Annexes to the annual report of the European Medicines Agency 2024

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Annex 1 – Members of the Management Board

Chair: Lorraine NOLAN
EMA contact: Hilde BOONE

Members

• European Parliament	Karin KADENBACH, Giovanni LA VIA
• European Commission	Sandra GALLINA, Joanna DRAKE (Alternates: Rainer BECKER, Irene NORSTEDT)
• Belgium	Hughes MALONNE (Alternate: Charles DENONNE)
• Bulgaria	Bogdan KIRILOV (Alternate: Svetlin Sofroniev SPIROV)
• Czechia	Tomáš BORÁŇ[1] (Alternate: Jiří BUREŠ)
• Denmark	Nils Falk BJERREGAARD[2] (Alternate: Mette AABOE HANSEN)
• Germany	Karl BROICH (Alternate: Lars-Christoph NICKEL)
• Estonia	Katrin KIISK (Alternate: Alar IRS)
• Ireland	Lorraine NOLAN (Alternate: Rita PURCELL)
• Greece	Dimitrios FILIPPOU (Alternate: Spyridon SAPOUNAS[3])
• Spain	María Jesús LAMAS DÍAZ (Alternate: Consuelo RUBIO MONTEJANO)
• France	Catherine PAUGAM-BURTZ[4a&4b] (Alternate: Franck FOURES)
• Croatia	Siniša TOMIĆ (Alternate: Danica KRAMARIĆ)
• Italy	Robert NISTICÒ[5] (Alternate: Armando MAGRELLI[6])
• Cyprus	Helena PANAYIOTOPOULOU (Alternate: Irini Chrysafi FANIDOU)
• Latvia	Indra DREIKA (Alternate: Sergejs AKULICČS)
• Lithuania	Dovilė MARCINKĖ [7a&7a] (Alternate: Rugilė PILVINIENĖ[8])
• Luxembourg	Anna CHIOTI (Alternate: Marcin WISNIEWSKI)
• Hungary	Rita Erzsébet PÁLFFYNÉ POÓR (Alternate: Beatrix HORVATH)

[1] Jacub Velik occupied the seat from January to April 2024
[2] Replaces Lars Bo Nielsen from November 2024
[3] Replaces Maria Gazouli in December 2023
[4a] Replaces Christelle Ratignier-Carbonneil from September 2024
[4b] Replaces Alexander de la Volpilière from December 2024
[5] Previously vacant
[6] Replaces Franceso Trotta from September 2024
[7a] Eglė Burbienė replaced Gytis Andrulionis from May 2024
[7b] Replaces Eglė Burbienė from September 2024
[8] Previously vacant.

• Malta	Anthony SERRACINO-INGLOTT (Alternate: John-Joseph BORG)
• Netherlands	Paula LOEKMEIJER (Alternate: Aimad TORQUI)
• Austria	Günter WAXENECKER (Alternate: Jan NEUHAUSER)
• Poland	Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
• Portugal	Rui SANTOS IVO (Alternate: Susana GUEDES POMBO)
• Romania	Răzvan Mihai PRISADA (Alternate: Andrei BACIU)
• Slovenia	Momir RADULOVIĆ (Alternate: Sabine ZALAR[9])
• Slovakia	Roman DORČIK[10] (Alternate: Katarína MASSÁNYIOVÁ)
• Finland	Eija PELKONEN (Alternate: Anna SIIRA)
• Sweden	Joakim BRANDBERG[11] (Alternate: Åsa KUMLIN HOWELL)
• Representatives of patients' organisations	Marco GRECO Virginie HIVERT
• Representative of doctors' organisations	Denis LACOMBE
• Representative of veterinarians' organisations	Christophe Buhot [12a&12b]

Observers

• Iceland	Runa HAUKSDOTTIR (Alternate: Bjarni Sigurðsson[13])
• Liechtenstein	Vlasta ZAVADOVA (Alternate: Martin STRICKER)
• Norway	Trygve OTTERSEN[14] (Alternate: Audun HÅGÅ[15a&15b])

[9] Previously vacant
[10] Replaces Peter Potúček from January 2024
[11] Replaces Björn Eriksson from November 2024
[12a] Despoina Iatridou resigned in early April 2024
[12b] Previously vacant from April 2024
[13] Replaces Sindri Kristjánsson from July 2024
[14] Replaces Audun Hågå from December 2024
[15a] Sayeh Ahrabi replaces Marit Hystad from January 2024
[15b] Replaces Sayeh Ahrabi from December 2024

Annex 2 - Members of the Committee for Medicinal Products for Human Use

Chair: Bruno SEPODES [1]

Members nominated by Member States

• Daniela PHILADELPHY (Austria)	Alternate: Christian GARTNER
• Christophe FOCKE (Belgium)	Alternate: Karin JANSSEN VAN DOORN
• Lyubina Racheva TODOROVA (Bulgaria)	Alternate: Gergana LAZAROVA
• Margareta BEGO (Croatia)	Alternate: Selma ARAPOVIC DZAKULA
• Emilia MAVROKORDATOU (Cyprus) [2]	Alternate: *Katerina Savvidou* [2]
• Tomas RADIMERSKY (Czechia)	Alternate: Petr VRBATA
• Thalia Marie Estrup BLICHER (Denmark)	Alternate: Boje Kvorning Pires EHMSEN [3]
• Alar IRS (Estonia)	Alternate: Edward LAANE
• Outi MAKI-IKOLA (Finland) *(Vice-Chair)* [4]	Alternate: Johanna LAHTEENVUO
• Alexandre MOREAU (France)	Alternate: Jean-Michel RACE
• Janet KOENIG (Germany) [5]	Alternate: Martin MENGEL [6]
• Aris ANGELIS (Greece) [7]	Alternate: Anastasia MOUNTAKI
• Robert PORSZASZ (Hungary)	Alternate: Beata Maria JAKLINE-ULLRICH
• Hrefna GUDMUNDSDOTTIR (Iceland)	Alternate: Hjalti KRISTINSSON
• Jayne CROWE (Ireland)	Alternate: Finbarr LEACY
• Paolo GASPARINI (Italy)	Alternate: Maria Grazia EVANDRI
• Elita POPLAVSKA (Latvia)	Alternate: *Awaiting nomination*
• Vlasta ZAVADOVA (Liechtenstein)	Alternate: *Awaiting nomination*
• Vilma PETRIKAITE (Lithuania)	Alternate: Larisa GOROBETS
• Martine TRAUFFLER (Luxembourg)	Alternate: Alexandra BRANCHU
• John Joseph BORG (Malta)	Alternate: Helen VELLA
• Peter MOL (Netherlands)	Alternate: Patrick VRIJLANDT
• Ingrid WANG (Norway)	Alternate: Eva SKOVLUND
• Ewa BALKOWIEC-ISKRA (Poland)	Alternate: Grzegorz CESSAK

[1] Elected as Chair as of September 2024, replacing Harald ENZMANN
[2] Emilia MAVROKORDATOU replaced Helena PANAYIOTOPOULOU with a swap of roles from alternate to member as of December 2024
[3] Replaced Aaron Emmanuel SOSA MEIJA as of October 2024
[4] Elected as Vice-Chair as of October 2024
[5] Janet KOENIG replaced Martina WEISE with a swap of roles from alternate to member as of August 2024
[6] Nominated as of August 2024
[7] Replaced Konstantina ALEXOPOULOU as of November 2024

• Fatima VENTURA (Portugal) [8] [9]	Alternate: Paulo PAIXAO [10]
• Simona BADOI (Romania)	Alternate: Dana Gabriela MARIN
• Francisek DRAFI (Slovakia)	Alternate: Jana KLIMASOVA
• Kristina NADRAH (Slovenia)	Alternate: Andreja KRANJC
• Carolina PRIETO FERNANDEZ (Spain) [11] [12]	Alternate: Antonio GOMEZ-OUTES [13]
• Kristina DUNDER (Sweden)	Alternate: Filip JOSEPHSON

Co-opted members

- Bruno DELAFONT *(*Biostatistics and clinical trial methodology)
- Blanka HIRSCHLEROVA (Quality (non-biologicals)) [14]
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Carla TORRE (Pharmacoepidemiology, especially for methodological analysis and interpretation of data in particular study designs) [15]
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[8] Bruno SEPODES (Vice-Chair) elected as Chair as of September 2024
[9] Swap of roles from alternate to member as of November 2024
[10] Nominated as of December 2024
[11] Maria Concepcion PRIETO YERRO resigned as of March 2024
[12] Swap of roles from alternate to member as of April 2024
[13] Nominated as of April 2024
[14] Specific area of expertise changed as of February 2024, previously 'Quality (non-biologicals) and Pharmacokinetics'
[15] Specific area of expertise changed as of February 2024, previously 'Pharmaco-Epidemiology'

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Ulla WANDEL LIMINGA [1]

Members nominated by Member States

• Jan NEUHAUSER (Austria)	Alternate: Sonja HRABCIK
• Jean-Michel DOGNE (Belgium)	Alternate: Jo ROBAYS
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: *Awaiting nomination* [2]
• Peter MAS (Croatia) [3] [4]	Alternate: Barbara KOVACIC BYTYQI [5]
• Elena KAISIS (Cyprus)	Alternate: Panagiotis PSARAS
• Eva JIRSOVA (Czechia)	Alternate: Jana LUKACISINOVA
• Marie Louise Schougaard CHRISTIANSEN (Denmark)	Alternate: Karin Susanne LINDENSTROM ERNEHOLM
• Maia UUSKULA (Estonia)	Alternate: Krõõt AAB
• Terhi LEHTINEN (Finland) [6]	Alternate: Kimmo JAAKKOLA
• Tiphaine VAILLANT (France)	Alternate: Zoubida AMIMOUR [7] [8]
• Martin HUBER (Germany)	Alternate: Gabrielle MAURER
• Georgia GKEGKA (Greece) [9]	Alternate: Maria POULIANITI [10]
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun STEFANSDOTTIR (Iceland)	Alternate: Gudrun THENGILSDOTTIR
• Rhea FITZGERALD (Ireland)	Alternate: Eamon O MURCHU
• Amelia CUPELLI (Italy)	Alternate: Emilio CLEMENTI [11] [12]
• Zane NEIKENA (Latvia)	Alternate: Diana LITENBOKA [13]
• Rugile PILVINIENE (Lithuania)	Alternate: Lina SEIBOKIENE
• Nadine PETITPAIN (Luxembourg)	Alternate: Anne-Cecile VUILEMIN
• John Joseph BORG (Malta)	Alternate: Benjamin MICALLEF
• Liana MARTIROSYAN (Netherlands) *(Vice-Chair)* [14]	Alternate: Bianca MULDER

[1] Elected as Chair as of September 2024, replacing Sabine STRAUS
[2] Yuliyan EFTIMOV's mandate ended as of July 2024
[3] Nikica MIROSEVIC SKVRCE resigned as of January 2024
[4] Swap of roles from alternate to member as of February 2024
[5] Nominated as of February 2024
[6] Replaced Kirsti VILLIKKA as of July 2024
[7] Nathalie GAULT resigned as of September 2024
[8] Nominated as of November 2024
[9] Georgia GKEGKA replaced Sofia TRANTZA with a swap of roles from alternate to member as of December 2024
[10] Nominated as of December 2024
[11] Valentina DI GIOVANNI resigned as of January 2024
[12] Nominated as of July 2024
[13] Replaced Zane STADE as of December 2024
[14] Elected as Vice-Chair as of September 2024

• David BENEE OLSEN (Norway)	Alternate: Karen PERILLE HARG
• Adam PRZYBYLKOWSKI (Poland)	Alternate: Katarzyna ZIOLKOWSKA
• Ana Sofia DINIZ MARTINS (Portugal)	Alternate: Carla TORRE
• Roxana DONDERA (Romania)	Alternate: Irina SANDU
• Anna MAREKOVA (Slovakia)	Alternate: Miroslava GOCOVA
• Polona GOLMAJER (Slovenia)	Alternate: Marjetka PLEMENTAS [15]
• Maria del Pilar RAYON (Spain)	Alternate: Monica MARTINEZ REDONDO
• Mari THORN (Sweden) [16] [17]	Alternate: Karin BOLIN [18]

Independent scientific experts nominated by the European Commission

- Annalisa CAPUANO
- Anette Kirstine STARK [19]
- Hedvig NORDENG
- Patricia McGETTIGAN
- Milou Daniel DRICI
- Teresa HERDEIRO

Members representing healthcare professionals nominated by the European Commission

• Roberto FRONTINI	Salvatore MESSANA

Members representing patients' organisations nominated by the European Commission

• Marko KORENJAK	Michal RATAJ

[15] Replaced Milena RADOHA-BERGOC as of March 2024
[16] Ulla WANDEL LIMINGA (Vice-Chair) elected as Chair as of September 2024
[17] Swap of roles from alternate to member as of September 2024
[18] Nominated as of October 2024
[19] Replaced Tania SCHINK as of July 2024

Annex 4 – Members of the Committee for Veterinary Medicinal Products

Chair: G. J. SCHEFFERLIE

Members and alternates

• Petra FALB (Austria)	Alternate: Manuela LEITNER
• Els DEWAELE (Belgium)	Alternate: Frédéric KLEIN
• Krasimir YANKOV ZLATKOV (Bulgaria)	Alternate: Nadya Ognyanova VLADIMIROVA
• Frane BOŽIĆ (Croatia)	Alternate: Hrvoje PAVASOVIC
• Leona NEPEJCHALOVÁ (Czechia)	Alternate: Jiří BUREŠ
• *awaiting nomination* (Cyprus)	Alternate: Alia MICHAELIDOU-PATSIA [1]
• Niels Christian KYVSGAARD (Denmark)	Alternate: Merete BLIXENKRONE-MØLLER
• Toomas TIIRATS (Estonia)	Alternate: *awaiting nomination*
• Minna LEPPÄNEN (Finland)	Alternate: Kristina LEHMANN
• Sylvie LOUET (France)	Alternate: Christine MIRAS
• Andrea GOLOMBIEWSKI (Germany)	Alternate: Esther WERNER
• Spyridon FARLOPOULOS (Greece)	Alternate: Amalia PAPADAKI
• Gabor KULCSÁR (Hungary)	Alternate: Eszter KOLLÁR-NAGY
• Paul McNEILL (Ireland)	Alternate: J. Gabriel BEECHINOR
• Fulvio MARSILIO (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Renāte KUŠĶE
• Snieguolė T. DZEKČIORIENĖ (Lithuania)	Alternate: *awaiting nomination*
• Caroline CONER (Luxembourg) [2]	Alternate: Despoina IATRIDDOU [3]
• Stephen SPITERI (Malta)	Alternate: Elena Maria VELLA
• Jacqueline POOT (Netherlands)	Alternate: Kim BOERKAMP
• Anna WACHNIK-ŚWIĘCICKA (Poland)	Alternate: Ewa AUGUSTYNOWICZ
• João Pedro DUARTE DA SILVA (Portugal)	Alternate: Inês FLOR DIAS
• Gabriela TUCHILA (Romania)	Alternate: Diana Laura BASSULA [4]
• Eva CHOBOTOVÁ (Slovakia)	Alternate: Katarína MASSÁNYIOVÁ
• Katarina ŠTRAUS (Slovenia)	Alternate: Urska PEUNIK [5] [6]

[1] Nominated as of March 2024
[2] Replaced Marc SCHMIT as of September 2024, with a swap of roles from alternate to member
[3] Nominated as of October 2024
[4] Replaced Lollita TABAN as of December 2024
[5] Boris KOLAR retired as of September 2024
[6] Nominated as of October 2024

- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTRÖM (Sweden) *(Vice-Chair)* Alternate: Hanna BREMER

EEA members

- Member: *awaiting nomination* Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) Alternate: Knud TORJESEN

Co-opted members

Co-opted member	**Expertise**
• Keith BAPTISTE[7]	Antimicrobials
• Rory BREATHNACH	General clinical veterinary practice
• Carina BERGMAN	Toxicology and residues
• Mary O'GRADY	Quality pharmaceuticals
• Ricardo CARAPETO GARCÍA[8]	Environmental risk assessment

[7] K. Baptiste re-elected as co-opted member 3 December 2024
[8] R. Carapeto Garcia re-elected as co-opted member 3 December 2024

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Tim LEEST [1]

Members nominated by Member States

- Brigitte BLOECHL-DAUM (Austria)
- *Awaiting nomination* (Belgium) [2]
- *Awaiting nomination* (Bulgaria)
- Dinko VITEZIC (Croatia)
- Ioannis KKOLOS (Cyprus)
- Jana MAZELOVA (Czechia)
- Sine Buhl NAESS-SCHMIDT (Denmark) [3] [4] [5]
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)
- Frauke NAUMANN-WINTER (Germany) (Vice-Chair) [6]
- Evangelia YANNAKI (Greece)
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- *Awaiting nomination* (Ireland) [7] [8]
- Enrico COSTA (Italy)
- Irena ROGOVSKA (Latvia)
- Vlasta ZAVADOVA (Liechtenstein)
- Ruta NAMENISKIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Luana MIFSUD BUHAGIAR (Malta) [9]
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)

[1] Elected as Chair as of September 2024, replacing Violeta STOYANOVA-BENINSKA
[2] Tim LEEST elected Chair as of September 2024
[3] Elisabeth PENNINGA resigned as of April 2024
[4] Boje Kvorning Pires EHMSEN nominated as of May 2024
[5] Replaced Boje Kvorning Pires EHMSEN as of November 2024
[6] Elected as Vice-Chair as of September 2024
[7] Emma FAGAN nominated as of January 2024
[8] Emma FAGAN resigned as of September 2024
[9] Nominated as of August 2024

- Joao ROCHA (Portugal)
- Olimpia NEAGU (Romania)
- Jana SCHWEIGERTOVA (Slovakia) [10] [11]
- *Awaiting nomination* (Slovenia)
- Gloria Maria PALOMO CARRASCO (Spain)
- Darius MATUSEVICIUS (Sweden)

Members nominated by the European Commission on the EMA's recommendation

- Ingeborg BARISIC
- Judit MOLNAR
- Fernando MENDEZ HERMIDA [12]

Members representing patients' organisations nominated by the European Commission

- Mariette DRIESSENS [13]
- Julian ISLA
- Ines ALVES

[10] Eva MALIKOVA resigned as of February 2024
[11] Nominated as of October 2024
[12] Replaced Armando MAGRELLI (Vice-Chair) as of June 2024
[13] Replaced Marie Pauline EVERS as of July 2024

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Emiel VAN GALEN

Members nominated by Member States

• Astrid OBMANN (Austria) [1]	Alternate: Brigitte HAUSER [2]
• Patricia BODART (Belgium)	Alternate: *Awaiting nomination*
• Iliana IONKOVA (Bulgaria)	Alternate: Radina DIMITROVA
• Ivan KOSALEC (Croatia)	Alternate: Darko TRUMBETIC
• Christina Sylvia CHRYSOSTOMOU (Cyprus)	Alternate: Alexandra DEMETRIOU
• Marketa PRIHODOVA (Czechia)	Alternate: Marie HEROUTOVA
• Nanna LUNDGAARD RASMUSSEN (Denmark)[3]	Alternate: Karoline HOLM FIELDING [4]
• *Awaiting nomination* (Estonia)	Alternate: *Awaiting nomination*
• Maria PAILE HYVARINEN (Finland)	Alternate: Sari KOSKI
• An LE (France)	Alternate: Helene LY
• Jacqueline WIESNER (Germany)	Alternate: Susanne FLEMISCH
• Ioanna CHINOU (Greece)	Alternate: Stavroula MAMOUCHA
• Julia PALLOS (Hungary)	Alternate: Rita NEMETH
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Jacqueline MASTERSON (Ireland) [5]	Alternate: *Awaiting nomination*
• Alessandro ASSISI (Italy)	Alternate: Anna Maria SERRILLI
• Inga SILE (Latvia)	Alternate: *Awaiting nomination*
• Gabriele BALCIUNAITE MURZIENE (Lithuania)	Alternate: *Awaiting nomination* [6]
• Sven BACK (Luxembourg)	Alternate: *Awaiting nomination*
• Everaldo ATTARD (Malta)	Alternate: Matthew CAMILLERI
• Burt H. KROES (Netherlands)	Alternate: Hilda KUIN
• Gro FOSSUM (Norway)	Alternate: Marianne Loiten DALHUS
• Wojciech DYMOWSKI (Poland)	Alternate: Ewa ANTKIEWICZ
• Ana Paula MARTINS (Portugal)	Alternate: Eva MENDES
• Carmen PURDEL (Romania)	Alternate: Ligia Elena DUTU

[1] Replaced Reinhard LANGER as of January 2024 with a swap of roles from alternate to member
[2] Nominated as of January 2024
[3] Swap of roles from alternate to member as of January 2024
[4] Nominated as of September 2024
[5] Swap of roles from alternate to member as of January 2024
[6] Asta KUBILIENE's mandate ended as of March 2024

- Dorota DISTLEROVA (Slovakia) [7] Alternate: Jaroslav TOTH
- Barbara RAZINGER (Slovenia) Alternate: *Awaiting nomination*
- Olga Maria PALOMINO (Spain) Alternate: *Awaiting nomination* [8]
- Erika SVEDLUND (Sweden)*(Vice-Chair)* Alternate: Malin Kyllikki HOBRO SODERBERG

Co-opted members

- Maria DA GRACA RIBEIRO CAMPOS (Clinical pharmacology)
- Heidi FOTH (Non-clinical toxicology)
- Maria Helena PINTO FERREIRA (General and family medicine)
- *Awaiting nomination* (Paediatrics)
- Pierre DUEZ (Clinical trials methodology and statistics)

Observers

- Bruno SPIELDENNER (EDQM)
- Melanie BALD (EDQM)

[7] Miroslava HORVATH PETRIKOVA's mandate ended as of January 2024
[8] Olga Teresa ESTEBAN resigned as of September 2024

Annex 7 – Committee for Advanced Therapies

Chair: Ilona G. REISCHL

Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany) Alternate: Egbert FLORY
- Vilma PETRIKAITE (Lithuania) [1] Alternate: Raimondas BENETIS
- John Joseph BORG (Malta) Alternate: Anthony SAMUEL
- *Awaiting nomination* (Portugal) [2] Alternate: Maria Isabel BORBA VIEIRA
- Sol RUIZ (Spain) Alternate: Marcos TIMON

Members nominated by Member States

- Silke DORNER Alternate: Corina SPREITZER
- Claire BEUNEU (Belgium) Alternate: Olga KHOLMANSKIKH
- Rozalina KULAKSAZOVA (Bulgaria) Alternate: Evelina SHUMKOVA
- Azra SELIMOVIC (Croatia) Alternate: Petra SOKOL
- Rafaella PONTOU (Cyprus) Alternate: Isavella KYRIAKIDOU
- Eva KOLOUCHOVÁ (Czechia) [3] Alternate: Radka NEJEZCHLEBOVÁ [4]
- Martin OLEKSIEWICZ (Denmark) [5] Alternate: Johanne Juhl KORSBAEK [6]
- Toivo MAIMETS (Estonia) Alternate: Pille SAALIK
- Heli SUILA (Finland) Alternate: Maija TARKKANEN
- Violaine CLOSSON CARELLA (France) Alternate: Jean-Michel RACE
- Maria GAZOULI (Greece) Alternate: Angeliki ROMPOTI
- Andras DONASZI-IVANOV (Hungary) [7] [8] Alternate: Viola BARDOCZY
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Joseph DE COURCEY (Ireland) [9] Alternate: Richard CARROLL [10]
- Concetta QUINTARELLI (Italy) Alternate: Barbara BONAMASSA
- Una RIEKSTINA (Latvia) Alternate: Liga KUNRADE [11]
- Vlasta ZAVADOVA (Liechtenstein) Alternate: *Awaiting nomination*

[1] Nominated as of January 2024
[2] Bruno SEPODES' mandate ended as of September 2024
[3] Replaced Petr SOUKUP as of January 2025
[4] Replaced Kristyna REHOROVA HRADILKOVA as of May 2024
[5] Replaced Ebru KARAKOC MADSEN as of April 2024
[6] Replaced Bibi Fatima Syed SHAH as of November 2024
[7] Anna Katalin BARANE GILICZE resigned as of May 2024
[8] Nominated as of July 2024
[9] Replaced Maura O'DONOVAN as of January 2024
[10] Nominated as of January 2024
[11] Nominated as of November 2024

- Alessia POCHESCI (Luxembourg) [12] Alternate: Nancy DE BREMAEKER [13]
- Emmely DE VRIES (Netherlands) Alternate: Berendina Maria VAN DEN HOORN
- Rune KJEKEN (Norway) Alternate: Ole Henrik MYRDAL [14]
- Dariusz SLADOWSKI (Poland) Alternate: Marcin KOLAKOWSKI
- Denisa MARGINA (Romania) [15] Alternate: Liviu NITULESCU [16]
- Katarina VAVROVA (Slovakia) Alternate: Margareta FOGELOVA
- Suzana VIDIC (Slovenia) [17] Alternate: Metoda LIPNIK-STANGELJ [18]
- Maria LUTTGEN *(*Sweden) Alternate: Charlotte ANDERBERG

Members representing clinicians nominated by the European Commission

- Paolo GASPARINI Alternate: Bernd GANSBACHER
- Alessandro AIUTI Alternate: Alessandra RENIERI

Members representing patients' organisations nominated by the European Commission

- Kerstin SOLLERBRANT Alternate: Mencia DE LEMUS BELMONTE
- Kieran BREEN *(Vice-Chair)* Alternate: Federica CHIARA

Observers

- *Awaiting nomination* (EDQM) Alternate: Catherine MILNE (EDQM)

[12] Nominated as of January 2024
[13] Replaced Guy BERCHEM as of February 2024, with a swap of roles from member to alternate
[14] Replaced Marit HYSTAD as of April 2024
[15] Replaced Silviu ISTRATE as of February 2024
[16] Replaced Alexandrina PREDA as of February 2024
[17] Suzana VIDIC swapped roles from alternate to member as of July 2024
[18] Metoda LIPNIK-STANGELJ swapped roles from member to alternate as of July 2024

Annex 8 – Members of the Paediatric Committee

Chair: Brian AYLWARD

Members nominated from within the CHMP

- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

Members nominated by Member States

- Johanna WERNSPERGER (Austria) Alternate: Agnes GYURASICS
- Marleen RENARD (Belgium) Alternate: Karen VAN MALDEREN
- Mila BAYCHEVA (Bulgaria) [1] Alternate: Shteryu BOYADZHIEV [2]
- Miroslav WEISS (Croatia) [3] Alternate: Irena SENECIC-CALA [4]
- Zena GUNTHER (Cyprus) Alternate: Maria Eleni AVRAAMIDOU
- Tereza BAZANTOVA (Czechia) Alternate: Pavlina CHLADOVA
- Louisa BRAUN EXNER (Denmark) Alternate: Britta Eilersen HJERRILD [5] [6]
- Jana LASS (Estonia) Alternate: Liisa SAARE
- Pauliina LEHTOLAINEN DALKILIC (Finland) Alternate: *Awaiting nomination*
- Sylvie BENCHETRIT (France) *(Vice-Chair)* Alternate: Florence FLAMEIN [7]
- Sabine SCHERER (Germany) Alternate: Yuansheng SUN
- Eleni KATSOMITI (Greece) Alternate: Anastasia MOUNTAKI
- Adrienn HORVATH (Hungary) Alternate: Robert PORSZASZ
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- *Awaiting nomination* (Ireland) Alternate: *Awaiting nomination*
- Sara GALLUZZO (Italy) Alternate: Cinzia CICERONI
- Dina APELE-FREIMANE (Latvia) Alternate: *Awaiting nomination*
- Vlasta ZAVADOVA (Liechtenstein) Alternate: *Awaiting nomination*
- *Awaiting nomination* (Lithuania) [8] Alternate: Sima NAUJOKIENE [9]
- Carola DE BEAUFORT (Luxembourg) Alternate: Olivier MOES
- John Joseph BORG (Malta) Alternate: Herbert LENICKER
- Maaike VAN DARTEL (Netherlands) [10] Alternate: *Awaiting nomination*

[1] Replaced Dimitar ROUSSINOV as of September 2024
[2] Nominated as of May 2024
[3] Replaced Maja PAVLOVIC as of February 2024
[4] Nominated as of February 2024
[5] Sine Buhl NAESS-SCHMIDT nominated as June 2024
[6] Replaced Sine Buhl NAESS-SCHMIDT as of November 2024
[7] Nominated as of August 2024
[8] Greta BUDUKEVICIUTE rsigned as of September 2024
[9] Nominated as of June 2024
[10] Replaced Roderick HOUWEN as of January 2025, with a swap of role from alternate to member

- Siri WANG (Norway) Alternate: Anette Solli KARLSEN
- Marek MIGDAL (Poland) Alternate: Monika TROJAN [11]
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) Alternate: Peter SZITANYI
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination*
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Sara VENNBERG (Sweden) Alternate: *Awaiting nomination*

Members representing healthcare professionals nominated by the European Commission

- Francesca ROCCHI Alternate: Jose Ignacio MALAGON CALLE
- Fernando CABANAS Alternate: Doina PLESCA
- Johannes TAMINIAU [12] Alternate: Pernille SKOVBY [13]

Members representing patients' organisations nominated by the European Commission

- Tomasz GRYBEK Alternate: Jaroslav STERBA
- Viviana GIANNUZZI Alternate: Patricia FELGUEIRAS SEABRA DURAO
- Victoria ROMERO PAZOS [14] Alternate: *Awaiting nomination*

[11] Nominated as of November 2024
[12] Replaced Daniele DE LUCA as of July 2024, with a swap of role from alternate to member
[13] Nominated as of July 2024
[14] Replaced Eric VERMEULEN as of July 2024, with a swap of role from alternate to member

Annex 9 – Working parties and working groups

List of standing and temporary working parties working with scientific committees.

When the mandate of a working party or experts group expired and no new chair election took place due to the business continuity plan, the records are marked "on hold" in the tables below.

Committee for Medicinal Products for Human Use (CHMP)

CHMP

	Chair
Biologics Working Party	Sean BARRY
Biosimilar Medicinal Products Working Party	René ANOUR
Cardiovascular Working Party	Alar IRS
Central Nervous System Working Party	André ALFERINK
Haematology Working Party	Daniela PHILADELPHY
Healthcare Professional Working Pary	N/A
Infectious Diseases Working Party	Maria Jesús FERNÁNDEZ CORTIZO
Methodology Working Party	Christian ROES
Non-clinical Working Party	Susanne BRENDLER-SCHWAAB
Oncology Working Party	Maria Jesus Fernandez CORTIZO
Scientific Advice Working Party	Paolo FOGGI
Rheumatology/Immunology Working Party	Caroline AURICHE BENICHOU
Vaccines Working Party	Mair POWELL

Other CHMP working parties

	Chair
Active Substance Master File Working Group	Nienke RODENHUIS
Geriatric Expert Group	N/A
Guidelines Consistency Group	Kristina DUNDER
(Invented) Name Review Group	N/A
Summary of Product Characteristics Advisory Group	N/A
Working Group on Quality Review of Documents	N/A

CHMP operational expert groups

	Chair
Nitrosamines Safety Operational Expert Group	N/A
Quality Innovation Group (QIG)	Marcel HOEFNAGEL

	Chair
Scientific Advisory Group on Cardiovascular Issues	N/A
Scientific Advisory Group on Infectious Diseases	N/A
Scientific Advisory Group on Neurology	N/A
Scientific Advisory Group on Vaccines	N/A

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

	Chair
CVMP Antimicrobial Working Party	Damien BOUCHARD
CVMP Efficacy Working Party	Cristina MUÑOZ MADERO
CVMP Environmental Risk Assessment	Ricardo CARAPETO GARCÍA
CVMP European Sales and Use of Antimicrobials for Veterinary Medicine Working Group	Sara SACRISTAN
CVMP Immunologicals Working Party	Esther WERNER
CVMP Novel Therapies and Technologies Working Party	Jaqueline POOT
CVMP Pharmacovigilance Working Party	James MOUNT
CVMP Quality Working Party	Blanka HIRSCHLEROVA
CVMP Safety Working Party	Carina BERGMAN
CVMP Scientific Advice Working Party	Frida HASSLUNG WIKSTRÖM

Other CVMP-associated groups

	Chair
Antimicrobial Advice Ad Hoc Expert Group	

Pharmacovigilance Risk Assessment Committee (PRAC)

	Chair
PRAC Interest group (IG) Impact	Liana MARTIROSYAN/EMA representative
Granularity and Periodicity Advisory Group (GPAG)	Jana LUKACISINOVA/EMA representative
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Martin HUBER/EMA representative
Signal Management Review Technical (SMART) Working Group work stream 2 (methods)	Eugene van PUIJENBROEK/EMA representative

Committee on Herbal Medicinal Products (HMPC)

HMPC temporary drafting groups

	Chair
Quality Drafting Group	Carmen PURDEL

Committee for Advanced Therapies (CAT)

CAT associated group

	Chair
European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group	On hold

Paediatric Committee(PDCO)

PDCO working groups

	Chair
Formulation Working Group	Brian AYLWARD (ad interim)

Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)

Other CMDh-associated groups

	Chair
ASMF Working Group	Nienke RODENHUIS
CMDh/CMDv CTS Working Group	Dino SOUMPASIS
Drafting Group on harmonisation of authorisation of allergens	Andreas BONERTZ
Multilingual Packaging Working Group	Nicole KAVANAGH
Non-Prescription Medicinal Products Task Force	Martin HUBER
Working Party on Pharmacovigilance Procedures Work Sharing	Maria Luisa CASINI
GCP Inspectors Working Group/CMDh Working Party	Jayne CROWE
CMDh/CMDv Working Party on Variation Regulation	Susanne WINTERSCHEID
CMDh/EMA Working Party on Paediatric Regulation	Siri WANG

Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv)

	Chair
Document Management Working Group	CMDv member from Member State holding EU Presidency
Borderline Products Working Group	Michelle WEGRAD ~~Jose JONIS~~
Legislation Working Group	Laetitia LE LETTY
Clinical Trials Working Group	Laetitia LE LETTY
SPC Harmonisation Working Group	Laetitia LE LETTY
CMDh/CMDv ASMF Working Group	Nienke RODENHUIS
CMDh/CMDv Working Party on Variation Regulation	Susanne WINTERSCHEID
CMDh/CMDv CTS Working Group	Dino SOUMPASIS

Joint working parties, working groups and advisory groups

	Chair
3Rs Working Party	Sonja BEKEN
Active Substance master File Working Group	N/A
Batch release testing OEG	N/A
Emergency Taskforce	Bruno SEPODES, Marco CAVALERI (EMA)
EU Innovation Network	Laurence O'DWYER, Falk EHMANN (EMA)
EudraVigilance Expert Working Group	Anja van HAREN, Rodrigo POSTIGO (EMA)
Healthcare Professionals' Working Party (HCPWP)	EMA rappresentative and Rosa GIULIANI
Inter-Committee Scientific Advisory Group on Oncology	Lothar BERGMANN
Medicine Shortages Single Point of Contact (SPOC) Working Party	N/A
Medical Device Shortages Single Point of Contact (SPOC) Working Party	Monica DIAS
Patients' and Consumers' Working Party (PCWP)	EMA representative and Marko KORENJAK
Quality Working Party	Blanka HIRSCHLEROVA
Signal Management Review Technical (SMART) Working Group	
Working Group on Quality Review of Documents	EMA representative

Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2024

This annex is available in an Excel spread sheet here.

Annex 11 – Guidelines and concept papers adopted by CHMP

3Rs Working Party

Reference number	Document	Status	Date
None			

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/548524/2008 Rev.1	Concept Paper on the Revision of the Guideline on Epidemiological Data on Blood Transmissible Infections	Concept paper on the revision adopted by CHMP for 2 months public consultation	April 2024
EMA/CHMP/BWP/303353/2010 Rev 3	CHMP Position Statement on Creutzfeldt-Jakob disease and plasma derived and urine-derived medicinal products	Revised position statement adopted by CHMP for publication	May 2024

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMA/CHMP/BMWP/35061/2024	Concept paper for the development of a Reflection Paper on a tailored clinical approach in Biosimilar development	Public consultation concluded	30 Apr 24

Cardiovascular Working Party

Reference number	Document	Status	Date
EMA/CHMP/464798/2024 Rev. 2 (previously EMA/CHMP/464798/2024 Rev. 1)	Draft Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities	Adopted by CHMP for release for public consultation	31 October 2024
EMA/CHMP/322756/2024	Concept paper on the need for a Reflection Paper on assessment of cardiovascular safety of oncology medicinal products	Adopted by CHMP for release for public consultation	1 August 2024
EMA/501950/2024 (CHMP/EWP/517497/2007/Rev 1)	Concept paper on the need for revision of the addendum on weight control in children to the guideline on clinical evaluation of medicinal products used in weight control	Adopted by CHMP for release for public consultation	14 November 2024

Haematology Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/144552 /2009 Rev. 2	Clinical investigation of recombinant and human plasma-derived factor IX products - Scientific guideline	Final	28 June 2024
EMA/CHMP/BPWP/277622 /2024 rev. 3	Core summary of product characteristics for human plasma-derived and recombinant coagulation factor IX products	Final	28 June 2024
EMA/CHMP/BPWP/518080 /2024	Guideline on the clinical requirements for non-replacement therapy in haemophilia A and B	Final	4 December 2024

Methodology Working Party

Reference number	Document	Status	Date
EMA/65012/2024	Concept Paper for the Development of a Guideline on Non-Inferiority and Equivalence Comparisons in Clinical Trials	Draft	16 February 2024
EMA/CHMP/150527/2024	Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence	Draft	3 May 2024
EMA/449486/2023	Implementation strategy of ICH Guideline M10 on bioanalytical method validation	Final	25 April 2024
MA/CHMP/CVMP/83833/2 023	Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle	Final	30 September 2024
EMA/CHMP/430688/2024	Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation application	Final	16 September 2024
EMA/503781/2024	Data Quality Framework for EU medicines regulation: 5 application to Real-World Data	Draft	29 November 2024
EMA/460496/2024	Implementation strategy of ICH Guideline M12 on drug interaction studies		2 December 2024
Product-specific Bioequivalence Guidelines			
EMA/497207/2024	Q&A on the need for bioequivalence studies with acid reducing agents		4 November 2024
EMA/CHMP/41624/2023	*Trametinib film-coated tablets 0.5 and 2mg product-*	*Draft*	*11 March 2024*

Reference number	Document	Status	Date
	specific bioequivalence guidance		
EMA/CHMP/172895/2023	Azacitidine powder for suspension for injection 25 mg/ml product-specific bioequivalence guidance	Draft	15 January 2024
EMA/41624/2023 EMA/339228/2024	Trametinib film-coated tablet 0.5 and 2mg product-specific bioequivalence guidance and Overview of comments	Final	19 December 2024
EMA/39771/2023	Dabrafenib hard capsule 50 and 75 mg product-specific bioequivalence guidance	Draft	11 March 2024
EMA/CHMP/518671/2023	Nilotinib hard capsules 50, 150 and 200 mg product-specific bioequivalence guidance	Draft	25 June 2024
EMA/94136/2024	*Methylphenidate prolonged-release tablet 18 mg, 27 mg, 36 mg and 54 mg and modified release capsule 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg product-specific bioequivalence guidance*	*Draft*	*25 June 2024*
EMA/94136/2024 EMA/479935/2024	Methylphenidate prolonged-release tablet 18 mg, 27 mg, 36 mg and 54 mg and modified release capsule 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg product-specific bioequivalence guidance and Overview of comments	Final	4 November 2024
EMA/219288/2024 EMA/219378/2024 EMA/219393/2024	Budesonide gastro-resistant hard capsules 3 mg and gastro-resistant granules 9 mg; prolonged release tablets, 9 mg; and gastro-resistant hard capsules 3 mg	Draft	25 June 2024
EMA/CHMP/254395/2024	Tolvaptan tablets 7.5, 15 and 30 mg and tolvaptan tablets 15, 30, 45, 60 and 90 mg product-specific bioequivalence guidance	Draft	26 July 2024

Reference number	Document	Status	Date
EMA/CHMP/890768/2024	*Paliperidone palmitate depot suspension for injection (every 3 months) 175, 263, 350 and 525 mg product-specific bioequivalence guidance*	*Draft*	*15 January 2024*
EMA/CHMP/890768/2024	Paliperidone palmitate depot suspension for injection (every 3 months) 175, 263, 350 and 525 mg product-specific bioequivalence guidance	Final	26 July 2024

Non-clinical Working Party

Reference number	Document	Status	Date
EMEA/CHMP/SWP/4447/00 Rev. 1- Corr.*	Guideline on the environmental risk assessment of medicinal products for human use	Final	Adopted at CHMP on the 15 February 2024

Oncology Working Party

Reference number	Document	Status	Date
EMA/CHMP/205/95 Rev.6	Guideline on the clinical evaluation of anticancer medicinal products - Revision 6	Final	23 January 2024

Quality Innovation Group*

Reference number	Document	Status	Date
EMEA/90634/2024	Preliminary QIG Considerations regarding Pharmaceutical Process Models	Published	29/02/2024

*The quality innovation group (QIG) is an operational expert group within the quality domain and reports to the quality domain governance.

Quality Working Party

Reference number	Document	Status	Date
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-2	Q&A on Note for Guidance on Maximum shelf-life for sterile products for human use after first opening or following reconstitution	Published	January 2024

Reference number	Document	Status	Date
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-2	Q&A on assessment of quality of finished products containing known active substances	Published	January 2024
EMA/CHMP/CVMP/QWP/5/2024	Q&A on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV)	Published	13/02/2024
EMA/CHMP/20607/2024	Draft revised Guideline on the pharmaceutical quality of inhalation and nasal products	Published for consultation	12/04/2024
EMA/CHMP/CVMP/QWP/17760/2009 Rev 3	Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev. 3: Defining the Scope of an NIRS Procedure	Published	02/05/2024
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1	Revision of the Quality of Medicines Q&A: Part 1 – Impurities Calculation of Thresholds for Impurities	Published	June 2024
EMA/CHMP/CVMP/QWP/262313/202424	Draft guideline on development and manufacture of oligonucleotides	Published for consultation	22/07/2024
EMA/CHMP/CVMP/QWP/422493/2024	Q&A regarding co-processed excipients used in solid oral dosage forms (H&V)	Published for consultation	11/09/2024
EMA/321776/2024	Draft revised guideline on the chemistry of active substances (H)	Published for consultation	25/07/2024
EMA/CHMP/QWP/708282/2018	Guideline on quality and equivalence of locally applied, locally acting cutaneous products	Published	01/10/2024

Reference number	Document	Status	Date
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1	Q&A on Adjustment to chromatographic separations test procedures as per Ph. Eur. general chapter 2.2.46	Published	October 2024
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1	Q&A on "Granules in Capsules for Opening"	Published	November 2024

Rheumatology/Immunology Working Party

Reference number	Document	Status	Date
EMA/CHMP/111529/2024	Reflection paper on regulatory requirements for the development of medicinal products for non-alcoholic steatohepatitis (NASH)	Final, published	04/04/2024
EMA/CHMP/72790/2024	Draft Guideline on allergen products development for 4 immunotherapy and allergy diagnosis in moderate to low-5 sized study populations	Draft for public consultation	15/02/2024
EMA/CHMP/101453/2024	Draft guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)	Draft for public consultation	12/04/2024
EMA/CHMP/315603/2024	Concept paper for the development of a guideline on the demonstration of therapeutic equivalence for nasal products	Concept paper for public consultation	25/07/2024

Vaccines Working Party

Reference number	Document	Status	Date
EMA/52912/2025	Addendum to the Guideline on clinical development of vaccines to address clinical trials in immunocompromised individuals	Published	February 2025
EMA/CHMP/453561/2023	Concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline	Public consultation closed	30 January 2024
EMA/453562/2023	Concept paper on the development of an addendum to the Guideline on clinical development of vaccines on clinical trials for vaccines for immunocompromised individuals	Public consultation closed	31 January 2024

Annex 12 – CVMP opinions in 2024 on medicinal products for veterinary use

Positive opinions

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
• Lexylan • Cefalexin	• Emdoka	• Cat, Cattle, Dog • Treatment of diseases caused by cefalexin susceptible micro-organisms at well accessible infection sites, within the limits of effective cefalexin concentrations.	• 21.09.2022 • 14.02.2024 • 208 • 303	• 08.04.2024 • 10.04.2024 • C 3355
• DIVENCE PENTA • Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine	• Laboratorios Hipra, S.A.	• Cattle • Immunisation of cattle	• 21.12.2022 • 14.02.2024 • 209 • 211	• 09.04.2024 • 10.04.2024 • C 3355
• Alcort • Hydrocortisone aceponate	• Nextmune Italy S.r.l.	• Dog • For symptomatic treatment of inflammatory and pruritic dermatoses in dogs. For alleviation of clinical signs associated with atopic dermatitis in dogs.	• 19.10.2022 • 14.02.2024 • 208 • 275	• 08.04.2024 • 10.04.2024 • C 3355

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
• Trilorale • Trilostane	• AXIENCE	• Dog • For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.	• 23.11.2022 • 13.03.2024 • 208 • 268	• 06.05.2024 • 07.05.2024 • C 3877
• Trilocur • Trilostane	• Emdoka	• Dog • For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.	• 23.11.2022 • 13.03.2024 • 208 • 268	• 06.05.2024 • 07.05.2024 • C 3877
• Nobilis Multriva RT+IBm+ND+Gm+REOm+ EDS • Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated)	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for: - reduction of egg drop caused by avian metapneumovirus (AMPV) - reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype) - reduction of mortality and clinical signs caused by Newcastle disease virus (NDV) - passive immunisation of the progeny of the vaccinated chickens to: reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal	• 23.11.2022 • 13.03.2024 • 208 • 268	• 06.05.2024 • 08.05.2024 • C 3877

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Decision • Notification • Official Journal
		disease virus (IBDV) reduce viraemia and clinical signs of disease caused by avian reovirus genotypes 1 and 4) - reduction of egg drop and eggshell defects caused by egg drop syndrome-1976 virus (EDSV)		
• Lotimax • Lotilaner	• Elanco GmbH	• Dog • For the treatment of flea and tick infestations and demodicosis (caused by Demodex canis) in dogs	• 15.01.2024 • 13.03.2024 • 58 • N/a	• 25.04.2024 • 29.04.2024 • C 3355
• DIVENCE Tetra • Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine	• Laboratorios Hipra, S.A.	• Cattle • Immunisation of cattle	• 15.02.2023 • 13.03.2024 • 208 • 184	• 10.05.2024 • 13.05.2024 • C 3877
• RESPIVAC aMPV • Turkey rhinotracheitis virus, live	• Laboratorios Hipra, S.A.	• Chicken • Active immunisation of chickens to reduce the detrimental effect caused by virulent avian metapneumovirus on the ciliary activity, which may be manifested in respiratory clinical signs	• 16.02.2023 • 18.04.2024 • 209 • 219	• 30.05.2024 • 03.06.2024 • C 3877

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
• Innovax-ND-H5 • Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant)	• Intervet International B.V.	• Chicken, Chicken (embryonated eggs) • For active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic Avian Influenza (HPAI) virus of the H5 type.	• 19.01.2024 • 18.04.2024 • 90 • N/a	• 22.05.2024 • 23.05.2024 • C3877
• Nobilis Multriva RT+IBm+ND+Gm+REOm • Avian Metapneumovirus, Infectious Bronchitis virus, Newcastle Disease virus and Egg Drop Syndrome virus vaccine, inactivated.	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for: - reduction of egg drop caused by avian metapneumovirus (AMPV) - reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype), 4/91-793B (GI-13 genotype) - reduction of mortality and clinical signs caused by Newcastle Disease virus (NDV) - passive immunisation of the progeny of the vaccinated chickens to - reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) variants of infectious bursal disease virus (IBDV) - reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) (genotypes 1 and 4).	• 15.02.2023 • 22.05.2024 • 208 • 254	• 05.07.2024 • 08.07.2024 • C 5166

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
• Nobilis Multriva RT+IBm+ND+EDS • Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease and avian reovirus vaccine (inactivated)	• Intervet International B.V.	• For the active immunisation of chickens for: - reduction of egg drop caused by avian metapneumovirus - reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype) - reduction of mortality and clinical signs caused by Newcastle disease virus - reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus. Onset of immunity: - IBV, NDV and EDSV: 4 weeks post-vaccination - AMPV: 5 weeks post-vaccination Duration of immunity: -AMPV, IBV, NDV and EDSV: 80 weeks of age Cross-protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype	• 15.02.2023 • 22.05.2024 • 208 • 254	• 17.07.2024 • 18.07.2024 • C 5166
• DIVENCE IBR Marker Live • Infectious bovine rhinotracheitis vaccine (live recombinant)	• Laboratorios Hipra, S.A.	• Cattle • Active immunisation of cattle from 10 weeks of age to reduce virus shedding,	• 10.05.2023 • 19.06.2024 • 209 • 197	• 09.08.2024 • 20.08.2024 • C 5667

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Decision • Notification • Official Journal
		hyperthermia and clinical signs caused by BoHV-1.		
• Porcilis PCV M Hyo ID • Porcine circovirus (inactivated, recombinant) and porcine enzootic pneumonia vaccine (inactivated)	• Intervet International B.V.	• Pig • For the active immunisation of pigs to reduce viremia, virus load in lungs and lymphoid tissues, and virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by Mycoplasma hyopneumoniae infection. To reduce the loss of daily weight gain and mortality during the finishing period in face of infections with PCV2 and/or M. hyopneumoniae.	• 12.07.2023 • 18.07.2024 • 209 • 163	• 30.08.2024 • 02.09.2024 • C 5667
• Cevac Salmune ETI K • Salmonella Enteritidis, Salmonella Typhimurium and Salmonella Infantis vaccine (inactivated) for chickens	• CEVA-Phylaxia Zrt.	• Chicken • For the active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of Salmonella Enteritidis, Salmonella Typhimurium and Salmonella Infantis.	• 21.12.2022 • 18.07.2024 • 210 • 365	• 30.08.2024 • 02.09.2024 • C 5667
• Cepeloron • Spironolactone	• Cp-Pharma Handelsgesellschaft mbH	• Dog • Treatment of congestive heart failure caused by degenerative mitral valve disease, in combination with standard	• 07.06.2023 • 18.07.2024 • 209 • 198	• 12.09.2024 • 13.09.2024 • C 6277

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
		therapy (including diuretic support, where necessary) in dogs.		
• Cirbloc M Hyo • Porcine circovirus and porcine enzootic pneumonia vaccine (inactivated)	• CEVA-Phylaxia Zrt.	• Pig • Active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and bacterial load and severity of lung lesions caused by Mycoplasma hyopneumoniae infection, and under field conditions, to reduce the loss in body weight gain.	• 13.07.2023 • 12.09.2024 • 210 • 218	• 24.10.2024 • 25.10.2024 • C 6971
• ArthriCox • Firocoxib	• Chanelle Pharmaceuticals Manufacturing Ltd	• Dog • Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which displays analgesic, anti-inflammatory and antipyretic properties.	• 16.03.2022 • 12.09.2024 • 210 • 701	• 24.10.2024 • 29.10.2024 • C 6971
• VAXXON ND CLONE • Newcastle disease vaccine live	• Vaxxinova International B.V.	• Chicken • For the active immunisation of chickens (broilers, future layers and breeders) from one day of age to reduce mortality and clinical signs of disease caused by infection with Newcastle disease virus.	• 20.09.2023 • 10.10.2024 • 209 • 177	• 22.11.2024 • 27.11.2024 • C 7468

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Decision** • **Notification** • **Official Journal**
• DuOtic • Betamethasone acetate / Terbinafine	• Dechra Regulatory B.V.	• Dog • For the treatment of otitis externa associated with Malassezia pachydermatis.	• 17.10.2023 • 10.10.2024 • 209 • 149	• 22.11.2024 • 25.11.2024 • C 7468
• BRAVECTO TriUNO • Fluralaner / Moxidectin / Pyrantel	• Intervet International B.V.	• Dog • For dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the same time. The veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease and angiostrongylosis.	• 20.09.2023 • 10.10.2024 • 209 • 177	• 22.11.2024 • 28.11.2024 • C 7468
• CARPROFEN ORION • Carprofen	• Orion Corporation	• Dog, Cat • Dog: Perioperative alleviation of pain and inflammation especially in orthopaedic and soft tissue (including ocular) operations. Cat: Perioperative alleviation of pain.	• 15.03.2023 • 07.11.2024 • 209 • 394	• 19.12.2024 • 20.12.2024 • C 476
• TOLFENAMIC ACID VMD • Tolfenamic acid	• VMD N.V.	• Dog, Cat, cattle, Pig • Cattle: pneumonia and mastitis Pig: Metritis Mastitis Agalactia syndrome Dog: inflamation and post-surgical pain Cat: Febrile syndromes	• 11.05.2023 • 05.12.2024 • 210 • 365	• 03.02.2025 • Pending • Pending

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Decision • Notification • Official Journal
• Poulvac Procerta HVT-IBD-ND • Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	• Zoetis Belgium	• Chicken, Chicken (embryonated eggs) • For active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to: - reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus - reduce mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus and - reduce mortality and clinical signs caused by Newcastle disease (ND) virus.	• 18.10.2023 • 05.12.2024 • 209 • 205	• 23.01.2025 • Pending • Pending
• Icthiovac ERM • Inactivated vaccine against yersiniosis in Atlantic salmon	• Laboratorios Hipra, S.A.	• Atlantic salmon • Active immunisation of Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of Yersinia ruckeri in freshwater.	• 20.09.2023 • 05.12.2024 • 209 • 233	• 23.01.2025 • Pending • Pending

Negative opinions

There were no negative opinions in 2024.

CVMP opinions in 2024 on establishment of MRLs

Positive opinions

Product • **Substance**	**Target species**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Regulation** • **Official Journal**
• Ketoprofen	• All ruminants • Bovine • Equidae • Porcine	• 21.12.2023 • 07.11.2024 • 180 • 143	• Pending • Pending • Pending

Negative opinions

There were no negative opinions on establishment of MRLs in 2024.

CVMP opinions on extensions of indication for medicinal products for veterinary use

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• YURVAC RHD • Rabbit haemorrhagic disease and RHDV2 vaccine (recombinant)	• Laboratorios Hipra S.A.	• QI08AV • For active immunisation of rabbits from 30 days of age onwards to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains.	• 12.09.2024	• 31.10.2024

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Simparica Trio • Sarolaner / Moxidectin / Pyrantel embonate	• Zoetis Belgium	• QP54AB52 • For dogs with, or at risk from, mixed external and internal parasitic infestations and treatment of sarcoptic mange, demodicosis, and for prevention of establishment of thelaziosis.	• 07.11.2024	• 19.12.2024
• Stronghold Plus • Sarolaner, Selamectin	• Zoetis Belgium	• QP54AA55 • For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.	• 19.06.2024	• 05.08.2024

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Metacam • Meloxicam	• Boehringer Ingelheim Vetmedica	• QM01AC06 • Cats: Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery. Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats. Guinea pigs: Alleviation of mild to moderate post-operative pain associated with soft tissues surgery such as male castration Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Horses: Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders; For the relief of pain associated with equine colic. Pigs: For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy. Cattle: For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle; For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle. For the relief of post-operative pain following dehorning in calves.	• 17.01.2024	• 29.02.2024

Annex 13 – Guidelines and concept papers adopted by CVMP in 2024

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/592906/2022	Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water - Annex on compatibility studies between veterinary medicinal products and biocidal products.	Adopted February 2024
EMA/CVMP/QWP/515653/2023	Draft guideline on stability testing for applications for variations to a marketing authorisation for veterinary medicinal products	Adopted April 2024 End of consultation 31 August 2024
EMA/CHMP/CVMP/QWP/17760/2009 Rev 3	Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev 3: Defining the Scope of an NIRS Procedure	Adopted April 2024
EMA/CHMP/CVMP/QWP/262313/2024	Draft guideline on the development and manufacture of oligonucleotides	Adopted July 2024 End of consultation 31 January 2025
EMA/CVMP/426245/2023	Draft guideline on risk management requirements for elemental impurities in veterinary medicinal products	Adopted September 2024 End of consultation 31 January 2025
EMA/CVMP/QWP/47285/2022	Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets	Adopted October 2024
EMA/CVMP/QWP/515653/2023	Guideline on stability testing for applications for variations to a marketing authorisation for veterinary medicinal products	Adopted November 2024

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/591282/2021	Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances	Adopted January 2024

Reference number	Document title	Status
EMA/CVMP/SWP/564774/2023	Draft concept paper on the revision of the guideline on user safety for pharmaceutical veterinary medicinal products	Adopted July 2024 End of consultation 31 October 2024
EMA/250170/2024	Questions and answers on standard animal weights for estimating worst-case consumer exposure scenarios	Adopted July 2024
EMA/CVMP/SWP/32027/2022	Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted October 2024

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/37280/2023	Draft Guideline on data requirements for veterinary medicinal products for zootechnical purposes	Adopted January 2024 End of consultation 31 May 2024
EMA/CVMP/627/2001-Rev.2	Draft guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted June 2024 End of consultation 31 October 2024
EMA/CVMP/344/1999-Rev.3	Draft guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted June 2024 End of consultation 31 October 2024
EMA/CVMP/EWP/259765/2024	Draft concept paper on the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats	Adopted July 2024 End of consultation 31 October 2024
EMA/CVMP/EWP/247519/2024	Draft Concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees	Adopted July 2024 End of consultation 31 October 2024
EMA/CVMP/256158/2024	Draft concept paper for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted July 2024 End of consultation 31 October 2024

Reference number	Document title	Status
EMA/CVMP/EWP/755916/2016	Draft guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances	Adopted September 2024 End of consultation 28 February 2025
EMA/CVMP/EWP/231668/2022	Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted October 2024

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009-Rev.15	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted July 2024
EMA/CVMP/PhVWP/228098/2024	List of changes to combined VeDDRA list of clinical terms	Adopted July 2024
EMA/CVMP/PhVWP/288284/2007-Rev.16	Revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted July 2024

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/365817/2022	Guideline on plasmid DNA vaccines for veterinary use	Adopted January 2024
EMA/CVMP/IWP/390313/2023	Draft guideline on live recombinant vector vaccines for veterinary use	Adopted January 2024 End of consultation 31 May 2024
EMA/CVMP/IWP/224724/2022	Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted October 2024

Reference number	Document title	Status
EMA/CVMP/IWP/228730/2022	Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets	Adopted October 2024
EMA/CVMP/IWP/390313/2023	Draft guideline on live recombinant vector vaccines for veterinary use	Adopted December 2024
EMA/CVMP/IWP/189026/2024	Draft concept paper for the development of a guideline on quality aspects of mRNA vaccines for veterinary use	Adopted December 2024 End of consultation 8 April 2025
EMA/CVMP/IWP/188413/2024	Draft concept paper for the revision of the Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)	Adopted December 2024 End of consultation 18 March 2025

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/430327/2009 Rev.1 [1]	Guideline on determining the fate of veterinary medicinal products in manure	Adopted July 2024
EMA/CVMP/ERA/349254/2014 Rev.1	Reflection paper on poorly extractable and/or non-radiolabelled substances	Adopted July 2024
EMA/CVMP/ERA/103555/2015 [1]	Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater	Adopted December 2024

CVMP Novel therapies and technologies

Reference number	Document title	Status
EMA/CVMP/NTWP/143787/2023	Concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations	Adopted April 2024 End of consultation 31 July 2024

[1] The amendments made are editorial, to align the content of the documents with newly published/updated guidance and to increase the clarity of text. No changes to the scientific content of the document have been made.

Replacement, Reduction, Refinement of animal testing (3Rs)

Reference number	Document title	Status

CVMP European Sales and Use of Antimicrobials for Veterinary Medicine Working Group

Reference number	Document title	Status
EMA/CVMP/ESUAVET/570091/2023	Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019-6 and its delegated and implementing regulations	Adopted April 2024

Regulation (EU) 2019/6 (Veterinary medicinal products)

[Topics covered by regular WPs are shown in the relevant thematic sections above]

Reference number	Document title	Status
EMA/CVMP/159047/2023	Scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the list of substances essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months	Adopted July 2024
EMA/CVMP/248499/2007 – Rev.1	Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted in November 2024

General

Reference number	Document title	Status
EMA/CVMP/841162/2022	VICH GL61 Pharmaceutical Development	Adopted March 2024 End of consultation 15 August 2024
EMA/CVMP/93401/2024	Questions and answers on classification of veterinary medicinal products	Adopted June 2024

Annex 14 – COMP opinions in 2024 on designation of orphan medicinal products

Positive COMP designation opinions

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated virus serotype 5 containing the human *RORA* gene	Ocugen Limited	Treatment of inherited retinal dystrophies due to dysfunction in the *ABCA4* gene	19/08/2024 13/09/2024 07/11/2024 (55 days/30 days)	19/11/2024 19/12/2024
Elebsiran	FGK Representative Service GmbH	Treatment of hepatitis delta virus infection	12/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
mRNA encoding Cas9-deaminase, single guide RNA against the human *TGM1* gene	Charite Universitaetsmedizin Berlin KöR	Treatment of autosomal recessive congenital ichthyosis	11/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Votoplam	PTC Therapeutics International Limited	Huntington's disease	30/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Felzartamab	Human Immunology Biosciences Ireland Limited	in solid organ transplantation	23/10/2024 15/08/2024 07/11/2024 (84 days/24 days)	19/11/2024 13/12/2024
Vosoritide	Biomarin International Limited	Treatment of hypochondroplasia	28/08/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Roginolisib	Transcrip Ireland Limited	Treatment of uveal melanoma	01/08/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19	PharmaLex GmbH	Treatment of myasthenia gravis	02/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Davunetide	AdRes EU B.V.	Treatment of activity-dependent neuroprotective protein (ADNP) syndrome	31/10/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Arsenic trioxide	Pharma IT ApS	Treatment of acute promyelocytic leukaemia	12/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Divesiran	Silence Therapeutics GmbH	Treatment of polycythemia vera	11/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
4-(4-(2-(Diethylamino)ethoxy)phenyl)-1-(4-methoxybenzyl)-1H-1,2,3-triazol-5-amine	Opis S.r.l.	Treatment of neurofibromatosis type 2	11/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Diazoxide choline	Soleno Therapeutics Europe Limited	Treatment of glycogen storage disease type I	29/08/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Allogeneic cardiosphere-derived cells	Adoh B.V.	Treatment of Duchenne muscular dystrophy	06/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Monepantel	Regenold GmbH	Treatment of Amyotrophic lateral sclerosis	30/08/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
2'-O-4'-C-(S)-Ethyl-P-thioadenylyl-(3'-O->5'-O)-2'-O-4'-C-(S)-ethyl-P-thioguanylyl-(3'-O->5'-O)-2'-O-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-fluoro-P-thioadenylyl-(3'-O->5'-O)-2'-fluoro-P-thiocytidylyl-(3'-O->5'-O)-2'-fluoro-P-thiouridylyl-(3'-O->5'-O)-2'-O-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-4'-C-(S)-ethyl-P-thiouridylyl-(3'-	Regintel Limited	Treatment of autosomal dominant polycystic kidney disease	21/10/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
O->5'-O)-2'-O-4'-C-(S)-ethyl-adenosine				
Mitapivat sulfate	Agios Netherlands B.V.	Treatment of sickle cell disease	31/10/2024 15/08/2024 07/11/2024 (84 days/24 days)	19/11/2024 13/12/2024
Tobevibart	FGK Representative Service GmbH	Treatment of hepatitis delta virus infection	12/09/2024 13/09/2024 07/11/2024 (55 days/24 days)	19/11/2024 13/12/2024
Colistimethate sodium	PureIMS B.V.	Treatment of cystic fibrosis	30/10/2024 15/08/2024 18/11/2024 (95 days/24 days)[1]	19/11/2024 13/12/2024
Coramitug	Novo Nordisk A/S	Treatment of ATTR amyloidosis	03/10/2024 15/07/2024 10/10/2024 (87 days/24 days)	18/10/2024 11/11/2024
Mesenchymal stem cells-derived small extracellular vesicles loaded with siRNA against phosphatase and tensin homolog	Scendea (NL) B.V.	Treatment of spinal cord injury	25/07/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024
7-Ethyl-10-hydroxycamptothecin	Gate2brain S.L.	Treatment of glioma	03/10/2024 15/07/2024 10/10/2024 (87 days/24 days)	18/10/2024 11/11/2024
Avenciguat	Boehringer Ingelheim International GmbH	Treatment of systemic sclerosis	08/08/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024
Curcumin, Resveratrol	ICON Clinical Research Limited	Treatment of Dercum disease	12/07/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024

[1] Legal 90 day deadline exceeded due to written procedure.

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
4-[[(4-Methoxyphenyl)thio]methyl]-N,N-dimethyl-1H-1,2,3-triazole-1-ethanamine	Miramoon Pharma S.L.	Treatment of non-syndromic inherited retinal dystrophies with a rod-dominant phenotype	15/07/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024
3-chloro-4-fluorophenyl-(4-fluoro-4-(((5-methylpyrimidin-2-ylmethyl)amino)methyl)piperidin-1yl)methanone	Neurolixis	Treatment of fragile X syndrome	08/07/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024
Felzartamab	Human Immunology Biosciences Ireland Limited	Treatment of primary IgA nephropathy	12/07/2024 15/08/2024 10/10/2024 (56 days/24 days)	18/10/2024 11/11/2024
H-L-tryphophanyl-L-seryl-glycyl-L-tryptophanyl-L-seryl-L-seryl-L-cysteinyl-L-seryl-L-arginyl-L-seryl-L-cysteinyl-glycyl-OH (disulfide bond), acetate salt	Axoltis Pharma	Treatment of amyotrophic lateral sclerosis	24/06/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Glecirasib	PPD Bulgaria EOOD	Treatment of pancreatic cancer	24/06/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Navenibart	PHARA	Treatment of hereditary angioedema	21/06/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Octreotide hydrochloride	Camurus AB	Treatment of autosomal dominant polycystic liver disease	09/07/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Genetically modified human adenovirus encoding human PH20 hyaluronidase	Theriva Biologics S.L.	Treatment of retinoblastoma	29/05/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Sodium selenate	Monash University	Treatment of frontotemporal dementia	04/07/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Ivosidenib	Les Laboratoires Servier	Treatment of chondrosarcoma	26/08/2024 17/06/2024 12/09/2024 (87 days/22 days)	19/09/2024 11/10/2024
Atacicept	Boyd Consultants Limited	Treatment of primary IgA nephropathy	12/07/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
4,9-Dimethyl-6-(4'-aminophenyl)-2H-furo[2,3-h]-1-benzopyran-2-one	Fondazione Per La Ricerca Sulla Fibrosi Cistica Ets	Treatment of cystic fibrosis	14/05/2024 17/06/2024 12/09/2024 (87 days/22 days)	19/09/2024 11/10/2024
3-(5-(2-Hydroxy-2-methylpropoxy)-6-methylpyrazin-2-yl)-1H-indole-7-carbonitrile	FGK Representative Service GmbH	Treatment of X-linked spinal and bulbar muscular atrophy (Kennedy's disease)	02/07/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024
Interleukin-12, human, recombinant	Allucent (DE) GmbH	Treatment of cutaneous T-cell lymphoma	26/08/2024 17/06/2024 12/09/2024 (87 days/22 days)	19/09/2024 11/10/2024
Adeno-associated virus vector serotype SAN011 encoding a microRNA against DMPK mRNA	Sanofi B.V.	Treatment of dystrophic myotonia type 1	15/08/2024 15/07/2024 12/09/2024 (59 days/22 days)	19/09/2024 11/10/2024

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Polihexanide	SIFI S.p.A.	Treatment of fungal keratitis	14/05/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
IgG-like T-cell engager binding to DLL3 and CD3	Boehringer Ingelheim International GmbH	Treatment of extrapulmonary neuroendocrine carcinoma	14/06/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Autologous CD34+ cells edited with a CRISPR/Cas9 system and transduced with an adeno-associated vector containing a codon-optimized version of *WAS* gene	Danaus Pharmaceuticals S.L.	Treatment of Wiskott-Aldrich syndrome	26/04/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
(R)-(3-(2'-cyclopropyl-3-(hydroxymethyl)-[1,1'-biphenyl]-4-yl) pyrrolidin-1-yl)(5-fluoropyridin-2-yl)methanone	Granzer Regulatory Consulting & Services GmbH	Treatment of punctate palmoplantar keratoderma	12/07/2024 22/04/2024 18/07/2024 (87 days/29 days)	23/07/2024 21/08/2024
Humanised IgG1 monoclonal antibody against misfolded immunoglobulin G , fused with pan-amyloid-reactive peptide p5R	Raremoon Consulting Esp S.L.	Treatment of ATTR amyloidosis	11/07/2024 22/04/2024 18/07/2024 (87 days/29 days)	23/07/2024 21/08/2024
Bemarituzumab	Amgen Europe B.V.	Treatment of gastric cancer	06/06/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
IgG-like T-cell engager binding to DLL3 and CD3	Boehringer Ingelheim International GmbH	Treatment of pulmonary neuroendocrine carcinoma	14/06/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024

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Humanised IgG1 monoclonal antibody against misfolded immunoglobulin G , fused with pan-amyloid-reactive peptide p5R	Raremoon Consulting Esp S.L.	Treatment of AL amyloidosis	11/07/2024 22/04/2024 18/07/2024 (87 days/29 days)	23/07/2024 21/08/2024
Interleukin 4 - interleukin 10 fusion protein	Synerkine Pharma B.V.	Treatment of complex regional pain syndrome	12/07/2024 22/04/2024 18/07/2024 (87 days/29 days)	23/07/2024 21/08/2024
4-Benzoyl-D-phenylalanyl-D-seryl-D-tryptophyl-D-seryl-2,3,4,5,6-pentafluoro-D-phenylalanyl-3-cyclohexyl-D-alanyl-D-arginyl-D-arginyl-D-arginyl-D-glutaminyl-D-arginyl-D-arginine acetate	Syneos Health Netherlands B.V.	Treatment of pancreatic cancer	04/07/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
4-(1H-Pyrrolo[2,3-b]pyridin-2-yl)phenol hydrochloride	SeaBeLife	Prevention of acute liver failure	22/04/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
(E)-2-((4-((4-Benzyl(ethyl)amino)phenyl)diazinyl)phenyl)amino-N,N,N-triethyl-2-oxoethan-1-aminium chloride	Kiora Pharmaceuticals GmbH	Treatment of syndromic inherited retinal dystrophies of the rod-dominant phenotype	21/06/2024 15/07/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Adeno-associated viral vector serotype 3B encoding human CYP27A1	Vivet Therapeutics S.A.S.	Treatment of inborn errors of primary bile acid synthesis	21/05/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Olezarsen sodium	Ionis Ireland Limited	Treatment of familial chylomicronemia syndrome	12/06/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024

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Sodium valproate	Cereno Scientific AB	Treatment of pulmonary arterial hypertension	22/05/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Gallium (68Ga) boclatixafortide	Pentixapharm AG	Diagnosis of marginal zone lymphoma	17/05/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Adeno-associated virus vector serotype 9 containing the human *GCDH* gene	Consorcio Centro De Investigacion Biomedica En Red	Treatment of glutaric aciduria	22/05/2024 17/06/2024 18/07/2024 (31 days/29 days)	23/07/2024 21/08/2024
Cannabidiol acid methyl ester	Scendea (NL) B.V.	Treatment of Prader-Willi syndrome	26/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Heterologous swine glyco-humanised polyclonal antibody against T lymphocytes	Xenothera	Treatment of Peripheral T cell Lymphoma	19/04/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Camrelizumab	PharmaLex GmbH	Treatment of hepatocellular carcinoma	16/06/2024 25/03/2024 20/06/2024 (87 days/29 days)	26/06/2024 25/07/2024
Rivoceranib mesilate	Elevar Therapeutics	Treatment of hepatocellular carcinoma	14/06/2024 25/03/2024 20/06/2024 (87 days/29 days)	26/06/2024 25/07/2024
(E)-2-((4-((4-Benzyl(ethyl)amino)phenyl)diazinyl)phenyl)amino-N,N,N-triethyl-2-oxoethan-1-aminium chloride	Kiora Pharmaceuticals GmbH	Treatment of non-syndromic inherited retinal dystrophies of the rod-dominant phenotype	12/06/2024 25/03/2024 20/06/2024 (87 days/29 days)	26/06/2024 25/07/2024

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Urokinase, catalytic domain, fused with a single-chain antibody against von Willebrand factor	TargED Biopharmaceuticals B.V.	Treatment of thrombotic thrombocytopenic purpura	14/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Adeno-associated virus vector serotype 8 containing the human *TYMP* gene (CpG-depleted)	Fundacio Hospital Universitari Vall D Hebron Institut De Recerca	Treatment of mitochondrial neurogastrointestinal encephalomyopathy	08/04/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Adeno-associated virus serotype A101 containing the codon-optimized human CFTRdeltaR	Pharma Gateway AB	Treatment of cystic fibrosis	26/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Afamelanotide	Clinuvel Europe Limited	Treatment of variegate porphyria	13/06/2024 25/03/2024 20/06/2024 (87 days/29 days)	26/06/2024 25/07/2024
Emavusertib	Orphix Consulting GmbH	Treatment of primary large B-cell lymphoma of immune-privileged sites	27/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Sodium phenylbutyrate, Ursodoxicoltaurine	Amylyx Pharmaceuticals EMEA B.V.	Treatment of Wolfram syndrome	16/04/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
Adeno-associated virus vector serotype rh.10 containing the human *FXN* gene	Scendea (NL) B.V.	Treatment of Friedreich's ataxia	26/03/2024 22/04/2024 20/06/2024	26/06/2024 25/07/2024 (59 days/29 days)
4-[[[4-[5-Chloro-2-[[trans-4-[[(1R)-2-methoxy-1-methyl-ethyl]amino]cyclohexyl]amino]-4-pyridinyl]-2-thiazolyl]amino]methyl]tetrahydro-2H-pyran-4-carbonitrile	Sellas Life Sciences Limited	Treatment of peripheral T-cell lymphoma	13/06/2024 25/03/2024 20/06/2024 (87 days/29 days)	26/06/2024 25/07/2024

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Befiradol fumarate	Neurolixis	Treatment of spinocerebellar ataxia	26/02/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
N-[(1R)-1-[(S)-(2-Chloro-3-fluorophenyl)hydroxymethyl]butyl]-7-fluoro-2,3-dihydro-2-oxo-1H-indole-4-carboxamide	Biomarin International Limited	Treatment of congenital alpha-1 antitrypsin deficiency	26/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
N,N'-([Cyclohexylmethylene]di-4,1-phenylene)bis(2-[1-pyrrolidinyl]acetamide)	RegSmart Life Science AB	Treatment of Creutzfeldt-Jakob disease	27/03/2024 22/04/2024 20/06/2024 (59 days/29 days)	26/06/2024 25/07/2024
2-(((2E)-3-(3-methoxy-4-(2-propyn-1-yloxy)phenyl)-1-oxo-2-propen-1-yl)amino)benzoic acid	AdRes EU B.V.	Treatment of systemic sclerosis	19/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
4-[[[4-[5-Chloro-2-[[trans-4-[[(1R)-2-methoxy-1-methyl-ethyl]amino]cyclohexyl]amino]-4-pyridinyl]-2-thiazolyl]amino]methyl]tetrahydro-2H-pyran-4-carbonitrile	Sellas Life Sciences Limited	Treatment of acute myeloid leukemia	22/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Human IgG1 monoclonal antibody against hepatitis B virus, surface antigen	Yes Pharmaceutical Development Services GmbH	Treatment of hepatitis D virus infection	20/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
(R)-(3-(2'-cyclopropyl-3-(hydroxymethyl)-[1,1'-biphenyl]-4-yl) pyrrolidin-1-yl)(5-fluoropyridin-2-yl)methanone	Granzer Regulatory Consulting & Services GmbH	Treatment of pachyonychia congenita	27/02/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Nizubaglustat	Azafaros B.V.	Treatment of GM1 gangliosidosis	16/05/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024

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Afatinib	Akigai AS	Treatment of complex regional pain syndrome	09/02/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Topiramate	Granzer Regulatory Consulting & Services GmbH	Treatment of neonatal encephalopathy	13/05/2024 26/02/2024 23/05/2024 (87 days/29 days)	30/05/2024 28/06/2024
Complement factor H, human, recombinant	Greenovation Biotech GmbH	Treatment of C3 glomerulopathy	27/02/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Nerandomilast	Boehringer Ingelheim International GmbH	Treatment of idiopathic pulmonary fibrosis	22/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
L-methionine	Imagine Institut Des Maladies Genetiques Necker Enfants Malades	Treatment of pulmonary alveolar proteinosis	27/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Sargramostim	CATS Consultants GmbH	Treatment of pulmonary alveolar proteinosis	06/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Uridine triacetate	Serb	Treatment of hereditary orotic aciduria	22/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
(R)-3-(1-Cyclopropyl-3-(2-fluoro-4-(trifluoromethoxy)benzyl)ureido)piperidine-1-carboxamide	Otsuka Pharmaceutical Netherlands B.V.	Treatment of hyperphenylalaninemia	19/03/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024

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Apilimod	Maxia Strategies-Europe Limited	Treatment of amyotrophic lateral sclerosis	07/03/2024 22/04/2024 23/05/2024 (31 days/29 days)	30/05/2024 28/06/2024
Ethyl(2E,4S)-4-({(2S)-2-[3-{[(5-methyl-1,2-oxazol-3-yl)carbonyl]amino}-2-oxopyridin-1(2H)-yl]pent-4-ynoyl}amino)-5-[(3S)-2-oxopyrrolidin-3-yl]pent-2-enoate, Pocapavir	Virodefense IRE Limited	Treatment of poliovirus infection	27/02/2024 25/03/2024 23/05/2024 (59 days/29 days)	30/05/2024 28/06/2024
Adeno-associated virus serotype 9 containing CRISPR/Cas13Y and guide RNA against the human *MECP2* gene	Granzer Regulatory Consulting & Services GmbH	Treatment of MECP2 duplication syndrome	25/01/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
Efineptakin alfa	Neoimmunetech Poland Sp. z o.o.	Treatment of acute radiation syndrome	21/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
Serdexmethylphenidate	Zevra Denmark A/S	Treatment of idiopathic hypersomnia	27/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
DNA plasmid containing the *COL7A1* gene	Branca Bunus Limited	Treatment of epidermolysis bullosa	23/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
2,4-Diamino-5-[[5-(1H-pyrazol-5-yl)-2-thienyl]methyl]-1H-pyrimidin-6-one	Pluvia AS	Treatment of hyperphenylalaninaemia	13/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
Afamelanotide	Clinuvel Europe Limited	Treatment of xeroderma pigmentosum	05/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024

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Adeno-associated virus serotype rh.74 vector containing the human *PKP2* gene isoform	Rocket Pharmaceuticals B.V.	Treatment of arrhythmogenic cardiomyopathy caused by pathogenic mutations in the *PKP2* gene	24/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
Quabodepistat	Otsuka Novel Products GmbH	Treatment of tuberculosis	11/04/2024 26/02/2024 18/04/2024 (83 days/28 days)	26/04/2024 24/05/2024
Allogeneic non-alloreactive T cells edited with mRNA to disrupt *TRAC* and *CD52* genes and transduced with lentiviral vector expressing a chimeric antigen receptor against CD22 and RQR8 depletion mechanism	Cellectis	Treatment of acute Lymphoblastic leukaemia	21/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
7-Ethyl-10-hydroxycamptothecin, irinotecan hydrochloride trihydrate	3R Pharma Consulting GmbH	Treatment of small cell lung cancer	06/02/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
N-(1,3-Benzothiazol-2-yl)-4-[(2-hydroxy-3-methoxyphenyl)methyl amino]benzenesulfonamide	FGK Representative Service GmbH	Treatment of platelet-activating anti-Platelet factor 4 (PF4) disorders	15/04/2024 26/01/2024 18/04/2024 (83 days/28 days)	26/04/2024 24/05/2024
Autologous CD34+ cells transduced with a lentiviral vector containing the human *RAG1* gene	Leids Universitair Medisch Centrum (LUMC)	Treatment of recombination-activating gene 1 (*RAG1*) deficiency	15/01/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024
Autologous induced pluripotent stem cells-derived thymic epithelial cells transduced with a lentiviral vector	Genewity B.V.	Treatment of DiGeorge's syndrome	25/01/2024 26/02/2024 18/04/2024 (52 days/28 days)	26/04/2024 24/05/2024

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encoding forkhead box protein N1				
Sevasemten	FGK Representative Service GmbH	Treatment of Duchenne muscular dystrophy	07/03/2024 04/01/2024 14/03/2024 (70 days/28 days)	19/03/2024 16/04/2024
Autologous adipose-derived stem cells	Regenera GmbH	Treatment of spinal cord injury	07/03/2024 04/01/2024 14/03/2024 (70 days/28 days)	19/03/2024 16/04/2024
Autologous adipose-derived mesenchymal stem cells embedded in an extracellular matrix with hydroxyapatite/beta-tricalcium phosphate particles	Novadip Biosciences	Treatment of congenital pseudarthrosis of long bones	22/02/2024 04/01/2024 14/03/2024 (70 days/28 days)	19/03/2024 16/04/2024
Humanised IgG1 (K322A) monoclonal antibody against disialoganglioside GD2	Somerville Development Partners B.V.	Treatment of neuroblastoma	04/12/2023 26/01/2024 14/03/2024 (48 days/28 days)	19/03/2024 16/04/2024
Annamycin	Moleculin Amsterdam B.V.	Treatment of acute myeloid leukaemia	06/03/2024 26/01/2024 14/03/2024 (48 days/28 days)	19/03/2024 16/04/2024
Acetylleucine	Intrabio Ireland Limited	Treatment of ataxia-oculomotor apraxia	23/02/2024 04/01/2024 14/03/2024 (70 days/28 days)	19/03/2024 16/04/2024
Autologous CD3-positive T-cells expressing a chimeric antigen receptor against B cell maturation agent	Raremoon Consulting Esp S.L.	Treatment of multiple myeloma	03/11/2023 04/01/2024 15/02/2024 (42 days/23 days)	27/02/2024 21/03/2024

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Alrefimotide acetate, riletamotide acetate, tapderimotide acetate	Ultimovacs ASA	Treatment of mesothelioma	07/02/2024 23/11/2023 15/02/2024 (84 days/23 days)	27/02/2024 21/03/2024
Mibavademab	Regeneron Ireland Designated Activity Company	Treatment of Berardinelli-Seip syndrome (congenital generalised lipodystrophy)	08/02/2024 23/11/2023 15/02/2024 (84 days/23 days)	27/02/2024 21/03/2024
Zatolmilast	Shionogi B.V.	Treatment of fragile X syndrome	05/12/2023 04/01/2023 15/02/2024 (42 days/23 days)	27/02/2024 21/03/2024
Sevasemten	FGK Representative Service GmbH	Treatment of Becker muscular dystrophy	15/12/2023 04/01/2023 15/02/2024 (42 days/23 days)	27/02/2024 21/03/2024
Mibavademab	Regeneron Ireland Designated Activity Company	Treatment of Lawrence syndrome (acquired generalised lipodystrophy)	12/02/2024 23/11/2023 15/02/2024 (84 days/23 days)	27/02/2024 21/03/2024
4-(4-Methyl-piperazin-1-yl)-N-{6-[2-(4-trifluoromethyl-benzyloxy)-ethoxy]-1H-indazol-3-yl}-benzamide hemioxalate	Nerviano Medical Sciences S.r.l.	Treatment of acute myeloid leukaemia	07/02/2024 04/01/2023 15/02/2024 (42 days/23 days)	27/02/2024 21/03/2024
Repagermanium	Scendea (NL) B.V.	Treatment of focal segmental glomerulosclerosis	13/11/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
Andecaliximab	Regulatory Pharma Net S.r.l.	Treatment of fibrodysplasia ossificans progressiva	21/11/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024

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Raludotatug deruxtecan	Daiichi Sankyo Europe GmbH	Treatment of ovarian cancer	24/10/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
Tinengotinib	Parexel International (IRL) Limited	Treatment of biliary tract cancer	11/01/2024 26/10/2023 18/01/2024 (84 days/27 days)	23/01/2024 19/02/2024
Ifinatamab deruxtecan	Daiichi Sankyo Europe GmbH	Treatment of small cell lung cancer	17/11/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
Carboplatin	Carthera	Treatment of glioma	11/01/2024 26/10/2023 18/01/2024 (84 days/27 days)	23/01/2024 19/02/2024
Plerixafor	4p-Pharma	Treatment of acute respiratory distress syndrome	10/01/2024 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
mRNA encoding the human *CFTR* gene	Arcturus Therapeutics Europe B.V.	Treatment of cystic fibrosis	09/01/2024 26/10/2023 18/01/2024 (84 days/27 days)	23/01/2024 19/02/2024
Donidalorsen	Otsuka Pharmaceutical Netherlands B.V.	Treatment of hereditary angioedema	18/10/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
Autologous CD3-positive T-cells expressing a chimeric antigen receptor against B cell maturation agent	Raremoon Consulting Esp S.L.	Treatment of AL amyloidosis	25/10/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024

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Human IgG1 monoclonal antibody targeting amyloid transthyretin	Alexion Europe	Treatment of ATTR amyloidosis	11/01/2024 26/10/2023 18/01/2024 (84 days/27 days)	23/01/2024 19/02/2024
Paclitaxel	Woodley Bioreg S.r.l.	Treatment of gastric cancer	21/11/2023 23/11/2023 18/01/2024 (56 days/27 days)	23/01/2024 19/02/2024
Adenine	Raremoon Consulting Esp S.L.	Treatment of epidermolysis bullosa	27/09/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Gorilla adenovirus vector expressing HPV6 and HPV11 antigens	Granzer Regulatory Consulting & Services GmbH	Treatment of recurrent respiratory papillomatosis	28/09/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Human heparan N-sulfatase, recombinant	3R Pharma Consulting GmbH	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	26/09/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Ziftomenib	MWB Consulting	Treatment of acute myeloid leukaemia	22/11/2023 26/10/2023 07/12/2023	14/12/2023 12/01/2024 (42 days/29 days)
Apilimod dimesilate	Maxia Strategies-Europe Limited	Treatment of amyotrophic lateral sclerosis	30/11/2023 14/09/2023 07/12/2023 (84 days/29 days)	14/12/2023 12/01/2024
Adeno-associated viral vector serotype 9 containing the human *MECP2* gene, an intron encoding a miRNA generating sequence, and complementary miRNA binding sites	Eusme Limited	Treatment of Rett syndrome	18/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024

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Cutamesine	3R Pharma Consulting GmbH	Treatment of alpha-thalassaemia X-linked intellectual disability syndrome (due to mutations in the *ATRX* gene)	14/09/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Tarlatamab	Amgen Europe B.V.	Treatment of small cell lung cancer	25/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Motixafortide	Granzer Regulatory Consulting & Services GmbH	Treatment of patients undergoing haematopoietic stem cell transplantation	23/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Mitapivat sulfate	Agios Netherlands B.V.	Treatment of thalassaemia alpha intermedia and major	20/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Thiophene methylimidazole pentahydrogen	Celluminova AB	Diagnosis of glioma	23/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
Anti-(insulin receptor) human monoclonal antibody	Rezolute (Bio) Ireland Limited	Treatment of insulinoma	30/11/2023 14/09/2023 07/12/2023 (84 days/29 days)	14/12/2023 12/01/2024
Golcadomide hydrochloride	Bristol-Myers Squibb Pharma EEIG	Treatment of diffuse large B-cell lymphoma	02/11/2023 14/09/2023 07/12/2023 (84 days/29 days)	14/12/2023 12/01/2024
Methyl-(1-{[6-{[(1S)-1-cyclopropylethyl]amino}-2-(pyrazolo[5,1-b][1,3]thiazol-7-yl)-pyrimidin-4-yl]carbonyl}piperidin-4-yl)carbamate mono(4-	Syneos Health Netherlands B.V.	Treatment of eosinophilic granulomatosis with polyangiitis	30/11/2023 14/09/2023 07/12/2023 (84 days/29 days)	14/12/2023 12/01/2024

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
methylbenzenesulfonate)				
Human coagulation factor X	BPL Bioproducts Laboratory GmbH	Treatment of acquired factor X deficiency	24/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024
(4R)-3-(4-fluoro-2-hydroxyphenyl)-4-methyl-4,5-dihydro-1H-pyrazole-1-carboximidamide hydrochloride	AnaMar AB	Treatment of systemic sclerosis	23/10/2023 26/10/2023 07/12/2023 (42 days/29 days)	14/12/2023 12/01/2024

Annex 15 – HMPC European Union herbal monographs in 2024

Abbreviations: TU – traditional use

WEU – well established use

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/379866/2023	Prunus avium peduncle	20/11/2024 / TU
Revision		
EMA/HMPC/372841/2016	Foeniculi amari fructus	31/01/2024 / TU
EMA/HMPC/372839/2016	Foeniculi dulcis fructus	31/01/2024 / TU
EMA/HMPC/24177/2023	Rhodiolae roseae rhizoma et radix	20/03/2024 / TU
EMA/HMPC/27744/2023	Ginseng radix	29/05/2024 / TU
EMA/HMPC/648100/2022	Pelargonii radix	29/05/2024 / TU
EMA/HMPC/513893/2021	Rosmarini aetheroleum	29/05/2024 / TU
EMA/HMPC/513940/2021	Rosmarini folium	29/05/2024 / TU
EMA/HMPC/320292/2023	Eucalypti aetheroleum	20/11/2024 / TU
EMA/HMPC/493453/2023	Pilosellae herba cum radice	20/11/2024 / TU

European Union List entries – adopted for transfer to Eur. Com.

Reference number	Document title	Adoption
First Assessment		
	none	
Revision		
EMA/HMPC/372843/2016	Foeniculi amari fructus	31/01/2024
EMA/HMPC/372840/2016	Foeniculi dulcis fructus	31/01/2024

European Union herbal monographs – Draft for consultation

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/150763/2015	Cisti cretici herba	24/07/2024 / TU
EMA/HMPC/239465/2024	Species pectorales	20/11/2024 / TU
Revision		
EMA/HMPC/261302/2022	Urticae herba	29/05/2024 / TU
EMA/HMPC/322646/2023	Urticae radix	29/05/2024 / TU
EMA/HMPC/885789/2022	Zingiberis rhizoma	29/05/2024 / WEU + TU
EMA/HMPC/887979/2022	Plantaginis lanceolatae folium	24/07/2024 / TU

European Union List entries – Draft for consultation

Reference number	Document title	Adoption
First Assessment		
	none	
Revision		
	none	

Monograph/ list entry review reports

Reference number	Document title	Adoption / Outcome
Final decision		
EMA/HMPC/509622/2023	Allii sativi bulbus	31/01/2024 / revision required*
EMA/HMPC/411828/2023	Matricariae aetheroleum	31/01/2024/ revision required*
EMA/HMPC/509451/2023	Silybi mariani fructus	31/01/2024 / no revision
EMA/HMPC/498679/2023	Species diureticae	31/01/2024 / revision required*
EMA/HMPC/313662/2023	Symphyti radix	31/01/2024 / no revision
EMA/HMPC/408278/2023	Malvae sylvestris flos	20/03/2024 / no revision
EMA/HMPC/408283/2023	Malvae folium	20/03/2024 / no revision
EMA/HMPC/32686/2024	Mastic (Pistaciae lentisci resina)	24/07/2024 / no revision
EMA/HMPC/237081/2024	Lecithinum ex soya	24/07/2024 / revision required*
EMA/HMPC/237034/2024	Soiae oleum raffinatum	24/07/2024 / no revision
EMA/HMPC/416377/2024	Lini semen	20/11/2024 / no revision
EMA/HMPC/438158/2024	Polypodii rhizoma	20/11/2024 / no revision
EMA/HMPC/438159/2024	Sambuci flos	20/11/2024 / no revision
EMA/HMPC/438161/2024	Verbasci flos	20/11/2024 / no revision

* When revision is required, the review report is not published.

Public statements

Reference number	Document title	Adoption
Drafts		
	none	
Final		
EMA/HMPC/522456/2021	Foeniculi amari fructus aetheroleum	29/05/2024
EMA/HMPC/308436/2023	Tribuli terrestris herba	20/11/2024

Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2024

First PIP applications (with or without partial waivers), product-specific waivers, modifications of agreed PIP

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Setmelanotide	Imcivree	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Rhythm Pharmaceuticals Inc.	12/19/2024	EMA/PE/00001 82239
Diazoxide choline		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Soleno Therapeutics Europe Limited	12/18/2024	P/0402/2024
Olorofim		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Shionogi B.V.	12/17/2024	P/0398/2024
Vibegron		Modification of Paediatric Investigation Plan	Positive (Waiver)	Renal and urinary disorders	Pierre Fabre Medicament	12/16/2024	EMA/PE/00002 21175
Pneumococcal polysaccharide serotype 10A conjugated to CRM197, Pneumococcal polysaccharide serotype 11A conjugated to CRM197, Pneumococcal polysaccharide serotype 12F conjugated to CRM197, Pneumococcal polysaccharide serotype 15A conjugated to CRM197, Pneumococcal polysaccharide serotype 15B de-O-acetylated conjugated to CRM197, Pneumococcal polysaccharide serotype 16F conjugated to CRM197, Pneumococcal polysaccharide serotype 17F conjugated to CRM197, Pneumococcal polysaccharide serotype 19A conjugated to CRM197, Pneumococcal polysaccharide serotype 20A conjugated to CRM197, Pneumococcal polysaccharide serotype 22F conjugated to		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Merck Sharp & Dohme B.V.	12/6/2024	EMA/PE/00002 21419

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
CRM197, Pneumococcal polysaccharide serotype 23A conjugated to CRM197, Pneumococcal polysaccharide serotype 23B conjugated to CRM197, Pneumococcal polysaccharide serotype 24F conjugated to CRM197, Pneumococcal polysaccharide serotype 3 conjugated to CRM197, Pneumococcal polysaccharide serotype 31 conjugated to CRM197, Pneumococcal polysaccharide serotype 33f conjugated to CRM197, Pneumococcal polysaccharide serotype 35B conjugated to CRM197, Pneumococcal polysaccharide serotype 6A conjugated to CRM197, Pneumococcal polysaccharide serotype 7F conjugated to CRM197, Pneumococcal polysaccharide serotype 8 conjugated to CRM197, Pneumococcal polysaccharide serotype 9N conjugated to CRM197							
Encaleret		Modification of Paediatric Investigation Plan	Positive	Endocrine disorders	Bridgebio Europe B.V.	12/6/2024	EMA/PE/00001 83137
Cangrelor tetrasodium		Modification of Paediatric Investigation Plan	Negative	Vascular disorders	Chiesi Farmaceutici S.p.A.	12/6/2024	EMA/PE/00002 21485
Tenapanor		Product Specific Waiver	Positive	Metabolism and nutrition disorders	Pharma Gateway AB	12/6/2024	EMA/PE/00002 20986
Zoliflodacin		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Entasis Therapeutics	12/6/2024	EMA/PE/00001 82808
Tralokinumab	Adtralza	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	LEO PHARMA A/S	12/6/2024	EMA/PE/00001 83430
Oxybutynin		Product Specific Waiver	Positive	Renal and urinary disorders	Ligalli B.V.	12/6/2024	EMA/PE/00001 82297

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Cedazuridine /decitabine	Inaqovi	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Otsuka Pharmaceutical Netherlands B.V.	12/6/2024	EMA/PE/00001 82217
Nirmatrelvir / ritonavir	Paxlovid	Modification of Paediatric Investigation Plan	Positive	Surgical and medical procedures	Pfizer Europe MA EEIG	12/6/2024	EMA/PE/00002 25184
Dermatophagoides pteronyssinus extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/6/2024	EMA/PE/00002 21424
Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens (V940/mrna-4157)		Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Merck Sharp & Dohme B.V.	12/6/2024	EMA/PE/00001 82525
Avalglucosidase alfa	Nexviadyme	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sanofi B.V.	12/6/2024	EMA/PE/00001 81300
Recombinant human apolipoprotein A-I		Product Specific Waiver	Positive	Congenital, familial and genetic disorders	Abionyx Pharma	12/6/2024	EMA/PE/00002 21511
Olea europaea pollen extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/6/2024	EMA/PE/00002 21772
Amlitelimab		Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Sanofi Winthrop Industrie	12/6/2024	EMA/PE/00001 82447
Bedaquiline (fumarate)	Sirturo	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Janssen Cilag International	12/6/2024	EMA/PE/00001 81219
Parietaria judaica pollen extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/6/2024	EMA/PE/00002 21664
Atazanavir (sulphate) / cobicistat	Evotaz	Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Bristol-Myers Squibb Pharma EEIG	12/6/2024	EMA/PE/00002 21021
Bemcentinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bergenbio ASA	12/6/2024	EMA/PE/00002 21199
Betula pendula pollen extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/6/2024	EMA/PE/00002 21803
Resiniferatoxin		Product Specific Waiver	Positive	Musculoskeletal and connective tissue disorders	Grunenthal gmbh	12/6/2024	EMA/PE/00001 82440

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Bexicaserin		Initial Paediatric Investigation Plan	Positive	Nervous system disorders	Longboard Pharmaceuticals Inc.	12/6/2024	P/0395/2024
Doruxapapogenum ralaplasmidum (pgx3024)	INO-3107	Initial Paediatric Investigation Plan	Positive	Infections and infestations	Inovio Pharmaceuticals Inc.	12/6/2024	P/0391/2024
Tulisokibart		Initial Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Merck Sharp & Dohme B.V.	12/6/2024	P/0390/2024
Tulisokibart		Initial Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Merck Sharp & Dohme B.V.	6/12/2024	P/0393/2024
Linaprazan glurate		Initial Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Cinclus Pharma Holding AB	6/12/2024	P/0392/2024
7-Ethyl-10-hydroxycamptothecin	CEB-01	Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cebiotex S.L.	12/6/2024	P/0394/2024
Zimislecel		Product Specific Waiver	Positive	Endocrine disorders	Vertex Pharmaceuticals (Ireland) Limited	12/6/2024	EMA/PE/00001 83758
Tolebrutinib		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Sanofi Winthrop Industrie	12/6/2024	EMA/PE/00001 81294
(S)-(4-amino-1,3-dihydrofuro[3,4-c][1,7]naphthyridin-8-yl)(3-(4-(trifluoromethyl)phenyl)morpholino)methanone		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Amgen Europe B.V.	12/6/2024	EMA/PE/00001 83083
Telisotuzumab adizutecan		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	12/6/2024	EMA/PE/00001 81441
Interleukin-23 receptor antagonist peptide (JNJ-77242113)		Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Janssen Cilag International	12/6/2024	EMA/PE/00001 83329
Xaluritamig		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Amgen Europe B.V.	12/6/2024	EMA/PE/00002 21674
Tadalafil, tamsulosin		Product Specific Waiver	Positive	Renal and urinary disorders	Midas Pharma gmbh	12/6/2024	EMA/PE/00001 83373
Precemtabart tocentecan		Product Specific Waiver	Positive	Neoplasms benign, malignant and	Merck Healthcare kgaa	12/6/2024	EMA/PE/00001 82333

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Lerodalcibep	Lerodalcibep	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	LIB Therapeutics Inc.	12/6/2024	EMA/PE/00001 81518
Inbakicept, nogapendekin alfa		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Serum Life Science Europe gmbh	12/6/2024	EMA/PE/00001 82345
Bizalimogene ralaplasmid / mavilimogene ralaplasmid / rocakinogene sifuplasmid		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Inovio Pharmaceuticals Inc.	12/6/2024	EMA/PE/00001 82462
Rilvegostomig		Product Specific Waiver	Positive	Gastrointestinal disorders	Astrazeneca AB	12/6/2024	EMA/PE/00001 81778
Resiquimod		Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eikon Therapeutics Inc.	12/6/2024	EMA/PE/00001 81238
Ascorbic acid, Macrogol 3350, Potassium chloride, Sodium ascorbate, Sodium chloride, Sodium sulphate (Plenvu)	Plenvu	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Norgine Limited	12/5/2024	EMA/PE/00002 21751
Budesonide / glycopyrronium bromide / formoterol (fumarate)	Trixeo aerosphere	Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Astrazeneca AB	12/5/2024	EMA/PE/00001 81335
Telisotuzumab adizutecan		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	12/5/2024	EMA/PE/00001 81236
Brexpiprazole	Rxulti	Modification of Paediatric Investigation Plan	Positive	Psychiatric disorders	Otsuka Pharmaceutical Netherlands B.V.	12/5/2024	EMA/PE/00001 83866
6'-([(1S,3S)-3-([5-(difluoromethoxy)-2-pyrimidinyl]amino)cyclopentyl]amino)-2H- [1,3'-bipyridin]-2-one (AZD0780)		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Astrazeneca AB	12/5/2024	P/0389/2024
Trastuzumab deruxtecan	Enhertu	Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe gmbh	5/12/2024	P/0397/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Amlodipine, ramipril, rosuvastatin		Product Specific Waiver	Positive	Vascular disorders	Adamed Pharma S.A.	12/5/2024	EMA/PE/00002 24486
Dengue tetravalent vaccine (live, attenuated)	Qdenga	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Takeda Vaccines Inc.	12/5/2024	EMA/PE/00002 24202
Regorafenib	Stivarga	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bayer AG	12/5/2024	EMA/PE/00001 82170
Cupressus arizonica pollen extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/5/2024	EMA/PE/00002 21695
Dapagliflozin / eplerenone		Product Specific Waiver	Positive	Cardiac disorders	Elpen Pharmaceutical Co. Inc.	12/5/2024	EMA/PE/00001 84400
Phleum pratense pollen extract		Initial Paediatric Investigation Plan	Positive (Waiver)	Immune system disorders	ROXALL Medicina España S.A.	12/5/2024	EMA/PE/00002 21500
Esepapogene zalarnarepvec		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hookipa Biotech gmbh	12/5/2024	EMA/PE/00002 21101
Mitapivat	Pyrukynd	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Agios Netherlands B.V.	11/27/2024	EMA/PE/00002 38074
Inebilizumab	Uplizna	Modification of Paediatric Investigation Plan	Positive	Surgical and medical procedures	Horizon Therapeutics Ireland DAC	11/27/2024	EMA/PE/00002 38005
Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage)	Efluelda	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur	11/25/2024	EMA/PE/00002 21589
Iclepertin		Modification of Paediatric Investigation Plan	Positive	Psychiatric disorders	Boehringer Ingelheim International gmbh	11/22/2024	EMA/PE/00001 83220
Tildrakizumab	Ilumetri	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Almirall S.A.	11/15/2024	EMA/PE/00001 82362
Abrocitinib	Cibinqo	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Pfizer Europe MA EEIG	11/13/2024	EMA/PE/00001 83059

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Adrenaline (epinephrine)	Eurneffy	Modification of Paediatric Investigation Plan	Positive	Cardiac disorders	ARS Pharmaceuticals IRL Limited	11/8/2024	EMA/PE/00002 21076
Tildrakizumab	Ilumetri	Initial Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Almirall S.A.	11/8/2024	P/0388/2024
Ravulizumab	Ultomiris	Initial Paediatric Investigation Plan	Positive	Renal and urinary disorders	Alexion Europe	11/8/2024	EMEA-001943-PIP07-24
Mosunetuzumab	Lunsumio	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Roche Registration gmbh	11/8/2024	EMA/PE/00001 81993
Apitegromab		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Yes Pharmaceutical Development Services gmbh	11/7/2024	EMA/PE/00002 21709
Lebrikizumab	Ebglyss	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Eli Lilly And Company Limited	10/31/2024	P/0382/2024
Teplizumab		Modification of Paediatric Investigation Plan	Positive	Endocrine disorders	Sanofi Winthrop Industrie	10/30/2024	EMA/PE/00002 21282
Sildenafil citrate, Testosterone		Product Specific Waiver	Positive	Psychiatric disorders	Freya Pharma Solutions Holding B.V.	10/25/2024	EMA/PE/00001 81891
Bitopertin		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Disc Medicine B.V.	10/25/2024	P/0352/2024
Venglustat		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sanofi B.V.	10/25/2024	P/0385/2024
Proline derivative		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Boehringer Ingelheim International gmbh	10/25/2024	P/0371/2024
3,3-Dimethyl-N-(6-methyl-5-{[2-(1-methyl-1H-pyrazol-4-yl)pyridine-4-yl]oxy}pyridine-2-yl)-2-oxopyrrolidine-1-carboxamide hydrochloride hydrate (ABSK021)		Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbisko Therapeutics Co. Ltd.	10/25/2024	P/0373/2024
(R)-3-(1-cyclopropyl-3-(2-fluoro-4-(trifluoromethoxy)benzyl)ureido)piperidine-1-carboxamide		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Jnana Therapeutics Inc.	10/25/2024	P/0357/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Idroxioleic acid, sodium	Milynvo	Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laminar Pharmaceuticals S.A.	10/25/2024	P/0369/2024
Mepolizumab	Nucala	Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Glaxosmithkline Trading Services Limited	10/25/2024	P/0367/2024
Ustekinumab	Stelara	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Janssen Cilag International	10/25/2024	P/0370/2024
Ambrisentan	Volibris	Modification of Paediatric Investigation Plan	Negative	Respiratory, thoracic and mediastinal disorders	Glaxosmithkline (Ireland) Limited	10/25/2024	P/0384/2024
Posaconazole	Noxafil	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	MSD Europe Belgium	10/25/2024	P/0376/2024
Teplizumab	Tzield	Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Sanofi Winthrop Industrie	10/25/2024	P/0386/2024
Dupilumab	Dupixent	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Sanofi Winthrop Industrie	10/25/2024	P/0353/2024
Upadacitinib	Rinvoq	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Abbvie Limited	10/25/2024	P/0354/2024
Vamorolone	Agamree	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Santhera Pharmaceuticals (Deutschland) gmbh	10/25/2024	P/0355/2024
Daunorubicin / cytarabine	Vyxeos liposomal	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Jazz Pharmaceuticals Ireland Limited	10/25/2024	P/0356/2024
Avapritinib	Ayvakyt	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Blueprint Medicines (Netherlands) B.V.	10/25/2024	P/0363/2024
Zirconium (89Zr) girentuximab senvedoxam		Product Specific Waiver	Positive	Renal and urinary disorders	Telix Innovations	10/25/2024	P/0362/2024
Lenacapavir sodium	Sunlenca	Initial Paediatric Investigation Plan	Positive	Infections and infestations	Gilead Sciences International Limited	10/25/2024	P/0372/2024
Brensocatib	Brinsupri	Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and	Insmed Netherlands B.V.	10/25/2024	P/0359/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				mediastinal disorders			
Fidrisertib		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Ipsen Pharma	10/25/2024	P/0360/2024
Pridopidine (hydrochloride)	Nurzigma	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Prilenia Therapeutics B.V.	10/25/2024	P/0364/2024
Mrna encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-cov-2 (mrna-1283)		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Moderna Biotech Spain S.L.	10/25/2024	P/0365/2024
Recombinant varicella zoster virus glycoprotein E adjuvanted (CRV-101)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Curevo Inc.	10/25/2024	P/0379/2024
Dexfadrostat phosphate		Product Specific Waiver	Positive	Endocrine disorders	Damian Pharma AG	10/25/2024	P/0366/2024
Recombinant human progranulin fused to an Fc fragment engineered to contain a human transferrin receptor 1 binding domain (DNL593)		Product Specific Waiver	Positive	Nervous system disorders	Denali Therapeutics Inc.	10/25/2024	P/0361/2024
Plinabulin	Plinabulin monohydrate	Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Beyondspring Pharmaceuticals Inc.	10/25/2024	P/0368/2024
ALK inhibitor (NVL-655)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nuvalent Inc.	10/25/2024	P/0378/2024
Zidesamtinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nuvalent Inc.	10/25/2024	P/0358/2024
Ibrexafungerp		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Scynexis Inc.	10/25/2024	EMA/PE/00002 25106
Dazukibart		Initial Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Pfizer Europe MA EEIG	10/24/2024	P/0377/2024
Romosozumab	Evenity	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	UCB Pharma	10/24/2024	P/0375/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Lomitapide (as lomitapide mesylate)	Lojuxta	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Chiesi Farmaceutici S.p.A.	10/24/2024	P/0374/2024
Tazobactam / ceftolozane	Zerbaxa	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Merck Sharp & Dohme B.V.	10/24/2024	P/0381/2024
Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1Motifs 13 (radamts13)	Adzynma	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Takeda Pharmaceuticals International AG	10/24/2024	P/0383/2024
Zipalertinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Taiho Pharma Netherlands B.V.	10/24/2024	P/0380/2024
Belatacept	Nulojix	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Bristol-Myers Squibb Services Unlimited Company	9/27/2024	P/0351/2024
Ganaxolone	Ztalmy	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Marinus Pharmaceuticals Inc.	9/27/2024	P/0350/2024
Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid	Menquadfi	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur Europe	9/24/2024	P/0349/2024
Pegcetacoplan	Aspaveli	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Swedish Orphan Biovitrum AB (publ)	9/24/2024	P/0348/2024
Mrna encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein, mrna encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein, mrna encoding Influenza B/Victoria, hemagglutinin glycoprotein, mrna-1283		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Moderna Biotech Spain S.L.	9/20/2024	EMA/PE/00002 27301

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Osilodrostat	Isturisa	Modification of Paediatric Investigation Plan	Positive	Endocrine disorders	Recordati Rare Diseases	9/13/2024	P/0325/2024
Recombinant varicella zoster virus (VZV) glycoprotein E	Shingrix	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Glaxosmithkline Biologicals	9/13/2024	P/0328/2024
Tasimelteon	Hetlioz	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Vanda Pharmaceuticals Netherlands B.V.	9/13/2024	P/0329/2024
Aldesleukin		Product Specific Waiver	Positive	Nervous system disorders	Iltoo Pharma	9/13/2024	P/0333/2024
Patiromer sorbitex calcium	Veltassa	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Vifor France	9/13/2024	P/0313/2024
Gemtuzumab Ozogamicin	Mylotarg	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	9/13/2024	P/0314/2024
Macimorelin acetate	Ghryvelin	Modification of Paediatric Investigation Plan	Positive	Endocrine disorders	Atnahs Pharma Netherlands B.V.	9/13/2024	P/0331/2024
Leriglitazone	Nezglyal	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Minoryx Therapeutics S.L.	9/13/2024	P/0330/2024
Cefiderocol	Fetcroja	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Shionogi B.V.	9/13/2024	P/0337/2024
Daratumumab	Darzalex	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	9/13/2024	P/0339/2024
Lasmiditan	Rayvow	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Eli Lilly And Company Limited	9/13/2024	P/0342/2024
Rezafungin Acetate	Rezzayo	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Mundipharma gmbh	9/13/2024	P/0343/2024
Deucravacitinib	SOTYKTU	Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Bristol-Myers Squibb Services Unlimited Company	9/13/2024	P/0319/2024
Spesolimab	Spevigo	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Boehringer Ingelheim International gmbh	9/13/2024	P/0341/2024
Tafasitamab	Minjuvi	Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Incyte Biosciences Distribution B.V.	9/13/2024	P/0344/2024
Ibrexafungerp citrate		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Scynexis Inc.	9/13/2024	P/0347/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Iptacopan	Fabhalta	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Novartis Europharm Limited	9/13/2024	P/0322/2024
Iptacopan		Initial Paediatric Investigation Plan	Positive	Nervous system disorders	Novartis Europharm Limited	9/13/2024	P/0324/2024
Etrasimod L-arginine	Velsipity	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Pfizer Europe MA EEIG	9/13/2024	P/0321/2024
Rimegepant	Vydura	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Pfizer Europe MA EEIG	9/13/2024	P/0320/2024
Human plasma derived C1-inhibitor (OCTA-C1-INH)		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Octapharma Pharmazeutika Produktionsgesellschaft mbh	9/13/2024	P/0323/2024
Sotrovimab	Xevudy	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Glaxosmithkline Trading Services Limited	9/13/2024	P/0334/2024
Seralutinib		Initial Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Gossamer Bio 002 Limited	9/13/2024	P/0327/2024
Zamtocabtagene autoleucel		Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Miltenyi Biotec gmbh	9/13/2024	P/0335/2024
Retatrutide	Retatrutide	Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Eli Lilly And Company Limited	9/13/2024	P/0336/2024
Hydroxycarbamide	Siklos paediatric dispersible tablets	Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Addmedica	9/13/2024	P/0345/2024
Belumosudil	Rezurock	Initial Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Sanofi Winthrop Industrie	9/13/2024	P/0346/2024
Mannose-1-phosphate		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Glycomine Inc.	9/13/2024	P/0332/2024
Recombinant humanized igg1, kappa light chain, long-acting monoclonal antibody		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Astria Therapeutics Inc.	9/13/2024	P/0316/2024
Rilonacept	Arcalyst (withdrawn), Rilonacept	Initial Paediatric Investigation Plan	Positive	Cardiac disorders	Kiniksa Pharmaceuticals (UK) Limited	9/13/2024	P/0317/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
	Regeneron (withdrawn)						
Rupatadine fumarate / Montelukast sodium		Product Specific Waiver	Negative	Respiratory, thoracic and mediastinal disorders	Noucor Health S.A.	9/13/2024	P/0318/2024
Empagliflozin / Derivative of 3-phenyl-3H,4H,6H,7H-pyrano[3,4-d]imidazol-4-one (BI 690517) / Empagliflozin		Product Specific Waiver	Positive	Cardiac disorders	Boehringer Ingelheim International gmbh	9/13/2024	P/0326/2024
Rememulgene arelactibac		Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Aurealis Oy	9/13/2024	P/0338/2024
Ebola Zaire Vaccine (rvsvΔG-ZEBOV-GP, live)	Ervebo	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Merck Sharp & Dohme B.V.	9/13/2024	P/0315/2024
Adeno-associated viral vector serotype 8 containing the 3' human otoferlin coding sequence / Adeno-associated viral vector serotype 8 containing the 5' human otoferlin coding sequence		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sensorion	9/11/2024	P/0340/2024
Avelumab	Bavencio	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merck Healthcare kgaa	8/22/2024	P/0312/2024
Pretomanid	Dovprela	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	The Global Alliance For TB Drug Development Inc.	8/20/2024	P/0295/2024
Ceftobiprole medocaril sodium	Zevtera and associated names	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Basilea Pharmaceutica Deutschland gmbh	8/16/2024	P/0299/2024
Midostaurin	Rydapt	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Novartis Europharm Limited	8/16/2024	P/0305/2024
Benralizumab	Fasenra	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Astrazeneca AB	8/16/2024	P/0307/2024
Human normal immunoglobulin		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	LFB Biotechnologies	8/16/2024	P/0303/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Bupropion hcl / Naltrexone hcl	Mysimba	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Orexigen Therapeutics Ireland Limited	8/16/2024	P/0280/2024
Tezepelumab	Tezspire	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Astrazeneca AB	8/16/2024	P/0281/2024
Ketamine / Sufentanil		Modification of Paediatric Investigation Plan	Positive	General disorders and administration site conditions	Cessatech A/S	8/16/2024	P/0282/2024
Rilpivirine (RPV) / Dolutegravir (DTG)	Juluca	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Viiv Healthcare Limited	8/16/2024	P/0283/2024
Tenofovir alafenamide / emtricitabine / cobicistat / darunavir	Symtuza	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Janssen Cilag International	8/16/2024	P/0284/2024
Fitusiran	Fitusiran	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sanofi B.V.	8/16/2024	P/0285/2024
Vadadustat	Vafseo	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Medice Arzneimittel Puetter gmbh & Co. KG	8/16/2024	P/0290/2024
Gadopiclenol	Elucirem	Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Guerbet	8/16/2024	P/0294/2024
Gadopiclenol	Elucirem	Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Guerbet	8/16/2024	P/0293/2024
Dexamethasone sodium phosphate encapsulated in human autologous erythrocytes		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Quince Therapeutics S.p.A.	8/16/2024	P/0291/2024
Vosoritide	Voxzogo	Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Biomarin International Limited	8/16/2024	P/0286/2024
Gilteritinib (as fumarate)	Xospata	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Astellas Pharma Europe B.V.	8/16/2024	P/0289/2024
Meloxicam / Bupivacaine	Zynrelef	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Heron Therapeutics B.V.	8/16/2024	P/0296/2024
Narsoplimab	Yartemlea	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Omeros Ireland Limited	8/16/2024	P/0297/2024
Cenobamate	Ontozry	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Aziende Chimiche Riunite Angelini	8/16/2024	P/0279/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
					Francesco A.C.R.A.F. S.p.A.		
Efgartigimod alfa	Vyvgart	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Argenx Benelux	8/16/2024	P/0298/2024
Survodutide		Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Boehringer Ingelheim International gmbh	8/16/2024	P/0259/2024
Osivelotor		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Pfizer Europe MA EEIG	8/16/2024	P/0302/2024
Humanised monoclonal antibody Fab fragment		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sanofi B.V.	8/16/2024	P/0304/2024
Fosigotifator sodium tromethamine		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Abbvie Limited	8/16/2024	P/0306/2024
Mezagitamab		Initial Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Takeda Pharmaceuticals International AG	8/16/2024	P/0292/2024
Transglutaminase 2 inhibitor (ZED1227)		Initial Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Dr. Falk Pharma gmbh	8/16/2024	P/0308/2024
Single-stranded 5' capped mrna encoding the has of the influenza virus strains A/H1N1, A/H3N2, and B/Victoria and the N-terminal domain (NTD) and receptor binding domain (RBD) of the SARS-cov-2 spike glycoprotein (mrna-1083)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Moderna Biotech Spain S.L.	8/16/2024	P/0309/2024
Copper (64Cu) oxodotreotide		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Curium Pet France	8/16/2024	P/0301/2024
Tarumase		Product Specific Waiver	Negative	Injury, poisoning and procedural complications	Solascure Limited	8/16/2024	P/0310/2024
Inobrodib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cellcentric Limited	8/16/2024	P/0287/2024
Efinopegdutide		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	MSD Europe Belgium	8/15/2024	P/0311/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Navepegritide		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Ascendis Pharma A/S	8/14/2024	P/0275/2024
Crinecerfont		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Neurocrine Therapeutics Limited	8/14/2024	P/0278/2024
Vonoprazan		Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Phathom Pharmaceuticals Inc.	8/14/2024	P/0277/2024
Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded		Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Medac Gesellschaft für klinische Spezialpräparate mbh	8/14/2024	P/0276/2024
Multivalent pneumococcal polysaccharide conjugate to carrier protein		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur	8/14/2024	P/0288/2024
COVID-19 Vaccine (chadox1-S [recombinant])	Vaxzevria	Modification of Paediatric Investigation Plan	Positive (Waiver)	Infections and infestations	Astrazeneca AB	8/14/2024	P/0273/2024
Buparlisib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adlai Nortye USA Inc.	8/14/2024	P/0274/2024
Anitocabtagene autoleucel		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Kite Pharma EU B.V.	8/14/2024	P/0300/2024
Acasunlimab		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Genmab A/S	7/24/2024	P/0272/2024
Lamivudine / Dolutegravir	Dovato	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Viiv Healthcare Limited	7/19/2024	P/0243/2024
Pegvaliase	Palynziq	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Biomarin International Limited	7/19/2024	P/0241/2024
Mexiletine hydrochloride	Namuscla	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Lupin Europe gmbh	7/19/2024	P/0227/2024
Raav8 viral vector encoding the human UGT1A1 transgene (raav8-hugt1a1)		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Genethon	7/19/2024	P/0228/2024
Niraparib tosylate monohydrate	Zejula	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and	Glaxosmithkline (Ireland) Limited	7/19/2024	P/0229/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Ralinepag		Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	United Therapeutics Corp.	7/19/2024	P/0230/2024
Ibrexafungerp		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Scynexis Inc.	7/19/2024	P/0240/2024
Lenacapavir sodium	Sunlenca	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Gilead Sciences International Limited	7/19/2024	P/0271/2024
Ublituximab	Briumvi	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Neuraxpharm Pharmaceuticals S.L.	7/19/2024	P/0254/2024
Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-M1 adjuvant	Nuvaxovid	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Novavax CZ a.s.	7/19/2024	P/0255/2024
SARS-cov-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion homodimer – XBB.1.16-XBB.1.16 variant	Bimervax	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Hipra Human Health S.L.	7/19/2024	P/0253/2024
Ensitrelvir	Zokovea	Initial Paediatric Investigation Plan	Positive	Infections and infestations	Shionogi B.V.	7/19/2024	P/0242/2024
Derivative of azabicycloheptane-carboxamide		Initial Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Boehringer Ingelheim International gmbh	7/19/2024	P/0252/2024
Autologous CD3-positive T cells transduced with a retroviral vector containing an anti-B cell maturation agent chimeric antigen receptor gene		Product Specific Waiver	Positive	Immune system disorders	Nexcella Inc.	7/19/2024	P/0233/2024
Fulzerasib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Zhejiang Genfleet Therapeutics Co. Ltd.	7/19/2024	P/0231/2024
3-tert-butyl-N-{(1R)-1-[4-(6-{6-[4-({1-[4-(2,4-dioxo-1,3-		Product Specific Waiver	Positive	Neoplasms benign, malignant and	Beigene Ireland Limited	7/19/2024	P/0232/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
diazinan-1-yl)phenyl]piperidin-4-yl}methyl)piperazin-1-yl]pyridin-3-yl}-7H-pyrrolo[2,3-d]pyrimidin-4-yl)-2-methylphenyl]ethyl}-1,2,4-oxadiazole-5-carboxamide				unspecified (incl cysts and polyps)			
4-Benzoyl-D-phenylalanyl-D-seryl-D-tryptophyl-D-seryl-2,3,4,5,6-pentafluoro-D-phenylalanyl-3-cyclohexyl-D-alanyl-D-arginyl-D-arginyl-D-arginyl-D-glutaminyl-D-arginyl-D arginine acetate		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Canbas Co. Ltd.	7/19/2024	P/0257/2024
Anti-human LAG-3 monoclonal antibody, human igg4 isotype		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Beigene Ireland Limited	7/19/2024	P/0256/2024
Trastuzumab-exatecan derivative antibody-drug conjugate		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Biontech SE	7/19/2024	P/0270/2024
Alvelestat (tosylate)		Product Specific Waiver	Positive	Congenital, familial and genetic disorders	Mereo Biopharma Ireland Limited	7/19/2024	P/0258/2024
Diclofenac (sodium) / thiocolchicoside		Product Specific Waiver	Positive	Musculoskeletal and connective tissue disorders	Doc Generici S.r.l.	7/19/2024	P/0251/2024
Ifinatamab deruxtecan		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe gmbh	7/19/2024	P/0250/2024
Regadenoson	Rapiscan	Modification of Paediatric Investigation Plan	Positive	Cardiac disorders	GE Healthcare AS	7/18/2024	P/0238/2024
Tofacitinib	Xeljanz	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Pfizer Europe MA EEIG	7/18/2024	P/0239/2024
Vedolizumab	Entyvio	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Takeda Pharma A/S	7/18/2024	P/0244/2024
Dermatophagoides farinae extracts	Acaroid	Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Allergopharma gmbh & Co. KG	7/18/2024	P/0245/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Dermatophagoides pteronyssinus extracts 100%	Acaroid	Modification of Paediatric Investigation Plan	Positive	Immune system disorders	Allergopharma gmbh & Co. KG	7/18/2024	P/0247/2024
Dermatophagoides pteronyssinus/Dermatophagoides farinae extracts (50%/50%)	Acaroid	Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Allergopharma gmbh & Co. KG	7/18/2024	P/0248/2024
Vonicog alfa	Veyvondi	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	BAXALTA INNOVATIONS gmbh	7/18/2024	P/0236/2024
Cariprazine hydrochloride	Reagila	Modification of Paediatric Investigation Plan	Positive	Psychiatric disorders	Gedeon Richter Plc.	7/18/2024	P/0235/2024
Allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells	Amesanar	Product Specific Waiver	Positive	Vascular disorders	Rheacell gmbh & Co. KG	7/18/2024	P/0237/2024
Donidalorsen		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Otsuka Pharmaceutical Netherlands B.V.	7/18/2024	P/0246/2024
Gefurulimab		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Alexion Europe	7/18/2024	P/0249/2024
Autologous CD3-positive T cells transduced with a retroviral vector containing an anti-B cell maturation agent chimeric antigen receptor gene		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nexcella Inc.	7/18/2024	P/0234/2024
Dostarlimab	Jemperli	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline Trading Services Limited	7/17/2024	P/0260/2024
Islatravir / doravirine		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	MSD Europe Belgium	7/17/2024	P/0268/2024
Ribociclib	Kisqali	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Novartis Europharm Limited	7/17/2024	P/0266/2024
Botaretigene sparoparvovec		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Janssen Cilag International	7/17/2024	P/0269/2024
Indapamide / Ramipril		Product Specific Waiver	Positive	Vascular disorders	Adamed Pharma S.A.	7/17/2024	P/0267/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Zanubrutinib	Brukinsa	Product Specific Waiver	Positive	Blood and lymphatic system disorders	Beigene Ireland Limited	7/10/2024	P/0226/2024
Setrusumab		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Mereo Biopharma Ireland Limited	7/5/2024	P/0225/2024
Epcoritamab	Tepkinly	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	6/27/2024	P/0224/2024
Brexucabtagene autoleucel	Tecartus	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Kite Pharma EU B.V.	6/20/2024	P/0221/2024
Iptacopan	Fabhalta	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Novartis Europharm Limited	6/20/2024	P/0222/2024
Mirdametinib		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Springworks Therapeutics Ireland Limited	6/20/2024	P/0223/2024
Sitagliptin / Dapagliflozin		Product Specific Waiver	Positive	Endocrine disorders	Althera Laboratories Limited	6/20/2024	P/0196/2024
Mecasermin rinfabate		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Ohb Neonatology Limited	6/14/2024	P/0187/2024
Linaclotide	Constella	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Abbvie Biotechnology gmbh	6/14/2024	P/0207/2024
Olokizumab	Artlegia	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Accelsiors gmbh	6/14/2024	P/0208/2024
Ertugliflozin	Steglatro	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	MSD Europe Belgium	6/14/2024	P/0189/2024
Relebactam monohydrate / cilastatin sodium / imipenem monohydrate	Recarbrio	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	MSD Europe Belgium	6/14/2024	P/0190/2024
Quizartinib	Vanflyta	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe gmbh	6/14/2024	P/0203/2024
Inebilizumab	Uplizna	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Horizon Therapeutics	6/14/2024	P/0206/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
					Ireland Designated Activity Company		
Calcifediol	Rayaldee	Modification of Paediatric Investigation Plan	Positive	Endocrine disorders	Vifor France	6/14/2024	P/0211/2024
Ianalumab		Initial Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Novartis Europharm Limited	6/14/2024	P/0198/2024
Rivoceranib	Tulvegio	Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Elevar Therapeutics Inc.	6/14/2024	P/0191/2024
Lebrikizumab	Ebglyss	Product Specific Waiver	Positive	Respiratory, thoracic and mediastinal disorders	Almirall S.A.	6/14/2024	P/0212/2024
Soticlestat		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Takeda Pharma A/S	6/14/2024	P/0194/2024
Pegcetacoplan	Aspaveli	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Apellis Ireland Limited	6/14/2024	P/0195/2024
Obefazimod		Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Abivax	6/14/2024	P/0205/2024
Brigimadlin	Fytemtu or Brypemdi (tentative, to be confirmed)	Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Boehringer Ingelheim International gmbh	6/14/2024	P/0199/2024
Gallium (68Ga) boclatixafortide		Product Specific Waiver	Positive	Endocrine disorders	Pentixapharm AG	6/14/2024	P/0213/2024
Derivative of pyrindin-2-yl)cyclopropanecarboxamide hydrochloride		Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Alumis Inc.	6/14/2024	P/0204/2024
Autologous viable CD45+CD3+ T-cells isolated and expanded from a melanoma metastasis		Initial Paediatric Investigation Plan	Positive (Waiver)	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Netherlands Cancer Institute	6/14/2024	P/0201/2024
Telisotuzumab conjugated to (2S)-2-(2-bromoacetamido)-N-[(2S)-1-({3-[(7S)-7-ethyl-7-hydroxy-8,11-dioxo-7,8,11,13-tetrahydro-2H,10H-[1,3]dioxolo[4,5-g]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-14-		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	6/14/2024	P/0192/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
yl]bicyclo[1.1.1]pentan-1-yl}amino)-1-oxopropan-2-yl]-3-methylbutanamide (ABBV-400)							
Derivative of 1,5,6,7-tetrahydro-4H-pyrrolo[3,2-c]pyridin-4-one		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bayer AG	6/14/2024	P/0209/2024
Ezetimibe / Rosuvastatin		Product Specific Waiver	Positive	Cardiac disorders	Verisfield S.M.S.A.	6/14/2024	P/0210/2024
(5asa,17ara)-20-Chloro-2-[(2S,5R)-2,5-dimethyl-4-(prop-2-enoyl)piperazin-1-yl]-14,17-difluoro-6-(propan-2-yl)-11,12-dihydro-4H-1,18-(ethanediylidene)pyrido[4,3-e]pyrimido[1,6-g][1,4,7,9]benzodioxadiazacyclododecin-4-one (MK-1084)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	MSD Europe Belgium	6/14/2024	P/0202/2024
Trofinetide		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Acadia Pharmaceuticals Inc.	6/14/2024	P/0188/2024
Fenofibrate / Rosuvastatin calcium		Product Specific Waiver	Positive	Metabolism and nutrition disorders	Verisfield S.M.S.A.	6/14/2024	P/0200/2024
Recombinant Influenza Hemagglutinin-strain B / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Winthrop Industrie	6/14/2024	P/0220/2024
Inebilizumab	Uplizna	Modification of Paediatric Investigation Plan	Positive	Surgical and medical procedures	Horizon Therapeutics Ireland Designated Activity Company	6/13/2024	P/0217/2024
Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2	Supemtek	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur Europe	6/13/2024	P/0218/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype)							
Recombinant adeno-associated virus Olig001 containing human aspartoacylase cdna		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Myrtelle Inc.	6/13/2024	P/0214/2024
Radiprodil		Initial Paediatric Investigation Plan	Positive	Nervous system disorders	Grin Therapeutics Inc.	6/13/2024	P/0197/2024
Human alpha-1 proteinase inhibitor, modified (serpinpc)		Initial Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Apcintex Limited	6/13/2024	P/0215/2024
Certepetide		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lisata Therapeutics Ireland Limited	6/13/2024	P/0216/2024
Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage	Fluarix (Influsplit for Germany)	Initial Paediatric Investigation Plan	Positive	Infections and infestations	Glaxosmithkline Biologicals	6/13/2024	P/0219/2024
Actinium-225-2-(4,7,10-tris-carboxymethyl-1,4,7,10 tetraaza-cyclododec-1-yl)-pentanedioic acid 3-iodo-D-Tyr-D-Phe-D-Lys-OH)-8-oyl-ε-(HO-Glu-ureido-Lys-OH)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	NDA Regulatory Science Limited	6/5/2024	P/0193/2024
Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid	Menquadfi	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur Europe	5/29/2024	P/0186/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Mavorixafor		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	X4 Pharmaceuticals (Austria) gmbh	5/23/2024	P/0185/2024
Mometasone furoate		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Orphix Consulting gmbh	5/17/2024	P/0184/2024
Ganaxolone	Ztalmy	Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Marinus Pharmaceuticals Inc.	5/17/2024	P/0183/2024
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)	Fluad	Product Specific Waiver	Positive	Infections and infestations	European Medicines Agency	5/16/2024	P/0180/2024
Zasocitinib		Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Takeda Pharma A/S	5/15/2024	P/0182/2024
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)	Flucelvax	Initial Paediatric Investigation Plan	Positive	Infections and infestations	European Medicines Agency	5/15/2024	P/0181/2024
Apixaban	Eliquis	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Bristol-Myers Squibb Services Unlimited Company	5/6/2024	P/0135/2024
13 Grass Aqueous Extract		Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Allergy Therapeutics (UK) Limited	5/6/2024	P/0177/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Clostridium botulinum neurotoxin type A (150 kd), free from complexing proteins	Xeomin (and Xeomeen), Bocouture	Product Specific Waiver	Positive	Nervous system disorders	Merz Pharmaceuticals gmbh	5/6/2024	P/0136/2024
Avatrombopag maleate	Doptelet	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Swedish Orphan Biovitrum AB (publ)	5/6/2024	P/0137/2024
Nivolumab	Opdivo	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Services Unlimited Company	5/6/2024	P/0138/2024
Brexucabtagene autoleucel	Tecartus	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Kite Pharma EU B.V.	5/6/2024	P/0176/2024
Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate	Riarify, Trydonis, Trimbow	Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Chiesi Farmaceutici S.p.A.	5/6/2024	P/0167/2024
Erdafitinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	5/6/2024	P/0145/2024
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) [qivc]	Flucelvax Tetra	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Seqirus Netherlands B.V.	5/6/2024	P/0168/2024
Onasemnogene abeparvovec	Zolgensma	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Novartis Europharm Limited	5/6/2024	P/0149/2024
Olaparib	Lynparza	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Astrazeneca AB	5/6/2024	P/0148/2024
Berotralstat	Orladeyo	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Biocryst Ireland Limited	5/6/2024	P/0151/2024
Levonorgestrel		Modification of Paediatric Investigation Plan	Positive	Surgical and medical procedures	Chemo Research S.L.	5/6/2024	P/0163/2024
Spesolimab	Spevigo	Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Boehringer Ingelheim International gmbh	5/6/2024	P/0157/2024
Amivantamab	Rybrevant	Product Specific Waiver	Positive	Neoplasms benign, malignant and	Janssen Cilag International	5/6/2024	P/0166/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Giroctocogene fitelparvovec		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Pfizer Europe MA EEIG	5/6/2024	P/0164/2024
Nivolumab / relatlimab	Opdualag	Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Services Unlimited Company	5/6/2024	P/0169/2024
Etavopivat		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Novo Nordisk A/S	5/6/2024	P/0158/2024
Live, attenuated, dengue virus, serotype 4 (DENV4) / Live, attenuated, dengue virus, serotype 3 (DENV3) / Live, attenuated, chimeric dengue virus, serotype 2 (DENV2) / Live, attenuated, dengue virus, serotype 1 (DENV1)		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	MSD Europe Belgium	5/6/2024	P/0165/2024
Live attenuated respiratory syncytial virus (RSV)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur	5/6/2024	P/0153/2024
Orforglipron		Initial Paediatric Investigation Plan	Positive	Endocrine disorders	Eli Lilly And Company Limited	5/6/2024	P/0178/2024
Tozorakimab		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Astrazeneca AB	5/6/2024	P/0144/2024
Tanimilast		Initial Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Chiesi Farmaceutici S.p.A.	5/6/2024	P/0170/2024
Sevasemten		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	FGK Representative Service gmbh	5/6/2024	P/0179/2024
Laruparetigene zovaparvovec		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	FGK Representative Service gmbh	5/6/2024	P/0159/2024
Messenger RNA encoding Cas9, single guide RNA targeting the human KLKB1 gene (NTLA-2002)		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Intellia Therapeutics Inc.	5/6/2024	P/0142/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Lutikizumab		Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Abbvie Limited	5/6/2024	P/0150/2024
Acetylcysteine amide		Product Specific Waiver	Positive	Vascular disorders	Arctic Therapeutics ehf.	5/6/2024	P/0139/2024
Petosemtamab		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merus N.V.	5/6/2024	P/0147/2024
Dapagliflozin (propanediol monohydrate) / baxdrostat		Product Specific Waiver	Positive	Renal and urinary disorders	Astrazeneca AB	5/6/2024	P/0146/2024
Carbachol / brimonidine tartrate		Product Specific Waiver	Positive	Eye disorders	Visus Therapeutics Inc.	5/6/2024	P/0160/2024
Fenofibrate / Ezetimibe / rosuvastatin calcium		Product Specific Waiver	Positive	Congenital, familial and genetic disorders	Althera Laboratories Limited	5/6/2024	P/0161/2024
Atorvastatin calcium / fenofibrate		Product Specific Waiver	Positive	Congenital, familial and genetic disorders	Althera Laboratories Limited	5/6/2024	P/0162/2024
Camreluzimab		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Luzsana Biotechnology Europe AG	5/6/2024	P/0154/2024
Volixibat potassium		Product Specific Waiver	Positive	Hepatobiliary disorders	Mirum Pharmaceuticals Inc.	5/6/2024	P/0155/2024
Human alpha-1-proteinase inhibitor immunoglobulin G fusion protein, recombinant		Product Specific Waiver	Positive	Respiratory, thoracic and mediastinal disorders	Inhibrx Inc.	5/6/2024	P/0156/2024
Ezetimibe / Pitavastatin		Product Specific Waiver	Positive	Metabolism and nutrition disorders	KRKA tovarna zdravil d.d. Novo mesto	5/6/2024	P/0143/2024
Loncastuximab tesirine	Zynlonta	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Swedish Orphan Biovitrum AB (publ)	5/6/2024	P/0152/2024
Hemopexin, human		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	CSL Behring gmbh	5/6/2024	P/0141/2024
Riletamotide / tapderimotide / alrefimotide		Product Specific Waiver	Positive	Neoplasms benign, malignant and	ULTIMOVACS ASA	5/6/2024	P/0140/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Atrasentan		Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Chinook Therapeutics Inc.	5/3/2024	P/0171/2024
Venglustat	Infilbray	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Sanofi B.V.	5/3/2024	P/0172/2024
N-(2-((2-(dimethylamino)ethyl)(methyl)amino)-5-((4-(1-methyl-1H-indol-3-yl)pyrimidin-2-yl)amino)-6-(2,2,2-trifluoroethoxy)pyridin-3-yl)acrylamide methanesulfonate		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Arrivent Biopharma Inc.	5/3/2024	P/0174/2024
Human rabies immune globulin		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Kamada Ireland Limited	5/3/2024	P/0175/2024
Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens (V940/mrna-4157)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	MSD Europe Belgium	5/3/2024	P/0173/2024
Selumetinib	Koselugo	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Astrazeneca AB	4/25/2024	P/0134/2024
Belimumab	Benlysta	Initial Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Glaxosmithkline Trading Services Limited	4/12/2024	P/0109/2024
Afamelanotide	Scenesse®	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Clinuvel Europe Limited	4/12/2024	P/0101/2024
Palonosetron / netupitant	Akynzeo	Product Specific Waiver	Positive	Surgical and medical procedures	Helsinn Birex Pharmaceuticals Limited	4/12/2024	P/0132/2024
Baricitinib	Olumiant	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Eli Lilly And Company Limited	4/12/2024	P/0117/2024
Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Recombinant Neisseria		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Glaxosmithkline Biologicals	4/12/2024	P/0118/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
meningitis group B Protein 961c / Recombinant Neisseria meningitis group B Protein 287- 953 / Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Recombinant Neisseria meningitis group B Protein 936-741 / Outer Membrane Vesicles (OMV) from N. Meningitidis Strain NZ 98/254							
In vitro expanded autologous human articular chondrocytes	Artobend	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	TETEC Tissue Engineering Technologies AG	4/12/2024	P/0114/2024
Alpelisib	Piqray	Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Novartis Europharm Limited	4/12/2024	P/0090/2024
Fidanacogene elaparvovec		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Pfizer Europe MA EEIG	4/12/2024	P/0115/2024
Catequentinib		Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Advenchen Laboratories LLC	4/12/2024	P/0110/2024
Efgartigimod alfa	Vyvgart	Product Specific Waiver	Positive	Eye disorders	Argenx Benelux	4/12/2024	P/0111/2024
Ruxolitinib (phosphate)	Opzelura, Jakavi	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Incyte Biosciences Distribution B.V.	4/12/2024	P/0102/2024
Garetosmab	Fopsivva	Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Regeneron Ireland Designated Activity Company	4/12/2024	P/0103/2024
Seltorexant		Modification of Paediatric Investigation Plan	Positive	Psychiatric disorders	Janssen Cilag International	4/12/2024	P/0104/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Multivalent pneumococcal polysaccharide conjugate to carrier protein		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur	4/12/2024	P/0113/2024
Tozinameran, Tozinameran / famtozinameran, Tozinameran/ riltozinameran, Raxtozinameran	Comirnaty	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Biontech SE	4/12/2024	P/0105/2024
Trimodulin (human igm, iga, igg solution)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Biotest AG	4/12/2024	P/0120/2024
Vamikibart		Modification of Paediatric Investigation Plan	Positive	Eye disorders	Roche Registration gmbh	4/12/2024	P/0091/2024
Milvexian		Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Janssen Cilag International	4/12/2024	P/0092/2024
Suvecaltamide Hydrochloride		Product Specific Waiver	Positive	Nervous system disorders	Jazz Pharmaceuticals Ireland Limited	4/12/2024	P/0121/2024
Povorcitinib		Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Incyte Biosciences Distribution B.V.	4/12/2024	P/0096/2024
CX-000359 mrna encoding the UL128 protein in the CMV glycoprotein complex pentamer / CX- 000594 mrna encoding the gl protein in the CMV glycoprotein complex pentamer / CX- 000712 mrna encoding the UL130 protein in the CMV glycoprotein complex pentamer / CX-005128 mrna encoding the UL131A protein in the CMV glycoprotein complex pentamer / CX-005282 m-RNA encoding the gh protein in the CMV glycoprotein complex pentamer / CX-000667 mrna encoding CMV gb (mrna-1647)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Moderna Biotech Spain S.L.	4/12/2024	P/0097/2024
Disitamab vedotin		Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seagen B.V.	4/12/2024	P/0126/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Losmapimod		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Fulcrum Therapeutics Inc.	4/12/2024	P/0116/2024
Enlicitide (decanoate)		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	MSD Europe Belgium	4/12/2024	P/0133/2024
Empasiprubart		Product Specific Waiver	Positive	Nervous system disorders	Argenx Benelux	4/12/2024	P/0093/2024
Ramipril / Nebivolol		Product Specific Waiver	Positive	Cardiac disorders	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	4/12/2024	P/0106/2024
Dapagliflozin / sitagliptin		Product Specific Waiver	Positive	Metabolism and nutrition disorders	Rontis Hellas Medical And Pharmaceutical Products S.A.	4/12/2024	P/0107/2024
Human hydroxysteroid-17ß-dehydrogenase type 1 (HSD17B1) enzyme inhibitor		Product Specific Waiver	Positive	Reproductive system and breast disorders	Organon N.V.	4/12/2024	P/0094/2024
Vixarelimab		Product Specific Waiver	Positive	Respiratory, thoracic and mediastinal disorders	Roche Registration gmbh	4/12/2024	P/0095/2024
Urea / Propylene glycol		Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Aco Hud Nordic AB	4/12/2024	P/0127/2024
Autologous T-cells expressing a chimeric antigenic receptor against G protein coupled receptor class C group 5 member D (GPRC5D) (BMS-986393)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Services Unlimited Company	4/12/2024	P/0128/2024
Zongertinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Boehringer Ingelheim International gmbh	4/12/2024	P/0108/2024
Human igg1 monoclonal antibody targeting amyloid transthyretin		Product Specific Waiver	Positive	Immune system disorders	Alexion Europe	4/12/2024	P/0112/2024
Filgotinib	Jyseleca	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Galapagos	4/12/2024	P/0119/2024
Mirikizumab	Omvoh	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Eli Lilly And Company Limited	4/11/2024	P/0130/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Mirikizumab	Omvoh	Initial Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Eli Lilly And Company Limited	4/11/2024	P/0129/2024
Aficamten		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Cytokinetics Inc.	4/11/2024	P/0123/2024
Cedazuridine / Decitabine	Inaqovi	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Otsuka Pharmaceutical Netherlands B.V.	4/11/2024	P/0124/2024
Iodine (131I) apamistamab		Initial Paediatric Investigation Plan	Positive	Surgical and medical procedures	Immedica Pharma AB	4/11/2024	P/0122/2024
GIPR antagonist/GLP-1R agonist (AMG 133)		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Amgen Europe B.V.	4/11/2024	P/0131/2024
Maplirpacept		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	4/11/2024	P/0125/2024
Recombinant influenza hemagglutinin-strain A (H1N1 subtype)/Recombinant influenza hemagglutinin-strain A (H3N2 subtype)/Recombinant influenza hemagglutinin-strain B (Victoria lineage)/Recombinant influenza hemagglutinin-strain B (Yamagata lineage) (RIV4)	Supemtek	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur Europe	4/5/2024	P/0098/2024
Pegcetacoplan	Aspaveli	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Swedish Orphan Biovitrum AB (publ)	4/5/2024	P/0099/2024
Raludotatug deruxtecan		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe gmbh	4/5/2024	P/0100/2024
Sargramostim	Sargramostim Partner Therapeutics	Initial Paediatric Investigation Plan	Positive	Injury, poisoning and procedural complications	Partner Therapeutics Inc.	3/27/2024	P/0089/2024
Glucagon analogue linked to a human immunoglobulin Fc fragment		Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Hanmi Pharmaceutical Co. Ltd.	3/21/2024	P/0086/2024
Ursodoxicoltaurine / sodium phenylbutyrate	ALBRIOZA	Product Specific Waiver	Positive	Nervous system disorders	Amylyx Pharmaceuticals EMEA B.V.	3/20/2024	P/0087/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Mirabegron	Betmiga	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Astellas Pharma Europe B.V.	3/15/2024	P/0085/2024
Chloroprocaine (hydrochloride)	Ampres, Associated names: Clorotekal, Decelex	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Sintetica gmbh	3/15/2024	P/0084/2024
Navepegritide		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Ascendis Pharma A/S	3/15/2024	P/0082/2024
L-Carnitine/Glucose/Calcium Chloride Dihydrate/Magnesium Chloride Hexahydrate/Sodium Lactate/Sodium Chloride		Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Iperboreal Pharma S.r.l.	3/15/2024	P/0083/2024
Borrelia outer surface protein A (ospa) serotypes (ST1-6) lipidated, fusion protein vaccine		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Pfizer Europe MA EEIG	3/15/2024	P/0080/2024
Cannabidiol		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Zynerba Pharmaceuticals Inc.	3/15/2024	P/0081/2024
Split influenza virus, inactivated containing antigens equivalent to B-like strain / 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		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Winthrop Industrie	3/15/2024	P/0088/2024
Azilsartan medoxomil	Edarbi	Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Takeda Development Centre Europe Limited	3/8/2024	P/0053/2024
Givinostat		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Italfarmaco S.p.A.	3/8/2024	P/0055/2024
Midostaurin	Rydapt	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and	Novartis Europharm Limited	3/8/2024	P/0068/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Oritavancin (diphosphate)	Tenkasi	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Menarini International Operations Luxembourg S.A.	3/8/2024	P/0074/2024
Dinutuximab beta	Qarziba	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Recordati Netherlands B.V.	3/8/2024	P/0076/2024
Sodium zirconium cyclosilicate	Lokelma	Modification of Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Astrazeneca AB	3/8/2024	P/0077/2024
Eluxadoline	Truberzi	Modification of Paediatric Investigation Plan	Positive	Gastrointestinal disorders	Abbvie Limited	3/8/2024	P/0078/2024
Satralizumab	Enspryng	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Roche Registration gmbh	3/8/2024	P/0069/2024
Upadacitinib	Rinvoq	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Abbvie Limited	3/8/2024	P/0079/2024
Upadacitinib	Rinvoq	Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Abbvie Limited	3/8/2024	P/0062/2024
Daridorexant	Quviviq	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Idorsia Pharmaceuticals Deutschland gmbh	3/8/2024	P/0054/2024
Isatuximab	Sarclisa	Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sanofi Winthrop Industrie	3/8/2024	P/0049/2024
Purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain)		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Sanofi Pasteur Europe	3/8/2024	P/0051/2024
Molgramostim		Modification of Paediatric Investigation Plan	Positive	Respiratory, thoracic and mediastinal disorders	Savara aps	3/8/2024	P/0063/2024
Ianalumab		Initial Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Novartis Europharm Limited	3/8/2024	P/0075/2024
Nedosiran	Rivfloza	Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Novo Nordisk A/S	3/8/2024	P/0064/2024
Fordadistrogene movaparvovec		Modification of Paediatric Investigation Plan	Positive (Waiver)	Congenital, familial and genetic disorders	Pfizer Europe MA EEIG	3/8/2024	P/0073/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Recombinant SARS-cov-2 spike protein	Vidprevtyn Beta	Modification of Paediatric Investigation Plan	Positive (Waiver)	Infections and infestations	Sanofi Pasteur Europe	3/8/2024	P/0072/2024
Orforglipron		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Eli Lilly And Company Limited	3/8/2024	P/0052/2024
Synthetic double-stranded sirna oligonucleotide directed against apolipoprotein C-III mrna and covalently linked to a ligand containing three N-acetylgalactosamine residues		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Arrowhead Pharmaceuticals Inc.	3/8/2024	P/0071/2024
Volrustomig		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Astrazeneca AB	3/8/2024	P/0070/2024
Belumosudil		Initial Paediatric Investigation Plan	Positive	Immune system disorders	Sanofi Winthrop Industrie	3/8/2024	P/0065/2024
Igg-like T cell engager binding to DLL3 and CD3		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Boehringer Ingelheim International gmbh	3/8/2024	P/0048/2024
SJP-0132		Product Specific Waiver	Positive	Eye disorders	Senju Pharmaceutical Co. Ltd.	3/8/2024	P/0066/2024
Zanzalintinib		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Exelixis Inc.	3/8/2024	P/0050/2024
Interferon gamma / Tumor necrosis factor-alpha / Granulocyte colony-stimulating factor / Interleukin-1 beta, human / Interleukin-2		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cel-Sci Corp.	3/8/2024	P/0057/2024
Anti-alpha-synuclein recombinant humanised monoclonal antibody		Product Specific Waiver	Positive	Nervous system disorders	European Medicines Agency	3/8/2024	P/0067/2024
2-(3,5-dichloro-1-methyl-indazol-4-yl)-1-[(1S,3R)-3-(hydroxymethyl)-5-(1-hydroxy-1-methyl-ethyl)-1-methyl-3,4-dihydro-1H-		Product Specific Waiver	Positive	Nervous system disorders	UCB Pharma	3/8/2024	P/0056/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
isoquinolin-2-yl]ethanone monohydrate							
Difelikefalin	Kapruvia	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Vifor Fresenius Medical Care Renal Pharma France	3/7/2024	P/0058/2024
Chikungunya virus virus-like particle vaccine / aluminum hydroxide		Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Bavarian Nordic A/S	3/7/2024	P/0059/2024
Tinlarebant		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Belite Bio Inc.	3/7/2024	P/0060/2024
Zenocutuzumab		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merus N.V.	3/7/2024	P/0061/2024
Frexalimab		Initial Paediatric Investigation Plan	Positive	Endocrine disorders	Sanofi Winthrop Industrie	2/23/2024	P/0047/2024
Pariglasgene brecaparvovec (DTX401)		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Ultragenyx Germany gmbh	2/15/2024	P/0044/2024
Acetyl-L-leucine ((s)-(acetylamino)-4-methylpentanoic acid)		Modification of Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	Intrabio Ireland Limited	2/14/2024	P/0043/2024
Bupivacaine	Exparel	Modification of Paediatric Investigation Plan	Positive	Surgical and medical procedures	Pacira Ireland Limited	2/9/2024	P/0021/2024
Influenza Virus Type B, Victoria lineage / Influenza Virus Type A, H3N2 / Influenza Virus Type A, H1N1	Fluenz	Initial Paediatric Investigation Plan	Positive	Infections and infestations	Astrazeneca AB	2/9/2024	P/0045/2024
Clobetasol propionate	Uvesol	Initial Paediatric Investigation Plan	Positive	Eye disorders	Laboratorios Salvat S.A.	2/9/2024	P/0042/2024
Blinatumomab		Initial Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Amgen Europe B.V.	2/7/2024	P/0040/2024
Abemaciclib	Verzenios	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eli Lilly And Company Limited	2/7/2024	P/0037/2024
Abemaciclib	Verzenios	Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Eli Lilly And Company Limited	2/7/2024	P/0038/2024
Atropine sulfate		Modification of Paediatric Investigation Plan	Positive	Eye disorders	Nevakar Inc.	2/7/2024	P/0039/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Tifcemalimab		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Shanghai Junshi Biosciences Co. Ltd.	2/6/2024	P/0016/2024
Sepiapterin		Initial Paediatric Investigation Plan	Positive	Congenital, familial and genetic disorders	PTC Therapeutics International Limited	2/2/2024	P/0041/2024
Rocatinlimab		Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Amgen Europe B.V.	2/1/2024	P/0023/2024
Fibroblast growth factor 21 analogue (NNC194-0499)/Semaglutide		Initial Paediatric Investigation Plan	Positive	Hepatobiliary disorders	Novo Nordisk A/S	2/1/2024	P/0022/2024
Cladribine		Product Specific Waiver	Positive	Nervous system disorders	Merck Europe B.V.	1/31/2024	P/0009/2024
Ferric citrate coordination complex (FCCC)		Initial Paediatric Investigation Plan	Positive	Renal and urinary disorders	Averoa	1/31/2024	P/0036/2024
Upadacitinib	RINVOQ	Modification of Paediatric Investigation Plan	Positive	Musculoskeletal and connective tissue disorders	Abbvie Limited	1/31/2024	P/0010/2024
Tralokinumab	Adtralza	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	LEO PHARMA A/S	1/31/2024	P/0012/2024
Gadopiclenol	Elucirem	Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Guerbet	1/31/2024	P/0013/2024
Gadopiclenol	Elucirem	Modification of Paediatric Investigation Plan	Positive	Vascular disorders	Guerbet	1/31/2024	P/0018/2024
Etripamil		Modification of Paediatric Investigation Plan	Positive	Cardiac disorders	Milestone Pharmaceuticals Inc.	1/31/2024	P/0011/2024
Deucravacitinib	Sotyktu	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Bristol-Myers Squibb Services Unlimited Company	1/31/2024	P/0008/2024
Nipocalimab		Product Specific Waiver	Positive	Blood and lymphatic system disorders	Janssen Cilag International	1/31/2024	P/0032/2024
(R)-1-(1-acryloylpiperidin-3-yl)-4-amino-3-(4-phenoxyphenyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one (SAR442168)		Modification of Paediatric Investigation Plan	Positive	Nervous system disorders	Sanofi Winthrop Industrie	1/31/2024	P/0019/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Remibrutinib		Initial Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Novartis Europharm Limited	1/31/2024	P/0020/2024
Pegcetacoplan	Aspaveli	Modification of Paediatric Investigation Plan	Positive	Renal and urinary disorders	Apellis Ireland Limited	1/31/2024	P/0030/2024
Ruxolitinib (phosphate)	Opzelura	Product Specific Waiver	Positive	Skin and subcutaneous tissue disorders	Incyte Biosciences Distribution B.V.	1/31/2024	P/0034/2024
Apitegromab		Initial Paediatric Investigation Plan	Positive	Nervous system disorders	Scholar Rock Inc.	1/31/2024	P/0014/2024
Dordaviprone		Initial Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chimerix IRL Limited	1/31/2024	P/0015/2024
Obicetrapib		Initial Paediatric Investigation Plan	Positive	Metabolism and nutrition disorders	Newamsterdam Pharma B.V.	1/31/2024	P/0025/2024
Ezetimibe / Obicetrapib		Product Specific Waiver	Positive	Congenital, familial and genetic disorders	Newamsterdam Pharma B.V.	1/31/2024	P/0017/2024
Ezetimibe / Obicetrapib		Product Specific Waiver	Positive	Metabolism and nutrition disorders	Newamsterdam Pharma B.V.	1/31/2024	P/0035/2024
Ceftobiprole medocaril sodium	Zevtera and associated names	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Basilea Pharmaceutica Deutschland gmbh	1/29/2024	P/0027/2024
Tocilizumab	Roactemra	Modification of Paediatric Investigation Plan	Positive (Waiver)	Infections and infestations	Roche Registration gmbh	1/29/2024	P/0028/2024
Regadenoson	Rapiscan	Modification of Paediatric Investigation Plan	Positive	Cardiac disorders	GE Healthcare AS	1/29/2024	P/0029/2024
Zigakibart		Initial Paediatric Investigation Plan	Positive	Renal and urinary disorders	Chinook Therapeutics Inc.	1/29/2024	P/0033/2024
Tinengotinib (TT-00420)		Product Specific Waiver	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Transthera Sciences (Nanjing) Inc.	1/29/2024	P/0031/2024
Ritlecitinib	Litfulo	Modification of Paediatric Investigation Plan	Positive	Skin and subcutaneous tissue disorders	Pfizer Europe MA EEIG	1/26/2024	P/0026/2024
Faricimab	Vabysmo	Product Specific Waiver	Positive	Eye disorders	Roche Registration gmbh	1/12/2024	P/0006/2024
Crizanlizumab	Adakveo	Modification of Paediatric Investigation Plan	Positive (Waiver)	Congenital, familial and genetic disorders	Novartis Europharm Limited	1/11/2024	P/0004/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Mrna encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-cov-2 (mrna-1283)		Initial Paediatric Investigation Plan	Positive	Infections and infestations	Moderna Biotech Spain S.L.	1/11/2024	P/0007/2024
Odronextamab	Ordspono	Modification of Paediatric Investigation Plan	Positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Regeneron Ireland Designated Activity Company	1/10/2024	P/0005/2024
Dengue tetravalent vaccine (live, attenuated) / Dengue tetravalent vaccine (live, attenuated) / Dengue tetravalent vaccine (live, attenuated) / Dengue tetravalent vaccine (live, attenuated)	Qdenga	Modification of Paediatric Investigation Plan	Positive	Infections and infestations	Takeda Vaccines Inc.	1/3/2024	P/0003/2024
Ivosidenib	Tibsovo	Modification of Paediatric Investigation Plan	Positive (Waiver)	Blood and lymphatic system disorders	Les Laboratoires Servier	1/3/2024	P/0001/2024
Mozafancogene autotemcel	Fanskya	Modification of Paediatric Investigation Plan	Positive	Blood and lymphatic system disorders	Rocket Pharmaceuticals Inc.	1/3/2024	P/0002/2024

Opinions on final/full compliance check (does not include interim/partial compliance check procedures)

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Selexipag	Respiratory, thoracic and mediastinal disorders	Janssen Cilag International	1/19/2024
Casirivimab	Infections and infestations	Roche Registration gmbh	1/19/2024
Imdevimab	Infections and infestations	Roche Registration gmbh	1/19/2024
Talimogene laherparepvec	Skin and subcutaneous tissue disorders	Amgen Europe B.V.	1/19/2024
Pegfilgrastim	Blood and lymphatic system disorders	Accord Healthcare S.L.U.	1/19/2024
Macitentan	Cardiac disorders	Janssen Cilag International	2/23/2024
Risdiplam	Congenital, familial and genetic disorders	ROCHE PHARMA AG	2/23/2024
Evinacumab	Metabolism and nutrition disorders	Ultragenyx Germany gmbh	2/23/2024
Human fibrinogen concentrate (BT524)	Congenital, familial and genetic disorders	Biotest Pharma gmbh	2/23/2024

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Hydrocortisone	Respiratory, thoracic and mediastinal disorders	Laboratoire Aguettant	2/23/2024
Blinatumomab	Blood and lymphatic system disorders	Amgen Europe B.V.	2/23/2024
Letermovir	Infections and infestations	Merck Sharp And Dohme	2/23/2024
Split influenza virus, inactivated containing antigens equivalent to B-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain	Infections and infestations	Sanofi Winthrop Industrie	3/19/2024
Birch pollen extract (Betula verrucosa)	Respiratory, thoracic and mediastinal disorders	Alk-Abello A/S	3/22/2024
Atropine sulfate	Eye disorders	Nevakar Inc.	3/22/2024
Bilastine	Eye disorders	Faes Farma S.A.	3/22/2024
Baloxavir marboxil	Infections and infestations	Roche Registration gmbh	4/26/2024
Canagliflozin	Endocrine disorders	Janssen Cilag International	4/26/2024
Methoxyflurane	General disorders and administration site conditions	Medical Developments UK Limited	4/26/2024
Maralixibat Chloride	Congenital, familial and genetic disorders	Mirum Pharmaceuticals Inc.	4/26/2024
Binimetinib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pierre Fabre Medicament	4/26/2024
Encorafenib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pierre Fabre Medicament	4/26/2024
Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Infections and infestations	Pfizer Europe MA EEIG	4/26/2024
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)	Infections and infestations	Seqirus Netherlands B.V.	5/31/2024
Landiolol (hydrochloride)	Cardiac disorders	Aop Orphan Pharmaceuticals gmbh	5/31/2024
Olipudase alfa	Congenital, familial and genetic disorders	Sanofi B.V.	5/31/2024
Recombinant influenza hemagglutinin-strain A (H1N1 subtype)/Recombinant influenza hemagglutinin-strain A (H3N2 subtype)/Recombinant influenza hemagglutinin-strain B (RIV3)	Infections and infestations	Sanofi Winthrop Industrie	6/28/2024

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage	Infections and infestations	Glaxosmithkline Biologicals	6/28/2024
Liraglutide	Endocrine disorders	Novo Nordisk A/S	6/28/2024
Ixekizumab	Musculoskeletal and connective tissue disorders	Eli Lilly And Company Limited	7/26/2024
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Infections and infestations	Seqirus Netherlands B.V.	7/26/2024
Avatrombopag	Blood and lymphatic system disorders	Swedish Orphan Biovitrum AB (publ)	7/26/2024
Efinaconazole	Infections and infestations	Almirall S.A.	7/26/2024
Estetrol monohydrate / Drospirenone	Surgical and medical procedures	Estetra	7/26/2024
Palbociclib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	7/26/2024
Brexucabtagene autoleucel	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Kite Pharma EU B.V.	9/6/2024
Trofinetide	Congenital, familial and genetic disorders	Comharsa Life Sciences Limited	9/6/2024
Influenza A virus subtype H1N1 haemagglutinin, recombinant, Influenza A virus subtype H3N2 haemagglutinin, recombinant, Influenza B virus Victoria lineage haemagglutinin, recombinant, Influenza B virus Yamagata lineage haemagglutinin, recombinant	Infections and infestations	Sanofi Pasteur	9/6/2024
Selumetinib	Congenital, familial and genetic disorders	Astrazeneca AB	10/18/2024
Glucagon	Endocrine disorders	Amphastar France Pharmaceuticals	10/18/2024
Lutetium (177Lu) oxodotreotide	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Advanced Accelerator Applications	10/18/2024
Concentrate of proteolytic enzymes enriched in bromelain	Injury, poisoning and procedural complications	Mediwound Germany gmbh	10/18/2024
Doxecitine, Doxribtimine	Congenital, familial and genetic disorders	UCB Pharma	10/18/2024

Annex 17 – Referral procedures overview 2024 – human medicines

Referrals made to the CHMP

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Medicinal products which have been authorised or are pending approval based on studies performed at Synapse Labs Pvt. Ltd., a contract research organisation (CRO) located in Kharadi, Pune, India (various)	20/07/2023	21/03/2024	Article 31 of Directive 2001/83/EC
Havrix and associated names (inactivated hepatitis A virus)	14/09/2023	27/06/2024	Article 30 of Directive 2001/83/EC
Ocaliva (obeticholic acid)	12/10/2023	29/07/2024	Article 20 of Regulation (EC) No 726/2004
Ibuprofen NVT and associated names (ibuprofen)	14/12/2023	22/02/2024	Article 29(4) of Directive 2001/83/EC
Micrazym and associated names (porcine pancreas enzymes)	25/01/2024	03/04/2024	Article 29(4) of Directive 2001/83/EC
Lorazepam Macure (lorazepam)	22/02/2024	27/06/2024	Article 13 of Commission Regulation (EC) No 1234/2008
Oxbryta (voxelotor)	29/07/2024	ongoing	Article 20 of Regulation (EC) No 726/2004

Referrals made to the PRAC

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Pseudoephedrine-containing medicinal products (pseudoephedrine) Aerinaze (desloratadine/ pseudoephedrine sulphate)	09/02/2023	25/01/2024	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Hydroxyprogesterone caproate-containing medicinal products (hydroxyprogesterone caproate)	12/05/2023	26/06/2024	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Metamizole-containing medicinal products (metamizole)	13/06/2024	18/09/2024	Article 107i of Directive 2001/83/EC
Finasteride- and dutasteride-containing medicinal products	03/10/2024	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Annex 18 – Arbitrations and referrals in 2024 – veterinary medicines

Type of procedure	Date Clock start CVMP opinion	Product Product name INN
130(4) of Regulation (EU) 2019/6	14/03/2024 23/04/2024	Kexxtone 32.4 g continuous-release intraruminal device for cattle Monensin

Annex 19 – Budget summaries 2023-2024

The summarised comparative budget statements for 2023 and 2024 are as follows:

	Budget 2023 [1]		2024 (budget)[2]		2024 (prov) [3]	
	€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
Revenue						
Fees and charges	387,090	*88.2%*	441,910	*89.8%*	441,835	*89.8%*
General EU contribution	14,421	*3.3%*	22,926	*4.7%*	22,924	*4.7%*
Special EU contribution for orphan medicinal products	10,733	*2.4%*	12,900	*2.6%*	12,900	*2.6%*
External assigned revenue	0	*0.0%*	0	*0.0%*	0	*0.0%*
Balance from previous year	24,982	*5.7%*	10,460	*2.1%*	10,459	*2.1%*
Other	1,585	*0.4%*	3,666	*0.7%*	4,010	*0.8%*
TOTAL REVENUE	**438,811**	*100.0%*	**491,862**	*100.0%*	**492,128**	*100.0%*
Expenditure						
Staff						
Staff in active employment	131,979	*29.7%*	141,015	*28.7%*	140,477	*28.6%*
Recruitment	133	*0.0%*	154	*0.0%*	96	*0.0%*
Duty travel	904	*0.2%*	821	*0.2%*	785	*0.2%*
Socio-medical infrastructure	2,886	*0.7%*	3,501	*0.7%*	3,494	*0.7%*
Training	1,065	*0.2%*	1,063	*0.2%*	1,060	*0.2%*
External services	19,977	*4.5%*	19,608	*4.0%*	19,579	*4.0%*
Receptions & events	120	*0.0%*	142	*0.0%*	142	*0.0%*
Total Title 1	**157,063**	*35.4%*	**166,304**	*33.8%*	**165,632**	*33.8%*
Building/equipment						
Investment in immovable property, renting of building and associated costs	17,363	*3.9%*	30,648	*6.2%*	30,523	*6.2%*
Information and communication technology	45,194	*10.2%*	43,602	*8.9%*	43,591	*8.9%*
Movable property and associated costs	636	*0.1%*	637	*0.1%*	626	*0.1%*
Current administrative expenditure	1,413	*0.3%*	1,657	*0.3%*	1,643	*0.3%*
Postage	19	*0.0%*	20	*0.0%*	20	*0.0%*
Other meetings	91	*0.0%*	114	*0.0%*	103	*0.0%*
Restaurant and catering	2,029	*0.5%*	1,054	*0.2%*	963	*0.2%*
Information and publishing	1,700	*0.4%*	1,460	*0.3%*	1,458	*0.3%*
Business consultancy and audit services	3,270	*0.7%*	2,920	*0.6%*	2,908	*0.6%*
Total Title 2	**71,714**	*16.2%*	**82,112**	*16.7%*	**81,836**	*16.7%*
Operational expenditure						
Meetings	4,744	*1.1%*	4,959	*1.0%*	4,952	*1.0%*
Evaluation of medicinal products	153,968	*34.7%*	177,502	*36.1%*	177,099	*36.1%*
Translations	4,201	*0.9%*	4,965	*1.0%*	4,957	*1.0%*
Scientific studies and services	12,176	*2.7%*	16,820	*3.4%*	16,813	*3.4%*
Expenditure on business related IT projects	40,180	*9.0%*	39,200	*8.0%*	39,196	*8.0%*
Total Title 3	**215,270**	*48.5%*	**243,446**	*49.5%*	**243,017**	*49.5%*
Provisional appropriation	0	*0.0%*	0	*0.0%*	0	*0.0%*
Total Title 9	**0**	*0.0%*	**0**	*0.0%*	**0**	*0.0%*
TOTAL EXPENDITURE	**444,047**	*100.0%*	**491,862**	*100.0%*	**490,485**	*100.0%*

Financial Year 2023: as per final accounts (incl. non-automatic carry forward); rounded to the nearest thousand Euro
Financial Year 2024: as per final budget
Financial Year 2024: as per provisional accounts; rounded to the nearest thousand Euro

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2024				POSTS 2025	
	Authorised		Actual as per 31.12.2024*		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	3	-	3
AD 14	-	12	-	12	-	12
AD 13	-	12	-	12	-	15
AD 12	-	61	-	61	-	64
AD 11	-	50	-	50	-	49
AD 10	-	57	-	57	-	59
AD 9	-	82	-	82	-	94
AD 8	-	78	-	78	-	81
AD 7	-	90	-	90	-	85
AD 6	-	55	-	55	-	43
AD 5	-	0	-	0	-	0
Total AD	**0**	**500**	**0**	**500**	**0**	**505**
AST 11	-	3	-	3	-	3
AST 10	-	7	-	7	-	7
AST 9	-	10	-	10	-	13
AST 8	-	15	-	15	-	19
AST 7	-	29	-	29	-	38
AST 6	-	35	-	35	-	26
AST 5	-	49	-	49	-	56
AST 4	-	32	-	32	-	22
AST 3	-	11	-	11	-	15
AST 2	-	0	-	0	-	0
AST 1	-	0	-	0	-	0
Total AST	**0**	**191**	**0**	**191**	**0**	**199**
Grand Total	**0**	**691**	**0**	**691**	**0**	**704**

*) EMA makes use of article 38(2) FR to offset workforce loss through part-time work undertaken by TA staff. In 2024 the average part-time loss was -13.1 FTE, allowing for the appointment of 4 additional staff not included above.

Other staff	Planned (FTE[1]) 2024	Actual (FTE[1]) 2024	Actual headcount 31.12.2024	Planned (FTE[1]) 2025
CONTRACT AGENTS	**203**	**211**	**218**	**203**
NATIONAL EXPERTS	**45**	**48**	**53**	**45**

[1] FTE=Full Time Equivalent

Annex 21 - Litigation activities of EMA in 2024

Actions before the Court of Justice of the European Union that are directed against EMA (pending or concluded in 2024)

1. **Case T-703/20, Mylan Ireland v EMA**

On 27 November 2020, the applicant brought an action for annulment against the decision of EMA to not validate an application for a generic medicinal product.

By its order of 25 October 2024, the General Court concluded that the proceedings had become devoid of purpose. Further, it held that the action was manifestly inadmissible in so far as it pertained to: (i) a plea of illegality raised against an opinion of the CHMP in relation to the designated reference medicinal product; and (ii) the request for the annulment of certain unidentified decisions. Each of the parties to the proceedings were ordered to bear their own costs.

2. **Case C-291/22 P, D & A Pharma v EMA**

On 2 May 2022, the applicant brought an appeal against the first instance judgment in Case T-556/20, which had ruled in favour of EMA.

By its judgment of 14 March 2024, the Court of Justice set aside the first instance judgment; annulled the Commission decision refusing the grant of a marketing authorisation for a medicinal product for human use; and ordered the applicant to pay the costs incurred by EMA in the first-instance proceedings, EMA to bear its own costs relating to the appellate proceedings and the European Commission to bear its own costs and to pay the costs incurred by the applicant at both stages of the court proceedings.

3. **Case T-623/22, SD v EMA**

On 7 October 2022, the applicant brought an action for annulment against the decision of EMA to grant partial access to documents relating to the authorisation of a COVID-19 vaccine. The proceedings remained pending in 2024.

N.B. A hearing was held on 6 March 2025.

4. **Case T-373/24, D & A Pharma v EMA**

On 22 July 2024, the applicant brought an action for annulment against EMA's decision refusing its request to retract from its website a scientific opinion adopted in 2017 that recommended the refusal of the grant of a marketing authorisation for a medicinal product for human use. The proceedings remained pending in 2024.

5. **Case T-520/24, CSL Behring v Commission and EMA**

On 7 October 2024, the applicant brought an action for annulment against the European Commission and EMA seeking the annulment of the Commission decision to grant a conditional marketing authorisation for an advanced therapy medicinal product. In particular, the applicant sought to challenge the soundness of the scientific assessment carried out by the CAT and the CHMP as well as the procedural validity of the assessment. The proceedings remained pending in 2024.

6. **Case T-666/24, Teva Pharma v EMA**

On 28 December 2024, the applicant brought an action for annulment against the decision of EMA to grant partial access (without certain redactions proposed by the applicant) to documents relating to EMA scientific advice for a medicinal product for human use. The proceedings remained pending in 2024.

Actions before the Court of Justice of the European Union that are not directed against EMA, but concern EMA's scientific assessments (pending or concluded in 2024)

7. **Case T-223/20, Orion v Commission**

On 23 April 2020, an action was brought against the decision of the European Commission to grant a marketing authorisation for a generic medicinal product for human use.

By its judgment of 13 November 2024, the General Court annulled the Commission decision granting a marketing authorisation, and ordered the European Commission to bear its own costs and to pay the costs incurred by the applicant.

8. **Case C-237/22 P, Mylan IRE Healthcare v Commission**

On 4 April 2022, Mylan submitted an appeal against the first instance judgment in Case T-303/16. The case relates to the soundness of a clinical superiority assessment for a candidate medicinal product by the CHMP.

On 22 September 2022, EMA was granted leave to intervene in support of the European Commission. A hearing was held on 20 September 2023.

By its judgment of 4 October 2024, the Court of Justice dismissed the appeal, and ordered the appellant to bear its own costs and to pay the costs incurred by the European Commission and EMA.

9. **Case T-416/22, Fresenius Kabi Austria and Others v Commission**

On 1 July 2022, an action for annulment was brought against the decision of the European Commission to suspend the national marketing authorisations for certain medicinal products for human use. In particular, the applicants sought to challenge the soundness of the scientific assessment of a post-authorisation study which preceded the adoption of the Commission decision.

On 4 January 2023, EMA was granted leave to intervene in support of the European Commission. A hearing was held on 14 November 2023.

By its judgment of 15 May 2024, the General Court dismissed the action, and ordered the applicants to bear their own costs and to pay the costs incurred by the European Commission. EMA was ordered to bear its own costs (as is typical for interveners).

10. **Case T-483/22, Sanofi v Commission**

On 4 August 2022, the applicant brought an action seeking the partial annulment of the decision of the European Commission to not recognize a certain active substance as a new active substance and to remove the medicinal product containing that active substance from the Union register of orphan medicinal products.

On 14 February 2023, EMA was granted leave to intervene in support of the European Commission. A hearing was held on 10 September 2024. The proceedings remained pending in 2024.

11. **Case T-594/18 RENV, Pharma Mar v Commission**

This case concerns the decision of the European Commission to not grant a marketing authorisation to a candidate medicinal product for human use. As a result of the appellate judgment of 23 June 2023 in Joined Cases C-6/21 P and C-16/21 P, the case has been referred back to the General Court and the costs have been reserved.

EMA did not participate to the first instance proceedings as an intervener; however, after being granted the status of an intervener in the appellate proceedings, it retained this status in Case T-594/18 RENV.

By its order of 15 November 2024, the General Court concluded that there was no longer any need to adjudicate on the proceedings, and ordered the European Commission to bear its own costs and to pay the costs incurred by the applicant at both stages of the court proceedings. EMA was ordered to bear its own costs in connection with the appellate proceedings in Joined Case C-6/21 P and C-16/21 P and the proceedings following the referral back to the General Court in Case T-594/18 RENV.

12. **Case T-12/24, Ferring Pharmaceuticals v Commission**

On 10 January 2024, the applicant brought an action for annulment against the decision of the European Commission to grant a marketing authorisation for a generic medicinal product. In particular, the applicant sought to challenge the soundness of the scientific assessment by the CHMP in relation to the bioequivalence of the generic medicinal product and the purported reference product.

On 26 August 2024, EMA was granted leave to intervene in support of the European Commission. The proceedings remained pending in 2024.

13. **Case T-455/24, Advanz Pharma v Commission**

On 3 September 2024, the applicant brought an action for annulment against the decision of the European Commission to revoke a conditional marketing authorisation for a medicinal product for human use. In particular, the applicant sought to challenge the soundness of the scientific assessment by the CHMP as well as the procedural validity of the assessment. The proceedings remained pending in 2024.

N.B. On 14 March 2025, EMA was granted leave to intervene in support of the European Commission.

14. **Case T-547/24, Novartis Europharm v Commission**

On 21 October 2024, the applicant brought an action for annulment against the Commission decision to grant a marketing authorisation for a generic medicinal product. The proceedings remained pending in 2024.

15. **Actions brought by the marketing authorisation holder of Tecfidera following the delivery of the first instance judgment in Case T-611/18**

The following actions were brought by the marketing authorisation holder for Tecfidera following the delivery of the first instance judgment of 5 May 2021 in Case T-611/18, *Pharmaceutical Works Polpharma v EMA.*

15.1. **Case T-269/22, Biogen Netherlands v Commission**

On 16 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for "Dimethyl fumarate Polpharma – dimethyl fumarate".

By its order of 10 April 2024, the General Court concluded that there was no longer any need to adjudicate on the action. Each of the parties to the proceedings were ordered to bear their own costs.

15.2. **Case T-278/22, Biogen Netherlands v Commission**

On 17 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for "Dimethyl fumarate Neuraxpharm – dimethyl fumarate".

By its order of 10 April 2024, the General Court concluded that there was no longer any need to adjudicate on the action. Each of the parties to the proceedings were ordered to bear their own costs.

15.3. **Case T-279/22, Biogen Netherlands v Commission**

On 17 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for "Dimethyl fumarate Mylan – dimethyl fumarate".

By its order of 10 April 2024, the General Court concluded that there was no longer any need to adjudicate on the action. Each of the parties to the proceedings were ordered to bear their own costs.

15.4. Case T-137/23, Biogen Netherlands v Commission

On 10 March 2023, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for "Dimethyl fumarate Teva – dimethyl fumarate".

By its order of 10 April 2024, the General Court concluded that there was no longer any need to adjudicate on the action. Each of the parties to the proceedings were ordered to bear their own costs.

15.5. Case T-327/23, Biogen Netherlands v Commission

On 9 June 2023, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for "Dimethyl fumarate Accord – dimethyl fumarate".

By its order of 10 April 2024, the General Court concluded that there was no longer any need to adjudicate on the action. Each of the parties to the proceedings were ordered to bear their own costs.

16. Actions brought by generic companies following the delivery of the appellate judgment in Joined Cases C-438/21 P to Case C-440/21 P

The following actions were brought by generic companies following the delivery of the appellate judgment of 16 March 2023 in Joined Cases C-438/21 P to Case C-440/21 P, *Commission and Others v Pharmaceutical Works Polpharma*.

16.1. Case T-226/23, Neuraxpharm Pharmaceuticals v Commission

On 2 May 2023, the applicant brought an action for annulment against a letter of the European Commission concerning the interpretation and consequences of the appellate judgment in Joined Cases C-438/21 P to C-440/21 P.

On 7 February 2024, the action was dismissed by an order of the General Court as inadmissible. The applicant was ordered to bear its own costs and to pay the costs incurred by the European Commission.

16.2. Case T-227/23, Mylan Ireland v Commission

On 2 May 2023, the applicant brought an action for annulment against a letter of the European Commission concerning the interpretation and consequences of the appellate judgment in Joined Cases C-438/21 P to C-440/21 P.

On 7 February 2024, the action was dismissed by an order of the General Court as inadmissible. The applicant was ordered to bear its own costs and to pay the costs incurred by the European Commission.

16.3. Case T-228/23, Zakłady Farmaceutyczne Polpharma v Commission

On 2 May 2023, the applicant brought an action for annulment against a letter of the European Commission concerning the interpretation and consequences of the appellate judgment in Joined Cases C-438/21 P to C-440/21 P.

On 7 February 2024, the action was dismissed by an order of the General Court as inadmissible. The applicant was ordered to bear its own costs and to pay the costs incurred by the European Commission.

16.4. **Case T-256/23, Mylan Ireland v Commission**

On 15 May 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. A hearing was held on 10 December 2024. The proceedings remained pending in 2024.

16.5. **Case T-257/23, Neuraxpharm Pharmaceuticals v Commission**

On 15 May 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.6. **Case T-258/23, Zakłady Farmaceutyczne Polpharma v Commission**

On 15 May 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.7. **Case T-278/23, Zentiva and Zentiva Pharma v Commission**

On 23 May 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.8. **Case T-299/23, Hexal v Commission**

On 30 May 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.9. **Case T-309/23, Aliud Pharma v Commission**

On 5 June 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.10. **Case T-351/23, Kern Pharma v Commission**

On 29 June 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

16.11. **Case T-393/23, Teva v Commission**

On 13 July 2023, the applicant brought an action for annulment against the decision of the European Commission granting an additional year of marketing protection for Tecfidera under Article 14(11) of Regulation (EC) No 726/2004. The proceedings remained pending in 2024.

17. **Actions brought by generic companies following the delivery of the appellate judgment in Joined Cases C-438/21 P to Case C-440/21 P; and the decision of the European Commission to revoke certain marketing authorisations for generic versions of Tecfidera**

17.1. **Case T-1181/23, Mylan Ireland v Commission**

On 22 December 2023, the applicant brought an action for annulment against the decision of the European Commission, which revoked a marketing authorisation for 'Dimethyl fumarate Mylan — dimethyl fumarate'. The proceedings remained pending in 2024.

17.2. **Case T-1182/23, Neuraxpharm Pharmaceuticals v Commission**

On 23 December 2023, the applicant brought an action for annulment against the decision of the European Commission, which revoked a marketing authorisation for 'Dimethyl fumarate Neuraxpharm — dimethyl fumarate'. The proceedings remained pending in 2024.

17.3. **Case T-1183/23, Zakłady Farmaceutyczne Polpharma v Commission**

On 23 December 2023, the applicant brought an action for annulment against the decision of the European Commission, which revoked a marketing authorisation for 'Dimethyl fumarate Polpharma — dimethyl fumarate'. The proceedings remained pending in 2024.

Annex 22 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2024	520	150 803

Initial decisions on access in 2024[1]

Access given	
Yes	358
Partial	0
No	21
Document is not held by the Agency	39
Request became RFI	30
Clarification is not received / Withdrawn by requester	148
Total closed	**596**
Pending[2]	342

Legal basis used for full or partial refusal

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	0	0
4.2 1st ind – Protection of commercial interest	9	0
4.2 2nd ind – Protection of court proceedings	1	0
4.2 3rd ind – Protection of inspections	1	0
4.3 1st par – Protection of decision making process	10	0
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	0	0
Total	**21**	**0**

Decision on confirmatory applications in 20243

Appeals	
Final refusal	4
Release	3
Partial	0
Request became RFI	0
Withdrawn by requester	6
Total closed	13
Pending[4]	2

[1] Including initial requests received in previous years but closed in 2024
[2] Requests ongoing (currently processed) and in queue (not started)
[3] Including appeals received in previous years but closed in 2024
[4] Requests ongoing (currently processed) and in queue (not started)

Legal basis used for full or partial refusal

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	0	0
4.2 1st ind – Protection of commercial interest	4	0
4.2 2nd ind – Protection of court proceedings	0	0
4.2 3rd ind – Protection of inspections	0	0
4.3 1st par – Protection of decision making process	0	0
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	0	0
Total	**4**	**0**

Affiliation (per initial requests and appeals in 2024)

Affiliation	Number of requests received	In %	Number of pages released[5]	In %
Not-for-profit organisation	12	2	31 405	20
EU Institution (EC etc)	1	0	0	0
Regulator outside EU	1	0	0	0
EU NCA	8	2	79	0
Patients or Consumer	34	7	9 956	7
Healthcare professional	17	3	10 036	7
Academia/Research institute	48	9	14 634	10
Legal	46	9	15 223	10
Media	28	5	2018	1
Pharmaceutical industry	260	50	49 364	33
Consultant	60	12	13 094	9
Other	5	0	4 994	3
Total	**520**	**100**	**150 803**	**100**

[5] Including initial requests and appeals received in previous years but closed in 2024

Annex 23 – Clinical Data Publication[1]

Number of documents published

Year	Number of documents published	Number of pages published
2024	5.817	2.354.748

Documents and Pages published per module

MODULE	Documents	Pages
Module 2.5	117	6.806
Module 2.7	343	42.186
Module 5	5.357	2.305.756

Number of procedures published by procedure type

Initial MAA	52
Extension of Indication	-
Grouped Type II Variation	5
Type II Variation	16
Post Authorisation Recommendation (PAM)	-

Anonymisation Risk Assessment Approach

Approach	Number of Procedures
Qualitative[2]	33
Quantitative[3]	19
Mixed[4]	20
Not Applicable[5]	1

[1] Only Covid-19 related procedures were published during 2022
[2] Qualitative approach: calculate the level of risk (e.g. high, medium, low) based on the characteristics of the source data (e.g. prevalence of the disease, trial sample size, number of sites) . External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency (europa.eu)
[3] Quantitative approach: calculate the probability of uniquely identifying an individual (the risk of re-identification is defined as a numerical value obtained through the *analysis of the clinical* data to be disclosed.) External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency (europa.eu)
[4] Mixed: a combination of the two.
[5] No anonymisation needed as no private personal data (PPD) was present in the documents

Annex 24 – Publications by Agency staff members and experts in 2024

Aiyegbusi OL, Cruz Rivera S, Roydhouse J, Kamudoni P, Alder Y, Anderson N, Baldwin RM, Bhatnagar V, Black J, Bottomley A, Brundage M, Cella D, Collis P, Davies EH, Denniston AK, Efficace F, Gardner A, Gnanasakthy A, Golub RM, Hughes SE, Jeyes F, Kern S, King-Kallimanis BL, Martin A, McMullan C, Mercieca-Bebber R, Monteiro J, Peipert JD, Quijano-Campos JC, Quinten C, Rantell KR, Regnault A, Sasseville M, Schougaard LMV, Sherafat-Kazemzadeh R, Snyder C, Stover AM, Verdi R, Wilson R, Calvert MJ.

Recommendations to address respondent burden associated with patient-reported outcome assessment. Nat Med. 2024 Mar;30(3):650-659. doi: 10.1038/s41591-024-02827-9. Epub 2024 Feb 29. PMID: 38424214.

Alcalde-Herraiz M, Xie J, Newby D, Prats C, Gill D, Gordillo-Marañón M, Prieto-Alhambra D, Català M, Prats-Uribe A.

Effect of genetically predicted sclerostin on cardiovascular biomarkers, risk factors, and disease outcomes. Nat Commun. 2024 Nov 13;15(1):9832. doi: 10.1038/s41467-024-53623-5. PMID: 39537602; PMCID: PMC11561231.

Almeida D, Umuhire D, Gonzalez-Quevedo R, António A, Burgos JG, Verpillat P, Bere N, Sepodes B, Torre C.

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