



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 21-24 June 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

21 June 2022, 14:00- 19:30, room 1C / virtual meeting

22 June 2022, 08:30- 19:30, room 1C / virtual meeting

23 June 2022, 08:30- 19:30, room 1C / virtual meeting

24 June 2022, 08:30- 13:00, room 1C / virtual meeting

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

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

Note on access to documents

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



Table of contents

| | | |
|-------------|--|-----------|
| 1. | Introductions | 9 |
| 1.1. | Welcome and declarations of interest of members, alternates and experts..... | 9 |
| 1.2. | Adoption of agenda | 9 |
| 1.3. | Adoption of the minutes | 9 |
| 2. | Opinions | 9 |
| 2.1. | Opinions on Products..... | 9 |
| 2.1.1. | Oxytocin - Orphan - EMEA-003148-PIP01-21 | 9 |
| 2.1.2. | Venglustat - Orphan - EMEA-001716-PIP06-21..... | 9 |
| 2.1.3. | Efruxifermin - EMEA-003114-PIP01-21 | 10 |
| 2.1.4. | Etrasimod L-arginine - EMEA-002713-PIP02-21 | 10 |
| 2.1.5. | Ritlecitinib - EMEA-002451-PIP02-21 | 10 |
| 2.1.6. | Deucravacitinib - EMEA-002350-PIP04-21 | 10 |
| 2.1.7. | Gliadin protease - EMEA-003116-PIP01-21 | 10 |
| 2.1.8. | Remibrutinib - EMEA-002582-PIP02-21 | 10 |
| 2.1.9. | (R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl) pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate - Orphan - EMEA-003133-PIP01-21 | 11 |
| 2.1.10. | Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21..... | 11 |
| 2.1.11. | A 2'-O-(2'-methoxyethyl) modified antisense oligonucleotide targeting prekallikrein (PKK) mRNA - EMEA-003112-PIP01-21 | 11 |
| 2.1.12. | EMEA-003098-PIP01-21 | 11 |
| 2.1.13. | Lademirsen - Orphan - EMEA-003064-PIP01-21 | 11 |
| 2.1.14. | Pegcetacoplan - Orphan - EMEA-002600-PIP03-21 | 12 |
| 2.1.15. | Vibegron - EMEA-001415-PIP02-21..... | 12 |
| 2.1.16. | RSV F protein - EMEA-003094-PIP02-21..... | 12 |
| 2.1.17. | Acetylsalicylic acid / rosuvastatin - EMEA-003206-PIP01-22..... | 12 |
| 2.1.18. | Ezetimibe / atorvastatin - EMEA-003205-PIP01-22 | 12 |
| 2.1.19. | EMEA-003223-PIP01-22 | 12 |
| 2.1.20. | Nipocalimab - Orphan - EMEA-002559-PIP05-22 | 13 |
| 2.1.21. | Gold (Au) - EMEA-003211-PIP01-22 | 13 |
| 2.1.22. | Modakafusp alfa - EMEA-003217-PIP01-22 | 13 |
| 2.1.23. | Humanised monoclonal antibody of IgG1 subtype targeting NRP1 - EMEA-003214-PIP01-2213 | |
| 2.1.24. | Magnesium lactate dihydrate / tramadol - EMEA-003216-PIP01-22..... | 13 |
| 2.1.25. | Pregabalin - EMEA-003221-PIP01-22 | 14 |
| 2.1.26. | Amlodipine / nebivolol - EMEA-003226-PIP01-22 | 14 |
| 2.1.27. | Valsartan / nebivolol - EMEA-003227-PIP01-22 | 14 |
| 2.2. | Opinions on Compliance Check | 14 |

| | | |
|-------------|---|-----------|
| 2.2.1. | Apixaban - EMEA-C-000183-PIP01-08-M08..... | 14 |
| 2.2.2. | Pegzilarginase - EMEA-C1-001925-PIP02-19 | 14 |
| 2.2.3. | Dulaglutide - EMEA-C-000783-PIP01-09-M06..... | 15 |
| 2.2.4. | Evolocumab - EMEA-C-001268-PIP01-12-M05..... | 15 |
| 2.3. | Opinions on Modification of an Agreed Paediatric Investigation Plan | 15 |
| 2.3.1. | Obinutuzumab - Orphan - EMEA-001207-PIP02-19-M01 | 15 |
| 2.3.2. | Chloroprocaine hydrochloride - EMEA-000639-PIP03-16-M02 | 15 |
| 2.3.3. | Bempedoic acid - EMEA-001872-PIP01-15-M02 | 15 |
| 2.3.4. | Etripamil - EMEA-002303-PIP01-17-M03 | 15 |
| 2.3.5. | Omecamtiv mecarbil - EMEA-001696-PIP01-14-M02 | 16 |
| 2.3.6. | Bimekizumab - EMEA-002189-PIP01-17-M03 | 16 |
| 2.3.7. | Deucravacitinib - EMEA-002350-PIP01-18-M02 | 16 |
| 2.3.8. | Fluciclovine (18F) - Orphan - EMEA-001644-PIP02-14-M03..... | 16 |
| 2.3.9. | Pegunigalsidase alfa - Orphan - EMEA-001828-PIP01-15-M03 | 16 |
| 2.3.10. | Cilofexor - Orphan - EMEA-002554-PIP02-19-M01 | 17 |
| 2.3.11. | Maralixibat chloride - Orphan - EMEA-001475-PIP02-13-M02 | 17 |
| 2.3.12. | Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M02 | 17 |
| 2.3.13. | Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M02 | 17 |
| 2.3.14. | Avibactam / ceftazidime - EMEA-001313-PIP01-12-M12 | 17 |
| 2.3.15. | Bulevirtide - Orphan - EMEA-002399-PIP01-18-M01 | 18 |
| 2.3.16. | Casirivimab - EMEA-002964-PIP01-21-M02..... | 18 |
| 2.3.17. | Enmetazobactam - EMEA-002240-PIP02-17-M01..... | 18 |
| 2.3.18. | Imdevimab - EMEA-002965-PIP01-21-M02 | 18 |
| 2.3.19. | Pretomanid - Orphan - EMEA-002115-PIP01-17-M05 | 18 |
| 2.3.20. | Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M02..... | 19 |
| 2.3.21. | Ritonavir / (1R,2S,5S)-N-{(1S)-1-cyano-2-[(3S)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3-[3-methyl-N-(trifluoroacetyl)-L-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide - EMEA-003081-PIP01-21-M01 | 19 |
| 2.3.22. | Eptinezumab - EMEA-002243-PIP01-17-M03..... | 19 |
| 2.3.23. | Lasmiditan - EMEA-002166-PIP01-17-M06..... | 19 |
| 2.3.24. | Ravulizumab - EMEA-001943-PIP03-20-M01 | 19 |
| 2.3.25. | Rimegepant - EMEA-002812-PIP02-20-M01 | 19 |
| 2.3.26. | Setmelanotide - Orphan - EMEA-002209-PIP01-17-M03 | 20 |
| 2.3.27. | Bosutinib - EMEA-000727-PIP01-09-M06 | 20 |
| 2.3.28. | Larotrectinib - EMEA-001971-PIP03-18-M02 | 20 |
| 2.3.29. | Lenvatinib - EMEA-001119-PIP02-12-M08 | 20 |
| 2.3.30. | Andexanet alfa - EMEA-001902-PIP01-15-M06..... | 20 |
| 2.3.31. | Setrusumab - Orphan - EMEA-002169-PIP01-17-M01 | 21 |
| 2.3.32. | Vamorolone - Orphan - EMEA-001794-PIP02-16-M05..... | 21 |

| | | |
|-------------|--|-----------|
| 2.3.33. | Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M03 | 21 |
| 2.3.34. | Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M08 | 21 |
| 2.3.35. | Brexpiprazole - EMEA-001185-PIP01-11-M08 | 21 |
| 2.3.36. | Vortioxetine - EMEA-000455-PIP02-10-M09 | 22 |
| 2.3.37. | COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA-002862-PIP01-20-M03 | 22 |
| 2.3.38. | Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21-M01 | 22 |
| 2.3.39. | Epcoritamab - Orphan - EMEA-002907-PIP01-20-M01 | 22 |
| 2.4. | Opinions on Re-examinations | 22 |
| 2.5. | Opinions on Review of Granted Waivers | 22 |
| 2.6. | Finalisation and adoption of Opinions..... | 22 |
| 2.7. | Partial Compliance Checks completed by EMA | 23 |
| 2.7.1. | Zilucoplan - EMEA-C1-002747-PIP01-20 | 23 |

3. Discussion of applications 23

| | | |
|-------------|--|-----------|
| 3.1. | Discussions on Products D90-D60-D30..... | 23 |
| 3.1.1. | Ex vivo expanded autologous human keratinocytes containing epidermal stem cells genetically modified with a gamma-retroviral (RV) vector expressing the full-length LAMB3 cDNA - Orphan - EMEA-003137-PIP01-21 | 23 |
| 3.1.2. | Tezepelumab - EMEA-001613-PIP04-21..... | 23 |
| 3.1.3. | EMEA-003143-PIP01-21 | 23 |
| 3.1.4. | Clazakizumab - EMEA-001371-PIP02-21 | 24 |
| 3.1.5. | Tocilizumab - EMEA-000309-PIP09-21..... | 24 |
| 3.1.6. | Ibrexafungerp citrate - EMEA-002535-PIP04-21 | 24 |
| 3.1.7. | Corticotropin - EMEA-003097-PIP01-21 | 24 |
| 3.1.8. | Cannabidiol - EMEA-003176-PIP01-21..... | 24 |
| 3.1.9. | Troriluzole - EMEA-003084-PIP02-21 | 24 |
| 3.1.10. | Zuranolone - EMEA-003119-PIP01-21 | 25 |
| 3.1.11. | Recombinant COVID-19 subunit nanoparticle - EMEA-003115-PIP01-21 | 25 |
| 3.1.12. | Milvexian - EMEA-003220-PIP01-22 | 25 |
| 3.1.13. | Zilebesiran - EMEA-003218-PIP01-22..... | 25 |
| 3.1.14. | Perflubutane - EMEA-003037-PIP02-22 | 25 |
| 3.1.15. | Danuglipron - EMEA-002944-PIP02-22 | 26 |
| 3.1.16. | Doxribtimine / doxycitine - Orphan - EMEA-003210-PIP01-22 | 26 |
| 3.1.17. | Insulin human (RDNA) - EMEA-003194-PIP02-22 | 26 |
| 3.1.18. | Synthetic peptide of 20 amino acids comprising a T cell epitope from pro-insulin - EMEA-002379-PIP01-22 | 26 |
| 3.1.19. | EMEA-003222-PIP01-22 | 26 |
| 3.1.20. | Satralizumab - Orphan - EMEA-001625-PIP04-22 | 26 |

| | | |
|---------|---|----|
| 3.1.21. | Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003212-PIP01-22..... | 27 |
| 3.1.22. | Fianlimab - EMEA-003207-PIP01-22..... | 27 |
| 3.1.23. | Humanised IgG2 monoclonal antibody against interleukin-6 - EMEA-003215-PIP01-22..... | 27 |
| 3.1.24. | Benzylamine derivative of benzofuran - EMEA-002974-PIP02-22 | 27 |
| 3.1.25. | Hydrochlorothiazide / amlodipine / telmisartan - EMEA-003229-PIP01-22..... | 27 |
| 3.1.26. | Perindopril tert-butylamin / rosuvastatin - EMEA-003228-PIP01-22 | 28 |
| 3.1.27. | Valsartan / rosuvastatin - EMEA-003240-PIP01-22 | 28 |
| 3.1.28. | Amlitelimab - EMEA-003233-PIP01-22 | 28 |
| 3.1.29. | CRN04777 - Orphan - EMEA-003242-PIP01-22..... | 28 |
| 3.1.30. | EMEA-003241-PIP01-22 | 28 |
| 3.1.31. | Inclacumab - EMEA-003219-PIP01-22 | 29 |
| 3.1.32. | Itolizumab - Orphan - EMEA-003208-PIP02-22..... | 29 |
| 3.1.33. | Cilgavimab / tixagevimab - EMEA-003079-PIP01-22 | 29 |
| 3.1.34. | Opelconazole - EMEA-003249-PIP01-22..... | 29 |
| 3.1.35. | Tetracycline / metronidazole / bismuth - EMEA-003224-PIP01-22..... | 29 |
| 3.1.36. | Enibarcimab - EMEA-003244-PIP01-22..... | 29 |
| 3.1.37. | Cemdisiran sodium - Orphan - EMEA-003237-PIP01-22..... | 30 |
| 3.1.38. | Pegcetacoplan - EMEA-002600-PIP04-22 | 30 |
| 3.1.39. | Pozelimab - EMEA-003238-PIP01-22..... | 30 |
| 3.1.40. | Suvecaltamide - EMEA-003248-PIP01-22..... | 30 |
| 3.1.41. | Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against human B cell maturation antigen (BCMA) and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003231-PIP01-22 | 30 |
| 3.1.42. | Gallium 68-labelled prostate-specific membrane antigen-11 (68Ga-PSMA-11) - EMEA-003236-PIP01-22 | 31 |
| 3.1.43. | Golidocitinib - EMEA-003246-PIP01-22..... | 31 |
| 3.1.44. | Lutetium (177Lu) edotreotide - Orphan - EMEA-003245-PIP01-22 | 31 |
| 3.1.45. | Monalizumab - EMEA-002751-PIP02-22..... | 31 |
| 3.1.46. | Obinutuzumab - Orphan - EMEA-001207-PIP04-22 | 31 |
| 3.1.47. | Oleclumab - EMEA-003234-PIP01-22 | 31 |
| 3.1.48. | Toripalimab - EMEA-003243-PIP01-22..... | 32 |
| 3.1.49. | Vepsitamab - EMEA-003230-PIP01-22..... | 32 |
| 3.1.50. | Xevinapant - Orphan - EMEA-003235-PIP01-22..... | 32 |
| 3.1.51. | Dimeric protein comprised of two disulfide-linked monomers, each being a fully human fusion protein consisting of a modified extracellular domain (ECD) of the human activin receptor type IIA (ActRIIA) fused to the fragment crystallizable (Fc) domain of human IgG1 Fc including the hinge region, CH2 and CH3 domains - EMEA-003239-PIP01-22 | 32 |
| 3.1.52. | Tinlarebant - Orphan - EMEA-003225-PIP01-22..... | 32 |
| 3.1.53. | (S)-lactic acid - EMEA-003247-PIP01-22..... | 33 |

| | | |
|-------------|---|-----------|
| 3.1.54. | Tirzepatide - EMEA-002360-PIP02-22..... | 33 |
| 3.1.55. | Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1 - Orphan - EMEA-003232-PIP01-22 | 33 |
| 3.1.56. | ABNCoV2 (AV2-cVLP-RBD SARS-CoV-2) - EMEA-003184-PIP01-22 | 33 |
| 3.2. | Discussions on Compliance Check..... | 33 |
| 3.2.1. | Human Fibrinogen - EMEA-C-001208-PIP01-11-M03 | 33 |
| 3.2.2. | Letemovir - EMEA-C1-001631-PIP01-14-M04..... | 34 |
| 3.2.3. | Tisagenlecleucel - EMEA-C-001654-PIP02-17-M01 | 34 |
| 3.2.4. | Ad26.ZEBOV (recombinant, replication-incompetent) - EMEA-C-002307-PIP01-17-M02.... | 34 |
| 3.2.5. | MVA-BN-Filo (recombinant, non-replicating) - EMEA-C-002308-PIP01-17-M02 | 34 |
| 3.3. | Discussions on Modification of an Agreed Paediatric Investigation Plan..... | 34 |
| 3.3.1. | Aliskiren hemifumarate - EMEA-000362-PIP01-08-M06 | 34 |
| 3.3.2. | Treprostinil - EMEA-000207-PIP01-08-M07 | 35 |
| 3.3.3. | Evinacumab - EMEA-002298-PIP01-17-M04 | 35 |
| 3.3.4. | Guselkumab - EMEA-001523-PIP04-19-M01..... | 35 |
| 3.3.5. | Odevixibat - Orphan - EMEA-002054-PIP03-20-M01 | 35 |
| 3.3.6. | Ustekinumab - EMEA-000311-PIP04-13-M05..... | 35 |
| 3.3.7. | Plasma kallikrein inhibitor - EMEA-002723-PIP01-19-M01 | 35 |
| 3.3.8. | Roxadustat - EMEA-001557-PIP01-13-M06 | 36 |
| 3.3.9. | Vonicog alfa - EMEA-001164-PIP01-11-M06..... | 36 |
| 3.3.10. | Apremilast - EMEA-000715-PIP02-11-M06..... | 36 |
| 3.3.11. | Apremilast - EMEA-000715-PIP05-13-M05..... | 36 |
| 3.3.12. | Baricitinib - EMEA-001220-PIP07-20-M01 | 36 |
| 3.3.13. | Belimumab - EMEA-000520-PIP02-13-M04 | 37 |
| 3.3.14. | Grisnilimab setaritox / dafsolimab setaritox - Orphan - EMEA-002087-PIP01-16-M01 | 37 |
| 3.3.15. | Upadacitinib - EMEA-001741-PIP04-17-M03..... | 37 |
| 3.3.16. | Baloxavir marboxil - EMEA-002440-PIP01-18-M03..... | 37 |
| 3.3.17. | BNT162b2 / tozinameran - EMEA-002861-PIP02-20-M04..... | 37 |
| 3.3.18. | Cabotegravir - EMEA-001418-PIP01-13-M05..... | 37 |
| 3.3.19. | Cobicistat - EMEA-000969-PIP01-10-M06 | 38 |
| 3.3.20. | Emtricitabine / tenofovir alafenamide - EMEA-001577-PIP02-14-M05..... | 38 |
| 3.3.21. | Lamivudine / dolutegravir - EMEA-001940-PIP01-16-M04..... | 38 |
| 3.3.22. | Rilpivirine - EMEA-000317-PIP02-18-M01 | 38 |
| 3.3.23. | Tenofovir alafenamide / rilpivirine / emtricitabine - EMEA-001679-PIP01-14-M02 | 38 |
| 3.3.24. | Zoliflodacin - EMEA-002599-PIP01-19-M01 | 39 |
| 3.3.25. | Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M05 | 39 |
| 3.3.26. | Ozanimod (hydrochloride) - EMEA-001710-PIP02-14-M07 | 39 |
| 3.3.27. | Peginterferon beta-1a - EMEA-001129-PIP01-11-M05 | 39 |
| 3.3.28. | Cabozantinib - Orphan - EMEA-001143-PIP01-11-M05 | 39 |

| | | |
|---------|---|----|
| 3.3.29. | Copanlisib - Orphan - EMEA-001757-PIP02-15-M03 | 39 |
| 3.3.30. | Durvalumab - EMEA-002028-PIP01-16-M03 | 40 |
| 3.3.31. | Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M06 | 40 |
| 3.3.32. | Lomitapide (as lomitapide mesylate) - EMEA-001124-PIP01-10-M05 | 40 |
| 3.3.33. | Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP02-13-M01 | 40 |
| 3.3.34. | Adrenaline (epinephrine) - EMEA-002749-PIP01-19-M02 | 40 |
| 3.3.35. | Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR) - EMEA-001490-PIP01-13-M03 | 41 |
| 3.3.36. | Tremelimumab - Orphan - EMEA-002029-PIP01-16-M03 | 41 |
| 3.3.37. | For 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-M02 | 41 |

4. Nominations 41

| | | |
|-------------|---|-----------|
| 4.1. | List of submissions of applications with start of procedure 11 July 2022 for Nomination of Rapporteur and Peer reviewer..... | 41 |
| 4.2. | Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver | 41 |
| 4.3. | Nominations for other activities | 42 |

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

6. Discussion on the applicability of class waivers 42

| | | |
|-------------|---|-----------|
| 6.1. | Discussions on the applicability of class waiver for products..... | 42 |
| 6.1.1. | AZD9833 (selective estrogen receptor degrader) - EMEA-01-2022 | 42 |
| 6.1.2. | Donanemab - EMEA-03-2022 | 42 |

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

| | | |
|-------------|--|-----------|
| 7.1. | Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver | 42 |
|-------------|--|-----------|

8. Annual reports on deferrals 42

9. Organisational, regulatory and methodological matters 43

| | | |
|-------------|---|-----------|
| 9.1. | Mandate and organisation of the PDCO..... | 43 |
| 9.1.1. | PDCO membership..... | 43 |
| 9.1.2. | Vote by Proxy | 43 |
| 9.1.3. | Mandate of PDCO Chairperson - call for nominations | 43 |
| 9.2. | Coordination with EMA Scientific Committees or CMDh-v | 43 |
| 9.2.1. | Committee for Medicinal Products for Human Use (CHMP) | 43 |
| 9.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 43 |
| 9.3.1. | Non-clinical Working Party: D30 Products identified | 43 |
| 9.3.2. | Formulation Working Group | 43 |

| | | |
|--------------|--|-----------|
| 9.4. | Cooperation within the EU regulatory network..... | 43 |
| 9.4.1. | European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)..... | 43 |
| 9.5. | Cooperation with International Regulators..... | 44 |
| 9.6. | Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee..... | 44 |
| 9.7. | PDCO work plan..... | 44 |
| 9.8. | Planning and reporting | 44 |
| 9.8.1. | EMA Business Pipeline activity and Horizon scanning | 44 |
| 10. | Any other business | 44 |
| 10.1. | COVID-19 update..... | 44 |
| 10.2. | Exparel liposomal - EMEA/H/C/004586/II/0005 PDCO consultation from CHMP | 44 |
| 10.3. | EU Survey Testing..... | 44 |
| 10.4. | Revision of the guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus | 44 |
| 11. | Breakout sessions | 45 |
| 11.1. | Neonatology | 45 |
| 11.2. | Vaccines | 45 |
| 11.3. | Paediatric oncology | 45 |
| 12. | Explanatory notes | 46 |

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 21-24 June 2022. See (current) June 2022 PDCO minutes (to be published post July 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 21-24 June 2022.

1.3. Adoption of the minutes

PDCO minutes for 17-20 May 2022.

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. Oxytocin - Orphan - EMEA-003148-PIP01-21

OT4B; Treatment of Prader-Willi syndrome

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Venglustat - Orphan - EMEA-001716-PIP06-21

Genzyme Europe B.V.; Treatment of Fabry disease

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

Note: Withdrawal request received on 15 June 2022

2.1.3. Efruxifermin - EMEA-003114-PIP01-21

Treatment of non-alcoholic fatty liver disease including non-alcoholic steatohepatitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. Etrasimod L-arginine - EMEA-002713-PIP02-21

Treatment of Crohn's disease

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. Ritlecitinib - EMEA-002451-PIP02-21

Treatment of ulcerative colitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.6. Deucravacitinib - EMEA-002350-PIP04-21

Treatment of ulcerative colitis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. Gliadin protease - EMEA-003116-PIP01-21

Treatment of coeliac disease

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

2.1.8. Remibrutinib - EMEA-002582-PIP02-21

Treatment of multiple sclerosis

Day 120 opinion

Action: For adoption

Neurology

2.1.9. (R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl) pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate - Orphan - EMEA-003133-PIP01-21

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 120 opinion

Action: For adoption

Other

2.1.10. Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21

Treatment of seasonal allergic rhinitis

Day 120 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.11. A 2'-O-(2'-methoxyethyl) modified antisense oligonucleotide targeting prekallikrein (PKK) mRNA - EMEA-003112-PIP01-21

Treatment of hereditary angioedema / Prevention of hereditary angioedema

Day 120 opinion

Action: For adoption

Pneumology - Allergology / Haematology-Hemostaseology

2.1.12. EMEA-003098-PIP01-21

Treatment of proteinuric chronic kidney disease

Day 120 opinion

Action: For adoption

Uro-nephrology

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

Genzyme Europe B.V.; Treatment of Alport syndrome

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.14. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.15. Vibegron - EMEA-001415-PIP02-21

Treatment of myoneurogenic bladder disorders

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.16. RSV F protein - EMEA-003094-PIP02-21

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Day 120 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.17. Acetylsalicylic acid / rosuvastatin - EMEA-003206-PIP01-22

Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.18. Ezetimibe / atorvastatin - EMEA-003205-PIP01-22

Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.19. EMEA-003223-PIP01-22

Treatment of palmoplantar pustulosis

Day 60 opinion

Action: For adoption

Dermatology

2.1.20. [Nipocalimab - Orphan - EMEA-002559-PIP05-22](#)

Janssen-Cilag International NV; Treatment of bullous pemphigoid

Day 60 opinion

Action: For adoption

Dermatology

2.1.21. [Gold \(Au\) - EMEA-003211-PIP01-22](#)

Treatment of amyotrophic lateral sclerosis (ALS)

Day 60 opinion

Action: For adoption

Neurology

2.1.22. [Modakafusp alfa - EMEA-003217-PIP01-22](#)

Treatment of multiple myeloma

Day 60 opinion

Action: For adoption

Oncology

2.1.23. [Humanised monoclonal antibody of IgG1 subtype targeting NRP1 - EMEA-003214-PIP01-22](#)

Treatment of diabetic retinopathy

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.24. [Magnesium lactate dihydrate / tramadol - EMEA-003216-PIP01-22](#)

Management of chronic pain in adults with osteoarthritis of the hip and/or knee

Day 60 opinion

Action: For adoption

Other

2.1.25. Pregabalin - EMEA-003221-PIP01-22

Treatment of neuropathic pain associated with diabetic peripheral neuropathy / Treatment of postherpetic neuralgia

Day 60 opinion

Action: For adoption

Pain / Neurology

2.1.26. Amlodipine / nebivolol - EMEA-003226-PIP01-22

Treatment of hypertension

Day 30 opinion

Action: For adoption

Cardiovascular Diseases

2.1.27. Valsartan / nebivolol - EMEA-003227-PIP01-22

Treatment of hypertension

Day 30 opinion

Action: For adoption

Cardiovascular Diseases

2.2. Opinions on Compliance Check

2.2.1. Apixaban - EMEA-C-000183-PIP01-08-M08

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.2.2. Pegzilarginase - EMEA-C1-001925-PIP02-19

Immedica Pharma AB; Treatment of hyperargininaemia

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

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

Eli Lilly & Company Limited; Treatment of type 2 diabetes mellitus

Day 30 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.4. [Evolocumab - EMEA-C-001268-PIP01-12-M05](#)

Amgen Europe B.V; Treatment of elevated cholesterol

Day 30 opinion

Action: For adoption

Cardiovascular Diseases

2.3. **Opinions on Modification of an Agreed Paediatric Investigation Plan**

2.3.1. [Obinutuzumab - Orphan - EMEA-001207-PIP02-19-M01](#)

Roche Registration GmbH; Treatment of systemic lupus erythematosus

Day 60 opinion

Action: For adoption

Antineoplastic and immunomodulating agents

2.3.2. [Chlorprocaine hydrochloride - EMEA-000639-PIP03-16-M02](#)

Sintetica GmbH; Peripheral nerve block (local anaesthesia by perineural injection)

Day 60 opinion

Action: For adoption

Anaesthesiology

2.3.3. [Bempedoic acid - EMEA-001872-PIP01-15-M02](#)

Esperion Therapeutics, Inc.; Treatment of elevated cholesterol

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. [Etripamil - EMEA-002303-PIP01-17-M03](#)

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular tachycardia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.5. Omecamtiv mecarbil - EMEA-001696-PIP01-14-M02

Cytokinetics, Inc.; Treatment of heart failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.6. Bimekizumab - EMEA-002189-PIP01-17-M03

UCB Biopharma SRL; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.7. Deucravacitinib - EMEA-002350-PIP01-18-M02

Bristol-Myers Squibb International Corporation; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.8. Fluciclovine (18F) - Orphan - EMEA-001644-PIP02-14-M03

Blue Earth Diagnostics Ireland Ltd; Diagnosis of amino acid metabolism in solid malignant tumours

Day 60 opinion

Action: For adoption

Diagnostic / Oncology

2.3.9. Pegunigalsidase alfa - Orphan - EMEA-001828-PIP01-15-M03

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.10. Cilofexor - Orphan - EMEA-002554-PIP02-19-M01

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (DB96.2)

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

Note: Withdrawal request received on 10 June 2022

2.3.11. Maralixibat chloride - Orphan - EMEA-001475-PIP02-13-M02

Mirum Pharmaceuticals; Treatment of Alagille syndrome

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.12. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M02

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

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.13. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M02

Principia Biopharma, Inc.; Treatment of immune thrombocytopenia

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.14. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M12

Pfizer Europe MA EEIG; Treatment of pneumonia / Treatment of infections due to aerobic gram-negative organisms / Treatment of urinary tract infections / Treatment of intra-abdominal infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. Bulevirtide - Orphan - EMEA-002399-PIP01-18-M01

Gilead Sciences International Ltd.; Treatment of chronic hepatitis D infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Casirivimab - EMEA-002964-PIP01-21-M02

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19) in hospitalised patients

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. Enmetazobactam - EMEA-002240-PIP02-17-M01

Allegra Therapeutics GmbH; Treatment of urinary tract infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.18. Imdevimab - EMEA-002965-PIP01-21-M02

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.19. Pretomanid - Orphan - EMEA-002115-PIP01-17-M05

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.20. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M02

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.21. Ritonavir / (1R,2S,5S)-N-{(1S)-1-cyano-2-[(3S)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3-[3-methyl-N-(trifluoroacetyl)-L-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide - EMEA-003081-PIP01-21-M01

Pfizer Europe MA EEIG; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.22. Eptinezumab - EMEA-002243-PIP01-17-M03

H. Lundbeck A/S; Prevention of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

2.3.23. Lasmiditan - EMEA-002166-PIP01-17-M06

Eli Lilly and Company Limited; Treatment of migraine with and without aura

Day 60 opinion

Action: For adoption

Neurology

2.3.24. Ravulizumab - EMEA-001943-PIP03-20-M01

Alexion Europe SAS; Treatment of myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.25. Rimegepant - EMEA-002812-PIP02-20-M01

Biohaven Pharmaceutical Ireland DAC; Treatment of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

2.3.26. Setmelanotide - Orphan - EMEA-002209-PIP01-17-M03

Rhythm Pharmaceuticals, Inc; Treatment of appetite and general nutrition disorders

Day 60 opinion

Action: For adoption

Nutrition

2.3.27. Bosutinib - EMEA-000727-PIP01-09-M06

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.28. Larotrectinib - EMEA-001971-PIP03-18-M02

Bayer AG; Treatment of malignant neoplasms of the central nervous system

Day 60 opinion

Action: For adoption

Oncology

2.3.29. Lenvatinib - EMEA-001119-PIP02-12-M08

Eisai GmbH; Treatment of osteosarcoma / Treatment of papillary thyroid carcinoma / Treatment of follicular carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.3.30. Andexanet alfa - EMEA-001902-PIP01-15-M06

AstraZeneca AB; Prevention of factor Xa inhibitor associated haemorrhage / Treatment of factor Xa inhibitor associated haemorrhage

Day 60 opinion

Action: For adoption

Other

Note: Withdrawal request received on 17 June 2022

2.3.31. Setrusumab - Orphan - EMEA-002169-PIP01-17-M01

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 60 opinion

Action: For adoption

Other

Note: Withdrawal request received on 10 June 2022

2.3.32. Vamorolone - Orphan - EMEA-001794-PIP02-16-M05

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Other

2.3.33. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M03

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 60 opinion

Action: For adoption

Other / Pneumology - Allergology

2.3.34. Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M08

ALK-Abelló A/S; Treatment of asthma / Treatment of allergic rhinitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.35. Brexpiprazole - EMEA-001185-PIP01-11-M08

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.36. Vortioxetine - EMEA-000455-PIP02-10-M09

H. Lundbeck A/S; Treatment of major depressive disorder

Day 60 opinion

Action: For adoption

Psychiatry

2.3.37. COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA-002862-PIP01-20-M03

AstraZeneca AB; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines

2.3.38. Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21-M01

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Day 30 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.39. Epcoritamab - Orphan - EMEA-002907-PIP01-20-M01

AbbVie Ltd; Treatment of mature B cell lymphoma

Day 30 opinion

Action: For adoption

Oncology

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. Zilucoplan - EMEA-C1-002747-PIP01-20

UCB Pharma S.A; Treatment of myasthenia gravis

Day 30 letter

Action: For information

Other / Neurology

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. Ex vivo expanded autologous human keratinocytes containing epidermal stem cells genetically modified with a gamma-retroviral (RV) vector expressing the full-length LAMB3 cDNA - Orphan - EMEA-003137-PIP01-21

Holostem Terapie Avanzate s.r.l.; Treatment of junctional epidermolysis bullosa (JEB)

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. Tezepelumab - EMEA-001613-PIP04-21

Treatment of chronic spontaneous urticaria

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. EMEA-003143-PIP01-21

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

3.1.4. Clazakizumab - EMEA-001371-PIP02-21

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

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.5. Tocilizumab - EMEA-000309-PIP09-21

Treatment of systemic sclerosis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Ibrexafungerp citrate - EMEA-002535-PIP04-21

Treatment of invasive candidiasis

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Corticotropin - EMEA-003097-PIP01-21

Treatment of infantile spasms

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Cannabidiol - EMEA-003176-PIP01-21

Treatment of fragile X syndrome (FXS)

Day 90 discussion

Action: For discussion

Psychiatry

3.1.9. Troriluzole - EMEA-003084-PIP02-21

Treatment of obsessive-compulsive disorder

Day 90 discussion

Action: For discussion

Psychiatry

3.1.10. Zuranolone - EMEA-003119-PIP01-21

Treatment of postpartum depression

Day 90 discussion

Action: For discussion

Psychiatry

3.1.11. Recombinant COVID-19 subunit nanoparticle - EMEA-003115-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Vaccines

3.1.12. Milvexian - EMEA-003220-PIP01-22

Prevention of thromboembolism

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.13. Zilebesiran - EMEA-003218-PIP01-22

Treatment of hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.14. Perflubutane - EMEA-003037-PIP02-22

Diagnostic evaluation of focal hepatic lesions

Day 60 discussion

Action: For discussion

Diagnostic / Oncology

3.1.15. Danuglipron - EMEA-002944-PIP02-22

Treatment of chronic weight management/obesity / Treatment of obesity

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.16. Doxribtimine / doxecitine - Orphan - EMEA-003210-PIP01-22

Zogenix ROI Limited; Treatment of thymidine kinase 2 deficiency

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.17. Insulin human (RDNA) - EMEA-003194-PIP02-22

Treatment of type 2 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.18. Synthetic peptide of 20 amino acids comprising a T cell epitope from pro-insulin - EMEA-002379-PIP01-22

Treatment of type 1 diabetes mellitus

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Vaccines

3.1.19. EMEA-003222-PIP01-22

Treatment of SCN8A developmental and epileptic encephalopathy

Day 60 discussion

Action: For discussion

Neurology

3.1.20. Satralizumab - Orphan - EMEA-001625-PIP04-22

Roche Registration GmbH; Treatment of autoimmune encephalitis

Day 60 discussion

Action: For discussion

Neurology

3.1.21. Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003212-PIP01-22

Treatment of mature B cell neoplasms

Day 60 discussion

Action: For discussion

Oncology

3.1.22. Fianlimab - EMEA-003207-PIP01-22

Treatment of melanoma

Day 60 discussion

Action: For discussion

Oncology

3.1.23. Humanised IgG2 monoclonal antibody against interleukin-6 - EMEA-003215-PIP01-22

Treatment of macular oedema

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.24. Benzylamine derivative of benzofuran - EMEA-002974-PIP02-22

Treatment of C3 glomerulopathy

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.25. Hydrochlorothiazide / amlodipine / telmisartan - EMEA-003229-PIP01-22

Treatment of hypertension / I10 essential primary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Perindopril tert-butylamin / rosuvastatin - EMEA-003228-PIP01-22

Prevention of cardiovascular events / Treatment of hypertension / Treatment of dyslipidaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.27. Valsartan / rosuvastatin - EMEA-003240-PIP01-22

Treatment of hypertension / Treatment of dyslipidaemia / Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.28. Amlitelimab - EMEA-003233-PIP01-22

Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.29. CRN04777 - Orphan - EMEA-003242-PIP01-22

Crinetics Pharmaceuticals, Inc.; Treatment of congenital hyperinsulinism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.30. EMEA-003241-PIP01-22

Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.31. Inclacumab - EMEA-003219-PIP01-22

Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.32. Itolizumab - Orphan - EMEA-003208-PIP02-22

Biocon Pharma Malta-I Limited; Treatment of acute graft versus host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.33. Cilgavimab / tixagevimab - EMEA-003079-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.34. Opelconazole - EMEA-003249-PIP01-22

Treatment of bronchopulmonary aspergillosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.35. Tetracycline / metronidazole / bismuth - EMEA-003224-PIP01-22

Treatment of helicobacter pylori infection

Day 30 discussion

Action: For discussion

Infectious Diseases / Gastroenterology-Hepatology

3.1.36. Enibarcimab - EMEA-003244-PIP01-22

Treatment of sepsis

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care / Cardiovascular Diseases

3.1.37. [Cemdisiran sodium - Orphan - EMEA-003237-PIP01-22](#)

Regeneron Ireland DAC; Treatment of generalized myasthenia gravis (gMG)

Day 30 discussion

Action: For discussion

Neurology

3.1.38. [Pegcetacoplan - EMEA-002600-PIP04-22](#)

Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.39. [Pozelimab - EMEA-003238-PIP01-22](#)

Treatment of generalized myasthenia gravis (gMG)

Day 30 discussion

Action: For discussion

Neurology

3.1.40. [Suvecaltamide - EMEA-003248-PIP01-22](#)

Treatment of essential tremor

Day 30 discussion

Action: For discussion

Neurology

3.1.41. [Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor \(CAR\) directed against human B cell maturation antigen \(BCMA\) and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003231-PIP01-22](#)

Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Gallium 68-labelled prostate-specific membrane antigen-11 (68Ga-PSMA-11) - EMEA-003236-PIP01-22

Visualisation of prostate specific membrane antigen in prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.43. Golidocitinib - EMEA-003246-PIP01-22

Treatment of relapsed or refractory peripheral T cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Lutetium (177Lu) edotreotide - Orphan - EMEA-003245-PIP01-22

ITM Solucin GmbH; Treatment of somatostatin receptor (SSTR)-positive tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Monalizumab - EMEA-002751-PIP02-22

Treatment of lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.46. Obinutuzumab - Orphan - EMEA-001207-PIP04-22

Roche Registration GmbH; Prevention of cytokine release syndrome

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Oleclumab - EMEA-003234-PIP01-22

Treatment of lung cancer / Treatment of pancreatic cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.48. Toripalimab - EMEA-003243-PIP01-22

Treatment of all conditions in the category of malignant neoplasms (except CNS, haematopoietic and lymphoid tissue)

Day 30 discussion

Action: For discussion

Oncology

3.1.49. Vepsitamab - EMEA-003230-PIP01-22

Treatment of gastrointestinal solid tumours malignant and unspecified expressing MUC17

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Xevinapant - Orphan - EMEA-003235-PIP01-22

Merck Healthcare KGaA; Treatment of squamous cell carcinoma of the head and neck

Day 30 discussion

Action: For discussion

Oncology

3.1.51. Dimeric protein comprised of two disulfide-linked monomers, each being a fully human fusion protein consisting of a modified extracellular domain (ECD) of the human activin receptor type IIA (ActRIIA) fused to the fragment crystallizable (Fc) domain of human IgG1 Fc including the hinge region, CH2 and CH3 domains - EMEA-003239-PIP01-22

Treatment of myelodysplastic syndrome (MDS) and myelofibrosis (MF)

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.52. Tinalrebant - Orphan - EMEA-003225-PIP01-22

Belite Bio, Inc; Treatment of Stargardt disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.53. (S)-lactic acid - EMEA-003247-PIP01-22

Treatment of degenerative disc disease

Day 30 discussion

Action: For discussion

Other

3.1.54. Tirzepatide - EMEA-002360-PIP02-22

Treatment of obesity

Day 30 discussion

Action: For discussion

Other

3.1.55. Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1 - Orphan - EMEA-003232-PIP01-22

Inozyme Pharma Ireland Limited; Treatment of ectonucleotide pyrophosphatase / phosphodiesterase 1 (ENPP1) deficiency

Day 30 discussion

Action: For discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.56. ABNCoV2 (AV2-cVLP-RBD SARS-CoV-2) - EMEA-003184-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.2. Discussions on Compliance Check

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

3.2.1. Human Fibrinogen - EMEA-C-001208-PIP01-11-M03

Octapharma Pharamzeutika Produktionsges.m.b.H; Treatment of congenital fibrinogen deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.2. [Letemovir - EMEA-C1-001631-PIP01-14-M04](#)

Merck Sharp & Dohme (Europe), Inc; Prevention of cytomegalovirus infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. [Tisagenlecleucel - EMEA-C-001654-PIP02-17-M01](#)

Novartis Europharm Limited; Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.2.4. [Ad26.ZEBOV \(recombinant, replication-incompetent\) - EMEA-C-002307-PIP01-17-M02](#)

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 30 discussion

Action: For discussion

Vaccines

3.2.5. [MVA-BN-Filo \(recombinant, non-replicating\) - EMEA-C-002308-PIP01-17-M02](#)

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 30 discussion

Action: For discussion

Vaccines

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

3.3.1. [Aliskiren hemifumarate - EMEA-000362-PIP01-08-M06](#)

NODEN PHARMA DAC; Treatment of hypertension / Treatment of heart failure

Day 30 discussion

Action: For discussion
Cardiovascular Diseases

3.3.2. Treprostinil - EMEA-000207-PIP01-08-M07

Ferrer Internacional, S.A.; Treatment of pulmonary arterial hypertension
Day 30 discussion
Action: For discussion
Cardiovascular Diseases

3.3.3. Evinacumab - EMEA-002298-PIP01-17-M04

Regeneron Ireland DAC; Treatment of elevated cholesterol
Day 30 discussion
Action: For discussion
Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Guselkumab - EMEA-001523-PIP04-19-M01

Janssen-Cilag International N.V.; Treatment of ulcerative colitis: ICD K51
Day 30 discussion
Action: For discussion
Gastroenterology-Hepatology

3.3.5. Odevixibat - Orphan - EMEA-002054-PIP03-20-M01

Albireo AB; Treatment of Alagille syndrome
Day 30 discussion
Action: For discussion
Gastroenterology-Hepatology

3.3.6. Ustekinumab - EMEA-000311-PIP04-13-M05

Janssen-Cilag International NV; Treatment of Crohn's disease
Day 30 discussion
Action: For discussion
Gastroenterology-Hepatology

3.3.7. Plasma kallikrein inhibitor - EMEA-002723-PIP01-19-M01

KalVista Pharmaceuticals Ltd; Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. [Roxadustat - EMEA-001557-PIP01-13-M06](#)

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. [Vonico alfa - EMEA-001164-PIP01-11-M06](#)

Baxalta Innovations GmbH; Treatment of Von Willebrand disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.10. [Apremilast - EMEA-000715-PIP02-11-M06](#)

Amgen Europe B.V.; Treatment of juvenile idiopathic arthritis (JIA) / Treatment of juvenile psoriatic arthritis (JPsA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. [Apremilast - EMEA-000715-PIP05-13-M05](#)

Amgen Europe.B.V; Treatment of Behçet's disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. [Baricitinib - EMEA-001220-PIP07-20-M01](#)

Eli Lilly and Company Limited; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. Belimumab - EMEA-000520-PIP02-13-M04

Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Griselimab setaritox / dafsolimab setaritox - Orphan - EMEA-002087-PIP01-16-M01

Xenikos B.V.; Treatment of acute graft versus host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.15. Upadacitinib - EMEA-001741-PIP04-17-M03

AbbVie Ltd; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.3.16. Baloxavir marboxil - EMEA-002440-PIP01-18-M03

Roche Registration GmbH; Prevention of influenza / Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. BNT162b2 / tozinameran - EMEA-002861-PIP02-20-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Cabotegravir - EMEA-001418-PIP01-13-M05

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Cobicistat - EMEA-000969-PIP01-10-M06

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Emtricitabine / tenofovir alafenamide - EMEA-001577-PIP02-14-M05

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.21. Lamivudine / dolutegravir - EMEA-001940-PIP01-16-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.22. Rilpivirine - EMEA-000317-PIP02-18-M01

Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.23. Tenofovir alafenamide / rilpivirine / emtricitabine - EMEA-001679-PIP01-14-M02

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.24. Zoliflodacin - EMEA-002599-PIP01-19-M01

Entasis Therapeutic Inc.; Treatment of gonococcal infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.25. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M05

Zogenix International Ltd; Treatment of Dravet syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.26. Ozanimod (hydrochloride) - EMEA-001710-PIP02-14-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.27. Peginterferon beta-1a - EMEA-001129-PIP01-11-M05

Biogen Idec Ltd; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.28. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M05

Ipsen Pharma; Treatment of malignant solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.3.29. Copanlisib - Orphan - EMEA-001757-PIP02-15-M03

Bayer AG; Treatment of mature B cell neoplasms / Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

Action: For discussion

Oncology

3.3.30. Durvalumab - EMEA-002028-PIP01-16-M03

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

Day 30 discussion

Action: For discussion

Oncology

3.3.31. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M06

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.32. Lomitapide (as lomitapide mesylate) - EMEA-001124-PIP01-10-M05

Amryt Pharmaceuticals DAC; Treatment of heterozygous and homozygous familial hypercholesterolaemia

Day 30 discussion

Action: For discussion

Other

3.3.33. Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP02-13-M01

GW Pharma (International) B.V; Treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.3.34. Adrenaline (epinephrine) - EMEA-002749-PIP01-19-M02

ARS Pharmaceuticals IRL, Limited; Treatment of allergic reactions

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.35. Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR) - EMEA-001490-PIP01-13-M03

Emergent Netherlands B.V.; Treatment of cholera disease caused by *Vibrio cholerae* serogroup O1

Day 30 discussion

Action: For discussion

Vaccines

3.3.36. Tremelimumab - Orphan - EMEA-002029-PIP01-16-M03

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

Day 30 discussion

Action: For discussion

Oncology

3.3.37. For 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-M02

Moderna Biotech Spain, S.L.; 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 11 July 2022 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

6.1.1. AZD9833 (selective estrogen receptor degrader) - EMEA-01-2022

AstraZeneca AB; The classes of oestrogen receptor modulator medicinal products for treatment of breast malignant neoplasms / Treatment of estrogen receptor positive, locally advanced or metastatic breast cancer / Treatment of hormone receptor positive breast cancer

Action: For adoption

6.1.2. Donanemab - EMEA-03-2022

Eli Lilly and Company Limited; All classes of medicinal products for treatment of Alzheimer's disease / Slowing disease progression in patients with early symptomatic Alzheimer's disease

Action: For adoption

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

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

No item

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. PDCO membership

Action: For information

9.1.2. Vote by Proxy

Action: For information

9.1.3. Mandate of PDCO Chairperson - call for nominations

Action: For information

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

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

9.3.1. Non-clinical Working Party: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. 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

9.8.1. EMA Business Pipeline activity and Horizon scanning

Q2/2022 Update of the Business Pipeline report for the human scientific committees

Action: For information

10. Any other business

10.1. COVID-19 update

Action: For information

10.2. Exparel liposomal - EMEA/H/C/004586/II/0005 PDCO consultation from CHMP

Action: For discussion

10.3. EU Survey Testing

Action: For information

10.4. Revision of the guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

PDCO members: Carine de Beaufort, Agnes Gyurasics

Action: For adoption

11. Breakout sessions

11.1. Neonatology

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

11.2. Vaccines

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

11.3. Paediatric oncology

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/