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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 22-25 June 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

22 June 2021, 11:00- 19:00

23 June 2021, 08:30- 19:00

24 June 2021, 08:30- 19:00

25 June 2021, 08:30- 13:00

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* 9.3.3: mention of minutes of meeting was removed.

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Table of contents

1.	Introductions	11
1.1.	Welcome and declarations of interest of members, alternates and experts.....	11
1.2.	Adoption of agenda	11
1.3.	Adoption of the minutes	11
2.	Opinions	11
2.1.	Opinions on Products.....	11
2.1.1.	Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells - EMEA-002886-PIP01-20	11
2.1.2.	Infigratinib - EMEA-002594-PIP02-20.....	11
2.1.3.	(1R,3S,5R)-2-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromo-3-methylpyridin-2-yl)-5-methyl-2-azabicyclo[3.1.0]hexane-3-carboxamide - Orphan - EMEA-002863-PIP01-20	12
2.1.4.	EMEA-002350-PIP03-20	12
2.1.5.	Fenebrutinib - EMEA-002349-PIP03-20.....	12
2.1.6.	Itraconazole - Orphan - EMEA-002787-PIP01-20	12
2.1.7.	Trimodulin - EMEA-002883-PIP01-20	12
2.1.8.	Zidebactam / cefepime - EMEA-002892-PIP01-20.....	13
2.1.9.	Ublituximab - EMEA-002889-PIP02-20	13
2.1.10.	Vatiquinone - Orphan - EMEA-001238-PIP02-20	13
2.1.11.	Afamitresgene autoleucel - Orphan - EMEA-002867-PIP01-20	13
2.1.12.	Allogeneic anti-CD19 CAR T cells produced using CRISPR/Cas9 to disrupt the T cell receptor alpha constant (TRAC) and β 2-microglobulin (B2M) genomic loci and a recombinant adeno-associated viral vector to deliver donor template for insertion of the anti-CD19 CAR expression cassette into the TRAC locus (CTX110) - EMEA-002881-PIP01-20.....	13
2.1.13.	Iptacopan - Orphan - EMEA-002705-PIP03-20.....	14
2.1.14.	Bardoxolone methyl - Orphan - EMEA-002488-PIP01-18.....	14
2.1.15.	Hydrochlorothiazide / Amlodipine / Ramipril - EMEA-002998-PIP01-21.....	14
2.1.16.	Empagliflozin - EMEA-000828-PIP07-21	14
2.1.17.	Semaglutide / insulin icodec - EMEA-002988-PIP01-21.....	14
2.1.18.	Aldafermin - EMEA-003005-PIP01-21	14
2.1.19.	Immunoglobulin G1 anti-SORT1 human monoclonal antibody - EMEA-002997-PIP01-21...	15
2.1.20.	Cetrelimab - EMEA-003006-PIP01-21.....	15
2.1.21.	Datopotamab deruxtecan - EMEA-002976-PIP02-21.....	15
2.1.22.	Gemcitabine - EMEA-003007-PIP01-21.....	15
2.1.23.	Gabapentin - EMEA-002994-PIP01-21	15
2.1.24.	Sivopixant - EMEA-003010-PIP01-21	16
2.2.	Opinions on Compliance Check	16
2.2.1.	Enalapril maleate - EMEA-C-001706-PIP01-14-M03	16

2.2.2.	Cobimetinib - EMEA-C-001425-PIP01-13-M05	16
2.2.3.	Elvitegravir / Cobicistat / emtricitabine / Tenofovir alafenamide - EMEA-C-001460-PIP01-13-M05	16
2.2.4.	Secukinumab - EMEA-C-000380-PIP02-09-M04	16
2.2.5.	Dimethyl fumarate - EMEA-C-000832-PIP01-10-M05	17
2.3.	Opinions on Modification of an Agreed Paediatric Investigation Plan	17
2.3.1.	Clevidipine - EMEA-000282-PIP01-08-M03.....	17
2.3.2.	Sacubitril/valsartan - EMEA-000316-PIP02-11-M05.....	17
2.3.3.	Baricitinib - EMEA-001220-PIP03-16-M02	17
2.3.4.	Dupilumab - EMEA-001501-PIP01-13-M07.....	17
2.3.5.	Lebrikizumab - EMEA-002536-PIP01-18-M01	18
2.3.6.	Ligelizumab - EMEA-001811-PIP02-15-M04	18
2.3.7.	Tralokinumab - EMEA-001900-PIP02-17-M05.....	18
2.3.8.	Liraglutide - EMEA-000128-PIP02-09-M04	18
2.3.9.	Ferric maltol - EMEA-001195-PIP01-11-M05	18
2.3.10.	Giroctocogene fitelparavec - Orphan - EMEA-002724-PIP01-19-M01	18
2.3.11.	Rurioctocog alfa pegol - EMEA-001296-PIP01-12-M04	19
2.3.12.	Tocilizumab - EMEA-000309-PIP04-17-M03	19
2.3.13.	Cenobamate - EMEA-002563-PIP02-19-M01	19
2.3.14.	Ocrelizumab - EMEA-000310-PIP03-10-M05.....	19
2.3.15.	Phenobarbital - EMEA-002532-PIP01-18-M01.....	19
2.3.16.	Temelimab - EMEA-002127-PIP01-17-M01.....	20
2.3.17.	Cabozantinib - Orphan - EMEA-001143-PIP01-11-M03	20
2.3.18.	Cemiplimab - EMEA-002007-PIP02-17-M01	20
2.3.19.	Ibrutinib - Orphan - EMEA-001397-PIP03-14-M06	20
2.3.20.	Quizartinib - Orphan - EMEA-001821-PIP01-15-M05	20
2.3.21.	Sirolimus - Orphan - EMEA-001416-PIP01-12-M03	20
2.3.22.	Andexanet alfa - EMEA-001902-PIP01-15-M05.....	21
2.3.23.	In vitro expanded autologous human articular chondrocytes - EMEA-002217-PIP01-17-M0221	
2.3.24.	Selexipag - EMEA-000997-PIP01-10-M05	21
2.3.25.	Xylitol / Procaine hydrochloride / Magnesium sulphate heptahydrate / Potassium chloride - EMEA-001171-PIP01-11-M02	21
2.3.26.	Lactobacillus reuteri - Orphan - EMEA-001895-PIP01-15-M01	21
2.3.27.	Fasinumab - EMEA-002059-PIP02-19-M01.....	22
2.3.28.	Seltorexant - EMEA-002746-PIP01-20-M01.....	22
2.3.29.	Vortioxetine - EMEA-000455-PIP02-10-M08	22
2.3.30.	Finerenone - EMEA-001623-PIP01-14-M04	22
2.3.31.	Ad26.ZEBOV - EMEA-002307-PIP01-17-M02	22
2.3.32.	Hepatitis B (rDNA) surface antigen adjuvanted - EMEA-001127-PIP02-11-M01.....	23

2.3.33.	MVA-BN-Filo - EMEA-002308-PIP01-17-M02	23
2.3.34.	Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup Y 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-M03	23
2.3.35.	Nirsevimab (MEDI8897) - EMEA-001784-PIP01-15-M03	23
2.4.	Opinions on Re-examinations	23
2.5.	Opinions on Review of Granted Waivers	23
2.6.	No items Finalisation and adoption of Opinions	24
2.7.	Partial Compliance Checks completed by EMA	24
2.7.1.	Deucravacitinib - EMEA-C2-002350-PIP01-18-M01	24
2.7.2.	Obeticholic acid - EMEA-C1-001304-PIP03-17	24
2.7.3.	Niraparib (as tosylate monohydrate) - EMEA-C1-002268-PIP02-18-M01	24
2.7.4.	Efgartigimod alfa - EMEA-C1-002597-PIP01-19-M01	24
2.7.5.	Tezepelumab - EMEA-C1-001613-PIP01-14-M04	24

3. Discussion of applications 25

3.1.	Discussions on Products D90-D60-D30.....	25
3.1.1.	EMEA-002870-PIP01-20	25
3.1.2.	Benralizumab - EMEA-001214-PIP05-19	25
3.1.3.	(S)-1-(5-((2,3-dihydro-[1,4]dioxino[2,3-b]pyridin-7-yl)sulfonyl)-3,4,5,6-tetrahydropyrrolo[3,4-c]pyrrol-2(1H)-yl)-3-hydroxy-2-phenylpropan-1-one - Orphan - EMEA-002924-PIP01-20	25
3.1.4.	Concizumab - Orphan - EMEA-002326-PIP04-20.....	25
3.1.5.	Baricitinib - EMEA-001220-PIP08-20	26
3.1.6.	Casirivimab - EMEA-002964-PIP01-21.....	26
3.1.7.	Imdevimab - EMEA-002965-PIP01-21	26
3.1.8.	Potassium Bitartrate / Citric Acid / L-Lactic Acid - EMEA-002917-PIP01-20	26
3.1.9.	Epcoritamab - EMEA-002907-PIP01-20.....	26
3.1.10.	Ligelizumab - EMEA-001811-PIP03-20	27
3.1.11.	Single chain urokinase plasminogen activator (scuPA) - Orphan - EMEA-002896-PIP01-20	27
3.1.12.	Sodium chloride solution 4.2% (w/v) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide - Orphan - EMEA-002935-PIP01-20.....	27
3.1.13.	Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20	27
3.1.14.	Bentricimab - EMEA-002766-PIP02-21	27
3.1.15.	Brepocitinib - EMEA-003011-PIP01-21	28
3.1.16.	Human Immunoglobulin G1 constant region – human ectodysplasin-A1 receptor-binding domain fusion protein - Orphan - EMEA-002995-PIP01-21	28
3.1.17.	Ulobetasol propionate - EMEA-003000-PIP01-21.....	28
3.1.18.	EMEA-002992-PIP01-21	28

3.1.19.	Ethinyl estradiol / Dienogest - EMEA-002229-PIP02-21	28
3.1.20.	Semaglutide - EMEA-001441-PIP06-21.....	28
3.1.21.	Recombinant adeno-associated viral (rAAV) vector expressing the human ornithine transcarbamylase (hOTC) gene - EMEA-002983-PIP01-21	29
3.1.22.	Sirolimus - EMEA-002982-PIP01-21	29
3.1.23.	6-[(3S,4S)-4-methyl-1-(pyrimidin-2-ylmethyl)pyrrolidin-3-yl]-3-tetrahydropyran-4-yl-7H-imidazo[1,5-a]pyrazin-8-one - Orphan - EMEA-002991-PIP01-21	29
3.1.24.	Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene - Orphan - EMEA-002730-PIP03-21.....	29
3.1.25.	Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene - Orphan - EMEA-002730-PIP04-21.....	29
3.1.26.	Efgartigimod alfa - Orphan - EMEA-002597-PIP04-21.....	30
3.1.27.	Apremilast - EMEA-000715-PIP06-21	30
3.1.28.	Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21	30
3.1.29.	Favipiravir - EMEA-002985-PIP01-21	30
3.1.30.	Givinostat - Orphan - EMEA-000551-PIP04-21	30
3.1.31.	EMEA-002993-PIP01-21	31
3.1.32.	EMEA-002635-PIP02-21	31
3.1.33.	Alectinib - EMEA-002431-PIP02-21	31
3.1.34.	Autologous T cells transduced with lentiviral vector containing a tandem chimeric antigen receptor directed against CD20 and CD19 - Orphan - EMEA-003009-PIP01-21	31
3.1.35.	Autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) genetically modified with the lentiviral vector IDUA LV, encoding for the human α -L-iduronidase (IDUA) cDNA - Orphan - EMEA-003001-PIP01-21	31
3.1.36.	EMEA-002990-PIP01-21	32
3.1.37.	Ralmitaront - EMEA-003003-PIP01-21.....	32
3.1.38.	EMEA-003002-PIP01-21	32
3.1.39.	Escherichia coli vaccine - EMEA-002996-PIP01-21	32
3.1.40.	Live, attenuated, dengue virus, serotype 4 (DENV4) / Live, attenuated, dengue virus, serotype 3 (DENV3) / Live, attenuated, chimeric dengue virus, serotype 2 (DENV2) / Live, attenuated, dengue virus, serotype 1 (DENV1) - EMEA-002999-PIP01-21	32
3.1.41.	Recombinant SARS-CoV-2 spike (S)-protein virus-like particle - EMEA-003008-PIP01-21	33
3.1.42.	Abelacimab - EMEA-003017-PIP01-21	33
3.1.43.	Bisoprolol / amlodipine / indapamide / perindopril (arginine) - EMEA-003015-PIP01-21....	33
3.1.44.	Dersimelagon - EMEA-002850-PIP02-21.....	33
3.1.45.	EMEA-003027-PIP01-21	33
3.1.46.	Prasterone / ethinylestradiol / levonorgestrel - EMEA-002960-PIP02-21	33
3.1.47.	EMEA-003019-PIP01-21	34
3.1.48.	Apraglutide - Orphan - EMEA-003016-PIP01-21.....	34
3.1.49.	Benralizumab - EMEA-001214-PIP07-21	34
3.1.50.	Izencitinib - EMEA-002757-PIP02-21.....	34

3.1.51.	Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene - Orphan - EMEA-003029-PIP01-21.....	34
3.1.52.	Mixture of 2 synthetic double-stranded N-Acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against hepatitis B virus - EMEA-002694-PIP02-21.....	35
3.1.53.	Azithromycin - EMEA-003021-PIP01-21	35
3.1.54.	Adeno-associated viral vector serotype rh.10 expressing beta-galactosidase - Orphan - EMEA-003020-PIP01-21	35
3.1.55.	Efgartigimod alfa - Orphan - EMEA-002597-PIP05-21.....	35
3.1.56.	2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting fused in sarcoma (FUS) pre-mRNA - EMEA-003024-PIP01-21.....	35
3.1.57.	Recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide - Orphan - EMEA-003022-PIP01-21	36
3.1.58.	Atezolizumab - EMEA-001638-PIP02-21	36
3.1.59.	Lorlatinib - EMEA-002669-PIP03-21	36
3.1.60.	Ociperlimab - EMEA-003028-PIP01-21	36
3.1.61.	Prednisolone - EMEA-003004-PIP01-21	36
3.1.62.	Selinexor - EMEA-002387-PIP02-21	37
3.1.63.	Vodobatinib - EMEA-003014-PIP01-21	37
3.1.64.	Vorasidenib - EMEA-002932-PIP02-21	37
3.1.65.	Recombinant humanized anti-blood dendritic cell antigen 2 (BDCA2) monoclonal antibody - EMEA-002555-PIP02-21	37
3.1.66.	Ligelizumab - EMEA-001811-PIP04-21	37
3.1.67.	Florbetaben (18F) - Orphan - EMEA-001090-PIP02-21	37
3.1.68.	A recombinant SARS-CoV-2 Spike (S)-trimer fusion protein - EMEA-002987-PIP01-21	38
3.1.69.	Pemigatinib - Orphan - EMEA-002370-PIP02-21	38
3.1.70.	Cendakimab - EMEA-002640-PIP01-19.....	38
3.1.71.	Ribitol - Orphan - EMEA-002887-PIP01-20.....	38
3.1.72.	Molnupiravir - EMEA-002940-PIP01-20.....	38
3.2.	Discussions on Compliance Check.....	39
3.2.1.	Ticagrelor - EMEA-C-000480-PIP01-08-M14.....	39
3.2.2.	Cipaglucosidase alfa - EMEA-C1-002447-PIP01-18-M01.....	39
3.2.3.	Liraglutide - EMEA-C3-000128-PIP02-09-M03	39
3.2.4.	Octocog alfa - EMEA-C-001064-PIP01-10-M03	39
3.2.5.	Doravirine / tenofovir disoproxil (fumarate) / lamivudine - EMEA-C2-001695-PIP01-14-M0439	
3.2.6.	Brentuximab vedotin - EMEA-C-000980-PIP01-10-M07.....	40
3.2.7.	Ceftolozane / Tazobactam - EMEA-C-001142-PIP01-11-M04	40
3.2.8.	Doravirine - EMEA-C2-001676-PIP01-14-M04	40
3.2.9.	Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C - Diphtheria CRM197	

Conjugate / Pneumococcal Polysaccharide Serotype 14 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 1 - Diphtheria CRM197 Conjugate - EMEA-002215-PIP01-17-M0340

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan..... 41

3.3.1.	Entrectinib - EMEA-002096-PIP01-16-M03.....	41
3.3.2.	Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M01.....	41
3.3.3.	Brodalumab - EMEA-001089-PIP02-13-M02.....	41
3.3.4.	Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M05.....	41
3.3.5.	Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M03.....	41
3.3.6.	Metreleptin - Orphan - EMEA-001701-PIP01-14-M02.....	42
3.3.7.	Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M0542	
3.3.8.	Tolvaptan - EMEA-001231-PIP02-13-M08.....	42
3.3.9.	Dupilumab - EMEA-001501-PIP04-19-M01.....	42
3.3.10.	Naldemedine - EMEA-001893-PIP01-15-M02.....	42
3.3.11.	Pegylated-fibroblast growth factor 21 (BMS-986036) - EMEA-002448-PIP01-18-M02.....	42
3.3.12.	Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M01.....	43
3.3.13.	Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 (INN: narsoplimab) - Orphan - EMEA-002479-PIP01-18-M01.....	43
3.3.14.	Aztreonam / Avibactam - EMEA-002283-PIP01-17-M02.....	43
3.3.15.	Cabotegravir - EMEA-001418-PIP01-13-M03.....	43
3.3.16.	Cabotegravir - EMEA-001418-PIP02-15-M02.....	43
3.3.17.	Remdesivir - EMEA-002826-PIP01-20-M02.....	44
3.3.18.	Bumetanide - EMEA-001303-PIP01-12-M04.....	44
3.3.19.	Lacosamide - EMEA-000402-PIP03-17-M05.....	44
3.3.20.	Autologous tumor-infiltrating lymphocytes (LN-144/LN-145) - EMEA-002776-PIP01-20-M0144	
3.3.21.	Bintrafusp alfa - Orphan - EMEA-002586-PIP01-19-M02.....	44
3.3.22.	Bosutinib - EMEA-000727-PIP01-09-M05.....	45
3.3.23.	Selumetinib - Orphan - EMEA-001585-PIP01-13-M05.....	45
3.3.24.	Bupropion HCl / Naltrexone HCl - EMEA-001373-PIP01-12-M04.....	45
3.3.25.	Eliglustat - Orphan - EMEA-000461-PIP02-11-M04.....	45
3.3.26.	Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M07.....	45
3.3.27.	Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16-M03.....	45
3.3.28.	Patiromer sorbitex calcium - EMEA-001720-PIP01-14-M02.....	46
3.3.29.	Bupivacaine - EMEA-000877-PIP03-17-M03.....	46
3.3.30.	Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M07.....	46
3.3.31.	Berotralstat - EMEA-002449-PIP02-18-M01.....	46

3.3.32.	Mometasone (furoate) / Glycopyrronium bromide / Indacaterol - EMEA-001812-PIP01-15-M01	46
3.3.33.	Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M03	47
3.3.34.	Recombinant Clostridioides difficile Toxoids A and B - EMEA-002112-PIP01-16-M01.....	47
3.3.35.	(R)-2-amino-3-phenylpropylcarbamate hydrochloride - EMEA-002184-PIP01-17-M01	47
3.3.36.	Dasiglucagon - Orphan - EMEA-002233-PIP01-17-M01	47
3.3.37.	Pretomanid - Orphan - EMEA-002115-PIP01-17-M03	47
3.3.38.	Pevonedistat - Orphan - EMEA-002117-PIP01-17-M02	48
3.3.39.	Pneumococcal polysaccharide serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate - EMEA-002330-PIP01-18-M01	48

4.	Nominations	48
4.1.	List of submissions of applications with start of procedure 12 July 2021 for Nomination of Rapporteur and Peer reviewer.....	49
4.2.	Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	49
4.3.	Nominations for other activities	49
5.	Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction	49
6.	Discussion on the applicability of class waivers	49
6.1.	Discussions on the applicability of class waiver for products.....	49

6.1.1.	Pegcetacoplan - EMEA-08-2021	49
6.1.2.	Darolutamide - EMEA-02-2021	49
6.1.3.	Trastuzumab deruxtecan - EMEA-03-2021	49
6.1.4.	EMEA-05-2021	50
6.1.5.	Abiraterone - EMEA-09-2021.....	50

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver 50

7.1.	Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver	50
-------------	--	-----------

8. Annual reports on deferrals 50

9. Organisational, regulatory and methodological matters 50

9.1.	Mandate and organisation of the PDCO.....	50
9.1.1.	Revision of the Summary Report template (B-F scientific document)	50
9.1.2.	Deadlines for paediatric applications 2020-2024	51
9.2.	Coordination with EMA Scientific Committees or CMDh-v	51
9.2.1.	Committee for Medicinal Products for Human Use (CHMP)	51
9.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	51
9.3.1.	Non-clinical Working Group: D30 Products identified	51
9.3.2.	Formulation Working Group	51
9.3.3.	Patients and Consumers Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 1-2 June 2021.....	51
9.3.4.	EMA Working Party review	51
9.4.	Cooperation within the EU regulatory network.....	51
9.4.1.	European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA).....	51
9.4.2.	Exchange between Clinical Trials Facilitation and Coordination Group (CTFG) and PDCO ...	51
9.4.3.	PDCO / Health technology assessment (HTA) interaction – update on current initiatives ...	52
9.5.	Cooperation with International Regulators.....	52
9.5.1.	Feedback from 6th Paediatric Oncology Strategy Forum on CAR T cell development.....	52
9.6.	Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee.....	52
9.7.	PDCO work plan.....	52
9.8.	Planning and reporting	52

10. Any other business 52

10.1.	COVID -19 update.....	52
10.2.	EU innovation network Horizon Scanning report on Genome Editing	52
10.3.	EMA Business Pipeline activity and Horizon scanning	52

11. Breakout sessions 52

11.1.	Internal PDCO Operations	52
--------------	---------------------------------------	-----------

11.2.	Vaccines	53
11.3.	Paediatric oncology	53
11.4.	Neonatology	53
12.	Explanatory notes	54

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 22-25 June 2021. See June 2021 PDCO minutes (to be published post July 2021 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 22-25 June 2021

1.3. Adoption of the minutes

PDCO minutes for 18-21 May 2021

2. Opinions

Some information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells - EMEA-002886-PIP01-20

Atopic dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Infigratinib - EMEA-002594-PIP02-20

Achondroplasia / Treatment of achondroplasia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. (1R,3S,5R)-2-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromo-3-methylpyridin-2-yl)-5-methyl-2-azabicyclo[3.1.0]hexane-3-carboxamide - Orphan - EMEA-002863-PIP01-20

Alexion Europe SAS; Paroxysmal nocturnal haemoglobinuria

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. EMEA-002350-PIP03-20

Treatment of systemic lupus erythematosus (SLE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.5. Fenebrutinib - EMEA-002349-PIP03-20

Multiple sclerosis / Treatment of multiple sclerosis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. Itraconazole - Orphan - EMEA-002787-PIP01-20

Laboratoires S.M.B. S.A.; Prevention of invasive mould disease

Day 120 opinion

Action: For adoption

Infectious Diseases / Oncology

2.1.7. Trimodulin - EMEA-002883-PIP01-20

Treatment of infections

Day 120 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care / Infectious Diseases / Pneumology – Allergology

Note: Withdrawal request received on 15 June 2021

2.1.8. Zidebactam / cefepime - EMEA-002892-PIP01-20

Treatment of complicated urinary tract infections

Day 120 opinion

Action: For adoption

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

2.1.9. Ublituximab - EMEA-002889-PIP02-20

Treatment of multiple sclerosis

Day 120 opinion

Action: For adoption

Neurology

2.1.10. Vatiquinone - Orphan - EMEA-001238-PIP02-20

PTC Therapeutics International Limited; Treatment of mitochondrial epilepsy, excluding Leigh Syndrome / Treatment of mitochondrial disease

Day 120 opinion

Action: For adoption

Neurology

2.1.11. Afamitresgene autoleucel - Orphan - EMEA-002867-PIP01-20

Adaptimmune Ltd; Treatment of soft tissue sarcoma

Day 120 opinion

Action: For adoption

Oncology

2.1.12. Allogeneic anti-CD19 CAR T cells produced using CRISPR/Cas9 to disrupt the T cell receptor alpha constant (TRAC) and β 2-microglobulin (B2M) genomic loci and a recombinant adeno-associated viral vector to deliver donor template for insertion of the anti-CD19 CAR expression cassette into the TRAC locus (CTX110) - EMEA-002881-PIP01-20

B cell lymphoblastic leukemia/ lymphoma/ Mature B cell neoplasms

Day 120 opinion

Action: For adoption

Oncology

2.1.13. Iptacopan - Orphan - EMEA-002705-PIP03-20

Novartis Europharm Limited; Paroxysmal nocturnal haemoglobinuria

Day 120 opinion

Action: For adoption

Other / Haematology-Hemostaseology

2.1.14. Bardoxolone methyl - Orphan - EMEA-002488-PIP01-18

Reata Pharmaceuticals Inc.; Treatment of Alport syndrome

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.15. Hydrochlorothiazide / Amlodipine / Ramipril - EMEA-002998-PIP01-21

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Empagliflozin - EMEA-000828-PIP07-21

Treatment of ischaemic heart disease

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.17. Semaglutide / insulin icodec - EMEA-002988-PIP01-21

Type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.18. Aldafermin - EMEA-003005-PIP01-21

Treatment of non-alcoholic steatohepatitis (NASH)

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.19. [Immunoglobulin G1 anti-SORT1 human monoclonal antibody - EMEA-002997-PIP01-21](#)

Treatment of dementia

Day 60 opinion

Action: For adoption

Neurology

2.1.20. [Cetrelimab - EMEA-003006-PIP01-21](#)

Treatment of urothelial carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.21. [Datopotamab deruxtecan - EMEA-002976-PIP02-21](#)

Treatment of breast cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.22. [Gemcitabine - EMEA-003007-PIP01-21](#)

Treatment of urothelial carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.23. [Gabapentin - EMEA-002994-PIP01-21](#)

Treatment of postherpetic neuralgia

Day 60 opinion

Action: For adoption

Pain / Neurology

2.1.24. Sivopixant - EMEA-003010-PIP01-21

Unexplained or refractory chronic cough

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.2. Opinions on Compliance Check

2.2.1. Enalapril maleate - EMEA-C-001706-PIP01-14-M03

Proveca Pharma Limited; Treatment of heart failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.2.2. Cobimetinib - EMEA-C-001425-PIP01-13-M05

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) with Ras, Raf or MEK pathway activation

Day 60 opinion

Action: For adoption

Oncology

2.2.3. Elvitegravir / Cobicistat / emtricitabine / Tenofovir alafenamide - EMEA-C-001460-PIP01-13-M05

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 opinion

Action: For adoption

Infectious Diseases

2.2.4. Secukinumab - EMEA-C-000380-PIP02-09-M04

Novartis Europharm Ltd; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 opinion

Action: For adoption

2.2.5. Dimethyl fumarate - EMEA-C-000832-PIP01-10-M05

Biogen Idec Ltd; Treatment of multiple sclerosis

Day 30 opinion

Action: For information. Adopted via written procedure on 14 June 2021

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Clevidipine - EMEA-000282-PIP01-08-M03

Chiesi Farmaceutici S.p.A.; Treatment of hypertensive disease

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Sacubitril/valsartan - EMEA-000316-PIP02-11-M05

Novartis Europharm Ltd.; Heart failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Baricitinib - EMEA-001220-PIP03-16-M02

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Dupilumab - EMEA-001501-PIP01-13-M07

Regeneron Pharmaceuticals, Inc; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. Lebrikizumab - EMEA-002536-PIP01-18-M01

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Ligelizumab - EMEA-001811-PIP02-15-M04

Novartis Europharm Limited; Treatment of chronic spontaneous urticaria

Day 60 opinion

Action: For adoption

Dermatology

2.3.7. Tralokinumab - EMEA-001900-PIP02-17-M05

LEO Pharma A/S; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.8. Liraglutide - EMEA-000128-PIP02-09-M04

Novo Nordisk A/S; Obesity

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.9. Ferric maltol - EMEA-001195-PIP01-11-M05

Norgine BV; Treatment of iron deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.10. Giroctocogene fitelparvovec - Orphan - EMEA-002724-PIP01-19-M01

Pfizer Europe MA EEIG; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.11. Rurioctocog alfa pegol - EMEA-001296-PIP01-12-M04

Baxalta Innovations GmbH; Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.12. Tocilizumab - EMEA-000309-PIP04-17-M03

Roche Registration GmbH; Treatment of cytokine release syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.13. Cenobamate - EMEA-002563-PIP02-19-M01

A.C.R.A.F. SpA; Treatment of epilepsy

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Ocrelizumab - EMEA-000310-PIP03-10-M05

Roche Registration GmbH; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.15. Phenobarbital - EMEA-002532-PIP01-18-M01

Proveca Pharma Limited; Treatment of epilepsy

Day 60 opinion

Action: For adoption

Neurology

2.3.16. Temelimab - EMEA-002127-PIP01-17-M01

GeNeuro SA; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.17. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M03

Ipsen Pharma; Treatment of malignant solid tumours

Day 60 opinion

Action: For adoption

Oncology

2.3.18. Cemiplimab - EMEA-002007-PIP02-17-M01

Regeneron Ireland DAC; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 60 opinion

Action: For adoption

Oncology

2.3.19. Ibrutinib - Orphan - EMEA-001397-PIP03-14-M06

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm

Day 60 opinion

Action: For adoption

Oncology

2.3.20. Quizartinib - Orphan - EMEA-001821-PIP01-15-M05

Daiichi Sankyo Europe GmbH; Treatment of acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.21. Sirolimus - Orphan - EMEA-001416-PIP01-12-M03

Santen Incorporated; Treatment of non-infectious uveitis affecting the posterior segment of the eye

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.22. [Andexanet alfa - EMEA-001902-PIP01-15-M05](#)

Alexion Europe SAS; Treatment of factor Xa inhibitor associated haemorrhage / Prevention of factor Xa inhibitor associated haemorrhage

Day 60 opinion

Action: For adoption

Other

Note: Withdrawal request received on 15 June 2021

2.3.23. [In vitro expanded autologous human articular chondrocytes - EMEA-002217-PIP01-17-M02](#)

TETEC Tissue Engineering Technologies AG; Treatment of cartilage disorders

Day 60 opinion

Action: For adoption

Other

2.3.24. [Selexipag - EMEA-000997-PIP01-10-M05](#)

Janssen-Cilag International NV; Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Other

2.3.25. [Xylitol / Procaine hydrochloride / Magnesium sulphate heptahydrate / Potassium chloride - EMEA-001171-PIP01-11-M02](#)

MIT Gesundheit GmbH; Cardioplegia

Day 60 opinion

Action: For adoption

Other

2.3.26. [Lactobacillus reuteri - Orphan - EMEA-001895-PIP01-15-M01](#)

Infant Bacterial Therapeutics AB; Prevention of necrotising enterocolitis

Day 60 opinion

Action: For adoption

Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

2.3.27. Fasinumab - EMEA-002059-PIP02-19-M01

Regeneron Ireland D.A.C.; Chronic pain / Chronic non-musculoskeletal pain / Chronic musculoskeletal pain

Day 60 opinion

Action: For adoption

Pain

2.3.28. Seltorexant - EMEA-002746-PIP01-20-M01

Janssen-Cilag International NV; Major depressive disorder (MDD)

Day 60 opinion

Action: For adoption

Psychiatry

2.3.29. Vortioxetine - EMEA-000455-PIP02-10-M08

H. Lundbeck A/S; Major depressive disorder

Day 60 opinion

Action: For adoption

Psychiatry

2.3.30. Finerenone - EMEA-001623-PIP01-14-M04

Bayer AG; Chronic Kidney Disease

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.31. Ad26.ZEBOV - EMEA-002307-PIP01-17-M02

Janssen Cilag International NV; Prevention of Ebola virus disease

Day 60 opinion

Action: For adoption

Vaccines

2.3.32. Hepatitis B (rDNA) surface antigen adjuvanted - EMEA-001127-PIP02-11-M01

Dynavax GmbH; Prevention of hepatitis B virus infection

Day 60 opinion

Action: For adoption

Vaccines

2.3.33. MVA-BN-Filo - EMEA-002308-PIP01-17-M02

Janssen Cilag International NV; Prevention of Ebola virus disease

Day 60 opinion

Action: For adoption

Vaccines

2.3.34. Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup Y 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-M03

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 60 opinion

Action: For adoption

Vaccines

2.3.35. Nirsevimab (MEDI8897) - EMEA-001784-PIP01-15-M03

AstraZeneca AB; Prevention of respiratory syncytial viral infections

Day 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

No items

2.5. Opinions on Review of Granted Waivers

No items

2.6. No items Finalisation and adoption of Opinions

No items

2.7. Partial Compliance Checks completed by EMA

The following partial compliance checks have been identified by the PME coordinator and PDCO rapporteur as not needing to be referred to the PDCO for discussion. The PDCO has been informed in writing.

2.7.1. Deucravacitinib - EMEA-C2-002350-PIP01-18-M01

Bristol-Myers Squibb International Corporation; Treatment of psoriasis

Day 30 letter

Action: For information

Dermatology

2.7.2. Obeticholic acid - EMEA-C1-001304-PIP03-17

Intercept Pharma International Limited; Treatment of non-alcoholic steatohepatitis

Day 30 letter

Action: For information

Gastroenterology-Hepatology

2.7.3. Niraparib (as tosylate monohydrate) - EMEA-C1-002268-PIP02-18-M01

GlaxoSmithKline (Ireland) Limited; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

Day 1 letter

Action: For information

Oncology

2.7.4. Efgartigimod alfa - EMEA-C1-002597-PIP01-19-M01

Argenx BV; Treatment of myasthenia gravis

Day 30 letter

Action: For information

Neurology

2.7.5. Tezepelumab - EMEA-C1-001613-PIP01-14-M04

AstraZeneca AB; Treatment of asthma

Day 60 letter

Action: For information. Adopted via written procedure on 14 June.

Pneumology - Allergology

3. Discussion of applications

Some information related to this section cannot be disclosed 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-002870-PIP01-20

General anesthesia

Day 90 discussion

Action: For discussion

Anaesthesiology

3.1.2. Benralizumab - EMEA-001214-PIP05-19

Treatment of eosinophilic esophagitis (EoE)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. (S)-1-(5-((2,3-dihydro-[1,4]dioxino[2,3-b]pyridin-7-yl)sulfonyl)-3,4,5,6-tetrahydropyrrolo[3,4-c]pyrrol-2(1H)-yl)-3-hydroxy-2-phenylpropan-1-one - Orphan - EMEA-002924-PIP01-20

Forma Therapeutics, Inc.; Treatment of sickle cell disease

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Concizumab - Orphan - EMEA-002326-PIP04-20

Novo Nordisk A/S; Treatment of congenital haemophilia A / Treatment of congenital haemophilia B

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Baricitinib - EMEA-001220-PIP08-20

Treatment of alopecia areata

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Casirivimab - EMEA-002964-PIP01-21

Treatment of coronavirus disease 2019 (COVID-19) / Prophylaxis of SARS-CoV-2 infection / Treatment and decreased transmission of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Imdevimab - EMEA-002965-PIP01-21

Prophylaxis of SARS-CoV-2 infection / Treatment and decreased transmission of coronavirus disease 2019 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.8. Potassium Bitartrate / Citric Acid / L-Lactic Acid - EMEA-002917-PIP01-20

Prevention of urogenital Chlamydia trachomatis (CT) infection and Neisseria gonorrhoeae (GC) infections in females / Prevention of urogenital Chlamydia trachomatis (CT) infection and Neisseria gonorrhoeae (GC) infection in females / Prevention of urogenital Chlamydia trachomatis (CT) infection and Neisseria gonorrhoeae (GC) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.9. Epcoritamab - EMEA-002907-PIP01-20

Treatment of mature B-cell lymphoma

Day 90 discussion

Action: For discussion

Oncology

3.1.10. Ligelizumab - EMEA-001811-PIP03-20

Treatment of food allergy

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.11. Single chain urokinase plasminogen activator (scuPA) - Orphan - EMEA-002896-PIP01-20

Lung Therapeutics, Inc.; Treatment of infectious pleural effusion

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.12. Sodium chloride solution 4.2% (w/v) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide - Orphan - EMEA-002935-PIP01-20

Parion Sciences, Inc.; Primary Ciliary Dyskinesia (PCD)

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.13. Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20

Prevention of disease caused by *Streptococcus pneumoniae*

Day 90 discussion

Action: For discussion

Vaccines

3.1.14. Bentracimab - EMEA-002766-PIP02-21

Treatment of ticagrelor associated haemorrhage / Prevention of ticagrelor associated haemorrhage

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.15. [Breprocitinib - EMEA-003011-PIP01-21](#)

Treatment of atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.16. [Human Immunoglobulin G1 constant region – human ectodysplasin-A1 receptor-binding domain fusion protein - Orphan - EMEA-002995-PIP01-21](#)

EspeRare Foundation; X-linked hypohidrotic ectodermal dysplasia (XLHED)

Day 60 discussion

Action: For discussion

Dermatology

3.1.17. [Ulobetasol propionate - EMEA-003000-PIP01-21](#)

The proposed condition is moderate to severe plaque psoriasis/ The proposed medicinal product is aimed as "treatment" / Treatment of psoriasis

Day 60 discussion

Action: For discussion

Dermatology

3.1.18. [EMEA-002992-PIP01-21](#)

Treatment of Fibrodysplasia Ossificans Progressiva (FOP)

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.19. [Ethinyl estradiol / Dienogest - EMEA-002229-PIP02-21](#)

Treatment of polycystic ovary syndrome

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.20. [Semaglutide - EMEA-001441-PIP06-21](#)

Treatment of obesity

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Note: Withdrawal request received on 3 June 2021

3.1.21. [Recombinant adeno-associated viral \(rAAV\) vector expressing the human ornithine transcarbamylase \(hOTC\) gene - EMEA-002983-PIP01-21](#)

Ornithine transcarbamylase deficiency (OTCD)

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.22. [Sirolimus - EMEA-002982-PIP01-21](#)

Ornithine transcarbamylase deficiency (OTCD)

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.23. [6-\[\(3S,4S\)-4-methyl-1-\(pyrimidin-2-ylmethyl\)pyrrolidin-3-yl\]-3-tetrahydropyran-4-yl-7H-imidazo\[1,5-a\]pyrazin-8-one - Orphan - EMEA-002991-PIP01-21](#)

IMARA Inc; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.24. [Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene - Orphan - EMEA-002730-PIP03-21](#)

Vertex Pharmaceuticals (Ireland) Limited; Treatment of severe sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.25. [Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene - Orphan - EMEA-002730-PIP04-21](#)

Vertex Pharmaceuticals (Ireland) Limited; Treatment of beta-thalassemia intermedia and major

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.26. Efgartigimod alfa - Orphan - EMEA-002597-PIP04-21

argenx BV; Treatment of immune thrombocytopenia

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.27. Apremilast - EMEA-000715-PIP06-21

Treatment of coronavirus disease (COVID-19)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

Note: Withdrawal request received on 17 June 2021

3.1.28. Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21

Pharming Group N.V.; Activated phosphoinositide 3-kinase δ syndrome (APDS)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.29. Favipiravir - EMEA-002985-PIP01-21

Treatment of coronavirus disease (COVID-19)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.30. Givinostat - Orphan - EMEA-000551-PIP04-21

Italfarmaco S.p.A.; Treatment of Duchenne muscular dystrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.31. EMEA-002993-PIP01-21

Treatment of narcolepsy

Day 60 discussion

Action: For discussion

Neurology

3.1.32. EMEA-002635-PIP02-21

Treatment of advanced or metastatic malignancies harbouring ALK, ROS1, or NTRK1-3 alterations

Day 60 discussion

Action: For discussion

Oncology

3.1.33. Alectinib - EMEA-002431-PIP02-21

Treatment of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 60 discussion

Action: For discussion

Oncology

3.1.34. Autologous T cells transduced with lentiviral vector containing a tandem chimeric antigen receptor directed against CD20 and CD19 - Orphan - EMEA-003009-PIP01-21

Miltenyi Biomedicine GmbH; Diffuse large B cell lymphoma / Mature aggressive B cell non-Hodgkin lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.35. Autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) genetically modified with the lentiviral vector IDUA LV, encoding for the human α -L-iduronidase (IDUA) cDNA - Orphan - EMEA-003001-PIP01-21

Orchard Therapeutics Netherlands B.V.; Treatment of Mucopolysaccharidosis type I, Hurler syndrome (MPS-IH)

Day 60 discussion

Action: For discussion

Other

3.1.36. EMEA-002990-PIP01-21

Major depressive disorder

Day 60 discussion

Action: For discussion

Psychiatry

3.1.37. Ralmitaront - EMEA-003003-PIP01-21

Treatment of schizophrenia

Day 60 discussion

Action: For discussion

Psychiatry

3.1.38. EMEA-003002-PIP01-21

Treatment of proteinuric chronic kidney disease

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.39. Escherichia coli vaccine - EMEA-002996-PIP01-21

Prevention of E.coli infections

Day 60 discussion

Action: For discussion

Vaccines

3.1.40. Live, attenuated, dengue virus, serotype 4 (DENV4) / Live, attenuated, dengue virus, serotype 3 (DENV3) / Live, attenuated, chimeric dengue virus, serotype 2 (DENV2) / Live, attenuated, dengue virus, serotype 1 (DENV1) - EMEA-002999-PIP01-21

Prevention of dengue disease

Day 60 discussion

Action: For discussion

Vaccines

3.1.41. Recombinant SARS-CoV-2 spike (S)-protein virus-like particle - EMEA-003008-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Vaccines

3.1.42. Abelacimab - EMEA-003017-PIP01-21

Prevention of venous thromboembolism associated with cancer

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.43. Bisoprolol / amlodipine / indapamide / perindopril (arginine) - EMEA-003015-PIP01-21

Treatment of (essential) primary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.44. Dersimelagon - EMEA-002850-PIP02-21

Treatment of erythropoietic protoporphyria / Treatment of X-linked Protoporphyria

Day 30 discussion

Action: For discussion

Dermatology

3.1.45. EMEA-003027-PIP01-21

Treatment of Hyperphenylalaninaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.46. Prasterone / ethinylestradiol / levonorgestrel - EMEA-002960-PIP02-21

Oral contraception and treatment of hypoactive sexual desire disorder (HSDD) secondary to combined oral contraceptive use

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.47. EMEA-003019-PIP01-21

Treatment of inborn errors of amino acid metabolism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.48. Apraglutide - Orphan - EMEA-003016-PIP01-21

VectivBio AG; Treatment of short bowel syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.49. Benralizumab - EMEA-001214-PIP07-21

Treatment of eosinophilic gastritis/eosinophilic gastroenteritis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.50. Izencitinib - EMEA-002757-PIP02-21

Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.51. Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene - Orphan - EMEA-003029-PIP01-21

Aruvant Sciences GmbH; Sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.52. Mixture of 2 synthetic double-stranded N-Acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against hepatitis B virus - EMEA-002694-PIP02-21

Treatment of chronic hepatitis D infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.53. Azithromycin - EMEA-003021-PIP01-21

Prevention of bronchopulmonary dysplasia

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.54. Adeno-associated viral vector serotype rh.10 expressing beta-galactosidase - Orphan - EMEA-003020-PIP01-21

Lysogene; Treatment of GM1 gangliosidosis

Day 30 discussion

Action: For discussion

Neurology

3.1.55. Efgartigimod alfa - Orphan - EMEA-002597-PIP05-21

argenx BV; Treatment of myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.1.56. 2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting fused in sarcoma (FUS) pre-mRNA - EMEA-003024-PIP01-21

Amyotrophic lateral sclerosis (ALS) patients with fused in sarcoma (FUS) mutations (FUS-ALS) ≥ 12 years of age

Day 30 discussion

Action: For discussion

Neurology

3.1.57. Recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide - Orphan - EMEA-003022-PIP01-21

Larimar Therapeutics Inc.; Friedreich's ataxia

Day 30 discussion

Action: For discussion

Neurology

3.1.58. Atezolizumab - EMEA-001638-PIP02-21

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

Day 30 discussion

Action: For discussion

Oncology

3.1.59. Lorlatinib - EMEA-002669-PIP03-21

ALK-aberrant neuroblastoma

Day 30 discussion

Action: For discussion

Oncology

3.1.60. Ociperlimab - EMEA-003028-PIP01-21

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

3.1.61. Prednisolone - EMEA-003004-PIP01-21

Treatment of prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.62. Selinexor - EMEA-002387-PIP02-21

Recurrent or advanced endometrial cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.63. Vodobatinib - EMEA-003014-PIP01-21

Chronic myeloid leukemia

Day 30 discussion

Action: For discussion

Oncology

3.1.64. Vorasidenib - EMEA-002932-PIP02-21

Treatment of glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.65. Recombinant humanized anti-blood dendritic cell antigen 2 (BDCA2) monoclonal antibody - EMEA-002555-PIP02-21

Lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.66. Ligelizumab - EMEA-001811-PIP04-21

Treatment of chronic inducible urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.1.67. Florbetaben (18F) - Orphan - EMEA-001090-PIP02-21

Life Molecular Imaging GmbH; Diagnosis of cardiac amyloidosis

Day 30 discussion

Action: For discussion

3.1.68. A recombinant SARS-CoV-2 Spike (S)-trimer fusion protein - EMEA-002987-PIP01-21

Prevention of COVID-19 disease

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.69. Pemigatinib - Orphan - EMEA-002370-PIP02-21

Incyte Biosciences Distribution B.V.; Treatment of myeloid/lymphoid neoplasms with eosinophilia and FGFR1 rearrangement

Day 30 discussion

Action: For discussion

Oncology

3.1.70. Cendakimab - EMEA-002640-PIP01-19

Eosinophilic esophagitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.71. Ribitol - Orphan - EMEA-002887-PIP01-20

Premier Research Group S.L.; Treatment of Limb-Girdle muscular dystrophy

Day 90 discussion

Action: For discussion

Other

3.1.72. Molnupiravir - EMEA-002940-PIP01-20

Treatment of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.2. Discussions on Compliance Check

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

3.2.1. Ticagrelor - EMEA-C-000480-PIP01-08-M14

AstraZeneca AB; Prevention of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.2.2. Cipaglusosidase alfa - EMEA-C1-002447-PIP01-18-M01

Amicus Therapeutics Europe Limited; Treatment of glycogen storage disease Type II (Pompe's disease)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. Liraglutide - EMEA-C3-000128-PIP02-09-M03

Novo Nordisk A/S; Treatment of obesity

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.4. Octocog alfa - EMEA-C-001064-PIP01-10-M03

Bayer AG; Treatment of hereditary Factor VIII deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.5. Doravirine / tenofovir disoproxil (fumarate) / lamivudine - EMEA-C2-001695-PIP01-14-M04

Merck Sharp & Dohme (Europe), Inc; Treatment of human immunodeficiency virus type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.6. Brentuximab vedotin - EMEA-C-000980-PIP01-10-M07

Takeda Pharma A/S; Treatment of anaplastic large cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.2.7. Ceftolozane / Tazobactam - EMEA-C-001142-PIP01-11-M04

Merck Sharp & Dohme (Europe), Inc.; Treatment of intra-abdominal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.8. Doravirine - EMEA-C2-001676-PIP01-14-M04

Merck Sharp & Dohme (Europe), Inc; Treatment of human immunodeficiency virus type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.9. Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 14 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 1 - Diphtheria CRM197 Conjugate - EMEA- 002215-PIP01-17-M03

Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by *Streptococcus pneumoniae*

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Entrectinib - EMEA-002096-PIP01-16-M03

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 30 discussion

Action: For discussion

3.3.2. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M01

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 30 discussion

Action: For discussion

3.3.3. Brodalumab - EMEA-001089-PIP02-13-M02

LEO Pharma A/S; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M05

Jubilant DraxImage Inc., dba Jubilant Radiopharma; Visualisation of myocardial perfusion for diagnostic purposes

Day 30 discussion

Action: For discussion

Diagnostic

3.3.5. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M03

Genzyme Europe B.V.; Glycogen storage disease (Pompe disease)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Metreleptin - Orphan - EMEA-001701-PIP01-14-M02

Amryt Pharmaceuticals DAC; Treatment of lipodystrophy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M05

Shire Pharmaceuticals Ireland Limited; Hypoparathyroidism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Tolvaptan - EMEA-001231-PIP02-13-M08

Otsuka Pharmaceutical Netherlands B.V.; Polycystic kidney disease (PKD)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.3.9. Dupilumab - EMEA-001501-PIP04-19-M01

Regeneron Ireland DAC; Eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.10. Naldemedine - EMEA-001893-PIP01-15-M02

Shionogi B.V.; Opioid-induced constipation (OIC)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Pegylated-fibroblast growth factor 21 (BMS-986036) - EMEA-002448-PIP01-18-M02

Bristol-Myers Squibb International Corporation; Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.12. [Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M01](#)

Pfizer Europe MA EEIG; Treatment of congenital factor IX deficiency (haemophilia B)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.13. [Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 \(INN: narsoplimab\) - Orphan - EMEA-002479-PIP01-18-M01](#)

Omeros Ireland Limited; Treatment in haematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.14. [Aztreonam / Avibactam - EMEA-002283-PIP01-17-M02](#)

Pfizer Europe MA EEIG; Treatment of infections caused by aerobic gram-negative bacteria

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. [Cabotegravir - EMEA-001418-PIP01-13-M03](#)

ViiV Healthcare UK Limited; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. [Cabotegravir - EMEA-001418-PIP02-15-M02](#)

ViiV Healthcare UK Limited; Prevention of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Remdesivir - EMEA-002826-PIP01-20-M02

Gilead Sciences International Ltd.; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Bumetanide - EMEA-001303-PIP01-12-M04

Les Laboratoires Servier; Autism spectrum disorder

Day 30 discussion

Action: For discussion

Neurology

3.3.19. Lacosamide - EMEA-000402-PIP03-17-M05

UCB Pharma S.A.; Treatment of generalized epilepsy and epilepsy syndromes

Day 30 discussion

Action: For discussion

Neurology

3.3.20. Autologous tumor-infiltrating lymphocytes (LN-144/LN-145) - EMEA-002776-PIP01-20-M01

Iovance Biotherapeutics, Inc.; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 30 discussion

Action: For discussion

Oncology

3.3.21. Bintrafusp alfa - Orphan - EMEA-002586-PIP01-19-M02

Merck Europe B.V.; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms)

Day 30 discussion

Action: For discussion

Oncology

3.3.22. Bosutinib - EMEA-000727-PIP01-09-M05

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukemia

Day 30 discussion

Action: For discussion

Oncology

3.3.23. Selumetinib - Orphan - EMEA-001585-PIP01-13-M05

AstraZeneca AB; Treatment of neurofibromatosis type 1 / Treatment of thyroid cancer / Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.3.24. Bupropion HCl / Naltrexone HCl - EMEA-001373-PIP01-12-M04

Orexigen Therapeutics Ireland Limited; Treatment of obesity

Day 30 discussion

Action: For discussion

Other

3.3.25. Eliglustat - Orphan - EMEA-000461-PIP02-11-M04

Genzyme Europe B.V.; Gaucher disease type 1 / Gaucher disease type 3

Day 30 discussion

Action: For discussion

Other

3.3.26. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M07

Omrix Biopharmaceuticals N.V.; Treatment of haemorrhage resulting from a surgical procedure / Treatment of cerebrospinal fluid leakage resulting from a surgical procedure

Day 30 discussion

Action: For discussion

Other

3.3.27. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16-M03

Lupin Europe GmbH; Treatment of myotonic disorders

Day 30 discussion

Action: For discussion

Other

3.3.28. Patiromer sorbitex calcium - EMEA-001720-PIP01-14-M02

Vifor Fresenius Medical Care Renal Pharma France; Hyperkalaemia

Day 30 discussion

Action: For discussion

Other

3.3.29. Bupivacaine - EMEA-000877-PIP03-17-M03

Pacira Ltd; Postsurgical analgesia

Day 30 discussion

Action: For discussion

Pain

3.3.30. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M07

Insmed Netherlands B.V.; Treatment of nontuberculous mycobacterial (NTM) lung infection / Treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.31. Berotralstat - EMEA-002449-PIP02-18-M01

BioCryst Ireland Limited; Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.32. Mometasone (furoate) / Glycopyrronium bromide / Indacaterol - EMEA-001812-PIP01-15-M01

Novartis Europharm Limited; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.33. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M03

Sanofi Pasteur; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.3.34. Recombinant Clostridioides difficile Toxoids A and B - EMEA-002112-PIP01-16-M01

Pfizer Europe MA EEIG; Prevention of Clostridioides difficile infection (CDI)

Day 30 discussion

Action: For discussion

Vaccines

3.3.35. (R)-2-amino-3-phenylpropylcarbamate hydrochloride - EMEA-002184-PIP01-17-M01

Jazz Pharmaceuticals Ireland Limited; Treatment of excessive daytime sleepiness

Day 30 discussion

Action: For discussion

Neurology

3.3.36. Dasiglucagon - Orphan - EMEA-002233-PIP01-17-M01

Zealand Pharma A/S; Treatment of hypoglycaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.37. Pretomanid - Orphan - EMEA-002115-PIP01-17-M03

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

Day 30 discussion

Action: For discussion

Infectious Diseases

Note: Withdrawal request received on 2 June 2021

3.3.38. Pevonedistat - Orphan - EMEA-002117-PIP01-17-M02

Takeda Pharma A/S; Treatment of acute myeloid leukaemia/ Treatment of myelodysplastic syndromes

Day 30 discussion

Action: For discussion

Oncology

- 3.3.39. Pneumococcal polysaccharide serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate - EMEA-002330-PIP01-18-M01
-

Pfizer Europe MA EEIG; Disease caused by Streptococcus pneumoniae

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

Information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

4.1. List of submissions of applications with start of procedure 12 July 2021 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

Information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Some information related to this section cannot be disclosed 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. Pegcetacoplan - EMEA-08-2021

All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema / Treatment of geographic atrophy secondary to age related macular degeneration

Action: For adoption

6.1.2. Darolutamide - EMEA-02-2021

The classes of androgen receptor modulator for treatment prostate malignant neoplasms / Treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC)

Action: For adoption

6.1.3. Trastuzumab deruxtecan - EMEA-03-2021

The class of Her / Epidermal growth factor-receptor antibody medicinal products for treatment intestinal malignant neoplasms / Treatment of adult patients with human epidermal growth factor receptor (HER)2-positive gastric cancer

Action: For adoption

6.1.4. EMEA-05-2021

All classes of medicinal products for treatment of Alzheimer's disease / Treatment of Alzheimer's disease

Action: For adoption

6.1.5. Abiraterone - EMEA-09-2021

The classes of androgen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products for treatment prostate malignant neoplasms / Treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy / Treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated / Treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen

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

9.1.1. Revision of the Summary Report template (B-F scientific document)

Action: For information

9.1.2. Deadlines for paediatric applications 2020-2024

Action: For adoption

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

No items

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 Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 1-2 June 2021

Agenda of meeting on 1-2 June 2021

Action: For information

9.3.4. EMA Working Party review

Action: For information

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.4.2. Exchange between Clinical Trials Facilitation and Coordination Group (CTFG) and PDCO

PDCO Member: Anette Solli Karlsen

Action: For information

9.4.3. PDCO / Health technology assessment (HTA) interaction – update on current initiatives

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Feedback from 6th Paediatric Oncology Strategy Forum on CAR T cell development

Action: For information

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

10.1. COVID -19 update

Action: For information

10.2. EU innovation network Horizon Scanning report on Genome Editing

Action: For information

10.3. EMA Business Pipeline activity and Horizon scanning

Q2/2021 Update of the Business Pipeline report for the human scientific committees

Action: For information

11. Breakout sessions

11.1. Internal PDCO Operations

Action: For discussion on Tuesday, 10:00 - 11:00

11.2. Vaccines

Action: For discussion on Tuesday, 13:00-14:00

11.3. Paediatric oncology

Action: For discussion on Wednesday, 13:00 - 14:00

11.4. Neonatology

Action: For discussion on Thursday, 13:00 - 14:00

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/