



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2022
EMA/PDCO/5821/2022
Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 18-21 January 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

18 January 2022, 11:00 - 19:00, Virtual meeting

19 January 2022, 08:30 - 19:00, Virtual meeting

20 January 2022, 08:30 - 19:00, Virtual meeting

21 January 2022, 08:30 - 13:00, Virtual meeting

Disclaimers

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.	Phospholipid esters from herring roe - EMEA-003053-PIP01-21	9
2.1.2.	Efgartigimod alfa - Orphan - EMEA-002597-PIP04-21.....	9
2.1.3.	Recombinant humanised anti-blood dendritic cell antigen 2 (BDCA2) monoclonal antibody - EMEA-002555-PIP02-21	10
2.1.4.	Acetyl-L-leucine ((s)-(acetylamino)-4-methylpentanoic acid) - Orphan - EMEA-002796-PIP01-20	10
2.1.5.	Firazorexton sesquihydrate - EMEA-002993-PIP01-21	10
2.1.6.	Givinostat - Orphan - EMEA-000551-PIP04-21	10
2.1.7.	Viltolarsen - Orphan - EMEA-002853-PIP01-20.....	10
2.1.8.	Pemigatinib - Orphan - EMEA-002370-PIP02-21	10
2.1.9.	Zamtocabtagene autoleucel - Orphan - EMEA-003009-PIP01-21.....	11
2.1.10.	Pabinafusp alfa - Orphan - EMEA-003033-PIP01-21	11
2.1.11.	EMEA-003052-PIP01-21	11
2.1.12.	EMEA-002946-PIP01-20	11
2.1.13.	Ralmitaront - EMEA-003003-PIP01-21.....	11
2.1.14.	L-Carnitine / glucose/ calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21	12
2.1.15.	COVID-19 vaccine (recombinant, adjuvanted) - EMEA-002987-PIP01-21.....	12
2.1.16.	<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	12
2.1.17.	EMEA-003120-PIP01-21	12
2.1.18.	Avexitide - Orphan - EMEA-003125-PIP01-21.....	12
2.1.19.	Parsaclisib (as hydrochloride) - Orphan - EMEA-002696-PIP02-21	13
2.1.20.	Human normal immunoglobulin - EMEA-003121-PIP01-21	13
2.1.21.	Ceralasertib - EMEA-003127-PIP01-21	13
2.1.22.	Cosibelimab - EMEA-003041-PIP01-21	13
2.1.23.	Nemtabrutinib - EMEA-003135-PIP01-21	13
2.1.24.	Sunvozertinib - EMEA-003132-PIP01-21.....	13
2.1.25.	Tarlatamab - EMEA-003138-PIP01-21	14

2.1.26.	Tucatinib - EMEA-002242-PIP02-21	14
2.1.27.	Vimseltinib - Orphan - EMEA-002802-PIP02-21	14
2.1.28.	Bemcentinib - EMEA-003123-PIP01-21	14
2.1.29.	EMEA-001649-PIP02-21	14
2.1.30.	Ocrevus - EMEA-000310-PIP04-21.....	15
2.2.	Opinions on Compliance Check	15
2.2.1.	Nirsevimab - EMEA-C2-001784-PIP01-15-M03	15
2.2.2.	Nivolumab - EMEA-C-001407-PIP01-12-M03.....	15
2.3.	Opinions on Modification of an Agreed Paediatric Investigation Plan	15
2.3.1.	Delgocitinib - EMEA-002329-PIP02-20-M01.....	15
2.3.2.	Spesolimab - EMEA-002475-PIP02-19-M02.....	15
2.3.3.	Tralokinumab - EMEA-001900-PIP02-17-M06.....	16
2.3.4.	Dienogest / ethinyl estradiol - EMEA-002229-PIP01-17-M03	16
2.3.5.	Pegvaliase - Orphan - EMEA-001951-PIP01-16-M02.....	16
2.3.6.	Etrasimod L-arginine - EMEA-002713-PIP01-19-M01.....	16
2.3.7.	Guselkumab - EMEA-001523-PIP05-19-M01.....	16
2.3.8.	Mirikizumab - EMEA-002208-PIP01-17-M02	16
2.3.9.	Efanesoctocog alfa - Orphan - EMEA-002501-PIP01-18-M02	17
2.3.10.	Glutamine - Orphan - EMEA-001996-PIP02-16-M01	17
2.3.11.	Apremilast - EMEA-000715-PIP02-11-M05.....	17
2.3.12.	Imlifidase - Orphan - EMEA-002183-PIP01-17-M01.....	17
2.3.13.	Casirivimab - EMEA-002964-PIP01-21-M01.....	17
2.3.14.	Cilgavimab - EMEA-002925-PIP01-20-M01	18
2.3.15.	Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M06.....	18
2.3.16.	Imdevimab - EMEA-002965-PIP01-21-M01	18
2.3.17.	Ridinilazole (hydrate) - EMEA-002250-PIP02-17-M01	18
2.3.18.	Tedizolid phosphate - EMEA-001379-PIP01-12-M06	18
2.3.19.	Tenofovir disoproxil - EMEA-000533-PIP01-08-M11	19
2.3.20.	Tixagevimab - EMEA-002900-PIP01-20-M01	19
2.3.21.	Isoflurane - EMEA-002320-PIP01-17-M02.....	19
2.3.22.	Delandistrogene moxeparvovec - Orphan - EMEA-002677-PIP01-19-M01	19
2.3.23.	Eculizumab - Orphan - EMEA-000876-PIP05-15-M05.....	19
2.3.24.	Eptinezumab - EMEA-002243-PIP01-17-M02.....	19
2.3.25.	Dinutuximab beta - Orphan - EMEA-001314-PIP01-12-M01	20
2.3.26.	Ex vivo expanded autologous human corneal epithelium cells containing stem cells - Orphan - EMEA-001082-PIP02-11-M03	20
2.3.27.	Vosoritide - Orphan - EMEA-002033-PIP01-16-M02	20
2.3.28.	Adrenaline (epinephrine) - EMEA-002749-PIP01-19-M01	20
2.3.29.	Modified allergen extract of birch pollen - EMEA-000932-PIP01-10-M02	20

2.3.30.	Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M04	21
2.3.31.	SARS CoV2 prefusion Spike delta TM (CoV2 preS dTM) protein, recombinant adjuvanted with AS03 - EMEA-002915-PIP01-20-M01.....	21
2.4.	Opinions on Re-examinations	21
2.5.	Opinions on Review of Granted Waivers	21
2.6.	Finalisation and adoption of Opinions.....	21
2.7.	Partial Compliance Checks completed by EMA	21
2.7.1.	Risdiplam - EMEA-C2-002070-PIP01-16-M06	21

3. Discussion of applications 22

3.1.	Discussions on Products D90-D60-D30.....	22
3.1.1.	Abelacimab - EMEA-003017-PIP01-21	22
3.1.2.	Dupilumab - EMEA-001501-PIP09-21	22
3.1.3.	EMEA-003027-PIP01-21	22
3.1.4.	Benzylamine derivative of benzofuran - EMEA-002974-PIP01-21	22
3.1.5.	Rozanolixizumab - Orphan - EMEA-002681-PIP02-21	22
3.1.6.	Censavudine - EMEA-003075-PIP01-21	23
3.1.7.	Invimestrocel - EMEA-002317-PIP02-21	23
3.1.8.	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	23
3.1.9.	Autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) genetically modified with the lentiviral vector IDUA LV, encoding for the human α -L-iduronidase (IDUA) cDNA - Orphan - EMEA-003001-PIP01-21	23
3.1.10.	Pamrevlumab - Orphan - EMEA-002979-PIP01-21	23
3.1.11.	Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP01-21	24
3.1.12.	Ex vivo expanded autologous human keratinocytes containing epidermal stem cells transduced with a LAMB3-encoding retroviral vector - Orphan - EMEA-003137-PIP01-21	24
3.1.13.	Tezepelumab - EMEA-001613-PIP04-21.....	24
3.1.14.	A nonreplicating, recombinant adeno-associated virus (AAV) serotype 9 (AAV9) gene transfer vector that contains a modified human ATP7B coding sequence - Orphan - EMEA-003131-PIP01-21	24
3.1.15.	Elamipretide - Orphan - EMEA-003128-PIP01-21	24
3.1.16.	EMEA-003116-PIP01-21	25
3.1.17.	Ibrexafungerp citrate - EMEA-002535-PIP04-21	25
3.1.18.	Nifurtimox - EMEA-003134-PIP01-21	25
3.1.19.	Ivermectin - EMEA-003136-PIP01-21	25
3.1.20.	Self-complementary adeno-associated viral vector serotype 9 containing the human CLN3 gene - Orphan - EMEA-003124-PIP01-21	25
3.1.21.	EMEA-003129-PIP01-21	26

3.1.22.	(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	26
3.1.23.	Anti TL1a mAb - EMEA-003111-PIP02-21	26
3.1.24.	Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21.....	26
3.1.25.	Zuranolone - EMEA-003119-PIP01-21	26
3.1.26.	<i>Borrelia</i> outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine - EMEA-003130-PIP01-21	26
3.1.27.	Recombinant COVID-19 subunit nanoparticle - EMEA-003115-PIP01-21	27
3.1.28.	Crovalimab - EMEA-002709-PIP02-21	27
3.1.29.	Acetylsalicylic acid / ticagrelor - EMEA-003146-PIP01-21.....	27
3.1.30.	Asundexian - EMEA-003144-PIP01-21	27
3.1.31.	Indapamide / telmisartan - EMEA-003151-PIP01-21	27
3.1.32.	Oxytocin - Orphan - EMEA-003148-PIP01-21	28
3.1.33.	Etrasimod L-arginine - EMEA-002713-PIP02-21	28
3.1.34.	EMEA-003143-PIP01-21	28
3.1.35.	EMEA-002927-PIP02-21	28
3.1.36.	Ianalumab - EMEA-002338-PIP03-21	28
3.1.37.	Secukinumab - EMEA-000380-PIP09-21	28
3.1.38.	Tocilizumab - EMEA-000309-PIP09-21.....	29
3.1.39.	A fully human IgG1 monoclonal antibody targeting an epitope in the receptor-binding domain of the spike glycoprotein of SARS-CoV-2 - EMEA-003118-PIP01-21	29
3.1.40.	Ensovibep - EMEA-003150-PIP01-21.....	29
3.1.41.	Remibrutinib - EMEA-002582-PIP02-21	29
3.1.42.	Cevostamab - Orphan - EMEA-003145-PIP01-21	29
3.1.43.	Human IgG4 monoclonal antibody against BCMA and CD3 - EMEA-003147-PIP01-21	30
3.1.44.	EMEA-003110-PIP02-21	30
3.1.45.	Odronextamab - EMEA-003149-PIP01-21	30
3.1.46.	Retifanlimab - Orphan - EMEA-002798-PIP02-21	30
3.1.47.	Sintilimab - EMEA-002919-PIP02-21	30
3.1.48.	EMEA-003141-PIP01-21	30
3.1.49.	Apitegromab - Orphan - EMEA-002951-PIP02-21.....	31
3.1.50.	Influenza virus A/turkey/Turkey/1/2005 (H5N1) NIBRG-23 strain, HA surface antigen - EMEA-002869-PIP03-21	31
3.1.51.	RSV F protein - EMEA-003094-PIP02-21.....	31
3.2.	Discussions on Compliance Check.....	31
3.2.1.	Dupilumab - EMEA-C-001501-PIP01-13-M07.....	31
3.2.2.	Ligelizumab - EMEA-C2-001811-PIP02-15-M04	31
3.2.3.	Albutrepenonacog alfa - EMEA-C-001107-PIP01-10-M04	32
3.2.4.	Cobicistate / atazanavir sulphate - EMEA-C2-001465-PIP01-13-M03.....	32

3.2.5.	Atogepant - EMEA-C1-002530-PIP01-18.....	32
3.2.6.	Eribulin - EMEA-C-001261-PIP01-11-M07	32
3.3.	Discussions on Modification of an Agreed Paediatric Investigation Plan.....	32
3.3.1.	Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M05.....	32
3.3.2.	Saxagliptin - EMEA-000200-PIP01-08-M09	33
3.3.3.	Eluxadoline - EMEA-001579-PIP01-13-M05.....	33
3.3.4.	Ozanimod hydrochloride - EMEA-001710-PIP04-17-M03.....	33
3.3.5.	Bezlotoxumab - EMEA-001645-PIP01-14-M04	33
3.3.6.	Brincidofovir - Orphan - EMEA-001904-PIP02-17-M01	33
3.3.7.	Cabotegravir - EMEA-001418-PIP02-15-M03.....	34
3.3.8.	Rilpivirine (hydrochloride) - EMEA-000317-PIP01-08-M13.....	34
3.3.9.	Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP01-08-M06.....	34
3.3.10.	Galcanezumab - EMEA-001860-PIP03-16-M07	34
3.3.11.	Leriglitzzone - Orphan - EMEA-002106-PIP01-16-M02.....	34
3.3.12.	Ofatumumab - EMEA-002397-PIP01-18-M02.....	34
3.3.13.	Siponimod (hemifumarate) - EMEA-000716-PIP01-09-M04	35
3.3.14.	(4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide - EMEA-002631-PIP01-19-M01.....	35
3.3.15.	Axicabtagene ciloleucel - Orphan - EMEA-002010-PIP01-16-M03.....	35
3.3.16.	Bempegaldesleukin - EMEA-002492-PIP01-18-M02.....	35
3.3.17.	Palbociclib - EMEA-002146-PIP01-17-M04	35
3.3.18.	Ponatinib - Orphan - EMEA-001186-PIP01-11-M03	36
3.3.19.	Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M05.....	36
3.3.20.	Fosdenopterin - Orphan - EMEA-001491-PIP01-13-M02.....	36
3.3.21.	Amikacin (sulfate) - Orphan - EMEA-000525-PIP01-08-M08.....	36
3.3.22.	Benralizumab - EMEA-001214-PIP01-11-M11	36
3.3.23.	(S)-(2-(5-chloro-4-methyl-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl)(4-methoxy-2-(2H-1,2,3-triazol-2-yl)phenyl)methanone hydrochloride - EMEA-002121-PIP03-19-M01 ...	36
3.3.24.	Esketamine hydrochloride - EMEA-001428-PIP03-15-M02.....	37
3.3.25.	Lisdexamfetamine dimesylate - EMEA-000553-PIP01-09-M05	37
3.3.26.	Etelcalcetide - EMEA-001554-PIP01-13-M03	37
3.3.27.	Ferumoxytol - EMEA-000373-PIP02-09-M05	37
3.3.28.	Recombinant influenza hemagglutinin-strain B (Yamagata lineage) / recombinant influenza hemagglutinin-strain B (Victoria lineage) / recombinant influenza hemagglutinin-strain A (H3N2 subtype) / recombinant influenza hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18-M02	37

4. Nominations 38

4.1. List of submissions of applications with start of procedure 31 January 2022 for Nomination of Rapporteur and Peer reviewer..... 38

4.2.	Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	38
4.3.	Nominations for other activities	38
5.	Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction	38
6.	Discussion on the applicability of class waivers	38
6.1.	Discussions on the applicability of class waiver for products.....	38
6.1.1.	Tramadol hydrochloride / magnesium lactate dihydrate- EMEA-12-2021	38
7.	Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver	39
7.1.	Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver	39
7.1.1.	Otilimab - EMEA-001882-PIP02-16-M02	39
8.	Annual reports on deferrals	39
9.	Organisational, regulatory and methodological matters	39
9.1.	Mandate and organisation of the PDCO.....	39
9.1.1.	PDCO membership.....	39
9.1.2.	Vote by proxy	39
9.2.	Coordination with EMA Scientific Committees or CMDh-v	39
9.2.1.	Committee for Medicinal Products for Human Use (CHMP)	39
9.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	40
9.3.1.	Non-clinical Working Group: D30 Products identified	40
9.3.2.	Formulation Working Group	40
9.4.	Cooperation within the EU regulatory network.....	40
9.4.1.	European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA).....	40
9.5.	Cooperation with International Regulators.....	40
9.6.	Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee.....	40
9.7.	PDCO work plan.....	40
9.7.1.	PDCO Work Plan 2022	40
9.8.	Planning and reporting	40
10.	Any other business	41
10.1.	COVID-19 update.....	41
10.2.	International Council for Harmonisation – ICH E11A – Paediatric Extrapolation ..	41
10.3.	Working party implementation update - call for nominations	41
11.	Breakout sessions	41
11.1.	Internal PDCO Operations	41

11.2.	Neonatology	41
11.3.	Paediatric oncology	41
11.4.	Vaccines	41
12.	Explanatory notes	42

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 18-21 January 2022. See January 2022 PDCO minutes (to be published post February 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 18-21 January 2022

1.3. Adoption of the minutes

PDCO minutes for 14-17 December 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. Phospholipid esters from herring roe - EMEA-003053-PIP01-21

Treatment of psoriasis

Day 120 opinion

Action: For adoption

Dermatology

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

argenx BV; Treatment of immune thrombocytopenia

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

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

Treatment of lupus erythematosus

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Acetyl-L-leucine ((s)-(acetylamino)-4-methylpentanoic acid) - Orphan - EMEA-002796-PIP01-20

IntraBio Ltd.; Treatment of Niemann-Pick disease type C

Day 120 opinion

Action: For adoption

Neurology

2.1.5. Firazorexton sesquihydrate - EMEA-002993-PIP01-21

Treatment of narcolepsy

Day 120 opinion

Action: For adoption

Neurology

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

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

Day 120 opinion

Action: For adoption

Neurology

2.1.7. Viltolarsen - Orphan - EMEA-002853-PIP01-20

NS Pharma, Inc.; Treatment of Duchenne muscular dystrophy

Day 120 opinion

Action: For adoption

Neurology

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

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

Day 120 opinion

Action: For adoption

Oncology

Note: Withdrawal request received on 13 January 2021

2.1.9. Zamtocabtagene autoleucel - Orphan - EMEA-003009-PIP01-21

Miltenyi Biomedicine GmbH; Treatment of mature B cell neoplasms

Day 120 opinion

Action: For adoption

Oncology

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

JCR Pharmaceuticals Co., Ltd.; Mucopolysaccharidosis type II

Day 120 opinion

Action: For adoption

Other

2.1.11. EMEA-003052-PIP01-21

Treatment of cystic fibrosis

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.12. EMEA-002946-PIP01-20

Treatment of major depressive disorder

Day 120 opinion

Action: For adoption

Psychiatry

2.1.13. Ralmitaront - EMEA-003003-PIP01-21

Treatment of schizophrenia

Day 120 opinion

Action: For adoption

Psychiatry

2.1.14. 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 120 opinion

Action: For adoption

Uro-nephrology

2.1.15. COVID-19 vaccine (recombinant, adjuvanted) - EMEA-002987-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Vaccines

2.1.16. *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 120 opinion

Action: For adoption

Vaccines

2.1.17. EMEA-003120-PIP01-21

Prevention of cardiovascular events in patients with chronic heart failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.18. Avexitide - Orphan - EMEA-003125-PIP01-21

EigerBio Europe Limited; Treatment of postbariatric hypoglycaemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.19. Parsaclisib (as hydrochloride) - Orphan - EMEA-002696-PIP02-21

Incyte Biosciences Distribution B.V.; Treatment of autoimmune haemolytic anaemia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.20. Human normal immunoglobulin - EMEA-003121-PIP01-21

Treatment of post-polio syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.21. Ceralasertib - EMEA-003127-PIP01-21

Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Day 60 opinion

Action: For adoption

Oncology

2.1.22. Cosibelimab - EMEA-003041-PIP01-21

Treatment of cutaneous squamous cell carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.23. Nemtabrutinib - EMEA-003135-PIP01-21

Treatment of mature B cell malignancies

Day 60 opinion

Action: For adoption

Oncology

2.1.24. Sunvozertinib - EMEA-003132-PIP01-21

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.25. [Tarlataamab - EMEA-003138-PIP01-21](#)

Treatment of neuroendocrine prostate cancer (NEPC) / Treatment of small cell lung cancer (SCLC)

Day 60 opinion

Action: For adoption

Oncology

2.1.26. [Tucatinib - EMEA-002242-PIP02-21](#)

Treatment of solid tumours / Treatment of malignant neoplasms with HER2 alterations

Day 60 opinion

Action: For adoption

Oncology

2.1.27. [Vimseltinib - Orphan - EMEA-002802-PIP02-21](#)

Deciphera Pharmaceuticals; Treatment of tenosynovial giant cell tumour

Day 60 opinion

Action: For adoption

Oncology

2.1.28. [Bemcentinib - EMEA-003123-PIP01-21](#)

Treatment of acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.1.29. [EMEA-001649-PIP02-21](#)

Treatment of fibrosing interstitial lung diseases (ILD)

Day 60 opinion

Action: For adoption

Pneumology – Allergology

2.1.30. Ocrevus - EMEA-000310-PIP04-21

Roche Registration GmbH; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.2. Opinions on Compliance Check

2.2.1. Nirsevimab - EMEA-C2-001784-PIP01-15-M03

AstraZeneca AB; Prevention of lower respiratory tract infection caused by respiratory syncytial virus

Day 60 letter

Action: For information

Infectious Diseases

2.2.2. Nivolumab - EMEA-C-001407-PIP01-12-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue)

Day 60 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Delgocitinib - EMEA-002329-PIP02-20-M01

LEO Pharma A/S; Treatment of chronic hand eczema

Day 60 opinion

Action: For adoption

Dermatology

2.3.2. Spesolimab - EMEA-002475-PIP02-19-M02

Boehringer Ingelheim International GmbH; Prevention of generalised pustular psoriasis / Treatment of generalised pustular psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Tralokinumab - EMEA-001900-PIP02-17-M06

LEO Pharma A/S; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Dienogest / ethinyl estradiol - EMEA-002229-PIP01-17-M03

Chemo Research; Prevention of pregnancy

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Pegvaliase - Orphan - EMEA-001951-PIP01-16-M02

BioMarin International Limited; Treatment of hyperphenylalaninaemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. Etrasimod L-arginine - EMEA-002713-PIP01-19-M01

Arena Pharmaceuticals, Inc.; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.7. Guselkumab - EMEA-001523-PIP05-19-M01

Janssen-Cilag International N.V.; Treatment of Crohn's disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. Mirikizumab - EMEA-002208-PIP01-17-M02

Eli Lilly and Company; Treatment of Crohn's disease / Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.9. Efanesoctocog alfa - Orphan - EMEA-002501-PIP01-18-M02

Bioverativ Therapeutics, Inc., a Sanofi Company; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.10. Glutamine - Orphan - EMEA-001996-PIP02-16-M01

Emmaus Medical Europe Ltd.; Treatment of sickle cell disease

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.11. Apremilast - EMEA-000715-PIP02-11-M05

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

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.12. Imlifidase - Orphan - EMEA-002183-PIP01-17-M01

Hansa Biopharma AB; Desensitisation treatment of highly sensitised kidney transplant patients with positive crossmatch against an available donor

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.13. Casirivimab - EMEA-002964-PIP01-21-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.14. Cilgavimab - EMEA-002925-PIP01-20-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M06

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Imdevimab - EMEA-002965-PIP01-21-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. Ridinilazole (hydrate) - EMEA-002250-PIP02-17-M01

Summit Limited; Treatment of *Clostridium difficile* infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.18. Tedizolid phosphate - EMEA-001379-PIP01-12-M06

Merck Sharp & Dohme (Europe), Inc.; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.19. Tenofovir disoproxil - EMEA-000533-PIP01-08-M11

Gilead Sciences International Limited; Treatment of chronic viral hepatitis B / Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.20. Tixagevimab - EMEA-002900-PIP01-20-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.21. Isoflurane - EMEA-002320-PIP01-17-M02

Sedana Medical AB; Sedation of mechanically ventilated patients

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.3.22. Delandistrogene moxeparvovec - Orphan - EMEA-002677-PIP01-19-M01

Roche Registration GmbH; Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.23. Eculizumab - Orphan - EMEA-000876-PIP05-15-M05

Alexion Europe SAS; Treatment of myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.24. Eptinezumab - EMEA-002243-PIP01-17-M02

H. Lundbeck A/S; Prevention of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

2.3.25. [Dinutuximab beta - Orphan - EMEA-001314-PIP01-12-M01](#)

EUSA Pharma (Netherlands) BV; Neuroblastoma

Day 60 opinion

Action: For adoption

Oncology

2.3.26. [Ex vivo expanded autologous human corneal epithelium cells containing stem cells - Orphan - EMEA-001082-PIP02-11-M03](#)

Holostem Therapie Avanzate S.r.l.; Limbal stem cell deficiency due to ocular burns

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.27. [Vosoritide - Orphan - EMEA-002033-PIP01-16-M02](#)

BioMarin International Limited; Treatment of achondroplasia

Day 60 opinion

Action: For adoption

Other

2.3.28. [Adrenaline \(epinephrine\) - EMEA-002749-PIP01-19-M01](#)

ARS Pharmaceuticals IRL, Limited; Treatment of allergic reactions

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.29. [Modified allergen extract of birch pollen - EMEA-000932-PIP01-10-M02](#)

ROXALL Medizin GmbH; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

- 2.3.30. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M04
-

Sanofi Pasteur; Prevention of influenza infection

Day 60 opinion

Action: For adoption

Vaccines

- 2.3.31. SARS CoV2 prefusion Spike delta TM (CoV2 preS dTM) protein, recombinant adjuvanted with AS03 - EMEA-002915-PIP01-20-M01
-

Sanofi Pasteur; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 opinion

Action: For adoption

Vaccines

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. Risdiplam - EMEA-C2-002070-PIP01-16-M06
-

Roche Registration GmbH; Treatment of spinal muscular atrophy

Day 30 letter

Action: For information

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. [Abelacimab - EMEA-003017-PIP01-21](#)

Prevention of venous thromboembolism associated with cancer

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. [Dupilumab - EMEA-001501-PIP09-21](#)

Treatment of chronic inducible cold urticaria

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. [EMEA-003027-PIP01-21](#)

Treatment of hyperphenylalaninaemia

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. [Benzylamine derivative of benzofuran - EMEA-002974-PIP01-21](#)

Treatment of paroxysmal nocturnal haemoglobinuria

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

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

UCB Pharma S.A.; Treatment of immune thrombocytopenia

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.6. Censavudine - EMEA-003075-PIP01-21

Treatment of Aicardi-Goutières syndrome

Day 90 discussion

Action: For discussion

Neurology

3.1.7. Invimestrocel - EMEA-002317-PIP02-21

Treatment of acute ischaemic stroke

Day 90 discussion

Action: For discussion

Neurology

3.1.8. 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

Advenchen Laboratories, LLC; Treatment of soft tissue sarcomas / Treatment of Ewing sarcoma

Day 90 discussion

Action: For discussion

Oncology

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

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

Day 90 discussion

Action: For discussion

Other

3.1.10. Pamrevlumab - Orphan - EMEA-002979-PIP01-21

FibroGen, Inc.; Treatment of Duchenne muscular dystrophy

Day 90 discussion

Action: For discussion

Other

3.1.11. [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 90 discussion

Action: For discussion

Vaccines

3.1.12. [Ex vivo expanded autologous human keratinocytes containing epidermal stem cells transduced with a LAMB3-encoding retroviral vector - Orphan - EMEA-003137-PIP01-21](#)

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

Day 60 discussion

Action: For discussion

Dermatology

3.1.13. [Tezepelumab - EMEA-001613-PIP04-21](#)

Treatment of chronic spontaneous urticaria

Day 60 discussion

Action: For discussion

Dermatology

3.1.14. [A nonreplicating, recombinant adeno-associated virus \(AAV\) serotype 9 \(AAV9\) gene transfer vector that contains a modified human ATP7B coding sequence - Orphan - EMEA-003131-PIP01-21](#)

Ultragenyx Germany GmbH; Treatment of Wilson disease

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.15. [Elamipretide - Orphan - EMEA-003128-PIP01-21](#)

Stealth BioTherapeutics Inc.; Treatment of Barth syndrome

Day 60 discussion

Action: For discussion

3.1.16. EMEA-003116-PIP01-21

Treatment of coeliac disease

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

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

Invasive candidiasis

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.18. Nifurtimox - EMEA-003134-PIP01-21

Treatment of Chagas disease

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.19. Ivermectin - EMEA-003136-PIP01-21

Treatment of head lice infestations / Topical treatment of head lice infestations

Day 60 discussion

Action: For discussion

Infectious Diseases / Dermatology

3.1.20. Self-complementary adeno-associated viral vector serotype 9 containing the human CLN3 gene - Orphan - EMEA-003124-PIP01-21

Amicus Therapeutics Europe Limited; Neuronal ceroid lipofuscinosis - CLN3

Day 60 discussion

Action: For discussion

Neurology

3.1.21. EMEA-003129-PIP01-21

Osteosarcoma

Day 60 discussion

Action: For discussion

Oncology

3.1.22. (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 60 discussion

Action: For discussion

Other

3.1.23. Anti TL1a mAb - EMEA-003111-PIP02-21

Treatment of asthma

Day 60 discussion

Action: For discussion

Other

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

Seasonal allergic rhinitis

Day 60 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.25. Zuranolone - EMEA-003119-PIP01-21

Treatment of postpartum depression

Day 60 discussion

Action: For discussion

Psychiatry

3.1.26. *Borrelia* outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine - EMEA-003130-PIP01-21

Prevention of Lyme disease

Day 60 discussion

Action: For discussion

Vaccines

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

Prevention of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Vaccines

3.1.28. Crovalimab - EMEA-002709-PIP02-21

Guillain Barre syndrome

Day 30 discussion

Action: For discussion

3.1.29. Acetylsalicylic acid / ticagrelor - EMEA-003146-PIP01-21

Prevention of atherothrombotic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.30. Asundexian - EMEA-003144-PIP01-21

Prevention of arterial thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.31. Indapamide / telmisartan - EMEA-003151-PIP01-21

Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

OT4B; Treatment of Prader-Willi syndrome

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.34. EMEA-003143-PIP01-21

Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.35. EMEA-002927-PIP02-21

Treatment of polymyalgia rheumatica

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.36. Ianalumab - EMEA-002338-PIP03-21

Treatment of systemic lupus erythematosus (SLE)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.37. Secukinumab - EMEA-000380-PIP09-21

Treatment of lichen planus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.38. Tocilizumab - EMEA-000309-PIP09-21

Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.39. A fully human IgG1 monoclonal antibody targeting an epitope in the receptor-binding domain of the spike glycoprotein of SARS-CoV-2 - EMEA-003118-PIP01-21

Treatment and prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.40. Ensovibep - EMEA-003150-PIP01-21

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.41. Remibrutinib - EMEA-002582-PIP02-21

Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.42. Cevostamab - Orphan - EMEA-003145-PIP01-21

Roche Registration GmbH; Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.43. Human IgG4 monoclonal antibody against BCMA and CD3 - EMEA-003147-PIP01-21

Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.44. EMEA-003110-PIP02-21

Treatment of neurofibromatosis type 1

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Odronextamab - EMEA-003149-PIP01-21

Aggressive mature B cell non-Hodgkin lymphoma (B-NHL)

Day 30 discussion

Action: For discussion

Oncology

3.1.46. Retifanlimab - Orphan - EMEA-002798-PIP02-21

Incyte Biosciences Distribution B.V.; Endometrial carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Sintilimab - EMEA-002919-PIP02-21

Oesophageal cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.48. EMEA-003141-PIP01-21

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Other

3.1.49. [Apitegromab - Orphan - EMEA-002951-PIP02-21](#)

Scholar Rock, Inc.; Spinal muscular atrophy

Day 30 discussion

Action: For discussion

Other / Neurology

3.1.50. [Influenza virus A/turkey/Turkey/1/2005 \(H5N1\) NIBRG-23 strain, HA surface antigen - EMEA-002869-PIP03-21](#)

Influenza due to identified zoonotic or pandemic influenza virus

Day 30 discussion

Action: For discussion

Vaccines

3.1.51. [RSV F protein - EMEA-003094-PIP02-21](#)

Prevention of respiratory tract disease caused by Respiratory syncytial virus

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. [Dupilumab - EMEA-C-001501-PIP01-13-M07](#)

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. [Ligelizumab - EMEA-C2-001811-PIP02-15-M04](#)

Novartis Europharm Limited; Treatment of chronic spontaneous urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.2.3. Albutrepenonacog alfa - EMEA-C-001107-PIP01-10-M04

CSL Behring GmbH; Treatment of hereditary factor IX deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.4. Cobicistate / atazanavir sulphate - EMEA-C2-001465-PIP01-13-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Atogepant - EMEA-C1-002530-PIP01-18

AbbVie Deutschland GmbH & Co. KG; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.2.6. Eribulin - EMEA-C-001261-PIP01-11-M07

Eisai GmbH; Treatment of soft tissue sarcoma

Day 30 discussion

Action: For discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M05

Amicus Therapeutics Europe Limited; Treatment of Fabry disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.2. Saxagliptin - EMEA-000200-PIP01-08-M09

AstraZeneca AB; Treatment of type 2 diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Eluxadoline - EMEA-001579-PIP01-13-M05

Allergan Pharmaceuticals International Limited; Treatment of diarrhoea-predominant irritable bowel syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.4. Ozanimod hydrochloride - EMEA-001710-PIP04-17-M03

Celgene Europe B.V.; Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.5. Bezlotoxumab - EMEA-001645-PIP01-14-M04

Merck Sharp & Dohme (Europe), Inc.; Prevention of recurrence of *Clostridioides difficile* infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.6. Brincidofovir - Orphan - EMEA-001904-PIP02-17-M01

SymBio Pharmaceuticals Limited; Treatment of adenovirus in immunocompromised patients

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Cabotegravir - EMEA-001418-PIP02-15-M03

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Rilpivirine (hydrochloride) - EMEA-000317-PIP01-08-M13

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP01-08-M06

GW Pharma (International) B.V.; Spasticity

Day 30 discussion

Action: For discussion

Neurology

3.3.10. Galcanezumab - EMEA-001860-PIP03-16-M07

Eli Lilly and Company Limited; Prevention of migraine headache

Day 30 discussion

Action: For discussion

Neurology

3.3.11. Leriglitazone - Orphan - EMEA-002106-PIP01-16-M02

Minoryx Therapeutics S.L.; Treatment of adrenoleukodystrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.12. Ofatumumab - EMEA-002397-PIP01-18-M02

Novartis Ireland Limited; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.13. Siponimod (hemifumarate) - EMEA-000716-PIP01-09-M04

Novartis Europharm Ltd; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.14. (4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide - EMEA-002631-PIP01-19-M01

Amgen Europe BV; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.15. Axicabtagene ciloleucel - Orphan - EMEA-002010-PIP01-16-M03

Kite Pharma EU B.V.; Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Bempegaldesleukin - EMEA-002492-PIP01-18-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.3.17. Palbociclib - EMEA-002146-PIP01-17-M04

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Ponatinib - Orphan - EMEA-001186-PIP01-11-M03

Incyte Biosciences Distribution B.V.; Treatment of chronic myeloid leukaemia / Treatment of Philadelphia chromosome positive acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M05

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.20. Fosdenopterin - Orphan - EMEA-001491-PIP01-13-M02

Comharsa Life Sciences Limited; Treatment of molybdenum cofactor deficiency type A

Day 30 discussion

Action: For discussion

Other

3.3.21. Amikacin (sulfate) - Orphan - EMEA-000525-PIP01-08-M08

Insmed Netherlands B.V.; Treatment of nontuberculous mycobacterial (NTM) lung infection

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.22. Benralizumab - EMEA-001214-PIP01-11-M11

AstraZeneca AB; Asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.23. (S)-(2-(5-chloro-4-methyl-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl)(4-methoxy-2-(2H-1,2,3-triazol-2-yl)phenyl)methanone hydrochloride - EMEA-002121-PIP03-19-M01

Idorsia Pharmaceuticals Deutschland GmbH; Treatment of insomnia

Day 30 discussion

Action: For discussion

Psychiatry

3.3.24. Esketamine hydrochloride - EMEA-001428-PIP03-15-M02

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

Day 30 discussion

Action: For discussion

Psychiatry

3.3.25. Lisdexamfetamine dimesylate - EMEA-000553-PIP01-09-M05

Shire Pharmaceuticals Contract Limited; Treatment of attention deficit hyperactivity disorder (ADHD)

Day 30 discussion

Action: For discussion

Psychiatry

3.3.26. Etelcalcetide - EMEA-001554-PIP01-13-M03

Amgen Europe B.V.; Treatment of hyperparathyroidism

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.27. Ferumoxytol - EMEA-000373-PIP02-09-M05

Covis Pharma Europe B.V.; Treatment of iron deficiency anaemia

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.3.28. Recombinant influenza hemagglutinin-strain B (Yamagata lineage) / recombinant influenza hemagglutinin-strain B (Victoria lineage) / recombinant influenza hemagglutinin-strain A (H3N2 subtype) / recombinant influenza hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18-M02

Sanofi Pasteur; Prevention of influenza infection

Day 30 discussion

Action: For discussion

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 31 January 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. Tramadol hydrochloride / magnesium lactate dihydrate- EMEA-12-2021

SciencePharma spółka z ograniczoną odpowiedzialnością spółka jawna; All classes of medicinal products for treatment of primary and secondary osteoarthritis; Management of chronic pain in adults with osteoarthritis of the hip and/or knee.

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

7.1.1. Otilimab - EMEA-001882-PIP02-16-M02

GlaxoSmithKline Trading Services Limited; Treatment of rheumatoid arthritis (RA) in adults

Proposed PIP indication: Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Action: For adoption

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

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. 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

9.7.1. PDCO Work Plan 2022

PDCO Chair: Koenraad Norga

Action: For adoption

9.8. Planning and reporting

No item

10. Any other business

10.1. COVID-19 update

Action: For information

10.2. International Council for Harmonisation – ICH E11A – Paediatric Extrapolation

Action: For information

10.3. Working party implementation update - call for nominations

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. Paediatric oncology

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

11.4. Vaccines

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/