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Annex 1 – Members of the Management Board

Chair: Lorraine NOLAN¹

EMA contact: Hilde BOONE

Members

- European Parliament Karin KADENBACH², Anthony BORG
- European Commission Sandra GALLINA, Joanna DRAKE³
(Alternates: Anna-Eva Ampelas⁴, Irene NORSTEDT)
- Belgium Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria Bogdan KIRILOV (Alternate: Svetlin SPIROV)
- Czechia Irena STOROVÁ (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 FILIPPOU⁵ (Alternate: Maria GAZOULI⁶)
- Spain María Jesús LAMAS DÍAZ (Alternate: Consuelo RUBIO MONTEJANO⁷)
- France Christelle RATIGNIER-CARBONNEIL (Alternate: Franck FOURES⁸)
- Croatia Siniša TOMIĆ (Alternate: Danica KRAMARIĆ)
- Italy Nicola MAGRINI (Alternate: Francesco TROTTA)
- Cyprus Helena PANAYIOTOPOULOU (Alternate: Irimi Chrysafi FANIDOU)
- Latvia Sergejs AKULICĀS⁹ (Alternate: Awaiting nomination¹⁰)
- Lithuania Gytis ANDRULIONIS (Alternate: Awaiting nomination¹¹)
- Luxembourg Anna CHIOTI (Alternate: Marcin WISNIEWSKI)
- Hungary Mátyás SZENTIVÁNYI (Alternate: Beatrix HORVATH)
- Malta Anthony SERRACINO-INGLOTT

¹ Replaced former Chair Christa WIRTHUMER-HOCHE from March 2022

² Replaced Matthias GROOTE from May 2022

³ Replaced Patrick CHILD from May 2022

⁴ Replaced Andrzej RYS from October 2022

⁵ Replaced Eleftherios PALLIS from March 2022

⁶ Previously vacant

⁷ Replaced César HERNÁNDEZ from September 2022

⁸ Replaced Jean-Pierre ORAND from November 2022

⁹ Previously vacant

¹⁰ Awaiting nomination

¹¹ Awaiting nomination

- Netherlands (Alternate: John-Joseph BORG)
- Austria Paula LOEKMEIJER (Alternate: Aimad TORQUI¹²)
REICHHART)
- Poland Christa WIRTHUMER-HOCHE (Alternate: Thomas)
- Portugal Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
- Romania Rui SANTOS IVO (Alternate: Susana GUEDES POMBO)
- Slovenia Răzvan Mihai PRISADA¹³ (Alternate: Andrei BACIU)
- Slovakia Momir RADULOVIĆ (Alternate: Andrej JANEZIČ¹⁴)
- Finland Peter POTÚČEK¹⁵ (Alternate: Marian GAJDOS¹⁶)
- Sweden Eija PELKONEN (Alternate: Johanna NYSTEDT)
- Representatives of patients' organisations Björn ERIKSSON (Alternate: Åsa KUMLIN HOWELL)
- Representative of doctors' organisations Marco GRECO
Virginie HIVERT¹⁷
- Representative of veterinarians' organisations Denis LACOMBE¹⁸
- Despoina IATRIDOU¹⁹

Observers

- Iceland Runa HAUKSDOTTIR (Alternate: Awaiting nomination²⁰)
- Liechtenstein Vlasta ZAVADOVA (Alternate: Martin STRICKER)
- Norway Audun HÅGÅ (Alternate: Marit HYSTAD²¹)

¹² Replaced Catharina LEGUIJT from September 2022

¹³ Previously vacant

¹⁴ Previously vacant

¹⁵ Replaced Zuzana BAŤOVÁ from February 2022

¹⁶ Replaced Judita HEDEROVA from July 2022

¹⁷ Replaced Ioannis NATSIS from June 2022

¹⁸ Replaced Wolf-Dieter LUDWIG from June 2022

¹⁹ Replaced Nancy DE BRIYNE from June 2022

²⁰ Awaiting nomination

²¹ Previously vacant

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

Chair: Harald ENZMANN

Members nominated by Member States

- | | |
|--|--|
| • Andrea LASLOP (Austria) | Alternate: Daniela PHILADELPHY |
| • Christophe FOCKE (Belgium) | Alternate: Karin JANSSEN VAN DOORN |
| • Ilko GETOV (Bulgaria) | Alternate: Velislava TODOROVA |
| • Margareta BEGO (Croatia) | Alternate: Selma ARAPOVIC DZAKULA |
| • Helena PANAYIOTOPOULOU (Cyprus) | Alternate: Emilia MAVROKORDATOU |
| • Ondrej SLANAR (Czechia) | Alternate: Tomas RADIMERSKY |
| • Thalia Marie Estrup BLICHER (Denmark) ^{1 2} | Alternate: Aaron Emmanuel SOSA MEJIA ³ |
| • Alar IRS (Estonia) | Alternate: Edward LAANE |
| • Outi MAKI-IKOLA (Finland) | Alternate: Johanna LAHTEENVUO |
| • Alexandre MOREAU (France) | Alternate: Jean-Michel RACE |
| • Martina WEISE (Germany) | Alternate: Janet KOENIG |
| • Konstantina ALEXOPOULOU (Greece) | Alternate: Anastasia MOUNTAKI |
| • Robert PORZASZ (Hungary) ⁴ | Alternate: <i>Awaiting nomination</i> ⁵ |
| • Hrefna GUDMUNDSDOTTIR (Iceland) | Alternate: Hjalti KRISTINSSON ^{6 7} |
| • Jayne CROWE (Ireland) | Alternate: Finbarr LEACY ^{8 9} |
| • Armando GENAZZANI (Italy) | Alternate: Maria Grazia EVANDRI ¹⁰ |
| • Elita POPLAVSKA (Latvia) | Alternate: <i>Awaiting nomination</i> |
| • Vlasta ZAVADOVA (Liechtenstein) | Alternate: <i>Awaiting nomination</i> |
| • Vilma PETRIKAITE (Lithuania) ^{11 12} | Alternate: Silvijus ABRAMAVICIUS |
| • Martine TRAUFFLER (Luxembourg) | Alternate: Alexandra BRANCHU ¹³ |
| • John Joseph BORG (Malta) | Alternate: Helen VELLA |
| • Johann Lodewijk HILLEGE (Netherlands) | Alternate: Paula Boudewina VAN HENNIK |

¹ Sinan B. SARAC resigned as of March 2022

² Swap of roles from alternate to member as of April 2022

³ Replaced Thalia Marie Estrup BLICHER as of April 2022

⁴ Robert PORZASZ nominated as of March 2022

⁵ Agnes GYURASICS resigned as of December 2022

⁶ Jan SJOBERG resigned as of June 2022

⁷ Hjalti KRISTINSSON nominated as of August 2022

⁸ Peter KIELY resigned as of July 2022

⁹ Nominated as of September 2022

¹⁰ Replaced Nicola MAGRINI as of February 2022

¹¹ Romaldas MACIULAITIS mandate ended as of October 2022

¹² Nominated as of November 2022

¹³ Replaced Carola DE BEAUFORT as of August 2022

- Ingrid WANG (Norway) Alternate: Eva SKOVLUND
- Ewa BALKOWIEC-ISKRA (Poland) Alternate: Grzegorz CESSAK
- Bruno SEPODES (Portugal) (*Vice-Chair*) Alternate: Fatima VENTURA
- Simona BADOI (Romania) Alternate: Dana Gabriela MARIN
- Francisek DRAFI (Slovakia) Alternate: Dorota DISTLEROVA
- Kristina NADRAH (Slovenia) Alternate: Nevenka TRSINAR BRODT
- Maria Concepcion PRIETO YERRO (Spain) Alternate: Blanca GARCIA-OCHOA
- Kristina DUNDER (Sweden) Alternate: Filip JOSEPHSON

Co-opted members

- Christian GARTNER (Medical statistics (clinical-trial methodology / epidemiology))
- 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))

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 ^{1 2}
- Maria POPOVA-KIRADJIEVA (Bulgaria) Alternate: Yuliyane EFTIMOV
- Nikica MIROSEVIC SKVRCE (Croatia) Alternate: Zeljana MARGAN KOLETIC
- Elena KAISIS (Cyprus) Alternate: Panagiotis PSARAS
- Eva JIRSOVA (Czechia) Alternate: Jana LUKACISINOVA
- Anette STARK (Denmark) Alternate: Hans Christian SIERSTED ³
- Maia UUSKULA (Estonia) Alternate: Krõõt AAB
- Kirsti VILLIKKA (Finland) Alternate: Kimmo JAAKKOLA
- Tiphaine VAILLANT (France) Alternate: Nathalie GAULT
- Martin HUBER (Germany) (*Vice-Chair*) Alternate: Brigitte KELLER-STANISLAWSKI
- Sofia TRANTZA (Greece) Alternate: Georgia GKEGKA
- Julia PALLOS (Hungary) ⁴ Alternate: Melinda PALFI ⁵
- Gudrun STEFANSDOTTIR (Iceland) Alternate: Gudrun THENGILSDOTTIR ⁶
- Rhea FITZGERALD (Ireland) Alternate: Ronan GRIMES
- Amelia CUPELLI (Italy) Alternate: Valentina DI GIOVANNI ^{7 8}
- Zane NEIKENA (Latvia) Alternate: Zane STADE
- Rugile PILVINIENE (Lithuania) Alternate: Lina SEIBOKIENE ⁹
- Nadine PETITPAIN (Luxembourg) Alternate: Anne-Cecile VUILEMIN
- John Joseph BORG (Malta) Alternate: Benjamin MICALLEF
- Menno VAN DER ELST (Netherlands) Alternate: Liana GROSS-MARTIROSYAN
- David BENEE OLSEN (Norway) Alternate: Karen PERILLE HARG
- Adam PRZYBYLKOWSKI (Poland) Alternate: Katarzyna ZIOLKOWSKA
- Ana Sofia DINIZ MARTINS (Portugal) Alternate: Ines RIBEIRO-VAZ ^{10 11}

¹ Laurence DE FAYS resigned as of March 2022

² Nominated as of July 2022

³ Marie Louise SCHOUGAARD CHRISTIANSEN replaced Hans Christian SIERSTED as of February 2022

⁴ Swap of roles with Melinda PALFI as of February 2022

⁵ Swap of roles with Julia PALLOS as of February 2022

⁶ Nominated as of September 2022

⁷ Ilaria BALDELLI's mandate expired as of June 2022

⁸ Nominated as of June 2022

⁹ Nominated as of March 2022

- Roxana DONDERA (Romania) Alternate: Alexandra-Maria SPURNI
- Anna MAREKOVA (Slovakia) ^{12 13} Alternate: Lucia KURAKOVA ¹⁴
- Polona GOLMAJER (Slovenia) Alternate: Milena RADOHA-BERGOČ
- Maria del Pilar RAYON (Spain) ^{15 16} Alternate: Monica MARTINEZ REDONDO ¹⁷
- Ulla WANDEL LIMINGA (Sweden) Alternate: Mari THORN ¹⁸

Independent scientific experts nominated by the European Commission

- Annalisa CAPUANO
- *Awaiting nomination* ¹⁹
- Hedvig NORDENG
- Patricia McGETTIGAN
- Milou Daniel DRICI
- Teresa HERDEIRO

Members representing healthcare professionals nominated by the European Commission

- Roberto FRONTINI ^{20 21} Salvatore MESSANA ^{22 23}

Members representing patients' organisations nominated by the European Commission

- Declan NOONE ^{24 25} Marko KORENJAK ^{26 27}

¹⁰ Marcia SILVA resigned as of October 2022

¹¹ Nominated as of November 2022

¹² Marek JURACKA resigned as of June 2022

¹³ Anna MAREKOVA replaced Marek JURACKA with a swap of role from alternate to member as from June 2022

¹⁴ Lucia KURAKOVA nominated as of June 2022

¹⁵ Eva SEGOVIA resigned as of September 2022

¹⁶ Swap of roles from alternat to member as of October 2022

¹⁷ Nominated as of October 2022

¹⁸ Replaced Annika FOLIN as of July 2022

¹⁹ Daniel MORALES resigned as of September 2022

²⁰ Raymond ANDERSON's mandate expired as of February 2022

²¹ Roberto FRONTINI nominated as of May 2022

²² Roberto FRONTINI's mandate expired as of February 2022

²³ Salvatore MESSANA nominated as of May 2022

²⁴ Cathalijne VAN DOORNE mandate expired as of February 2022

²⁵ Declan NOONE nominated as of May 2022

²⁶ Virginie HIVERT's mandate expired as of February 2022

²⁷ Marko KORENJAK nominated as of May 2022

Annex 4 – Members of the Committee for Veterinary Medicinal Products

Chair: G. J. SCHEFFERLIE¹ (vice-chair: F. HASSLUNG WIKSTRÖM²)

EMA contact: Barbara Freischem

Members and alternates

- Petra FALB (Austria) Alternate: Manuela LEITNER
- Bruno URBAIN (Belgium) Alternate: Frédéric KLEIN
- Krasimir YANKOV ZLATKOV³ ⁴(Bulgaria) Alternate: Nadya Ognyanova VLADIMIROVA⁵
- Frane BOŽIĆ (Croatia) Alternate: Hrvoje PAVASOVIC
- Member: Leona NEPEJCHALOVÁ (Czechia) Alternate: Jiří BUREŠ
- Christodoulos PIPIS (Cyprus) Alternate: Alia MICHAELIDOU-PATSIA
- Niels Christian KYVSGAARD (Denmark) Alternate: Merete BLIXENKRONE-MØLLER
- Toomas TIIRATS (Estonia) Alternate: *awaiting nomination*
- Minna LEPPÄNEN (Finland) Alternate: Tita-Maria MUHONEN
- Sylvie LOUET (France) Alternate: Christine MIRAS
- Esther WERNER (Germany) Alternate: Andrea GOLOMBIEWSKI
- Spyridon FARLOPOULOS (Greece) Alternate: Amalia PAPADAKI
- Gabor KULCSÁR (Hungary) Alternate: Eszter KOLLÁR-NAGY⁶ ⁷
- Paul McNEILL⁸ (Ireland) Alternate: J. Gabriel BEECHINOR
- Paolo PASQUALI (Italy) Alternate: Antonio BATTISTI
- Zanda AUCE (Latvia) Alternate: Santa ANSONSKA
- Snieguolė T. DZEKČIORIENĖ (Lithuania) Alternate: Nijolė STANKEVIČIENĖ
- Marc SCHMIT (Luxembourg) Alternate: Caroline CONER
- Stephen SPITERI (Malta) Alternate: Elena Maria VELLA
- Jacqueline POOT (Netherlands) Alternate: Kim BOERKAMP
- Anna WACHNIK-ŚWIĘCICKA (Poland) Alternate: Ewa AUGUSTYNOWICZ
- João Pedro DUARTE DA SILVA (Portugal) Alternate: Inês FLOR DIAS
- Gabriela TUCHILA (Romania)⁹ Alternate: Lollita TABAN

¹ GJ Schefferlie elected as Chair May 2022 (mandate start 14 June 2022), replacing David Murphy

² F. Hasslung Wikström elected as Vice-Chair June 2022 (mandate start 12 July 2022), replacing GJ Schefferlie

³ S. Branchev resigned position as member Sept 2022

⁴ K. Zlatkov appointed member for Bulgaria November 2022

⁵ Appointment of N. Ognyanova Vladimirova as of 11 July 2022 (position previously vacant)

⁶ M. Nemes-Terenyi left April 2022

⁷ Appointment of E. Kollár-Nagy as of 24 May 2022

⁸ Role swap, with P. McNeill becoming member and J.G. Beechinor becoming alternate, as of 23 July 2022

⁹ Role swap, with G Tuchila becoming the member and L. Taban the alternate, as of January 2022

- Eva CHOBOTOVÁ (Slovakia)¹⁰ Alternate: Katarína MASSÁNYIOVÁ¹¹
- Katarina ŠTRAUS (Slovenia) Alternate: Boris KOLAR
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTRÖM (Sweden) Alternate: Hanna BREMER^{12 13}

EEA members

- Member: *awaiting nomination*¹⁴ Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) Alternate: Annelin ASKDAL BJELLAND

Co-opted members

Co-opted member

- Keith BAPTISTE
- Rory BREATHNACH
- Carina BERGMAN^{15 16}
- Mary O'GRADY
- Ricardo CARAPETO GARCÍA

Expertise

- Antimicrobials
- General clinical veterinary practice
- Toxicology and residues¹⁷
- Quality pharmaceuticals
- Environmental risk assessment

¹⁰ J. Hederová left, role swap for E. Chobotová from alternate to member – May 2022

¹¹ Appointment of K. Massányiová as Slovakia alternate as of 8 May 2022

¹² Position vacant following appointment of C.Bergman as co-opted member in July 2022

¹³ H. Bremer nominated alternate for Sweden in December 2022

¹⁴ P. Zsolt Fekete resigned November 2022

¹⁵ Following election as Chair in May 2022, GJ Schefferlie no longer co-opted member

¹⁶ C.Bergman elected co-opted member – toxicology & residues in July 2022

¹⁷ Amendment of relevant scientific competence for this co-opted member position from MRLs/residues to Toxicology & residues – July 2022

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA

Members nominated by Member States

- Brigitte SCHWARZER-DAUM (Austria)
- Tim LEEST (Belgium)
- Lyubina Racheva TODOROVA (Bulgaria)
- Dinko VITEZIC (Croatia)
- Elli LOIZIDOU (Cyprus)
- Jana MAZELOVA (Czechia) ¹
- Elisabeth PENNINGA (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)
- Frauke NAUMANN-WINTER (Germany)
- *Awaiting nomination* (Greece) ^{2 3 4 5 6}
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- *Awaiting nomination* (Ireland) ⁷
- Enrico COSTA (Italy)
- Irena ROGOVSKA (Latvia)
- Vlasta ZAVADOVA (Liechtenstein)
- Ruta MAMENISKIENE (Lithuania) ⁸
- Michel HOFFMANN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)

¹ Replaced Lenka GAIDADZI as of January 2022

² George DIMOPOULOS's mandate ended as of January 2022

³ Nominated as of March 2022

⁴ Vasileios PAPADOPOULOS resigned as of September 2022

⁵ Nominated as of October 2022

⁶ Dimitrios FILIPPOU resigned as of December 2022

⁷ Geraldine O'DEA resigned as of October 2022

⁸ Ausra MATULEVICIENE's mandate expired as of July 2022

- Joao ROCHA (Portugal) ⁹
- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)
- *Awaiting nomination* (Slovenia)
- Gloria Maria PALOMO CARRASCO (Spain)
- Darius MATUSEVICIUS (Sweden)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Armando MAGRELLI (*Vice-Chair*)

Members representing patients' organisations nominated by the European Commission

- Marie Pauline EVERS
- Julian ISLA
- Ines ALVES

⁹ Replaced Dinah DUARTE as of June 2022

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: *Awaiting nomination*
- Iliana IONKOVA (Bulgaria) Alternate: Radina DIMITROVA ^{1 2}
- Ivan KOSALEC (Croatia) Alternate: Darko TRUMBETIC
- Christina Sylvia CHRYSOSTOMOU (Cyprus) ³ Alternate: Alexandra DEMETRIOU ⁴
- Marketa PRIHODOVA (Czechia) Alternate: Marie HEROUTOVA
- *Awaiting nomination* (Denmark) ⁵ Alternate: Nanna LUNDGAARD RASMUSSEN ⁶
- *Awaiting nomination* (Estonia) Alternate: *Awaiting nomination*
- Maria PAILE HYVARINEN (Finland) Alternate: Sari KOSKI
- An LE (France) Alternate: *Awaiting nomination*
- Jacqueline WIESNER (Germany) Alternate: Susanne FLEMISCH
- Ioanna CHINO (Greece) Alternate: Stavroula MAMOUCHA
- Julia PALLOS (Hungary) ⁷ Alternate: Rita NEMETH
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Sarah KELLAGHAN (Ireland) Alternate: Jacqueline MASTERSON
- Alessandro ASSISI (Italy) Alternate: Anna Maria SERRILLI
- Baiba JANSONE (Latvia) Alternate: Evita SKUKAUSKA
- Greta BUDUKEVICIUTE (Lithuania) ⁸ Alternate: Asta KUBILIENE
- Sven BACK (Luxembourg) Alternate: Jane MURRAY
- Everaldo ATTARD (Malta) Alternate: Matthew CAMILLERI
- Burt H. KROES (Netherlands) Alternate: Hilda KUIN
- Gro FOSSUM (Norway) ⁹ Alternate: Marianne Loiten DALHUS ¹⁰
- Wojciech DYMOWSKI (Poland) Alternate: Ewa ANTKIEWICZ ¹¹

¹ Valentin KOTEV resigned as of February 2022

² Radina DIMITROVA nominated as of May 2022

³ Replaced Antri KOUROUFEXI as of September 2022

⁴ Replaced Maria YIANNITSAROU as of September 2022

⁵ Steffen BAGER's mandate ended as of September 2022

⁶ Replaced Rahat NAZMI as of April 2022

⁷ Replaced Zsuzsanna BIRO-SANDOR as of September 2022

⁸ Replaced Jurate ANTANAVICIENE as of July 2022

⁹ Nominated as of January 2022 with a swap of roles from alternate to member

¹⁰ Nominated as of January 2022

¹¹ Replaced Katarzyna TOMASZEWSKA as of March 2022

- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Carmen PURDEL (Romania) Alternate: Ligia Elena DUTU
- Miroslava HORVATH PETRIKOVA (Slovakia) Alternate: Jaroslav TOTH ¹²
- 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)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Maria Helena PINTO FERREIRA (General and family medicine)
- Peter VOITL (Paediatrics)

Observers

- Bruno SPIELDENNER (EDQM) ^{13 14}
- Melanie BALD (EDQM)

¹² Nominated as of July 2022

¹³ Ulrich ROSE's mandate ended as of February 2022

¹⁴ Bruno SPIELDENNER nominated as of May 2022

Annex 7 – Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ

Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany) Alternate: Egbert FLORY
- *Awaiting nomination* (Lithuania) ¹ 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

- Ilona G. REISCHL (Austria) (*Vice-Chair*) Alternate: Silke DORNER
- Claire BEUNEU (Belgium) Alternate: Belaid SEKKALI
- Rozalina KULAKSAZOVA (Bulgaria) Alternate: Evelina SHUMKOVA
- Azra SELIMOVIC (Croatia) Alternate: Petra SOKOL
- Rafaella PONTOU (Cyprus) Alternate: Isavella KYRIAKIDOU
- Petr SOUKUP (Czechia) ² Alternate: Kristyna REHOROVA HRADILKOVA ³
- Ebru KARAKOC MADSEN (Denmark) ⁴ Alternate: Bibi Fatima Syed SHAH ^{5 6}
- Toivo MAIMETS (Estonia) Alternate: Pille SAALIK
- Heli SUIILA (Finland) Alternate: Maija TARKKANEN
- Violaine CLOSSON CARELLA (France) Alternate: Jean-Michel RACE
- Maria GAZOULI (Greece) Alternate: Angeliki ROMPOTI
- Katalin LENGYEL (Hungary) Alternate: Balazs SARKADI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland) Alternate: Niamh CURRAN
- Concetta QUINTARELLI (Italy) Alternate: Barbara BONAMASSA
- Una RIEKSTINA (Latvia) Alternate: *Awaiting nomination*
- Vlasta ZAVADOVA (Liechtenstein) Alternate: *Awaiting nomination*
- Nancy DE BREMAEKER (Luxembourg) Alternate: Guy BERCHEM
- Carla HERBERTS (Netherlands) Alternate: Babs FABRIEK
- Rune KJEKEN (Norway) Alternate: *Awaiting nomination* ⁷

¹ Romaldas MACIULAITIS's mandate ended as of October 2022

² Petr SOUKUP replaced Tomas BORAN as from April 2022 with a swap of role from alternate to member

³ Kristyna REHOROVA HRADILKOVA replaced Petr SOUKUP as of April 2022

⁴ Swap of role from alternate to member as of June 2022

⁵ Ebru KARAKOC MADSEN became member as of June 2022

⁶ Nominated as of November 2022

- Dariusz SLADOWSKI (Poland) Alternate: Marcin KOLAKOWSKI
- Silviu ISTRATE (Romania) Alternate: Alexandrina PREDA
- Katarina VAVROVA (Slovakia) ⁸ Alternate: Margareta FOGELOVA ^{9 10}
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Suzana VIDIC
- Lisbeth BARKHOLT (Sweden) Alternate: Maria LUTTGEN

Members representing clinicians nominated by the European Commission

- Paolo GASPARINI ¹¹ Alternate: Bernd GANSBACHER ^{12 13}
- Alessandro AIUTI Alternate: Alessandra RENIERI

Members representing patients' organisations nominated by the European Commission

- Kerstin SOLLERBRANT Alternate: Mencia DE LEMUS BELMONTE ^{14 15}
- Kieran BREEN Alternate: Federica CHIARA ^{16 17}

Observers

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

⁷ Maja SOMMERFELT GRØNVOLD resigned as of June 2022

⁸ Katarina VAVROVA replaced Lukas SLOVAK as from October 2022 with a swap of role from alternate to member

⁹ Katarina VAVROVA Replaced Alexandra PADOVA as of January 2022

¹⁰ Nominated as of October 2022

¹¹ Nominated as of July 2022

¹² Frederic BERNARD's mandate ended as of June 2022

¹³ Bernd GANSBACHER swapped roles from member to alternate as from July 2022

¹⁴ Lydie MEHEUS's mandate ended as of June 2022

¹⁵ Mencia DE LEMUS BELMONTE nominated as of July 2022

¹⁶ Roland POCHE's mandate expired as of June 2022

¹⁷ Nominated as of July 2022

Annex 8 – Members of the Paediatric Committee

Chair: Brian AYLWARD ¹

Members nominated from within the CHMP

- *Awaiting nomination* (Hungary) ² Alternate: Robert PORZASZ ³
- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

Members nominated by Member States

- Karl-Heinz HUEMER (Austria) Alternate: Johanna WERNSPERGER
- Marleen RENARD (Belgium) Alternate: Karen VAN MALDEREN
- Dimitar ROUSSINOV (Bulgaria) Alternate: Vessela BOUDINOVA
- Maja PAVLOVIC (Croatia) ^{4 5} Alternate: *Awaiting nomination* ⁶
- Zena GUNTHER (Cyprus) ⁷ Alternate: Maria Eleni AVRAAMIDOU ⁸
- Tomas BORAN (Czechia) ⁹ Alternate: Tereza BAZANTOVA
- Nanna BORUP JOHANSEN (Denmark) Alternate: Louisa BRAUN EXNER ¹⁰
- Irja LUTSAR (Estonia) Alternate: Jana LASS
- Pauliina LEHTOLAINEN DALKILIC (Finland) Alternate: Anne PAAVOLA
- Sylvie BENCHETRIT (France) (*Vice-Chair*) ¹¹ Alternate: Dominique PLOIN
- Sabine SCHERER (Germany) Alternate: Yuansheng SUN
- Eleni KATSOMITI (Greece) Alternate: Anastasia MOUNTAKI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- *Awaiting nomination* (Ireland) ¹² Alternate: *Awaiting nomination*
- *Awaiting nomination* (Italy) ¹³ Alternate: *Awaiting nomination*
- Dina APELE-FREIMANE (Latvia) Alternate: *Awaiting nomination*
- Vlasta Zavadova (Liechtenstein) Alternate: *Awaiting nomination*
- Dovile ZACHARKIENE (Lithuania) Alternate: Silvijus ABRAMAVICIUS
- Carola DE BEAUFORT (Luxembourg) ¹⁴ Alternate: Olivier MOES ¹⁵

¹ Replaced Koenraad NORGA as of September 2022

² Agnes GYURASICS's mandate ended as of December 2022

³ Nominated as of March 2022

⁴ Milivoj NOVAK's mandate ended as of April 2022

⁵ Maja PAVLOVIC nominated as of September 2022

⁶ Arnes RESIC's mandate ended as of April 2022

⁷ Replaced Georgios SAVVA as of February 2022

⁸ Replaced Elena KAISIS as of February 2022

⁹ Nominated as of January 2022

¹⁰ Nominated as of April 2022

¹¹ Sylvie BENCHETRIT elected as Vice-Chair as of October 2022

¹² Brian AYLWARD elected as Chair as of September 2022

¹³ Sara GALLUZZO's mandate ended as of November 2022

¹⁴ Nominated as of May 2022

- 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: *Awaiting nomination*
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) Alternate: Peter SZITANYI
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination*
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Kristin KARLSSON (Sweden) ¹⁶ Alternate: Sara VENNBERG

Members representing healthcare professionals nominated by the European Commission

- Johannes TAMINIAU Alternate: Fabio MIDULLA
- Fernando CABANAS Alternate: Doina PLESCA
- Francesca ROCCHI Alternate: Jose Ignacio MALAGON CALLE ¹⁷

Members representing patients' organisations nominated by the European Commission

- Jaroslav STERBA Alternate: Milena STEVANOVIC
- Dimitrios ATHANASIOU Alternate: *Awaiting nomination* ¹⁸
- Tomasz GRYBEK ¹⁹ Alternate: *Awaiting nomination* ²⁰

¹⁵ Replaced Martine TRAUFLER as of May 2022

¹⁶ Replaced Eva AGURELL as of June 2022

¹⁷ Replaced Catherine CORNU as of October 2022

¹⁸ Tomasz GRYBEK became member as of November 2022

¹⁹ Replaced Nora KRIAUAITE as of November 2022

²⁰ Michal ODERMARSKY resigned as of August 2022

Annex 9 – Working parties and working groups

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

As part of the EMA business continuity plan, many working party meetings and expert groups were temporarily suspended or reduced in 2021.

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 BERRY
Biosimilar Medicinal Products Working Party	- Position open
Cardiovascular Working Party	Alar IRS
Central Nervous System Working Party	Andre ALFERINK
Haematology Working Party	Daniela PHILADELPHY
Healthcare Professional Working Party	
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	Anja SCHIEL
Rheumatology/Immunology Working Party	Caroline AURICHE BENICHO
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	

CHMP operational expert groups

Chair	
Nitrosamines Safety Operational Expert Group	
Quality Innovation Expert 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 Immunologicals Working Party	Esther WERNER
CVMP Novel Therapies and Technologies Working Party	Jaqueline POOT
CVMP Pharmacovigilance Working Party	Els DEWAELE
CVMP Quality Working Party	Blanka HIRSCHLEROVA
CVMP Safety Working Party	Carina BERGMAN
CVMP Scientific Advice Working Party	Frida HASSLUNG WIKSTRÖM

Other CVMP-associated groups

Chair	
Antimicrobia Advice Ad Hoc Expert Group	

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 GROSS-MARTIROSYAN/EMA representative
Granularity and Periodicity Advisory Group (GPAG)	Menno van der ELST

Chair	
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Menno van der ELST/EMA representative
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)

HMPC working parties

Chair	
Working Party on European Union Monographs and European Union List	On hold

HMPC temporary drafting groups

Chair	
Organisational Matters Drafting Group	On hold
Quality Drafting Group	On hold

Committee for Advanced Therapies (CAT)

CAT associated group

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

Paediatric Committee(PDCO)

PDCO working groups

Chair	
Formulation Working Group	Brian AYLWARD (ad interim)

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

Other CMDh-associated groups

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

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

	Chair
Document Management Working Group	CMDv member from Member State holding EU Presidency
Autogenous Vaccines Working Group	Mariette SALERY
Borderline Products Working Group	Jose JONIS
Legislation Working Group	Laetitia LE LETTY
Working Group on Improvement of DCP/MRP	Mariette SALERY
SPC Harmonisation Working Group	Laetitia LE LETTY
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
Active Substance master File Working Group	
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 2022

This annex is available in an Excel spread sheet [here](#).

Annex 11 – Guidelines and concept papers adopted by CHMP

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/QWP/IWG/694114/2019	Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need	Final	22 April 2022
EMA/CHMP/BWP/721411/2022	PMF dossier requirements. Questions and Answers for PMF Holders	Final	15 September 2022
EMA/CHMP/CMDh/CAT/BWP/828612/2022	Reflection paper on criteria to be considered for the 6 evaluation of new active substance (NAS) status of 7 biological substances	Draft for consultation	10 November 2022

Patients' and Consumers' Working Party

Reference number	Document	Status	Date
EMA/CHMP/257298/2018	Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance	Final	22 April 2021

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/QWP/IWG/694114/2019	BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need	Final	22 April 2022
EMA/CHMP/600383/2022	Concept paper on the revision of the guideline on the chemistry of active substances	Final	11 July 2022
EMA/CHMP/QWP/735422/2022	Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Peptides	Final	15 September 2022
EMA/CHMP/QWP/735423/2022	Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Oligonucleotides	Final	15 September 2022

Annex 12 – CVMP opinions in 2022 on medicinal products for veterinary use

Positive opinions

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Decision • Notification • Official Journal
<ul style="list-style-type: none"> • RenuTend • Tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells 	<ul style="list-style-type: none"> • Boehringer Ingelheim Vetmedica GmbH 	<ul style="list-style-type: none"> • Horses • To improve healing of injuries of tendons and suspensory ligaments in horses 	<ul style="list-style-type: none"> • 16/12/2020 • 16/02/2022 • 208 • 219 	<ul style="list-style-type: none"> • 19/04/2022 • Pending • Pending • Pending
<ul style="list-style-type: none"> • Chanaxin • Tulathromycin 	<ul style="list-style-type: none"> • Chanelle Pharmaceuticals Manufacturing Ltd 	<ul style="list-style-type: none"> • Cattle, Pigs, Sheep • Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the group must be established before the product is used. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin. Pigs Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus 	<ul style="list-style-type: none"> • 21/10/2020 • 16/02/2022 • 208 • 275 	<ul style="list-style-type: none"> • 19/04/2022 • Pending • Pending • Pending

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Decision • Notification • Official Journal
		pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica susceptible to tulathromycin. The presence of the disease in the group must be established before the product is used. The veterinary medicinal product should only be used if pigs are expected to develop the disease within 2-3 days. Sheep Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.		
<ul style="list-style-type: none"> • Evanovo • Coccidiosis vaccine live for chickens 	<ul style="list-style-type: none"> • Laboratorios Hipra, S.A. 	<ul style="list-style-type: none"> • Chickens (embryonated eggs) • For the active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis 	<ul style="list-style-type: none"> • 12/05/2021 • 15/06/2022 • 208 • 191 	<ul style="list-style-type: none"> • 27/07/2022 • 28/07/2022 • C 331 • 31/08/2022

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Decision • Notification • Official Journal
		caused by Eimeria acervulina, Eimeria maxima and Eimeria praecox, and for the reduction of clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by Eimeria tenella		
<ul style="list-style-type: none"> • DogStem • Equine umbilical cord-derived mesenchymal stem cells 	<ul style="list-style-type: none"> • EquiCord S.L. 	<ul style="list-style-type: none"> • Dogs • Reduction of pain and lameness associated with osteoarthritis in dogs 	<ul style="list-style-type: none"> • 09/06/2021 • 15/06/2022 • 208 • 163 	<ul style="list-style-type: none"> • 31/11/2022 • Pending • Pending • Pending
<ul style="list-style-type: none"> • Coxatab • Firocoxib 	<ul style="list-style-type: none"> • CP-Pharma Handelsgesellschaft mbH 	<ul style="list-style-type: none"> • Dogs • For the relief of pain and inflammation associated with osteoarthritis in dogs. For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs. 	<ul style="list-style-type: none"> • 08/07/2021 • 15/06/2022 • 207 • 135 	<ul style="list-style-type: none"> • 12/08/2022 • 16/08/2022 • C 376 • 30/09/2022
<ul style="list-style-type: none"> • Cortadem • Hydrocortisone aceponate 	<ul style="list-style-type: none"> • Alfasan Nederland B.V. 	<ul style="list-style-type: none"> • Dogs • For symptomatic treatment of inflammatory and pruritic dermatoses in dogs. For alleviation of clinical signs 	<ul style="list-style-type: none"> • 16/12/2020 • 15/06/2022 • 209 • 337 	<ul style="list-style-type: none"> • 27/07/2022 • 29/07/2022 • C 331 • 31/08/2022

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Decision • Notification • Official Journal
		associated with atopic dermatitis.		
<ul style="list-style-type: none"> • AdTab • Lotilaner 	<ul style="list-style-type: none"> • Elanco GmbH 	<ul style="list-style-type: none"> • Cats, Dogs • For the treatment of flea and tick infestations and demodicosis in dogs. For the treatment of flea and tick infestations on cats 	<ul style="list-style-type: none"> • 16/05/2022 • 14/07/2022 • 59 • 0 	<ul style="list-style-type: none"> • 13/09/2022 • Pending • Pending • Pending
<ul style="list-style-type: none"> • Momentamax Ultra • Gentamicin / Posaconazole / Mometasone furoate 	<ul style="list-style-type: none"> • Intervet International B.V. 	<ul style="list-style-type: none"> • Dogs • Treatment of acute otitis externa or acute exacerbation of recurrent otitis externa caused by mixed bacterial and fungal infections with Staphylococcus pseudintermedius susceptible to gentamicin and Malassezia pachydermatis susceptible to posaconazole. 	<ul style="list-style-type: none"> • 12/05/2021 • 06/10/2022 • 210 • 302 	<ul style="list-style-type: none"> • 22/11/2022 • Pending • Pending • Pending
<ul style="list-style-type: none"> • Neoleish • Canine leishmaniasis vaccine (recombinant DNA plasmid) 	<ul style="list-style-type: none"> • CZ Veterinaria, S.A. 	<ul style="list-style-type: none"> • Dogs • For the active immunization of Leishmania negative dogs from 6 months of age to reduce the risk to develop an active infection and/or clinical disease after exposure to 	<ul style="list-style-type: none"> • 21/10/2020 • 10/11/2022 • 209 • 541 	<ul style="list-style-type: none"> • 20/12/2022 • Pending • Pending • Pending

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Decision • Notification • Official Journal
		Leishmania infantum		
<ul style="list-style-type: none"> • Brucellin Aquilon • Brucella abortus, strain AQ1302, protein extract 	<ul style="list-style-type: none"> • Aquilon Cyl S.L. 	<ul style="list-style-type: none"> • Pigs • For in vivo diagnosis of Brucella-infected pigs through a positive skin reaction after a positive serological Brucella test. Brucellin Aquilon has been specifically designed as a second line diagnostic test to differentiate Brucella-infected pigs, from the age of 5 months, from the Brucella-free pigs having given false positive serological reactions (FPSR) in brucellosis serological tests based on anti-O-PS antibodies (e.g. Rose Bengal). 	<ul style="list-style-type: none"> • 11/08/2021 • 08/12/2022 • 210 • 274 	<ul style="list-style-type: none"> • Pending • Pending • Pending • Pending

Negative opinions

There were no negative opinions in 2022.

CVMP opinions in 2022 on establishment of MRLs

Positive opinions

Product <ul style="list-style-type: none">• Substance	Target species	EMA/CVMP <ul style="list-style-type: none">• Validation• Opinion• Active time• Clock stop	European Commission <ul style="list-style-type: none">• Opinion received• Regulation• Official Journal
<ul style="list-style-type: none">• Praziquantel	<ul style="list-style-type: none">• All ruminants except bovine; <i>Equidae</i>; fin fish	<ul style="list-style-type: none">• 11/08/2021• 0/09/2022• 210• 183	<ul style="list-style-type: none">• Pending• Pending• Pending

Negative opinions

There were no negative opinions on establishment of MRLs in 2022.

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

Product <ul style="list-style-type: none">• Brandname• INN	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none">• ATC Code• Summary of indication	EMA/CVMP opinion	European Commission decision date
<ul style="list-style-type: none">• Credelio• Lotilaner	<ul style="list-style-type: none">• Elanco GmbH	<ul style="list-style-type: none">• QP53BE04• To add a new therapeutic indication for the treatment of demodicosis (caused by <i>Demodex canis</i>) in dogs	<ul style="list-style-type: none">• 19/01/2022	<ul style="list-style-type: none">• 16/03/2022

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CVMP opinion	European Commission decision date
<ul style="list-style-type: none"> • Advocate • Imidacloprid / Moxidectin 	<ul style="list-style-type: none"> • Bayer Animal Health GmbH 	<ul style="list-style-type: none"> • QP54AB52 • To add a new therapeutic indication for the treatment of the lungworm <i>Troglostrongylus brevior</i> (adults) in cats 	<ul style="list-style-type: none"> • 16/03/2022 	<ul style="list-style-type: none"> • 05/05/2022
<ul style="list-style-type: none"> • Soprelorin • Deslorelin acetate 	<ul style="list-style-type: none"> • Virbac S.A. 	<ul style="list-style-type: none"> • QH01CA93 • To add a new therapeutic indication (in female dogs) and to add a non-food producing target species (male cats). In addition, the MAH took the opportunity to implement editorial changes in the product information 	<ul style="list-style-type: none"> • 12/05/2022 	<ul style="list-style-type: none"> • 14/06/2022

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CVMP opinion	European Commission decision date
<ul style="list-style-type: none"> • Bravecto • Fluralaner 	<ul style="list-style-type: none"> • Intervet International B.V. 	<ul style="list-style-type: none"> • QP53BE02 • To add two new therapeutic indications for Bravecto chewable tablets for dogs: for the treatment of tick infestations with Ixodes hexagonus and for reduction of the risk of infection with Dipylidium caninum via transmission by Ctenocephalides felis for up to 12 weeks 	<ul style="list-style-type: none"> • 15/06/2022 	<ul style="list-style-type: none"> • 15/07/2022
<ul style="list-style-type: none"> • Simparica Trio • Sarolaner / Moxidectin / Pyrantel embonate 	<ul style="list-style-type: none"> • Zoetis Belgium 	<ul style="list-style-type: none"> • QP54AB52 • To add a new therapeutic indication for reduction of the risk of infection with Babesia canis via transmission by Dermacentor reticulatus for up to 28 days after treatment and to update SPC section 5.1 regarding the onset of efficacy for Ixodes ricinus ticks 	<ul style="list-style-type: none"> • 06/10/2022 	<ul style="list-style-type: none"> • 30/11/2022

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CVMP opinion	European Commission decision date
<ul style="list-style-type: none"> • Simparica Trio • Sarolaner / Moxidectin / Pyrantel embonate 	<ul style="list-style-type: none"> • Zoetis Belgium 	<ul style="list-style-type: none"> • QP54AB52 • To add three new therapeutic indications: for the treatment of sarcoptic mange (<i>Sarcoptes scabiei</i> var. <i>canis</i>), for the treatment of demodicosis (<i>Demodex canis</i>), and for the prevention of establishment of thelaziosis (adult <i>Thelazia callipaeda</i> eyeworm infection) 	<ul style="list-style-type: none"> • 08/12/2022 	<ul style="list-style-type: none"> • 01/03/2023
<ul style="list-style-type: none"> • Nexgard • Afoxolaner 	<ul style="list-style-type: none"> • Boehringer Ingelheim Vetmedica GmbH 	<ul style="list-style-type: none"> • QP53BE01 • To add two new therapeutic indications for the treatment of tick infestations with <i>Hyalomma marginatum</i> and for the treatment of ear mite infestation (caused by <i>Otodectes cynotis</i>), and to amend the product information to allow the use of the product in breeding, pregnant and lactating female dogs 	<ul style="list-style-type: none"> • 08/12/2022 	<ul style="list-style-type: none"> • Pending

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CVMP opinion	European Commission decision date
<ul style="list-style-type: none"> • Nexgard Spectra • Afoxolaner/Milbemycin oxime 	<ul style="list-style-type: none"> • Boehringer Ingelheim Vetmedica GmbH 	<ul style="list-style-type: none"> • QP54AB51 • To add two new therapeutic indications for the treatment of tick infestations with <i>Hyalomma marginatum</i> and for the treatment of ear mite infestation (caused by <i>Otodectes cynotis</i>), and to amend the product information to allow the use of the product in breeding, pregnant and lactating female dogs 	<ul style="list-style-type: none"> • 08/12/2022 	<ul style="list-style-type: none"> • Pending
<ul style="list-style-type: none"> • Credelio Plus • Lotilaner/Milbemycin oxime 	<ul style="list-style-type: none"> • Elanco GmbH 	<ul style="list-style-type: none"> • QP54AB51 • To add a new therapeutic indication for the treatment of demodicosis (caused by <i>Demodex canis</i>). 	<ul style="list-style-type: none"> • 08/12/2022 	<ul style="list-style-type: none"> • 24/01/2023

Annex 13 – Guidelines and concept papers adopted by CVMP in 2022

CVMP Quality

Reference number	Document title	Status
EMA/HMPC/CHMP/CVMP/201116/20051 Rev. 3	Guideline on quality of herbal medicinal products/traditional herbal medicinal products	Adopted January 2022
EMA/HMPC/CHMP/CVMP/162241/20051 Rev. 3	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products	Adopted January 2022
EMA/CVMP/QWP/697426/2021	Draft Concept paper on the need for amendment of Guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water – Annex on the concomitant use of veterinary medicinal products and biocides.	Adopted January 2022 for consultation End of consultation: 30 April 2022
List of questions and answers on titanium dioxide	List of questions and answers on titanium dioxide	Adopted June 2022
EMA/CHMP/QWP/735422/2022	Draft Concept Paper on the establishment of a Guideline on the development and manufacture of synthetic peptides	Adopted September 2022 for consultation End of consultation: 20 December 2022
EMA/CHMP/QWP/735423/2022	Draft Concept Paper on the establishment of a Guideline on the development and manufacture of synthetic oligonucleotides	Adopted September 2022 for consultation End of consultation: 20 December 2022
EMA/CVMP/QWP/684556/2022	Guideline on development pharmaceuticals for veterinary medicinal products ¹	Adopted December 2022
EMA/CVMP/QWP/707366/2017 - Rev.1	Guideline on the chemistry of active substances for veterinary medicinal products ¹	Adopted December 2022

¹ Revised to align to new provisions of Regulation (EU) 2019/6

Reference number	Document title	Status
EMA/CVMP/QWP/907965/2022	Guideline on control of impurities of pharmacopoeial substances: compliance with the European Pharmacopoeia general monograph "substances for pharmaceutical use" and general chapter "control of impurities in substances for pharmaceutical use" ²	Adopted December 2022
EMA/CVMP/QWP/339588/2005 - Rev.1	Guideline on parametric release ²	Adopted December 2022
EMA/CVMP/QWP/857608/2022	Guideline on declaration of storage conditions: A) in the product information of pharmaceutical veterinary medicinal products; B) for active substances ²	Adopted December 2022
EMA/CVMP/QWP/709423/2022	Guideline on Stability Testing: Stability testing of existing active substances and related finished products ²	Adopted December 2022
EMA/CVMP/QWP/711629/2022	Guideline on additional Quality requirements for products intended for incorporation into animal feed ²	Adopted December 2022
EMA/CVMP/QWP/544461/2007 - Rev.1	Guideline on the quality aspects of single-dose veterinary spot-on products ²	Adopted December 2022
EMA/CVMP/QWP/908160/2022	Guideline on the quality of modified release dosage forms for veterinary use	Adopted December 2022

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/591282/2021	Draft Guideline on determination of the need for an MRL evaluation for biological substances	Adopted January 2022 for consultation End of consultation: 29 April 2022
EMA/CVMP/SWP/735325/2012 Rev.2	Revised Guideline on determination of withdrawal periods for edible tissues, and injection site residues ¹	Adopted March 2022

² Revised to align to new provisions of Regulation (EU) 2019/6

Reference number	Document title	Status
EMA/CVMP/SWP/735418/2012 Rev.1	Revised Guideline on determination of withdrawal periods for milk ¹	Adopted March 2022
EMA/CVMP/SWP/185470/2004 Rev.1	Revised Guideline on injection site residues ¹	Adopted March 2022
EMA/CVMP/345236/2020	Guideline on safety and residue data requirements for the establishment of Maximum Residue Limits (MRL) in minor species	Adopted March 2022

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/278031/2015	Guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats	Adopted June 2022
EMA/CVMP/EWP/222080/2022	Concept paper on the revision of the guideline for veterinary medicinal products for zootechnical purposes	Adopted July 2022 for consultation End of consultation: 31 October 2022
EMA/CVMP/EWP/799840/2022	Questions and answers document on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products'	Adopted December 2022

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009 - Rev.13	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2022
EMA/CVMP/PhVWP/237953/2022	List of changes to combined VeDDRA list of clinical terms	Adopted June 2022
EMA/CVMP/PhVWP/288284/2007 - Rev. 14	Revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2022

Reference number	Document title	Status
EMA/CVMP/150343/2016-Rev.3	Revision of the questions and answers on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL))	Adopted September 2023

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/387275/2020	Draft reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6	Adopted January 2022 for consultation End of consultation: 29 April 2022
EMA/CVMP/AWP/201064/2022	Draft Concept paper on the development of a guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6	Adopted September 2022 for consultation End of consultation: 31 January 2023

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/105506/2007 - Rev.2	Revised guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines	Adopted January 2022
EMA/CVMP/IWP/258755/2021	Guideline on data requirements for vaccine antigen master files (VAMF)	Adopted January 2022
EMA/CVMP/IWP/283631/2021	Guideline on data requirements for vaccine platform technology master files (vPTMF)	Adopted January 2022
EMA/CVMP/IWP/251947/2021	Guideline on data requirements for authorisation of immunological veterinary medicinal products (IVMPs) in exceptional circumstances	Adopted January 2022
EMA/CVMP/IWP/260956/2021	Guideline on clinical trials with immunological veterinary medicinal products (IVMPs)	Adopted January 2022

Reference number	Document title	Status
EMA/CVMP/IWP/206555/2010 - Rev.2	Draft revised guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted January 2022 for consultation End of consultation: 22 March 2022
EMA/CVMP/IWP/206555/2010 - Rev.2	Revised guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted June 2022

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/622045/2020	Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6	Adopted February 2022
EMA/CVMP/ERA/245311/2021	Reflection paper on the interpretation of Article 72 of Regulation (EU) 2019/6	Adopted March 2022
EMA/CVMP/ERA/172074/2008 - Rev.7	Updated Questions and Answers document on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of VICH guidelines 6 and 38	Adopted May 2022
EMA/CVMP/ERA/31905/2022	Draft Reflection paper on the environmental risk assessment of ectoparasitocidal veterinary medicinal products used in cats and dogs	Adopted December 2022 for consultation End of consultation: 31 March 2023

CVMP Novel therapies and technologies

Reference number	Document title	Status
EMA/CVMP/NTWP/438290/2021	Concept paper on quality, safety and efficacy of bacteriophages as veterinary medicines	Adopted January 2022 for consultation End of consultation: 29 April 2022

Reference number	Document title	Status
EMA/CVMP/NTWP/470741/2021	Concept paper on the development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy	Adopted January 2022 for consultation End of consultation: 29 April 2022
EMA/CVMP/NTWP/179287/2022	Draft Guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy	Adopted November 2022 for consultation Ed of consultation: 28 February 2023

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

None.

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/565615/2021 - Rev.1	Question and answer document on requirements for pre-clinical studies submitted in support of a marketing authorisation application for a veterinary medicinal product	Adopted January 2022
EMA/CVMP/116512/2021	Draft reflection paper on the criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6	Adopted February 2022 for consultation End of consultation: 31 May 2022
EMA/CVMP/65618/2022	Concept paper on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6	Adopted March 2022 for consultation End of consultation: 30 April 2022
EMA/CVMP/127488/2021	Procedural advice for veterinary vaccine antigen master file (VAMF) certification	Adopted April 2022
EMA/CVMP/32995/2006 – Rev. 1	Revised procedural advice on accelerated assessment of marketing authorisation applications pursuant to Article 44(3) of Regulation (EU) No 2019/6	Adopted April 2022

Reference number	Document title	Status
EMA/CVMP/184591/2022	Draft procedural advice document for vaccine platform technology master file (vPTMF) certification	Adopted May 2022 for consultation End of consultation: 20 July 2022
EMA/CVMP/IWP/466888/2017 - Rev.2	Updated Questions and Answers document on data requirements for multi-strain dossiers for inactivated vaccines	Adopted May 2022
EMA/CVMP/273040/2022	Draft Guideline on the application of Article 34 of Regulation (EU) 2019/6 (classification of veterinary medicinal products - prescription status)	Adopted July 2022 for consultation End of consultation: 31 October 2022
EMA/CVMP/116512/2021	Reflection paper on the criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6	Adopted October 2022
EMA/CVMP/64911/2021	Draft reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations	Adopted November 2022 for consultation Ed of consultation: 28 February 2023

General

Reference number	Document title	Status
EMA/CVMP/VICH/502/1999	Revised guideline VICH GL18(R2) on impurities: residual solvents in new veterinary medicinal products, active substances and excipients	Adopted January 2022 for consultation End of consultation: 10 June 2022
EMA/CVMP/499555/2021	Draft report on the development of a harmonised approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin	Adopted April for consultation End of consultation: 13 September 2022
EMA/CVMP/VICH/832/1999-Rev.1	VICH GL07(R) – Anthelmintics – General requirements	Adopted June 2022 for consultation End of consultation: 1 November 2022

Reference number	Document title	Status
EMA/CVMP/VICH/839/1999-Rev.1	VICH GL12(R) – Anthelmintics – Bovines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/840/1999-Rev.1	VICH GL13(R) – Anthelmintics – Ovines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/841/1999-Rev.1	VICH GL14(R) – Anthelmintics – Caprines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/833/1999-Rev.1	VICH GL15(R) – Anthelmintics – Equines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/834/1999-Rev.1	VICH GL16(R) – Anthelmintics – Porcines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/835/1999-Rev.1	VICH GL19(R) – Anthelmintics – Canines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/545/2000-Rev.1	VICH GL20(R) – Anthelmintics – Felines	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/CVMP/VICH/546/2000-Rev.1	VICH GL21(R) – Anthelmintics – Chickens	Adopted June 2022 for consultation End of consultation: 1 November 2022
EMA/241392/2022 (not published yet)	Mandate, objectives and rules of procedure for the European Sales and Use of Veterinary Antimicrobials Working Group	Adopted November 2022
EMA/CVMP/617330/2022	CVMP work plan for 2023	Adopted December 2022

Annex 14 – COMP opinions in 2022 on designation of orphan medicinal products

Positive COMP designation opinions

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP	European Commission
			<ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	<ul style="list-style-type: none"> • Opinion received • Date of decision
Vatiquinone	PTC Therapeutics International Limited - Ireland	Treatment of mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes	26/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Autologous CD34+ cells edited with CRISPR/Cas9 and transduced with an adeno-associated virus vector serotype 6 containing the codon-optimized version of <i>PKLR</i> gene	Consorcio Centro de Investigacion Biomedica en Red - Spain	Treatment of pyruvate kinase deficiency	26/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Bovactant	Aerogen Pharma Limited - Ireland	Treatment of respiratory distress syndrome	26/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Epcoritamab	Abbvie Deutschland GmbH & Co. KG - Germany	Treatment of diffuse large B-cell lymphoma	26/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Cannabidiol	EUDRAC GmbH - Germany	Treatment of fragile X syndrome	25/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Enzastaurin hydrochloride	Dlrc Pharma Services Limited - Ireland	Treatment of Ehlers-Danlos syndrome	25/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Valemetostat tosilate	Daiichi Sankyo Europe GmbH - Germany	Treatment of peripheral T-cell lymphoma	25/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Pyridoxal 5'-phosphate	Amsterdam UMC - Netherlands	Treatment of pyridoxamine 5'-phosphate oxidase	22/10/2021 23/11/2021 20/01/2022	25/01/2022 24/02/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
		deficiency	(58/30)	
18-mer antisense oligonucleotide complementary to SCN1A mRNA, sodium salt	Insidereg Limited - Ireland	Treatment of Dravet Syndrome	21/10/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Aldesleukin	Iltoo Pharma - France	Treatment of amyotrophic lateral sclerosis	28/09/2021 26/10/2021 20/01/2022 (86/30)	25/01/2022 24/02/2022
[Ala1,3,12,Gln10,Arg11,Trp14]PTH(1-14)/[Ala18,22,Lys26]PTHrP(15-36)COOH	Amolyt Pharma - France	Treatment of hypoparathyroidism	27/09/2021 23/11/2021 20/01/2022 (58/30)	25/01/2022 24/02/2022
Gadolinium-chelated polysiloxane nanoparticles	Nh Theraguix - France	Treatment of pancreatic cancer	30/08/2021 26/10/2021 20/01/2022 (86/30)	25/01/2022 24/02/2022
Emactuzumab	Synox Therapeutics Limited - Ireland	Treatment of tenosynovial giant-cell tumour, local and diffuse type	23/11/2021 04/01/2022 17/02/2022 (44/22)	23/02/2022 17/03/2022
Codergocrine mesylate, oxitriptan	Purposeful I.K.E. - Greece	Treatment of fragile X syndrome	22/11/2021 04/01/2022 17/02/2022 (44/22)	23/02/2022 17/03/2022
Heterologous human adult liver-derived stem cells	Unicyte S.r.l. Italy	Treatment of argininosuccinic aciduria	22/11/2021 04/01/2022 17/02/2022 (44/21)	23/02/2022 16/03/2022
Treprostinil sodium	Unither Therapeutik GmbH - Germany	Treatment of idiopathic pulmonary fibrosis	22/11/2021 04/01/2022 17/02/2022 (44/21)	23/02/2022 16/03/2022
Adeno-associated virus serotype HSC15, containing human homology arms, expressing human phenylalanine hydroxylase	Diamond Pharma Services Ireland Limited - Ireland	Treatment of phenylalanine hydroxylase deficiency	22/11/2021 04/01/2022 17/02/2022 (44/22)	23/02/2022 17/03/2022
Alisporivir	Fondazione Telethon Ets - Italy	Treatment of collagen VI-related myopathies	22/11/2021 04/01/2022 17/02/2022 (44/21)	23/02/2022 16/03/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Adeno-associated virus serotype HSC 15 expressing human iduronate 2-sulfatase	Diamond Pharma Services Ireland Limited - Ireland	Treatment of mucopolysaccharidosis type II (Hunter syndrome)	19/11/2021 04/01/2022 17/02/2022 (44/22)	23/02/2022 17/03/2022
(S)-12-fluoro-4-(2-methylpyridin-3-yl)-7a,8,13,14-tetrahydro-7H-[1,2,4]triazolo[4',3':1,6]pyridido[3,2-b]benzofuro[4,3-fg][1,4]oxazoline	Pharma Gateway AB - Sweden	Treatment of sickle cell disease	18/11/2021 04/01/2022 17/02/2022 (44/21)	23/02/2022 16/03/2022
Tropatepine hydrochloride	Laboratoires Delbert - France	Treatment of narcolepsy	26/10/2021 23/11/2022 17/02/2022 (86/21)	23/02/2022 16/03/2022
Dersimelagon	Mitsubishi Tanabe Pharma GmbH - Germany	Treatment of erythropoietic protoporphyria	25/10/2021 04/01/2022 17/02/2022 (44/21)	23/02/2022 16/03/2022
Hymecromone	Ros Lynch	Treatment of spinal cord injury	13/06/2021 23/11/2022 17/02/2022 (86/21)	23/02/2022 16/03/2022
Adeno-associated virus vector serotype 9 encoding human gigaxonin gene	Raremoon Consulting Esp S.L. - Spain	Treatment of giant axonal neuropathy	07/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Adeno-associated virus serotype 9 containing human <i>MYBPC3</i> gene	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of hypertrophic cardiomyopathy due to mutations in the <i>MYBPC3</i> gene encoding cardiac myosin-binding protein C	07/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
(2S)-4-[2-methoxyethyl]-4-(5,6,7,8-tetrahydro-1,8-naphthyridin-2-yl)butyl]amino]-2-(quinazolin-4-ylamino)butanoic acid	Pharma Gateway AB - Sweden	Treatment of primary sclerosing cholangitis	07/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Adeno-associated virus serotype C102 containing the human <i>GLA</i> gene	Pharma Gateway AB - Sweden	Treatment of Fabry disease	07/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Adeno-associated viral	MDC RegAffairs GmbH	Treatment of	07/12/2021	23/03/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
vector serotype 8 encoding B-domain deleted liver specific codon optimized bioengineered chimeric human porcine factor VIII, under a synthetic hepatic combinatorial bundle promoter	- Germany	haemophilia A	25/01/2022 17/03/2022 (51/21)	13/04/2022
Glofitamab	Roche Registration GmbH - Germany	Treatment of mantle cell lymphoma	06/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Obecabtagene autoleucel	Autolus GmbH - Germany	Treatment of acute lymphoblastic leukaemia	06/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Belzupacap sarotalocan	FGK Representative Service GmbH - Germany	Treatment of uveal melanoma	06/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Devimistat	IQVIA RDS Ireland Limited - Ireland	Treatment of biliary tract cancer	06/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
Tiratricol	Rare Thyroid Therapeutics International AB - Sweden	Treatment of resistance to thyroid hormone type Beta	07/12/2021 25/01/2022 17/03/2022 (51/21)	23/03/2022 13/04/2022
N-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-sn-glycero-3-phosphatidylethanolamine	Icoat Medical AB - Sweden	Treatment of solid organ transplantation	23/11/2021 04/01/2022 17/03/2022 (72/21)	23/03/2022 13/04/2022
Cannabidiol	GW Pharma (International) B.V. - Netherlands	Treatment of epilepsy with myoclonic-atonic seizures	19/11/2021 04/01/2022 17/03/2022 (72/21)	23/03/2022 13/04/2022
Norucholic acid	Dr. Falk Pharma GmbH - Germany	Treatment of primary biliary cholangitis	19/11/2021 04/01/2022 17/03/2022 (72/21)	23/03/2022 13/04/2022
Pasireotide	Recordati Rare Diseases - France	Treatment of noninsulinoma	24/01/2022 14/02/2022	20/04/2022 16/05/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
		pancreatogenous hypoglycemia syndrome	13/04/2022 (58/26)	
Streptococcus pyogenes, group A, type 3, strain Su, inactivated	Pharma Gateway AB - Sweden	Treatment of lymphatic malformations	24/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Chimeric peptide of human glucagon-like peptide-1, glucagon and gastric inhibitory polypeptide analogues linked to a human immunoglobulin Fc fragment	JVM Europe B.V. - Netherlands	Treatment of idiopathic pulmonary fibrosis	24/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Autologous peripheral blood-derived CD4 T-cells CRISPR-edited at the CD40LG locus	Fondazione Telethon Ets - Italy	Treatment of hyper IgM syndromes	21/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Elezanumab	Abbvie Deutschland GmbH & Co. KG - Germany	Treatment of spinal cord injury	21/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Adeno-associated virus serotype 8 expressing the human gamma-sarcoglycan gene	Atamy Therapeutics - France	Treatment of limb-girdle muscular dystrophy	20/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Elamipretide	Scendea (NL) B.V. - Netherlands	Treatment of myopathic mitochondrial DNA depletion syndrome	20/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Icerguastat acetate	Inflectis Bioscience S.A.S - France	Treatment of amyotrophic lateral sclerosis	14/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Ibudilast	Healx Technology Limited - Ireland	Treatment of fragile X syndrome	14/01/2022 14/02/2022 13/04/2022 (58/26)	20/04/2022 16/05/2022
Cannabidiol	Tetra Bio-Pharma Europe Limited - Malta	Treatment of epidermolysis bullosa	07/12/2022 25/01/2022 13/04/2022 (78/26)	20/04/2022 16/05/2022
Adeno-associated virus	Pharma Gateway AB -	Treatment of inherited	07/12/2022	20/04/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
serotype R100 containing the human <i>RPGRorf15</i> gene isoform	Sweden	retinal dystrophies due to defects in the RPGR gene	25/01/2022 13/04/2022 (78/26)	16/05/2022
Fusion protein composed of the first 2 immunoglobulin-like domains of the human Roundabout guidance receptor 2 fused to a human IgG1 crystallised fragment	Pfizer Europe MA EEIG - Belgium	Treatment of focal segmental glomerulosclerosis	06/12/2022 25/01/2022 13/04/2022 (78/26)	20/04/2022 16/05/2022
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD123	INSERM UMR 1098 - France	Treatment of blastic plasmacytoid dendritic cell neoplasm	30/11/2022 25/01/2022 13/04/2022 (78/26)	20/04/2022 16/05/2022
Govorestat	Veristat Spain S.L. - Spain	Treatment of galactosaemia	30/11/2022 25/01/2022 13/04/2022 (78/26)	20/05/2022 21/06/2022
Tamoxifen citrate	Fondazione Telethon Ets - Italy	Treatment of neuronal ceroid lipofuscinosis	25/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Eltanexor	Karyopharm Europe GmbH - Germany	Treatment of myelodysplastic syndromes	25/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Sirolimus	Raremoon Consulting Esp S.L. - Spain	Treatment of lymphatic malformations	24/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Pirfenidone	Regintel Limited - Ireland	Treatment of idiopathic pulmonary fibrosis	24/02/2022 25/03/2022 12/05/2022 (48/35)	20/05/2022 21/06/2022
Amitriptyline	AlgoTherapeutix - France	Treatment of erythromelalgia	24/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Diflunisal	Turnkey Pharmaconsulting Ireland Limited -	Treatment of ATTR amyloidosis	24/02/2022 25/03/2022 12/05/2022	20/05/2022 21/06/2022

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O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanilyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanilyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenine, sodium salt				
Escherichia coli, strain Nissle 1917, expressing high affinity phenylalanine transporter, phenylalanine ammonia lyase and L-amino acid deaminase	Orphix Consulting GmbH - Germany	Treatment of hyperphenylalaninemia	21/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Humanised IgG4 monoclonal antibody against A proliferation-inducing ligand	Tmc Pharma (EU) Limited - Ireland	Treatment of primary IgA nephropathy	21/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Lithium carbonate	Centre Hospitalier Universitaire De Dijon - France	Treatment of TBR1-related disorder	09/02/2022 25/03/2022 12/05/2022 (48/32)	20/05/2022 21/06/2022
Doxorubicin	Thermosome GmbH - Germany	Treatment of soft tissue sarcoma	25/02/2022 14/02/2022 12/05/2022 (87/32)	20/05/2022 21/06/2022
Losartan	3R Pharma Consulting GmbH - Germany	Treatment of osteogenesis	23/01/2022 25/03/2022	20/05/2022 21/06/2022

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		imperfecta	12/05/2022 (48/32)	
3-(1-(2',3'-Dimethoxy-[1,1'-biphenyl]-4-yl)-1H-1,2,3-triazol-4-yl)benzoic acid	Chemicare S.r.l. - Italy	Treatment of gain-of-function mutations of STIM1 and ORAI1 related diseases	23/01/2022 14/02/2022 12/05/2022 (87/32)	20/05/2022 21/06/2022
Sodium (4Z,7Z,10R,11E,13E,15Z,17S,19Z)10,17-Dihydroxydocosa-4,7,11,13,15,19-hexaenoate	Granzer Regulatory Consulting & Services GmbH - Germany	Prevention of retinopathy of prematurity	21/01/2022 14/02/2022 12/05/2022 (87/32)	20/05/2022 21/06/2022
Ropeginterferon alfa-2b	Aop Orphan Pharmaceuticals GmbH - Austria	Treatment of chronic myeloid leukemia	07/12/2022 14/02/2022 12/05/2022 (87/32)	20/05/2022 21/06/2022
4-[[[(3S)-1-benzylpyrrolidin-3-yl]-methylamino]-2-fluoro-5-methyl-N-(1,3-thiazol-4-yl)benzenesulfonamide	Neurocrine Therapeutics Limited - Ireland	Treatment of SCN8A developmental and epileptic encephalopathy	24/02/2022 25/03/2022 16/05/2022 (52/32)	20/05/2022 21/06/2022
Panobinostat	Scendea (NL) B.V. - Netherlands	Treatment of glioma	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
(S)-1-(4-(1-(3,4,5-trimethoxyphenyl)-1H-imidazol-4-ylamino)thieno[2,3-d]pyrimidin-2-yl)pyrrolidine-2-carboxamide	Biocryst Ireland Limited - Ireland	Treatment of fibrodysplasia ossificans progressiva	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Human decorin fused to the truncated homing peptide CRK	Tampereen Korkeakoulusäätiö Sr - Finland	Treatment of epidermolysis bullosa	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
3-(1,3-benzodioxol-5-yl)-5-(3-bromophenyl)-1H-pyrazole	Teva B.V. - Netherlands	Treatment of multiple system atrophy	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
(R)-3-(2,3-dihydroxypropyl)-6-fluoro-5-(2-fluoro-4-iodophenylamino)-8-	Diamond Pharma Services Ireland Limited - Ireland	Treatment of familial adenomatous polyposis	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022

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methylpyrido[2,3-d]pyrimidine-4,7(3H,8H)-dione				
Pyridoxal 5'-phosphate	Amsterdam UMC - Netherlands	Treatment of pyridoxal 5'-phosphate homeostasis protein deficiency	24/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Humanised IgG4 monoclonal antibody against active complement component 1, subcomponent s	Genzyme Europe B.V. - Netherlands	Treatment of autoimmune haemolytic anaemia	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Liraglutide	Pietro Maffei - Italy	Treatment of Wolfram syndrome	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Autologous naive regulatory T cells transduced with a lentiviral vector encoding for a chimeric antigen receptor to recognise the HLA-A*02 antigen	Sangamo Therapeutics France S.A.S. - France	Treatment in solid organ transplantation	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Toripalimab	Tmc Pharma (EU) Limited - Ireland	Treatment of nasopharyngeal cancer	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Fosmanogepix	Pfizer Europe MA EEIG - Belgium	Treatment of invasive aspergillosis	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Fosmanogepix	Pfizer Europe MA EEIG - Belgium	Treatment of invasive candidiasis	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
W253R/R275S tissue plasminogen activator	Op2Lysis - France	Treatment of non-traumatic spontaneous intracerebral haemorrhage	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Odronextamab	Regeneron Ireland Designated Activity Company - Ireland	Treatment of diffuse large B-cell lymphoma	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022

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Odronextamab	Regeneron Ireland Designated Activity Company - Ireland	Treatment of follicular lymphoma	23/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
2,4,6,7,8,9-hexahydro-4-((2-methylphenyl)methyl)-7-(phenylmethyl)imidazo(1,2-a)pyrido(3,4-e)pyrimidin-5(1H)-one	Chimerix IRL Limited - Ireland	Treatment of glioma	22/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Berzosertib	Merck Europe B.V. - Netherlands	Treatment of small cell lung cancer	22/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Erlotinib	Imagine Institut Des Maladies Genetiques Necker Enfants Malades - France	Treatment of pachyonychia congenita	21/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Zilucoplan	UCB Pharma - Belgium	Treatment of myasthenia gravis	21/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Parsaclisib	Incyte Biosciences Distribution B.V. - Netherlands	Treatment of autoimmune haemolytic anaemia	17/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Efgartigimod alfa	Argenx - Belgium	Treatment of pemphigus	15/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Vilobelimab	InflaRx GmbH - Germany	Treatment of pyoderma gangrenosum	14/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Sodium phenylbutyrate	Renantos Pharmavertriebsgesellschaft mbH - Germany	Treatment of maple syrup urine disease	11/03/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Heterologous swine glyco-humanised polyclonal antibody against T lymphocytes	Xenothera - France	Treatment in solid organ transplantation	25/02/2022 25/03/2022 16/06/2022 (83/24)	24/06/2022 18/07/2022
Salmonella enterica,	Premier Research	Treatment of	16/02/2022	24/06/2022

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subsp. enterica, serovar Typhimurium, strain YS1646, live	Group S.L. - Spain	schwannoma	25/03/2022 16/06/2022 (83/24)	18/07/2022
mRNA encoding modified human ornithine transcarbamylase	Arcturus Therapeutics Europe B.V. - Netherlands	Treatment of ornithine transcarbamylase deficiency	09/02/2022 19/04/2022 16/06/2022 (58/24)	24/06/2022 18/07/2022
Hydroquinidine hydrochloride	Teofarma S.r.l. - Italy	Treatment of Brugada syndrome	24/01/2022 25/03/2022 16/06/2022 (83/24)	24/06/2022 18/07/2022
Thiostrepton	EMA Regulatory Submissions Expediter Limited - Ireland	Treatment of malignant mesothelioma	11/01/2022 25/03/2022 16/06/2022 (83/24)	24/06/2022 18/07/2022
Bezafibrate	Amsterdam UMC - Netherlands	Treatment of primary sclerosing cholangitis	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Amphotericin B	Insight Drug Regulatory - Luxembourg	Treatment of cryptococcosis	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Autologous human bone marrow-derived haematopoietic and mesenchymal stem cells depleted of erythrocytes, monocytes and lymphocytes	Neuroplast B.V. - Netherlands	Treatment of frontotemporal dementia	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Nanatinostat, valganciclovir	Pharma Gateway AB - Sweden	Treatment of peripheral T-cell lymphoma	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Humanised IgG1 tetraivalent monoclonal antibody against death receptor 5	Tmc Pharma (EU) Limited - Ireland	Treatment of chondrosarcoma	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Allogeneic adult liver-derived stem cells	Unicyte S.r.l. - Italy	Treatment of urea cycle disorders	20/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Batoclimab	Pharma Gateway AB -	Treatment of	19/05/2022	22/07/2022

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	Sweden	myasthenia gravis	14/06/2022 14/07/2022 (30/19)	10/08/2022
Epetraborole	Dlrc Pharma Services Limited - Ireland	Treatment of nontuberculous mycobacterial lung disease	19/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Lithium carbonate	Amsterdam UMC - Netherlands	Treatment of familial adenomatous polyposis	18/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Vutrisiran	Alnylam Netherlands B.V. - Netherlands	Treatment of Stargardt's disease	18/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Clarithromycin, clofazimine, rifabutin	Regintel Limited - Ireland	Treatment of nontuberculous mycobacterial lung disease	18/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
(7S)-8,8-dimethyl-7- {[(2E)-3-phenyl-2-propen-1-yl]oxy}-7,8-dihydro-2H,6H-pyrano[3,2-g]chromen-2-one	Global Medical Services Sp. z o.o. - Poland	Treatment of Hutchinson-Gilford progeria syndrome	18/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Gold	Clene Netherlands B.V. - Netherlands	Treatment of amyotrophic lateral sclerosis	17/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Sotuletinib	Novartis Europharm Limited - Ireland	Treatment of amyotrophic Lateral Sclerosis	17/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Tamibarotene	Syros Pharmaceuticals (Ireland) Limited - Ireland	Treatment of myelodysplastic syndrome (MDS)	16/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Autologous CD34+ haematopoietic stem and progenitor cells genetically modified with a lentiviral vector encoding for the N-acetylgalactosamine 6-sulfatase cDNA	Fondazione Telethon Ets - Italy	Treatment of mucopolysaccharidosis Type IV A, Morquio A syndrome	16/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022

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H-Lys-Lys-Gly-Asp-Asn-Ile-Met-Val-Thr-Phe-Arg-Asn-Gln-Ala-Ser-Arg-Pro-Tyr-Gly-Lys-Lys-OH	S-Cubed Pharmaceutical Services ApS - Denmark	Treatment of haemophilia A	10/05/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Toll-like receptor 4 agonist	Hephaistos-Pharma - France	Treatment of osteosarcoma	26/04/2022 14/06/2022 14/07/2022 (30/19)	22/07/2022 10/08/2022
Allogeneic placenta-derived decidual stromal cells	MDC RegAffairs GmbH - Germany	Treatment of graft-versus-host-disease	24/03/2022 19/04/2022 14/07/2022 (86/19)	22/07/2022 10/08/2022
Calmangafodipir	Egetis Therapeutics AB - Sweden	acute liver failure	23/03/2022 19/04/2022 14/07/2022 (86/19)	22/07/2022 10/08/2022
Mazindol	Propharma Group The Netherlands B.V. - Netherlands	Treatment of idiopathic hypersomnia	21/03/2022 19/04/2022 14/07/2022 (86/19)	22/07/2022 10/08/2022
Oxygen, sodium chloride solution 0.9%	Dlrc Pharma Services Limited - Ireland	Treatment of amyotrophic lateral sclerosis	24/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Ropeginterferon alfa-2b	Aop Orphan Pharmaceuticals GmbH - Austria	Treatment of essential thrombocythaemia	23/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Selinexor	Karyopharm Europe GmbH - Germany	Treatment of myelofibrosis	22/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Eculizumab	Alexion Europe - France	Treatment of Guillain-Barré syndrome	22/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Velusetrag	Alfasigma S.p.A. - Italy	Treatment of intestinal pseudo-obstruction	21/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Adeno-associated viral vector serotype 8 containing the 3' human	Sensorion - France	Treatment of otoferlin gene-mediated hearing loss	21/06/2022 12/07/2022 08/09/2022	15/09/2022 11/10/2022

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otoferlin coding sequence, adeno-associated viral vector serotype 8 containing the 5' human otoferlin coding sequence			(58/26)	
Methyl(R)-4-((3S,5R,7R,8R,9S,10S,13R,14S,17R)-7-hydroxy-10,13-dimethyl-3-((4-((pyridin-3-ylmethyl)amino)butyl)amino)hexadecahydro-1H-cyclopenta[a]phenanthren-17-yl)pentanoate	MAXIA STRATEGIES- EUROPE Limited - Ireland	Treatment of Rett syndrome	21/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Acetylleucine	IntraBio Ireland Limited - Ireland	Treatment of GM1 Gangliosidosis	21/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
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)	Abbvie Deutschland GmbH & Co. KG - Germany	Treatment of vanishing white matter disease	20/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Adeno-associated viral vector serotype rh.10 encoding the <i>CLN2</i> gene	Pharma Gateway AB - Sweden	Treatment of neuronal ceroid lipofuscinosis	20/06/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Aglatimagene besadenovec	Propharma Group The Netherlands B.V. - Netherlands	Treatment of glioma	20/05/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Human IgG4k monoclonal antibody against CD89	Jjp Biologics Sp. z o.o. - Poland	Treatment of linear IgA bullous dermatosis	20/05/2022 14/06/2022 08/09/2022 (86/26)	15/09/2022 11/10/2022
Inaxaplin	Vertex Pharmaceuticals (Ireland) Limited - Ireland	Treatment of apolipoprotein L1-mediated kidney disease	20/05/2022 14/06/2022 08/09/2022 (86/26)	15/09/2022 11/10/2022
Etidronate disodium	Qualix Dot S.L. - Spain	Treatment of ABCC6	19/05/2022	15/09/2022

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		deficiency	14/06/2022 08/09/2022 (58/26)	11/10/2022
Epeleuton	Afimmune Limited - Ireland	Treatment of sickle cell disease	19/05/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Crofelemer	Napo Therapeutics S.p.A. - Italy	Treatment of microvillous Inclusion disease	19/05/2022 14/06/2022 08/09/2022 (86/26)	15/09/2022 11/10/2022
Isotretinoin	Granzer Regulatory Consulting & Services GmbH - Germany	Treatment of autosomal recessive congenital ichthyosis	11/05/2022 14/06/2022 08/09/2022 (86/26)	15/09/2022 11/10/2022
Autologous T cells transduced with a lentiviral vector expressing a chimeric antigen receptor against CLL-1	ELC Group s.r.o. - Czech Republic	Treatment of acute myeloid leukaemia	31/03/2022 12/07/2022 08/09/2022 (58/26)	15/09/2022 11/10/2022
Copper nanocluster conjugated to acetate, histidinate and ascorbate	Satt Sayens - France	Treatment of Menkes disease	15/07/2022 15/08/2022 06/10/2022 (52/29)	13/10/2022 11/11/2022
Adeno-associated virus serotype 5 vector encoding C1-esterase inhibitor	Biomarin International Limited - Ireland	Treatment of hereditary angioedema	14/07/2022 15/08/2022 06/10/2022 (52/28)	13/10/2022 10/11/2022
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	EUDRAC GmbH - Germany	Treatment of biliary tract cancer	14/07/2022 15/08/2022 06/10/2022 (52/28)	13/10/2022 10/11/2022
Rovatiirelin	MDC RegAffairs GmbH - Germany	Treatment of spinocerebellar ataxia	14/07/2022 15/08/2022 06/10/2022 (52/29)	13/10/2022 11/11/2022
(R)-deuteropioglitazone hydrochloride	Poxel - France	Treatment of adrenoleukodystrophy	12/07/2022 15/08/2022 06/10/2022	13/10/2022 11/11/2022

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Adeno-associated viral vector serotype 9 containing the human <i>ABCD1</i> gene	Voisin Consulting Life Sciences - France	Treatment of adrenoleukodystrophy	08/07/2022 15/08/2022 06/10/2022 (52/29)	13/10/2022 11/11/2022
Cannabidiol	EUDRAC GmbH - Germany	Treatment of 22q11.2 deletion syndrome	24/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Tricaprilin	Veristat Spain S.L. - Spain	Treatment of West Syndrome	23/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Pegcetacoplan,	Apellis Ireland Limited - Ireland	Treatment of C3 glomerulopathy with or without immune complexes	22/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Atorvastatin	Mario Negri Institute For Pharmacological Research - Italy	Treatment of familial cerebral cavernous malformations	16/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Propranolol	Mario Negri Institute For Pharmacological Research - Italy	Treatment of familial cerebral cavernous malformations	16/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Iodine (¹²⁴ I) evuzamitide	Regresponse Limited - Ireland	Diagnosis of AL amyloidosis	14/06/2022 12/07/2022 06/10/2022 (86/29)	13/10/2022 11/11/2022
Delpazolid	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of tuberculosis	17/05/2022 12/07/2022 06/10/2022 (86/28)	13/10/2022 10/11/2022
Copper (⁶⁴ Cu) oxodotreotide	Curium Pet France - France	Diagnosis of neuroendocrine neoplasms	31/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Duvelisib	Secura Bio Limited - Ireland	Treatment of peripheral T-cell lymphoma	31/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Adeno-associated virus serotype rh79 containing	EMA Regulatory Submissions Expediter	Treatment of ornithine transcarbamylase	31/08/2022 14/09/2022	17/11//2022 09/12/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
the human <i>OTC</i> gene, adeno-associated virus serotype rh79 encoding a meganuclease for targeted editing of the human <i>PCSK9</i> gene	Limited - Ireland	deficiency	10/11/2022 (57/22)	
Utreloxastat	PTC Therapeutics International Limited - Ireland	Treatment of amyotrophic Lateral Sclerosis	31/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Recombinant adeno-associated virus Olig001 containing human aspartoacylase cDNA	Voisin Consulting Life Sciences - France	Treatment of Canavan disease	31/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
(2S)-4-[2-methoxyethyl-[4-(5,6,7,8-tetrahydro-1,8-naphthyridin-2-yl)butyl]amino]-2-(quinazolin-4-ylamino)butanoic acid	Pharma Gateway AB - Sweden	Treatment of idiopathic pulmonary fibrosis	30/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Potassium 2-chloro-3-(1-hydroxy-5,6,7,8-tetrahydronaphthalen-2-yl)-6-oxo-5-phenyl-6,7-dihydrothieno[2,3-b]pyridin-4-olate monohydrate	Poxel - France	Treatment of adrenoleukodystrophy	30/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
16-base single stranded RNA targeting miR-23b linked to oleic acid	Arthex Biotech S.L. - Spain	Treatment of myotonic disorders	26/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Briquilimab	Boyd Consultants Limited - Ireland	Treatment in haematopoietic stem cell transplantation	23/08/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Autologous T-cells transduced with a lentiviral vector encoding a chimeric antigen receptor against CD7	Granzer Regulatory Consulting & Services GmbH - Germany	Treatment of acute lymphoblastic leukaemia	28/07/2022 14/09/2022 10/11/2022 (57/22)	17/11//2022 09/12/2022
Serplulimab	Henlius Europe GmbH - Germany	Treatment of small cell lung cancer	14/07/2022 15/08/2022 10/11/2022	17/11//2022 09/12/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
			(87/22)	
Iodine (¹²⁴ I) evuzamitide	Regresponse Limited - Ireland	Diagnosis of ATTR amyloidosis	13/07/2022 15/08/2022 10/11/2022 (87/22)	17/11//2022 09/12/2022
Mebendazole	Healx Technology Limited - Ireland	Treatment of autosomal dominant polycystic kidney disease	22/06/2022 15/08/2022 10/11/2022 (87/22)	17/11//2022 09/12/2022
Upifitamab rilsodotin	Dlrc Pharma Services Limited - Ireland	Treatment of ovarian cancer	13/06/2022 15/08/2022 10/11/2022 (87/22)	17/11//2022 09/12/2022
Autologous CD34+ cells transduced with a lentiviral vector encoding the human <i>NCF1</i> gene	3R Pharma Consulting GmbH - Germany	Treatment of chronic granulomatous disease	28/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
N1,N14-diethyl-3S,12S-dihydroxyhomospermine tetrahydrochloride	PPD Bulgaria EOOD - Bulgaria	Treatment of pancreatic cancer	28/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Opelconazole	Tmc Pharma (EU) Limited - Ireland	Treatment of invasive aspergillosis	27/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Adeno-associated viral vector serotype 2 containing the human <i>SLC6A3</i> gene	FGK Representative Service GmbH - Germany	Treatment of dopamine transporter deficiency syndrome	27/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Efzofitimod	FGK Representative Service GmbH - Germany	Treatment of sarcoidosis	27/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Retifanlimab	Incyte Biosciences Distribution B.V. - Netherlands	Treatment of Merkel cell carcinoma	23/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Autologous hematopoietic cells genetically modified with a lentiviral vector containing the human <i>RAG2</i> gene	Leiden University Medical Center - Netherlands	Treatment of recombination-activating gene 2 deficient severe combined immunodeficiency	19/09/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP	European Commission
			<ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	<ul style="list-style-type: none"> • Opinion received • Date of decision
Nanatinostat, valganciclovir	Pharma Gateway AB - Sweden	Treatment of diffuse large B-cell lymphoma	30/08/2022 14/09/2022 08/12/2022 (85/30)	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. - Italy	Treatment of Duchenne muscular dystrophy	30/08/2022 14/09/2022 08/12/2022 (85/30)	14/12/2022 13/01/2023
Vorasidenib hemicitrate hemihydrate	Les Laboratoires Servier - France	Treatment of glioma	22/08/2022 26/10/2022 08/12/2022 (43/30)	14/12/2022 13/01/2023
Octreotide acetate	Amryt Pharmaceuticals Designated Activity Company - Ireland	Treatment of carcinoid syndrome	23/06/2022 14/09/2022 08/12/2022 (85/30)	14/12/2022 13/01/2023

Negative COMP opinions

Product INN	Sponsor	Summary of indication	EMA/COMP	European Commission
			<ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	<ul style="list-style-type: none"> • Opinion received • Date of decision
Melatonin	Worphmed S.r.l. - Italy	Prevention of spaceflight-related radiation and microgravity	26/11/2021 25/01/2022 13/04/2022 (78/29)	15/09/2022 14/10/2022
Melatonin	Industria Farmaceutica Galenica Senese S.r.l. - Italy	Treatment of retinopathy of prematurity	22/03/2022 19/04/2022 14/07/2022 (86/41)	18/10/2022 28/11/2022

Annex 15 – HMPC European Union herbal monographs in 2022

Abbreviations: TU – traditional use

WEU – well established use

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/180400/2018	Species digestivae	30/03/2022 / TU
EMA/HMPC/49135/2017	Vaccinii macrocarpi fructus	23/11/2022 / TU
Revision		
EMA/HMPC/489142/2020	Centellae asiaticae herba	30/03/2022 / TU
EMA/HMPC/114726/2021	Agropyri repentis rhizoma	30/03/2022 / TU
EMA/HMPC/7695/2021	Hyperici herba	23/11/2022 / WEU + TU

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

Reference number	Document title	Adoption
First Assessment		
	none	
Revision		
	none	

European Union herbal monographs – Draft for consultation

Reference number	Document title	Adoption / Outcome
First Assessment		
	none	
Revision		
EMA/HMPC/372839/2016	Foeniculi dulcis fructus	20/07/2022 / TU
EMA/HMPC/372841/2016	Foeniculi amari fructus	20/07/2022 / TU
EMA/HMPC/241320/2021	Juniperi pseudofructus	20/07/2022 / TU
EMA/HMPC/367011/2021	Fumariae herba	21/09/2022 / TU
EMA/HMPC/513893/2021	Rosmarini aetheroleum	23/11/2022 / TU
EMA/HMPC/513940/2021	Rosmarini folium	23/11/2022 / TU

European Union List entries – Draft for consultation

Reference number	Document title	Adoption
First Assessment		

Reference number	Document title	Adoption
	none	
Revision		
EMA/HMPC/372840/2016	Foeniculi dulcis fructus	23/11/2022
EMA/HMPC/372843/2016	Foeniculi amari fructus	23/11/2022

Monograph/ list entry review reports

Reference number	Document title	Adoption / Outcome
Final decision		
EMA/HMPC/2199/2022	Aloes folii succus siccatus	26/01/2022 / no revision
EMA/HMPC/639126/2021	Cichorii intybi radix	26/01/2022 / no revision
EMA/HMPC/679823/2021	Eucalypti aetheroleum	26/01/2022 / revision required*
EMA/HMPC/679833/2021	Eucalypti folium	26/01/2022 / no revision
EMA/HMPC/690227/2021	Fraxini folium	26/01/2022 / no revision
EMA/HMPC/681054/2021	Fucus vesiculosus	26/01/2022 / no revision
EMA/HMPC/493697/2021	Marrubii herba	26/01/2022 / no revision
EMA/HMPC/515985/2021	Origani dictamni herba	26/01/2022 / no revision
EMA/HMPC/642185/2021	Rhodiolae roseae rhizoma	26/01/2022 / revision required*
EMA/HMPC/18311/2022	Sennae folium	26/01/2022 / no revision
EMA/HMPC/18310/2022	Sennae fructus	26/01/2022 / no revision
EMA/HMPC/489006/2020	Urticae folium	26/01/2022 / no revision
EMA/HMPC/498250/2021	Arnicae flos	30/03/2022 / revision required*
EMA/HMPC/172961/2022	Frangulae cortex	30/03/2022 / no revision
EMA/HMPC/353727/2021	Hippocastani cortex	30/03/2022 / revision required*
EMA/HMPC/683869/2021	Liquiritiae radix	30/03/2022 / revision required*
EMA/HMPC/172975/2022	Rhamni purshianae cortex	30/03/2022 / no revision
EMA/HMPC/172974/2022	Rhei radix	30/03/2022 / no revision
EMA/HMPC/683892/2021	Urticae radix	18/05/2022 / revision required*
EMA/HMPC/30571/2022	Camelliae sinensis fructus fermentatum	20/07/2022 / no revision
EMA/HMPC/166164/2022	Curcuma xanthorrhizae rhizoma	20/07/2022 / no revision
EMA/HMPC/693261/2021	Juglandis folium	20/07/2022 / no revision
EMA/HMPC/176350/2022	Ginseng radix	20/07/2022 / revision required*
EMA/HMPC/648153/2022	Eschscholziae herba	21/09/2022 / no revision
EMA/HMPC/615965/2022	Epilobii herba	21/09/2022 / no revision
EMA/HMPC/626568/2022	Agrimoniae herba	23/11/2022 / no revision
EMA/HMPC/684020/2021	Paullinae semen	23/11/2022 / no revision

Reference number	Document title	Adoption / Outcome
EMA/HMPC/176303/2022	Tiliae flos	23/11/2022 / no revision

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

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/522456/2021	Foeniculi amari fructus aetheroleum	20/07/2022
Final		
EMA/HMPC/509931/2019	Salviae miltiorrhizae radix et rhizoma	30/03/2022

Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2022

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
avibactam / ceftazidime	Zavicefta	PM	Infectious Diseases	Pfizer Europe MA EEIG	07/01/2022	P/0001/2022
dexmedetomidine (hydrochloride)	N/A	PM	Psychiatry	BioXcel Therapeutics, Inc.	07/01/2022	P/0002/2022
brivaracetam	Briviact (in Italy: Nubriveo)	PM	Neurology	UCB Pharma S.A.	18/01/2022	P/0003/2022
baricitinib	Olumiant	PM	Immunology- Rheumatology- Transplantation	Eli Lilly and Company Limited	31/01/2022	P/0004/2022
talimogene laherparepvec	IMLYGIC	PM	Oncology	Amgen Europe B.V.	31/01/2022	P/0005/2022
alectinib	Alecensa	P	Oncology	Roche Registration GmbH	31/01/2022	P/0006/2022
vorasidenib (as hemicitrate, hemihydrate salt)	N/A	P	Oncology	Les Laboratoires Servier (LLS)	31/01/2022	P/0007/2022
single strain of non-genetically modified prevotella histicola (edp1815)	N/A	P	Dermatology	Evelo Biosciences, Inc.	31/01/2022	P/0008/2022
pembrolizumab / favezelimab	N/A	W	Oncology	Merck, Sharp & Dohme (Europe) Inc	31/01/2022	P/0009/2022
aumolertinib	N/A	W	Oncology	SFL Pharmaceuticals Deutschland GmbH	31/01/2022	P/0010/2022
gantenerumab	N/A	W	Neurology	Roche Registration GmbH	31/01/2022	P/0011/2022
derivative of pyrrolopyrimidine	N/A	W	Cardiovascular Diseases	AstraZeneca AB	31/01/2022	P/0012/2022
budesonide / glycopyrronium bromide / formoterol (fumarate)	Trixeo Aerosphere	PM	Pneumology - Allergology	AstraZeneca AB	31/01/2022	P/0013/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
gemtuzumab ozogamicin	Mylotarg	PM	Oncology	Pfizer Europe MA EEIG	31/01/2022	P/0014/2022
onasemnogene abeparvec	Zolgensma	PM	Neurology	Novartis Gene Therapy EU Limited	31/01/2022	P/0015/2022
avapritinib	AYVAKYT	PM	Oncology	Blueprint Medicines (Netherlands) B.V.	31/01/2022	P/0016/2022
phenobarbital	N/A	PM	Neurology	Proveca Pharma Limited	31/01/2022	P/0017/2022
izencitinib	N/A	P	Gastroenterology-Hepatology	Theravance Biopharma Ireland Limited	31/01/2022	P/0018/2022
cysteamine (hydrochloride)	CYSTADROPS	PM	Ophthalmology	Recordati Rare Diseases SARL	03/02/2022	P/0019/2022
ribociclib	Kisqali	P	Oncology	Novartis Europharm Limited	31/01/2022	P/0020/2022
poly(oxy-1,2-ethanediyl), alpha-hydro-omega-methoxy, ether with n-[[[2-[[[6-[[[1-[3-[[3-(2,3-dihydroxypropoxy)propyl]amino]-3-oxopropyl]-2,5-dioxo-3-pyrrolidinyl]thio]hexyl]amino]ethyl]amino]carbonyl]-2-methylalanyl-teriparatide (2:1) (transcon pth)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Ascendis Pharma Bone Diseases A/S	31/01/2022	P/0021/2022
lanadelumab	TAKHZYRO	PM	Other	Takeda Pharmaceuticals International AG Ireland Branch	31/01/2022	P/0022/2022
ck-3773274	N/A	P	Cardiovascular Diseases	Cytokinetics Inc.	31/01/2022	P/0023/2022
vadadustat	Vafseo	PM	Haematology-Hemostaseology	Otsuka Pharmaceutical Development & Commercialisation Europe GmbH	31/01/2022	P/0024/2022
2-amino-n-(4-hydroxybicyclo[2.2.2]octan-1-yl)-5-	N/A	P	Endocrinology-Gynaecology-	Incyte Biosciences Distribution B.V	31/01/2022	P/0025/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
(4-((1r,5s)-3- (tetrahydro-2h-pyran-4-yl)-3-azabicyclo[3.1.0]hexan-1-yl)phenyl)nicotinamide fumarate dihydrate (incb-00928)			Fertility-Metabolism			
expec9v	N/A	P	Vaccines	Janssen-Cilag International NV	04/02/2022	P/0026/2022
fostamatinib	Tavlesse	W	Immunology- Rheumatology- Transplantation / Haematology- Hemostaseology	Instituto Grifols, S.A.	31/01/2022	P/0027/2022
colchicine	Cadrexan	W	Cardiovascular Diseases	Pharmascience International Limited	31/01/2022	P/0028/2022
acetylsalicylic acid / rosuvastatin calcium	N/A	W	Cardiovascular Diseases	Lanova Farmaceutici SRL	31/01/2022	P/0029/2022
mitapivat	PYRUKYND	PM	Haematology- Hemostaseology	Agios Netherlands B.V.	31/01/2022	P/0030/2022
ethinylestradiol / dienogest	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Chemo Research	31/01/2022	P/0031/2022
nirogacestat hydrobromide	N/A	P	Oncology	SpringWorks Therapeutics, Inc	31/01/2022	P/0032/2022
allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded (mc0518)	N/A	PM	Immunology- Rheumatology- Transplantation	medac Gesellschaft für klinische Spezialpräparate mbH	01/02/2022	P/0033/2022
insulin efsitora alfa	N/A	W	Endocrinology- Gynaecology- Fertility-Metabolism	Eli Lilly and Company	04/02/2022	P/0034/2022
benralizumab	Fasenra	P	Haematology- Hemostaseology	AstraZeneca AB	31/01/2022	P/0035/2022
tildacerfont	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Spruce Biosciences, Inc.	31/01/2022	P/0036/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
derivative of 6-[2-(pyridin-2-yl)phenoxy]methyl}-1,2,3,4-tetrahydroisoquinoline	N/A	P	Uro-nephrology	Boehringer Ingelheim International GmbH	31/01/2022	P/0037/2022
benralizumab	FASENRA	P	Gastroenterology-Hepatology	AstraZeneca AB	31/01/2022	P/0038/2022
dupilumab	Dupixent	PM	Dermatology	sanofi-aventis groupe	31/01/2022	P/0039/2022
cabotegravir	Vocabria	PM	Infectious Diseases	ViiV Healthcare UK Limited	31/01/2022	P/0040/2022
atazanavir (sulphate) / cobicistat	EVOTAZ	PM	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	29/01/2022	P/0041/2022
split influenza virus, inactivated containing antigens equivalent to the b-like strain (yamagata lineage) / split influenza virus, inactivated containing antigens equivalent to the b-like strain (victoria lineage) / split influenza virus, inactivated containing antigens equivalent to the a/h3n2-like strain / split influenza virus, inactivated containing antigens equivalent to the a/h1n1-like strain	Efluelda	PM	Vaccines	Sanofi Pasteur	10/02/2022	P/0042/2022
acetyl-l-leucine ((s)-(acetylamino)-4-methylpentanoic acid) (ib1001)	N/A	P	Neurology	IntraBio Ltd.	10/02/2022	P/0043/2022
casirivimab	RONAPREVE	PM	Infectious Diseases	Roche Registration GmbH	03/02/2022	P/0044/2022
imdevimab	RONAPREVE	PM	Infectious Diseases	Roche Registration GmbH	03/02/2022	P/0045/2022
sars cov2 prefusion spike delta tm (cov2 pres dtm) adjuvanted with as03	Vidprevtyn	PM	Vaccines	Sanofi Pasteur	14/02/2022	P/0046/2022
tixagevimab	N/A	PM	Infectious Diseases	AstraZeneca AB	11/02/2022	P/0047/2022
cilgavimab	N/A	PM	Infectious Diseases	AstraZeneca AB	11/02/2022	P/0048/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
spesolimab	N/A	PM	Dermatology	Boehringer Ingelheim International GmbH	18/02/2022	P/0049/2022
tedizolid phosphate	Sivextro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	24/02/2022	P/0050/2022
vosoritide	Voxzogo	PM	Other	BioMarin International Limited	11/03/2022	P/0051/2022
delandistrogene moxeparvec	N/A	PM	Neurology	Roche Registration GmbH	11/03/2022	P/0052/2022
etrasimod l-arginine	N/A	PM	Gastroenterology- Hepatology	Arena Pharmaceuticals, Inc.	11/03/2022	P/0053/2022
adrenaline (epinephrine)	N/A	PM	Pneumology - Allergology	ARS Pharmaceuticals IRL, Limited	11/03/2022	P/0054/2022
recombinant humanized anti-blood dendritic cell antigen 2 (bdca2) monoclonal antibody (biib059)	N/A	P	Immunology- Rheumatology- Transplantation	Biogen Netherlands B.V.	11/03/2022	P/0055/2022
ralmitaront	N/A	P	Psychiatry	Roche Registration GmbH	11/03/2022	P/0056/2022
avexitide (acetate)	N/A	W	Endocrinology- Gynaecology- Fertility-Metabolism	EigerBio Europe Limited	11/03/2022	P/0057/2022
sunvozertinib	DZD9008	W	Oncology	Dizal (Jiangsu) Pharmaceutical Co., Ltd	11/03/2022	P/0058/2022
nemtabrutinib	N/A	W	Oncology	Merck Sharp & Dohme (Europe), Inc.	11/03/2022	P/0059/2022
l-carnitine/glucose/calcium chloride dihydrate/magnesium chloride hexahydrate/sodium lactate/sodium chloride	Glucothera Plus	P	Uro-nephrology	Iperboreal Pharma Srl	07/03/2022	P/0060/2022
cosibelimab	N/A	W	Oncology	Checkpoint Therapeutics, Inc.	11/03/2022	P/0061/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
givinostat	N/A	P	Neurology	Italfarmaco S.p.A.	11/03/2022	P/0062/2022
2-{(3s)-7-fluoro-4-[(3-oxo-3,4-dihydro-2h-1,4-benzoxazin-6-yl)carbonyl]-3,4-dihydro-2h-1,4-benzoxazin-3-yl}-n-methylacetamide (azd9977) / dapagliflozin	N/A	W	Cardiovascular Diseases	AstraZeneca AB	11/03/2022	P/0063/2022
ceralasertib	N/A	W	Oncology	AstraZeneca AB	11/03/2022	P/0064/2022
guselkumab	Tremfya	PM	Gastroenterology-Hepatology	Janssen-Cilag International N.V.	11/03/2022	P/0065/2022
ex vivo expanded autologous human corneal epithelium cells containing stem cells	Holoclar	PM	Ophthalmology	Holostem Terapie Avanzate S.r.l.	11/03/2022	P/0066/2022
fostemsavir (tromethamine)	RUKOBIA	PM	Infectious Diseases	ViiV Healthcare UK Ltd	11/03/2022	P/0067/2022
glutamine	Xyndari	PM	Haematology-Hemostaseology	Emmaus Medical Europe Ltd.	11/03/2022	P/0068/2022
zamtocabtagene autoleucel	N/A	P	Oncology	Miltenyi Biomedicine GmbH	11/03/2022	P/0069/2022
covid-19 vaccine (recombinant, adjuvanted)	N/A	P	Vaccines	Clover Biopharmaceuticals Ireland Limited	11/03/2022	P/0070/2022
deutivacaftor (vx-121/ tez/d-iva) / tezacaftor / (14s)-8-[3-(2-{dispiro[2.0.2 ⁴].1 ³]}heptan-7-yl}ethoxy)-1h-pyrazol-1-yl]-12,12-dimethyl-2lambda ⁶ -thia-3,9,11,18,23-penta-azatetracyclo[17.3.1.1 ^{11,14} .0 ^{5,10}]]tetracos-1(22),5,7,9,19(23),20-hexaene-2,2,4-trione calcium salt hydrate	N/A	P	Pneumology - Allergology	Vertex Pharmaceuticals (Ireland) Limited	11/03/2022	P/0071/2022
phospholipid esters from herring roe (hro350)	N/A	P	Dermatology	Arctic Bioscience (previously Arctic Nutrition AS)	11/03/2022	P/0072/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
tenofovir disoproxil	Viread	PM	Infectious Diseases	Gilead Sciences International Limited	11/03/2022	P/0073/2022
eculizumab	SOLIRIS	PM	Neurology	Alexion Europe SAS	11/03/2022	P/0074/2022
modified allergen extract of birch pollen	CLUSTOID Birke	RPM	Pneumology - Allergology	ROXALL Medizin GmbH	11/03/2022	P/0075/2022
imlifidase	Idefirix	PM	Immunology- Rheumatology- Transplantation	Hansa Biopharma AB	11/03/2022	P/0076/2022
tucatinib	Tukysa	W	Oncology	Seagen B.V.	11/03/2022	P/0077/2022
efgartigimod alfa	N/A	P	Haematology- Hemostaseology	argenx BV	11/03/2022	P/0078/2022
(1s,3s)-3-({2-methyl-6-[1-methyl-5-({[methyl(propyl)carbamoyl]oxy}methyl)-1h-1,2,3-triazol-4-yl]pyridin-3-yl}oxy)cyclohexane-1-carboxylic acid (bms-986278)	N/A	W	Pneumology - Allergology	Bristol-Myers Squibb EEIG	11/03/2022	P/0079/2022
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 (menabcwy)	N/A	P	Vaccines	Pfizer Europe MA EEIG	11/03/2022	P/0080/2022
nifurtimox	Lampit	P	Infectious Diseases	Bayer AG, Leverkusen	11/03/2022	P/0081/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
mij821	N/A	P	Psychiatry	Novartis Europharm Limited	11/03/2022	P/0082/2022
viltolarsen	VILTEPSO	P	Neurology	NS Pharma, Inc.	11/03/2022	P/0083/2022
vimseltinib	DCC-3014	W	Oncology	Deciphera Pharmaceuticals	11/03/2022	P/0084/2022
parsaclisib (as hydrochloride)	N/A	W	Haematology-Hemostaseology	Incyte Biosciences Distribution B.V.	11/03/2022	P/0085/2022
isoflurane	Sedaconda and associated names	PM	Neonatology - Paediatric Intensive Care	Sedana Medical AB	11/03/2022	P/0086/2022
ridinilazole (hydrate)	N/A	PM	Infectious Diseases	Summit Limited	11/03/2022	P/0087/2022
mirikizumab	N/A	PM	Gastroenterology-Hepatology	Eli Lilly and Company	11/03/2022	P/0088/2022
pegvaliase	Palynziq	PM	Endocrinology-Gynaecology-Fertility-Metabolism	BioMarin International Limited	11/03/2022	P/0089/2022
tarlatamab	N/A	W	Oncology	Amgen Europe BV	11/03/2022	P/0090/2022
eptinezumab	Vyepti	PM	Neurology	H. Lundbeck A/S	11/03/2022	P/0091/2022
ethinyl estradiol / dienogest	N/A	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Chemo Research	11/03/2022	P/0092/2022
dinutuximab beta	Qarziba	PM	Oncology	EUSA Pharma (Netherlands) BV	11/03/2022	P/0093/2022
human normal immunoglobulin	Flebogamma 5% DIF	W	Immunology-Rheumatology-Transplantation	Instituto Grifols, S.A.	11/03/2022	P/0094/2022
efanesoctocog alfa	N/A	PM	Haematology-Hemostaseology	Swedish Orphan Biovitrum AB (Publ)	11/03/2022	P/0095/2022
tralokinumab	Adtralza	PM	Dermatology	LEO Pharma A/S	11/03/2022	P/0096/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
lisdexamfetamine (dimesylate)	Elvanse and associated names	PM	Psychiatry	Takeda Pharmaceuticals International AG, Ireland Branch	17/03/2022	P/0097/2022
delgocitinib	N/A	PM	Dermatology	LEO Pharma A/S	11/03/2022	P/0098/2022
bempegaldesleukin	N/A	PM	Oncology	Nektar Therapeutics	18/03/2022	P/0099/2022
recombinant influenza hemagglutinin-strain b (yamagata lineage) / recombinant influenza hemagglutinin-strain b (victoria lineage) / recombinant influenza hemagglutinin-strain a (h3n2 subtype) / recombinant influenza hemagglutinin-strain a (h1n1 subtype)	Supemtek	PM	Vaccines	Sanofi Pasteur	18/03/2022	P/0100/2022
rilpivirine (hydrochloride)	EDURANT	PM	Infectious Diseases	Janssen-Cilag International NV	17/03/2022	P/0101/2022
cabotegravir	N/A	PM	Infectious Diseases	ViiV Healthcare UK Limited	17/03/2022	P/0102/2022
censavudine	N/A	P	Neurology	Transposon Therapeutics, Inc.	21/03/2022	P/0103/2022
etranacogene dezaparvovec	Hemgenix	PM	Haematology-Hemostaseology	CSL Behring GmbH	25/03/2022	P/0104/2022
autologous cd34+ hematopoietic stem and progenitor cells (hspcs) genetically modified with the lentiviral vector idua lv, encoding for the human α -l-iduronidase (idua) gene (otl-203)	N/A	P	Other	Orchard Therapeutics (Netherlands) B.V.	13/04/2022	P/0105/2022
saxgliptin	Onglyza	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	13/04/2022	P/0106/2022
amikacin (sulfate)	Arikayce	PM	Pneumology - Allergology	Insmed Netherlands B.V.	13/04/2022	P/0107/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
human igg4 monoclonal antibody against bcma and cd3 (abbv-383)	N/A	W	Oncology	AbbVie Ltd	13/04/2022	P/0108/2022
ferumoxytol	N/A	PM	Uro-nephrology / Haematology- Hemostaseology	Covis Pharma Europe B.V.	13/04/2022	P/0109/2022
cannabidiol / delta-9-tetrahydrocannabinol	Sativex	PM	Neurology	GW Pharma (International) B.V	13/04/2022	P/0110/2022
telmisartan / indapamide	N/A	W	Cardiovascular Diseases	KRKA, d.d., Novo mesto	13/04/2022	P/0111/2022
cevostamab	N/A	W	Oncology	Roche Registration GmbH	13/04/2022	P/0112/2022
acetylsalicylic acid / ticagrelor	N/A	W	Cardiovascular Diseases	PharOS Pharmaceutical Oriented Services Single Member Ltd	13/04/2022	P/0113/2022
axicabtagene ciloleucel	Yescarta	W	Oncology	Kite Pharma EU B.V.	13/04/2022	P/0114/2022
leriglitazone	N/A	PM	Neurology	Minoryx Therapeutics S.L.	13/04/2022	P/0115/2022
daridorexant	QUVIVIQ	PM	Psychiatry	Idorsia Pharmaceuticals Deutschland GmbH	13/04/2022	P/0116/2022
palbociclib	IBRANCE	PM	Oncology	Pfizer Europe MA EEIG	13/04/2022	P/0117/2022
rozanolixizumab	N/A	P	Haematology- Hemostaseology	UCB Pharma S.A	13/04/2022	P/0118/2022
siponimod (hemifumarate)	Mayzent	PM	Neurology	Novartis Europharm Ltd	13/04/2022	P/0119/2022
dupilumab	Dupixent	P	Dermatology	Sanofi-Aventis Groupe	15/04/2022	P/0120/2022
ofatumumab	Kesimpta	PM	Neurology	Novartis Ireland Limited	15/04/2022	P/0121/2022
ponatinib	Iclusig	PM	Oncology	Incyte Biosciences Distribution B.V.	13/04/2022	P/0122/2022
tapotoclax	Tapotoclax	PM	Oncology	Amgen Europe BV	15/04/2022	P/0123/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
adalimumab conjugated with (4s)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4ar,4bs,5s,6as,6bs,8r,9ar,10as,10bs)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonooxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2h,8h-naphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl]anilino}-5-oxopentanoic acid; abbv-154	N/A	W	Immunology- Rheumatology- Transplantation	AbbVie Ltd	15/04/2022	P/0124/2022
benzylamine derivative of benzofuran (bcx9930)	N/A	P	Haematology- Hemostaseology	BioCryst Ireland Limited	15/04/2022	P/0125/2022
migalastat (hydrochloride)	Galafold	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Amicus Therapeutics Europe Limited	13/04/2022	P/0126/2022
abelacimab	N/A	P	Cardiovascular Diseases	Anthos Therapeutics, Inc.	13/04/2022	P/0127/2022
eluxadoline	Truberzi (EU marketing authorisation for Truberzi, MA number: EU/1/16/1126/001-006, granted on 19 September 2016, has been withdrawn on MAH request, for business reason, on 18 December 2020)	PM	Gastroenterology- Hepatology	AbbVie Ltd	13/04/2022	P/0128/2022
benralizumab	Fasenra	PM	Pneumology - Allergology	AstraZeneca AB	13/04/2022	P/0129/2022
secukinumab	COSENTYX	W	Immunology- Rheumatology- Transplantation	Novartis Europharm Limited	13/04/2022	P/0130/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
ozanimod hydrochloride	Zeposia	PM	Gastroenterology-Hepatology	Bristol-Myers Squibb Pharma EEIG	13/04/2022	P/0131/2022
fosdenopterin	NULIBRY	PM	Other	Zydus France S.A.S.	13/04/2022	P/0132/2022
etelcalcetide	Parsabiv	PM	Uro-nephrology	Amgen Europe B.V.	13/04/2022	P/0133/2022
inotuzumab ozogamicin	Besponsa	PM	Oncology / Haematology-Hemostaseology	Pfizer Europe MA EEIG	13/04/2022	P/0134/2022
bezlotoxumab	ZINPLAVA	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/04/2022	P/0135/2022
esketamine (hydrochloride)	Spravato	PM	Psychiatry	Janssen-Cilag International NV	13/04/2022	P/0136/2022
invimestrocel	N/A	P	Neurology	ReGenesys BVBA (Athersys)	13/04/2022	P/0137/2022
catequentinib	N/A	P	Oncology	Advenchen Laboratories, LLC	13/04/2022	P/0138/2022
retifanlimab	ZYNYZ	W	Oncology	Incyte Biosciences Distribution B.V.	13/04/2022	P/0139/2022
sintilimab	N/A	W	Oncology	Eli Lilly and Company Limited	13/04/2022	P/0140/2022
influenza virus a/turkey/turkey/1/2005 (h5n1) nibrg-23 strain, ha surface antigen	N/A	P	Vaccines	Seqirus Netherlands B.V.	13/04/2022	P/0141/2022
galcanezumab	Emgality	PM	Neurology	Eli Lilly and Company Limited	13/04/2022	P/0142/2022
pamrevlumab	N/A	P	Other	FibroGen, Inc.	13/04/2022	P/0143/2022
influenza virus surface antigens (haemagglutinin and neuraminidase) of strain a/h5n1	N/A	P	Vaccines	Seqirus Netherlands B.V.	13/04/2022	P/0144/2022
adeno-associated viral vector serotype rh.10 expressing beta-galactosidase (lys-gm101)	N/A	P	Neurology	Lysogene	13/05/2022	P/0145/2022
latozinemab	N/A	W	Neurology	Alector, Inc.	13/05/2022	P/0146/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
odevixibat	Bylvay	PM	Gastroenterology- Hepatology	Albireo AB	13/05/2022	P/0147/2022
venetoclax	Venclyxto	PM	Oncology / Haematology- Hemostaseology	AbbVie Ltd	13/05/2022	P/0148/2022
(s)-6-hydroxy-2,5,7,8-tetramethyl-n- ((r)-piperidin-3-yl)chroman-2- carboxamide hydrochloride (kh176)	N/A	PM	Other	Khondrion BV	13/05/2022	P/0149/2022
mitapivat	PYRUKYND	P	Haematology- Hemostaseology	Agios Netherlands B.V.	13/05/2022	P/0150/2022
ibutamoren mesylate	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Lumos Pharma, Inc.	13/05/2022	P/0151/2022
amlodipine / indapamide / atorvastatin / perindopril (arginine)	Liperplixam, Atorplixam	W	Cardiovascular Diseases	Les Laboratoires Servier	20/05/2022	P/0152/2022
human igg4-based bispecific antibody binding to both b-cell maturation antigen (bcma) and cluster of differentiation 3 (cd3) (regn5458)	N/A	W	Oncology	Regeneron Ireland DAC	13/05/2022	P/0153/2022
lenvatinib	Kisplyx, Lenvima	PM	Oncology	Eisai GmbH	13/05/2022	P/0154/2022
luspatercept	Reblozyl	PM	Haematology- Hemostaseology	Bristol-Myers Squibb Pharma EEIG	13/05/2022	P/0155/2022
deucravacitinib	N/A	P	Immunology- Rheumatology- Transplantation	Bristol-Myers Squibb International Corporation	13/05/2022	P/0156/2022
tolvaptan	Samsca, Jinarc	PM	Endocrinology- Gynaecology- Fertility-Metabolism / Uro-nephrology	Otsuka Pharmaceutical Netherlands B.V.	13/05/2022	P/0157/2022
(2s) 4 [2 methoxyethyl [4 (5,6,7,8 tetrahydro 1,8 naphthyridin 2 yl)butyl] amino] 2 (quinazolin 4 ylamino)butanoic acid	N/A	P	Pneumology - Allergology	Pliant Therapeutics Inc.	13/05/2022	P/0158/2022
potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous	IZINOVA and associated names	PM	Gastroenterology- Hepatology	IPSEN Consumer Healthcare	13/05/2022	P/0159/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
eslicarbazepine acetate	Zebinix	PM	Neurology	BIAL - Portela & Ca, SA	13/05/2022	P/0160/2022
dapagliflozin	Forxiga	W	Endocrinology- Gynaecology- Fertility-Metabolism	AstraZeneca AB	13/05/2022	P/0161/2022
virus-like particle of sars-cov-2 spike protein (recombinant, adjuvant) (covlp)	N/A	P	Vaccines	Medicago Inc.	13/05/2022	P/0162/2022
cefiderocol	Fetroja	PM	Infectious Diseases	Shionogi B.V.	13/05/2022	P/0163/2022
bis-choline tetrathiomolybdate	N/A	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Alexion Europe S.A.S.	13/05/2022	P/0164/2022
izaflortaucupir (18f)	N/A	W	Neurology	Life Molecular Imaging GmbH	13/05/2022	P/0165/2022
regdanvimab	Regkirona	PM		Celltrion Healthcare Hungary Kft.	13/05/2022	P/0166/2022
anti-cd40l humanized monoclonal antibody (sar441344)	N/A	W	Neurology	Sanofi Winthrop Industrie	13/05/2022	P/0167/2022
human, recombinant, non-fucosylated igg1k monoclonal antibody targeting ox-40 receptor on activated t cells (amg 451)	N/A	PM	Dermatology	Amgen Europe B.V.	13/05/2022	P/0168/2022
infigratinib	N/A	W	Oncology	Helsinn Birex Pharmaceuticals Ltd.	13/05/2022	P/0169/2022
remibrutinib	N/A	PM	Dermatology	Novartis Europharm Limited	13/05/2022	P/0170/2022
zinc gluconate / alisitol / retinyl palmitate	Shylicine	P	Gastroenterology- Hepatology	Vanessa Research Magyarorszag Kft/Vanessa Research Hungary ltd	13/05/2022	P/0171/2022
pseudoephedrine / bilastine	N/A	W	Pneumology - Allergology	FAES FARMA, S.A.	13/05/2022	P/0172/2022

Active substance(s)	Invented name	PDCO 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	P	Gastroenterology-Hepatology	Boehringer Ingelheim International GmbH	13/05/2022	P/0173/2022
tirzepatide	N/A	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly and Company Ltd	13/05/2022	P/0174/2022
betibeglogene autotemcel	Zynteglo	RPM	Haematology-Hemostaseology	bluebird bio (Netherlands) B.V.	13/05/2022	P/0175/2022
zandelisib	N/A	W	Oncology	Kyowa Kirin Holdings B.V.	13/05/2022	P/0176/2022
ketamine (hydrochloride) / sufentanil (citrate)	N/A	PM	Pain	Cessatech A/S	13/05/2022	P/0177/2022
dupilumab	Dupilixent	W	Dermatology	Sanofi-Aventis Group	13/05/2022	P/0178/2022
cemiplimab	cemiplimab	PM	Oncology	Regeneron Ireland DAC	13/05/2022	P/0179/2022
brincidofovir	N/A	PM	Infectious Diseases	Chimerix IRL Limited	13/05/2022	P/0180/2022
sacituzumab govitecan	Trodelyv	W	Oncology	Gilead Sciences International Ltd.	13/05/2022	P/0181/2022
adeno-associated virus vector serotype 1 containing the human grn gene	N/A	W	Neurology	Passage Bio, Inc.	13/05/2022	P/0182/2022
3,4-dimethyl-n-(2-phenyl-1h-pyrrolo[2,3-b]pyridin-5-yl)-1h-pyrazole-5-carboxamide	N/A	W	Oncology	Cogent Biosciences, Inc	13/05/2022	P/0183/2022
sars-cov-2 virus, beta-propiolactone inactivated adjuvanted with cpg 1018 (vla2001)	N/A	P	Vaccines	Valneva Austria GmbH	13/05/2022	P/0184/2022
aztreonam / avibactam	N/A	PM	Infectious Diseases	Pfizer Europe MA EEIG	13/05/2022	P/0185/2022
humanised klb/fgfr1c monoclonal antibody (mk-3655)	N/A.	P	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	16/05/2022	P/0186/2022
mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	25/05/2022	P/0187/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
ravulizumab	Ultomiris	PM	Uro-nephrology	Alexion Europe SAS	10/06/2022	P/0188/2022
ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology- Hemostaseology	Alexion Europe SAS	10/06/2022	P/0189/2022
erdafitinib	BALVERSA	PM	Oncology	Janssen-Cilag International N.V.	10/06/2022	P/0190/2022
ravulizumab	Ultomiris	PM	Uro-nephrology	Alexion Europe SAS	10/06/2022	P/0191/2022
sirolimus	N/A	P	Gastroenterology- Hepatology	Selecta Biosciences, Inc.	10/06/2022	P/0192/2022
recombinant adeno-associated viral (raav) vector expressing the human ornithine transcarbamylase (hotc) gene	N/A	P	Gastroenterology- Hepatology	Selecta Biosciences, Inc.	10/06/2022	P/0193/2022
sugemalimab	N/A	W	Oncology	EQRx Inc.	10/06/2022	P/0194/2022
efinaconazole	Jublia	PM	Infectious Diseases / Dermatology	Almirall, S.A.	10/06/2022	P/0195/2022
posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	09/06/2022	P/0196/2022
apraglutide	N/A	P	Gastroenterology- Hepatology	VectivBio AG	09/06/2022	P/0197/2022
upadacitinib	RINVOQ	PM	Immunology- Rheumatology- Transplantation	AbbVie Ltd	02/06/2022	P/0198/2022
flortaucupir f18	Tauvid	W	Neurology	Eli Lilly and Co. Ltd.	21/06/2022	P/0199/2022
loxapine	ADASUVE	PM	Psychiatry	Ferrer Internacional, S.A.	10/06/2022	P/0200/2022
nemolizumab	N/A	PM	Dermatology	Galderma International S.A.S	21/06/2022	P/0201/2022
clonidine	Clonidine Extended Release Tablets	W	Neurology	Proveca Pharma Ltd	10/06/2022	P/0202/2022
methylphenidate (hydrochloride)	N/A	P	Neurology	Laboratorios Lesvi, S.L.	10/06/2022	P/0203/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
omaveloxolone	N/A	P	Neurology	Reata Ireland Limited	10/06/2022	P/0204/2022
zanubrutinib	Brukinsa	W	Oncology	BeiGene Ireland Ltd.	10/06/2022	P/0205/2022
sodium chloride solution 4.2% (w/v) (p-1037) / 3,5-diamino-6-chloro-n-(n-(4-(4-(2-(hexyl((2s,3r,4r,5r)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamiimidoyl)pyrazine-2-carboxamide	idrevloride for 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamiimidoyl)pyrazine-2-carboxamide	PM	Pneumology - Allergology	Parion Sciences, Inc.	10/06/2022	P/0206/2022
anti-tgfbeta fully human monoclonal antibody (nis793)	N/A	W	Oncology	Novartis Europharm Limited	10/06/2022	P/0207/2022
canagliflozin	Invokana	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	10/06/2022	P/0208/2022
dopamine (hydrochloride)	Neoatrimon	PM	Neonatology - Paediatric Intensive Care / Cardiovascular Diseases	Brepcó Biopharma Limited	10/06/2022	P/0209/2022
reparixin	N/A	P	Infectious Diseases	Dompé farmaceutici S.p.A.	10/06/2022	P/0210/2022
whole-cell heat-inactivated bacterial strains of escherichia coli, klebsiella pneumoniae, proteus vulgaris and enterococcus faecalis	Uromune	P	Vaccines / Infectious Diseases / Uro-nephrology	Inmunotek S.L.	10/06/2022	P/0211/2022
indapamide / perindopril arginine	N/A	W	Cardiovascular Diseases	Les Laboratoires Servier	10/06/2022	P/0212/2022
inebilizumab	Uplizna	PM	Neurology	Horizon Therapeutics Ireland DAC	10/06/2022	P/0213/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
lanadelumab	TAKHZYRO	PM	Other	Takeda Pharmaceuticals International AG Ireland Branch	10/06/2022	P/0214/2022
tisagenlecleucel	Kymriah	PM	Oncology	Novartis Europharm Limited	10/06/2022	P/0215/2022
dersimelagon	N/A	P	Dermatology	Mitsubishi Tanabe Pharma GmbH	10/06/2022	P/0216/2022
cedazuridine / decitabine	INAQOVI	P	Oncology / Haematology-Hemostaseology	Otsuka Pharmaceutical Netherlands B.V.	10/06/2022	P/0217/2022
cannabidiol	Epidyolex	PM	Neurology	GW Pharma (International) B.V.	08/06/2022	P/0218/2022
split influenza virus, inactivated containing antigens equivalent to the b-like strain (yamagata lineage) / split influenza virus, inactivated containing antigens equivalent to the b-like strain (victoria lineage) / split influenza virus, inactivated containing antigens equivalent to the a/h3n2-like strain / split influenza virus, inactivated containing antigens equivalent to the a/h1n1-like strain	Efluelda	PM	Vaccines	Sanofi Pasteur	10/06/2022	P/0219/2022
alprazolam	N/A	P	Neurology	UCB Pharma SA.	10/06/2022	P/0220/2022
remdesivir	Veklury	PM	Infectious Diseases	Gilead Sciences International Ltd.	24/06/2022	P/0221/2022
neisseria meningitidis serogroup w polysaccharide conjugated to tetanus toxoid (menacyw) / neisseria meningitidis serogroup y polysaccharide conjugated to tetanus toxoid / neisseria meningitidis serogroup c polysaccharide conjugated to tetanus toxoid / neisseria meningitidis serogroup a	MenQuadfi	PM	Vaccines	Sanofi Pasteur	24/06/2022	P/0222/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
polysaccharide conjugated to tetanus toxoid						
botulinum toxin type e	N/A	W	Dermatology	Allergan Pharmaceuticals Ireland	08/07/2022	P/0223/2022
autologous bone marrow-derived mononuclear cell enriched white blood cells	N/A	W	Cardiovascular Diseases	Ixaka Iberia SLU	08/07/2022	P/0224/2022
benralizumab	Fasenra	P	Pneumology - Allergology	AstraZeneca AB	08/07/2022	P/0225/2022
mometasone (furoate) / indacaterol (acetate)	Aectura Breezhaler and its duplicate authorization Bemrist Breezhaler	PM	Pneumology - Allergology	Novartis Europharm Limited	08/07/2022	P/0226/2022
peptide klbpvqlwv / peptide smpppgtrv / peptide ylqlvfgiev / peptide rllqetelv / peptide ylsgadlnl / peptide lltfwnppv / peptide imighlvgv / peptide kvaeivhfl / peptide kvfgslafv / pan hla dr-binding epitope d-ala-lys-cha-val-ala-ala-trp-thr-leu-lys-ala-ala-d-ala (ose2101)	N/A	W	Oncology	OSE Immunotherapeutics	08/07/2022	P/0227/2022
mixture of 2 synthetic double-stranded n-acetyl-galactosamine conjugated sirna oligonucleotides that are directed against hepatitis b virus (jnj-73763989)	N/A	P	Infectious Diseases	Janssen-Cilag International NV	08/07/2022	P/0228/2022
lurbinectedin	Zepzelca	W	Oncology	Pharma Mar, S.A.	08/07/2022	P/0229/2022
delandistrogene moxeparovec	N/A	PM	Neurology	Roche Registration GmbH	08/07/2022	P/0230/2022
liposomal ciclosporin a (l-csa)	N/A	PM	Immunology- Rheumatology- Transplantation	Zambon S.p.A.	08/07/2022	P/0231/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
sibeprenlimab	N/A	P	Uro-nephrology	Otsuka Pharmaceutical Netherlands B.V.	08/07/2022	P/0232/2022
botulinum toxin type a	N/A	W	Other	Galderma International S.A.S.	08/07/2022	P/0233/2022
cannabidiol	Epidyolex	P	Neurology	GW Pharma (International) B.V	08/07/2022	P/0234/2022
trabectedin	Yondelis	W	Oncology	Pharma Mar, S.A.	08/07/2022	P/0235/2022
oritavancin (diphosphate)	Tenkasi	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	08/07/2022	P/0236/2022
ixazomib	NINLARO	PM	Oncology	Takeda Pharma A/S	08/07/2022	P/0237/2022
daratumumab	DARZALEX	PM	Oncology	Janssen-Cilag International NV	08/07/2022	P/0238/2022
pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Apexxnar	PM	Vaccines	Pfizer Europe MA EEIG	08/07/2022	P/0239/2022
parsaclisib (hydrochloride)	N/A	W	Oncology	Incyte Biosciences Distribution B.V.	08/07/2022	P/0240/2022
semaglutide / cagrilintide	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	08/07/2022	P/0241/2022
daprodustat	Jesduvroq	PM	Uro-nephrology / Haematology- Hemostaseology	GlaxoSmithKline Trading Services Limited	08/07/2022	P/0242/2022
nirsevimab	Beyfortus	PM	Vaccines	AstraZeneca AB	08/07/2022	P/0243/2022
vadadustat	Vafseo	PM	Haematology- Hemostaseology	Akebia Europe Limited	08/07/2022	P/0244/2022
hepatitis b (rdna) surface antigen adjuvanted	HEPLISAV B	W	Vaccines	Dynavax GmbH	08/07/2022	P/0245/2022
lonafarnib	N/A	P	Infectious Diseases	EigerBio Europe Limited	08/07/2022	P/0246/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
lacosamide	VIMPAT	PM	Neurology	UCB Pharma S.A.	08/07/2022	P/0247/2022
dexmedetomidine (hydrochloride)	N/A	PM	Psychiatry	BioXcel Therapeutics, Inc.	08/07/2022	P/0248/2022
garadacimab	N/A	PM	Haematology-Hemostaseology	CSL Behring GmbH	08/07/2022	P/0249/2022
severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-m1 adjuvant	NUVAXOVID	PM	Vaccines	Novavax CZ, a.s.	08/07/2022	P/0250/2022
autologous cd3+cd4+cd25+cd127-foxp3+ polyclonal regulatory t cells ex vivo expanded	N/A	P	Other / Endocrinology-Gynaecology-Fertility-Metabolism	PolTreg SA	08/07/2022	P/0251/2022
224 radium adsorbed in calcium carbonate microparticles	Radspherin	W	Oncology	Oncoinvent AS	08/07/2022	P/0252/2022
autologous tumour-infiltrating lymphocytes (tils) isolated from a patient's cancer tissue and expanded ex vivo (itil-168)	N/A	P	Oncology	Instil Bio, Inc.	08/07/2022	P/0253/2022
bepirovirsen	N/A	P	Infectious Diseases	GlaxoSmithKline Trading Services Limited	08/07/2022	P/0254/2022
respiratory syncytial virus stabilised prefusion f subunit vaccine	N/A	P	Vaccines	Pfizer Europe MA EEIG	08/07/2022	P/0255/2022
elasomeran / imelasomeran / elasomeran	under discussion	PM	Vaccines / Infectious Diseases	MODERNA BIOTECH SPAIN, S.L.	30/06/2022	P/0256/2022
epcoritamab	Epkinly, Tepkinly	PM	Oncology	AbbVie Ltd	08/07/2022	P/0257/2022
avibactam / ceftazidime	Zavicefta	PM	Infectious Diseases	Pfizer Europe MA EEIG	11/07/2022	P/0258/2022
leniolisib phosphate	Joenja	PM	Immunology-Rheumatology-Transplantation	Pharming Technologies B.V.	15/07/2022	P/0259/2022
omecamtiv mecarbil	N/A	PM	Cardiovascular Diseases	Cytokinetics, Inc.	22/07/2022	P/0260/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
recombinant covid-19 subunit nanoparticle (adjuvanted with as03) (gbp510)	N/A	P	Vaccines	SK Chemicals GmbH	15/07/2022	P/0261/2022
rilzabrutinib	N/A	PM	Immunology- Rheumatology- Transplantation	Principia Biopharma, Inc.	18/07/2022	P/0262/2022
upadacitinib	RINVOQ	PM	Immunology- Rheumatology- Transplantation	AbbVie Ltd	13/07/2022	P/0263/2022
modified vaccinia ankara - bavarian nordic virus (smallpox)	IMVANEX	PM	Vaccines	Bavarian Nordic A/S	13/07/2022	P/0264/2022
ivacaftor / tezacaftor / elexacaftor	Kaftrio	PM	Other / Pneumology - Allergology	Vertex Pharmaceuticals (Ireland) Limited	22/07/2022	P/0265/2022
avacopan	TAVNEOS	PM	Immunology- Rheumatology- Transplantation	ChemoCentryx Ireland Ltd.	27/07/2022	P/0266/2022
gadopiclenol	Altivity	PM	Diagnostic	Guerbet	04/08/2022	P/0267/2022
gliadin protease	N/A	P	Immunology- Rheumatology- Transplantation / Gastroenterology- Hepatology	Takeda Pharmaceuticals International AG	11/08/2022	P/0268/2022
(1r,2r)-2-[4-(5-methyl-1h-pyrazol-3-yl) benzoyl]-n-(4-oxo-6,7-dihydro-5h-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (azd5718)	N/A	P	Uro-nephrology	AstraZeneca AB	11/08/2022	P/0269/2022
bulevirtide	Hepcludex	PM	Infectious Diseases	Gilead Sciences International Ltd.	10/08/2022	P/0270/2022
(r)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl)pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate (ipn60130)	N/A	P	Other	Ipsen Pharma	10/10/2022	P/0271/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
ezetimibe / atorvastatin	N/A	W	Cardiovascular Diseases	Verisfield Single Member S.A.	10/08/2022	P/0272/2022
magnesium lactate dihydrate / tramadol (hydrochloride)	Tramag Plus	W	Other	Orphinic Scientific Bis Sp. z o.o.	10/08/2022	P/0273/2022
2'-o-(2'-methoxyethyl) modified antisense oligonucleotide targeting prekallikrein mrna (isis 721744)	N/A	P	Pneumology - Allergology / Haematology-Hemostaseology	Ionis Pharmaceuticals	10/08/2022	P/0274/2022
n-(6-(((2r,3s)-3,4-dihydroxybutan-2-yl)oxy)-2-((4-fluorobenzyl)thio)pyrimidin-4-yl)-3-methylazetidine-1-sulfonamide (rist-4721)	N/A	W	Dermatology	Aristea Therapeutics, Inc.	11/08/2022	P/0275/2022
valsartan / nebivolol (hydrochloride)	N/A	W	Cardiovascular Diseases	Menarini Ricerche S.p.A.	11/08/2022	P/0276/2022
fidanacogene elaparovec	N/A	PM	Haematology-Hemostaseology	Pfizer Europe MA EEIG	10/08/2022	P/0277/2022
deucravacitinib	N/A	PM	Dermatology	Bristol-Myers Squibb International Corporation	26/08/2022	P/0278/2022
bosutinib	Bosulif	PM	Oncology	Pfizer Europe MA EEIG	10/08/2022	P/0279/2022
lenvatinib	Kisplyx, Lenvima	PM	Oncology	Eisai GmbH	11/08/2022	P/0280/2022
acetylsalicylic acid / rosuvastatin (calcium)	CIP-39 (temporary name)	W	Cardiovascular Diseases	CIPROS S.r.l.	11/08/2022	P/0281/2022
modakafusp alfa	N/A	W	Oncology	Takeda Pharma A/S	11/08/2022	P/0282/2022
humanized monoclonal antibody of igg1 subtype targeting nrp1	N/A	W	Ophthalmology	Boehringer Ingelheim International GmbH	11/08/2022	P/0283/2022
pegcetacoplan	Aspaveli	P	Uro-nephrology	Apellis Ireland Limited	11/08/2022	P/0284/2022
oxytocin	OTWILLO	P	Endocrinology-Gynaecology-Fertility-Metabolism	OT4B	11/08/2022	P/0285/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
deucravacitinib	N/A	P	Immunology- Rheumatology- Transplantation	Bristol-Myers Squibb International Corporation	11/08/2022	P/0286/2022
doxribtimine / doxecitine	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Zogenix ROI Limited	11/08/2022	P/0287/2022
vibegron	N/A	P	Uro-nephrology	Urovant Sciences GmbH	11/08/2022	P/0288/2022
larotrectinib	VITRAKVI	PM	Oncology	Bayer AG	11/08/2022	P/0289/2022
pegunigalsidase alfa	Elfabrio	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Chiesi Farmaceutici S.p.A	11/08/2022	P/0290/2022
lasmiditan	Reyvow	PM	Neurology	Eli Lilly and Company Limited	11/08/2022	P/0291/2022
pretomanid	Dovprela	PM	Infectious Diseases	Global Alliance for TB Drug Development	11/08/2022	P/0292/2022
ravulizumab	ULTOMIRIS	PM	Neurology	Alexion Europe SAS	11/08/2022	P/0293/2022
brexpiprazole	Rxulti	PM	Psychiatry	Otsuka Pharmaceutical Development & Commercialisation Europe GmbH	10/08/2022	P/0294/2022
vamorolone	Agamree	PM	Other	ReveraGen BioPharma Ltd	11/08/2022	P/0295/2022
obinutuzumab	Gazyvaro	PM		Roche Registration GmbH	10/08/2022	P/0296/2022
dermatophagoides farinae / dermatophagoides pteronyssinus	ACARIZAX and associated names	PM	Pneumology - Allergology	ALK-Abelló A/S	10/08/2022	P/0297/2022
maralixibat chloride	LIVMARLI	PM	Gastroenterology- Hepatology	Mirum Pharmaceuticals	10/08/2022	P/0298/2022
rimegepant	Vydura	PM	Neurology	Biohaven Pharmaceutical Ireland DAC	10/08/2022	P/0299/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
casirivimab	RONAPREVE	PM	Infectious Diseases	Roche Registration GmbH	10/08/2022	P/0300/2022
gold (au)	N/A	W	Neurology	Clene Netherlands B.V.	09/08/2022	P/0301/2022
efruxifermin	N/A	P	Gastroenterology-Hepatology	Akero Therapeutics, Inc.	10/08/2022	P/0302/2022
ritlecitinib	N/A	P	Gastroenterology-Hepatology	Pfizer Europe MA EEIG	10/08/2022	P/0333/2022
chloroprocaine (hydrochloride)	Ampres (invented name in the RMS) Associated names: Clorotekal, Decelex	RPM	Anaesthesiology	Sintetica GmbH	10/08/2022	P/0334/2022
fluciclovine (18f)	Axumin	W	Diagnostic / Oncology	Blue Earth Diagnostics Ireland Ltd	10/08/2022	P/0335/2022
lademirsén	N/A	P	Uro-nephrology	Genzyme Europe B.V.	10/08/2022	P/0336/2022
vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	10/08/2022	P/0337/2022
amlodipine (besilate) / nebivolol (hydrochloride)	N/A	W	Cardiovascular Diseases	Menarini Ricerche S.p.A.	10/08/2022	P/0338/2022
bimekizumab	Bimzelx	PM	Dermatology	UCB Biopharma SRL	10/08/2022	P/0339/2022
enmetazobactam / cefepime	AAI101	PM	Infectious Diseases	Allegra Therapeutics GmbH	10/08/2022	P/0340/2022
eptinezumab	Vyepti	PM	Neurology	H. Lundbeck A/S	10/08/2022	P/0341/2022
rezafungin acetate	Rezzayo	PM	Infectious Diseases	Mundipharma GmbH	10/08/2022	P/0342/2022
imdevimab	RONAPREVE	PM	Infectious Diseases	Roche Registration GmbH	10/08/2022	P/0343/2022
nipocalimab	N/A	W	Dermatology	Janssen-Cilag International NV	10/08/2022	P/0344/2022
remibrutinib	N/A	P	Neurology	Novartis Europharm Limited	10/08/2022	P/0345/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
etrasimod l-arginine	N/A	P	Gastroenterology-Hepatology	Arena Pharmaceuticals, Inc.	10/08/2022	P/0346/2022
azelastine (hydrochloride) / mometasone (furoate)	N/A	P	Oto-rhino-laryngology	Lek Pharmaceuticals d.d.	10/08/2022	P/0347/2022
setmelanotide	IMCIVREE	PM	Nutrition	Rhythm Pharmaceuticals, Inc	10/08/2022	P/0348/2022
etripamil	N/A	PM	Cardiovascular Diseases	Milestone Pharmaceuticals, Inc.	10/08/2022	P/0349/2022
rsv pref protein	N/A	P	Vaccines / Infectious Diseases	Janssen-Cilag International NV	10/08/2022	P/0350/2022
bempedoic acid	Nilemdo	PM	Cardiovascular Diseases	Esperion Therapeutics, Inc.	11/08/2022	P/0351/2022
apremilast	Otezla	PM	Immunology-Rheumatology-Transplantation	Amgen Europe B.V.	11/08/2022	P/0352/2022
apremilast	Otezla	PM	Immunology-Rheumatology-Transplantation	Amgen Europe.B.V	11/08/2022	P/0353/2022
tocilizumab	RoActemra	P	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	10/08/2022	P/0354/2022
tezepelumab	N/A	P	Dermatology	Amgen Europe B.V.	12/08/2022	P/0355/2022
tenofovir alafenamide / rilpivirine / emtricitabine	Odefsey	PM	Infectious Diseases	Gilead Sciences International Ltd.	11/08/2022	P/0356/2022
cabozantinib	COMETRIQ, CABOMETYX	PM	Oncology	Ipsen Pharma	11/08/2022	P/0357/2022
zuranolone	N/A	P	Psychiatry	Biogen Netherlands B.V.	22/08/2022	P/0358/2022
peginterferon beta-1a	Plegridy	PM	Neurology	Biogen Idec Ltd	22/08/2022	P/0359/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
cobicistat	Tybost	PM	Infectious Diseases	Gilead Sciences International Ltd.	22/08/2022	P/0360/2022
gallium 68-labelled prostate-specific membrane antigen-11 (68ga-psma-11)	isoPROtrace-11, 10 micrograms, kit for radiopharmaceutical preparation	W	Oncology	ROTOP Pharmaka GmbH	09/09/2022	P/0361/2022
lomitapide	Lojuxta	PM	Other	Amryt Pharmaceuticals DAC	19/09/2022	P/0362/2022
vonicoq alfa	VEYVONDI	PM	Haematology-Hemostaseology	Baxalta Innovations GmBH	07/09/2022	P/0363/2022
baricitinib	Olumiant	PM	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	09/09/2022	P/0364/2022
finerenone	Kerendia	PM	Cardiovascular Diseases	Bayer AG	09/09/2022	P/0365/2022
durvalumab	IMFINZI	PM	Oncology	AstraZeneca AB	09/09/2022	P/0366/2022
tremelimumab	IMJUDO	PM	Oncology	AstraZeneca AB	09/09/2022	P/0367/2022
odevixibat	Bylvay	PM	Gastroenterology-Hepatology	Albireo AB	09/09/2022	P/0368/2022
grisnilimab setaritox / dafsolimab setaritox	T-Guard - immunotoxin-combination, consisting of an anti-CD3 and anti-CD7 monoclonal antibody, each conjugated to ricin toxin A chain	PM	Immunology-Rheumatology-Transplantation	Xenikos B.V.	09/09/2022	P/0369/2022
ibrexafungerp citrate	N/A	P	Infectious Diseases	SCYNEXIS, Inc.	09/09/2022	P/0370/2022
tetracycline (hydrochloride) / metronidazole (benzoate) / bismuth (subcitrate)	N/A	W	Infectious Diseases / Gastroenterology-Hepatology	Verisfield Single Member S.A.	09/09/2022	P/0371/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
suvecaltamide (hydrochloride)	N/A	W	Neurology	Jazz Pharmaceuticals Ireland Ltd	09/09/2022	P/0372/2022
cannabidiol / delta-9-tetrahydrocannabinol	Sativex	W	Pain	GW Pharma (International) B.V	09/09/2022	P/0373/2022
xevinapant	N/A	W	Oncology	Merck Healthcare KGaA	09/09/2022	P/0374/2022
ex vivo expanded autologous human keratinocytes containing epidermal stem cells genetically modified with a gamma-retroviral (rv) vector expressing the full-length lamb3 cDNA (hologene 5)	HOLOGENE 5	P	Dermatology	Holostem Terapie Avanzate s.r.l.	09/09/2022	P/0375/2022
perindopril (tert-butylamin) / rosuvastatin (calcium)	N/A	W	Cardiovascular Diseases	KRKA, d.d., Novo mesto	19/09/2022	P/0376/2022
hydrochlorothiazide / amlodipine / telmisartan	N/A	W	Cardiovascular Diseases	Krka, d.d., Novo mesto	19/09/2022	P/0377/2022
tozinameran	Comirnaty	PM	Infectious Diseases	BioNTech Manufacturing GmbH	09/09/2022	P/0378/2022
plasma kallikrein inhibitor	N/A	PM	Haematology-Hemostaseology	KalVista Pharmaceuticals Ltd	27/09/2022	P/0379/2022
etranacogene dezaparovec	Hemgenix	PM	Haematology-Hemostaseology	CSL Behring GmbH	09/09/2022	P/0380/2022
zoliflodacin	N/A	PM	Infectious Diseases	Entasis Therapeutic Inc.	09/09/2022	P/0381/2022
efanesoctocog alfa	N/A	PM	Haematology-Hemostaseology	Swedish Orphan Biovitrum AB (Publ).	10/10/2022	P/0382/2022
baloxavir marboxil	Xofluza	PM	Infectious Diseases	Roche Registration GmbH	09/09/2022	P/0383/2022
corticotropin	Synthetic adrenocorticotropic hormone acetate (Syn-ACTH)	P	Neurology	Amzell B.V.	23/09/2022	P/0384/2022
copanlisib dihydrochloride	Aliqopa	PM	Oncology	Bayer AG	09/09/2022	P/0385/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
golidocitinib	N/A	W	Oncology	Dizal (Jiangsu) Pharmaceuticals Co., Ltd.	09/09/2022	P/0386/2022
valsartan / rosuvastatin	N/A	W	Cardiovascular Diseases	Teva B.V.	09/09/2022	P/0387/2022
oleclumab	N/A	W	Oncology	AstraZeneca AB	09/09/2022	P/0388/2022
autologous cd4+ and cd8+ t cells transduced with lentiviral vector encoding a chimeric antigen receptor (car) directed against human b cell maturation antigen (bcma) and preserving the t cell phenotype of the leukapheresis starting material (phe885)	N/A	W	Oncology	Novartis Europharm Limited	09/09/2022	P/0389/2022
fenfluramine (hydrochloride)	Fintepla	PM	Neurology	Zogenix International Ltd	09/09/2022	P/0390/2022
lamivudine / dolutegravir	Dovato	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/09/2022	P/0391/2022
ozanimod (hydrochloride)	Zeposia	PM	Neurology	Bristol-Myers Squibb Pharma EEIG	09/09/2022	P/0392/2022
clazakizumab	N/A	P	Immunology- Rheumatology- Transplantation	CSL Behring GmbH	09/09/2022	P/0393/2022
evinacumab	Evkeeza	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Ultragenyx Germany GmbH	09/09/2022	P/0394/2022
belimumab	Benlysta	PM	Immunology- Rheumatology- Transplantation	Glaxo Group Limited	09/09/2022	P/0395/2022
cabotegravir	Vocabria	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/09/2022	P/0396/2022
rilpivirine	Rekambys	PM	Infectious Diseases	Janssen-Cilag International NV	09/09/2022	P/0397/2022
inotuzumab ozogamicin	Besponsa	PM	Oncology / Haematology-	Pfizer Europe MA EEIG	09/09/2022	P/0398/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
			Hemostaseology			
guselkumab	Tremfya	PM	Gastroenterology- Hepatology	Janssen-Cilag International N.V.	09/09/2022	P/0399/2022
roxadustat	Evrenzo	PM	Haematology- Hemostaseology	Astellas Pharma Europe B.V.	09/09/2022	P/0400/2022
ustekinumab	STELARA	PM	Gastroenterology- Hepatology	Janssen-Cilag International NV	09/09/2022	P/0401/2022
emtricitabine / tenofovir alafenamide	Descovy	PM	Infectious Diseases	Gilead Sciences International Ltd.	09/09/2022	P/0402/2022
pegcetacoplan	ASPAVELI	W	Neurology	Apellis Netherlands B.V.	09/09/2022	P/0403/2022
adrenaline (epinephrine)	N/A	PM	Pneumology - Allergology	ARS Pharmaceuticals IRL, Limited	09/09/2022	P/0404/2022
monalizumab	N/A	W	Oncology	AstraZeneca AB	09/09/2022	P/0405/2022
vepsitamab	N/A	W	Oncology	Amgen Europe B.V.	09/09/2022	P/0406/2022
dimeric protein comprised of two disulfide-linked monomers, each being a fully human fusion protein consisting of a modified extracellular domain of the human activin receptor type iia fused to the fragment crystallizable domain of human igg1 fc including the hinge region, ch2 and ch3 domains (ker-050)	N/A	W	Oncology / Haematology- Hemostaseology	Keros Therapeutics, Inc.	09/09/2022	P/0407/2022
toripalimab	N/A	W	Oncology	TopAlliance Biosciences, Inc.	09/09/2022	P/0408/2022
etrasimod l-arginine	N/A	PM	Gastroenterology- Hepatology	Arena Pharmaceuticals, Inc.	29/09/2022	P/0409/2022
rozanolixizumab	Rystiggo	PM	Neurology	UCB Pharma S.A.	29/09/2022	P/0410/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
burosumab: human recombinant igg1 monoclonal antibody to fibroblast growth factor 23 (fgf23); krn23	Crysvita	PM	Other	Kyowa Kirin Holdings B.V.	30/09/2022	P/0411/2022
alpelisib	Vijoice	PM	Other	Novartis Europharm Limited	30/09/2022	P/0412/2022
diroximel fumarate (biib098)	Vumerity	W	Neurology	Biogen Netherlands B.V	29/09/2022	P/0413/2022
sotatercept	N/A	PM	Cardiovascular Diseases	Merck Sharp & Dohme B.V.	29/09/2022	P/0414/2022
epcoritamab	Epkinly, Tepkinly	PM	Oncology	AbbVie Ltd	29/09/2022	P/0415/2022
atropine (sulphate)	N/A	PM	Ophthalmology	Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus	28/10/2022	P/0416/2022
taniborbactam / cefepime	N/A	PM	Infectious Diseases	Venatorx Pharmaceuticals, Inc.	28/10/2022	P/0417/2022
pridopidine (hydrochloride)	N/A	W	Neurology	Prilenia Therapeutics B.V.	28/10/2022	P/0418/2022
lidocaine (hydrochloride monohydrate)	N/A	W	Pain	Acumen Dental Limited	28/10/2022	P/0419/2022
3-(1,3-benzodioxol-5-yl)-5-(3-bromophenyl)-1h-pyrazole	N/A	W	Neurology	Teva B.V.	28/10/2022	P/0420/2022
golimumab	Simponi	PM	Gastroenterology-Hepatology	Janssen Biologics B.V.	28/10/2022	P/0421/2022
maribavir	Livtency	PM	Infectious Diseases	Takeda Pharmaceuticals International AG Ireland Branch	28/10/2022	P/0422/2022
secukinumab	COSENTYX	PM	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	28/10/2022	P/0423/2022
ocrelizumab	Ocrevus	PM	Neurology	Roche Registration GmbH	28/10/2022	P/0424/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
yellow fever virus, strain vyf-247	N/A	P	Vaccines	Sanofi Pasteur	28/10/2022	P/0425/2022
odronextamab	N/A	P	Oncology	Regeneron Ireland DAC	28/10/2022	P/0426/2022
treprostinil (sodium)	Tresuvi	P	Cardiovascular Diseases	AOP Orphan Pharmaceuticals GmbH	28/10/2022	P/0427/2022
ambrisentan	Volibris	PM	Cardiovascular Diseases	Glaxo Group Limited	28/10/2022	P/0428/2022
recombinant fusion protein linking iduronate 2-sulfatase to engineered fc with binding site for transferrin receptor (dnl310)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Denali Therapeutics Inc.	28/10/2022	P/0429/2022
fluorine (18f) psma-1007	ProstaLumin	W	Diagnostic	BIOKOSMOS S.A.	28/10/2022	P/0430/2022
fusion protein composed of the first 2 immunoglobulin (ig)-like domains of the human robo2 fused to human igg1 fc (pf-06730512)	N/A	P	Uro-nephrology	Pfizer Europe MA EEIG	28/10/2022	P/0431/2022
efavaleukin alfa	N/A	P	Immunology-Rheumatology-Transplantation	Amgen Europe B.V.	28/10/2022	P/0432/2022
cenerimod	N/A	P	Immunology-Rheumatology-Transplantation	Idorsia Pharmaceuticals Deutschland GmbH	28/10/2022	P/0433/2022
finerenone	Kerendia	PM	Uro-nephrology	Bayer AG	28/10/2022	P/0434/2022
guselkumab	Tremfya	PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	28/10/2022	P/0435/2022
maralixibat chloride	LIVMARLI	PM	Gastroenterology-Hepatology	Mirum Pharmaceuticals	28/10/2022	P/0436/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
meningococcal group y oligosaccharides conjugated to corynebacterium diphtheriae crm197 protein (menabcwy) / recombinant neisseria meningitis group b protein 961c / recombinant neisseria meningitis group b protein 287- 953 / meningococcal group c oligosaccharides conjugated to corynebacterium diphtheriae crm197 protein / meningococcal group a oligosaccharides conjugated to corynebacterium diphtheriae crm197 protein / meningococcal group w-135 oligosaccharides conjugated to corynebacterium diphtheriae crm197 protein / recombinant neisseria meningitis group b protein 936-741 / outer membrane vesicles (omv) from n. meningitidis strain nz 98/254	Penmenvy	PM	Vaccines	GlaxoSmithKline Biologicals SA	28/10/2022	P/0437/2022
bupivacaine	EXPAREL liposomal	PM	Pain	Pacira Ltd	28/10/2022	P/0438/2022
tofacitinib	XELJANZ	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	28/10/2022	P/0439/2022
eliglustat	cerdelga	PM	Other	Genzyme Europe B.V.	28/10/2022	P/0440/2022
cefiderocol	Fetcroja	PM	Infectious Diseases	Shionogi B.V.	28/10/2022	P/0441/2022
monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised f protein derived from the rsv a2 strain	N/A	PM	Vaccines / Infectious Diseases	Janssen-Cilag International NV	28/10/2022	P/0442/2022
marstacimab	N/A	PM	Haematology- Hemostaseology	Pfizer Europe MAA EEIG	28/10/2022	P/0443/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
gepotidacin	N/A	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	28/10/2022	P/0444/2022
gepotidacin	N/A	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	28/10/2022	P/0445/2022
ritlecitinib	Litfulo	PM	Dermatology	Pfizer Europe MA EEIG	28/10/2022	P/0446/2022
levonorgestrel	Olevia	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Chemo Research, S.L.	28/10/2022	P/0447/2022
satralizumab	Enspryng	P	Neurology	Roche Registration GmbH	28/10/2022	P/0448/2022
branaplam	N/A	P	Neurology	Novartis Europharm Limited	28/10/2022	P/0449/2022
ianalumab	N/A	P	Immunology- Rheumatology- Transplantation	Novartis Europharm Limited	28/10/2022	P/0450/2022
trilaciclib (dihydrochloride)	N/A	W	Oncology	G1 Therapeutics, Inc.	28/10/2022	P/0451/2022
batoclimab	N/A	W	Ophthalmology	Immunovant Sciences, GmbH	28/10/2022	P/0452/2022
vosoritide	Voxzogo	PM	Other	BioMarin International Limited	24/10/2022	P/0453/2022
vericiguat	Verquvo	PM	Cardiovascular Diseases	Bayer AG	28/10/2022	P/0454/2022
atidarsagene autotemcel	Libmeldy	PM	Other	Orchard Therapeutics (Netherlands) B.V.	28/10/2022	P/0455/2022
enasidenib	Idhifa	PM	Oncology / Haematology- Hemostaseology	Bristol-Myers Squibb Pharma EEIG	28/10/2022	P/0456/2022
3,6-diamino-2,5-bis{n-[(1r)-1-carboxy-2-hydroxyethyl]carbamoyl}pyrazine	N/A	PM	Diagnostic / Uro- nephrology	MediBeacon Inc.	28/10/2022	P/0457/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
(mb-102)						
insulin human (ntra-2112/elgn-2112)	N/A	PM	Gastroenterology-Hepatology	ELGAN Pharma Ltd	28/10/2022	P/0458/2022
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	28/10/2022	P/0459/2022
rosuvastatin (calcium) / telmisartan	N/A	W	Cardiovascular Diseases	Adamed Pharma S.A.	28/10/2022	P/0460/2022
tadalafil / finasteride	N/A	W	Other	Adamed Pharma S.A.	28/10/2022	P/0461/2022
resmetirom	N/A	P	Gastroenterology-Hepatology	Madrigal Pharmaceuticals EU Limited	28/10/2022	P/0462/2022
freeze-dried allergen extract of betula pendula pollen	Birke Prick Test RX	P	Pneumology - Allergology	ROXALL Medizin GmbH	28/10/2022	P/0463/2022
beremagene geperpavec	Vyjuvek	P	Dermatology	Krystal Biotech, Inc.	28/10/2022	P/0464/2022
covid-19 vaccine (recombinant, adjuvanted)	BIMERVAX	P	Vaccines / Infectious Diseases	HIPRA Human Health S.L.U.	04/11/2022	P/0465/2022
tozinameran, tozinameran / famtozinameran	Comirnaty	PM	Infectious Diseases	BioNTech Manufacturing GmbH	07/11/2022	P/0466/2022
glycopyrronium bromide	Axhidrox	PM	Dermatology	Dr. August Wolff GmbH & Co. KG - Arzneimittel	17/11/2022	P/0467/2022
glucagon analogue linked to a human immunoglobulin fc fragment (hm15136)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Hanmi Pharm. Co., Ltd.	18/11/2022	P/0468/2022
efavaleukin alfa	N/A"	P	Other	Amgen Europe B.V.	14/11/2022	P/0469/2022
bedaquiline (fumarate)	SIRTURO	PM	Infectious Diseases	Janssen-Cilag International NV	16/11/2022	P/0470/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
namilumab	N/A	W	Immunology- Rheumatology- Transplantation	Kinevant Sciences GmbH	01/12/2022	P/0471/2022
pemigatinib	Pemazyre	W	Oncology	Incyte Biosciences Distribution B.V.	01/12/2022	P/0472/2022
batoclimab	N/A	P	Neurology	Immunovant Sciences, GmbH	01/12/2022	P/0473/2022
derivative of 3-phenyl-3h,4h,6h,7h-pyrano[3,4-d]imidazol-4-one	N/A	P	Uro-nephrology	Boehringer Ingelheim International GmbH	01/12/2022	P/0474/2022
exenatide (acetate)	N/A	P	Neurology	Invex Therapeutics Ltd	01/12/2022	P/0475/2022
sulbactam (sul-dur) / durlobactam	N/A	PM	Infectious Diseases	Entasis Therapeutics Inc.	01/12/2022	P/0476/2022
ataluren	Translarna	RPM	Neurology	PTC Therapeutics International, Limited	02/12/2022	P/0477/2022
saxagliptin	Onglyza	PM	Endocrinology- Gynaecology- Fertility-Metabolism	AstraZeneca AB	02/12/2022	P/0478/2022
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	N/A	W	Oncology / Haematology- Hemostaseology	Blueprint Medicines (Netherlands) B.V.	02/12/2022	P/0479/2022
sirolimus	N/A	P	Dermatology	Desitin Arzneimittel GmbH	02/12/2022	P/0480/2022
semaglutide	N/A	P	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	02/12/2022	P/0481/2022
2-[4-methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indan-2-carboxylic acid	N/A	W	Immunology- Rheumatology- Transplantation	Horizon Therapeutics Ireland DAC	02/12/2022	P/0482/2022
lacutamab	N/A	W	Oncology	Innate Pharma SA	02/12/2022	P/0483/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
camidanlumab tesirine	N/A	P	Oncology	ADC Therapeutics SA	02/12/2022	P/0484/2022
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 20 – 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	N/A	P	Vaccines	Merck Sharp & Dohme (Europe), Inc.	02/12/2022	P/0485/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
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 polysaccharide serotype 7f – diphtheria crm197 conjugate / pneumococcal polysaccharide serotype 6a – diphtheria crm197 conjugate / pneumococcal polysaccharide serotype 3 – diphtheria crm197 conjugate						
ruxolitinib (phosphate)	Opzelura	P	Dermatology	Incyte Biosciences Distribution B.V.	02/12/2022	P/0486/2022
encorafenib	Braftovi	RPM	Oncology	Pierre Fabre Médicament	02/12/2022	P/0487/2022
binimetinib	Mektovi	RPM	Oncology	Pierre Fabre Médicament	02/12/2022	P/0488/2022
recombinant human a disintegrin and metalloprotease with thrombospondin type-1 motifs 13	N/A	PM	Haematology-Hemostaseology	Takeda Pharmaceuticals International AG Ireland Branch	02/12/2022	P/0489/2022
brodalumab	Kyntheum	PM	Dermatology	LEO Pharma A/S	02/12/2022	P/0490/2022
voxelotor	Oxbryta	PM	Haematology-Hemostaseology	Global Blood Therapeutics Netherlands B. V.	02/12/2022	P/0491/2022
vusolimogene oderparepvec	N/A	W	Oncology	Replimune, Inc.	02/12/2022	P/0492/2022
1-{6-[(4m)-4-(5-chloro-6-methyl-1h-indazol-4-yl)-5-methyl-3-(1-methyl-1h-indazol-5-yl)-1h-pyrazol-	N/A	W	Oncology	Novartis Europharm Limited	02/12/2022	P/0493/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
1-yl]-2-azaspiro[3.3]heptan-2-yl}prop-2-en-1-one						
isatuximab	Sarclisa	PM	Oncology	Sanofi-Aventis Recherche & Développement	02/12/2022	P/0494/2022
inclisiran (sodium)	Leqvio	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Novartis Europharm Ltd.	02/12/2022	P/0495/2022
dolutegravir / rilpivirine	JULUCA	PM	Infectious Diseases	ViiV Healthcare UK Limited	02/12/2022	P/0496/2022
risankizumab	Skyrizi	PM	Immunology- Rheumatology- Transplantation / Dermatology / Gastroenterology- Hepatology	AbbVie Ltd	02/12/2022	P/0497/2022
manganese chloride tetrahydrate	Orviglance	P	Diagnostic	Ascelia Pharma AB	02/12/2022	P/0498/2022
cyanocobalamin / pyridoxine (hydrochloride) / thiamine (hydrochloride) / diclofenac (potassium)	N/A	W	Pain / Immunology- Rheumatology- Transplantation	Verisfield Single Member S.A.	02/12/2022	P/0499/2022
gadoquatrane (bay 1747846)	N/A	PM	Diagnostic	Bayer AG	01/12/2022	P/0500/2022
peanut flour	N/A	PM	Other	Cambridge Allergy Ltd	02/12/2022	P/0501/2022
obinutuzumab	Gazyvaro	P	Oncology	Roche Registration GmbH	01/12/2022	P/0502/2022
(1r,2s,5s)-n-((1s)-1-cyano-2-((3s)-2-oxopyrrolidin-3-yl)ethyl)-3-((2s)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide/ ritonavir / (1r,2s,5s)-n-((1s)-1-cyano-2-[(3s)-2-oxopyrrolidin-3-yl]ethyl)-6,6-dimethyl-3-[3-methyl-n-	Paxlovid	PM	Infectious Diseases	Pfizer Europe MA EEIG	01/12/2022	P/0503/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
(trifluoroacetyl)-l-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide						
tenofovir disoproxil (fumarate) / lamivudine / doravirine	Delstrigo	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	02/12/2022	P/0504/2022
doravirine	Pifeltro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	02/12/2022	P/0505/2022
bilastine	Bilaxten and associated names	PM	Ophthalmology	Faes Farma S.A.	02/12/2022	P/0506/2022
lanthanum carbonate hydrate	"Fosrenol" in the RMS (Sweden) and associated name "Foznol"	RPM	Uro-nephrology	Takeda Pharmaceuticals International AG Ireland Branch	02/12/2022	P/0507/2022
vedolizumab	Entyvio	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	02/12/2022	P/0508/2022
nipocalimab	N/A	W	Neurology	Janssen-Cilag International NV	02/12/2022	P/0509/2022
emactuzumab	N/A	P	Oncology	Synox Therapeutics Limited	02/12/2022	P/0510/2022
tigulixostat	N/A	W	Endocrinology-Gynaecology-Fertility-Metabolism	LG Chem, Ltd.	02/12/2022	P/0511/2022
cobolimab	N/A	W	Oncology	GlaxoSmithKline Trading Services Limited	02/12/2022	P/0512/2022
givinostat	N/A	PM	Neurology	Italfarmaco S.p.A.	04/12/2022	P/0513/2022
upadacitinb (abt-494)	RINVOQ	PM	Gastroenterology-Hepatology	AbbVie Ltd	06/12/2022	P/0514/2022
odevixibat	Bylvay	PM	Gastroenterology-Hepatology	Albireo AB	06/12/2022	P/0515/2022
acetylsalicylic acid / rivaroxaban	N/A	W	Cardiovascular Diseases	PharOS Pharmaceutical Oriented Services Single Member Ltd	30/12/2022	P/0516/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
imetelstat	N/A	PM	Oncology	Geron Corporation	30/12/2022	P/0517/2022
entospletinib	N/A	PM	Oncology	Kronos Bio Inc.	30/12/2022	P/0518/2022
obefazimod	N/A	P	Gastroenterology- Hepatology	Abivax	30/12/2022	P/0519/2022
stiripentol	N/A	P	Uro-nephrology	Biocodex SA	30/12/2022	P/0520/2022
live, attenuated, dengue virus, serotype 4 (denv4) / live, attenuated, dengue virus, serotype 3 (denv3) / live, attenuated, chimeric dengue virus, serotype 2 (denv2) / live, attenuated, dengue virus, serotype 1 (denv1)	N/A	P	Vaccines	Merck Sharp & Dohme (Europe), Inc.	30/12/2022	P/0521/2022
humanized monoclonal igg1-based antibody (ro7204239)	N/A	P	Neurology	Roche Registration GmbH	30/12/2022	P/0522/2022
dolutegravir / hiv-1 maturation inhibitor (gsk3640254)	N/A	P	Infectious Diseases	ViiV Healthcare UK Limited	30/12/2022	P/0523/2022
hiv-1 maturation inhibitor (gsk3640254)	N/A	P	Infectious Diseases	ViiV Healthcare UK Limited	30/12/2022	P/0524/2022
treprostinil (palmitil)	N/A	W	Pneumology - Allergology	Insmmed Netherlands B.V.	30/12/2022	P/0525/2022
aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen	Depiquick Bäume-Mix	RPM	Pneumology - Allergology	LETI Pharma GmbH	30/12/2022	P/0526/2022
aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen	Depiquick Birke	RPM	Pneumology - Allergology	LETI Pharma GmbH	30/12/2022	P/0527/2022
lenvatinib	Kispilyx, Lenvima	PM	Oncology	Eisai GmbH	30/12/2022	P/0528/2022
linaclotide	Constella	PM	Gastroenterology- Hepatology	AbbVie Deutschland GmbH & Co KG	30/12/2022	P/0529/2022

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
eplerenone / torasemide	N/A	W	Cardiovascular Diseases	WIN MEDICA S.A.	30/12/2022	P/0530/2022
siponimod (hemifumarate)	Mayzent	PM	Neurology	Novartis Europharm Ltd	30/12/2022	P/0531/2022
messenger rna encoding cas9 and single guide rna targeting the human ttr gene	N/A	W	Cardiovascular Diseases / Neurology	Intellia Therapeutics, Inc.	30/12/2022	P/0532/2022
posoleucel	N/A	P	Infectious Diseases	AlloVir International DAC	30/12/2022	P/0533/2022
eplontersen	N/A	W	Neurology	AstraZeneca AB	30/12/2022	P/0534/2022
lefamulin	XENLETA	PM	Infectious Diseases	Nabriva Therapeutics DAC	30/12/2022	P/0535/2022
setrusumab	N/A	PM	Other	Mereo Biopharma 3 Ltd	30/12/2022	P/0536/2022
ofatumumab	Kesimpta	PM	Neurology	Novartis Ireland Limited	30/12/2022	P/0537/2022
ezepegind	N/A	W	Neurology	Alzprotect S.A.S., France	30/12/2022	P/0538/2022
modified vaccinia ankara - bavarian nordic virus (smallpox)	IMVANEX	PM	Vaccines	Bavarian Nordic A/S	30/12/2022	P/0539/2022
tecovirimat (monohydrate)	Tecovirimat SIGA	PM	Infectious Diseases	SIGA Technologies, Inc.	30/12/2022	P/0540/2022
dupilumab	Dupixent	PM	Gastroenterology- Hepatology	Regeneron Ireland DAC	30/12/2022	P/0541/2022
covid-19 vaccine (ad26.cov2-s [recombinant])	JCOVDEN	W	Vaccines / Infectious Diseases	Janssen-Cilag International N.V.	30/12/2022	P/0542/2022
depemokimab	N/A	P	Pneumology - Allergology	GlaxoSmithKline Trading Services Limited	30/12/2022	P/0543/2022
enzastaurin (hydrochloride)	N/A	P	Other	Aytu BioPharma Inc.	30/12/2022	P/0544/2022
nemolizumab	N/A	PM	Dermatology	Galderma International S.A.S	04/01/2022	P/0545/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision Date	Decision Number
inclacumab	N/A	P	Haematology-Hemostaseology	Global Blood Therapeutics Netherlands B.V.	30/12/2022	P/0545/2022
pridopidine (hydrochloride)	N/A	P	Neurology	Prilenia Therapeutics B.V.	30/12/2022	P/0546/2022
indapamide / valsartan	N/A	W	Cardiovascular Diseases	KRKA, d.d., Novo mesto	30/12/2022	P/0547/2022
aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen	Depigoid Bäume-Mix	RPM	Pneumology - Allergology	LETI Pharma GmbH	30/12/2022	P/0548/2022
aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of betula alba pollen	Depigoid Birke	RPM	Pneumology - Allergology	LETI Pharma GmbH	30/12/2022	P/0549/2022
mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	01/12/2022	P/0550/2022
griectocogene fitelparvovec	N/A	PM	Haematology-Hemostaseology	Pfizer Europe MA EEIG	04/01/2022	P/0555/2021

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
methoxy polyethylene glycol-epoetin beta	Haematology-Hemostaseology	Roche Registration GmbH	20/05/2022
apixaban	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	24/06/2022
sacubitril/valsartan	Cardiovascular Diseases	Novartis Europharm Ltd	20/05/2022
brivaracetam	Neurology	UCB Pharma S.A.	14/10/2022
alogliptin	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Development Centre Europe Ltd	11/11/2022
linagliptin	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	16/12/2022
lisdexamfetamine dimesylate	Psychiatry	Takeda Pharmaceuticals International AG, Ireland Branch	25/05/2022
dulaglutide	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company Limited	24/06/2022
edoxaban tosilate	Cardiovascular Diseases / Haematology-Hemostaseology	Daiichi Sankyo Europe GmbH	11/11/2022
empagliflozin	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	16/12/2022
eculizumab	Neurology	Alexion Europe SAS	14/10/2022
treosulfan	Immunology-Rheumatology-Transplantation	medac Gesellschaft für klinische Spezialpräparate mbH	25/03/2022
nintedanib esylate	Pneumology - Allergology	Boehringer Ingelheim International GmbH	22/07/2022
dopamine (hydrochloride)	Neonatology - Paediatric Intensive Care	BrePco Biopharma Limited	14/10/2022
albutrepenonacog alfa	Haematology-Hemostaseology	CSL Behring GmbH	21/01/2022

naloxegol (as naloxegol oxalate)	Gastroenterology-Hepatology	Kyowa Kirin Pharmaceutical Development Limited	11/11/2022
dabrafenib	Oncology	Novartis Europharm Limited	11/11/2022
dabrafenib	Oncology	Novartis Europharm Limited	27/09/2022
recombinant 10 kda culture filtrate protein of mycobacterium tuberculosis (rcfp-10) / recombinant dimer of mycobacterium tuberculosis 6 kda early secretory antigenic target (rdesat-6)	Diagnostic	Vakzine Projekt Management GmbH	11/11/2022
pitolisant	Neurology	BIOPROJET PHARMA	20/05/2022
trametinib	Oncology	Novartis Europharm Limited	11/11/2022
trametinib	Oncology	Novartis Europharm Limited	27/09/2022
agomelatine	Psychiatry	Les Laboratoires Servier	14/10/2022
human fibrinogen	Haematology-Hemostaseology	Octapharma Pharamzeutika Produktionsges.m.b.H	24/06/2022
baricitinib	Dermatology	Eli Lilly and Company	11/11/2022
eribulin	Oncology	Eisai GmbH	25/02/2022
evolocumab	Cardiovascular Diseases	Amgen Europe B.V	24/06/2022
ibrutinib	Oncology	Janssen-Cilag International NV	25/02/2022
nivolumab	Oncology	Bristol-Myers Squibb Pharma EEIG	21/01/2022
cabotegravir	Infectious Diseases	ViiV Healthcare UK Limited	20/05/2022
maralixibat chloride	Gastroenterology-Hepatology	Mirum Phamraceuticals	11/10/2022
dupilumab	Dermatology	Regeneron Pharmaceuticals, Inc.,	25/02/2022
tisagenlecleucel	Oncology	Novartis Europharm Limited	24/06/2022
pandemic influenza vaccine (h5n1) (surface antigen, inactivated, adjuvanted)	Vaccines	Seqirus S.r.l.	16/12/2022
lanadelumab	Other	Takeda Pharmaceuticals International AG Ireland Branch	09/09/2022

ad26.zebov (recombinant, replication-incompetent)	Vaccines	Janssen-Cilag International NV	24/06/2022
mva-bn-filo (recombinant, non-replicating)	Vaccines	Janssen-Cilag International NV	24/06/2022
oteseconazole	Infectious Diseases	Gedeon Richter Plc.	16/12/2022
artesunate	Infectious Diseases	Amivas Ireland Limited	09/09/2022
influenza virus a/turkey/turkey/1/2005 (h5n1) nibrg-23 strain, ha surface antigen	Vaccines	Seqirus Netherlands B.V.	09/09/2022
nifurtimox	Infectious Diseases	Bayer AG	09/09/2022

Annex 17 – Referral procedures overview 2022 – 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
Lidocain/Prilocain IDETEC and associated names (lidocaine/prilocaine)	25/03/2021	Application withdrawn ¹	Article 29(4) of Directive 2001/83/EC
Etifoxine-containing medicinal products (etifoxine)	24/06/2021	27/01/2022	Article 31 of Directive 2001/83/EC
Nasolam and associated names (midazolam)	14/10/2021	18/02/2022 ²	Article 29(4) of Directive 2001/83/EC
Daruph and Anafezyn and associated names (dasatinib (anhydrous))	27/01/2022	15/09/2022	Article 29(4) of Directive 2001/83/EC
Medicinal products which have been authorised or are pending approval based on studies performed at Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, Gujarat, India (various)	27/01/2022	19/05/2022	Article 31 of Directive 2001/83/EC
Rubraca (rucaparib)	22/04/2022	21/07/2022	Article 20 of Regulation (EC) No 726/2004
Rambis and associated names (ramipril/bisoprolol fumarate)	23/06/2022	15/12/2022	Article 29(4) of Directive 2001/83/EC
Gelisia and associated names (timolol maleate)	10/11/2022	15/12/2022	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
Amfepramone-containing medicinal products	11/02/2021	10/11/2022	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Nomegestrol-containing medicinal products or chlormadinone-containing medicinal products	30/09/2021	01/09/2022	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome	13/01/2022	10/11/2022	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

¹ Application was withdrawn by applicant on 26 January 2022

² Date of the revised Opinion. Initial Opinion was adopted on 27 January 2022

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Janus Kinase inhibitors (JAKi) (tofacitinib, abrocitinib, baricitinib. Upadacitinib, filgotinib)	10/02/2022	10/11/2022	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Pholcodine-containing medicinal products	01/09/2022	14/12/2022	Article 107i of Directive 2001/83/EC
Topiramate-containing medicinal products (topiramate)	01/09/2022	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Annex 18 – Arbitrations and referrals in 2022 – veterinary medicines

Type of procedure	Date <ul style="list-style-type: none"> • Clock start • CVMP opinion 	Product <ul style="list-style-type: none"> • Product name • INN
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 19/01/2022 • 14/07/2022 	<ul style="list-style-type: none"> • Veterinary medicinal products containing toltrazuril to be administered orally to chickens • Toltrazuril
Referral under Article 82 of Regulation (EU) 2019/6	<ul style="list-style-type: none"> • 11/05/2022 • 08/12/2022 	<ul style="list-style-type: none"> • Veterinary medicinal products containing N-methyl pyrrolidone as an excipient • NMP (excipient)

Annex 19 – Budget summaries 2021-2022

The summarised comparative budget statements for 2021 and 2022 are as follows:

		2021 (final) ¹		2022 (budget) ²		2022 (prov.) ³	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
Revenue							
100	Fees and charges	341,638	89.4%	372,276	88.3%	364,882	88.0%
200	General EU contribution	25,450	6.7%	32,125	7.6%	32,416	7.8%
201	Special EU contribution for orphan medicinal products	12,187	3.2%	12,876	3.1%	12,895	3.1%
600	External assigned revenue	0	0.0%	0	0.0%	0	0.0%
700	Balance from previous year	0	0.0%	4,369	1.0%	4,369	1.1%
5+9	Other	2,881	0.8%	169	0.0%	301	0.1%
TOTAL REVENUE		382,156	100.0%	421,815	100.0%	414,863	100.0%
Expenditure							
Staff							
11	Staff in active employment	106,812	29.2%	119,001	28.2%	117,411	28.8%
12	Staff recruitment	211	0.1%	250	0.1%	203	0.0%
13	Duty travel	25	0.0%	650	0.2%	389	0.1%
14	Socio-medical infrastructure	1,647	0.5%	2,474	0.6%	2,434	0.6%
15	Training	649	0.2%	1,060	0.3%	1,012	0.2%
16	External services	16,084	4.4%	17,521	4.2%	17,301	4.2%
17	Representation expenses	54	0.0%	145	0.0%	92	0.0%
<i>Total Title 1</i>		125,482	34.3%	141,101	33.5%	138,842	34.0%
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	14,813	4.1%	15,775	3.7%	14,880	3.6%
21	Expenditure on corporate data processing	26,269	7.2%	31,116	7.4%	30,449	7.5%
22	Movable property [..]	588	0.2%	632	0.1%	581	0.1%
23	Other administrative expenditure	1,025	0.3%	1,896	0.4%	1,334	0.3%
24	Postage	31	0.0%	56	0.0%	20	0.0%
25	Expenditure on other meetings	342	0.1%	215	0.1%	165	0.0%
26	Restaurant & catering	602	0.2%	1,066	0.3%	1,023	0.3%
27	Information & publishing	2,028	0.6%	1,923	0.5%	1,808	0.4%
28	Business consultancy & audit svcs.	2,060	0.6%	2,580	0.6%	1,985	0.5%
<i>Total Title 2</i>		47,758	13.1%	55,259	13.1%	52,245	12.8%
Operational expenditure							
300	Meetings	143	0.0%	2,782	0.7%	2,194	0.5%
301	Evaluation of medicines	143,176	39.2%	150,374	35.6%	145,994	35.8%
302	Translations	4,773	1.3%	4,983	1.2%	4,072	1.0%
303	Scientific studies & svcs.	14,707	4.0%	28,686	6.8%	27,605	6.8%
31	Expenditure on business related IT projects	29,452	8.1%	38,630	9.2%	37,373	9.2%
<i>Total Title 3</i>		192,251	52.6%	225,455	53.4%	217,238	53.2%
90	Provisional appropriation	0	0.0%	0	0.0%	0	0.0%
<i>Total Title 9</i>		0	0.0%	0	0.0%	0	0.0%
TOTAL EXPENDITURE		365,491	100.0%	421,815	100.0%	408,325	100.0%

¹ Financial Year 2021: as per final accounts; rounded to nearest thousand Euro

² Financial Year 2022: as per final budget

³ Financial Year 2022: as per provisional accounts; rounded to nearest thousand Euro

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2022				POSTS 2023	
	Authorised		Actual as per 31.12.2022		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	-	10	-	9	-	12
AD 13	-	13	-	13	-	12
AD 12	-	50	-	50	-	57
AD 11	-	52	-	52	-	49
AD 10	-	50	-	50	-	53
AD 9	-	62	-	62	-	66
AD 8	-	77	-	77	-	87
AD 7	-	97	-	97	-	89
AD 6	-	60	-	60	-	67
AD 5	-	3	-	3	-	0
Total AD	0	477	0	473	0	495
AST 11	-	2	-	2	-	2
AST 10	-	7	-	7	-	7
AST 9	-	10	-	10	-	10
AST 8	-	13	-	13	-	14
AST 7	-	19	-	19	-	25
AST 6	-	26	-	26	-	31
AST 5	-	43	-	43	-	43
AST 4	-	42	-	42	-	43
AST 3	-	23	-	23	-	12
AST 2	-	0	-	0	-	0
AST 1	-	0	-	0	-	0
Total AST	0	185	0	185	0	187
Grand Total	0	662	0	658	0	682

Other staff	Planned (FTE ¹) 2022	Actual (FTE ¹) 2022	Actual headcount 31.12.2022	Planned (FTE ¹) 2023
CONTRACT AGENTS	223	192	207	203
NATIONAL EXPERTS	30	25	30	45

¹ FTE=Full Time Equivalent

Annex 21 - Litigation activities of EMA in 2022

Actions before the Court of Justice of the European Union that are directed against EMA (pending or concluded in 2022)

1. Case T-556/20, *D&A Pharma v Commission and EMA*

On 4 September 2020, the applicant brought an action against the European Commission and EMA in connection with the decision of the European Commission to refuse the grant of a conditional marketing authorisation for a medicinal product for human use.

By its [judgment](#) of 2 March 2022, the General Court rejected the application for annulment and the applicant was ordered to bear the costs and those incurred by the Commission and EMA.

On 2 May 2022, the applicant submitted an appeal against the judgment at first instance.

2. Case T-570/20, *Kedrion v EMA*

On 11 September 2020, the applicant brought an action against the decision of EMA to refuse access, pursuant to Regulation (EC) No 1049/2001 to a document inserted in the Plasma Master File submitted by another pharmaceutical company.

On 26 January 2022, the General Court delivered its [judgment](#) in Case T-570/20 annulling the contested decision without addressing the merits of EMA's refusal to disclose the contested document, and motivating the annulment with the lack of sufficient justification in EMA's decision letter. EMA was ordered to pay its own costs and those incurred by the applicant.

3. 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.

4. 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 2022.

5. Case T-418/21, *Alauzun and Others v Commission and EMA*

On 12 July 2021, a group of natural persons brought an action against the European Commission and EMA in connection with the decision of the European Commission extending the indication of an authorised COVID-19 vaccine to persons of 12 years of age and older.

On 14 January 2022, the Court issued an [order](#) rejecting the action as inadmissible and ordered the applicants to bear the legal costs.

6. 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.

On 6 October 2022, Advocate General Medina delivered her [opinion](#) in the appellate proceedings. In her opinion, she proposed that the Court of Justice should set aside the judgment of the General Court, reject the application for annulment of Pharmaceutical Works Polpharma, and also order the applicant to bear the costs of the proceedings.

7. Case T-713/21, Agentur für Globale Gesundheitsverantwortung v EMA

On 5 November 2021, the applicant brought an action against the decision of EMA to grant partial access, pursuant to Regulation (EC) No 1049/2001, to a document containing information on a study relating to a COVID-19 vaccine.

After the submission of EMA's defence, the applicant applied, on 3 May 2022, for the discontinuance of the court proceedings. By [order](#) of 8 July 2022 of the President of the Eighth Chamber of the General Court, the case was removed from the register and the applicant was ordered to pay its own costs and those incurred by EMA.

8. Case T-806/21, NV v EMA

On 27 December 2021, an action was initiated against a decision of EMA that did not recognise that the illness of a staff member was allegedly caused by their work.

By [order](#) of 12 December 2022, the case was removed from the register.

9. 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.

10. 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.

11. 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.

12. 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.

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 2022)

13. Case T-303/16, Mylan IRE Healthcare v Commission

On 14 June 2016, an action was brought against the decision of the European Commission, adopted in the framework of Article 29 of Directive 2001/83/EC, concerning a number of marketing authorisations of nationally authorised medicinal products for human use.

By its [judgment](#) of 26 January 2022, the General Court rejected the application for annulment against the Commission.

14. 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 2022.

15. Joined Cases C-6/20 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*.

On 12 October 2022, a hearing was held before the Court of Justice.

16. Case T-138/21, *Virbac v Commission*

On 4 March 2021, the applicant brought an action against the decision of the European Commission to grant a marketing authorisation for a medicinal product for veterinary use.

On 29 July 2022, the applicant applied for the discontinuance of the Court proceedings. By [order](#) of 31 August 2022, the case was removed from the register.

17. Case T-464/21, *Faller and Others v Commission*

By [order](#) of 7 February 2022, the General Court rejected as inadmissible an action for annulment against a decision of the European Commission relating to the grant of a conditional marketing authorisation for a COVID-19 vaccine.

18. 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. On 22 September 2022, EMA was granted leave to intervene in support of the European Commission by the President of the Court of Justice. EMA submitted its statement in intervention on 24 October 2022.

19. 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.

EMA submitted an application for leave to intervene in support of the European Commission on 26 October 2022.

20. Case T-483/22, *Genzyme Europe 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 Nexviadyne (avalglucosidase alfa) as a new active substance and to remove the medicinal product from the Union register of orphan medicinal products.

EMA submitted an application for leave to intervene in support of the European Commission on 15 December 2022.

21. 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.

Annex 22 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2022	676	216 666

Initial decisions on access in 2022¹

Access given	
Yes	330
Partial	2
No	14
Document is not held by the Agency	42
Request became RFI	100
Clarification is not received / Withdrawn by requester	227
Total closed	715
Pending ²	392

Legal basis used for full or partial refusal

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	0	0
4.2 1 st ind – Protection of commercial interest	12	0
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	2	1
4.3 2 nd par – Protection of the Agency's decision making process	0	1
4.5 – Protection of Member States	0	0
Total	14	2

¹ Including initial requests received in previous years but closed in 2022

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

Decision on confirmatory applications in 2022³

Appeals	
Final refusal	2
Release	9
Partial	0
Request became RFI	0
Withdrawn by requester	1
Total closed	12
Pending ⁴	3

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	2	0
4.2 1 st ind – Protection of commercial interest	0	0
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	0	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	2	0

³ Including appeals received in previous years but closed in 2022

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

Affiliation (per initial requests and appeals in 2022)

Affiliation	Number of requests received	In %	Number of pages released⁵	In %
Not-for-profit organisation	19	3	37562	17
EU Institution (EC etc)	1	0	0	0
Regulator outside EU	4	0	0	0
EU NCA	1	0	0	0
Patients or Consumer	59	9	9337	4
Healthcare professional	26	4	79423	37
Academia/Research institute	72	11	23977	11
Legal	43	6	9958	5
Media	19	3	7322	3
Pharmaceutical industry	358	53	36815	17
Consultant	67	10	9223	4
Other	7	1	3049	1
Total	676	100	216666	100

⁵ Including initial requests and appeals received in previous years but closed in 2022

Annex 23 – Clinical Data Publication

Only Covid-19 related procedures were published during 2022.

Number of documents published

Year	Number of documents published	Number of pages published
2022	742	206.771

Documents and Pages published per module

MODULE	Documents	Pages
Module 2.5	55	4.509
Module 2.7	44	3.407
Module 5	643	198.855

Number of procedures published by procedure type

Initial MAA	5
Extension of Indication	10
Renewal	1
Type II Variation	29
Post Authorisation Recommendation (PAM)	1

Anonymisation Risk Assessment Approach

Approach	Number of Procedures
Qualitative ¹	23
Quantitative ²	13
Mixed ³	2
Not Applicable ⁴	8

¹ Qualitative approach: calculate the level of risk (e.g. high, medium, low) based on the characteristics of the source data (e.g. prevalence of the disease, trial sample size, number of sites) . [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

² Quantitative approach: calculate the probability of uniquely identifying an individual (the risk of re-identification is defined as a numerical value obtained through the *analysis of the clinical* data to be disclosed.) [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

³ Mixed: a combination of the two.

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

Annex 24 – Publications by Agency staff members and experts in 2022

Abed I, Gonzalez-Quevedo R, Mura M, Dias M, da Rocha Dias S, García Burgos J.

Commentary on the European Medicines Agency's extended mandate: Protecting public health in times of crisis and improving availability of medicines and medical devices.

Br J Clin Pharmacol. 2023 Jan;89(1):5-10. doi: 10.1111/bcp.15567. Epub 2022 Nov 7. PMID: 36345231.

Abend AM, Zhang L, Fredro-Kumbaradzi E, Hoffelder T, Cohen MJ, Anand O, Delvadia P, Mandula H, Zhang Z, Kotzagiorgis E, Lum S, Pereira VG, Barker A, Lavrich D, Kraemer J, Sharp-Suarez S.

Current Approaches for Dissolution Similarity Assessment, Requirements, and Global Expectations

AAPS J. 2022 Mar 29;24(3):50. doi: 10.1208/s12248-022-00691-4. PMID: 35352186.

Arlett P, Kjaer J, Broich K, Cooke E.

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