Annexes to the annual report of the European Medicines Agency 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Annex 1 – Members of the Management Board

Chair: Rui Santos Ivo
EMA contact: Hilde BOONE

Members

• European Parliament	Kristina GARUOLIENE[1], Cristian BUŞOI[2]
• European Commission	Sandra GALLINA, Joanna DRAKE (Alternates: Rainer BECKER, Pilar AGUAR-FERNÁNDEZ[3])
• Belgium	Hughes MALONNE (Alternate: Charles DENONNE)
• Bulgaria	Bogdan KIRILOV (Alternate: Svetlin Sofroniev SPIROV)
• Czechia	Tomáš BORÁŇ (Alternate: Jiří BUREŠ)
• Denmark	Nils Falk BJERREGAARD (Alternate: Mette AABOE HANSEN)
• Germany	Karl BROICH (Alternate: Lars-Christoph NICKEL)
• Estonia	Katrin KIISK (Alternate: Alar IRS)
• Ireland	Lorraine NOLAN (Alternate: Rita PURCELL)
• Greece	Spyridon SAPOUNAS[4] (Alternate: Diomidis LYMPERIS[5a&5b])
• Spain	María Jesús Lamas Díaz (Alternate: Consuelo RUBIO MONTEJANO)
• France	Catherine PAUGAM-BURTZ (Alternate: Franck FOURES)
• Croatia	Siniša TOMIĆ (Alternate: Danica KRAMARIĆ)
• Italy	Robert NISTICÒ (Alternate: Armando MAGRELLI)
• Cyprus	Helena PANAYIOTOPOULOU (Alternate: Irini Chrysafi FANIDOU)
• Latvia	Indra DREIKA (Alternate: Sergejs AKULICČS)
• Lithuania	Dovilė MARCINKÈ (Alternate: Rugilė PILVINIENĖ)
• Luxembourg	Anna CHIOTI (Alternate: Marcin WISNIEWSKI)
• Hungary	Vacant[6] (Alternate: Beatrix HORVATH)
• 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)

[1] Replaces Karin Kadenbach from June 2025
[2] Replaces Giovani La Via from June 2025
[3] Replaces Irene Norstedt from September 2025
[4] Spyridon Sapounas swapped roles and become member in August 2025
[5a] Evangelos Manolopoulos swapped roles and become alternate from August 2025
[5b] Replaces Evangelos Manolopoulos from November 2025
[6] Replaces Rita Erzsébet PÁLFFYNÉ POÓR from September 2025

• Portugal	Rui SANTOS IVO (Alternate: Susana GUEDES POMBO)
• Romania	Răzvan Mihai PRISADA (Alternate: Andrei BACIU)
• Slovenia	Momir RADULOVIĆ (Alternate: Sabine ZALAR)
• Slovakia	Roman DORČIK (Alternate: Katarína MASSÁNYIOVÁ)
• Finland	Eija PELKONEN (Alternate: Anna SIIRA)
• Sweden	Ann LINDBERG[7] (Alternate: Åsa KUMLIN HOWELL)
• Representatives of patients' organisations	Marko KORENJAK[8], Virginie HIVERT
• Representative of doctors' organisations	Denis LACOMBE
• Representative of veterinarians' organisations	Christophe BUHOT

Observers

• Iceland	Runa HAUKSDOTTIR (Alternate: Bjarni SIGURðSSON)
• Liechtenstein	Vlasta ZAVADOVA (Alternate: Fabian KURZEMANN[9])
• Norway	Trygve OTTERSEN (Alternate: Sayeh AHRABI[10])

[7] Replaces Joakim Brandberg from June 2025
[8] Replaces Marco Greco from June 2025
[9] Replaces Martin Stricker from August 2025
[10] Replaces Audun Hågå from October 2025

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

Chair: Bruno SEPODES

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)	Alternate: Katerina SAVVIDOU [1]
• Tomas RADIMERSKY (Czechia)	Alternate: Petr VRBATA
• Thalia Marie Estrup BLICHER (Denmark)	Alternate: Boje Kvorning Pires EHMSEN
• Alar IRS (Estonia)	Alternate: Edward LAANE
• Outi MAKI-IKOLA (Finland) *(Vice-Chair)*	Alternate: Johanna LAHTEENVUO
• Alexandre MOREAU (France)	Alternate: Nicolas BEIX [2]
• Janet KOENIG (Germany)	Alternate: Martin MENGEL
• Aris ANGELIS (Greece)	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
• Fatima VENTURA (Portugal)	Alternate: Paulo PAIXAO
• Simona BADOI (Romania)	Alternate: Dana Gabriela MARIN
• Francisek DRAFI (Slovakia)	Alternate: Jana KLIMASOVA

[1] Nominated as of January 2025
[2] Replaced Jean-Michel RACE as of September 2025

- Kristina NADRAH (Slovenia) Alternate: Andreja KRANJC
- Carolina PRIETO FERNANDEZ (Spain) Alternate: Antonio GOMEZ-OUTES
- Kristina DUNDER (Sweden) Alternate: Filip JOSEPHSON

Co-opted members

- Bruno DELAFONT *(*Biostatistics and clinical trial methodology)
- Blanka HIRSCHLEROVA (Quality (non-biologicals))
- 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)
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Ulla WANDEL LIMINGA

Members nominated by Member States

• Jan NEUHAUSER (Austria)	Alternate: Sonja RADOWAN
• Jean-Michel DOGNE (Belgium)	Alternate: Jo ROBAYS
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Stanislav STOILOV [1]
• Petar MAS (Croatia)	Alternate: Barbara KOVACIC BYTYQI
• Panagiotis PSARAS (Cyprus) [2]	Alternate: Elena KAISIS [3]
• Eva JIRSOVA (Czechia)	Alternate: Veronika MACUROVA [4] [5]
• Marie Louise Schougaard CHRISTIANSEN (Denmark)	Alternate: Karin Susanne LINDENSTROM ERNEHOLM
• Maia UUSKULA (Estonia)	Alternate: Krõõt AAB
• Terhi LEHTINEN (Finland)	Alternate: Kimmo JAAKKOLA
• Tiphaine VAILLANT (France)	Alternate: Zoubida AMIMOUR
• Martin HUBER (Germany)	Alternate: Dirk MENTZER [6]
• Georgia GKEGKA (Greece)	Alternate: Maria POULIANITI
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun STEFANSDOTTIR (Iceland)	Alternate: *Awaiting nomination* [7]
• Rhea FITZGERALD (Ireland)	Alternate: Eamon O MURCHU
• Amelia CUPELLI (Italy)	Alternate: Emilio CLEMENTI
• Zane NEIKENA (Latvia)	Alternate: Diana LITENBOKA
• Rugile PILVINIENE (Lithuania)	Alternate: Lina SEIBOKIENE
• Anne-Cecile VUILEMIN (Luxembourg) [8]	Alternate: Magdalena WIELOWIEYSKA [9]
• John Joseph BORG (Malta)	Alternate: Benjamin MICALLEF
• Liana MARTIROSYAN (Netherlands) *(Vice-Chair)*	Alternate: Bianca MULDER
• David BENEE OLSEN (Norway)	Alternate: Karen PERILLE HARG
• Adam PRZYBYLKOWSKI (Poland)	Alternate: Katarzyna ZIOLKOWSKA

[1] Nominated as of October 2025
[2] Swap of roles from alternate to member as October 2025
[3] Swap of roles from member to alternate as of October 2025
[4] Jana LUKACISINOVA resigned as of August 2025
[5] Nominated as of September 2025
[6] Replaced Gabrielle MAURER as of October 2025
[7] Gudrun THENGILSDOTTIR resigned as of June 2025
[8] Anne-Cecile VUILEMIN replaced Nadine PETITPAIN with a swap of roles from alternate to member as of February 2025
[9] Replaced Anne-Cecile VUILEMIN as of February 2025

• Ana Sofia DINIZ MARTINS (Portugal)	Alternate: Carla TORRE
• Roxana DONDERA (Romania)	Alternate: Irina SANDU
• Miroslava GOCOVA (Slovakia) [10]	Alternate: Jana PECHEROVA [11]
• Polona GOLMAJER (Slovenia)	Alternate: Marjetka PLEMENTAS
• Maria del Pilar RAYON (Spain)	Alternate: Maria MARTINEZ GONZALEZ [12]
• Mari THORN (Sweden)	Alternate: Karin BOLIN

Independent scientific experts nominated by the European Commission

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

Members representing healthcare professionals nominated by the European Commission

• Roberto FRONTINI	Martin VOTAVA [13]

Members representing patients' organisations nominated by the European Commission

• Yiannoula KOULLA [14]	Michal RATAJ [15] [16]

[10] Miroslava GOCOVA replaced Anna MAREKOVA with a swap of roles from alternate to member as of December 2025
[11] Nominated as of December 2025
[12] Replaced Monica MARTINEZ REDONDO as of September 2025
[13] Replaced Salvatore MESSANA as of May 2025
[14] Replaced Marko KORENJAK as of May 2025
[15] Michal RATAJ's mandate ended as of April 2025
[16] Nominated as of December 2025

Annex 4 – Members of the Committee for Veterinary Medicinal Products

Chair: Gerrit Johan SCHEFFERLIE

Members and alternates

• Petra FALB (Austria)	Alternate: Manuela LEITNER
• Els DEWAELE (Belgium)	Alternate: Frederic KLEIN
• Krasimir YANKOV ZLATKOV (Bulgaria)	Alternate: Tsvetanka VALOVA [1] [2]
• Irena ZARKOVIC (Croatia) [3]	Alternate: Irena CALETA [4]
• *Awaiting nomination* (Cyprus)	Alternate: Alia MICHAELIDOU-PATSIA
• Leona NEPEJCHALOVA (Czechia)	Alternate: Jiri BURES
• Niels Christian KYVSGAARD (Denmark)	Alternate: Merete BLIXENKRONE-MOLLER
• Toomas TIIRATS (Estonia)	Alternate: *awaiting nomination*
• Minna LEPPANEN (Finland)	Alternate: Kristina LEHMANN
• Sylvie LOUET (France)	Alternate: Christine MIRAS
• Andrea GOLOMBIEWSKI (Germany)	Alternate: Esther WERNER
• Spyridon FARLOPOULOS (Greece)	Alternate: Amalia PAPADAKI
• Gabor KULCSAR (Hungary)	Alternate: Eszter KOLLAR-NAGY
• *Awaiting nomination* (Iceland)	Alternate: *awaiting nomination*
• Paul McNEILL (Ireland)	Alternate: Alice BLENNERHASSETT [5]
• Fulvio MARSILIO (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Renāte KUSKE
• *Awaiting nomination* (Liechtenstein)	Alternate: *awaiting nomination*
• Nijole STANKEVICIENE (Lithuania) [6]	Alternate: Vaida KURAPKIENE [7]
• Caroline CONER (Luxembourg)	Alternate: Despoina IATRIDOU
• Stephen SPITERI (Malta)	Alternate: Elena Maria VELLA
• Jacqueline POOT (Netherlands)	Alternate: Kim BOERKAMP
• Hanne BERGENDAHL (Norway)	Alternate: Knud TORJESEN
• Ewa AUGUSTYNOWICZ (Poland) [8]	Alternate: Marcin GLANDA [9]

[1] Nadya Ognyanova VLADIMIROVA retired as of March 2025
[2] Nominated as of May 2025
[3] Replaced Frane BOŽIĆ as of July 2025
[4] Replaced Hrvoje PAVASOVIC as of August 2025
[5] Replaced J. Gabriel BEECHINOR as of June 2025
[6] Replaced Snieguolė T. DZEKČIORIENĖ as of February 2025
[7] Nominated as of February 2025
[8] Replaced Anna WACHNIK-ŚWIĘCICKA as of March 2025 with a swap of roles from alternate to member
[9] Nominated as of April 2025

- João Pedro DUARTE DA SILVA (Portugal) Alternate: Ines FLOR DIAS
- Gabriela TUCHILA (Romania) Alternate: Diana Laura STAN
- Eva CHOBOTOVA (Slovakia) Alternate: Katarína MASSANYIOVA
- Urska PEAUNIK (Slovenia) [10] Alternate: Mojca OGRIZ [11]
- Cristina MUNOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTROM (Sweden) (*vice-chair*)Alternate: Hanna BREMER

Co-opted members

- Keith BAPTISTE (Antimicrobials and antimicrobial resistance)
- Rory BREATHNACH (General veterinary practice)
- Carina BERGMAN (Toxicology)
- Mary O'GRADY (Quality (pharmaceuticals))
- Ricardo CARAPETO GARCIA (Environmental risk assessment)

[10] Replaced Katarina STRAUSS as of December 2025 with a swap of roles from alternate to member
[11] Nominated as of December 2025

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Tim LEEST

Members nominated by Member States

- Brigitte BLOECHL-DAUM (Austria)
- Alexandru MIHAIL SIMION (Belgium) [1]
- *Awaiting nomination* (Bulgaria)
- Ivica BRNCIC (Croatia) [2]
- Ioannis KKOLOS (Cyprus)
- Jana MAZELOVA (Czechia)
- Sine Buhl NAESS-SCHMIDT (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)
- Frauke NAUMANN-WINTER (Germany) (*Vice-Chair*)
- Evangelia YANNAKI (Greece)
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- *Awaiting nomination* (Ireland)
- Enrico COSTA (Italy)
- Irena ROGOVSKA (Latvia)
- Vlasta ZAVADOVA (Liechtenstein)
- Ruta MAMENISKIENE (Lithuania)
- *Awaiting nomination* (Luxembourg) [3]
- Luana MIFSUD BUHAGIAR (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Joao ROCHA (Portugal)
- Olimpia NEAGU (Romania)

[1] Nominated as of February 2025
[2] Replaced Dinko VITEZIC as of January 2025
[3] Michel HOFFMAN's mandate ended as of December 2025

- *Jana SCHWEIGERTOVA* (Slovakia)
- *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

Members representing patients' organisations nominated by the European Commission

- Mariette DRIESSENS
- Julian ISLA
- Ines ALVES

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Emiel VAN GALEN

Members nominated by Member States

• Astrid OBMANN (Austria)	Alternate: Brigitte HAUSER
• Patricia BODART (Belgium)	Alternate: Daniela RUSEVA [1]
• Iliana IONKOVA (Bulgaria)	Alternate: Denitsa MOMEKOVA [2]
• Ivan KOSALEC (Croatia)	Alternate: Darko TRUMBETIC
• Christina Sylvia CHRYSOSTOMOU (Cyprus)	Alternate: Alexandra DEMETRIOU
• Marketa PRIHODOVA (Czechia)	Alternate: Kristyna VESELA [3]
• Nanna LUNDGAARD RASMUSSEN (Denmark)	Alternate: Karoline HOLM FIELDING
• *Awaiting nomination* (Estonia)	Alternate: *Awaiting nomination*
• Maria PAILE HYVARINEN (Finland)	Alternate: Sari KOSKI
• An LE (France)	Alternate: Helene LY
• Jacqueline WIESNER (Germany)	Alternate: Valerie NIEDERWIESER [4]
• Ioanna CHINOU (Greece)	Alternate: Stavroula MAMOUCHA
• Julia PALLOS (Hungary)	Alternate: *Awaiting nomination* [5]
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Jacqueline MASTERSON (Ireland)	Alternate: *Awaiting nomination*
• Alessandro ASSISI (Italy)	Alternate: Anna Maria SERRILLI
• Inga SILE (Latvia)	Alternate: *Awaiting nomination*
• Gabriele BALCIUNAITE MURZIENE (Lithuania)	Alternate: *Awaiting nomination*
• Jean-Luc BUEB (Luxembourg) [6]	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: Tomasz STAWARSKI [7] [8]
• Ana Paula MARTINS (Portugal)	Alternate: *Awaiting nomination* [9]

[1] Nominated as of February 2025
[2] Replaced Radina DIMITROVA as of May 2025
[3] Replaced Marie HEROUTOVA as of January 2025
[4] Replaced Susanne FLEMISH as of December 2025
[5] Rita NEMETH resigned as of July 2025
[6] Replaced Sven BACK as of October 2025
[7] Ewa ANTKIEWICZ's mandate ended as of January 2025
[8] Nominated as from March 2025
[9] Eva MENDES's mandate ended as of June 2025

- Carmen PURDEL (Romania) Alternate: Ligia Elena DUTU
- Dorota DISTLEROVA (Slovakia) Alternate: Jaroslav TOTH
- Barbara RAZINGER (Slovenia) Alternate: Nina KOCEVAR GLAVAC [10]
- Olga Maria PALOMINO (Spain) Alternate: Margarita BERROCAL NAVAS [11]
- 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)

[10] Nominated as of August 2025
[11] Nominated as of January 2025

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) Alternate: Raimondas BENETIS
- John Joseph BORG (Malta) Alternate: *Awaiting nomination* [1]
- Sol RUIZ (Spain) Alternate: Marcos TIMON

Members nominated by Member States

- Silke DORNER (Austria) 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 KOLOUCHOVA (Czechia) Alternate: Radka NEJEZCHLEBOVA
- Martin OLEKSIEWICZ (Denmark) Alternate: Johanne Juhl KORSBAEK
- 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
- Viola BARDOCZY (Hungary) [2] [3] Alternate: Agnes ZOTTER [4]
- Péter Zsolt FEKETE (Iceland) [5] Alternate: *Awaiting nomination*
- Joseph DE COURCEY (Ireland) Alternate: Richard CARROLL
- Concetta QUINTARELLI (Italy) Alternate: Barbara BONAMASSA
- Una RIEKSTINA (Latvia) Alternate: Liga KUNRADE
- Vlasta ZAVADOVA (Liechtenstein) Alternate: *Awaiting nomination*
- Alessia POCHESCI (Luxembourg) Alternate: Nancy DE BREMAEKER
- Emmely DE VRIES (Netherlands) Alternate: Berendina Maria VAN DEN HOORN
- Rune KJEKEN (Norway) Alternate: Ole Henrik MYRDAL
- Dariusz SLADOWSKI (Poland) Alternate: Marcin KOLAKOWSKI

[1] Anthony SAMUEL resigned as of April 2025
[2] Andras DONASZI-IVANOV resigned as of February 2025
[3] Swap of roles from alternate to member as of April 2025
[4] Nominated as of April 2025
[5] Nominated as of February 2025

- Maria Isabel BORBA VIEIRA (Portugal) [6] Alternate: *Awaiting nomination*
- Denisa MARGINA (Romania) Alternate: Liviu NITULESCU
- Margareta FOGELOVA (Slovakia) [7] Alternate: Denisa PARTELOVA [8]
- Suzana VIDIC (Slovenia) Alternate: Metoda LIPNIK-STANGELJ
- Maria LUTTGEN *(*Sweden) Alternate: Charlotte ANDERBERG

Members representing clinicians nominated by the European Commission

- Julio DELGADO GONZALEZ [9] Alternate: Bernd GANSBACHER
- Alessandra RENIERI [10] [11] Alternate: *Awaiting nomination*

Members representing patients' organisations nominated by the European Commission

- Federica CHIARA [12] Alternate: Kerstin SOLLERBRANT [13]
- Kieran BREEN *(Vice-Chair)* Alternate: Donatella CAPONE [14]

Observers

- Catherine MILNE [15] (EDQM) Alternate: Olga KOLAJ-ROBIN [16] (EDQM)

[6] Nominated as of January 2025 with a swap of roles from alternate to member
[7] Replaced Katarina VAVROVA as of July 2025 with a swap of roles from alternate to member
[8] Nominated as of July 2025
[9] Replaced Paolo GASPARINI as of July 2025
[10] Michal KOSTACKY replaced Alessandro AIUTI as of July 2025
[11] Replaced Michal KOSTACKY as of December 2025 with a swap of role from alternate to member
[12] Replaced Kerstin SOLLERBRANT as of July 2025, with a swap of roles from alternate to member
[13] Replaced Mencia DE LEMUS BELMONTE as of July 2025 with a swap of roles from member to alternate
[14] Replaced Federica CHIARA as of July 2025
[15] Swap of roles from alternate to member as of October 2025
[16] Nominated as of October 2025

Annex 8 – Members of the Paediatric Committee

Chair: Sabine SCHERER [1]

Members nominated from within the CHMP

- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

Members nominated by Member States

- Johanna WERNSPERGER (Austria) Alternate: Agnes GYURASICS
- Karen VAN MALDEREN (Belgium) [2] Alternate: *Awaiting nomination*
- Shteryu BOYADZHIEV (Bulgaria) [3] Alternate: Dimitar ROUSSINOV [4]
- Miroslav WEISS (Croatia) Alternate: Irena SENECIC-CALA
- Zena GUNTHER (Cyprus) Alternate: Andria ELIADOU [5]
- Tereza BAZANTOVA (Czechia) Alternate: Pavlina CHLADOVA
- Louisa BRAUN EXNER (Denmark) Alternate: Britta Eilersen HJERRILD
- Jana LASS (Estonia) Alternate: Liisa SAARE
- Pauliina LEHTOLAINEN DALKILIC (Finland) Alternate: *Awaiting nomination*
- Sylvie BENCHETRIT (France) *(Vice-Chair)* Alternate: *Awaiting nomination* [6]
- Yuansheng SUN (Germany) [7] Alternate: Birgit AHRENS [8]
- Eleni KATSOMITI (Greece) Alternate: Theodoros KARAMPINAS [9]
- Adrienn HORVATH (Hungary) Alternate: Robert PORSZASZ
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Brian AYLWARD (Ireland) [10] 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) Alternate: *Awaiting nomination* [11]
- Carola DE BEAUFORT (Luxembourg) Alternate: Olivier MOES

[1] Replaced Brian AYLWARD as of September 2025
[2] Replaced Marleen RENARD as of July 2025 with a swap of roles from alternate to member
[3] Replaced Mila BAYCHEVA as of December 2025 with a swap of roles from alternate to member
[4] Nominated as of December 2025
[5] Replaced Maria Eleni AVRAAMIDOU as of January 2025
[6] Florence FLAMEIN resigned as of December 2025
[7] Replaced Sabine SCHERER as of December 2025 with a swap of roles from alternate to member
[8] Nominated as of December 2025
[9] Replaced Anastasia MOUNTAKI as of July 2025
[10] Nominated as of September 2025
[11] Sima NAUJOKIENE resigned as of January 2025

- John Joseph BORG (Malta) — Alternate: Deo DEBATTISTA [12] [13]
- Maaike VAN DARTEL (Netherlands) — Alternate: Karijn PIJNENBURG-KLEIZEN [14]
- Siri WANG (Norway) — Alternate: Anette Solli KARLSEN
- Marek MIGDAL (Poland) — Alternate: Monika TROJAN
- 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: David KHAN

Members representing healthcare professionals nominated by the European Commission

- Francesca ROCCHI — Alternate: Jose Ignacio MALAGON CALLE
- Fernando CABANAS — Alternate: Doina PLESCA
- Johannes TAMINIAU — Alternate: Pernille SKOVBY

Members representing patients' organisations nominated by the European Commission

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

[12] Herbert LENICKER resigned as of July 2025
[13] Nominated as of October 2025
[14] Nominated as of January 2025

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)

Quality domain

Working parties	Chair
Biologics Working Party (BWP)	Sean BARRY
Biosimilar Medicinal Products Working Party (BMWP)	René ANOUR
Quality Working Party (QWP)	Blanka HIRSCHLEROVA

Operational expert groups:	Chair
Biologics Working Party Plasma Master File Quality Operational Expert Group (PMF OEG)	Jens REINHARDT
Biologics Working Party Vaccines Quality Operational Expert Group (BV OEG)	Koenraad BRUSSELMANS
Quality Innovation Group (QIG)	Marcel HOEFNAGEL
Paediatric Formulation Operational Expert Group (PFOEG)	Jana LASS

Non-clinical domain

Working parties	Chair
Non-clinical Working Party	Susanne BRENDLER-SCHWAAB
3Rs Working Party	Sonja BEKEN

Operational expert groups	Chair
Nitrosamines Safety Operational Expert Group	Marianne SCHMIDT

European specialised expert groups	Chair
Environmental Risk Assessment European Specialised Expert Community (ERA ESEC)	N/A
Non-Clinical and New Approach Methodologies European Specialised Expert Community	N/A

Methodology domain

Working parties	Chair
Methodology Working Party	Christian B. (Kit) ROES

Operational expert groups	Chair
Biostatistics OEG	N/A
Modelling and Simulation OEG	N/A
Clinical Pharmacology OEG	N/A

European specialised expert groups	Chair
Methodology ESEC	N/A

Clinical domain

Working parties	Chair
Cardiovascular Working Party (CVSWP)	Alar IRS
Central Nervous System Working Party (CNSWP)	Ewa BALKOWIEC-ISKRA
Haematology Working Party (HAEMWP)	Daniela PHILADELPHY
Infectious Diseases Working Party (IDWP)	Maja SOMMERFELT GRØNVOLD
Oncology Working Party (ONCWP)	Pierre DEMOLIS
Rheumatology/Immunology Working Party[1]	Caroline AURICHE-BENICHOU
Vaccines Working Party (VWP)	Sol RUIZ

Scientific advisory groups	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
Inter-Committee Scientific Advisory Group on Oncology	Lothar BERGMANN

Operational expert groups	Chair
Companion Diagnostic (CDx) Expert Group	Jörg ENGELBERGS

[1] The working party's name was changed to Immune and Inflammatory Diseases Working Party in February 2026

European specialised expert groups	Chair
Haematology European Specialised Expert Community	N/A
Oncology European Specialised Expert Community	N/A
Cardiovascular Diseases European Specialised Expert Community	N/A

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
Working Group on Quality Review of Documents	N/A
Scientific Advice Working Party	Paolo FOGGI
Summary of Product Characteristics Advisory Group	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	Mark MONTFORTS
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	Paul McNEILL

Other CVMP-associated groups

	Chair
Antimicrobial Advice Ad Hoc Expert Group	

Pharmacovigilance Risk Assessment Committee (PRAC)

Other PRAC-associated groups

Working groups	Chair
Granularity and Periodicity Advisory Group (GPAG)	Petar MAS/EMA representative
PRAC Interest group on Measuring the Impact of Pharmacovigilance Activities (PRAC IG Impact)	Liana MARTIROSYAN/EMA representative
PRAC Risk Minimisation Alliance (PRISMA) Group	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)

Joint working parties, working groups and advisory groups

	Chair
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)

	Chair
Healthcare Professionals' Working Party (HCPWP)	EMA rappresentative and Rosa GIULIANI
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
Working Group on Quality Review of Documents	EMA representative

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	Priscilla SCHOONDERMARK
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

Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2025

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
EMA/CHMP/55697/2025	Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation[1]	Draft for public consultation	October 2025
EMA/CHMP/CVMP/3Rs/742466/2015 Rev. 1	Reflection paper on the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs	Draft revision for public consultation	February 2025
EMA/CHMP/CVMP/3Rs/164002/2016 Rev. 1	Reflection paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Draft revision for public consultation	February 2025

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/82416/2025	Guideline on the quality aspects of mRNA vaccines	Draft guideline adopted by CHMP for 6 months public consultation	March 2025
EMA/CHMP/BWP/91140/2025	Concept paper on the revision of the guideline on the Scientific Data Requirements for a Plasma Master File (PMF)	Concept paper for the revision adopted by CHMP for 3 months public consultation	March 2025
EMA/CHMP/BWP/548524/2008 Rev.2	Guideline on epidemiological data on blood transmissible infections	Draft revised chapter 9 adopted by CHMP for 2 months public consultation	June 2025
EMA/CHMP/BWP/1/2024	Guideline on quality aspects of phage therapy medicinal products	Draft guideline adopted by CHMP for 6 months public consultation	October 2025
https://www.ema.europa.eu/en/human-regulatory-overview/research-and-	Questions and Answers for biological medicinal products	Additional Q and As adopted by CHMP for publication	January 2025 June 2025 December 2025

[1] Joint activity of 3Rs Working Party and Non-clinical Working Party

Reference number	Document	Status	Date
development/scientific-guidelines/biological-guidelines/questions-answers-biological-medicinal-products			
EMA/CHMP/BWP/153612/2025. Rev 2	Questions and Answers for Plasma Master File Holders on PMF requirements	Revised Q and A adopted by CHMP for publication	May 2025
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-questions-answers-introduction/quality-medicines-questions-answers-part-1	Questions and Answers for phasing out the rabbit pyrogen test	New Q and As adopted by CHMP for publication	May 2025

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMA/CHMP/BMWP/60916/2025	Reflection Paper on a tailored clinical approach in Biosimilar development	Public consultation started	27 Mar 25

Cardiovascular Working Party

Reference number	Document	Status	Date
EMA/369563/2025 Rev. 2 (previously EMA/CHMP/464798/2024 Rev. 1)	Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities – Revision 2	Final Guideline adopted by CHMP	December 2025

Central Nervous System Working Party

Reference number	Document	Status	Date
CHMP/EWP/566/98 Rev.3	Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders – Revision 3	Final guideline adopted by CHMP	February 2025
EMA/CHMP/185423/2010 Rev.3	Guideline on clinical investigation of medicinal products in the treatment of depression - Revision 3	Final	January 2025

Reference number	Document	Status	Date
EMA/231314/2025	Concept paper on the need for revision of the guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease	Concept paper for public consultation	July 2025
EMA/322471/2025	Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of Parkinson’s disease	Concept paper for public consultation	November 2025

Haematology Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/59529/2026 rev 2	Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) - Revision 2	Draft for public consultation	December 2025
EMA/CHMP/BPWP/143744/2011 Rev.2	Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration (SCIg/IMIg) - Revision 2	Draft for public consultation	December 2025

Healthcare Professionals Working Party

Reference number	Document	Status	Date

Infectious Diseases Working Party

Reference number	Document	Status	Date
EMA/283093/2016 Rev. 1	Draft guideline on the clinical evaluation of medicinal products intended for the treatment of chronic hepatitis B (CHB) – Revision 1	Draft for public consultation	September 2025

Methodology Working Party

Reference number	Document	Status	Date
EMA/5875/2025	Concept paper on the development of a Guideline on assessment and reporting of	Concept paper for public consultation	February 2025

Reference number	Document	Status	Date
	mechanistic models used in the context of model informed drug development		
EMA/460496/2024	Implementation strategy of ICH Guideline M12 on drug interaction studies	Final	February 2025
EMA/99865/2025	Reflection paper on use of real-world data in non interventional studies to generate real-world evidence for regulatory purposes	Final	March 2025
EMA/787647/2022	Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data sources and studies - Version 2.0	Final	April 2025
EMA/124631/2025	Concept paper on a guideline on investigation of drug interactions in the gastrointestinal tract	Final	May 2025
EMA/CHMP/225255/2025	Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making	Concept paper for public consultation	July 2025
EMA/301654/2025	Draft guideline on non-inferiority and equivalence comparisons in clinical trials	Draft for public consultation	November 2025
EMA/282050/2025	Concept paper on the guideline revision on good pharmacogenomic practice	Concept Paper for public consultation	December 2025

Product-specific Bioequivalence Guidelines

Reference number	Document	Status	Date
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	Final	February 2025
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	February 2025

Reference number	Document	Status	Date
EMA/518671/2023; EMA/479330/2024	Nilotinib hard capsules 50, 150 and 200 mg product-specific bioequivalence guidance and Overview of comments	Final	February 2025
EMA/CHMP/254395/2024; EMA/339228/2024	Tolvaptan tablets with the dose range 7.5, 15 and 30 mg and tolvaptan tablets with the dose range 15, 30, 45, 60 and 90 mg product-specific bioequivalence guidance and Overview of comments	Final	April 2025
EMA/CHMP/512475/2020 Rev. 1*	Acenocoumarol tablet 1 mg and 4 mg product-specific bioequivalence guidance	Final	June 2026
EMA/151689/2025 Rev. 1	Apixaban film-coated tablet 2.5 and 5 mg product-specific bioequivalence guidance	Final	June 2026
EMA/151692/2025 Rev. 1	Dabigatran etexilate hard capsule 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/315243/2014 Rev. 1	Memantine film-coated tablets 5, 10, 15 and 20 mg, oral solution 5 mg product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/356877/2017 Rev.2	Paracetamol oral use immediate release formulations product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/591346/2022/ Rev. 1*	Metformin immediate-release film-coated tablets 500, 850 and 1000 mg and 1000 mg/5ml oral solution product-specific bioequivalence guidance	Final	June 2025
EMA/151698/2025 Rev. 1	Oseltamivir hard capsules 30, 45 and 75 mg, powder for oral suspension 6 mg/ml and 12 mg/ml product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/315247/2014 Rev. 1	Posaconazole oral suspension 40 mg/ml product-specific bioequivalence guidance	Final	June 2025
EMA/151699/2025 Rev. 2	Prasugrel film-coated tablets 5 mg and 10 mg product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/315234/2014 Rev.3	Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg	Final	June 2025

Reference number	Document	Status	Date
	product-specific bioequivalence guidance		
EMA/CHMP/675842/2014 Rev. 1	Repaglinide tablets 0.5, 1 and 2 mg product-specific bioequivalence guidance	Final	June 2025
EMA/CHMP/559890/2021/ Rev. 1*	Ursodeoxycholic acid capsule 250 mg, film-coated tablet 150 mg, 300 mg, 450 mg, 500 mg, 600 mg and suspension 50mg/ml (250mg/5ml) product-specific bioequivalence	Final	June 2025
EMA/CHMP/315236/2014 Rev. 1	Voriconazole tablets 50, 200 mg and powder for oral suspension 40 mg/ml product-specific bioequivalence guidance	Final	June 2025
EMA/151700/2025 Rev. 1*	Draft Sirolimus coated tablets 0.5, 1 and 2 mg, oral solution 1 mg/ml product-specific bioequivalence guidance	Draft for public consultation	July 2025
EMA/151687/2025 Rev. 1*	Draft Aliskiren film-coated tablet 150 mg and 300 mg product-specific bioequivalence guidance	Draft for public consultation	July 2025
EMA/151695/2025 Rev. 1	Draft Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance	Draft for public consultation	July 2025
EMA/151702/2025 Rev. 1*	Draft Ledipasvir/sofosbuvir film-coated tablet 45 mg/200 mg and 90 mg/400 mg, coated granules 33.75mg/150mg and 45mg/200mg product-specific bioequivalence guidance	Draft for public consultation	July 2025
EMA/495648/2024	Aprepitant hard capsules 80 mg, 125 mg, 80 mg + 125 mg (combination) product-specific bioequivalence guidance	Final	July 2025
EMA/151690/2025 Rev. 1	Asenapine sublingual tablets 5 and 10 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/172895/2023; EMA/264768/2024	Azacitidine powder for suspension for injection 25 mg/ml product-specific bioequivalence guidance and Overview of comments	Final	July 2025
EMA/151691/2025 Rev. 1	Carglumic acid dispersible tablets 200 mg product-specific bioequivalence guidance	Final	July 2025

Reference number	Document	Status	Date
EMA/CHMP/800759/2017 Rev. 1*	Cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/35552/2019 Rev. 1*	Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/39771/2023; EMA/339228/2024	Dabrafenib hard capsule 50 and 75 mg product-specific bioequivalence guidance and Overview of comments	Final	July 2025
EMA/CHMP/805532/2016 Rev. 1*	Emtricitabine/rilpivirine/tenofovir disoproxil film-coated tablets 200 mg/25 mg/245 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/675839/2014 Rev. 1*	Emtricitabine/Tenofovir Disoproxil film-coated tablets 200mg/245 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/160445/2016 Rev. 1*	Entecavir film-coated tablets 0.5 and 1 mg, oral solution 0.05mg/ml product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/154812/2016 Rev.2*	Fingolimod capsules 0.25 and 0.5 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/176098/2020 Rev. 1	Levothyroxine tablets 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg and 200 mcg (and additional strengths within the range) product-specific bioequivalence guidance	Final	July 2025
EMA/418520/2024	Paclitaxel (nanoparticle albumin-bound) powder for suspension for infusion 5mg/ml product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/901584/2022 Rev. 1*	Pirfenidone film-coated tablets 267, 537 and 801 mg, and hard capsules 267 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/356878/2017 Rev. 1*	Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/160650/2016 Rev. 1*	Rivaroxaban film-coated tablets 2.5, 10, 15 and 20mg product-specific bioequivalence guidance	Final	July 2025

Reference number	Document	Status	Date
EMA/CHMP/158934/2016 Rev.1*	Sitagliptin film-coated tablets 25, 50 and 100 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/159744/2016 Rev.1*	Tacrolimus granules for oral suspension 0.2 and 1 mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/177281/2016 Rev.1*	Ticagrelor film-coated tablets 90mg product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/474974/2016 Rev.1*	Vortioxetine hydrobromide immediate release tablets 5 mg, 10 mg, 15 mg, and 20 mg; vortioxetine lactate oral drops solution 20 mg/ml product-specific bioequivalence guidance	Final	July 2025
EMA/CHMP/159882/2016 Rev.1*	Zonisamide hard capsules 25, 50 and 100 mg, orodispersible tablets 25, 50, 100 and 300 mg product-specific bioequivalence guidance	Final	July 2025
EMA/226445/2025	Draft Eltrombopag film-coated tablets 12.5 mg, 25 mg, 50 mg, 75 mg and powder for oral suspension 25 mg product-specific bioequivalence guidance	Draft for public consultation	September 2025
EMA/226444/2025	Draft Melatonin prolonged release-tablets 2 mg product-specific bioequivalence guidance	Draft for public consultation	September 2025
EMA/CHMP/356874/2017 Rev. 1	Dolutegravir film-coated tablets 10 mg, 25 mg and 50 mg product-specific bioequivalence guidance	Final	November 2025
EMA/CHMP/356876/2017 Rev.2	Ibuprofen oral use immediate release formulations 200–800 mg product-specific bioequivalence guidance	Final	November 2025

Non-clinical Working Party

Reference number	Document	Status	Date
EMA/CHMP/55697/2025	Reflection paper on lessons learned from the COVID-19 4 pandemic: Scientific considerations on non-clinical aspects	Draft	Adopted by CHMP for release for 3 month public consultation on 10 June 2025
EMA/CHMP/55697/2025	Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation ** Joint activity of 3Rs Working Party and Non-clinical Working Party*	Draft	Adopted by CHMP for release for consultation 6 October 2025
EMA/CHMP/187129/2016	Information for the package leaflet regarding dextrans used as excipients in medicinal products for human use	Final	Date of publication 9 December 2025

Oncology Working Party

Reference number	Document	Status	Date
EMA/122980/2025	Concept paper on the revision of the guideline on the evaluation of anticancer medicinal products and appendices - Revision 7	For public consultation	April 2025

Quality Working Party

Reference number	Document	Status	Date
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-questions-answers-introduction/quality-medicines-questions-answers-part-1	Questions and Answers for phasing out the rabbit pyrogen test	Published	May 2025
EMEA/CHMP/QWP/49313/2005 rev.1	Guideline on the pharmaceutical quality of inhalation and nasal products	Published	July 2025
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-	Q&A on skip testing	Published	October 2025

Reference number	Document	Status	Date
overview/research-development/scientific-guidelines/quality-medicines-questions-answers-introduction/quality-medicines-questions-answers-part-2			
N/A – refer to website: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/classification-changes-questions-answers	Q&A on novel or complex manufacturing process in Q.I.b.1/Q.II.b.4	Published	November 2025
EMA/CHMP/QWP/363827/2025	Guideline on Radiopharmaceuticals	Draft guideline adopted by CHMP for 5 months public consultation	December 2025
EMA/CHMP/CVMP/QWP/367182/2025	Guideline on synthetic peptides	Published	December 2025
EMA/CHMP/QWP/441071/2011- Rev.3	Guideline on stability testing for applications for variations to a marketing authorisation	Published	December 2025

Rheumatology/Immunology Working Party

Reference number	Document	Status	Date
EMA/67201/2025	Draft guideline on the clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome - Revision 2	Draft update for public consultation	February 2025
EMA/161669/2025	Guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations	Final new guideline	June 2025
EMA/179449/2025	Concept paper on the new reflection paper on the clinical investigation of medicinal products for the treatment of systemic sclerosis	Concept paper for public consultation	June 2025
CPMP/EWP/4151/00 Rev. 2	Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma	Final updated guideline	July 2025

Reference number	Document	Status	Date
	and chronic obstructive pulmonary disease (COPD) - Revision 2		
CHMP/EWP/438/04 Rev. 1	Draft Guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis	Draft update for public consultation	September 2025
EMA/CHMP/290364/2025	Concept paper on new guidance on the clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis (IPF)	Concept paper for public consultation	September 2025
EMA/CHMP/312843/2025	Concept paper on a paediatric update on the guideline on the development of new medicinal products for the treatment of Ulcerative Colitis	Concept paper for public consultation	October 2025
EMA/CHMP/312837/2025	Concept paper on a paediatric update of the guideline on clinical investigation of medicinal products for the management of Crohn's disease	Concept paper for public consultation	October 2025
EMA/58320/2025 rev. 2	Guideline on the clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome - Revision 2	Final updated guideline	November 2025

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	Final	February 2025

Annex 12 – CVMP opinions in 2025 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**
• Bluevac 3 • Bluetongue virus vaccine (inactivated)	• CZ Vaccines S.A.U.	• Sheep, Cattle • Sheep: For active immunisation of sheep to reduce the viraemia, preventing mortality and to reduce clinical signs caused by the serotype 3 of the bleutongue virus. Cattle: For active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.	• 18/10/2024 • 15/01/2025 • 89 • 0	• 20/02/2025 • 21/02/2025 • C 1825
• Syvazul BTV 3 • Bluetongue virus vaccine (inactivated)	• Laboratorios Syva S.A.	• Sheep, Cattle • Sheep: For active immunization of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue serotype 3. Onset of immunity: 4 weeks after completion of the primary vaccination scheme. The duration of immunity has not been established. Cattle: for active immunisation of cattle to reduce viraemia caused by bluetongue serotype 3. Onset of immunity: 3 weeks after completion of the primary vaccination scheme. The duration of immunity has not been established.	• 11/10/2024 • 15/01/2025 • 89 • 0	• 20/02/2025 • 21/02/2025 • C 1825
• Nobilis Multriva REOm • Avian reovirus vaccine (inactivated)	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for passive immunisation of the progeny of the vaccinated chickens to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.	• 12/06/2024 • 15/01/2025 • 179 • 38	• 27/02/2025 • 03/03/2025 • C 1825

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**
• Elmaro • Maropitant citrate monohydrate	• Elanco GmbH	• Dog, Cat • For the treatment and prevention of nausea and vomiting	• 20/12/2023 • 12/02/2025 • 209 • 211	• 28/03/2025 • 01/04/2025 • C 1955
• Vectormune HVT-AIV • Avian influenza vaccine (live recombinant)	• Ceva Sante Animale	• Chicken (one day-old chick) • For active immunisation of one-day-old chickens	• 15/03/2023 • 12/02/2025 • 209 • 491	• 28/03/2025 • 01/04/2025 • C 1955
• Omeprazole TriviumVet • Omeprazole	• TriviumVet DAC	• Dog • As an aid in the treatment of NSAID-induced gastric ulceration in dogs	• 10/05/2023 • 12/02/2025 • 208 • 436	• 02/04/2025 • 03/04/2025 • C 2785
• Hepizovac • Epizootic haemorrhagic disease vaccine (inactivated)	• CZ Vaccines S.A.U.	• Cattle • For the active immunisation of cattle to prevent viraemia caused by serotype 8 of the Epizootic Haemorrhagic Disease Virus	• 14/12/2024 • 13/03/2025 • 90 • 0	• 23/04/2025 • 25/04/2025 • C 2785
• Prazivetin • Praziquantel	• Vethellas S.A.	• Gilthead • For the treatment of ectoparasitic infestations of the gills caused by the monogenean Sparicotyle chrysophrii	• 11/05/2023 • 13/03/2025 • 210 • 463	• 23/04/2025 • 28/04/2025 • C 2785
• Prevestrus vet • Finrozole	• Vetcare Oy	• Dog (bitch) • For the suppression of clinical signs of oestrus and prevention of pregnancy in bitches. To shorten the pro-oestrus and oestrus period, reduce clinical signs of heat and reduce the risk of pregnancy	• 10/05/2023 • 13/03/2025 • 210 • 463	• 23/04/2025 • 25/04/2025 • C 2785

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 IBm+ND+EDS • Infectious bronchitis, Newcastle disease and egg drop syndrome virus vaccine (inactivated)	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for: - 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) - reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).	• 10/07/2024 • 13/03/2025 • 180 • 66	• 25/04/2025 • 28/04/2025 • C 2785
• Emevet • Maropitant	• CP-Pharma Handelsgesellschaft mbH	• Dog • Prevention of nausea induced by chemotherapy in dogs. Prevention of vomiting induced by motion sickness in dogs. Prevention and treatment of vomiting, in conjunction with Maropitant solution for injection and in combination with other supportive measures in dogs	• 20/02/2024 • 09/04/2025 • 208 • 205	• 02/06/2025 • 04/06/2025 • C 4099
• Nobilis Multriva Gm+REOm • Avian infectious bursal disease and avian reovirus vaccine (inactivated)	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for 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 disease virus (IBDV), and to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4	• 11/12/2024 • 09/04/2025 • 119 • 0	• 02/06/2025 • 03/06/2025 • C 4099
• Nobilis Multriva IBm+ND • Avian infectious bronchitis virus and Newcastle disease virus vaccine (inactivated)	• Intervet International B.V.	• Chicken • For the active immunisation of chickens for: - reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1	• 18/09/2024 • 09/04/2025 • 178 • 25	• 02/06/2025 • 03/06/2025 • C 4099

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
		genotype) and 4/91-793B (GI-13 genotype); - reduction of mortality and clinical signs caused by Newcastle disease virus (NDV)		
• Fluralaner Intervet • Fluralaner	• Intervet International B.V.	• Dog • For the treatment of tick and flea infestations in dogs. This veterinary medicinal product is a systemic insecticide and acaricide that provides: - immediate and persistent flea (Ctenocephalides canis and C. felis) killing activity for 1 month; - immediate and persistent tick (Dermacentor reticulatus, Ixodes hexagonus, I. ricinus and Rhipicephalus sanguineus) killing activity for 1 month. It can also be used as part of a treatment strategy for the control of flea allergy dermatitis. In addition, it reduces the risk of infection with Babesia canis canis and Dipylidium caninum via transmission from D. reticulatus and C. felis, respectively	• 18/10/2023 • 15/05/2025 • 208 • 367	• 27/06/2025 • 09/07/2025 • C 4099
• Nobilis Multriva IBm+ND+Gm+REOm+EDS • 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 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	• 15/5/2024 • 15/05/2025 • 180 • 185	• 27/06/2025 • 01/07/2025 • C 4099

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
		virulent (CS89) and classical (STC) strains of infectious bursal disease virus (IBDV); ▫ reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4; - reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV)		
• Innovax-ND-IBD-ILT • Avian infectious laryngotracheitis, infectious bursal disease, Marek's disease and Newcastle disease vaccine (live recombinant)	• Intervet International B.V.	• Chicken (embryonated eggs), Chicken • For active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs: - to reduce mortality and clinical signs caused by Newcastle disease (ND) virus; - to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus, Marek's disease (MD) virus and infectious bursal disease (IBD) virus	• 20/02/2024 • 15/05/2025 • 209 • 240	• 04/07/2025 • 07/07/2025 • C 4668
• Numelvi • Atinvicitinib	• Intervet International B.V.	• Dog • Treatment of pruritus associated with allergic dermatitis in dogs. Treatment of clinical manifestations of atopic dermatitis in dogs.	• 10/07/2024 • 12/06/2025 • 209 • 128	• 24/07/2025 • 31/07/2025 • C 4668
• Zenrelia • Ilunocitinib	• Elanco GmbH	• Dog • Treatment of pruritus associated with allergic dermatitis in dogs. Treatment of clinical manifestations of atopic dermatitis in dogs	• 20/12/2023 • 12/06/2025 • 210 • 330	• 24/07/2025 • 25/07/2025 • C 4668

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**
• BioBhyo • Swine dysentery vaccine (inactivated)	• Aquilon Cyl S.L.	• Pig • For the active immunisation of pigs to reduce the occurrence of dysenteric diarrhoea.	• 20/03/2024 • 12/06/2025 • 210 • 239	• 30/07/2025 • 08/08/2025 • C 1043
• BRAVECTO CombiUNO • Fluralaner / Milbemycin oxime	• 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 only indicated when use against ticks or fleas and one or more of the other target parasites is indicated at the same time. For the treatment of tick and flea infestations on dogs providing immediate and persistent flea (Ctenocephalides felis and C. canis) killing activity and immediate and persistent tick (Dermacentor reticulatus, Ixodes hexagonus, I. ricinus, and Rhipicephalus sanguineus) killing activity for 1 month. The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD). For reduction of the risk of infection with Babesia canis canis via transmission by D. reticulatus for 1 month. The effect is indirect due to the product's activity against the vector	• 20/03/2024 • 12/06/2025 • 210 • 239	• 30/07/2025 • 04/08/2025 • C 4668
• CEVAC REOMUNE • Avian reovirus vaccine (inactivated)	• Filavie	• Chicken • For active immunisation of broiler breeders to provide a passive immunisation to the progeny to reduce clinical signs of tenosynovitis induced by avian reovirus	• 22/12/2022 • 17/07/2025 • 210 • 729	• 28/08/2025 • 29/08/2025 • C 5097

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**
		infection serotype S1133 and variant serotype 11-12523.		
• Hemosyvet • Etamsylate	• Axience	• Dog, Goat, Horse, Cattle, Sheep, Cat, Pig • Prevention and treatment of surgical, post traumatic, obstetric and gynaecological haemorrhages.	• 15/05/2024 • 17/07/2025 • 209 • 219	• 24/10/2025 • 27/10/2025 • C 6344
• Portela • Relfovetmab	• Zoetis Belgium	• Cat • For the alleviation of pain associated with osteoarthritis (OA) in cats.	• 07/08/2024 • 10/09/2025 • 209 • 190	• 27/10/2025 • 28/10/2025 • C 6344
• Vaxxitek HVT+IBD+H5 • Avian influenza vaccine (live recombinant)	• Boehringer Ingelheim Vetmedica GmbH	• Chicken (embryonated eggs), Turkey, Chicken • For active immunisation of one-day-old chicks or 18-day-old embryonated chicken eggs: to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza virus (HPAI) virus of the H5 subtype, including the circulating clade 2.3.4.4b. For active immunisation of one-day-old turkeys: to reduce mortality, clinical signs and virus excretion due to infection with HPAI virus of the H5 subtype, including the circulating clade 2.3.4.4b.	• 11/07/2025 • 09/10/2025 • 90 • 0	• 19/11/2025 • 19/11/2025 • C 6746

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**
• Lenivia • Izenivetmab	• Zoetis Belgium	• Dog • For the alleviation of pain associated with osteoarthritis in dogs.	• 10/07/2024 • 09/10/2025 • 210 • 246	• 21/11/2025 • 26/11/2025 • C 6746
• Vaxxinact H5 • Avian influenza vaccine (subunit recombinant)	• Boehringer Ingelheim Vetmedica GmbH	• Chicken, Duck, Turkey • Active immunization of chickens, ducks (Pekin, Mulard and Muscovy) and turkeys against HPAI infection (Highly Pathogenic Avian Influenza) related to H5, including the circulating clade 2.3.4.4b.	• 30/07/2025 • 06/11/2025 • 90 • 0	• 04/12/2025 • 08/12/2025 • C 402
• Ecovaxxin MS • Mycoplasma synoviae vaccine (live)	• Eco Animal Health Europe Limited	• Chicken • For active immunisation of future layer and future breeder chickens from 4 weeks of age to reduce air sac lesions, foot pad lesions (synovitis), ovarian regressions and egg production losses caused by Mycoplasma synoviae infections.	• 109/03/2025 • 06/11/2025 • 180 • 52	• 18/12/2025 • 21/12/2025 • C 402
• Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A. • Epizootic haemorrhagic disease vaccine (recombinant protein)	• Laboratorios Syva S.A.	• Cattle • For active immunisation of cattle to reduce viraemia and fever caused by epizootic haemorrhagic disease virus serotype 8. Onset of immunity: 2 weeks after completion of the primary vaccination scheme Duration of immunity: Not established yet.	• 11/07/2025 • 04/12/2025 • 120 • 26	• 29/01/2026 • pending • pending
• Firocoxib CP-Pharma • Firocoxib	• CP-Pharma Handelsgesellschaft mbH	• Dog • For the relief of pain and inflammation associated with osteoarthritis in dogs. For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.	• 06/10/2025 • 04/12/2025 • 59 • 0	• 26/01/2026 • 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
• Varenzin • Molidustat	• Elanco GmbH	• Cat • For the management of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats, by increasing haematocrit/packed cell volume.	• 10/07/2024 • 04/12/2025 • 209 • 303	• 22/01/2026 • pending • pending

Negative opinions

There were no negative opinions in 2025.

CVMP opinions in 2025 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
• Fluralaner	• Fin Fish	• 15/05/2024 • 12/02/2025 • 207 • 66	• 12/02/2025 • 2025/1098 • L 1908
• Lidocaine	• Porcine	• 19/03/2024 • 04/12/2025 • 209 • 212	• 04/12/2025 • Pending • Pending

Negative opinions

There were no negative opinions on establishment of MRLs in 2025.

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**
• Nobivac L4 • Canine leptospirosis vaccine (inactivated)	• Intervet International B.V.	• QI07AB01 • For active immunisation of dogs to induce immunity against Leptospira strains	• 17/07/2025	• 21/08/2025
• Nobivac LoVo L4 • Canine leptospira vaccine	• Intervet International B.V.	• QI07AB01 • For active immunisation of dogs	• 17/07/2025	• 21/08/2025
• 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	• 12/02/2025	• 02/04/2025
• Stronghold Plus • Selamectin / Sarolaner	• 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.	• 15/05/2025	• 27/06/2025
• Daxocox • Enficoxib	• Ecuphar NV	• QM01AH95 • For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.	• 12/06/2025	• 24/07/2025

Product • **Brandname** • **INN**	**Marketing authorisation holder**	**Therapeutic Area** • **ATC Code** • **Summary of indication**	**EMA/CVMP opinion**	**European Commission decision date**
• BRAVECTO TriUNO • Fluralaner / Moxidectin / Pyrantel	• Intervet International B.V.	• QP54AB52 • 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, prevention of angiostrongylosis and treatment of Angiostrongylus vasorum	• 10/9/2025	• 27/10/2025
• Dexdomitor • Dexmedetomidine	• Orion Corporation	• QN05CM18 • Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.	• 04/12/2025	• 22/01/2026
• Nexgard • Afoxolaner	• Boehringer Ingelheim Vetmedica GmbH	• QP53BE01 • Treatment and prevention of flea and tick infestation in dogs. Treatment of demodicosis and sarcoptic mange as well as ear mite infestations.	• 04/12/2025	•
• Nexgard Spectra • Afoxolaner / Milbemycin oxime	• Boehringer Ingelheim Vetmedica GmbH	• QP54AB51 • For dogs with, or at risk from, mixed infestations by external and internal parasites. The veterinary medicinal product is only indicated when use against ticks, fleas, or mites and one or more of the other target parasites is indicated at the same time.	• 04/12/2025	• 24/07/2025

Product • **Brandname** • **INN**	Marketing authorisation holder	Therapeutic Area • **ATC Code** • **Summary of indication**	EMA/CVMP opinion	European Commission decision date
• Syvazul BTV 3 • Bluetongue virus vaccine (inactivated)	• Laboratorios Syva S.A.	• QA04AA02 • Sheep: For active immunization of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue serotype 3. Onset of immunity: 4 weeks after completion of the primary vaccination scheme. The duration of immunity has not been established. Cattle: for active immunisation of cattle to reduce viraemia caused by bluetongue serotype 3. Onset of immunity: 3 weeks after completion of the primary vaccination scheme. The duration of immunity has not been established.	• 17/07/2025	• 28/08/2025
• Frontpro • Afoxolaner	• Boehringer Ingelheim Vetmedica GmbH	• QP53BE01 • Treatment of flea and tick infestations in dogs.	• 06/11/2025	• 18/12/2025
• Credelio	• Elanco GmbH	• QP53BE04 • For the treatment of flea and tick infestations and demodicosis (caused by Demodex canis) in dogs For the treatment of flea and tick infestations on cats	• 06/11/2025	• 22/12/2025
• Credelio Plus • Lotilaner / Milbemycin oxime	• Elanco GmbH	• QP54AB51 • For use in dogs with, or at risk from, mixed infestations/infections of ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm and treatment of demodicosis	• 06/11/2025	• 18/12/2025
• Lotimax • Lotilaner	• Elanco GmbH	• QP53BE04 • For the treatment of flea and tick infestations and demodicosis (caused by Demodex canis) in dogs	• 06/11/2025	• 18/12/2025

Annex 13 – Guidelines and concept papers adopted by CVMP in 2025

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/85848/2025	Concept paper on the need for Revision of Note for Guidance on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water	Adopted for consultation June 2025 End of consultation 31 October 2025
EMA/CVMP/QWP/59158/2025	Guideline on in-use stability testing of veterinary medicinal products	Adopted September 2025
EMA/CHMP/CVMP/QWP/367182/2025	Guideline on the Development and Manufacture of Synthetic Peptides	Adopted December 2025

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/564861/2023	Concept paper on the development of a guideline on consumer safety of active substances of immunological veterinary medicinal products acting against endogenous targets	Adopted for consultation May 2025 End of consultation 31 August 2025

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/37280/2023	Guideline on data requirements for veterinary medicinal products for zootechnical purposes	Adopted January 2025
EMA/CVMP/627/2001 Rev.2	Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted February 2025
EMA/CVMP/344/1999 Rev.3	Guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted February 2025
EMA/CVMP/EWP/755916/2016	Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances	Adopted July 2025

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009-Rev.16	Combined VeDDRA list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products	Adopted June 2025
EMA/CVMP/PhVWP/118833/2025	List of changes to combined VeDDRA list of clinical terms	Adopted June 2025
EMA/CVMP/PhVWP/288284/2007 Rev.17	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse events in animals and humans	Adopted June 2025

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/706442/2013	Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food producing animal species	Adopted January 2025
EMA/CVMP/AWP/109142/2025	Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species	Adopted for consultation November 2025 End of consultation 31 May 2026

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/205351/2006-Rev.2	Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus	Adopted September 2025
EMA/CVMP/IWP/224985/2025	Guideline on duration of immunity achieved by veterinary vaccines	Adopted September 2025

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/75412/2023	Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product	Adopted for consultation April 2025 End of consultation 31 October 2025
EMA/CVMP/ERA/499198/2024	Concept paper for the development of a guideline on the methodology of environmental risk assessment for ectoparasiticidal VMPs for cats and dogs	Adopted for consultation June 2025 End of consultation 31 October 2025

CVMP Novel therapies and technologies

Reference number	Document title	Status
N/a		

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

Reference number	Document title	Status
EMA/CHMP/CVMP/3Rs/164002/2016	Reflection paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Adopted for consultation January 2025 End of consultation 30 June 2025

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

Reference number	Document title	Status
N/a		

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/55240/2025	Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations Potential criteria to support the demonstration of a reduction in the antimicrobial or antiparasitic resistance, or an improvement of the benefit risk balance	Adopted May 2025
EMA/CVMP/29892/2024	Scientific advice under Article 114(3) of Regulation (EU) 2019/6 on veterinary medicinal products - List of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in medicinal products for human use authorised in the Union, which may be used in food-producing aquatic species in accordance with Article 114(1)	Adopted May 2025

General

Reference number	Document title	Status
EMA/CVMP/PhVWP/133883/2004 Rev.8	Mandate, objectives, and rules of procedure for the Committee for Veterinary Medicinal Products (CVMP) Pharmacovigilance Working Party (PhVWP-V)	Adopted March 2025
EMA/CVMP/VICH/525/2000	VICH GL22(R) Studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing (Revision 1)	Adopted September 2025
EMA/CVMP/VICH/526/2000	VICH GL23 Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing (revision 2)	Adopted September 2025

Reference number	Document title	Status
EMA/CVMP/VICH/250843/2021	VICH GL62 on target animal safety of veterinary monoclonal antibody products (VMAPs)	Adopted for consultation September 2025 End of consultation 15 February 2026

Annex 14 – COMP opinions in 2025 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**
Iniparib	Raremoon Consulting Esp S.L.	Treatment of glioma	• 28/08/2025 • 15/09/2025 • 13/11/2025 • (58 days/25 days)	• 14/11/2025 • 09/12/2025
Puliretgene parvec	Laura Nae	Treatment of inherited retinal dystrophy due to dysfunction in the *CYP4V2*-gene	• 29/08/2025 • 15/09/2025 • 10/11/2025 • (55 days/25 days)	• 14/11/2025 • 09/12/2025
Adeno-associated virus vector serotype 6.2 containing human *TERT* gene	Telomere Therapeutics S.L.	Treatment ofidiopathic pulmonary fibrosis	• 26/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Zimberelimab	Gilead Sciences Ireland Unlimited Company	Treatment of gastric cancer	• 13/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Human IgG1 monoclonal antibody against Tumor necrosis factor receptor superfamily member 1B	BioInvent International AB	Treatment of cutaneous T-cell lymphoma	• 29/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Biotin	Lydian Limited	Treatment of biotin-thiamine-responsive basal ganglia disease (BTBGD)	• 14/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Humanised IgG1 kappa monoclonal antibody against pregnancy-associated plasma protein A	Glaxosmithkline Trading Services Limited	Treatment of autosomal dominant polycystic kidney disease	• 21/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Domvanalimab	Gilead Sciences Ireland Unlimited Company	Treatment of oesophageal cancer	• 13/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Cyclo(arginyl-glycyl-aspartyl-D-tyrosyl-lysyl)-nizaracianine-1	Curadel Surgical Innovations B.V.	Diagnosis of pancreatic cancer	• 20/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Zimberelimab	Gilead Sciences Ireland Unlimited Company	Treatment of oesophageal cancer	• 13/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Autologous peripheral blood-derived CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector containing the human *MAN2B1* gene	Fondazione Telethon Ets	Treatment of alpha-mannosidosis	• 12/06/2025 • 15/08/2025 • 06/11/2025 • (83 days/25 days)	• 14/11/2025 • 09/12/2025
Rezatapopt	Somerville Development Partners B.V.	Treatment of ovarian cancer	• 28/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Efdoralprin alfa	Sanofi B.V.	Treatment of alpha-1 antitrypsin deficiency	• 05/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Amsulostat	Pharma Gateway AB	Treatment of myelofibrosis	• 28/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
[4-(6-aminopyridazin-3-yl)piperidin-1-yl][5-(4-fluorophenoxy)-4-methoxypyridin-2-yl]methanone	Boehringer Ingelheim International GmbH	Treatment of focal segmental glomerulosclerosis	• 11/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Domvanalimab	Gilead Sciences Ireland Unlimited Company	Treatment of gastric cancer	• 13/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025
N-[[(2S)-4-[(4-Methyl-1H-imidazol-5-yl)methyl]-3-oxo-2-(phenylmethyl)-1-piperazinyl]carbonyl]-L-leucine trihydrate	Serum Life Science Europe GmbH	Treatment of cutaneous T-cell lymphoma	• 27/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/25 days)	• 14/11/2025 • 09/12/2025
Potravitug	FGK Representative Service GmbH	Treatment of in solid organ transplantation	• 28/08/2025 • 15/09/2025 • 06/11/2025 • (51 days/31 days)	• 14/11/2025 • 15/12/2025
Surovatamig	AstraZeneca AB	Treatment of B-lymphoblastic leukaemia/lymphoma	• 09/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
Orvepitant maleate	Granzer Regulatory Consulting & Services GmbH	Treatment of idiopathic pulmonary fibrosis	• 15/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Leuconostoc citreum, strain G511, Live	Harvest Integrated Research Organization Ireland Limited	Treatment of primary sclerosing cholangitis	• 24/06/2025 • 15/07/2025 • 08/10/2025 • (84 days/37 days)	• 15/10/2025 • 21/11/2025
Antisense oligonucleotide against ABCA4 pre-mRNA	Astherna B.V.	Treatment of non-syndromic inherited retinal dystrophies due to defects in the *ABCA4* gene	• 11/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
Zanidatamab	Jazz Pharmaceuticals Ireland Limited	Treatment of oesophageal cancer	• 14/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
2-(3-Chlorophenyl)-N-[6-(trifluoromethyl)-1,3-benzothiazol-2-yl]acetamide	Molefy Pharma S.L.	Treatment of amyotrophic lateral sclerosis	• 26/06/2025 • 15/07/2025 • 08/10/2025 • (84 days/37 days)	• 15/10/2025 • 21/11/2025
2'-O-(2-Methoxyethyl) modified antisense oligonucleotide against MECP2 pre-mRNA	Ionis Ireland Limited	Treatment of MECP2 Duplication Syndrome	• 15/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
N-(6-Amino-5-ethylpyridin-3-yl)-2-((2R,5S)-5-methyl-2-(2-(1-methylpiperidin-4-yl)benzo[d]thiazol-5-yl)piperidin-1-yl)-2-oxoacetamide	PPD Bulgaria EOOD	Treatment of pancreatic cancer	• 26/06/2025 • 15/07/2025 • 08/10/2025 • (84 days/37 days)	• 15/10/2025 • 21/11/2025
(S)-1-(2,2-Difluoroethyl)-3-(difluoromethyl)-N-(1-(3-(2-methoxypyridin-4-yl)-1,2,4-oxadiazol-5-yl)ethyl)-1H-pyrazole-5-carboxamide	UCB Pharma	Treatment of KCNT1-related epilepsy and neurodevelopmental disorders	• 11/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Nangibotide	Inotrem	Treatment of sickle cell disease	• 26/06/2025 • 15/07/2025 • 08/10/2025 • (84 days/37 days)	• 15/10/2025 • 21/11/2025
Felzartamab	Biogen Netherlands B.V.	Treatment of primary membranous nephropathy	• 10/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
Infigratinib	BridgeBio Europe B.V.	Treatment of hypochondroplasia	• 15/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
Resecabtagene autoleucel	Cabaletta Bio (Germany) GmbH	Treatment of systemic sclerosis	• 15/07/2025 • 15/08/2025 • 08/10/2025 • (53 days/37 days)	• 15/10/2025 • 21/11/2025
Soquelitinib	Voisin Consulting Life Sciences	Treatment of peripheral T-cell lymphoma	• 17/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Bevantolol hydrochloride	Som Innovation Biotech S.A.	Treatment of Huntington’s disease	• 23/05/2025 • 17/06/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Mezagitamab	Takeda Pharmaceuticals International AG Ireland Branch	Treatment of primary IgA nephropathy	• 16/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Sutacimig	Hemab ApS	Treatment of Glanzmann thrombasthenia	• 20/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Synthetic siRNA oligonucleotide against hepatitis B virus X gene transcripts, conjugated to N-acetylgalactosamine, sodium salt	Ribocure Pharmaceuticals AB	Treatment of hepatitis D virus infection	• 25/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Autologous peripheral blood-derived CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector containing the murine *Glb1* gene	Fondazione Telethon Ets	Treatment of Glb1-related disorders	• 19/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Ceruloplasmin	Kedrion S.p.A.	Treatment of congenital aceruloplasminemia	• 30/05/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Glial cell line-derived neurotrophic factor, sodium butyrate	CATS Consultants GmbH	Treatment of Hirschsprung's disease	• 26/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Unasnemab	Mitsubishi Tanabe Pharma GmbH	Treatment of amyotrophic lateral sclerosis	• 25/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Human IgG1 monoclonal antibody against B7-H3, conjugated to N-((2R,10S)-10-Benzyl-2-cyclopropyl-1-(((1S,9S)-9-ethyl-5-fluoro-9-hydroxy-4-methyl-10,13-dioxo-2,3,9,10,13,15-hexahydro-1H,12H-benzo[de]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-1-yl)amino)-1,6,9,12,15-pentaoxo-3-oxa-	Glaxosmithkline Trading Services Limited	Treatment of pulmonary neuroendocrine carcinoma	• 25/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
5,8,11,14-tetraazahexadecan-16-yl)-6-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)hexanamide				
Fenfluramine hydrochloride	UCB Pharma	Treatment of Rett syndrome	• 24/06/2025 • 15/07/2025 • 11/09/2025 • (57 days/35 days)	• 17/09/2025 • 22/10/2025
Humanised IgG1 monoclonal antibody against butyrophilin-3A receptor	Imcheck Therapeutics	Treatment of acute myeloid leukaemia	• 22/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Alpibectir, Ethionamide	Bioversys S.A.S.	Treatment of tuberculosis	• 20/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Sonpiretigene isteparvovec	Granzer Regulatory Consulting & Services GmbH	Treatment of non-syndromic inherited retinal dystrophies of the cone-dominant phenotype	• 22/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Methotrexate	Helio Vision Germany GmbH	Treatment of primary large B-cell lymphomas of immune privileged sites	• 25/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Sonpiretigene isteparvovec	Granzer Regulatory Consulting & Services GmbH	Treatment of non-syndromic inherited retinal dystrophies of the rod-dominant phenotype	• 22/05/202 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Sonpiretigene isteparvovec	Granzer Regulatory Consulting & Services GmbH	Treatment of syndromic inherited retinal dystrophies of the cone-dominant phenotype	• 22/05/2025 • 17/06/2025 • 17/07/2025	• 24/07/2025 • 22/08/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (29 days/29 days)	
Zilurgisertib	Incyte Biosciences Distribution B.V.	Treatment of fibrodysplasia ossificans progressiva	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Varegacestat	Somerville Development Partners B.V.	Treatment of soft tissue sarcoma	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Temozolomide	Orphelia Pharma S.A.S.	Treatment of glioma	• 24/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Brepocitinib	Scendea (NL) B.V.	Treatment of idiopathic inflammatory myopathy	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Sonpiretigene isteparvovec	Granzer Regulatory Consulting & Services GmbH	Treatment of non-syndromic macular dystrophy	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
3-Tert-butyl-N{(1R)-1-{4-(6-{6-[4-({1-[4-(2,4-dioxo-1,3-diazinam-1-yl)phenyl]piperidin-4-yl}methyl)piperazin-1-yl]pyridine-3-yl}-7H-pyrrolo[2,3-d]pyrimidin-4-yl)-2-methylphenyl]ethyl}-1,2,4-oxadiazole-5-carboxamide	Beone Medicines Ireland Limited	Treatment of lymphoplasmacytic lymphoma	• 25/05/2025 • 17/06/2025 • 17/07/2025	• 24/07/2025 • 22/08/2025
mRNA encoding Cas12HF endonuclease, Single guide RNA against the human *HAO1* gene	Zwiers Regulatory Consultancy B.V.	Treatment of primary hyperoxaluria	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Cladribine	Lipomed GmbH	Treatment of acute myeloid leukaemia	• 04/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Leniolisib	Pharming Technologies B.V.	Treatment of common variable immunodeficiency (CVID)	• 22/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Lentiviral vector containing the human *MMUT* transgene	Genespire S.r.l.	Treatment of methylmalonic acidemia	• 19/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Pegtarazimod	Clinipace GmbH	Treatment of graft-versus-host disease	• 26/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Mecasermin rinfabate	Orphix Consulting GmbH	Prevention of bronchopulmonary dysplasia	• 26/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
7-Ethyl-10-hydroxycamptothecin	Cebiotex S.L.	Treatment of pancreatic cancer	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Mezagitamab	Takeda Pharmaceuticals International AG Ireland Branch	Treatment of immune thrombocytopenia	• 26/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025

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 9 vector containing the human *NDP* gene	ESPL Regulatory Consulting Limited	Treatment of NDP gene-related disorders	• 22/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Rilzabrutinib	Sanofi B.V.	Treatment of immunoglobulin G4-related disease	• 15/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
RNA, [P-deoxy-P-(dimethylamino)](2',3'-dideoxy-2',3'-imino-2',3'-seco)(2'a->5') (C-A-G-C-A-G-C-A-G-C-A-G-C-A-G-C-A-G-C-A-G-C-A-[2'a-[39-[[1-acetyl-L-prolyl-L-lysyl-L-lysyl-L-lysyl-L-arginyl-L-lysyl-L-valyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-(L-phenylalanylglycyl-L-phenylalanylglycyl-L-arginylglycyl-L-arginyl-L-gamma-glutamyl)-L-lysyl]amino]-1-oxo-4,7,10,13,16,19,22,25,28,31,34,37-dodecaoxanonatriacont-1-yl]]G), (8'->1')-lactam	Vertex Pharmaceuticals (Ireland) Limited	Treatment of dystrophic myotonia	• 18/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Emugrobart	Roche Registration GmbH	Treatment of spinal muscular atrophy	• 22/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Acetylcysteine amide	Arctic Therapeutics hf.	Treatment of hereditary cerebral amyloid angiopathies	• 27/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Darovasertib	Pharma Gateway AB	Treatment of uveal melanoma	• 21/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Sonpiretigene isteparvovec	Granzer Regulatory	Treatment of syndromic inherited retinal dystrophies of the rod-dominant phenotype	• 22/05/2025 • 17/06/2025 • 17/07/2025	• 24/07/2025 • 22/08/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
	Consulting & Services GmbH		• (29 days/29 days)	
IgG1 trispecific monoclonal antibody against T-cell receptor CD3, B-cell maturation antigen and G protein-coupled receptor class C group 5 member D	Janssen Cilag International	Treatment of multiple myeloma	• 27/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Adeno-associated viral vector serotype ShH10 containing a codon-optimised human *NDP* gene	ESPL Regulatory Consulting Limited	Treatment of NDP gene-related disorders	• 23/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
RNA editing antisense oligonucleotide against the Z mutation of the human SERPINA1 mRNA transcript, sodium salt	Parexel International (IRL) Limited	Treatment of alpha-1 antitrypsin deficiency	• 26/03/2025 • 17/06/2025 • 17/07/2025 • (30 days/29 days)	• 24/07/2025 • 22/08/2025
Gildeuretinol, Gildeuretinol acetate	Voisin Consulting Life Sciences	Treatment of non-syndromic inherited retinal dystrophies due to defects in the *ABCA4* gene	• 27/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
4-(2-{[2-Amino-6-(3-chloro-2-methylphenyl)pyrimidin-4-yl]amino}ethyl)benzene-1-sulfonamide	Oxcia AB	Treatment of acute myeloid leukaemia	• 26/03/2025 • 22/04/2025 • 17/07/2025 • (85 days/29 days)	• 24/07/2025 • 22/08/2025
Admilparant	Bristol-Myers Squibb Pharma EEIG	Treatment of idiopathic pulmonary fibrosis	• 21/05/2025 • 17/06/2025 • 17/07/2025 • (29 days/29 days)	• 24/07/2025 • 22/08/2025
Allogeneic cultured postnatal thymus-derived tissue	Scendea (NL) B.V.	Treatment of congenital athymia	• 22/05/2025 • 17/06/2025 • 17/07/2025	• 24/07/2025 • 22/08/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (29 days/29 days)	
Nuvisertib	Parexel International (IRL) Limited	Treatment of myelofibrosis	• 25/02/2025 • 25/03/2025 • 12/06/2025 • (78 days/25 days)	• 23/06/2025 • 18/07/2025
Elafibranor	Ipsen Pharma	Treatment of primary sclerosing cholangitis	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Resecabtagene autoleucel	Cabaletta Bio (Germany) GmbH	Treatment of idiopathic Inflammatory myopathy	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Phosphorodiamidate morpholino oligonucleotide against the CUG repeat expansion of the *DMPK* gene mRNA transcript, conjugated to a cell penetrating peptide	Yes Pharmaceutical Development Services GmbH	Treatment of dystrophic myotonia	• 27/02/2025 • 25/03/2025 • 12/06/2025 • (78 days/25 days)	• 23/06/2025 • 18/07/2025
Octreotide hydrochloride	Camurus AB	Treatment of autosomal dominant polycystic kidney disease	• 19/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Adeno-associated viral vector serotype 9 containing the human *CTNNB1* gene	Fundacija CTNNB1 Ustanova Za Raziskave Na Podrocju Genske Terapije	Treatment of CTNNB1 syndrome	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Human bispecific monoclonal antibody targeting ALK1 and BMPRII	Maxia Strategies-Europe Limited	Treatment of hereditary haemorrhagic telangiectasia	• 27/03/2025 • 22/04/2025 • 12/06/2025	• 23/06/2025 • 18/07/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (50 days/25 days)	
Luminol monosodium	MetrioPharm Deutschland GmbH	Treatment of Duchenne muscular dystrophy	• 26/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Palmitoyl-conjugated tricyclo-DNA antisense oligonucleotide 5'-Palm-C6-*GGA GAT GgC AGT TTC-3	SQY Therapeutics	Treatment of Duchenne muscular dystrophy	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Avutometinib, Defactinib	Verastem Europe GmbH	Treatment of ovarian cancer	• 27/02/2025 • 25/03/2025 • 12/06/2025 • (78 days/25 days)	• 23/06/2025 • 18/07/2025
Ribavirin	Pharmadev Healthcare Limited	Treatment of hepatitis E	• 30/01/2025 • 25/03/2025 • 12/06/2025 • (79 days/25 days)	• 23/06/2025 • 18/07/2025
Curcumin	Curlim	Treatment of Charcot-Marie-Tooth disease	• 26/03/2025 • 22/04/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Telitacicept	Pharmaceutical Research Associates Group B.V.	Treatment of myasthenia gravis	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Ivosidenib	Les Laboratoires Servier	Treatment of myelodysplastic syndromes	• 25/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Sonlicromanol hydrochloride	Khondrion B.V.	Treatment of inherited mitochondrial oxidative phosphorylation defects	• 20/02/2025 • 25/03/2025 • 12/06/2025 • (78 days/25 days)	• 23/06/2025 • 18/07/2025
Methotrexate	Helio Vision Germany GmbH	Treatment of non-syndromic inherited retinal dystrophies of the rod-dominant phenotype	• 14/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Aglatimagene besadenovec	FGK Representative Service GmbH	Treatment of pancreatic cancer	• 26/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Allogeneic peripheral blood-derived T-cells, fratricide-resistant, transduced with a lentivirus vector expressing a chimeric antigen receptor against CD7	Yes Pharmaceutical Development Services GmbH	Treatment of acute lymphoblastic leukaemia	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Humanised IgG1 kappa monoclonal antibody against tyrosine-protein phosphatase non-receptor type substrate 1, signal-regulatory protein beta-1 and signal-regulatory protein gamma	FGK Representative Service GmbH	Treatment of haemophagocytic lymphohistiocytosis	• 27/03/2025 • 22/04/2025 • 12/06/2025 • (50 days/25 days)	• 23/06/2025 • 18/07/2025
Exidavnemab	BioArctic AB	Treatment of multiple system atrophy	• 18/02/2025 • 25/03/2025 • 21/05/2025 • (56 days/29 days)	• 22/05/2025 • 20/06/2025
Empasiprubart	Argenx	Treatment of multifocal motor neuropathy	• 21/02/2025 • 25/03/2025 • 21/05/2025 • (56 days/29 days)	• 22/05/2025 • 20/06/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Humanised IgG1 monoclonal antibody against adrenocorticotropic hormone	H. Lundbeck A/S	Treatment of congenital adrenal hyperplasia	• 24/02/2025 • 25/03/2025 • 21/05/2025 • (56 days/29 days)	• 22/05/2025 • 20/06/2025
3-((4-(1-((1-(6-(((S)-2,6-Dioxopiperidin-3-yl)carbamoyl)pyridin-3-yl)piperidin-4-yl)methyl)piperidin-4-yl)phenyl)amino)-5-((R)-3-(3-methyl-2-oxoimidazolidin-1-yl)piperidin-1-yl)pyrazine-2-carboxamide	Eliquent Life Sciences Limited	Treatment of lymphoplasmacytic lymphoma	• 26/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
3-(Carbamoylamino)-5-[2-(3-fluorophenyl)ethynyl]-N-[(3S)-piperidin-3-yl]thiophene-2-carboxamide hydrochloric acid	Parexel International (IRL) Limited	Treatment of acute myeloid leukaemia	• 27/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
1-(3-Bromobenzyl)-N3-(3,4-dichlorophenyl)-1H-1,2,4-triazole-3,5-diamine	Roca Therapeutics	Treatment of radiation induced maculopathy	• 31/12/2024 • 26/02/2025 • 15/05/2025 • (78 days/29 days)	• 22/05/2025 • 20/06/2025
Beta-lapachone	Opis S.r.l.	Treatment of primary sclerosing cholangitis	• 04/02/2025 • 25/03/2025 • 15/05/2025 • (51 days/29 days)	• 22/05/2025 • 20/06/2025
Bezuclastinib	FGK Representative Service GmbH	Treatment of mastocytosis	• 26/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
Humanised IgG4 bispecific monoclonal antibody against sclerostin and dickkopf-related protein 1	Worldwide Clinical Trials	Treatment of osteogenesis imperfecta	• 22/01/2025 • 26/02/2025 • 15/05/2025 • (78 days/29 days)	• 22/05/2025 • 20/06/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Dipalmitoyl hydroxyproline	Arriello s.r.o.	Treatment of Netherton syndrome	• 27/01/2025 • 26/02/2025 • 15/05/2025 • (78 days/29 days)	• 22/05/2025 • 20/06/2025
2-[[Hydroxy[(R)-2-[((5Z,8Z,11Z,14Z)-eicosa-5,8,11,14-tetraenoyl)oxy]-3-(octadecyloxy)propoxy]phosphoryl]oxy]ethan-1-amine	3R Pharma Consulting GmbH	Treatment of Rett syndrome	• 25/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
Alpha-N-acetyl glucosaminidase fused to a humanised monoclonal antibody against transferrin receptor	JCR Europe B.V.	Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	• 17/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
4-Amino-1-[(2R,4S,5S)-5-(1,2-dihydroxyethyl)-4-hydroxyoxolan-2-yl]pyrimidin-2-one	Hemispherian AS	Treatment of glioma	• 27/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
Sodium 2-(3'(-3-(1-(4-(tert-butyl)benzyl)-4-ethyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-3-yl)propyl)-4-ethoxy-[1,1'-biphenyl]-3-yl)acetate	Pharma Gateway AB	Treatment of hepatocellular carcinoma	• 27/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
2-(2-(2-[2-(4-Benzothiazol-2-yl-phenoxy)-ethoxy]-ethoxy)-ethoxy)-ethanol	Somerville Development Partners B.V.	Treatment of amyotrophic lateral sclerosis	• 25/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
(R)-3-(5-Dimethylcarbamoyl-pent-1-enyl)-N-(2-hydroxy-1methylethyl)benzamide	Somerville Development Partners B.V.	Treatment of fragile X syndrome	• 12/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Iloprost	MWB Consulting	Treatment of systemic sclerosis	• 24/01/2025 • 26/02/2025 • 15/05/2025 • (78 days/29 days)	• 22/05/2025 • 20/06/2025
Adeno-associated virus encoding small hairpin RNA against ATXN2 mRNA	Scendea (NL) B.V.	Treatment of amyotrophic lateral sclerosis	• 27/02/2025 • 25/03/2025 • 15/05/2025 • (50 days/29 days)	• 22/05/2025 • 20/06/2025
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1	Inozyme Pharma Ireland Limited	Treatment of calciphylaxis	• 28/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Tertomotide	Pharmaceutical Research Associates Group B.V.	Treatment of progressive supranuclear palsy	• 27/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Equine polyclonal immunoglobulin F(ab')2 fragments against ricin	Fabentech	Treatment of ricin poisoning	• 27/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Adeno-associated viral vector serotype 2i8 containing the human LAMP2 isoform B transgene	AskBio France	Treatment of Danon disease	• 27/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Radiprodil	RLM Consulting	Treatment of GRIN-related neurodevelopmental disorder	• 30/12/2024 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Florbetaben (18F)	Life Molecular Imaging GmbH	Diagnosis of ATTR amyloidosis	• 29/11/2024 • 27/01/2025 • 15/04/2025 • (78 days/24 days)	• 28/04/2025 • 22/05/2025
Tranilast	Boyd Consultants Limited	Treatment of idiopathic pulmonary fibrosis	• 27/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Doxorubicin, liposomal, pegylated	InnoMedica Deutschland GmbH	Treatment of soft tissue sarcoma	• 29/11/2024 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Induced pluripotent stem cells-derived myogenic progenitor cells	Biopatents IP Consultancy	Treatment of Becker muscular dystrophy	• 24/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
1-{4-[2-(5-ethoxymethyl-2-methyl-phenylamino)-oxazol-5-yl]-phenyl}-imidazolidin-2-one	AB Science	Treatment of acute myeloid leukaemia	• 24/12/2024 • 26/02/2025 • 15/04/2025	• 28/04/2025 • 22/05/2025
Taladegib	Orphix Consulting GmbH	Treatment of idiopathic pulmonary fibrosis	• 24/01/2025 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Humanised IgG1 monoclonal antibody against human epidermal growth factor receptor 2	Henlius Europe GmbH	Treatment of gastric cancer	• 16/12/2024 • 26/02/2025 • 15/04/2025 • (48 days/24 days)	• 28/04/2025 • 22/05/2025
Fragment antibody targeting human TfR1 conjugated to phosphorodiamidate morpholino oligomer	Pharma Gateway AB	Treatment of Duchenne muscular dystrophy	• 13/12/2024 • 27/01/2025 • 20/03/2025	• 25/03/2025 • 16/04/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (52 days/22 days)	
Adeno-associated viral vector serotype LK03 containing the human *CFI* gene	Purespring Therapeutics Ireland Limited	Treatment of primary IgA nephropathy	• 25/11/2024 • 06/01/2025 • 20/03/2025 • (73 days/22 days)	• 25/03/2025 • 16/04/2025
Parahydroxybenzoic acid	Universidad De Granada	Treatment of primary ubiquinone deficiency	• 15/12/2024 • 27/01/2025 • 20/03/2025 • (52 days/22 days)	• 25/03/2025 • 16/04/2025
Sirolimus	Scendea (NL) B.V.	Treatment of familial adenomatous polyposis	• 13/12/2024 • 27/01/2025 • 20/03/2025 • (52 days/22 days)	• 25/03/2025 • 16/04/2025
Nipocalimab	Janssen Cilag International	Prevention of fetal and neonatal alloimmune thrombocytopenia	• 13/12/2024 • 27/01/2025 • 20/03/2025 • (52 days/22 days)	• 25/03/2025 • 16/04/2025
Vamikibart	Roche Registration GmbH	Treatment of non-Infectious uveitis	• 22/11/2024 • 06/01/2025 • 20/03/2025 • (73 days/22 days)	• 25/03/2025 • 16/04/2025
Humanised IgG1 monoclonal antibody against muscle specific kinase	Argenx	Treatment of spinal muscular atrophy	• 16/12/2024 • 27/01/2025 • 20/03/2025 • (52 days/22 days)	• 25/03/2025 • 16/04/2025
Small-interfering RNA against soluble fms-like tyrosine kinase-1 e15a mRNA, Small-interfering RNA against soluble fms-like tyrosine kinase-1 i13 mRNA	Comanche Biopharma (Europe) Limited	Treatment of pre-eclampsia	• 16/12/2024 • 27/01/2025 • 20/03/2025	• 25/03/2025 • 16/04/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (52 days/22 days)	
Deucrictibant monohydrate	Pharvaris Netherlands B.V.	Treatment of bradykinin-mediated angioedema	• 25/10/2024 • 25/11/2024 • 19/02/2025 • (86 days/27 days)	• 26/02/2025 • 25/03/2025
Ixodes ricinus contact phase inhibitor	Bioxodes	Treatment of non-traumatic spontaneous intracerebral haemorrhage	• 25/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Bexmarilimab	Faron Pharmaceuticals Oy	Treatment of myelodysplastic syndromes	• 22/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Adeno-associated virus vector serotype 8 containing the human *F9* gene	Regeneron Ireland Designated Activity Company	Treatment of haemophilia B	• 22/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Allopurinol	Consorcio Centro De Investigacion Biomedica En Red	Treatment of Marfan syndrome	• 17/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Extract from Cannabis flower, containing high levels of cannabidiolic acid and <0.3% of tetrahydrocannabinol, Extraction solvent: olive oil, virgin	Granzer Regulatory Consulting & Services GmbH	Treatment of Rett syndrome	• 28/10/2024 • 25/11/2024 • 19/02/2025 • (86 days/27 days)	• 26/02/2025 • 25/03/2025
Povetacicept	Vertex Pharmaceuticals (Ireland) Limited	Treatment of primary IgA nephropathy	• 21/11/2024 • 06/01/2025 • 19/02/2025	• 26/02/2025 • 25/03/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (44 days/27 days)	
Single guide RNA containing a sequence complementary to human *ALB* locus gene, intron 1, target region, ziclumeran	Regeneron Ireland Designated Activity Company	Treatment of haemophilia B	• 22/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Ianalumab	Novartis Europharm Limited	Treatment of immune thrombocytopenia	• 21/11/2024 • 06/01/2025 • 19/02/2025 • (44 days/27 days)	• 26/02/2025 • 25/03/2025
Epertinib	3R Pharma Consulting GmbH	Treatment of amyotrophic lateral sclerosis	• 25/09/2024 • 28/10/2024 • 23/01/2025 • (87 days/27 days)	• 30/01/2025 • 26/02/2025
Volixibat potassium	Mirum Pharmaceuticals International B.V.	Treatment of primary sclerosing cholangitis	• 27/09/2024 • 28/10/2024 • 23/01/2025 • (87 days/27 days)	• 30/01/2025 • 26/02/2025
Adeno-associated virus vector serotype SNY001 containing the human *PAH* gene	Sanofi B.V.	Treatment of hyperphenylalaninemia	• 24/10/2024 • 25/11/202 • 23/01/2025 • (59 days/27 days)	• 30/01/2025 • 26/02/2025
Adeno-associated virus sector serotype rh74 containing the human *SGCG* gene	Sarepta Therapeutics Ireland Limited	Treatment of limb-girdle muscular dystrophy	• 27/09/2024 • 28/10/2024 • 23/01/2025 • (87 days/28 days)	• 30/01/2025 • 27/02/2025
Paltusotine	Voisin Consulting Life Sciences	Treatment of acromegaly	• 28/10/2024 • 25/11/2024 • 23/01/2025	• 30/01/2025 • 26/02/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (59 days/27 days)	
(R)-(3-(2'-cyclopropyl-3-(hydroxymethyl)-[1,1'-biphenyl]-4-yl)pyrrolidin-1-yl)(5-hydroxy-6-methylpyridin-2-yl)methanone	Granzer Regulatory Consulting & Services GmbH	Treatment of Olmsted syndrome	• 28/10/2024 • 25/11/2024 • 23/01/2025 • (59 days/27 days)	• 30/01/2025 • 26/02/2025
Adeno-associated virus serotype rh.10 containing the human *PKP2* gene	Scendea (NL) B.V.	Treatment of arrhythmogenic cardiomyopathy caused by pathogenic mutations in the *PKP2* gene	• 28/10/2024 • 25/11/2024 • 23/01/2025 • (59 days/27 days)	• 30/01/2025 • 26/02/2025
Hydroxocobalamin acetate	Day Zero ehf.	Treatment of homocystinuria and/or methylmalonic acidaemia due to genetic defects of intracellular cobalamin processing	• 19/09/2024 • 28/10/2024 • 23/01/2025 • (87 days/27 days)	• 30/01/2025 • 26/02/2025
Autologous CD34+ cell enriched population containing haematopoietic stem and progenitor cells transduced ex vivo with a lentiviral vector encoding the human *ADA2* gene	ESPL Regulatory Consulting Limited	Treatment of adenosine deaminase 2 deficiency (DADA2)	• 25/10/2024 • 25/11/2024 • 23/01/2025 • (59 days/28 days)	• 30/01/2025 • 27/02/2025
Tafasitamab	Incyte Biosciences Distribution B.V.	Treatment of follicular lymphoma	• 22/10/2024 • 25/11/2024 • 23/01/2025 • (59 days/27 days)	• 30/01/2025 • 26/02/2025
Adeno-associated virus serotype 9 containing the human *RPE65* gene	Granzer Regulatory Consulting & Services GmbH	Treatment of inherited retinal dystrophy due to defects in the *RPE65* gene	• 30/08/2024 • 13/09/2024 • 05/12/2024 • (83 days/30 days)	• 17/12/2024 • 16/01/2025
Camostat mesilate	Pangenix Pharma Limited	Treatment of chronic pancreatitis	• 28/08/2024 • 13/09/2024 • 05/12/2024	• 17/12/2024 • 16/01/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (83 days/30 days)	
Alvelestat	Mereo Biopharma Ireland Limited	Treatment of congenital alpha-1 antitrypsin deficiency	• 21/08/2024 • 13/09/2024 • 05/12/2024 • (83 days/30 days)	• 17/12/2024 • 16/01/2025
Elraglusib	Actuate Therapeutics Limited	Treatment of pancreatic cancer	• 21/05/2024 • 28/10/2024 • 05/12/2024 • (38 days/30 days)	• 17/12/2024 • 16/01/2025
[4-(Methyl-1H-pyrazol-4-yl)-benzyl]-(6[7-(3-pyrrolidin-1-yl-propoxy)-imidazo[1,2-a]pyridin-3-yl]-pyrimidin-4-yl]-amine	Voisin Consulting Life Sciences	Treatment of gastrointestinal stromal tumours	• 26/09/2024 • 28/10/2024 • 05/12/2024 • (38 days/30 days)	• 17/12/2024 • 16/01/2025
Elraglusib	Actuate Therapeutics Limited	Treatment of soft tissue sarcoma	• 21/05/2024 • 28/10/2024 • 05/12/2024 • (38 days/30 days)	• 17/12/2024 • 16/01/2025
Allogenic umbilical cord-derived osteoblast cells	Opis S.r.l.	Treatment of non-traumatic osteonecrosis	• 28/08/2024 • 13/09/202 • 05/12/2024 • (83 days/30 days)	• 17/12/2024 • 16/01/2025
Clofutriben	Scendea (NL) B.V.	Treatment of Cushing's syndrome of endogenous origin	• 30/09/2024 • 28/10/2024 • 05/12/2024 • (38 days/30 days)	• 17/12/2024 • 16/01/2025
Rilzabrutinib	Sanofi B.V.	Treatment of autoimmune haemolytic anaemia	• 30/09/2024 • 28/10/2024 • 05/12/2024	• 17/12/2024 • 16/01/2025

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			• (38 days/30 days)	
Volixibat potassium	Mirum Pharmaceuticals International B.V.	Treatment of primary biliary cholangitis	• 30/08/2024 • 13/09/2024 • 05/12/2024 • (83 days/30 days)	• 17/12/2024 • 16/01/2025
N-(2-Methoxyethyl)-6-methyl-N-[(3-methyl-2-thienyl)methyl]-2-oxo-1,2-dihydropyridine-4-carboxamide	AdRes EU B.V.	Treatment of glycogen storage disease type IV	• 30/09/2024 • 28/10/2024 • 05/12/2024 • (38 days/30 days)	• 17/12/2024 • 16/01/2025

Negative COMP designation opinions

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Trilaciclib	Pharmacosmos A/S	Treatment of small cell lung cancer	• 26/03/202 • 22/04/2025 • 06/11/2025 • (197 days/pending EC decision	• 14/11/2025 • 09/12/2025

Annex 15 – HMPC European Union herbal monographs in 2025

Abbreviations: TU – traditional use

WEU – well established use

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/150763/2015	Cisti cretici herba	19/03/2025 / TU
EMA/HMPC/239465/2024	Species pectorales	09/07/2025 / TU
Revision		
EMA/HMPC/261302/2022	Urticae herba	22/01/2025 / TU
EMA/HMPC/322646/2023	Urticae radix	22/01/2025 / TU
EMA/HMPC/885789/2022	Zingiberis rhizoma	07/05/2025 / TU
EMA/HMPC/887979/2022	Plantaginis lanceolatae folium	09/07/2025 / TU

European Union List entries – adopted for transfer to European Commission

None

European Union herbal monographs – Draft for consultation

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/884573/2022	Hyperici herba/Cimicifugae rhizoma	22/01/2025 / TU
EMA/HMPC/509424/2023	Maydis stigma	24/09/2025 / TU
Revision		
EMA/HMPC/329435/2024	Allii sativi bulbus	19/03/2025 / TU
EMA/HMPC/524586/2024	Arnicae flos	19/03/2025 / TU
EMA/HMPC/234781/2024	Crataegi folium cum flore	19/03/2025 / TU
EMA/HMPC/584455/2023	Ononidis radix	07/05/2025 / TU
EMA/HMPC/10134/2024	Fragariae folium	09/07/2025 / TU
EMA/HMPC/108399/2024	Liquiritiae radix	09/07/2025 / TU
EMA/HMPC/85836/2025	Species diureticae	09/07/2025 / TU

European Union List entries – Draft for consultation

None

Monograph/ list entry review reports

Reference number	Document title	Adoption / Outcome
Final decision		
EMA/HMPC/331773/2024	Avenae fructus	22/01/2025 / no revision
EMA/HMPC/331773/2024	Avenae herba	22/01/2025 / no revision
EMA/HMPC/432136/2024	Cynarae folium	22/01/2025 / no revision
EMA/HMPC/432213/2024	Oleae folium	22/01/2025 / no revision
EMA/HMPC/3544/2025	Gentianae radix	19/03/2025 / no revision
EMA/HMPC/8694/2025	Lupuli flos	19/03/2025 / no revision
EMA/HMPC/419121/2024	Meliloti herba	19/03/2025 / no revision
EMA/HMPC/320360/2024	Uvae ursi folium	19/03/2025 / no revision
EMA/HMPC/524873/2024	Melissae folium	07/05/2025 / revision required*
EMA/HMPC/13776/2025	Ribis nigri folium	07/05/2025 / revision required*
EMA/HMPC/432223/2024	Vitis viniferae folium	07/05/2025 / no revision
EMA/HMPC/12880/2025	Calendulae flos	09/07/2025 / no revision
EMA/HMPC/216179/2025	Primulae flos	24/09/2025 / no revision
EMA/HMPC/216180/2025	Primulae radix	24/09/2025 / no revision
EMA/HMPC/301260/2025	Althaeae radix	19/11/2025 / no revision
EMA/HMPC/296779/2025	Carvi aetheroleum	19/11/2025 / no revision
EMA/HMPC/296784/2025	Carvi fructus	19/11/2025 / no revision
EMA/HMPC/8411/2025	Cimicifugae rhizoma	19/11/2025 / no revision
EMA/HMPC/81467/2025	Curcumae longae rhizome	19/11/2025 / no revision
EMA/HMPC/299389/2025	Equiseti herba	19/11/2025 / revision required*
EMA/HMPC/297627/2025	Oenotherae oleum	19/11/2025 / no revision

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

Public statements

None

Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2025

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	Applicant	Decision Date	Decision Number
Propranolol hydrochloride		Initial Paediatric Investigation Plan	Paediatric Investigation Plan	Cardiac disorders	Proveca Pharma Limited	4/15/2025	EMA/PE/00001 82928
Adeno-associated viral vector serotype 1 containing the 3' portion of human OTOF gene, Adeno-associated viral vector serotype 1 containing the 5' portion of human OTOF gene		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Regeneron Ireland Designated Activity Company	8/8/2025	EMA/PE/00001 82782
Cemiplimab / fianlimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Regeneron Ireland Designated Activity Company	8/6/2025	EMA/PE/00002 33980
Tanruprubart		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Annexon Inc.	12/4/2025	EMA/PE/00002 49275
Polypeptide consisting of a glucagon-like peptide-1 receptor agonist and an amylin receptor agonist, connected by a linker with 4 glycine residues, and connected to a C18 fatty acid side chain		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	Novo Nordisk A/S	6/13/2025	EMA/PE/00001 83092
Human polyclonal immunoglobulin G against thymocyte		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Sab Biotherapeutics Inc.	7/2/2025	EMA/PE/00001 82592

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Zorevunersen		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Pharma Gateway AB	8/8/2025	EMA/PE/00002 26201
Eneboparatide		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Endocrine disorders	Amolyt Pharma	4/16/2025	EMA/PE/00001 82225
(R)-N-(3-(2-Chloro-5-fluorophenyl)-6-(5-cyano-[1,2,4]triazolo[1,5-a]pyridin-6-yl)-1-oxoisoindolin-4-yl)-3-fluoro-5-(trifluoromethyl)benzamide (RLY-2608)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Relay Therapeutics Inc.	12/5/2025	EMA/PE/00002 44067
Benzoyl peroxide / tretinoin		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Skin and subcutaneous tissue disorders	Galenica AB	10/31/2025	EMA/PE/00002 74560
Iloperidone		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Psychiatric disorders	Vanda Pharmaceuticals Netherlands B.V.	6/12/2025	EMA/PE/00002 23040
Mrna encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein, mrna encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein, mrna encoding Influenza B/Victoria, hemagglutinin glycoprotein		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Moderna Biotech Spain S.L.	1/3/2025	EMA/PE/00002 26753
Nitrosomonas eutropha, strain D23, Live		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a	Skin and subcutaneous tissue disorders	Aobiome Therapeutics Corp.	9/10/2025	EMA/PE/00002 32853

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Wasp venom (Vespula spp)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Inmunotek S.L.	10/31/2025	EMA/PE/00002 45209
Apis mellifera venom		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Inmunotek S.L.	10/31/2025	EMA/PE/00002 45992
Sonelokimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	FGK Representati ve Service GmbH	4/15/2025	EMA/PE/00002 32757
Remibrutinib		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Novartis Europharm Limited	4/14/2025	EMA/PE/00002 32758
Telitacicept		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Remegen Ltd.	3/21/2025	EMA/PE/00002 32759
Riliprubart		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Sanofi B.V.	5/16/2025	EMA/PE/00002 32760
Frexalimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Sanofi Winthrop Industrie	4/14/2025	EMA/PE/00002 32762

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Icotrokinra		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Janssen Cilag International	3/20/2025	EMA/PE/00002 32763
Zasocitinib		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Takeda Pharma A/S	3/21/2025	EMA/PE/00002 32764
Sargramostim		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Partner Therapeutics Inc.	4/14/2025	EMA/PE/00002 32765
Pegozafermin		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Hepatobiliary disorders	89Bio Lithuania UAB	3/20/2025	EMA/PE/00002 32769
Tacrolimus		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Eye disorders	Laboratoires Thea	3/21/2025	EMA/PE/00002 32771
7-fluoro-1-isopropyl-3-methyl-8-(6-(3-(piperidin-1-yl)propoxy)pyridin-3-yl)-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one (AZD1390)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AstraZeneca AB	4/16/2025	EMA/PE/00002 32774

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Lunsekimig		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Sanofi Winthrop Industrie	4/14/2025	EMA/PE/00002 32776
Zosurabalpin		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Roche Registration GmbH	5/16/2025	EMA/PE/00002 32777
Duvakitug		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Sanofi Winthrop Industrie	5/16/2025	EMA/PE/00002 32778
Probenecid		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	PannTheraPi	5/15/2025	EMA/PE/00002 32780
Lenacapavir sodium / Islatravir		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Merck Sharp & Dohme B.V.	3/20/2025	EMA/PE/00002 32781
(1R,2S)-1-(6-Bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	The Global Alliance For TB Drug Development Inc.	5/15/2025	EMA/PE/00002 32782
Adeno-associated viral vector serotype 9 containing the human MECP2 gene		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Taysha Gene Therapies Inc.	4/14/2025	EMA/PE/00002 32894
Trivalent mrna vaccine encoding for nov VP1 (mrna-1403)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a	Infections and infestations	Moderna Biotech Spain S.L.	9/10/2025	EMA/PE/00002 32895

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Antisense oligonucleotide against patatin like phospholipase domain containing 3, conjugated to N-acetylgalactosamine, sodium salt		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Hepatobiliary disorders	AstraZeneca AB	2/21/2025	EMA/PE/00002 32896
Atacicept		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Vera Therapeutics Inc.	5/16/2025	EMEA-002004-PIP04-23
Imlifidase		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Hansa Biopharma AB	4/14/2025	EMEA-002183-PIP03-23
Sonelokimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	FGK Representati ve Service GmbH	3/21/2025	EMEA-002568-PIP02-23
Firsocostat / cilofexor		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Hepatobiliary disorders	Gilead Sciences International Limited	5/16/2025	EMEA-002828-PIP01-20
Avenciguat		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Boehringer Ingelheim International GmbH	4/14/2025	EMEA-003002-PIP04-23
Recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Larimar Therapeutics Inc.	7/10/2025	EMEA-003022-PIP01-21

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Ensitrelvir		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	Shionogi B.V.	2/12/2025	EMEA-003192-PIP03-23
Crofelemer		Initial Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Napo Therapeutics S.p.A.	12/5/2025	EMEA-003296-PIP02-24
Povorcitinib		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Incyte Biosciences Distribution B.V.	6/12/2025	EMEA-003313-PIP02-23
Axatilimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Incyte Biosciences Distribution B.V.	4/15/2025	EMEA-003385-PIP01-22
Allogeneic faecal microbiota, pooled (maat013)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Maat Pharma	4/16/2025	EMEA-003435-PIP02-23
Sonrotoclax		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Beone Medicines Ireland Limited	4/16/2025	EMEA-003489-PIP01-23
Sonrotoclax		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Nervous system disorders	Beone Medicines Ireland Limited	4/16/2025	EMEA-003489-PIP02-23
Mezagitamab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a	Renal and urinary disorders	Takeda Pharmaceuticals	1/28/2025	EMEA-003502-PIP02-24

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver		International AG		
Budigalimab		Initial Paediatric Investigation Plan	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	1/28/2025	EMEA-003532-PIP01-23
Livmoniplimab		Initial Paediatric Investigation Plan	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Limited	1/28/2025	EMEA-003533-PIP01-23
Humanized igg4 Monoclonal Antibody against fixa and FX (NXT007)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Roche Registration GmbH	1/15/2025	P/0403/2024
Oveporexton		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Takeda Pharma A/S	3/19/2025	EMEA-003553-PIP01-23
Letetresgene autoleucel		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adaptimmune B.V.	1/3/2025	P/0401/2024
Rocatinlimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Amgen Europe B.V.	1/3/2025	EMEA-002886-PIP03-24
Golcadomide		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a	Blood and lymphatic	Bristol-Myers Squibb Services	1/3/2025	P/0400/2024

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver	system disorders	Unlimited Company		
Luliconazole		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Sato Pharmaceutical Co. Ltd.	1/27/2025	P/0006/2025
2-isopropyl-3H-naphtho[1,2-d]imidazole-4,5-dione		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Abliva AB	1/29/2025	P/0002/2025
Heterologous intestinal microbiota from healthy donors		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Mikrobiomik Healthcare Company S.L.	1/29/2025	P/0003/2025
Human metapneumovirus, prefusion F protein, virus-like particle (IVX-241) / Respiratory syncytial virus,prefusion F protein, virus-like particle (IVX-121)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	AstraZeneca AB	1/28/2025	P/0001/2025
Adeno-associated virus serotype 9 vector containing the human LAMP2 isoform B transgene		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Rocket Pharmaceuticals B.V.	1/27/2025	P/0004/2025
Dasiglucagon		Initial Paediatric Investigation Plan	Negative	Congenital, familial and genetic disorders	Zealand Pharma A/S	3/20/2025	EMA/PE/00002 32755
Etavopivat		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Novo Nordisk A/S	4/15/2025	EMA/PE/00002 32761

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
VE303-07: Bacilli, strain from cluster XVII, (closest relative: Clostridium_AQ innocuum) liveve303-07 / VE303-06: Clostridia, strain from cluster xiva, (closest relative: Dorea_A longicatena) Live / VE303-05: Clostridia, strain from cluster xiva, (closest relative: Blautia sp001304935) Live / VE303-03: Clostridia, strain from cluster xiva, (closest relative: Sellimonas intestinalis) Live / VE303-02: Clostridia, strain from cluster IV, (closest relative: Anaerotruncus colihominis) liveve303-02 / VE303-01: Clostridia, strain from cluster xiva (closest relative: Enterocloster bolteae) Live / VE303-08: Clostridia, strain from cluster IV, (closest relative: Flavonifractor plautii), Live / VE303-04: Clostridia, strain from cluster xiva, (closest relative: Clostridium_Q symbiosum) Live (VE303)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Vedanta Biosciences Inc.	5/16/2025	EMA/PE/00002 32767
Ruzasvir / bemnifosbuvir (RZR/BEM)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Atea Pharmaceuti cals Inc.	9/12/2025	EMA/PE/00002 32779
Mibavademab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Regeneron Ireland Designated Activity Company	10/31/2025	EMA/PE/00002 36281

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Vosoritide		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Biomarin International Limited	8/8/2025	EMA/PE/00001 81364
Ambrisentan, tadalafil		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Adalvo Limited	8/8/2025	EMA/PE/00002 28795
Calcium chloride dihydrate, D-GLUCOSE, Levocarnitine, Magnesium chloride hexahydrate, Sodium chloride, Sodium lactate, Xylitol		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Renal and urinary disorders	Iperboreal Pharma S.r.l.	1/3/2025	EMA/PE/00002 25241
Afimkibart		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Roche Registration GmbH	5/16/2025	EMA/PE/00001 82809
Balstilimab		Initial Paediatric Investigation Plan	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Agenus Inc.	1/28/2025	EMA/PE/00002 28283
Naronapride (dihydrochloride trihydrate)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Dr. Falk Pharma GmbH	7/11/2025	EMA/PE/00001 83673
Ibezapolstat		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	S-cubed Pharmaceutical Services ApS	9/12/2025	EMA/PE/00002 21837

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Icotrokinra		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Janssen Cilag International	9/10/2025	EMA/PE/00002 35091
Adeno-associated virus serotype 5 containing the human NR2E3 gene		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Ocugen Limited	10/31/2025	EMA/PE/00002 35131
Tebipenem pivoxil		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Glaxosmithkline Trading Services Limited	10/31/2025	EMA/PE/00002 26457
L-acetylleucine		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Intrabio Ireland Limited	7/11/2025	EMA/PE/00001 82349
Autologous regulatory T lymphocytes CD3+ CD4+ CD25+ CD127- foxp3+, ex-vivo expanded (poltreg-T1D)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Immune system disorders	Poltreg S.A.	6/12/2025	EMA/PE/00001 83462
Empagliflozin, vicadrostat		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Boehringer Ingelheim International GmbH	12/5/2025	EMA/PE/00001 81383
Japanese encephalitis virus, strain SA14-14-2, Live		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Infections and infestations	[INACTIVE] Substipharm Biologics S.A.	10/31/2025	EMA/PE/00002 32655
Barzolvolimab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Celldex Therapeutics Inc.	10/31/2025	EMA/PE/00001 82917

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Zelpultide alfa		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Respiratory, thoracic and mediastinal disorders	Granzer Regulatory Consulting & Services GmbH	9/9/2025	EMA/PE/00002 32514
4-Methyl-5-[3-methyl-7-[(6-morpholinopyridazin-3-yl)amino]imidazo[4,5-b]pyridin-5-yl]oxy-pyridine-2-carbonitrile, fumaric acid (GLPG3667)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Galapagos	12/5/2025	EMA/PE/00001 81741
3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one (AZD5004)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	AstraZeneca AB	9/12/2025	EMA/PE/00002 32891
Human amylin analogue, amylin receptor selective, long-acting, N-terminally lipidated		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	AstraZeneca AB	8/8/2025	EMA/PE/00002 26147
Brogidirsen		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Medpace Finland Oy	6/12/2025	EMA/PE/00001 80736
3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	AstraZeneca AB	9/12/2025	EMA/PE/00002 34669

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one (AZD5004)							
Ibuzatrelvir		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Pfizer Europe MA EEIG	9/12/2025	EMA/PE/00002 29195
Pneumococcal polysaccharide conjugate vaccine (25-valent, adsorbed) (25vpnc)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Pfizer Europe MA EEIG	10/31/2025	EMA/PE/00002 33967
Montelukast (sodium) / rupatadine (fumarate)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Respiratory, thoracic and mediastinal disorders	Noucor Health S.A.	12/5/2025	EMA/PE/00002 32522
Afimkibart		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Roche Registration GmbH	6/12/2025	EMA/PE/00002 23258
4-Methyl-5-[3-methyl-7-[(6-morpholinopyridazin-3-yl)amino]imidazo[4,5-b]pyridin-5-yl]oxy-pyridine-2-carbonitrile,fumaric acid (GLPG3667)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Galapagos	12/5/2025	EMA/PE/00001 81706
Adeno-associated viral vector serotype S3 containing codon-optimised expression cassette encoding human beta-glucocerebrosidase variant		Initial Paediatric Investigation Plan	Negative	Gaucher's disease	Spur Therapeutics (Ireland) Limited	10/31/2025	EMA/PE/00002 38890

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Botensilimab		Initial Paediatric Investigation Plan	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Agenus Inc.	1/28/2025	EMA/PE/00002 28365
Sodium phenylbutyrate		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Eye disorders	Laboratoires Thea	12/5/2025	EMA/PE/00002 48811
5-bromo-N-(prop-2-yn-1-yl)-2-(1H-1,2,4-triazol-1-yl)pyrimidine-4,6-diamine (PBF-999)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	[INACTIVE] Palo Biofarma S.L.	12/5/2025	EMA/PE/00002 39580
Cagrilintide		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Novo Nordisk A/S	12/5/2025	EMA/PE/00002 26188
Bi 1569912		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Psychiatric disorders	Boehringer Ingelheim International GmbH	1/3/2025	EMA/PE/00001 81243
Atumelnant		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Scendea (NL) B.V.	9/10/2025	EMA/PE/00002 33437
Ex vivo fused normal allogeneic human myoblast with Autologous human myoblast derived from duchenne muscular dystrophy affected donor		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Dystrogen Therapeutics Technology Polska Sp. z o.o.	12/5/2025	EMA/PE/00001 81169

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Tegoprubart		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Eledon Pharmaceuticals Inc.	7/11/2025	EMA/PE/00002 32482
Baricitinib		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Endocrine disorders	Eli Lilly Nederland B.V.	9/10/2025	EMA/PE/00002 36886
Lumateperone		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Psychiatric disorders	Intra-Cellular Therapies Inc.	12/5/2025	EMA/PE/00002 30092
Duvakitug		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Sanofi Winthrop Industrie	5/15/2025	EMA/PE/00001 84114
Betula pendula pollen enriched allergoid, mannan-conjugated, polymerised		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Inmunotek S.L.	12/5/2025	EMA/PE/00002 40462
Atogepant		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Abbvie Limited	9/11/2025	EMA/PE/00002 41150
Emicizumab		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Roche Registration GmbH	9/11/2025	EMA/PE/00001 81043
Citric acid		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Genfit	9/10/2025	EMA/PE/00002 32554

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Arachis hypogaea		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Immune system disorders	Alk-Abello A/S	9/10/2025	EMA/PE/00001 83193
Equine polyclonal immunoglobulin F(ab')2 fragments against ricin		Initial Paediatric Investigation Plan	Paediatric Investigation Plan	Injury, poisoning and procedural complications	Fabentech	12/5/2025	EMA/PE/00002 39743
Adeno-associated virus serotype 9 expressing a transcription factor for the SCN1A gene		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Pharma Gateway AB	10/31/2025	EMA/PE/00002 32458
Dermatophagoides pteronyssinus allergoid, glutaraldehyde-modified (CLUXIN D. Pteronyssinus)		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medicina España S.A.	12/5/2025	EMA/PE/00002 76029
Glecaprevir, pibrentasvir		Initial Paediatric Investigation Plan	Waiver	Infections and infestations	Abbvie Deutschland GmbH & Co. KG	12/4/2025	EMA/PE/00002 52916
Dermatophagoides farinae allergoid, glutaraldehyde-modified, Dermatophagoides pteronyssinus allergoid, glutaraldehyde-modified		Initial Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medicina España S.A.	12/5/2025	EMA/PE/00002 76076
Imlifidase	Idefirix	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Hansa Biopharma AB	1/28/2025	EMA/PE/00002 25594
Eptinezumab	Vyepti	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	H. Lundbeck A/S	1/28/2025	EMA/PE/00002 23490

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Apitegromab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Scholar Rock Netherlands B.V.	9/10/2025	EMA/PE/00002 65081
Lucerastat		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Idorsia Pharmaceuti cals Deutschland GmbH	7/11/2025	EMA/PE/00002 47449
Brensocatib	BRINSUPRI	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Respiratory, thoracic and mediastinal disorders	Insmed Netherlands B.V.	3/19/2025	EMA/PE/00002 41855
Belumosudil		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Sanofi Winthrop Industrie	9/12/2025	EMA/PE/00002 65979
Lerodalcibep		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	LIB Therapeutics Inc.	5/5/2025	EMA/PE/00002 42923
Givinostat		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Italfarmaco S.p.A.	10/31/2025	EMA/PE/00002 74914
Avalotcagene ontaparvovec		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Ultragenyx Germany GmbH	12/5/2025	EMA/PE/00002 80994
Donidalorsen		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Congenital, familial and	Otsuka Pharmaceuti cal	8/6/2025	EMA/PE/00002 58356

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver	genetic disorders	Netherlands B.V.		
Tirzepatide	Mounjaro	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Eli Lilly And Company Limited	7/11/2025	EMA/PE/00002 45851
Regdanvimab	Regkirona	Modification of Paediatric Investigation Plan	Waiver	Infections and infestations	Celltrion Healthcare Hungary Kft.	10/31/2025	EMA/PE/00002 71957
Deucrictibant		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Pharvaris Netherlands B.V.	8/18/2025	EMA/PE/00002 66353
Cobolimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkl ine Trading Services Limited	9/12/2025	EMA/PE/00002 46904
Lacosamide	VIMPAT	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Nervous system disorders	UCB Pharma	4/16/2025	EMA/PE/00002 36274

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Alanine, arginine, aspartic acid, calcium chloride dihydrate, deferoxamine mesilate, glycine, histidine, L-tryptophan, magnesium chloride hexahydrate, N-acetylhistidine monohydrate, N-hydroxy-3,4-dimethoxy-N-methyl-benzamide, oxogluric acid, potassium chloride, sodium chloride	Custoplex-Köhler	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Injury, poisoning and procedural complications	Dr. Franz Koehler Chemie GmbH	4/14/2025	EMA/PE/00002 29486
Allogeneic bone marrow-derived pooled mesenchymal stromal cells ex-vivo expanded		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Medac Gesellschaft für klinische Spezialpräpa rate mbH	4/16/2025	EMA/PE/00002 38064
Naldemedine tosilate	Rizmoic	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Gastrointestinal disorders	Shionogi B.V.	1/28/2025	EMA/PE/00002 26303
Ketamine, sufentanil		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	General disorders and administration site conditions	Cessatech A/S	1/24/2025	EMA/PE/00002 28333
Tofacitinib citrate	XELJANZ	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Pfizer Europe MA EEIG	1/28/2025	EMA/PE/00002 22532
Regorafenib	Stivarga	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bayer AG	12/18/2025	EMA/PE/00002 95398
Vamikibart		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Eye disorders	Roche Registration GmbH	9/10/2025	EMA/PE/00002 65600

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Ustekinumab	STELARA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Janssen Cilag International	6/12/2025	EMA/PE/00002 45485
Abemaciclib	Verzenios	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Nervous system disorders	Eli Lilly And Company Limited	8/8/2025	EMA/PE/00002 58705
Modified allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae	CLUSTOID Dermatophagoides pteronyssinus/Dermatophagoides farinae	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	9/11/2025	EMA/PE/00002 66385
Povorcitinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Incyte Biosciences Distribution B.V.	8/8/2025	EMA/PE/00002 60971
Benralizumab	Fasenra	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	AstraZeneca AB	7/11/2025	EMA/PE/00002 53868
Mixture of heat-inactivated, non-lysate, bacterial concentrates of Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris and Enterococcus faecalis (1:1:1:1)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Inmunotek S.L.	1/3/2025	EMA/PE/00002 24273

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Neisseria Meningitidis Group A Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group C Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group W-135 Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group Y Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, nmbpbas1, rnmb1, rnmb2, rnmb3 (menpenta vaccine)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Sanofi R&D Vaccins	1/28/2025	EMA/PE/00002 22938
Apixaban	Eliquis	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Vascular disorders	Bristol-Myers Squibb Pfizer EEIG	10/31/2025	EMA/PE/00002 75545
Alectinib hydrochloride	Alecensa	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Roche Registration GmbH	10/31/2025	EMA/PE/00002 39133
Cabotegravir	Vocabria	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Viiv Healthcare UK Limited	9/12/2025	EMA/PE/00002 65460
Dermatophagoides farinae extract, dermatophagoides pteronyssinus extract	SULGEN-SPRAY Dermatophagoides pteronyssinus/Dermatophagoides farinae	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	ROXALL Medizin GmbH	10/31/2025	EMA/PE/00002 76237

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Cipaglucosidase alfa	Pombiliti	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Amicus Therapeutics Europe Limited	1/3/2025	EMA/PE/00002 23351
Emapalumab	Gamifant	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Immune system disorders	Swedish Orphan Biovitrum AB (publ)	7/11/2025	EMA/PE/00002 25490
Arimoclomol (citrate)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Zevra Denmark A/S	6/12/2025	EMA/PE/00002 47846
Clevidipine	Cleviprex 0.5 mg/ml emulsion for injection	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Vascular disorders	Chiesi Farmaceutici S.p.A.	3/21/2025	EMA/PE/00002 32890
Nerandomilast		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Boehringer Ingelheim International GmbH	8/8/2025	EMA/PE/00002 57003
Venetoclax	Venclyxto	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Blood and lymphatic system disorders	Abbvie Limited	1/3/2025	EMA/PE/00001 82075
Gepotidacin		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Glaxosmithkline Trading Services Limited	3/21/2025	EMA/PE/00002 28373
Cedazuridine / decitabine	Inaqovi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Otsuka Pharmaceutical Netherlands B.V.	6/26/2025	EMA/PE/00002 46985

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Cariprazine hydrochloride	Reagila	Modification of Paediatric Investigation Plan	Negative	Psychiatric disorders	Gedeon Richter Plc.	1/6/2025	EMA/PE/00002 24597
Dasiglucagon	Zegalogue	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Endocrine disorders	Zealand Pharma A/S	1/3/2025	EMA/PE/00001 81174
Molnupiravir		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	Merck Sharp & Dohme B.V.	1/3/2025	EMA/PE/00002 23608
Cannabidiol	Epidyolex	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	[INACTIVE] Jazz Pharma ceuticals Netherlands B.V.	1/3/2025	EMA/PE/00002 24912
Danicopan	Voydeya	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Alexion Europe	1/28/2025	EMA/PE/00002 27558
Cipaglucosidase alfa	Pombiliti	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Amicus Therapeutics Europe Limited	10/31/2025	EMA/PE/00002 61752
SARS-cov-2 virus, variant LP.8.1, spike protein, receptor binding domain fusion homodimer, Damlecovatein, Selvacovatein	BIMERVAX	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Hipra Human Health S.L.	12/4/2025	EMA/PE/00002 90050
Chikungunya virus, strain Senegal 37997, protein C complexed with protein E1 and protein E2		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Bavarian Nordic A/S	12/5/2025	EMA/PE/00002 85826
Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated (VLA1553)	Ixchiq	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	Valneva Austria GmbH	10/31/2025	EMA/PE/00002 65459

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Asciminib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Novartis Europharm Limited	9/12/2025	EMA/PE/00002 65109
Ketamine, sufentanil		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	General disorders and administration site conditions	Cessatech A/S	6/13/2025	EMA/PE/00002 45997
Vamorolone	Agamree	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Santhera Pharmaceuti cals (Deutschland) GmbH	6/26/2025	EMA/PE/00002 44420
Marstacimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Pfizer Europe MA EEIG	1/28/2025	EMA/PE/00002 26246
Sipavibart		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	AstraZeneca AB	3/20/2025	EMA/PE/00002 25778
Inebilizumab	UPLIZNA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Horizon Therapeutics Ireland DAC	7/10/2025	EMA/PE/00002 52649
Sparsentan		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Vifor (Internationa l) AG	5/16/2025	EMA/PE/00002 26166

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Parathyroid hormone	Natpar	Modification of Paediatric Investigation Plan	Waiver	Endocrine disorders	Takeda Pharmaceuticals International AG	1/28/2025	EMA/PE/00002 25073
Perampanel	Fycompa	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Eisai Europe Limited	8/8/2025	EMA/PE/00002 54635
Triheptanoin	Dojolvi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Ultragenyx Germany GmbH	9/12/2025	EMA/PE/00002 65055
Luspatercept	Reblozyl	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Bristol-Myers Squibb Pharma EEIG	9/12/2025	EMA/PE/00002 64209
Iptacopan		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Novartis Europharm Limited	9/12/2025	EMA/PE/00002 66418
Tabelecleucel		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Blood and lymphatic system disorders	Pierre Fabre Medicament	1/3/2025	EMA/PE/00001 83827
Nerandomilast		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Boehringer Ingelheim International GmbH	1/28/2025	EMA/PE/00002 27908
Pegcetacoplan	ASPAVELI	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Renal and urinary disorders	Swedish Orphan Biovitrum AB (publ)	1/3/2025	EMA/PE/00002 24283

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Eubacterial spores, purified from allogeneic faecal donations		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Aimmune Nestle Health Science US R&D LLC	4/14/2025	EMA/PE/00002 38977
Modified vaccinia Ankara – bavarian nordic live virus	IMVANEX	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Bavarian Nordic A/S	1/28/2025	EMA/PE/00002 23819
Ravulizumab	Ultomiris	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Blood and lymphatic system disorders	Alexion Europe	1/3/2025	EMA/PE/00002 21296
Ravulizumab	Ultomiris	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Renal and urinary disorders	Alexion Europe	1/3/2025	EMA/PE/00002 21604
Vosoritide	Voxzogo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Biomarin International Limited	7/11/2025	EMA/PE/00002 35382
Mavorixafor		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	[INACTIVE] X4 Pharmaceuticals (Austria) GmbH	9/12/2025	EMA/PE/00002 45070
Clesrovimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Merck Sharp & Dohme B.V.	8/6/2025	EMA/PE/00002 66764
Garetosmab	FOPSIVVA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Congenital, familial and genetic disorders	Regeneron Ireland Designated	9/11/2025	EMA/PE/00002 66406

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver		Activity Company		
Ravulizumab	Ultomiris	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Blood and lymphatic system disorders	Alexion Europe	4/14/2025	EMA/PE/00002 29605
Eslicarbazepine acetate	Zebinix	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Bial Portela & Ca S.A.	7/10/2025	EMA/PE/00002 48063
Atogepant	AQUIPTA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Abbvie Limited	1/3/2025	EMA/PE/00002 25746
Rebisufligene etisparvovec		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Ultragenyx Germany GmbH	9/10/2025	EMA/PE/00002 65916
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of igg1		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Musculoskeletal and connective tissue disorders	Inozyme Pharma Ireland Limited	1/3/2025	EMA/PE/00002 25681
Ceftobiprole medocaril sodium	Zevtera and associated names	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Basilea Pharmaceutica Deutschland GmbH	1/28/2025	EMA/PE/00002 27526
Fenfluramine hydrochloride	Fintepla	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	UCB Pharma	4/14/2025	EMA/PE/00002 33398

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Evenamide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Newron Pharmaceuticals S.p.A.	1/3/2025	EMA/PE/00002 23288
Vadadustat	Vafseo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Medice Arzneimittel Puetter GmbH & Co. KG	7/11/2025	EMA/PE/00002 45403
Zuranolone		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Psychiatric disorders	Biogen Netherlands B.V.	1/28/2025	EMA/PE/00002 24092
Mrna-1283		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Moderna Biotech Spain S.L.	6/12/2025	EMA/PE/00002 42381
Encaleret		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Endocrine disorders	BridgeBio Europe B.V.	7/10/2025	EMA/PE/00002 53047
Ustekinumab	STELARA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Janssen Cilag International	3/21/2025	EMA/PE/00002 32680
Nipocalimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Janssen Cilag International	4/14/2025	EMA/PE/00002 38984
Tirzepatide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Endocrine disorders	Eli Lilly And Company Limited	4/16/2025	EMA/PE/00002 37950

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Enlicitide (decanoate)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Merck Sharp & Dohme B.V.	3/19/2025	EMA/PE/00002 28536
Satralizumab	Enspryng	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Roche Registration GmbH	4/14/2025	EMA/PE/00002 28512
Lutetium (177Lu) edotreotide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	ITM Solucin GmbH	7/11/2025	EMA/PE/00002 52926
Pariglasgene brecaparvovec		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Ultragenyx Germany GmbH	8/8/2025	EMA/PE/00002 61407
Infigratinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	QED Therapeutics Inc.	1/3/2025	EMA/PE/00002 23498
Mirikizumab	Omvoh	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Eli Lilly And Company Limited	1/28/2025	EMA/PE/00002 32930
Cenobamate	Ontozry	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Nervous system disorders	Aziende Chimiche Riunite Angelini Francesco	8/6/2025	EMA/PE/00002 50233

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
					A.C.R.A.F. S.p.A.		
Neisseria meningitidis group B fhbp protein subfamily A, Neisseria meningitidis group B fhbp protein subfamily B	Trumenba	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Pfizer Europe MA EEIG	8/8/2025	EMA/PE/00002 54741
Betula pollen extract	CLUSTOID Birke	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	5/16/2025	EMA/PE/00002 42278
Chloroprocaine hydrochloride	Ampres, Associated names: Clorotekal, Decelex	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Sintetica GmbH	4/24/2025	EMA/PE/00002 41152
Teplizumab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Sanofi Winthrop Industrie	1/16/2025	EMA/PE/00002 43095
Tolebrutinib		Modification of Paediatric Investigation Plan	Waiver	Nervous system disorders	Sanofi Winthrop Industrie	6/13/2025	EMA/PE/00002 45698
Blinatumomab	Blincyto	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Amgen Europe B.V.	1/3/2025	EMA/PE/00002 21213
Rezafungin acetate	Rezzayo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Mundipharm a GmbH	4/14/2025	EMA/PE/00002 37220
Maribavir	Livtencity	Modification of Paediatric Investigation Plan	Paediatric Investigation	Infections and infestations	Takeda Pharmaceuti cals	1/3/2025	EMA/PE/00001 82607

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			Plan and a deferral		International AG		
Denecimig		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Novo Nordisk A/S	4/16/2025	EMA/PE/00002 34140
Catequentinib (dihydrochloride)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Advenchen Laboratories LLC	3/21/2025	EMA/PE/00002 27963
Etrasimod	Velsipity	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Pfizer Europe MA EEIG	1/3/2025	EMA/PE/00001 84081
Deucrictibant monohydrate		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Pharvaris Netherlands B.V.	1/28/2025	EMA/PE/00002 27462
Navenibart		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Astria Therapeutics Inc.	6/12/2025	EMA/PE/00002 45644
Hydroxypropylbetadex	Trappsol®Cyclo™	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Cyclo Therapeutics Inc.	8/28/2025	EMA/PE/00002 61186
Risankizumab	Skyrizi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Abbvie Limited	6/27/2025	EMA/PE/00002 54020

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Ocrelizumab	Ocrevus	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Roche Registration GmbH	8/18/2025	EMA/PE/00002 65579
Modified allergen extract of Dermatophagoides pteronyssinus	CLUSTOID Dermatophagoides pteronyssinus	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	9/11/2025	EMA/PE/00002 66206
Daridorexant	QUVIVIQ	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Idorsia Pharmaceuti cals Deutschland GmbH	4/16/2025	EMA/PE/00002 33864
Ivacaftor, tezacaftor	Symkevi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Vertex Pharmaceuti cals (Ireland) Limited	1/28/2025	EMA/PE/00002 27394
Icotrokinra		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Janssen Cilag International	9/12/2025	EMA/PE/00002 56633
Vosoritide	Voxzogo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Biomarin International Limited	4/16/2025	EMA/PE/00002 24087
Fosigotifator sodium tromethamine		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Nervous system disorders	Abbvie Limited	4/7/2025	EMA/PE/00002 29973
Imetelstat sodium		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Geron Corp.	12/5/2025	EMA/PE/00002 79867

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Plozasiran		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Arrowhead Pharmaceuticals Inc.	9/9/2025	EMA/PE/00002 61820
Posaconazole	Noxafil	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Merck Sharp & Dohme B.V.	9/12/2025	EMA/PE/00002 64356
Erenumab	Aimovig	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Novartis Europharm Limited	10/31/2025	EMA/PE/00002 73584
Tecovirimat (monohydrate)	Tecovirimat SIGA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Siga Technologies Netherlands B.V.	10/31/2025	EMA/PE/00002 66688
Rezafungin acetate	Rezzayo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Mundipharma GmbH	12/22/2025	EMA/PE/00002 85623
Modified allergen extract of birch, alder and hazel pollen	CLUSTOID Birke/Erle/Hasel	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	12/5/2025	EMA/PE/00002 85476
Nomlabofusp		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Larimar Therapeutics Inc.	12/5/2025	EMA/PE/00002 85506
Meropenem trihydrate, Vaborbactam	Vaborem	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Menarini International Operations Luxembourg S.A.	4/15/2025	EMA/PE/00002 31022

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Enlicitide (decanoate)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Merck Sharp & Dohme B.V.	8/8/2025	EMA/PE/00002 71969
Bictegravir / lenacapavir		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Gilead Sciences Ireland Unlimited Company	8/8/2025	EMA/PE/00002 52831
Benralizumab	Fasenra	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	AstraZeneca AB	7/10/2025	EMA/PE/00002 41178
Zuranolone		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Psychiatric disorders	Biogen Netherlands B.V.	12/5/2025	EMA/PE/00002 85851
Obinutuzumab	Gazyvaro	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Roche Registration GmbH	12/5/2025	EMA/PE/00002 81615
Finerenone	Kerendia	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Cardiac disorders	Bayer AG	5/16/2025	EMA/PE/00002 41538
Rocatinlimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Amgen Europe B.V.	2/19/2025	EMA/PE/00002 30710
Tacrolimus		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Immune system disorders	Proveca Pharma Limited	9/11/2025	EMA/PE/00002 58601

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Cobicistat	Tybost	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Gilead Sciences International Limited	9/12/2025	EMA/PE/00002 47051
Insulin human		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Elgan Pharma Ltd.	8/8/2025	EMA/PE/00002 48436
Esketamine hydrochloride	Spravato	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Psychiatric disorders	Janssen Cilag International	1/28/2025	EMA/PE/00002 24110
Azithromycin		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Dermapharm AG	8/8/2025	EMA/PE/00002 46478
Mirikizumab	Omvoh	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Eli Lilly And Company Limited	8/8/2025	EMA/PE/00002 61403
Taldefgrobep alfa		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Biohaven Bioscience Ireland Limited	10/31/2025	EMA/PE/00002 73059
Brincidofovir		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Infections and infestations	Symbio Pharma Ireland Limited	9/12/2025	EMA/PE/00002 31875
Rilpivirine	Rekambys	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Infections and infestations	Janssen Cilag International	9/12/2025	EMA/PE/00002 63493

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Frexalimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	Sanofi Winthrop Industrie	12/5/2025	EMA/PE/00002 76344
Sepofarsen		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Laboratoires Thea	12/5/2025	EMA/PE/00002 78749
Azamidugene autotemcel		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	[INACTIVE] Orchard Therapeutics (Netherlands) B.V.	1/28/2025	EMA/PE/00002 24175
Respiratory syncytial virus, subgroup A, stabilized prefusion F antigen/Respiratory syncytial virus, subgroup B, stabilized prefusion F antigen		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Infections and infestations	Pfizer Europe MA EEIG	9/10/2025	EMA/PE/00002 63099
Deucravacitinib	SOTYKTU	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Bristol-Myers Squibb Pharma EEIG	3/21/2025	EMA/PE/00002 28305
Indacaterol acetate, Mometasone furoate	Atectura Breezhaler and its duplicate authorization Bemrist Breezhaler	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Novartis Europharm Limited	12/5/2025	EMA/PE/00002 78853

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Alanine, Arginine, Aspartic acid, Calcium chloride dihydrate, Deferoxamine mesilate, Glycine, Histidine, L-TRYPTOPHAN, Magnesium chloride hexahydrate, N-acetylhistidine monohydrate, N-hydroxy-3,4-dimethoxy-N-methyl-benzamide, OXOGLURIC ACID, Potassium chloride, Sodium chloride	Custoplex-Köhler	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	Dr. Franz Koehler Chemie GmbH	4/14/2025	EMA/PE/00002 29606
Filgotinib maleate	Jyseleca	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Alfasigma S.p.A.	4/16/2025	EMA/PE/00002 32302
Ganaxolone	ZTALMY	Modification of Paediatric Investigation Plan	Negative	Congenital, familial and genetic disorders	Immedica Pharma AB	12/5/2025	EMA/PE/00002 82624
Ritlecitinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Pfizer Europe MA EEIG	4/14/2025	EMA/PE/00002 36669
Sarilumab	Kevzara	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Sanofi Winthrop Industrie	4/15/2025	EMA/PE/00001 84035
Tofacitinib citrate	XELJANZ	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Pfizer Europe MA EEIG	4/14/2025	EMA/PE/00002 26763
Mirikizumab	Omvoh	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Gastrointestinal disorders	Eli Lilly And Company Limited	1/28/2025	EMA/PE/00002 32848

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Respiratory syncytial virus, subgroup A, stabilized prefusion F protein 847A, Respiratory syncytial virus, subgroup B, stabilized prefusion F protein 847B	Abrysvo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Pfizer Europe MA EEIG	3/21/2025	EMA/PE/00002 29144
Avelumab	Bavencio	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Nervous system disorders	Merck Healthcare KGaA	10/31/2025	EMA/PE/00002 62903
Avalglucosidase alfa	Nexviadyme	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Congenital, familial and genetic disorders	Sanofi B.V.	4/14/2025	EMA/PE/00002 38632
Efgartigimod alfa	Vyvgart	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Argenx	3/21/2025	EMA/PE/00002 31366
Spesolimab	Spevigo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Boehringer Ingelheim International GmbH	3/19/2025	EMA/PE/00002 32315
Ixazomib	NINLARO	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Takeda Pharma A/S	4/14/2025	EMA/PE/00002 25846
Bictegravir / emtricitabine / tenofovir alafenamide	Biktarvy	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Gilead Sciences International Limited	1/28/2025	EMA/PE/00002 26217

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Abemaciclib	Verzenios	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Nervous system disorders	Eli Lilly And Company Limited	1/28/2025	EMA/PE/00002 28776
Dexamethasone sodium phosphate encapsulated in human autologous erythrocytes		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Quince Therapeutics S.p.A.	12/5/2025	EMA/PE/00002 61512
Ponatinib	Iclusig	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Incyte Biosciences Distribution B.V.	4/28/2025	EMA/PE/00002 61034
Setmelanotide	IMCIVREE	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Rhythm Pharmaceuti cals Inc.	5/6/2025	EMA/PE/00002 45434
Efsudenermin alfa		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	EspeRare Foundation	6/13/2025	EMA/PE/00002 45423
Disitamab vedotin		Modification of Paediatric Investigation Plan	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	6/13/2025	EMA/PE/00002 43984
Enmetazobactam / cefepime	EXBLIFEP	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Allecra Therapeutics GmbH	7/10/2025	EMA/PE/00002 47019
Remibrutinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Nervous system disorders	Novartis Europharm Limited	8/8/2025	EMA/PE/00002 46973

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Nedosiran		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Novo Nordisk A/S	1/3/2025	EMA/PE/00002 25245
Efgartigimod alfa	Vyvgart	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Argenx	1/28/2025	EMA/PE/00002 26957
Emtricitabine / tenofovir alafenamide	Descovy	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Gilead Sciences Ireland Unlimited Company	9/12/2025	EMA/PE/00002 65190
Dostarlimab	Jemperli	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline (Ireland) Limited	10/7/2025	EMA/PE/00002 70085
Atacicept		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Vera Therapeutics Inc.	12/5/2025	EMA/PE/00002 82316
Ribitol		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	BridgeBio Europe B.V.	1/3/2025	EMA/PE/00002 24955
Finerenone	Kerendia	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Bayer AG	4/14/2025	EMA/PE/00002 35999

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Fluocinolone acetonide	ILUVIEN 190 micrograms intravitreal implant in applicator and associated names	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Eye disorders	[INACTIVE] Alimera Sciences Limited	3/21/2025	EMA/PE/00002 33122
Insulin lispro	BC222 insulin lispro	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	Adocia	6/13/2025	EMA/PE/00002 45146
Zigakibart		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Novartis Europharm Limited	8/6/2025	EMA/PE/00002 61065
Brigatinib	ALUNBRIG	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Blood and lymphatic system disorders	Takeda Pharma A/S	4/15/2025	EMA/PE/00002 36723
Ianalumab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Novartis Europharm Limited	4/15/2025	EMA/PE/00002 29480
Obefazimod		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	[INACTIVE] Abivax	3/20/2025	EMA/PE/00001 89672
Delandistrogene moxeparvovec		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Roche Registration GmbH	3/21/2025	EMA/PE/00002 33797
Abelacimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Vascular disorders	Anthos Therapeutics Inc.	1/28/2025	EMA/PE/00002 26657

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Cefepime, zidebactam	Company code: WCK 5222	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Wockhardt Bio AG	10/31/2025	EMA/PE/00002 74927
Ponatinib	Iclusig	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Incyte Biosciences Distribution B.V.	8/28/2025	EMA/PE/00002 66809
Treprostinil	Trisuva	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Respiratory, thoracic and mediastinal disorders	Aop Orphan Pharmaceuti cals GmbH	10/31/2025	EMA/PE/00002 73289
Guselkumab	Tremfya	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Gastrointestinal disorders	Janssen Cilag International	7/10/2025	EMA/PE/00002 49046
Atazanavir, cobicistat	EVOTAZ	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Immune system disorders	Bristol-Myers Squibb Pharma EEIG	12/5/2025	EMA/PE/00002 85577
Vosoritide	Voxzogo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Biomarin International Limited	1/28/2025	EMA/PE/00002 24768
Anifrolumab	Saphnelo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	AstraZeneca AB	10/31/2025	EMA/PE/00002 46211
Lerodalcibep		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Metabolism and nutrition disorders	LIB Therapeutics Inc.	5/22/2025	EMA/PE/00002 74147

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Galcanezumab	Emgality	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Eli Lilly And Company Limited	6/12/2025	EMA/PE/00002 27737
Roxadustat	Evrenzo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Astellas Pharma Europe B.V.	12/5/2025	EMA/PE/00002 85801
Troriluzole		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Biohaven Bioscience Ireland Limited	12/5/2025	EMA/PE/00002 84702
Chikungunya virus virus-like particle vaccine		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Bavarian Nordic A/S	3/21/2025	EMA/PE/00002 33803
Famtozinameran, riltozinameran, tozinameran	Comirnaty	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	BioNTech Manufacturing GmbH	1/8/2025	EMA/PE/00002 21583
Clobetasol propionate	Uvesol	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Injury, poisoning and procedural complications	Laboratorios Salvat S.A.	12/5/2025	EMA/PE/00002 65739
Milvexian		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Vascular disorders	Janssen Cilag International	10/31/2025	EMA/PE/00002 67631

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Upadacitinib	RINVOQ	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Abbvie Limited	8/8/2025	EMA/PE/00002 58727
Azilsartan medoxomil	Edarbi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Vascular disorders	Takeda Pharma A/S	4/14/2025	EMA/PE/00002 37559
Borrelia outer surface protein A (ospa) serotypes (ST1-6) lipidated, fusion protein vaccine		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Pfizer Europe MA EEIG	4/14/2025	EMA/PE/00002 28372
Apremilast	Otezla	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a waiver	Musculoskeletal and connective tissue disorders	Amgen Europe B.V.	3/20/2025	EMA/PE/00002 31892
Difelikefalin	Kapruvia	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Vifor Fresenius Medical Care Renal Pharma France	5/16/2025	EMA/PE/00002 37641
Cagrilintide, semaglutide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Novo Nordisk A/S	5/15/2025	EMA/PE/00002 40529
Dolutegravir sodium, Rilpivirine hydrochloride	Juluca	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Infections and infestations	Viiv Healthcare UK Limited	5/16/2025	EMA/PE/00002 40971

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Lebrikizumab	Ebglyss	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Eli Lilly And Company Limited	5/15/2025	EMA/PE/00002 41034
Efgartigimod alfa	Vyvgart	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Argenx	1/28/2025	EMA/PE/00002 27425
Relmapirazin		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Investigations	Medibeacon GmbH	9/11/2025	EMA/PE/00002 67155
Ocrelizumab	Ocrevus	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Roche Registration GmbH	4/14/2025	EMA/PE/00002 37224
Bupivacaine	EXPAREL	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Pacira Ireland Limited	4/15/2025	EMA/PE/00002 35857
Sebetralstat		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Kalvista Pharmaceuti cals Limited	5/15/2025	EMA/PE/00002 33998
Davesomeran, Elasomeran, Imelasomeran, Andusomeran, SARS-cov-2 JN.1 mrna	Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Moderna Biotech Spain S.L.	3/20/2025	EMA/PE/00002 28531

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Garetosmab	FOPSIVVA	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Regeneron Ireland Designated Activity Company	4/15/2025	EMA/PE/00002 28269
Famtozinameran / riltozinameran / tozinameran	Comirnaty	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	BioNTech Manufacturin g GmbH	10/31/2025	EMA/PE/00002 81435
Bempedoic acid	Nilemdo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Metabolism and nutrition disorders	Esperion Therapeutics Inc.	6/12/2025	EMA/PE/00002 38109
Brivaracetam	Briviact (in Italy: Nubriveo)	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	UCB Pharma	5/16/2025	EMA/PE/00002 40232
Levonorgestrel		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Chemo Research S.L.	5/16/2025	EMA/PE/00002 40469
Voclosporin	Orelvo	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Otsuka Pharmaceuti cal Netherlands B.V.	3/19/2025	EMA/PE/00002 28081
Modified allergen extract of Dermatophagoides farinae		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	9/12/2025	EMA/PE/00002 66354

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Darvadstrocel	Alofisel	Modification of Paediatric Investigation Plan	Waiver	Musculoskeletal and connective tissue disorders	Takeda Pharma A/S	5/20/2025	EMA/PE/00002 44768
Live, attenuated, dengue virus, serotype 1 (DENV1) / Live, attenuated, chimeric dengue virus, serotype 2 (DENV2) / Live, attenuated, dengue virus, serotype 3 (DENV3) /Live, attenuated, dengue virus, serotype 4 (DENV4)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Merck Sharp & Dohme B.V.	6/12/2025	EMA/PE/00002 41641
Venetoclax	Venclyxto	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Blood and lymphatic system disorders	Abbvie Limited	7/11/2025	EMA/PE/00002 35929
Risankizumab	Skyrizi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Abbvie Deutschland GmbH & Co. KG	10/31/2025	EMA/PE/00002 74326
Odevixibat sesquihydrate	Bylvay	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Hepatobiliary disorders	Albireo AB	7/10/2025	EMA/PE/00002 40317
Alprazolam		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	UCB Pharma	1/28/2025	EMA/PE/00002 30484
Fitusiran	Fitusiran	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Sanofi B.V.	6/13/2025	EMA/PE/00002 42247
Tenofovir alafenamide	Vemlidy	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Infections and infestations	Gilead Sciences	12/5/2025	EMA/PE/00002 90483

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver		International Limited		
Cemdisiran	cemdisiran	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Regeneron Ireland Designated Activity Company	8/4/2025	EMA/PE/00002 55611
Alfa-D-Mannose 1-phosphate		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Glycomine Inc.	8/8/2025	EMA/PE/00002 56410
Inotuzumab ozogamicin	Besponsa	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Pfizer Europe MA EEIG	7/11/2025	EMA/PE/00002 46309
Indacaterol (acetate) / glycopyrronium (bromide) / mometasone (furoate) (QVM149)	Enerzair Breezhaler and its duplicate authorization Zimbus Breezhaler	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Novartis Europharm Limited	6/13/2025	EMA/PE/00002 44179
Tezepelumab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	AstraZeneca AB	4/16/2025	EMA/PE/00002 40018
Solriamfetol	Sunosi	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Atnahs Pharma Netherlands B.V.	7/11/2025	EMA/PE/00002 40214
Migalastat hydrochloride	Galafold	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Amicus Therapeutics Europe Limited	7/11/2025	EMA/PE/00002 48880

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Pimicotinib hydrochloride hydrate		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbisko Therapeutics Co. Ltd.	4/14/2025	EMA/PE/00002 37724
Fenebrutinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Roche Registration GmbH	10/31/2025	EMA/PE/00002 25671
Infigratinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	QED Therapeutics Inc.	10/31/2025	EMA/PE/00002 75375
Yellow fever virus, strain vyf-247, Live		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Sanofi Winthrop Industrie	12/5/2025	EMA/PE/00002 82176
Nemvaleukin alfa		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Mural Oncology Inc.	3/21/2025	EMA/PE/00002 31113
Tinlarebant		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Belite Bio Inc.	8/8/2025	EMA/PE/00002 59152

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Etelcalcetide	Parsabiv	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	Amgen Europe B.V.	8/8/2025	EMA/PE/00002 57670
Leniolisib phosphate	Joenja	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Pharming Technologies B.V.	7/10/2025	EMA/PE/00002 48263
Iptacopan		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Novartis Europharm Limited	6/13/2025	EMA/PE/00002 45173
SARS-cov-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda	Nuvaxovid	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Infections and infestations	Novavax CZ a.s.	4/14/2025	EMA/PE/00002 34339
Asundexian		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Vascular disorders	Bayer AG	4/16/2025	EMA/PE/00002 35658
Cangrelor (tetrasodium)	Kengrexal	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Surgical and medical procedures	Chiesi Farmaceutici S.p.A.	4/16/2025	EMA/PE/00002 39079
Atrasentan		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Novartis Europharm Limited	5/16/2025	EMA/PE/00002 31576
Satralizumab	Enspryng	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Nervous system disorders	Roche Registration GmbH	7/11/2025	EMA/PE/00002 45099

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
			deferral and a waiver				
Venglustat	Infilbray	Modification of Paediatric Investigation Plan	Negative	Congenital, familial and genetic disorders	Sanofi B.V.	6/12/2025	EMA/PE/00002 43861
Derivative of azabicycloheptane-carboxamide (BI 1291583)		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	Boehringer Ingelheim International GmbH	5/16/2025	EMA/PE/00002 38807
Erenumab	Aimovig	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Novartis Europharm Limited	6/12/2025	EMA/PE/00002 42151
Sepofarsen		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Laboratoires Thea	6/12/2025	EMA/PE/00002 45980
Inebilizumab	Uplizna	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	[INACTIVE] Horizon Therapeutics Ireland Designated Activity Company	7/10/2025	EMA/PE/00002 53573
Zasocitinib		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Takeda Pharma A/S	9/10/2025	EMA/PE/00001 84112
Zilovertamab vedotin		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified	Merck Sharp & Dohme B.V.	10/31/2025	EMA/PE/00002 67736

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				(incl cysts and polyps)			
Rocatinlimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Amgen Europe B.V.	10/2/2025	EMA/PE/00002 73488
Enasidenib	Idhifa	Modification of Paediatric Investigation Plan	Waiver	Blood and lymphatic system disorders	Bristol-Myers Squibb Pharma EEIG	10/31/2025	EMA/PE/00002 67058
Niraparib (tosylate monohydrate)	Zejula	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline (Ireland) Limited	10/7/2025	EMA/PE/00002 69425
Gilteritinib	Xospata	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Astellas Pharma Europe B.V.	12/5/2025	EMA/PE/00002 81376
Palopegteriparatide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Endocrine disorders	Ascendis Pharma Bone Diseases A/S	5/16/2025	EMA/PE/00002 41327
Pozelimab	pozelimab	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Regeneron Ireland Designated Activity Company	8/4/2025	EMA/PE/00002 57243
Nipocalimab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Janssen Cilag International	8/6/2025	EMA/PE/00002 58527

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Aficamten		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Cytokinetics Inc.	9/12/2025	EMA/PE/00002 56837
Dermatophagoides pteronyssinus extract	SULGEN-SPRAY Dermatophagoides pteronyssinus	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Respiratory, thoracic and mediastinal disorders	ROXALL Medizin GmbH	10/31/2025	EMA/PE/00002 76154
Tralokinumab	Adtralza	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	LEO PHARMA A/S	8/6/2025	EMA/PE/00002 56717
Omaveloxolone		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Congenital, familial and genetic disorders	Biogen Netherlands B.V.	8/8/2025	EMA/PE/00002 46210
Sparsentan		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Renal and urinary disorders	Vifor (International) AG	8/8/2025	EMA/PE/00002 52576
Nemolizumab		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Skin and subcutaneous tissue disorders	Galderma International	8/8/2025	EMA/PE/00002 55564
Allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Rheacell GmbH & Co. KG	10/1/2025	EMA/PE/00002 74272
[4-(6-aminopyridazin-3-yl)piperidin-1-yl][5-(4-		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a	Renal and urinary disorders	Boehringer Ingelheim	8/8/2025	EMA/PE/00002 56668

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
fluorophenoxy)-4-methoxypyridin-2-yl]methanone			deferral and a waiver		International GmbH		
Fosigotifator sodium tromethamine		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Nervous system disorders	Abbvie Deutschland GmbH & Co. KG	9/11/2025	EMA/PE/00002 75389
Pegvaliase	Palynziq	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral	Congenital, familial and genetic disorders	Biomarin International Limited	9/12/2025	EMA/PE/00002 66048
Elasomeran, Elasomeran / imelasomeran, Elasomeran / davesomeran, Andusomeran, SARS-cov-2 JN.1 mrna	Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Surgical and medical procedures	Moderna Biotech Spain S.L.	10/31/2025	EMA/PE/00002 74908
Ertugliflozin	Steglatro	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Endocrine disorders	Merck Sharp & Dohme B.V.	12/4/2025	EMA/PE/00002 80889
Brivaracetam	Briviact (in Italy: Nubriveo)	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	UCB Pharma	10/31/2025	EMA/PE/00002 77843
Guselkumab	Tremfya	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Musculoskeletal and connective tissue disorders	Janssen Cilag International	10/31/2025	EMA/PE/00002 76186
Blinatumomab	Blincyto	Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Blood and lymphatic system disorders	Amgen Europe B.V.	12/5/2025	EMA/PE/00002 85937

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Radiprodil		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Nervous system disorders	Grin Therapeutics Inc.	8/1/2025	EMA/PE/00002 49626
Efzimfotase alfa		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan	Congenital, familial and genetic disorders	Alexion Europe	7/10/2025	EMA/PE/00002 48697
Nirogacestat hydrobromide		Modification of Paediatric Investigation Plan	Paediatric Investigation Plan and a deferral and a waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Springworks Therapeutics Ireland Limited	12/5/2025	EMA/PE/00002 86014
Padeliporfin (dipotassium)		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Steba Biotech S.A.	4/16/2025	EMA/PE/00002 37903
Hafnium oxide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	4/14/2025	EMA/PE/00002 39193
Imsamotide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	IO Biotech ApS	9/11/2025	EMA/PE/00002 80539
Bispecific antibody against vascular endothelial growth factor A and programmed death-ligand 1		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified	BioNTech SE	6/13/2025	EMA/PE/00002 44638

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				(incl cysts and polyps)			
Double-stranded rnai against HSD17B13 gene mrna, conjugated to N-acetyl galactosamine		Product Specific Waiver	Waiver	Hepatobiliary disorders	Glaxosmithkline Trading Services Limited	8/6/2025	EMA/PE/00002 54280
Vidofludimus calcium		Product Specific Waiver	Waiver	Nervous system disorders	Immunic AG	4/14/2025	EMA/PE/00002 27151
Lonigutamab		Product Specific Waiver	Waiver	Eye disorders	Acelyrin Inc.	1/28/2025	EMA/PE/00001 81050
Telmisartan / indapamide		Product Specific Waiver	Waiver	Vascular disorders	KRKA tovarna zdravil d.d. Novo mesto	12/5/2025	EMA/PE/00002 90204
Amlodipine, candesartan, indapamide		Product Specific Waiver	Waiver	Vascular disorders	Midas Pharma GmbH	8/8/2025	EMA/PE/00002 49207
Amlodipine / indapamide / telmisartan		Product Specific Waiver	Waiver	Vascular disorders	[INACTIVE] George Medicines Pty Limited	8/6/2025	EMA/PE/00002 58613
Casdatifan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Arcus Biosciences Inc.	10/31/2025	EMA/PE/00002 72718

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Humanised igg1 monoclonal antibody against B7H4 receptor conjugated to N-((2R,10S)-10-benzyl-2-cyclopropyl-1-(((1S,9S)-9-ethyl-5-fluoro-9-hydroxy-4-methyl-10,13-dioxo-2,3,9,10,13,15-hexahydro-1H,12H-benzo[de]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-1-yl)amino)-1,6,9,12,15-pentaoxo-3-oxa-5,8,11,14-tetraazahexadecan-16-yl)-6-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)hexanamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline Trading Services Limited	7/11/2025	EMA/PE/00002 53350
Efgartigimod alfa	Vyvgart	Product Specific Waiver	Waiver	Musculoskeletal and connective tissue disorders	Argenx	1/3/2025	EMA/PE/00002 25023
Celecoxib tramadol hydrochloride		Product Specific Waiver	Waiver	General disorders and administration site conditions	Alfrapharma S.r.l.	9/10/2025	EMA/PE/00002 66758
Pasritamig		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	6/12/2025	EMA/PE/00002 34649
Empagliflozin / sitagliptin		Product Specific Waiver	Waiver	Endocrine disorders	Althera Laboratories Limited	3/21/2025	EMA/PE/00002 30006
Ezetimibe, rosuvastatin		Product Specific Waiver	Waiver	Cardiac disorders	Sun Pharmaceutical Industries (Europe) B.V.	3/21/2025	EMA/PE/00002 30564

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Nucresiran		Product Specific Waiver	Waiver	Immune system disorders	Alnylam Netherlands B.V.	5/16/2025	EMA/PE/00002 36704
Avutometinib, defactinib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Verastem Europe GmbH	6/13/2025	EMA/PE/00002 45064
Fezolinetant		Product Specific Waiver	Waiver	Vascular disorders	Astellas Pharma Europe B.V.	8/8/2025	EMA/PE/00002 56262
Izalontamab brengitecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	8/8/2025	EMA/PE/00002 47324
Dupilumab	Dupixent	Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	Sanofi Winthrop Industrie	1/28/2025	EMA/PE/00002 26288
5,8-dichloro-2-[(4-methoxy-6-methyl-2-oxo-1,2-dihydropyridin-3-yl)methyl]-7-[(R)-methoxy(oxetan-3-yl)methyl]-3,4-dihydroisoquinolin-1(2H)-one		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	1/28/2025	EMA/PE/00001 82245
Zimberelimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gilead Sciences Ireland Unlimited Company	10/31/2025	EMA/PE/00002 69538
Surabgene lomparvovec		Product Specific Waiver	Waiver	Eye disorders	Abbvie Limited	3/19/2025	EMA/PE/00002 32939

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Human igg1 kappa monoclonal antibody against TREM2		Product Specific Waiver	Waiver	Nervous system disorders	Novartis Europharm Limited	8/8/2025	EMA/PE/00002 56674
Azacitidine, cedazuridine		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Taiho Pharma Netherlands B.V.	6/13/2025	EMA/PE/00002 43891
Humanised igg1 monoclonal antibody against B7H4 receptor conjugated to N-((2R,10S)-10-benzyl-2-cyclopropyl-1-(((1S,9S)-9-ethyl-5-fluoro-9-hydroxy-4-methyl-10,13-dioxo-2,3,9,10,13,15-hexahydro-1H,12H-benzo[de]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-1-yl)amino)-1,6,9,12,15-pentaoxo-3-oxa-5,8,11,14-tetraazahexadecan-16-yl)-6-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)hexanamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline Trading Services Limited	7/10/2025	EMA/PE/00002 53356
Diclofenac (potassium) / orphenadrine (citrate) / paracetamol		Product Specific Waiver	Waiver	Musculoskeletal and connective tissue disorders	Verisfield S.M.S.A.	9/12/2025	EMA/PE/00002 69204
Atigotatug / nivolumab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	3/21/2025	EMA/PE/00002 32936

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
(R)-N-(3-(2-Chloro-5-fluorophenyl)-6-(5-cyano-[1,2,4]triazolo[1,5-a]pyridin-6-yl)-1-oxoisoindolin-4-yl)-3-fluoro-5-(trifluoromethyl)benzamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Relay Therapeutics Inc.	8/8/2025	EMA/PE/00002 53679
Ulixacaltamide hydrochloride		Product Specific Waiver	Waiver	Nervous system disorders	Transcrip Ireland Limited	1/3/2025	EMA/PE/00002 25592
2-[4-[4-(Aminomethyl)-1-oxo-2H-phthalazin-6-yl]-2-methylpyrazol-3-yl]-4-chloro-6-cyclopropyloxy-3-fluorobenzonitrile		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	10/31/2025	EMA/PE/00002 74925
[2-Chloro-3-(trifluoromethyl)phenyl][(4R)-1-(5-fluoro-2-pyrimidinyl)-4-methyl-1,4,6,7-tetrahydro-5H-[1,2,3]triazolo[4,5-c]pyridin-5-yl]methanone		Product Specific Waiver	Waiver	Nervous system disorders	Janssen Cilag International	3/27/2025	EMA/PE/00002 39927
Acetylsalicylic acid, rivaroxaban		Product Specific Waiver	Waiver	Vascular disorders	Adamed Pharma S.A.	4/16/2025	EMA/PE/00002 38858
Tislelizumab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Beone Medicines Ireland Limited	6/12/2025	EMA/PE/00002 35505
Aglatimagene besadenovec		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	FGK Representative Service GmbH	9/12/2025	EMA/PE/00002 66224
Rinatabart sesutecan		Product Specific Waiver	Waiver	Investigations	Genmab A/S	1/28/2025	EMA/PE/00002 30375

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Senaparib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Shanghai Impact Therapeutics Co. Ltd.	4/15/2025	EMA/PE/00002 38610
Pacibekitug		Product Specific Waiver	Waiver	Endocrine disorders	Tourmaline Bio Inc.	1/3/2025	EMA/PE/00002 24958
Trilaciclib		Product Specific Waiver	Waiver	Surgical and medical procedures	Pharmacosm os A/S	5/16/2025	EMA/PE/00002 41250
Ifinatamab deruxtecan		Product Specific Waiver	Waiver	Gastrointestinal disorders	Daiichi Sankyo Europe GmbH	3/21/2025	EMA/PE/00002 32638
Visugromab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Catalym GmbH	3/19/2025	EMA/PE/00002 33807
Zampilimab		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Chiesi Farmaceutici S.p.A.	1/3/2025	EMA/PE/00002 27674
Colchicine		Product Specific Waiver	Waiver	Cardiac disorders	Agepha Pharma s.r.o.	8/8/2025	EMA/PE/00002 61344
Bempedoic acid/ ezetimibe/ atorvastatin		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Daiichi Sankyo Europe GmbH	7/10/2025	EMA/PE/00002 57220
Mirabegron/solifenacin		Product Specific Waiver	Waiver	Renal and urinary disorders	Propharma Group The Netherlands B.V.	6/13/2025	EMA/PE/00002 40600

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Sodium 2-(3'(-3-(1-(4-(tert-butyl)benzyl)-4-ethyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-3-yl)propyl)-4-ethoxy-[1,1'-biphenyl]-3-yl)acetate		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pharma Gateway AB	5/15/2025	EMA/PE/00002 32449
Lunsekimig		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Sanofi Winthrop Industrie	5/16/2025	EMA/PE/00002 40621
Mitazalimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Alligator Bioscience AB	5/16/2025	EMA/PE/00002 35924
Givinostat		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Italfarmaco S.p.A.	1/3/2025	EMA/PE/00002 23656
Izalontamab brengitecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	8/8/2025	EMA/PE/00002 59562
Benzoyl peroxide (hydrous)		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	[INACTIVE] Galenica AB	3/21/2025	EMA/PE/00002 33717
Rinatabart sesutecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Genmab A/S	10/31/2025	EMA/PE/00002 62513
Rinatabart sesutecan		Product Specific Waiver	Waiver	Neoplasms benign,	Genmab A/S	1/3/2025	EMA/PE/00002 24883

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				malignant and unspecified (incl cysts and polyps)			
Relacorilant		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Propharma Group The Netherlands B.V.	1/28/2025	EMA/PE/00002 26088
[225ac]ac-psma-617		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Novartis Europharm Limited	1/3/2025	EMA/PE/00002 21462
Paltusotine		Product Specific Waiver	Waiver	Endocrine disorders	Scendea (NL) B.V.	1/28/2025	EMA/PE/00002 23523
2-[4-[4-(Aminomethyl)-1-oxo-2H-phthalazin-6-yl]-2-methylpyrazol-3-yl]-4-chloro-6-cyclopropyloxy-3-fluorobenzonitrile		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	10/31/2025	EMA/PE/00002 72873
Sacituzumab govitecan	Trodelvy	Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gilead Sciences Ireland Unlimited Company	1/28/2025	EMA/PE/00002 28097
Cetrelimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	4/16/2025	EMA/PE/00002 30610

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Darovasertib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pharma Gateway AB	5/15/2025	EMA/PE/00002 21389
Bisoprolol, dapagliflozin		Product Specific Waiver	Waiver	Cardiac disorders	Teva B.V.	8/8/2025	EMA/PE/00002 57065
Zalfermin		Product Specific Waiver	Waiver	Hepatobiliary disorders	Novo Nordisk A/S	8/8/2025	EMA/PE/00002 39490
Human (scfv)2-Fab fusion protein against CD40L		Product Specific Waiver	Waiver	Eye disorders	H. Lundbeck A/S	5/16/2025	EMA/PE/00002 39082
Seralutinib		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Gossamer Bio 002 Limited	9/12/2025	EMA/PE/00002 38591
Etimumotide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	IO Biotech ApS	9/11/2025	EMA/PE/00002 80542
Mesdopetam		Product Specific Waiver	Waiver	Nervous system disorders	Integrative Research Laboratories AB	1/17/2025	EMA/PE/00002 28114
(2R,5S)-Tetrahydro-5-(2-methyl-1H-furo[3,2-b]imidazo[4,5-d]pyridin-1-yl)-2H-pyran-2-acetonitrile (2R,3R)-2,3-dihydroxysuccinate (2:1)		Product Specific Waiver	Waiver	Nervous system disorders	Biohaven Bioscience Ireland Limited	10/31/2025	EMA/PE/00002 65367
Aglatimagene besadenovec		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	FGK Representati ve Service GmbH	9/12/2025	EMA/PE/00002 66681

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Rilvegostomig		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AstraZeneca AB	8/8/2025	EMA/PE/00002 47656
Dapagliflozin, ramipril		Product Specific Waiver	Waiver	Renal and urinary disorders	Egis Pharmaceuti cals Plc.	12/5/2025	EMA/PE/00002 85712
Elraglusib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Actuate Therapeutics Limited	9/11/2025	EMA/PE/00002 47775
Bempedoic acid / ezetimibe / atorvastatin		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Daiichi Sankyo Europe GmbH	7/10/2025	EMA/PE/00002 57216
Ifinatamab deruxtecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe GmbH	3/21/2025	EMA/PE/00002 33446
Empasiprubart		Product Specific Waiver	Waiver	Nervous system disorders	Argenx	4/14/2025	EMA/PE/00002 36239
(S)-N-(5-(4-(1-(benzo[d][1,3]dioxol-5-yl)ethyl)piperazin-1-yl)-1,3,4-thiadiazol-2-yl)acetamide hydrochloride		Product Specific Waiver	Waiver	Nervous system disorders	Ferrer Internacional S.A.	10/31/2025	EMA/PE/00002 73273
[4-(Methyl-1H-pyrazol-4-yl)-benzyl]-(6[7-(3-pyrrolidin-1-yl-propoxy)-imidazo[1,2-a]pyridin-3-yl]-pyrimidin-4-yl]-amine		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified	Voisin Consulting Life Sciences	4/14/2025	EMA/PE/00002 38070

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				(incl cysts and polyps)			
Rinatabart sesutecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Genmab A/S	1/28/2025	EMA/PE/00002 30373
Maridebart cafraglutide		Product Specific Waiver	Waiver	Surgical and medical procedures	Amgen Europe B.V.	4/24/2025	EMA/PE/00002 39753
Zelenectide pevedotin		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bicycletx Limited	1/28/2025	EMA/PE/00002 28821
(12M)-(1S,2S)-N-((63S,4S,Z)-11-ethyl-12-(2-((S)-1-methoxyethyl)-5-(4-methylpiperazin-1-yl)pyridin-3-yl)-10,10-dimethyl-5,7-dioxo-61,62,63,64,65,66-hexahydro-11H-8-oxa-2(4,2)-thiazola-1(5,3)-indola-6(1,3)-pyridazinacycloundecaphane-4-yl)-2-methylcyclopropane-1-carboxamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Revolution Medicines Inc.	5/16/2025	EMA/PE/00002 41119
Dapagliflozin, metformin, sitagliptin		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Althera Laboratories Limited	10/31/2025	EMA/PE/00002 75819
Opevesostat tosilate		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merck Sharp & Dohme B.V.	10/31/2025	EMA/PE/00002 69725

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Erdafitinib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	8/8/2025	EMA/PE/00002 57743
Setidegrasib		Product Specific Waiver	Waiver	Congenital, familial and genetic disorders	Astellas Pharma Europe B.V.	10/31/2025	EMA/PE/00002 61863
Laroprovstat, rosuvastatin calcium		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	AstraZeneca AB	12/5/2025	EMA/PE/00002 58636
Clostridium botulinum neurotoxin serotype A/B		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	Ipsen Pharma	8/8/2025	EMA/PE/00002 64852
Divesiran		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Silence Therapeutics GmbH	9/12/2025	EMA/PE/00002 48792
Autologous T-cells transduced with a lentiviral vector expressing a chimeric antigen receptor against BCMA and GPRC5D		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Bristol-Myers Squibb Pharma EEIG	5/16/2025	EMA/PE/00002 40548
Dapagliflozin, rosuvastatin		Product Specific Waiver	Waiver	Cardiac disorders	Egis Pharmaceuticals Plc.	12/5/2025	EMA/PE/00002 85704
Luveltamab tazevibulin		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sutro Biopharma Inc.	5/15/2025	EMA/PE/00002 42080
Bisoprolol / dapagliflozin		Product Specific Waiver	Waiver	Cardiac disorders	Egis Pharmaceuticals Plc.	8/6/2025	EMA/PE/00002 61062

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Botulinum toxin type A		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	Relife S.r.l.	3/20/2025	EMA/PE/00002 32171
Methyl (1R,2S,3S,5S)-8-[(E)-4-(18F)fluoranylbut-2-enyl]-3-(4-methylphenyl)-8-azabicyclo[3.2.1]octane-2-carboxylate		Product Specific Waiver	Waiver	Nervous system disorders	GE Healthcare Limited	10/7/2025	EMA/PE/00002 62901
Humanised afucosylated igg1 monoclonal antibody against CCR8		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	3/21/2025	EMA/PE/00001 83637
Bexmarilimab		Product Specific Waiver	Negative	Blood and lymphatic system disorders	Faron Pharmaceuti cals Oy	9/10/2025	EMA/PE/00002 66716
Human igg1 monoclonal antibody against prostate specific membrane antigen conjugated to opadotin		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	4/15/2025	EMA/PE/00002 34980
Senaparib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Shanghai Impact Therapeutics Co. Ltd.	4/15/2025	EMA/PE/00002 38615
Taladegib		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Endeavor Biomedicines Inc.	4/14/2025	EMA/PE/00002 38063

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Autologous enriched T cells transduced with a lentiviral vector encoding a chimeric antigen receptor against CD19 and BCMA and preserving the T cell phenotype of the leukapheresis starting material		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	AstraZeneca AB	10/2/2025	EMA/PE/00002 79344
Etimumotide, imsamotide		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	IO Biotech ApS	4/14/2025	EMA/PE/00002 35991
Ivonescimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Summit (Oxford) Limited	6/12/2025	EMA/PE/00002 45628
Ivonescimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Summit (Oxford) Limited	6/12/2025	EMA/PE/00002 45862
Curcumin, resveratrol		Product Specific Waiver	Waiver	Surgical and medical procedures	Caliway Biopharmaceuticals Co. Ltd.	12/5/2025	EMA/PE/00002 77921
Emavusertib		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Curis Inc.	8/8/2025	EMA/PE/00002 46794
Ferumoxtran		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Exdra GmbH	7/10/2025	EMA/PE/00002 52572

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Empagliflozin, metformin, sitagliptin		Product Specific Waiver	Waiver	Endocrine disorders	Althera Laboratories Limited	12/5/2025	EMA/PE/00002 75307
Clostridium botulinum A, strain PM-12759 Hall-A, botulin A conjugated to protein NTNH, hemagglutinin HA17, hemagglutinin HA34, hemagglutinin HA23 and hemagglutinin HA48		Product Specific Waiver	Waiver	Nervous system disorders	Abbvie Limited	5/16/2025	EMA/PE/00002 22352
Ezetimibe, rosuvastatin		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Sun Pharmaceuti cal Industries (Europe) B.V.	1/28/2025	EMA/PE/00002 28360
Domvanalimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gilead Sciences Ireland Unlimited Company	10/31/2025	EMA/PE/00002 68747
Bempedoic acid/ ezetimibe/ rosuvastatin calcium		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Daiichi Sankyo Europe GmbH	9/12/2025	EMA/PE/00002 63718
Adeno-associated virus vector serotype 9 encoding the human GRN gene		Product Specific Waiver	Waiver	Nervous system disorders	Aviadobio Limited	10/31/2025	EMA/PE/00002 74187
Levodopa / Carbidopa (monohydrate)		Product Specific Waiver	Waiver	Nervous system disorders	Zambon S.p.A.	6/24/2025	EMA/PE/00002 58095
Visugromab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified	Catalym GmbH	12/5/2025	EMA/PE/00002 65619

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				(incl cysts and polyps)			
Humanised igg1 monoclonal antibody against CLDN6 conjugated to monomethyl auristatin E via a cathepsin hydrolysable dipeptide VC linker		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Torl Biotherapeutics LLC	12/5/2025	EMA/PE/00002 77997
Aceclidine hydrochloride		Product Specific Waiver	Waiver	Eye disorders	Lenz Therapeutics Inc.	12/5/2025	EMA/PE/00002 86212
Bimekizumab		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	UCB Pharma	10/31/2025	EMA/PE/00002 73517
Minoxidil / finasteride		Product Specific Waiver	Waiver	Skin and subcutaneous tissue disorders	Verisfield S.M.S.A.	10/31/2025	EMA/PE/00002 67560
Itepekimab		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Sanofi Winthrop Industrie	3/21/2025	EMA/PE/00002 29841
Human coagulation factor X		Product Specific Waiver	Waiver	Congenital, familial and genetic disorders	BPL Bioproducts Laboratory GmbH	10/31/2025	EMA/PE/00002 74376
Empagliflozin / rosuvastatin		Product Specific Waiver	Waiver	Cardiac disorders	Egis Pharmaceuticals Plc.	12/5/2025	EMA/PE/00002 85709
Budigalimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Deutschland GmbH & Co. KG	12/5/2025	EMA/PE/00002 82463
Arginase inhibitor (AZD8965)		Product Specific Waiver	Waiver	Respiratory, thoracic and	AstraZeneca AB	12/5/2025	EMA/PE/00002 85484

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				mediastinal disorders			
Quemliclustat		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Arcus Biosciences Inc.	4/16/2025	EMA/PE/00002 34516
Igg1 trispecific monoclonal antibody against T-cell receptor CD3, B-cell maturation antigen and G protein-coupled receptor class C group 5 member D		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Janssen Cilag International	5/16/2025	EMA/PE/00002 39491
Taletrectinib adipate		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nuvation Bio Ireland Limited	12/5/2025	EMA/PE/00002 91142
Coramitug		Product Specific Waiver	Waiver	Immune system disorders	Novo Nordisk A/S	1/28/2025	EMA/PE/00002 23677
Humanised igg1 monoclonal antibody against SEZ6, 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-yl]bicyclo[1.1.1]pentan-1-yl}amino)-1-oxopropan-2-yl]-3-methylbutanamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abbvie Deutschland GmbH & Co. KG	5/16/2025	EMA/PE/00002 35869
Senaparib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and	Shanghai Impact	4/15/2025	EMA/PE/00002 37870

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)	Therapeutics Co. Ltd.		
Serplulimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Accord Healthcare S.L.U.	7/11/2025	EMA/PE/00002 58486
(R)-N-(4-([1,2,4]-Triazolo[1,5-c]-pyrimidin-7-yloxy)-3-methylphenyl)-5-((3,3-difluoro-1-methylpiperidin-4-yl)oxy)-6-methoxyquinazolin-4-amine		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Roche Registration GmbH	12/5/2025	EMA/PE/00002 86495
Bismuth (subcitrate) / metronidazole (benzoate) / tetracycline (hydrochloride)		Product Specific Waiver	Waiver	Infections and infestations	Verisfield S.M.S.A.	8/8/2025	EMA/PE/00002 61280
Zimislecel		Product Specific Waiver	Waiver	Endocrine disorders	Vertex Pharmaceuticals (Ireland) Limited	7/11/2025	EMA/PE/00002 48789
Humanised igg1 monoclonal antibody against GPRC5D conjugated to vedotin		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	AstraZeneca AB	8/8/2025	EMA/PE/00002 57432
Dapagliflozin, linagliptin, metformin		Product Specific Waiver	Waiver	Endocrine disorders	Verisfield S.M.S.A.	10/31/2025	EMA/PE/00002 73395
Human igg1 monoclonal antibody against folate receptor alfa conjugated to samrotecan		Product Specific Waiver	Waiver	Reproductive system and breast disorders	AstraZeneca AB	9/12/2025	EMA/PE/00002 61338
Dapagliflozin, rosuvastatin		Product Specific Waiver	Waiver	Endocrine disorders	Egis Pharmaceuticals Plc.	10/31/2025	EMA/PE/00002 75729

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Lunbotinib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ellipses Pharma Limited	8/8/2025	EMA/PE/00002 55694
Mirabegron/solifenacin		Product Specific Waiver	Waiver	Renal and urinary disorders	Propharma Group The Netherlands B.V.	6/13/2025	EMA/PE/00002 44980
Linaprazan glurate		Product Specific Waiver	Waiver	Infections and infestations	[INACTIVE] Cinclus Pharma Holding AB (publ)	6/12/2025	EMA/PE/00002 41632
Opevesostat tosilate		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merck Sharp & Dohme B.V.	10/31/2025	EMA/PE/00002 69700
Bempedoic acid, Ezetimibe, Rosuvastatin calcium		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	Daiichi Sankyo Europe GmbH	9/10/2025	EMA/PE/00002 56917
Oxymetazoline		Product Specific Waiver	Waiver	Eye disorders	Santen Oy	9/12/2025	EMA/PE/00002 66753
Zabilugene almadenorepvec		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Theriva Biologics S.L.	5/15/2025	EMA/PE/00002 39504
Calcium carbonate / Cholecalciferol + Risedronate sodium		Product Specific Waiver	Waiver	Musculoskeletal and connective tissue disorders	Kappler Pharma Consult GmbH	5/15/2025	EMA/PE/00002 41614

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
(12M)-(1S,2S)-N-((63S,4S,Z)-11-ethyl-12-(2-((S)-1-methoxyethyl)-5-(4-methylpiperazin-1-yl)pyridin-3-yl)-10,10-dimethyl-5,7-dioxo-61,62,63,64,65,66-hexahydro-11H-8-oxa-2(4,2)-thiazola-1(5,3)-indola-6(1,3)-pyridazinacycloundecaphane-4-yl)-2-methylcyclopropane-1-carboxamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Revolution Medicines Inc.	7/10/2025	EMA/PE/00002 40204
Atirmociclib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	10/31/2025	EMA/PE/00002 67622
Sacituzumab tirumotecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Merck Sharp & Dohme B.V.	3/19/2025	EMA/PE/00002 27611
(((S)-1-Carboxy-5-(6-([18F]fluoro)-2-methylnicotinamide)pentyl)carbamoyl)-l-glutamic acid		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Itel Telecomunicazioni S.r.l.	7/11/2025	EMA/PE/00002 45622
Puxitatug samrotecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AstraZeneca AB	4/14/2025	EMA/PE/00002 42035

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
Gemcitabine hydrochloride		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Janssen Cilag International	4/14/2025	EMA/PE/00002 30592
Baxdrostat, Dapagliflozin propanediol		Product Specific Waiver	Waiver	Cardiac disorders	AstraZeneca AB	5/16/2025	EMA/PE/00002 41527
Buloxibutid sodium		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Vicore Pharma AB	5/15/2025	EMA/PE/00002 42940
Baxdrostat		Product Specific Waiver	Waiver	Endocrine disorders	AstraZeneca AB	4/14/2025	EMA/PE/00002 27014
Mifepristone, misoprostol		Product Specific Waiver	Waiver	Pregnancy, puerperium and perinatal conditions	Adoh B.V.	6/12/2025	EMA/PE/00002 45149
Empagliflozin, rosuvastatin		Product Specific Waiver	Waiver	Endocrine disorders	Egis Pharmaceuti cals Plc.	10/31/2025	EMA/PE/00002 75739
Dapagliflozin, ramipril		Product Specific Waiver	Waiver	Cardiac disorders	Egis Pharmaceuti cals Plc.	10/31/2025	EMA/PE/00002 75751
Unasnemab		Product Specific Waiver	Waiver	Nervous system disorders	Tanabe Pharma GmbH	8/8/2025	EMA/PE/00001 81151
Laroprovstat, Rosuvastatin calcium		Product Specific Waiver	Waiver	Metabolism and nutrition disorders	AstraZeneca AB	12/5/2025	EMA/PE/00002 58643
Allogeneic induced pluripotent stem cells, master cell bank-derived gene-modified ovarian support cells		Product Specific Waiver	Waiver	Reproductive system and breast disorders	Gameto Inc.	9/12/2025	EMA/PE/00002 64931
Hafnium oxide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and	Janssen Cilag International	9/11/2025	EMA/PE/00002 28297

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				unspecified (incl cysts and polyps)			
Dapagliflozin, ramipril		Product Specific Waiver	Waiver	Endocrine disorders	Egis Pharmaceuticals Plc.	12/5/2025	EMA/PE/00002 85716
Timbetasin acetate		Product Specific Waiver	Waiver	Eye disorders	Premier Research Group S.L.	8/8/2025	EMA/PE/00002 57626
Izalontamab brengitecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	8/8/2025	EMA/PE/00002 56940
Aglatimagene besadenovec		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	FGK Representative Service GmbH	9/12/2025	EMA/PE/00002 66684
Humanized igg1 monoclonal antibody against thymic stromal lymphopoietin		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Glaxosmithkline Trading Services Limited	10/31/2025	EMA/PE/00002 85210
Sibeprenlimab		Product Specific Waiver	Waiver	Musculoskeletal and connective tissue disorders	Otsuka Pharmaceutical Netherlands B.V.	12/5/2025	EMA/PE/00002 77915
Dapagliflozin, sitagliptin		Product Specific Waiver	Waiver	Endocrine disorders	Elpen Pharmaceutical Co. Inc.	12/5/2025	EMA/PE/00002 85585
Sintilimab		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified	Innovent Biologics (USA) Inc.	10/31/2025	EMA/PE/00002 86058

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
				(incl cysts and polyps)			
Dapagliflozin, linagliptin		Product Specific Waiver	Waiver	Endocrine disorders	Verisfield S.M.S.A.	10/31/2025	EMA/PE/00002 72162
Medroxyprogesterone acetate		Product Specific Waiver	Waiver	Reproductive system and breast disorders	Laboratoires Majorelle	8/8/2025	EMA/PE/00002 28411
Ifinatamab deruxtecan		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Daiichi Sankyo Europe GmbH	8/8/2025	EMA/PE/00002 66564
Empagliflozin / rosuvastatin		Product Specific Waiver	Waiver	Renal and urinary disorders	Egis Pharmaceuti cals Plc.	12/5/2025	EMA/PE/00002 85708
2-Methoxy-N-{4-methoxy-6-[(1H-pyrazol-1-yl)methyl]-1,2-benzoxazol-3-yl}benzene-1-sulfonamide		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pfizer Europe MA EEIG	9/12/2025	EMA/PE/00002 57399
Zoldonrasib		Product Specific Waiver	Waiver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Revolution Medicines Inc.	12/5/2025	EMA/PE/00002 86050
3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-		Product Specific Waiver	Waiver	Endocrine disorders	AstraZeneca AB	7/11/2025	EMA/PE/00002 46516

Active substance(s)	Invented name	Application type	PDCO Opinion Outcome	Therapeutic area	Applicant	Decision Date	Decision Number
yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one, Dapagliflozin propanediol monohydrate							
Autologous T cells transduced with an lentiviral vector to express a chimeric antigen receptor against CD19		Product Specific Waiver	Waiver	Blood and lymphatic system disorders	Galapagos	12/5/2025	EMA/PE/00002 82140
Humanised igg4 monoclonal antibody against protein S100-A4		Product Specific Waiver	Waiver	Respiratory, thoracic and mediastinal disorders	Calluna Pharma AS	10/31/2025	EMA/PE/00002 84826
Dapagliflozin, rosuvastatin		Product Specific Waiver	Waiver	Renal and urinary disorders	Egis Pharmaceuti cals Plc.	12/5/2025	EMA/PE/00002 85697

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

Active substance(s)	Therapeutic area (s)	Applicant	PDCO opinion date
Abemaciclib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eli Lilly And Company Limited	12/12/2025
Lacosamide	Nervous system disorders	UCB Pharma	12/12/2025
Vosoritide	Congenital, familial and genetic disorders	Biomarin International Limited	12/12/2025
Dostarlimab	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline (Ireland) Limited	10/17/2025
Niraparib (tosylate monohydrate)	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Glaxosmithkline (Ireland) Limited	10/17/2025
Ustekinumab	Gastrointestinal disorders	Janssen Cilag International	11/14/2025
Ceftolozane, tazobactam	Infections and infestations	Merck Sharp & Dohme B.V.	12/12/2025
Ocrelizumab	Nervous system disorders	Roche Registration GmbH	11/14/2025
Ponatinib	Blood and lymphatic system disorders	Incyte Biosciences Distribution B.V.	10/17/2025
Neisseria meningitidis group B fhbp protein subfamily A, Neisseria meningitidis group B fhbp protein subfamily B	Surgical and medical procedures	Pfizer Europe MA EEIG	10/17/2025
Ribociclib	Nervous system disorders	Novartis Europharm Limited	10/17/2025
Daunorubicin / cytarabine	Blood and lymphatic system disorders	Jazz Pharmaceuticals Ireland Limited	11/14/2025
Osilodrostat	Endocrine disorders	Recordati Rare Diseases	11/14/2025
Emapalumab	Immune system disorders	Swedish Orphan Biovitrum AB (publ)	10/17/2025
Risankizumab	Skin and subcutaneous tissue disorders	Abbvie Deutschland GmbH & Co. KG	9/12/2025
Gemtuzumab ozogamicin	Blood and lymphatic system disorders	Pfizer Europe MA EEIG	10/17/2025
Delgocitinib	Skin and subcutaneous tissue disorders	LEO PHARMA A/S	9/12/2025

Active substance(s)	Therapeutic area (s)	Applicant	PDCO opinion date
Recombinant Vesicular Stomatitis virus (strain indiana) with a deletion of the envelope glycoprotein, replaced with the Zaire ebolavirus (strain Kikwit-1995) surface glycoprotein	Infections and infestations	Merck Sharp & Dohme B.V.	9/12/2025
Ceftobiprole medocaril sodium	Infections and infestations	Basilea Pharmaceutica Deutschland GmbH	9/12/2025
Brexucabtagene autoleucel	Blood and lymphatic system disorders	Kite Pharma EU B.V.	7/25/2025
Arimoclomol citrate	Congenital, familial and genetic disorders	Zevra Denmark A/S	7/25/2025
Ketamine/sufentanil	General disorders and administration site conditions	Cessatech A/S	7/24/2025
Ustekinumab	Gastrointestinal disorders	Janssen Cilag International	7/25/2025
Peginterferon beta-1A	Nervous system disorders	Biogen Netherlands B.V.	6/20/2025
Denecimig	Congenital, familial and genetic disorders	Novo Nordisk A/S	9/12/2025
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 CRM197, Pneumococcal polysaccharide serotype 23A conjugated to	Infections and infestations	Merck Sharp & Dohme B.V.	7/25/2025

Active substance(s)	Therapeutic area (s)	Applicant	PDCO opinion date
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			
Ferric maltol	Metabolism and nutrition disorders	Norgine B.V.	5/23/2025
Berotralstat	Congenital, familial and genetic disorders	Biocryst Ireland Limited	7/25/2025
Leriglitazone	Congenital, familial and genetic disorders	Minoryx Therapeutics S.L.	6/20/2025
Tirzepatide	Endocrine disorders	Eli Lilly And Company Limited	6/20/2025
Dupilumab	Skin and subcutaneous tissue disorders	Sanofi Winthrop Industrie	6/20/2025
Ixazomib	Blood and lymphatic system disorders	Takeda Pharma A/S	7/25/2025
Apadamtase alfa	Blood and lymphatic system disorders	Takeda Pharmaceuticals International AG	7/23/2025
Cobicistat, Darunavir ethanolate, Emtricitabine, Tenofovir alafenamide fumarate	Infections and infestations	Janssen Cilag International	7/25/2025
Rurioctocog alfa pegol	Congenital, familial and genetic disorders	BAXALTA INNOVATIONS GmbH	5/23/2025
Selpercatinib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eli Lilly And Company Limited	6/20/2025

Active substance(s)	Therapeutic area (s)	Applicant	PDCO opinion date
Tedizolid	Infections and infestations	Merck Sharp & Dohme B.V.	6/20/2025
Gadopiclenol	Nervous system disorders	Guerbet	3/28/2025
Gadopiclenol	Investigations	Guerbet	3/28/2025
Onasemnogene abeparvovec	Congenital, familial and genetic disorders	Novartis Europharm Limited	4/25/2025
Gadoquatrane	Investigations	Bayer AG	4/25/2025
Dolutegravir / lamivudine	Infections and infestations	Viiv Healthcare UK Limited	5/23/2025
Cannabidiol	Nervous system disorders	Jazz Pharmaceuticals Ireland Limited	4/25/2025
Furosemide	Metabolism and nutrition disorders	Proveca Pharma Limited	2/28/2025
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)	Infections and infestations	Sanofi Winthrop Industrie	3/28/2025
Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. Meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. Meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. Meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (menacyw)	Infections and infestations	Sanofi Winthrop Industrie	3/28/2025
Ravulizumab	Blood and lymphatic system disorders	Alexion Europe	3/28/2025
Ravulizumab	Renal and urinary disorders	Alexion Europe	3/28/2025
Dienogest, ethinylestradiol	Reproductive system and breast disorders	Chemo Research S.L.	1/31/2025
Beremagene geperpavec	Congenital, familial and genetic disorders	Krystal Biotech Inc.	4/25/2025
Cilastatin sodium, Imipenem monohydrate, Relebactam monohydrate	Infections and infestations	Merck Sharp & Dohme B.V.	3/28/2025

Active substance(s)	Therapeutic area (s)	Applicant	PDCO opinion date
Nivolumab	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bristol-Myers Squibb Pharma EEIG	3/28/2025
Eravacycline	Infections and infestations	Paion Pharma GmbH	3/28/2025
Cemiplimab	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Regeneron Ireland Designated Activity Company	3/28/2025
Dinutuximab beta	Nervous system disorders	Recordati Netherlands B.V.	1/31/2025
Cobicistat, Darunavir ethanolate	Infections and infestations	Janssen Cilag International	2/28/2025
Sotrovimab	Infections and infestations	Glaxosmithkline Trading Services Limited	2/28/2025
Larotrectinib	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bayer AG	2/28/2025
Lomitapide	Congenital, familial and genetic disorders	Chiesi Farmaceutici S.p.A.	2/28/2025
Human fibrinogen	Nervous system disorders	Omrix Biopharmaceuticals	1/31/2025
Ibrexafungerp	Infections and infestations	Scynexis Inc.	1/31/2025
Odevixibat sesquihydrate	Congenital, familial and genetic disorders	Albireo AB	1/31/2025
Guselkumab	Skin and subcutaneous tissue disorders	Janssen Cilag International	1/31/2025

Annex 17 – Referral procedures overview 2025 – 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
Mysimba (naltrexone hydrochloride/ bupropion hydrochloride)	14/09/2023	27/03/2025	Article 20 of Regulation (EC) No 726/2004
Azithromycin-containing medicinal products for systemic use (azithromycin)	09/11/2023	19/06/2025[1]	Article 31 of Directive 2001/83/EC
Oxbryta (voxelotor)	29/07/2024	16/10/2025	Article 20 of Regulation (EC) No 726/2004
Ipidacrine-containing medicinal products (ipidacrine)	22/05/2025	ongoing	Article 31 of Directive 2001/83/EC
Sodium oxybate-containing syrup and oral solution for alcohol dependence (sodium oxybate)	19/06/2025	ongoing	Article 31 of Directive 2001/83/EC
Tecovirimat SIGA (tecovirimat)	24/07/2025	ongoing	Article 20 of Regulation (EC) No 726/2004
Melatomed and associated names (melatonin)	16/10/2025	11/12/2025	Article 29(4) of Directive 2001/83/EC

Referrals made to the PRAC

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Finasteride-and dutasteride-containing medicinal products	03/10/2024	19/06/2025	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
IXCHIQ (Chikungunya vaccine (live))	05/05/2025	24/07/2025	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Levamisole-containing medicinal products (levamisole)	04/09/2025	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

[1] Revised opinion, initial opinion adopted on 22/05/2025

Annex 18 – Arbitrations and referrals in 2025 – veterinary medicines

Type of procedure	Date Clock start CVMP opinion	Product Product name INN
Article 141(1)(i) of Regulation (EU) 2019/6	• 17/07/2025 • pending	• Quarter-based selective dry cow therapy • Various active substances
Article 54(8) of Regulation (EU) 2019/6	• 01/10/2025 • 04/12/2025	• Phenoxypen WSP, 325 mg/g powder for use in drinking water for chickens • Phenoxymethylpenicillin
Article 141(1)(i) of Regulation (EU) 2019/6	• 06/10/2025 • pending	• Veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications • Amoxicillin
Article 82 of Regulation (EU) 2019/6	• 06/11/2025 • pending	• Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep • Albendazole

Annex 19 – Budget summaries 2024-2025

The summarised comparative budget statements for 2024 and 2025 are as follows:

		Budget 2024 [1]		2025 (budget)[2]		2025 (prov) [3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
Revenue							
100	Fees and charges	387,090	*88.2%*	549,320	*91.5%*	539,896	*91.4%*
200	General EU contribution	14,421	*3.3%*	48,893	*8.1%*	48,900	*8.3%*
201	Special EU contribution for orphan medicinal products	10,733	*2.4%*	0	*0.0%*	0	*0.0%*
600	External assigned revenue	0	*0.0%*	0	*0.0%*	0	*0.0%*
700	Balance from previous year	24,982	*5.7%*	21	*0.0%*	21	*0.0%*
5+9	Other	1,585	*0.4%*	1,996	*0.3%*	1,672	*0.3%*
	TOTAL REVENUE	**438,811**	*100.0%*	**600,230**	*100.0%*	**590,490**	*100.0%*
Expenditure							
Staff							
11	Staff in active employment	140,477	*28.6%*	159,489	*26.6%*	159,264	*26.9%*
12	Recruitment	96	*0.0%*	275	*0.0%*	202	*0.0%*
13	Duty travel	785	*0.2%*	1,010	*0.2%*	881	*0.1%*
14	Socio-medical infrastructure	3,494	*0.7%*	3,842	*0.6%*	3,799	*0.6%*
15	Training	1,060	*0.2%*	1,178	*0.2%*	1,047	*0.2%*
16	External services	19,579	*4.0%*	23,194	*3.9%*	23,035	*3.9%*
17	Receptions & events	142	*0.0%*	275	*0.0%*	254	*0.0%*
	Total Title 1	**165,632**	*33.8%*	**189,263**	*31.5%*	**188,482**	*31.8%*
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	30,523	*6.2%*	34,303	*5.7%*	34,104	*5.8%*
21	Information and communication technology	43,591	*8.9%*	50,600	*8.4%*	50,273	*8.5%*
22	Movable property and associated costs	626	*0.1%*	669	*0.1%*	660	*0.1%*
23	Current administrative expenditure	1,643	*0.3%*	1,183	*0.2%*	1,113	*0.2%*
24	Postage	20	*0.0%*	30	*0.0%*	26	*0.0%*
25	Other meetings	103	*0.0%*	149	*0.0%*	124	*0.0%*
26	Restaurant and catering	963	*0.2%*	2,314	*0.4%*	2,314	*0.4%*
27	Information and publishing	1,458	*0.3%*	2,013	*0.3%*	1,964	*0.3%*
28	Business consultancy and audit services	2,908	*0.6%*	3,801	*0.6%*	3,758	*0.6%*
	Total Title 2	**81,836**	*16.7%*	**95,062**	*15.8%*	**94,336**	*15.9%*
Operational expenditure							
300	Meetings	4,952	*1.0%*	5,973	*1.0%*	5,809	*1.0%*
301	Evaluation of medicinal products	177,099	*36.1%*	240,017	*40.0%*	234,673	*39.6%*
302	Translations	4,957	*1.0%*	5,397	*0.9%*	5,349	*0.9%*
303	Scientific studies and services	16,813	*3.4%*	24,008	*4.0%*	23,914	*4.0%*
31	Expenditure on business related IT projects	39,196	*8.0%*	40,510	*6.7%*	40,466	*6.8%*
	Total Title 3	**243,017**	*49.5%*	**315,905**	*52.6%*	**310,212**	*52.3%*
900	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	**490,485**	*100.0%*	**600,230**	*100.0%*	**593,029**	*100.0%*

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

[2] Financial Year 2025: as per final budget

[3] Financial Year 2025: as per provisional accounts; rounded to the nearest thousand Euro (incl. non-automatic carry forward)

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2025				POSTS 2026	
	Authorised		Actual as per 31.12.2025*		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	1	-	3
AD 14	-	12	-	11	-	13
AD 13	-	15	-	15	-	18
AD 12	-	64	-	64	-	64
AD 11	-	49	-	49	-	51
AD 10	-	59	-	59	-	60
AD 9	-	94	-	94	-	109
AD 8	-	81	-	81	-	76
AD 7	-	85	-	85	-	93
AD 6	-	43	-	43	-	29
AD 5	-	0	-	0	-	0
Total AD	**0**	**505**	**0**	**502**	**0**	516
AST 11	-	3	-	3	-	3
AST 10	-	7	-	7	-	7
AST 9	-	13	-	13	-	15
AST 8	-	19	-	19	-	23
AST 7	-	38	-	38	-	41
AST 6	-	26	-	26	-	40
AST 5	-	56	-	56	-	42
AST 4	-	22	-	22	-	16
AST 3	-	15	-	15	-	16
AST 2	-	0	-	0	-	0
AST 1	-	0	-	0	-	0
Total AST	**0**	199	**0**	199	**0**	203
Grand Total	**0**	**704**	**0**	**701**	**0**	**719**

Other staff	Planned (FTE[1]) 2025	Actual (FTE[1]) 2025	Actual headcount 31.12.2025	Planned (FTE[1]) 2026
CONTRACT AGENTS	**203**	**204**	**230**	**203**
NATIONAL EXPERTS	**45**	**45**	**52**	**45**

[1] FTE=Full Time Equivalent

Annex 21 - Litigation activities of EMA in 2025

Actions before the Court of Justice of the European Union that are directed against EMA (pending or concluded in 2025)

1. 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 the COVID-19 vaccine, Comirnaty. A hearing was held on 6 March 2025.

By its judgment of 19 November 2025, the General Court declared that there was no longer any need to adjudicate on the action regarding data previously disclosed by EMA and dismissed the remainder of the action. The General Court ordered EMA to bear its own costs, and to pay half of those incurred by the applicant due to the previous disclosure of data by EMA.

(On 29 January 2026, the applicant lodged an appeal against the first-instance judgment in Case C-38/26 P.)

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

On 22 July 2024, the applicant brought an action for annulment against the decision of EMA to refuse the applicant's request to retract from its website a scientific opinion adopted in 2017 that recommended the refusal of the grant of a marketing authorisation for the candidate medicinal product, Alcover Granules.

By order of 7 May 2025, the General Court dismissed the action as inadmissible and ordered the applicant to bear its own costs and pay those incurred by EMA.

The order of the General Court in Case T-373/24 is currently under appeal before the Court of Justice in Case C-467/25 P (please see below).

3. 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 decision of the Commission to grant a conditional marketing authorisation for the advanced therapy medicinal product, Beqvez (previously, Durveqtix). 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.

Following the adoption of the Commission decision to withdraw the contested marketing authorisation at the marketing authorisation holder's request, the Commission and EMA applied for a declaration that the action had become devoid of purpose and that there was no longer any need to adjudicate on it.

By order of 11 November 2025, the General Court ruled that there was no longer any need to adjudicate on the action and ordered each party to bear its own costs.

4. 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 the medicinal product, Ferrinject. The proceedings remained pending in 2025.

In parallel, the applicant sought interim relief to suspend the operation of the contested decision in Case T-666/24 R. By its order of 27 March 2025, the President of the General Court dismissed the application and reserved the costs.

(A hearing was held on 26 February 2026.)

5. Case T-265/25 – *IW v Commission and EMA*

On 17 April 2025, the applicant brought an action seeking compensation for damages allegedly incurred following the administration of the COVID-19 Vaccine AstraZeneca.

(By order of 27 February 2026, the General Court rejected the action as manifestly inadmissible.)

6. Case C-467/25 P – *D&A Pharma v EMA*

On 15 July 2025, the appellant lodged an appeal against the order of the General Court in Case T-373/24, alleging that the General Court made a manifest error in holding that the appellant had failed to establish an interest in the annulment of EMA's refusal, in to retract from its website a scientific opinion adopted in 2017 concerning Alcover Granules.

The proceedings remained pending in 2025.

7. Case T-610/25 – *Mylan Healthcare v EMA*

On 8 September 2025, the applicant brought an action for annulment against the decision of EMA to grant partial access to a periodic safety update report for the medicinal product, Dynmista, alleging an infringement of the right to the protection of its commercial interests.

(By order of 27 January 2026, the General Court removed the case from the Register following a request for the discontinuance of the proceedings by the applicant.)

8. Case T-844/25 – *Biohaven Bioscience Ireland and Biohaven Therapeutics v EMA*

On 10 December 2025, the applicant brought an action for annulment again the decision of EMA to publish a European Public Assessment Report concerning its withdrawal of an application for marketing authorisation for Dazluma, alleging, in particular, that the entire report ("withdrawal EPAR") should temporarily qualify as commercially confidential information whilst patent proceedings remain ongoing.

In parallel, the applicant has sought interim relief to suspend the operation of the contested decision in Case T-844/25 R.

The proceedings in both actions remained pending in 2025.

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 2025)

9. 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 theactive substance of Nexviadyme as a new active substance and to remove the medicinal product 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.

By its judgment of 24 September 2025, the General Court dismissed the action and ordered the applicant to bear its own costs and those incurred by the Commission, while EMA was ordered to bear its own costs.

10. 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 version of the medicinal product, Firmagon. 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. A hearing was held on 18 September 2025.

The proceedings remained pending in 2025.

11. 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 the conditional marketing authorisation for the medicinal product, Ocaliva. 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.

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

In parallel, the applicant sought interim relief to suspend the operation of the contested decision in Case T-455/24 R. By order of 26 November 2024, the President of the General Court dismissed the application. Said findings were subsequently challenged by the applicant. By order of 29 April 2025 in Case C-859/24 P(R), the Vice-President dismissed the appeal and ordered the applicant-at-first-instance to pay the costs.

The main action remained pending in 2025.

(A hearing was held on 15 January 2026.)

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

On 21 October 2024, the applicant brought an action for annulment against the decision of the European Commission to grant a marketing authorisation for a generic version of the medicinal product, Tasigna.

By order of 13 May 2025, the General Court removed the case from the Register following a request for the discontinuance of the proceedings by the applicant.

13. Case T-278/25, *Duchenne Research & Advocacy v Commission*

On 30 April 2025, the applicant brought an action for annulment against the decision of the European Commission which refused the renewal of the conditional marketing authorisation for Translarna.

In parallel, the applicant sought interim relief to suspend the operation of the contested decision in Case T-278/25 R. By its order of 2 July 2025, the President of the General Court dismissed the application and reserved the costs.)

(By its order of 12 January 2026, the General Court rejected the main action as inadmissible.)

14. Case T-637/25, *Merck Europe v Commission*

On 21 September 2025, the applicant brought an action for annulment against a letter of the European Commission concerning the terms of the marketing authorisation for the centrally authorised medicinal product, Mavenclad.

In parallel, the applicant sought interim relief to suspend the operation of the contested decision in Case T-637/25 R. By its order of 12 December 2025, the President of the General Court dismissed the application and reserved the costs.

The proceedings in the main action remained pending in 2025.

15. 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*.

15.1. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-785/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-806/25 P.

15.2. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. The Court held that the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-786/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-807/25 P.

15.3. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-787/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-808/25 P.

15.4. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. The Court held that the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-788/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-809/25 P.

15.5. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-791/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-812/25 P.

15.6. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-792/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-813/25 P.

15.7. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-789/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-810/25 P.

15.8. 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.

By its judgment of 24 September 2025, the General Court annulled the decision of the European Commission on the basis that the additional year of marketing protection was granted outside the eight year period laid down in Article 14(11) of Regulation (EC) No 726/2004. In the view of the Court, the requirement to comply with a judgment in accordance with Article 266 TFEU cannot entail the alteration of a time limit laid down in EU law.

On 4 December 2025, an appeal was lodged by the intervener-at-first-instance, Biogen Netherlands against the first-instance judgment in Case C-790/25 P; and, on 10 December 2025, an appeal was lodged by the European Commission in Case C-811/25 P.

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; and the decision of the European Commission to revoke certain marketing authorisations for generic versions of Tecfidera

16.1. 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'. A hearing was held on 19 June 2025.

(By its judgment of 11 February 2026, the General Court dismissed the action and ordered the applicant to bear its own costs and those incurred by the Commission.)

16.2. 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'. A hearing was held on 19 June 2025.

(By its judgment of 11 February 2026, the General Court dismissed the action and ordered the applicant to bear its own costs and those incurred by the Commission.)

16.3. 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'. A hearing was held on 19 June 2025.

(By its judgment of 11 February 2026, the General Court dismissed the action and ordered the applicant to bear its own costs and those incurred by the Commission.)

Annex 22 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2025	732	207,730

Initial decisions on access in 2025[1]

Access given	Number of requests
Yes/Partial	309
No/Refusal	14
Document is not held by the Agency	52
Request became RFI	19
Clarification is not received / Withdrawn by requester	81
Total closed	**475**
On-going[2]	65
Pending[3]	421

Legal basis used for refusal

Legal basis	Number of requests
4.1.(a)– Protection of the public interest	1
4.1(b) – Protection of privacy	0
4.2 1st ind – Protection of commercial interest	10
4.2 2nd ind – Protection of court proceedings	0
4.2 3rd ind – Protection of inspections	0
4.3 1st par – Protection of decision-making process	3
4.3 2nd par – Protection of the Agency's decision-making process	0
4.5 – Protection of Member States	0
Total	**14**

Decision on confirmatory applications (appeals) in 2025[4]

Appeals	Number of appeals
Final refusal	5
Release/Partial release	5
Request became RFI	0
Withdrawn by requester	0
Document is not held by the Agency	1
Total closed	11
On-going[5]	3

[1] Including initial requests received in previous years but closed in 2025
[2] Requests on-going (currently being processed)
[3] Requests pending in queue (not started)
[4] Including appeals received in previous years but closed in 2025
[5] Appeals on-going (currently being processed)

Legal basis used for refusal

Legal basis	Number of appeals
4.1(a) – Protection of public interest	1
4.1(b) – Protection of privacy	2
4.2 1st ind – Protection of commercial interest	7
4.2 2nd ind – Protection of court proceedings	0
4.2 3rd ind – Protection of inspections	0
4.3 1st par – Protection of decision-making process	1
4.3 2nd par – Protection of the Agency's decision-making process	0
4.5 – Protection of Member States	1
Total[6]	**12**

Affiliation (per initial requests and appeals received in 2025)

Affiliation	Number of requests received	In %	Number of pages released[7]	In %
Not-for-profit organisation	7	1	696	0
EU Institution (EC etc)	4	1	0	0
Regulator outside EU	1	0	0	0
EU NCA	3	0	2,182	1
Patients or Consumer	47	6	11,395	5
Healthcare professional	29	5	30,395	15
Academia/Research institute	137	18	19,895	10
Legal	65	9	18,734	9
Media	11	2	4,282	2
Pharmaceutical industry	336	45	68,333	33
Consultant	86	12	48,697	23
Other	6	1	3,121	2
Total	**732**	**100**	**207,730**	**100**

[6] More than one article can be applicable as a legal basis used for refusal/partial release
[7] Including initial requests and appeals received in previous years but closed in 2025

Annex 23 – Clinical Data Publication

Number of documents published

Year	Number of documents published	Number of pages published
2025	5,370	2,439,274

Documents and Pages published per module

Module	Documents	Pages
Module 2.5	121	7,614
Module 2.7	388	50,338
Module 5	4,861	2,381,322

Number of procedures published by procedure type

Initial MAA	49
Extension of Indication	19
Grouped Type II Variation	1
Type II Variation	17
Line Extension	6
Post Authorisation Recommendation (PAM)	-

Anonymisation Risk Assessment Approach

Approach	Number of Procedures
Qualitative[1]	40
Quantitative[2]	31
Mixed[3]	17
Not Applicable[4]	4

[1] 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)

[2] 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)

[3] Mixed: a combination of the two.

[4] No anonymisation needed as no private personal data (PPD) was present in the documents

Annex 24 – Publications by Agency staff members and experts in 2025

Aarum S, Popp C, Hunter A, Skvarc M, Reischl I, Zander H, Zinserling J, van Leeuwen P, Sutch J, Chesworth T, Kapeller E, Emmendoerffer A, Gravanis I, Bouygues C, Vincenzi C, Berntgen M.
Multistakeholder scientific advice for medicinal products used in combination with a medical device or a companion diagnostic in the EU-summary of a Focus group discussion. Front Med (Lausanne). 2025 Jul 10;12:1593644. doi: 10.3389/fmed.2025.1593644.

Abed I, Bennett V, Cuddy B, Dang S, García Burgos J, Di Giorgio D, Lamas M, Radulovic M, Simões N, Santos Ivo R, Malonne H, Dias M.
The impact of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) to address shortages of human and veterinary medicines across Europe. Front Public Health. 2025 Oct 7;13:1673681. doi: 10.3389/fpubh.2025.1673681.

Ahnfelt E, Lagerlund O, Klint J, Fladvad M, Jarvis C, Chen TJ, Telonis P, Fitzmartin R.
Advancing Global Harmonization: Implementing Global Dose Form Attributes for Medicinal Products Identification. Ther Innov Regul Sci. 2025 Nov;59(6):1306-1315. doi: 10.1007/s43441-025-00838-3.

Amdal CD, Falk RS, Alanya A, Schlichting M, Roychoudhury S, Bhatnagar V, Wintner LM, Regnault A, Ingelgård A, Coens C, le Cessie S, Holzner B, Chang J, Taphoorn M, Cislo P, Giesinger JM, Cappelleri JC, Pawar V, Ten Seldam S, Papadopoulos EJ, Calvert MJ, Joseph KL, Bottomley A, Griebsch I, Arraras JI, Astrup GL, Basch E, Belančić A, Brundage M, Campbell A, Rerhou Rantell K, Cocks K, Cherny N, Eremenco S, Ferrer M, Fiero MH, Gerlinger C, Goetghebeur E, Grouven U, Lauer A, Aiyegbusi OL, Machingura A, Mizusawa J, Molenberghs G, Aa Petersen M, Reijneveld JC, Ringash J, Rumpold G, Rutherford C, Quinten C, Sail K, Sasseville M, Sauerbrei W, Schiel A, Smith AW, Snyder C, Velikova G, Wang XS, Bjordal K, Pe M, SISAQOL-IMI Consortium.
SISAQOL-IMI consensus-based guidelines to design, analyse, interpret, and present patient-reported outcomes in cancer clinical trials. Lancet Oncol. 2025 Dec;26(12):e683-e693. doi: 10.1016/S1470-2045(25)00520-0.

Arlett P, Ehmann F, Herold R, Korakianiti E, Moscariello P, Barbier L, Gravanis I, Pétavy F, Cormier E, Thomson A, Vamvakas S, Thirstrup S.
A Fast Path from Innovation to Safe and Effective Medicines. Clin Pharmacol Ther. 2025 Dec;118(6):1392-1404. doi: 10.1002/cpt.70107.

Arlett P, Umuhire D, Verpillat P, Foggi P, Wändel Liminga U, Sepodes B, Lunzer M, Aylward B, Vamvakas S, Roes K, Pétavy F, Thirstrup S, Lamas M, Cooke E, Broich K.
Clinical Evidence 2030. Clin Pharmacol Ther. 2025 Apr;117(4):884-886. doi: 10.1002/cpt.3596.

Barbier L, Herold R, Thirstrup S.
Delivering on the Promises of Medicines Innovation - Promoting and Achieving Excellence in Regulatory Science in Europe. DIA Global Forum 2025; 17(9)

Barbier L, Moscariello P, Leufkens HG, Herold R, Pasmooij AMG.
A new European platform for advancing regulatory science research. Nat Rev Drug Discov. 2025 Jul;24(7):485-486. doi: 10.1038/d41573-025-00024-y.

Barniol J, Rugo K, Hendrix M, Harvey Allchurch M, Tubic B, Ahmeti A, Kontić M, Boljević Stanojević G, Strojmanovska B, Hadjihamza M, Zelić P.
Accession to the EU: How Can the EMA Pre-Accession Assistance Program Help? DIA Global Forum 2025; 17(2)

Beck AE, Kampman M, Huynh C, Simon C, Plueschke K, Cohet C, Verpillat P, Robinson K, Arlett P.
Collaborative Real-World Evidence Among Regulators: Lessons and Perspectives. Clin Pharmacol Ther. 2025 Feb;117(2):368-373. doi: 10.1002/cpt.3457.

Bell J, Drury T, Mütze T, Pipper CB, Guizzaro L, Mitroiu M, Rantell KR, Wolbers M, Wright D.
Estimation Methods for Estimands Using the Treatment Policy Strategy; a Simulation Study Based on the PIONEER 1 Trial. Pharm Stat. 2025 Mar-Apr;24(2):e2472. doi: 10.1002/pst.2472.

Berdel WE, Davy JM, Al M, Haan RR, Cavaleri M.
Centralised ethics review of clinical trials in a public health emergency in the EU. Lancet. 2025 Nov 22;406(10518):2418. doi: 10.1016/S0140-6736(25)02054-9.

Bergman J, Guizzaro L, Abellan JJ, Lasch F.
Estimands in equivalence trials and non-inferiority trials: a cross-sectional study of EMA scientific advice to drug developers. Trials. 2025 Sep 24;26(1):348. doi: 10.1186/s13063-025-09068-2.

Bivi N, Graham D, Joglekar L, McGuire K, Stoop J, Zoghbi J, Baker B, Bandukwala A, Bond S, Buoninfante A, Chen J, Dysinger M, Engelbergs J, Fiscella M, Garofolo F, Hopper S, Jones B, King L, Murphy R, Palmer R, Sanderink G, Seyda A, Tang H, Van Tuyl A, Wagner L, Walravens K, Wang K, Zander H, Zhu L, Li M, Lin YD, Natalia M, Standifer N, Eck S, Goihberg P, Grugan K, Hedrick MN, Hopkins G, Kar S, Keller S, McGrath S, O'Gorman B, Stevens C, Stevens E, Terszowski G, Trampont PC, Yao S, Joyce A, Kumar S, Owen C, Pine S, Yearwood G, Cao L, Clausen V, Coble K, Culbert A, Gupta S, Hughes R, Liu S, Lu K, Martello R, Reese KJ, Stubenrauch KG, Wen Y.
2024 White paper on recent issues in bioanalysis: Impact of LDT in US and IVDR in EU; AI/ML for High Parameter Flow Cytometry; The rise of Olink Technology; CDx for AAV Gene Therapies; Integrative Bioanalysis by Multiple Platforms; Super Sensitive ADA/NAb LBA (PART 2A - Recommendations on Advanced Strategies for Biomarkers, IVD/CDx Assays (BAV), Cell Based Assays (CBA), and Ligand-Binding Assays (LBA) PART 2B - Regulatory Agencies' Input on Biomarkers, IVD/CDx, and Biomarker Assay Validation). Bioanalysis. 2025 Feb;17(4):211-248. doi: 10.1080/17576180.2024.2442218.

Blanquie O, Guizzaro L, Herold R, Haberkamp M, Elferink A, Balabanov P, Ehmann F.
EU regulatory horizons for Alzheimer's disease. Lancet Neurol. 2025 Feb; 24(2):96-97. Doi:10.1016/S1474-4422(25)00004-3.

Bonertz A, Drai C, Hartenstein D, Kaul S, Mitrevski M, Zubeldia JM.
European Medicines Agency (EMA) commentary on EMA/CHMP Guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations. Br J Clin Pharmacol. 2025 May;91(5):1293-1296. doi: 10.1002/bcp.70048.

Broekman KE, van Gils MPMQ, Baron A, Poplavska E, Mol PGM.
Letter to the editor re: fatal intracranial haemorrhage after belzutifan initiation. ESMO Open. 2025 Aug;10(8):105537. doi: 10.1016/j.esmoop.2025.105537.

Browne K, Bałkowiec-Iskra E, Elferink A, Haberkamp M, Straus S, Sepodes B, Silva F, Butlen-Ducuing F, Jansen J, Silva I, Balabanov P, Garcia Burgos J, Thirstrup S.
Applying the EU Regulatory Framework to Determine the Benefit-Risk Profile of Psychedelics. ACS Pharmacol Transl Sci. 2025 Jul 18;8(8):2830-2838. doi: 10.1021/acsptsci.5c00456.

Browne K, Garcia Burgos J, Jirsová E, Ruepp R, Bonkat G, Vinker S, Marrocco W, Villanueva T.
The case for more prudent prescribing of fluoroquinolones in primary care. Eur J Gen Pract. 2025 Dec;31(1):2584496. doi: 10.1080/13814788.2025.2584496.

Buoninfante A, Cavaleri M.
Reply to "Investigating a role for NSAIDs in the pathophysiology of vaccine-associated myocarditis". NPJ Vaccines. 2025 Nov 24;10(1):249. doi: 10.1038/s41541-025-01285-9.

Buoninfante A, Cavaleri M.
T cells responses after vaccination: a regulatory perspective. Front Immunol. 2025 Jun 12;16:1584738. doi: 10.3389/fimmu.2025.1584738.

Butlen-Ducuing F, Silva F, Silva I, Balabanov P, Thirstrup S.
Applying the EU regulatory framework for the clinical use of psychedelics. Lancet Psychiatry. 2025 Jan;12(1):7-9. doi: 10.1016/S2215-0366(24)00203-7.

Cardoso Borges F, van der Graaf WTA, Saesen R, Aebi S, Amariutei AE, Bekelman J, Gorlia T, Hulstaert F, Huys I, Kluetz P, Morris MJ, Patil V, Prindiville SA, Schilsky RL, Thomson A, Treweek S, Weller M, Zuidgeest M, Retel V, Lacombe D.
Defining the role of pragmatic clinical trials in cancer clinical research: outcomes of a collaborative workshop hosted by the European Organisation for Research and Treatment of Cancer. Lancet Oncol. 2025 May;26(5):e253-e263. doi: 10.1016/S1470-2045(24)00756-3.

Carmona Araújo A, Guerreiro JP, Bulhosa C, Martins AP, Alves da Costa F, Goulão J.
Morbimortality consequences of use and misuse of psychoactive medicines in Portugal. Br J Clin Pharmacol. 2025 Nov;91(11):3225-3235. doi: 10.1002/bcp.70171.

Cavaleri M, de Sousa CMA, Hacker A, Higgs ES, Lumpkin MM, Maia CS, Mathur R, Fimbo AM, Reis A, Shin KS, Vaughn DW, Zhang W, Moorthy V.
A roadmap for fostering timely regulatory and ethics approvals of international clinical trials in support of global health research systems. Lancet Glob Health. 2025 Apr;13(4):e769-e777. doi: 10.1016/S2214-109X(24)00515-1.

Celis P, Farinelli G, Hidalgo-Simon A, Meij P, Tihaya M, Schüssler-Lenz M, Timón M.
EMA commentary on the guideline on quality, nonclinical and clinical aspects of medicinal products containing genetically modified cells. Br J Clin Pharmacol. 2024 May;90(5):1203-1212. doi: 10.1111/bcp.16047.

Cooke E, Rendi-Wagner P.
Rising antimicrobial resistance in Europe: EMA and ECDC outline urgent actions to achieve EU targets. Lancet Reg Health Eur. 2025 Nov 18;59:101539. doi: 10.1016/j.lanepe.2025.101539.

Cooke E, Sepodes B.
Thirty years of Europe's centralized procedure for approving medicines. Nat Med. 2025 Sep;31(9):2831-2832. doi: 10.1038/s41591-025-03826-0.

Correia Pinheiro L, Arlett P, Roes K, Musuamba Tshinanu F, Westman G, Frias Z, Hamann H, Berenguer Jornet J, Khan I, Larsen J, Broich K, Cooke E.
Artificial Intelligence in European Medicines Regulation: From Vision to Action. Harnessing the Capabilities of Artificial Intelligence for the Benefit of Public and Animal Health. Clin Pharmacol Ther. 2025 Feb;117(2):335-336. doi: 10.1002/cpt.3494.

Costa E, Ajith V, Al Khaldi AF, Isgrò A, Lee KJ, Luigetti R, Pasmooij AMG, Stoyanova-Beninska V, Trachsel E, Vaillancourt J, Thirstrup S.
Addressing global regulatory challenges in rare disease drug development. Drug Discov Today. 2025 Oct;30(10):104462. doi: 10.1016/j.drudis.2025.104462.

Crisafulli S, Bate A, Brown JS, Candore G, Chandler RE, Hammad TA, Lane S, Maro JC, Norén GN, Pariente A, Russom M, Salas M, Segec A, Shakir S, Spini A, Toh S, Tuccori M, van Puijenbroek E, Trifirò G; Real-World Evidence and Big Data Special Interest Group of the International Society of Phar macovigilance.

Interplay of Spontaneous Reporting and Longitudinal Healthcare Databases for Signal Management: Position Statement from the Real-World Evidence and Big Data Special Interest Group of the International Society of Pharmacovigilance. Drug Saf. 2025 Sep;48(9):959-976. doi: 10.1007/s40264-025-01548-3.

De Lisa R, de Andres-Trelles F, Bax R, Galluzzo S, Alward B, Thomson A, Karres D, Brunner HI, Ruperto N, Egger GF.
New medicines for childhood-onset systemic lupus erythematosus: an EU perspective on paediatric drug development. Front Med (Lausanne). 2025 Jul 10;12:1583140. doi: 10.3389/fmed.2025.1583140.

Del Giacco S, Canonica GW, Agache I, Price D, Roche N, Schunemann H, Allan K, Ansotegui I, Barbaglia S, Bernstein JA, Bonini M, Bosnic-Anticevich S, Bousquet J, Braido F, Carter V, Chong-Neto HJ, Di Bona D, Fletton K, Gonzalez Diaz S, Ayyar Gupta V, Hubbard R, Iaccarino J, Eguiluz-Gracia I, Jacomelli C, Kocks J, Krishnan J, Mahler V, Morais-Almeida M, Moreles D, Muti P, Palkonen S, Papadopoulos NG, Pawankar R, Reeb C, Reddel H, Rojo I, Ryan D, Sodhi L, Torres M, Winders T, Wilson KC.
Expert Perspectives on Next Generation Health Guidelines: How to Integrate RWE in EBM. Pragmat Obs Res. 2025 Sep 11;16:169-177. doi: 10.2147/POR.S487342.

Destoop M, Mohr P, Butlen F, Kéri P, Samochowiec J, De Picker L, Fiorillo A, Kuypers KPC, Dom G.
Use of psychedelic treatments in psychiatric clinical practice: an EPA policy paper. Eur Psychiatry. 2025 Jan 10;68(1):e3. doi: 10.1192/j.eurpsy.2024.1806.

Devane D, Briel M, Bhagani S, Boesten N, Buchholz S, De Luca EC, Guedj J, Koryakina A, Kothari K, Lacombe K, Mallon PW, Massonnaud CR, O'Dwyer J, Olsen IC, Saif-Ur-Rahman KM, Schwenke JM, Thomas J, Yazdanpanah Y, Zgaga L, Louw J.
Protocol for a core outcome set for pharmacological treatments in hospitalised patients with acute viral respiratory infections (COSAVRI). PLoS One. 2025 Sep 9;20(9):e0330288. doi: 10.1371/journal.pone.0330288.

Dijkstra JN, Henzi BC, Mathews KD, Erasmus CE, Knox R, Willis T, de Valle K, ENMC 279th Workshop Study Group.
279th ENMC international workshop: Classification, clinical care, outcome measures and biomarkers in childhood onset facioscapulohumeral dystrophy: towards standardizing clinical care and ensuring clinical trial readiness. Hoofddorp, The Netherlands, 1-3 November 2024. Neuromuscul Disord. 2025 Oct;55:106236. doi: 10.1016/j.nmd.2025.106236.

DuBois SG, Moreno L, Bagatell R, Cheung NK, Gray JC, Locatelli F, Reynolds CP, Rossig C, Sondel PM, Drezner N, Kholmanshikh O, Bird N, Day L, Ludwinski D, Scobie N, Pons Sanz V, Ball S, Hammer B, Alvarez Rojo I, Meager D, Sveistrup J, Berlanga P, Casanova M, Glade-Bender J, Macy M, Morgenstern DA, Owens C, Weigel BJ, Pappo A, Nysom K, Anderson J, Ligas F, Lesa G, Donoghue M, Karres D, Vassal G.
Paediatric Strategy Forum for medicinal product development of agents targeting GD2 ganglioside in children and adolescents with cancer. Eur J Cancer. 2025 Dec 9;231:116093. doi: 10.1016/j.ejca.2025.116093.

Edwards M, Blanquie O, Ehmann F.
Insights into new approach methodology innovation: an EMA perspective. Nat Rev Drug Discov. 2025 May;24(5):325-326. doi: 10.1038/d41573-025-00052-8.

Edwards M, Blanquie O, Moriarty O, Beken S, Ehmann F.
New approach methodologies: EU regulatory horizons. Nat Rev Drug Discov. 2025 March 24. doi: https://doi.org/10.1038/d41573-025-00053-7.

Essink SCM, Zomerdijk IM, Goedecke T, Straus SMJM, Gardarsdottir H, De Bruin ML.
Duration of Time Intervals for Risk Minimization Measure Effectiveness Studies. Clin Pharmacol Ther. 2025 Apr;117(4):1106-1114. doi: 10.1002/cpt.3569.

Excler JL, Saluja T, Wilder-Smith A, Kaminski RW, MacLennan CA, Cavaleri M, Kim JH.
Non-typhoidal Salmonella combination vaccines: clinical development plan and regulatory considerations. Vaccine. 2025 Aug 30;62:127515. doi: 10.1016/j.vaccine.2025.127515.

Fink M, Lutters B, O'Connor DB, Ganan Jimenez A, Holborow R.
Navigating global regulatory pathways for orphan medical devices. RF Quarterly 2025;5(4):4-12.

Flory E, Walter M, Closson-Carella V, Celis P, Schuessler-Lenz M, Reischl I.
Medicinal Products Based on Adeno-Associated Viral Vectors: A Regulatory Perspective on the Potential Risk of Insertion-Mediated Tumorigenesis. Hum Gene Ther. 2025 Nov;36(21-22):1405-1414. doi: 10.1177/10430342251366314.

Fuggle N, Laslop A, Rizzoli R, Al-Daghri N, Alokail M, Balkowiec-Iskra E, Beaudart C, Bruyère O, Bemden AB, Burlet N, Cavalier E, Cerreta F, Chandran M, Cherubini A, da Silva Rosa MMC, Conaghan P, Cortet B, Jentoft AC, Curtis EM, D'Amelio P, Dawson-Hughes B, Dennison EM, Hiligsmann M, Kaufman JM, Maggi S, Matijevic R, McCloskey E, Messina D, Pinto D, Yerro MCP, Radermecker RP, Rolland Y, Torre C, Veronese N, Kanis JA, Cooper C, Reginster JY, Harvey NC.
Treatment of Osteoporosis and Osteoarthritis in the Oldest Old. Drugs. 2025 Mar;85(3):343-360. doi: 10.1007/s40265-024-02138-w.

Garcia Burgos J, Thirstrup S, Cooke E.
The European Medicines Agency and The Lancet Regional Health-Europe join forces to protect public health. Lancet Reg Health Eur. 2025 May 21;53:101331. doi: 10.1016/j.lanepe.2025.101331.

Garcia Burgos J, Jirsova E, Kranz J, Bonkat G.
A Call To Prevent Inappropriate Prescribing of Fluoroquinolones from the European Medicines Agency and the European Association of Urology Guidelines Panel for Urological Infections. Eur Urol. 2025 Nov;88(5):427-429. doi: 10.1016/j.eururo.2025.07.015.

Garcia Burgos J, Thirstrup S.
EMA approvals of new medicinal products and new biosimilar products in January and February 2025. Lancet Reg Health Eur. 2025 Apr 1;51:101279. doi: 10.1016/j.lanepe.2025.101279.

García-Arieta A, Tam A, Tiseyra F, Fernandes EAF, Soares KCC, Pereira RS, Potthast H, Mettke K, Chang YW, Hsu LF, Su YL, Martínez ZR, Divinsky M, Blake K, Braddy AC, Rodrigues C, Toh T, Aurela EG, González LCA, Jones B, Kim SH, Ahn C, Yun E, Kuribayashi R, Shimojo K, Kasuga M, Makino J, Raffel J, van Oudtshoorn J, Tabane P, Alzenaidy B, AlHarbi M, Alharf A, BinAjlan A, Walther C, Roost MS, Crane C, Lee K.
A survey of regulatory recommendations for waivers of in vivo bioequivalence studies of generic products for certain dosage forms by participating regulators and organisations of the International Pharmaceutical Regulators Programme. Part 2. J Pharm Pharm Sci. 2025 Oct 20;28:14721. doi: 10.3389/jpps.2025.14721.

Gobat N, Slack C, Hannah S, Salzwedel J, Bladon G, Garcia Burgos J, Purvis B, Molony-Oates B, Siegfried N, Cheah PY, Conway M, Kamuya D, Davies A, Johnson T, Tholanah M, Mugamba S, Mutengu NL, Machingaidze S, Schwartz L, Rägo L, von Harbou K.
Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice. Lancet Glob Health. 2025 Apr;13(4):e716-e731. doi: 10.1016/S2214-109X(24)00521-7.

Gonzalez Dorta H, Verbeeck J, Crevecoeur J, Morales DR, Loedy N, Cohet C, Willem L, Molenberghs G, Hens N, Kurz X, Quinten C, Abrams S.
Utilising the Benefit Risk Assessment of Vaccines (BRAVE) toolkit to evaluate the benefits and risks of Vaxzevria in the EU: a population-based study. Lancet Digit Health. 2025 May;7(5):100861. doi: 10.1016/j.landig.2025.02.001.

Gonzalez Tome M, Gonzalez-Quevedo R, Escudeiro Dos Santos M, Dornbusch HJ, Straus S, Cooke E.
Meningococcal B Vaccines as a Paradigm of Safe and Effective Vaccines for Children. Vaccines (Basel). 2025 Jul 21;13(7):770. doi: 10.3390/vaccines13070770.

Gonzalez-Quevedo R, Garcia Burgos J, Greco M, Straus S, Liminga UW, Sepodes B.
European Medicines Agency seeks stakeholders' views on its reflection paper on patient experience data. Br J Clin Pharmacol. 2025 Dec;91(12):3301-3303. doi: 10.1002/bcp.70330.

Gravanis I, Berntgen M, Vamvakas S, Demolis P, Foggi P.
Challenges and ongoing initiatives towards better integrated EU scientific advice. Front Med (Lausanne). 2025 Jan 27;12:1473346. doi: 10.3389/fmed.2025.1473346.

Guillen E, Barry S, Jost N, Ekman N, Knippel V, Kuhlmann-Gottke J, Maier J, Weise M, Laslop A, Anour R, van Zandbergen G, Kirsch-Stefan N.
The Tailored Biosimilar Approach: Expectations and Requirements. Drugs. 2025 May;85(5):601-608. doi: 10.1007/s40265-025-02168-y.

Hermans AMM, Bakker E, Starokozhko V, den Otter L, Elferink AJA, Bradshaw A, Guizzaro L, Mol PGM, Pasmooij AMG.
Biomarkers for neurodegenerative diseases in regulatory decision-making by the European Medicines Agency. Alzheimers Dement (N Y). 2025 Mar 27;11(1):e70072. doi: 10.1002/trc2.70072.

Hernán Pérez de la Ossa D, Haas F, Bream RN, Kotzagiorgis E, Tiitso K, Jekerle V.
Learning from the EMA experience: common CMC deficiencies in marketing authorisation applications over the past decade. Drug Discov Today. 2025 Sep;30(9):104444. doi: 10.1016/j.drudis.2025.104444.

Hidalgo-Simon A, Pothet C, Cooke E, Thirstrup S.
Academic development of advanced therapies-How to foster their future in the clinic. Br J Clin Pharmacol. 2025 Apr;91(4):1080-1083. doi: 10.1002/bcp.70024.

Huber C, Zinserling J, Benda N, Vetter T, Rueckbeil M.
Methodological Insights on Biomarker-Based Patient Selection: A Review of Scientific Advice Procedures at the European Medicines Agency. Clin Pharmacol Ther. 2025 May;117(5):1226-1235. doi: 10.1002/cpt.3558.

Ibarz-Pavon AB, Bielsky MC, Bose R, Cavaleri M, Crump JA, Hombach J, Kaslow DC, Khaman F, MacLennan CA, Mehring-LeDoare K, Pollard AJ, Quadri F, John J, Wilder-Smith A.
Consultation report - considerations for a regulatory pathway for bivalent Salmonella Typhi/Paratyphi A vaccines for use in endemic countries. Vaccine. 2025 May 22;56:127189. doi: 10.1016/j.vaccine.2025.127189.

Kaminski RW, Pavlinac PB, Platts-Mills JA, Rogawski McQuade ET, Hausdorff WP, Isbrucker RA, Vannice KS, Cavaleri M, Kochhar S, Mehring-LeDoare K, Enwere G, Wilder-Smith A, Kotloff KL, Sow S, Giersing BK.
WHO Workshop Report: Regulatory Science to Inform Clinical Pathways for Shigella Vaccines Intended for Use in Children in Low- and Middle-Income Countries. Vaccines (Basel). 2025 Apr 23;13(5):439. doi: 10.3390/vaccines13050439.

Karres D, Pino-Barrio MJ, Benchetrit S, Benda N, Cochat P, Galluzzo S, García-Solís A, Gonzalez S, de Lisa R, Khan D, Lankester R, Lentz F, Martínez-Ortega PA, Montilla S, Morales DR, Tshinanu FM, Sánchez SP, Montero AR, Scherer S, Thomson A, Garrido BT, Umuhire D, Wang S, Bax R, Hedberg N.
Evidence generation throughout paediatric medicines life cycle: findings from collaborative work between European Medicines Agency (EMA) and EUnetHTA on use of extrapolation. Br J Pharmacol. 2025 Feb;182(3):484-494. doi: 10.1111/bph.17396.

Kas MJH, Penninx BWJH, Knudsen GM, Cuthbert B, Falkai P, Sachs GS, Ressler KJ, Bałkowiec-Iskra E, Butlen-Ducuing F, Leboyer M, Marston H, Luthman J, Mantua V.

Precision psychiatry roadmap: towards a biology-informed framework for mental disorders. Mol Psychiatry. 2025 Aug;30(8):3846-3855. doi: 10.1038/s41380-025-03070-5.

Kristyanto H, Rey Torre S, Cunney A, Dunder K, Bego M, Sepodes B, Castelnovo T.
The European Medicines Agency evaluation of nemolizumab (Nemluvio) for the treatment of moderate-to-severe atopic dermatitis and prurigo nodularis. Br J Dermatol. 2025 Oct 17;193(5):996-998. doi: 10.1093/bjd/ljaf259.

Kuaban A, Croker AK, Keefer J, Valentino LA, Bierer BE, Boateng S, DiMichele D, Fogarty P, Gibson CM, Hood AM, Hubbard L, Isgrò A, Knobe K, Lake L, Martin I, Reid M, Roberts JC, Tomlinson W, Tunji-Ajayi L, Van Spall HGC, Voltz-Girolt C, Wheeler AP, Mast AE, Seremetis S.
The roadmap to integrate diversity, equity, and inclusion in hematology clinical trials: an American Society of Hematology initiative. Blood Adv. 2025 Feb 25;9(4):687-695. doi: 10.1182/bloodadvances.2024013945.

Kurz X, Cohet C, Perez-Gutthann S, Rao S, Gardarsdottir H.
Strengthening Pharmacoepidemiology in a Changing Research Environment: The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Pharmacoepidemiol Drug Saf. 2025 Nov;34(11):e70263. doi: 10.1002/pds.70263.

Lasch F, Carvalho JRB, Pothet C.
Demonstration of Major Therapeutic Advantage From a Review of EU Conditional Marketing Authorizations in Oncology and Hematology. Clin Pharmacol Ther. 2025 Apr;117(4):1098-1105. doi: 10.1002/cpt.3554. Epub 2025 Jan 7.

Le Doare K, Benassi V, Cavaleri M, Enwere G, Giersing B, Goldblatt D, Heath P, Hombach J, Isbrucker R, Karampatsas K, Madhi SA, Smith AW.
Clinical and regulatory development strategies for GBS vaccines intended for maternal immunisation in low- and middle-income countries. Vaccine. 2025 Jun 11;58:127131. doi: 10.1016/j.vaccine.2025.127131.

Loedy N, Gonzalez Dorta H, Abrams S, Crèvecoeur J, Morales DR, Cohet C, Willem L, Molenberghs G, Hens N, Kurz X, Quinten C, Verbeeck J.
An extension of the Benefit Risk Assessment of VaccinEs toolkit to evaluate Comirnaty and Spikevax vaccination in the European Union. Eur J Public Health. 2025 Oct 1;35(5):1007-1013. doi: 10.1093/eurpub/ckaf135.

Lynggaard H, McKendrick S, Baird M, Kerwash E, Lanius V, Lasch F, Wright D.
Applying the estimand framework to clinical pharmacology trials with a case study in bioequivalence. Br J Clin Pharmacol. 2025 Feb;91(2):310-324. doi: 10.1111/bcp.16347.

Magrelli A, O'Connor DJ, Stoyanova-Beninska V.
Editorial: The changing focus of regulatory frameworks around the globe and the opportunities for harmonization. Front Med (Lausanne). 2025 Jul 10;12:1645278. doi: 10.3389/fmed.2025.1645278.

Mbaelachi N.
Celebrating its past, European Medicines Agency looks to the future of public communication. Medical Writing. 2025; 34(2):18-20. doi: 10.56012/ofdv3305

Meln I, Cnossen V, Corti N, Andeweg A, Baay M, Chiu C, Coia J, Cornely O, Cox RJ, Dasyam D, De Keersmaecker SCJ, Deming M, Waldock J, Engelhardt OG, Guo M, Haj-Ali Saflo O, Hensen A, Jeeninga R, Kolstoe S, Krut O, Kuijper EJ, Leal L, Mazur N, Mohn KGI, Morel S, Osterhaus A, Moreira AP, Smits WK, Sridhar S, Toomey D, van Gerven J, Vehreschild MJGT, Yarzabal JP, Zimmer-Harwood P, Neels P, Olesen OF, Roestenberg M, Kamerling IMC.
Regulatory workshop on standardisation of clinical procedures, endpoints and data robustness of human challenge studies - A stakeholder meeting report. Biologicals. 2025 May;90:101818. doi: 10.1016/j.biologicals.2025.101818.

Mitroiu M, Teerenstra S, Oude Rengerink K, Pétavy F, Roes KCB.
Possible Data-Generating Models of Longitudinal Continuous Outcomes and Intercurrent Events to Investigate Estimands. Stat Biopharm Res. 2025; 17(2), 247–259. https://doi.org/10.1080/19466315.2024.2369266.

Moon K, Coxon C, Årdal C, Botgros R, Djebara S, Durno L, Fiore CR, Perrin JB, Dixon DM, Cavaleri M.
Considerations and perspectives on phage therapy from the transatlantic taskforce on antimicrobial resistance. Nat Commun. 2025 Dec 4;16(1):10883. doi: 10.1038/s41467-025-64608-3.

Moorthy V, Devereaux PJ, Sui-Lin Teh C, Rooslamiati I, Adeyemi OD, Hamid S, Zanoletty A, Nyarko K, Zhang W, Farrar J, Abubakar I.
Tracking maturity of the enabling environment for clinical trials. Lancet. 2025 Jul 12;406(10499):113-116. doi: 10.1016/S0140-6736(25)01279-6.

Morales DR, Gardarsdottir H.
From Evidence to Impact: Closing the Loop in Pharmacovigilance With Real-World Data. Pharmacoepidemiol Drug Saf. 2025 Nov;34(11):e70244. doi: 10.1002/pds.70244.

Nett RJ, Brault AC, Lambert AJ, Agnihothram S, Barrett ADT, Barzon L, Clements DE, Durbin A, Kretschmer M, Monath TP, Mura M, Pierson TC, Prutzman K, Slifka MK, Suthar MS, Whitehead SS, Staples JE.
Summary of human West Nile virus vaccine meeting, 2024: Investigating barriers to development. Vaccine. 2025 Dec 5;68:127938. doi: 10.1016/j.vaccine.2025.127938.

Norén GN, Donegan K, Muñoz MA, Alshammari TM, Pratt N, Candore G, Morales D, Rijnbeek P, Bate A, Postigo R, Toh S, Trifirò G, Gabarro MS, Cave A, Ryan PB.
Recommendations to Enable Broader Use of Real-World Evidence to Inform Decision-Making Throughout Pharmacovigilance Signal Management. Pharmacoepidemiol Drug Saf. 2025 Oct;34(10):e70231. doi: 10.1002/pds.70231.

Palomo GM, Pose-Boirazian T, Naumann-Winter F, Costa E, Duarte DM, Kalland ME, Malikova E, Matusevicius D, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S.
Navigating the orphan medicinal product designation: Evidence requirements for gene therapies in Europe. Mol Ther. 2025 Jun 4;33(6):2834-2841. doi: 10.1016/j.ymthe.2024.10.015.

Pandya L, Norstedt I, Seychell M, Cooke E, de la Mata Barranco I, Blomberg N, Temmerman M, Makanga M.
Europe-Africa collaboration: working together to strengthen health research, implementation, and equitable systems. Lancet Glob Health. 2025 Aug;13(8):e1338-e1340. doi: 10.1016/S2214-109X(25)00201-3.

Pariser AR, Stoyanova-Beninska V, Iliach O, Jundi R, Lee KJ, Morikawa H, Parker S, Pothet C, Rizzi M, Vaillancourt J, Hidalgo-Simon A.
Non-oncologic orphan drug approvals across the world: Types of evidence required and time to approval. Drug Discov Today. 2025 Dec;30(12):104529. doi: 10.1016/j.drudis.2025.104529.

Paul P, Colin PJ, Musuamba Tshinanu F, Versantvoort C, Manolis E, Blake K.
Current Use of Physiologically Based Pharmacokinetic modeling in New Medicinal Product Approvals at EMA. Clin Pharmacol Ther. 2025 Mar;117(3):808-817. doi: 10.1002/cpt.3525.

Pe M, Voltz-Girolt C, Bell J, Bhatnagar V, Bogaerts J, Booth C, Garcia Burgos J, Cappelleri JC, Coens C, Demolis P, Enzmann H, Giesinger JM, Gilbert A, Groenvold M, Kluetz P, Piccinin C, Postmus D, Quinten C, Ryll B, Sasseville M, Schlichting M, Schuerer H, Schiel A, Shaw JW, Smith AW, Tezuka S, Torre C, van der Graaf WTA, Wieseler B, Wittenbecher F, Reijneveld JC, Mol P.
Using patient-reported outcomes and health-related quality of life data in regulatory decisions on cancer

treatment: highlights from an EMA-EORTC workshop. Lancet Oncol. 2025 Jun;26(6):687-690. doi: 10.1016/S1470-2045(25)00150-0.

Pearson AD, Chi S, Laetscht TW, Marshall L, Raetz E, George RE, Chesler L, Karres D, Scobie N, Knoderer H, Weigel B, Teachey D, Sonke GS, Seibel N, Pappo A, Nysom K, Muscal J, Molenaar J, McDonough J, Macy ME, Ludwinski D, Lin C, Ligas F, Lesa G, Knox L, Kirschbaum M, Kieran M, Kholmanskikh O, Jacobson A, Heenen D, Hawkins DS, Glade Bender J, Fox E, Demolis P, de Rojas T, Cox MC, Chauvin B, Blanc P, Vassal G.
Paediatric strategy forum for medicinal product development of cyclin-dependent kinase inhibitors in children and adolescents ACCELERATE in collaboration with the European Medicines Agency With participation of the Food and Drug Administration. Eur J Cancer. 2025 Aug 26;226:115629. doi: 10.1016/j.ejca.2025.115629.

Pearson AD, Mueller S, Filbin MG, Grill J, Hawkins C, Jones C, Donoghue M, Drezner N, Weiner S, Russo M, Dun MD, Allen JE, Alonso M, Benaim E, Buenger V, de Rojas T, Desserich K, Fox E, Friend J, Glade Bender J, Hargrave D, Jensen M, Kholmanskikh O, Kieran MW, Knoderer H, Koschmann C, Lesa G, Ligas F, Lipsman N, Ludwinski D, Marshall L, McDonough J, McNicholl AG, Mirsky D, Monje M, Nysom K, Pappo A, Rosenfield A, Scobie N, Slaughter J, Smith M, Souweidane M, Straathof K, Ward L, Weigel B, Zamoryakhin D, Karres D, Vassal G.
Paediatric strategy forum for medicinal product development in diffuse midline gliomas in children and adolescents ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration. Eur J Cancer. 2025 Feb 25;217:115230. doi: 10.1016/j.ejca.2025.115230.

Pignatti F, Herold R, Demolis P, Rohr UP.
Novel PET RANO BM 1.0 criteria: Regulatory perspectives on new endpoint definitions in brain metastases. Neuro Oncol. 2025 Jul 30;27(6):1407-1408. doi: 10.1093/neuonc/noaf067.

Pignatti F, Josephson F, Demolis P, Tenhunen O, Péan E, Postmus D.
Expedited Approval in Oncology: A Study of European Regulators' Perspectives and Trade-Offs. Clin Pharmacol Ther. 2025 Sep;118(3):642-648. doi: 10.1002/cpt.3708.

Pignatti F, Mol P, Quinten C, Postmus D, Schiel A, Sasseville M, Tezuka S, Bhatnagar V, Kluetz P.
Use of patient-reported outcomes to inform symptom and functional outcomes in cancer drug regulatory decisions: challenges and future directions. Lancet Oncol. 2025 Jun;26(6):664-666. doi: 10.1016/S1470-2045(25)00151-2.

Plueschke K, Jonker C, Kankanen H, Vetter T, Sepodes B, Naehrlich L, Hillert J, Crane G, Straus S, Foggi P, Martin S, Kyriakopoulou C, Mol P, Day F, Breen K, Bennett N, de Lemus Belmonte M, Bennett S, Verpillat P, Roes KCB, Cochino A, Schaefer F, Hernández-Rivas JM, McGettigan P, Arlett P.
Optimizing Patient Registries for Regulatory Decision Making - Key Learnings From an HMA/EMA Multistakeholder Workshop. Clin Pharmacol Ther. 2025 Sep;118(3):551-560. doi: 10.1002/cpt.3733.

Postmus D, Cornelissen JJ, Bogaerts J, Roes KC, Hillege HL, Pignatti F.
Beyond traditional endpoints: A multi-state modelling approach to integrating morbidity and mortality in cancer treatments evaluation. Eur J Cancer. 2025 Oct 1;228:115704. doi: 10.1016/j.ejca.2025.115704.

Poulard IC, Ausborn S, Harvey Allchurch M, Palmi V, Ganan A, Joos A, Deavin A, Beauchesne C, Shah P, Krishnan J, Askri C.
Reliance into Action : Understanding EMA Documents to Streamline Reliance for Marketing Authorization Applications. Ther Innov Regul Sci. 2025 Sep;59(5):1032-1041. doi: 10.1007/s43441-025-00824-9.

Ruepp R, Botgros R, Le Ber V, Brandt F, Pantke E, Fuerst-Wilmes M, Gomez-Outes A, Fernandez-Cortizo MJ.
Changes to the use of medicines containing the antibiotic azithromycin. Fam Med Community Health. 2025 Dec 25;13(4):e003699. doi: 10.1136/fmch-2025-003699.

Schaefer R, Donaldson L, Chigome A, Escudeiro Dos Santos M, Lamprianou S, Ndembi N, Nwokike JI, Nyambayo P, Palmi V, Renaud F, Gonzalez Tome M, Miller V.
Antiretroviral Use for HIV Prevention During Pregnancy: The Need to Strengthen Regulatory and Surveillance Systems in Africa. Drug Saf. 2025 Mar;48(3):209-216. doi: 10.1007/s40264-024-01494-6.

Schneider KL, Alves de Sousa L, Sava I, Heß S, Umuhire D, Morales DR.
The European Health Data Space in communicable diseases surveillance and monitoring of medicines and vaccines: achievements of a pilot project examining the user journey. Eur J Public Health. 2025 Sep 1;35(Supplement_3):iii5-iii10. doi: 10.1093/eurpub/ckaf115.

Sepodes B, Garcia Burgos J, Thirstrup S.
EMA approvals of new medicinal products and new biosimilar products in July and August 2025. Lancet Reg Health Eur. 2025;57:101469. doi:10.1016/j.lanepe.2025.101469

Sepodes B, Garcia Burgos J, Thirstrup S.
EMA approvals of new medicinal products and new biosimilar products in March and April 2025. Lancet Reg Health Eur. 2025 May 20;54:101330. doi:10.1016/j.lanepe.2025.101330.

Sepodes B, Garcia Burgos J, Thirstrup S.
EMA approvals of new medicinal products and new biosimilar products in May and June 2025. Lancet Reg Health Eur. 2025 Jul 8;55:101389. doi:10.1016/j.lanepe.2025.101389.

Sepodes B, Garcia Burgos J, Thirstrup S.
European Medicines Agency approvals of new medicines in September and October 2025. Lancet Reg Health Eur. 2025 Nov 20;59:101542. doi: 10.1016/j.lanepe.2025.101542.

Silva F, Butlen-Ducuing F, Guizzaro L, Balabanov P.
A review of psychedelics trials completed in depression, informed by European regulatory perspectives. Neurosci Appl. 2025 Feb 26;4:105516. doi: 10.1016/j.nsa.2025.105516.

Smith MY, Davis R, Bahri P, Saragoussi D, Nguyen V, Toyserkani GA, Hamilton A.
Using Mixed Methods to Evaluate Risk Minimisation Programs in Europe and the USA: An Innovative Blueprint. Drug Saf. 2025 Jul;48(7):821-838. doi: 10.1007/s40264-025-01533-w.

Stacchiotti S, Pantziarka P, Leonard H, Voltz C, Abatedaga L, Bouche G, Bouygues C, Bovee JVMG, Van der Graaf WTA, Rojas T, D'Ambrosio L, Donoghue M, Enzmann H, Feeney G, Foggi P, Frezza AM, Herold R, Jones RL, Kasper B, Roes K, Marreaud S, Miceli R, Robinson D, Sommer J, Tap WD, Tydings C, Trama A, Houdt WV, van Oortmerssen G, Wagner AJ, Widemann B, Gelderblom H, Gronchi A, Napolitano A, Dufresne A, Fumagalli ER, Baldi G, Marquina G, Koseła-Paterczyk H, Martin Javier JB, Junker N, Rutkowski P, Oyen WJG, Lacombe D, Pignatti F, Demolis P.
How to foster new treatment development in ultra-rare tumours? Joint EMA-EORTC multi-stakeholder workshops on ultra-rare sarcomas as a model for rare cancers. Cancer Treat Rev. 2025 Nov;140:103003. doi: 10.1016/j.ctrv.2025.103003.

Stewart B, Lepola P, Egger GF, Ali F, Allen AJ, Croker AK, Davidson AJ, Dicks P, Faust SN, Green D, Hovinga C, Klein AV, Langham R, Nakamura H, Pioppo L, Ramroop S, Sakiyama M, Sanchez Vigil de la Villa I, Sato J, Snyder DL, Turner MA, Zaidi S, Zimmerman K, Lacaze-Masmonteil T.
Requirements and special considerations for drug trials with children across six jurisdictions: 1. Clinical trial application review in the regulatory approval process. Front Med (Lausanne). 2025 Apr 15;12:1542408. doi: 10.3389/fmed.2025.1542408.

Stewart B, Lepola P, Egger GF, Ali F, Allen AJ, Croker AK, Davidson AJ, Dicks P, Faust SN, Green D, Hovinga C, Klein AV, Langham R, Nakamura H, Pioppo L, Ramroop S, Sakiyama M, Sanchez Vigil de la Villa I, Sato J, Snyder DL, Turner MA, Zaidi S, Zimmerman K, Lacaze-Masmonteil T.
Requirements and special considerations for drug trials with children across six jurisdictions: 2. Ethics review in

the regulatory approval process. Front Med (Lausanne). 2025 Feb 11;12:1539787. doi: 10.3389/fmed.2025.1539787.

Szmigiel A, da Rocha MM, Browne K, Morales D, Olsen DB, Warren-Gash C, Douglas I, Bhaskaran K, Carreira H.
Association Between β-Adrenoreceptor Agonists and Antagonists and Parkinson's Disease: Systematic Review and Meta-Analysis. Pharmacoepidemiol Drug Saf. 2025 Apr;34(4):e70140. doi: 10.1002/pds.70140.

Tampach S, Vidal A, Marnane I, De Coen W, Heuer O, das Neves CG, Gross-Helmert K, Garofalakis G, Bronzwaer S.
Scientific cooperation among Europe's One Health agencies. One Health. 2025 Jul 5;21:101129. doi: 10.1016/j.onehlt.2025.101129.

Tannergren C, Arora S, Babiskin A, Borges L, Chatterjee P, Cheng YH, Dallmann A, Govada A, Heimbach T, Hingle M, Kollipara S, Kotzagiorgis E, Lindahl A, Mackie C, Malamatari M, Mitra A, Moody R, Pepin X, Polli J, Raines K, Rullo G, Sanghavi M, Savkur R, Singh R, Sjögren E, Suarez-Sharp S, Thomas S, Veerasingham S, Wei K, Wu F, Xu Y, Yoon M, Rege B.
Current State and New Horizons in Applications of Physiologically Based Biopharmaceutics Modeling (PBBM): A Workshop Report. Mol Pharm. 2025 Jan 6;22(1):5-27. doi: 10.1021/acs.molpharmaceut.4c01148.

Tavares D, Chien H-T, Sheean ME, Theunissen P, van Meer P, Van Malderen K.
From guideline to practice: three years of ICH S11 insights and recommendations. Front Med (Lausanne). 2025 Feb 10;12:1518936. doi: 10.3389/fmed.2025.1537001.

Thanarajasingam G, Major A, Bhatnagar V, Dueck AC, Smedby KE, El-Galaly TC, Geissler J, Habermann T, Kluetz PG, Seymour JF, Tzogani K, Villa D, Bröckelmann PJ.
Beyond maximum grade: introduction to The Lancet Haematology Adverse Events Reporting Series. Lancet Haematol. 2025 Jun;12(6):e403-e406. doi: 10.1016/S2352-3026(25)00027-4.

Vogel M, Escher SE, Weiler E, Londenberg A, Deppenmeier U, Whomsley R.
Quantitative Investigation of Nitrosamine Drug Substance-Related Impurities (NDSRIs) Under Artificial Gastric Conditions by Liquid Chromatography-Tandem Mass Spectrometry and Structure-Activity Relationship Analysis. Drug Test Anal. 2025 Sep;17(9):1772-1784. doi: 10.1002/dta.3874.

Walder L, Pallocca G, Bastos LF, Beekhuijzen M, Busquet F, Constantino H, Corvaro M, Courtot L, Escher B, Fernandez R, Gougeon E, Hansell L, Herzler M, Holden L, Hornek-Gausterer R, Irizar A, Kandarova H, Kern P, Kolle S, Lacasse K, Lee I, Macmillan DS, Maxwell G, Moriarty O, Nadzialek S, Pochat J, Reid K, Revel M, Ritskes-Hoitinga M, Sobanski T, Stoddart G, Underhill D, Veillette M, Vriend J, Westmoreland C, Baines J.
EU roadmap for phasing out animal testing for chemical safety assessments: Recommendations from a multi-stakeholder roundtable. ALTEX. 2025;42(3):435-450. doi: 10.14573/altex.2503241.

Yusufujiang M, Damen JAA, Idema DL, Schuit E, Moons KGM, de Jong VMT.
Network meta-analysis of prediction models using aggregate or individual participant data - a scoping review and recommendations for reporting and conduct. J Clin Epidemiol. 2025 Dec;188:112006. doi: 10.1016/j.jclinepi.2025.112006.

Zafiropoulos N, Pignatti F, Kouroumalis A, Guizzaro L, Karres D, Demolis P, Tenhunen O, Janssens R, Taams A, Bloem LT, Koenig F, Posch M.
A model structure for describing uncertainties in benefit-risk assessment of oncology drug applications. Front Med (Lausanne). 2025 Oct 15;12:1589578. doi: 10.3389/fmed.2025.1589578.

Zanello G, Stoyanova-Beninska V, Iliach O, Scherman D, Parker S, Pearce DA.
Regulatory sandboxes: A new frontier for rare disease therapies. Rare 2025;3:100110.
doi: 10.1016/j.rare.2025.100110.

Zaragoza Domingo S, Pinkham A, Tinoco D, Kottner J, Balabanov P, Butlen-Ducuing F.
Use of Standard Methodology for Novel Outcomes in Clinical Trials: Advantages for New Therapeutics in Neurosciences. Clin Schizophr Relat Psychoses. 2025;19(1).

Zebachi S, Tanniou J, Bakker E, de Vries ST, Di Bidino R, Xoxi E, Glaser A, Savarese G, Hillert J, Mol PGM, Plueschke K, Amzal B, Hayek GY, Moreira J.
Navigating the Real World: A Scoping Review of Structured Frameworks to Effectively Identify, Evaluate, and Select Real-World Data Sources for Fit-for-Purpose Studies. Clin Pharmacol Ther. 2025 Oct;118(4):894-905.
doi: 10.1002/cpt.3746. Epub 2025 Jul 2.

Zosso-Pavic M, Pignatti F, Wolfer A, Li Q, Demolis P, Rohr UP, Tenhunen O.
Navigating the complexity: reflections on the development of perioperative cancer treatments. Lancet Oncol. 2025 Jun;26(6):675-678. doi: 10.1016/S1470-2045(25)00217-7.