



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 29 January - 01 February 2019

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

29 January 2019, 14:00- 19:00, room 3A

30 January 2019, 08:30- 19:00, room 3A

31 January 2019, 08:30- 19:00, room 3A

01 February 2019, 08:30- 13:00, room 3A

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



Table of contents

1.	Introductions	9
1.1.	Welcome and declarations of interest of members, alternates and experts.....	9
1.2.	Adoption of agenda	9
1.3.	Adoption of the minutes	9
2.	Opinions	9
2.1.	Opinions on Products.....	9
2.1.1.	Mavacamten - EMEA-002231-PIP01-17	9
2.1.2.	Dihomo- γ -linolenic acid (DGLA) - EMEA-002364-PIP02-18	9
2.1.3.	Chemically modified recombinant human sulfamidase - Orphan - EMEA-002380-PIP01-18	10
2.1.4.	(6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid - Orphan - EMEA-002069-PIP02-17.....	10
2.1.5.	Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17	10
2.1.6.	Guselkumab - EMEA-001523-PIP03-18.....	10
2.1.7.	EMEA-002240-PIP02-17	10
2.1.8.	Pretomanid - Orphan - EMEA-002115-PIP01-17.....	11
2.1.9.	Ridinilazole - EMEA-002250-PIP02-17	11
2.1.10.	Isoflurane - EMEA-002320-PIP01-17	11
2.1.11.	Avapritinib - Orphan - EMEA-002358-PIP02-18.....	11
2.1.12.	Spartalizumab - EMEA-002351-PIP01-18	11
2.1.13.	(R)-azasetron (as besylate) - Orphan - EMEA-002165-PIP02-18	12
2.1.14.	EMEA-002324-PIP01-17	12
2.1.15.	EMEA-002191-PIP02-17	12
2.1.16.	Molgramostim - Orphan - EMEA-002282-PIP01-17.....	12
2.1.17.	Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18	12
2.1.18.	Amlodipine besylate / rosuvastatin calcium - EMEA-002456-PIP01-18	13
2.1.19.	EMEA-002475-PIP01-18	13
2.1.20.	EMEA-002470-PIP01-18	13
2.1.21.	Norethisterone acetate / estradiol / relugolix - EMEA-002428-PIP01-18.....	13
2.1.22.	Pyrimidinyl-aminopyridine dual leucine zipper kinase inhibitor - EMEA-002469-PIP02-18..	13
2.1.23.	Genetically modified mycobacterium bovis BCG - EMEA-002461-PIP01-18.....	14
2.1.24.	Empagliflozin - EMEA-000828-PIP06-18	14
2.2.	Opinions on Compliance Check	14
2.2.1.	Avibactam / ceftazidime - EMEA-C2-001313-PIP01-12-M08	14

2.2.2.	Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-C1-001715-PIP01-14-M01	14
2.3.	Opinions on Modification of an Agreed Paediatric Investigation Plan	15
2.3.1.	Ambrisentan - Orphan - EMEA-000434-PIP01-08-M05.....	15
2.3.2.	Tralokinumab - EMEA-001900-PIP02-17-M02.....	15
2.3.3.	Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M06.....	15
2.3.4.	Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M01	15
2.3.5.	Tofacitinib - EMEA-000576-PIP03-12-M02	15
2.3.6.	Ustekinumab - EMEA-000311-PIP04-13-M01.....	16
2.3.7.	Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M01.....	16
2.3.8.	Apremilast - EMEA-000715-PIP02-11-M03.....	16
2.3.9.	Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M03	16
2.3.10.	EMEA-001838-PIP01-15-M02	16
2.3.11.	Lefamulin - EMEA-002075-PIP01-16-M01	17
2.3.12.	Erenumab - EMEA-001664-PIP02-15-M03.....	17
2.3.13.	Galcanezumab - EMEA-001860-PIP03-16-M02	17
2.3.14.	satralizumab humanised anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M02	17
2.3.15.	Lacosamide - EMEA-000402-PIP03-17-M03.....	17
2.3.16.	Peginterferon beta-1a - EMEA-001129-PIP01-11-M03	18
2.3.17.	Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M01	18
2.3.18.	Dabrafenib mesylate - EMEA-001147-PIP01-11-M06.....	18
2.3.19.	carotuximab - Orphan - EMEA-002138-PIP01-17-M01	18
2.3.20.	Olaratumab - Orphan - EMEA-001760-PIP01-15-M03	19
2.3.21.	Rituximab - EMEA-000308-PIP01-08-M04.....	19
2.3.22.	Trametinib dimethyl sulfoxide - EMEA-001177-PIP01-11-M05	19
2.3.23.	Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP02-10-M03	19
2.3.24.	Autologous cartilage derived cultured chondrocytes - EMEA-001823-PIP01-15-M01	20
2.3.25.	Methoxyflurane - EMEA-000334-PIP01-08-M08	20
2.3.26.	Dermatophagoides farinae / Dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M04	20
2.3.27.	Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001016-PIP01-10-M01	20
2.3.28.	Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001017-PIP01-10-M01	20
2.3.29.	Chemically modified extract of trees pollen from Birch and Alder - EMEA-001012-PIP01-10-M01	21
2.3.30.	Chemically modified extract of trees pollen from Birch and Alder - EMEA-001013-PIP01-10-M01	21

2.3.31.	Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001011-PIP01-10-M01	21
2.3.32.	Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001014-PIP01-10-M01	21
2.3.33.	Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily A; Escherichia coli) - EMEA-001037-PIP02-11-M05	21
2.4.	Opinions on Re-examinations	22
2.4.1.	Empagliflozin - EMEA-000828-PIP04-16-M02	22
2.5.	Opinions on Review of Granted Waivers	22
2.6.	Finalisation and adoption of opinions	22
2.7.	Partial Compliance Checks completed by EMA	22
2.7.1.	Venetoclax - EMEA-002018-PIP02-16-M01.....	22
2.7.2.	Pembrolizumab - EMEA-C1-001474-PIP02-16-M01	22
2.7.3.	Edoxaban (tosylate) - EMEA-C3-000788-PIP02-11-M08.....	23
2.7.4.	Baricitinib - EMEA-C1-001220-PIP03-16	23
2.7.5.	Eculizumab - EMEA-C1-000876-PIP03-14-M02	23

3. Discussion of applications 23

3.1.	Discussions on Products D90-D60-D30.....	23
3.1.1.	EMEA-002378-PIP01-18	23
3.1.2.	Hepcidin-25 acetate (synthetic human hepcidin) - Orphan - EMEA-002083-PIP01-16	23
3.1.3.	EMEA-001710-PIP03-17	24
3.1.4.	EMEA-002374-PIP01-18	24
3.1.5.	Voclosporin - EMEA-002264-PIP01-17	24
3.1.6.	Oteseconazole - EMEA-002392-PIP01-18.....	24
3.1.7.	Ofatumumab - EMEA-002397-PIP01-18.....	24
3.1.8.	Abemaciclib - EMEA-002342-PIP01-18	25
3.1.9.	EMEA-002348-PIP01-18	25
3.1.10.	Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signaling domains - Orphan - EMEA-002369-PIP01-18.....	25
3.1.11.	Vinorelbine - EMEA-002365-PIP01-18	25
3.1.12.	Aflibercept - EMEA-000236-PIP05-18	25
3.1.13.	Nintedanib - Orphan - EMEA-001006-PIP05-18.....	26
3.1.14.	EMEA-002307-PIP01-17	26
3.1.15.	EMEA-002308-PIP01-17	26
3.1.16.	EMEA-002451-PIP01-18	26
3.1.17.	EMEA-002464-PIP01-18	26
3.1.18.	Trifarotene EMEA-001492-PIP02-18.....	27
3.1.19.	EMEA-002448-PIP01-18	27

3.1.20.	C1 esterase inhibitor (human) - EMEA-000568-PIP02-18	27
3.1.21.	Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18	27
3.1.22.	Baloxavir marboxil - EMEA-002440-PIP01-18	27
3.1.23.	Hydrocortisone - EMEA-002305-PIP01-17	28
3.1.24.	Padsevonil - EMEA-002466-PIP01-18	28
3.1.25.	Larotrectinib - Orphan - EMEA-001971-PIP03-18	28
3.1.26.	Marizomib - EMEA-002452-PIP01-18	28
3.1.27.	Aldesleukin- EMEA-002492-PIP01-18	28
3.1.28.	Zanubrutinib - EMEA-002354-PIP02-18	29
3.1.29.	Pneumococcal Polyssacharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate - EMEA-002330-PIP01-18.....	29
3.1.30.	Recombinant respiratory syncytial virus fusion (RSV F) glycoprotein - EMEA-001985-PIP01-18	30
3.1.31.	Rosuvastatin calcium / fenofibrate - EMEA-002509-PIP01-18	30
3.1.32.	EMEA-002481-PIP01-18	30
3.1.33.	Serlopitant - EMEA-002496-PIP01-18.....	30
3.1.34.	Gadopicienol - EMEA-001949-PIP02-18	30
3.1.35.	Levonorgestrel - EMEA-002474-PIP02-18	30
3.1.36.	Norursodeoxycholic acid - Orphan - EMEA-002485-PIP01-18.....	31
3.1.37.	AAV2/S3-FRE1-TI-FIXco1 vector - Orphan - EMEA-002518-PIP01-18	31
3.1.38.	Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 - Orphan - EMEA-002479-PIP01-18	31

3.1.39.	Anti-CD7 mAb conjugated to ricin toxin A chain / anti-CD3 mAb conjugated to ricin toxin A chain - Orphan - EMEA-002087-PIP01-16	31
3.1.40.	Secukinumab - EMEA-000380-PIP05-18	31
3.1.41.	Upadacitinib - EMEA-001741-PIP06-18	32
3.1.42.	Artesunate - Orphan - EMEA-002402-PIP02-18	32
3.1.43.	Delafloxacin - EMEA-001080-PIP03-18	32
3.1.44.	Equine Immunoglobulin F(ab') ₂ fragments targeting Shiga toxin - Orphan - EMEA-002444-PIP02-18	32
3.1.45.	Tazobactam sodium / cefepime hydrochloride - EMEA-002483-PIP01-18	32
3.1.46.	EMEA-002419-PIP02-18	33
3.1.47.	Crizotinib - EMEA-001493-PIP03-18	33
3.1.48.	Flucytosine - Orphan - EMEA-002437-PIP02-18	33
3.1.49.	L-asparaginase - Orphan - EMEA-000341-PIP03-18	33
3.1.50.	Rivoceranib mesylate - Orphan - EMEA-002489-PIP01-18	33
3.1.51.	Rogaratinib - EMEA-002439-PIP01-18	34
3.1.52.	EMEA-002504-PIP01-18	34
3.1.53.	Tislelizumab - EMEA-002480-PIP01-18	34
3.1.54.	Vocimagene amiretrorepvec - Orphan - EMEA-002505-PIP02-18	34
3.1.55.	Cenergermin - Orphan - EMEA-001729-PIP02-18	34
3.1.56.	EMEA-002484-PIP01-18	34
3.1.57.	Orvepitant - EMEA-002510-PIP01-18	35
3.1.58.	Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues - Orphan - EMEA-002493-PIP01-18	35
3.2.	Discussions on Compliance Check.....	35
3.2.1.	Sebelipase alfa - EMEA-C-001331-PIP01-12-M02	35
3.2.2.	Rabeprazole (sodium) - EMEA-C-000055-PIP01-07-M06	35
3.2.3.	Rituximab - EMEA-C-000308-PIP02-11-M01	36
3.2.4.	Denosumab - EMEA-C-000145-PIP01-07-M09	36
3.2.5.	Pembrolizumab - EMEA-C-001474-PIP01-13-M01	36
3.2.6.	Conestat Alfa - EMEA-C-000367-PIP01-08-M08	36
3.2.7.	Peanut allergen extract - EMEA-C1-001481-PIP01-13-M03	36
3.3.	Discussions on Modification of an Agreed Paediatric Investigation Plan.....	37
3.3.1.	Corifollitropin alfa - EMEA-000306-PIP01-08-M04	37
3.3.2.	Rivaroxaban - EMEA-000430-PIP01-08-M11	37
3.3.3.	Ertugliflozin L-PGA - EMEA-001533-PIP01-13-M02	37
3.3.4.	Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M04	37
3.3.5.	Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M0337	
3.3.6.	Luspatercept - Orphan - EMEA-001521-PIP01-13-M03	38

3.3.7.	Nonacog beta pegol (glycopegylated recombinant coagulation factor IX) - Orphan - EMEA-000731-PIP01-09-M03	38
3.3.8.	Roxadustat - EMEA-001557-PIP01-13-M03	38
3.3.9.	Tofacitinib citrate - EMEA-000576-PIP01-09-M10.....	38
3.3.10.	Upadacitinib - EMEA-001741-PIP02-16-M01.....	38
3.3.11.	Upadacitinib - EMEA-001741-PIP03-16-M01.....	39
3.3.12.	Ceftolozane / tazobactam - EMEA-001142-PIP01-11-M03	39
3.3.13.	Etravirine - EMEA-000222-PIP01-08-M09	39
3.3.14.	Oritavancin diphosphate - EMEA-001270-PIP01-12-M02.....	39
3.3.15.	Inebilizumab - Orphan - EMEA-001911-PIP01-15-M02	39
3.3.16.	Teriflunomide - EMEA-001094-PIP01-10-M05.....	40
3.3.17.	Regorafenib - EMEA-001178-PIP01-11-M04	40
3.3.18.	Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M07	40
3.3.19.	Idarucizumab - EMEA-001438-PIP01-13-M01.....	40
3.3.20.	Selexipag - EMEA-000997-PIP01-10-M02	40
3.3.21.	Fevipirant - EMEA-001315-PIP02-16-M01	41
3.3.22.	Peanut flour - EMEA-001734-PIP01-14-M04.....	41
3.3.23.	Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup W-135 polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16-M01 .	41

4. Nominations 41

4.1.	List of letters of intent received for submission of applications with start of procedure 01 April 2019 for Nomination of Rapporteur and Peer reviewer	41
4.2.	Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.	41
4.3.	Nominations for other activities	42

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction 42

6. Discussion on the applicability of class waivers 42

6.1.	Discussions on the applicability of class waiver for products.....	42
6.1.1.	EMEA-17-2018	42

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver 42

7.1.	Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver	42
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8.	Annual reports on deferrals	42
9.	Organisational, regulatory and methodological matters	42
9.1.	Mandate and organisation of the PDCO.....	42
9.2.	Coordination with EMA Scientific Committees or CMDh-v	43
9.2.1.	Committee for Medicinal Products for Human Use (CHMP)	43
9.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	43
9.3.1.	Non-clinical Working Group: D30 Products identified	43
9.3.2.	Formulation Working Group	43
9.3.3.	Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)	43
9.4.	Cooperation within the EU regulatory network.....	43
9.4.1.	European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA).....	43
9.5.	Cooperation with International Regulators.....	43
9.6.	Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee.....	43
9.7.	PDCO work plan.....	44
9.8.	Planning and reporting	44
10.	Any other business	44
11.	Breakout sessions	44
11.1.1.	Paediatric oncology	44
11.1.2.	Neonatology	44
11.1.3.	Inventory	44
11.1.4.	Systemic lupus erythematosus	44
12.	Explanatory notes	45

1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 29 January-01 February 2019. See 29 January-01 February 2019 PDCO minutes (to be published post 26 February – 01 March 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 29 January-01 February 2019.

1.3. Adoption of the minutes

PDCO minutes for 11-14 December 2018.

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Mavacamten - EMEA-002231-PIP01-17

Treatment of Hypertrophic Cardiomyopathy / Treatment of obstructive Hypertrophic Cardiomyopathy

Day 120 Opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. Dihomo- γ -linolenic acid (DGLA) - EMEA-002364-PIP02-18

Treatment of atopic dermatitis / Treatment of mild to moderate atopic dermatitis

Day 120 Opinion

Action: For adoption

Dermatology

2.1.3. [Chemically modified recombinant human sulfamidase - Orphan - EMEA-002380-PIP01-18](#)

Swedish Orphan Biovitrum AB (publ); Mucopolysaccharidosis type IIIA (MPS IIIA)

Day 120 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. [\(6aR,10aR\)-1-Hydroxy-6,6-dimethyl-3-\(2-methyl-2-octanyl\)-6a,7,10,10a-tetrahydro-6H-benzo\[c\]chromene-9-carboxylic acid - Orphan - EMEA-002069-PIP02-17](#)

Corbus Pharmaceuticals Holdings Inc; Treatment of systemic sclerosis

Day 120 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.5. [Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17](#)

Nohla Therapeutics, Inc.; Treatment in haematopoietic stem cell transplantation (HSCT) in patients with malignant disease / Patients with high risk haematologic malignancies undergoing myeloablative cord blood transplant (CBT)

Day 120 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. [Guselkumab - EMEA-001523-PIP03-18](#)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis (PsA) and juvenile idiopathic arthritis (JIA)) / Treatment of juvenile idiopathic arthritis (juvenile psoriatic arthritis (jPsA))

Day 120 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. [EMEA-002240-PIP02-17](#)

Treatment of urinary tract infections

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.8. Pretomanid - Orphan - EMEA-002115-PIP01-17

Global Alliance for TB Drug Development; Treatment of multidrug-resistant tuberculosis

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.9. Ridinilazole - EMEA-002250-PIP02-17

Treatment of Clostridium difficile infection (CDI) and reducing the recurrence of CDI

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.10. Isoflurane - EMEA-002320-PIP01-17

Sedation

Day 120 Opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.1.11. Avapritinib - Orphan - EMEA-002358-PIP02-18

Blueprint Medicines Corporation; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients with advanced solid tumors harboring mutations in either KIT or PDGFR α .

Day 120 Opinion

Action: For adoption

Oncology

2.1.12. Spartalizumab - EMEA-002351-PIP01-18

Treatment of melanoma / Treatment of adolescent patients with melanoma containing BRAF V600 activating mutations

Day 120 Opinion

Action: For adoption

Oncology

2.1.13. (R)-azasetron (as besylate) - Orphan - EMEA-002165-PIP02-18

Sensorion SA; Treatment of sudden sensorineural hearing loss, Prevention of cisplatin-induced ototoxicity

Day 120 Opinion

Action: For adoption

Oto-rhino-laryngology

2.1.14. EMEA-002324-PIP01-17

Treatment of cystic fibrosis

Day 120 Opinion

Action: For adoption

Pneumology - Allergology

2.1.15. EMEA-002191-PIP02-17

Treatment of cystic fibrosis

Day 120 Opinion

Action: For adoption

Pneumology - Allergology

2.1.16. Molgramostim - Orphan - EMEA-002282-PIP01-17

Savara ApS; Treatment of pulmonary alveolar proteinosis / Treatment of children from 6 to less than 18 years with autoimmune pulmonary alveolar proteinosis

Day 120 Opinion

Action: For adoption

Pneumology - Allergology

2.1.17. Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18

Prevention of influenza infection

Day 120 Opinion

Action: For adoption

Vaccines

2.1.18. Amlodipine besylate / rosuvastatin calcium - EMEA-002456-PIP01-18

Treatment of hypertension, Treatment of dyslipidemia, Treatment of ischemic coronary artery disorders, Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.19. EMEA-002475-PIP01-18

Treatment of patients with acute or chronic generalized pustular psoriasis (GPP) and for the prevention of flares.

Day 60 Opinion

Action: For adoption

Dermatology

2.1.20. EMEA-002470-PIP01-18

Actinic keratosis in adults

Day 60 Opinion

Action: For adoption

Dermatology

2.1.21. Norethisterone acetate / estradiol / relugolix - EMEA-002428-PIP01-18

Treatment of symptoms associated with uterine fibroids

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.22. Pyrimidinyl-aminopyridine dual leucine zipper kinase inhibitor - EMEA-002469-PIP02-18

Treatment of amyotrophic lateral sclerosis

Day 60 Opinion

Action: For adoption

Neurology

2.1.23. Genetically modified mycobacterium bovis BCG - EMEA-002461-PIP01-18

Non-muscle invasive bladder cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.24. Empagliflozin - EMEA-000828-PIP06-18

Treatment of chronic kidney disease

Day 60 Opinion

Action: For adoption

Uro-nephrology

2.2. Opinions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

2.2.1. Avibactam / ceftazidime - EMEA-C2-001313-PIP01-12-M08

Pfizer Limited; Treatment of urinary tract infections

Day 60 letter

Action: For adoption

Infectious Diseases

2.2.2. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-C1-001715-PIP01-14-M01

Seqirus Netherlands B.V.; Prevention of influenza infection

Day 60 letter

Action: For adoption

Vaccines

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M05

Glaxo Group Limited; Treatment of pulmonary arterial hypertension / Idiopathic (IPAH) and Familial (FPAH) pulmonary hypertension; Associated pulmonary hypertension (APAH)

Day 60 Opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Tralokinumab - EMEA-001900-PIP02-17-M02

LEO Pharma A/S; Treatment of atopic dermatitis

Day 60 Opinion

Action: For adoption

Dermatology

2.3.3. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M06

Takeda Development Centre Europe Ltd; Type 2 diabetes mellitus

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M01

Genzyme Europe B.V.; ICD-10: E74.0; Glycogen storage disease (Pompe disease) / Long-term use as an enzyme replacement therapy (ERT) for the treatment of patients with a confirmed diagnosis of Pompe disease (acid α -glucosidase deficiency)

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Tofacitinib - EMEA-000576-PIP03-12-M02

Pfizer Limited; Ulcerative colitis / Treatment of children and adolescents aged 2 to <18 years of age with moderate to severe ulcerative colitis.

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Ustekinumab - EMEA-000311-PIP04-13-M01

Janssen-Cilag International NV; Treatment of Crohn's disease

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.7. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M01

Novartis Europharm Limited; Treatment of sickle cell disease / Prevention of vaso-occlusive crises in patients with sickle cell disease

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Apremilast - EMEA-000715-PIP02-11-M03

Celgene Europe B.V.; Treatment of juvenile idiopathic arthritis (JIA), Treatment of juvenile psoriatic arthritis (JPsA)

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.9. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M03

Basilea Pharmaceutica International Ltd.; Treatment of mucormycosis, Treatment of invasive aspergillosis

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.10. EMEA-001838-PIP01-15-M02

Janssen-Cilag International NV; Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV)

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.11. Lefamulin - EMEA-002075-PIP01-16-M01

Nabriva Therapeutics AG; Treatment of community-acquired pneumonia

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.12. Erenumab - EMEA-001664-PIP02-15-M03

Novartis Europharm Limited; Prevention of migraine headaches / Prophylaxis of migraine

Day 60 Opinion

Action: For adoption

Neurology

2.3.13. Galcanezumab - EMEA-001860-PIP03-16-M02

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 60 Opinion

Action: For adoption

Neurology

2.3.14. satralizumab humanised anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M02

CHUGAI PHARMA EUROPE LTD.; Treatment of neuromyelitis optica

Day 60 Opinion

Action: For adoption

Neurology

2.3.15. Lacosamide - EMEA-000402-PIP03-17-M03

UCB Pharma S.A.; Treatment of generalized epilepsy and epilepsy syndromes: Epilepsy - generalized idiopathic epilepsy and epilepsy syndromes [G40.3] Epilepsy - Other generalized epilepsy and epileptic syndromes [G40.4] / Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in pediatric patients with idiopathic generalized epilepsy (IGE) (4 years to <18 years)

Day 60 Opinion

Action: For adoption

Neurology

2.3.16. Peginterferon beta-1a - EMEA-001129-PIP01-11-M03

Biogen Idec Ltd; Multiple Sclerosis / Treatment of relapsing remitting forms of Multiple Sclerosis

Day 60 Opinion

Action: For adoption

Neurology

2.3.17. Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M01

Acerta Pharma, BV; Treatment of mature B cell neoplasms / Treatment of children from 1 to <18 years of age with previously untreated mature B-cell neoplasms (e.g., diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL) and primary mediastinal B-cell lymphoma (PMBCL)), Treatment of children from 1 to <18 years of age with relapsed/refractory mature B-cell neoplasms (e.g., diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL) and primary mediastinal B-cell lymphoma (PMBCL)).

Day 60 Opinion

Action: For adoption

Oncology

2.3.18. Dabrafenib mesylate - EMEA-001147-PIP01-11-M06

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 60 opinion

Action: For adoption

Oncology

2.3.19. carotuximab - Orphan - EMEA-002138-PIP01-17-M01

TRACON Pharma Limited-Charles Theuer; Treatment of soft tissue sarcoma

Day 60 Opinion

Action: For adoption

Oncology

2.3.20. Olaratumab - Orphan - EMEA-001760-PIP01-15-M03

Eli Lilly and Company Limited; Treatment of Soft Tissue Sarcoma, Treatment of Osteosarcoma / Treatment of recurrent rhabdomyosarcoma in children aged from birth to less than 18 years in combination with a standard-of-care chemotherapy regimen, First-line treatment of osteosarcoma in children aged from 5-18 years in combination with a standard-of-care chemotherapy regimen

Day 60 Opinion

Action: For adoption

Oncology

2.3.21. Rituximab - EMEA-000308-PIP01-08-M04

Roche Registration GmbH; Treatment of diffuse large B-cell lymphoma, Treatment of autoimmune arthritis / Treatment of mature B-cell malignancies, that is, diffuse large B-cell lymphoma, Burkitt and Burkitt-like lymphoma/leukaemia

Day 60 Opinion

Action: For adoption

Oncology

2.3.22. Trametinib dimethyl sulfoxide - EMEA-001177-PIP01-11-M05

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 60 Opinion

Action: For adoption

Oncology

2.3.23. Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP02-10-M03

Novartis Europharm limited; Secondary thrombocytopenia / Treatment of thrombocytopenia secondary to treatment of myeloid or lymphoid malignancies or solid tumours

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.24. Autologous cartilage derived cultured chondrocytes - EMEA-001823-PIP01-15-M01

TETEC AG; Treatment of cartilage disorders

Day 60 opinion

Action: For adoption

Other

2.3.25. Methoxyflurane - EMEA-000334-PIP01-08-M08

Medical Developments UK Ltd; Treatment of acute pain / 1. Self administration to conscious patients with minor trauma and associated pain, under supervision of personnel trained in its use, 2. For the management of acute pain associated with short surgical procedures, such as the change of dressings, dislocations and injections.

Day 60 Opinion

Action: For adoption

Pain

2.3.26. Dermatophagoides farinae / Dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M04

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / house dust mite allergic asthma, house dust mite allergic rhinitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.3.27. Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001016-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.28. Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001017-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.29. [Chemically modified extract of trees pollen from Birch and Alder - EMEA-001012-PIP01-10-M01](#)

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.30. [Chemically modified extract of trees pollen from Birch and Alder - EMEA-001013-PIP01-10-M01](#)

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.31. [Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001011-PIP01-10-M01](#)

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.32. [Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001014-PIP01-10-M01](#)

Granzer Regulatory Consulting & Services; Allergic rhinitis / Allergic rhinoconjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology / Oto-rhino-laryngology

2.3.33. [Neisseria meningitidis serogroup B recombinant lipoprotein \(subfamily B; Escherichia coli\) / Neisseria meningitidis serogroup B recombinant lipoprotein \(subfamily A; Escherichia coli\) - EMEA-001037-PIP02-11-M05](#)

Pfizer Europe MA EEIG; Invasive meningococcal disease caused by N meningitidis serogroup B.

Day 60 Opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

2.4.1. Empagliflozin - EMEA-000828-PIP04-16-M02

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.5. Opinions on Review of Granted Waivers

No items.

2.6. Finalisation and adoption of opinions

No items.

2.7. Partial Compliance Checks completed by EMA

For the following partial compliance checks, no need to refer them to PDCO Committee for discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Venetoclax - EMEA-002018-PIP02-16-M01

AbbVie Limited; Treatment of haematopoietic and lymphoid malignant neoplasms;
Treatment of solid tumour malignant neoplasms.

Day 1 letter

Action: For information

Oncology

2.7.2. Pembrolizumab - EMEA-C1-001474-PIP02-16-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of Hodgkin lymphoma

Day 1 letter

Action: For information

Oncology

2.7.3. Edoxaban (tosylate) - EMEA-C3-000788-PIP02-11-M08

Daiichi Sankyo Europe GmbH; Prevention of arterial thromboembolism

Day 1 letter

Action: For information

Cardiovascular Diseases / Haematology-Hemostaseology

2.7.4. Baricitinib - EMEA-C1-001220-PIP03-16

Eli Lilly and Company; Treatment of atopic dermatitis

Day 1 letter

Action: For information

Immunology-Rheumatology-Transplantation

2.7.5. Eculizumab - EMEA-C1-000876-PIP03-14-M02

Alexion Europe SAS; Treatment of neuromyelitis optica spectrum disorders

Day 1 letter

Action: For information

Neurology

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. EMEA-002378-PIP01-18

Treatment of acute heart failure

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Hepcidin-25 acetate (synthetic human hepcidin) - Orphan - EMEA-002083-PIP01-16

La Jolla Pharmaceutical II B.V.; Treatment of iron overload

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Haematology-Hemostaseology

3.1.3. EMEA-001710-PIP03-17

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. EMEA-002374-PIP01-18

Treatment of systemic lupus erythematosus (SLE)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.5. Voclosporin - EMEA-002264-PIP01-17

Treatment of systemic lupus erythematosus / Treatment of active lupus nephritis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Oteseconazole - EMEA-002392-PIP01-18

Treatment of vulvovaginal candidiasis

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Ofatumumab - EMEA-002397-PIP01-18

Treatment of Multiple Sclerosis / Treatment of relapsing remitting multiple sclerosis

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Abemaciclib - EMEA-002342-PIP01-18

Ewing's Sarcoma (ES) / Treatment of relapsed/refractory Ewing sarcoma in children and young adults, in combination with irinotecan and temozolomide

Day 90 discussion

Action: For discussion

Oncology

3.1.9. EMEA-002348-PIP01-18

B-cell Acute Lymphoblastic Leukemia / Treatment of relapse or refractory B-cell acute lymphoblastic leukemia

Day 90 discussion

Action: For discussion

Oncology

3.1.10. Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signaling domains - Orphan - EMEA-002369-PIP01-18

Celgene Europe B.V.; Treatment of mature B-cell neoplasms / Treatment of pediatric BCMA+ relapsed or refractory B non-Hodgkin lymphoma

Day 90 discussion

Action: For discussion

Oncology

3.1.11. Vinorelbine - EMEA-002365-PIP01-18

Treatment of rhabdomyosarcoma / Maintenance therapy after 1st relapse treatment, Treatment of relapsed or refractory rhabdomyosarcoma, Maintenance therapy for high-risk rhabdomyosarcoma patients achieving complete remission after frontline treatment

Day 90 discussion

Action: For discussion

Oncology

3.1.12. Aflibercept - EMEA-000236-PIP05-18

Treatment of retinopathy of prematurity (ROP)

Day 90 discussion

Action: For discussion

Ophthalmology

3.1.13. [Nintedanib - Orphan - EMEA-001006-PIP05-18](#)

Boehringer Ingelheim International GmbH; Treatment of fibrosing interstitial lung diseases (ILD) / Treatment of fibrosing interstitial lung diseases (ILD) in paediatric patients

Day 90 discussion

Action: For discussion

Pneumology - Allergology / Oncology

3.1.14. [EMEA-002307-PIP01-17](#)

Prevention of Ebola virus disease / Prevention of Ebola virus disease (EVD) in children aged ≥ 1 year

Day 90 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.15. [EMEA-002308-PIP01-17](#)

Prevention of Ebola virus disease / Prevention of Ebola virus disease (EVD) in children aged ≥ 1 year

Day 90 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.16. [EMEA-002451-PIP01-18](#)

Alopecia Areata

Day 60 discussion

Action: For discussion

Dermatology

3.1.17. [EMEA-002464-PIP01-18](#)

Treatment of atopic dermatitis / Treatment of patients with moderate-to-severe atopic dermatitis.

Day 60 discussion

Action: For discussion

Dermatology

3.1.18. Trifarotene EMEA-001492-PIP02-18

Treatment of lamellar ichthyosis

Day 60 discussion

Action: For discussion

Dermatology

3.1.19. EMEA-002448-PIP01-18

Treatment of non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.20. C1 esterase inhibitor (human) - EMEA-000568-PIP02-18

Treatment of hereditary angioedema

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18

Breath Therapeutics GmbH; Treatment of bronchiolitis obliterans syndrome (BOS)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. Baloxavir marboxil - EMEA-002440-PIP01-18

Prevention of Influenza, Treatment of Influenza/Treatment of influenza type A/B in otherwise healthy, high risk and hospitalised patients/Prevention (post exposure prophylaxis) of influenza type A/B. Reduction of transmission of influenza type A/B.

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.23. Hydrocortisone - EMEA-002305-PIP01-17

Prevention of bronchopulmonary dysplasia

Day 60 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.24. Padsevonil - EMEA-002466-PIP01-18

Treatment of focal-onset seizures (FOS) in patients with epilepsy / Treatment of FOS in paediatric patients (≥ 2 to < 18 years of age) with epilepsy.

Day 60 discussion

Action: For discussion

Neurology

3.1.25. Larotrectinib - Orphan - EMEA-001971-PIP03-18

Bayer AG; Treatment of malignant neoplasms of the central nervous system (CNS) / Treatment of paediatric patients with a primary CNS tumour with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion

Day 60 discussion

Action: For discussion

Oncology

3.1.26. Marizomib - EMEA-002452-PIP01-18

Treatment of malignant glial tumors / Treatment of patients (paediatric) with diffuse intrinsic pontine glioma (DIPG) who have received radiation therapy.

Day 60 discussion

Action: For discussion

Oncology

3.1.27. Aldesleukin- EMEA-002492-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, and lymphoid tissue) / treatment of a relapsed or refractory paediatric malignant solid tumour in paediatric patients less than 18 years old, treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old

Day 60 discussion

Action: For discussion

Oncology

3.1.28. [Zanubrutinib - EMEA-002354-PIP02-18](#)

Treatment of mature B-cell neoplasms excluding lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia), Treatment of lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / Treatment of primary mediastinal B-cell lymphoma, Treatment of Burkitt lymphoma, Treatment of diffuse large B-cell lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.29. [Pneumococcal Polyssacharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate - EMEA-002330-PIP01-18](#)

Disease caused by *Streptococcus pneumoniae*

Day 60 discussion

Action: For discussion

Vaccines

3.1.30. Recombinant respiratory syncytial virus fusion (RSV F) glycoprotein - EMEA-001985-PIP01-18

Prevention of respiratory syncytial virus (RSV) disease in infants via maternal immunization

Day 60 discussion

Action: For discussion

Vaccines

3.1.31. Rosuvastatin calcium / fenofibrate - EMEA-002509-PIP01-18

Mixed dislipidemia, i.e. hypertriglyceridemia combined with hypercholesterolemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. EMEA-002481-PIP01-18

Moderate to severe atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.33. Serlopitant - EMEA-002496-PIP01-18

Treatment of prurigo nodularis

Day 30 discussion

Action: For discussion

Dermatology

3.1.34. Gadopiclenol - EMEA-001949-PIP02-18

Diagnostic / Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions.

Day 30 discussion

Action: For discussion

Diagnostic

3.1.35. Levonorgestrel - EMEA-002474-PIP02-18

Contraception

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.36. [Norursodeoxycholic acid - Orphan - EMEA-002485-PIP01-18](#)

Dr. Falk Pharma GmbH; Primary sclerosing cholangitis (PSC)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.37. [AAV2/S3-FRE1-TI-FIXco1 vector - Orphan - EMEA-002518-PIP01-18](#)

Freeline Therapeutics Limited; Haemophilia B

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.38. [Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 - Orphan - EMEA-002479-PIP01-18](#)

Omeros London Limited; Treatment of haematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA).

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.39. [Anti-CD7 mAb conjugated to ricin toxin A chain / anti-CD3 mAb conjugated to ricin toxin A chain - Orphan - EMEA-002087-PIP01-16](#)

Xenikos BV; Steroid refractory acute graft versus host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.40. [Secukinumab - EMEA-000380-PIP05-18](#)

Hidradenitis suppurativa

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.41. Upadacitinib - EMEA-001741-PIP06-18

Treatment of Vasculitides

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.42. Artesunate - Orphan - EMEA-002402-PIP02-18

ACE Pharmaceuticals BV; Plasmodia infections / Treatment of severe malaria caused by Plasmodium falciparum in children aged 1 month to 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.43. Delafloxacin - EMEA-001080-PIP03-18

Treatment of community acquired pneumonia (CAP)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.44. Equine Immunoglobulin F(ab')₂ fragments targeting Shiga toxin - Orphan - EMEA-002444-PIP02-18

Chemo Research, S.L.; Prevention of Shiga-toxin producing Escherichia Coli haemolytic uremic syndrome

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.45. Tazobactam sodium / cefepime hydrochloride - EMEA-002483-PIP01-18

Treatment of complicated urinary tract infections (cUTI)

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care / Infectious Diseases / Uro-nephrology

3.1.46. EMEA-002419-PIP02-18

Prostate-specific membrane antigen (PSMA)-expressing metastatic, castration-resistant, prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Crizotinib - EMEA-001493-PIP03-18

Anaplastic lymphoma kinase (ALK)-positive inflammatory myofibroblastic tumour (IMT), ALK-positive anaplastic large cell lymphoma (ALCL) / Treatment of paediatric patients with relapsed/refractory systemic ALK-positive ALCL, Treatment of paediatric patients with unresectable or relapsed/refractory ALK-positive IMT

Day 30 discussion

Action: For discussion

Oncology

3.1.48. Flucytosine - Orphan - EMEA-002437-PIP02-18

Tocagen Inc; Treatment of glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.49. L-asparaginase - Orphan - EMEA-000341-PIP03-18

ERYTECH Pharma S.A.; Treatment of pancreatic cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Rivoceranib mesylate - Orphan - EMEA-002489-PIP01-18

LSK BioPharma Limited; Treatment of gastric cancer / Treatment of adult patients with advanced or metastatic gastric cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.51. Rogaratinib - EMEA-002439-PIP01-18

Treatment of urothelial carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.52. EMEA-002504-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms expressing CEACAM5 protein

Day 30 discussion

Action: For discussion

Oncology

3.1.53. Tislelizumab - EMEA-002480-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Day 30 discussion

Action: For discussion

Oncology

3.1.54. Vocimagene amiretrorepvec - Orphan - EMEA-002505-PIP02-18

Tocagen Inc.; Treatment of glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.55. Cenergermin - Orphan - EMEA-001729-PIP02-18

Dompé farmaceutici S.p.A.; Treatment of dry eye disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.56. EMEA-002484-PIP01-18

Asthma / Use as an add-on controller medication in the treatment of adults, adolescents

and children (>5 years of age) with inadequately controlled asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.57. Orvepitant - EMEA-002510-PIP01-18

Treatment of refractory chronic cough

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.58. Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues - Orphan - EMEA-002493-PIP01-18

Dicerna EU Limited; Treatment of primary hyperoxaluria

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

3.2.1. Sebelipase alfa - EMEA-C-001331-PIP01-12-M02

Alexion Europe SAS; Treatment of lysosomal acid lipase deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Gastroenterology-Hepatology

3.2.2. Rabeprazole (sodium) - EMEA-C-000055-PIP01-07-M06

Eisai Ltd.; Treatment of gastro-oesophageal reflux disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.3. Rituximab - EMEA-C-000308-PIP02-11-M01

Roche Registration GmbH; Treatment of granulomatosis with polyangiitis (Wegener's)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.4. Denosumab - EMEA-C-000145-PIP01-07-M09

Amgen Europe B.V.; Treatment of giant cell tumour of bone

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Pembrolizumab - EMEA-C-001474-PIP01-13-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue).

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Conestat Alfa - EMEA-C-000367-PIP01-08-M08

Pharming Group N.V.; Treatment of hereditary angioedema (HAE)

Day 30 discussion

Action: For discussion

Other

3.2.7. Peanut allergen extract - EMEA-C1-001481-PIP01-13-M03

DBV Technologies S.A.; Treatment of peanut allergy

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Corifollitropin alfa - EMEA-000306-PIP01-08-M04

Merck Sharp & Dohme B.V.; Inability to achieve pregnancy, Treatment of hypogonadotropic hypogonadism / female adults, boys

Day 30 discussion

Action: For discussion

3.3.2. Rivaroxaban - EMEA-000430-PIP01-08-M11

Bayer AG; Treatment of thromboembolic events, Prevention of thromboembolic events / Treatment (secondary prevention) of venous thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Ertugliflozin L-PGA - EMEA-001533-PIP01-13-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M04

Amicus Therapeutics UK Limited; Treatment of Fabry disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M03

Shire Pharmaceuticals Ireland Limited; Treatment of hypoparathyroidism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Luspatercept - Orphan - EMEA-001521-PIP01-13-M03

Celgene Europe B.V.; Anemias due to chronic disorders / Treatment of anaemia in patients with beta-thalassemia intermedia and major

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. Nonacog beta pegol (glycopegylated recombinant coagulation factor IX) - Orphan - EMEA-000731-PIP01-09-M03

Novo Nordisk A/S; ICD10-D67-Hereditary factor IX deficiency / Treatment and prophylaxis of bleeding in patient with Haemophilia B (congenital factor IX deficiency)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. Roxadustat - EMEA-001557-PIP01-13-M03

Astellas Pharma Europe B.V.; Treatment of anaemia due to chronic disorders

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Tofacitinib citrate - EMEA-000576-PIP01-09-M10

Pfizer Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) / Juvenile idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Upadacitinib - EMEA-001741-PIP02-16-M01

AbbVie Ltd; Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.3.11. Upadacitinib - EMEA-001741-PIP03-16-M01

AbbVie Ltd; Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.3.12. Ceftolozane / tazobactam - EMEA-001142-PIP01-11-M03

Merck Sharp & Dohme (Europe), Inc.; Treatment of abdominal and gastrointestinal infections, Treatment of urinary tract infections / Treatment of complicated urinary tract infections (cUTI), Treatment of complicated intra-abdominal infections (cIAI)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Etravirine - EMEA-000222-PIP01-08-M09

Janssen-Cilag International NV; Treatment of HIV-1 virus infection / Treatment of HIV-1 infection in antiretroviral treatment-experienced adolescents and children from 2 months of age and older

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Oritavancin diphosphate - EMEA-001270-PIP01-12-M02

Rempex London Ltd; Treatment of skin and subcutaneous tissue bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Inebilizumab - Orphan - EMEA-001911-PIP01-15-M02

Viela Bio; Neuromyelitis optica spectrum disorder (NMOSD)

Day 30 discussion

Action: For discussion

Neurology

3.3.16. Teriflunomide - EMEA-001094-PIP01-10-M05

Genzyme Europe B.V. / Sanofi-Aventis groupe; Multiple sclerosis / Treatment of children and adolescents from 10 to less than 18 years of age with relapsing forms of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Regorafenib - EMEA-001178-PIP01-11-M04

Bayer AG; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of paediatric patients with a solid malignant tumour(s) integrated with anti-cancer therapy

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M07

MediWound Germany GmbH; Treatment of burns of external body surfaces / Removal of eschar in deep partial and/or full thickness burns

Day 30 discussion

Action: For discussion

Other

3.3.19. Idarucizumab - EMEA-001438-PIP01-13-M01

Boehringer Ingelheim international GmbH; Prevention of dabigatran associated haemorrhage, Treatment of dabigatran associated haemorrhage

Day 30 discussion

Action: For discussion

Other

3.3.20. Selexipag - EMEA-000997-PIP01-10-M02

Janssen Cilag International NV; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Other

3.3.21. Fevipirant - EMEA-001315-PIP02-16-M01

Novartis EuroPharm Limited; Treatment of uncontrolled persistent asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.22. Peanut flour - EMEA-001734-PIP01-14-M04

Aimmune Therapeutics Inc; Peanut oral immunotherapy for the reduction in clinical reactivity to accidental exposure in peanut children and adults

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.23. Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup W-135 polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16-M01

Sanofi Pasteur; Prevention of meningococcal disease

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4.1. List of letters of intent received for submission of applications with start of procedure 01 April 2019 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Discussions on the applicability of class waiver for products

6.1.1. EMEA-17-2018

Roche Registration GmbH; All classes of medicinal products for treatment of Alzheimer's disease / Treatment of Alzheimer's disease.

Action: For adoption

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

No items.

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

No items.

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

PCWP and HCPWP revised Rules of procedure

PCWP revised Mandate and composition

HCPWP revised Mandate and composition

Action: For adoption

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Action: For information

9.5. Cooperation with International Regulators

No items.

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

No items.

9.7. PDCO work plan

No items.

9.8. Planning and reporting

No items.

10. Any other business

No items.

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 12:30 - 13:30, room 3G

11.1.2. Neonatology

Action: For discussion on Thursday, 12:30 - 13:30, room 3H

11.1.3. Inventory

Action: For discussion on Thursday, 12:30 - 13:30, room 3A

11.1.4. Systemic lupus erythematosus

Action: For discussion on Thursday, 12:30 - 13:30, room 3L

12. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)

A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)

A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)

The development plan for a medicine can be modified at a later stage as knowledge increases. Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.

In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)

As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived. For more information on the classes of diseases subject to waivers, see [class waivers](#).

Annual reports on deferrals (section 8)

If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/