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Annex 1 – Members of the Management Board

Chair: Lorraine NOLAN

EMA contact: Hilde BOONE

Members

- European Parliament Karin KADENBACH, Giovanni LA VIA¹
- European Commission Sandra GALLINA, Joanna DRAKE
(Alternates: Rainer BECKER^{2a&2b}, Irene NORSTEDT)
- Belgium Hughes MALONNE³ (Alternate: Charles DENONNE⁴)
- Bulgaria Bogdan KIRILOV (Alternate: Svetlin Sofroniev SPIROV)
- Czechia Katerina PODRAZILOVA⁵ (Alternate: Jiří BUREŠ)
- Denmark Lars BO NIELSEN (Alternate: Mette AABOE HANSEN)
- Germany Karl BROICH (Alternate: Lars - Christoph NICKEL)
- Estonia Katrin KIISK (Alternate: Alar IRS)
- Ireland Lorraine NOLAN (Alternate: Rita PURCELL)
- Greece Dimitrios FILIPPOU (Alternate: Maria GAZOULI⁶)
- Spain María Jesús LAMAS DÍAZ (Alternate: Consuelo RUBIO MONTEJANO)
- France Christelle RATIGNIER-CARBONNEIL (Alternate: Franck FOURES)
- Croatia Siniša TOMIĆ (Alternate: Danica KRAMARIĆ)
- Italy *Awaiting nomination*^{7a,7b} (Alternate: Francesco TROTTA)
- Cyprus Helena PANAYIOTOPOULOU (Alternate: Irini Chrysafi FANIDOU)
- Latvia Indra DREIKA⁸ (Alternate: Sergejs AKULICŠ⁹)
- Lithuania Gytis ANDRULIONIS (Alternate: *Vacant*)
- Luxembourg Anna CHIOTI (Alternate: Marcin WISNIEWSKI)
- Hungary Rita Erzsébet PÁLFFYNÉ POÓR¹⁰ (Alternate: Beatrix HORVATH)
- Malta Anthony SERRACINO-INGLOTT (Alternate: John-Joseph BORG)

¹ Replaced Anthony BORG from July 2023.

^{2a} Olga SOLOMON replaced Anna-Eva AMPELAS from March 2023.

^{2b} Replaced Olga SOLOMON from December 2023.

³ Replaced Xavier DE CUYPER from September 2023.

⁴ Replaced Greet MUSCH from September 2023.

⁵ Replaced Irena STOROVÁ from October 2023.

⁶ Previously vacant.

^{7a} Guido RASI replaced Nicola MAGRINI from March 2023.

^{7b} Awaiting nomination from September 2023.

⁸ Replaced Sergejs AKULICŠ from March 2023.

⁹ Previously vacant.

¹⁰ Replaced Mátyás SZENTIVÁNYI from August 2023.

- Netherlands Paula LOEKMEIJER (Alternate: Aimad TORQUI)
- Austria Günter WAXENECKER¹¹ (Alternate: Jan NEUHAUSER¹²)
- Poland Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
- Portugal Rui SANTOS IVO (Alternate: Susana GUEDES POMBO)
- Romania Răzvan Mihai PRISADA (Alternate: Andrei BACIU)
- Slovenia Momir RADULOVIĆ (Alternate: *Vacant*)
- Slovakia Peter POTÚČEK (Alternate: Katarína MASSÁNYIOVÁ¹³)
- Finland Eija PELKONEN (Alternate: Anna SIIRA¹⁴)
- Sweden Björn ERIKSSON (Alternate: Åsa KUMLIN HOWELL)
- Representatives of patients' organisations Marco GRECO
Virginie HIVERT
- Representative of doctors' organisations Denis LACOMBE
- Representative of veterinarians' organisations Despoina IATRIDOU

Observers

- Iceland Runa HAUKSDOTTIR (Alternate: *Vacant*¹⁵)
- Liechtenstein Vlasta ZAVADOVA (Alternate: Martin STRICKER)
- Norway Audun HÅGÅ (Alternate: Marit HYSTAD)

¹¹ Replaced Christa WIRTHUMER-HOCHE from April 2023.

¹² Replaced Thomas REICHHART from April 2023.

¹³ Replaced Marián GAJDOŠ from February 2023.

¹⁴ Replaced Johanna NYSTEDT from August 2023.

¹⁵ Awaiting nomination.

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

Chair: Harald ENZMANN

Members nominated by Member States

• Daniela PHILADELPHY (Austria) ¹	Alternate: Christian GARTNER ²
• Christophe FOCKE (Belgium)	Alternate: Karin JANSSEN VAN DOORN
• Lyubina Racheva TODOROVA (Bulgaria) ³	Alternate: Gergana LAZAROVA ⁴
• Margareta BEGO (Croatia)	Alternate: Selma ARAPOVIC DZAKULA
• Helena PANAYIOTOPOULOU (Cyprus)	Alternate: Emilia MAVROKORDATOU
• Tomas RADIMERSKY (Czechia) ⁵	Alternate: Petr VRBATA ⁶
• Thalia Marie Estrup BLICHER (Denmark)	Alternate: Aaron Emmanuel SOSA MEJIA
• Alar IRS (Estonia)	Alternate: Edward LAANE
• Outi MAKI-IKOLA (Finland)	Alternate: Johanna LAHTENVUO
• Alexandre MOREAU (France)	Alternate: Jean-Michel RACE
• Martina WEISE (Germany)	Alternate: Janet KOENIG
• Konstantina ALEXOPOULOU (Greece)	Alternate: Anastasia MOUNTAKI
• Robert PORZASZ (Hungary)	Alternate: Beata Maria JAKLINE-ULLRICH ⁷
• Hrefna GUDMUNDSDOTTIR (Iceland)	Alternate: Hjalti KRISTINSSON
• Jayne CROWE (Ireland)	Alternate: Finbarr LEACY
• Paolo GASPARINI (Italy) ⁸	Alternate: Maria Grazia EVANDRI
• Elita POPLAVSKA (Latvia)	Alternate: <i>Awaiting nomination</i>
• Vlasta ZAVADOVA (Liechtenstein)	Alternate: <i>Awaiting nomination</i>
• Vilma PETRIKAITE (Lithuania)	Alternate: Larisa GOROBETS ⁹
• Martine TRAUFFLER (Luxembourg)	Alternate: Alexandra BRANCHU
• John Joseph BORG (Malta)	Alternate: Helen VELLA
• Peter MOL (Netherlands) ¹⁰	Alternate: Patrick VRIJLANDT ^{11,12}

¹ Daniela PHILADELPHY replaced Andrea LASLOP with a swap of role from alternate to member as of January 2023.

² Nominated as of January 2023.

³ Replaced Ilko GETOV as of August 2023.

⁴ Replaced Velislava TODOROV as of August 2023.

⁵ Tomas RADIMERSKY replaced Ondrej SLANAR with a swap of role from alternate to member as from April 2023.

⁶ Nominated as of April 2023.

⁷ Nominated as of January 2023.

⁸ Replaced Armando GENAZZANI as of August 2023.

⁹ Replaced Silvijus ABRAMAVICIUS as of February 2023.

¹⁰ Replaced Johann Lodewijk HILLEGE as of July 2023.

¹¹ Paula Boudewina VAN HENNIK resigned as from January 2023.

¹² Nominated as of July 2023.

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| • Ingrid WANG (Norway) | Alternate: Eva SKOVLUND |
| • Ewa BALKOWIEC-ISKRA (Poland) | Alternate: Grzegorz CESSAK |
| • Bruno SEPODES (Portugal) (<i>Vice-Chair</i>) | Alternate: Fatima VENTURA |
| • Simona BADOI (Romania) | Alternate: Dana Gabriela MARIN |
| • Francisek DRAFI (Slovakia) | Alternate: Jana KLIMASOVA ¹³ |
| • Kristina NADRAH (Slovenia) | Alternate: Andreja KRANJC ^{14,15} |
| • Maria Concepcion PRIETO YERRO (Spain) | Alternate: Carolina PRIETO FERNANDEZ ¹⁶ |
| • Kristina DUNDER (Sweden) | Alternate: Filip JOSEPHSON |

Co-opted members

- Bruno DELAFONT (Biostatistics and clinical trial methodology)^{17,18}
- Blanka HIRSCHLEROVA (Quality (non-biologicals) and Pharmacokinetics)
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Carla TORRE (Pharmaco-Epidemiology)
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

¹³ Replaced Dorota DISTLEROVA as of November 2023

¹⁴ Nevenka TRSINAR BRODT resigned as of January 2023

¹⁵ Nominated as of April 2023

¹⁶ Replaced Blanca GARCIA-OCHOA as of May 2023

¹⁷ Christian GARTNER became alternate for a member state as of January 2023

¹⁸ Nominated as of March 2023

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Sabine STRAUS

Members nominated by Member States

• Jan NEUHAUSER (Austria)	Alternate: Sonja HRABCIK
• Jean-Michel DOGNE (Belgium)	Alternate: Jo ROBAYS
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Yuliyana EFTIMOV
• Nikica MIROSEVIC SKVRCE (Croatia)	Alternate: Peter MAS ^{1,2}
• Elena KAISIS (Cyprus)	Alternate: Panagiotis PSARAS
• Eva JIRSOVA (Czechia)	Alternate: Jana LUKACISINOVA
• Marie Louise Schougaard CHRISTIANSEN (Denmark) ³	Alternate: Karin Susanne LINDENSTROM ERNEHOLM ⁴
• Maia UUSKULA (Estonia)	Alternate: Krõõt AAB
• Kirsti VILLIKKA (Finland)	Alternate: Kimmo JAAKKOLA
• Tiphaine VAILLANT (France)	Alternate: Nathalie GAULT
• Martin HUBER (Germany) (<i>Vice-Chair</i>)	Alternate: Gabrielle MAURER ⁵
• Sofia TRANTZA (Greece)	Alternate: Georgia GKEGKA
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun STEFANSDOTTIR (Iceland)	Alternate: Gudrun THENGILSDOTTIR
• Rhea FITZGERALD (Ireland)	Alternate: Eamon O MURCHU ^{6,7}
• Amelia CUPELLI (Italy)	Alternate: Valentina DI GIOVANNI
• Zane NEIKENA (Latvia)	Alternate: Zane STADE
• Rugile PILVINIENE (Lithuania)	Alternate: Lina SEIBOKIENE
• Nadine PETITPAIN (Luxembourg)	Alternate: Anne-Cecile VUILEMIN
• John Joseph BORG (Malta)	Alternate: Benjamin MICALLEF
• Liana GROSS-MARTIROSYAN (Netherlands) ⁸	Alternate: Bianca MULDER ⁹
• David BENEE OLSEN (Norway)	Alternate: Karen PERILLE HARG

¹ Željana MARGAN KOLETIC's mandate ended as of October 2023

² Nominated as of November 2023

³ Marie Louise Schougaard CHRISTIANSEN replaced Anette STARK with a swap of roles from alternate to member as of June 2023

⁴ Nominated as of September 2023

⁵ Replaced Brigitte KELLER-STANISLAWSKI as of January 2023

⁶ Ronan GRIMES resigned as of February 2023

⁷ Nominated as of March 2023

⁸ Liana GROSS-MARTIROSYAN replaced Menno VAN DER ELST with a swap of roles from alternate to member as of December 2023

⁹ Nominated as of December 2023

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| • Adam PRZYBYLKOWSKI (Poland) | Alternate: Katarzyna ZIOLKOWSKA |
| • Ana Sofia DINIZ MARTINS (Portugal) | Alternate: Carla TORRE ^{10, 11} |
| • Roxana DONDERA (Romania) | Alternate: Irina SANDU ¹² |
| • Anna MAREKOVA (Slovakia) | Alternate: Miroslava GOCOVA ¹³ |
| • Polona GOLMAJER (Slovenia) | Alternate: Milena RADOHA-BERGOC |
| • Maria del Pilar RAYON (Spain) | Alternate: Monica MARTINEZ REDONDO |
| • Ulla WANDEL LIMINGA (Sweden) | Alternate: Mari THORN |

Independent scientific experts nominated by the European Commission

- Annalisa CAPUANO
- Tania SCHINK¹⁴
- Hedvig NORDENG
- Patricia McGETTIGAN
- Milou Daniel DRICI
- Teresa HERDEIRO

Members representing healthcare professionals nominated by the European Commission

- Roberto FRONTINI Salvatore MESSANA

Members representing patients' organisations nominated by the European Commission

- Marko KORENJAK^{15, 16} Michal RATAJ¹⁷

¹⁰ Ines RIBEIRO-VAZ's mandate ended as of August 2023.

¹¹ Nominated as of November 2023.

¹² Replaced Alexandra-Maria SPURNI as of February 2023.

¹³ Replaced Lucia KURAKOVA as of April 2023.

¹⁴ Nominated as of March 2023.

¹⁵ Declan NOONE resigned as of July 2023.

¹⁶ Swap of roles from alternate to member as of December 2023.

¹⁷ Nominated as of December 2023.

Annex 4 – Members of the Committee for Veterinary Medicinal Products

Chair: G. J. SCHEFFERLIE (Vice-chair: F. HASSLUNG WIKSTRÖM)

Members and alternates

• Petra FALB (Austria)	Alternate: Manuela LEITNER
• Els Dewaele (Belgium)	Alternate: Frédéric KLEIN
• Krasimir YANKOV ZLATKOV (Bulgaria)	Alternate: Nadya Ognyanova VLADIMIROVA
• Frane BOŽIĆ (Croatia)	Alternate: Hrvoje PAVASOVIC
• Leona NEPEJCHALOVÁ (Czechia)	Alternate: Jiří BUREŠ
• <i>Awaiting nomination</i> ¹ (Cyprus)	Alternate: <i>Awaiting nomination</i> ²
• Niels Christian KYVSGAARD (Denmark)	Alternate: Merete BLIXENKRONE-MØLLER
• Toomas TIIRATS (Estonia)	Alternate: <i>Awaiting nomination</i>
• Minna LEPPÄNEN (Finland)	Alternate: Kristina Lehmann
• Sylvie LOUET (France)	Alternate: Christine MIRAS
• Andrea GOLOMBIEWSKI (Germany) ³	Alternate: Esther WERNER ⁴
• Spyridon FARLOPOULOS (Greece)	Alternate: Amalia PAPADAKI
• Gabor KULCSÁR (Hungary)	Alternate: Eszter KOLLÁR-NAGY
• Paul McNEILL (Ireland)	Alternate: J. Gabriel BEECHINOR
• Fulvio MARSILIO ⁵ (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Renāte KUŠĶE ^{6,7}
• Snieguolė T. DZEKČIORIENĖ (Lithuania)	Alternate: <i>Awaiting nomination</i> ⁸
• Marc SCHMIT (Luxembourg)	Alternate: Caroline CONER
• Stephen SPITERI (Malta)	Alternate: Elena Maria VELLA
• Jacqueline POOT (Netherlands)	Alternate: Kim BOERKAMP
• Anna WACHNIK-ŚWIECICKA (Poland)	Alternate: Ewa AUGUSTYNOWICZ
• João Pedro DUARTE DA SILVA (Portugal)	Alternate: Inês FLOR DIAS
• Gabriela TUCHILA (Romania)	Alternate: Lolita TABAN
• Eva CHOBOTOVÁ (Slovakia)	Alternate: Katarína MASSÁNYIOVÁ

¹ Mandate expired for C. PIPIS, position vacant.

² Mandate expired for A. MICHAELIDOU-PATSIA, position vacant.

³ Role swap of E. WERNER from member to alternate, January 2023.

⁴ Role swap of A. GOLOMBIEWSKI from alternate to member, January 2023.

⁵ Appointment of F. MARSILIO as new member from Italy, replacing P. PASQUALI, September 2023.

⁶ Termination of membership of S. ANSONSKA, January 2023.

⁷ Appointment of R. KUŠĶE as alternate, May 2023.

⁸ Mandate expired for N. STANKEVIČIENĖ, position vacant.

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| • Katarina ŠTRAUS (Slovenia) | Alternate: Boris KOLAR |
| • Cristina MUÑOZ MADERO (Spain) | Alternate: Consuelo RUBIO MONTEJANO |
| • Frida HASSLUNG-WIKSTRÖM (Sweden) | Alternate: Hanna BREMER |

EEA members

- | | |
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| • Member: <i>Awaiting nomination</i> | Alternate: <i>Awaiting nomination</i> |
| • Hanne BERGENDAHL (Norway) | Alternate: Knud TORJESEN ^{9,10} |

Co-opted members

Co-opted member

- Keith BAPTISTE
- Rory BREATHNACH
- Carina BERGMAN
- Mary O'GRADY
- Ricardo CARAPETO GARCÍA

Expertise

Antimicrobials

General clinical veterinary practice

Toxicology and residues

Quality pharmaceuticals

Environmental risk assessment

⁹ Mandate expired for A. ASKDAL BJELLAND, April 2023. Position vacant.

¹⁰ Appointment of K. Torjesen as alternate, August 2023.

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA

Members nominated by Member States

- Brigitte BLOECHL-DAUM (Austria)
- Tim LEEST (Belgium)
- *Awaiting nomination* (Bulgaria)¹
- Dinko VITEZIC (Croatia)
- Ioannis KKOLOS (Cyprus)²
- Jana MAZELOVA (Czechia)
- Elisabeth PENNINGA (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)
- Frauke NAUMANN-WINTER (Germany)
- Evangelia YANNAKI (Greece)³
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- *Awaiting nomination* (Ireland)
- Enrico COSTA (Italy)
- Irena ROGOVSKA (Latvia)
- Vlasta ZAVADOVA (Liechtenstein)
- Ruta NAMENISKIENE (Lithuania)⁴
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Joao ROCHA (Portugal)
- Olimpia NEAGU (Romania)

¹ Lyubina Racheva TODOROVA resigned as of September 2023.

² Replaced Elli LOIZIDOU as of July 2023.

³ Nominated as of May 2023.

⁴ Nominated as of January 2023.

- Eva MALIKOVA (Slovakia)
- *Awaiting nomination* (Slovenia)⁵
- Gloria Maria PALOMO CARRASCO (Spain)
- Darius MATUSEVICIUS (Sweden)

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

- Ingeborg BARISIC
- Judit MOLNAR^{6,7}
- Armando MAGRELLI (*Vice-Chair*)

Members representing patients' organisations nominated by the European Commission

- Marie Pauline EVERS
- Julian ISLA
- Ines ALVES

⁵ Martin MOZINA's mandate expired as of January 2023.

⁶ Giuseppe CAPOVILLA's mandate expired as of May 2023.

⁷ Nominated as of June 2023.

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Emiel VAN GALEN

Members nominated by Member States

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

¹ Nominated as of November 2023.

² Sarah KELLAGHAN's mandate ended as of November 2023.

³ Replaced Baiba JANSONE as of January 2023.

⁴ Evita SKUKAUSKA's mandate ended as of January 2023.

⁵ Replaced Greta BUDUKEVICIUTE as of June 2023.

⁶ Jane MURRAY's mandate ended as of May 2023.

- Miroslava HORVATH PETRIKOVA (Slovakia) Alternate: Jaroslav TOTH
- Barbara RAZINGER (Slovenia) Alternate: *Awaiting nomination*
- Olga Maria PALOMINO (Spain) Alternate: Olga Teresa ESTEBAN
- 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)
- *Awaiting nomination* (Experimental/non-clinical pharmacology)⁷
- Maria Helena PINTO FERREIRA (General and family medicine)
- *Awaiting nomination* (Paediatrics)⁸

Observers

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

⁷ Gert LAEKEMAN's mandate ended as of November 2023.

⁸ Peter VOITL's mandate ended as of November 2023.

Annex 7 – Committee for Advanced Therapies

Chair: Ilona G. REISCHL¹

Members nominated from within the CHMP

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| • Jan MUELLER-BERGHAUS (Germany) | Alternate: Egbert FLORY |
| • <i>Awaiting nomination</i> (Lithuania) | Alternate: Raimondas BENETIS |
| • John Joseph BORG (Malta) | Alternate: Anthony SAMUEL |
| • Bruno SEPODES (Portugal) | Alternate: Maria Isabel BORBA VIEIRA |
| • Sol RUIZ (Spain) | Alternate: Marcos TIMON |

Members nominated by Member States

- | | |
|--|--|
| • Silke DORNER ² | Alternate: Corina SPREITZER ³ |
| • Claire BEUNEU (Belgium) | Alternate: Olga KHOLMANSEIKH ^{4,5} |
| • Rozalina KULAKSAZOVA (Bulgaria) | Alternate: Evelina SHUMKOVA |
| • Azra SELIMOVIC (Croatia) | Alternate: Petra SOKOL |
| • Rafaella PONTOU (Cyprus) | Alternate: Isavella KYRIAKIDOU |
| • Petr SOUKUP (Czechia) | Alternate: Kristyna REHOROVA HRADILKOVA |
| • Ebru KARAKOC MADSEN (Denmark) | Alternate: Bibi Fatima Syed SHAH |
| • 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 |
| • Anna Katalin BARANE GILICZE (Hungary) ^{6,7} | Alternate: Viola BARDOCZY ⁸ |
| • <i>Awaiting nomination</i> (Iceland) | Alternate: <i>Awaiting nomination</i> |
| • Maura O'DONOVAN (Ireland) | Alternate: <i>Awaiting nomination</i> ⁹ |
| • Concetta QUINTARELLI (Italy) | Alternate: Barbara BONAMASSA |
| • Una RIEKSTINA (Latvia) | Alternate: <i>Awaiting nomination</i> |
| • Vlasta ZAVADOVA (Liechtenstein) | Alternate: <i>Awaiting nomination</i> |
| • Nancy DE BREMAEKER (Luxembourg) | Alternate: Guy BERCHER |

¹ Elected as Chair as of January 2023, replacing Martina SCHUSSLER-LENZ.

² Replaced Ilona G. REISCHL as of February 2023, with a swap of roles from alternate to member.

³ Nominated as of February 2023.

⁴ Belaid SEKKALI resigned as of February 2023.

⁵ Nominated as of June 2023.

⁶ Katalin LENGYEL resigned as of August 2023.

⁷ Nominated as of November 2023.

⁸ Replaced Balazs SARKADI as of December 2023.

⁹ Niamh CURRAN resigned as of December 2023.

- Emmely DE VRIES (Netherlands)^{10,11,12} Alternate: Berendina Maria VAN DEN HOORN¹³
- Rune KJEKEN (Norway) Alternate: Marit HYSTAD¹⁴
- Dariusz SLADOWSKI (Poland) Alternate: Marcin KOLAKOWSKI
- Silviu ISTRATE (Romania) Alternate: Alexandrina PREDA
- Katarina VAVROVA (Slovakia) Alternate: Margareta FOGELOVA
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Suzana VIDIC
- Maria LUTTGEN (Sweden)^{15,16} Alternate: Charlotte ANDERBERG¹⁷

Members representing clinicians nominated by the European Commission

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

Members representing patients' organisations nominated by the European Commission

- Kerstin SOLLERBRANT Alternate: Mencia DE LEMUS BELMONTE
- Kieran BREEN (*Vice-Chair*)¹⁸ Alternate: Federica CHIARA

Observers

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

¹⁰ Carla HERBETS resigned as of May 2023.

¹¹ Hendrikus OVELGONNE was nominated as of June 2023.

¹² Replaced Johannes Hendrikus OVELGONNE as of October 2023.

¹³ Replaced Babs FABRIEK as of October 2023.

¹⁴ Nominated as of February 2023.

¹⁵ Lisbeth BARKHOLT resigned as of May 2023.

¹⁶ Swap of roles from alternate to member as of June 2023.

¹⁷ Nominated as of June 2023.

¹⁸ Elected as Vice-Chair as of July 2023.

Annex 8 – Members of the Paediatric Committee

Chair: Brian AYLWARD

Members nominated from within the CHMP

- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

Members nominated by Member States

- Johanna WERNSPERGER (Austria)¹ Alternate: Agnes GYURASICS²
- Marleen RENARD (Belgium) Alternate: Karen VAN MALDEREN
- Dimitar ROUSSINOV (Bulgaria) Alternate: *Awaiting nomination*³
- Maja PAVLOVIC (Croatia) Alternate: *Awaiting nomination*
- Zena GUNTHER (Cyprus) Alternate: Maria Eleni AVRAAMIDOU
- Tereza BAZANTOVA (Czechia)⁴ Alternate: Pavlina CHLADOVA⁵
- Louisa BRAUN EXNER (Denmark)⁶ Alternate: *Awaiting nomination*
- Jana LASS (Estonia)⁷ Alternate: Liisa SAARE⁸
- Pauliina LEHTOLAINEN DALKILIC (Finland) Alternate: Anne PAAVOLA
- Sylvie BENCHETRIT (France) (*Vice-Chair*) Alternate: *Awaiting nomination*⁹
- Sabine SCHERER (Germany) Alternate: Yuansheng SUN
- Eleni KATSOMITI (Greece) Alternate: Anastasia MOUNTAKI
- Adrienn HORVATH (Hungary)¹⁰ Alternate: Robert PORZASZ
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- *Awaiting nomination* (Ireland) Alternate: *Awaiting nomination*
- Sara GALLUZZO (Italy)¹¹ Alternate: Cinzia CICERONI¹²
- Dina APELE-FREIMANE (Latvia) Alternate: *Awaiting nomination*
- Vlasta ZAVADOVA (Liechtenstein) Alternate: *Awaiting nomination*
- Greta BUDUKEVICIUTE (Lithuania)^{13,14} Alternate: *Awaiting nomination*^{15,16}

¹ Replaced Karl-Heinz HUEMER as of May 2023, with a swap of role from alternate to member.

² Nominated as of October 2023.

³ Vessela BOUDINOVA resigned as of August 2023.

⁴ Replaced Tomas BORAN as of September 2023, with a swap of role from alternate to member.

⁵ Nominated as of September 2023.

⁶ Replaced Nann BORUP JOHANSEN as of July 2023, with a swap of roles from alternate to member.

⁷ Replaced Irja LUTSAR as of October 2023, with a swap of roles from alternate to member.

⁸ Nominated as of October 2023.

⁹ Dominique PLOIN resigned as of December 2023.

¹⁰ Nominated as of January 2023.

¹¹ Nominated as of February 2023.

¹² Nominated as of February 2023.

¹³ Dovile ZACHARKIENE's mandate ended as of August 2023.

¹⁴ Swap of roles from alternate to member as of December 2023.

¹⁵ Greta BUDUKEVICIUTE replaced Silvijus ABRAMAVICIUS as of February 2023.

¹⁶ Greta BUDUKEVICIUTE became member as of December 2023.

• Carola DE BEAUFORT (Luxembourg)	Alternate: Olivier MOES
• John Joseph BORG (Malta)	Alternate: Herbert LENICKER
• Roderick HOUWEN (Netherlands)	Alternate: Maaïke VAN DARTEL
• Siri WANG (Norway)	Alternate: Anette Solli KARLSEN
• Marek MIGDAL (Poland)	Alternate: <i>Awaiting nomination</i>
• Helena FONSECA (Portugal)	Alternate: Hugo TAVARES
• Peter SISOVSKY (Slovakia)	Alternate: Peter SZITANYI
• Stefan GROSEK (Slovenia)	Alternate: <i>Awaiting nomination</i>
• Fernando DE ANDRES TRELLES (Spain)	Alternate: Maria Jesus FERNANDES CORTIZO
• Sara VENNBERG (Sweden) ¹⁷	Alternate: <i>Awaiting nomination</i> ¹⁸

Members representing healthcare professionals nominated by the European Commission

• Francesca ROCCHI	Alternate: Jose Ignacio MALAGON CALLE
• Fernando CABANAS	Alternate: Doina PLESCA
• Daniele DE LUCA ¹⁹	Alternate: Johannes TAMINIAU ²⁰

Members representing patients' organisations nominated by the European Commission

• Tomasz GRYBEK	Alternate: Jaroslav STERBA ²¹
• Viviana GIANNUZZI ²²	Alternate: Patricia FELGUEIRAS SEABRA DURAO ²³
• Eric VERMEULEN ²⁴	Alternate: Victoria ROMERO PAZOS ²⁵

¹⁷ Replaced Kristin KARLSSON as of March 2023, with a swap of role from alternate to member.

¹⁸ Sara VENNBERG became member as of March 2023.

¹⁹ Replaced Johannes TAMINIAU as of August 2023.

²⁰ Replaced Fabio MIDULLA as of August 2023, with a swap of role from member to alternate.

²¹ Replaced Milena STEVANOVIC as of August 2023, with swap of role from member to alternate.

²² Replaced Dimitrios ATHANASIOU as of August 2023.

²³ Nominated as of August 2023.

²⁴ Replaced Jaroslav STERBA as of August 2023.

²⁵ Nominated as of August 2023.

Annex 9 – Working parties and working groups

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

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

Committee for Medicinal Products for Human Use (CHMP)

CHMP

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

Other CHMP working parties

	Chair
Active Substance Master File Working Group	N/A
Geriatric Expert Group	N/A
Guidelines Consistency Group	N/A
Healthcare Professionals Working Party	N/A
(Invented) Name Review Group	N/A
Patient and Consumers' Working Party	N/A
Radiopharmaceuticals Drafting Group	N/A
Summary of Product Characteristics Advisory Group	N/A
Working Group on Quality Review of Documents	N/A

CHMP operational expert groups

Chair	
Nitrosamines Safety Operational Expert Group	N/A
Quality Innovation Group (QIG)	Marcel HOEFNAGEL
Scientific Advisory Group on Cardiovascular Issues	Franz Xaver KLEBER
Scientific Advisory Group on Infectious Diseases	Emilia CERCENADO MANSILLA
Scientific Advisory Group on Neurology	Serge BAKCHINE
Scientific Advisory Group on Vaccines	Jean Daniel LELIEVRE
Intercommittee Scientific Advisory Group on Oncology	Lothar BERGMANN

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

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

Other CVMP-associated groups

Chair	
Antimicrobials Advice Ad Hoc Expert Group	N/A

Pharmacovigilance Risk Assessment Committee (PRAC)

Chair	
PRAC working group on efficiency and effectiveness for PRAC plenary meetings	Martin HUBER/EMA representatives
PRAC Interest group (IG) Impact	Liana MARTIROSYAN/EMA representative
Granularity and Periodicity Advisory Group (GPAG)	Menno van der ELST
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Menno van der ELST/EMA representative

Chair	
Signal Management Review Technical (SMART) Working Group work stream 2 (methods)	Eugene van PUIJENBROEK/EMA representative

Committee for Orphan Medicinal Products (COMP)

COMP temporary working groups

Chair	
Protocol assistance working group	N/A

Committee on Herbal Medicinal Products (HMPC)

No active HMPC working parties during 2023.

Committee for Advanced Therapies (CAT)

No active CAT working parties during 2023.

Paediatric Committee(PDCO)

PDCO working groups

Chair	
Formulation Working Group	Brian AYLWARD (ad interim)

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

Other CMDh-associated groups

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

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

Chair	
Document Management Working Group	CMDv member from Member State holding EU Presidency
Autogenous Vaccines Working Group	Mariette SALERY
Borderline Products Working Group	Jose JONIS
Legislation 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

Joint working parties, working groups and advisory groups

Chair	
3Rs Working Party	Sonja BEKEN
Batch release testing OEG	N/A
Active Substance master File Working Group	N/A
Healthcare Professionals' Working Party (HCPWP)	EMA representative and Ulrich JÄGER
Patients' and Consumers' Working Party (PCWP)	EMA representative and Kaisa IMMONEN
Quality Working Party	Blanka HIRSCHLEROVA
Working Group on Quality Review of Documents	EMA representative

Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2023

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/CVMP/452614/2023	Concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)	Published for public consultation	20/11/2023

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/CVMP/QIG/GMP/QWP/BWP/397209/2023	Questions and Answers on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing	Published	12/10/2023
EMA/CHMP/531552/2023	EMA–FDA joint Q&As on Quality and GMP aspects of PRIME/Breakthrough therapy applications	Published	19/12/2023

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
None			

Cardiovascular Working Party

Reference number	Document	Status	Date
EMA/CHMP/20507/2023	Paediatric addendum to CHMP guidelines on the clinical investigations of medicinal products for the prevention and treatment of thromboembolic disease	Published	26/01/2023
CPMP/EWP/1080/00 Rev.2	Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	Published	22/06/2023

Central Nervous System Working Party

Reference number	Document	Status	Date
None			

Haematology Working Party

Reference number	Document	Status	Date
EMA/CHMP/453562/2023	Draft guideline on the clinical requirements for non replacement therapy in haemophilia A and B	Published for public consultation	01/11/2023

Healthcare Professionals Working Party

Reference number	Document	Status	Date

Infectious Diseases Working Party

Reference number	Document	Status	Date
None			

Methodology Working Party

Reference number	Document	Status	Date
None			

Non-clinical Working Party

Reference number	Document	Status	Date
EMA/CHMP/332530/2015	Information for the package leaflet regarding proline used as an excipient in medicinal products for human use	Adopted	20 March 2023
EMA/CHMP/190743/2016	Information for the package leaflet regarding polysorbates used as excipients in medicinal products for human use	Adopted	04 December 2023

Oncology Working Party

Reference number	Document	Status	Date
EMA/CHMP/205/95 Rev.6	Guideline on the clinical evaluation of anticancer medicinal products - Revision 6	Finalised	18/11/2023

Patients' and Consumers' Working Party

Reference number	Document	Status	Date

Quality Innovation Group

Reference number	Document	Status	Date
EMA/CHMP/CVMP/QIG/GMP/QWP/BWP/397209/2023	Questions and Answers on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing	Published	12/10/2023

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/QWP/298182/2023	Concept Paper on the revision of the Guideline on Radiopharmaceuticals	Published for 3 months public consultation	21/07/2023
EMA/CHMP/CVMP/QIG/GMP/QWP/BWP/397209/2023	Questions and Answers on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing	Published	12/10/2023
EMA/CHMP/QWP/505156/2023	Q & A on implementation of Ph.Eur. Medicinal Product Monographs	Published	15/12/2023
EMA/CHMP/531552/2023	EMA–FDA joint Q&As on Quality and GMP aspects of PRIME/Breakthrough therapy applications	Published	19/12/2023

Rheumatology/Immunology Working Party

Reference number	Document	Status	Date
EMA/CHMP/299976/2018	Reflection paper on regulatory requirements for the development of medicinal products for primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC)	Published	12/2023
EMA/CHMP/536854/2023	Reflection paper on regulatory requirements for the development of medicinal products for Acute Kidney Injury (AKI)	Published	18/12/2023
EMA/CHMP/83033/2023	Questions and answers on data requirements when transitioning to low global warming potential	Published	08/11/2023

Reference number	Document	Status	Date
	(LGWP) propellants in oral pressurised metered dose inhalers		
EMA/CHMP/175067/2023	Concept paper on revision of the Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome	Published	04/05/2023

Scientific Advice Working Party

Reference number	Document	Status	Date
None			

Vaccines Working Party

Reference number	Document	Status	Date
EMA/CHMP/VWP/164653/05 Rev. 1	Guideline on clinical evaluation of vaccines	Published	01/02/2023

Annex 12 – CVMP opinions in 2023 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
- Prolevare - Oclacitinib maleate	Zoetis Belgium SA	- Dog - Treatment of pruritus associated with allergic dermatitis in dogs. Treatment of clinical manifestations of Atopic Dermatitis in dogs	12/09/2022 15/02/2023 88 68	24/04/2023 25/04/2023 - C 192
- Innovax-ILT-IBD - Avian infectious laryngotracheitis, infectious bursal disease and Marek's disease vaccine (live recombinant)	Intervet International B.V.	- Chicken - For active immunisation of one-day-old chicks or embryonated chicken eggs	12/01/2022 15/02/2023 209 190	14/04/2023 17/04/2023 - C 192
- Eurican L4 - Canine leptospirosis vaccine (inactivated)	Boehringer Ingelheim Vetmedica GmbH	- Dog - Active immunisation of dogs to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by: - Leptospira interrogans serogroup Canicola serovar Canicola - Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae; - Leptospira interrogans serogroup Icterohaemorrhagiae serovar Copenhageni - Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa	20/10/2021 15/02/2023 208 275	31/03/2023 04/04/2023 - C 153

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
		- Leptospira interrogans serogroup Australis serovar Bratislava		
- Bovilis Nasalgen-C - Bovine coronavirus vaccine, (live attenuated)	Intervet International B.V.	- Cattle - For the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus	17/11/2021 15/02/2023 208 247	31/03/2023 04/04/2023 - C 153
- Newflend ND H9 - Newcastle disease and avian influenza vaccine (live, recombinant)	Ceva-Phylaxia Co. Ltd	- Chicken - For the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs: - to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV) - to reduce clinical signs, lesions, and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9)	11/08/2021 23/03/2023 210 379	16/05/2023 17/05/2023 - C 232
- Eluracat - Capromorelin tartrate	Elanco GmbH	- Cat - For body weight gain in cats experiencing poor appetite or unintended weight loss	14/12/2021 16/05/2023 209 309	29/06/2023 03/07/2023 - C 269
- YURVAC RHD - Rabbit haemorrhagic disease and RHDV2 vaccine (recombinant)	Laboratorios Hipra, S.A.	- Rabbit - For active immunisation of rabbits from 30 days of age onwards to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains	08/06/2022 13/07/2023 208 192	11/09/2023 12/09/2023 - C 298

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
• Prevexxion RN+HVT • Marek's disease vaccine (live recombinant)	• Boehringer Ingelheim Vetmedica GmbH	• Chicken • For active immunisation of one-day-old chicks to prevent mortality and reduce clinical signs and lesions caused by MD virus (including very virulent MD virus)	• 19/10/2022 • 07/09/2023 • 179 • 144	• 24/10/2023 • 26/10/2023 • C 1561
• Poulvac Procerta HVT-IBD • Live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus	• Zoetis Belgium	• Chicken • For active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to: - reduce mortality, clinical signs and lesions caused by Marek's disease virus; and - prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease virus	• 10/08/2022 • 07/09/2023 • 210 • 183	• 26/10/2023 • 27/10/2023 • C 1561
• Oxmax • Hemoglobin betafumaril (bovine)	• New Alpha Innovation Biopharmaceutical Ireland Limited	• Dog • Indicated as an adjunct therapy in the management of canine haemorrhagic shock. A beneficial effect of treatment was demonstrated for 24 hour survival rate when Oxmax was administered concomitantly with low dose resuscitative fluids (Lactated Ringer's solution)	• 21/03/2019 • 07/09/2023 • 210 • 1422	• 19/10/2023 • 20/10/2023 • C 1561
• Loxitab • Meloxicam	• CP-Pharma Handelsgesellschaft mbH	• Dog • Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs	• 10/08/2022 • 07/09/2023 • 208 • 185	• 19/10/2023 • 24/10/2023 • C 1561

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
- Senvelgo - Velagliflozin	Boehringer Ingelheim Vetmedica GmbH	- Cat - For the reduction of hyperglycaemia in cats with non-insulin-dependent diabetes mellitus	11/05/2022 05/10/2023 210 302	20/11/2023 22/11/2023 - C 1562
- Nobivac LoVo L4 - Canine leptospira vaccine	Intervet International B.V.	- Dog - For active immunisation of dogs against: - L. interrogans serogroup Canicola serovar Canicola to reduce infection and urinary excretion - L. interrogans serogroup Icterohaemorrhagiae serovar Copenhageni to reduce infection and urinary excretion - L. interrogans serogroup Australis serovar Bratislava to reduce infection - L. kirschneri serogroup Grippotyphosa serovar Bananal/Liangguang to reduce infection and urinary excretion	24/11/2022 05/10/2023 209 107	20/11/2023 22/11/2023 - C 1562
- Bovilis Cryptium - Bovine Cryptosporidium parvum vaccine	Intervet International B.V.	- Cattle - Stimulation of active immunity against C. parvum glycoprotein Gp40 in pregnant heifers and cows. When the colostrum of such heifers and cows, which contains antibodies against glycoprotein Gp40, is ingested by calves, it passively immunises the calves against C. parvum	08/06/2022 05/10/2023 210 274	23/11/2023 24/11/2023 - C 1562

Negative opinions

There were no negative opinions in 2023.

CVMP opinions in 2023 on establishment of MRLs

Positive opinions

Product • Substance	Target species	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Regulation • Official Journal
• Ketoprofen	• Poultry	• 12/01/2021 • 16/05/2023 • 209 • 276	• 16/05/2023 • Pending • Pending
• Sodium Salicylate	• Poultry other than Turkey	• 19/10/2022 • 05/10/2023 • 207 • 144	• 05/10/2023 • Pending • Pending

Negative opinions

There were no negative opinions on establishment of MRLs in 2023.

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
• Zeleris • Florfenicol/Meloxicam	• CEVA Santé Animale	• QJ01BA99 • For therapeutic treatment of bovine respiratory disease (BRD) due to Histophilus somni, Mannheimia haemolytica, Pasteurella multocida and Mycoplasma bovis associated with pyrexia	• 15/02/2023	• 31/03/2023

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CVMP opinion	European Commission decision date
• Suvaxyn PRRS MLV • Porcine respiratory and reproductive syndrome virus vaccine (live)	• Zoetis Belgium SA	• QI09AD03 • For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1)	• 15/02/2023	• 31/03/2023
• Bravecto Plus • Fluralaner/Moxidectin	• Intervet International B.V.	• QP54AB52 • For cats with, or at risk from, mixed parasitic infestations by ticks or fleas and ear mites, gastrointestinal nematodes, heartworm or lungworm. 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.	• 15/02/2023	• 31/03/2023
• Gumbohatch • Avian infectious bursal disease vaccine (live)	• Laboratorios Hipra, S.A.	• QI01AD09 • For active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.	• 20/04/2023	• 05/06/2023
• NexGard Combo • Esafoxolaner/Eprinomectin/Praziquantel	• Boehringer Ingelheim Vetmedica GmbH	• QP54AA54 • For cats with, or at risk from mixed infections by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time. Persistent tick killing activity from 7 days to four weeks after treatment against Ixodes hexagonus and Rhipicephalus sanguineus	• 13/07/2023	• 24/08/2023

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CVMP opinion	European Commission decision date
• Frontpro • Afoxolaner	• Boehringer Ingelheim Vetmedica GmbH	• QP53BE01 • Treatment of flea and tick infestations in dogs.	• 07/12/2023	25/01/2024

Annex 13 – Guidelines and concept papers adopted by CVMP in 2023

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/592906/2022	Annex to the Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water on compatibility studies between veterinary medicinal products and biocidal products	Adopted in March 2023 for consultation End of consultation 30 June 2023
EMA/CVMP/QWP/307647/2023	Revised guideline on excipients in the dossier for application for marketing authorisation for veterinary medicinal products	Adopted in July 2023
EMA/CVMP/QWP/47285/2022	Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets	Adopted in July 2023 for consultation End of consultation 31 January 2024
EMA/CVMP/QWP/348098/2023	Draft concept paper on a guideline on stability testing for variations for veterinary medicinal products	Adopted in October 2023 for consultation End of consultation 5 January 2024
EMA/CHMP/CVMP/QWP/387541/2023	Draft joint (human and veterinary) guideline on development and manufacture of synthetic peptides	Adopted in October 2023 for consultation End of consultation 30 April 2024
EMA/CHMP/CVMP/QIG/GMP/QWP/BWP/397209/2023	Q&A on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing	Adopted in October 2023
EMA/CHMP/CVMP/QWP/17760/2009 – Rev.3	Draft addendum to the guideline on the use of near infrared spectroscopy (NIRS)	Adopted in November 2023 for consultation End of consultation 22 December 2023

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/32272/2022	Q&A on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016)	Adopted January 2023
EMA/CVMP/SWP/104211/2023	Draft concept paper on the revision of the Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)	Adopted in September 2023 for consultation End of consultation 30 November 2023
EMA/CVMP/SWP/32027/2022	Draft guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted in September 2023 for consultation End of consultation 31 January 2024

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/310225/2014	Reflection paper on resistance in ectoparasites	Adopted January 2023
EMA/CVMP/EWP/56030/2023	Draft concept paper on the revision of the guideline for the demonstration of efficacy of ectoparasiticides	Adopted in July 2023 for consultation End of consultation 31 October 2023
EMA/CVMP/EWP/231668/2022	Draft guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted in July 2023 for consultation End of consultation 31 January 2024
EMA/CVMP/EWP/133/1999 - Rev.1	Revised guideline on the conduct of pharmacokinetic studies in target animal species	Adopted in December 2023

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009-Rev.14	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted in June 2023
EMA/CVMP/PhVWP/218994/2023	List of changes to combined VeDDRA list of clinical terms	Adopted in June 2023
EMA/CVMP/PhVWP/288284/2007-Rev.15	Revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted in June 2023
EMA/CVMP/PhVWP/399363/2023	Draft revised guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)	Adopted in October 2023 for consultation End of consultation 13 November 2023
EMA/CVMP/PhVWP/399363/2023	Revised guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)	Adopted in December 2023
EMA/CVMP/150343/2016-Rev.4	Revised Q&A on describing adverse events in the product information SPC and package leaflet)	Adopted in December 2023

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/933465/2022	Q&A on the guideline on the SPC for VMPs containing antimicrobial substances – antibiotic clinical breakpoints that may be included in section 4.2 of the SPC for generic VMPs	Adopted June 2023
EMA/CVMP/882931/2022	Draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators	Adopted in June 2023 for consultation End of consultation 31 July 2023
EMA/CVMP/AWP/933451/2022	Draft concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals	Adopted in July 2023 for consultation End of consultation 31 October 2023

Reference number	Document title	Status
EMA/CVMP/882931/2022	Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators	Adopted October 2023

CVMP Immunologocals

Reference number	Document title	Status
EMA/CVMP/IWP/365817/2022	Draft guideline on plasmid DNA vaccines for veterinary use	Adopted in February 2023 for consultation End of consultation 23 June 2023
EMA/CVMP/IWP/161133/2023	Draft concept paper for the revision of the guideline on live recombinant vector vaccines for veterinary use (EMA/CVMP/004/04)	Adopted in June 2023 for consultation End of consultation 22 September 2023
EMA/CVMP/IWP/170689/2016	Revised guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats	Adopted July 2023
EMA/CVMP/IWP/228730/2022	Draft guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets	Adopted in September 2023 for consultation End of consultation 31 January 2024
EMA/CVMP/IWP/224724/2022	Draft guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6	Adopted in September 2023 for consultation End of consultation 31 January 2024

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/31905/2021	Revised reflection paper on the environmental risk assessment of ectoparasitocidal veterinary medicinal products used in cats and dogs	Adopted November 2023

CVMP Novel therapies and technologies

Reference number	Document title	Status
EMA/CVMP/NTWP/32862/2022	Draft revised guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy	Adopted in January 2023 for consultation End of consultation 31 May 2023
EMA/CVMP/NTWP/179287/2022	Revised guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy	Adopted in June 2023
EMA/CVMP/NTWP/32862/2022	Revised guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy	Adopted October 2023

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

Reference number	Document title	Status
EMA/CHMP/CVMP/452614/2023	Draft concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)	Adopted in November 2023 for consultation End of consultation 28 February 2024

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

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

Reference number	Document title	Status
EMA/CVMP/273040/2022	Guideline on the application of Article 34 of Regulation (EU) 2019/6 (classification of veterinary medicinal products - prescription status)	Adopted January 2023
EMA/INS/GMP/533512/2023	Scientific advice to the European Commission on the implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the GMP for veterinary medicinal products and active substances used as starting materials	Adopted December 2023

General

Reference number	Document title	Status
EMA/CVMP/184591/2022	Procedural advice for vaccine platform technology master file (vPTMF) certification	Adopted in January 2023
EMA/CHMP/CVMP/83833/2023	Draft reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle	Adopted in July 2023 for consultation End of consultation 31 December 2023
EMA/CVMP/196216/2021	Draft VICH GL60: Good Manufacturing Practice for active ingredients used in Veterinary Medicinal Products	Adopted in October 2023 for consultation End of consultation 25 March 2023
EMA/CVMP/248499/2007 – Rev.1	Draft revised guideline on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted in December 2023 for consultation End of consultation 30 June 2024
EMA/364980/2017 - Rev. 2	Revised Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures	Adopted in December 2023

Annex 14 – COMP opinions in 2023 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
Autologous T lymphocytes containing a T-cell receptor against Epstein–Barr virus	Carthagenetics Iberica S.L.	Treatment of peripheral T-cell lymphoma	29/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
3,3-Dimethyl-N-(6-methyl-5-{[2-(1-methyl-1H-pyrazol-4-yl)pyridine-4-yl]oxy}pyridine-2-yl)-2-oxopyrrolidine-1-carboxamide hydrochloride hydrate	Amador Bioscience	Treatment of tenosynovial giant-cell tumour, local and diffuse type	29/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Ovine polyclonal fragment antigen-binding against ricin	Serb	Treatment of ricin poisoning	24/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Bersiporocin	Propharma Group The Netherlands B.V.	Treatment of idiopathic pulmonary fibrosis	23/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Cutamesine	3R Pharma Consulting GmbH	Treatment of amyotrophic lateral sclerosis	10/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Allogeneic umbilical cord-derived mesenchymal stromal cells, pooled	ESPL Regulatory Consulting Limited	Treatment of perinatal asphyxia	07/08/2023 14/09/2023 09/11/2023	• 17/11/2023 • 13/12/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Methyl 4-(2-acetamidoethylsulfanyl)-4-oxobutanoate	Abliva AB	Treatment of Leigh syndrome	24/07/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
2'-O, 4'-C-Methylene-P-thio-adenylyl-(3'->5')-2'-O, 4'-C-methylene-P-thioguanlyl-(3'->5')-2'-O, 4'-C-methylene-P-thio-adenylyl-(3'->5')-2'-deoxy-P-thioadenylyl-(3'->5')-2'-deoxy-P-thio-thymidylyl-(3'->5')-2'-deoxy-P-thio-guanlyl-(3'->5')-2'-deoxy-P-thio-guanlyl-(3'->5')-2'-deoxy-P-thio-cytidylyl-(3'->5')-2'-deoxy-P-thio-adenylyl-(3'->5')-2'-deoxy-P-thio-cytidylyl-(3'->5')-2'-deoxy-P-thio-adenylyl-(3'->5')-2'-deoxy-P-thio-thymidylyl-(3'->5')-2'-deoxy-P-thio-cytidylyl-(3'->5')-2'-O, 4'-C-methylene-5-methyl-P-thio-cytidylyl-(3'->5')-2'-O, 4'-C-methylene-5-methyl-P-thio-uridylyl-(3'->5')-2'-O, 4'-C-methylene-5-methyl-P-thio-uridylyl-(3'->5')-2'-O, 4'-C-methyleneguanosine	Ultragenyx Germany GmbH	Treatment of Angelman syndrome	25/08/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Selumetinib	AstraZeneca AB	Treatment of glioma	14/07/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Riboflavin	iniuva GmbH	Treatment of medium-chain acyl-coenzyme A dehydrogenase deficiency	13/07/2023 16/08/2023 05/10/2023 (50 days/26 days)	• 13/10/2023 • 08/11/2023
Brogidirsen	Medpace Finland Oy	Treatment of Duchenne muscular dystrophy	13/07/2023 16/08/2023 09/11/2023 (85 days/26 days)	• 17/11/2023 • 13/12/2023

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 CLDN6 conjugated to monomethyl auristatin E via a cathepsin hydrolysable dipeptide VC linker	Insight Drug Regulatory	Treatment of ovarian cancer	12/07/2023 16/08/2023 09/10/2023 (54 days/26 days)	• 13/10/2023 • 08/11/2023
Elesclomol-copper	Veristat Spain S.L.	Treatment of Menkes disease	12/07/2023 16/08/2023 05/10/2023 (50 days/26 days)	• 13/10/2023 • 08/11/2023
Golcadomide hydrochloride	Bristol-Myers Squibb Pharma EEIG	Treatment of follicular lymphoma	11/07/2023 16/08/2023 09/11/2023 (85 days/26 days)	• 17/11/2023 • 13/12/2023
Messenger RNA encoding Cas9, Single guide RNA targeting the human <i>KLKB1</i> gene	Pharma Gateway AB	Treatment of hereditary angioedema	11/07/2023 16/08/2023 05/10/2023 (50 days/26 days)	• 13/10/2023 • 08/11/2023
Marstacimab	Pfizer Europe MA EEIG	Treatment of haemophilia B	11/07/2023 16/08/2023 09/11/2023 (85 days/26 days)	• 17/11/2023 • 13/12/2023
Adeno-associated viral vector serotype rh10 encoding miRNA against SOD1 mRNA	uniQure Biopharma B.V	Treatment of amyotrophic lateral sclerosis	11/07/2023 16/08/2023 05/10/2023 (50 days/26 days)	• 13/10/2023 • 08/11/2023
2-(3-(3,5-Dimethyltriazol-4-yl)-5-((S)-oxan-4-yl(phenyl)methyl)pyrido(3,2-b)indol-7-yl)propan-2-ol	Bristol-Myers Squibb Pharma EEIG	Treatment of myelofibrosis	23/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Alpelisib	Novartis Europharm Limited	Treatment of lymphatic malformations	23/06/2023 11/07/2023	• 18/09/2023 • 13/10/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			07/09/2023 (58 days/25 days)	
Oregovomab	IQVIA RDS Spain S.L.	Treatment of ovarian cancer	22/06/2023 11/07/2023 05/10/2023 (86 days/26 days)	• 13/10/2023 • 08/11/2023
Sodium selenate	Monash University	Treatment of progressive supranuclear palsy	22/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Human IgG1 (296-cysteine,301-glycine,306-cysteine) monoclonal antibody against TREM2	Pharma Gateway AB	Treatment of CSF1R-related leukoencephalopathy	21/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Sodium oxybate	Avadel Ireland	Treatment of narcolepsy	21/06/2023 11/07/2023 07/09/2023	• 18/09/2023 • 13/10/2023
Glycerol phenylbutyrate	Immedica Pharma AB	Treatment of STXBP1 developmental and epileptic encephalopathy	21/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Setanaxib	Calliditas Therapeutics France S.A.S.	Treatment of Alport syndrome	21/06/2023 11/07/2023 05/10/2023 (86 days/26 days)	• 13/10/2023 • 08/11/2023
Adeno-associated viral vector serotype 9 containing the human <i>PLA2G6</i> gene	FGK Representative Service GmbH	Treatment of infantile neuroaxonal dystrophy	21/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Rucosopasem manganese	Agos Healthcare Limited	Treatment of pancreatic cancer	20/06/2023 11/07/2023	• 13/10/2023 • 08/11/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP - Submission - Start date - Opinion - Active time	European Commission - Opinion received - Date of decision
			05/09/2023 (86 days/26 days)	
Resminostat	4 SC AG	Treatment of cutaneous T-cell lymphoma	20/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	18/09/2023 13/10/2023
N-{(2S,3R)-4,4-Difluoro-1-(2-hydroxy-2-methylpropanoyl)-2-[(2,3',5'-trifluoro[1,1'-biphenyl]-3-yl)methyl]pyrrolidin-3-yl}ethanesulfonamide	Takeda Pharma A/S	Treatment of narcolepsy	19/06/2023 11/07/2023 09/10/2023 (90 days/26 days)	13/10/2023 08/11/2023
Adeno-associated viral vector serotype 9 containing the human <i>NPC1</i> gene	FGK Representative Service GmbH	Treatment of Niemann-Pick disease, type C	19/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	18/09/2023 13/10/2023
5-bromo-N-(prop-2-yn-1-yl)-2-(1H-1,2,4-triazol-1-yl)pyrimidine-4,6-diamine	Palo Biofarma S.L.	Treatment of Prader-Willi syndrome	16/06/2023 11/07/2023 05/10/2023 (86 days/26 days)	13/10/2023 08/11/2023
1-(4-((1R,2S,3R)-1,2,3,4-Tetrahydroxybutyl)-1H-imidazol-2-yl) ethanone oxime	AC Biotech	Treatment of pancreatic cancer	14/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	18/09/2023 13/10/2023
(R)-(3-(2'-cyclopropyl-3-(hydroxymethyl)-[1,1'-biphenyl]-4-yl) pyrrolidin-1-yl)(5-fluoropyridin-2-yl)methanone	Granzer Regulatory Consulting & Services GmbH	Treatment of Olmsted syndrome	07/06/2023 11/07/2023 07/09/2023 (58 days/25 days)	18/09/2023 13/10/2023
(S)-N-(1-(3-Fluoro-2'-methoxy-[1,1'-biphenyl]-4-yl)-2-oxopiperidin-3-yl)-5-(pyridin-2-yl)thiophene-2-sulfonamide	Selabtec Sciences S.L.	Treatment of soft tissue sarcoma	25/05/2023 14/09/2023 09/11/2023 (56 days/26 days)	17/11/2023 13/12/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Ulefnersen	Ionis Development (Ireland) Limited	Treatment of amyotrophic lateral sclerosis	22/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Adeno-associated virus vector serotype 9/rh74 containing the human <i>CAPN3</i> gene and a target sequence of cardiac-specific microRNA	Atamyo Therapeutics	Treatment of limb-girdle muscular dystrophy	22/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Humanised IgG1 monoclonal antibody against TfR1 conjugated to exon 44 specific phosphorodiamidate morpholino oligonucleotide via a non-cleavable linker	MWB Consulting	Treatment of Duchenne muscular dystrophy	22/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Setmelanotide	Rhythm Pharmaceuticals Netherlands B.V.	Treatment of acquired hypothalamic obesity	20/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Adeno-associated virus serotype 9 vector containing the human LAMP2 isoform B transgene	Rocket Pharmaceuticals B.V.	Treatment of Danon disease	19/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting PLP1 pre-mRNA	Ionis Development (Ireland) Limited	Treatment of Pelizaeus-Merzbacher disease	19/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Humanised IgG4 monoclonal antibody against C1q	Kinesys Consulting NL B.V.	Treatment of Guillain-Barré syndrome	19/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Mitazalimab	Alligator Bioscience AB	Treatment of pancreatic cancer	19/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Cedazuridine, decitabine	Otsuka Pharmaceutical Netherlands B.V.	Treatment of myelodysplastic syndromes	19/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Eplontersen	AstraZeneca AB	Treatment of transthyretin-mediated amyloidosis	19/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Allogeneic amniotic fluid-derived mesenchymal stem cells with lung specificity	Amniotics AB (publ)	Treatment of primary graft dysfunction following lung transplantation	17/05/2023 14/09/2023 09/11/2023 (56 days/26 days)	• 17/11/2023 • 13/12/2023
Herpes simplex virus-1, derived from strain F, with deletions on genes gamma (1) 34.5 and UL39	Regenold GmbH	Treatment of glioma	17/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Lithium carbonate	Laboratoires Delbert	Treatment of Kleine Levin syndrome	15/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Virus-like particle containing Cas9/gRNA ribonucleoprotein targeting the human <i>HTT</i> gene	Laura Nae	Treatment of Huntington's disease	11/05/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Certeptide	Lisata Therapeutics Ireland Limited	Treatment of pancreatic cancer	03/05/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Tasimelteon	Vanda Pharmaceuticals Netherlands B.V.	Treatment of Smith-Magenis syndrome	25/04/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023
Ambroxol hydrochloride	CATS Consultants GmbH	Treatment of Gaucher disease	11/04/2023 16/08/2023 05/10/2023 (50 days/26 days)	• 13/10/2023 • 08/11/2023
Adeno-associated virus vector serotype 9 containing the <i>PKP2</i> gene	Qdossier B.V.	Treatment of arrhythmogenic right ventricular cardiomyopathy due to plakophilin-2 gene mutations	05/04/2023 13/06/2023 13/07/2023 (30 days/27 days)	• 20/07/2023 • 16/08/2023
Sildenafil citrate	Charite Universitaetsmedizin Berlin KöR	Treatment of Leigh syndrome	28/03/2023 11/07/2023 07/09/2023 (58 days/25 days)	• 18/09/2023 • 13/10/2023
Rituximab	4p-Pharma	Treatment of primary membranous nephropathy	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Allogeneic peripheral blood-derived haematopoietic stem and progenitor cells, regulatory T cells and conventional T cells	Phortas GmbH	Treatment in hematopoietic stem cell transplantation	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Tarperprumig	Alexion Europe	Treatment of sickle cell disease	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Nomacopan	Akari Malta Limited	Treatment of in haematopoietic stem cell transplantation	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Messenger ribonucleic acid coding for coiled-coil domain-containing protein 40	Ethris GmbH	Treatment of primary ciliary dyskinesia	27/03/2023 19/04/2023 15/06/2023	• 26/06/2023 • 25/07/2023
Vonafexor	Enyo Pharma	Treatment of Alport syndrome	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Cannabidiol	Universitat Autònoma De Barcelona	Treatment of Leigh syndrome	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Relacorilant	Granzer Regulatory Consulting & Services GmbH	Treatment of ovarian cancer	27/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Ulviprubart	PHARA	Treatment of inclusion body myositis	26/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Taldefgrobep alfa	Biohaven Bioscience Ireland Limited	Treatment of spinal muscular atrophy	24/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Alprostadiil	Oresund Pharma ApS	Treatment of in solid organ transplantation	24/03/2023 19/04/2023 13/07/2023 (85 days/27 days)	• 20/07/2023 • 16/08/2023
Paclitaxel obaluronate	Fidia Farmaceutici S.p.A.	Treatment of malignant mesothelioma	24/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Ilginatib maleate	Syneos Health Netherlands B.V.	Treatment of myelofibrosis	24/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Chimeric human-murine IgG1 kappa monoclonal antibody against TNF alfa	FGK Representative Service GmbH	Treatment of sarcoidosis	24/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Zedenoleucel	Scendea (NL) B.V.	Treatment of acute myeloid leukaemia	22/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Humanised IgG1 monoclonal antibody against muscle specific kinase	Argenx	Treatment of congenital myasthenic syndromes	22/03/2023 19/04/2023 15/06/2023 (57 days/29 days)	• 26/06/2023 • 25/07/2023
Mitapivat sulfate	Agios Netherlands B.V.	Treatment of thalassaemia intermedia and major	16/03/2023 13/06/2023 07/09/2023 (86 days/25 days)	• 18/09/2023 • 13/10/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Fasudil hydrochloride	MDC RegAffairs GmbH	Treatment of amyotrophic lateral sclerosis	27/02/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
Allogeneic faecal microbiota, pooled	Maat Pharma	Treatment in allogeneic haematopoietic stem cell transplantation	27/02/2023 19/04/2023 13/07/2023 (85 days/27 days)	• 20/07/2023 • 16/08/2023
5-(3,4-Dichloro-phenyl)-N-((1R,2R)-2-hydroxy-cyclohexyl)-6-(2,2,2-trifluoro-ethoxy)-nicotinamide	Veristat Spain S.L.	Treatment of Alport syndrome	27/02/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
Omadacycline	Paratek Ireland Limited	Treatment of nontuberculous mycobacterial lung disease	24/02/2023 22/03/2023 15/06/2023 (85 days/29 days)	• 26/06/2023 • 25/07/2023
(3S,3'S,3a'S,10a'S)-6-chloro-3'-(3-chloro-2-fluorophenyl)-1'-(cyclopropylmethyl)-6'-methyl-2-oxo-1,2,3',3a',10',10a'-hexahydro-1'H-spiro[indole-3,2'-pyrrolo[2',3':4,5]pyrrolo[1,2-b]indazole]-7'-carboxylic acid	Boehringer Ingelheim International GmbH	Treatment of soft tissue sarcoma	26/02/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
Lusvertikimab	OSE Immunotherapeuti cs	Treatment of acute lymphoblastic leukaemia	23/02/2023 22/03/2023 15/06/2023 (85 days/29 days)	• 26/06/2023 • 25/07/2023
Nicotinamide mononucleotide	Lgd	Treatment of sickle cell disease	22/02/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Rhizobium rhizogenes, lipopolysaccharide	Crazy Science & Business S.L.	Treatment of congenital diaphragmatic hernia	16/02/2023 22/03/2023 15/06/2023 (85 days/29 days)	• 26/06/2023 • 25/07/2023
Autologous dendritic cells pulsed with allogeneic tumour cell lysate	Amphera B.V.	Treatment of pancreatic cancer	13/02/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
Adeno-associated virus vector serotype 8 encoding the ABCA4 protein, C-region, adeno-associated virus vector serotype 8 encoding the ABCA4 protein, N-region	Splicebio S.L.	Treatment of inherited retinal dystrophies due to dysfunction in the ABCA4 gene	30/01/2023 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
Humanised IgG4 monoclonal antibody against active complement component 1, subcomponent s	Sanofi Winthrop Industrie	Treatment of chronic inflammatory demyelinating polyneuropathy	26/01/2023 20/02/2023 20/04/2023 (59 days/27 days)	• 25/04/2023 • 22/05/2023
Exenatide	Boyd Consultants Limited	Treatment of moderate and severe closed traumatic brain injury	26/01/2023 20/02/2023 17/05/2023 (86 days/26 days)	• 25/05/2023 • 20/06/2023
Doruxapapogene ralaplasmid	PHARA	Treatment of recurrent respiratory papillomatosis	26/01/2023 20/02/2023 20/04/2023 (59 days/27days)	• 25/04/2023 • 22/05/2023
Idronoxil	CATS Consultants GmbH	Treatment of soft tissue sarcoma	26/01/2023 20/02/2023 20/04/2023 (59 days/27days)	• 25/04/2023 • 22/05/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP - Submission - Start date - Opinion - Active time	European Commission - Opinion received - Date of decision
[(2S,3S,4E,6S,7R,10R)-7,10-dihydroxy-3,7-dimethyl-12-oxo-2-[(2E,4E,6R)-6-pyridin-2-ylhepta-2,4-dien-2-yl]-1-oxacyclododec-4-en-6-yl]4-methylpiperazine-1-carboxylate	Voisin Consulting Life Sciences	Treatment of myelodysplastic syndromes	26/01/2023 20/02/2023 17/05/2023 (86 days/26 days)	25/05/2023 20/06/2023
Fingolimod	Consorcio Centro De Investigacion Biomedica En Red	Treatment of hypomyelinating leukodystrophy-18	25/01/2023 20/02/2023 20/04/2023 (59 days/27days)	25/04/2023 22/05/2023
Aspacytarabine	Granzer Regulatory Consulting & Services GmbH	Treatment of myelodysplastic syndromes	24/01/2023 20/02/2023 20/04/2023 (59 days/27days)	25/04/2023 22/05/2023
Adeno-associated virus serotype 9 expressing a transcription factor for the <i>SCN1A</i> gene	Pharma Gateway AB	Treatment of Dravet syndrome	24/01/2023 20/02/2023 20/04/2023 (59 days/27days)	25/04/2023 22/05/2023
Pemafibrate	Kowa Pharmaceutical Europe GmbH	Treatment of primary biliary cholangitis	23/01/2023 22/03/2023 15/06/2023 (85 days/29 days)	26/06/2023 25/07/2023
2-((2-fluoro-4-iodophenyl)amino)-N-(2-hydroxyethoxy)-1-methyl-1H-pyrrolo[2,3-b]pyridine-3-carboxamide	CATS Consultants GmbH	Treatment of neurofibromatosis type 1	23/01/2023 20/02/2023 20/04/2023 (59 days/27days)	25/04/2023 22/05/2023
Autologous CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector encoding the interferon alpha-2 gene	Genenta Science S.p.A.	Treatment of glioma	20/01/2023 20/02/2023 17/05/2023 (86 days/26 days)	25/05/2023 20/06/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Efzofitimid	FGK Representative Service GmbH	Treatment of systemic sclerosis	18/01/2023 20/02/2023 17/05/2023 (86 days/26 days)	• 25/05/2023 • 20/06/2023
Autologous blood-derived tumour and hypoxia educated macrophages	Hemera S.r.l.	Treatment of spinal cord injury	16/01/2023 20/02/2023 20/04/2023 (59 days/27 days)	• 25/04/2023 • 22/05/2023
Evorpacept	Alx Oncology Limited	Treatment of gastric cancer	22/12/2022 22/03/2023 17/05/2023 (56 days/26 days)	• 25/05/2023 • 20/06/2023
2-{4-[4-(4-{5-[(1S)-1-amino-1-(4-fluorophenyl)ethyl]pyrimidin-2-yl}piperazin-1-yl)pyrrolo[2,1-f][1,2,4]triazin-6-yl]-1H-pyrazol-1-yl}ethan-1-ol	Blueprint Medicines (Netherlands) B.V.	Treatment of mastocytosis	06/12/2022 25/01/2023 23/03/2023 (57 days/24 days)	• 28/03/2023 • 21/04/2023
Govorestat	Veristat Spain S.L.	Treatment of Charcot-Marie-Tooth disease	05/12/2022 25/01/2023 20/04/2023 (85 days/27 days)	• 25/04/2023 • 22/05/2023
Bortezomib	Accord Healthcare S.L.U.	Treatment of patients with light chain (AL) amyloidosis	05/12/2022 22/03/2023 05/10/2023 (197 days/26days)	• 26/06/2023 • 08/11/2023
Escherichia coli, strain Nissle 1917, expressing high affinity phenylalanine transporter, modified phenylalanine ammonia lyase (S92G, H133M, I167K, L432I, V470A) and L-amino acid deaminase	Orphix Consulting GmbH	Treatment of hyperphenylalaninaemia	05/12/2022 25/01/2023 23/03/2023 (56 days/24 days)	• 28/03/2023 • 21/04/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Lurbinectedin	Pharma Mar S.A.	Treatment of soft tissue sarcoma	02/12/2022 25/01/2023 23/03/2023 (57 days/24 days)	• 28/03/2023 • 21/04/2023
Humanised IgG1 kappa fragment antibody targeting Tfr1 conjugated to P125 oligonucleotide	Pharma Gateway AB	Treatment of myotonic disorders	02/12/2022 25/01/2023 20/04/2023 (85 days/27 days)	• 25/04/2023 • 22/05/2023
Adeno-associated viral vector serotype 1 containing the 3' portion of human <i>OTOF</i> gene, Adeno-associated viral vector serotype 1 containing the 5' portion of human <i>OTOF</i> gene	Boyd Consultants Limited	Treatment of otoferlin gene-mediated hearing loss	25/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
5,5-dimethyl-3-[2-(7-methylspiro[2H-benzofuran-3,1'-cyclopropane]-4-yl)oxypyrimidin-5-yl]imidazolidine-2,4-dione	Quality Regulatory Clinical Ireland Limited	Treatment of fragile X syndrome	24/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
Vactosertib	Sirius Regulatory Consulting Eu Limited	Treatment of osteosarcoma	24/11/2022 22/03/2023 15/02/2023 (85 days/29 days)	• 26/06/2023 • 25/07/2023
Indole-3-carboxaldehyde	Adienne S.r.l.	Treatment of primary CTLA-4 checkpoint related immunodeficiencies	24/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
Bezuclastinib	FGK Representative Service GmbH	Treatment of gastrointestinal stromal tumours	24/11/2022 04/01/2023 16/02/2023	• 21/02/2023 • 20/03/2023
Anagrelide hydrochloride monohydrate	Sartar Therapeutics Ltd.	Treatment of gastrointestinal stromal tumours	23/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
6-(4-(1-amino-3-hydroxycyclobutyl)phenyl)-1-ethyl-7-phenyl-1H-pyrido[2,3-b][1,4]oxazin-2(3H)-one, L-tartrate salt	FGK Representative Service GmbH	Treatment of hereditary haemorrhagic telangiectasia	23/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
Fenfluramine hydrochloride	Zogenix ROI Limited	Treatment of CDKL5 deficiency disorder	22/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
Autologous adipose-derived mesenchymal stem cells	nicole BEARD	Treatment of oesophageal atresia	17/11/2022 25/01/2023 23/03/2023 (57 days/24 days)	• 28/03/2023 • 21/04/2023
Guanabenz acetate	Amsterdam UMC	Treatment of vanishing white matter disease	10/11/2022 04/01/2023 16/02/2023 (43 days/27 days)	• 21/02/2023 • 20/03/2023
Autologous CD34+ cells transduced with a lentiviral vector containing the human GAA gene	Erasmus Universitair Medisch Centrum Rotterdam (Erasmus MC)	Treatment of glycogen storage disease type II (Pompe's disease)	26/10/2022 23/11/2022 19/01/2023 (54 days/20 days)	• 26/01/2023 • 15/02/2023
(2S,3R,4R,5S)-1-[5-(2-Fluoro-biphenyl-4-ylmethoxy)-pentyl]-2-hydroxymethyl-piperidine-3,4,5-triol	Azafaros B.V.	Treatment of GM2 gangliosidosis	26/10/2022 24/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Fosmanogepix	Pfizer Europe MA EEIG	Treatment of scedosporiosis	26/10/2022 23/11/2022 16/02/2023 (84 days/27 days)	• 21/02/2023 • 20/03/2023
Fosmanogepix	Pfizer Europe MA EEIG	Treatment of fusariosis	26/10/2022 24/11/2022	• 26/01/2023 • 15/02/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			19/01/2023 (62 days/20 days)	
Fosmanogepix	Pfizer Europe MA EEIG	Treatment of mucormycosis	26/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Fosmanogepix	Pfizer Europe MA EEIG	Treatment of lomentosporiosis	26/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Crisdesalazine	MDC RegAffairs GmbH	Treatment of amyotrophic lateral sclerosis	25/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Melatonin	ESPL Regulatory Consulting Limited	Treatment of perinatal asphyxia	24/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Isotretinoin	Granzer Regulatory Consulting & Services GmbH	Treatment of recessive X-linked ichthyosis	24/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Bitopertin	Disc Medicine B.V.	Treatment of erythropoietic protoporphyria	21/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
H-L-tryphophanyl-L-seryl-glycyl-L-tryptophanyl-L-seryl-L-seryl-L-cysteinyl-L-seryl-L-arginyl-L-seryl-L-cysteinyl-glycyl-OH (disulfide bond), acetate salt	Axoltis Pharma	Treatment of spinal cord injury	21/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 9 expressing fukutin-related protein	Brainvectis	Treatment of limb-girdle muscular dystrophy	19/10/2022 24/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Humanised IgG1 monoclonal antibody against TfR1 conjugated to double stranded siRNA oligonucleotide against DUX4 mRNA via a non-cleavable linker	MWB Consulting	Treatment of facioscapulohumeral muscular dystrophy	18/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Patidistrogene bexoparvovec	Sarepta Therapeutics Ireland Limited	Treatment of limb-girdle muscular dystrophy	18/10/2022 23/11/2022 19/01/2023 (56 days/20 days)	• 26/01/2023 • 15/02/2023
Autologous CD34+ cells transduced with a lentiviral vector encoding the human <i>NCF1</i> gene	3R Pharma Consulting GmbH	Treatment of chronic granulomatous disease	28/09/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023
N1,N14-diethyl-3S,12S-dihydroxyhomospermine tetrahydrochloride	PPD Bulgaria EOOD	Treatment of pancreatic cancer	28/09/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023
(3beta,24S)-25,25,25-trifluoro-3-methyl-26,27-dinorergost-5-ene-3,24-diol	Raremoon Consulting Esp S.L.	Treatment of Huntington's disease	27/09/2022 26/10/2022 19/01/2022 (84 days/20 days)	• 26/01/2023 • 15/02/2023
Opelconazole	Tmc Pharma (EU) Limited	Treatment of invasive aspergillosis	27/09/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 2 containing the human <i>SLC6A3</i> gene	FGK Representative Service GmbH	Treatment of dopamine transporter deficiency syndrome	27/09/2022 26/10/2022 08/12/2022	• 14/12/2022 • 13/01/2023
Efzofitimod	FGK Representative Service GmbH	Treatment of sarcoidosis	27/09/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023
Retifanlimab	Incyte Biosciences Distribution B.V.	Treatment of Merkel cell carcinoma	23/09/2022 26/10/2022 08/12/2022	• 14/12/2022 • 13/01/2023
Autologous hematopoietic cells genetically modified with a lentiviral vector containing the human <i>RAG2</i> gene	Academisch Ziekenhuis Leiden	Treatment of recombination-activating gene 2 deficient severe combined immunodeficiency	19/09/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023
Nanatinostat, valganciclovir	Pharma Gateway AB	Treatment of diffuse large B-cell lymphoma	30/08/2022 14/09/2022 08/12/2022 (84 days/30 days)	• 14/12/2022 • 13/01/2023
3-(1-(2',3'-dimethoxy-[1,1'-biphenyl]-4-yl)-1H-1,2,3-triazol-4-yl)benzoic acid	Chemicare S.r.l.	Treatment of Duchenne muscular dystrophy	30/08/2022 14/09/2022 08/12/2022 (84 days/30 days)	• 14/12/2022 • 13/01/2023
Humanised IgG1 monoclonal antibody against annexin-A1	Rapport Global Strategic Services Ireland Limited	Treatment of pancreatic cancer	26/08/2022 26/10/2022 19/01/2023 (84 days/20 days)	• 26/01/2023 • 15/02/2023
Vorasidenib hemicitrate hemihydrate	Les Laboratoires Servier	Treatment of glioma	22/08/2022 26/10/2022 08/12/2022 (42 days/30 days)	• 14/12/2022 • 13/01/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Octreotide acetate	Amryt Pharmaceuticals Designated Activity Company	Treatment of carcinoid syndrome	23/06/2022 14/09/2022 08/12/2022 (84 days/30 days)	• 14/12/2022 • 13/01/2023

Annex 15 – HMPC European Union herbal monographs in 2023

Abbreviations: TU – traditional use

WEU – well established use

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/32402/2022	Cnici benedicti herba	20/09/2023 / TU
Revision		
EMA/HMPC/241320/2021	Juniperi pseudo-fructus (galbulus)	15/03/2023 / TU
EMA/HMPC/367011/2021	Fumariae herba	12/05/2023 / TU
EMA/HMPC/596130/2022	Hippocastani cortex	22/11/2023 / TU

European Union List entries – adopted for transfer to European Commission

None in 2023

European Union herbal monographs – Draft for consultation

Reference number	Document title	Adoption / Outcome
First Assessment		
	None	
Revision		
EMA/HMPC/596130/2022	Hippocastani cortex	25/01/2023 / TU
EMA/HMPC/27744/2023	Ginseng radix	12/05/2023 / TU
EMA/HMPC/24177/2023	Rhodiola roseae rhizoma et radix	19/07/2023 / TU
EMA/HMPC/648100/2022	Pelargonii radix	20/09/2023 / TU

European Union List entries – Draft for consultation

None in 2023

Monograph/ list entry review reports

Reference number	Document title	Adoption / Outcome
Final decision		
EMA/HMPC/877234/2022	Crataegi folium cum flore	15/03/2023 / revision required*
EMA/HMPC/709373/2022	Helichrysi flos	15/03/2023 / no revision
EMA/HMPC/885024/2022	Ginkgo folium	12/05/2023 / revision required*
EMA/HMPC/26468/2023	Matricariae flos	12/05/2023 / revision required*

Reference number	Document title	Adoption / Outcome
EMA/HMPC/883967/2022	Myrtilli fructus siccus	12/05/2023 / no revision
EMA/HMPC/883967/2022	Myrtilli fructus recens	12/05/2023 / no revision
EMA/HMPC/883123/2022	Ricini oleum	12/05/2023 / no revision
EMA/HMPC/767595/2022	Rubi idaei folium	12/05/2023 / no revision
EMA/HMPC/261330/2022	Sisymbrii officinalis herba	12/05/2023 / no revision
EMA/HMPC/104943/2023	Capsici fructus	19/07/2023 / no revision
EMA/HMPC/765808/2022	Melaleucae aetheroleum	19/07/2023 / no revision
EMA/HMPC/765801/2022	Origani majoranae herba	19/07/2023 / no revision
EMA/HMPC/767588/2022	Ononidis radix	20/09/2023 / revision required*
EMA/HMPC/303882/2023	Pilosellae herba	20/09/2023 / revision required*
EMA/HMPC/769368/2022	Polygoni avicularis herba	20/09/2023 / revision required*
EMA/HMPC/321020/2023	Pruni africanae cortex	20/09/2023 / no revision
EMA/HMPC/320996/2023	Rosae flos	20/09/2023 / no revision
EMA/HMPC/320997/2023	Sideritis herba	20/09/2023 / no revision
HMPC/308522/2023	Fragariae folium	22/11/2023 / revision required*

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

Public statements

None in 2023

Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2023

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

P: P, RP: PIP refused, PM: PIP PM, RPM: PIP RPM, W: product specific waiver agreed, RW: product specific waiver refused

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Rosuvastatin (calcium) / fenofibrate	N/A	W	Cardiovascular Diseases	Althera Laboratories Ltd	12/01/2023	P/0001/2023
Ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals (Ireland) Ltd	06/01/2023	P/0002/2023
Humanized igg1 monoclonal antibody against GD2 (naxitamab)	DANYELZA	P	Oncology	Y-mAbs Therapeutics A/S	30/01/2023	P/0003/2023
Perflubutane	Sonazoid	P	Diagnostic / Oncology	GE Healthcare AS	30/01/2023	P/0004/2023
Icerguastat	N/A	W	Neurology	InFlectis BioScience S.A.S	30/01/2023	P/0005/2023
Fenofibrate / rosuvastatin	N/A	W	Cardiovascular Diseases	Laboratoires SMB s.a.	30/01/2023	P/0006/2023
Nedosiran	Rivfloza	PM	Uro-nephrology	Novo Nordisk A/S	10/02/2023	P/0007/2023
Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded (MC0518)	N/A	PM	Immunology- Rheumatology- Transplantation	medac Gesellschaft für klinische Spezialpräparate mbH	30/01/2023	P/0008/2023
Calcium chloride / aprotinin / thrombin / fibrinogen	Silketal, Kolfib	W	Other	Kedrion S.p.A.	31/01/2023	P/0009/2023
Avatrombopag (maleate)	Doptelet	PM	Haematology- Hemostaseology	Swedish Orphan Biovitrum AB	31/01/2023	P/0010/2023
Ziltivekimab	N/A	W	Cardiovascular Diseases	Novo Nordisk A/S	31/01/2023	P/0011/2023
Macitentan	Opsumit	PM	Cardiovascular Diseases	Janssen-Cilag International NV	31/01/2023	P/0012/2023
Efgartigimod alfa	N/A	W	Dermatology	argenx BV	31/01/2023	P/0013/2023
Retifanlimab	Zynyz	W	Oncology	Incyte Biosciences Distribution B.V.	31/01/2023	P/0014/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Landiolol (hydrochloride)	Rapibloc, Landiobloc, Raploc, Runrapiq	W	Cardiovascular Diseases	AOP Orphan Pharmaceuticals GmbH	31/01/2023	P/0015/2023
Evoncabtagene pazurgedleucel	N/A	PM	Oncology	CRISPR Therapeutics AG	31/01/2023	P/0016/2023
Human, recombinant, non-fucosylated igg1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab)	N/A	PM	Dermatology	Amgen Europe B.V.	31/01/2023	P/0017/2023
SARS-cov-2 virus, beta-propiolactone inactivated adjuvanted with cpg 1018 (VLA2001)	COVID-19 Vaccine (inactivated, adjuvanted) Valneva suspension for injection	PM	Vaccines	Valneva Austria GmbH	31/01/2023	P/0018/2023
Zuranolone	N/A	PM	Psychiatry	Biogen Netherlands B.V.	31/01/2023	P/0019/2023
Azelastine (hydrochloride) / Mometasone (furoate)	N/A	PM	Oto-rhino-laryngology	Lek Pharmaceuticals d.d.	31/01/2023	P/0020/2023
Asundexian	N/A	P	Cardiovascular Diseases	Bayer AG	31/01/2023	P/0021/2023
Thiocolchicoside / diclofenac	N/A	W	Pain	Verisfield Single Member S.A.	31/01/2023	P/0022/2023
Avexitide (acetate)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	EigerBio Europe Limited	31/01/2023	P/0023/2023
Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material (YTB323)	N/A	P	Oncology	Novartis Europharm Limited	31/01/2023	P/0024/2023
Eftilagimod alpha	N/A	W	Oncology	Immutep SAS	31/01/2023	P/0025/2023
Eftilagimod alpha	N/A	W	Oncology	Immutep S.A.S	31/01/2023	P/0026/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Cobicistat / atazanavir (sulphate)	EVOTAZ	PM	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	31/01/2023	P/0027/2023
Satralizumab	Enspryng	P	Neurology	Roche Registration GmbH	31/01/2023	P/0028/2023
Tenofovir alafenamide / emtricitabine / cobicistat / darunavir	Symtuza	PM	Infectious Diseases	Janssen-Cilag International NV	31/01/2023	P/0029/2023
Galcanezumab	Emgality	PM	Neurology	Eli Lilly and Company Limited	31/01/2023	P/0030/2023
Isoflurane	Sedaconda and associated names	PM	Neonatology - Paediatric Intensive Care	Sedana Medical AB	31/01/2023	P/0031/2023
Setanaxib	N/A	W	Gastroenterology- Hepatology	Calliditas Therapeutics France SAS	31/01/2023	P/0032/2023
Tirzepatide	N/A	P	Other	Eli Lilly and Company	31/01/2023	P/0033/2023
Triheptanoin	Dojolvi	P	Endocrinology- Gynaecology- Fertility- Metabolism	Ultragenyx Germany GmbH	31/01/2023	P/0034/2023
Cyanocobalamin / pyridoxine (hydrochloride) / thiamine (hydrochloride) / Diclofenac (sodium)	N/A	W	Pain	Verisfield Single Member S.A.	31/01/2023	P/0035/2023
Orphenadrine (citrate) / Diclofenac	N/A	W	Pain	Verisfield Single Member S.A.	31/01/2023	P/0036/2023
Lanadelumab	TAKHZYRO	W	Other	Takeda Pharmaceuticals International AG Ireland Branch	31/01/2023	P/0037/2023
Lamivudine / abacavir / dolutegravir	TRIUMEQ	PM	Infectious Diseases	ViiV Healthcare UK Limited	31/01/2023	P/0038/2023
Cobicistat / darunavir	REZOLSTA	PM	Infectious Diseases	Janssen-Cilag International NV	31/01/2023	P/0039/2023
Depemokimab	N/A	P	Haematology- Hemostaseology	GlaxoSmithKline Trading Services Limited	06/02/2023	P/0040/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
2'-MOE antisense oligonucleotide targeting apoc-III (ISIS 678354)	N/A	P	Cardiovascular Diseases	Ionis Pharmaceuticals, Inc	31/01/2023	P/0041/2023
Acetylsalicylic acid / Rivaroxaban	N/A	W	Haematology-Hemostaseology	Alfred E. Tiefenbacher (GmbH & Co. KG)	31/01/2023	P/0042/2023
Tetanus toxoid	Tetana	W	Vaccines	IBSS BIOMED S.A.	31/01/2023	P/0043/2023
Troriluzole (hydrochloride)	N/A	P	Neurology	Biohaven Pharmaceutical Ireland DAC	31/01/2023	P/0044/2023
Fianlimab	N/A	P	Oncology	Regeneron Ireland DAC	31/01/2023	P/0045/2023
Exagamglogene autotemcel	Casgevy	PM	Haematology-Hemostaseology	Vertex Pharmaceuticals (Ireland) Limited	24/01/2023	P/0046/2023
Cefepime / enmetazobactam (aai101)	EXBLIFEP	PM	Infectious Diseases	Allegra Therapeutics GmbH	24/01/2023	P/0047/2023
Garadacimab	N/A	PM	Haematology-Hemostaseology	CSL Behring GmbH	30/01/2023	P/0048/2023
Neisseria meningitidis serogroup B fhbp subfamily B / Neisseria meningitidis serogroup B fhbp subfamily A / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein	N/A	PM	Vaccines	Pfizer Europe MA EEIG	30/01/2023	P/0055/2023
Crovalimab	N/A	PM	Haematology-Hemostaseology	Roche Registration GmbH	30/01/2023	P/0056/2023
Methylphenidate (hydrochloride)	Arxbium	PM	Neurology	Laboratorios Lesvi, S.L.	24/01/2023	P/0057/2023
Respiratory syncytial virus stabilised prefusion f subunit vaccine	Abrysvo	PM	Vaccines	Pfizer Europe MA EEIG	24/01/2023	P/0058/2023
Hydrochlorothiazide / Amlodipine / candesartan (cilexetil)	N/A	W	Cardiovascular Diseases	Adamed Pharma S.A.	21/02/2023	P/0059/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Afamelanotide	SCENESSE®	PM	Other	Clinuvel Europe Limited	03/02/2023	P/0060/2023
Cariprazine (hydrochloride)	Reagila	RPM	Psychiatry	Gedeon Richter Plc.	24/02/2023	P/0061/2023
Fordadistrogene movaparvovec	N/A	PM	Neurology	Pfizer Europe MA EEIG	24/02/2023	P/0062/2023
Baricitinib	Olumiant	PM	Immunology- Rheumatology- Transplantation	Eli Lilly and Company Limited	03/03/2023	P/0063/2023
Insulin lispro (BC222)	BC222 insulin lispro	P	Endocrinology- Gynaecology- Fertility- Metabolism	ADOCIA	10/03/2023	P/0064/2023
Cemdisiran	cemdisiran	P	Neurology	Regeneron Ireland DAC	10/03/2023	P/0065/2023
Varicella virus OKA strain (live, attenuated)	N/A	W	Vaccines / Infectious Diseases	GlaxoSmithKline Biologicals SA	10/03/2023	P/0066/2023
Camlipixant	N/A	W	Pneumology - Allergology	GSK Trading Services Limited	10/03/2023	P/0067/2023
Budesonide / glycopyrronium bromide / formoterol (fumarate)	Trixeo aerosphere	PM	Pneumology - Allergology	AstraZeneca AB	10/03/2023	P/0068/2023
Gilteritinib (as fumarate)	Xospata	PM	Oncology / Haematology- Hemostaseology	Astellas Pharma Europe B.V.	10/03/2023	P/0069/2023
Lumasiran	Oxlumo	PM	Uro-nephrology	Alnylam UK Limited	10/03/2023	P/0070/2023
Drospirenone / estetrol	Drovelis, Lydisilka	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Estetra SRL	10/03/2023	P/0071/2023
Humanised IgG2 monoclonal antibody against interleukin-6 (RO7200220)	N/A	P	Ophthalmology	Roche Registration GmbH	10/03/2023	P/0072/2023
Ibutamoren mesilate	N/A	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Lumos Pharma, Inc.	10/03/2023	P/0073/2023
(S)-2-hydroxy-6-((4-(2-(2-hydroxyethyl) nicotinoyl) morpholin-3-yl) methoxy) benzaldehyde	N/A	P	Haematology- Hemostaseology	Pfizer Europe MA EEIG	10/03/2023	P/0074/2023

Active substance(s)	Invented name	PDco Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Eladocagene exuparvovec	Upstaza	PM	Neurology	PTC Therapeutic International Limited	10/03/2023	P/0075/2023
Clascoterone	N/A	P	Dermatology	Cassiopea S.p.A	10/03/2023	P/0076/2023
Pozelimab	pozelimab	P	Neurology	Regeneron Ireland DAC	10/03/2023	P/0077/2023
Begelomab	BEGESAND	PM	Other / Immunology- Rheumatology- Transplantation	ADIENNE S.r.l SU	10/03/2023	P/0078/2023
Inotuzumab ozogamicin	Besponsa	PM	Oncology / Haematology- Hemostaseology	Pfizer Europe MA EEIG	10/03/2023	P/0079/2023
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	13/03/2023	P/0080/2023
Enpatoran	N/A	W	Immunology- Rheumatology- Transplantation / Dermatology	Merck Europe B.V.	10/03/2023	P/0081/2023
Varicella virus OKA strain (live, attenuated) / Rubella virus Wistar RA 27/3 strain (live, attenuated) / Measles virus Schwarz strain (live, attenuated) / Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated)	N/A	W	Vaccines / Infectious Diseases	GlaxoSmithKline Biologicals SA	10/03/2023	P/0082/2023
Upifitamab rilsodotin	N/A	W	Oncology	Mersana Therapeutics Inc.	10/03/2023	P/0083/2023
Lutetium (177Lu) edotreotide	N/A	P	Oncology	ITM Solucin GmbH	10/03/2023	P/0084/2023
Danuglipron	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism	Pfizer Europe MA EEIG	10/03/2023	P/0085/2023
Risdiplam	Evrysdi	PM	Neurology	Roche Registration GmbH	10/03/2023	P/0086/2023
Evinacumab	Evkeeza	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Ultragenyx Germany GmbH	10/03/2023	P/0087/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Selexipag	Upravi	PM	Other	Janssen-Cilag International NV	10/03/2023	P/0088/2023
Sotorasib	Lumykras	W	Oncology	Amgen Europe BV	10/03/2023	P/0089/2023
Relebactam (MK-7655A) / cilastatin sodium / imipenem Monohydrate	RECARBRIO	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	10/03/2023	P/0090/2023
Quizartinib	VANFLYTA	PM	Oncology	Daiichi Sankyo Europe GmbH	10/03/2023	P/0091/2023
Zilebesiran (sodium)	N/A	P	Cardiovascular Diseases	Alnylam Netherlands B.V.	10/03/2023	P/0092/2023
Brivaracetam	Briviact (in Italy: Nubriveo)	PM	Neurology	UCB Pharma S.A.	10/03/2023	P/0093/2023
Obecabtagene autoleucel	N/A	P	Oncology	Autolus GmbH	10/03/2023	P/0094/2023
Hydroxypropyl- β -cyclodextrin	Trappsol@Cycl o™	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Cyclo Therapeutics Inc	10/03/2023	P/0095/2023
Pembrolizumab	KEYTRUDA	W	Oncology	Merck, Sharp & Dohme (Europe) Inc	10/03/2023	P/0096/2023
Crinecerfont	N/A	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Neurocrine Therapeutics Ltd.	10/03/2023	P/0097/2023
Baloxavir marboxil	Xofluza	PM	Infectious Diseases	Roche Registration GmbH	10/03/2023	P/0098/2023
Clazakizumab	N/A	W	Cardiovascular Diseases / Uro-nephrology	CSL Behring GmbH	10/03/2023	P/0099/2023
Glucagon analogue linked to a human immunoglobulin Fc fragment	N/A	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Hanmi Pharm. Co., Ltd.	10/03/2023	P/0100/2023
Doxazosin (mesylate) / Finasteride	N/A	W	Uro-nephrology	Midas Pharma GmbH	10/03/2023	P/0101/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Tofacitinib	XELJANZ	PM	Immunology- Rheumatology- Transplantation	Pfizer Europe MA EEIG	24/03/2023	P/0102/2023
Defatted powder of peanuts	Palforzia	PM	Pneumology - Allergology	Aimmune Therapeutics Inc	24/03/2023	P/0103/2023
Oritavancin (diphosphate)	Tenkasi	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	13/04/2023	P/0104/2023
Obeticholic acid	Ocaliva	PM	Gastroenterology- Hepatology	Advanz Pharma Limited	13/04/2023	P/0105/2023
Patiromer calcium	Veltassa	PM	Other	Vifor Fresenius Medical Care Renal Pharma France	14/04/2023	P/0106/2023
Carfilzomib	Kyprolis	PM	Oncology	Amgen Europe BV	14/04/2023	P/0107/2023
Efzofitimid	N/A	W	Immunology- Rheumatology- Transplantation	FGK Representative Service GmbH	14/04/2023	P/0108/2023
Fitusiran	Fitusiran	PM	Haematology- Hemostaseology	Sanofi B.V.	14/04/2023	P/0109/2023
Remimazolam (besylate)	Byfavo	PM	Anaesthesiology	PAION Deutschland GmbH	14/04/2023	P/0110/2023
Acalabrutinib	Calquence	W	Oncology	Acerta Pharma, BV	14/04/2023	P/0111/2023
Tedizolid phosphate	SIVEXTRO	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/04/2023	P/0112/2023
Filgotinib	Jyseleca	PM	Immunology- Rheumatology- Transplantation	Galapagos NV	13/04/2023	P/0113/2023
Satralizumab	Enspryng	PM	Neurology	Roche Registration GmbH	13/04/2023	P/0114/2023
Botaretigene sparoparvovec	N/A	PM	Ophthalmology	Janssen-Cilag International NV Turnhoutseweg 30	13/04/2023	P/0115/2023
Meningococcal group Y oligosaccharide conjugated to Corynebacterium diptheriae CRM197 protein (meny-CRM) / Meningococcal group W-135 oligosaccharide conjugated to	Menveo	W	Vaccines	GlaxoSmithKline Biologicals Srl	13/04/2023	P/0116/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Corynebacterium diphtheriae CRM197 protein (menw-CRM) / Meningococcal group C oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (menc-CRM) / Meningococcal group A oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (mena-CRM)						
Pudexacianinium chloride	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism / Diagnostic / Oncology / Gastroenterology- Hepatology / Uro- nephrology	Astellas Pharma Europe BV	14/04/2023	P/0117/2023
Vilobelimab	N/A	P	Infectious Diseases	InflaRx GmbH	13/04/2023	P/0118/2023
Cilgavimab (AZD1061) / tixagevimab (AZD8895)	Evusheld	P	Infectious Diseases	AstraZeneca AB	13/04/2023	P/0119/2023
Finasteride / Tadalafil	Prostabam	W	Uro-nephrology	Dr. Pfleger Arzneimittel GmbH	13/04/2023	P/0120/2023
Lamivudine / Dolutegravir	Dovato	PM	Infectious Diseases	ViiV Healthcare UK Limited	14/04/2023	P/0121/2023
Acoltremon	N/A	W	Ophthalmology	Aerie Pharmaceuticals Ireland, Ltd	14/04/2023	P/0122/2023
Denosumab	Prolia, Xgeva	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Amgen Europe B.V.	14/04/2023	P/0123/2023
Eculizumab	SOLIRIS	W	Neurology	Alexion Europe SAS	14/04/2023	P/0124/2023
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1 (INZ-701)	N/A	P	Other / Endocrinology- Gynaecology- Fertility- Metabolism /	Inozyme Pharma Ireland Limited	18/04/2023	P/0125/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
			Cardiovascular Diseases			
Gadopiclenol	Elucirem	PM	Diagnostic	Guerbet	28/04/2023	P/0126/2023
Sodium ({(2S)-1,4-bis[2-(4-chloro-3-fluorophenoxy)acetamido]bicyclo[2.2.2]octan-2-yl}oxy)methyl hydrogen phosphate-2-amino-2-(hydroxymethyl)propane-1,3-diol (1/1/1)	N/A	W	Neurology	Calico Life Sciences LLC	14/04/2023	P/0127/2023
Ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology-Hemostaseology	Alexion Europe SAS	14/04/2023	P/0128/2023
Utreloxastat	N/A	W	Neurology	PTC Therapeutics International	13/04/2023	P/0129/2023
Zilovetamab vedotin	N/A	P	Oncology	Merck Sharp & Dohme (Europe) Inc.	13/04/2023	P/0130/2023
Temozolomide	N/A	PM	Oncology	Accord Healthcare S.L.U.	13/04/2023	P/0131/2023
Remibrutinib	N/A	PM	Dermatology	Novartis Europharm Limited	13/04/2023	P/0132/2023
Selpercatinib	Retsevmo	PM	Oncology	Eli Lilly and Company	13/04/2023	P/0133/2023
Lebrikizumab	N/A	PM	Dermatology	Eli Lilly and Company Limited	13/04/2023	P/0134/2023
Osilodrostat	ISTURISA	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Recordati Rare Diseases SARL	14/04/2023	P/0135/2023
Delgocitinib	N/A	PM	Dermatology	LEO Pharma A/S	14/04/2023	P/0136/2023
Lutetium 177-labelled radiohybrid prostate-specific membrane antigen-10.1 ((177Lu) rhpsma-10.1)	N/A	W	Oncology	Blue Earth Therapeutics Ltd	14/04/2023	P/0137/2023
(3S)-3-(5-{4-[(1-{4-[(1R,2S)-6-hydroxy-2-phenyl-1,2,3,4-tetrahydronaphthalen-1-yl]phenyl}piperidin-4-yl)methyl]piperazin-1-yl}-1-oxo-1,3-dihydro-2H-isoindol-2-yl)piperidine-2,6-dione	N/A	W	Oncology	Pfizer Europe MA EEIG	14/04/2023	P/0138/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
AV2-cVLP-RBD SARS-CoV-2 (ABNCoV2)	VIDKAPSI	P	Vaccines / Infectious Diseases	Bavarian Nordic A/S	14/04/2023	P/0139/2023
Ciclosporin	N/A	W	Ophthalmology	Novaliq GmbH	14/04/2023	P/0140/2023
Zilucoplan	zilqivik (pending CHMP adoption), zilbrysq (pending CHMP adoption)	PM	Other / Neurology	UCB Pharma SA	14/04/2023	P/0141/2023
Rimegepant	Vydura	PM	Neurology	Pfizer Europe MA EEIG	14/04/2023	P/0142/2023
Gadopiclenol	Elucirem	PM	Diagnostic	Guerbet	21/04/2023	P/0143/2023
Isatuximab	Sarclisa	PM	Oncology	Sanofi-Aventis Recherche & Développement	21/04/2023	P/0144/2023
Sparsentan	N/A	PM	Uro-nephrology	Vifor (International) AG	21/04/2023	P/0145/2023
Acetyl-L-leucine ((s)-(acetylamino)-4-methylpentanoic acid) (IB001)	N/A	PM	Neurology	IntraBio Ltd.	21/04/2023	P/0146/2023
Binimetinib	Mektovi	PM	Oncology	Pierre Fabre Médicament	21/04/2023	P/0147/2023
Encorafenib	Braftovi	PM	Oncology	Pierre Fabre Médicament	21/04/2023	P/0148/2023
Anifrolumab	Saphnelo	PM	Immunology-Rheumatology-Transplantation	AstraZeneca AB	21/04/2023	P/0149/2023
Repotrectinib	N/A	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	26/04/2023	P/0150/2023
2-amino-5-(carbamylamino)pentanoic acid (L-citrulline)	N/A	P	Haematology-Hemostaseology	ASK Pharmaceuticals GmbH (ASK)	24/04/2023	P/0151/2023
Elasomeran/davesomeran / elasomeran/imelsomeram / elasomeran	Spikevax bivalent Original/Omicr	PM	Vaccines	Moderna Biotech Spain, S.L.	24/04/2023	P/0152/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
	on BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax					
Pembrolizumab / favezelimab	N/A	P	Oncology	Merck Sharp & Dohme (Europe) Inc.	12/05/2023	P/0153/2023
N-(4-(4-amino-5-(3-fluoro-4-((4-methylpyrimidin-2-yl)oxy)phenyl)-7-methyl-7H-pyrrolo[2,3-d]pyrimidin-6-yl)phenyl)methacrylamide (hydrochloride) (RLY-4008)	N/A	W	Oncology	Relay Therapeutics Inc.	12/05/2023	P/0154/2023
Gepotidacin	N/A	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	12/05/2023	P/0155/2023
Valoctocogene roxaparvovec	Roctavian	PM	Haematology-Hemostaseology	BioMarin International Limited	12/05/2023	P/0156/2023
Indapamide / ramipril	N/A	W	Cardiovascular Diseases	Zakłady Farmaceutyczne Polpharma S.A.	12/05/2023	P/0157/2023
Ezetimibe / atorvastatin	N/A	W	Cardiovascular Diseases	Pharmaplot PC	12/05/2023	P/0158/2023
Efgartigimod alfa	Vyvgart	PM	Neurology	argenx BV	12/05/2023	P/0159/2023
Meloxicam / bupivacaine	ZYNRELEF	PM	Pain	Heron Therapeutics B.V.	12/05/2023	P/0160/2023
Thiocolchicoside / diclofenac	N/A	W	Pain	Verisfield Single Member S.A.	12/05/2023	P/0161/2023
Cariprazine hydrochloride	Reagila	PM	Psychiatry	Gedeon Richter Plc.	12/05/2023	P/0162/2023
Nipocalimab	N/A	W	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	15/05/2023	P/0163/2023
Iptacopan	N/A	PM	Other	Novartis Europharm Limited	15/05/2023	P/0164/2023
Idrevloride	N/A	PM	Pneumology - Allergology	Parion Sciences, Inc.	15/05/2023	P/0165/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain	N/A	PM	Gastroenterology- Hepatology	Boehringer Ingelheim International GmbH	15/05/2023	P/0166/2023
Autologous CD34+ hematopoietic stem and progenitor cells (hspcs) genetically modified with the lentiviral vector IDUA LVV, encoding for the human α -L-iduronidase (IDUA) gene (OTL-203)	N/A	PM	Other	Orchard Therapeutics (Netherlands) B.V.	15/05/2023	P/0167/2023
Albaconazole	N/A	P	Infectious Diseases	Palau Pharma, S.L.	15/05/2023	P/0168/2023
Palmitoyl-KSS-MHGDPTLHEYMLDLQPETT (HPV-16 E7 1-20) / Palmitoyl-KSS-YMLDLQPETT (HPV-16 E7 11-20) / Palmitoyl-KSS-GQAEPDRAHYNIVTF (HPV-16 E7 43-57) / Palmitoyl-KSS-KKLLMGTLGIVCPICSQKP(HPV-16 E7 82-98) / Palmitoyl-KSS-LLMGTLGIV (HPV-16 E7 82-90) /Palmitoyl-KSS-ELQTTIHDIIILECVYCKQQLL (HPV-16 E6 25-45) / [(2R)-2,3-bis[[(Z)-octadec-9-enoyl]oxy]propyl]-trimethylazanium chloride (R-DOTAP chloride)	N/A	W	Oncology	PDS Biotechnology Corp.	15/05/2023	P/0169/2023
Elosulfase alfa	Vimizim 1mg/ml concentrate for solution for infusion	PM	Endocrinology- Gynaecology- Fertility- Metabolism	BioMarin International Limited	15/05/2023	P/0170/2023
Romosozumab	EVENITY	PM	Endocrinology- Gynaecology- Fertility- Metabolism	UCB Pharma S.A.	15/05/2023	P/0171/2023
Migalastat (hydrochloride)	Galafold	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Amicus Therapeutics Europe Limited	15/05/2023	P/0172/2023
Benralizumab	Fasenra	PM	Pneumology - Allergology	AstraZeneca AB	15/05/2023	P/0173/2023
Pembrolizumab / vibostolimab	N/A	P	Oncology	Merck Sharp & Dohme (Europe) Inc.	15/05/2023	P/0174/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Lasmiditan	Rayvow	PM	Neurology	Eli Lilly and Company Limited	15/05/2023	P/0175/2023
Dasiglucagon	N/A	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Zealand Pharma A/S	15/05/2023	P/0176/2023
Tolvaptan	Samsca, Jinarc	PM	Endocrinology- Gynaecology- Fertility- Metabolism / Uro-nephrology	Otsuka Pharmaceutical Netherlands B.V.	15/05/2023	P/0177/2023
Itolizumab	Bmab600, EQ001	P	Immunology- Rheumatology- Transplantation	Biocon Pharma Malta-I Limited	15/05/2023	P/0178/2023
Finerenone	Kerendia	PM	Uro-nephrology	Bayer AG	17/05/2023	P/0179/2023
Recombinant humanized monoclonal antibody (immunoglobulin gamma-1 with kappa light chains, IgG1κ) directed against integrin αvβ8 produced in Chinese Hamster Ovary (CHO) cells	N/A	W	Oncology	Pfizer Europa MA EEIG	15/05/2023	P/0180/2023
1-((S)-4-((R)-7-(6-amino-4-methyl-3-(trifluoromethyl)pyridin-2-yl)-6-chloro-8-fluoro-2-(((S)-1-methylpyrrolidin-2-yl)methoxy)quinazolin-4-yl)-3-methylpiperazin-1-yl)prop- 2-en-1-one adipate	N/A	W	Oncology	Roche Registration GmbH	15/05/2023	P/0181/2023
2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting fused in sarcoma (FUS) pre-mRNA (ION363)	N/A	P	Neurology	Ionis Pharmaceuticals	15/05/2023	P/0182/2023
Maribavir	Livtensity	PM	Infectious Diseases	Takeda Pharmaceuticals International AG Ireland Branch	19/05/2023	P/0183/2023
Aticaprant	N/A	P	Psychiatry	Janssen-Cilag International N.V.	19/05/2023	P/0184/2023
Ezetimibe / pitavastatin	N/A	W	Cardiovascular Diseases	Verisfield Single Member S.A.	15/05/2023	P/0185/2023
Tralokinumab	Adtralza	PM	Dermatology	LEO Pharma A/S	05/06/2023	P/0186/2023
Atrasentan	N/A	P	Uro-nephrology	Chinook Therapeutics, Inc.	15/05/2023	P/0187/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Adeno-associated viral vector serotype 9 expressing codon-optimized human GRN gene (LY3884963)	N/A	W	Neurology	Prevail Therapeutics, a Wholly-Owned Subsidiary of Eli Lilly and Company	15/05/2023	P/0188/2023
Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR)	Vaxchora	PM	Vaccines	Bavarian Nordic A/S	15/05/2023	P/0189/2023
Guselkumab	Tremfya	PM	Gastroenterology-Hepatology	Janssen-Cilag International NV	15/05/2023	P/0190/2023
Ocrelizumab	Ocrevus	P	Neurology	Roche Registration GmbH	26/05/2023	P/0191/2023
Vatiquinone	N/A	PM	Neurology	PTC Therapeutics International	26/05/2023	P/0192/2023
Tenofovir alafenamide / rilpivirine / emtricitabine	Odefsey	W	Infectious Diseases	Gilead Sciences International Ltd.	12/05/2023	P/0193/2023
Chlorhexidine (digluconate) / Isopropyl alcohol	N/A	W	Infectious Diseases	Ecolab Deutschland GmbH	06/06/2023	P/0194/2023
Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345)	N/A	P	Vaccines	Moderna Biotech Spain, S.L.	15/05/2023	P/0195/2023
Ataluren	Translarna	PM	Neurology	PTC Therapeutics International, Limited	15/05/2023	P/0196/2023
Odronextamab	N/A	PM	Oncology	Regeneron Ireland DAC	15/05/2023	P/0197/2023
Humanised VHH-type bispecific antibody against Complement component 5 and serum albumin (ALXN1720)	N/A	P	Neurology	Alexion Europe SAS	22/05/2023	P/0198/2023
Amphotericin B	N/A	W	Infectious Diseases	Matinas BioPharma Holdings Inc.	13/06/2023	P/0199/2023
Posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	05/06/2023	P/0200/2023
Secukinumab	cosentyx	W	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	13/06/2023	P/0201/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Baricitinib	Olumiant	PM	Immunology- Rheumatology- Transplantation	Eli Lilly and Company Limited	13/06/2023	P/0202/2023
Efinaconazole	Jublia	PM	Infectious Diseases / Dermatology	Almirall, S.A.	13/06/2023	P/0203/2023
Zapomeran	N/A	P	Vaccines	Arcturus Therapeutics Europe B.V.	05/06/2023	P/0204/2023
Deutetrabenazine	N/A	W	Neurology	Teva B.V.	14/06/2023	P/0205/2023
Treprostinil	Remodulin	PM	Cardiovascular Diseases	Ferrer Internacional, S.A.	14/06/2023	P/0206/2023
Sodium hyaluronate / xylometazoline hydrochloride	N/A	W	Oto-rhino-laryngology	Jadran galenski laboratorij	14/06/2023	P/0207/2023
Efgartigimod alfa	N/A	P	Immunology- Rheumatology- Transplantation	argenx BV	14/06/2023	P/0208/2023
Bilastine	Bilaxten and associated names	PM	Ophthalmology	Faes Farma S.A.	14/06/2023	P/0209/2023
3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine (mesylate) / Alpha-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride	Custoplex-Köhler	PM	Cardiovascular Diseases	Dr. Franz Köhler Chemie GmbH	14/06/2023	P/0210/2023
Adsorbed modified allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae	PURETHAL D. pteronyssinus + D. farinae	PM	Pneumology - Allergology	HAL Allergy BV	14/06/2023	P/0211/2023
Brodalumab	Kyntheum	W	Dermatology	LEO Pharma A/S	14/06/2023	P/0212/2023
3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alpha-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride	Custoplex-Köhler	PM	Cardiovascular Diseases	Dr. Franz Köhler Chemie GmbH	14/06/2023	P/0213/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Cenobamate	ONTOZRY	PM	Neurology	Angelini Pharma S.p.A	14/06/2023	P/0214/2023
Denecimig	N/A	PM	Haematology-Hemostaseology	Novo Nordisk A/S	14/06/2023	P/0215/2023
(S)-lactic acid	N/A	W	Other	Stayble Therapeutics AB	14/06/2023	P/0216/2023
Ethinylestradiol / dienogest	N/A	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Chemo Research	14/06/2023	P/0217/2023
Inhibitor of receptor-interacting serine/threonine-protein kinase 1 (RIPK1) (SAR443820)	N/A	W	Neurology	Sanofi Winthrop Industrie	14/06/2023	P/0218/2023
Asunercept	N/A	P	Infectious Diseases	Apogenix AG	14/06/2023	P/0219/2023
Carbidopa monohydrate / levodopa	Infudopa IntraV	W	Neurology	Dizlin Pharmaceuticals AB	14/06/2023	P/0220/2023
Landiolol (hydrochloride)	Rapibloc, Landiobloc, Raploc, Runrapiq	PM	Cardiovascular Diseases	AOP Orphan Pharmaceuticals GmbH	14/06/2023	P/0221/2023
Crofelemer	N/A	P	Gastroenterology-Hepatology	Napo Therapeutics S.p.A.	14/06/2023	P/0222/2023
Salbutamol sulfate	N/A	W	Pneumology - Allergology	Teva B.V.	26/06/2023	P/0223/2023
Indapamide / candesartan (cilexetil)	N/A	W	Cardiovascular Diseases	KRKA, d.d., Novo mesto	14/06/2023	P/0224/2023
Adult differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19 specificity (A3B1) conjugated with the co-stimulatory regions 4-1BB and CD3z (ARI-0001)	Varnimcabbage autoleucel, ARI-0001	P	Oncology	Hospital Clinic of Barcelona	14/06/2023	P/0225/2023
Obeldesivir	N/A	P	Infectious Diseases	Gilead Sciences International Ltd.	14/06/2023	P/0226/2023
Gallium (68Ga) boclatixafortide	N/A	W	Other	PentixaPharm GmbH	14/06/2023	P/0227/2023
Fosmanogepix	N/A	P	Infectious Diseases	Pfizer Europe MA EEIG	14/06/2023	P/0228/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Ponesimod	Ponvory	PM	Other / Neurology	Janssen-Cilag International NV	14/06/2023	P/0234/2023
Sotrovimab	Xevudy	PM	Infectious Diseases	GlaxoSmithKline Trading Services Ltd	14/06/2023	P/0235/2023
Derivative of (3S,3'S,3a'S,10a'S)-3'-phenyl-3',3a',10',10a'-tetrahydro-1'H-spiro[indoline-3,2'-pyrrolo[2',3':4,5]pyrrolo[1,2-b]indazol]-2-one	N/A	W	Oncology	Boehringer Ingelheim International GmbH	14/06/2023	P/0236/2023
Upadacitinib	RINVOQ	PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	14/06/2023	P/0237/2023
Regdanvimab	Regkirona	PM	Infectious Diseases	Celltrion Healthcare Hungary Kft.	14/06/2023	P/0238/2023
Belzutifan	WELIREG	W	Oncology	Merck, Sharp & Dohme (Europe) Inc	14/06/2023	P/0239/2023
Givinostat	Duvyzat	PM	Neurology	Italfarmaco S.p.A.	14/06/2023	P/0240/2023
Irinotecan	ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for dispersion for infusion	W	Oncology	Les Laboratoires Servier	14/06/2023	P/0241/2023
Tenofovir alafenamide / Emtricitabine / Bictegravir	Biktarvy	PM	Infectious Diseases	Gilead Sciences International Ltd.	14/06/2023	P/0242/2023
Birch Bark Extract	Filsuvez	PM	Dermatology	Amryt Pharmaceuticals DAC	16/06/2023	P/0243/2023
Rivaroxaban / amlodipine (besilate)	N/A	W	Cardiovascular Diseases	Teva B.V.	14/07/2023	P/0244/2023
Influenza virus Type B, whole virion, inactivated / Influenza virus Type A H3N2, whole virion, inactivated / Influenza virus Type A H1N1, whole virion, inactivated	4Fluart szuszpenziós injekció	W	Vaccines	Fluart Innovative Vaccines Kft	14/07/2023	P/0245/2023
Pneumococcal polysaccharide serotype 33F conjugated to CRM197 carrier protein and	Apexxnar	PM	Vaccines	Pfizer Europe MA EEIG	14/07/2023	P/0246/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 7F conjugated to CRM197 carrier protein and						

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype						
Spesolimab	Spevigo	P	Dermatology	Boehringer Ingelheim International GmbH	14/07/2023	P/0247/2023
Immunoglobulin G4 [228-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5715 γ 4-chain), disulphide with human monoclonal REGN5715 κ -chain, dimer (REGN5715) / Immunoglobulin G4 [227-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5714 γ 4-chain), disulphide with human monoclonal REGN5714 κ -chain, dimer (REGN5714) / Immunoglobulin G4 [224-proline], anti-(Betula alleghaniensis allergen Bet v 1) (human monoclonal REGN5713 γ 4-chain), disulphide with human monoclonal REGN5713 κ -chain, dimer (REGN5713)	N/A	P	Pneumology - Allergology	Regeneron Ireland DAC	14/07/2023	P/0248/2023
Beremagene geperpavec	Vyjuvek	PM	Dermatology	Krystal Biotech, Inc.	05/07/2023	P/0249/2023
Deucravacitinib	SOTYKTU	W	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	14/07/2023	P/0250/2023
Soticlestat	N/A	PM	Neurology	Takeda Pharma A/S	14/07/2023	P/0251/2023
Efgartigimod alfa	vyvgart	PM	Haematology-Hemostaseology	argenx BV	14/07/2023	P/0252/2023
(4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-	Tapotoclax	PM	Oncology	Amgen Europe BV	14/07/2023	P/0253/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide (AMG 176)						
Sodium 2,2-dimethylbutyrate (HST5040)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Hemoshear Therapeutics Inc.	14/07/2023	P/0254/2023
Modrna encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qirv)	N/A	P	Vaccines	Pfizer Europe MA EEIG	14/07/2023	P/0255/2023
Therapeutic DNA plasmid vaccine targeting HPV16 E6 and E7 proteins (VB10.16)	N/A	W	Oncology	Nykode Therapeutics ASA	14/07/2023	P/0256/2023
Cobicistat / darunavir	REZOLSTA	PM	Infectious Diseases	Janssen-Cilag International NV	14/07/2023	P/0257/2023
Sarilumab	Kevzara	PM	Immunology-Rheumatology-Transplantation	Sanofi Winthrop Industrie	13/07/2023	P/0258/2023
Quizartinib	VANFLYTA	PM	Oncology	Daiichi Sankyo Europe GmbH	13/07/2023	P/0259/2023
Opicapone	Ongentys; Ontilyv	W	Neurology	Bial Portela & Ca S.A.	14/07/2023	P/0260/2023
Benzo[b]thiophene-3-carbonitrile, 2-amino-4-[(4aS)-8-chloro-10-fluoro-2,3,4,4a,5,6-hexahydro-12-oxo-3-(1-oxo-2-propen-1-yl)-1H,12H-pyrazino[2,1-d][1,5]benzoxazocin-9-yl]-7-fluoro-, (4R)- (LY3537982)	N/A	W	Oncology	Eli Lilly and Company	14/07/2023	P/0261/2023
Fuzuloparib	N/A	W	Oncology	Luzsana Biotechnology Europe	14/07/2023	P/0262/2023
Magrolimab	N/A	PM	Oncology	Gilead Sciences International Ltd	14/07/2023	P/0263/2023
Rocatinlimab	N/A	PM	Dermatology	Amgen Europe B.V	14/07/2023	P/0264/2023
Lenacapavir / Bictegravir	N/A	P	Infectious Diseases	Gilead Sciences International Ltd.	14/07/2023	P/0265/2023
Acetylsalicylic acid / rosuvastatin (Calcium)	N/A	W	Cardiovascular Diseases	Swyssi AG	14/07/2023	P/0266/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Gilteritinib (as fumarate)	Xospata	PM	Oncology / Haematology-Hemostaseology	Astellas Pharma Europe B.V.	14/07/2023	P/0267/2023
Izokibep	N/A	P	Immunology-Rheumatology-Transplantation	ACELYRIN, INC.	14/07/2023	P/0268/2023
Adapalene (micronized) / Benzoyl peroxide (hydrous) / Clindamycin phosphate	N/A	P	Dermatology	Bausch Health Ireland Limited	14/07/2023	P/0269/2023
1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3- fluorophenyl)ethan-1-one (BBP-671)	N/A	P	Other	Bridge Bio Europe B.V.	14/07/2023	P/0270/2023
Nizaracianine triflutate	N/A	P	Diagnostic	Curadel Surgical Innovations, Inc.	14/07/2023	P/0271/2023
Nipocalimab	N/A	P	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	14/07/2023	P/0272/2023
Povidone-iodine	Nasodine 0.5%w/v Nasal Spray	W	Infectious Diseases	ESPL Regulatory Consulting Limited	14/07/2023	P/0273/2023
Milvexian	N/A	P	Cardiovascular Diseases	Janssen-Cilag International N.V.	07/08/2023	P/0274/2023
Talimogene laherparepvec (Imlygic)	Imlygic	PM	Oncology	Amgen Europe B.V.	14/07/2023	P/0275/2023
Recombinant parathyroid hormone (Natpar)	Natpar	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Pharmaceuticals International AG Ireland Branch	14/07/2023	P/0276/2023
Nemolizumab	N/A	PM	Dermatology	Galderma International S.A.S	14/07/2023	P/0277/2023
Mavacamten	CAMZYOS	PM	Cardiovascular Diseases	Bristol-Myers Squibb Pharma EEIG	14/07/2023	P/0278/2023
Posoleucel	N/A	P	Infectious Diseases	AlloVir International DAC	14/07/2023	P/0279/2023
±3,4-methylenedioxymethamphetamine hydrochloride (MDMA)	N/A	P	Psychiatry	MAPS Europe B.V.	14/07/2023	P/0280/2023
Avapritinib	AYVAKYT	PM	Oncology	Blueprint Medicines (Netherlands) B.V.	14/07/2023	P/0281/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Secukinumab	Cosentyx	W	Immunology- Rheumatology- Transplantation	Novartis Europharm Limited	14/07/2023	P/0282/2023
Influenza recombinant H7 haemagglutinin	N/A	P	Vaccines	Sanofi Pasteur	14/07/2023	P/0283/2023
Modified vaccinia Ankara - Bavarian Nordic virus (smallpox) (Imvanex)	IMVANEX	PM	Vaccines	Bavarian Nordic A/S	14/07/2023	P/0284/2023
Tirzepatide	Mounjaro	PM	Other	Eli Lilly and Company	24/07/2023	P/0285/2023
Tazemetostat	N/A	W	Oncology	Ipsen Pharma	25/07/2023	P/0286/2023
Obeticholic acid	Ocaliva	PM	Gastroenterology- Hepatology	Advanz Pharma Limited	04/08/2023	P/0287/2023
Rilzabrutinib	N/A	W	Haematology- Hemostaseology	Sanofi B.V.	04/08/2023	P/0288/2023
Ritlecitinib	N/A	P	Dermatology	Pfizer Europe MAA EEIG	04/08/2023	P/0289/2023
Dersimelagon	N/A	P	Other	Mitsubishi Tanabe Pharma GmbH	04/08/2023	P/0290/2023
XEN1101	N/A	P	Neurology	Xenon Pharmaceuticals Inc.	04/08/2023	P/0291/2023
Enomimeran, gindameran, ontasameran, vibosameran (BNT111)	N/A	P	Oncology	BioNTech SE	04/08/2023	P/0292/2023
Volrustomig	Volrustomig	W	Oncology	AstraZeneca AB	04/08/2023	P/0293/2023
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Mysimba	PM	Other	Orexigen Therapeutics Ireland Limited	11/08/2023	P/0294/2023
Ibrutinib	Imbruvica	PM	Immunology- Rheumatology- Transplantation	Janssen-Cilag International NV	11/08/2023	P/0295/2023
Semaglutide	Wegovy	W	Endocrinology- Gynaecology- Fertility- Metabolism	Novo Nordisk A/S	11/08/2023	P/0296/2023
Dupilumab	Dupixent	PM	Dermatology	Sanofi Winthrop Industrie	11/08/2023	P/0297/2023
Satralizumab	Enspryng	W	Ophthalmology / Neurology	Roche Registration GmbH	11/08/2023	P/0298/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Erenumab	Aimovig	PM	Neurology	Novartis Europharm Limited	11/08/2023	P/0299/2023
Mexiletine (hydrochloride)	Namuscla	PM	Other	Lupin Europe GmbH	11/08/2023	P/0300/2023
durvalumab	IMFINZI	PM	Oncology	AstraZeneca AB	11/08/2023	P/0301/2023
Tremelimumab	IMJUDO	PM	Oncology	AstraZeneca AB	11/08/2023	P/0302/2023
Autologous dendritic cells pulsed with allogeneic tumour cell lysate	N/A	W	Oncology	Amphera BV	11/08/2023	P/0303/2023
Repagermanium	N/A	P	Uro-nephrology	Dimerix Bioscience Pty Ltd	11/08/2023	P/0304/2023
MVA-BN-RSV vaccine (construct MVA-mBN294B)	N/A	P	Vaccines / Infectious Diseases	Bavarian Nordic A/S	11/08/2023	P/0305/2023
Dirloctocogene samoparvovec	N/A	P	Haematology-Hemostaseology	Spark Therapeutics Ireland Limited	11/08/2023	P/0306/2023
Semaglutide / cagrilintide	N/A	W	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	04/08/2023	P/0307/2023
Tofacitinib	XELJANZ	PM	Immunology-Rheumatology-Transplantation	Pfizer Europe MA EEIG	07/08/2023	P/0308/2023
Cabozantinib	COMETRIQ, CABOMETYX	PM	Oncology	Ipsen Pharma	07/08/2023	P/0309/2023
Mocravimod	N/A	P	Haematology-Hemostaseology	Priothera SAS	07/08/2023	P/0310/2023
Povorcitinib	N/A	P	Dermatology	Incyte Biosciences Distribution B.V.	07/08/2023	P/0311/2023
Abemaciclib	Verzenios	PM	Oncology	Eli Lilly and Company Limited	09/08/2023	P/0312/2023
Abemaciclib	Verzenios	PM	Oncology	Eli Lilly and Company Limited	09/08/2023	P/0313/2023
mRNA encoding modified human ornithine transcarbamylase (ARCT-810)	N/A	P	Other	Arcturus Therapeutics Europe B.V.	09/08/2023	P/0314/2023
Furosemide	N/A	P	Cardiovascular Diseases	Proveca Pharma Limited	09/08/2023	P/0315/2023

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Mavodelpar	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism	Reneo Pharmaceuticals Inc	09/08/2023	P/0316/2023
Sotuletinib	N/A	W	Neurology	Novartis Europharm Limited	09/08/2023	P/0317/2023
Zimberelimab	N/A	W	Oncology	Gilead Sciences International Ltd.	11/08/2023	P/0318/2023
Zimberelimab	N/A	W	Oncology	Gilead Sciences International Ltd.	11/08/2023	P/0319/2023
Ketamine (hydrochloride) / Sufentanil (citrate)	N/A	PM	Pain	Cessatech A/S	11/08/2023	P/0320/2023
Olaparib	Lynparza	PM	Oncology	AstraZeneca AB	11/08/2023	P/0321/2023
Inclisiran (sodium)	Leqvio	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Novartis Europharm Ltd.	11/08/2023	P/0322/2023
Interleukin-23 receptor antagonist peptide	N/A	P	Dermatology	Janssen-Cilag International NV	11/08/2023	P/0323/2023
Encaleret	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism	Calcilytix Therapeutics, Inc a BridgeBio Company	11/08/2023	P/0324/2023
Delandistrogene moxeparvovec	N/A	PM	Neurology	Roche Registration GmbH	08/08/2023	P/0325/2023
(S)-2-(5-((3-ethoxypyridin-2-yl)oxy)pyridin-3-yl)-N-(tetrahydrofuran 3 yl) pyrimidine-5-carboxamide (PF-06865571)	ervogastat	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	08/08/2023	P/0326/2023
Single-stranded 5' capped mrna encoding the has of the influenza virus strains A and B (mrna-1010)	N/A	P	Vaccines	Moderna Biotech Spain S.L.	08/08/2023	P/0327/2023
Atezolizumab / Tiragolumab	N/A	W	Oncology	Roche Registration GmbH	08/08/2023	P/0328/2023
Domvanalimab	N/A	W	Oncology	Gilead Sciences International Ltd.	08/08/2023	P/0329/2023
Domvanalimab	N/A	W	Oncology	Gilead Sciences International Ltd.	08/08/2023	P/0330/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts	N/A	PM	Dermatology	CUTISS AG	10/08/2023	P/0331/2023
Clotrimazole	Clotic	W	Oto-rhino-laryngology	Laboratorios Salvat, S.A.	09/08/2023	P/0332/2023
Vesleteplirsén	N/A	P	Neurology	Sarepta Therapeutics Ireland	08/09/2023	P/0333/2023
Concentrate of proteolytic enzymes enriched in bromelain	EscharEx	W	Other	MediWound Germany GmbH	09/08/2023	P/0334/2023
Repotrectinib	N/A	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	09/08/2023	P/0335/2023
Bosutinib	Bosulif	PM	Oncology	Pfizer Europe MA EEIG	07/08/2023	P/0336/2023
Iclepertin	N/A	PM	Psychiatry	Boehringer Ingelheim International GmbH	11/08/2023	P/0337/2023
Apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	17/08/2023	P/0338/2023
Nivolumab	OPDIVO	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	17/08/2023	P/0339/2023
Tedizolid phosphate	SIVEXTRO	PM	Infectious Diseases	MSD Europe Belgium SRL	17/08/2023	P/0340/2023
Ustekinumab	STELARA	PM	Gastroenterology-Hepatology	Janssen-Cilag International NV	08/09/2023	P/0341/2023
Ivonescimab	N/A	W	Oncology	Summit Therapeutics Sub Inc.	08/09/2023	P/0342/2023
Ramipril / nebivolol (hydrochloride)	N/A	W	Cardiovascular Diseases	Menarini Ricerche S.p.A.	08/09/2023	P/0343/2023
Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens (V940, mRNA-4157)	N/A	W	Oncology	Merck Sharp & Dohme (Europe) Inc.	08/09/2023	P/0344/2023

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Obinutuzumab	Gazyvaro	P	Immunology- Rheumatology- Transplantation	Roche Registration GmbH	08/09/2023	P/0345/2023
Guselkumab	Tremfya	PM	Immunology- Rheumatology- Transplantation	Janssen-Cilag International NV	08/09/2023	P/0346/2023
Semaglutide	Wegovy	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Novo Nordisk A/S	08/09/2023	P/0347/2023
Humanised monoclonal antibody derivative against fibroblast growth factor receptor 3	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism	Sanofi B.V.	08/09/2023	P/0348/2023
Binimetinib	Mektovi	W	Oncology	Pierre Fabre Médicament	08/09/2023	P/0349/2023
Pemafibrate	N/A	W	Gastroenterology- Hepatology	Kowa Pharmaceutical Europe AG	08/09/2023	P/0350/2023
Encorafenib	Braftovi	W	Oncology	Pierre Fabre Médicament	08/09/2023	P/0351/2023
Avacopan	TAVNEOS	PM	Immunology- Rheumatology- Transplantation	Amgen Europe B.V.	08/09/2023	P/0352/2023
Ravulizumab	Ultomiris	PM	Haematology- Hemostaseology	Alexion Europe SAS	08/09/2023	P/0353/2023
Sodium ({(2S)-1,4-bis[2-(4-chloro-3-fluorophenoxy)acetamido]bicyclo[2.2.2]octan-2-yl}oxy)methyl hydrogen phosphate-2-amino-2-(hydroxymethyl)propane-1,3-diol (1/1/1)	N/A	P	Neurology	Calico Life Sciences LLC	08/09/2023	P/0354/2023
The HAV is an acellular tubular graft composed of human collagen types I and III and other extracellular matrix proteins, including fibronectin and vitronectin.	N/A	W	Other	Humacyte Global, Inc.	08/09/2023	P/0355/2023
5-{4-[(7-ethyl-6-oxo-5,6-dihydro-1,5-naphthyridin-3-yl)methyl]-1-piperazinyl}-N-methyl-2-pyridinecarboxamide	N/A	W	Oncology	AstraZeneca AB	08/09/2023	P/0356/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Danicopan	Voydeya	PM	Haematology-Hemostaseology	Alexion Europe SAS	08/09/2023	P/0357/2023
Concizumab	Alhemo	PM	Haematology-Hemostaseology	Novo Nordisk A/S	08/09/2023	P/0358/2023
Baloxavir marboxil	Xofluza	PM	Infectious Diseases	Roche Registration GmbH	08/09/2023	P/0359/2023
Norucholic acid	N/A	PM	Gastroenterology-Hepatology	Dr. Falk Pharma GmbH	08/09/2023	P/0360/2023
Rozanolixizumab	Rystiggo	PM	Neurology	UCB Pharma S.A	08/09/2023	P/0361/2023
Dexmedetomidine	N/A	P	Anaesthesiology	Cessatech A/S	08/09/2023	P/0362/2023
Substituted 3,7-dihydro-1H-purine-2,6-dione	N/A	P	Psychiatry	Boehringer Ingelheim International GmbH	08/09/2023	P/0363/2023
Substituted 3,7-dihydro-1H-purine-2,6-dione	N/A	P	Psychiatry	Boehringer Ingelheim International GmbH	08/09/2023	P/0364/2023
Ezetimibe / Rosuvastatin	Rosuvastatin Ezetimibe/Pharmazac	W	Cardiovascular Diseases	Pharmazac S.A.	08/09/2023	P/0365/2023
3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate	N/A	W	Psychiatry	COMPASS Pathfinder Limited	08/09/2023	P/0366/2023
Abemaciclib	Verzenios	W	Oncology	Eli Lilly and Company Limited	08/09/2023	P/0367/2023
Etranacogene dezaparvovec	Hemgenix	PM	Haematology-Hemostaseology	CSL Behring GmbH	08/09/2023	P/0368/2023
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1	N/A	PM	Other / Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Inozyme Pharma Ireland Limited	08/09/2023	P/0369/2023
Funobactam	N/A	P	Infectious Diseases	Evopoint Biosciences USA, Inc.	08/09/2023	P/0370/2023
Dex Pramipexole dihydrochloride monohydrate	N/A	P	Pneumology - Allergology	Areteia Therapeutics	08/09/2023	P/0371/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Trimodulin	N/A	P	Neonatology - Paediatric Intensive Care / Infectious Diseases	Biotest AG	08/09/2023	P/0372/2023
Davesomeran / Imelasomeran / Elasomeran	Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax	PM	Vaccines	Moderna Biotech Spain, S.L.	08/09/2023	P/0373/2023
Lerociclib (dihydrochloride)	N/A	W	Oncology	EQRx International, Inc.	08/09/2023	P/0374/2023
Obicetrapib	N/A	W	Cardiovascular Diseases	NewAmsterdam Pharma BV	08/09/2023	P/0375/2023
Risankizumab	Skyrizi	PM	Gastroenterology-Hepatology	AbbVie Ltd	08/09/2023	P/0376/2023
Brexucabtagene autoleucel	Brexucabtagene autoleucel	PM	Oncology	Kite Pharma EU B.V.	08/09/2023	P/0377/2023
Fremanezumab	AJOVY	PM	Neurology	Teva GmbH	08/09/2023	P/0378/2023
ravulizumab	Ultomiris	PM	Uro-nephrology	Alexion Europe SAS	08/09/2023	P/0379/2023
Fostemsavir (tromethamine)	RUKOBIA	PM	Infectious Diseases	ViiV Healthcare UK Ltd	07/09/2023	P/0380/2023
Teprotumumab	N/A	W	Ophthalmology	Horizon Therapeutics Ireland Designated Activity Company	07/09/2023	P/0381/2023
Vedolizumab	Entyvio	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	07/09/2023	P/0382/2023
Upadacitinib	RINVOQ	P	Dermatology	AbbVie Ltd	07/09/2023	P/0383/2023
Guselkumab	Tremfya	PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	07/09/2023	P/0384/2023
Enfortomab vedotin	Padcev	W	Oncology	Astellas Pharma Europe B.V.	07/09/2023	P/0385/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Tenofovir alafenamide	Vemlidy	PM	Infectious Diseases	Gilead Sciences International Ltd.	07/09/2023	P/0386/2023
Derivative of 6-[2-(pyridin-2-yl)phenoxy]methyl}-1,2,3,4-tetrahydroisoquinoline	N/A	P	Gastroenterology-Hepatology	Boehringer Ingelheim International GmbH	07/09/2023	P/0387/2023
Ravulizumab (ALXN1210)	Ultomiris	W	Uro-nephrology	Alexion Europe SAS	07/09/2023	P/0388/2023
Botaretigene sparoparvovec	N/A	PM	Ophthalmology	Janssen-Cilag International NV Turnhoutseweg 30	08/09/2023	P/0389/2023
Recombinant human tissue nonspecific alkaline phosphatase (TNSALP) fragment crystallizable (Fc) deca aspartate fusion protein (ALXN1850)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe SAS	08/09/2023	P/0390/2023
Risankizumab	Skyrizi	PM	Gastroenterology-Hepatology	AbbVie Ltd	13/09/2023	P/0391/2023
Ivacaftor / tezacaftor / elexacaftor	Kaftrio	PM	Other	Vertex Pharmaceuticals (Ireland) Limited	28/09/2023	P/0392/2023
BNT162b2 / tozinameran /famtozinameran / riltozinameran	Comirnaty	PM	Infectious Diseases	BioNTech Manufacturing GmbH	28/09/2023	P/0393/2023
Valemetostat tosilate	N/A	W	Oncology	Daiichi Sankyo Europe GmbH	29/09/2023	P/0394/2023
Bezuclastinib	N/A	W	Oncology	Cogent Biosciences, Inc	06/10/2023	P/0395/2023
Dupilumab	Dupixent	PM	Dermatology	Sanofi Winthrop Industrie	27/10/2023	P/0396/2023
Eravacycline	Xerava	PM	Infectious Diseases	PAION Deutschland GmbH	27/10/2023	P/0397/2023
Brivaracetam	Briviact (in Italy: Nubriveo)	PM	Neurology	UCB Pharma S.A.	27/10/2023	P/0398/2023
Eptinezumab	Vyepti	PM	Neurology	H. Lundbeck A/S	27/10/2023	P/0399/2023
Evenamide	N/A	PM	Psychiatry	Newron Pharmaceuticals S.p.A.	27/10/2023	P/0400/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Enpatoran	N/A	P	Immunology- Rheumatology- Transplantation	Merck Europe B.V.	27/10/2023	P/0401/2023
Inhibitor of receptor-interacting protein kinase 1 (ABBV-668)	N/A	P	Gastroenterology- Hepatology	AbbVie Ltd	27/10/2023	P/0402/2023
Nemvaleukin alfa	N/A	P	Oncology	Mural Oncology, Inc.	27/10/2023	P/0403/2023
Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254 / Recombinant Neisseria meningitidis group B fHbp 2-3-1.13NB fusion protein / Recombinant Neisseria meningitis group B Protein 961c / Recombinant Neisseria meningitis group B Protein 287-953 / Recombinant Neisseria meningitis group B Protein 936-741	N/A	P	Vaccines	GlaxoSmithKline Biologicals SA	27/10/2023	P/0404/2023
Tiragolumab	N/A	W	Oncology	Roche Registration GmbH	27/10/2023	P/0405/2023
Pertussis Filamentous Haemagglutinin (FHA) / Genetically detoxified Pertussis Toxin (ptgen)	Pertagen aPgen, Pertagen	W	Vaccines	BIONET EUROPE	27/10/2023	P/0406/2023
Tezepelumab	Tezspire	P	Gastroenterology- Hepatology	AstraZeneca AB	25/10/2023	P/0407/2023
Carfilzomab	Kryprolis	PM	Oncology	Amgen Europe B.V	27/10/2023	P/0408/2023
Actinium chloride (non-carrier added)	N/A	W	Oncology	ITM Medical Isotopes GmbH	27/10/2023	P/0409/2023
Synthetic double-stranded sirna oligonucleotide directed against antithrombin mrna and covalently linked to a ligand containing three N-acetylgalactosamine residues	Fitusiran	PM	Haematology- Hemostaseology	Sanofi B.V.	27/10/2023	P/0410/2023

Active substance(s)	Invented name	PDco Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Deucricitabant	N/A	P	Haematology-Hemostaseology	Pharvaris Netherlands BV	25/10/2023	P/0411/2023
Onasemnogene abeparvovec	Zolgensma	PM	Neurology	Novartis Europharm Limited	27/10/2023	P/0412/2023
Ulviprubart	N/A	W	Other / Immunology-Rheumatology-Transplantation	Abcuro, Inc.	25/10/2023	P/0413/2023
Cemiplimab	cemiplimab	PM	Oncology	Regeneron Ireland DAC	27/10/2023	P/0414/2023
Angiotensin II acetate	Giapreza 2.5 mg/mL concentrate for solution for infusion	PM		PAION Deutschland GmbH	25/10/2023	P/0415/2023
Vonicog alfa	VEYVONDI	PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	25/10/2023	P/0416/2023
Selexipag	Upravi	PM	Other	Janssen-Cilag International NV	25/10/2023	P/0417/2023
Palonosetron / fosnetupitant	AKYNZEO	PM	Other	Helsinn Birex Pharmaceuticals Limited	25/10/2023	P/0418/2023
Peginterferon beta-1a	Plegridy	PM	Neurology	Biogen Idec Ltd	25/10/2023	P/0419/2023
Rozanolixizumab	N/A	P	Neurology	UCB Pharma S.A.	27/10/2023	P/0420/2023
Ciraparantag	N/A	P	Haematology-Hemostaseology	NORGINE BV	27/10/2023	P/0421/2023
Fazirsiran	N/A	P	Gastroenterology-Hepatology	Takeda Pharma A/S	27/10/2023	P/0422/2023
NVX-CoV2373	NUVAXOVID	PM	Vaccines	Novavax CZ, a.s.	27/10/2023	P/0423/2023
Pembrolizumab / vibostolimab	N/A	P	Oncology	Merck Sharp & Dohme (Europe) Inc.	27/10/2023	P/0424/2023
2-((R)-3-(1-(1-((R)-1-(2,4-dichlorophenyl)ethyl)-3-(trifluoromethyl)-1H-pyrazolo[3,4-b]pyrazin-6-yl)azetidin-3-yl)piperidin-1-yl)ethan-1-ol, benzenesulfonate	N/A	W	Oncology	RAPT Therapeutics Inc	27/10/2023	P/0425/2023
Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R,4R)-	dorocubicel	P	Immunology-Rheumatology-	ExCellThera	27/10/2023	P/0426/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate (ECT-001-CB)			Transplantation / Oncology / Haematology-Hemostaseology			
2-[3-(dimethyl-1H-1,2,3-triazol-5-yl)-5-[(S)-oxan-4-yl(phenyl)methyl]-5H-pyrido[3,2-b]indol-7-yl]propan-2-ol	N/A	W	Haematology-Hemostaseology	Bristol-Myers Squibb Pharma EEIG	27/10/2023	P/0427/2023
Derivative of 6-(piperidine-1-carbonyl)pyridin-3-ol (BI 764198)	N/A	P	Uro-nephrology	Boehringer Ingelheim International GmbH	27/10/2023	P/0428/2023
Humanised igg1 monoclonal antibody against TROP2, conjugated to a topoisomerase I inhibitor belotecan-derivative	N/A	W	Oncology	Merck Sharp & Dohme (Europe) Inc.	27/10/2023	P/0429/2023
Inaxaplin	N/A	P	Uro-nephrology	Vertex Pharmaceuticals (Ireland) Limited	27/10/2023	P/0430/2023
Modified, recombinant version of the human myeloid-derived growth factor	N/A	W	Cardiovascular Diseases	Boehringer Ingelheim International GmbH (BI)	27/10/2023	P/0431/2023
A self-complementary adeno-associated virus [AAV] serotype 8 virus particle encoding the human ornithine transcarbamylase [OTC] gene sequence (DTX301)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Ultragenyx Germany GmbH	27/10/2023	P/0432/2023
Zanidatamab	ZIIHERA	W	Oncology	Jazz Pharmaceuticals Ireland Limited	27/10/2023	P/0433/2023
Belrestotug	N/A	W	Oncology	GlaxoSmithKline Trading Services Limited	27/10/2023	P/0434/2023
Xalnesiran	N/A	P	Infectious Diseases	Roche Registration GmbH	27/10/2023	P/0435/2023
Amlodipine / rosuvastatin	N/A	W	Cardiovascular Diseases	LANOVA FARMACEUTICI SRL	27/10/2023	P/0436/2023
Uproleselan	N/A	P	Oncology	GlycoMimetics, Inc.	27/10/2023	P/0437/2023
Pabinafusp alfa	N/A	P	Other	JCR Pharmaceuticals Co., Ltd.	27/10/2023	P/0438/2023

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Remdesivir	Veklury	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/10/2023	P/0439/2023
Autologous tumor-infiltrating lymphocytes (LN-144/LN-145)	AMTAGVI	PM	Oncology	Iovance Biotherapeutics, Inc.	27/10/2023	P/0440/2023
Luspatercept	Reblozyl	P	Haematology-Hemostaseology	Bristol-Myers Squibb Pharma EEIG	27/10/2023	P/0441/2023
Tovorafenib	N/A	PM	Oncology	Day One Biopharmaceuticals , Inc	27/10/2023	P/0442/2023
Iptacopan	N/A	PM	Other	Novartis Europharm Limited	27/10/2023	P/0443/2023
Ruzotolimod	N/A	P	Infectious Diseases	Roche Registration GmbH	27/10/2023	P/0444/2023
Neisseria meningitidis serogroup B Protein-based active substance / Recombinant Neisseria meningitidis Serogroup B protein 3 / Recombinant Neisseria meningitidis Serogroup B protein 2 / Recombinant Neisseria meningitidis Serogroup B protein 1 / Neisseria Meningitidis Group Y Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein / Neisseria Meningitidis Group W-135 Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein / Neisseria Meningitidis Group C Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein / Neisseria Meningitidis Group A Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein	N/A	P	Vaccines	Sanofi Pasteur	27/10/2023	P/0445/2023
Upadacitinib	RINVOQ	P	Dermatology	AbbVie Ltd	27/10/2023	P/0446/2023
Ritonavir / Nirmatrelvir	Paxlovid	PM	Infectious Diseases	Pfizer Europe MA EEIG	27/10/2023	P/0447/2023
Lisocabtagene maraleucel	Breyanzi	W	Oncology	Bristol-Myers Squibb Pharma EEIG	27/10/2023	P/0448/2023
Blinatumomab	BLINCYTO	PM	Oncology	Amgen Europe B.V.	27/10/2023	P/0449/2023
Iptacopan	N/A	P	Other	Novartis Europharm Limited	27/10/2023	P/0450/2023

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Upadacitinib	RINVOQ	P	Dermatology	AbbVie Ltd	27/10/2023	P/0451/2023
Upadacitinib	RINVOQ	PM	Immunology- Rheumatology- Transplantation / Gastroenterology- Hepatology	AbbVie Ltd	31/10/2023	P/0452/2023
Remibrutinib	N/A	PM	Dermatology	Novartis Europharm Limited	13/11/2023	P/0453/2023
Abrocitinib	abrocitinib	PM	Dermatology	Pfizer Europe MA EEIG	09/11/2023	P/0454/2023
Letermovir	PREVMIS	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	17/11/2023	P/0455/2023
Povidone (iodinated)	IODIL	W	Ophthalmology	Medivis Srl	01/12/2023	P/0456/2023
Macitentan	Opsumit	PM	Cardiovascular Diseases	Janssen-Cilag International NV	01/12/2023	P/0457/2023
Relatlimab / nivolumab	Opdualag	W	Oncology	Bristol-Myers Squibb Pharma EEIG	01/12/2023	P/0458/2023
Tixagevimab (AZD8895)	Evusheld	PM	Infectious Diseases	AstraZeneca AB	01/12/2023	P/0459/2023
Cilgavimab (AZD1061)	Evusheld	PM	Infectious Diseases	AstraZeneca AB	01/12/2023	P/0460/2023
Lutetium (177Lu) oxodotreotide	Lutathera	PM	Oncology	Advanced Accelerator Applications	01/12/2023	P/0461/2023
Bemnifosbuvir	N/A	PM	Infectious Diseases	Atea Pharmaceuticals, Inc	01/12/2023	P/0462/2023
Cemdisiran	cemdisiran	P	Haematology- Hemostaseology	Regeneron Ireland DAC	01/12/2023	P/0463/2023
Pozelimab	pozelimab	P	Haematology- Hemostaseology	Regeneron Ireland DAC	01/12/2023	P/0464/2023
Candesartan / Atorvastatin / Amlodipine	N/A	W	Cardiovascular Diseases	Teva B.V.	01/12/2023	P/0465/2023
Indapamide / Ramipril	N/A	W	Cardiovascular Diseases	Egis Pharmaceuticals PLC	01/12/2023	P/0466/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Dalbavancin hydrochloride	Xydalba	PM	Infectious Diseases	AbbVie Ltd	01/11/2023	P/0467/2023
Liraglutide	Saxenda	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Novo Nordisk A/S	13/12/2023	P/0468/2023
Tapentadol (hydrochloride)	Palexia, Tapentadol Libra-Pharm, Tapentadol Aachen Pharma GRT	PM	Pain	Grünenthal GmbH	01/12/2023	P/0469/2023
Lacosamide	VIMPAT	RPM	Neurology	UCB Pharma S.A.	01/12/2023	P/0470/2023
Inebilizumab	UPLIZNA	P	Neurology	Horizon Therapeutics Ireland Designated Activity Company (DAC)	01/12/2023	P/0471/2023
Naproxen / Paracetamol	N/A	W	Pain	GSK Consumer Healthcare SARL, a Haleon group company	01/12/2023	P/0472/2023
Fusion protein consisting of relaxin and Fc domain of IgG1	N/A	W	Cardiovascular Diseases	AstraZeneca AB	01/12/2023	P/0473/2023
Derivative of a benzoimidazole substituted pyrimidine	N/A	W	Oncology	Pfizer Europe MA EEIG	01/12/2023	P/0474/2023
Humanised IgG1 monoclonal antibody against integrin beta-6 conjugated to monomethyl auristatin E via a valine-citrulline linker	N/A	W	Oncology	Seagen B.V.	01/12/2023	P/0475/2023
Sebetralstat	N/A	PM	Haematology- Hemostaseology	KalVista Pharmaceuticals Ltd	01/12/2023	P/0476/2023
Denecimig	N/A	PM	Haematology- Hemostaseology	Novo Nordisk A/S	01/12/2023	P/0477/2023
Tirzepatide	Mounjaro	PM	Other	Eli Lilly and Company	01/12/2023	P/0478/2023
Seltorexant	N/A	PM	Psychiatry	Janssen-Cilag International NV	01/12/2023	P/0479/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Cobolimab	N/A	P	Oncology	GlaxoSmithKline Trading Services Limited	01/12/2023	P/0480/2023
Tetrahydrouridine / Decitabine	N/A	P	Haematology-Hemostaseology	Novo Nordisk A/S	01/12/2023	P/0481/2023
Ravulizumab	ULTOMIRIS	PM	Neurology	Alexion Europe SAS	30/11/2023	P/0482/2023
Pegzilarginase	Loargys	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Immedica Pharma AB	30/11/2023	P/0483/2023
Human fibrinogen concentrate	N/A	PM	Haematology-Hemostaseology	Biotest AG	30/11/2023	P/0484/2023
Zanamivir	Relenza (inhalation powder), Dectova (solution for infusion)	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	01/12/2023	P/0485/2023
Glyceryl trinitrate	Glicerín-trinitrát Egis	W	Cardiovascular Diseases	Egis Pharmaceuticals PLC	30/11/2023	P/0486/2023
Govorestat	Nugalviq	P	Endocrinology-Gynaecology-Fertility-Metabolism / Neurology	Applied Therapeutics, Inc	30/11/2023	P/0487/2023
Maralixibat chloride	LIVMARLI	PM	Gastroenterology-Hepatology	Mirum Pharmaceuticals	04/12/2023	P/0488/2023
Venglustat	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Sanofi B.V.	01/12/2023	P/0489/2023
Ezetimibe / rosuvastatin	N/A	W	Cardiovascular Diseases	Pharmaplot PC	01/12/2023	P/0490/2023
Ilginatib maleate	N/A	W	Oncology	NS Pharma, Inc.	01/12/2023	P/0491/2023
Risankizumab	Skyrizi	PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	01/12/2023	P/0492/2023

Active substance(s)	Invented name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Mometasone (furoate) / glycopyrronium bromide / indacaterol	Enerzair Breezhaler and its duplicate authorization Zimbus Breezhaler	PM	Pneumology - Allergology	Novartis Europharm Limited	01/12/2023	P/0493/2023
Humanized IgG1 blocking monoclonal antibody targeting CD39 (IPH5201)	N/A	W	Other	Innate Pharma SA	01/12/2023	P/0494/2023
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	Ervebo	PM	Vaccines	MSD Europe Belgium SRL	01/12/2023	P/0495/2023
Pridopidine (hydrochloride)	Nurzigma	PM	Neurology	Prilenia Therapeutics B.V.	01/12/2023	P/0496/2023
Glycopyrronium bromide	Axhidrox	PM	Dermatology	Dr. August Wolff GmbH & Co. KG - Arzneimittel	01/12/2023	P/0497/2023
Gotistobart	N/A	W	Oncology	OncoC4, Inc.	01/12/2023	P/0498/2023
Alprazolam	N/A	PM	Neurology	UCB Pharma SA.	01/12/2023	P/0499/2023
Treprostinil (sodium)	Tresuvi	PM	Cardiovascular Diseases	AOP Orphan Pharmaceuticals GmbH	01/12/2023	P/0500/2023
Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated	IXCHIQ	PM	Vaccines	Valneva Austria GmbH	24/11/2023	P/0501/2023
Mirabegron	Betmiga	W	Uro-nephrology	Astellas Pharma Europe B.V.	01/12/2023	P/0502/2023
Iron as ferric maltol	FERACCRU	PM	Haematology-Hemostaseology	Norgine BV	29/12/2023	P/0503/2023
AZD3152	N/A	P	Immunology-Rheumatology-Transplantation	AstraZeneca AB	29/12/2023	P/0504/2023
Broadly neutralizing anti-HIV human monoclonal antibody	N/A	P	Infectious Diseases	ViiV Healthcare UK Limited	29/12/2023	P/0505/2023
Elinzanetant	N/A	W	Endocrinology-Gynaecology-Fertility-Metabolism	Bayer AG	29/12/2023	P/0506/2023
Rilvegostomig	Rilvegostomig	W	Oncology	AstraZeneca AB	29/12/2023	P/0507/2023
Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Arexvy	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	29/12/2023	P/0508/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins (pGX3002 - Bizalimogene ralaplasmid) / DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins (pGX3001-mavilimogene ralaplasmid)	N/A	W	Vaccines / Infectious Diseases	Inovio Pharmaceuticals Inc.	29/12/2023	P/0509/2023
Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal	N/A	PM	Vaccines	MSD Europe Belgium S.R.L.	29/12/2023	P/0510/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate						
Zinc gluconate / alisitol / retinyl palmitate	Shylicine	PM	Gastroenterology-Hepatology	Vanessa Research Spain S.L.	29/12/2023	P/0511/2023
Interleukin-23 receptor antagonist peptide	N/A	PM	Dermatology	Janssen-Cilag International NV	29/12/2023	P/0512/2023
Inebilizumab	Uplizna	PM	Neurology	Horizon Therapeutics Ireland DAC	29/12/2023	P/0513/2023
Oregovomab	N/A	W	Oncology	CanariaBio Inc.	29/12/2023	P/0514/2023
Vamorolone	Agamree	PM	Other	Santhera Pharmaceuticals (Deutschland) GmbH	29/12/2023	P/0515/2023
3-(4-acetamidophenyl)-2-(S)-methoxypropionic acid, or (S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid	N/A	P	Dermatology	Nogra Pharma Limited	29/12/2023	P/0516/2023
Complement factor b antisense oligonucleotide (RO7434656)	N/A	P	Uro-nephrology	Roche Registration GmbH	29/12/2023	P/0517/2023
Allogeneic cultured postnatal thymus-derived tissue	RETHYMIC	P	Immunology-Rheumatology-Transplantation	Enzyvant Therapeutics Ireland Limited	29/12/2023	P/0518/2023
Satralizumab	Enspryng	PM	Neurology	Roche Registration GmbH	29/12/2023	P/0519/2023
Baricitinib	Olumiant	PM	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	29/12/2023	P/0520/2023
Modified messenger ribonucleic acid encoding human propionyl-coenzyme a carboxylase alpha and beta subunits encapsulated into lipid nanoparticles	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Moderna Biotech Spain, S.L.	29/12/2023	P/0521/2023
Cendakimab	N/A	PM	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	29/12/2023	P/0522/2023

Active substance(s)	Invented name	PDco Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Fully human IgG1 RB-1 YTE anti-RSV F monoclonal antibody	N/A	PM	Infectious Diseases	MSD Europe Belgium SRL	29/12/2023	P/0523/2023
Rilzabrutinib	N/A	PM	Immunology- Rheumatology- Transplantation	Sanofi B.V.	29/12/2023	P/0524/2023
Humanised IgG1kappa Monoclonal Antibody directed against IGF-1R	N/A	W	Endocrinology- Gynaecology- Fertility- Metabolism	Viridian Therapeutics, Inc.	29/12/2023	P/0525/2023
Filgotinib	Jyseleca	PM	Gastroenterology- Hepatology	Galapagos NV	29/12/2023	P/0526/2023
Baxdrostat	N/A	W	Cardiovascular Diseases	AstraZeneca AB	29/12/2023	P/0527/2023
Etrasimod	Velsipity	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	29/12/2023	P/0528/2023
Venglustat	Infilbray	PM	Endocrinology- Gynaecology- Fertility- Metabolism	Sanofi B.V.	29/12/2023	P/0529/2023
Vaborbactam / meropenem	Vaborem	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	29/12/2023	P/0530/2023
Inebilizumab	UPLIZNA	P	Immunology- Rheumatology- Transplantation	Horizon Therapeutics Ireland Designated Activity Company (DAC)	29/12/2023	P/0531/2023
Retifanlimab	ZYNYZ	W	Oncology	Incyte Biosciences Distribution B.V.	29/12/2023	P/0532/2023
Delgocitinib	N/A	PM	Dermatology	LEO Pharma A/S	29/12/2023	P/0533/2023
Mirikizumab	Omvoh	PM	Gastroenterology- Hepatology	Eli Lilly and Company	29/12/2023	P/0534/2023
Lotilaner	N/A	W	Ophthalmology / Infectious Diseases	Tarsus Pharmaceuticals, Inc.	29/12/2023	P/0535/2023

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Olutasidenib	Rezlidhia	W	Oncology	Rigel Pharmaceuticals B.V.	29/12/2023	P/0536/2023
Taldefgrobep alfa	N/A	P	Other	Biohaven Bioscience Ireland Limited	29/12/2023	P/0537/2023
Diflunisal	Attruzan or Attruzal or Diflunisal Tablets 250 mg AO Pharma	W	Neurology	AO Pharma AB	29/12/2023	P/0538/2023
Sitagliptin / Dapagliflozin	N/A	W	Endocrinology- Gynaecology- Fertility- Metabolism	KRKA, d.d., Novo mesto	29/12/2023	P/0539/2023
Modified mRNA encoding human methylmalonyl-coenzyme A mutase containing a polymorphism at position 671	N/A	P	Endocrinology- Gynaecology- Fertility- Metabolism	Moderna Biotech Spain, S.L.	29/12/2023	P/0540/2023
Birch bark extract	Filsuvez	PM	Dermatology	Amryt Pharmaceuticals DAC	14/12/2023	P/0541/2023
Amlitelimab	N/A	P	Dermatology	Sanofi Winthrop Industrie	21/12/2023	P/0542/2023
Cedazuridine / decitabine	INAQOVI	P	Oncology / Haematology- Hemostaseology	Otsuka Pharmaceutical Netherlands B.V.	21/12/2023	P/0543/2023
Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R,4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate (ECT-001-CB)	Zemcelpro	PM	Immunology- Rheumatology- Transplantation / Oncology / Haematology- Hemostaseology	ExCellThera	20/12/2023	P/0544/2023
Mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	04/01/2023	P/0550/2022
Avibactam / ceftazidime	Zavicefta	PM	Infectious Diseases	Pfizer Europe MA EEIG	04/01/2023	P/0551/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
Tazobactam / ceftolozane	ZERBAXA	PM	Infectious Diseases	MSD Europe Belgium SRL	04/01/2023	P/0552/2022
Aztreonam / avibactam	N/A	PM	Infectious Diseases	Pfizer Europe MA EEIG	04/01/2023	P/0553/2022
Ixekizumab	Taltz	PM	Immunology-Rheumatology-Transplantation	Eli Lilly and Company (Ireland) Limited	14/07/2023	P/0555/2022

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Ataluren	Neurology	PTC Therapeutics International, Limited	13/10/2023
Saxagliptin	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	21/07/2023
Rilpivirine (hydrochloride)	Infectious Diseases	Janssen-Cilag International NV	23/06/2023
Cysteamine hydrochloride	Ophthalmology	Recordati Rare Diseases	08/09/2023
Ivacaftor [N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide]	Other	Vertex Pharmaceuticals (Ireland) Limited	20/01/2023
Fluticasone furoate / vilanterol	Pneumology - Allergology	Glaxo Group Limited	20/01/2023
Vortioxetine	Psychiatry	H. Lundbeck A/S	20/01/2023
Eliglustat	Other	Sanofi B.V.	10/11/2023
Belimumab	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	15/12/2023
Tenofovir (disoproxil fumarate)	Infectious Diseases	Gilead Sciences Intl Ltd	20/01/2023
Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)	Vaccines	Seqirus S.r.l.	26/05/2023
Lanthanum carbonate hydrate	Uro-nephrology	Takeda Pharmaceuticals International AG Ireland Branch	23/06/2023
Apremilast	Immunology-Rheumatology-Transplantation / Dermatology	Amgen Europe B.V.	10/11/2023
Bosutinib	Oncology	Pfizer Europe MA EEIG	15/12/2023
Ruxolitinib (phosphate)	Oncology	Novartis Europharm Limited	13/10/2023
Ruxolitinib (phosphate)	Oncology	Novartis Europharm Limited	13/10/2023

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Elosulfase alfa	Endocrinology-Gynaecology-Fertility-Metabolism	BioMarin International Limited	23/06/2023
Ixekizumab	Dermatology	Eli Lilly and Company	13/10/2023
Ex vivo expanded autologous human corneal epithelial cells containing stem cells	Ophthalmology	Holostem Therapie Avanzate S.r.l.	21/07/2023
Teriflunomide	Neurology	Sanofi Aventis Groupe	23/06/2023
Lenvatinib	Oncology	Eisai GmbH	26/05/2023
Lenvatinib	Oncology	Eisai GmbH	13/10/2023
Alirocumab	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis recherche & développement	24/02/2023
Abacavir (ABC) / Lamivudine (3TC) / Dolutegravir (DTG)	Infectious Diseases	ViiV Healthcare UK Limited	08/09/2023
Dermatophagoides pteronyssinus / Dermatophagoides farinae	Pneumology - Allergology	ALK-Abelló A/S	15/12/2023
Isavuconazonium (sulfate)	Infectious Diseases	Basilea Pharmaceutica Deutschland GmbH	21/07/2023
Avibactam / Ceftazidime	Infectious Diseases	Pfizer Europe MA EEIG	10/11/2023
Crizotinib	Oncology	Pfizer Europe MA EEIG	31/03/2023
Dupilumab	Gastroenterology-Hepatology	Regeneron Ireland DAC	21/07/2023
Human Thrombin (Component 2) / Human Fibrinogen (component 1)	Other	Instituto Grifols, S.A.	26/04/2023
Bezlotoxumab	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	24/02/2023
Palovarotene	Other	Ipsen Pharma	10/11/2023
Peanut (Arachis hypogaea) allergen powder (previously known as Peanut flour)	Pneumology - Allergology	Aimmune Therapeutics Ireland Ltd	23/06/2023
Nirsevimab	Infectious Diseases	AstraZeneca AB	13/10/2023
Dry aqueous extract of paullinia cupana seed / liquid ethanolic extract 30 per cent (w/w) of allium cepa fresh bulb and citrus limon fresh fruit / dry hydroethanolic extract of theobroma cacao seed	Dermatology	LEGACY HEALTHCARE (FRANCE)SAS	26/04/2023
Larotrectinib	Oncology	Bayer AG	31/03/2023
Entrectinib	Oncology	Roche Registration GmbH	31/03/2023
Isatuximab	Oncology	Sanofi-Aventis Recherche & Développement	15/12/2023
Bulevirtide	Infectious Diseases	Gilead Sciences Ireland UC	08/09/2023
Eladocagene exuparvovec	Neurology	PTC Therapeutics International Limited	26/05/2023

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Spesolimab	Dermatology	Boehringer Ingelheim International GmbH	23/06/2023
Efanesoctocog alfa	Haematology-Hemostaseology	Swedish Orphan Biovitrium	26/04/2023
Remdesivir	Infectious Diseases	Gilead Sciences International Ltd.	15/12/2023
Vorasidenib (as hemicitrate, hemihydrate salt)	Oncology	Les Laboratoires Servier	15/12/2023
Crisantaspase	Oncology	Jazz Pharmaceuticals Ireland Limited	26/05/2023
Methylphenidate hydrochloride	Psychiatry	Laboratorios Lesvi S.L.	02/02/2023
Clascoterone	Dermatology	Cassiopea S.p.A	23/06/2023

Annex 17 – Referral procedures overview 2023 – 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
Colistimethate sodium-containing medicinal products (colistimethate sodium)	26/01/2023	ongoing	Article 5(3) of Regulation (EC) No 726/2004
Adakveo (crizanlizumab)	26/01/2023	25/05/2023	Article 20 of Regulation (EC) No 726/2004
Medicinal products which have been authorised or are pending approval based on studies performed at Synapse Labs Pvt. Ltd., a contract research organisation (CRO) located in Kharadi, Pune, India (various)	20/07/2023	ongoing ¹	Article 31 of Directive 2001/83/EC
Havrix and associated names (inactivated hepatitis A virus)	14/09/2023	ongoing	Article 30 of Directive 2001/83/EC
Mysimba (naltrexone hydrochloride/Bupropion hydrochloride)	14/09/2023	ongoing	Article 20 of Regulation (EC) No 726/2004
Ocaliva (obeticholic acid)	12/10/2023	ongoing	Article 20 of Regulation (EC) No 726/2004
Azithromycin-containing medicinal products for systemic use (azithromycin)	09/11/2023	ongoing	Article 31 of Directive 2001/83/EC
Ibuprofen NVT 400 mg soft capsules and associated names (ibuprofen)	14/12/2023	ongoing	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
Topiramate-containing medicinal products (topiramate)	01/09/2022	11/10/2023	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Pseudoephedrine-containing medicinal products (pseudoephedrine)	09/02/2023	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Hydroxyprogesterone-containing medicinal products (hydroxyprogesterone)	12/05/2023	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

¹ Re-examination started on 14/02/2024

Annex 18 – Arbitrations and referrals in 2023 – veterinary medicines

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
Referral under Article 33(4) of Directive 2001/82/EC	• 25/08/2022 • 15/02/2023	• Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats • butafosfan and cyanocobalamin (vitamin B12)
Referral under Article 33(4) of Directive 2001/82/EC	• 25/08/2022 • 15/02/2023	• Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats • butafosfan and cyanocobalamin (vitamin B12)
Referral under 54(8) of Regulation 2019/6	• 13/09/2023 • pending	• Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs • Procaine benzylpenicillin

Annex 19 – Budget summaries 2022-2023

The summarised comparative budget statements for 2022 and 2023 are as follows:

		Budget 2022 ¹		2023 (budget) ²		2023 (prov) ³	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
Revenue							
100	Fees and charges	364,882	88.0%	398,209	88.8%	387,090	88.2%
200	General EU contribution	32,416	7.8%	14,310	3.2%	14,421	3.3%
201	Special EU contribution for orphan medicinal products	12,895	3.1%	10,734	2.4%	10,733	2.4%
600	External assigned revenue	0	0.0%	0	0.0%	0	0.0%
700	Balance from previous year	4,368	1.1%	24,983	5.6%	24,982	5.7%
5+9	Other	301	0.1%	367	0.1%	1,585	0.4%
	TOTAL REVENUE	414,863	100.0%	448,603	100.0%	438,811	100.0%
Expenditure							
Staff							
11	Staff in active employment	117,412	28.8%	132,227	29.5%	131,979	29.7%
12	Recruitment	203	0.0%	200	0.0%	133	0.0%
13	Duty travel	389	0.1%	1,031	0.2%	904	0.2%
14	Socio-medical infrastructure	2,434	0.6%	3,000	0.7%	2,886	0.7%
15	Training	1,012	0.2%	1,135	0.3%	1,065	0.2%
16	External services	17,301	4.2%	20,155	4.5%	19,977	4.5%
17	Receptions & events	92	0.0%	137	0.0%	120	0.0%
	Total Title 1	138,842	34.0%	157,885	35.2%	157,063	35.4%
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	14,881	3.6%	17,475	3.9%	17,363	3.9%
21	Information and communication technology	30,449	7.5%	45,650	10.2%	45,194	10.2%
22	Movable property and associated costs	581	0.1%	640	0.1%	636	0.1%
23	Current administrative expenditure	1,334	0.3%	1,473	0.3%	1,413	0.3%
24	Postage	20	0.0%	24	0.0%	19	0.0%
25	Other meetings	165	0.0%	107	0.0%	91	0.0%
26	Restaurant and catering	1,023	0.3%	2,029	0.5%	2,029	0.5%
27	Information and publishing	1,808	0.4%	1,719	0.4%	1,700	0.4%
28	Business consultancy and audit services	1,985	0.5%	3,470	0.8%	3,270	0.7%
	Total Title 2	52,245	12.8%	72,588	16.2%	71,714	16.2%
Operational expenditure							
300	Meetings	2,193	0.5%	4,992	1.1%	4,744	1.1%
301	Evaluation of medicinal products	145,994	35.8%	155,684	34.7%	153,968	34.7%
302	Translations	4,072	1.0%	4,318	1.0%	4,201	0.9%
303	Scientific studies and services	27,605	6.8%	12,686	2.8%	12,176	2.7%
31	Expenditure on business related IT projects	37,373	9.2%	40,450	9.0%	40,180	9.0%
	Total Title 3	217,238	53.2%	218,130	48.6%	215,270	48.5%
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	408,325	100.0%	448,603	100.0%	444,047	100.0%

¹ Financial Year 2022: as per final accounts; rounded to the nearest thousand Euro

² Financial Year 2023: as per final budget

³ Financial Year 2023: as per provisional accounts; rounded to the nearest thousand Euro

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2023				POSTS 2024	
	Authorised		Actual as per 31.12.2023		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	0	-	3
AD 14	-	12	-	3	-	12
AD 13	-	12	-	11	-	12
AD 12	-	57	-	52	-	61
AD 11	-	49	-	49	-	50
AD 10	-	53	-	53	-	57
AD 9	-	66	-	66	-	82
AD 8	-	87	-	87	-	78
AD 7	-	89	-	89	-	90
AD 6	-	67	-	67	-	55
AD 5	-	0	-	0	-	0
Total AD	0	495	0	477	0	500
AST 11	-	2	-	2	-	3
AST 10	-	7	-	7	-	7
AST 9	-	10	-	10	-	10
AST 8	-	14	-	14	-	15
AST 7	-	25	-	25	-	29
AST 6	-	31	-	31	-	35
AST 5	-	43	-	43	-	49
AST 4	-	43	-	43	-	32
AST 3	-	12	-	12	-	11
AST 2	-	0	-	0	-	0
AST 1	-	0	-	0	-	0
Total AST	0	187	0	187	0	191
Grand Total	0	682	0	664	0	691

Other staff	Planned (FTE ¹) 2023	Actual (FTE ¹) 2023	Actual headcount 31.12.2023	Planned (FTE ¹) 2024
CONTRACT AGENTS	203	204	216	203
NATIONAL EXPERTS	30	42	47	45

¹ FTE=Full Time Equivalent

Annex 21 - Litigation activities of EMA in 2023

Actions before the Court of Justice of the European Union that are directed against EMA (pending or concluded in 2023)

1. Case T-653/20, *Mylan Ireland v EMA*

On 28 October 2020, the applicant brought an action against the decision of EMA to not validate an application for a generic medicinal product.

On 6 December 2022, the applicant notified the General Court that it wished to discontinue the proceedings in Case T-653/20.

By [order](#) of 17 February 2023, the case was removed from the register.

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

On 27 November 2020, the applicant brought an action against the decision of EMA to not validate an application for a generic medicinal product. The proceedings remained pending in 2023.

3. Case C-440/21 P, *EMA v Pharmaceutical Works Polpharma*

On 15 July 2021, EMA brought an appeal against the judgment of the General Court of 5 May 2021 in Case T-611/18, *Pharmaceutical Works Polpharma v EMA*. Appeals were also submitted by the interveners in the first instance; and the cases were joined for the purpose of the proceedings (Joined Cases C-438/21 P to C-440/21 P).

By its [judgment](#) of 16 March 2023, the Court of Justice set aside the first instance judgment in Case T-611/18, dismissed the action brought by Pharmaceutical Works Polpharma (the "Respondent"), and ordered the Respondent to bear its own costs and to pay those incurred by the Commission, Biogen and EMA in the context of the first instance and appellate proceedings.

4. Case C-136/22 P, *D & A Pharma v EMA*

On 25 February 2022, the applicant brought an appeal against the first-instance judgment in Case T-381/21, which had ruled in favour of EMA.

On 13 July 2023, the Court of Justice delivered its [judgment](#) in this case, by which it dismissed the appeal and ordered D & A Pharma to bear its own costs and to pay those of EMA relating to the appeal.

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

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

On 7 September 2023, Advocate General Medina delivered her [opinion](#) in the appellate proceedings. In her opinion, she proposed that the Court of Justice should set aside the first instance judgment in Case T-556/20, uphold the action for annulment and order the Commission and EMA to pay the costs incurred in the context of the first instance and appellate proceedings.

N.B. By its [judgment](#) of 14 March 2024, the Court of Justice set aside the first instance judgment; annulled the decision of the Commission refusing the grant of a marketing authorisation for Hopveus; and ordered the Commission to pay the costs incurred by the appellant at both stages of the court proceedings.

6. Case T-574/22, ViiV Healthcare v EMA

On 15 September 2022, the applicant submitted an action for annulment against the decision of EMA to suspend the validation of an application for marketing authorisation.

On 8 September 2023, the applicant applied for the discontinuance of the court proceedings. By [order](#) 5 October 2023, the case was removed from the register.

7. Case T-623/22, SD v EMA

On 7 October 2022, the applicant brought an action for annulment against the decision of EMA to grant partial access to documents relating to the authorisation of a COVID-19 vaccine. The proceedings remained pending in 2023.

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 2023)

8. Case T-223/20, Orion v Commission

On 23 April 2020, an action was brought against the decision of the European Commission to grant a marketing authorisation for a generic medicinal product for human use. The proceedings remained pending in 2023.

9. Joined Cases C-6/21 P and C-16/21 P, Germany and Estonia v Pharma Mar and Commission

On 17 September 2021, EMA was granted leave to intervene in support of the forms of order sought by two Member States in their respective appeals against the judgment of the General Court of 28 October 2020 in Case T-594/18, *Pharma Mar v Commission*. The appellate proceedings revolved, in pertinent part, around the correct interpretation of the notion of a “research organisation” for the purpose of the handling of competing interests of experts who are involved in EMA’s scientific assessments.

By its [judgment](#) of 22 June 2023, the Court of Justice set aside the first instance judgment, referred the case back to the General Court in order to examine the remaining elements of the case and reserved the costs.

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

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

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

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

On 1 July 2022, an action for annulment was brought against the decision of the European Commission to suspend the national marketing authorisations for medicinal products for human use which contain the active substance “hydroxyethyl starch (HES), solutions for infusion”. In particular, the applicants seek to challenge the soundness of the scientific assessment of a post-authorisation study which preceded the adoption of the Commission decision.

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

12. 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 to recognize the active substance of Nexviadyme (avalglucosidase alfa) 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. The proceedings remained pending in 2023.

13. Case T-786/22, Frajese v Commission

On 18 December 2022, the applicant brought an action for annulment against the decision of the European Commission to grant full marketing authorisations to two COVID-19 vaccines.

On 27 July 2023, the General Court issued an [order](#) rejecting the action as inadmissible and ordered the applicant to bear the legal costs.

14. Case T-108/23, UY v Commission

On 22 February 2023, the applicant brought an action for annulment against the decision of the European Commission to grant a full marketing authorisation to a COVID-19 vaccine.

On 11 December 2023, the General Court issued an [order](#) rejecting the action as inadmissible and ordered the applicant to bear the legal costs.

15. Case 109/23, UY v Commission

On 23 February 2023, the applicant brought an action for annulment against the decision of the European Commission to grant a full marketing authorisation to a COVID-19 vaccine.

On 11 December 2023, the General Court issued an [order](#) rejecting the action as inadmissible and ordered the applicant to bear the legal costs.

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

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

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

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

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

17.1. Case T-268/22, Biogen Netherlands v Commission

On 16 May 2022, the applicant brought an action for annulment against the decision of the European Commission refusing to grant an additional year of marketing protection under Article 14(11) of Regulation (EC) No 726/2004 for Tecfidera.

On 16 October 2023, the General Court issued an [order](#) that there is no longer any need to adjudicate on the action, as the action had become devoid of purpose.

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

On 16 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for “Dimethyl fumarate Polpharma – dimethyl fumarate”. The proceedings remained pending in 2023.

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

On 17 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for “Dimethyl fumarate Neuraxpharm – dimethyl fumarate”. The proceedings remained pending in 2023.

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

On 17 May 2022, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for “Dimethyl fumarate Mylan – dimethyl fumarate”. The proceedings remained pending in 2023.

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

On 10 March 2023, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for “Dimethyl fumarate Teva – dimethyl fumarate”. The proceedings remained pending in 2023.

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

On 9 June 2023, the applicant brought an action for annulment against the decision of the European Commission granting marketing authorisation for “Dimethyl fumarate Accord – dimethyl fumarate”. The proceedings remained pending in 2023.

18. 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*.

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

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

N.B. On 7 February 2024, the action was dismissed by an [order](#) of the General Court as inadmissible.

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

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

N.B. On 7 February 2024, the action was dismissed by an [order](#) of the General Court as inadmissible.

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

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

N.B. On 7 February 2024, the action was dismissed by an [order](#) of the General Court as inadmissible.

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

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

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

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

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

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

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

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

18.8. Case T-299/23, Hexal v Commission

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

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

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

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

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

18.10. Case T-393/23, Teva v Commission

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

19. 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

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

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

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

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

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

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

Annex 22 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2023	709	156 448

Initial decisions on access in 2023¹

Access given	
Yes	353
Partial	3
No	6
Document is not held by the Agency	40
Request became RFI	48
Clarification is not received / Withdrawn by requester	93
Total closed	543
Pending ²	490

Legal basis used for full or partial refusal

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

¹ Including initial requests received in previous years but closed in 2023

² Requests ongoing (currently processed) and in queue (not started)

Decision on confirmatory applications in 2023³ Legal basis used for full or partial refusal

Appeals		Legal basis	Full	Partial
Final refusal	11	4.1(a) – Protection of public interest	0	0
Release	2	4.1(b) – Protection of privacy	8	0
Partial	0	4.2 1 st ind – Protection of commercial interest	1	0
Request became RFI	1	4.2 2 nd ind – Protection of court proceedings	0	0
Withdrawn by requester	1	4.2 3 rd ind – Protection of inspections	0	0
Total closed	15	4.3 1 st par – Protection of decision making process	2	0
Pending ⁴	4	4.3 2 nd par – Protection of the Agency's decision making process	0	0
		4.5 – Protection of Member States	0	0
		Total	11	0

Affiliation (per initial requests and appeals in 2023)

Affiliation	Number of requests received	In %	Number of pages released⁵	In %
Not-for-profit organisation	17	2	11 590	7
EU Institution (EC etc)	2	0	0	0
Regulator outside EU	0	0	0	0
EU NCA	1	0	0	0
Patients or Consumer	56	8	17 050	11
Healthcare professional	150	22	31 307	20
Academia/Research institute	61	9	33 632	21
Legal	50	7	8 515	6
Media	22	3	2 610	2
Pharmaceutical industry	275	39	42 361	27
Consultant	73	10	5 285	3
Other	2	0	4 098	3
Total	709	100	156 448	100

³ Including appeals received in previous years but closed in 2023

⁴ Requests ongoing (currently processed) and in queue (not started)

⁵ Including initial requests and appeals received in previous years but closed in 2023

Annex 23 – Clinical Data Publication¹

Number of documents published

Year	Number of documents published	Number of pages published
2023	714	380.884

Documents and Pages published per module

MODULE	Documents	Pages
Module 2.5	49	3.292
Module 2.7	73	5.327
Module 5	592	372.265

Number of procedures published by procedure type

Initial MAA	4
Extension of Indication	3
Grouped Type II Variation	13
Type II Variation	20
Post Authorisation Recommendation (PAM)	1

Anonymisation Risk Assessment Approach

Approach	Number of Procedures
Qualitative ²	27
Quantitative ³	7
Mixed ⁴	3
Not Applicable ⁵	4

¹ Only Covid-19 related procedures were published during 2022

² Qualitative approach: calculate the level of risk (e.g. high, medium, low) based on the characteristics of the source data (e.g. prevalence of the disease, trial sample size, number of sites) . [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

³ Quantitative approach: calculate the probability of uniquely identifying an individual (the risk of re-identification is defined as a numerical value obtained through the *analysis of the clinical data* to be disclosed.) [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

⁴ Mixed: a combination of the two.

⁵ No anonymisation needed as no private personal data (PPD) was present in the documents

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Patient Centricity: Design and Conduct of Clinical Trials in Orphan Diseases: Third of Three Sets of Expanded Proceedings from the 2020 ISCTM Autumn Conference on Pediatric Drug Development. *Innov Clin Neurosci.* 2023 Jan-Mar;20(1-3):25-31. PMID: 37122576; PMCID: PMC10132279.

Butlen-Ducuing F, Haberkamp M, Aislaitner G, Bałkowiec-Iskra E, Mattila T, Doucet M, Kollb-Sielecka M, Balabanov P, Leuchs AK, Elferink A.

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