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Human Medicines Division

Paediatric Committee (PDCO)

Minutes for the meeting on 20-23 July 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

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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 12

2.1.1. EMEA-002870-PIP01-20 12

2.1.2. Benralizumab - EMEA-001214-PIP05-19 12

2.1.3. Cendakimab - EMEA-002640-PIP01-19 12

2.1.4. (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 13

2.1.5. Concizumab - Orphan - EMEA-002326-PIP04-20 13

2.1.6. Baricitinib - EMEA-001220-PIP08-20 13

2.1.7. Tocilizumab - EMEA-000309-PIP07-21 13

2.1.8. Casirivimab - EMEA-002964-PIP01-21 14

2.1.9. Imdevimab - EMEA-002965-PIP01-21 14

2.1.10. Potassium bitartrate / citric acid / L-lactic acid - EMEA-002917-PIP01-20 14

2.1.11. Epcoritamab - EMEA-002907-PIP01-20 15

2.1.12. Ribitol - Orphan - EMEA-002887-PIP01-20 15

2.1.13. Ligelizumab - EMEA-001811-PIP03-20 15

2.1.14. Single chain urokinase plasminogen activator (scuPA) - Orphan - EMEA-002896-PIP01-20 15

2.1.15. 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 16

2.1.16. Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20 16

2.1.17. Florbetaben (^{18}F) - Orphan - EMEA-001090-PIP02-21 16

2.1.18. Bisoprolol (fumarate) / amlodipine / indapamide / perindopril (arginine) - EMEA-003015-PIP01-21 17

2.1.19. Prasterone / levonorgestrel / ethinylestradiol - EMEA-002960-PIP02-21 17

2.1.20. Atezolizumab - EMEA-001638-PIP02-21 17

2.1.21. Ociperlimab - EMEA-003028-PIP01-21 18

2.1.22. Prednisolone - EMEA-003004-PIP01-21 18

2.1.23. Selinexor - EMEA-002387-PIP02-21 19

2.1.24. Ligelizumab - EMEA-001811-PIP04-21 19

2.1.25. Molnupiravir - EMEA-002940-PIP01-20 19

2.1.26. Efgartigimod alfa - Orphan - EMEA-002597-PIP05-21 20

2.1.27. Azithromycin - EMEA-003021-PIP01-21 20
2.2. Opinions on Compliance Check 20
2.2.1. Octocog alfa - EMEA-C-001064-PIP01-10-M03 20
2.2.2. Tadalafil - EMEA-C-000452-PIP02-10-M06 21
2.2.3. Turoctocog alfa pegol - EMEA-C-001174-PIP02-12-M02 21
2.2.4. Relebactam / cilastatin sodium / imipenem monohydrate - EMEA-C3-001809-PIP01-15-M0221
2.2.5. Cannabidiol - EMEA-C3-001964-PIP01-16-M03 22
2.2.6. Dexmedetomidine (hydrochloride) - EMEA-C1-002758-PIP01-19 22
2.2.7. Mirabegron - EMEA-C3-000597-PIP03-15-M03 22
2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan 23
2.3.1. Entrectinib - EMEA-002096-PIP01-16-M03 23
2.3.2. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M01 23
2.3.3. Brodalumab - EMEA-001089-PIP02-13-M02 23
2.3.4. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M05 23
2.3.5. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M03 24
2.3.6. Dasiglucagon - Orphan - EMEA-002233-PIP01-17-M01 24
2.3.7. Metreleptin - Orphan - EMEA-001701-PIP01-14-M02 24
2.3.8. Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M0525
2.3.9. Tolvaptan - EMEA-001231-PIP02-13-M08 25
2.3.10. Dupilumab - EMEA-001501-PIP04-19-M01 25
2.3.11. Naldemedine - EMEA-001893-PIP01-15-M02 26
2.3.12. Pegylated-fibroblast growth factor 21 (BMS-986036) - EMEA-002448-PIP01-18-M02 26
2.3.13. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M01 26
2.3.14. Narsoplimab - Orphan - EMEA-002479-PIP01-18-M01 27
2.3.15. Aztreonam / avibactam - EMEA-002283-PIP01-17-M02 27
2.3.16. Cabotegravir - EMEA-001418-PIP01-13-M03 27
2.3.17. Cabotegravir - EMEA-001418-PIP02-15-M02 28
2.3.18. Remdesivir - EMEA-002826-PIP01-20-M02 28
2.3.19. Bumetanide - EMEA-001303-PIP01-12-M04 28
2.3.20. Lacosamide - EMEA-000402-PIP03-17-M05 28
2.3.21. Solriamfetol - EMEA-002184-PIP01-17-M01 29
2.3.22. Autologous tumour-infiltrating lymphocytes (LN-144/LN-145) - EMEA-002776-PIP01-20-M01 29
2.3.23. Bintrafusp alfa - Orphan - EMEA-002586-PIP01-19-M02 29
2.3.24. Bosutinib - EMEA-000727-PIP01-09-M05 30
2.3.25. Pevonedistat - Orphan - EMEA-002117-PIP01-17-M02 30
2.3.26. Selumetinib - Orphan - EMEA-001585-PIP01-13-M05 30
2.3.27. Bupropion HCl / naltrexone HCl - EMEA-001373-PIP01-12-M04 31
2.3.28. Eliglustat - Orphan - EMEA-000461-PIP02-11-M04 31

2.3.29. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M07 31

2.3.30. Mexiletine (hydrochloride) - Orphan - EMEA-002012-PIP01-16-M03 32

2.3.31. Patiromer calcium - EMEA-001720-PIP01-14-M02 32

2.3.32. Bupivacaine - EMEA-000877-PIP03-17-M03 32

2.3.33. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M07 32

2.3.34. Berotralstat - EMEA-002449-PIP02-18-M01 33

2.3.35. Mometasone (furoate) / glycopyrronium bromide / indacaterol - EMEA-001812-PIP01-15-M01 33

2.3.36. 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-M0333

2.3.37. 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-M01 34

2.3.38. Recombinant *Clostridioides difficile* Toxoids A and B - EMEA-002112-PIP01-16-M01..... 35

2.3.39. 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 35
2.4. Opinions on Re-examinations 35
2.5. Opinions on Review of Granted Waivers 36
2.6. Finalisation and adoption of Opinions 36
2.7. Partial Compliance Checks completed by EMA 36
2.7.1. Tabelecleucel - EMEA-C1-002025-PIP04-19 36
2.7.2. Remdesivir - EMEA-C2-002826-PIP01-20-M01 36
2.7.3. Gadopiclenol - EMEA-C1-001949-PIP01-16-M04 36
2.7.4. Gadopiclenol - EMEA-C1-001949-PIP02-18-M01 36
2.7.5. Cipaglucosidase alfa - EMEA-C2-002447-PIP01-18-M01 37
3. Discussion of applications 37
3.1. Discussions on Products D90-D60-D30 37
3.1.1. PCSK9-targeted, antisense oligonucleotide (ASO) - EMEA-002962-PIP01-21 37
3.1.2. EMEA-002944-PIP01-20 37
3.1.3. Drospirenone - EMEA-001495-PIP02-21 37
3.1.4. Glepaglutide - EMEA-002926-PIP01-20 37
3.1.5. Semaglutide - EMEA-001441-PIP05-20 37
3.1.6. EMEA-002927-PIP01-20 38
3.1.7. Islatravir - EMEA-002938-PIP01-20 38
3.1.8. Pritelivir - EMEA-002180-PIP02-19 38
3.1.9. EMEA-002963-PIP01-21 38
3.1.10. EMEA-002984-PIP01-21 38
3.1.11. Crisantaspase - EMEA-002934-PIP01-20 38
3.1.12. Loncastuximab tesirine - EMEA-002665-PIP02-20 39
3.1.13. Brensocatib - EMEA-002905-PIP01-20 39
3.1.14. Thienopyrimidine Derivative - EMEA-002901-PIP01-20 39
3.1.15. Ravulizumab - EMEA-001943-PIP02-20 39
3.1.16. EMEA-002873-PIP01-20 39
3.1.17. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20 39
3.1.18. Abelacimab - EMEA-003017-PIP01-21 40
3.1.19. Dersimelagon - EMEA-002850-PIP02-21 40
3.1.20. EMEA-003027-PIP01-21 40
3.1.21. EMEA-003019-PIP01-21 40
3.1.22. Apraglutide - Orphan - EMEA-003016-PIP01-21 40
3.1.23. Benralizumab - EMEA-001214-PIP07-21 40
3.1.24. Izencitinib - EMEA-002757-PIP02-21 40

3.1.25. Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene - Orphan - EMEA-003029-PIP01-21 41
3.1.26. Recombinant humanized anti-blood dendritic cell antigen 2 (BDCA2) monoclonal antibody - EMEA-002555-PIP02-21 41
3.1.27. Mixture of 2 synthetic double-stranded N-Acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against hepatitis B virus - EMEA-002694-PIP02-21 41
3.1.28. Adeno-associated viral vector serotype rh.10 expressing beta-galactosidase - Orphan - EMEA-003020-PIP01-21 41
3.1.29. A 2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting fused in sarcoma (FUS) pre-mRNA - EMEA-003024-PIP01-21 41
3.1.30. Recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide - Orphan - EMEA-003022-PIP01-21 41
3.1.31. Lorlatinib - EMEA-002669-PIP03-21 42
3.1.32. Pemigatinib - Orphan - EMEA-002370-PIP02-21 42
3.1.33. Vodobatinib - EMEA-003014-PIP01-21 42
3.1.34. Vorasidenib - EMEA-002932-PIP02-21 42
3.1.35. A recombinant SARS-CoV-2 Spike (S)-trimer fusion protein - EMEA-002987-PIP01-21 42
3.1.36. Amlodipine / zofenopril - EMEA-003036-PIP01-21 42
3.1.37. Ezetimibe / rosuvastatin - EMEA-001447-PIP02-21 43
3.1.38. Ezetimibe / rosuvastatin - EMEA-003018-PIP01-21 43
3.1.39. Ezetimibe / rosuvastatin - EMEA-003039-PIP01-21 43
3.1.40. Dupilumab - EMEA-001501-PIP09-21 43
3.1.41. Phospholipid esters from herring roe - EMEA-003053-PIP01-21 43
3.1.42. Bilastine - EMEA-000347-PIP06-21 43
3.1.43. Manganese chloride - EMEA-003035-PIP01-21 43
3.1.44. Perflubutane - EMEA-003037-PIP01-21 44
3.1.45. Ibutamoren mesilate - Orphan - EMEA-003032-PIP01-21 44
3.1.46. Pyridoxine / doxylamine - EMEA-001608-PIP02-21 44
3.1.47. Zinc gluconate / alisitol / retinyl palmitate - Orphan - EMEA-002198-PIP01-21 44
3.1.48. Mitapivat - Orphan - EMEA-002684-PIP02-21 44
3.1.49. Rozanolixizumab - Orphan - EMEA-002681-PIP02-21 44
3.1.50. Rusfertide - Orphan - EMEA-003045-PIP01-21 45
3.1.51. Autologous bone marrow derived CD34+cells transduced with the lentiviral vector CL20-4i-EF1α-hγc-OPT - Orphan - EMEA-003050-PIP01-21 45
3.1.52. Otilimab - EMEA-001882-PIP04-21 45
3.1.53. Tocilizumab - EMEA-000309-PIP06-21 45
3.1.54. Anti-C1s Humanized IgG4 Monoclonal Antibody - EMEA-002903-PIP03-21 45
3.1.55. Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R,4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate - Orphan - EMEA-003025-PIP02-2145
3.1.56. Reparixin - Orphan - EMEA-001693-PIP03-21 46
3.1.57. Alprazolam - EMEA-003043-PIP01-21 46

3.1.58. Anti-neonatal Fc receptor human monoclonal antibody - EMEA-002559-PIP04-21 46
3.1.59. Efgartigimod alfa - EMEA-002597-PIP06-21 46
3.1.60. Invimestrocel - EMEA-002317-PIP02-21 46
3.1.61. Izaflortaucipir (18F) - Orphan - EMEA-003040-PIP01-21 46
3.1.62. Ocrelizumab - EMEA-000310-PIP04-21 46
3.1.63. Ravulizumab - EMEA-001943-PIP05-21 47
3.1.64. Rozanolixizumab - EMEA-002681-PIP03-21 47
3.1.65. 1-[({4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6- methoxyquinolin-7-yl}oxy)methyl]cyclopropan-1-amine bishydrocloride - Orphan - EMEA-002486-PIP04-21 . 47
3.1.66. 5'-capped mRNA encoding HPV16 oncoprotein E7 / 5’-capped mRNA encoding HPV16 oncoprotein E6 - EMEA-003023-PIP01-21 47
3.1.67. Alnuctamab - EMEA-003046-PIP01-21 47
3.1.68. Anti-CD123 IgG1 humanised monoclonal antibody conjugated to N1-(2-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)ethyl)-N6-((S)-1-(((S)-1-((3-((((S)-8-methoxy-6-oxo-11,12,12a,13-tetrahydro-6H-benzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)-5-((((S)-8-methoxy-6-oxo-12a,13-dihydro-6Hbenzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)phenyl)amino)-1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)adipamide - Orphan - EMEA-003044-PIP01-2147
3.1.69. B cell maturation antigen antibody-drug conjugate comprised of an immunoglobulin G1 humanized antibody conjugated covalently to the dibenzocyclooctyne noncleavable linker maytansinoid warhead - EMEA-003047-PIP01-21 48
3.1.70. Batiraxcept - EMEA-003042-PIP01-21 48
3.1.71. Plinabulin - EMEA-003054-PIP01-21 48
3.1.72. Pralsetinib - EMEA-002575-PIP03-21 48
3.1.73. Senaparib - EMEA-003034-PIP01-21 48
3.1.74. Tazemetostat - Orphan - EMEA-003055-PIP01-21 49
3.1.75. Humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide - EMEA-002957-PIP02-21 49
3.1.76. EMEA-003048-PIP01-21 49
3.1.77. Ofloxacin / dexamethasone - EMEA-003031-PIP01-21 49
3.1.78. Lutetium (^{177}Lu) - EMEA-003038-PIP01-21 49
3.1.79. Pabinafusp alfa - Orphan - EMEA-003033-PIP01-21 49
3.1.80. Depemokimab - EMEA-003051-PIP01-21 49
3.1.81. EMEA-003052-PIP01-21 50
3.1.82. L-Carnitine / glucose /calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21 50
3.1.83. *Neisseria meningitidis* serogroup B fHbp subfamily B / *Neisseria meningitidis* serogroup B fHbp subfamily A / *Neisseria meningitidis* group Y polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group C polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group A polysaccharide conjugated to tetanus toxoid carrier protein - EMEA-002814-PIP02-21 50
3.1.84. SARS-CoV-2, produced in Vero cells, Inactivated - EMEA-003057-PIP01-21 50
3.1.85. Yellow fever virus - EMEA-003030-PIP01-21 50
3.2. Discussions on Compliance Check 51

3.2.1. Ganaxolone - EMEA-C1-002341-PIP01-18-M01 51
3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan..... 51
3.3.1. Remimazolam - EMEA-001880-PIP02-19-M03 51
3.3.2. Edoxaban tosylate - EMEA-000788-PIP02-11-M11 51
3.3.3. Dulaglutide - EMEA-000783-PIP01-09-M06 51
3.3.4. Empagliflozin - EMEA-000828-PIP01-09-M09 51
3.3.5. Linagliptin - EMEA-000498-PIP01-08-M10..... 52
3.3.6. Recombinant human glutamic acid dexarboxylase (rhGAD65) - EMEA-000609-PIP01-09-M0352
3.3.7. Semaglutide - EMEA-001441-PIP03-17-M02 52
3.3.8. Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18-M01..... 52
3.3.9. Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M02 52
3.3.10. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M05..... 52
3.3.11. Oteseconazole - EMEA-002392-PIP01-18-M02..... 52
3.3.12. 5-[[4-[2-[5-(1-Hydroxyethyl)-2-pyridinyl]ethoxy]phenyl]methyl]-2,4-thiazolidinedione hydrochloride - Orphan - EMEA-002106-PIP01-16-M01 53
3.3.13. Galcanezumab - EMEA-001860-PIP03-16-M06 53
3.3.14. Ganaxolone - Orphan - EMEA-002341-PIP01-18-M02..... 53
3.3.15. Ozanimod hydrochloride - EMEA-001710-PIP02-14-M06..... 53
3.3.16. Abemaciclib - EMEA-002342-PIP01-18-M02 53
3.3.17. Abemaciclib - EMEA-002342-PIP02-18-M01 53
3.3.18. Brigatinib - EMEA-002296-PIP01-17-M03 54
3.3.19. Imatinib (as imatinib mesylate) - EMEA-002643-PIP01-19-M01..... 54
3.3.20. Palbociclib - EMEA-002146-PIP01-17-M03 54
3.3.21. Temozolomide - EMEA-002634-PIP01-19-M01..... 54
3.3.22. Fluocinolone acetonide - EMEA-000801-PIP03-16-M01 54
3.3.23. Ivacaftor / tezacaftor - Orphan - EMEA-001640-PIP01-14-M07..... 54
3.3.24. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M02..... 55
3.3.25. Nintedanib - EMEA-001006-PIP05-18-M01..... 55
3.3.26. Mirabegron - EMEA-000597-PIP03-15-M04 55
3.3.27. Ebola Zaire Vaccine (rVSVΔ G-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M02 55

4. Nominations 55

4.1. List of letters of intent received for submission of applications with start of procedure 17 August 2021 for Nomination of Rapporteur and Peer reviewer..... 55
4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver 55
4.3. Nominations for other activities 56

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction 56

5.1. New Scientific Advice 56

5.2. Final Scientific Advice (Reports and Scientific Advice letters) 56

6. Discussion on the applicability of class waivers 56

6.1. Discussions on the applicability of class waiver for products 56

6.1.1. Icenticaftor - EMEA-06-2021 56

6.1.2. EQ143 - EMEA-07-2021 56

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver 57

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver 57

8. Annual reports on deferrals 57

9. Organisational, regulatory and methodological matters 57

9.1. Mandate and organisation of the PDCO 57

9.1.1. Update on PDCO member(s)/alternate(s) mandate status 57

9.2. Coordination with EMA Scientific Committees or CMDh-v 57

9.2.1. Committee for Medicinal Products for Human Use (CHMP) 57

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 58

9.3.1. Non-clinical Working Group: D30 Products identified 58

9.3.2. Formulation Working Group 58

9.3.3. CHMP List of Questions to the SWP and NcWG of the PDCO 58

9.3.4. Patients and Consumers Working Party (PCWP) / Healthcare Professionals Working Party (HCPWP) meeting on 1-2 June 2021 58

9.3.5. Call for interest for nomination of PDCO members to join temporary ad-hoc group on complex trials Q&A - call for experts 58

9.4. Cooperation within the EU regulatory network 59

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA) 59

9.4.2. Study supporting the Impact Assessment of the revision of the EU legislation on medicines for children and rare diseases | Follow-up interview European Commission 59

9.5. Cooperation with International Regulators 59

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee 59

9.7. PDCO work plan 59

9.8. Planning and reporting 59

10. Any other business 60

10.1. COVID -19 update 60

11. Breakout sessions 60
11.1. Internal PDCO Operations 60
11.2. Paediatric oncology 60
11.3. Vaccines 60
12. List of participants 61
13. Explanatory notes 64

1. Introductions

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

The Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), the meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 17 or more members were present in the room).

Due to restricted involvement, the Chair Koenraad Norga deputised chairing the meeting to the Vice-Chair Sabine Scherer for the agenda topic(s) 3.1.16., 3.1.54. and 3.1.82.

1.2. Adoption of agenda

The agenda for 20-23 July 2021 meeting was adopted.

1.3. Adoption of the minutes

The minutes for 22-25 June 2021 meeting were adopted and will be published on the EMA website.

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. EMEA-002870-PIP01-20

General anaesthesia

Day 120 opinion

Anaesthesiology

Note: Withdrawal request received on 21 July 2021

2.1.2. Benralizumab - EMEA-001214-PIP05-19

AstraZeneca AB; Treatment of eosinophilic esophagitis (EoE)

Day 120 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

In a written response the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for paediatric patients from 2 years to less than 18 years of age, in the condition of treatment of eosinophilic esophagitis was adopted. The PDCO agreed on a waiver in a subset of children (from birth to less than 2 years of age) on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. The PDCO granted a deferral for the completion of this PIP.

2.1.3. Cendakimab - EMEA-002640-PIP01-19

Celgene Europe B.V.; Treatment of eosinophilic esophagitis

Day 120 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

In a written response the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for patients from 2 years of age, in the condition of treatment of eosinophilic esophagitis was adopted. The PDCO agreed on a waiver in the subset of children below 2 years of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. The PDCO granted a deferral for the completion of this PIP.

2.1.4. (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 120 opinion

Haematology-Hemostaseology

Note: Withdrawal request received on 21 July 2021

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

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

Day 120 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

Based on the assessment of this application, the PDCO adopted a positive opinion for the PIP for the proposed medicine for children from 1 to less than 18 years of age, in the condition treatment of congenital haemophilia A and treatment of congenital haemophilia B. The PDCO granted a deferral for the completion of this PIP.
The PDCO granted a waiver for the paediatric population from birth to less than 1 year of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2.1.6. Baricitinib - EMEA-001220-PIP08-20

Eli Lilly and Company Limited; Treatment of alopecia areata

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of Committee discussion:

The PDCO adopted a positive opinion for the PIP, including a waiver in children from birth to less than 6 years of age on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subsets and a deferral.

2.1.7. Tocilizumab - EMEA-000309-PIP07-21

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee the PDCO agreed on a PIP for tocilizumab in the treatment of coronavirus disease 2019 (COVID-19) with a deferral.

2.1.8. Casirivimab - EMEA-002964-PIP01-21

Regeneron Ireland DAC; Prevention of coronavirus disease 19 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee the PDCO agreed on a PIP for casirivimab for all subsets of the paediatric population from birth to 18 years of age in the condition of treatment of coronavirus disease 2019 (COVID-19), and prevention of SARS-CoV-2 infection.

2.1.9. Imdevimab - EMEA-002965-PIP01-21

Regeneron Ireland DAC; Prevention of coronavirus disease 19 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee the PDCO agreed on a PIP for imdevimab for all subsets of the paediatric population from birth to 18 years of age in the condition of treatment of coronavirus disease 2019 (COVID-19), and prevention of SARS-CoV-2 infection.

2.1.10. Potassium bitartrate / citric acid / L-lactic acid - EMEA-002917-PIP01-20

Evofem, Inc.; Prevention of urogenital *Chlamydia trachomatis* (CT) infection and *Neisseria gonorrhoeae* (GC) infection

Day 120 opinion

Infectious Diseases

Summary of Committee discussion:

The PDCO granted on its own motion a product-specific waiver for all subsets of the paediatric population on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2.1.11. Epcoritamab - EMEA-002907-PIP01-20

AbbVie Ltd; Treatment of mature B cell malignancies

Day 120 opinion

Oncology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for patients from 1 year to less than 18 years of age, in the condition of treatment of mature B cell malignancies was adopted. The PDCO agreed on a waiver in a subset of children on the grounds of the disease not occurring. The PDCO granted a deferral for the completion of this PIP.

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

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

Day 120 opinion

Other

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for the paediatric population from birth to less than 18 years of age, in the condition of treatment of Limb-Girdle muscular dystrophy was adopted.
The PDCO granted a deferral for the completion of this PIP.

2.1.13. Ligelizumab - EMEA-001811-PIP03-20

Novartis Europharm Limited; Treatment of food allergy

Day 120 opinion

Pneumology - Allergology

Summary of Committee discussion:

The PDCO adopted a positive opinion for the PIP, including a waiver from birth to less than 6 months of age on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subsets and a deferral.

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

Lung Therapeutics, Inc.; Treatment of pleural effusion

Day 120 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the assessment of this application, the PDCO concluded on a positive opinion for the PIP for single chain urokinase plasminogen activator (scuPA) for all subsets of the paediatric population (birth to less than 18 years of age) in the condition of treatment of pleural effusion, as well as a deferral.

2.1.15. 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.; Treatment of primary ciliary dyskinesia (PCD)

Day 120 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the assessment of this application, the PDCO adopted a positive opinion for the PIP for the proposed medicine for children from 2 to less than 18 years of age, in the condition treatment of primary ciliary dyskinesia.
The PDCO granted a waiver for the paediatric population from birth to less than 2 years of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

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

Sanofi Pasteur; Prevention of disease caused by *Streptococcus pneumoniae*

Day 120 opinion

Vaccines

Summary of Committee discussion:

Based on the assessment of this application, the PDCO adopted a positive opinion for the PIP for the proposed medicine for children from 42 days to less than 18 years of age, in the condition prevention of disease caused by *Streptococcus pneumoniae*. The PDCO granted a deferral for the completion of this PIP.
The PDCO granted a waiver for the paediatric population from birth to less than 42 days of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2.1.17. Florbetaben (^{18}F) - Orphan - EMEA-001090-PIP02-21

Life Molecular Imaging GmbH; Diagnosis of cardiac amyloidosis

Day 60 opinion

Summary of Committee discussion:

Based on the assessment of this application, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for florbetaben (^{18}F) for all subsets of the paediatric population (birth to less than 18 years of age) in the condition of diagnosis of cardiac amyloidosis on the grounds that the condition does not occur in the paediatric population.

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

Les Laboratoires Servier; Treatment of hypertension

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

The PDCO re-discussed at day 60 during the July 2021 plenary meeting.
The PDCO adopted a positive opinion on a product specific waiver for perindopril (arginine) / indapamide / amlodipine / bisoprolol (fumarate) for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition of treatment of hypertension on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

Gedeon Richter Plc.; Treatment of hypoactive sexual desire disorder secondary to combined oral contraceptive use in women requiring contraception

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

Based on the assessment of this application and discussions at the Paediatric Committee the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for levonorgestrel / ethinylestradiol / prasterone for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of hypoactive sexual desire disorder (HSDD) secondary to combined oral contraception (COC) use in women requiring contraception on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.
The PDCO emphasises that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need.

2.1.20. Atezolizumab - EMEA-001638-PIP02-21

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, hematopoietic and lymphoid tissue neoplasms and melanoma)

Day 60 opinion

Oncology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the assessment of this application and discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for the proposed medicine (solution for injection, subcutaneous use) for all subsets of the paediatric population (from birth to less than 18 years of age) for the condition 'treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, hematopoietic and lymphoid tissue neoplasms and melanoma)'.

2.1.21. Ociperlimab - EMEA-003028-PIP01-21

BeiGene Ireland Limited; Treatment of oesophageal carcinoma / Treatment of endometrial carcinoma / Treatment of breast cancer / Treatment of head and neck epithelial malignant neoplasms / Treatment of cervical cancer / Treatment of gastric and gastroesophageal junction adenocarcinoma / Treatment of hepatocellular carcinoma / Treatment of intestinal malignant neoplasms / Treatment of lung cancer

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for ociperlimab for all subsets of the paediatric population (0 to 18 years of age) in the conditions of treatment of lung cancer, based on the ground that the disease does not occur; treatment of breast cancer, based on the ground that the disease does not occur; treatment of endometrial carcinoma, based on the ground that the disease does not occur; treatment of hepatocellular carcinoma, based on the ground of lack of significant therapeutic benefit; treatment of oesophageal carcinoma, based on the ground that the disease does not occur; treatment of gastric and gastroesophageal junction adenocarcinoma, based on the ground that the because disease does not occur; treatment of head and neck epithelial malignant neoplasms, based on the ground that the disease does not occur; treatment of intestinal malignant neoplasm, based on the ground that the disease does not occur; treatment of cervical cancer, based on the ground that the disease does not occur in the paediatric population.
The PDCO emphasises that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. The PDCO identified treatment of melanoma in adolescent patients, to be included in the adult development and treatment of osteosarcoma as an unmet need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.22. Prednisolone - EMEA-003004-PIP01-21

Alfred E. Tiefenbacher (GmbH & Co. KG); Treatment of prostate malignant neoplasms

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for prednisolone for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of prostate malignant neoplasms.

2.1.23. Selinexor - EMEA-002387-PIP02-21

Karyopharm Europe GmbH; Treatment of endometrial carcinoma

Day 60 opinion

Oncology

Summary of Committee discussion:

The PDCO re-discussed at Day 60 during the July 2021 plenary meeting a request for a product-specific waiver for selinexor for the treatment of endometrial carcinoma. Selinexor is an inhibitor of exportin 1 (XPO-1) and it increases the concentration of several tumour suppressor proteins in the nucleus causing G1-G2 arrest followed by genomic fidelity review. As a result, cells with genomic damage are induced to undergo apoptosis. The PDCO adopted a positive opinion on a product specific waiver for selinexor for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition of the treatment of endometrial carcinoma on the grounds that the condition/disease does not occur in the paediatric population.

2.1.24. Ligelizumab - EMEA-001811-PIP04-21

Novartis Europharm Limited; Treatment of chronic inducible urticaria

Day 60 opinion

Dermatology

Summary of Committee discussion:

The PDCO adopted a positive opinion at Day 60, including a waiver in children from birth to less than 2 years of age on the grounds that clinical studies with ligelizumab cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset and a deferral.

2.1.25. Molnupiravir - EMEA-002940-PIP01-20

Merck Sharp & Dohme (Europe), Inc.; Treatment of coronavirus disease 2019 (COVID-19)

Day 90 opinion

Infectious Diseases

Summary of Committee discussion:

In the written response the applicant addressed the remaining issues raised by the Committee.

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for the paediatric population from birth to less than 18 years of age in the condition of treatment of coronavirus disease 2019 (COVID-19) was adopted. The PDCO granted a deferral for the completion of this PIP.

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

argenx BV; Treatment of myasthenia gravis

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the assessment of this application, a positive opinion for the PIP for the proposed medicine for children from 2 years to less than 18 years of age, in the condition of treatment of myasthenia gravis was adopted. The PDCO agreed on a waiver in a subset of children on the grounds of lack of safety. The PDCO granted a deferral for the completion of this PIP.

2.1.27. Azithromycin - EMEA-003021-PIP01-21

Aspire Pharma Limited; Prevention of bronchopulmonary dysplasia

Day 60 opinion

Neonatology - Paediatric Intensive Care

Summary of Committee discussion:

Based on the assessment of this application, the PDCO concluded on a positive opinion for azithromycin in the condition of prevention of bronchopulmonary dysplasia in preterm neonates born prior to gestational week 30, as well as a waiver in preterm neonates born at gestational week 30 or later, and the paediatric population from birth at term to less than 18 years of age, on the grounds that the condition does not occur in the specified subsets of the paediatric population.

2.2. Opinions 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.

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

Bayer AG; Treatment of hereditary Factor VIII deficiency

Day 60 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-001064-PIP01-10-M02.

The PDCO adopted on 23 July 2021 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0060/2018) of 16 March 2018.

2.2.2. Tadalafil - EMEA-C-000452-PIP02-10-M06

Eli Lilly and Company Limited; Treatment of pulmonary arterial hypertension

Day 30 opinion

Cardiovascular Diseases

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-000452-PIP02-10

The PDCO adopted on 23 July 2021 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision P/0376/2020 of 11 September 2020.

2.2.3. Turoctocog alfa pegol - EMEA-C-001174-PIP02-12-M02

Novo Nordisk A/S; Treatment of hereditary Factor VIII deficiency

Day 30 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-001174-PIP02-12-M02.

Clarification to the points raised for study 5 was provided by the applicant before D30.
The PDCO adopted on 23 July 2021 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0142/2017) of 7 June 2017.

2.2.4. Relebactam / cilastatin sodium / imipenem monohydrate - EMEA-C3-001809-PIP01-15-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of infections caused by Gram-negative organisms

Day 30 letter

Infectious Diseases

Summary of Committee discussion:

The PDCO discussed the completed study(ies) and considered that these are compliant with the latest Agency's Decision (P/0279/2020) of 24 July 2020.

The PDCO finalised this partially completed compliance procedure on 23 July 2021.

2.2.5. Cannabidiol - EMEA-C3-001964-PIP01-16-M03

GW Pharma (International) B.V.; Treatment of seizures associated with Dravet syndrome, Lennox-Gastaut syndrome and infantile spasms

Day 30 letter

Neurology

Summary of Committee discussion:

The PDCO discussed the compliance check request.
Studies 5 and 7 were considered to have been performed in compliance with the latest Decision.
The PDCO discussed the completed study(ies) and considered that these are compliant with the latest Agency's Decision (P/0033/2021) of 29 January 2021.
The PDCO finalised this partially completed compliance procedure on 23 July 2021.

2.2.6. Dexmedetomidine (hydrochloride) - EMEA-C1-002758-PIP01-19

BioXcel Therapeutics, Inc.; Treatment of bipolar disorder

Day 30 letter

Psychiatry

Summary of Committee discussion:

A PIP modification should be requested to address the issues prior to submission of a new compliance request.
The PDCO discussed the completed studies and considered that these are not compliant with the latest Agency's Decision (P/0019/2021) of 29 January 2021.
The PDCO finalised this partially completed compliance procedure on 23 July 2021.

2.2.7. Mirabegron - EMEA-C3-000597-PIP03-15-M03

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 letter

Uro-nephrology

Summary of Committee discussion:

The PDCO considered study 11 to have been performed in compliance with the latest Decision.
The PDCO discussed the completed study(ies) and considered that these are compliant with the latest Agency's Decision (P/0056/2017) of 16 March 2017.
The PDCO finalised this partially completed compliance procedure on 23 July 2021.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. 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 60 opinion

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0092/2020 of 18 March 2020.
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 60 opinion

Summary of Committee discussion:

The PDCO adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0014/2019 of 3 January 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

LEO Pharma A/S; Treatment of psoriasis

Day 60 opinion

Dermatology

Summary of Committee discussion:

At the July meeting 2021 the PDCO noted that no further information had been received by the applicant. Therefore the PDCO considered that delay of the date of completion of Study 3 was considered appropriate.
The PDCO, therefore, adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0189/2018 of 17 July 2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Diagnostic

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed request to extend the study timelines could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0391/2019 of 4 December 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Genzyme Europe B.V.; Treatment of Pompe disease

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0174/2020 of 13 May 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Zealand Pharma A/S; Treatment of hypoglycaemia

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0220/2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Amryt Pharmaceuticals DAC; Treatment of lipodystrophy

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

The PDCO re-discussed at Day 60 during the July 2021 plenary meeting a modification for metreleptin for the treatment of lipodystrophy. The applicant requested to delay completion of a clinical study.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0314/2016 of 25 November 2016).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Shire Pharmaceuticals Ireland Limited; Treatment of hypoparathyroidism

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0460/2020 of 4 December 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Otsuka Pharmaceutical Netherlands B.V.; Treatment of polycystic kidney disease / Treatment of dilutional hyponatraemia

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

Summary of Committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that some proposed changes could be accepted. The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0002/2020 of 03 January 2020. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Regeneron Ireland DAC; Treatment of eosinophilic esophagitis

Day 60 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0059/2020 of 10 February 2020.
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Shionogi B.V.; Opioid-induced constipation

Day 60 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0044/2017 of 17 February 2017).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0387/2020 of 1 October 2020).

2.3.13. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M01

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

Day 60 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0222/2020 of 17 June 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.14. Narsoplimab - Orphan - EMEA-002479-PIP01-18-M01

Omeros Ireland Limited; Treatment in haematopoietic stem cell transplantation

Day 60 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted with some revisions.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0400/2019 of 4 December 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.15. Aztreonam / avibactam - EMEA-002283-PIP01-17-M02

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

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0028/2021 of 29 January 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.16. Cabotegravir - EMEA-001418-PIP01-13-M03

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

Day 60 opinion

Infectious Diseases

Note: Withdrawal request received on 23 July 2021

2.3.17. Cabotegravir - EMEA-001418-PIP02-15-M02

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

Day 60 opinion

Infectious Diseases

Note: Withdrawal request received on 23 July 2021

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

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

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the overall rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0060/2021 of 5 February 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Les Laboratoires Servier; Treatment of autism spectrum disorder

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0170/2021 of 9 April 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

UCB Pharma S.A.; Treatment of generalised epilepsy and epileptic syndromes

Day 60 opinion

Neurology

Summary of Committee discussion:

In July 2021 the PDCO noted the responses of the applicant to the issues raised at D30. Most of the issues were considered resolved and revised key elements were overall

supported.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0330/2020 of 21 August 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.21. Solriamfetol - EMEA-002184-PIP01-17-M01

Jazz Pharmaceuticals Ireland Limited; Treatment of obstructive sleep apnoea / Treatment of narcolepsy

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0207/2018 of 17 July 2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.22. Autologous tumour-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 60 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0022/2021 of 29 January 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.23. 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 60 opinion

Oncology

Note: Withdrawal request received on 19 July 2021

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

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0270/2020 of 17 July 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Oncology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0386/2019 of 29 November 20219).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as

set in the Agency's latest decision (P/0279/2019 of 16 August 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.27. Bupropion HCl / naltrexone HCl - EMEA-001373-PIP01-12-M04

Orexigen Therapeutics Ireland Limited; Treatment of obesity

Day 60 opinion

Other

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0365/2017 of 1 December 2017).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Genzyme Europe B.V.; Treatment of Gaucher disease Type 2 / Treatment of Gaucher disease Type 1 and Type 3

Day 60 opinion

Other

Summary of Committee discussion:

In July 2021 the PDCO noted the responses of the applicant and confirmed the points raised at D30.
Therefore, the PDCO considered that the proposed changes could be accepted and adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0298/2018 of 12 September 2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Other

Summary of Committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0051/2021 issued on 27 January 2021.
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.30. Mexiletine (hydrochloride) - Orphan - EMEA-002012-PIP01-16-M03

Lupin Europe GmbH; Treatment of myotonic disorders

Day 60 opinion

Other

Summary of Committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0425/2019 of 4 December 2019. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.31. Patiromer calcium - EMEA-001720-PIP01-14-M02

Vifor Fresenius Medical Care Renal Pharma France; Treatment of hyperkalaemia

Day 60 opinion

Other

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0027/2017 of 31 January 2017).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

Pain

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0113/2021 of 17 March 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0346/2018 of 8 November 2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

BioCryst Ireland Limited; Treatment of hereditary angioedema

Day 60 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0061/2020 of 10 February 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.35. Mometasone (furoate) / glycopyrronium bromide / indacaterol - EMEA-001812-PIP01-15-M01

Novartis Europharm Limited; Treatment of asthma

Day 60 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0195/2016 of 15 July 2016).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.36. 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 60 opinion

Vaccines

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0244/2019 of 17 July 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.37. 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-M01

Pfizer Europe MA EEIG; Disease caused by *Streptococcus pneumoniae*

Day 60 opinion

Vaccines

Summary of Committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0159/2020 of 17/04/2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

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

Day 60 opinion

Vaccines

Summary of Committee discussion:

In the written response prior to Day 60 the applicant addressed the remaining issues raised by the committee at Day 30. Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0019/2018 of 30/01/2018. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.39. 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 60 opinion

Vaccines

Note: Withdrawal request received on 20 July 2021

2.4. Opinions on Re-examinations

No item

2.5. Opinions on Review of Granted Waivers

No item

2.6. Finalisation and adoption of Opinions

No item

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. Tabelecleucel - EMEA-C1-002025-PIP04-19

Atara Biotherapeutics Inc; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder

Day 30 letter

Immunology-Rheumatology-Transplantation / Oncology

2.7.2. Remdesivir - EMEA-C2-002826-PIP01-20-M01

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

Day 30 letter

Infectious Diseases

2.7.3. Gadopiclenol - EMEA-C1-001949-PIP01-16-M04

Guerbet; Detection and visualisation of areas with disruption of the blood brain barrier and/or abnormal vascularity for diagnostic purposes

Day 30 letter

Diagnostic

2.7.4. Gadopiclenol - EMEA-C1-001949-PIP02-18-M01

Guerbet; Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions for diagnostic purposes

Day 30 letter

Diagnostic

2.7.5. Cipaglucosidase alfa - EMEA-C2-002447-PIP01-18-M01

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

Day 30 letter

Endocrinology-Gynaecology-Fertility-Metabolism

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. PCSK9-targeted, antisense oligonucleotide (ASO) - EMEA-002962-PIP01-21

Treatment of elevated cholesterol / Treatment of mixed dyslipidaemia

Day 90 discussion

Cardiovascular Diseases

3.1.2. EMEA-002944-PIP01-20

Treatment of type 2 diabetes mellitus

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Drospirenone - EMEA-001495-PIP02-21

Treatment of endometriosis

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Glepaglutide - EMEA-002926-PIP01-20

Treatment of short bowel syndrome

Day 90 discussion

Gastroenterology-Hepatology

3.1.5. Semaglutide - EMEA-001441-PIP05-20

Treatment of non-alcoholic steatohepatitis / Treatment of non-alcoholic steatohepatitis

(NASH)

Day 90 discussion

Gastroenterology-Hepatology

3.1.6. EMEA-002927-PIP01-20

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

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.7. Islatravir - EMEA-002938-PIP01-20

Prevention of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Infectious Diseases

3.1.8. Pritelivir - EMEA-002180-PIP02-19

Treatment of herpes simplex virus disease

Day 90 discussion

Infectious Diseases

3.1.9. EMEA-002963-PIP01-21

Treatment of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Infectious Diseases

3.1.10. EMEA-002984-PIP01-21

Treatment of onychomycosis

Day 90 discussion

Infectious Diseases

3.1.11. Crisantaspase - EMEA-002934-PIP01-20

Treatment of acute lymphoblastic leukaemia / lymphoma / acute lymphoblastic leukaemia / lymphoma

Day 90 discussion

Oncology

3.1.12. Loncastuximab tesirine - EMEA-002665-PIP02-20

Treatment of mature B cell neoplasms

Day 90 discussion

Oncology

3.1.13. Brensocatib - EMEA-002905-PIP01-20

Non-cystic fibrosis bronchiectasis (NCFBE)

Day 90 discussion

Pneumology - Allergology

3.1.14. Thienopyrimidine Derivative - EMEA-002901-PIP01-20

Treatment of fibrosing interstitial lung disease

Day 90 discussion

Pneumology - Allergology

3.1.15. Ravulizumab - EMEA-001943-PIP02-20

Treatment in haematopoietic stem cell transplantation

Day 90 discussion

Uro-nephrology / Haematology-Hemostaseology

3.1.16. EMEA-002873-PIP01-20

Active immunisation for the prevention of disease caused by chikungunya virus

Day 90 discussion

Vaccines

3.1.17. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Day 90 discussion

Vaccines

3.1.18. Abelacimab - EMEA-003017-PIP01-21

Prevention of venous thromboembolism associated with cancer

Day 60 discussion

Cardiovascular Diseases

3.1.19. Dersimelagon - EMEA-002850-PIP02-21

Treatment of X-linked protoporphyria / Treatment of erythropoietic protoporphyria

Day 60 discussion

Dermatology

3.1.20. EMEA-003027-PIP01-21

Treatment of hyperphenylalaninaemia

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.21. EMEA-003019-PIP01-21

Treatment of inborn errors of amino acid metabolism

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

VectivBio AG; Treatment of short bowel syndrome

Day 60 discussion

Gastroenterology-Hepatology

3.1.23. Benralizumab - EMEA-001214-PIP07-21

Treatment of eosinophilic gastritis/eosinophilic gastroenteritis

Day 60 discussion

Gastroenterology-Hepatology

3.1.24. Izencitinib - EMEA-002757-PIP02-21

Treatment of Crohn's disease

Day 60 discussion

Gastroenterology-Hepatology

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

Aruvant Sciences GmbH; Treatment of sickle cell disease

Day 60 discussion

Haematology-Hemostaseology

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

Treatment of lupus erythematosus

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.27. 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 60 discussion

Infectious Diseases

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

Lysogene; Treatment of GM1 gangliosidosis

Day 60 discussion

Neurology

3.1.29. A 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 60 discussion

Neurology

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

Larimar Therapeutics Inc.; Treatment of Friedreich's ataxia

Day 60 discussion

Neurology

3.1.31. Lorlatinib - EMEA-002669-PIP03-21

ALK-aberrant neuroblastoma

Day 60 discussion

Oncology

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

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

Day 60 discussion

Oncology

3.1.33. Vodobatinib - EMEA-003014-PIP01-21

Chronic myeloid leukaemia

Day 60 discussion

Oncology

3.1.34. Vorasidenib - EMEA-002932-PIP02-21

Treatment of glioma

Day 60 discussion

Oncology

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

Prevention of COVID-19 disease

Day 60 discussion

Vaccines / Infectious Diseases

3.1.36. Amlodipine / zofenopril - EMEA-003036-PIP01-21

Treatment of essential hypertension

Day 30 discussion

Cardiovascular Diseases

3.1.37. Ezetimibe / rosuvastatin - EMEA-001447-PIP02-21

Prevention of cardiovascular events

Day 30 discussion

Cardiovascular Diseases

3.1.38. Ezetimibe / rosuvastatin - EMEA-003018-PIP01-21

Prevention of cardiovascular events / Treatment of hypercholesterolemia

Day 30 discussion

Cardiovascular Diseases

3.1.39. Ezetimibe / rosuvastatin - EMEA-003039-PIP01-21

Treatment of hypercholesterolemia / Prevention of cardiovascular events

Day 30 discussion

Cardiovascular Diseases

3.1.40. Dupilumab - EMEA-001501-PIP09-21

Treatment of chronic inducible cold urticaria

Day 30 discussion

Dermatology

3.1.41. Phospholipid esters from herring roe - EMEA-003053-PIP01-21

Treatment of psoriasis

Day 30 discussion

Dermatology

3.1.42. Bilastine - EMEA-000347-PIP06-21

Treatment of acute type I hypersensitivity reactions either alone, or in severe cases as an adjunctive agent

Day 30 discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

3.1.43. Manganese chloride - EMEA-003035-PIP01-21

Diagnostic evaluation of liver lesions by magnetic resonance imaging

Day 30 discussion

Diagnostic / Oncology

3.1.44. Perflubutane - EMEA-003037-PIP01-21

Diagnostic evaluation of focal hepatic lesions

Day 30 discussion

Diagnostic / Oncology

3.1.45. Ibutamoren mesilate - Orphan - EMEA-003032-PIP01-21

Lumos Pharma, Inc.; Treatment of growth hormone deficiency

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.46. Pyridoxine / doxylamine - EMEA-001608-PIP02-21

Treatment of nausea and vomiting of pregnancy

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.47. Zinc gluconate / alisitol / retinyl palmitate - Orphan - EMEA-002198-PIP01-21

Vanessa Research Magyarorszag Kft/Vanessa Research Hungary Ltd; Treatment of microvillus inclusion disease

Day 30 discussion

Gastroenterology-Hepatology

3.1.48. Mitapivat - Orphan - EMEA-002684-PIP02-21

Agios Netherlands B.V.; Treatment of thalassaemia

Day 30 discussion

Haematology-Hemostaseology

3.1.49. Rozanolixizumab - Orphan - EMEA-002681-PIP02-21

UCB Pharma S.A; Treatment of immune thrombocytopenia

Day 30 discussion

Haematology-Hemostaseology

3.1.50. Rusfertide - Orphan - EMEA-003045-PIP01-21

Protagonist Therapeutics, Inc.; Treatment of polycythaemia vera

Day 30 discussion

Haematology-Hemostaseology

3.1.51. Autologous bone marrow derived CD34+cells transduced with the lentiviral vector CL20-4i-EF1α-hγc-OPT - Orphan - EMEA-003050-PIP01-21

Mustang Bio, Inc.; Treatment of X-linked severe combined immunodeficiency (XSCID)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.52. Otilimab - EMEA-001882-PIP04-21

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.53. Tocilizumab - EMEA-000309-PIP06-21

Treatment of systemic sclerosis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.54. Anti-C1s Humanized IgG4 Monoclonal Antibody - EMEA-002903-PIP03-21

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 30 discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

3.1.55. Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R,4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate - Orphan - EMEA-003025-PIP02-21

ExCellThera; 2020-ICD-10-CM Diagnosis code: Z94.84T (allogeneic haematopoietic stem cell transplantation)

Day 30 discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

3.1.56. Reparixin - Orphan - EMEA-001693-PIP03-21

Dompé farmaceutici S.p.A.; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Infectious Diseases

3.1.57. Alprazolam - EMEA-003043-PIP01-21

Treatment of epileptic seizures

Day 30 discussion

Neurology

3.1.58. Anti-neonatal Fc receptor human monoclonal antibody - EMEA-002559-PIP04-21

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 30 discussion

Neurology

3.1.59. Efgartigimod alfa - EMEA-002597-PIP06-21

Chronic inflammatory demyelinating polyradiculoneuropathy

Day 30 discussion

Neurology

3.1.60. Invimestrocel - EMEA-002317-PIP02-21

Treatment of acute ischaemic stroke / Acute ischaemic stroke

Day 30 discussion

Neurology

3.1.61. Izaflortaucipir (18F) - Orphan - EMEA-003040-PIP01-21

Life Molecular Imaging GmbH; Diagnosis of corticobasal degeneration / Diagnosis of progressive supranuclear palsy

Day 30 discussion

Neurology

3.1.62. Ocrelizumab - EMEA-000310-PIP04-21

Treatment of multiple sclerosis

Day 30 discussion

Neurology

3.1.63. Ravulizumab - EMEA-001943-PIP05-21

Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Neurology

3.1.64. Rozanolixizumab - EMEA-002681-PIP03-21

Myelin oligodendrocyte glycoprotein antibody-associated disease

Day 30 discussion

Neurology

3.1.65. 1-[({4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6- methoxyquinolin-7-yl}oxy)methyl]cyclopropan-1-amine bishydrocloride - Orphan - EMEA-002486-PIP04-21

Advenchen Laboratories, LLC.; Treatment of soft tissue sarcomas

Day 30 discussion

Oncology

3.1.66. 5'-capped mRNA encoding HPV16 oncoprotein E7 / 5’-capped mRNA encoding HPV16 oncoprotein E6 - EMEA-003023-PIP01-21

First-line treatment in combination with pembrolizumab for adult patients with metastatic or recurrent unresectable head and neck squamous cell carcinoma (excluding nasopharyngeal carcinoma) whose tumour is human papilloma virus 16 positive (HPV16+) and expresses programmed death-ligand 1 (PD L1) with a combined positive score ≥ 1

Day 30 discussion

Oncology

3.1.67. Alnuctamab - EMEA-003046-PIP01-21

Treatment of mature B cell neoplasms

Day 30 discussion

Oncology

3.1.68. Anti-CD123 IgG1 humanised monoclonal antibody conjugated to N1-(2-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)ethyl)-N6-((S)-1-(((S)-1-((3-((((S)-8-methoxy-6-oxo-11,12,12a,13-tetrahydro-6H-benzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)-5-((((S)-8-methoxy-6-oxo-12a,13-dihydro-6Hbenzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)phenyl)amino)-1-

oxopropan-2-yl)amino)-1-oxopropan-2-yl)adipamide - Orphan - EMEA-003044-PIP01-21

Immunogen BioPharma (Ireland) Limited; Treatment of blastic plasmacytoid dendritic cell neoplasm

Day 30 discussion

Oncology

3.1.69. B cell maturation antigen antibody-drug conjugate comprised of an immunoglobulin G1 humanized antibody conjugated covalently to the dibenzocyclooctyne noncleavable linker maytansinoid warhead - EMEA-003047-PIP01-21

Treatment of mature B cell neoplasms

Day 30 discussion

Oncology

3.1.70. Batiraxcept - EMEA-003042-PIP01-21

Ovarian cancer / Treatment of ovarian cancer

Day 30 discussion

Oncology

3.1.71. Plinabulin - EMEA-003054-PIP01-21

Chemotherapy-induced neutropenia

Day 30 discussion

Oncology

3.1.72. Pralsetinib - EMEA-002575-PIP03-21

Treatment of all conditions included in the category of malignant neoplasms (except thyroid neoplasms)

Day 30 discussion

Oncology

3.1.73. Senaparib - EMEA-003034-PIP01-21

Metastatic castrate-resistant prostate cancer

Day 30 discussion

Oncology

3.1.74. Tazemetostat - Orphan - EMEA-003055-PIP01-21

Epizyme, Inc.; Treatment of mature B cell neoplasms / Soft tissue sarcomas / Mature B cell neoplasms / Treatment of soft tissue sarcomas

Day 30 discussion

Oncology

3.1.75. Humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide - EMEA-002957-PIP02-21

Treatment of diabetic retinopathy

Day 30 discussion

Ophthalmology

3.1.76. EMEA-003048-PIP01-21

Treatment of dry eye disease

Day 30 discussion

Ophthalmology

3.1.77. Ofloxacin / dexamethasone - EMEA-003031-PIP01-21

Bacterial infections of the eye showing a severe inflammatory reaction / Pre and post-operative eye surgeries where infection and inflammation may coexist

Day 30 discussion

Ophthalmology

3.1.78. Lutetium (^{177}Lu) - EMEA-003038-PIP01-21

Radiolabelling agent

Day 30 discussion

Other

3.1.79. Pabinafusp alfa - Orphan - EMEA-003033-PIP01-21

JCR Pharmaceuticals Co., Ltd.; Mucopolysaccharidosis Type II

Day 30 discussion

Other

3.1.80. Depemokimab - EMEA-003051-PIP01-21

Treatment of nasal polyposis

Day 30 discussion

Pneumology - Allergology

3.1.81. EMEA-003052-PIP01-21

Treatment of cystic fibrosis

Day 30 discussion

Pneumology - Allergology

3.1.82. L-Carnitine / glucose /calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21

Treatment of patients in need of peritoneal dialysis

Day 30 discussion

Uro-nephrology

3.1.83. *Neisseria meningitidis* serogroup B fHbp subfamily B / *Neisseria meningitidis* serogroup B fHbp subfamily A / *Neisseria meningitidis* group Y polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group C polysaccharide conjugated to tetanus toxoid carrier protein / *Neisseria meningitidis* group A polysaccharide conjugated to tetanus toxoid carrier protein - EMEA-002814-PIP02-21

Invasive disease caused by *Neisseria meningitidis* group A, B, C, W and Y from 2 months of age

Day 30 discussion

Vaccines

3.1.84. SARS-CoV-2, produced in Vero cells, Inactivated - EMEA-003057-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Vaccines

3.1.85. Yellow fever virus - EMEA-003030-PIP01-21

Prevention of yellow fever disease

Day 30 discussion

Vaccines

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. Ganaxolone - EMEA-C1-002341-PIP01-18-M01

Marinus Pharmaceuticals Inc.; Treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 30 discussion

Neurology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Remimazolam - EMEA-001880-PIP02-19-M03

PAION Deutschland GmbH; Sedation / General anaesthesia

Day 30 discussion

Anaesthesiology

3.3.2. Edoxaban tosylate - EMEA-000788-PIP02-11-M11

Daiichi Sankyo Europe GmbH; Treatment of venous thromboembolism / Prevention of arterial thromboembolism / Prevention of venous thromboembolism

Day 30 discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.3. Dulaglutide - EMEA-000783-PIP01-09-M06

Eli Lilly and Company; Treatment of type 2 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Empagliflozin - EMEA-000828-PIP01-09-M09

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Linagliptin - EMEA-000498-PIP01-08-M10

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Recombinant human glutamic acid dexarboxylase (rhGAD65) - EMEA-000609-PIP01-09-M03

Diamyd Medical AB; Treatment of type 1 diabetes

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Semaglutide - EMEA-001441-PIP03-17-M02

Novo Nordisk A/S; Treatment of obesity

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18-M01

OxThera AB; Treatment of hyperoxaluria

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.3.9. Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M02

Baxalta Innovations GmbH own by Takeda Pharmaceutical International AG; Treatment of thrombotic thrombocytopenic purpura

Day 30 discussion

Haematology-Hemostaseology

3.3.10. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M05

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

Day 30 discussion

Infectious Diseases

3.3.11. Oteseconazole - EMEA-002392-PIP01-18-M02

Gedeon Richter Plc.; Treatment of vulvovaginal candidiasis

Day 30 discussion

Infectious Diseases

3.3.12. 5-[[4-[2-[5-(1-Hydroxyethyl)-2-pyridinyl]ethoxy]phenyl]methyl]-2,4-thiazolidinedione hydrochloride - Orphan - EMEA-002106-PIP01-16-M01

Minoryx Therapeutics S.L.; Adrenoleukodystrophy (ALD)

Day 30 discussion

Neurology

3.3.13. Galcanezumab - EMEA-001860-PIP03-16-M06

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Neurology

3.3.14. Ganaxolone - Orphan - EMEA-002341-PIP01-18-M02

Marinus Pharmaceuticals Inc.; Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 30 discussion

Neurology

3.3.15. Ozanimod hydrochloride - EMEA-001710-PIP02-14-M06

Celgene Europe B.V.; Treatment of multiple sclerosis

Day 30 discussion

Neurology

3.3.16. Abemaciclib - EMEA-002342-PIP01-18-M02

Eli Lilly and Company Limited; Treatment of Ewing's sarcoma

Day 30 discussion

Oncology

3.3.17. Abemaciclib - EMEA-002342-PIP02-18-M01

Eli Lilly and Company Limited; Treatment of neuroblastoma / Treatment of glioma

Day 30 discussion

Oncology

3.3.18. Brigatinib - EMEA-002296-PIP01-17-M03

Takeda Pharm A/S; Anaplastic large cell lymphoma (ALCL) / Non-small cell lung cancer (NSCLC) / Inflammatory myofibroblastic tumours (IMT)

Day 30 discussion

Oncology

3.3.19. Imatinib (as imatinib mesylate) - EMEA-002643-PIP01-19-M01

Accord Healthcare S.L.U.; Treatment of Ph+ acute lymphoblastic leukaemia / Treatment of Ph+ chronic myeloid leukaemia

Day 30 discussion

Oncology

3.3.20. Palbociclib - EMEA-002146-PIP01-17-M03

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma

Day 30 discussion

Oncology

3.3.21. Temozolomide - EMEA-002634-PIP01-19-M01

Accord Healthcare S.L.U.; Treatment of malignant glioma

Day 30 discussion

Oncology

3.3.22. Fluocinolone acetonide - EMEA-000801-PIP03-16-M01

Alimera Sciences Limited; Treatment of chronic non-infectious uveitis / secondary prevention of chronic non-infectious uveitis

Day 30 discussion

Ophthalmology

3.3.23. Ivacaftor / tezacaftor - Orphan - EMEA-001640-PIP01-14-M07

Vertex Pharmaceuticals (Ireland) Limited; Cystic fibrosis

Day 30 discussion

Other / Pneumology - Allergology

3.3.24. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M02

Vertex Pharmaceuticals (Ireland) Limited; Cystic fibrosis

Day 30 discussion

Other / Pneumology - Allergology

3.3.25. Nintedanib - EMEA-001006-PIP05-18-M01

Boehringer Ingelheim International GmbH; Treatment of fibrosing interstitial lung diseases (ILD)

Day 30 discussion

Pneumology - Allergology / Oncology

3.3.26. Mirabegron - EMEA-000597-PIP03-15-M04

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 discussion

Uro-nephrology

3.3.27. Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of Ebola disease

Day 30 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 letters of intent received for submission of applications with start of procedure 17 August 2021 for Nomination of Rapporteur and Peer reviewer

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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.

5.1. New Scientific Advice

5.2. Final Scientific Advice (Reports and Scientific Advice letters)

No item

6. Discussion on the applicability of class waivers

6.1. Discussions on the applicability of class waiver for products

6.1.1. Icenticaftor - EMEA-06-2021

Novartis Europharm Ltd; All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation) / Treatment of chronic obstructive pulmonary disease

Summary of discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: cystic fibrosis.

6.1.2. EQ143 - EMEA-07-2021

SFL Pharmaceuticals Deutschland GmbH; The class of pyrimidine - and pyrimidine analogue - containing medicinal products for treatment of lung malignant neoplasms / As monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations / As monotherapy for the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC

Summary of discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was not confirmed because the product does not belong to the class of pyrimidine- and pyrimidine analogue-containing medicinal products for treatment of lung malignant neoplasms.

Other potential paediatric interests of this medicine suggested by PDCO: T790M mutations are being detected in several cancer types, including glioblastoma multiforme, high-grade gliomas and soft tissue sarcomas. Mutations in the EGFR have been identified in a distinct subset of paediatric-type bithalamic gliomas with a unique DNA methylation pattern, therefore EGFR targeted therapies should be a relevant target for paediatric tumours as well.

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 item

8. Annual reports on deferrals

The members of the PDCO took note of the products listed in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Update on PDCO member(s)/alternate(s) mandate status

The PDCO Chair welcomed Dimitar Roussinov representing Bulgaria as the renominated Member.

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

No item

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

Summary of Committee discussion:

The chair of the Non-clinical Working Group (NcWG) identified the products which will require NcWG evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of Committee discussion:

The Chair of the Formulation Working Group (FWG) identified the products which will require FWG evaluation and discussion.

9.3.3. CHMP List of Questions to the SWP and NcWG of the PDCO

PDCO member: Karen van Malderen

The prepared answers to the CHMP questions were endorsed with no further changes.

9.3.4. Patients and Consumers Working Party (PCWP) / Healthcare Professionals Working Party (HCPWP) meeting on 1-2 June 2021

The agenda for the Patients and Consumers Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 1-2 June 2021 was presented for information.

Minutes of meeting on 1-2 June 2021

Summary of Committee discussion:

During the first day of the 'Patients and Consumers' (PCWP) and 'Healthcare Professionals' (HCPWP) Working Parties joint meeting, the Agency introduced the latest updates on COVID-19. EMA also presented ongoing activities related with the impact of pharmacovigilance activities on healthcare and patient safety. An update on the implementation of the Clinical Trials regulation was provided.

On the second day, the PCWP/HCPWP discussion focused on communication and stakeholder engagement topics linked with EMA's future extended mandate and Big Data. The final part of the meeting was dedicated to topic prioritisation for 2022, key dates and activities.

9.3.5. Call for interest for nomination of PDCO members to join temporary ad-hoc group on complex trials Q&A – call for experts

Summary of Committee discussion:

The European Commission (DG Santé B4) has initiated the development of a question and answer document on 'complex clinical trials' in collaboration with EMA and the clinical trials facilitation group (CTFG). A first draft is now available, spanning a large scope of topics (master protocols, Bayesian methodology, use of external control, biomarkers, safety, transparency and study integrity). As the next important step, the EC/EMA/CTFG drafting group is now looking for volunteers from the network to contribute to this first draft and subsequent activities expected to span over the rest of 2021, and possibly beyond. Interested members should contact by 30 July 2021.

9.4. Cooperation within the EU regulatory network

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

No item

9.4.2. Study supporting the Impact Assessment of the revision of the EU legislation on medicines for children and rare diseases | Follow-up interview European Commission

Public consultation for the revision of the Paediatric Regulation

Summary of Committee discussion:

The study supporting the impact assessment of the revision of the EU paediatric legislation was presented and discussed with the committee.

9.5. Cooperation with International Regulators

No item

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

No item

9.7. PDCO work plan

No item

9.8. Planning and reporting

No item

10. Any other business

10.1. COVID -19 update

No item

11. Breakout sessions

11.1. Internal PDCO Operations

Summary of Committee discussion:

The committee discussed topics regarding the PDCO plenary meeting.

11.2. Paediatric oncology

Summary of Committee discussion:

The group was informed of the next Accelerate strategy forum on multi-targeted kinase inhibitors in Bone Sarcomas. In addition, it exchanged views on issues related to the oncology products discussed at the PDCO plenary.

11.3. Vaccines

Summary of Committee discussion:

Discussion on paediatric aspects of COVID-19 vaccines.

The Chair thanked all participants and closed the meeting.

12. List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 20-23 July 2021 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Koenraad Norga	Chair	Belgium	When chairing the meeting: To be replaced for discussions, final deliberations and voting When not chairing the meeting: No participation in final deliberations and voting	3.1.16. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20 3.1.54. Otilimab - EMEA-001882-PIP04-21 3.1.82. Depemokimab - EMEA-003051-PIP01-21
Karl-Heinz Huemer	Member	Austria	No interests declared	
Johanna Wernsperger	Alternate	Austria	No interests declared	
Marleen Renard	Member	Belgium	No restrictions applicable to this meeting	
Karen Van Malderen	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Tereza Bazantova	Alternate	Czechia	No interests declared	
Nanna Borup Johansen	Member	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Pauliina Lehtolainen-Dalkilic	Member	Finland	No interests declared	
Anne Paavola	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Dominique Ploin	Alternate	France	No interests declared	
Sabine Scherer	Member (Vice-Chair)	Germany	No interests declared	
Yuansheng Sun	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP	Hungary	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	member)			
Brian Aylward	Member	Ireland	No interests declared	
Sara Galluzzo	Member	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No restrictions applicable to this meeting	
Dovile Zacharkiene	Member	Lithuania	No interests declared	
Silvijus Abramavicius	Alternate	Lithuania	No restrictions applicable to this meeting	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
John-Joseph Borg	Member	Malta	No interests declared	
Herbert Lenicker	Alternate	Malta	No interests declared	
Roderick Houwen	Member	Netherlands	No restrictions applicable to this meeting	
Maaike van Dartel	Alternate	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Anette Solli Karlsen	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Peter Sisovsky	Member	Slovakia	No interests declared	
Peter Szitanyi	Alternate	Slovakia	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesus Fernández Cortizo	Alternate	Spain	No interests declared	
Eva Agurell	Member	Sweden	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Fernando Cabanas	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Francesca Rocchi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Jaroslav	Member	Patients’	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sterba		Organisation Representative		
Tomasz Grybek	Alternate	Patients' Organisation Representative	No interests declared	
Michal Odermarsky	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
María Estela Moreno Martín	Expert - via telephone*	Spain	No interests declared	
Lutz Wiesner	Expert - via telephone*	Germany	No interests declared	
Gaby Wangorsch	Expert - via telephone*	Germany - PEI	No interests declared	
Meeting run with support from relevant EMA staff				
* Experts were evaluated against the agenda topics or activities they participated in				

13. 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/