

# Annexes – 2019 annual report of the European Medicines Agency

Annex 1 – Members of the Management Board .....	2
Annex 2 - Members of the Committee for Medicinal Products for Human Use.....	4
Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee.....	6
Annex 4 – Members of the Committee for Medicinal Products for Veterinary Use.....	8
Annex 5 – Members of the Committee on Orphan Medicinal Products .....	10
Annex 6 – Members of the Committee on Herbal Medicinal Products.....	11
Annex 7 – Committee for Advanced Therapies.....	13
Annex 8 – Members of the Paediatric Committee .....	15
Annex 9 – Working parties and working groups .....	17
Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2019 ....	23
Annex 11 – Guidelines and concept papers adopted by CHMP.....	24
Annex 12 – CVMP opinions on medicinal products for veterinary use in 2019.....	27
Annex 13 – Guidelines and concept papers adopted by CVMP in 2019.....	36
Annex 14 – COMP opinions on designation of orphan medicinal products in 2019.....	38
Annex 15 – HMPC European Union herbal monographs in 2019.....	53
Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2019.	55
Annex 17 – Referral procedures overview 2019 – human medicines.....	98
Annex 18 – Arbitrations and referrals in 2019 – veterinary medicines.....	101
Annex 19 – Budget summaries 2018–2019 .....	103
Annex 20 – European Medicines Agency establishment plan .....	104
Annex 21 – Access to documents requests in 2019 .....	105
Annex 22 – Publications by Agency staff members and experts in 2019 .....	108

## Annex 1 – Members of the Management Board

Chair: Christa WIRTHUMER-HOCHE

EMA contact: Noël WATHION; Silvia FABIANI

### Members

- European Parliament Björn LEMMER, Tonio BORG
- European Commission Anne BUCHER, Carlo PETTINELLI  
(Alternates: Andrzej RYS, Stefano SORO)
- Belgium Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria Bogdan KIRILOV <sup>1</sup> (Alternate: Svetlin SPIROV<sup>2</sup>)
- Czech Republic Irena STOROVÁ (Alternate: Jiří BUREŠ)
- Denmark Thomas SENDEROVITZ (Alternate: Mette AABOE HANSEN)
- Germany Karl BROICH (Alternate: Lars - Christoph NICKEL<sup>3</sup>)
- Estonia Kristin RAUDSEPP (Alternate: Alar IRS)
- Ireland Lorraine NOLAN (Alternate: Rita PURCELL)
- Greece Eleftherios PALLIS<sup>4</sup> (Alternate: Charalambos KANDILOROS<sup>5</sup>)
- Spain María Jesús LAMAS DÍAZ (Alternate: César HERNÁNDEZ)
- France Dominique MARTIN (Alternate: Jean-Pierre ORAND)
- Croatia Vili Beros<sup>6</sup> (Alternate: Siniša TOMIĆ)
- Italy Luca LI BASSI (Alternate: Giuseppe AMATO)
- Cyprus Loizos PANAYI (Alternate: Irimi Chrysafi FANIDOU<sup>7</sup>)
- Latvia Svens HENKUZENS (Alternate: Janis ZVEJNIEKS)
- Lithuania Gytis ANDRULIONIS<sup>8</sup> (Alternate: Awaiting nomination)
- Luxembourg Laurent MERTZ (Alternate: Françoise BERTHET<sup>9</sup>)
- Hungary Mátyás SZENTIVÁNYI (Alternate: Beatrix HORVATH)
- Malta Anthony SERRACINO-INGLOTT<sup>10</sup>

---

<sup>1</sup> Replaced Assena STOIMENOVA as of February 2019

<sup>2</sup> Replaced Bogdan KIRILOV as of February 2019

<sup>3</sup> Replaced Thomas MULLER as of June 2019

<sup>4</sup> Replaced Ekaterini ANTONIOU as of December 2019

<sup>5</sup> Replaced Ioannis MALEMIS as of December 2019

<sup>6</sup> Nominated as of February 2019

<sup>7</sup> Replaced Anna PAPHITOU as of February 2019

<sup>8</sup> Replaced Gintautas BARCYS as of November 2018

<sup>9</sup> Replaced Jacqueline GENOUX-HAMES as of March 2019

<sup>10</sup> Replaced John-Joseph BORG as of October 2019

- Netherlands (Alternate: John-Joseph BORG<sup>11</sup>)
- Austria Hugo HURTS (Alternate: Constant VAN BELKUM)
- Poland Christa WIRTHUMER-HOCHE (Alternate: Thomas REICHHART)
- Portugal Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
- Romania Rui SANTOS IVO (Alternate: Awaiting nomination)
- Slovenia Marius Daniel ȘIȘU<sup>12</sup> (Alternate: Roxana STROE<sup>13</sup>)
- Slovakia Momir RADULOVIĆ (Alternate Awaiting nomination)
- Finland Zuzana BAŤOVÁ (Alternate: Judita HEDEROVA)
- Sweden Eija PELKONEN (Alternate: Esa HEINONEN)
- United Kingdom Catarina FORSMAN (Alternate: SARA ROSENMULLER)
- Representatives of patients' organisations Awaiting nomination (Alternate: Jonathan MOGFORD)
- Representative of doctors' organisations Marco GRECO<sup>14</sup>  
Ioannis NATSIS<sup>15</sup>
- Representative of veterinarians' organisations Wolf-Dieter LUDWIG
- Nancy DE BRIYNE

### **Observers**

- Iceland Runa HAUKSDOTTIR (Alternate: Einar MAGNUSSON)
- Liechtenstein Marc BÜRZLE<sup>16</sup> (Alternate: Martin STRICKER)
- Norway Audun HÅGÅ (Alternate: Karen Marie ULSHAGEN<sup>17</sup>)

---

<sup>11</sup> Replaced Gavril FLORES as of October 2019

<sup>12</sup> Replaced Adriana COTEL as of February 2019

<sup>13</sup> Replaced Ada GEORGESCU as of February 2019

<sup>14</sup> Nominated as of June 2019

<sup>15</sup> Nominated as of June 2019

<sup>16</sup> Replaced Brigitte BATLINER as of August 2019

<sup>17</sup> Replaced Ivar VOLLSET as of May 2019

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

Chair: Harald ENZMANN

EMA contact: Anabela MARCAL

### Members

• Andrea LASLOP (Austria)	Alternate: Milena STAIN
• Bart VAN DER SCHUEREN (Belgium)	Alternate: Christophe FOCKE
• Mila VLASKOVSKA (Bulgaria)	Alternate: Dariya DIMITROVA <sup>1</sup>
• Margareta BEGO (Croatia) <sup>2 3</sup>	Alternate: Selma ARAPOVIC DZAKULA
• Loizos PANAYI (Cyprus) <sup>4</sup>	Alternate: Emilia MAVROKORDATOU <sup>5</sup>
• Ondrej SLANAR (Czech Republic)	Alternate: Tomas RADIMERSKY <sup>6</sup>
• Sinan B. SARAC (Denmark)	Alternate: Mark AINSWORTH
• Alar IRS (Estonia)	Alternate: <i>Awaiting nomination</i>
• Outi MAKI-IKOLA (Finland)	Alternate: Tuomo LAPVETELAINEN
• Alexandre MOREAU (France)	Alternate: Jean-Michel RACE <sup>7</sup>
• Martina WEISE (Germany)	Alternate: Janet KOENIG
• Constantinos MARKOPOULOS (Greece)	Alternate: Eleftheria NIKOLAIDI
• Melinda SOBOR (Hungary) <sup>8</sup>	Alternate: Agnes GYURASICS <sup>9</sup>
• Kolbeinn GUDMUNDSSON (Iceland)	Alternate: Hrefna GUDMUNDSDOTTIR
• Jayne CROWE (Ireland)	Alternate: Peter KIELY
• Daniela MELCHIORRI (Italy)	Alternate: Guiseppa PISTRITTO <sup>10 11</sup>
• Natalja KARPOVA (Latvia) <sup>12</sup>	Alternate: <i>Awaiting nomination</i> <sup>13 14</sup>
• Romaldas MACIULAITIS (Lithuania)	Alternate: Rugile PILVINIENE
• Martine TRAUFLER (Luxembourg) <sup>15</sup>	Alternate: Carola DE BEAUFORT
• John Joseph BORG (Malta)	Alternate: Helen VELLA

---

<sup>1</sup> Replaced Assena STOIMENOVA as of August 2019

<sup>2</sup> Katarina VUCIC resigned as of April 2019

<sup>3</sup> Nominated as of June 2019

<sup>4</sup> Replaced Emilia MAVROKORDATOU as of May 2019, with a swap of role from alternate to member

<sup>5</sup> Replaced Loizos PANAYI as of May 2019, with a swap of role from member to alternate

<sup>6</sup> Replaced Tomas BORAN as of September 2019

<sup>7</sup> Replaced Joseph EMMERICH as of September 2019

<sup>8</sup> Replaced Agnes GYURASICS as of June 2019

<sup>9</sup> Swap of role from member to alternate as of June 2019

<sup>10</sup> Mario MELAZZINI resigned as of June 2019

<sup>11</sup> Nominated as of August 2019

<sup>12</sup> Replaced Juris POKROTNIEKS as of February 2019, with a swap of role from alternate to member

<sup>13</sup> Maris KODOLS replaced Natalja KARPOVA as of February 2019

<sup>14</sup> Maris KODOLS resigned as of November 2019

<sup>15</sup> Replaced Jacqueline GENOUX-HAMES as of June 2019

- Johann Lodewijk HILLEGE (Netherlands) Alternate: Paula Boudewina VAN HENNIK
- Bjorg BOLSTAD (Norway) <sup>16</sup> Alternate: Ingrid WANG <sup>17</sup>
- Ewa BALKOWIEC-ISKRA (Poland) Alternate: Marcin KOLAKOWSKI
- Bruno SEPODES (Portugal) (*Vice-Chair*) Alternate: Fatima VENTURA
- Simona BADOI (Romania) Alternate: Dana Gabriela MARIN
- Francisek DRAFI (Slovakia) Alternate: Eva MALIKOVA
- Rajko KENDA (Slovenia) Alternate: Nevenka TRSINAR BRODT
- Maria Concepcion PRIETO YERRO (Spain) Alternate: Jorge CAMERERO JIMENEZ
- Kristina DUNDER (Sweden) Alternate: Filip JOSEPHSON
- Nithyanandan NAGERCOIL (United Kingdom) <sup>18 19</sup> Alternate: Marie-Christine BIELSKY <sup>20</sup>

### ***Co-opted members***

- Christian GARTNER (Medical statistics (clinical-trial methodology / epidemiology)) <sup>21 22</sup>
- Blanka HIRSCHLEROVA (Quality (non-biologicals) and Pharmacokinetics)
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Koenraad NORGA (Pharmacology)
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

---

<sup>16</sup> Replaced Svein RUNE ANDERSEN as of February 2019, with a swap of role from alternate to member

<sup>17</sup> Replaced Bjorg BOLSTAD of February 2019

<sup>18</sup> Greg MARKEY resigned as of July 2019

<sup>19</sup> Nominated as of August 2019, with a swap of role from alternate to member

<sup>20</sup> Replaced Nithyanandan NAGERCOIL as of August 2019

<sup>21</sup> Robert James HEMMINGS resigned as of February 2019

<sup>22</sup> Nominated as of June 2019

## Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Sabine STRAUS

EMA contact: Anabela MARCAL

### Members

- Jan NEUHAUSER (Austria) Alternate: Sonja HRABCIK <sup>1</sup>
- Jean-Michel DOGNE (Belgium) Alternate: Laurence DE FAYS
- Maria POPOVA-KIRADJIEVA (Bulgaria) Alternate: Yuliyana EFTIMOV
- Nikica MIROSEVIC SKVRCE (Croatia) Alternate: Zeljana MARGAN KOLETIC
- Helena PANAYIOTOPOULOU (Cyprus) <sup>2</sup> Alternate: Panagiotis PSARAS <sup>3</sup>
- Eva JIRSOVA (Czech Republic) Alternate: Jana LUKACISINOVA
- Anette STARK (Denmark) <sup>4</sup> Alternate: Hans Christian SIERSTED <sup>5 6</sup>
- Maia UUSKULA (Estonia) Alternate: Katrin KIISK
- Kirsti VILLIKKA (Finland) Alternate: Kimmo JAAKKOLA
- Ghania CHAMOUNI (France) Alternate: Adrien INOUBLI
- Martin HUBER (Germany) (*Vice-Chair*) Alternate: Brigitte KELLER-STANISLAWSKI
- Agni KAPOU (Greece) Alternate: Sofia TRANTZA
- Julia PALLOS (Hungary) Alternate: Melinda PALFI
- Gudrun STEFANSDOTTIR (Iceland) Alternate: Gudrun Kristin STEINGRIMSDOTTIR
- Rhea FITZGERALD (Ireland) Alternate: Ronan GRIMES
- Amelia CUPELLI (Italy) Alternate: Iliana BALDELLI <sup>7</sup>
- Zane NEIKENA (Latvia) Alternate: Zane STADE
- Rugile PILVINIENE (Lithuania) <sup>8</sup> Alternate: Ruta KERPAUSKIENE
- Marcel BRUCH (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

---

<sup>1</sup> Replaced Daniela PHILADELPHY as of April 2019

<sup>2</sup> Replaced Andrei ANDREOU as of May 2019

<sup>3</sup> Replaced Ioannis KKOLOS as of May 2019

<sup>4</sup> Replaced Doris STENVER as of February 2019, with a swap of role from alternate to member

<sup>5</sup> Anette STARK swapped roles from alternate to member as from February 2019

<sup>6</sup> Nominated as of May 2019

<sup>7</sup> Nominated as of June 2019

<sup>8</sup> Replaced Jolanta GULBINOVIC as of January 2019

- Ana Sofia DINIZ MARTINS (Portugal) Alternate: Marcia SILVA
- Roxana STROE (Romania) Alternate: Alexandra-Maria SPURNI <sup>9</sup>
- Michal RADIK (Slovakia) Alternate: Tatiana MAGALOVA
- Gabriela JAZBEC (Slovenia) Alternate: Jasmina KLOPCIC
- Eva SEGOVIA (Spain) Alternate: Maria del PINAR RAYON
- Ulla WANDEL LIMINGA (Sweden) Alternate: Annika FOLIN
- Julie WILLIAMS (United Kingdom) Alternate: Patrick BATTY

### ***Independent scientific experts nominated by the European Commission***

- Birgitta GRUNDMARK
- Daniel MORALES
- Hedvig NORDENG
- Antoine PARIENTE
- Livia PULJAK
- Stefan WEILER

### ***Members representing healthcare professionals nominated by the European Commission***

- Raymond ANDERSON Alternate: Roberto FRONTINI <sup>10 11 12</sup>

### ***Members representing patients' organisations nominated by the European Commission***

- Cathalijne VAN DOORNE <sup>13</sup> Alternate: Virginie HIVERT <sup>14</sup>

---

<sup>9</sup> Replaced Andreia RULEA as of January 2019

<sup>10</sup> Ylva BOTTIGER replaced Kirsten MYHR as of March 2019

<sup>11</sup> Ylva BOTTIGER resigned as of April 2019

<sup>12</sup> Nominated as of June 2019

<sup>13</sup> Replaced Marco GRECO as of March 2019

<sup>14</sup> Replaced Albert VAN DER ZEIJDEN as of March 2019

## Annex 4 – Members of the Committee for Medicinal Products for Veterinary Use

Chair: David MURPHY (vice-chair: G. J. SCHEFFERLIE)

EMA contact: Isaura DUARTE

### **Members and alternates**

- Petra FALB (Austria) Alternate: Ines LIDNER
- Bruno URBAIN (Belgium) Alternate: Frédéric KLEIN
- Emil Iliev KOZHUHAROV (Bulgaria) Alternate: Svetoslav BRANCHEV
- Frane BOŽIĆ (Croatia) Alternate: Svjetlana TERZIĆ
- Member: *awaiting nomination* Alternate: Leona NEPEJCHALOVÁ
- Alia MICHAELIDOU-PATSIA (Cyprus) Alternate: *awaiting nomination*
- Niels Christian KYVSGAARD (Denmark)<sup>1</sup> Alternate: Merete BLIXENKRONE-MØLLER
- Toomas TIIRATS (Estonia) Alternate: *awaiting nomination*
- Tita-Maria MUHONEN (Finland) Alternate: Katariina KIVILAHTI-MANTYLA
- Jean-Claude ROUBY (France) Alternate: Sylvie LOUET
- Gesine HAHN (Germany) Alternate: Esther WERNER
- Angeliki TSIGOURI (Greece)<sup>2</sup> Alternate: Spyridon FARLOPOULOS<sup>3</sup>
- Gabor KULCSÁR (Hungary) Alternate: Melinda NEMES-TERENYI<sup>4</sup>
- J. Gabriel BEECHINOR (Ireland) Alternate: Paul MCNEILL<sup>5</sup>
- Paolo PASQUALI (Italy) Alternate: Antonio BATTISTI
- Zanda AUCE (Latvia) Alternate: Renate MAKOVSKA
- Snieguolė T. DZEKČIORIENĖ<sup>6</sup> (Lithuania) Alternate: Nijolė STANKEVIČIENĖ<sup>7</sup>
- Marc SCHMIT (Luxembourg) Alternate: *awaiting nomination*<sup>8</sup>
- Stephen SPITERI (Malta) Alternate: *awaiting nomination*
- Peter HEKMAN (Netherlands) Alternate: Jacqueline POOT
- Anna WACHNIK-ŚWIĘCICKA (Poland) Alternate: Ewa AUGUSTYNOWICZ
- João Pedro DUARTE DA SILVA (Portugal)<sup>9</sup> Alternate: Cristina GONÇALVES SANTOS<sup>10</sup>

---

<sup>1</sup> Replaced Ellen-Margrethe Vestergaard as of April meeting

<sup>2</sup> Replaced Ioannis MALEMIS as of July meeting

<sup>3</sup> Replaced Angeliki TSIGOURI as of July meeting

<sup>4</sup> Replaced Tibor SOÓS as of June meeting

<sup>5</sup> Replaced Mary O'Grady as of November meeting

<sup>6</sup> Replaced Petras MACIULSKIS as of February meeting

<sup>7</sup> Mandate began on 6 November

<sup>8</sup> Marcel BRUCH mandate expired on 31 August

<sup>9</sup> Replaced Maria AZEVEDO MENDES as of January meeting

<sup>10</sup> Nominated as of January meeting



- Lollita TABAN (Romania) Alternate: Gabriela TUCHILA<sup>11</sup>
- Judita HEDEROVÁ (Slovakia) Alternate: Eva CHOBOTOVÁ
- Katarina ŠTRAUS (Slovenia) Alternate: Maja TURK
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTRÖM (Sweden) Alternate: Eva LANDER PERSSON
- Miguel ESCRIBANO<sup>12</sup> (United Kingdom) Alternate: Rory COONEY

### **EEA members**

- Member: *awaiting nomination* Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) Alternate: Tonje HØY

### **Co-opted members**

#### **Co-opted member**

- Keith BAPTISTE
- Rory BREATHNACH
- G. Johan SCHEFFERLIE
- Mary O'GRADY<sup>13</sup>
- Ricardo CARAPETO GARCÍA<sup>14</sup>

#### **Expertise**

- Antimicrobials
- General clinical veterinary practice
- MRLs/residues
- Quality pharmaceuticals
- Environmental risk assessment

---

<sup>11</sup> Replaced Simona STURZU as of January meeting

<sup>12</sup> Replaced Helen JUKES as of November meeting

<sup>13</sup> Elected on November meeting, replaced Wilhelm SCHLUMBOHM

<sup>14</sup> Elected on February meeting, replaced Jason WEEKS

## Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA  
EMA contact: Anabela MARCAL

### **Members**

- Brigitte BLOECHL-DAUM (Austria)
- Tim LEEST (Belgium)
- Lyubina Racheva TODOROVA (Bulgaria)
- Dinko VITEZIC (Croatia)
- Nectaroula COOPER (Cyprus) <sup>1</sup>
- Lenka KOVAROVA (Czech Republic) <sup>2</sup>
- Elisabeth PENNINGA (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Annie LORENCE (France)
- Frauke NAUMANN-WINTER (Germany)
- Nikolaos SYPSAS (Greece)
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy) (*Vice-Chair*)
- Irena ROGOVSKA (Latvia)
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway) <sup>3</sup>
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)
- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)
- Martin MOZINA (Slovenia)
- Gloria Maria PALOMO CARRASCO (Spain) <sup>4</sup>
- Darius MATUSEVICIUS (Sweden)
- Daniel O'CONNOR (United Kingdom)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Bruno SEPODES

### **Members representing patients' organisations nominated by the European Commission**

- Marie Pauline EVERS
- Julian ISLA
- Angelo Loris BRUNETTA

---

<sup>1</sup> Replaced Elena KAISIS as of February 2019

<sup>2</sup> Replaced Katerina KOPECKOVA as of January 2019

<sup>3</sup> Replaced Ingrid WANG as of February 2019

<sup>4</sup> Replaced Fernando MENDEZ HERMIDA as of September 2019

## Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: *Awaiting election*<sup>1</sup>

EMA contact: Anabela MARCAL

### Members

- |   |  |
|---|--|
| • Reinhard LANGER (Austria)                           | Alternate: Astrid OBMANN                           |
| • Patricia BODART (Belgium) <sup>2</sup>              | Alternate: <i>Awaiting nomination</i>              |
| • Iliana IONKOVA (Bulgaria)                           | Alternate: Dafna MARINKEVA <sup>3</sup>            |
| • Ivan KOSALEC (Croatia)                              | Alternate: Darko TRUMBETIC                         |
| • Maria STAVROU (Cyprus)                              | Alternate: Elli LOIZIDOU                           |
| • Marie HEROUTOVA (Czech Republic)                    | Alternate: Marketa PRIHODOVA                       |
| • Steffen BAGER (Denmark)                             | Alternate: Karoline Holm FELDING <sup>4</sup>      |
| • <i>Awaiting nomination</i> (Estonia)                | Alternate: <i>Awaiting nomination</i>              |
| • Eeva Sofia LEINONEN (Finland)                       | Alternate: Sari KOSKI                              |
| • An LE (France)                                      | Alternate: <i>Awaiting nomination</i>              |
| • Jacqueline WIESNER (Germany)                        | Alternate: Susanne FLEMISCH <sup>5</sup>           |
| • Ioanna CHINOI (Greece)                              | Alternate: Zoe KARAMPOURMPOUNI                     |
| • Zsuzsanna BIRO-SANDOR (Hungary)                     | Alternate: Rita NEMETH                             |
| • <i>Awaiting nomination</i> (Iceland)                | Alternate: <i>Awaiting nomination</i>              |
| • Sheena KENNEDY (Ireland) <sup>6</sup>               | Alternate: <i>Awaiting nomination</i> <sup>7</sup> |
| • Alessandro ASSISI (Italy)                           | Alternate: Anna Maria SERRILLI                     |
| • Evita SKUKAUSKA (Latvia)                            | Alternate: Baiba JANSONE                           |
| • Rugile PILVINIENE (Lithuania)                       | Alternate: Audronis LUKOSIUS                       |
| • Marcel BRUCH (Luxembourg)                           | Alternate: Clemence VARRET <sup>8 9</sup>          |
| • Everaldo ATTARD (Malta)                             | Alternate: Matthew CAMILLERI <sup>10</sup>         |
| • Emiel VAN GALEN (Netherlands) ( <i>Vice-chair</i> ) | Alternate: Burt H. KROES                           |
| • Steinar MADSEN (Norway)                             | Alternate: Gro FOSSUM                              |

---

<sup>1</sup> Marisa DELBO's mandate as Chair ended as of November 2019

<sup>2</sup> Replaced Heidi NEEF as of May 2019

<sup>3</sup> Nominated as of January 2019

<sup>4</sup> Replaced Nina DURR as of September 2019

<sup>5</sup> Replaced Birgit MERZ as of December 2019

<sup>6</sup> Nominated as of September 2019

<sup>7</sup> Una MOCKLER resigned as of July 2019

<sup>8</sup> Jacqueline GENOUX-HAMES' mandate ended as of June 2019

<sup>9</sup> Nominated as of August 2019

<sup>10</sup> Replaced Andre MANGANI as of October 2019

- Wojciech DYMOWSKI (Poland) Alternate: Katarzyna TOMASZEWSKA
- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Carmen PURDEL (Romania) <sup>11</sup> Alternate: Ligia Elena DUTU
- Miroslava PETRIKOVA (Slovakia) Alternate: Milan NAGY
- Barbara RAZINGER (Slovenia) <sup>12</sup> Alternate: *Awaiting nomination* <sup>13</sup>
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: Cristina MARTINEZ GARCIA
- Karin Erika SVEDLUND (Sweden) Alternate: Malin Kyllikki HOBRO SODERBERG
- Linda ANDERSON (United Kingdom) Alternate: Elizabeth GRIFFITHS

### ***Co-opted members***

- Ewa BALKOWIEC ISKRA (Clinical pharmacology)
- Heidi FOTH (Toxicology)
- Silvia GIROTTO (Paediatric medicine)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Maria Helena PINTO FERREIRA (General and family medicine)

### ***Observers***

- Ulrich ROSE (EDQM)
- Melanie BALD (EDQM)

---

<sup>11</sup> Replaced Raluca IAVORSZKY as of February 2019

<sup>12</sup> Replaced Samo KREFT as of June 2019

<sup>13</sup> Barbara RAZINGER became member as of June 2019

## Annex 7 – Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ

EMA contact: Patrick CELIS

### Members

#### Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany) Alternate: Egbert FLORY
- Romaldas MACIULAITIS (Lithuania) Alternate: Vitalis BRIEDIS
- John Joseph BORG (Malta) Alternate: Anthony SAMUEL
- Bruno SEPODES (Portugal) Alternate: Margarida MENEZES-FERREIRA
- Sol RUIZ (Spain) Alternate: Marcos TIMON

#### Members nominated by Member States

- Ilona G. REISCHL (Austria) (*Vice-Chair*) Alternate: Corina SPREITZER
- Claire BEUNEU (Belgium) Alternate: Belaid SEKKALI
- Rozalina KULAKSAZOVA (Bulgaria) Alternate: Evelina SHUMKOVA
- Mirna GOLEMOVIC (Croatia) Alternate: Petra SOKOL <sup>1 2</sup>
- Rafaella PONTOU (Cyprus) <sup>3</sup> Alternate: Isavella KYRIAKIDOU <sup>4</sup>
- Ivana HAUNEROVA (Czech Republic) Alternate: Ondrej PALAN <sup>5</sup>
- Anne PASTOFT (Denmark) Alternate: Nanna Aaby KRUSE
- Toivo MAIMETS (Estonia) Alternate: Pille SAALIK
- Heli SUILA (Finland) Alternate: Olli TENHUNEN
- Violaine CLOSSON CARELLA (France) Alternate: Nathalie MORGENSZTEJN <sup>6</sup>
- Asterios TSIFTSOGLU (Greece) Alternate: Angeliki ROBOTI
- Katalin LENGYEL (Hungary) Alternate: Balazs SARKADI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland) Alternate: Niamh CURRAN
- Paolo GASPARINI (Italy) Alternate: Giulio POMPILIO
- Una RIEKSTINA (Latvia) Alternate: Liga SAULITE
- Guy BERCHEM (Luxembourg) Alternate: Anne-Cécile VUILEMIN

---

<sup>1</sup> Nenad MEDIC's mandate ended as of February 2019

<sup>2</sup> Nominated as of April 2019

<sup>3</sup> Replaced Marina IERIDI as of May 2019

<sup>4</sup> Replaced Maria VASSILIOU as of May 2019

<sup>5</sup> Replaced Tomas BORAN as of January 2019

<sup>6</sup> Nominated as of June 2019

- Carla HERBERTS (Netherlands) <sup>7</sup> Alternate: Johannes H. OVELGONNE <sup>8</sup>
- Rune KJEKEN (Norway) <sup>9</sup> Alternate: Maja SOMMERFELT GRØNVOLD <sup>10</sup>
- Dariusz SLADOWSKI (Poland) Alternate: Anna CIESLIK
- Alina MUSETESCU (Romania) <sup>11</sup> Alternate: Gianina-Nicoleta ANDREI
- Lukas SLOVAK (Slovakia) Alternate: *Awaiting nomination*
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Nevenka TRSINAR BRODT
- Lisbeth BARKHOLT (Sweden) Alternate: Bjorn CARLSSON
- John JOHNSTON (United Kingdom) <sup>12</sup> Alternate: Louise BISSET <sup>13 14</sup>

### **Members representing clinicians nominated by the European Commission**

- Bernd GANSBACHER Alternate: *Awaiting nomination* <sup>15 16</sup>
- Alessandro AIUTI <sup>17</sup> Alternate: Alessandra RENIERI <sup>18</sup>

### **Members representing patients' organisations nominated by the European Commission**

- Kerstin SOLLERBRANT <sup>19</sup> Alternate: Lydie MEHEUS <sup>20</sup>
- Kieran BREEN Alternate: Roland POCHE <sup>21</sup>

### **Observers**

- Karl-Heinz BUCHHEIT (EDQM) Alternate: Catherine MILNE (EDQM)

---

<sup>7</sup> Replaced Johannes H. OVELGONNE as of April 2019, with a swap of role from alternate to member

<sup>8</sup> Replaced Carla HERBERTS as of April 2019, with a swap of role from member to alternate

<sup>9</sup> Replaced Helga HAUGUM OLSEN as of January 2019

<sup>10</sup> Replaced Rune KJEKEN as of January 2019

<sup>11</sup> Replaced Simona BADOI as of December 2019

<sup>12</sup> Replaced Christiane NIEDERLAENDER as of July 2019

<sup>13</sup> John JOHNSTON replaced James MCBLAINE as of January 2019

<sup>14</sup> Replaced John JOHNSTON as of July 2019

<sup>15</sup> Birgitte Klindt POULSEN replaced Willem FIBBE as of July 2019

<sup>16</sup> Birgitte Klindt POULSEN resigned as of September 2019

<sup>17</sup> Replaced Marc TURNER as of July 2019

<sup>18</sup> Replaced Francisco BLANCO as of July 2019

<sup>19</sup> Replaced Mariette DRIESSENS as of July 2019

<sup>20</sup> Replaced Erik BRIERS as of July 2019

<sup>21</sup> Replaced Michele LIPUCCI DI PAOLA as of July 2019

## Annex 8 – Members of the Paediatric Committee

Chair: Koenraad NORGA <sup>1</sup>

EMA contact: Anabela MARCAL

### Members

- Karl-Heinz HUEMER (Austria) Alternate: Johanna WERNSPERGER
- *Awaiting nomination* (Belgium) <sup>2</sup> Alternate: Karen VAN MALDEREN
- Dimitar ROUSSINOV (Bulgaria) Alternate: Vessela BOUDINOVA
- Milivoj NOVAK (Croatia) <sup>3 4</sup> Alternate: Arnes RESIC <sup>5 6</sup>
- Georgios SAVVA (Cyprus) Alternate: Eirini PERIKLEOUS
- Tereza BAZANTOVA (Czech Republic) <sup>7</sup> Alternate: Petra DOMINIKOVA <sup>8</sup>
- Kirstine Moll HARBOE (Denmark) Alternate: *Awaiting nomination* <sup>9</sup>
- Irja LUTSAR (Estonia) Alternate: Jana LASS
- Ann Marie TOTTERMAN (Finland) Alternate: Pia ANNUNEN
- Sylvie BENCHETRIT (France) Alternate: Dominique PLOIN
- Sabine SCHERER (Germany) (*Vice-Chair*) <sup>10</sup> Alternate: Yuansheng SUN
- Eleni KATSOMITI (Greece) Alternate: Anastasia MOUNTAKI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Brian AYLWARD (Ireland) Alternate: *Awaiting nomination*
- Sara GALLUZZO (Italy) Alternate: *Awaiting nomination* <sup>11</sup>
- Dina APELE-FREIMANE (Latvia) Alternate: Kristine SUPE
- Sigita BUROKIENE (Lithuania) Alternate: *Awaiting nomination* <sup>12</sup>
- John Joseph BORG (Malta) Alternate: Herbert LENICKER
- Roel BOLT (Netherlands) <sup>13</sup> Alternate: Maaïke VAN DARTEL <sup>14</sup>
- Siri WANG (Norway) Alternate: Anette Solli KARLSEN
- Marek MIGDAL (Poland) Alternate: *Awaiting nomination*

---

<sup>1</sup> Elected as Chair as of September 2019, replacing Dirk MENTZER

<sup>2</sup> Koenraad NORGA elected as Chair as of September 2019

<sup>3</sup> Adriana ANDRIC's mandate ended as of January 2019

<sup>4</sup> Nominated as of April 2019

<sup>5</sup> Suzana MIMICA MATANOVIC's mandate ended as of January 2019

<sup>6</sup> Nominated as of April 2019

<sup>7</sup> Replaced Jaroslav STERBA as of January 2019

<sup>8</sup> Replaced Peter SZITANYI as of January 2019

<sup>9</sup> Mona Ring GATKE resigned as of January 2019

<sup>10</sup> Elected as Vice-Chair as of October 2019

<sup>11</sup> Alessandro JENKNER's mandate ended as of November 2019

<sup>12</sup> Goda VAITKEVICIENE resigned as of June 2019

<sup>13</sup> Replaced Maaïke VAN DARTEL as of July 2019

<sup>14</sup> Maaïke VAN DARTEL became alternate as of July 2019

- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) Alternate: Peter SZITANYI <sup>15</sup>
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination* <sup>16</sup>
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Ninna GULLBERG (Sweden) Alternate: Eva AGURELL
- Angeliki SIAPKARA (United Kingdom) Alternate: Martina RIEGL

### ***Members nominated from within the CHMP***

- Agnes GYURASICS (Hungary) Alternate: Melinda SOBOR <sup>17</sup>
- Carola DE BEAUFORT (Luxembourg) Alternate: Martine TRAUFFLER <sup>18</sup>
- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

### ***Members representing healthcare professionals nominated by the European Commission***

- Francesca ROCCHI Alternate: Catherine CORNU
- Fernando CABANAS Alternate: Jorrit GERRITSEN
- Johannes TAMINIAU Alternate: Doina PLESCA

### ***Members representing patients' organisations nominated by the European Commission***

- Günter Karl-Heinz AUERSWALD Alternate: Paola BAIARDI
- Michal ODERMARSKY Alternate: Milena STEVANOVIC
- Dimitrios ATHANASIOU Alternate: Viviana GIANNUZZI

---

<sup>15</sup> Nominated as of February 2019

<sup>16</sup> Janez JAZBEC resigned as of February 2019

<sup>17</sup> Nominated as of June 2019

<sup>18</sup> Replaced Jacqueline GENOUX-HAMES as of June 2019



## Annex 9 – Working parties and working groups

### Committee for Medicinal Products for Human Use (CHMP)

#### CHMP standing working parties

	Chair	EMA contact
Biologics Working Party	Sol RUIZ	Veronika JEKERLE
Quality Working Party	Keith PUGH	Simona GOVER/Piotr KRAUZE
Safety Working Party	Jan-Willem VAN DER LAAN	Milton BONELLI
Scientific Advice Working Party	Anja SCHIEL	Spiros VAMVAKAS

#### CHMP temporary working parties

	Chair	EMA contact
Biosimilar Medicinal Products Working Party	Elena WOLFF-HOLZ	Silvy DA ROCHA DIAS/Liese BARBIER/Malgorzata ZIENOWICZ
Biostatistics Working Party	Anja SCHIEL	Frank PETAVY
Blood Products Working Party	Jacqueline KERR	Caroline VOLTZ
Cardiovascular Working Party	Kristina DUNDER	Anna BACZYNSKA
Central Nervous System Working Party	Karl BROICH	Marta KOLLB-SIELECKA
Infectious Diseases Working Party	Maria Jesús FERNÁNDES CORTIZO	Radu BOTGROS
Modelling and Simulation Working Party	Kristin KARLSSON <sup>1</sup>	Efthymios MANOLIS
Oncology Working Party	Pierre DEMOLIS/Sinan B. SARAC	Irene PAPADOULI
Pharmacogenomics Working Party	Krishna PRASAD/Marcus PAULMICHL	Falk EHMANN
Pharmacokinetics Working Party	Jan WELINK/Henrike POTTHAST	Kevin BLAKE/Anita ANDERSSON
Rheumatology/Immunology Working Party	Jan MUELLER-BERGHAUS	Margot MARTIN
Vaccines Working Party	Mair POWELL	Manuela MURA

<sup>1</sup> Elected in June 2018, replaced Ine Skottheim RUSTEN

## Drafting groups

	Chair	EMA contact
Gastroenterology Drafting Group	Mark AINSWORTH	Joachim MUSAUS
Radiopharmaceuticals Drafting Group	Anabel CORTES BLANCO	Silvy DA ROCHA DIAS/Daniel BECKER
Respiratory Drafting Group	Karolina TORNEKE	Catherine DRAI
Excipients Drafting Group	Dominique MASSET	Florence BORRELLY- KONYAKHIN

## CHMP scientific advisory groups

	Chair	EMA contact
Scientific Advisory Group on Cardiovascular Issues	N/A	Heidi JANSSEN
Scientific Advisory Group on Anti-infectives	N/A	Eric PELFRENE
Scientific Advisory Group on Diabetes/Endocrinology	N/A	Eberhard BLIND
Scientific Advisory Group on HIV / Viral Diseases	Daniel VITTECOQ (Vice-Chair)	Sabrina SPINOSA
Scientific Advisory Group on Neurology	Serge BAKCHINE	Pavel BALABANOV
Scientific Advisory Group on Psychiatry	N/A	Florence BUTLEN
Scientific Advisory Group on Vaccines	Andrew POLLARD	Manuela MURA

## Other CHMP-associated groups

	Chair	EMA contact
(Invented) Name Review Group	Alexios SKARLATOS	Ana ZANOLETTY PEREZ
Working Group on Quality Review of Documents	Alexios SKARLATOS	Monica BUCH
Geriatric Expert Group	Katarina VUCIC	Francesca CERRETA
Summary of Product Characteristics Advisory Group	Laurent BRASSART	Laurent BRASSART
Guidelines Consistency Group	Aranzazu SANCHO-LOPEZ <sup>2</sup>	Andrea TAFT
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Esther MARTINEZ
Good Clinical Practice Inspectors Working Group	Ana RODRIGUEZ	Ana RODRIGUEZ

<sup>2</sup> Elected in July 2018, replaced Barbara VAN ZWIETEN BOOT

	Chair	EMA contact
Good Laboratory Practice Inspectors Working Group	Maria Antonietta ANTONELLI	Maria Antonietta ANTONELLI
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Monika MAYR

## **Committee for Medicinal Products for Veterinary Use (CVMP)**

### **CVMP working parties**

	Chair	EMA contact
CVMP Antimicrobial Working Party (AWP)	Christine SCHWARZ <sup>3</sup>	Zoltan KUNSAGI
CVMP Efficacy Working Party (EWP-V)	Cristina MUÑOZ MADERO	Barbara CYRUS/Valentin NICORESCU
CVMP Environmental Risk Assessment (ERAWP)	Ricardo CARAPETO GARCÍA <sup>4</sup>	Julia FABREGA
CVMP Immunologicals Working Party (IWP)	Esther WERNER	Noemi GARCIA DEL BLANCO
CVMP Pharmacovigilance Working Party (PhVWP-V)	Els DEWAELE	Raquel GOPAL/Jos OLAERTS
CVMP Safety Working Party (SWP-V)	Stefan SCHEID	Sebastian GIRAULT
Quality Working Party	Keith PUGH	Simona GOVER/Piotr KRAUZE
Scientific Advice Working Party (SAWP-V)	Frida HASSLUNG WIKSTRÖM <sup>5</sup>	Vladimir PUCOVSKY

### **Other CVMP-associated groups**

	Chair	EMA contact
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)	Jean-Claude ROUBY	Noemi GARCIA DEL BLANCO
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Esther MARTINEZ
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Monika MAYR

<sup>3</sup> From February 2019

<sup>4</sup> From February 2019

<sup>5</sup> Since May 2019

## **Pharmacovigilance Risk Assessment Committee (PRAC)**

	<b>Chair</b>	<b>EMA contact</b>
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Menno van der ELST <sup>6</sup> / Georgy GENOV	Georgy GENOV/Aniello SANTORO
Signal Management Review Technical (SMART) Working Group work stream 2 (methods)	Eugene van PUIJENBROEK, Jim SLATTERY	Jim SLATTERY/Gianmario CANDORE/Cosimo ZACCARIA
Granularity and Periodicity Advisory Group (GPAG)	Menno van der ELST	Margaux PHILIPPE <sup>7</sup>

## **Committee for Orphan Medicinal Products (COMP)**

### **COMP temporary working groups**

	<b>Chair</b>	<b>EMA contact</b>
Protocol assistance working group	n/a	Matthias HOFER
Non-clinical Working Group	n/a	Maria SHEEAN

## **Committee on Herbal Medicinal Products (HMPC)**

### **HMPC working parties**

	<b>Chair</b>	<b>EMA contact</b>
Working Party on European Union Monographs and European Union List	Ioanna CHINOI	Wieland PESCHEL

### **HMPC temporary drafting groups**

	<b>Chair</b>	<b>EMA contact</b>
Organisational Matters Drafting Group	Gert LAEKEMAN	Wieland PESCHEL
Quality Drafting Group	Linda ANDERSON	Wieland PESCHEL

### **Other HMPC-associated groups**

	<b>Chair</b>	<b>EMA contact</b>
Good Manufacturing Practice Inspection Services Group	Brendan CUDDY	Esther MARTINEZ

<sup>6</sup> Replaced Sabine STRAUS in September 2018.

<sup>7</sup> Replaced Robin RUEPP in September 2018

## **Committee for Advanced Therapies (CAT)**

### **CAT associated group**

	<b>Chair</b>	<b>EMA contact</b>
European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group	To be appointed	Patrick CELIS

## **Paediatric Committee (PDCO)**

### **PDCO working groups**

	<b>Chair</b>	<b>EMA contact</b>
Formulation Working Group	Brian AYLWARD	Giovanni LESA
Non-clinical Working Group	Jaqueline CARLEER	Janina KARRES

## **Human Scientific Committees' Working Parties**

	<b>Chair</b>	<b>EMA contact</b>
Patients' and Consumers' Working Party (PCWP)	Juan GARCIA BURGOS and Kaisa IMMONEN	Nathalie BERE
Healthcare Professionals' Working Party (HCPWP)	Juan GARCIA BURGOS and Ulrich JÄGER	Ivana SILVA

## **Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)**

### **Other CMDh-associated groups**

	<b>Chair</b>	<b>EMA contact</b>
Working Party on Pharmacovigilance Procedures Work Sharing	Maria Luisa CASINI	
Non-Prescription Medicinal Products Task Force	Martin HUBER	Silvy DA ROCHA DIAS

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

	<b>Chair</b>	<b>EMA contact</b>
Document Management Working Group	CMDv member from Member State giving EU Presidency	Ornela ADEMI/Janos KOVACS
Packaging and Labelling Working Group	Iveta OBROVSKA	Ornela ADEMI/Janos KOVACS

	Chair	EMA contact
Notice to Applicants Working Group	Paula KAJASTE	Ornela ADEMI/Janos KOVACS
Autogenous Vaccines Working Group	Mariette SALERY	Ornela ADEMI/Janos KOVACS
Borderline Products Working Group	Jose JONIS	Ornela ADEMI/Janos KOVACS
Legislation Working Group	Dries MINNE	Ornela ADEMI/Janos KOVACS
Working Group on Improvement of DCP/MRP	Mariette SALERY	Ornela ADEMI/Janos KOVACS
TOPRA Working Party	Paula KAJASTE	Ornela ADEMI/Janos KOVACS
Working Group on EU Network Training Centre	Laetitia LE LETTY	Ornela ADEMI/Janos KOVACS
CMDv Brexit Working Group	Laetitia LE LETTY	Ornela ADEMI/Janos KOVACS

### ***Joint working parties, working groups and advisory groups***

	Chair	EMA contact
Joint CHMP/CVMP Quality Working Party (QWP)	Keith PUGH	Brendan CUDDY/Simona GOVER/Piotr KRAUZE
Joint CMDh-CMDv-EMA-EDQM Active Substance Master File Working Group	Nienke RODENHUIS	Alberto GANAN JIMENEZ
Joint CHMP/CVMP Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products	Ellen-Margrethe VESTERGAARD	Michael EMPL
Inter-Committee Scientific Advisory Group on Oncology	Jonas BERGH (Vice-Chair)	Francesco PIGNATTI
Working Group on Quality Review of Documents		
Joint PRAC/PDCO working group		Roberto De LISA/Vanessa FRADIN-DA ROS/Geraldine PORTIER
Joint CMDh-CMDv Variation Regulation Working Party	Susanne WINTERSCHIED	Silvy DA ROCHA DIAS
EMA/CMDh Working Party on Paediatric Regulation	Sarah BRANCH	Silvy DA ROCHA DIAS
GCP Inspectors WG/CMDh Working Party	Jayne CROWE	Maria Antonietta ANTONELLI
Extrapolation working group	Gerard PONS	
CTS Working Group	Dino SOUMPASIS	

## **Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2019**

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
None			

### ***Biosimilar Medicinal Product Working Party***

Reference number	Document	Status	Date
None			

### ***Biostatistics Working Party***

Reference number	Document	Status	Date
EMA/CHMP/539146/2013	Guideline on investigation of subgroups in confirmatory clinical trials	Final	31 January 2019

### ***Blood Products Working Party***

Reference number	Document	Status	Date
None			

### ***Cardiovascular Working Party***

Reference number	Document	Status	Date
None			

### ***Committee for Advanced Therapies (CAT)***

Reference number	Document	Status	Date
None			

### ***Central Nervous System Working Party***

Reference number	Document	Status	Date
None			

### ***Excipients Drafting Group***

Reference number	Document	Status	Date
None			

### ***Gastroenterology Drafting Group***

Reference number	Document	Status	Date
None			

### ***Geriatric Expert Group***

Reference number	Document	Status	Date
None			



## ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/353369/2013	ICH guideline Q3D(R1) on elemental impurities	Adopted, step 5	28 March 2019
EMA/CHMP/ICH/544570/1998	ICH guideline E8(R1) on general considerations for clinical studies	Draft for public consultation, step 2b	25 April 2019
EMA/CHMP/ICH/173706/2019	ICH guideline E19 on optimisation of safety data collection	Draft for public consultation, step 2b	28 March 2019
EMA/CHMP/ICH/172948/2019	ICH guideline M10 on bioanalytical method validation	Draft for public consultation, step 2b	28 February 2019

## Infectious Diseases Working Party

Reference number	Document	Status	Date
None			

## Modelling and Simulation Working Party

Reference number	Document	Status	Date
None			

## Oncology Working Party

Reference number	Document	Status	Date
None			

## Pharmacogenomics Working Party

Reference number	Document	Status	Date
None			

## Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMA/CHMP/790333/2018	Cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 mg and 80 mg product-specific bioequivalence guidance	Final	19 September 2019
EMA/CHMP/802491/2018	Ezetimibe tablet 10 mg product-specific bioequivalence guidance	Final	19 September 2019
EMA/CHMP/291499/2018	Apixaban film-coated tablets 2.5 and 5 mg product-specific bioequivalence guidance	Final	25 July 2019
EMA/CHMP/257026/2018	Gefitinib film-coated tablet 250 mg product-specific bioequivalence guidance	Final	25 July 2019
EMA/CHMP/291571/2018	Octreotide acetate depot powder and solvent for suspension for injection 10 mg, 20 mg and 30 mg product-specific bioequivalence guidance	Final	31 January 2019

Reference number	Document	Status	Date
EMA/CHMP/790261/2018	Alectinib hard capsule 150 mg product-specific bioequivalence guidance	Final	19 September 2019
EMA/CHMP/802679/2018	Palbociclib hard capsule 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance	Final	19 September 2019
EMA/CHMP/35552/2019	Colchicine tablet 0.5 mg and 1 mg product-specific bioequivalence guidance	Final	19 September 2019
EMA/CHMP/154812/2016	Fingolimob capsules 0.25 and 0.5 mg product-specific bioequivalence guidance	Final	25 July 2019
EMA/CHMP/97470/2019	Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance	Draft for public consultation	26 April 2019

#### **Quality Working Party**

Reference number	Document	Status	Date
EMA/CHMP/QWP/BWP/25 9165/2019	Guideline on the quality requirements for drug-device combinations	Draft for public consultation	29 May 2019

#### **Radiopharmaceutical Drafting Group**

Reference number	Document	Status	Date
None			

#### **Respiratory Drafting Group**

Reference number	Document	Status	Date
None			

#### **Rheumatology/Immunology Working Party**

Reference number	Document	Status	Date
EMA/CHMP/774470/2018	Guideline on clinical investigation of medicinal products for the treatment of gout	Final	14 November 2019

#### **Safety Working Party**

Reference number	Document	Status	Date
None			

#### **Vaccines Working Party**

Reference number	Document	Status	Date
None			

## Annex 12 – CVMP opinions on medicinal products for veterinary use in 2019

### Positive opinions

<b>Product</b> <ul style="list-style-type: none"> <li>• Invented name</li> <li>• INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• Target species</li> <li>• Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• Validation</li> <li>• Opinion</li> <li>• Active time</li> <li>• Clock stop</li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>• Opinion received</li> <li>• Transmission to EC</li> <li>• Decision</li> <li>• Notification</li> <li>• Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>• Chanhold</li> <li>• selamectin</li> </ul>	<ul style="list-style-type: none"> <li>• Chanelle Pharmaceuticals Manufacturing Ltd.</li> </ul>	<ul style="list-style-type: none"> <li>• Cats and Dogs</li> <li>• To treat and prevent flea infestations in cats and dogs, by killing adult fleas, their larvae and their eggs on the animal, and in the litters of pregnant or nursing cats or dogs. It can also be used as part of a treatment for flea allergy dermatitis (skin inflammation); to prevent heartworm disease in cats and dogs; to treat ear mites in cats and dogs; to treat adult intestinal roundworms and intestinal hookworms in cats; to treat adult intestinal roundworms in dogs; to treat biting lice infestations in cats and dogs; to treat sarcoptic mange (scabies) in dogs.</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2017</li> <li>• 21/02/2019</li> <li>• 210</li> <li>• 309</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2019</li> <li>• 27/03/2019</li> <li>• 17/04/2019</li> <li>• 24/04/2019</li> <li>• C 180 24/05/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Felisecto Plus</li> <li>• Selamectin/sarolaner</li> </ul>	<ul style="list-style-type: none"> <li>• Zoetis Belgium SA</li> </ul>	<ul style="list-style-type: none"> <li>• Cats</li> <li>• For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.</li> </ul>	<ul style="list-style-type: none"> <li>• 17/12/2018</li> <li>• 21/02/2019</li> <li>• 59</li> <li>• 0</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2019</li> <li>• 26/03/2019</li> <li>• 26/04/2019</li> <li>• 30/04/2019</li> <li>• C 180 24/05/2019</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Forceris</li> <li>• Toltrazuril/iron (as gleptoferron)</li> </ul>	<ul style="list-style-type: none"> <li>• Ceva Santé Animale</li> </ul>	<ul style="list-style-type: none"> <li>• Piglets</li> <li>• For the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in piglets in farms with a confirmed history of coccidiosis caused by <i>Cystoisospora suis</i>.</li> </ul>	<ul style="list-style-type: none"> <li>• 09/08/2017</li> <li>• 21/02/2019</li> <li>• 210</li> <li>• 351</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2019</li> <li>• 27/03/2019</li> <li>• 23/04/2019</li> <li>• 25/04/2019</li> <li>• C 180 24/05/2019</li> </ul>
<ul style="list-style-type: none"> <li>• ReproCyc ParvoFLEX</li> <li>• Porcine parvovirus vaccine (inactivated)</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Pigs</li> <li>• For active immunisation of gilts and sows from the age of 5 months to protect progeny against transplacental infection caused by porcine parvovirus.</li> </ul>	<ul style="list-style-type: none"> <li>• 21/03/2018</li> <li>• 21/02/2019</li> <li>• 210</li> <li>• 127</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2019</li> <li>• 20/03/2019</li> <li>• 26/04/2019</li> <li>• 30/04/2019</li> <li>• C 180 24/05/2019</li> </ul>
<ul style="list-style-type: none"> <li>• HorStem</li> <li>• Equine umbilical cord mesenchymal stem cells</li> </ul>	<ul style="list-style-type: none"> <li>• EquiCord-Ymas S.L.</li> </ul>	<ul style="list-style-type: none"> <li>• Horses</li> <li>• Reduction of lameness associated with mild to moderate degenerative joint disease (osteoarthritis) in horses.</li> </ul>	<ul style="list-style-type: none"> <li>• 08/06/2016</li> <li>• 21/02/2019</li> <li>• 210</li> <li>• 645</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2019</li> <li>• 02/04/2019</li> <li>• 19/06/2019</li> <li>• 21/06/2019</li> <li>• C 252 26/07/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Afoxolaner Merial</li> <li>• Afoxolaner</li> </ul>	<ul style="list-style-type: none"> <li>• MERIAL</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• Treatment of flea and tick infestations in dogs. The product can be used as part of a treatment strategy for the control of flea allergy dermatitis; treatment of demodicosis); treatment of sarcoptic mange.</li> </ul>	<ul style="list-style-type: none"> <li>• 21/01/2019</li> <li>• 21/03/2019</li> <li>• 59</li> <li>• 0</li> </ul>	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 24/04/2019</li> <li>• 20/05/2019</li> <li>• 22/05/2019</li> <li>• C 218 28/06/2019</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Baycox Iron</li> <li>• Toltrazuril/iron(III) ion</li> </ul>	<ul style="list-style-type: none"> <li>• Bayer Animal Health GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Piglets</li> <li>• For the concurrent prevention of clinical signs of coccidiosis (such as diarrhoea) in neonatal piglets on farms with a confirmed history of coccidiosis caused by <i>Cystoisospora suis</i>, and prevention of iron deficiency anaemia.</li> </ul>	<ul style="list-style-type: none"> <li>• 18/12/2017</li> <li>• 21/03/2019</li> <li>• 210</li> <li>• 246</li> </ul>	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 17/04/2019</li> <li>• 20/05/2019</li> <li>• 22/05/2019</li> <li>• C 218 28/06/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Evicto</li> <li>• Selamectin</li> </ul>	<ul style="list-style-type: none"> <li>• Virbac S.A.</li> </ul>	<ul style="list-style-type: none"> <li>• Cats and Dogs</li> <li>• Treatment of biting lice infestations (<i>Trichodectes canis</i>); treatment of sarcoptic mange (caused by <i>Sarcoptes scabiei</i>); treatment of adult intestinal roundworms (<i>Toxocara canis</i>).</li> </ul>	<ul style="list-style-type: none"> <li>• 09/08/2018</li> <li>• 22/05/2019</li> <li>• 209</li> <li>• 78</li> </ul>	<ul style="list-style-type: none"> <li>• 22/05/2019</li> <li>• 25/06/2019</li> <li>• 19/07/2019</li> <li>• 23/07/2019</li> <li>• C 334 04/10/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Nasym</li> <li>• Bovine respiratory syncytial virus vaccine (live)</li> </ul>	<ul style="list-style-type: none"> <li>• Laboratorios Hipra S.A.</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle</li> <li>• Active immunisation of cattle to reduce virus shedding and respiratory, clinical signs caused by bovine respiratory syncytial virus infection.</li> </ul>	<ul style="list-style-type: none"> <li>• 21/02/2018</li> <li>• 22/05/2019</li> <li>• 209</li> <li>• 246</li> </ul>	<ul style="list-style-type: none"> <li>• 22/05/2019</li> <li>• 01/07/2019</li> <li>• 29/07/2019</li> <li>• 31/07/2019</li> <li>• C 334 04/10/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Simparica Trio</li> <li>• Sarolaner, moxidectin and pyrantel embonate</li> </ul>	<ul style="list-style-type: none"> <li>• Zoetis Belgium SA</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• For dogs with, or at risk from, mixed external and internal parasitic infestations.</li> </ul>	<ul style="list-style-type: none"> <li>• 08/08/2018</li> <li>• 18/07/2019</li> <li>• 209</li> <li>• 135</li> </ul>	<ul style="list-style-type: none"> <li>• 18/07/2019</li> <li>• 14/08/2019</li> <li>• 17/09/2019</li> <li>• 19/09/2019</li> <li>• C 369 30/10/2019</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>Gumbohatch</li> <li>Avian infectious bursal disease vaccine (live)</li> </ul>	<ul style="list-style-type: none"> <li>Laboratorios Hipra S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Chickens</li> <li>For active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.</li> </ul>	<ul style="list-style-type: none"> <li>16/05/2018</li> <li>12/09/2019</li> <li>210</li> <li>274</li> </ul>	<ul style="list-style-type: none"> <li>12/09/2019</li> <li>08/10/2019</li> <li>12/11/2019</li> <li>14/11/2019</li> <li>C 435 27/12/2019</li> </ul>
<ul style="list-style-type: none"> <li>Nobivac Myxo-RHD Plus</li> <li>Myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>Rabbits</li> <li>For active immunisation of rabbits from 5 weeks of age onwards to reduce mortality and clinical signs of myxomatosis and rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV1) and RHD type 2 virus (RHDV2).</li> </ul>	<ul style="list-style-type: none"> <li>25/10/2018</li> <li>12/09/2019</li> <li>210</li> <li>113</li> </ul>	<ul style="list-style-type: none"> <li>12/09/2019</li> <li>10/10/2019</li> <li>19/11/2019</li> <li>21/11/2019</li> <li>C 435 27/12/2019</li> </ul>
<ul style="list-style-type: none"> <li>Mirataz</li> <li>Mirtazapine</li> </ul>	<ul style="list-style-type: none"> <li>Aniserve GmbH</li> </ul>	<ul style="list-style-type: none"> <li>Cats</li> <li>For bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions.</li> </ul>	<ul style="list-style-type: none"> <li>18/12/2017</li> <li>10/10/2019</li> <li>208</li> <li>451</li> </ul>	<ul style="list-style-type: none"> <li>10/10/2019</li> <li>06/11/2019</li> <li>10/12/2019</li> <li>12/12/2019</li> <li>C 33 31/01/2020</li> </ul>
<ul style="list-style-type: none"> <li>Neptra</li> <li>Florfenicol/terbinafine hydrochloride/mometasone furoate</li> </ul>	<ul style="list-style-type: none"> <li>Bayer Animal Health GmbH</li> </ul>	<ul style="list-style-type: none"> <li>Dogs</li> <li>For the treatment of canine otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of susceptible strains of bacteria sensitive to florfenicol (<i>Staphylococcus pseudintermedius</i>) and fungi sensitive to terbinafine (<i>Malassezia pachydermatis</i>).</li> </ul>	<ul style="list-style-type: none"> <li>08/08/2018</li> <li>10/10/2019</li> <li>210</li> <li>218</li> </ul>	<ul style="list-style-type: none"> <li>10/10/2019</li> <li>13/11/2019</li> <li>10/12/2019</li> <li>12/12/2019</li> <li>C 33 31/01/2020</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Stelfonta</li> <li>• Tigilanol tiglate</li> </ul>	<ul style="list-style-type: none"> <li>• QBiotech Netherlands B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• Treatment of non-resectable, non-metastatic cutaneous and subcutaneous mast cell tumours in dogs</li> </ul>	<ul style="list-style-type: none"> <li>• 24/10/2018</li> <li>• 07/11/2019</li> <li>• 210</li> <li>• 169</li> </ul>	<ul style="list-style-type: none"> <li>• 07/11/2019</li> <li>• 11/12/2019</li> <li>• 15/01/2020</li> <li>• Pending</li> <li>• pending</li> </ul>
<ul style="list-style-type: none"> <li>• Aservo EquiHaler</li> <li>• Ciclesonide</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Horses</li> <li>• For the alleviation of clinical signs of severe equine asthma</li> </ul>	<ul style="list-style-type: none"> <li>• 26/09/2018</li> <li>• 07/11/2019</li> <li>• 210</li> <li>• 197</li> </ul>	<ul style="list-style-type: none"> <li>• 07/11/2019</li> <li>• 04/12/2019</li> <li>• 28/01/2020</li> <li>• Pending</li> <li>• Pending</li> </ul>

### ***Negative opinions***

There were no negative opinions in 2019

## CVMP opinions in 2019 on establishment of MRLs

### Positive opinions

<b>Product</b> <ul style="list-style-type: none"><li>• Substance</li></ul>	<b>Target species</b>	<b>EMA/CVMP</b> <ul style="list-style-type: none"><li>• Validation</li><li>• Opinion</li><li>• Active time</li><li>• Ck stop</li></ul>	<b>European Commission</b> <ul style="list-style-type: none"><li>• Opinion received</li><li>• Regulation</li><li>• Official Journal</li></ul>
<ul style="list-style-type: none"><li>• Ciclesonide</li></ul>	<ul style="list-style-type: none"><li>• Horses</li></ul>	<ul style="list-style-type: none"><li>• 21/03/2018</li><li>• 21/02/2019</li><li>• 210</li><li>• 127</li></ul>	<ul style="list-style-type: none"><li>• 21/02/2019</li><li>• 2020/43</li><li>• L 15</li></ul>
<ul style="list-style-type: none"><li>• Bambermycin</li></ul>	<ul style="list-style-type: none"><li>• Rabbits</li></ul>	<ul style="list-style-type: none"><li>• 10/05/2017</li><li>• 16/04/2019</li><li>• 209</li><li>• 497</li></ul>	<ul style="list-style-type: none"><li>• 16/04/2019</li><li>• 2020/42</li><li>• L 15</li></ul>
<ul style="list-style-type: none"><li>• Dicyclanil</li></ul>	<ul style="list-style-type: none"><li>• Sheep</li></ul>	<ul style="list-style-type: none"><li>• 17/12/2018</li><li>• 10/10/2019</li><li>• 2017</li><li>• 89</li></ul>	<ul style="list-style-type: none"><li>• 10/10/2019</li><li>• Pending</li><li>• Pending</li></ul>

### Negative opinions

There were no negative opinions on establishment of MRLs in 2019.



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

<b>Product</b> <ul style="list-style-type: none"> <li>• Brandname</li> <li>• INN</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic Area</b> <ul style="list-style-type: none"> <li>• ATC Code</li> <li>• Summary of indication</li> </ul>	<b>EMA/CVMP opinion</b>	<b>European Commission decision date</b>
<ul style="list-style-type: none"> <li>• Bravecto Plus</li> <li>• fluralaner / moxidectin</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• QP54AB52</li> <li>• For cats with, or at risk from, mixed parasitic infestations by ticks or fleas and ear mites, gastrointestinal nematodes or heartworm. For the treatment of tick and flea infestations in cats providing immediate and persistent flea and tick killing activity for 12 weeks. For the treatment of infestations with ear mites. For the treatment of infections with intestinal roundworm (4th stage larvae, immature adults and adults of <i>Toxocara cati</i>) and hookworm (4th stage larvae, immature adults and adults of <i>Ancylostoma tubaeforme</i>). When administered repeatedly at a 12-week interval, the product continuously prevents heartworm disease caused by <i>Dirofilaria immitis</i>.</li> </ul>	<ul style="list-style-type: none"> <li>• 22/05/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 04/07/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Advocate</li> <li>• imidacloprid / moxidectin</li> </ul>	<ul style="list-style-type: none"> <li>• Bayer Animal Health GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• QP54AB52</li> <li>• For dogs, cats and ferrets suffering from, or at risk from, mixed parasitic infections.</li> </ul>	<ul style="list-style-type: none"> <li>• 20/06/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 29/07/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Broadline</li> <li>• fipronil / (S)-methoprene / eprinomectin / praziquantel</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• QP54AA54</li> <li>• For cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites.</li> </ul>	<ul style="list-style-type: none"> <li>• 18/07/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 29/08/2019</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>• Brandname</li> <li>• INN</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic Area</b> <ul style="list-style-type: none"> <li>• ATC Code</li> <li>• Summary of indication</li> </ul>	<b>EMA/CVMP opinion</b>	<b>European Commission decision date</b>
<ul style="list-style-type: none"> <li>• NexGard Spectra</li> <li>• afoxolaner / milbemycin oxime</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• QP54AB51</li> <li>• Treatment of flea and tick infestations when the concurrent prevention of heartworm disease (<i>Dirofilaria immitis</i> larvae), angiostrongylosis (reduction in level of immature adults (L5) and adults of <i>Angiostrongylus vasorum</i>) and/or treatment of gastrointestinal nematode infestations is indicated.</li> </ul>	<ul style="list-style-type: none"> <li>• 18/07/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 19/08/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Bravecto</li> <li>• fluralaner</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• QP53BE02</li> <li>• For the treatment of tick and flea infestations in dogs.</li> </ul>	<ul style="list-style-type: none"> <li>• 12/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 18/10/2019</li> </ul>
<ul style="list-style-type: none"> <li>• Bravecto Plus</li> <li>• fluralaner / moxidectin</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• QP54AB52</li> <li>• For cats with, or at risk from, mixed parasitic infestations by ticks or fleas and ear mites, gastrointestinal nematodes or heartworm. For the treatment of tick and flea infestations in cats providing immediate and persistent flea and tick killing activity for 12 weeks. For the treatment of infestations with ear mites. For the treatment of infections with intestinal roundworm (4th stage larvae, immature adults and adults of <i>Toxocara cati</i>) and hookworm (4th stage larvae, immature adults and adults of <i>Ancylostoma tubaeforme</i>). When administered repeatedly at a 12-week interval, the product continuously prevents heartworm disease caused by <i>Dirofilaria immitis</i>.</li> </ul>	<ul style="list-style-type: none"> <li>• 07/11/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 19/12/2019</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>• Brandname</li> <li>• INN</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic Area</b> <ul style="list-style-type: none"> <li>• ATC Code</li> <li>• Summary of indication</li> </ul>	<b>EMA/CVMP opinion</b>	<b>European Commission decision date</b>
<ul style="list-style-type: none"> <li>• Onsior</li> <li>• robenacoxib</li> </ul>	<ul style="list-style-type: none"> <li>• Elanco GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• QM01AH91</li> <li>• For the treatment of pain and inflammation associated with chronic osteoarthritis in dogs. Treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs and with soft tissue surgery in cats. For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in cats.</li> </ul>	<ul style="list-style-type: none"> <li>• 05/12/2019</li> </ul>	<ul style="list-style-type: none"> <li>• 20/01/2020</li> </ul>

## Annex 13 – Guidelines and concept papers adopted by CVMP in 2019

### CVMP Quality

Reference number	Document title	Status
<a href="#">Quality of medicines questions and answers: Part 1</a>	Use of peptone in the manufacture of active substance	Adopted March 2019

### CVMP novel therapies

Reference number	Document title	Status
<a href="#">EMA/CVMP/ADVENT/803494/2016 - Rev.1</a>	Revised Questions and Answers on allogeneic stem cell-based products for veterinary use: Specific questions on extraneous agents	Adopted June 2019
<a href="#">EMA/CVMP/ADVENT/751229/2016 - Rev.1</a>	Revised Questions and Answers on allogeneic stem cell-based products for veterinary use: specific questions on sterility	Adopted June 2019

### General

Reference number	Document title	Status
<a href="#">EMA/CVMP/VICH/517152/2013</a>	VICH GL57: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species	Adopted March 2019
<a href="#">EMA/CVMP/VICH/467/2003</a>	VICH GL36(R2) Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI	Adopted March 2019
<a href="#">EMA/CVMP/CHMP/682199/2017</a>	Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobial veterinary medicinal products	Adopted June 2019
<a href="#">Veterinary Post-authorisation webpage</a>	Update of the veterinary post-authorisation guidance on the EMA public website	Finalised June 2019

Reference number	Document title	Status
<a href="#">EMA/CVMP/461776/2017</a>	CVMP Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU	Adopted for consultation in October 2019  End of consultation 30 April 2020
<a href="#">EMA/CVMP/539861/2019</a>	Concept paper for the revision of scientific guidelines on limited market for veterinary medicinal products	Adopted for consultation November 2019  End of consultation 31 January 2020
<a href="#">EMA/CVMP/VICH/335918/2016</a>	VICH GL58 Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	Adopted December 2019
<a href="#">EMA/CVMP/CHMP/682198/2017</a>	Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Categorisation of antimicrobials	Adopted December 2019

## Annex 14 – COMP opinions on designation of orphan medicinal products in 2019

### Positive COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> <li>• Submission</li> <li>• Start date</li> <li>• Opinion</li> <li>• Active time</li> </ul>	EC <ul style="list-style-type: none"> <li>• Opinion received</li> <li>• Date of decision</li> </ul>
Setmelanotide	TMC Pharma (EU) Limited - Ireland	Treatment of Alström syndrome	<ul style="list-style-type: none"> <li>• 25/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 09/12/2019</li> <li>• 09/01/2020</li> </ul>
Adeno-associated virus serotype 9 vector containing human N-acetylgalactosamine-6-sulfate sulfatase gene	Esteve Pharmaceuticals S.A. - Spain	Treatment of mucopolysaccharidosis type IVA (Morquio A Syndrome)	<ul style="list-style-type: none"> <li>• 27/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Dimethyl fumarate	Consortio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of adrenoleukodystrophy	<ul style="list-style-type: none"> <li>• 27/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> </ul>
Nicarpidine	Bit Pharma GmbH - Austria	Treatment of non-traumatic subarachnoid haemorrhage	<ul style="list-style-type: none"> <li>• 23/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 09/12/2019</li> <li>• 09/01/2020</li> </ul>
Tripotassium citrate monohydrate and potassium hydrogen carbonate	Advicenne S.A. - France	Treatment of cystinuria	<ul style="list-style-type: none"> <li>• 28/08/2019</li> <li>• 13/09/2019</li> <li>• 05/12/2019</li> <li>• (83 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
2-(3,7-dimethyl-octa-2, 6-dienyl)-6-ethylamino-3-hydroxy-5-pentyl-[1,4]benzoquinone	Emerald Health Pharmaceuticals Espana S.L. - Spain	Treatment of Huntington's disease	<ul style="list-style-type: none"> <li>• 20/08/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene	Vertex Pharmaceuticals (Ireland) Limited - Ireland	Treatment of sickle cell disease	<ul style="list-style-type: none"> <li>• 28/08/2019</li> <li>• 13/09/2019</li> <li>• 05/12/2019</li> <li>• (83 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
Motixafortide	Granzer Regulatory Consulting & Services - Germany	Treatment of pancreatic cancer	<ul style="list-style-type: none"> <li>• 28/08/2019</li> <li>• 13/09/2019</li> <li>• 05/12/2019</li> <li>• (83 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Adeno-associated virus serotype 2/6 encoding human alpha-galactosidase A cDNA	ERA Consulting GmbH - Germany	Treatment of Fabry disease	<ul style="list-style-type: none"> <li>• 27/08/2019</li> <li>• 13/09/2019</li> <li>• 05/12/2019</li> <li>• (83 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Romilkimab	Sanofi-Aventis Groupe - France	Treatment of systemic sclerosis	<ul style="list-style-type: none"> <li>• 26/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Ziritaxestat	Galapagos N.V. - Belgium	Treatment of systemic sclerosis	<ul style="list-style-type: none"> <li>• 26/09/2019</li> <li>• 29/10/2019</li> <li>• 05/12/2019</li> <li>• (37 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 10/12/2019</li> <li>• 09/01/2020</li> </ul>
Lactobacillus plantarum	MDC RegAffairs GmbH - Germany	Treatment of amyotrophic lateral sclerosis	<ul style="list-style-type: none"> <li>• 16/07/2019</li> <li>• 12/08/2019</li> <li>• 15/11/2019</li> <li>• (95 days/27 days)<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>• 18/11/2019</li> </ul>
Adeno-associated virus vector encoding human phenylalanine hydroxylase	BioMarin International Limited - Ireland	Treatment of phenylalanine hydroxylase deficiency	<ul style="list-style-type: none"> <li>• 27/08/2019</li> <li>• 13/09/2019</li> <li>• 15/11/2019</li> <li>• (63 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
5,7-dichloro-2-((ethylamino)methyl)-8-hydroxy-3-methylquinazolin-4(3H)-one mesilate	Alterity Therapeutics UK Limited - United Kingdom	Treatment of multiple system atrophy	<ul style="list-style-type: none"> <li>• 08/08/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
Pamrevlumab	Voisin Consulting S.A.R.L. - France	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> <li>• 15/07/2019</li> <li>• 12/08/2019</li> <li>• 07/11/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 18/11/2019</li> </ul>

<sup>1</sup> The Committee adopted the opinion by written procedure following its November meeting therefore the maximum procedure time of 90 days was exceeded.

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
Navitoclax	AbbVie Deutschland GmbH & Co. KG - Germany	Treatment of myelofibrosis	<ul style="list-style-type: none"> <li>• Submission</li> <li>• Start date</li> <li>• Opinion</li> <li>• Active time</li> </ul>	<ul style="list-style-type: none"> <li>• Opinion received</li> <li>• Date of decision</li> </ul>
			<ul style="list-style-type: none"> <li>• 23/08/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
H-Leu-Pro-Pro-Leu-Pro-Tyr-Pro-OH	AdRes EU B.V. – Netherlands	Treatment of amyotrophic Lateral Sclerosis	<ul style="list-style-type: none"> <li>• 23/08/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
2-(isopropylamino)-3-methyl-5-(6-methyl-5-((2-(1-methyl-1H-pyrazol-4-yl)pyridin-4-yl)oxy)pyridin-2-yl)pyrimidin-4(3H)-one	Pharma Gateway AB – Sweden	Treatment of tenosynovial giant cell tumour, localised and diffuse type	<ul style="list-style-type: none"> <li>• 22/08/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
Efgartigimod alfa	Argenx B.V.B.A. - Belgium	Treatment of immune thrombocytopenia	<ul style="list-style-type: none"> <li>• 25/06/2019</li> <li>• 12/08/2019</li> <li>• 07/11/2019</li> <li>• (87 days /27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
Synthetic double-stranded siRNA oligonucleotide directed against SERPINA1 mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylglactosamine residues	Dicerna Ireland Limited – Ireland	Treatment of congenital alpha-1 antitrypsin deficiency	<ul style="list-style-type: none"> <li>• 19/07/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 18/11/2019</li> </ul>
(E)-2-((2S,4S)-4-(((2R,4S,5S,6S)-4-amino-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-2,5,12-trihydroxy-7-methoxy-6,11-dioxo-1,2,3,4,6,11-hexahydrotetracen-2-yl)-10-(carboxymethyl)-1-hydroxy-13-(2-(2-(2-((E)-3-(3-((3-hydroxy-3,3-diphosphonopropyl)(methyl)amino)propoxy)benzylidene)hydrazine-1-carbonothioyl)hydrazineyl)-2-oxoethyl)-8-oxo-5-thioxo-3,4,6,7,10,13-hexaazapentadec-2-en-15-oic acid	Atlanthera - France	Treatment of osteosarcoma	<ul style="list-style-type: none"> <li>• 17/07/2019</li> <li>• 13/09/2019</li> <li>• 07/11/2019</li> <li>• (55 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> </ul>
Exendin (9-39)	Eigerbio Europe Limited - Ireland	Treatment of congenital hyperinsulinism	<ul style="list-style-type: none"> <li>• 17/07/2019</li> <li>• 12/08/2019</li> <li>• 10/10/2019</li> <li>• (59 days /28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 15/10/2019</li> <li>• 13/11/2019</li> </ul>



<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
Replication-incompetent, non-integrating, herpes simplex virus 1 vector expressing the human transglutaminase-1 enzyme	IDEA Innovative Drug European Associates (Ireland) Limited - Ireland	Treatment of autosomal recessive congenital ichthyosis	<ul style="list-style-type: none"> <li>• 21/05/2019</li> <li>• 14/07/2019</li> <li>• 10/10/2019</li> <li>• (87 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
(2S,3R,4R,5S)-2-(hydroxymethyl)-1-pentylpiperidine-3,4,5-triol	Idorsia Pharmaceuticals Deutschland GmbH - Germany	Treatment of GM2 gangliosidosis	<ul style="list-style-type: none"> <li>• 16/07/2019</li> <li>• 12/08/2019</li> <li>• 10/10/2019</li> <li>• (59 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
Ganaxolone	Pharma Gateway AB - Sweden	Treatment of CDKL5 deficiency disorder	<ul style="list-style-type: none"> <li>• 26/06/2019</li> <li>• 15/07/2019</li> <li>• 10/10/2019</li> <li>• (87 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti CD19 CD28/CD3-zeta chimeric antigen receptor and cultured	Kite Pharma EU B.V. - Netherlands	Treatment of mantle cell lymphoma	<ul style="list-style-type: none"> <li>• 17/07/2019</li> <li>• 12/08/2019</li> <li>• 10/10/2019</li> <li>• (59 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
Chimeric fibrin-reactive IgG1k monoclonal antibody 11-1F4	Real Regulatory Limited - Ireland	Treatment of AL Amyloidosis	<ul style="list-style-type: none"> <li>• 15/07/2019</li> <li>• 12/08/2019</li> <li>• 10/10/2019</li> <li>• (59 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
Camsirubicin	Monopar Therapeutics S.A.R.L - France	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 14/07/2019</li> <li>• 10/10/2019</li> <li>• (87 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
4-((E)-(5-(2-(2-((S)-2-((S)-1-(L-threonyl-L-lysyl)pyrrolidine-2-carboxamido)-5-guanidinopentanamido)acetamido)-2-carboxyethyl)-2-hydroxyphenyl)diazonyl)phenyl (2-(trimethylammonio)ethyl) phosphate	Granzer Regulatory Consulting & Services - Germany	Treatment of non-infectious uveitis	<ul style="list-style-type: none"> <li>• 25/06/2019</li> <li>• 15/07/2019</li> <li>• 10/10/2019</li> <li>• (87 days/28 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/10/2019</li> <li>• 13/11/2019</li> </ul>
2'-O-(2-methoxyethyl)-D-ribose antisense oligonucleotide targeting glial fibrillary acidic protein messenger ribonucleic acid	Ionis Development (Ireland) Limited - Ireland	Treatment of Alexander disease	<ul style="list-style-type: none"> <li>• 26/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
(S)-2-isobutyrylamino-pentanedioic acid 5-amide 1- {[(2S,5S,8S,11R,12S,15S,18S,21R)-2,8-bis-((S)-sec-butyl)-21-hydroxy-5-(4-hydroxy-benzyl)-15-isobutyl-4,11-dimethyl-3,6,9,13,16,22-hexaoxo-10-oxa-1,4,7,14,17-pentaaza-bicyclo[16.3.1]docos-12-yl]-amide}	MDC RegAffairs GmbH - Germany	Treatment of Netherton syndrome	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Leriglitzazone	Minoryx Therapeutics S.L. – Spain	Treatment of Friedreich’s ataxia	<ul style="list-style-type: none"> <li>• 18/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Pemigatinib	Incyte Biosciences Distribution B.V. – Netherlands	Treatment of myeloid/lymphoid neoplasms with eosinophilia and rearrangement of PDGFRA, PDGFRB, or FGFR1, or with PCM1-JAK2	<ul style="list-style-type: none"> <li>• 24/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
2-(3-(4-(1H-indazol-5-ylamino)quinazolin-2-yl)phenoxy)-N-isopropylacetamide-methane sulfonic acid salt	Quality Regulatory Clinical Ireland Limited - Ireland	Treatment of graft-versus-host disease	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene	Vertex Pharmaceuticals (Ireland) Limited - Ireland	Treatment of beta-thalassaemia intermedia and major	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Besilesomab	Therapharm Deutschland GmbH - Germany	Treatment of haematopoietic stem cell transplantation	<ul style="list-style-type: none"> <li>• 22/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Combination of two adeno-associated viral vectors of serotype 8 containing the 5'- and the 3'- half coding sequences of human ABCA4 fused to inteins	Fondazione Telethon - Italy	Treatment of Stargardt's disease	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
Propranolol hydrochloride	Recordati Rare Diseases - France	Treatment of retinopathy of prematurity	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/09/2019</li> <li>• 17/10/2019</li> </ul>
(16E)-14-methyl-20-oxa-5,7,14,26-tetraaza-tetracyclo[19.3.1.1(2,6).1(8,12)]heptacosane-1(25),2(26),3,5,8(27),9,11,16,21,23-decaene-citric acid	Clinical Network Services (NL) B.V. - Netherlands	Treatment of glioma	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Anti-neonatal Fc receptor human monoclonal antibody	Biopharma Excellence GmbH - Germany	Treatment of haemolytic disease of the foetus and newborn	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Lonapegsomatropin	Ascendis Pharma Endocrinology Division A/S - Denmark	Treatment of growth hormone deficiency	<ul style="list-style-type: none"> <li>• 26/06/2019</li> <li>• 15/07/2019</li> <li>• 12/09/2019</li> <li>• (59 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
18-(p-(131I)-iodophenyl)octadecyl phosphocholine	Voisin Consulting S.A.R.L. - France	Treatment of multiple myeloma	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Paclitaxel	Boyd Consultants Limited - Ireland	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> <li>• 22/03/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
4-oxo-4H-chromene-2-carboxylic acid (2-(2-(4-(2-(6,7-dimethoxy-3,4-dihydro-1H-isoquinolin-2-yl)-ethyl)-phenyl)-2H-tetrazol-5-yl)-4,5-dimethoxy-phenyl)-amide	Boyd Consultants Limited - Ireland	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> <li>• 22/03/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>
Nirogacestat	Voisin Consulting S.A.R.L. - France	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> <li>• 21/05/2019</li> <li>• 17/06/2019</li> <li>• 12/09/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 20/09/2019</li> <li>• 17/10/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
Setmelanotide	TMC Pharma (EU) Limited - Ireland	Treatment of Bardet Biedl syndrome (BBS).	<ul style="list-style-type: none"> <li>• 20/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>
Recombinant self-complementary adeno-associated viral vector serotype 9 containing the human CLN6 gene	Amicus Therapeutics Europe Limited – Ireland	Treatment of neuronal ceroid lipofuscinosis	<ul style="list-style-type: none"> <li>• 09/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Recombinant self-complementary adeno-associated viral vector serotype 9 containing the human CLN3 gene	Amicus Therapeutics Europe Limited – Ireland	Treatment of neuronal ceroid lipofuscinosis	<ul style="list-style-type: none"> <li>• 09/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Acetazolamide	Laboratorios Tillomed Spain S.L.U. - Spain	Treatment of periodic Paralysis	<ul style="list-style-type: none"> <li>• 24/04/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>
Clofazimine	Sebastian Canisius - Germany	Treatment of non-tuberculous mycobacterial lung disease	<ul style="list-style-type: none"> <li>• 22/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-hydroxy-,15,15'-diester with N-acetyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutaminy-L-alpha-aspartyl-L-tryptophylglycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-L-threonyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-carboxy-L-lysine cyclic (2.fwdarw.12)-(disulfide); where two identical synthetic peptide domains are covalently linked at the ends of the polyethylene glycol chain	Apellis Ireland Limited - Ireland	Treatment of C3 glomerulopathy	<ul style="list-style-type: none"> <li>• 23/03/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
1-(2,2-diphenyltetrahydrofuran-3-yl)-N,N-dimethylmethanamine hydrochloride	Anavex Germany GmbH - Germany	Treatment of Rett Syndrome	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b> <ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<b>EC</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
4-(2-chloro-4-methoxy-5-methylphenyl)-N-[(1S)-2-cyclopropyl-1-(3-fluoro-4-methylphenyl)ethyl]-5-methyl-N-(2-propynyl)-1,3-thiazol-2-amine	Neurocrine Therapeutics Limited - Ireland	Treatment of congenital adrenal hyperplasia	<ul style="list-style-type: none"> <li>• 23/04/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>
Gallium citrate	Clinical Network Services (NL) B.V. - Netherlands	Treatment of cystic fibrosis	<ul style="list-style-type: none"> <li>• 20/03/2019</li> <li>• 23/04/2019</li> <li>• 18/07/2019</li> <li>• (86 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Temozolomide	Orphelia Pharma S.A.S. - France	Treatment of neuroblastoma	<ul style="list-style-type: none"> <li>• 13/03/2019</li> <li>• 23/04/2019</li> <li>• 18/07/2019</li> <li>• (86 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Relacorilant	Granzer Regulatory Consulting & Services - Germany	Treatment of pancreatic Cancer	<ul style="list-style-type: none"> <li>• 23/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>
Veledimex	Ziopharm Oncology Limited - Ireland	Treatment of glioma	<ul style="list-style-type: none"> <li>• 15/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Adenoviral vector serotype 5 encoding the human interleukin-12 p70 transgene under the control of activator ligand veledimex	Ziopharm Oncology Limited - Ireland	Treatment of glioma	<ul style="list-style-type: none"> <li>• 15/05/2019</li> <li>• 17/06/2019</li> <li>• 18/07/2019</li> <li>• (31 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 25/07/2019</li> <li>• 21/08/2019</li> </ul>
Peginterferon lambda-1a	Eiger Biopharmaceuticals Europe Limited - United Kingdom	Treatment of hepatitis D Virus Infection	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 23/04/2019</li> <li>• 18/07/2019</li> <li>• (86 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 26/07/2019</li> <li>• 21/08/2019</li> </ul>
Mavorixafor	Voisin Consulting S.A.R.L. - France	Treatment of WHIM syndrome	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 27/06/2019</li> <li>• 25/07/2019</li> </ul>
Parsaclisib	Incyte Biosciences Distribution B.V. - Netherlands	Treatment of marginal zone lymphoma	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
Recombinant mutated extracellular domain of the human acetylcholine receptor subunit alpha1	Toleranzia AB - Sweden	Treatment of myasthenia gravis	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 20/06/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
Pevonedistat	Takeda Pharma A/S - Denmark	Treatment of acute myeloid leukemia	<ul style="list-style-type: none"> <li>• 20/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
2-(hydroxymethyl)-2-(methoxymethyl)-1-azabicyclo[2.2.2]octan-3-one	Aprea Therapeutics AB - Sweden	Treatment of myelodysplastic syndromes	<ul style="list-style-type: none"> <li>• 20/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
N-((R)-2,3-dihydroxypropoxy)-3,4-difluoro-2-(2-fluoro-4-iodophenylamino)-benzamide	Voisin Consulting S.A.R.L. - France	Treatment of neurofibromatosis type 1	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
7-ethyl-10-hydroxy-camptothecin	Cebiotex S.L. - Spain	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> <li>• 27/02/2019</li> <li>• 25/03/2019</li> <li>• 20/06/2019</li> <li>• 87/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
Elafibranor	Genfit - France	Treatment of primary Biliary Cholangitis	<ul style="list-style-type: none"> <li>• 19/03/2019</li> <li>• 23/04/2019</li> <li>• 20/06/2019</li> <li>• (58 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 28/06/2019</li> <li>• 25/07/2019</li> </ul>
Imidazolyl ethanamide pentandioic acid	Myelo Therapeutics GmbH - Germany	Treatment of acute radiation syndrome	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Sodium benzoate, sodium phenylacetate	Dipharma B.V. - Netherlands	Treatment of hyperargininaemia	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Sodium benzoate, sodium phenylacetate	Dipharma B.V. - Netherlands	Treatment of argininosuccinic aciduria	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
5'-cEtG-sp-cEt5MeU-sp-cEt5MeU-sp-dT-sp-dA-sp-dT-sp-dT-sp-dA-sp-dT-sp-dA-sp-dG-sp-dG-sp-dG-sp-cEt5MeC-sp-cEt5MeU-sp-cEt5MeU-3'	Dynacure S.A.S. – France	Treatment of centronuclear myopathies	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Recombinant adeno-associated viral vector containing a bioengineered capsid serotype AAV-rh74 and a codon-optimised expression cassette to drive the expression of a secretable form of human acid alpha-glucosidase	Spark Therapeutics Ireland Limited – Ireland	Treatment of glycogen storage disease type II (Pompe's disease)	<ul style="list-style-type: none"> <li>• 28/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Reldesemtiv	Pharma Gateway AB - Sweden	Treatment of spinal muscular atrophy	<ul style="list-style-type: none"> <li>• 27/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Rasagiline	TMC Pharma (EU) Limited - Ireland	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> <li>• 25/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Recombinant human coagulation factor VIII Fc - von Willebrand factor - XTEN fusion protein	Swedish Orphan Biovitrum AB (publ) - Sweden	Treatment of haemophilia A	<ul style="list-style-type: none"> <li>• 23/01/2019</li> <li>• 25/02/2019</li> <li>• 23/05/2019</li> <li>• (87 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
2-(2-{{2-(1H-benzimidazol-2-yl)ethyl}amino}ethyl)-N-[(3-fluoropyridine-2-yl)methyl]-1,3-oxazole-4-carboxamide trihydrochloride	Vifor France S.A. - France	Treatment of beta-thalassaemia intermedia and major	<ul style="list-style-type: none"> <li>• 27/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
(S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidine-3-yl)chroman-2-carboxamide hydrochloride	Khondrion B.V. - Netherlands	Treatment of maternally-inherited diabetes and deafness	<ul style="list-style-type: none"> <li>• 05/02/2019</li> <li>• 25/02/2019</li> <li>• 23/05/2019</li> <li>• (87 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Gaboxadol monohydrate	FGK Representative Service GmbH – Germany	Treatment of Angelman syndrome	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 23/05/2019</li> <li>• (87 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
Regorafenib	Bayer AG - Germany	Treatment of glioma	<ul style="list-style-type: none"> <li>• 26/02/2019</li> <li>• 25/03/2019</li> <li>• 23/05/2019</li> <li>• (59 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/05/2019</li> <li>• 28/06/2019</li> </ul>
Sodium benzoate, sodium phenylacetate	Dipharma B.V. - Netherlands	Treatment of carbamoyl-phosphate synthase-1 deficiency	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 29/04/2019</li> <li>• (63 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Sodium benzoate, sodium phenylacetate	Dipharma B.V. - Netherlands	Treatment of citrullinaemia type 1	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 29/04/2019</li> <li>• (63 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
(S)-3-((3-(1-((6-(3,4-dimethoxyphenyl)pyrazin-2-yl)amino)ethyl)phenyl)carbamoyl)-5-methylpyridin-1-ium	MWB Consulting S.A.R.L. - France	Treatment of pulmonary arterial hypertension	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 29/04/2019</li> <li>• (63 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Relacorilant	Granzer Regulatory Consulting & Services - Germany	Treatment of endogenous Cushing syndrome	<ul style="list-style-type: none"> <li>• 06/12/2018</li> <li>• 18/01/2019</li> <li>• 17/04/2019</li> <li>• (89 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Allogeneic skin-derived ABCB5-positive mesenchymal stem cells	Rheacell GmbH & Co. KG - Germany	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 17/04/2019</li> <li>• (51 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Diacerein	WORPHMED World Orphan Medicines Limited - United Kingdom	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> <li>• 14/12/2018</li> <li>• 25/02/2019</li> <li>• 17/04/2019</li> <li>• (51 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
N-(trans-3-(5-((R)-1-hydroxyethyl)-1,3,4-oxadiazol-2-yl)cyclobutyl)-3-phenylisoxazole-5-carboxamide	Voisin Consulting S.A.R.L. - France	Treatment of cystic fibrosis	<ul style="list-style-type: none"> <li>• 24/01/2019</li> <li>• 25/02/2019</li> <li>• 17/04/2019</li> <li>• (51 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Emixustat hydrochloride	Pharma Gateway AB - Sweden	Treatment of Stargardt Disease	<ul style="list-style-type: none"> <li>• 23/01/2019</li> <li>• 25/02/2019</li> <li>• 17/04/2019</li> <li>• (51 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>



<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
(S)-5-(1-(6-chloro-2-oxo-1,2-dihydroquinolin-3-yl)ethylamino)-1-methyl-6-oxo-1,6-dihydropyridine-2-carbonitrile	Pharma Gateway AB - Sweden	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> <li>• 23/01/2019</li> <li>• 25/02/2019</li> <li>• 17/04/2019</li> <li>• (51 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/05/2019</li> <li>• 29/05/2019</li> </ul>
Zanubrutinib	BeiGene Ireland Limited - Ireland	Treatment of lymphoplasmacytic lymphoma	<ul style="list-style-type: none"> <li>• 31/01/2019</li> <li>• 18/01/2019</li> <li>• 17/04/2019</li> <li>• (89 days/30 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/04/2019</li> <li>• 29/05/2019</li> </ul>
Modified messenger ribonucleic acid encoding human propionyl-coenzyme A carboxylase alpha and beta subunits encapsulated into lipid nanoparticle	Pharma Gateway AB - Sweden	Treatment of propionic acidaemia	<ul style="list-style-type: none"> <li>• 06/12/2018</li> <li>• 18/01/2019</li> <li>• 21/03/2019</li> <li>• (62 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
Sodium benzoate, sodium phenylacetate	Dipharma B.V. - Netherlands	Treatment of ornithine transcarbamylase deficiency	<ul style="list-style-type: none"> <li>• 06/12/2018</li> <li>• 18/01/2019</li> <li>• 21/03/2019</li> <li>• (62 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
Human culture expanded autologous mesenchymal stromal cells	IQVIA RDS Ireland Limited - Ireland	Treatment of amyotrophic lateral sclerosis	<ul style="list-style-type: none"> <li>• 06/12/2018</li> <li>• 18/01/2019</li> <li>• 21/03/2019</li> <li>• (62 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
3-(3-(3,5-bis(trifluoromethyl)phenyl)-1H-pyrazol-1-yl)propanoic acid	TMC Pharma (EU) Limited - Ireland	Treatment of Stargardt's disease	<ul style="list-style-type: none"> <li>• 21/11/2018</li> <li>• 03/01/2019</li> <li>• 21/03/2019</li> <li>• (77 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
Balipodect	Takeda Pharma A/S - Denmark	Treatment of fragile X syndrome	<ul style="list-style-type: none"> <li>• 22/11/2018</li> <li>• 03/01/2019</li> <li>• 21/03/2019</li> <li>• (77 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
Autologous human bone marrow-derived haematopoietic and mesenchymal stem cells depleted of erythrocytes, monocytes and lymphocytes	Neuroplast B.V. - Netherlands	Treatment of spinal cord injury	<ul style="list-style-type: none"> <li>• 19/11/2018</li> <li>• 03/01/2019</li> <li>• 21/03/2019</li> <li>• (77 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 29/03/2019</li> <li>• 24/04/2019</li> </ul>
Marzeptacog alfa (activated)	Voisin Consulting S.A.R.L. - France	Treatment of haemophilia B	<ul style="list-style-type: none"> <li>• 22/11/2018</li> <li>• 03/01/2019</li> <li>• 21/02/2019</li> <li>• (49 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 06/03/2019</li> <li>• 01/04/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
			<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
4-hydroxy-6-{2-[4-(trifluoromethyl)phenyl]ethyl}pyridazin-3(2H)-one	Takeda Pharma A/S - Denmark	Treatment of Friedreich's ataxia	<ul style="list-style-type: none"> <li>• 20/11/2018</li> <li>• 03/01/2019</li> <li>• 21/02/2019</li> <li>• (49 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 06/03/2019</li> <li>• 01/04/2019</li> </ul>
Codon-optimised human cystic fibrosis transmembrane conductance regulator messenger ribonucleic acid complexed with lipid-based nanoparticles	Real Regulatory Limited - Ireland	Treatment of cystic fibrosis	<ul style="list-style-type: none"> <li>• 25/10/2018</li> <li>• 26/11/2018</li> <li>• 21/02/2019</li> <li>• (87 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 05/03/2019</li> <li>• 01/04/2019</li> </ul>
Adeno-associated viral vector serotype rh10 containing the human cholesterol 24-hydroxylase gene	Brainvectis - France	Treatment of Huntington's disease	<ul style="list-style-type: none"> <li>• 25/10/2018</li> <li>• 26/11/2018</li> <li>• 21/02/2019</li> <li>• (87 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 06/03/2019</li> <li>• 01/04/2019</li> </ul>
1-[(3S)-3-{4-amino-3-[(3,5-dimethoxyphenyl)ethynyl]-1H-pyrazolo[3,4-d]pyrimidin-1-yl}pyrrolidin-1-yl]-2-propen-1-one	Taiho Pharma Europe Limited - United Kingdom	Treatment of biliary tract cancer	<ul style="list-style-type: none"> <li>• 26/10/2018</li> <li>• 03/01/2019</li> <li>• 21/02/2019</li> <li>• (49 days/27 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 05/03/2019</li> <li>• 01/04/2019</li> </ul>
2-[3-(2-chloro-4-{[5-cyclopropyl-3-(2,6-dichlorophenyl)-1,2-oxazol-4-yl]methoxy}phenyl)-3-hydroxyazetid-1-yl]pyridine-4-carboxylic acid—2-amino-2-(hydroxymethyl)propane-1,3-diol (1/1)	Gilead Sciences Ireland UC - Ireland	Treatment of primary sclerosing cholangitis	<ul style="list-style-type: none"> <li>• 16/11/2018</li> <li>• 03/01/2019</li> <li>• 21/02/2019</li> <li>• (49 days/26 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 06/03/2019</li> <li>• 01/04/2019</li> </ul>
Allogeneic cultured postnatal thymus tissue, allogeneic cultured postnatal thymus-derived tissue	Enzyvant Therapeutics Ireland Limited - Ireland	Treatment of severe combined immunodeficiency due to FOXP1 deficiency	<ul style="list-style-type: none"> <li>• 26/11/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
9-cis, 12-cis-11,11-D2-linoleic acid ethyl ester	FGK Representative Service GmbH - Germany	Treatment of infantile neuroaxonal dystrophy	<ul style="list-style-type: none"> <li>• 19/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Humanised IgG1 monoclonal antibody targeting human transferrin receptor conjugated to human iduronate-2-sulfatase	Artemida Pharma Europe Limited - Ireland	Treatment of mucopolysaccharidosis II (Hunter's syndrome)	<ul style="list-style-type: none"> <li>• 22/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
Lentiviral vector encoding human coagulation factor IX	Fondazione Telethon - Italy	Treatment of haemophilia B	<ul style="list-style-type: none"> <li>• 24/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Risdiplam	Roche Registration GmbH - Germany	Treatment of 5q spinal muscular atrophy	<ul style="list-style-type: none"> <li>• 24/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Losartan	3R Pharma Consulting GmbH - Germany	Treatment of dystrophic epidermolysis bullosa	<ul style="list-style-type: none"> <li>• 24/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Allogeneic anti-Epstein Barr virus cytotoxic T lymphocytes expanded ex vivo	Common Services Agency (National Health Services - Scotland) – United Kingdom	Treatment of post-transplant lymphoproliferative disorder	<ul style="list-style-type: none"> <li>• 25/10/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Allogeneic cultured postnatal thymus tissue, allogeneic cultured postnatal thymus-derived tissue	Enzyvant Therapeutics Ireland Limited - Ireland	Treatment of CHARGE syndrome	<ul style="list-style-type: none"> <li>• 26/11/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Poly(N-acetyl, N-arginyl)glucosamine	Accelsiors CRO And Consultancy Services Ltd. - Hungary	Treatment of cystic fibrosis	<ul style="list-style-type: none"> <li>• 05/11/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Lurbinectedin	Pharma Mar S.A. - Spain	Treatment of small cell lung cancer	<ul style="list-style-type: none"> <li>• 18/09/2018</li> <li>• 29/10/2018</li> <li>• 24/01/2019</li> <li>• (87 days/25 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 01/02/2019</li> <li>• 26/02/2019</li> </ul>
Autologous adult live cultured osteoblasts	Clinical Network Services (UK) Limited – United Kingdom	Treatment of non-traumatic osteonecrosis	<ul style="list-style-type: none"> <li>• 27/09/2018</li> <li>• 29/10/2018</li> <li>• 24/01/2019</li> <li>• (87 days/24 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 02/02/2019</li> <li>• 26/02/2019</li> </ul>
Allogeneic cultured postnatal thymus tissue, allogeneic cultured postnatal thymus-derived tissue	Enzyvant Therapeutics Ireland Limited – Ireland	Treatment of DiGeorge syndrome	<ul style="list-style-type: none"> <li>• 26/11/2018</li> <li>• 26/11/2018</li> <li>• 24/01/2019</li> <li>• (59 days/23 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 03/02/2019</li> <li>• 26/02/2019</li> </ul>

### **Negative COMP designation opinions**

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP</b>	<b>EC</b>
Naltrexone	Able AB - Sweden	Treatment of fibromyalgia	<ul style="list-style-type: none"> <li>• <b>Submission</b></li> <li>• <b>Start date</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> </ul>
Melatonin, Sorafenig	Worphmed S.r.l. - Italy	Treatment of hepatocellular carcinoma	<ul style="list-style-type: none"> <li>• 21/03/2019</li> <li>• 23/04/2019</li> <li>• 18/07/2019</li> <li>• (87 days/31 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 19/11/2019</li> <li>• 19/12/2019</li> </ul>
			<ul style="list-style-type: none"> <li>• 04/04/2019</li> <li>• 17/06/2019</li> <li>• 23/09/2019</li> <li>• (99 days/29 days)</li> </ul>	<ul style="list-style-type: none"> <li>• 16/01/2020</li> <li>• 13/02/2020</li> </ul>

## Annex 15 – HMPC European Union herbal monographs in 2019

Abbreviations: TU – traditional use

WEU – well established use

LE – list entry

MO – monograph

### **European Union herbal monographs - Final**

Reference number	Document title	Adoption / Outcome*
<b>First Assessment</b>		
EMA/HMPC/294187/2013	Silybi mariani fructus	04/06/2018 / TU
EMA/HMPC/432278/2015	Fragariae folium	20/11/2018 / TU
EMA/HMPC/749510/2016	Malvae folium	20/11/2018 / TU
EMA/HMPC/749511/2016	Malvae sylvestris flos	20/11/2018 / TU
<b>Revision</b>		
EMA/HMPC/750269/2016	Uvae ursi folium	30/01/2018 / TU
EMA/HMPC/48745/2017	Cimicifugae rhizoma	27/03/2018 / WEU
EMA/HMPC/606742/2017	Agni casti fructus	27/03/2018 / TU + WEU
EMA/HMPC/437450/2017	Calendulae flos	27/03/2018 / TU
EMA/HMPC/194014/2017	Cynarae folium	27/03/2018 / TU
EMA/HMPC/611512/2016	Sambuci flos	27/03/2018 / TU
EMA/HMPC/611537/2016	Verbasci flos	27/03/2018 / TU
EMA/HMPC/444244/2015	Pelargonii radix	05/06/2018 / TU
EMA/HMPC/737380/2018	Echinaceae pallidae radix	05/06/2018 / TU
EMA/HMPC/753041/2017	Oenotherae biennis oleum	05/06/2018 / TU
EMA/HMPC/329755/2017	Curcumae longae rhizoma	25/09/2018 / TU
EMA/HMPC/625849/2015	Sennae folium	25/09/2018 / WEU
EMA/HMPC/228761/2016	Sennae fructus	25/09/2018 / WEU
EMA/HMPC/607861/2017	Gentianae radix	20/11/2018 / TU
EMA/HMPC/188804/2017	Rusci aculeati rhizoma	20/11/2018 / TU

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

Reference number	Document title	Adoption *
<b>First Assessment</b>		
	none	
<b>Revision</b>		
	none	

### **European Union herbal monographs - Draft**

Reference number	Document title	Adoption / Outcome*
<b>First Assessment</b>		
EMA/HMPC/432278/2015	Fragariae folium	27/03/2018 / TU
EMA/HMPC/749510/2016	Malvae folium	05/06/2018 / TU
EMA/HMPC/749511/2016	Malvae sylvestris flos	05/06/2018 / TU
<b>Revision</b>		
EMA/HMPC/188804/2017	Rusci aculeati rhizoma	30/01/2018 / TU
EMA/HMPC/45508/2017	Hyperici herba (TU)	30/01/2018 / TU
EMA/HMPC/607861/2017	Gentianae radix	27/03/2018 / TU

### **European Union List entries - Draft**

Reference number	Document title	Adoption *
<b>First Assessment</b>		
	none	
<b>Revision</b>		
	none	

### **Monograph/ list entry reviews**

Reference number	Document title	Adoption / Outcome
<b>Final decision</b>		
EMA/HMPC/732731/2017	Avenae fructus	27/03/2018 / no revision
EMA/HMPC/732731/2017	Avenae herba	27/03/2018 / no revision
EMA/HMPC/627591/2017	Polypodii rhizoma	05/06/2018 / no revision
EMA/HMPC/178578/2018	Hippocastani semen	05/06/2018 / revision required
EMA/HMPC/364552/2018	Myrrha	24/03/2018 / no revision
EMA/HMPC/179592/2018	Trigonellae foenugraeci semen	24/03/2018 / revision required
EMA/HMPC/637898/2018	Echinaceae angustifoliae radix	20/11/2018 / no revision

### **Public statements**

Reference number	Document title	Adoption
<b>Drafts</b>		
	none	
<b>Final</b>		
EMA/HMPC/461814/2016	Glycini semen	05/06/2018 / PS

## Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2019

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

P: PIP agreed, RP: PIP refused, PM: PIP Modification agreed, RPM: PIP Modification refused, 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
Venetoclax	Venclyxto	PM	Haematology- Hemostaseology Oncology	AbbVie Ltd	04/01/2019	P/0001/2019
Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti CD19 CD28/CD3-zeta chimeric antigen receptor and cultured (KTE-X19)		PM	Oncology	Kite Pharma EU B.V.	03/01/2019	P/0002/2019
Pimodivir		PM	Infectious Diseases	Janssen-Cilag International NV	03/01/2019	P/0003/2019
Axicabtagene ciloleucel		PM	Oncology	Kite Pharma EU B.V.	03/01/2019	P/0004/2019
Palbociclib	Ibrance	W	Oncology	Pfizer Europe MA EEIG	03/01/2019	P/0005/2019
Darunavir / cobicistat	Rezolsta	PM	Infectious Diseases	Janssen-Cilag International NV	03/01/2019	P/0006/2019
Semaglutide		P	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	03/01/2019	P/0007/2019
Tisagenlecleucel	Kymriah	PM	Oncology	Novartis Europharm Limited	03/01/2019	P/0008/2019
Bilastine	Bilaxten and associated names	P	Ophthalmology	Faes Farma S.A.	03/01/2019	P/0009/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Entrectinib		PM	Oncology	Roche Registration GmbH	04/01/2019	P/0010/2019
Levodopa / carbidopa monohydrate / entacapone		W	Neurology	LobSor Pharmaceuticals AB	03/01/2019	P/0011/2019
Anti-VEGF and anti-DLL4 dual variable domain immunoglobulin (ABT-165)		W	Oncology	AbbVie Ltd.	03/01/2019	P/0012/2019
Bupivacaine / meloxicam (HTX-011)		P	Anaesthesiology	Heron Therapeutics, B.V.	03/01/2019	P/0013/2019
Rezafungin acetate		P	Infectious Diseases	Cidara Therapeutics, Inc.	03/01/2019	P/0014/2019
Synthetic double-stranded siRNA oligonucleotide targeted against transthyretin mRNA, with six phosphorothioate linkages in the backbone, and nine 2'-fluoro and thirty-five 2'-O-methyl nucleoside residues in the sequence, which is covalently linked via a phosphodiester group to a ligand containing three N-acetylgalactosamine residues (ALN-65492)		W	Cardiovascular Diseases	Alnylam Netherlands BV	03/01/2019	P/0015/2019
Sildenafil	Revatio	PM	Other	Pfizer Limited	03/01/2019	P/0016/2019
Dolutegravir	Tivicay	PM	Infectious Diseases	ViiV Healthcare UK Ltd.	03/01/2019	P/0017/2019
Dolutegravir / abacavir / lamivudine	Triumeq	PM	Infectious Diseases	ViiV Healthcare UK Limited	03/01/2019	P/0018/2019
Germanium (68Ge) chloride / Gallium (68Ga) chloride		W	Other	ITG Isotope Technologies Garching GmbH	03/01/2019	P/0019/2019
Bruton's tyrosine kinase inhibitor		W	Immunology- Rheumatology- Transplantation	Principia Biopharma, Inc.	03/01/2019	P/0020/2019



Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Ibrutinib	Imbruvica	P	Immunology- Rheumatology- Transplantation	Janssen-Cilag International N.V.	03/01/2019	P/0021/2019
Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)),adjuvanted	Humenza	PM	Vaccines	Sanofi Pasteur SA	04/01/2019	P/0022/2019
Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage)		P	Vaccines	Sanofi Pasteur	04/01/2019	P/0023/2019
Telmisartan / indapamide		W	Cardiovascular Diseases	PRO.MED.CS a.s.	11/01/2019	P/0024/2019
Guselkumab	Tremfya	P	Immunology- Rheumatology- Transplantation	Janssen-Cilag International NV	22/02/2019	P/0025/2019
Avapritinib		P	Oncology	Blueprint Medicines (Netherlands) B.V.	22/02/2019	P/0026/2019
2-hydroxypropyl-β-cyclodextrin (HP-β-CD)		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Mallinckrodt Pharmaceuticals Ireland Ltd	29/01/2019	P/0027/2019
Ocrelizumab	Ocrevus	PM	Neurology	Roche Registration GmbH	29/01/2019	P/0028/2019
Birch pollen extract		PM	Pneumology - Allergology	Allergy Therapeutics (UK) Ltd	29/01/2019	P/0029/2019
Regadenoson	Rapiscan	PM	Cardiovascular Diseases	GE Healthcare AS	29/01/2019	P/0030/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PCDO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Empagliflozin	Jardiance	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Boehringer Ingelheim International GmbH	11/02/2019	P/0031/2019
Fibroblast activation protein alpha-targeted interleukin 2 variant immunocytokine		W	Oncology	Roche Registration GmbH	29/01/2019	P/0032/2019
Amantadine (hydrochloride)		W	Neurology	Adamas Pharmaceuticals LLC	29/01/2019	P/0033/2019
Azilsartan medoxomil	Edarbi	PM	Cardiovascular Diseases	Takeda Development Centre (Europe) Ltd.	29/01/2019	P/0034/2019
Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800)	IZINOVA (and associated names)	PM		IPSEN Pharma	29/01/2019	P/0035/2019
Semaglutide	Ozempic	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	29/01/2019	P/0036/2019
Binimetinib	Mektovi	W	Oncology	PIERRE FABRE MEDICAMENT	29/01/2019	P/0037/2019
Givosiran		W	Endocrinology- Gynaecology- Fertility-Metabolism	Alynlam UK Limited	29/01/2019	P/0038/2019
Rilpivirine	Edurant	P	Infectious Diseases	Janssen-Cilag International N.V.	29/01/2019	P/0039/2019
Fostemsavir (tromethamine)		PM	Infectious Diseases	ViiV Healthcare UK Ltd	29/01/2019	P/0040/2019
Ianalumab		P	Gastroenterology- Hepatology	Novartis Europharm Limited	29/01/2019	P/0041/2019
Etripamil		P	Cardiovascular Diseases	Milestone Pharmaceuticals Inc.	29/01/2019	P/0042/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein (RO7239361)		PM	Neurology	Roche Registration GmbH	29/01/2019	P/0043/2019
Pexidartinib		W	Oncology	Daiichi Sankyo Inc	29/01/2019	P/0044/2019
Filgotinib		P	Gastroenterology- Hepatology	Gilead Sciences International Ltd.	29/01/2019	P/0045/2019
Turoctocog alfa pegol		W	Haematology- Hemostaseology	Novo Nordisk A/S	29/01/2019	P/0046/2019
Rifamycin		W		CRINOS S.P.A.	29/01/2019	P/0047/2019
Ramipril / atorvastatin / amlodipine		W	Cardiovascular Diseases	Midas Pharma GmbH	29/01/2019	P/0048/2019
Encorafenib	Braftovi	W	Oncology	PIERRE FABRE MEDICAMENT	29/01/2019	P/0049/2019
Ozanimod		P	Gastroenterology- Hepatology	Celgene Europe Limited	29/01/2019	P/0050/2019
Human ciliary neurotrophic factor		W	Ophthalmology	Neurotech Pharmaceuticals Inc	29/01/2019	P/0051/2019
Technetium (99mTc) trofolostat chloride		W	Oncology	ROTOP Pharmaka GmbH	29/01/2019	P/0052/2019
Dienogest / ethinyl estradiol (LPRI-424)		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Exeltis France S.A.	29/01/2019	P/0053/2019
Rilpivirine / dolutegravir	Juluca	PM	Infectious Diseases	ViiV Healthcare UK Limited	11/02/2019	P/0054/2019
Gadopiclesol		PM	Diagnostic	GUERBET	11/02/2019	P/0055/2019
Naloxegol	Moventig	PM	Gastroenterology- Hepatology	Kyowa Kirin Pharmaceutical Development Limited	11/02/2019	P/0056/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)		PM	Vaccines	Seqirus Netherlands B.V.	25/02/2019	P/0057/2019
Pretomanid		P	Infectious Diseases	Global Alliance for TB Drug Development	26/02/2019	P/0058/2019
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	28/02/2019	P/0059/2019
Crizanlizumab		PM	Haematology-Hemostaseology	Novartis Europharm Limited	28/02/2019	P/0060/2019
Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody		PM	Neurology	CHUGAI PHARMA EUROPE LTD.	08/03/2019	P/0061/2019
Acalabrutinib		PM	Oncology	Acerta Pharma, BV	15/03/2019	P/0062/2019
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	22/03/2019	P/0063/2019
Rituximab	MabThera	PM	Oncology	Roche Registration GmbH	22/03/2019	P/0064/2019
Dabrafenib (mesilate)	Tafinlar	PM	Oncology	Novartis Europharm Limited	22/03/2019	P/0065/2019
Lefamulin		PM	Infectious Diseases	Nabriva Therapeutics AG	22/03/2019	P/0066/2019
Peginterferon beta-1a	Plegridy	PM	Neurology	Biogen Idec Ltd	22/03/2019	P/0067/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Upadacitinib (ABT-494)		PM	Gastroenterology- Hepatology Immunology- Rheumatology- Transplantation	AbbVie Ltd	22/03/2019	P/0068/2019
Upadacitinib (ABT-494)		PM	Gastroenterology- Hepatology Immunology- Rheumatology- Transplantation	AbbVie Ltd	22/03/2019	P/0069/2019
Eltrombopag	Revolade	W	Haematology- Hemostaseology	Novartis Europharm limited	22/03/2019	P/0070/2019
Tofacitinib	Xeljanz	PM	Gastroenterology- Hepatology	Pfizer Limited	22/03/2019	P/0071/2019
Carotuximab		PM	Oncology	TRACON Pharma International Limited	22/03/2019	P/0072/2019
Avalglucosidase alfa		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Genzyme Europe B.V.	22/03/2019	P/0073/2019
Autologous cartilage derived cultured chondrocytes		PM	Other	TETEC AG	22/03/2019	P/0074/2019
N-benzyl-2-(5-(4-(2-morpholinoethoxy)phenyl)pyridin-2-yl) acetamide (KX2-391)		W	Dermatology	Almirall S.A.	22/03/2019	P/0075/2019
Trametinib (dimethyl sulfoxide)	Mekinist	PM	Oncology	Novartis Europharm Limited	22/03/2019	P/0076/2019
Ambrisentan	Volibris	PM	Cardiovascular Diseases	Glaxo Group Limited	22/03/2019	P/0077/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Genetically modified Mycobacterium bovis BCG		W	Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	22/03/2019	P/0078/2019
Rosuvastatin (calcium) / Amlodipine (besylate)		W	Cardiovascular Diseases	Abbott Laboratories Limited	22/03/2019	P/0079/2019
Apremilast	Otezla	PM	Immunology- Rheumatology- Transplantation	Celgene Europe B.V.	22/03/2019	P/0080/2019
3-({5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl}methyl)-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridin-2-one) (JNJ-53718678)		PM	Infectious Diseases	Janssen-Cilag International NV	22/03/2019	P/0081/2019
Empagliflozin	Jardiance	W	Uro-nephrology	Boehringer Ingelheim International GmbH	22/03/2019	P/0082/2019
Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis		RPM	Oto-rhino-laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0083/2019
Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis		RPM	Oto-rhino-laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0084/2019
Chemically modified extract of trees pollen from birch and alder		RPM	Oto-rhino-laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0085/2019
Chemically modified extract of trees pollen from birch and alder		RPM	Oto-rhino-laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0086/2019
Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae		RPM	Oto-rhino-laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0087/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4)		P	Vaccines	Sanofi Pasteur	22/03/2019	P/0088/2019
Spartalizumab		P	Oncology	Novartis Europharm Limited	22/03/2019	P/0089/2019
ivacaftor / tezacaftor/ potassium (benzenesulfonyl){[6-(3-{2-[1-(trifluoromethyl)cyclopropyl]ethoxy}-1H-pyrazol-1-yl)-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridin-3-yl]carbonyl}azanide (VX-659)		P	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd	22/03/2019	P/0090/2019
N-(1,3-dimethyl-1H-pyrazole-4-sulfonyl)-6-[3-(3,3,3-trifluoro-2,2-dimethylpropoxy)-1H-pyrazol-1-yl]-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridine-3-carboxamide (VX-445) / tezacaftor / ivacaftor		P	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd	22/03/2019	P/0091/2019
Isoflurane		P	Neonatology - Paediatric Intensive Care	Sedana Medical AB	22/03/2019	P/0092/2019
1-[[[(2S,3S)-2-carboxylato-3-methyl-4,4,7-trioxo-4-{6}-thia-1-azabi-cyclo[3.2.0]heptan-3-yl]methyl]-3-methyl-1H-1,2,3-triazol-3-ium (AAI101)		P	Infectious Diseases	Allegra Therapeutics GmbH	22/03/2019	P/0093/2019
Molgramostim		P	Pneumology - Allergology	Savara ApS	22/03/2019	P/0094/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
(6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid (lenabasum)		P	Immunology- Rheumatology- Transplantation	Corbus Pharmaceuticals Holdings Inc	22/03/2019	P/0095/2019
Ustekinumab	Stelara	PM	Gastroenterology- Hepatology	Janssen-Cilag International NV	22/03/2019	P/0096/2019
Alogliptin	Vipidia	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Takeda Development Centre Europe Ltd	22/03/2019	P/0097/2019
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) (rLP2086)		PM	Vaccines	Pfizer Europe MA EEIG	22/03/2019	P/0098/2019
Pyrimidinyl-aminopyridine dual leucine zipper kinase inhibitor (GDC-0134)		RW	Neurology	Roche Registration GmbH	22/03/2019	P/0099/2019
Isavuconazonium (sulfate)	Cresemba	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	22/03/2019	P/0100/2019
Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae)		RPM	Oto-rhino- laryngology	Granzer Regulatory Consulting & Services	22/03/2019	P/0101/2019
Dihomo- $\gamma$ -linolenic acid (DS107)		P	Dermatology	DS Biopharma Ltd.	22/03/2019	P/0102/2019
Upadacitinib		W	Immunology- Rheumatology- Transplantation	AbbVie Ltd	25/03/2019	P/0103/2019
Tralokinumab		PM	Dermatology	LEO Pharma A/S	25/03/2019	P/0104/2019
(R)-azasetron (besylate) (SENS-401)		P	Oto-rhino- laryngology	Sensorion SA	22/03/2019	P/0105/2019



Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Mavacamten		P	Cardiovascular Diseases	MyoKardia, Inc.	22/03/2019	P/0106/2019
Erenumab	Aimovig	PM	Neurology	Novartis Europharm Limited	22/03/2019	P/0107/2019
Relugolix / estradiol / norethisterone acetate		W	Endocrinology- Gynaecology- Fertility-Metabolism	Myovant Sciences Ireland Limited	22/03/2019	P/0108/2019
Ridinilazole		P	Infectious Diseases	Summit (Oxford) Limited	22/03/2019	P/0109/2019
N-hydroxy-5-methylfuran-2-sulfonamide (BMS-986231)		P	Cardiovascular Diseases	Bristol-Myers Squibb International Corporation	22/03/2019	P/0110/2019
Galcanezumab	Emgality	PM	Neurology	Eli Lilly and Company Limited	22/03/2019	P/0111/2019
Olaratumab	Lartruvo	W	Oncology	Eli Lilly and Company Limited	22/03/2019	P/0112/2019
Chemically modified recombinant human sulfamidase		P	Endocrinology- Gynaecology- Fertility-Metabolism	Swedish Orphan Biovitrum AB (publ)	29/03/2019	P/0113/2019
Peanut flour		PM	Pneumology - Allergology	Aimmune Therapeutics Inc	29/03/2019	P/0114/2019
Aflibercept	Eylea	P	Ophthalmology	Bayer AG	04/04/2019	P/0115/2019
Monovalent, live, recombinant, replication-incompetent adenoviral serotype 26 vectored vaccine expressing the full length glycoprotein of the Ebola virus Mayinga variant [Ad26.ZEBOV]		P	Infectious Diseases	Janssen Cilag International N.V.	28/03/2019	P/0116/2019

Active substance(s)	Invented Name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara vectored vaccine, expressing the EBOV Mayinga glycoprotein, the Sudan virus Gulu GP, the Marburg virus Musoke GP, and the Tai Forest virus nucleoprotein [MVA-BN-Filo]		P	Infectious Diseases	Janssen Cilag International N.V.	28/03/2019	P/0117/2019
Cenegermin	Oxervate	W	Ophthalmology	Dompé farmaceutici S.p.A.	17/04/2019	P/0118/2019
Orvepitant		W	Pneumology - Allergology	NeRRe Therapeutics Ltd	17/04/2019	P/0119/2019
Rosuvastatin (calcium) / fenofibrate		W	Cardiovascular Diseases	Mylan Healthcare GmbH	17/04/2019	P/0120/2019
Etravirine	Intelence	PM	Infectious Diseases	Janssen-Cilag International NV	17/04/2019	P/0121/2019
Ofatumumab		P	Neurology	Novartis Europharm Limited	05/06/2019	P/0122/2019
Selexipag	Uptravi	PM	Other	Janssen Cilag International NV	17/04/2019	P/0123/2019
Abemaciclib	Verzenios	P	Oncology	Eli Lilly and Company Limited	17/04/2019	P/0124/2019
Delafloxacin		P	Infectious Diseases	A. Menarini - Industrie Farmaceutiche Riunite - s.r.l.	17/04/2019	P/0125/2019
Rivaroxaban	Xarelto	PM	Cardiovascular Diseases	Bayer AG	17/04/2019	P/0126/2019
177Lu-PSMA-617		W	Oncology	Succurro Clinical Research Limited	17/04/2019	P/0127/2019
Glecaprevir / pibrentasvir	Maviret	PM	Infectious Diseases	AbbVie Ltd	17/04/2019	P/0128/2019
Inebilizumab		PM	Neurology	Viela Bio	17/04/2019	P/0129/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Luspatercept		PM	Haematology- Hemostaseology	Celgene Europe B.V.	17/04/2019	P/0130/2019
Oritavancin diphosphate	Orbactiv	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	17/04/2019	P/0131/2019
N2'-Deacetyl-N2'-[4-methyl-4-(oxobutyldithio)-1-oxopentyl]-maytansine-hu769_4D4 Antibody		W	Oncology	Sanofi-Aventis Recherche & Développement	17/04/2019	P/0132/2019
Tenofovir alafenamide (as fumarate)	Vemlidy	PM	Infectious Diseases	Gilead Sciences International Ltd.	17/04/2019	P/0133/2019
Tofacitinib	Xeljanz	PM	Immunology- Rheumatology- Transplantation	Pfizer Limited	17/04/2019	P/0134/2019
Serlopitant		W	Dermatology	Menlo Therapeutics Inc.	17/04/2019	P/0135/2019
Recombinant parathyroid hormone	Natpar	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Shire Pharmaceuticals Ireland Limited	17/04/2019	P/0136/2019
Migalastat (hydrochloride)	Galafold	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Amicus Therapeutics UK Limited	17/04/2019	P/0137/2019
L-asparaginase		W	Oncology	ERYTECH Pharma S.A.	17/04/2019	P/0138/2019
Nonacog beta pegol	Refixia	PM	Haematology- Hemostaseology	Novo Nordisk A/S	17/04/2019	P/0139/2019
Rivoceranib (mesylate)		W	Oncology	LSK BioPharma Limited	17/04/2019	P/0140/2019
Ertugliflozin	Steglatro	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	17/04/2019	P/0141/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Tislelizumab		W	Oncology	Celgene Europe B.V.	17/04/2019	P/0142/2019
Corifollitropin alfa		PM		Merck Sharp & Dohme B.V.	17/04/2019	P/0143/2019
Secukinumab	Cosentyx	W	Immunology- Rheumatology- Transplantation	Novartis Europharm Limited	17/04/2019	P/0144/2019
Gadopiclenol		P	Diagnostic	GUERBET	17/04/2019	P/0145/2019
Roxadustat		PM	Haematology- Hemostaseology	Astellas Pharma Europe B.V.	17/04/2019	P/0146/2019
Oteseconazole		P	Infectious Diseases	Mycovia Pharmaceuticals Inc	17/04/2019	P/0147/2019
Anti-IL-21 humanized immunoglobulin G1-kappa monoclonal antibody (BOS161721)		P	Immunology- Rheumatology- Transplantation	Boston Pharmaceuticals, Inc.	17/04/2019	P/0148/2019
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains (bb2121)		P	Oncology	Celgene Europe B.V.	17/04/2019	P/0149/2019
Nintedanib	Ofev Vargatef	P	Oncology Pneumology - Allergology	Boehringer Ingelheim International GmbH	17/04/2019	P/0150/2019
Idarucizumab	Praxbind	PM	Other	Boehringer Ingelheim international GmbH	17/04/2019	P/0151/2019
Voclosporin		P	Immunology- Rheumatology- Transplantation	Aurinia Pharmaceuticals Ltd.	17/04/2019	P/0152/2019
Ozanimod		P	Gastroenterology- Hepatology	Celgene Europe Limited	17/04/2019	P/0153/2019

Active substance(s)	Invented Name	PCDO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Ceftolozane / tazobactam	Zerbaxa	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	17/04/2019	P/0154/2019
Liposomal vinorelbine (tartrate)		P	Oncology	TLC Biopharmaceuticals B.V.	17/04/2019	P/0155/2019
Rogaratinib		W	Oncology	Bayer AG	17/04/2019	P/0156/2019
Fevipirant		PR	Pneumology - Allergology	Novartis EuroPharm Limited	17/04/2019	P/0157/2019
Regorafenib	Stivarga	PM	Oncology	Bayer AG	17/04/2019	P/0158/2019
Angiotensin II (LJPC-501)		PM	Cardiovascular Diseases	La Jolla Pharmaceutical II B.V.	15/04/2019	P/0159/2019
Finerenone		PM	Uro-nephrology	Bayer AG	17/04/2019	P/0160/2019
Inactivated patient's own (autologous) microorganism (Escherichia coli, Candida spp., Enterococcus spp., Streptococcus spp., Staphylococcus spp., Prevotella intermedia, Fusobacterium nucleatum and others)		W	Dermatology Oto-rhino-laryngology Pneumology - Allergology Uro-nephrology	SymbioVaccin GmbH	17/04/2019	P/0161/2019
Onasemnogenum abeparvovecum		PM	Neurology	AveXis Netherlands B.V.	17/04/2019	P/0162/2019
Quizartinib		PM	Oncology	Daiichi Sankyo Europe GmbH	26/04/2019	P/0163/2019
Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)		PM	Vaccines	Sanofi Pasteur	05/06/2019	P/0164/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Baricitinib	Olumiant	PM	Immunology- Rheumatology- Transplantation	Eli Lilly and Company Limited	15/05/2019	P/0165/2019
Fc- and CDR-modified humanised monoclonal antibody against C5		PM	Haematology- Hemostaseology	Alexion Europe SAS	15/05/2019	P/0166/2019
Niraparib	Zejula	W	Oncology	Janssen Research & Development	15/05/2019	P/0167/2019
Humanized antibody targeting B cell maturation antigen conjugated with maleimidocaproyl monomethyl auristatin F		W	Oncology	GlaxoSmithKline Trading Services	15/05/2019	P/0168/2019
Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)		PM	Vaccines	Sanofi Pasteur	11/10/2019	P/0169/2019
Mometasone (furoate monohydrate) / olopatadine (hydrochloride) (GSP 301 NS)		P	Oto-rhino- laryngology	Glenmark Pharmaceuticals Europe Ltd.	15/05/2019	P/0170/2019
Carfilzomib	Kyprolis	W	Haematology- Hemostaseology	Amgen Europe BV	15/05/2019	P/0171/2019
Omecamtiv mecarbil		PM	Cardiovascular Diseases	Amgen Europe B.V.	15/05/2019	P/0172/2019
Imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A)		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	15/05/2019	P/0173/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Adalimumab	Humira	PM	Dermatology Gastroenterology- Hepatology Immunology- Rheumatology- Transplantation Ophthalmology	AbbVie Limited	15/05/2019	P/0174/2019
Recombinant human lecithin cholesterol acyltransferase		W	Cardiovascular Diseases	AstraZeneca AB	15/05/2019	P/0175/2019
Asfotase alfa	Strensiq	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Alexion Europe SAS	15/05/2019	P/0176/2019
Dusquetide		P	Gastroenterology- Hepatology	Soligenix UK Limited	15/05/2019	P/0177/2019
Ustekinumab	Stelara	P	Immunology- Rheumatology- Transplantation	Janssen-Cilag International NV	15/05/2019	P/0178/2019
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993)	Trimbaw and associated names	P	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	15/05/2019	P/0179/2019
Ibandronic acid (in the form of ibandronate sodium monohydrate)		W	Other	Pharma Patent Kft.	15/05/2019	P/0180/2019
Efpeglenatide		P	Endocrinology- Gynaecology- Fertility-Metabolism	Sanofi-aventis recherche et développement	15/05/2019	P/0181/2019
Colecalciferol		W	Other	Pharma Patent Kft.	15/05/2019	P/0182/2019
Clarithromycin (in combination with pantoprazole + amoxicillin)		W	Other	Micro Labs GmbH	15/05/2019	P/0183/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Amoxicillin (in combination with pantoprazole + clarithromycin)		W	Other	Micro Labs GmbH	15/05/2019	P/0184/2019
Salbutamol sulfate / budesonide		RP	Pneumology - Allergology	AstraZeneca AB	15/05/2019	P/0185/2019
Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues (fitusiran)		P	Haematology- Hemostaseology	Genzyme Europe B.V.	15/05/2019	P/0186/2019
Candesartan / atorvastatin / amlodipine		W	Cardiovascular Diseases	Midas Pharma GmbH	15/05/2019	P/0187/2019
Pantoprazole (in combination with amoxicillin + clarithromycin)		W	Other	Micro Labs GmbH	15/05/2019	P/0188/2019
Deferiprone		PM	Haematology- Hemostaseology	Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) - Coordinator for DEEP Project (HEALTH-F4-2010-261483)	15/05/2019	P/0189/2019
Ruxolitinib (phosphate)	Jakavi	PM	Oncology	Novartis Europharm Limited	15/05/2019	P/0190/2019
N-(trans-3-(5-((R)-1-hydroxyethyl)-1,3,4-oxadiazol-2-yl) cyclobutyl)-3-phenylisoxazole-5-		P	Pneumology - Allergology	SFL Regulatory Services GmbH	17/05/2019	P/0191/2019
Seladelpar		W	Gastroenterology- Hepatology	CymaBay Ireland Limited	15/05/2019	P/0192/2019
Isatuximab		PM	Oncology	Sanofi-Aventis Recherche & Développement	13/05/2019	P/0193/2019



Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Gilteritinib (as fumarate)		PM	Haematology- Hemostaseology	Astellas Pharma Europe B.V.	15/05/2019	P/0194/2019
Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins	Xeomin Bocouture	PM	Neurology Ophthalmology	Merz Pharmaceuticals GmbH	15/05/2019	P/0195/2019
Macrogol 3350 / sodium ascorbate / sodium sulfate / ascorbic acid / sodium chloride / potassium chloride (NER1006)	Plenvu	PM	Gastroenterology- Hepatology	Norgine Limited	19/05/2019	P/0196/2019
Semaglutide		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk	06/12/2019	P/0197/2019
Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor (JCAR017, lisocabtagene maraleucel)		PM	Oncology	Celgene Europe B.V.	06/12/2019	P/0198/2019
Ravulizumab (ALXN1210)		PM	Haematology- Hemostaseology	Alexion Europe SAS	06/12/2019	P/0199/2019
Emiplacel		W	Other	Pluristem Ltd.	06/12/2019	P/0200/2019
Ibrutinib	Imbruvica	PM	Oncology	Janssen-Cilag International N.V.	06/12/2019	P/0201/2019
Abemaciclib	Verzenios	W	Oncology	Eli Lilly and Company Limited	06/12/2019	P/0202/2019
Palbociclib	Ibrance	PM	Oncology	Pfizer Europe MA EEIG	06/12/2019	P/0203/2019
Obeticholic acid	Ocaliva	PM	Gastroenterology- Hepatology	Intercept Pharma Ltd.	06/12/2019	P/0204/2019
Rilpivirine (hydrochloride)	Edurant	PM	Infectious Diseases	Janssen-Cilag International NV	06/12/2019	P/0205/2019
Daratumumab	Darzalex	PM	Oncology	Janssen-Cilag International NV	06/12/2019	P/0206/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Atezolizumab	Tecentriq	PM	Oncology	Roche Registration GmbH	06/12/2019	P/0207/2019
Glu-NH-CO-NH-Lys-(Ahx)-[N,N9-bis[2-hydroxy-5-(carboxyethyl) benzyl]ethylenediamine-N,N9-diacetic acid (PSMA11-HBED-CC)	HBED Trasis	W	Oncology	Trasis S.A.	06/12/2019	P/0208/2019
Lenvatinib	Lenvima Kisplyx	PM	Oncology	Eisai Europe Ltd	06/12/2019	P/0209/2019
Dexamethasone		RP	Ophthalmology	Ocular Therapeutix, Inc.	06/12/2019	P/0210/2019
Sutimlimab		W	Haematology-Hemostaseology	Bioverativ USA, Inc.	14/06/2019	P/0211/2019
Ramipril / bisoprolol		W	Cardiovascular Diseases	Midas Pharma GmbH	06/12/2019	P/0212/2019
Lentiviral vector containing the human ABCA4 gene (SAR422459)		P	Ophthalmology	Sanofi-Aventis Recherche & Développement	14/06/2019	P/0213/2019
Capivasertib		W	Oncology	AstraZeneca AB	06/12/2019	P/0214/2019
2-(2-(3-Butoxy-phenyl)-ethylamino)-N,N-dimethyl-acetamide hydrochloride		RW	Psychiatry	Newron Pharmaceuticals SpA	14/06/2019	P/0215/2019
Tisotumab vedotin		W	Oncology	Genmab A/S	06/12/2019	P/0216/2019
Perampanel	Fycompa	PM	Neurology	Eisai Europe Limited	06/12/2019	P/0217/2019
Adeno-associated viral vector serotype 5 containing a B domain deleted variant of human coagulation factor VIII gene (BMN 270)		P	Haematology-Hemostaseology	BioMarin International Limited	17/06/2019	P/0218/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) (RIV4)		PM	Vaccines	Sanofi Pasteur	17/06/2019	P/0219/2019
Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody		PM	Neurology	Roche Registration GmbH	17/06/2019	P/0220/2019
Terbinafine (hydrochloride)		PM	Dermatology	Polichem, S.A.	17/06/2019	P/0221/2019
5'-hydroxy-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-Pthiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-1-glycerol-3-thiophosphoryl-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thio-7-deazaguanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-Pthioadenylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-5'-hydroxy-2'-deoxythymidine docosodium salt (tilsotolimod or IMO-2125)		W	Oncology	Idera Pharmaceuticals Inc.	21/06/2019	P/0222/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	21/06/2019	P/0223/2019
Birch, hazel and alder pollen extracts		PM	Pneumology - Allergology	Allergy Therapeutics (UK) Ltd	07/05/2019	P/0224/2019
Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts 50% / 50%		PM	Pneumology - Allergology	Allergy Therapeutics (UK) Ltd	07/05/2019	P/0225/2019
Tedizolid (phosphate)	Sivextro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe) Inc.	07/05/2019	P/0226/2019
Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII		RP	Dermatology	Krystal Biotech, Inc.	08/07/2019	P/0227/2019
Moxetumomab pasudotox		W	Oncology	AstraZeneca AB	16/07/2019	P/0228/2019
Tropifexor		P	Gastroenterology- Hepatology	Novartis Europharm Limited	16/07/2019	P/0229/2019
Emricasan		P	Gastroenterology- Hepatology	Novartis Europharm Limited	16/07/2019	P/0230/2019
Diphtheria toxoid / tetanus toxoid / pertussis toxoid / pertussis filamentous haemagglutinin / pertactin		RP	Infectious Diseases	Vakzine Projekt Management GmbH	16/07/2019	P/0231/2019
Bempedoic acid / ezetimibe		W	Cardiovascular Diseases Other	Esperion Therapeutics, Inc.	16/07/2019	P/0232/2019
Bempedoic acid		W	Cardiovascular Diseases Other	Esperion Therapeutics, Inc.	16/07/2019	P/0233/2019
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human $\beta$ T87Q-globin gene (LentiGlobin BB305)		P	Haematology- Hemostaseology	bluebird bio France	16/07/2019	P/0234/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Afatinib	Giotrif	PM	Oncology	Boehringer Ingelheim International GmbH	16/07/2019	P/0235/2019
Testosterone		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Acerus Biopharma Inc.	16/07/2019	P/0236/2019
Fentanyl (hydrochloride)		PM	Pain	Incline Therapeutics Europe Ltd.	16/07/2019	P/0237/2019
Esketamine (hydrochloride)		PM	Psychiatry	Janssen-Cilag International NV	16/07/2019	P/0238/2019
Baricitinib	Olumiant	PM	Dermatology	Eli Lilly and Company Limited	16/07/2019	P/0239/2019
Concentrate of proteolytic enzymes in bromelain	NexoBrid	PM	Other	MediWound Germany GmbH	16/07/2019	P/0240/2019
Bemarituzumab		W	Oncology	Five Prime Therapeutics, Inc.	17/07/2019	P/0241/2019
Dexamethasone (sodium phosphate) / levofloxacin		RP	Oto-rhino- laryngology	NTC srl	17/07/2019	P/0242/2019
(2S,4R)-1-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromopyridin-2-yl)-4-fluoropyrrolidine-2-carboxamide (ACH-0144471)		P	Uro-nephrology	Achillion Pharmaceuticals, Inc.	17/07/2019	P/0243/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Pneumococcal polysaccharide serotype 1 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 4 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 5 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6B – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 9V – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 14 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 18C – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 19F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 23F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate (15-valent pneumococcal polysaccharide conjugate vaccine [V114])		PM	Vaccines	Merck Sharp & Dohme (Europe), Inc.	17/07/2019	P/0244/2019
Tremelimumab		PM	Oncology	AstraZeneca AB	17/07/2019	P/0245/2019
Venetoclax	Venclyxto	PM	Haematology-Hemostaseology	AbbVie Ltd	17/07/2019	P/0246/2019
Balovaptan		PM	Neurology	Roche Registration GmbH	16/07/2019	P/0247/2019
Galcanezumab	Emgality	PM	Neurology	Eli Lilly and Company Limited	16/07/2019	P/0248/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Momelotinib		W	Oncology	Sierra Oncology Inc.	17/07/2019	P/0249/2019
1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropanecarboxamide (VX-661) / ivacaftor	Symkevi	PM	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	17/07/2019	P/0250/2019
Eravacycline	Xerava	PM	Infectious Diseases	Tetraphase Pharmaceuticals, Inc.	16/07/2019	P/0251/2019
Eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	16/07/2019	P/0252/2019
Tocilizumab	RoActemra	PM	Immunology- Rheumatology- Transplantation	Roche Registration GmbH	16/07/2019	P/0253/2019
Bisoprolol fumarate / ramipril		W	Cardiovascular Diseases	Neopharmed Gentili S.p.A.	17/07/2019	P/0254/2019
Brimonidine		RP	Ophthalmology	Bausch Health Ireland Limited	16/07/2019	P/0255/2019
Durvalumab		PM	Oncology	AstraZeneca AB	16/07/2019	P/0256/2019
Heparin (sodium)		W	Cardiovascular Diseases	B. Braun Melsungen AG	16/07/2019	P/0257/2019
Lonafarnib		P	Other	Eiger BioPharmaceuticals Europe Limited	16/07/2019	P/0258/2019
Rosuvastatin (calcium) / ezetimibe		W	Cardiovascular Diseases	Abbott Laboratories Limited	29/07/2019	P/0259/2019
Belatacept	Nulojix	PM	Immunology- Rheumatology- Transplantation	Bristol-Myers Squibb Pharma EEIG	16/07/2019	P/0260/2019
Ixazomib	Ninlaro	PM	Oncology	Takeda Pharm A/S	16/07/2019	P/0261/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
6-cyclopropaneamido-4-{[2-methoxy-3-(1-methyl-1H-1,2,4 triazol-3-yl)phenyl]amino}-N-(2H3)methylpyridazine-3-carboxamide (BMS-986165)		P	Dermatology	Bristol-Myers Squibb International Corporation	19/07/2019	P/0262/2019
Tezepelumab		PM	Pneumology - Allergology	AstraZeneca AB	19/07/2019	P/0263/2019
Human normal immunoglobulin		PM	Immunology- Rheumatology- Transplantation	Grifols Therapeutics LLC	23/07/2019	P/0264/2019
Lanadelumab (DX-2930)	Takhzyro	PM	Other	Shire Pharmaceuticals Ireland Limited	23/07/2019	P/0265/2019
BLU-667		W	Oncology	Blueprint Medicines (Netherlands) B.V.	26/07/2019	P/0266/2019
Fosnetupitant / palonosetron	Akynzeo	PM	Other	Helsinn Birex Pharmaceuticals Limited	25/07/2019	P/0267/2019
Hydrogen Peroxide (45%)		RP	Dermatology	Aclaris Therapeutics Inc.	25/07/2019	P/0268/2019
Octenidine (dihydrochloride)	Laryngomedin Octenidin Antisept and associated names	PM	Oto-rhino-laryngology	Cassella-med GmbH & Co. KG	14/08/2019	P/0269/2019
Istradefylline		W	Neurology	Kyowa Kirin Limited	14/08/2019	P/0270/2019
Delamanid	Deltyba	PM	Infectious Diseases	Otsuka Pharmaceutical Development & Commercialisation Europe GmbH	14/08/2019	P/0271/2019



<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Eslicarbazepine (acetate)	Zebinix	PM	Neurology	BIAL - Portela & Ca, SA	14/08/2019	P/0272/2019
Oxalobacter formigenes Strain HC-1		P	Endocrinology- Gynaecology- Fertility-Metabolism Uro-nephrology	OxThera AB	14/08/2019	P/0273/2019
Humanized anti-CD19, Fc engineered, monoclonal antibody (XmAb5871)		P	Immunology- Rheumatology- Transplantation	Xencor, Inc.	16/08/2019	P/0274/2019
Human immunoglobulin (Ig) G4-variant monoclonal antibody that binds and neutralizes soluble human		P	Dermatology	Eli Lilly and Company	16/08/2019	P/0275/2019
Vedolizumab	Entyvio	P	Gastroenterology- Hepatology Immunology- Rheumatology- Transplantation	Takeda Pharma A/S	14/08/2019	P/0276/2019
Saxagliptin	Onglyza	PM	Endocrinology- Gynaecology- Fertility-Metabolism	AstraZeneca AB	16/08/2019	P/0277/2019
Relugolix / estradiol / norethisterone acetate		RP	Endocrinology- Gynaecology- Fertility-Metabolism	Myovant Sciences Ireland Limited	16/08/2019	P/0278/2019
Selumetinib		PM	Oncology	AstraZeneca AB	16/08/2019	P/0279/2019
Ixekizumab	Taltz	PM	Immunology- Rheumatology- Transplantation	Eli Lilly Nederland B.V.	16/08/2019	P/0280/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Botulinum toxin type A		W	Dermatology	Allergan Pharmaceuticals International Limited	16/08/2019	P/0281/2019
Bosutinib	Bosulif	PM	Oncology	Pfizer Europe MA EEIG	14/08/2019	P/0282/2019
Human chorionic gonadotrophin		W	Endocrinology- Gynaecology- Fertility-Metabolism	Regulis Consulting Europe Ltd	16/08/2019	P/0283/2019
Reslizumab	Cinqaero	PM	Pneumology - Allergology	Teva Pharmaceuticals Europe	30/09/2019	P/0284/2019
Fluciclovine (18F)	Axumin	PM	Diagnostic Oncology	Blue Earth Diagnostics Ireland Ltd	16/08/2019	P/0285/2019
Eteplirsen		PM	Neurology	Sarepta Therapeutics Ireland Limited	16/08/2019	P/0286/2019
Recombinant human monoclonal antibody to GM-CSF (GSK3196165)		PM	Immunology- Rheumatology- Transplantation	GlaxoSmithKline Trading Services Limited	16/08/2019	P/0287/2019
Anti-neonatal Fc receptor human monoclonal antibody		W	Other	Momenta Pharmaceuticals, Inc.	16/08/2019	P/0288/2019
EGFR-cMET bispecific antibody		W	Oncology	Janssen-Cilag International N.V.	16/08/2019	P/0289/2019
Gallium 68-labelled Prostate-Specific Membrane Antigen-11 (68Ga-PSMA-11)		W	Diagnostic Oncology	Endocyte, Inc.	16/08/2019	P/0290/2019
Lasmiditan		PM	Neurology	Eli Lilly and Company Limited	14/08/2019	P/0291/2019
Daunorubicin / cytarabine	Vyxeos	PM	Oncology	Jazz Pharmaceuticals Ireland Limited	14/08/2019	P/0292/2019
Ciclosporin		W	Ophthalmology	Sun Pharmaceutical Industries Europe BV	14/08/2019	P/0293/2019
Tafasitamab		W	Oncology	MorphoSys AG	16/08/2019	P/0294/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Mifepristone		W	Endocrinology- Gynaecology- Fertility-Metabolism	Laboratorios Litaphar S.L.	14/08/2019	P/0295/2019
Bulevirtide		P	Infectious Diseases	MYR GmbH	26/08/2019	P/0296/2019
Brivaracetam	Briviact and associated names	PM	Neurology	UCB Pharma S.A.	08/12/2019	P/0297/2019
Bempegaldesleukin		P	Oncology	Nektar Therapeutics	14/08/2019	P/0298/2019
Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) like strain used (NIBRG-14) Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used (PR8-IBCDC-RG2)	Adjuvanrix Prepandrix	PM	Vaccines	GlaxoSmithKline Biologicals SA	14/08/2019	P/0299/2019
Baloxavir marboxil		P	Infectious Diseases	Roche Registration GmbH	02/09/2019	P/0300/2019
Infigratinib		W	Oncology	QED THERAPEUTICS	10/09/2019	P/0301/2019
Levonorgestrel		P	Endocrinology- Gynaecology- Fertility-Metabolism	Chemo Research, S.L.	10/09/2019	P/0302/2019
Dostarlimab		P	Oncology	GlaxoSmithKline (Ireland) Limited	10/09/2019	P/0303/2019
Equine Immunoglobulin F(ab') <sub>2</sub> fragments targeting Shiga toxin (NEAST)		P	Infectious Diseases	Chemo Research, S.L.	10/09/2019	P/0304/2019
Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897)		PM	Infectious Diseases	AstraZeneca AB	10/09/2019	P/0305/2019
Cobimetinib	Cotellic	PM	Oncology	Roche Registration GmbH	10/09/2019	P/0306/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Botulinum toxin type A		W	Cardiovascular Diseases	Allergan Pharmaceutical International Limited	10/09/2019	P/0307/2019
Zofenopril / nebivolol		W	Cardiovascular Diseases	Menarini Ricerche SpA	10/09/2019	P/0308/2019
Atropine (sulfate) / obidoxime (chloride)		W	Other	Emergent Netherlands B.V.	10/09/2019	P/0309/2019
Recombinant adeno-associated viral vector serotype 2 carrying the gene for the human aromatic L-amino acid decarboxylase protein		P	Neurology	PTC Therapeutic International Limited	10/09/2019	P/0310/2019
Tirzepatide		P	Endocrinology- Gynaecology- Fertility-Metabolism	Ely Lilly and Company	10/09/2019	P/0311/2019
Liposomal ciclosporin A (L-CsA)		P	Immunology- Rheumatology- Transplantation	Breath Therapeutics GmbH	11/09/2019	P/0312/2019
Niraparib (tosylate monohydrate)	Zejula	P	Oncology	GlaxoSmithKline (Ireland) Limited	10/09/2019	P/0313/2019
Eptinezumab		P	Neurology	Alder BioPharmaceuticals Limited	11/09/2019	P/0314/2019
Onasemnogene abeparvovec		PM	Neurology	AveXis EU Ltd	11/09/2019	P/0315/2019
Odevixibat		PM	Gastroenterology- Hepatology	Albireo AB	11/09/2019	P/0316/2019
Fosmetpantotenat		P	Neurology	Retrophin Europe Limited	11/09/2019	P/0317/2019
Larotrectinib		PM	Oncology	Bayer AG	11/09/2019	P/0318/2019
Dolutegravir (DTG) / lamivudine (3TC)	Dovato	PM	Infectious Diseases	ViiV Healthcare BV	11/09/2019	P/0319/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Pegvorhialuronidase alfa		P	Oncology	Halozyme Inc	11/09/2019	P/0320/2019
Liquid ethanolic extract 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L.		PM	Dermatology	Legacy Healthcare	10/09/2019	P/0321/2019
Upadacitinib		PM	Immunology- Rheumatology- Transplantation	AbbVie Ltd	11/09/2019	P/0322/2019
Tisagenlecleucel	Kymriah	PM	Oncology	Novartis Europharm Limited	11/09/2019	P/0323/2019
Finerenone		PM	Uro-nephrology	Bayer AG	10/09/2019	P/0324/2019
Trifarotene (CD5789)		P	Dermatology	Premier Research Group SLU	11/09/2019	P/0325/2019
Semaglutide	Ozempic	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	10/09/2019	P/0326/2019
Etrolizumab		PM	Gastroenterology- Hepatology	Roche Registration GmbH	11/09/2019	P/0327/2019
Dermatophagoides pteronyssinus / dermatophagoides farinae	ACARIZAX and associated names	PM	Pneumology - Allergology	ALK-Abelló A/S	11/09/2019	P/0328/2019
Lonococog alfa	Afstyla	PM	Haematology- Hemostaseology	CSL Behring GmbH	10/09/2019	P/0329/2019
Ferric maltol	Feraccru	PM	Haematology- Hemostaseology	Norgine BV	11/09/2019	P/0330/2019
Cabozantinib	Cometriq	PM	Oncology	Ipsen Pharma	11/09/2019	P/0331/2019
Lomitapide	Lojuxta	PM	Other	Amryt Pharmaceuticals DAC	10/09/2019	P/0332/2019
Pazopanib	Votrient	PM	Oncology	Novartis Europharm Limited	11/09/2019	P/0333/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Recombinant <i>Neisseria meningitidis</i> group B NHBA fusion protein / recombinant <i>Neisseria meningitidis</i> group B NadA protein / recombinant <i>Neisseria meningitidis</i> group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from <i>Neisseria meningitidis</i> group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4	Bexsero	PM	Vaccines	GSK Vaccines S.r.l.	11/09/2019	P/0334/2019
Ataluren	Translarna	PM	Neurology	PTC Therapeutics International, Limited	11/09/2019	P/0335/2019
PEGylated-fibroblast growth factor 21 (BMS-986036)		P	Gastroenterology-Hepatology	Bristol-Myers Squibb International Corporation	10/09/2019	P/0336/2019
Pretomanid		PM	Infectious Diseases	Global Alliance for TB Drug Development	10/09/2019	P/0337/2019
Birch bark extract		P	Dermatology	Amryt Research Limited	11/09/2019	P/0338/2019
Human fibrinogen / human thrombin	Evicel Evarrest	PM	Other	Omrix Biopharmaceuticals N.V.	10/09/2019	P/0339/2019
Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) / influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage)		W	Vaccines	Adimmune Corporation	10/09/2019	P/0340/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Fevipiprant		PM	Pneumology - Allergology	Novartis EuroPharm Limited	10/09/2019	P/0341/2019
Recombinant Hepatitis B Vaccine		RW	Vaccines	VBI Vaccines Inc.	10/09/2019	P/0342/2019
Rosuvastatin / Ramipril		W	Cardiovascular Diseases	Egis Pharmaceuticals PLC	11/09/2019	P/0343/2019
Sacubitril/valsartan	Entresto	PM	Cardiovascular Diseases	Novartis Europharm Ltd.	11/09/2019	P/0344/2019
Empagliflozin	Jardiance	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Boehringer Ingelheim International GmbH	11/09/2019	P/0345/2019
Fexapotide (triflutate)		W	Uro-nephrology	FGK Representative Service GmbH	11/09/2019	P/0346/2019
Belantamab mafodotin		W	Oncology	GlaxoSmithKline Trading Services Limited	11/09/2019	P/0347/2019
2-hydroxypropyl- $\beta$ -cyclodextrin (HP- $\beta$ -CD)		PM	Endocrinology- Gynaecology- Fertility-Metabolism	Mallinckrodt Pharmaceuticals Ireland Ltd	10/09/2019	P/0348/2019
Risdiplam		PM	Neurology	Roche Registration GmbH	16/09/2019	P/0349/2019
Mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	30/09/2019	P/0350/2019
Ecopipam (hydrochloride)		P	Psychiatry	Emalex Biosciences, Inc.	04/10/2019	P/0351/2019
Human fibrinogen		W	Haematology- Hemostaseology	Biotest AG	04/10/2019	P/0352/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Autologous human T cells genetically modified ex-vivo with a lentiviral vector encoding a chimeric antigen receptor (CAR) for B-cell maturation antigen (BCMA) (JNJ-68284528)		W	Oncology	Janssen-Cilag International N.V.	04/10/2019	P/0353/2019
7-(2-Methoxy-3,5-dimethylpyridin-4-yl)-1-[(3S)-tetrahydrofuran-3-yl]-1,5-dihydro-4H-pyrazolo[4,3-c]quinolin-4-one maleate		W	Neurology	Eisai Ltd	04/10/2019	P/0354/2019
Timolol (as timolol maleate) / bimatoprost		W	Ophthalmology	Laboratoires Théa	04/10/2019	P/0355/2019
Aprocitentan		W	Cardiovascular Diseases	Idorsia Pharmaceuticals Deutschland GmbH	04/10/2019	P/0356/2019
2-(3-(1-carboxy-5-[(6-[18F]fluoropyridine-3-carbonyl)-amino]-pentyl)-ureido)-pentanedioic acid		W	Oncology	Curium Netherlands BV	04/10/2019	P/0357/2019
Sitagliptin	Januvia (and associated names)	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	04/10/2019	P/0358/2019
Lurasidone (hydrochloride)	Latuda	PM	Psychiatry	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.	04/11/2019	P/0359/2019
Avacopan		RPM	Immunology-Rheumatology-Transplantation	ChemoCentryx Ireland Ltd.	04/11/2019	P/0360/2019
Ganaxolone		P	Neurology	Marinus Pharmaceuticals Inc.	04/11/2019	P/0361/2019
Letemovir	Prevymis	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	04/11/2019	P/0362/2019



<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Lubiprostone	Amitiza	PM	Gastroenterology- Hepatology	Sucampo AG	04/11/2019	P/0363/2019
Remimazolam (as besylate)		P	Anaesthesiology	PAION Deutschland GmbH	04/11/2019	P/0364/2019
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium bromide (CHF 5993)	Trimbow and associated names	PM	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	07/11/2019	P/0365/2019
Canakinumab	Ilaris	W	Immunology- Rheumatology- Transplantation	Novartis Europharm Limited	07/11/2019	P/0366/2019
Daclatasvir	Daklinza	W	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	08/11/2019	P/0367/2019
Sodium thiosulfate (STS)		PM	Oncology	Fennec Pharmaceuticals, Inc.	08/11/2019	P/0368/2019
Selpercatinib		P	Oncology	Eli Lilly and Company Limited	08/11/2019	P/0369/2019
Ambrisentan	Volibris	PM	Cardiovascular Diseases	Glaxo Group Limited	08/11/2019	P/0370/2019
Peginterferon beta-1a	Plegridy	PM	Neurology	Biogen Idec Ltd	14/11/2019	P/0371/2019
Influenza virus inactivated split virion (haemagglutinin and neuraminidase) of strain A (H1N1)/Influenza virus inactivated split virion (haemagglutinin and neuraminidase) of strain A (H3N2)/Influenza virus inactivated split virion (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ Influenza virus inactivated split virion (haemagglutinin and neuraminidase) of strain B (Yamagata lineage)		W	Vaccines	Seqirus GmbH	15/11/2019	P/0372/2019

<b>Active substance(s)</b>	<b>Invented Name</b>	<b>PDCO Opinion</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>Decision date</b>	<b>Decision Number</b>
Avatrombopag (maleate)	Doptelet	PM	Haematology- Hemostaseology	Dova Pharmaceuticals Ireland Limited	22/11/2019	P/0373/2019
Dupilumab	Dupixent	PM	Dermatology	Regeneron Pharmaceuticals, Inc	22/11/2019	P/0374/2019
Bimekizumab		PM	Dermatology	UCB Biopharma SPRL	04/12/2019	P/0375/2019
Abemaciclib	Verzenios	PM	Oncology	Eli Lilly and Company Limited	04/12/2019	P/0376/2019
Dalbavancin	Xydalba	PM	Infectious Diseases	Allergan Pharmaceuticals International Limited	04/12/2019	P/0377/2019
Rivogenlecleucel		PM	Immunology- Rheumatology- Transplantation	Bellicum Pharma Ltd	04/12/2019	P/0378/2019
Crizanlizumab		PM	Haematology- Hemostaseology	Novartis Europharm Limited	04/12/2019	P/0379/2019
Gefapixant (citrate)		W	Pneumology - Allergology	Merck Sharp & Dohme (Europe), Inc.	04/12/2019	P/0380/2019
Naloxegol	Moventig	PM	Gastroenterology- Hepatology	Kyowa Kirin Pharmaceutical Development Limited	04/12/2019	P/0381/2019
Chloroprocaine (hydrochloride)	Ampres	PM	Anaesthesiology	Sintetica GmbH	04/12/2019	P/0382/2019
Liraglutide	Saxenda	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Novo Nordisk A/S	04/12/2019	P/0383/2019
Ruxolitinib (phosphate)	Jakavi	PM	Oncology	Novartis Europharm Limited	04/12/2019	P/0384/2019
Loxapine	Adasuve	PM	Psychiatry	Ferrer Internacional, S.A.	04/12/2019	P/0385/2019
Pevonedistat		PM	Oncology	Takeda Pharma A/S	29/11/2019	P/0386/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains (bb2121)		PM	Oncology	Celgene Europe B.V.	04/12/2019	P/0387/2019
Apremilast	Otezla	PM	Immunology- Rheumatology- Transplantation	Celgene Europe B.V.	04/12/2019	P/0388/2019
Apremilast	Otezla	PM	Immunology- Rheumatology- Transplantation	Celgene Europe B.V.	04/12/2019	P/0389/2019
Satoreotide trizoxetan		W	Diagnostic	Ipsen Pharma	04/12/2019	P/0390/2019
Rubidium (82Rb) chloride	Ruby-Fill (82Sr/82Rb Generator)	PM	Other	Jubilant DraxImage Inc.	04/12/2019	P/0391/2019
177Lu-Satoreotide tetraxetan		W	Oncology	Ipsen Pharma	04/12/2019	P/0392/2019
(3S,7S)-22-(3-(((2-((5-(2-Carboxyethyl)-2-hydroxybenzyl)(carboxymethyl)amino)ethyl)(carboxymethyl)amino)methyl)-4-hydroxyphenyl)-5,13,20-trioxo-4,6,12,19-tetraazadocosane-1,3,7-tricarboxylic acid (PSMA-11)		W	Diagnostic	Advanced Nuclear Medicine Ingredients (ANMI)	04/12/2019	P/0393/2019
Vonicog alfa	Veyvondi	PM	Haematology- Hemostaseology	Baxalta Innovations GmbH	04/12/2019	P/0394/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
A fully humanized immunoglobulin G4 proline, alanine, alanine (IgG4 PAA) based bispecific antibody directed against cluster of differentiation 3 (CD3) receptor complex and G Protein Coupled Receptor Family C Group 5 Member D (GPRC5D) (JNJ-64407564)		W	Oncology	Janssen-Cilag International N.V.	04/12/2019	P/0395/2019
Atazanavir (sulfate) / ritonavir		P	Infectious Diseases	Pharmaceutical Oriented Services Ltd	04/12/2019	P/0396/2019
Diclofenac (sodium) / Thiocolchicoside		W	Pain	WIN MEDICA S.A.	04/12/2019	P/0397/2019
Zanubrutinib		P	Oncology	BeiGene Ireland, Ltd	04/12/2019	P/0398/2019
Crizotinib	Xalkori	P	Oncology	Pfizer Europe MA EEIG	04/12/2019	P/0399/2019
OMS721 (narsoplimab)		P	Haematology- Hemostaseology	Omeros London Limited	04/12/2019	P/0400/2019
Larotrectinib	VITRAKVI	P	Oncology	Bayer AG	04/12/2019	P/0401/2019
3-[5-[(1R,2S)-2-(2,2-difluoropropanoylamino)-1-(2,3-dihydro-1,4-benzodioxin-6-yl)propoxy]indazol-1-yl]-N-[(3R)-tetrahydrofuran-3-yl]benzamide (AZD7594)		P	Pneumology - Allergology	AstraZeneca AB	20/12/2019	P/0402/2019
Marizomib		P	Oncology	Celgene Europe B.V.	04/12/2019	P/0403/2019
Volanesorsen	Waylivra	PM	Endocrinology- Gynaecology- Fertility-Metabolism	Akcea Therapeutics	04/12/2019	P/0404/2019
Iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (131I-omburtamab)		P	Oncology	Y-mAbs Therapeutics A/S	04/12/2019	P/0405/2019
Ivosidenib		RP	Oncology	Agios Pharmaceuticals, Inc.	04/12/2019	P/0406/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Hydrocortisone (hemisuccinate)		P	Neonatology - Paediatric Intensive Care	Laboratoire Aguettant	04/12/2019	P/0407/2019
Bilastine	Bilaxten and associated names	PM	Ophthalmology	Faes Farma S.A.	04/12/2019	P/0408/2019
Maralixibat chloride (LUM001)		PM	Gastroenterology- Hepatology	SFL Regulatory Services GmbH	06/12/2019	P/0409/2019
Teduglutide	Revestive	PM	Gastroenterology- Hepatology	Shire Pharmaceuticals Ireland Limited	06/12/2019	P/0410/2019
Fremanezumab	AJOVY	PM	Neurology	Teva GmbH	04/12/2019	P/0411/2019
Aciclovir	Sitavig and associated names	W	Dermatology	Vectans Pharma	04/12/2019	P/0412/2019
Sufentanil (citrate) / ketamine (hydrochloride)		P	Pain	Copenhagen University Hospital, Rigshospitalet	06/12/2019	P/0413/2019
Itacitinib		PM	Immunology- Rheumatology- Transplantation	Incyte Biosciences Distribution B.V	06/12/2019	P/0414/2019
Zanamivir	Relenza	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	04/12/2019	P/0415/2019
Sitravatinib (malate)		W	Oncology	Mirati Therapeutics, Inc.	04/12/2019	P/0416/2019
Loxoprofen (sodium hydrate)		W	Pain	Lead Chemical Co., Ltd	04/12/2019	P/0417/2019
Rimiducid		PM	Immunology- Rheumatology- Transplantation	Beliicum Pharma Ltd	06/12/2019	P/0418/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Eflornithine (hydrochloride monohydrate) / sulindac		RP	Oncology	Cancer Prevention Pharma (Ireland) Limited	06/12/2019	P/0419/2019
Iclaprim (mesylate)		P	Infectious Diseases	Motif Bio plc	04/12/2019	P/0420/2019
Ibrutinib	Imbruvica	PM	Immunology- Rheumatology- Transplantation	Janssen-Cilag International N.V.	06/12/2019	P/0421/2019
Phenobarbital		P	Neurology	Proveca Limited	06/12/2019	P/0422/2019
Artesunate		P	Infectious Diseases	ACE Pharmaceuticals BV	05/12/2019	P/0423/2019
Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues (fitusiran)		PM	Haematology- Hemostaseology	Genzyme Europe B.V.	04/12/2019	P/0424/2019
Mexiletine (hydrochloride)	Namuscla	PM	Other	Lupin Europe GmbH	04/12/2019	P/0425/2019
Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues (DCR-PHXC)		P	Uro-nephrology	Dicerna EU Limited	06/12/2019	P/0426/2019
Savolitinib		W	Oncology	AstraZeneca AB	04/12/2019	P/0427/2019
Duvelisib		W	Oncology	Verastem, Inc.	06/12/2019	P/0428/2019
Ezetimibe / atorvastatin		W	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc	06/12/2019	P/0429/2019
Brigatinib	Alunbrig	PM	Oncology	Takeda Pharm A/S	05/12/2019	P/0430/2019
Lumacaftor / ivacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Ltd	06/12/2019	P/0431/2019

Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Agomelatine	Valdoxan and associated names	PM	Psychiatry	Les Laboratoires Servier	06/12/2019	P/0432/2019
Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti CD19 CD28/CD3-zeta chimeric antigen receptor and cultured (KTE-X19)		W	Oncology	Kite Pharma EU B.V.	06/12/2019	P/0433/2019

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Pembrolizumab	Oncology	Merck Sharp & Dohme (Europe), Inc.	01/02/2019
Rabeprazole (sodium)	Gastroenterology-Hepatology	Eisai Ltd.	01/02/2019
Rituximab	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	01/02/2019
Conestat alfa	Other	Pharming Group N.V.	01/03/2019
Sebelipase alfa	Endocrinology-Gynaecology-Fertility-Metabolism / Gastroenterology-Hepatology	Alexion Europe SAS	01/03/2019
Denosumab	Oncology	Amgen Europe B.V.	01/03/2019
Beclometasone (dipropionate) / formoterol (fumarate dihydrate)	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	26/04/2019

<b>Active substance(s)</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>PDCO opinion date</b>
N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid	Vaccines	Pfizer Europe MA EEIG	26/04/2019
Sofosbuvir	Infectious Diseases	Gilead Sciences Ireland UC	26/04/2019
Sofosbuvir / ledipasvir	Infectious Diseases	Gilead Sciences Ireland UC	26/04/2019
Split influenza virus, inactivated containing antigen equivalent to A/ California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted (INN: Pandemic Influenza vaccine (H1N1) (split virion, inactivated))	Vaccines	Sanofi Pasteur SA	26/04/2019
Turoctocog alfa	Haematology-Hemostaseology	Novo Nordisk A/S	26/04/2019
Anidulafungin	Infectious Diseases	Pfizer Limited	26/04/2019
Emicizumab	Haematology-Hemostaseology	Roche Registration GmbH	26/04/2019
Peginterferon alfa-2a	Infectious Diseases	Roche Registration GmbH	29/05/2019
Efmoroctocog alfa	Haematology-Hemostaseology	Swedish Orphan Biovitrum AB (publ)	29/05/2019
Rituximab	Oncology	Roche Registration GmbH	29/05/2019
Ustekinumab	Immunology-Rheumatology-Transplantation / Dermatology	Janssen-Cilag International NV	29/05/2019
Etravirine	Infectious Diseases	Janssen-Cilag International NV	28/06/2019
Terbinafine (hydrochloride)	Dermatology	Polichem, S.A	26/07/2019
Dabigatran etexilate mesilate	Cardiovascular Diseases / Haematology-Hemostaseology	Boehringer Ingelheim International GmbH	23/08/2019
Caplacizumab	Haematology-Hemostaseology	ABLIX NV	23/08/2019
Atezolizumab	Oncology	Roche Registration GmbH	20/09/2019



Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Sildenafil citrate	Other	Pfizer Limited	20/09/2019
Tapentadol (hydrochloride)	Pain	Grünenthal GmbH	20/09/2019
Emtricitabine / tenofovir alafenamide	Infectious Diseases	Gilead Sciences International Ltd.	20/09/2019
Rivaroxaban	Cardiovascular Diseases	Bayer AG	20/09/2019
Sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21)	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma France	20/09/2019
Asfotase alfa	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe S.A.S.	18/10/2019
Decitabine	Oncology	Janssen-Cilag International NV	18/10/2019
Nonacog beta pegol	Haematology-Hemostaseology	Novo Nordisk A/S	15/11/2019
Recombinant Neisseria Meningitidis serogroup B NHBA fusion protein / recombinant Neisseria Meningitidis serogroup B NadA protein / recombinant Neisseria Meningitidis serogroup B fHbp fusion protein / Outer Membrane Vesicles (OMV) from Neisseria Meningitidis serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4	Vaccines	GSK Vaccines S.r.l.	15/11/2019
Potassium citrate monohydrated / potassium hydrogen carbonate	Uro-nephrology	ADVICENNE	15/11/2019
Ragweed pollen extract ( <i>Ambrosia artemisiifolia</i> )	Pneumology - Allergology	ALK Abelló A/S	15/11/2019
Glecaprevir / Pibrentasvir	Infectious Diseases	AbbVie Ltd	11/12/2019
Octenidine (dihydrochloride)	Oto-rhino-laryngology	Cassella-med GmbH & Co. KG	11/12/2019
Vestronidase alfa	Endocrinology-Gynaecology-Fertility-Metabolism	Ultragenyx Germany GmbH	11/12/2019
Lurasidone (hydrochloride)	Psychiatry	Aziende Chimiche Riunite Angelini Francesco -ACRAF S.p.A	11/12/2019
Sodium thiosulfate (STS)	Oncology / Oto-rhino-laryngology	Fennec Pharmaceuticals, Inc.	11/12/2019

## Annex 17 – Referral procedures overview 2019 – 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
Omega-3 acid ethyl esters – containing medicinal products for oral use in secondary prevention after myocardial infarction (various)	22/03/2018	28/03/2019 <sup>1</sup>	Article 31 of Directive 2001/83/EC
Septanest and associated names (articaine (hydrochloride)/ adrenaline (tartrate))	28/06/2018	28/03/2019	Article 30 of Directive 2001/83/EC
Bacterial lysates-containing medicinal products for respiratory conditions (Haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus mitis / streptococcus pneumoniae / streptococcus pyogenes, Haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes, Streptococcus pneumoniae / streptococcus agalactiae / staphylococcus aureus / haemophilus influenzae, Haemophilus influenzae / klebsiella ozaenae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes / streptococcus viridans, Haemophilus influenzae / membrane fraction of klebsiella pneumoniae / ribosomal fractions of klebsiella pneumoniae / streptococcus pneumoniae / streptococcus pyogenes, Escherichia Coli/ Klebsiella Pneumoniae / Staphylococcus Aureus / Staphylococcus Epidermidis / Streptococcus Salivarius / Streptococcus Pneumoniae/ Streptococcus Pyogenes / Haemophilus Influenzae / Corynebacterium Pseudodiphtheriticum / Moraxella Catarrhalis)	28/06/2018	27/06/2019	Article 31 of Directive 2001/83/EC
Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group (candesartan, irbesartan, losartan, olmesartan, valsartan)	16/07/2018	31/01/2019	Article 31 of Directive 2001/83/EC

<sup>1</sup> Opinion post re-examination

<b>Procedure name (international non-proprietary name (INN) or common name)</b>	<b>Start of procedure</b>	<b>End of procedure</b>	<b>Type of referral</b>
Syner-Kinase and associated names (urokinase)	26/07/2018	28/02/2019	Article 29(4) of Directive 2001/83/EC
Basiron AC and associated names (benzoyl peroxide)	15/11/2018	28/03/2019	Article 13 of Regulation (EC) No 1234/2008
Norethisterone and ethinylestradiol (norethisterone and ethinylestradiol)	13/12/2018	26/04/2019	Article 5(3) of Regulation (EC) No 726/2004
Direct Oral Anticoagulants (DOACs)	31/01/2019	ongoing	Article 5(3) of Regulation (EC) No 726/2004
Lartruvo (olaratumab)	31/01/2019	26/04/2019	Article 20 of Regulation (EC) No 726/2004
Methocarbamol/paracetamol-containing medicinal products (methocarbamol/paracetamol)	29/05/2019	ongoing	Article 31 of Directive 2001/83/EC
Flurbiprofen Geiser (flurbiprofen)	27/06/2019	17/10/2019	Article 29(4) of Directive 2001/83/EC
Nitrosamine impurities in human medicinal products containing chemically synthesised active pharmaceutical ingredients	19/09/2019	ongoing	Article 5(3) of Regulation (EC) No 726/2004
Ranitidine-containing medicinal products (ranitidine)	19/09/2019	ongoing	Article 31 of Directive 2001/83/EC
Budesonide SUN and associated names (budesonide)	17/10/2019	ongoing	Article 29(4) of Directive 2001/83/EC

### ***Referrals made to the PRAC***

<b>Procedure name (international non-proprietary name (INN) or common name)</b>	<b>Start of procedure</b>	<b>End of procedure</b>	<b>Type of referral</b>
Methotrexate containing medicinal products (methotrexate)	12/04/2018	22/08/2019	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Fenspiride-containing medicinal products (fenspiride)	14/02/2019	29/05/2019	Article 107i of Directive 2001/83/EC
Fluorouracil and fluorouracil related substances (capecitabine, fluorouracil, tegafur, flucytosine)	15/03/2019	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Estradiol-containing (0.01% w/w) medicinal products for topical use (estradiol)	11/04/2019	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Lemtrada (alemtuzumab)	11/04/2019	14/11/2019	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

<b>Procedure name (international non-proprietary name (INN) or common name)</b>	<b>Start of procedure</b>	<b>End of procedure</b>	<b>Type of referral</b>
Xeljanz (tofacitinib)	16/05/2019	14/11/2019	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Leuprorelin-containing depot medicinal products (leuprorelin)	14/06/2019	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Cyproterone-containing medicinal products (cyproterone)	11/07/2019	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Picato (ingenol mebutate)	05/09/2019	ongoing	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

## Annex 18 – Arbitrations and referrals in 2019 – veterinary medicines

Type of procedure	Date <ul style="list-style-type: none"> <li>• Clock start</li> <li>• CVMP opinion</li> </ul>	Product <ul style="list-style-type: none"> <li>• Product name</li> <li>• INN</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 14/02/2018</li> <li>• 21/02/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep</li> <li>• Closantel</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 10/10/2018</li> <li>• 18/07/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing paromomycin to be administered parenterally to pigs</li> <li>• Paromomycin</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 10/10/2018</li> <li>• 20/06/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep</li> <li>• Tylosin</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 23/01/2019</li> <li>• 05/12/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs</li> <li>• Tylosin base</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 20/02/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof</li> <li>• Amoxicillin</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 33(4) of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 17/07/2019</li> <li>• 05/12/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Ketabel 100 mg/ml solution for injection and associated names</li> <li>• Ketamine</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 34 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 17/07/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Adjusol and its associated names</li> <li>• Sulfadiazine and Trimethoprim</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 11/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names and generic products thereof</li> <li>• Dinoprost tromethamine</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 34 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 11/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Ronaxan and its associated names</li> <li>• Doxycycline hyclate</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 09/10/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof</li> <li>• Azaperone</li> </ul>
<ul style="list-style-type: none"> <li>• Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>• 06/11/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral</li> </ul>

<b>Type of procedure</b>	<b>Date</b>	<b>Product</b>
	<ul style="list-style-type: none"> <li>• <b>Clock start</b></li> <li>• <b>CVMP opinion</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Product name</b></li> <li>• <b>INN</b></li> </ul>
<ul style="list-style-type: none"> <li>• Procedure under Article 45 of Regulation (EC) 726/2004</li> </ul>	<ul style="list-style-type: none"> <li>• 07/11/2019</li> </ul>	<p style="margin-left: 20px;">powder for in-feed use to be administered to pigs</p> <ul style="list-style-type: none"> <li>• Tiamulin hydrogen fumarate</li> </ul> <ul style="list-style-type: none"> <li>• Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs</li> <li>• Porcine respiratory and reproductive syndrome (PRRS) virus vaccine (live)</li> </ul>

## Annex 19 – Budget summaries 2018–2019

The summarised comparative budget statements for 2018 and 2019 are as follows:

		2018 (final) <sup>1</sup>		2019 (budget) <sup>2</sup>		2019 (prov.) <sup>3</sup>	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
<b>Revenue</b>							
100	Fees and charges	284,157	89.6%	297,174	85.7%	293,953	89.1%
200	General EU contribution	10,503	3.3%	8,534	2.5%	9,326	2.8%
201	Special EU contribution for orphan medicinal products	11,857	3.7%	12,495	3.6%	11,703	3.5%
300	Contribution from EEA	0	0.0%	0	0.0%	0	0.0%
600	External assigned revenue	92	0.0%	38	0.0%	95	0.0%
700	Balance from previous year	10,231	3.2%	28,271	8.2%	14,468	4.4%
5+9	Other	240	0.1%	250	0.1%	193	0.1%
	<b>TOTAL REVENUE</b>	<b>317,081</b>	<b>100.0%</b>	<b>346,762</b>	<b>100.0%</b>	<b>329,738</b>	<b>100.0%</b>
<b>Expenditure</b>							
<b>Staff</b>							
11	Staff in active employment	104,196	34.0%	108,757	31.4%	106,654	31.2%
12	Staff recruitment	480	0.2%	355	0.1%	310	0.1%
13	Duty travel	1,761	0.6%	1,239	0.4%	1,197	0.4%
14	Socio-medical infrastructure	924	0.3%	3,537	1.0%	2,928	0.9%
15	Training	537	0.2%	261	0.1%	247	0.1%
16	Social welfare	4,581	1.5%	3,960	1.1%	3,935	1.2%
17	Representation expenses	106	0.0%	128	0.0%	116	0.0%
	<i>Total Title 1</i>	<b>112,584</b>	<b>36.7%</b>	<b>118,237</b>	<b>34.1%</b>	<b>115,387</b>	<b>33.8%</b>
<b>Building/equipment</b>							
20	Investment in immovable property, renting of building and associated costs	21,723	7.1%	50,969	14.7%	50,932	14.9%
21	Expenditure on corporate data processing	23,731	7.7%	22,729	6.6%	22,522	6.6%
22	Movable property [...]	705	0.2%	811	0.2%	795	0.2%
23	Other administrative expenditure	1,325	0.4%	5,497	1.6%	5,460	1.6%
24	Postage	78	0.0%	124	0.0%	123	0.0%
25	Expenditure on other meetings	349	0.1%	306	0.1%	304	0.1%
26	Restaurant & catering	838	0.3%	1,932	0.6%	1,925	0.6%
27	Information & publishing	987	0.3%	1,000	0.3%	1,000	0.3%
28	Business consultancy & audit svcs.	1,562	0.5%	696	0.2%	673	0.2%
	<i>Total Title 2</i>	<b>51,298</b>	<b>16.7%</b>	<b>84,064</b>	<b>24.2%</b>	<b>83,734</b>	<b>24.5%</b>
<b>Operational expenditure</b>							
300	Meetings	7,635	2.5%	6,705	1.9%	6,499	1.9%
301	Evaluation of medicines	114,144	37.2%	123,161	35.5%	121,590	35.6%
302	Translations	4,280	1.4%	3,966	1.1%	3,964	1.2%
303	Scientific studies & svcs.	2,864	0.9%	2,979	0.9%	2,978	0.9%
31	Expenditure on business related IT projects	13,798	4.5%	7,650	2.2%	7,617	2.2%
	<i>Total Title 3</i>	<b>142,721</b>	<b>46.5%</b>	<b>144,461</b>	<b>41.7%</b>	<b>142,648</b>	<b>41.7%</b>
90	Provisional appropriation	0	0.0%	0	0.0%	0	0.0%
	<i>Total Title 9</i>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>TOTAL EXPENDITURE</b>	<b>306,603</b>	<b>100.0%</b>	<b>346,762</b>	<b>100.0%</b>	<b>341,769</b>	<b>100.0%</b>
<sup>1</sup> Financial Year 2018: as per final accounts; rounded to nearest thousand Euro <sup>2</sup> Financial Year 2019: as per final budget <sup>3</sup> Financial Year 2019: as per provisional accounts; rounded to nearest thousand Euro							

## Annex 20 – European Medicines Agency establishment plan

Category and grade	TEMPORARY POSTS					
	POSTS 2019				POSTS 2020	
	Authorised		Actual as per 31.12.2019		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	3	-	3
AD 14	-	7	-	7	-	8
AD 13	-	11	-	10	-	12
AD 12	-	43	-	43	-	44
AD 11	-	43	-	43	-	47
AD 10	-	43	-	43	-	44
AD 9	-	43	-	43	-	46
AD 8	-	59	-	59	-	66
AD 7	-	65	-	65	-	76
AD 6	-	23	-	23	-	46
AD 5	-	25	-	25	-	3
<b>Total AD</b>	<b>0</b>	<b>365</b>	<b>0</b>	<b>364</b>	<b>0</b>	<b>395</b>
AST 11	-	2	-	2	-	2
AST 10	-	7	-	7	-	7
AST 9	-	7	-	6	-	8
AST 8	-	16	-	16	-	19
AST 7	-	22	-	22	-	15
AST 6	-	27	-	25	-	15
AST 5	-	35	-	33	-	39
AST 4	-	57	-	55	-	52
AST 3	-	46	-	46	-	44
AST 2	-	7	-	7	-	0
AST 1	-	0	-	0	-	0
<b>Total AST</b>	<b>0</b>	<b>226</b>	<b>0</b>	<b>219</b>	<b>0</b>	<b>201</b>
<b>Grand Total</b>	<b>0</b>	<b>591</b>	<b>0</b>	<b>583</b>	<b>0</b>	<b>596</b>

Other staff	Planned (FTE <sup>1</sup> ) 2019	Actual (FTE <sup>1</sup> ) 2019	Actual headcount 31.12.2019	Planned (FTE <sup>1</sup> ) 2020
<b>CONTRACT AGENTS</b>	<b>230</b>	<b>187</b>	<b>199</b>	<b>228</b>
<b>NATIONAL EXPERTS</b>	<b>33</b>	<b>28</b>	<b>31</b>	<b>33</b>

<sup>1</sup> FTE=Full Time Equivalent



## Annex 21 – Access to documents requests in 2019

### *Requests received and pages released*

Year	Number of requests received	Number of pages released
<b>2019</b>	783	318,013

### *Initial decisions on access in 2019<sup>1</sup>    Legal basis used for full or partial refusal*

Access given	
Yes	436
Partial	7
No	27
Not Applicable <sup>2</sup>	149
<b>Total closed</b>	<b>619</b>
Pending <sup>3</sup>	430

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	0	0
4.2 1 <sup>st</sup> ind – Protection of commercial interest	17	5
4.2 2 <sup>nd</sup> ind – Protection of court proceedings	1	0
4.2 3 <sup>rd</sup> ind – Protection of inspections	5	0
4.3 1 <sup>st</sup> par – Protection of decision making process	4	0
4.3 2 <sup>nd</sup> par – Protection of the Agency’s decision making process	0	1
4.5 – Protection of Member States	0	0
<b>Total</b>	<b>27</b>	<b>6</b>

<sup>1</sup> Including initial requests received in previous years but closed in 2019

<sup>2</sup> Request became RFI / Document is not held by the Agency / Clarification is not received / Withdrawn

<sup>3</sup> Requests ongoing (currently processed) and in queue (not started)

*Decision on confirmatory applications in 2019<sup>4</sup>*

Appeals	
Final refusal	6
Release	1
Partial	0
Not Applicable <sup>5</sup>	1
<b>Total closed</b>	<b>8</b>
Pending <sup>6</sup>	2

*Legal basis used for full or partial refusal*

<b>Legal basis</b>	<b>Full</b>	<b>Partial</b>
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	3	0
4.2 1 <sup>st</sup> ind – Protection of commercial interest	0	0
4.2 2 <sup>nd</sup> ind – Protection of court proceedings	1	0
4.2 3 <sup>rd</sup> ind – Protection of inspections	3	0
4.3 1 <sup>st</sup> par – Protection of decision making process	0	0
4.3 2 <sup>nd</sup> par – Protection of the Agency’s decision making process	0	0
4.5 – Protection of Member States	1	0
<b>Total</b>	<b>8</b>	<b>0</b>

<sup>4</sup> Including appeals received in previous years but closed in 2019

<sup>5</sup> Withdrawn

<sup>6</sup> Requests ongoing (currently processed) and in queue (not started)

**Affiliation (per initial requests and appeals in 2019)**

Affiliation	Number of requests received	In %	Number of pages released <sup>7</sup>	In %
Not-for-profit organisation	23	3	4,566	1
EU Institution (EC etc)	1	0	0	0
Regulator outside EU	2	0	0	0
EU NCA	1	0	0	0
Patients or Consumer	61	8	96,996	30
Healthcare professional	29	4	98,469	31
Academia/Research institute	72	9	27,946	9
Legal	61	8	8,907	3
Media	30	4	2,560	1
Pharmaceutical industry	406	52	65,932	21
Consultant	97	12	12,637	4
Other	0	0	0	0
<b>Total</b>	<b>783</b>	<b>100</b>	<b>318,013</b>	<b>100</b>

---

<sup>7</sup> Including initial requests and appeals received in previous years but closed in 2019

## Annex 22 – Publications by Agency staff members and experts in 2019

### **Arlett P.**

Building an evidence base on the place of Industry-Sponsored Programs in drug safety surveillance. *Drug Saf.* 2019 May;42(5):581-582. doi: 10.1007/s40264-018-00791-1.

### **Bahri P, Rågo L; CIOMS Working Group on Vaccine Safety.**

CIOMS Guide to Vaccine Safety Communication - Executive summary. *Vaccine.* 2019 Jan 14;37(3):401-408. doi: 10.1016/j.vaccine.2018.11.082. Epub 2018 Dec 13.

### **Barkholt L, Voltz-Girolt C, Raine J, Salmonson T, Schüssler-Lenz M.**

European regulatory experience with advanced therapy medicinal products. *Nat Rev Drug Discov.* 2019 Jan;18(1):8-9. doi: 10.1038/nrd.2018.200. Epub 2018 Nov 30.

### **Bernabe RDLC, van Thiel GJM, Breekveldt NS, Gispén-de Wied CC, van Delden JJM.**

Ethics in clinical trial regulation: ethically relevant issues from EMA inspection reports, 2008 to 2012. *Curr Med Res Opin.* 2019 Apr;35(4):637-645. doi: 10.1080/03007995.2018.1528214. Epub 2018 Oct 29.

### **Bhattacharyya A, Gallo P, Crisp A, LaVange L, Molenberghs G, Pétavy F, Seltzer J.**

The changing landscape of data monitoring committees-Perspectives from regulators, members, and sponsors. *Biom J.* 2019 Sep;61(5):1232-1241. doi: 10.1002/bimj.201700307. Epub 2018 Dec 27.

### **Brosch S, de Ferran AM, Newbould V, Farkas D, Lengsavath M, Tregunno P.**

Establishing a framework for the use of social media in pharmacovigilance in Europe. *Drug Saf.* 2019 Aug;42(8):921-930. doi: 10.1007/s40264-019-00811-8.

### **Brown, P. & Bahri, P.**

'Engagement' of patients and healthcare professionals in regulatory pharmacovigilance: establishing a conceptual and methodological framework. *Eur J Clin Pharmacol.* 2019 Sep;75(9):1181-1192. doi: 10.1007/s00228-019-02705-1. Epub 2019 Jun 25.

### **Cave A, Kurz X, Arlett P.**

Real world data for regulatory decision making: challenges and possible solutions for Europe. *Clin Pharmacol Ther.* 2019 Jul;106(1):36-39. doi: 10.1002/cpt.1426. Epub 2019 Apr 10.

### **Coppola P, Andersson A, Cole S.**

The Importance of the Human Mass Balance Study in Regulatory submissions. *CPT Pharmacometrics Syst Pharmacol.* 2019 Nov;8(11):792-804. doi: 10.1002/psp4.12466. Epub 2019 Oct 25.

### **De Wit M, Cooper C, Tugwell P, Bere N, Kirwan J, Conaghan PG, Roberts C, Aujoulat I, Al-Daghri N, Araujo de Carvalho I, Barker M, Bedlington N, Brandi ML, Bruyere O, Burlet N, Halbout P, Hilgsmann M, Jiwa F, Kanis JA, Laslop A, Lawrence W, Pinto D, Prieto Yerro C, Rabenda V, Rizzoli R, Scholte-Voshaar M, Vlaskoyska M, Reginster JY.**

Practical guidance for engaging patients in health research, treatment guidelines and regulatory processes: Results of an expert group meeting organized by the World Health Organization (WHO) and the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO). *Aging Clin Exp Res* (2019). <https://doi.org/10.1007/s40520-019-01193-8>

### **Eichler HG, Bedlington N, Boudes M, Bouvy JC, Broekmans AW, Cerreta F, Faulkner SD, Forda S, Joos A, Le Cam Y, Mayer M, Pirard V, Corriol-Rohou S; ADAPT SMART Consortium.**

Medicines Adaptive Pathways to Patients: why, when and how to engage? *Clin Pharmacol Ther.* 2019 May;105(5):1148-1155. doi: 10.1002/cpt.1121. Epub 2018 Sep 11.

### **Eichler HG, Bloechl-Daum B, Broich K, Kyrle PA, Oderkirk J, Rasi G, Ivo RS, Schuurman A, Senderovitz T, Slawomirski L, Wenzl M, Paris V.**

Data rich, information poor; can we use electronic health records to create a learning healthcare system for pharmaceuticals? *Clin Pharmacol Ther.* 2019 Apr;105(4):912-922. doi: 10.1002/cpt.1226. Epub 2018 Oct 14.

### **Eichler HG, Enzmann H, Rasi G.**

Added therapeutic benefit and drug licensing.

Nat Rev Drug Discov. 2019 Sep;18(9):651-652. doi: 10.1038/d41573-019-00068-x.

**Gini R, Fournie X, Dolk H, Kurz X, Verpillat P, Simondon F, Strassmann V, Apostolidis K, Goedecke T.**

The ENCePP Code of Conduct: A best practise for scientific independence and transparency in noninterventional postauthorisation studies.

Pharmacoepidemiol Drug Saf. 2019 Apr;28(4):422-433. doi: 10.1002/pds.4763. Epub 2019 Mar 5.

**Haberkamp M, Moseley J, Athanasiou D, de Andres-Trelles F, Elferink A, Rosa MM, Magrelli A.**

**European regulators' views on a wearable-derived performance measurement of Ambulation for DMD regulatory trials.**

Neuromuscul Disord. 2019 Jul;29(7):514-516. doi: 10.1016/j.nmd.2019.06.003.

**Hedenmalm K, Blake K, Donegan K, Macia MA, Gil M, Williams J, Montero D, Candore G, Morales D, Kurz X, Arlett P.**

A European multicentre drug utilisation study of the impact of regulatory measures on prescribing of codeine for pain in children.

Pharmacoepidemiol Drug Saf. 2019 Aug;28(8):1086-1096. doi: 10.1002/pds.4836. Epub 2019 Jun 20.

**Hedenmalm K, Slattey J, Skibicka-Stepien I, Kurz X, Morales D.**

Prescribing patterns of tramadol in adults in IMS® primary care databases in France and Germany between 1 January 2006 and 30 June 2016.

Eur J Clin Pharmacol. 2019 May;75(5):707-716. doi: 10.1007/s00228-018-02622-9. Epub 2019 Jan 23.

**Hedenmalm K, Kurz X, Morales D.**

Effect of withdrawal of fusafungine from the market on prescribing of antibiotics and other alternative treatments in Germany: a pharmacovigilance impact study.

Eur J Clin Pharmacol. 2019 Jul;75(7):979-984. doi: 10.1007/s00228-019-02650-z. Epub 2019 Mar 5.

**Herold R, Camarero J, Melchiorri D, Sebris Z, Enzmann H, Pignatti F.**

Revocation of the conditional marketing authorisation of a cancer medicine: The olaratumab experience.

Eur J Cancer. 2019 Dec;123:25-27. doi: 10.1016/j.ejca.2019.09.020. Epub 2019 Oct 23.

**Hidalgo-Simon A.**

From laboratory to patient - the evolving path to become a medicine.

Molecular Frontiers Journal Vol. 03, No. 02, pp. 138-146 (2019).

<https://doi.org/10.1142/S2529732519400121>

**Hines PA, Hiu Yu L, Guy RH, Brand A, Papaluca-Amati M.**

Scanning the horizon: a systematic literature review of methodologies.

BMJ Open. 2019 May 27;9(5):e026764. doi: 10.1136/bmjopen-2018-026764.

**Hines PA, Guy RH, Humphreys AJ, Papaluca-Amati M.**

The European Medicines Agency's goals for regulatory science to 2025.

Nat Rev Drug Discov. 2019 Jun;18(6):403-404. doi: 10.1038/d41573-019-00071-2.

**Jauregui B, Hudson LD, Becnel LB, Navarro Almario E, Fitzmartin R, Pétavy F, Seigneuret N, Malone JK, Zhou FL, Galvez J, Jackson T, Harmon N, Kush RD.**

The Turning Point for Clinical Research: Global Data Standardization.

Applied Clinical Trials Online, 22 January 2019. <http://www.appliedclinicaltrialsonline.com/turning-point-clinical-research-global-data-standardization>

**Kehoe T, Blind E, Janssen H.**

Regulatory Aspects of the Development of Drugs for Metabolic Bone Diseases.

Br J Clin Pharmacol. 2019 Jun;85(6):1208-1212. doi: 10.1111/bcp.13791. Epub 2018 Dec 3.

**Lenić I, Blake K, Garcia-Arieta A, Potthast H, Welink J.**

Overview of the European Medicines Agency's experience with biowaivers in centralized applications.

Clin Transl Sci. 2019 Sep;12(5):490-496. doi: 10.1111/cts.12642. Epub 2019 May 27.

**Lienhardt C, Vernon AA, Cavaleri M, Nambiar S, Nahid P.**

Development of new TB regimens: how to harmonize trial design, product registration requirements and public health guidance?

PLoS Med. 2019 Sep 6;16(9):e1002915. doi: 10.1371/journal.pmed.1002915. eCollection 2019 Sep.

**Lim R, Lee DK, Sabourin P, Ferguson J, Metcalf M, Smith M, Corriol-Rohou S, Eichler HG, Lumpkin M, Hirsch G, Chen IM, O'Rourke B, Schiel A, Crabb N, Aronson N, Pezalla E, Boutin M, Binder L, Wilhelm L.**

Recognizing that Evidence is Made, Not Born.

Clin Pharmacol Ther. 2019 Apr;105(4):844-856. doi: 10.1002/cpt.1317. Epub 2019 Jan 4.

**Marshall S, Madabushi R, Manolis E, Krudys K, Staab A, Dykstra K, Visser SAG.**

Model-informed Drug Discovery and Development (MID3): Current Industry Good Practice & Regulatory Expectations and Future Perspectives.

CPT Pharmacometrics Syst Pharmacol. 2019 Feb;8(2):87-96. doi: 10.1002/psp4.12372. Epub 2019 Feb 1.

**Mavris M, Furia Helms A, Bere N.**

Engaging patients in medicines regulation: a tale of two agencies.

Nat Rev Drug Discov. 2019 Nov;18(12):885-886. doi: 10.1038/d41573-019-00164-y.

**McGettigan P, Alonso Olmo C, Plueschke K, Castillon M, Nogueras Zondag D, Bahri, Kurz X, Mol PGM.**

Patient Registries: An Underused Resource for Medicines Evaluation: Operational proposals for increasing the use of patient registries in regulatory assessments.

Drug Saf. 2019 Nov;42(11):1343-1351. doi: 10.1007/s40264-019-00848-9.

**Morales DR, Pacurariu A, Slattery J, Pinheiro L, McGettigan P, Kurz X.**

Association between peripheral neuropathy and exposure to oral fluoroquinolone or amoxicillin-clavulanate Therapy.

JAMA Neurol. 2019 Jul 1;76(7):827-833. doi: 10.1001/jamaneurol.2019.0887.

**Morales DR, Slattery J, Pacurariu A, Pinheiro L, McGettigan P, Kurz X.**

Relative and Absolute Risk of Tendon Rupture with Fluoroquinolone and Concomitant Fluoroquinolone/Corticosteroid Therapy: Population-Based Nested Case-Control Study.

Clin Drug Investig. 2019 Feb;39(2):205-213

**Morales DR, Slattery J, Pacurariu A, Pinheiro L, McGettigan P, Kurz X.**

Correction to: Relative and Absolute Risk of Tendon Rupture with Fluoroquinolone and Concomitant Fluoroquinolone/Corticosteroid Therapy: Population-Based Nested Case-Control Study.

Clin Drug Investig. 2019 Feb;39(2):215. doi: 10.1007/s40261-019-00755-y.

**Morgan EM, Munro JE, Horonjeff J, Horgan B, Shea B, Feldman BM, Clairman H, Bingham CO 3rd, Thornhill S, Strand V, Alongi A, Magni-Manzoni S, van Rossum MAJ, Vesely R, Vojinovic J, Brunner HI, Harris JG, Horton DB, Lovell DJ, Mannion M, Rahimi H, Ravelli A, Ringold S, Ruperto N, Schrandt MS, Shenoi S, Shiff NJ, Toupin-April K, Tzaribachev N, Weiss P, Consolaro A.**

Establishing an Updated Core Domain Set for Studies in Juvenile Idiopathic Arthritis: A Report from the OMERACT 2018 JIA Workshop.

J Rheumatol. 2019 Aug;46(8):1006-1013. doi: 10.3899/jrheum.181088. Epub 2019 Feb 15.

**Nielsen SM, Tugwell P, de Wit MPT, Boers M, Beaton DE, Woodworth TG, Escorpizo R, Shea B, Toupin-April K, Guillemin F, Strand V, Singh JA, Kloppenburg M, Furst DE, Wells GA, Smolen JS, Vesely R, Boonen A, Storgaard H, Voshaar M, March L, Christensen R; Contextual Factors Working Group.**

Identifying provisional generic contextual factor domains for clinical trials in rheumatology: Survey results from an OMERACT initiative.

J Rheumatol. 2019 Sep;46(9):1159-1163. doi: 10.3899/jrheum.181081. Epub 2019 Jan 15.

**Nordenmalm S, Kimland E, Ligas F, Lehmann B, Claverol J, Nafria B, Tötterman AM, Pelle B.**

Children's views on taking medicines and participating in clinical trials.

Arch Dis Child. 2019 Sep;104(9):900-905. doi: 10.1136/archdischild-2018-31651

**O'Connor DJ, Shean ME, Hofer MP, Tsigkos S, Mariz S, Fregonese L, Larsson K, Hivert V, Westermark K, Naumann-Winter F, Stoyanova-Beninska V, Barišić I, Capovilla G, Magrelli A, Sepodes B.**

Defining orphan conditions in the context of the European orphan regulation: challenges and evolution.

Nat Rev Drug Discov. 2019 Jul;18(7):479-480. doi: 10.1038/nrd.2018.128.

**Ollivier C, Mulugeta YL, Ruggieri L, Saint-Raymond A, Yao L.**

Paediatric extrapolation: A necessary paradigm shift.

Br J Clin Pharmacol. 2019 Apr;85(4):675-679. doi: 10.1111/bcp.13809. Epub 2018 Dec 18.

**Ollivier C, Sun H, Amchin W, Beghetti M, Berger RMF, Breitenstein S, Garnett C, Gullberg N, Hassel P, Ivy D, Kawut SM, Klein A, Lesage C, Migdal M, Niје B, Odermarsky M, Strait J, de Graeff PA, Stockbridge N.**

New Strategies for the Conduct of Clinical Trials in Pediatric Pulmonary Arterial Hypertension: Outcome of a Multistakeholder Meeting With Patients, Academia, Industry, and Regulators, Held at the European Medicines Agency on Monday, June 12, 2017.

J Am Heart Assoc. 2019 May 21;8(10):e011306.

**Ollivier C, Thomson A, Manolis E, Blake K, Karlsson KE, Knibbe CAJ, Pons G, Hemmings R.**

Commentary on the EMA Reflection Paper on the use of extrapolation in the development of medicines for paediatrics.

Br J Clin Pharmacol. 2019 Apr;85(4):659-668. doi: 10.1111/bcp.13883. Epub 2019 Feb 28.

**Olmo CA, McGettigan P, Kurz X.**

Barriers and opportunities for use of patient registries in medicines regulation.

Clin Pharmacol Ther. 2019 Jul;106(1):39-42. doi: 10.1002/cpt.1414. Epub 2019 Apr 10.

**Pearson ADJ, Scobie N, Norga K, Ligas F, Chiodin D, Burke A, Minard-Colin V, Adamson P, Marshall LV, Balakumaran AO, Benettaib B, Bhargava P, Bollard CM, Bolotin E, Bomken S, Buechner J, Burkhardt B, Caron H, Copland C, Demolis P, Egorov A, Farhan M, Zugmaier G, Gross T, Horton-Taylor D, Klapper W, Lesa G, Marcus R, Miles RR, Nottage K, Pacaud L, Ricafort R, Schrappe M, Sterba J, Vezan R, Weiner S, Kim SY, Reaman G, Vassal G.**

ACCELERATE and European Medicine Agency Paediatric Strategy Forum for medicinal product development for mature B-cell malignancies in children.

Eur J Cancer. 2019 Mar;110:74-85. doi: 10.1016/j.ejca.2019.01.013. Epub 2019 Feb 14.

**Pelfrene E, Harvey Allchurch M, Ntamabyaliro N, Nambasa V, Ventura FV, Nagercoil N, et al.**

The European Medicines Agency's scientific opinion on oral fexinidazole for human African trypanosomiasis.

PLoS Negl Trop Dis 13(6): e0007381. <https://doi.org/10.1371/journal.pntd.0007381>

**Pelfrene E, Sebris Z, Cavaleri M.**

Comment on Fauconnier, A. Phage Therapy Regulation: From Night to Dawn.

Viruses. 2019 Aug 22;11(9). pii: E771. doi: 10.3390/v11090771.

**Pelfrene E, Mura M, Cavaleiro Sanches A, Cavaleri M.**

Monoclonal antibodies targeting infectious agents: a promising future?

Clin Microbiol Infect. 2019 Jan;25(1):60-64. doi: 10.1016/j.cmi.2018.04.024. Epub 2018 Apr 30.

**Schneeweiss S, Rassen JA, Brown JS, Rothman KJ, Happe L, Arlett P, Dal Pan G, Goettsch W, Murk W, Wang SV.**

Graphic Depiction of Longitudinal Study Designs in Healthcare Databases.

Ann Intern Med. 2019 Mar 19;170(6):398-406. doi: 10.7326/M18-3079.

**Selker HP, Eichler HG, Stockbridge NL, McElwee NE, Dere WH, Cohen T, Erban JK, Seyfert-Margolis VL, Honig PK, Kaitin KI, Oye KA, D'Agostino RB Sr.**

Efficacy and Effectiveness Too (EE2) Trials: Clinical Trial Designs to Generate Evidence on Efficacy and on Effectiveness in Wide Practice.

Clin Pharmacol Ther. 2019 Apr;105(4):857-866. doi: 10.1002/cpt.1347. Epub 2019 Feb 12.

**Smith LEH, Hellström A, Stahl A, Fielder A, Chambers W, Moseley J, Toth C, Wallace D, Darlow BA, Aranda JV, Hallberg B, Davis JM; Retinopathy of Prematurity Workgroup of the International Neonatal Consortium.**

Development of a Retinopathy of Prematurity Activity Scale and Clinical Outcome Measures for Use in Clinical Trials.

JAMA Ophthalmol. 2019 Mar 1;137(3):305-311. doi: 10.1001/jamaophthalmol.2018.5984.

**Stephenson D, Hill D, Cedarbaum JM, Tome M, Vamvakas S, Romero K, Conrado DJ, Dexter DT, Seibyl J, Jennings D, Nicholas T, Matthews D, Xie Z, Imam S, Maguire P, Russell D, Gordon MF, Stebbins GT, Somer E, Gallagher J, Roach A, Basseches P, Grosset D, Marek K; Critical Path for Parkinson's Consortium.**

The qualification of an enrichment biomarker for clinical trials targeting early stages of Parkinson's disease.

J Parkinsons Dis. 2019;9(3):553-563. doi: 10.3233/JPD-191648.

**Sultana J, Zaccaria C, de Lisa R, Rossi F, Capuano A, Ferrajolo C.**

Good Pharmacovigilance Practice in Paediatrics: An Overview of the Updated European Medicines Agency Guidelines.

Paediatr Drugs. 2019 Oct;21(5):317-321. doi: 10.1007/s40272-019-00350-w.

**Tanniou J, Smid SC, van der Tweel I, Teerenstra S, Roes KCB.**

Level of evidence for promising subgroup findings: the case of trends and multiple subgroups. Stat Med. 2019 Jun 30;38(14):2561-2572. doi: 10.1002/sim.8133. Epub 2019 Mar 13.

**Torcel-Pagnon L, Bauchau V, Mahy P, Tin Tin Htar M, van der Sande M, Mahé C, Krause TG, Charrat A, Simondon F, Kurz X; ADVANCE Consortium.**

Guidance for the governance of public-private collaborations in vaccine post-marketing settings in Europe. Vaccine. 2019 May 31;37(25):3278-3289. doi: 10.1016/j.vaccine.2019.04.073. Epub 2019 May 6.

**Tzogani K, Florez B, Markey G, Caleno M, Olimpieri OM, Melchiorri D, Hovgaard DJ, Sarac SB, Penttilä K, Lapveteläinen T, Salmonson T, Bergh J, Gisselbrecht C, Pignatti F.**

The European Medicines Agency review of ixazomib (Ninlaro) for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. ESMO Open. 2019 Sep 8;4(5):e000570. doi: 10.1136/esmoopen-2019-000570. eCollection 2019.

**van der Laan JW, van Malderen K, de Jager N, Duarte D, Egger GF, Lavergne F, Roque CG, Vieira I, Wiesner L, Carleer J.**

Evaluation of Juvenile Animal Studies for Pediatric CNS-Targeted Compounds: A Regulatory Perspective. Int J Toxicol. 2019 Nov/Dec;38(6):456-475. doi: 10.1177/1091581819883569. Epub 2019 Oct 29.

**van Stekelenborg J, Ellenius J, Maskell S, Bergvall T, Caster O, Dasgupta N, Dietrich J, Gama S, Lewis D, Newbould V, Brosch S, Pierce CE, Powell G, Ptaszyńska-Neophytou A, Wiśniewski AFZ, Tregunno P, Norén GN, Pirmohamed M.**

Recommendations for the use of Social Media in Pharmacovigilance: Lessons from IMI WEB-RADR. Drug Saf. 2019 Dec;42(12):1393-1407. doi: 10.1007/s40264-019-00858-7.

**Vannice KS, Casseti MC, Eisinger RW, Hombach J, Knezevic I, Marston HD, Wilder-Smith A, Cavaleri M, Krause PR.**

Demonstrating vaccine effectiveness during a waning epidemic: a WHO/NIH meeting report on approaches to development and licensure of Zika vaccine candidates. Vaccine. 2019 Feb 4;37(6):863-868. doi: 10.1016/j.vaccine.2018.12.040. Epub 2019 Jan 11.

**Vermeer NS, Giezen TJ, Zastavnik S, Wolff-Holz E, Hidalgo-Simon A.**

Identifiability of Biologicals in Adverse Drug Reaction Reports Received From European Clinical Practice Clin Pharmacol Ther. 2019 Apr;105(4):962-969. doi: 10.1002/cpt.1310. Epub 2019 Jan 11.

**Whomsley R, Brendler-Schwaab S, Griffin E, Jensen J, Moermond C, Scholz B, Sortvik Nilssen L, Stemplewski H, Roennefahrt I.**

Commentary on the Draft Revised Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use. Environmental Sciences Europe. Vol 31, Article number: 17 (2019)

**Wolff-Holz E, Tiiitso K, Vleminckx C, Weise M.**

Evolution of the EU Biosimilar Framework: past and future. BioDrugs. 2019 Dec;33(6):621-634. doi: 10.1007/s40259-019-00377-y.