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Paediatric Committee (PDCO)

Draft Agenda for the meeting on 07-10 September 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

07 September 2021, 14:00- 19:00, virtual meeting

08 September 2021, 08:30- 19:00, virtual meeting

09 September 2021, 08:30- 19:00, virtual meeting

10 September 2021, 08:30- 13:00, virtual meeting

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Table of contents

| | | |
|-----------|--|-----------|
| 1. | Introductions | 10 |
| 1.1. | Welcome and declarations of interest of members, alternates and experts..... | 10 |
| 1.2. | Adoption of agenda | 10 |
| 1.3. | Adoption of the minutes | 10 |
| 2. | Opinions | 10 |
| 2.1. | Opinions on Products | 10 |
| 2.1.1. | PCSK9-targeted, antisense oligonucleotide (ASO) - EMEA-002962-PIP01-21..... | 10 |
| 2.1.2. | EMEA-002944-PIP01-20 | 10 |
| 2.1.3. | Drospirenone - EMEA-001495-PIP02-21 | 11 |
| 2.1.4. | Glepaglutide - EMEA-002926-PIP01-20 | 11 |
| 2.1.5. | Semaglutide - EMEA-001441-PIP05-20 | 11 |
| 2.1.6. | EMEA-002927-PIP01-20 | 11 |
| 2.1.7. | Islatravir - EMEA-002938-PIP01-20 | 11 |
| 2.1.8. | Pritelivir - EMEA-002180-PIP02-19 | 11 |
| 2.1.9. | EMEA-002963-PIP01-21 | 12 |
| 2.1.10. | Terbinafine EMEA-002984-PIP01-21 | 12 |
| 2.1.11. | Crisantaspase - EMEA-002934-PIP01-20 | 12 |
| 2.1.12. | Loncastuximab tesirine - EMEA-002665-PIP02-20..... | 12 |
| 2.1.13. | Brensocatib - EMEA-002905-PIP01-20 | 12 |
| 2.1.14. | Thienopyrimidine derivative - EMEA-002901-PIP01-20 | 13 |
| 2.1.15. | Ravulizumab - EMEA-001943-PIP02-20..... | 13 |
| 2.1.16. | EMEA-002873-PIP01-20 | 13 |
| 2.1.17. | Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20 | 13 |
| 2.1.18. | Zofenopril / amlodipine - EMEA-003036-PIP01-21 | 13 |
| 2.1.19. | Ezetimibe / rosuvastatin - EMEA-001447-PIP02-21 | 13 |
| 2.1.20. | Ezetimibe / rosuvastatin - EMEA-003018-PIP01-21 | 14 |
| 2.1.21. | Ezetimibe / rosuvastatin - EMEA-003039-PIP01-21 | 14 |
| 2.1.22. | Manganese chloride - EMEA-003035-PIP01-21 | 14 |
| 2.1.23. | Perflubutane - EMEA-003037-PIP01-21 | 14 |
| 2.1.24. | Pyridoxine / doxylamine - EMEA-001608-PIP02-21 | 14 |
| 2.1.25. | Rusfertide - Orphan - EMEA-003045-PIP01-21 | 15 |
| 2.1.26. | Tocilizumab - EMEA-000309-PIP06-21 | 15 |
| 2.1.27. | Anti-C1s humanized IgG4 monoclonal antibody - EMEA-002903-PIP03-21..... | 15 |
| 2.1.28. | Anti-neonatal Fc receptor human monoclonal antibody - EMEA-002559-PIP04-21..... | 15 |
| 2.1.29. | Efgartigimod alfa - EMEA-002597-PIP06-21 | 15 |

| | | |
|-------------|---|-----------|
| 2.1.30. | Izaflortaucipir (¹⁸ F) - Orphan - EMEA-003040-PIP01-21 | 15 |
| 2.1.31. | Ravulizumab - EMEA-001943-PIP05-21 | 16 |
| 2.1.32. | 5'-capped mRNA encoding HPV16 oncoprotein E6 and E7 / 5'-capped mRNA encoding HPV16 oncoprotein E6 and E7 - EMEA-003023-PIP01-21 | 16 |
| 2.1.33. | Alnuctamab - EMEA-003046-PIP01-21 | 16 |
| 2.1.34. | 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-PIP01-2116 | 16 |
| 2.1.35. | 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 | 17 |
| 2.1.36. | Batiraxcept - EMEA-003042-PIP01-21 | 17 |
| 2.1.37. | Pralsetinib - EMEA-002575-PIP03-21 | 17 |
| 2.1.38. | Senaparib - EMEA-003034-PIP01-21 | 17 |
| 2.1.39. | Humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide - EMEA-002957-PIP02-21 | 17 |
| 2.1.40. | EMEA-003048-PIP01-21 | 18 |
| 2.1.41. | Ofloxacin / dexamethasone - EMEA-003031-PIP01-21 | 18 |
| 2.1.42. | Lutetium (¹⁷⁷ Lu) - EMEA-003038-PIP01-21 | 18 |
| 2.1.43. | Depemokimab - EMEA-003051-PIP01-21 | 18 |
| 2.1.44. | Yellow fever virus - EMEA-003030-PIP01-21 | 18 |
| 2.2. | Opinions on Compliance Check | 18 |
| 2.2.1. | Ganaxolone - EMEA-C1-002341-PIP01-18-M01 | 19 |
| 2.3. | Opinions on Modification of an Agreed Paediatric Investigation Plan | 19 |
| 2.3.1. | Remimazolam - EMEA-001880-PIP02-19-M03 | 19 |
| 2.3.2. | Edoxaban tosylate - EMEA-000788-PIP02-11-M11 | 19 |
| 2.3.3. | Dulaglutide - EMEA-000783-PIP01-09-M06 | 19 |
| 2.3.4. | Empagliflozin - EMEA-000828-PIP01-09-M09 | 19 |
| 2.3.5. | Linagliptin - EMEA-000498-PIP01-08-M10 | 20 |
| 2.3.6. | Recombinant human glutamic acid decarboxylase (rhGAD65) - EMEA-000609-PIP01-09-M0320 | |
| 2.3.7. | Semaglutide - EMEA-001441-PIP03-17-M02 | 20 |
| 2.3.8. | Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18-M01 | 20 |
| 2.3.9. | Recombinant human A disintegrin and metalloprotease with thrombospondin type-1 motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M02 | 20 |
| 2.3.10. | Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M05 | 21 |
| 2.3.11. | Oteseconazole - EMEA-002392-PIP01-18-M02 | 21 |
| 2.3.12. | 5-[[4-[2-[5-(1-Hydroxyethyl)-2-pyridinyl]ethoxy]phenyl]methyl]-2,4-thiazolidinedione hydrochloride - Orphan - EMEA-002106-PIP01-16-M01 | 21 |
| 2.3.13. | Galcanezumab - EMEA-001860-PIP03-16-M06 | 21 |
| 2.3.14. | Ganaxolone - Orphan - EMEA-002341-PIP01-18-M02 | 21 |

| | | |
|-------------|---|-----------|
| 2.3.15. | Ozanimod hydrochloride - EMEA-001710-PIP02-14-M06 | 21 |
| 2.3.16. | Abemaciclib - EMEA-002342-PIP01-18-M02 | 22 |
| 2.3.17. | Abemaciclib - EMEA-002342-PIP02-18-M01 | 22 |
| 2.3.18. | Brigatinib - EMEA-002296-PIP01-17-M03 | 22 |
| 2.3.19. | Imatinib (as imatinib mesylate) - EMEA-002643-PIP01-19-M01 | 22 |
| 2.3.20. | Palbociclib - EMEA-002146-PIP01-17-M03 | 22 |
| 2.3.21. | Temozolomide - EMEA-002634-PIP01-19-M01 | 23 |
| 2.3.22. | Fluocinolone acetonide - EMEA-000801-PIP03-16-M01 | 23 |
| 2.3.23. | Ivacaftor / tezacaftor - Orphan - EMEA-001640-PIP01-14-M07 | 23 |
| 2.3.24. | Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M02..... | 23 |
| 2.3.25. | Nintedanib - EMEA-001006-PIP05-18-M01..... | 23 |
| 2.3.26. | Mirabegron - EMEA-000597-PIP03-15-M04..... | 23 |
| 2.3.27. | Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M02..... | 24 |
| 2.3.28. | CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2) - EMEA-002893-PIP01-20-M01 | 24 |
| 2.3.29. | Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) (Comirnaty) - EMEA-002861-PIP02-20-M02 | 24 |
| 2.4. | Opinions on Re-examinations | 24 |
| 2.5. | Opinions on Review of Granted Waivers | 24 |
| 2.6. | Finalisation and adoption of Opinions..... | 24 |
| 2.7. | Partial Compliance Checks completed by EMA | 25 |
| 2.7.1. | <i>Neisseria meningitidis</i> serogroup W polysaccharide conjugated to tetanus toxoid / <i>N. meningitidis</i> serogroup Y polysaccharide conjugated to tetanus toxoid / <i>N. meningitidis</i> serogroup A polysaccharide conjugated to tetanus toxoid / <i>N. meningitidis</i> serogroup C polysaccharide conjugated to tetanus toxoid - EMEA-C2-001930-PIP01-16-M03..... | 25 |
| 2.7.2. | Durvalumab - EMEA-C2-002028-PIP01-16-M02..... | 25 |
| 3. | Discussion of applications | 25 |
| 3.1. | Discussions on Products D90-D60-D30..... | 25 |
| 3.1.1. | Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain - EMEA-002942-PIP01-20 | 25 |
| 3.1.2. | Marzeptacog alfa (activated) - Orphan - EMEA-002270-PIP03-20..... | 25 |
| 3.1.3. | Marzeptacog alfa (activated) - Orphan - EMEA-002270-PIP04-20..... | 26 |
| 3.1.4. | Ravulizumab - EMEA-001943-PIP04-20..... | 26 |
| 3.1.5. | Lutetium (¹⁷⁷ Lu) oxodotretotide - Orphan - EMEA-002950-PIP01-20 | 26 |
| 3.1.6. | Magrolimab - Orphan - EMEA-002819-PIP01-20 | 26 |
| 3.1.7. | 2'-O-(2-methoxyethyl) phosphorothioate antisense oligonucleotide targeting CD49d RNA - Orphan - EMEA-002981-PIP01-21 | 26 |
| 3.1.8. | <i>Neisseria meningitidis</i> serogroup B protein-based active substance / Recombinant <i>Neisseria meningitidis</i> serogroup B protein 1 / Recombinant <i>Neisseria meningitidis</i> serogroup B protein 3 / Recombinant <i>Neisseria meningitidis</i> serogroup B protein 2 - EMEA-002954-PIP02-21 | 27 |
| 3.1.9. | Dupilumab - EMEA-001501-PIP09-21..... | 27 |

| | | |
|---------|--|----|
| 3.1.10. | Phospholipid esters from herring roe - EMEA-003053-PIP01-21 | 27 |
| 3.1.11. | Bilastine - EMEA-000347-PIP06-21 | 27 |
| 3.1.12. | Ibutamoren mesilate - Orphan - EMEA-003032-PIP01-21 | 27 |
| 3.1.13. | Zinc gluconate / alisitol / retinyl palmitate - Orphan - EMEA-002198-PIP01-21 | 28 |
| 3.1.14. | Mitapivat - Orphan - EMEA-002684-PIP02-21 | 28 |
| 3.1.15. | Rozanolixizumab - Orphan - EMEA-002681-PIP02-21 | 28 |
| 3.1.16. | Autologous bone marrow derived CD34+cells transduced with the lentiviral vector CL20-4i-EF1 α -hyc-OPT - Orphan - EMEA-003050-PIP01-21..... | 28 |
| 3.1.17. | ECT-001-CB (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 | 28 |
| 3.1.18. | Reparixin - Orphan - EMEA-001693-PIP03-21 | 29 |
| 3.1.19. | Alprazolam - EMEA-003043-PIP01-21 | 29 |
| 3.1.20. | Invimestrocel - EMEA-002317-PIP02-21..... | 29 |
| 3.1.21. | Rozanolixizumab - EMEA-002681-PIP03-21 | 29 |
| 3.1.22. | 1-[(4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6-methoxyquinolin-7-yl)oxy)methyl]cyclopropan-1-amine bishydrochloride - Orphan - EMEA-002486-PIP04-21 . | 29 |
| 3.1.23. | Plinabulin - EMEA-003054-PIP01-21 | 29 |
| 3.1.24. | Tazemetostat - Orphan - EMEA-003055-PIP01-21 | 30 |
| 3.1.25. | Pabinafusp alfa - Orphan - EMEA-003033-PIP01-21 | 30 |
| 3.1.26. | EMEA-003052-PIP01-21 | 30 |
| 3.1.27. | L-Carnitine / glucose / calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21 | 30 |
| 3.1.28. | <i>Neisseria meningitidis</i> serogroup B fHbp subfamily B / <i>Neisseria meningitidis</i> serogroup B fHbp subfamily A / <i>Neisseria meningitidis</i> group Y polysaccharide conjugated to tetanus toxoid carrier protein / <i>Neisseria meningitidis</i> group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / <i>Neisseria meningitidis</i> group C polysaccharide conjugated to tetanus toxoid carrier protein / <i>Neisseria meningitidis</i> group A polysaccharide conjugated to tetanus toxoid carrier protein - EMEA-002814-PIP02-21 | 30 |
| 3.1.29. | SARS-CoV-2, produced in Vero cells (inactivated) - EMEA-003057-PIP01-21 | 31 |
| 3.1.30. | Amlodipine / ramipril - EMEA-003070-PIP01-21 | 31 |
| 3.1.31. | Furosemide / eplerenone - EMEA-003065-PIP01-21 | 31 |
| 3.1.32. | Humanised KLB / FGFR1c monoclonal antibody - EMEA-003058-PIP01-21 | 31 |
| 3.1.33. | Semaglutide / cagrilintide - EMEA-003059-PIP01-21 | 31 |
| 3.1.34. | Tezepelumab - EMEA-001613-PIP03-21 | 32 |
| 3.1.35. | Clazakizumab - EMEA-001371-PIP02-21 | 32 |
| 3.1.36. | Human normal immunoglobulin - EMEA-003076-PIP01-21 | 32 |
| 3.1.37. | Retinol palmitate - Orphan - EMEA-003073-PIP01-21 | 32 |
| 3.1.38. | Cannabidiol - EMEA-001964-PIP03-21 | 32 |
| 3.1.39. | Censavudine - EMEA-003075-PIP01-21 | 33 |
| 3.1.40. | Verdiperstat - Orphan - EMEA-002708-PIP02-21 | 33 |

| | | |
|-------------|--|-----------|
| 3.1.41. | Adagrasib - EMEA-003068-PIP01-21..... | 33 |
| 3.1.42. | Adagrasib - EMEA-003068-PIP02-21..... | 33 |
| 3.1.43. | Adavosertib - EMEA-003069-PIP01-21..... | 33 |
| 3.1.44. | Autologous tumour-infiltrating lymphocytes (TILs) isolated from a patient's cancer tissue and expanded ex vivo - EMEA-003072-PIP01-21..... | 33 |
| 3.1.45. | Ofranergene obadenovec - Orphan - EMEA-003062-PIP01-21..... | 34 |
| 3.1.46. | Pamrevlumab - EMEA-002979-PIP03-21..... | 34 |
| 3.1.47. | Vibostolimab / pembrolizumab - EMEA-003063-PIP01-21..... | 34 |
| 3.1.48. | Cedazuridine - EMEA-003071-PIP01-21..... | 34 |
| 3.1.49. | Otenaproxesul - EMEA-003061-PIP01-21..... | 34 |
| 3.1.50. | Benralizumab - EMEA-001214-PIP08-21..... | 35 |
| 3.1.51. | Bis-(3-deoxy-3-(4-(3-fluorophenyl)-1H-1,2,3-triazol-1-yl)-beta-D-galactopyranosyl) sulfane - Orphan - EMEA-003060-PIP01-21..... | 35 |
| 3.1.52. | Depemokimab - EMEA-003051-PIP02-21..... | 35 |
| 3.1.53. | Depemokimab - EMEA-003051-PIP03-21..... | 35 |
| 3.1.54. | Human alpha1-proteinase inhibitor (also called alpha-1 Antitrypsin) - EMEA-001525-PIP02-21..... | 35 |
| 3.1.55. | Pamrevlumab - EMEA-002979-PIP02-21..... | 36 |
| 3.1.56. | Ilofotase alfa - EMEA-003067-PIP01-21..... | 36 |
| 3.1.57. | Lademirsen - Orphan - EMEA-003064-PIP01-21..... | 36 |
| 3.1.58. | Influenza virus surface antigen (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP02-21..... | 36 |
| 3.1.59. | Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP01-21..... | 36 |
| 3.1.60. | Inactivated poliovirus: type 3 (Saukett strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 1 (Mahoney strain) / Bordetella pertussis antigen: Pertactin / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertussis toxoid / Tetanus toxoid / Diphtheria toxoid - EMEA-003066-PIP01-21..... | 36 |
| 3.1.61. | RSV F protein - EMEA-003094-PIP01-21..... | 37 |
| 3.1.62. | Whole-cell heat-inactivated bacterial strains of <i>Escherichia coli</i> / <i>Klebsiella pneumoniae</i> / <i>Proteus vulgaris</i> / <i>Enterococcus faecalis</i> - EMEA-003026-PIP02-21..... | 37 |
| 3.1.63. | Evenamide - EMEA-002519-PIP03-21..... | 37 |
| 3.1.64. | Satralizumab - EMEA-001625-PIP02-21..... | 37 |
| 3.2. | Discussions on Compliance Check..... | 37 |
| 3.2.1. | Lonococog alfa - EMEA-C-001215-PIP01-11-M07..... | 38 |
| 3.2.2. | Olipudase alfa - EMEA-C1-001600-PIP01-13-M02..... | 38 |
| 3.2.3. | Ravulizumab - EMEA-C3-002077-PIP01-16-M04..... | 38 |
| 3.2.4. | Ceftobiprole medocaril (sodium) - EMEA-C1-000205-PIP02-11-M04..... | 38 |
| 3.2.5. | Oseltamivir (phosphate) - EMEA-C-000365-PIP01-08-M12..... | 38 |
| 3.2.6. | Nivolumab / relatlimab - EMEA-C-002727-PIP01-19-M01..... | 38 |
| 3.2.7. | Ponatinib (as hydrochloride) - EMEA-C2-001186-PIP01-11-M02..... | 39 |
| 3.2.8. | Tremelimumab - EMEA-C2-002029-PIP01-16-M02..... | 39 |

| | | |
|-------------|---|-----------|
| 3.2.9. | Zanubrutinib - EMEA-C1-002354-PIP02-18..... | 39 |
| 3.2.10. | Bupivacaine - EMEA-C1-000877-PIP03-17-M03..... | 39 |
| 3.2.11. | Mirabegron - EMEA-C4-000597-PIP03-15-M03..... | 39 |
| 3.2.12. | Ravulizumab - EMEA-C2-001943-PIP01-16-M06..... | 40 |
| 3.3. | Discussions on Modification of an Agreed Paediatric Investigation Plan..... | 40 |
| 3.3.1. | Bilastine - EMEA-000347-PIP02-16-M03..... | 40 |
| 3.3.2. | 3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alfa-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride - EMEA-002735-PIP03-20-M01..... | 40 |
| 3.3.3. | Azilsartan medoxomil - EMEA-000237-PIP01-08-M10..... | 40 |
| 3.3.4. | Macitentan - Orphan - EMEA-001032-PIP01-10-M04..... | 40 |
| 3.3.5. | Vericiguat - EMEA-001636-PIP01-14-M02..... | 41 |
| 3.3.6. | Glycopyrronium bromide - EMEA-002383-PIP01-18-M01..... | 41 |
| 3.3.7. | Cotadutide - EMEA-002287-PIP01-17-M03..... | 41 |
| 3.3.8. | Evinacumab - EMEA-002298-PIP01-17-M03..... | 41 |
| 3.3.9. | Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M05..... | 41 |
| 3.3.10. | Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M07..... | 41 |
| 3.3.11. | Marstacimab - Orphan - EMEA-002285-PIP02-19-M01..... | 42 |
| 3.3.12. | Vonicog alfa - EMEA-001164-PIP01-11-M05..... | 42 |
| 3.3.13. | Upadacitinib - EMEA-001741-PIP01-14-M05..... | 42 |
| 3.3.14. | Baloxavir marboxil - EMEA-002440-PIP01-18-M02..... | 42 |
| 3.3.15. | Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M05..... | 42 |
| 3.3.16. | Dalbavancin hydrochloride - EMEA-000016-PIP01-07-M08..... | 42 |
| 3.3.17. | Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M04..... | 43 |
| 3.3.18. | Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M04..... | 43 |
| 3.3.19. | Pretomanid - Orphan - EMEA-002115-PIP01-17-M04..... | 43 |
| 3.3.20. | Rilpivirine (RPV) / dolutegravir (DTG) - EMEA-001750-PIP01-15-M05..... | 43 |
| 3.3.21. | Sotrovimab - EMEA-002899-PIP01-20-M01..... | 43 |
| 3.3.22. | Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19-M01..... | 44 |
| 3.3.23. | Tenofovir alafenamide / emtricitabine / bictegravir - EMEA-001766-PIP01-15-M04..... | 44 |
| 3.3.24. | Erenumab - EMEA-001664-PIP02-15-M05..... | 44 |
| 3.3.25. | Perampanel - EMEA-000467-PIP01-08-M15..... | 44 |
| 3.3.26. | Soticlestat - EMEA-002572-PIP02-19-M01..... | 44 |
| 3.3.27. | Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M02..... | 45 |
| 3.3.28. | Cabozantinib - Orphan - EMEA-001143-PIP01-11-M04..... | 45 |
| 3.3.29. | Cyclophosphamide - EMEA-002644-PIP01-19-M01..... | 45 |
| 3.3.30. | Larotrectinib - EMEA-001971-PIP02-16-M04..... | 45 |
| 3.3.31. | Regorafenib - EMEA-001178-PIP01-11-M06..... | 45 |
| 3.3.32. | Ruxolitinib phosphate - EMEA-000901-PIP04-17-M02..... | 45 |

| | | |
|---------|---|----|
| 3.3.33. | Selpercatinib - EMEA-002544-PIP01-18-M01 | 46 |
| 3.3.34. | Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M04 | 46 |
| 3.3.35. | Vamorolone - Orphan - EMEA-001794-PIP02-16-M04..... | 46 |
| 3.3.36. | Methoxflurane - EMEA-000334-PIP01-08-M10..... | 46 |
| 3.3.37. | Molgramostim - Orphan - EMEA-002282-PIP01-17-M01..... | 46 |
| 3.3.38. | Tezepelumab - EMEA-001613-PIP01-14-M05 | 47 |
| 3.3.39. | Lumasiran sodium - Orphan - EMEA-002079-PIP01-16-M02..... | 47 |
| 3.3.40. | Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16-M04..... | 47 |
| 3.3.41. | NVX-CoV2373 - EMEA-002941-PIP01-20-M01 | 47 |

4. Nominations 47

| | | |
|-------------|--|-----------|
| 4.1. | List of submissions of applications with start of procedure 14 September 2021 for Nomination of Rapporteur and Peer reviewer..... | 47 |
| 4.2. | Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver | 48 |
| 4.3. | Nominations for other activities | 48 |

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction 48

6. Discussion on the applicability of class waivers 48

| | | |
|-------------|---|-----------|
| 6.1. | Discussions on the applicability of class waiver for products..... | 48 |
|-------------|---|-----------|

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver 48

| | | |
|-------------|--|-----------|
| 7.1. | Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver | 48 |
| 7.1.1. | Stivarga - EMEA-001178-PIP01-11-M05..... | 48 |

8. Annual reports on deferrals 48

9. Organisational, regulatory and methodological matters 49

| | | |
|-------------|---|-----------|
| 9.1. | Mandate and organisation of the PDCO | 49 |
| 9.1.1. | Pilot – Relaunch of face to face Scientific Committee Meetings..... | 49 |
| 9.1.2. | PDCO Rules of Procedure – revision..... | 49 |
| 9.2. | Coordination with EMA Scientific Committees or CMDh-v | 49 |
| 9.2.1. | Committee for Medicinal Products for Human Use (CHMP)..... | 49 |
| 9.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 49 |
| 9.3.1. | Non-clinical Working Group: D30 Products identified | 49 |
| 9.3.2. | Formulation Working Group..... | 49 |
| 9.3.3. | Patients and Consumers Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 21-22 September 2021 | 49 |

| | | |
|--------------|---|-----------|
| 9.4. | Cooperation within the EU regulatory network..... | 49 |
| 9.4.1. | European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA) | 49 |
| 9.5. | Cooperation with International Regulators..... | 50 |
| 9.6. | Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee..... | 50 |
| 9.7. | PDCO work plan..... | 50 |
| 9.8. | Planning and reporting | 50 |
| 10. | Any other business | 50 |
| 10.1. | COVID -19 update..... | 50 |
| 10.2. | Project Lifecycle Regulations Submissions Raw Data (LRSR) | 50 |
| 10.3. | Project on paediatric first-line tuberculosis medicines | 50 |
| 11. | Breakout sessions | 50 |
| 11.1. | Internal PDCO Operations | 50 |
| 11.2. | Neonatology | 50 |
| 11.3. | Vaccines | 50 |
| 11.4. | Paediatric oncology | 51 |
| 11.5. | PDCO-SAWP interaction and process improvement | 51 |
| 12. | Explanatory notes | 51 |

1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 07-10 September 2021. See September 2021 PDCO minutes (to be published post October 2021 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 07-10 September 2021

1.3. Adoption of the minutes

PDCO minutes for 20-23 July 2021

2. Opinions

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

2.1. Opinions on Products

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

Treatment of elevated cholesterol / Treatment of mixed dyslipidaemia

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. EMEA-002944-PIP01-20

Treatment of type 2 diabetes mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Drospirenone - EMEA-001495-PIP02-21

Treatment of endometriosis

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. Glepaglutide - EMEA-002926-PIP01-20

Treatment of short bowel syndrome

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. Semaglutide - EMEA-001441-PIP05-20

Treatment of non-alcoholic steatohepatitis (NASH)

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.6. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. Islatravir - EMEA-002938-PIP01-20

Prevention of human immunodeficiency virus (HIV-1) infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. Pritelivir - EMEA-002180-PIP02-19

Treatment of herpes simplex virus disease

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.9. EMEA-002963-PIP01-21](#)

Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.10. Terbinafine EMEA-002984-PIP01-21](#)

Treatment of onychomycosis

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.11. Crisantaspase - EMEA-002934-PIP01-20](#)

Treatment of acute lymphoblastic leukaemia / lymphoma

Day 120 opinion

Action: For adoption

Oncology

[2.1.12. Loncastuximab tesirine - EMEA-002665-PIP02-20](#)

Treatment of mature B-cell neoplasms

Day 120 opinion

Action: For adoption

Oncology

[2.1.13. Brensocatib - EMEA-002905-PIP01-20](#)

Treatment of non-cystic fibrosis bronchiectasis (NCFBE)

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.14. Thienopyrimidine derivative - EMEA-002901-PIP01-20

Treatment of fibrosing interstitial lung disease

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.15. Ravulizumab - EMEA-001943-PIP02-20

Treatment in haematopoietic stem cell transplantation

Day 120 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.1.16. EMEA-002873-PIP01-20

Active immunisation for the prevention of disease caused by chikungunya virus

Day 120 opinion

Action: For adoption

Vaccines

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

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Day 120 opinion

Action: For adoption

Vaccines

2.1.18. Zofenopril / amlodipine - EMEA-003036-PIP01-21

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Prevention of cardiovascular events

Day 60 opinion

Action: For adoption
Cardiovascular Diseases

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

Prevention of cardiovascular events / Treatment of hypercholesterolemia
Day 60 opinion
Action: For adoption
Cardiovascular Diseases

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

Treatment of hypercholesterolemia / Prevention of cardiovascular events
Day 60 opinion
Action: For adoption
Cardiovascular Diseases

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

Diagnostic evaluation of liver lesions by magnetic resonance imaging
Day 60 opinion
Action: For adoption
Diagnostic / Oncology

2.1.23. Perflubutane - EMEA-003037-PIP01-21

Diagnostic evaluation of focal hepatic lesions
Day 60 opinion
Action: For adoption
Diagnostic / Oncology

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

Treatment of nausea and vomiting of pregnancy
Day 60 opinion
Action: For adoption
Endocrinology-Gynaecology-Fertility-Metabolism

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

Protagonist Therapeutics, Inc.; Treatment of polycythaemia vera

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.26. Tocilizumab - EMEA-000309-PIP06-21

Treatment of systemic sclerosis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.27. Anti-C1s humanized IgG4 monoclonal antibody - EMEA-002903-PIP03-21

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

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

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 60 opinion

Action: For adoption

Neurology

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

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 60 opinion

Action: For adoption

Neurology

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

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

Day 60 opinion

Action: For adoption

Neurology

2.1.31. Ravulizumab - EMEA-001943-PIP05-21

Treatment of amyotrophic lateral sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.1.32. 5'-capped mRNA encoding HPV16 oncoprotein E6 and E7 / 5'-capped mRNA encoding HPV16 oncoprotein E6 and E7 - EMEA-003023-PIP01-21

Treatment of head and neck squamous cell carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.33. Alnuctamab - EMEA-003046-PIP01-21

Treatment of mature B cell malignancies

Day 60 opinion

Action: For adoption

Oncology

2.1.34. 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 60 opinion

Action: For adoption

Oncology

2.1.35. 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 60 opinion

Action: For adoption

Oncology

2.1.36. Batiraxcept - EMEA-003042-PIP01-21

Treatment of ovarian cancer / Treatment of fallopian tube cancer / Treatment of primary peritoneal cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.37. Pralsetinib - EMEA-002575-PIP03-21

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

Day 60 opinion

Action: For adoption

Oncology

2.1.38. Senaparib - EMEA-003034-PIP01-21

Metastatic castrate-resistant prostate cancer

Day 60 opinion

Action: For adoption

Oncology

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

Treatment of diabetic retinopathy

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.40. EMEA-003048-PIP01-21

Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

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

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

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.42. Lutetium (¹⁷⁷Lu) - EMEA-003038-PIP01-21

Radiolabelling agent

Day 60 opinion

Action: For adoption

Other

2.1.43. Depemokimab - EMEA-003051-PIP01-21

Treatment of nasal polyposis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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

Prevention of Yellow Fever disease

Day 60 opinion

Action: For adoption

Vaccines

Note: Withdrawal request received on 27 August 2021

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. [Ganaxolone - EMEA-C1-002341-PIP01-18-M01](#)

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

Day 60 letter

Action: For adoption

Neurology

2.3. [Opinions on Modification of an Agreed Paediatric Investigation Plan](#)

2.3.1. [Remimazolam - EMEA-001880-PIP02-19-M03](#)

PAION Deutschland GmbH; Sedation / General anaesthesia

Day 60 opinion

Action: For adoption

Anaesthesiology

2.3.2. [Edoxaban tosylate - EMEA-000788-PIP02-11-M11](#)

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.3. [Dulaglutide - EMEA-000783-PIP01-09-M06](#)

Eli Lilly and Company; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. [Empagliflozin - EMEA-000828-PIP01-09-M09](#)

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. [Linagliptin - EMEA-000498-PIP01-08-M10](#)

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. [Recombinant human glutamic acid dextranase \(rhGAD65\) - EMEA-000609-PIP01-09-M03](#)

Diamyd Medical AB; Treatment of type 1 diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. [Semaglutide - EMEA-001441-PIP03-17-M02](#)

Novo Nordisk A/S; Treatment of obesity

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.8. [Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18-M01](#)

OxThera AB; Treatment of hyperoxaluria

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

2.3.9. [Recombinant human A disintegrin and metalloprotease with thrombospondin type-1 motifs 13 \(rADAMTS13\) - Orphan - EMEA-001160-PIP01-11-M02](#)

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

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

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

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

Day 60 opinion

Action: For adoption

Infectious Diseases

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

Gedeon Richter Plc.; Treatment of vulvovaginal candidiasis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. 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 60 opinion

Action: For adoption

Neurology

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

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

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

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

Day 60 opinion

Action: For adoption

Neurology

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

Celgene Europe B.V.; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

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

Eli Lilly and Company Limited; Treatment of Ewing sarcoma

Day 60 opinion

Action: For adoption

Oncology

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

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

Day 60 opinion

Action: For adoption

Oncology

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

Takeda Pharm A/S; Treatment of inflammatory myofibroblastic tumors (IMT) / Treatment of non-small cell lung cancer (NSCLC) / Treatment of anaplastic large cell lymphoma (ALCL)

Day 60 opinion

Action: For adoption

Oncology

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

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

Day 60 opinion

Action: For adoption

Oncology

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

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma

Day 60 opinion

Action: For adoption

Oncology

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

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

Day 60 opinion

Action: For adoption

Oncology

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

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

Day 60 opinion

Action: For adoption

Ophthalmology

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

Vertex Pharmaceuticals (Ireland) Limited; Cystic Fibrosis

Day 60 opinion

Action: For adoption

Other / Pneumology - Allergology

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

Vertex Pharmaceuticals (Ireland) Limited; Cystic Fibrosis

Day 60 opinion

Action: For adoption

Other / Pneumology - Allergology

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

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology / Oncology

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

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

Day 60 opinion

Action: For adoption

Uro-nephrology

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

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

Day 60 opinion

Action: For adoption

Vaccines

2.3.28. CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2) - EMEA-002893-PIP01-20-M01

MODERNA BIOTECH SPAIN, S.L.; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.3.29. Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) (Comirnaty) - EMEA-002861-PIP02-20-M02

BioNTech Manufacturing GmbH; Prevention of coronavirus disease 2019 (COVID-19)

Day 3 opinion

Action: For information. Adopted via written procedure on 20 August 2021

Vaccines / Infectious Diseases

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. *Neisseria meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid - EMEA-C2-001930-PIP01-16-M03

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 30 letter

Action: For information

Vaccines

2.7.2. Durvalumab - EMEA-C2-002028-PIP01-16-M02

AstraZeneca AB; Treatment of malignant neoplasms of lymphoid tissue

Day 30 letter

Action: For information

Oncology

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. Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain - EMEA-002942-PIP01-20

Treatment of non-alcoholic steatohepatitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.2. Marzeptacog alfa (activated) - Orphan - EMEA-002270-PIP03-20

Catalyst Biosciences, Inc.; Treatment of haemophilia A

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.3. [Marzeptacog alfa \(activated\) - Orphan - EMEA-002270-PIP04-20](#)

Catalyst Biosciences, Inc.; Treatment of haemophilia B

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. [Ravulizumab - EMEA-001943-PIP04-20](#)

Aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder

Day 90 discussion

Action: For discussion

Neurology

3.1.5. [Lutetium \(¹⁷⁷Lu\) oxodotreotide - Orphan - EMEA-002950-PIP01-20](#)

Advanced Accelerator Applications; Gastroenteropancreatic neuroendocrine tumours (GEP-NETs)

Day 90 discussion

Action: For discussion

Oncology

3.1.6. [Magrolimab - Orphan - EMEA-002819-PIP01-20](#)

Gilead Sciences International Ltd; Treatment of myelodysplastic syndromes (including juvenile myelomonocytic leukaemia) / Treatment of acute myeloid leukaemia

Day 90 discussion

Action: For discussion

Oncology

3.1.7. [2'-O-\(2-methoxyethyl\) phosphorothioate antisense oligonucleotide targeting CD49d RNA - Orphan - EMEA-002981-PIP01-21](#)

Antisense Therapeutics Limited; Treatment of Duchenne muscular dystrophy

Day 90 discussion

Action: For discussion

Other

3.1.8. *Neisseria meningitidis* serogroup B protein-based active substance / Recombinant *Neisseria meningitidis* serogroup B protein 1 / Recombinant *Neisseria meningitidis* serogroup B protein 3 / Recombinant *Neisseria meningitidis* serogroup B protein 2 - EMEA-002954-PIP02-21

Prevention of meningococcal disease

Day 90 discussion

Action: For discussion

Vaccines

3.1.9. Dupilumab - EMEA-001501-PIP09-21

Treatment of chronic inducible cold urticaria

Day 60 discussion

Action: For discussion

Dermatology

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

Treatment of psoriasis

Day 60 discussion

Action: For discussion

Dermatology

3.1.11. Bilastine - EMEA-000347-PIP06-21

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

Day 60 discussion

Action: For discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

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

Lumos Pharma, Inc.; Treatment of growth hormone deficiency

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.13. [Zinc gluconate / alisitol / retinyl palmitate - Orphan - EMEA-002198-PIP01-21](#)

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

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.14. [Mitapivat - Orphan - EMEA-002684-PIP02-21](#)

Agios Netherlands B.V.; Treatment of thalassaemia

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. [Rozanolixizumab - Orphan - EMEA-002681-PIP02-21](#)

UCB Pharma S.A; Treatment of immune thrombocytopenia

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. [Autologous bone marrow derived CD34+cells transduced with the lentiviral vector CL20-4i-EF1 \$\alpha\$ -hyc-OPT - Orphan - EMEA-003050-PIP01-21](#)

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

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. [ECT-001-CB \(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; Allogeneic haematopoietic stem cell transplantation

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

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

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

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.19. Alprazolam - EMEA-003043-PIP01-21

Treatment of epileptic seizures

Day 60 discussion

Action: For discussion

Neurology

3.1.20. Invimestrocel - EMEA-002317-PIP02-21

Acute ischaemic stroke / Treatment of acute ischaemic stroke

Day 60 discussion

Action: For discussion

Neurology

3.1.21. Rozanolixizumab - EMEA-002681-PIP03-21

Treatment of myelin oligodendrocyte glycoprotein antibody-associated disease

Day 60 discussion

Action: For discussion

Neurology

3.1.22. 1-[(4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6-methoxyquinolin-7-yl)methyl]cyclopropan-1-amine bishydrochloride - Orphan - EMEA-002486-PIP04-21

Advenchen Laboratories, LLC.; Treatment of soft tissue sarcomas

Day 60 discussion

Action: For discussion

Oncology

3.1.23. Plinabulin - EMEA-003054-PIP01-21

Chemotherapy-induced neutropenia

Day 60 discussion

Action: For discussion

Oncology

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

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

Day 60 discussion

Action: For discussion

Oncology

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

JCR Pharmaceuticals Co., Ltd.; Mucopolysaccharidosis type II

Day 60 discussion

Action: For discussion

Other

3.1.26. EMEA-003052-PIP01-21

Treatment of cystic fibrosis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.27. 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 60 discussion

Action: For discussion

Uro-nephrology

3.1.28. *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 60 discussion

Action: For discussion

Vaccines

3.1.29. SARS-CoV-2, produced in Vero cells (inactivated) - EMEA-003057-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Vaccines

3.1.30. Amlodipine / ramipril - EMEA-003070-PIP01-21

Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.31. Furosemide / eplerenone - EMEA-003065-PIP01-21

Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. Humanised KLB / FGFR1c monoclonal antibody - EMEA-003058-PIP01-21

Non-alcoholic steatohepatitis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.33. Semaglutide / cagrilintide - EMEA-003059-PIP01-21

Treatment of obesity

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.34. Tezepelumab - EMEA-001613-PIP03-21

Eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.35. Clazakizumab - EMEA-001371-PIP02-21

Treatment of chronic active antibody mediated rejection (AMR) in kidney transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.36. Human normal immunoglobulin - EMEA-003076-PIP01-21

Primary immunodeficiency diseases / Antibody deficiency

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.37. Retinol palmitate - Orphan - EMEA-003073-PIP01-21

PROVEPHARM SAS; Prevention of bronchopulmonary dysplasia

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.38. Cannabidiol - EMEA-001964-PIP03-21

Treatment of epilepsy with myoclonic atonic seizures (EMAS)

Day 30 discussion

Action: For discussion

Neurology

3.1.39. Censavudine - EMEA-003075-PIP01-21

Aicardi-Goutières syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.40. Verdiperstat - Orphan - EMEA-002708-PIP02-21

Biohaven Pharmaceutical Ireland DAC; Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.41. Adagrasib - EMEA-003068-PIP01-21

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Adagrasib - EMEA-003068-PIP02-21

Treatment of colorectal cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.43. Adavosertib - EMEA-003069-PIP01-21

Treatment of malignant pancreatic neoplasms / Treatment of malignant endometrial neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Autologous tumour-infiltrating lymphocytes (TILs) isolated from a patient's cancer tissue and expanded ex vivo - EMEA-003072-PIP01-21

Treatment of advanced melanoma

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Ofranergene obadenovec - Orphan - EMEA-003062-PIP01-21

Vascular Biogenics Ltd. (VBL Therapeutics); Treatment of ovarian cancer / Treatment of primary peritoneal cancer / Treatment of fallopian tube cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.46. Pamrevlumab - EMEA-002979-PIP03-21

Treatment of pancreatic cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Vibostolimab / pembrolizumab - EMEA-003063-PIP01-21

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

Day 30 discussion

Action: For discussion

Oncology

3.1.48. Cedazuridine - EMEA-003071-PIP01-21

Acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.49. Otenaproxesul - EMEA-003061-PIP01-21

Treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.1.50. Benralizumab - EMEA-001214-PIP08-21

Non-cystic fibrosis bronchiectasis with an eosinophilic phenotype

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.51. Bis-(3-deoxy-3-(4-(3-fluorophenyl)-1H-1,2,3-triazol-1-yl)-beta-D-galactopyranosyl) sulfane - Orphan - EMEA-003060-PIP01-21

Galecto Biotech AB; Idiopathic pulmonary fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.52. Depemokimab - EMEA-003051-PIP02-21

Eosinophilic granulomatosis with polyangiitis (EGPA)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.53. Depemokimab - EMEA-003051-PIP03-21

Treatment of hypereosinophilic syndrome (HES)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.54. Human alpha1-proteinase inhibitor (also called alpha-1 Antitrypsin) - EMEA-001525-PIP02-21

Treatment of emphysema secondary to congenital deficiency of alpha-1 antitrypsin

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.55. Pamrevlumab - EMEA-002979-PIP02-21

Idiopathic pulmonary fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.56. Ilofotase alfa - EMEA-003067-PIP01-21

Treatment of sepsis-associated acute kidney injury

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.57. Lademirsén - Orphan - EMEA-003064-PIP01-21

Genzyme Europe B.V.; Treatment of Alport syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.58. Influenza virus surface antigen (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP02-21

Influenza due to identified zoonotic or pandemic influenza virus

Day 30 discussion

Action: For discussion

Vaccines

3.1.59. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP01-21

Influenza due to identified zoonotic or pandemic influenza virus

Day 30 discussion

Action: For discussion

Vaccines

3.1.60. Inactivated poliovirus: type 3 (Saukett strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 1 (Mahoney strain) / Bordetella pertussis antigen: Pertactin / *Bordetella pertussis* antigen: Filamentous Haemagglutinin /

Bordetella pertussis antigen: Pertussis toxoid / Tetanus toxoid / Diphtheria toxoid - EMEA-003066-PIP01-21

Prevention of infectious diseases caused by *Corynebacterium diphtheriae*, *Clostridium tetani*, *Bordetella pertussis*, Poliovirus types 1, 2 and 3

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.61. RSV F protein - EMEA-003094-PIP01-21

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.62. Whole-cell heat-inactivated bacterial strains of *Escherichia coli* / *Klebsiella pneumoniae* / *Proteus vulgaris* / *Enterococcus faecalis* - EMEA-003026-PIP02-21

Prevention of recurrent urinary tract infections (R-UTIs)

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases / Uro-nephrology

3.1.63. Evenamide - EMEA-002519-PIP03-21

Treatment of schizophrenia

Day 90 discussion

Action: For discussion

Psychiatry

3.1.64. Satralizumab - EMEA-001625-PIP02-21

Treatment of myasthenia gravis

Day 90 discussion

Action: For discussion

Neurology

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. Lonoctocog alfa - EMEA-C-001215-PIP01-11-M07](#)

CSL Behring GmbH; Treatment of haemophilia A

Day 30 discussion

Action: For discussion

[3.2.2. Olipudase alfa - EMEA-C1-001600-PIP01-13-M02](#)

Genzyme Europe B.V.; Treatment of Niemann-Pick disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

[3.2.3. Ravulizumab - EMEA-C3-002077-PIP01-16-M04](#)

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

[3.2.4. Ceftobiprole medocaril \(sodium\) - EMEA-C1-000205-PIP02-11-M04](#)

Basilea Pharmaceutica International Ltd; Treatment of pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

[3.2.5. Oseltamivir \(phosphate\) - EMEA-C-000365-PIP01-08-M12](#)

Roche Registration GmbH; Treatment and prevention of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

[3.2.6. Nivolumab / relatlimab - EMEA-C-002727-PIP01-19-M01](#)

Bristol-Myers Squibb International Corporation; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.2.7. Ponatinib (as hydrochloride) - EMEA-C2-001186-PIP01-11-M02

Incyte Biosciences Distribution B.V.; Treatment of chronic myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

Note: Withdrawal request received on 3 September 2021

3.2.8. Tremelimumab - EMEA-C2-002029-PIP01-16-M02

AstraZeneca AB; Treatment of malignant neoplasms of lymphoid tissue

Day 30 discussion

Action: For discussion

Oncology

3.2.9. Zanubrutinib - EMEA-C1-002354-PIP02-18

BeiGene Ireland Ltd; Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma)

Day 30 discussion

Action: For discussion

Oncology

3.2.10. Bupivacaine - EMEA-C1-000877-PIP03-17-M03

Pacira Ltd; Postsurgical analgesia

Day 30 discussion

Action: For discussion

Pain

3.2.11. Mirabegron - EMEA-C4-000597-PIP03-15-M03

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

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.12. Ravulizumab - EMEA-C2-001943-PIP01-16-M06

Alexion Europe SAS; Treatment of atypical haemolytic uremic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Bilastine - EMEA-000347-PIP02-16-M03

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 30 discussion

Action: For discussion

3.3.2. 3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alfa-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride - EMEA-002735-PIP03-20-M01

Dr. Franz Köhler Chemie GmbH; Heart transplantation

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Azilsartan medoxomil - EMEA-000237-PIP01-08-M10

Takeda Development Centre Europe Ltd; Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Macitentan - Orphan - EMEA-001032-PIP01-10-M04

Janssen-Cilag International NV; Treatment of pulmonary arterial hypertension / Treatment of systemic sclerosis / Treatment of idiopathic pulmonary fibrosis

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.5. Vericiguat - EMEA-001636-PIP01-14-M02

Bayer AG; Treatment of left ventricular failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.6. Glycopyrronium bromide - EMEA-002383-PIP01-18-M01

Dr. August Wolff GmbH & Co. KG - Arzneimittel; Treatment of hyperhidrosis

Day 30 discussion

Action: For discussion

Dermatology

3.3.7. Cotadutide - EMEA-002287-PIP01-17-M03

AstraZeneca AB; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Evinacumab - EMEA-002298-PIP01-17-M03

Regeneron Ireland DAC; Treatment of elevated cholesterol

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.9. Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M05

AstraZeneca AB; Hyperkalaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.10. Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M07

Kyowa Kirin Pharmaceutical Development Limited; Treatment of opioid-induced constipation

Day 30 discussion

Action: For discussion

3.3.11. Marstacimab - Orphan - EMEA-002285-PIP02-19-M01

Pfizer Europe MAA EEIG; Treatment of congenital haemophilia A / Treatment of congenital haemophilia B

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.12. Vonicog alfa - EMEA-001164-PIP01-11-M05

Baxalta Innovations GmbH; Treatment of Von Willebrand disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.13. Upadacitinib - EMEA-001741-PIP01-14-M05

AbbVie Ltd; Treatment of chronic idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Baloxavir marboxil - EMEA-002440-PIP01-18-M02

Roche Registration GmbH; Treatment of influenza / Prevention of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M05

Basilea Pharmaceutica International Ltd.; Treatment of pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Dalbavancin hydrochloride - EMEA-000016-PIP01-07-M08

Allergan Pharmaceuticals International Limited; Treatment of acute bacterial skin and skin

structure infections (ABSSSI)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M04

Menarini International Operations Luxembourg S.A.; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Pretomanid - Orphan - EMEA-002115-PIP01-17-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Rilpivirine (RPV) / dolutegravir (DTG) - EMEA-001750-PIP01-15-M05

ViiV Healthcare UK Limited; B24 Unspecified Human Immunodeficiency Virus (HIV) disease

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.21. Sotrovimab - EMEA-002899-PIP01-20-M01

GlaxoSmithKline Trading Services Ltd; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.22. [Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19-M01](#)

SIGA Technologies, Inc.; Orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia complications)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.23. [Tenofovir alafenamide / emtricitabine / bictegravir - EMEA-001766-PIP01-15-M04](#)

Gilead Sciences International Ltd.; Treatment of Human Immunodeficiency Virus [HIV] disease resulting in other conditions [ICD-10: B23]

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.24. [Erenumab - EMEA-001664-PIP02-15-M05](#)

Novartis Europharm Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.25. [Perampanel - EMEA-000467-PIP01-08-M15](#)

Eisai Europe Limited; Treatment of treatment-resistant epilepsies

Day 30 discussion

Action: For discussion

Neurology

3.3.26. [Soticlestat - EMEA-002572-PIP02-19-M01](#)

Takeda Pharma A/S; Dravet syndrome / Lennox-Gastaut syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.27. Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M02

Acerta Pharma, BV; Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.3.28. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M04

Ipsen Pharma; Treatment of malignant solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.3.29. Cyclophosphamide - EMEA-002644-PIP01-19-M01

Accord Healthcare S.L.U.; Treatment of all malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.3.30. Larotrectinib - EMEA-001971-PIP02-16-M04

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

Day 30 discussion

Action: For discussion

Oncology

3.3.31. Regorafenib - EMEA-001178-PIP01-11-M06

Bayer AG; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

Action: For discussion

Oncology

3.3.32. Ruxolitinib phosphate - EMEA-000901-PIP04-17-M02

Novartis Europharm Limited; Chronic Graft versus Host disease

Day 30 discussion

Action: For discussion

Oncology

3.3.33. Selpercatinib - EMEA-002544-PIP01-18-M01

Eli Lilly and Company; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 30 discussion

Action: For discussion

Oncology

3.3.34. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M04

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.35. Vamorolone - Orphan - EMEA-001794-PIP02-16-M04

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.3.36. Methoxflurane - EMEA-000334-PIP01-08-M10

Medical Developments UK Ltd; Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

3.3.37. Molgramostim - Orphan - EMEA-002282-PIP01-17-M01

Savara Aps; Treatment of pulmonary alveolar proteinosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.38. Tezepelumab - EMEA-001613-PIP01-14-M05

AstraZeneca AB; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.39. Lumasiran sodium - Orphan - EMEA-002079-PIP01-16-M02

Alnylam UK Limited; Treatment of primary hyperoxaluria type 1

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.40. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16-M04

Seqirus Netherlands; Influenza

Day 30 discussion

Action: For discussion

Vaccines

3.3.41. NVX-CoV2373 - EMEA-002941-PIP01-20-M01

Novavax CZ, a.s.; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

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

4.1. List of submissions of applications with start of procedure 14 September 2021 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. **Nominations for other activities**

Action: For adoption

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

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

6. **Discussion on the applicability of class waivers**

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

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

No item

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**

7.1.1. **Stivarga - EMEA-001178-PIP01-11-M05**

Bayer; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Proposed indication: Treatment in adults in glioblastoma multiforme (GBM), sarcoma (such as bone sarcoma or non-adipocytic soft tissue sarcoma)

Action: For adoption

Oncology

8. **Annual reports on deferrals**

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Pilot – Relaunch of face to face Scientific Committee Meetings

Action: For discussion

9.1.2. PDCO Rules of Procedure – revision

Action: For adoption

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

No 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

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Patients and Consumers Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 21-22 September 2021

Agenda of meeting on 21-22 September 2021

Action: For information

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. 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

Action: For information

10.2. Project Lifecycle Regulations Submissions Raw Data (LRSR)

Action: For discussion

10.3. Project on paediatric first-line tuberculosis medicines

Action: For information

11. Breakout sessions

11.1. Internal PDCO Operations

Action: For discussion on Tuesday, 11:00-12:00

11.2. Neonatology

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

11.3. Vaccines

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

11.4. Paediatric oncology

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

11.5. PDCO-SAWP interaction and process improvement

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

12. Explanatory notes

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

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

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

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

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

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

The development plan for a medicine can be modified at a later stage as knowledge increases.

Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.

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

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

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

Annual reports on deferrals (section 8)

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

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