working party has finished its mandate but the pool of expertise will be kept. The WP will be put in dormance.	
63	Reactivation of the ROP Working Party	
	<b>VIII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION</b>	
	Dates for 2015 - 16-17 June - 17-18 November	

151<sup>st</sup> Session Nominations – Item 7.1**GROUPS OF EXPERTS**

<b><u>Group 1</u></b>	
The Netherlands	Dr Marja CLAASSEN-WILLEMSE Industry – ( <b><u>Specialist</u></b> : validation of RMM, microbiological QC, disinfection validation)
The Netherlands	Prof.Dr Edwin Roy VAN DEN HEUVEL University – ( <b><u>Specialist</u></b> : Statistics Microbiology)
<b><u>Group 6</u></b>	
Spanish	Dr Guillermo FRANCO (replacing Dr Carrasco) Industry – ( <b><u>Specialist</u></b> : Structural elucidation and analytical methods for carbohydrates, specially glycosaminoglycans and particularly heparin and derivatives, development and management of research projects.
Danish	Mrs Eva RAUHE BAEKDAHL NPA / Licensing authority / OMCL / Inspectorate
<b><u>Group 7</u></b>	
Portugal	Mrs Dalia Maria DIAS BARBOSA Industry
<b><u>Group 9G</u></b>	
Belgium	Dr Valentijn VERGOTE Industry

<b>Group 10B</b>		Dr Ruud VERVOORT	Industry
The Netherlands			
<b>Group 10C</b>		Mrs Rita PIMENTEL (replacing Ms SIMOES)	Authority
Portugal			
<b>Group 10D</b>		Dr Zdenko CASAR	Industry / University
Slovenia			
<b>Group 11</b>		Dr Gerd JILGE (replacing Dr Henk)	Industry - ( <b>Specialist</b> : API's Quality Control)
Germany			
<b>Group 13B</b>		Mr Paul ANDERSON	Industry
United Kingdom			
<b>Group 15</b>		Dr Filiz SENGUN	OMCL
Turkey			
<b>Group15V</b>		Dr Musa ALKAN	Inspectorate
Turkey		Dr Rory COONEY	Licensing authority - ( <b>Specialist</b> : Scientific regulation of veterinary vaccines with particular interest/experience in cattle, avian, canine and feline bacterial and viral vaccines: also mycobacteria with particular background in TB.
United Kingdom			

	Experience in quality control tests and standards and reduction/refinement/replacement.
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**Group 16**

Turkey	Mrs Banu BABÜR	<b>Specialist:</b> organic materials, plastic materials, plastic containers, closures, and medical devices for 2 years.
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**Procedure 4 (P4)**

Spain	Dr Isabel DORRONSORO DIAZ	Licensing authority
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**WORKING PARTIES****Bacterial endotoxins (BET)**

Germany	Dr Michael RIETH	Industry
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**General Methods (MG)**

Spain	Dr Rocio FERNANDEZ-GRANDA	Licensing authority / OMCL
Germany	Dr Christoph SAAL	Industry

**Mycoplasmas (MYC)**

Germany	Mr Jan-Oliver KARO (replacing Dr Nübling)	Licensing authority
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**Paediatric formulary (PaedForm)**

Serbia	Dr Zarko JOVIC	Licensing authority / OMCL
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**Process analytical technology (PAT)**

Belgium	Prof. Dr Thomas DE BEER	University
Swiss	Dr Lorenz LIESUM	Industry

**Sutures (SUT)**

United Kingdom	Mrs Lynne FERRIS	Industry
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