EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Annual report 2009

## Annexes

The main body of this annual report is available on the website of the European Medicines Agency (EMA) at: http://www.ema.europa.eu/htms/general/direct/ar.htm

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

© European Medicines Agency, 2010. Reproduction is authorised provided the source is acknowledged.

# Contents

# Annex 1 – Members of the Management Board

Chair: Pat O'MAHONY
EMA contact: Nerimantas STEIKUNAS

## *Members*

| | |
|---|---|
| European Parliament | Guiseppe NISTICÓ, Björn LEMMER<br>(Substitute: Jozef HOLOMÁŇ) |
| European Commission | Heinz ZOUREK, Isabel de la MATA<br>(Alternates: Georgette LALIS, Bernard MERKEL) |
| Belgium | Xavier DE CUYPER (Alternate: André LHOIR) |
| Bulgaria | Jasmina MIRCHEVA[1] (Alternate: Meri BORISLAVOVA PEYTCHEVA) |
| Czech Republic | Lenka BALÁŽOVÁ (Alternate: Jiří BUREŠ) |
| Denmark | Jytte LYNGVIG (Alternate: Paul SCHÜDER) |
| Germany | Walter SCHWERDTFEGER (Alternate: Hans-Peter HOFMANN[2]) |
| Estonia | Kristin RAUDSEPP (Alternate: Alar IRS) |
| Ireland | Pat O'MAHONY (Alternate: Rita PURCELL) |
| Greece | Awaiting nomination[3] (Alternate: Dimitra PATARGIA) |
| Spain | Cristina AVENDAÑO-SOLÀ (Alternate: Laura Franqueza GARCÍA) |
| France | Jean MARIMBERT (Alternate: Marc MORTUREUX[4]) |
| Italy | Guido RASI (Alternate: Silvia FABIANI) |
| Cyprus | Panayiota KOKKINOU (Alternate: George ANTONIOU) |
| Latvia | Inguna ADOVICA (Alternate: Dace ĶIKUTE) |
| Lithuania | Mindaugas BŪTA (Alternate: Jonas MILIUS[5]) |
| Luxembourg | Mariette BACKES-LIES (Alternate: Claude A HEMMER) |
| Hungary | Tamás L PAÁL (Alternate: Beatrix HORVÁTH) |
| Malta | Patricia VELLA BONANNO (Alternate: Kenneth MIFSUD) |
| Netherlands | Aginus A W KALIS (Alternate: Rob DE HAAN) |
| Austria | Marcus MÜLLNER (Alternate: Christian KALCHER) |
| Poland | Wojceich MATUSEVICZ[6] (Alternate: Jacek SPLAWINSKI) |
| Portugal | Vasco A J MARIA (Alternate: Fernando d'ALMEIDA BERNARDO) |
| Romania | Daniel Boda[7] (Alternate: Rodica BADESCU) |

[1] Replaced Emil Ivanov Hristov as of the June 2009 meeting.
[2] Replaced Ilse-Dore SCHÜTT as of June 2007 meeting.
[3] Replacement of Dimitrios VAGIONAS was Vasilis KONTOZAMANIS as of June 2009 meeting. Nomination awaited as of October 2009 meeting.
[4] Replaced Pascale BRIAND as of October 2009 meeting.
[5] Replaced Juozas JOKIMAS as of June 2009 meeting.
[6] Replaced Elżbieta WOJTASIK as of October 2009 meeting.

| | |
|---|---|
| Slovenia | Martina CVELBAR (Alternate: Vesna KOBLAR) |
| Slovakia | Ján MAZÁG (Alternate: Dagmar STARÁ) |
| Finland | Sinikka RAJANIEMI[8] (Alternate: Pekka JÄRVINEN) |
| Sweden | Christina ÅKERMAN (Alternate: Johan LINDBERG[9]) |
| United Kingdom | Kent WOODS (Alternate: Steve DEAN) |
| Representatives of patients' organisations | Mary BAKER, Mike O'DONOVAN |
| Representative of doctors' organisations | Lisette TIDDENS-ENGWIRDA |
| Representative of veterinarians' organisations | Henk VAARKAMP |

### *Observers*

| | |
|---|---|
| Iceland | Rannveig GUNNARSDÓTTIR (Alternate: Ingolf J PETERSEN) |
| Liechtenstein | Brigitte BATLINER (Alternate: Sabine ERNE) |
| Norway | Gro Ramsten WESENBERG (Alternate: Hans HALSE) |

[7] Replaced Magdalena BADULESCU as of June 2009 meeting.
[8] Replaced Marja-Liisa PATARNEN as of December 2009 meeting.
[9] Replaced Anders BROSTRÖM as of June 2009 meeting.

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

Chair: Eric ABADIE
EMA contact: Anthony HUMPHREYS

## *Members*

| | |
|---|---|
| • George AISLAITNER (Greece) | Alternate Catherine MORAITI |
| • Viorel Robert ANCUCEANU (Romania) | Alternate: Raluca CIRSTEA |
| • John Joseph BORG (Malta) | Alternate: Patricia VELLA BONANNO |
| • János BORVENDÉG (Hungary) | Alternate: Agnes GYURASICS |
| • Gonzalo CALVO ROJAS (Spain) | Alternate: Concepcion PRIETO YERRO |
| • Pierre DEMOLIS (France) | Alternate: Philipe LECHAT |
| • Harald ENZMANN (Germany) | Alternate: Martina WEISE[1] |
| • Jens ERSBØLL (Denmark)[2] | Alternate: Jens ERSBØLL[3] |
| • Jacqueline GENOUX-HAMES (Luxembourg) | Alternate: awaiting nomination |
| • Ian HUDSON (United Kingdom) | Alternate: Rafe SUVARNA |
| • Alar IRS (Estonia) | Alternate: Irja LUTSAR |
| • Arthur ISSEYEGH (Cyprus) | Alternate: Panayiota KOKKINOU |
| • Jaana KALLIO (Finland) | Alternate: Kristiina AIROLA[4] |
| • Andrea LASLOP (Austria)[5] | Alternate: Hans WINKLER[6] |
| • Metoda LIPNIK-STANGELJ (Slovenia) | Alternate: Nevenka TRSINAR |
| • David LYONS (Ireland) | Alternate: Patrick SALMON |
| • Romaldas MAČIULAITIS (Lithuania) | Alternate: Rugile PILVINIENE |
| • Ján MAZÁG (Slovakia) | Alternate: awaiting nomination |
| • Pieter NEELS (Belgium) | Alternate: Jean-François BAURAIN[7] |
| • Giuseppe NISTICÒ (Italy) | Alternate: Daniela MELCHIORRI[8] |
| • Sif ORMARSDÓTTIR (Iceland) | Alternate: Kolbeinn GUDMUNDSSON[9] |
| • Michał PIROŻYŃSKI (Poland) | Alternate: Piotr SIEDLECKI |
| • Juris POKROTNIEKS (Latvia) | Alternate: Natalja KARPOVA |
| • Tomas SALMONSON (Sweden) (vice-chair) | Alternate: Bengt LJUNGBERG |

[1] Replaced Karl BROICH as of September 2009 meeting.
[2] Replaced Steffen THIRSTRUP as of December 2009 meeting.
[3] Jens ERSBØLL was an alternate member until December 2009.
[4] Replaced Outi LAPATTO-REINILUOTO as of October 2009 meeting.
[5] Replaced Heribert PITTNER as of January 2009 meeting.
[6] Replaced Andrea LASLOP as of January 2009 meeting.
[7] Replaced Bruno FLAMION as of June 2009 meeting.
[8] Replaced Antonio ADDIS as of November 2009 meeting.
[9] Replaced Magnús JOHANNSSON as of October 2009.

- Beatriz SILVA LIMA (Portugal) — Alternate: Cristina SAMPAIO
- Eva SKOVLUND (Norway) — Alternate: Liv MATHIESEN
- Mila VLASKOVSKA(Bulgaria)[10] — Alternate: Elena MASSEVA[11]
- Barbara VAN ZWIETEN-BOOT (Netherlands) — Alternate: Pieter DE GRAEFF
- Martin VOTAVA (Czech Republic) — Alternate: Ondřej SLANAŘ

### *Co-opted members*

- Robert James HEMMINGS (United Kingdom)
- Hubert G.M. LEUFKENS (Netherlands)[12]
- Jean-Louis ROBERT (Luxembourg) (co-opted)
- Sol RUIZ (Spain) (co-opted)
- Christian SCHNEIDER (Germany)

### *Working parties, ad hoc groups and scientific advisory groups*

**Scientific Advice Working Party**
Chair: Bruno FLAMION — EMA contact: Spiros VAMVAKAS

**Biologics Working Party**
Chair: Jean-Hugues TROUVIN — EMA contact: Peter RICHARDSON

**Blood Products Working Party**
Chair: Rainer SEITZ — EMA contact: Peter RICHARDSON

**Working Party on Cell-based Products**
Chair: Paula SALMIKANGAS — EMA contact: Peter RICHARDSON

**Efficacy Working Party**
Chair: Barbara VAN ZWIETEN-BOOT — EMA contact: Francesco PIGNATTI

**Gene Therapy Working Party**
Chair: Klaus CICHUTEK — EMA contact: Marisa PAPALUCA AMATI

**Joint CHMP/CVMP Quality Working Party**
Chair: Jean-Louis ROBERT — EMA contact: David COCKBURN

**Pharmacogenomics Working Party**
Chair: Eric ABADIE — EMA contact: Marisa PAPALUCA AMATI

**Pharmacovigilance Working Party**
Chair: June RAINE — EMA contact: Henry FITT

**Safety Working Party**
Chair: Beatriz SILVA LIMA — EMA contact: Francesco PIGNATTI

**Vaccine Working Party**
Chair: Michael PFLEIDERER — EMA contact: Peter RICHARDSON

[10] Replaced Dimiter TERZIIVANOV NIKOLOV as of November 2009 meeting.
[11] Replaced Ivanka ATANASOVA as of November 2009 meeting.
[12] Elected as co-opted member from November 2009 meeting.

**Ad Hoc Working Party on Similar Biological (Biosimilar) Medicinal Products**
Chair: Christian SCHNEIDER EMA contact: Marco CAVALERI

**Scientific Advisory Group on Anti-infectives**
Chair: Barbara BANNISTER EMA contact: Marco CAVALERI

**Scientific Advisory Group on Cardiovascular Issues**
Chair: To be elected[13] EMA contact: Eberhard BLIND

**Scientific Advisory Group on Central Nervous System**
Chair: Michael DONAGHY EMA contact: Manuel HAAS

**Scientific Advisory Group on Diabetes/ Endocrinology**
Chair: Edwin GALE EMA contact: Eberhard BLIND

**Scientific Advisory Group on Diagnostics**
Chair: Jean-Noël TALBOT EMA contact: Francesco PIGNATTI

**Scientific Advisory Group on HIV/Viral Diseases**
Chair: Ian WELLER EMA contact: Marco CAVALERI

**Scientific Advisory Group on Oncology**
Chair: Michel MARTY EMA contact: Francesco PIGNATTI

**Invented Name Review Group**
Chair: Zaïde FRIAS EMA contact: Zaïde FRIAS

**EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations**
Chair: Frits LEKKERKERKER/Isabelle MOULON EMA contact: Isabelle MOULON

**EMA/CHMP Working Group with Healthcare Professionals' Organisations**
Chair: Noël WATHION/Giuseppe NISTICO EMA contact: Isabelle MOULON

**Working Group on Quality Review of Documents**
Chair: Isabelle MOULON EMA contact: Isabelle MOULON

[13] Henry DARGIE until September 2009.

# Annex 3 – Members of the Committee for Medicinal Products for Veterinary Use

Chair: Gérard MOULIN (Vice-Chair: Anja HOLM)
EMA contact: David MACKAY

### *Members*

| | |
|---|---|
| • Ewa AUGUSTYNOWICZ[1] (Poland) | Alternate: Anna LUTYŃSKA[2] |
| • Jean-Pierre BINDER[3] (Austria) | Alternate: Barbara ZEMANN[4] |
| • Jiří BUREŠ (Czech Republic) | Alternate: Alfred HERA |
| • João Pedro DUARTE DA SILVA[5] (Portugal) | Alternate: Berta SAO BRAZ[6] |
| • Irmeli HAPPONEN (Finland) | Alternate: Kristina LEHMANN |
| • Judita HEDEROVÁ (Slovakia) | Alternate: Eva CHOBOTOVÁ |
| • Anja HOLM (Denmark) (vice-chair) | Alternate: Ellen-Margrethe VESTERGAARD |
| • Tonje HØY (Norway) | Alternate: Hanne BERGENDAHL |
| • Damyan ILIEV (Bulgaria) | Alternate: Ilian GETCHEV |
| • Ruth KEARSLEY (United Kingdom) | Alternate: Anna-Maria BRADY |
| • Ioannis MALEMIS (Greece) | Alternate: Georgios BATZIAS |
| • Kenneth MIFSUD (Malta) | Alternate: Joseph VELLA |
| • Manfred MOOS (Germany) | Alternate: Cornelia IBRAHIM |
| • Paul MÕTSKÜLA (Estonia) | Alternate: Helen MAHLA |
| • Cristina MUÑOZ (Spain)[7] | Alternate: Consuelo Rubio MONTEJANO[8] |
| • David MURPHY (Ireland)[9] | Alternate: Gabriel BEECHINOR[10] |
| • Jean-Claude ROUBY (France) | Alternate: Michael HOLZHAUSER-ALBERTI |
| • Halldór RUNÓLFSSON (Iceland) | Alternate: Johann LENHARDSSON |
| • G Johan SCHEFFERLIE (Netherlands) | Alternate: Peter HEKMAN |
| • Valda SEJANE (Latvia) | Alternate: awaiting nomination |
| • Tibor SOÓS (Hungary) | Alternate: Gábor KULCSÁR |
| • Stane SRČIČ (Slovenia) | Alternate: Katarina STRAUS |
| • Lollita Sanda Camelia TABAN (Romania) | Alternate: Simona STURZU |

[1] Replaced Franciszek ŻMUDZIŃSKI as of December 2009 meeting.
[2] Alternate since December 2009 meeting.
[3] Replaced Eugen OBERMAYR.
[4] Replaced Jean-Pierre BINDER.
[5] Replaced Selene VEIGA as of September 2009 meeting.
[6] Replaced Berta Maria FERNANDES.
[7] Replaced Consuelo Rubio MONTEJANO.
[8] Replaced Gema CORTEZ.
[9] Replaced Gabriel BEECHINOR as of April 2009 meeting.
[10] Replaced David MURPHY as of April 2009 meeting.

- Maria TOLLIS (Italy) Alternate: Virgilio DONINI
- Karolina TÖRNEKE (Sweden) Alternate: Henrik HOLST
- Bruno URBAIN (Belgium) Alternate: Frédéric DESCAMPS
- Marc WIRTOR (Luxembourg) Alternate: Maurice HOLPER
- Awaiting nomination (Cyprus) Alternate: Ioanna TALIOTI
- Awaiting nomination (Lithuania) Alternate: Zilvinas ILEVICIUS[11]

### *Co-opted members*

- Rory BREATHNACH (Ireland)
- Peter EKSTRÖM (Sweden)
- Christian FRIIS (Denmark)
- Boris KOLAR (Slovenia)
- Wilhelm SCHLUMBOHM (Germany)

### *Working parties, ad hoc groups and scientific advisory groups*

**Efficacy Working Party**
Chair: Michael HOLZHAUSER-ALBERTI EMA contact: Jill KIEFFER

**Safety Working Party**
Chair: Johan G SCHEFFERLIE EMA contact: Isaura DUARTE

**Immunologicals Working Party**
Chair: Jean-Claude ROUBY EMA contact: Jill KIEFFER

**Scientific Advice Working Party**
Chair: Rory BREATHNACH EMA contact: Jill KIEFFER

**Pharmacovigilance Working Party**
Chair: Cornelia IBRAHIM EMA contact: Isaura DUARTE

**Scientific Advisory Group on Antimicrobials**
Chair: Karolina TÖRNEKE EMA contact: Isaura DUARTE

**Joint CHMP/CVMP Quality Working Party**
Vice-chair (veterinary products): Piet-Hein OVERHAUS EMA contact: David COCKBURN

**Environmental Risk Assessment (temporary working party)**
Chair: Joop A DE KNECHT EMA contact: Isaura DUARTE

**Environmental Risk Assessment (temporary working party)**
Chair: Joop A DE KNECHT EMA contact: Isaura DUARTE

**Coordination group for Mutual recognition and Decentralised procedures (veterinary)**
Chair: Esther WERNER EMA contact: Melanie LEIVERS

[11] Replaced Juozas JOKIMAS as of June 2009 meeting.

# Annex 4 – Members of the Committee on Orphan Medicinal Products

Chair: Kerstin WESTERMARK
EMA contact: Jordi LLINARES GARCIA

## *Members*

- Björn BEERMANN (Sweden)
- Brigitte BLÖCHL-DAUM (Austria)
- János BORVENDÉG (EMA representative)
- Heidrun BOSCH-TRABERG (Denmark)
- Mariana TODOROVA (Bulgaria)
- Birthe BYSKOV HOLM (patients' organisation representative) (vice-chair)
- Maurizio CLEMENTI[1] (Italy)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Marie Pauline EVERS (patients' organisation representative)
- Lars GRAMSTAD (Norway)
- Lesley GREENE[2] (patients' organisation representative)
- Emmanuel HÉRON (France)
- Ioannis KKOLOS (Cyprus)
- Dainis KRIEVINS[3] (Latvia)
- Kateřina KUBÁČKOVÁ (Czech Republic)
- Tatiana FOLTÁNOVÁ[4] (Slovak Republic)
- André LHOIR (Belgium)
- David LYONS (EMA representative)
- Segundo MARIZ[5] (United Kingdom)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Martin MOŽINA (Slovenia)

[1] Replaced Domenica TARUSCIO as of June 2009 meeting.
[2] Replaced Yann LE CAM as of July 2009 meeting.
[3] Replaced Agnis ZVAIGZNE as of July 2009 meeting.
[4] Replaced Magdaléna KUŽELOVÁ as of June 2009 meeting.
[5] Replaced Greg MARKEY as of April 2009 meeting.

- Veijo SAANO (Finland)
- Flavia SALEH (Romania)
- Patrick SALMON (Ireland)
- Miranda SIOUTI (Greece)
- Bruno SEPODES (EMA representative)
- Sigurður B. THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Albertha VOORDOUW (the Netherlands)

## *Ad hoc groups*

**Significant Benefit ad hoc Group**
Chair: Kerstin WESTERMARK EMA contact: Jordi LLINARES GARCIA

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

Chair: Konstantin KELLER
European Medicines Agency contact: Anthony HUMPHREYS

## *Members*

| | |
|---|---|
| • Linda ANDERSON (United Kingdom) | Alternate: Sue HARRIS |
| • Everaldo ATTARD (Malta) | Alternate: Gabriel MICALLEF |
| • Mariette BACKES-LIES (Luxembourg) | Alternate: Jacqueline GENOUX-HAMES |
| • Steffen BAGER (Denmark) | Alternate: Kristine HVOLBY |
| • Zsuzsanna BIRÓ-SÁNDOR (Hungary) | Alternate: awaiting nomination [1] |
| • Ioanna CHINOU (Greece) (vice-chair) | Alternate: Eleni SKALTSA |
| • Per CLAESON (Sweden) | Alternate: Ubonwan CLAESON |
| • Marisa DELBÒ (Italy) | Alternate: Monica CAPASSO |
| • Wojciech DYMOWSKI[2] (Poland) | Alternate: awaiting nomination [3] |
| • Nadia GRIGORAS (Romania) | Alternate: Robert ANCUCEANU |
| • Sinead HARRINGTON (Ireland) | Alternate: Cathal GALLAGHER |
| • Marie HEROUTOVÁ (Czech Republic) | Alternate: Helena LÁTALOVÁ |
| • Dace KALKE (Latvia) | Alternate: Vita GULEVSKA |
| • Artūras KAŽEMEKAITIS (Lithuania) | Alternate: awaiting nomination [4] |
| • Thorbjörg KJARTANDSDÓTTIR (Iceland) | Alternate: Vilborg HALLDORSDOTTIR |
| • Werner KNÖSS (Germany) | Alternate: Jacqueline WIESNER[5] |
| • Samo KREFT (Slovenia) | Alternate: Barbara RAZINGER-MIHOVEC |
| • Gloria GARCÍA LORENTE (Spain) | Alternate: Adela NÚÑEZ VELÁZQUEZ |
| • Steinar MADSEN (Norway) | Alternate: Gro FOSSUM |
| • Ana Paula MARTINS (Portugal) | Alternate: Eva MENDES (as of May 2009) |
| • Heidi NEEF (Belgium) | Alternate: Arnold J. VLIETINCK |
| • Stefan NIKOLOV (Bulgaria) | Alternate: Elena MUSTAKEROVA |
| • Peter POTÚČEK (Slovakia) | Alternate: Milan NAGY |
| • Heribert PITTNER (Austria) | Alternate: Reinhard LÄNGER |
| • Antoine SAWAYA (France) | Alternate: Jacqueline VIGUET POUPELLOZ |

[1] Nóra Piroska FÜLÖP resigned as of February 2009.
[2] Replaced Michal RÓŻAŃSKI as of November 2009.
[3] Iwona DROZDZ-JABLOŃSKA resigned as of December 2009.
[4] Kristina RAMANAUSKIENĖ resigned as of December 2009.
[5] Formerly named Jacqueline KOCH.

- Anneli TÖRRÖNEN (Finland) Alternate: Sari KOSKI
- Panayiotis TRIANTAFYLLIS (Cyprus) Alternate: Maria STAVROU
- Emiel VAN GALEN (Netherlands) Alternate: Burt H. KROES
- Marje ZERNANT (Estonia) Alternate: Evelin SAAR[6]

### *Co-opted members*

- Gioacchino CALAPAI (Clinical pharmacology)
- Silvia GIROTTO (Paediatric medicine) as of January 2009
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Olavi PELKONEN (Toxicology)
- Maria Helena PINTO FERREIRA (General and family medicine)

### *Observers*

- Melanie BALD (EDQM)
- Michael WIERER (EDQM)
- Josipa CVEK (Croatia)
- Ivan KOSALEC (Croatia)
- Merjem HADZIHAMZA (The Former Yugoslav Republic of Macedonia)
- Rajna KOSTOSKA (The Former Yugoslav Republic of Macedonia)
- Oyku MUMCU ARISAN (Turkey)
- F. Handan ÖZTUNCA (Turkey)

### *Working parties and drafting groups*

**Working party on Community Monographs and Community List**
Chair: Ioanna CHINOU (as of January 2009) EMA contact: Anthony HUMPHREYS

**Organisational Matters Drafting Group**
Chair: Emiel VAN GALEN EMA contact: Anthony HUMPHREYS

**Quality Drafting Group**
Chair: Burt H. KROES EMA contact: Anthony HUMPHREYS

[6] Replaced Ain RAAL as of January 2009.

# Annex 6 – Members of the Paediatric Committee

Chair: Daniel BRASSEUR
EMA contact: Paolo TOMASI

### *Members nominated by the CHMP*

| | |
|---|---|
| Robert ANCUCEANU (Romania) | Alternate: Raluca CIRSTEA |
| Alar IRS (Estonia) | Alternate: Irja LUTSAR |
| Romaldas MAČIULAITIS (Lithuania) | Alternate: Rugile PILVINIENE |
| Jan MAZÁG (Slovakia) | Alternate: awaiting nomination |

### *Members nominated by Member States*

| | |
|---|---|
| Fernando de ANDRÉS TRELLES (Spain) | Alternate: Maria Jesús FERNÁNDES CORTIZO |
| Dina APELE-FREIMANE (Latvia) | Alternate: Ilze BĀRENE |
| Carine de BEAUFORT (Luxembourg) | Alternate: awaiting nomination |
| John Joseph BORG (Malta) | Alternate: Herbert LENICKER |
| Kevin CONNOLLY (Ireland) | Alternate: Yvonne LOONEY |
| Hugo DEVLIEGER (Belgium) | Alternate: Jacqueline CARLEER |
| Helena FONSECA (Portugal) | Alternate: Hugo TAVARES[1] |
| Agnes GYURASICS (Hungary) | Alternate: Tamás MACHAY |
| Marta GRANSTRÖM (Sweden) | Alternate: Viveca Lena ODLIND |
| Janez JAZBEC (Slovenia) | Alternate: awaiting nomination |
| Dobrin KONSTANTINOV[2] (Bulgaria) | Alternate: Margarita GUIZOVA[3] |
| Pirjo LAITINEN-PARKKONEN (Finland) | Alternate: Ann Marie KAUKONEN |
| Christoph MALE (Austria) | Alternate: Karl-Heinz HUEMER |
| Dirk MENTZER (Germany) | Alternate: Birka LEHMANN |
| Marek MIGDAL (Poland) | Alternate: awaiting nomination |
| Hubert MOTTL (Czech Republic) | Alternate: Peter SZITANYI |
| Marianne ORHOLM (Denmark) | Alternate: Karen TORNØE |
| Gylfi OSKARSSON (Iceland) | Alternate: Kolbeinn GUDMUNDSSON |
| Gérard PONS (France) (vice-chair) | Alternate: Sophie FORNAIRON |
| Paolo ROSSI (Italy) | Alternate: Francesca ROCCHI |
| Alexandra SOLDATOU (Greece) | Alternate: awaiting nomination [4] |

[1] Replaced Cristina TRINDADE, April 2009.
[2] Replaced Margarita GUIZOVA as of October 2009.
[3] Replaced Dobrin KONSTANTINOV as of November 2009.

| | |
|---|---|
| Johannes TAMINIAU (The Netherlands) | Alternate: Hendrik van den BERG |
| Andreas TELOUDES (Cyprus) | Alternate: Stefanos CHRISTODOULOU |
| Matthew THATCHER (United Kingdom) | Alternate: Timothy CHAMBERS |
| Siri WANG (Norway) | Alternate: Ine BLANKENBERG SKOTTHEIM[5] |

### *Representatives of patients' and healthcare professionals' organisations*

| | |
|---|---|
| Jean-Pierre ABOULKER (Healthcare professional) | Alternate: Alexandra COMPAGNUCCI |
| Adriana CECI (Health professional) | Alternate: Paolo PAOLUCCI |
| Awaiting nomination (Healthcare professional) | Alternate: awaiting nomination |
| Annagrazia ALTAVILLA (Patient organisation) | Alternate: awaiting nomination [6] |
| Michal ODERMARSKY (Patientcare organisation) | Alternate: Milena STEVANOVIC |
| Tsveta SCHYNS-LIHARSKA (Patient organisation) | Alternate: Karen AIACH |

[4] Angeliki ROBOTI resigned in March 2009.
[5] Replaced Ingvild AALØKKEN as of October 2009.
[6] Dominique GIOCANTI resigned in April 2009.

# Annex 7 – National competent authority partners

Further information on the national competent authorities is also available on the national authorities' Internet sites: http://www.hma.eu/human_heads.html and http://www.hma.eu/veterinary_heads.html

BELGIUM

Xavier DE CUYPER
Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Eurostation Blok 2
Victor Hortaplein 40 bus 40
B-1060 Brussels

Tel. (32-2) 524 84 00
Fax (32-2) 524 80 03
E-Mail: xavier.decuyper@fagg-afmps.be

BULGARIA

Alexander YANKOV
Изпълнителна агенция по лекарствата
8, Damyan Gruev str.
BG – 1303 Sofia

Tel. (359-2) 890 35 55
Fax (359-2) 890 34 34
E-Mail: alexander.yankov@bda.bg

Jeko BAICHEV
Национална ветеринарномедицинска служба
National Veterinary Service
бул. "Пенчо Славейков" № 15А
15a, Pencho Slaveykov Blvd.
BG – 1606 Sofia

Tel. (359-2) 91 59 821
Fax (359-2) 91 59 846
E-Mail: j.baichev@nvms.government.bg

CZECH REPUBLIC

Martin BENEŠ
Director
Státní ústav pro kontrolu léčiv
Šrobárova 48
CZ – 100 41 Praha 10

Tel. (420-2) 72 18 58 34
Fax (420-2) 72 73 99 95
E-Mail: martin.benes@sukl.cz
Internet: http://www.sukl.cz

Alfred HERA
Director
Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 56ª
Medlánky
CZ – 621 00 Brno

Tel. (420-541) 21 00 22
Fax (420-541) 21 26 07
E-mail: hera@uskvbl.cz
Internet: http://www.uskvbl.cz

## DENMARK

Jytte LYNGVIG
Direktør
Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København S

Tel. (45-44) 88 95 95
Fax (45-44) 88 95 99
E-mail: jyl@dkma.dk
Internet: http://www.dkma.dk

## GERMANY

Johannes LÖWER
Bundesamt für Sera and Impfstoffe Bundesinstitut für Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
D – 53175 Bonn

Tel. (49-6103) 77 10 00
Fax (49-6103) 77 12 40
E-mail: leitung@bfarm.de

Reinhard KROKER
Leiter des Fachbereichs
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Diedersdorfer Weg 1
D – 12277 Berlin

Tel. (49-1888) 412 23 64
Fax (49-1888) 412 29 65
E-mail: reinhard.kroker@bvl.bund.de
Internet: http://www.bvl.bund.de

## ESTONIA

Kristin RAUDSEPP
Director Gerneral
Ravimiamet
Ravila Str 19
EE – 50411 Tartu

Tel. (372-7) 37 41 40
Fax (372-7) 37 41 42
E-mail: kristin.raudsepp@ravimiamet.ee
Internet: http://www.ravimiamet.ee

GREECE

National Organization for Medicines
284 Mesogeion Av.
Holargos
GR – 155 62 Athens

Tel. (30-210) 650 72 00
Fax (30-210) 654 53 53
E-mail: president@eof.gr
Internet: http://www.eof.gr

SPAIN

Cristina AVENDAÑO SOLÁ
Director
Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial Las Mercedes
Edificio 8
C/Campezo 1
E – 28022 Madrid

Tel. (34-90) 251 01 00
E-mail: sdaem@aemps.es

FRANCE

Jean MARIMBERT
Directeur Général
Agence Française de Sécurité Sanitaire des Produits de Santé
143-147, boulevard Anatole France
F – 93285 Saint-Denis Cedex

Tel. (33-1) 55 87 30 14
Fax (33-1) 55 87 30 12
E-mail: jean.marimert@afssaps.sante.fr
Internet: http://afssaps.sante.fr

Patrick DEHAUMONT
Directeur ANMV
Agence Française de Sécurité Sanitaire des Aliments
Laboratoire des Médicaments Vétérinaires
BP 90 203 Javené
F – 35302 Fougères Cedex

Tel. (33-2) 99 94 78 78
Fax (33-2) 99 94 78 99
E-mail: p.dehaumont@anmv.afssa.fr
Internet: http://www.afssa.fr

IRELAND

Pat O'MAHONY
Chief executive officer
Irish Medicines Board - Bord Leigheasra na hÉirann
Earlsfort Centre
Earlsfort Terrace
IRL – Dublin 2

Tel. (353-1) 634 34 53
Fax (353-1) 661 47 64
E-mail: pat.omahony@imb.ie
Internet: http://www.imb.ie

ITALY

Guido RASI
Agenzia Italiana del Farmaco
Viale della Sierra Nevada 60
I – 00144 Roma

Tel. (39-06) 59 78 42 05
Fax (39-06) 59 78 40 54
E-mail: g.rasi@aifa.gov.it

Romano MARABELLI
Direttore Generale
Ministero della Salute
Servizi Veterinari Roma
Piazzale Marconi 25
I – 00144 Roma

Tel. (39-06) 59 94 69 45
Fax (39-06) 59 94 62 17
E-mail: alimentivet@sanita.it
Internet: http://www.ministerosalute.it

Enrico GARACI
President
Istituto Superiore di Sanità
Viale Regina Elena 299
IT – 00161 Roma

Tel. (39-06) 44 86 94 55
Fax (39-06) 44 86 94 40
E-mail: presidenza@iss.it
Internet: http://www.iss.it

CYPRUS

Panayiota KOKKINOU
Ministry of Health
Pharmaceutical services
7-9 Larnacos Avenue
CY – 1475 Nicosia

Tel. (357-22) 40 71 03
Fax (357-22) 40 71 49
E-mail: pkokkinou@phs.moh.gov.cy
Internet: http://moi.gov.cy

Charalambos KAKOYIANNIS
Ministry of Agriculture, Natural Resources and Environment
Athalassa
CY – 1417 Nicosia

Tel. (357-22) 80 52 00/1
Fax (357-22) 30 52 11
E-Mail: director@vs.moa.gov.cy
Internet: http://www.moa.gov.cy

LATVIA

Inguna ADOVIČA
Director
Zāļu valsts aģentūra
Jersikas iela 15
LV – 1003 Riga IV

Tel. (371-70) 784 31
Fax (371-70) 784 28
E-mail: inguna.adovica@vza.gov.lv
Internet: http://www.vza.gov.lv

LITHUANIA

Gintautas BARCYS
Valstybinė vaistų kontrolės tarnyba
Traku g. 14
LT – 01132 Vilnius

Tel. (370-5) 263 92 64
Fax. (370-5) 263 92 65
E-mail: gintautasbarcys@vvkt.lt
Internet: http://www.vvkt.lt

Jonas MILIUS
Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas
J. Kairiukscio g. 10
LT – 08409 Vilnius

Tel. (370-5) 278 04 70
Fax (370-5) 278 04 71
E-mail: jmilius@vet.lt
Internet: http://www.nmvrvi.lt

LUXEMBOURG

Mariette BACKES-LIES
Pharmacien-Inspecteur - Chef de Division
Ministère de la Santé
Direction de la Santé
Division de la Pharmacie et des Médicaments
Villa Louvigny – 1er étage
Parc de la Ville – Allée Marconi
L – 2120 Luxembourg

Tel. (352) 478 55 90
Fax (352) 26 20 01 47
E-mail: luxdpm@ms.etat.lu
Internet: http://www.ms.etat.lu

HUNGARY

Zsuzsanna SZEPEZDI
Országos Gyógyszer Intézet
PO Box 450
HU – 1372 Budapest

Tel. (36-1) 886 93 00
Fax (36-1) 886 94 60
E-mail: szepezdi.zsuzsa@ogyi.hu
Internet: http://www.ogyi.hu

Gábor KULCSÁR
Mezőgazdasági Szakigazgatási Hivatal Központ,
Állatgyógyászati Termékek Igazgatósága
Szállás u. 8
HU – 1107 Budapest

Tel. (36-1) 433 08 27
Fax (36-1) 262 28 39
E-mail: kulcsarg@oai.hu
Internet: http://www.ivmp.gov.hu

MALTA

Patricia VELLA BONANNO
Medicines Authority
203, Level
3, Rue D'Argens
MT – GRZ 1368 Gzira

Tel. (356-23) 43 90 00
Fax (356-23) 43 91 61
E-mail: patricia.vella@gov.mt
Internet: http://www.gov.mt

Joseph VELLA
Ministry for Rural Affairs and the Environment
Food and Veterinary Regulation Division
The Abattoir
Albert Town
MT – CMR 02 Marsa

Tel. (356-21) 24 26 94
Fax (356-21) 23 81 05
E-mail: joseph-john.vella@gov.mt
Internet: http://www.gov.mt

NETHERLANDS

Aginus A W KALIS
Executive Director
College Ter Beoordeling van Geneesmiddelen
Agentschap
Kalvermarkt 53
NL – 2511 CB Den Haag

Tel. (31-70) 356 74 50
Fax (31-70) 356 75 15
E-mail: aaw.kalis@cbg-meb.nl
Internet: http://www.cbg-meb.nl

AUSTRIA

Marcus MÜLLNER
Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)
Schnirchgasse 9
A – 1030 Vienna

Tel. (43-50) 55 53 60 00
Fax (43 50) 55 53 60 09
E-Mail: marcus.muellner@ages.at
Internet: http://www.ages.at/

Hubert HRABCIK
Bundesministerium für Gesundheit und Frauen
Radetzkystraße 2
A – 1030 Wien

Tel. (43-1) 711 00 47 17
Fax (43-1) 711 00 48 30
E-mail: hubert.hrabcik@bmgf.gv.at
Internet: http://www.bmgf.gv.at

POLAND

Grzegorz CESSAK
Urząd Rejestracji Produktów Leczniczych Wyrobow Medycznych i Produktów Biobójczych
Ząbkowska 41
PL – 03-736 Warszawa

Tel. (48-22) 492 13 60
Fax (48-22) 492 13 69
E-Mail: grzegorz.cessak@urpl.gov.pl
Internet: http://www.urpl.gov.pl

PORTUGAL

Vasco A J MARIA
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED)
Parque de Saúde de Lisboa
Av. do Brasil, 53
PT – 1749-004 Lisboa

Tel. (351-21) 798 71 09
Fax (351-21) 798 71 20
E-mail: vasco.maria@infarmed.pt
Internet: http://www.infarmed.pt

Carlos AGRELA PINHEIRO
Direcção Geral de Veterinária
Largo da Academia Nacional de Belas Artes, 2
PT – 1249-105 Lisboa

Tel. (351-21) 323 96 54
Fax (351-21) 346 35 18
E-mail: dirgeral@dgv.min-agricultura.pt
Internet: http://www.min-agricultura.pt

ROMANIA

Daniel BODA
Nationa Medicines Agency
Str. Aviator Sănătescu 48
Sector 1
RO – 011478 Bucharest

Tel. (402-13) 17 11 02
Fax (402-13) 16 34 97
E-Mail : daniel.boda@anm.ro

Gabriel PREDOI
National Sanitary Veterinary and Food Safety Authority
Str. Negostori nr.1 bis
Sector 2
RO – 023951 Bucharest

Tel. (402-13) 15 78 75
Fax (402-13) 12 49 67
E-Mail: predoi@ansv.ro

Razvan TIRU
National Sanitary Veterinary and Food Safety Authority
Str. Negostori nr.1 bis
Sector 2
RO – 023951 Bucharest

Tel. (402-13) 15 78 75
Fax (402-13) 12 49 67
E-Mail: tiru@ansv.ro

SLOVENIA

Vesna KOBLAR
Director
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
Einšpilerjeva ulica 6
SI - 1000 Ljubljana

Tel. (386-8) 20 00 502
Fax (386-8) 20 00 510
E-Mail: vesna.koblar@jazmp.si
Internet: http://www.jazmp.si

Martina CVELBAR
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
Ptujska ulica 21
SI - 1000 Ljubljana

Tel. (386-8) 20 00 508
Fax (386-8) 20 00 510
E-Mail: martina.cvelbar@jazmp.si
Internet: http://www.jazmp.si

SLOVAKIA

Ján MAZÁG
Director
Štátny ústav pre kontrolu liečiv
Kvetná 11
SK – 825 08 Bratislava 26

Tel. (421-2) 50 70 11 19
Fax (421-2) 55 56 41 27
E-mail: martinec@sukl.sk
Internet: http://www.sukl.sk

Ladislav SOVÍK
Director
Ústav štátnej kontroly veterinárnych biopreparátov a liečiv
Biovetská 4
SK – 949 01 Nitra

Tel. (421-37) 651 55 03
Fax (421-37) 651 79 15
E-mail: uskvbl@flynet.sk
Internet: http://www.uskvbl.sk

FINLAND

Sinikka RAJANIEMI
Lääkealan turvallisuus- ja kehittämiskeskus Fimea
P.O.Box 55
FIN – 00301 Helsinki

Tel. (358-9) 47 33 42 00
Fax (358-9) 47 33 43 50
E-Mail : sinikka.rajaniemi@fimea.fi
Internet: http://www.fimea.fi

SWEDEN

Christina ÅKERMAN
Läkemedelsverket
Dag Hammarskjölds väg 42
S – 751 83 Uppsala

Tel. (46-18) 17 46 00
Fax (46-18) 54 85 66
E-mail: christina.akerman@mpa.se
Internet: http://www.mpa.se

UNITED KINGDOM

Kent WOODS
Chief Executive
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
UK – London SW8 5NQ

Tel. (44-20) 70 84 25 46
Fax (44-20) 70 84 25 48
E-mail: kent.woods@mhra.gsi.gov.uk
Internet: http://www.mhra.gov.uk

Steve DEAN
Chief Executive
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
UK – Surrey KT15 3LS

Tel. (44-1932) 33 83 01
Fax (44-1932) 33 66 18
E-mail: s.dean@vmd.defra.gsi.gov.uk
Internet: http://www.vmd.gov.uk

ICELAND

Rannveig GUNNARSDÓTTIR
Director
Lyfjastofnun
Eidistorg 13-15
PO Box 180
IS – 172 Seltjarnarnes

Tel. (354) 520 21 00
Fax (354) 561 21 70
E-mail: rannveig.gunnarsdottir@lyfjastofnun.is
Internet: http://www.lyfjastofnun.is

LIECHTENSTEIN

Brigitte BATLINER
Kontrollstelle für Arzneimittel, beim Amt für
Lebensmittelkontrolle und Veterinärwesen
Postplatz 2
Postfach 37
FL – 9494 Schaan

Tel. (423) 236 73 25
Fax (423) 236 73 10
E-mail: brigitte.batliner@alkvw.llv.li
Internet: http://www.llv.li

NORWAY

Gro Ramsten WESENBERG
Director General
Statens legemiddelverk
Sven Oftedals vei 8
N – 0950 Oslo

Tel. (47-22) 89 77 01
Fax (47-22) 89 77 99
E-mail: gro.wesenberg@legemiddelverket.no
Internet: http://www.legemiddelverket.no
http://www.noma.no

# Annex 8 – Budget summaries 2008–2009

The summarised comparative budget statements for 2008 and 2009 are as follows:

| | | 2008 (final)[1] | | 2009 (budget)[2] | | 2009 (final)[3] | |
|---|---|---|---|---|---|---|---|
| | | € '000 | % | € '000 | % | € '000 | % |
| | **Revenue** | | | | | | |
| 100 | Fees | 132,179 | *69.07* | 140,966 | *72.52* | 141,023 | *71.90* |
| 200 | General EU contribution including surplus from previous year (reserve) | 42,385 | *22.49* | 41,290 | *21.24* | 41,220 | *21.02* |
| 201 | Special EU contribution for orphan medicinal products | 3,755 | *1.99* | 5,500 | *2.83* | 5,632 | *2.87* |
| 300 | Contribution from EEA | 956 | *0.51* | 888 | *0.46* | 873 | *0.45* |
| 600 | Community programmes | 576 | *0.31* | 360 | *0.19* | 103 | *0.05* |
| 500+ 900 | Other | 8,541 | *4.53* | 5,385 | *2.77* | 7,283 | *3.71* |
| | | | | | | | |
| **TOTAL REVENUE** | | **182,392** | *100.00* | **194,389** | *100.00* | **196,135** | *100.00* |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Expenditure** | | | | | | | |
| **Staff** | | | | | | | |
| 11 | Staff in active employment | 49,200 | *28.40* | 54,898 | *28.24* | 51,988 | *27.85* |
| 13 | Mission expenses | 605 | *0.35* | 789 | *0.41* | 663 | *0.36* |
| 14 | Socio-medical infrastructure | 429 | *0.25* | 570 | *0.29* | 535 | *0.29* |
| 15 | Exchange of civil servants and experts | 1,866 | *1.08* | 3,910 | *2.01* | 2,636 | *1.41* |
| 16 | Social welfare | 92 | *0.05* | 114 | *0.06* | 97 | *0.05* |
| 17 | Entertainment and representation expenses | 33 | *0.02* | 38 | *0.02* | 37 | *0.02* |
| 18 | Staff insurances | 1,573 | *0.91* | 1,867 | *0.96* | 1,786 | *0.96* |
| | *Total Title 1* | *53,798* | *31.06* | *62,186* | *31.99* | *57,742* | *30.93* |
| **Building/equipment** | | | | | | | |
| 20 | Investment in immovable property, renting of building and associated costs | 18,641 | *10.76* | 16,754 | *8.62* | 16,056 | *8.60* |
| 21 | Expenditure on data processing | 25,375 | *14.65* | 29,595 | *15.22* | 29,589 | *15.85* |
| 22 | Movable property and associated costs | 1,668 | *0.96* | 2,779 | *1.43* | 2,598 | *1.39* |
| 23 | Other administrative expenditure | 778 | *0.45* | 1,264 | *0.65* | 1,128 | *0.60* |
| 24 | Postage and communications | 771 | *0.45* | 848 | *0.44* | 818 | *0.44* |
| 25 | Expenditure on formal and other meetings | 63 | *0.04* | 104 | *0.05* | 92 | *0.05* |
| | *Total Title 2* | *47,296* | *27.51* | *51,344* | *26.41* | *50,281* | *26.93* |
| **Operational expenditure** | | | | | | | |
| 300 | Meetings | 7,259 | *4.19* | 8,059 | *4.15* | 7,660 | *4.10* |
| 301 | Evaluations | 60,181 | *34.74* | 67,419 | *34.68* | 66,487 | *35.61* |
| 302 | Translation | 3,937 | *2.27* | 4,345 | *2.24* | 3,991 | *2.14* |
| 303 | Studies and consultants | 82 | *0.05* | 80 | *0.04* | 63 | *0.03* |
| 304 | Publications | 281 | *0.16* | 298 | *0.15* | 197 | *0.11* |
| 305 | Community programmes | 379 | *0.22* | 300 | *0.15* | 272 | *0.15* |
| | *Total Title 3* | *72,120* | *41.64* | *80,501* | *41.41* | *78,670* | *42.14* |
| **Provisional appropriation** | | | | | | | |
| 900 | Provisional appropriation | 0 | 0.00 | 358 | 0.19 | 0 | 0.00 |
| | *Total Title 9* | *0* | *0.00* | *358* | *0.19* | *0* | *0.00* |
| **TOTAL EXPENDITURE** | | **173,213** | *100.00* | **194,389** | *100.00* | **186,693** | *100.00* |

[1] Financial Year 2008: as per final accounts.
[2] Financial Year 2009: as per final budget including Amending Budget 01-2009.
[3] Financial Year 2009: as per provisional accounts.

# Annex 9 – European Medicines Agency Establishment Plan

| Function group & Grade | Temporary posts | | | | | |
|---|---|---|---|---|---|---|
| | Posts 2009 | | | | Posts 2010 | |
| | Authorised | | Actual as per 31.12.2009 | | Authorised | |
| | Permanent posts | Temporary posts | Permanent posts | Temporary posts | Permanent posts | Temporary posts |
| AD 16 | - | 1 | - | - | - | 1 |
| AD 15 | - | 3 | - | 1 | - | 4 |
| AD 14 | - | 4 | - | 4 | - | 5 |
| AD 13 | - | 6 | - | 6 | - | 6 |
| AD 12 | - | 36 | - | 27 | - | 37 |
| AD 11 | - | 34 | - | 28 | - | 36 |
| AD 10 | - | 34 | - | 15 | - | 32 |
| AD 9 | - | 35 | - | 37 | - | 35 |
| AD 8 | - | 40 | - | 26 | - | 43 |
| AD 7 | - | 38 | - | 19 | - | 38 |
| AD 6 | - | 34 | - | 68 | - | 39 |
| AD 5 | - | 17 | - | 36 | - | 34 |
| *Total grade AD* | *0* | *282* | *0* | *267* | *0* | *310* |
| AST 11 | - | - | - | 1 | - | 2 |
| AST 10 | - | 6 | - | 1 | - | 4 |
| AST 9 | - | 5 | - | 2 | - | 8 |
| AST 8 | - | 12 | - | 3 | - | 13 |
| AST 7 | - | 15 | - | 13 | - | 18 |
| AST 6 | - | 38 | - | 16 | - | 35 |
| AST 5 | - | 39 | - | 16 | - | 35 |
| AST 4 | - | 46 | - | 34 | - | 46 |
| AST 3 | - | 30 | - | 50 | - | 36 |
| AST 2 | - | 25 | - | 21 | - | 40 |
| AST 1 | - | 32 | - | 87 | - | 20 |
| *Total grade AST* | *0* | *248* | *0* | *244* | *0* | *257* |
| **Grand Total** | **0** | **530** | **0** | **511** | **0** | **567** |

| **Contract agents** | Planned (FTE[1]) 2009 | Actual (FTE) 2009 | Actual as per 31.12.2009 | Planned (FTE) 2010 |
|---|---|---|---|---|
| **Total** | **85** | **85** | **92** | **125** |

| **National experts** | Planned (FTE) 2009 | Actual (FTE) 2009 | Actual as per 31.12.2009 | Planned (FTE) 2010 |
|---|---|---|---|---|
| **Total** | **28** | **19** | **20** | **19** |

[1] FTE = Full Time Equivalent.

# Annex 10 – CHMP opinions in 2009 on medicinal products for human use

## *CHMP positive opinions in 2009 on non-orphan medicinal products for human use*

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Synflorix<br>• Pneumococcal Polysaccharide serotype | • GlaxoSmithKline Bilogicals | • J07AL52<br>• Prevention of invasive disease and acute otitis media in infants and children caused by Streptococcus pneumoniae serotypes | • 30.01.2008<br>• 22.01.2009<br>• 209 days<br>• 149 days | • 19.02.2009<br>• 30.03.2009<br>• 31.03.2009<br>• OJ C 101, 01.05.2009, p. 3 |
| • Conbriza<br>• Bazedoxifene | • Wyeth Europa Ltd. | • G03XC02<br>• Treatment of postmenopausal osteoporosis in women at increased risk of fracture | • 27.09.2007<br>• 19.02.2009<br>• 202 days<br>• 309 days | • 23.03.2009<br>• 17.04.2009<br>• 21.04.2009<br>• OJ C 121, 29.05.2009, p. 3 |
| • Lunivia<br>• eszopiclone | • Sepracor Pharmaceuticals, Ltd. | • N05CF04<br>• Treatment of insomnia | • 15.08.2007<br>• 19.02.2009<br>• 205 days<br>• 230 days | • Withdrawn after opinion |
| • Exalief<br>• eslicarbazepine acetate | • BIAL-Portela & C, S.A. | • N03AF04<br>• Adjunctive therapy in adults with partial-onset seizure with or without secondary generalisation | • 26.03.2008<br>• 19.02.2009<br>• 205 days<br>• 125 days | • 23.03.2009<br>• 21.04.2009<br>• 22.04.2009<br>• OJ C 121, 29.05.2009, p. 3 |
| • Zebinix<br>• eslicarbazepine acetate | • BIAL-Portela & C, S.A. | • N03AF04<br>• Adjunctive therapy in adults with partial-onset seizure with or without secondary generalisation | • 26.03.2008<br>• 19.02.2009<br>• 205 days<br>• 125 days | • 20.03.2009<br>• 21.04.2009<br>• 23.04.2009<br>• OJ C 121, 29.05.2009, p. 3 |
| • Removab<br>• Catumaxomab | • Fresenius Biotech GmbH | • L01XC09<br>• Intraperitoneal treatment of malignant ascites in patients with EpCAM positive carcinomas | • 30.01.2008<br>• 19.02.2009<br>• 203 days<br>• 183 days | • 19.03.2009<br>• 20.04.2009<br>• 22.04.2009<br>• OJ C 121, 29.05.2009, p. 3 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Modigraf<br>• tacrolimus | • Astellas Pharma Europe B.V. | • L04 AD02<br>• Prophylaxis of transplant rejection in kidney, liver or heart allograft recipients; treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products | • 26.12.2007<br>• 19.03.2009<br>• 205 days<br>• 244 days | • 17.04.2009<br>• 15.05.2009<br>• 20.05.2009<br>• OJ C 146, 26.06.2009, p. 6 |
| • Ellaone<br>• ulipristal | • Laboratories HRA Pharma | • Not yet assigned<br>• Emergency contraception within 5 days of unprotected sexual intercourse or contraceptive failure | • 25.06.2008<br>• 19.03.2009<br>• 203 days<br>• 63 days | • 20.04.2009<br>• 15.05.2009<br>• 20.05.2009<br>• OJ C 146, 26.06.2009, p. 6 |
| • Qutenza<br>• capsaicin | • Quadramed | • N01BX04<br>• Treatment of peripheral neuropathic pain in non-diabetic adults | • 27.09.2007<br>• 19.03.2009<br>• 202 days<br>• 337 days | • 17.04.2009<br>• 15.05.2009<br>• 20.05.2009<br>• OJ C 146, 26.06.2009, p. 6 |
| • Renvela<br>• sevelamer carbonate | • Genzyme Europe B.V. | • VO3AE02<br>• Control of hyperphosphataemia in adults receiving haemodialysis or peritoneal dialysis, or with chronic kidney disease not on dialysis | • 26.03.2008<br>• 19.03.2009<br>• 204 days<br>• 154 days | • 07.05.2009<br>• 10.06.2009<br>• 12.06.2009<br>• OJ C 178, 31.07.2009, p. 12 |
| • Iressa<br>• gefitinib | • Astra Zeneca AB | • LO1XE02<br>• Treatment of adults with locally advanced or metastatic non small cell lung cancer with activating mutations of EGFR TK | • 28.05.2008<br>• 23.04.2009<br>• 210 days<br>• 119 days | • 27.05.2009<br>• 24.06.2009<br>• 26.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Instanyl<br>• fentanyl citrate | • Nycomed Danmark ApS | • N02A B03<br>• Breakthrough pain in cancer patients receiving chronic opioid treatment for background pain | • 26.12.2007<br>• 23.04.2009<br>• 205 days<br>• 279 days | • 26.05.2009<br>• 20.07.2009<br>• 23.07.2009<br>• OJ C 231, 25.09.2009, p. 3 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Victoza<br>• liraglutide | • Novo Nordisk A.S | • A10 BX07<br>• Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with metformin or a sulphonylurea, or metformin and a sulphonylurea, or metformin and a thiazolidinedione | • 25.06.2008<br>• 23.04.2009<br>• 204 days<br>• 98 days | • 21.05.2009<br>• 30.06.2009<br>• 02.07.2009<br>• OJ C 178, 31.07.2009, p. 16 |
| • Pantecta Control<br>• pantoprazole | • Nycomed GmbH | • A02BC02<br>• Short-term treatment of reflux symptoms in adults | • 23.11.2008<br>• 24.04.2009<br>• 80 days<br>• 8 days | • 04.05.2009<br>• 12.06.2009<br>• 16.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Pantoloc Control<br>• pantoprazole | • Nycomed GmbH | • A02BC02<br>• Short-term treatment of reflux symptoms in adults | • 23.11.2008<br>• 24.04.2009<br>• 80 days<br>• 8 days | • 04.05.2009<br>• 12.06.2009<br>• 16.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Controloc Control<br>• pantoprazole | • Nycomed GmbH | • A02BC02<br>• Short-term treatment of reflux symptoms in adults | • 23.11.2008<br>• 24.04.2009<br>• 80 days<br>• 8 days | • 12.06.2009<br>• 16.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Somac Control<br>• pantoprazole | • Nycomed GmbH | • A02BC02<br>• Short-term treatment of reflux symptoms in adults | • 23.11.2008<br>• 24.04.2009<br>• 80 days<br>• 8 days | • 04.05.2009<br>• 12.06.2009<br>• 16.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Pantozol Control<br>• pantoprazole | • Nycomed GmbH | • A02BC02<br>• Short-term treatment of reflux symptoms in adults | • 28.05.2008<br>• 24.04.2009<br>• 197 days<br>• 70 days | • 04.05.2009<br>• 12.06.2009<br>• 16.06.2009<br>• OJ C 178, 31.07.2009, p. 15 |
| • Vedrop<br>• tocofersolan | • The Orphan Pharmaceutical Company | • A11HA08<br>• Vitamin E deficiency due to digestive malabsorption in children suffering from congenital chronic cholestasis or hereditary chronic cholestasis | • 27.09.2007<br>• 29.05.2009<br>• 210 days<br>• 273 days | • 22.06.2009<br>• 24.07.2009<br>• 23.07.2009<br>• OJ C 231, 25.09.2009, p. 3 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Mozobil<br>• plerixafor | • Genzyme Europe B.V. | • L03AX16<br>• In combination with G-CSF to enhance mobilisation of haematopoietic stem cells for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma | • 25.06.2008<br>• 29.05.2009<br>• 207 days<br>• 131 days | • 07.07.2009<br>• 03.08.2009<br>• 04.08.2009<br>• OJ C 231, 25.09.2009, p. 4 |
| • Samsca<br>• tolvaptan | • Otsuka Pharmaceutical Europe, Ltd. | • C03XA01<br>• Treatment of adults with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion | • 27.02.2008<br>• 29.05.2009<br>• 207 days<br>• 250 days | • 30.06.2009<br>• 03.08.2009<br>• 08.08.2009<br>• OJ C 231, 25.09.2009, p. 20 |
| • Javlor<br>• vinflunine ditartrate | • Pierre Fabre Medicament | • L01CA05<br>• Treatment of adults with advanced. metastatic transitional cell carcinoma of urothetial tract | • 27.02.2008<br>• 25.06.2009<br>• 196 days<br>• 288 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Onglyza<br>• saxagliptin | • Bristol Myers Squibb.AstraZeneca EEIG | • A10BH03<br>• Adults with type 2 diabetes mellitus to improve glycaemic control in combination with metformin, with a sulphonylurea, or with a thiazolidinedione | • 23.07.2008<br>• 25.06.2009<br>• 205 days<br>• 132 days | • 22.07.2009<br>• 01.10.2009<br>• 05.10.2009<br>• OJ C 288, 27.11.2009, p. 1 |
| • ChondroCelect<br>• ChondroCelect | • TiGenix NV | • Not yet assigned<br>• Repair treatment of symptomatic cartilaginous defects of the femoral condyle of the knee in adults | • 20.06.2007<br>• 25.06.2009<br>• 195 days<br>• 361 days | • 27.07.2009<br>• 05.10.2009<br>• 07.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Cimzia<br>• certolizumab pegol | • UCB Pharma SA | • L04AB05<br>• Treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drugs is inadequate | • 25.06.2008<br>• 25.06.2009<br>• 205 days<br>• 160 days | • 22.07.2009<br>• 01.10.2009<br>• 06.10.2009<br>• OJ C 288, 27.11.2009, p. 1 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Simponi<br>• golimumab | • Centocor BV | • L04AB06<br>• Treatment of moderate to severe, active rheumatoid arthritis, active and progressive psoriatic arthritis and severe, active ankylosing spondylitis in adults | • 26.03.2008<br>• 25.06.2009<br>• 177 days<br>• 279 days | • 22.07.2009<br>• 01.10.2009<br>• 06.10.2009<br>• OJ C 288, 27.11.2009, p. 1 |
| • Pandemic Influenza Vaccine H5N1 Baxter | • Baxter AG | • J07BB01<br>• Prophylaxis of influenza in an officially declared pandemic situation | • 10.07.2009<br>• 23.07.2009<br>• 13 days<br>• 0 days | • 20.08.2009<br>• 16.10.2009<br>• 20.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Pandemrix Influenza Vaccine H5N1 GSK Biologicals<br>• H5N1 split antigen influenza vaccine | • GlaxoSmithKlineBiologicals S.A. | • J07BB02<br>• Prophylaxis of influenza in an officialy declared pandemic situation | • 15.07.2009<br>• 23.07.2009<br>• 8 days<br>• 0 days | • 10.04.2008<br>• 19.10.2009<br>• 21.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Exforge HCT<br>• amlodipine besylate.valsartan. hydrochlorothiazide | • Novartis Europharm Ltd. | • C09DX01<br>• Treatment of essential hypertension as substitution therapy in adults | • 24.09.2008<br>• 23.07.2009<br>• 206 days<br>• 96 days | • 19.08.2009<br>• 16.10.2009<br>• 20.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Foclivia<br>• Influenza virus surface antigens | • Chiron Behring GmbH | • J07BB02<br>• Prophylaxis of influenza in an officialy declared pandemic situation | • 14.07.2009<br>• 23.07.2009<br>• 9 days<br>• 0 days | • 07.08.2009<br>• 19.10.2009<br>• 21.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Biopoin<br>• epoetin theta | • CT Arznemittel GmbH | • B03XA01<br>• Treatment of symptomatic anaemia associated with chronic renal failure in adults, or in adult cancer patients with non-myeloid malignancies receiving chemotherapy | • 25.06.2008<br>• 23.07.2009<br>• 205 days<br>• 188 days | • 24.08.2009<br>• 23.10.2009<br>• 27.10.2009<br>• OJ C 288, 27.11.2009, p. 3 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Eporatio<br>• epoetin theta | • Ratiopharm GmbH | • B03XA01<br>• Treatment of symptomatic anaemia associated with chronic renal failure in adults, or in adult cancer patients with non-myeloid malignancies receiving chemotherapy | • 25.06.2008<br>• 23.07.2009<br>• 205 days<br>• 188 days | • 19.08.2009<br>• 29.10.2009<br>• 02.11.2009<br>• OJ C 288, 27.11.2009, p. 3 |
| • Ratioepo<br>• epoetin theta | • Ratiopharm GmbH | • B03XA01<br>• Treatment of symptomatic anaemia associated with chronic renal failure in adults, or in adult cancer patients with non-myeloid malignancies receiving chemotherapy | • 25.06.2008<br>• 23.07.2009<br>• 205 days<br>• 188 days | • Withdrawn after opinion |
| • Dafiro HCT<br>• amlodipine besylate.valsartan. hydrochlorothiazid e | • Novartis Europharm Ltd. | • C09DX01<br>• Treatment of essential hypertension as substitution therapy in adults | • 29.03.2009<br>• 23.07.2009<br>• 89 days<br>• 27 days | • 19.08.2009<br>• 04.11.2009<br>• 06.11.2009<br>• OJ C 22, 29.01.2010, p. 2 |
| • Copalia HCT<br>• amlodipine besylate.valsartan. hydrochlorothiazid e | • Novartis Europharm Ltd. | • C09DX01<br>• Treatment of essential hypertension as substitution therapy in adults | • 29.03.2009<br>• 23.07.2009<br>• 89 days<br>• 27 days | • 19.08.2009<br>• 04.11.2009<br>• 06.11.2009<br>• OJ C 22, 29.01.2010, p. 2 |
| • Resolor<br>• Prucalopride succinate | • Movetis NV | • A03AE04<br>• Symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief | • 28.05.2008<br>• 23.07.2009<br>• 206 days<br>• 215 days | • 30.07.2009<br>• 15.10.2009<br>• 19.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Imprida HCT<br>• amlodipine besylate.valsartan. hydrochlorothiazid e | • Novartis Europharm Ltd. | • C09 DX01<br>• Treatment of essential hypertension as substitution therapy in adults | • 29.03.2009<br>• 23.07.2009<br>• 89 days<br>• 27 days | • 19.08.2009<br>• 15.10.2009<br>• 19.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Multaq<br>• dronedarone hydrochloride | • Sanofi Aventis | • Not yet assigned<br>• Clinically stable adults with a history of, or current non-permanent atrial fibrillation | • 23.07.2008<br>• 24.09.2009<br>• 183 days<br>• 245 days | • 21.10.2009<br>• 26.11.2009<br>• 01.12.2009<br>• OJ C 22, 29.01.2010, p. 2 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Oslif Breezhaler<br>• indacaterol | • Novartis Europharm Ltd. | • R03 AC18<br>• Maintenance bronchodilator treatment of airflow obstruction in adults with chronic obstructive pulmonary disease | • 26.07.2009<br>• 24.09.2009<br>• 60 days<br>• 0 days | • 21.10.2009<br>• 30.11.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Hirobriz Breezhaler<br>• indacaterol maleate | • Novartis Europharm Ltd | • R03 AC18<br>• Maintenance bronchodilator treatment of airflow obstruction in adults with chronic obstructive pulmonary disease | • 26.07.2009<br>• 24.09.2009<br>• 60 days<br>• 0 days | • 01.10.2009<br>• 30.11.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Onbrez Breezhaler<br>• indacaterol | • Novartis Europharm Ltd. | • R03 AC18<br>• Maintenance bronchodilator treatment of airflow obstruction in adults with chronic obstructive pulmonary disease | • 28.01.2009<br>• 24.09.2009<br>• 178 days<br>• 61 days | • 01.10.2009<br>• 30.11.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Prevenar 13<br>• Pneumococcal Sacharide conjugated vaccine Wyeth | • Wyeth Lederle Vaccines S.A. | • JO7AL02<br>• Active child immunisation for the prevetion of invasive disease pneumonia and acute otitis media caused by Streptococcus pneumoniae | • 24.12.2008<br>• 24.09.2009<br>• 204 days<br>• 70 days | • 26.10.2009<br>• 09.12.2009<br>• 11.12.2009<br>• OJ C 22, 29.01.2010, p. 18 |
| • Zutectra<br>• human hepatitis B immunoglobulin | • Biotest Pharma GmbH | • J06BB04<br>• Prevention of hepatitis B virus re-infection in HBV-DNA negative adults after liver transplantation for hepatitis B induced liver failure | • 19.11.2008<br>• 24.09.2009<br>• 204 days<br>• 105 days | • 22.10.2009<br>• 30.11.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Zenas (name changed to Firdapse)<br>• diaminopyridine | • EUSA Pharma SAS | • NO7 XX05<br>• Symptomatic treatment of Lambert-Eaton myasthenic syndrome in adults | • 25.06.2008<br>• 22.10.2009<br>• 196 days<br>• 288 days | • 18.12.2009<br>• 23.12.2009<br>• 28.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |
| • Scintimun<br>• besilesomab | • CIS bio International | • V09 HA03<br>• Scintigraphic imaging for determining the location of sites on inflammation. infection in peripheral bone in adults with suspected osteomyelitis | • 23.07.2008<br>• 22.10.2009<br>• 203 days<br>• 253 days | • 28.10.2009<br>• |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Silodyx<br>• silodosin | • Recordati Ireland Ltd. | • G04CA04<br>• Treatment of the signs and symptoms of benign prostatic hyperplasia | • 24.07.2009<br>• 19.11.2009<br>• 85 days<br>• 33 days | • 16.12.2009<br>• |
| • Urorec<br>• silodosin | • Recordati Ireland Ltd. | • G04CA04<br>• Treatment of the signs and symptoms of benign prostatic hyperplasia | • 19.11.2008<br>• 19.11.2009<br>• 205 days<br>• 160 days | • 16.12.2009<br>• |
| • Elonva<br>• corifollitropin alfa | • N.V.Organon | • G03 GA09<br>• Controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in assisted reproduction | • 24.12.2008<br>• 19.11.2009<br>• 205 days<br>• 125 days | • 25.11.2009<br>• |
| • Prolia<br>• denosumab | • Amgen Europe B.V. | • M05BX04<br>• Treatment of osteoporosis in postmenopausal women at increased risk of fractures; treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures | • 28.01.2009<br>• 17.12.2009<br>• 212 days<br>• 111 days | • |
| • Menveo<br>• MenACWY | • Novartis Vaccines and Diagnostics S.r.l. | • J07AH<br>• Active immunization of adolescents and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y | • 19.11.2008<br>• 17.12.2009<br>• 205 days<br>• 188 days | • 20.01.2010<br>• |
| • ImmunoGam<br>• human hepatitis B immunoglobulin | • Cangene Europe Limited | • J06BB04<br>• Immunoprophylaxis of hepatitis B | • 20.08.2008<br>• 17.12.2009<br>• 205 days<br>• 279 days | • 20.01.2010<br>• |
| • Ristaben<br>• sitagliptin | • Merck Sharp & Dohme | • A10BH01<br>• Type 2 diabetes mellitus to improve glycaemic control as mono, dual or triple oral therapy; as add-on to insulin (with or without metformin) | • 17.10.2009<br>• 17.12.2009<br>• 61 days<br>• 0 days | • |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Ristfor<br>• sitagliptin phosphate, monohydrate | • Merck Sharp & Dohme | • A10BH01<br>• Type 2 diabetes mellitus to improve glycaemic control in combination with metformin, or with a sulphonylurea, or as triple combination therapy with a PPARγ agonist; as add-on to insulin and metformin | • 17.10.2009<br>• 17.12.2009<br>• 61 days<br>• 0 days | • |

## *CHMP positive opinions in 2009 on orphan medicinal products for human use*

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Nymusa<br>• caffeine citrate | • Chiesi Farmaceutici SpA | • N06BC01<br>• Treatment of primary apnoea of premature newborns | • 28.05.2008<br>• 23.04.2009<br>• 204 days<br>• 126 days | • 25.05.2009<br>• 02.07.2009<br>• 06.07.2009<br>• OJ C 231, 25.09.2009, p. 3 |
| • Afinitor<br>• everolimus | • Novartis Europharm Ltd | • L01X E10<br>• Treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy | • 23.07.2008<br>• 29.05.2009<br>• 206 days<br>• 104 days | • 25.06.2009<br>• 03.08.2009<br>• 05.08.2009<br>• OJ C 231, 25.09.2009, p. 20 |
| • Cayston<br>• aztreonam Lysine | • Gilead Sciences International Ltd | • J01DF01<br>• Improve respiratory symptoms and lung function in cystic fibrosis patients with Pseudomonas aeruginosa | • 26.03.2008<br>• 25.06.2009<br>• 204 days<br>• 154 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |
| • Arcalyst<br>• rilonacept | • Regeneron UK Ltd. | • L04AC0<br>• Treatment of cryopyrin-associated periodic syndromes with severe symptoms, including familial cold autoinflammatory syndrome and Muckle-Wells syndrome | • 23.07.2008<br>• 23.07.2009<br>• 197 days<br>• 168 days | • 25.08.2009<br>• 23.10.2009<br>• 27.10.2009<br>• OJ C 288, 27.11.2009, p. 3 |
| • Ilaris<br>• canakinumab | • Novartis Europharm Ltd | • L04AC0<br>• Treatment of cryopyrin associated periodic syndromes | • 24.12.2008<br>• 23.07.2009<br>• 176 days<br>• 35 days | • 18.08.2009<br>• 23.10.2009<br>• 27.10.2009<br>• OJ C 288, 27.11.2009, p. 3 |
| • Revolade<br>• eltrombopag | • GSK Group Ltd. | • B02BX05<br>• Chronic immune (idiopathic) thrombocytopenic purpura splenectomised adults refractory to other treatments second line; treatment for non-splenectomised adults where surgery is contraindicated | • 24.12.2008<br>• 17.12.2009<br>• 199 days<br>• 159 days | • 15.01.2010<br>• |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Tepadina<br>• thiotepa | • Adienne S.r.L. | • L01 AC01<br>• In combination for the conditioning treatment prior to haemotopoietic progenitor cell transplantation | • 23.07.2008<br>• 17.12.2009<br>• 206 days<br>• 306 days | • 24.06.2009<br>• |

## *CHMP positive opinions in 2009 on generic medicinal products for human use (including hybrid, informed consent and well-established use applications)*

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Fertavid<br>• follitropin beta | • N.V.Organon | • G03G A06<br>• Treatment of female infertility; treatment of deficient spermatogenesis in males due to hypogonadotrophic hypogonadism | • 27.07.2008<br>• 22.01.2009<br>• 89 days<br>• 90 days | • 19.02.2009<br>• 19.03.2009<br>• 23.03.2009<br>• OJ C 101, 01.05.2009, p. 3 |
| • Ribavirin Teva<br>• ribavirin | • Teva Pharma B.V. | • J05 A B04<br>• Treatment of chronic hepatitis C in combination with peginterferon alfa-2b (adults) or interferon alfa-2b | • 28.05.2008<br>• 22.01.2009<br>• 203 days<br>• 36 days | • 18.02.2009<br>• 31.03.2009<br>• 02.04.2009<br>• OJ C 101, 01.05.2009, p. 3 |
| • Rivastigmine Teva<br>• rivastigmine hydrogen tartrate | • Teva Pharma B.V. | • N06 D A03<br>• Treatment of mild to moderately severe Alzheimer's dementia and mild to moderateldementia in Parkinson's disease | • 23.07.2008<br>• 19.02.2009<br>• 177 days<br>• 34 days | • 18.03.2009<br>• 17.04.2009<br>• 21.04.2009<br>• OJ C 121, 29.05.2009, p. 3 |
| • Nimvastid<br>• rivastigmine | • Krka, d.d., Novo mesto | • N06D A03<br>• Treatment of mild to moderately severe Alzheimer's dementia and mild to moderate dementia in Parkinson's disease | • 25.06.2008<br>• 19.03.2009<br>• 198 days<br>• 69 days | • 16.04.2009<br>• 11.05.2009<br>• 13.05.2009<br>• OJ C 146, 26.06.2009, p. 6 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Repaglinide Teva<br>• repaglinide | • Teva Pharma B.V. | • A10B X02<br>• Type 2 diabetes when hyperglycaemia cannot be controlled by diet, weight reduction and exercise; in combination with metformin in type 2 diabetes | • 24.09.2008<br>• 23.04.2009<br>• 177 days<br>• 34 days | • 26.05.2009<br>• 29.06.2009<br>• 01.07.2009<br>• OJ C 178, 31.07.2009, p. 16 |
| • Ribavirin Teva Pharma BV<br>• ribavirin | • Teva | • J05AB04<br>• Treatment of hepatitis C | • 24.09.2008<br>• 23.04.2009<br>• 177 days<br>• 34 days | • 21.05.2009<br>• 01.07.2009<br>• 03.07.2009<br>• OJ C 231, 25.09.2009, p. 3 |
| • Topotecan Actavis<br>• topotecan | • Actavis Group PTC ehf | • L01XX17<br>• As monotherapy for treatment of small cell lung cancer; in combination with cisplatin for carcinoma of the cervix | • 25.06.2008<br>• 29.05.2009<br>• 206 days<br>• 132 days | • 22.07.2009<br>• 24.07.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |
| • Clopidogrel Hexal<br>• clopidogrel besilate | • Acino Pharma GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 22.02.2009<br>• 29.05.2009<br>• 87 days<br>• 9 days | • 24.07.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 4 |
| • Clopidogrel 1A Pharma<br>• clopidogrel besilate | • Acino Pharma GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 20.08.2008<br>• 29.05.2009<br>• 204 days<br>• 78 days | • 24.06.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 4 |
| • Clopidogrel Teva<br>• clopidogrel hydrogen sulphate | • Teva Pharma BV | • BO1AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 20.08.2008<br>• 29.05.2009<br>• 204 days<br>• 78 days | • 24.06.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 4 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Grepid<br>• clopidogrel besylate | • Pharmathen S.A. | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 20.08.2008<br>• 29.05.2009<br>• 204 days<br>• 78 days | • 26.06.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 4 |
| • Clopidogrel Acino<br>• clopidogrel besilate | • Acino Pharma GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 28.04.2009<br>• 29.05.2009<br>• 30 days<br>• 0 days | • 24.06.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 3 |
| • Clopidogrel ratiopharm GmbH<br>• clopidogrel besilate | • Acino Pharma GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 28.04.2009<br>• 29.05.2009<br>• 30 days<br>• 0 days | • 24.06.2009<br>• 28.07.2009<br>• 31.07.2009<br>• OJ C 231, 25.09.2009, p. 4 |
| • Topotecan Teva<br>• Topotecan hydrochloride | • Teva Pharma BV | • L01XX17<br>• As monotherapy for treatment of carcinoma of the ovary and small cell lung cancer; in combination with cisplatin for carcinoma of the cervix | • 22.10.2008<br>• 25.06.2009<br>• 177 days<br>• 69 days | • 22.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 231, 25.09.2009, p. 3 |
| • Clopidogrel Teva Pharma (formerly HCS)<br>• clopidogrel | • Teva Pharma B.V. | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Clopidogrel Qualimed<br>• clopidogrel | • Qualimed | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 23.09.2009<br>• 25.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Vizarsin<br>• sildenafil citrate | • Krka d.d. Novo mesto | • G04BE03<br>• Treatment of men with erectile dysfunction | • 22.10.2008<br>• 25.06.2009<br>• 197 days<br>• 49 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |
| • Clopidogrel Krka<br>• clopidogrel hydrogen sulphate | • Krka, d.d. Nove Mesto | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 20.08.2008<br>• 25.06.2009<br>• 197 days<br>• 112 days | • 23.07.2009<br>• 23.09.2009<br>• 25.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Zyllt<br>• clopidogrel hydrogen sulphate | • Krka, d.d. Nove Mesto | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; in acute coronary syndrome | • 20.08.2008<br>• 25.06.2009<br>• 197 days<br>• 112 days | • 23.07.2009<br>• 28.09.2009<br>• 30.09.2009<br>• OJ C 260, 30.10.2009, p. 8 |
| • Clopidogrel Acino Pharma GmbH<br>• clopidogrel | • Acino Pharma GmbH | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 23.04.2009<br>• 25.06.2009<br>• 55 days<br>• 8 days | • 23.07.2009<br>• 28.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Clopidogrel TAD<br>• clopidogrel | • Tad Pharma GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 23.09.2009<br>• 25.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Zopya<br>• clopidogrel | • Norpharm Regulatory Services Ltd. | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Zylagren<br>• clopidogrel | • Krka, d.d Novo mesto | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80days<br>• 12days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Clopidogrel Acino Pharma<br>• clopidogrel | • Acino Pharma GmbH | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 04.06.2009<br>• 25.06.2009<br>• 21 days<br>• 0 days | • 23.07.2009<br>• 28.09.2009<br>• 30.09.2009<br>• OJ C 260, 30.10.2009, p. 8 |
| • Clopidogrel Mylan<br>• clopidogrel | • Mylan S.A.S. | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 21.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 7 |
| • Clopidogrel DURA<br>• clopidogrel | • Mylan dura GmbH | • B01 AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 25.03.2009<br>• 25.06.2009<br>• 80 days<br>• 12 days | • 23.07.2009<br>• 28.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |
| • Clopidogrel Sandoz<br>• clopidogrel | • Acino Pharma GmbH | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 04.06.2009<br>• 25.06.2009<br>• 21 days<br>• 0 days | • 24.07.2009<br>• 23.09.2009<br>• 23.09.2009<br>• OJ C 260, 30.10.2009, p. 6 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Clopidogrel ratiopharm<br>• clopidogrel besilate | • Acino Pharma GmbH | • BO1AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 04.06.2009<br>• 25.06.2009<br>• 21 days<br>• 0 days | • 23.07.2009<br>• 23.09.2009<br>• 25.09.2009<br>• OJ C 260, 30.10.2009, p. 8 |
| • Irbesartan Teva<br>• irbesartan | • Teva Pharma BV | • C09CA04<br>• Treatment of essential hypertension; treatment of renal disease in patients with hypertension and type 2 diabetes mellitus | • 19.11.2008<br>• 23.07.2009<br>• 196 days<br>• 50 days | • 19.08.2009<br>• 23.10.2009<br>• 04.11.2009<br>• OJ C 288, 27.11.2009, p. 3 |
| • Clopidogrel Mylan Pharma<br>• clopidogrel | • Mylan S.A.S. | • B01AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 24.06.2009<br>• 23.07.2009<br>• 21 days<br>• 0 days | • 19.08.2009<br>• 16.10.2009<br>• 20.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Alendronate sodium.colecalciferol MSD<br>• alendronic acid.colcalciferol | • Merck Sharp and Dohme Ltd. | • M05BB03<br>• Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency | • 24.05.2009<br>• 23.07.2009<br>• 60 days<br>• 0 days | • 18.08.2009<br>• 16.10.2009<br>• 20.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Enyglide<br>• repaglinide | • Krka d.d. | • A10B X02<br>• Patients with Type 2 diabetes; in combination with metformin in Type 2 diabetes | • 24.09.2008<br>• 23.07.2009<br>• 209 days<br>• 96 days | • 19.08.2009<br>• 14.10.2009<br>• 16.10.2009<br>• OJ C 288, 27.11.2009, p. 2 |
| • Lamivudine Teva<br>• lamivudine | • Teva pharma BV | • J05AF05<br>• Treatment of chronic hepatitis B in adults | • 24.12.2008<br>• 23.07.2009<br>• 176 days<br>• 35 days | • 21.01.2008<br>• 23.10.2009<br>• 27.10.2009<br>• OJ C 288, 27.11.2009, p. 3 |
| • Repaglinide Krka<br>• repaglinide | • Krka d.d. | • A10B X02<br>• Patients with Type 2 diabetes | • 24.09.2008<br>• 23.07.2009<br>• 206 days<br>• 96 days | • 19.08.2009<br>• 04.11.2009<br>• 06.11.2009<br>• OJ C 22, 29.01.2010, p. 2 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Sildenafil Teva<br>• sildenafil citrate | • Teva Pharma B.V. | • G04BE03<br>• Treatment of men with erectile dysfunction | • 22.10.2008<br>• 24.09.2009<br>• 208 days<br>• 129 days | • 01.10.2009<br>• 30.11.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Olanzapine Glenmark Europe<br>• olanzapine | • Glenmark Generics (Europe)Ltd | • N05 AH03<br>• Treatment of schizophrenia and moderate to severe manic episode | • 19.11.2008<br>• 24.09.2009<br>• 207 days<br>• 102 days | • 28.10.2009<br>• 03.12.2009<br>• 07.12.2009<br>• OJ C 22, 29.01.2010, p. 18 |
| • Nevirapine Teva<br>• nevirapine | • Teva Pharma BV | • J05 AG 01<br>• Treatment of HIV-1 infection in combination with anti-retroviral medicinal products | • 28.01.2009<br>• 24.09.2009<br>• 180 days<br>• 59 days | • 22.10.2009<br>• 11.12.2009<br>• 02.12.2009<br>• OJ C 22, 29.01.2010, p. 3 |
| • Rivastigmine 1A Pharma<br>• rivastigmine | • 1 A Pharma GmbH | • N06D A03<br>• Treatment of mild to moderately severe Alzheimer's dementia and mild to moderate dementia in Parkinson's disease | • 24.05.2009<br>• 24.09.2009<br>• 30 days<br>• 93 days | • 21.10.2009<br>• 11.12.2009<br>• 16.12.2009<br>• OJ C 22, 29.01.2010, p. 21 |
| • Irbesartan Hydrochlorothiazide Teva<br>• irbesartan hydrochlorothiazide | • Teva Pharma B.V. | • C09DA04<br>• Treatment of essential hypertension in adults not adequately controlled on irbesartan or hydrochlorothiazide alone | • 24.12.2008<br>• 24.09.2009<br>• 148 days<br>• 35 days | • 22.10.2009<br>• 26.11.2009<br>• 01.12.2009<br>• OJ C 22, 29.01.2010, p. 2 |
| • Rivastigmine Hexal<br>• rivastigmine | • Hexal AG | • N06 DA03<br>• Treatment of mild to moderately severe Alzheimer's dementia and mild to moderate dementia in Parkinson's disease | • 24.05.2009<br>• 24.09.2009<br>• 30 days<br>• 93 days | • 21.10.2009<br>• 11.12.2009<br>• 15.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |
| • Rivastigmine Sandoz<br>• rivastigmine | • Sandoz Pharmaceuticals GmbH | • N06D A03<br>• Treatment of mild to moderately severe Alzheimer's dementia and mild to moderate dementia in Parkinson's disease | • 24.05.2009<br>• 24.09.2009<br>• 30 days<br>• 93 days | • 22.10.2009<br>• 11.12.2009<br>• 15.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Lamivudine Teva Pharma BV<br>• lamivudine | • Teva Pharma B.V. | • J05AF05<br>• Treatment of chronic hepatitis B in adults | • 24.12.2008<br>• 24.09.2009<br>• 176 days<br>• 35 days | • 01.10.2009<br>• 10.12.2009<br>• 14.12.2009<br>• OJ C 22, 29.01.2010, p. 18 |
| • Sildenafil Actavis<br>• sildenafil citrate | • Actavis Group PTC ehf | • G04B E03<br>• Treatment of men with erectile dysfunction | • 19.11.2008<br>• 24.09.2009<br>• 208 days<br>• 159 days | • 29.09.2009<br>• 10.12.2009<br>• 14.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |
| • Olazax Disperzi<br>• olanzapine | • Glenmark Generics (Europe)Ltd | • N05 AH03<br>• Treatment of schizophrenia and moderate to severe manic episode | • 19.11.2008<br>• 24.09.2009<br>• 207 days<br>• 102 days | • 01.10.2009<br>• 10.12.2009<br>• 14.12.2009<br>• OJ C 22, 29.01.2010, p. 18 |
| • Olazax<br>• olanzapine | • Glenmark Generics (Europe)Ltd | • N05 AH03<br>• Treatment of schizophrenia and moderate to severe manic episode | • 19.11.2008<br>• 24.09.2009<br>• 207 days<br>• 102 days | • 28.10.2009<br>• 11.12.2009<br>• 15.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |
| • Olanzapine Glenmark<br>• olanzapine | • Glenmark Generics (Europe)Ltd | • N05 AH03<br>• Treatment of schizophrenia and moderate to severe manic episode | • 19.11.2008<br>• 24.09.2009<br>• 207 days<br>• 102 days | • 28.10.2009<br>• 03.12.2009<br>• 07.12.2009<br>• OJ C 22, 29.01.2010, p. 18 |
| • Sildenafil Ratiopharm<br>• sildenafil citrate | • Ratiopharm GmbH | • G04B E03<br>• Treatment of men with erectile dysfunction | • 22.10.2008<br>• 22.10.2009<br>• 206 days<br>• 159 days | • 19.11.2009<br>• 23.12.2009<br>• 28.12.2009<br>• OJ C 22, 29.01.2010, p. 19 |
| • Leflunomide Winthrop<br>• leflunomide | • Sanofi Aventis | • L04 AA13<br>• Treatment of adults with active rheumatoid arthritis or active psoriatic arthritis | • 22.02.2009<br>• 22.10.2009<br>• 208 days<br>• 31 days | • 28.10.2009<br>• |
| • Docetaxel Teva<br>• docetaxel | • Teva Pharma B.V. | • L01 CD02<br>• Breast cancer, Non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, head and neck cancer | • 24.12.2008<br>• 19.11.2009<br>• 207 days<br>• 123 days | • 25.11.2009<br>• |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Telmisartan Teva<br>• telmisartan | • Teva Pharma B.V. | • C09 CA07<br>• Treatment of essential hypertension | • 25.03.2009<br>• 19.11.2009<br>• 180 days<br>• 59 days | • 25.11.2009<br>• |
| • Temozolomide Teva<br>• temozolomide | • Teva Pharma BV | • L01A X03<br>• Treatment of adults with newly-diagnosed glioblastoma multiforme; children and adults with malignant glioma showing recurrence or progression | • 25.02.2009<br>• 19.11.2009<br>• 210 days<br>• 57 days | • 17.12.2009<br>• |
| • Temomedac<br>• temozolomide | • ALFRED E. TIEFENBACHER (GmbH & Co. KG) | • L01A X03<br>• Treatment of adults with newly-diagnosed glioblastoma multiforme; children and adults with malignant glioma showing recurrence or progression | • 25.02.2009<br>• 19.11.2009<br>• 210 days<br>• 57 days | • 16.12.2009<br>• |
| • DuoCover<br>• clopidogrel hydrogensulphate. acetylsalicylic acid | • Sanofi Pharma Bristol Myers Squibb SNC | • B01AC30<br>• Prevention of atherothrombotic events in adults taking both clopidogrel and acetylsalicylic acid; continuation of therapy in non-ST segment elevation acute coronary syndrome and ST segment elevation acute myocardial infarction | • 25.03.2009<br>• 17.12.2009<br>• 172 days<br>• 95 days | • |
| • DuoPlavin<br>• clopidogrel hydrogensulphate. acetylsalicylic acid | • Sanofi Pharma Bristol Myers Squibb SNC | • B01AC30<br>• Prevention of atherothrombotic events in adults taking both clopidogrel and acetylsalicylic acid; continuation of therapy in non-ST segment elevation acute coronary syndrome and ST segment elevation acute myocardial infarction | • 25.03.2009<br>• 17.12.2009<br>• 172 days<br>• 95 days | • |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA/CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Temozolomide Sandoz<br>• temozolomide | • Sandoz Pharmaceuticals GmbH | • L01A X03<br>• Treatment of adults with newly-diagnosed glioblastoma multiforme; children and adults with malignant glioma showing recurrence or progression | • 25.02.2009<br>• 17.12.2009<br>• 208 days<br>• 87 days | • 28.01.2010<br>• |
| • Temozolomide HEXAL<br>• temozolomide | • HEXAL AG | • L01A X03<br>• Treatment of adults with newly-diagnosed glioblastoma multiforme; children and adults with malignant glioma showing recurrence or progression | • 25.02.2009<br>• 17.12.2009<br>• 208 days<br>• 87 days | • 28.01.2009<br>• |
| • Temozolomide Hospira<br>• temozolomide | • Hospira UK Limited | • L01A X03<br>• Treatment of adults with newly-diagnosed glioblastoma multiforme; children and adults with malignant glioma showing recurrence or progression | • 25.02.2009<br>• 17.12.2009<br>• 208 days<br>• 87 days | • 25.01.2010<br>• |

## *CHMP negative opinions in 2009 on medicinal products for human use*

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Emerflu<br>• H5N1 split antigen influenza vaccine Alum adjuvanted | • Sanofi Pasteur MSD | • JO7BB<br>• Prophylaxis of influenza in an officially declared pandemic situation | • 23.05.2007<br>• 19.03.2009<br>• 204 days<br>• 462 days | |
| • Nenad<br>• lisuride | • Axxonis Pharma AG | • N04B C, G02B C<br>• Treatment of moderate to severe idiopathic restless legs syndrome | • 28.05.2008<br>• 19.11.2009<br>• 207 days<br>• 333 days | |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Oncophage<br>• vitespen | • Antigenics Therapeutics Limited | • Not yet assigned<br>• Adjuvant treatment for localized renal cell carcinoma patients at increased risk of recurrence | • 22.10.2008<br>• 19.11.2009<br>• 207 days<br>• 186 days | |
| • Cerepro<br>• sitimagene ceradenovec | • Ark Therapeutics Ltd. | • L01XX37<br>• Treatment of patients with operable high grade glioma in conjuction with ganciclovir sodium | • 24.12.2008<br>• 17.12.2009<br>• 206 days<br>• 152 days | |
| • Biferonex<br>• interferon-beta-1a | • BioPartners GmbH | • L03 AB<br>• Treatment of ambulatory patients with relapsing remitting multiple sclerosis | • 15.08.2007<br>• 19.02.2009<br>• 205 days<br>• 349 days | |
| • Gemesis<br>• becaplermin | • Biomimetic Therapeutics | • Not yet assigned<br>• Treatment of periodontally related defects | • 26.03.2008<br>• 23.07.2009<br>• 204 days<br>• 280 days | |
| • Milnacipran hydrochloride<br>• milnacipran hydrochloride | • Pierre Fabre Medicament | • Not yet assigned<br>• Treatment of fibromyalgia syndrome | • 25.06.2008<br>• 23.07.2009<br>• 175 days<br>• 217 days | |
| • Impulsor<br>• milnacipran | • Pierre Fabre Medicament | • Not yet assigned<br>• Treatment of fibromyalgia syndrome | • 18.01.2009<br>• 23.07.2009<br>• 59 days<br>• 127 days | |

## *Centralised applications for medicinal products for human use – withdrawals in 2009 prior to opinion*

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop |
|---|---|---|---|
| • Factive<br>• gemifloxacin mesylate | • Menarini International Operation | • J01MA15<br>• Treatment of bacterial infections | • 26.03.2008<br>• 17.06.2009<br>• 196 days<br>• 260 days |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop |
|---|---|---|---|
| • Vorinostat MSD<br>• vorinostat | • Merck Sharp & Dohme | • L01XX38<br>• Treatment of patients with cutaneous T-cell lymphoma having progressive, persistent or recurrent disease subsequent to other therapies | • 21.11.2007<br>• 13.02.2009<br>• 202 days<br>• 251 days |
| • Cylatron (Pegintrerferon alfa-2b Schering Plough)<br>• pegintrerferon alfa-2b | • Schering Plough Europe | • L03AB10<br>• Adjuvant treatment for patients with stage III melanoma evidenced by microscopic, non-palpable nodal involvement | • 27.09.2007<br>• 11.03.2009<br>• 194 days<br>• 337 days |
| • Opaxio (previously CT-2103)<br>• Paclitaxel poliglumex | • Canary Wharf Life Science Ltd. | • L01CD03<br>• First-line monotherapy of PS2 patients with advanced non-small cell lung cancer | • 26.03.2008<br>• 21.09.2009<br>• 177 days<br>• 367 days |
| • Ramvocid<br>• oritavancin | • Targanta Therapeutics Corporation | • J01XA05<br>• Treatment of complicated skin and soft tissue infections caused by susceptible isolates of gram-positive microorganisms | • 25.06.2008<br>• 20.08.2009<br>• 177 days<br>• 244 days |
| • Zunrisa<br>• casopitant mesylate | • Glaxo Group limited | • A04AD13<br>• Prevention of nausea and vomiting in patients receiving initial and repeat courses of highly and moderately emetogenic cancer chemotherapy and of post-operative nausea and vomiting | • 23.07.2008<br>• 25.09.2009<br>• 174 days<br>• 255 days |
| • Contusugene ladenovec<br>• contusugene ladenovec | • Gendux | • Not yet assigned<br>• Treatment of recurrent or refractory squamous cell carcinoma of the head and neck as monotherapy | • 20.08.2008<br>• 12.06.2009<br>• 120 days<br>• 176 days |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop |
|---|---|---|---|
| • Clopidogrel Teva Pharma (hydrobromide)<br>• clopidogrel hydrobromide | • Teva Pharma B.V. | • BO1AC04<br>• Prevention of atherothrombotic events in adults suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease | • 20.08.2008<br>• 22.04.2009<br>• 176 days<br>• 69 days |
| • Mersarex<br>• iclaprim mesylate | • Arpida A.S | • J01EA03<br>• Treatment of complicated skin and soft-tissue infections | • 20.08.2008<br>• 19.10.2009<br>• 208 days<br>• 217 days |
| • Bosatria<br>• mepolizumab.SB 240563 | • Glaxo Group Limited | • LO4 AC06<br>• Treatment of adult hypereosinophilic syndrome without the FIP1L1-PDGRF fusion gene, to reduce or eliminate the need for corticosteroid therapy and to reduce eosinophil count | • 24.09.2008<br>• 28.07.2009<br>• 178 days<br>• 129 days |
| • Recothrom<br>• thrombin alfa | • Bayer Schering Pharma AG | • B02BC06<br>• Supportive treatment in surgery for improvement of haemostasis where standard surgical techniques are insufficient | • 24.09.2008<br>• 11.12.2009<br>• 197 days<br>• 249 days |
| • Sliwens (Previously known as Eplivanserin)<br>• eplivanserin hemifumarate | • sanofi-aventis | • N05CM<br>• Treatment of chronic insomnia characterised by difficulties with sleep; maintenance as measured by duration and number of nocturnal awakenings | • 24.12.2008<br>• 18.12.2009<br>• 181 days<br>• 178 days |
| • Ethyl Eicosapent Soft Gelatin Capsules<br>• ethyl eicosapent | • Amarin Neuroscience Limited | • Not yet assigned<br>• Treatment of Huntington's disease | • 25.03.2009<br>• 01.12.2009<br>• 120 days<br>• 131 days |

| **Product**<br>• Brandname<br>• INN | **Marketing authorisation holder** | **Therapeutic Area**<br>• ATC Code<br>• Summary of indication | **EMA.CHMP**<br>• Validation<br>• Opinion<br>• Active Time<br>• Clock stop |
|---|---|---|---|
| • Zactima<br>• vandetanib | • Astra Zeneca AB | • Not yet assigned<br>• In combination with chemotherapy for treatment of locally advanced or metastatic non small cell lung cancer in patients who have received prior anticancer therapy | • 22.07.2009<br>• 27.10.2009<br>• 97 days<br>• 0 days |

# Annex 11 – CVMP opinions in 2009 on medicinal products for veterinary use

## *CVMP Opinions in 2009 on Medical Products for Veterinary Use*

### Positive Opinions

| **Product**<br>• Invented name<br>• INN/Common name | **Marketing authorisation holder** | **Therapeutic area**<br>• Target species<br>• Summary of indication | **EMA/CVMP**<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • Netvax<br>• Clostridium perfringens type A toxoid | Schering-Plough, United Kingdom | • Chickens<br>• Necrotic enteritis | • 10/02/2007<br>• 11/02/2009<br>• 210<br>• 379 | • 16/03/2009<br>• 16/04/2009<br>• 20/04/2009<br>• OJ C 121/12 |
| • BTVPUR Alsap 8<br>• Blutongue virus serotype 8 antigen | Mérial, France | • Sheep, cattle<br>• Prevention of Blue Tongue virus serotype 8 | • 25/03/2008<br>• 11/02/2009<br>• 175<br>• 149 | • 12/02/2009<br>• 17/03/2009<br>• 19/03/2009<br>• OJ C 101/12 |
| • Improvac<br>• GnRF analogue-protein conjugate | Pfizer, United Kingdom | • Male pigs<br>• Control of boar taint | • 14/08/2007<br>• 11/03/2009<br>• 210<br>• 365 | • 08/04/2009<br>• 11/05/2009<br>• 13/05/2009<br>• OJ C 146/13 |
| • Leucofeligen FeLV/RCP<br>• vaccine against feline calicivirosis, feline viral rhinotrachietis, feline panleucopenia and feline leukaemia | Virbac France | • Cats<br>• Immunisation against feline calicivirosis, viral rhinotracheitis, panleucopenia ad leukaemia | • 18/03/2008<br>• 11/03/2009<br>• 210<br>• 147 | • 20/05/2009<br>• 25/06/2009<br>• 29/06/2009<br>• OJ C 178/22 |
| • Leucogen<br>• inactivated feline leukaemia virus | Virbac, France | • Cats<br>• Immunisation against feline leukaemia | • 18/03/2008<br>• 11/03/2008<br>• 210<br>• 147 | • 20/05/2009<br>• 17/06/2009<br>• 19/06/2009<br>• OJ C 178/22 |
| • Melovem<br>• meloxicam | Dopharma, The Netherlands | • Cattle, pigs<br>• Musculo-skeletal | • 15/07/2008<br>• 13/05/2009<br>• 155<br>• 119 | • 10/06/2009<br>• 07/07/2009<br>• 09/07/2009<br>• OJ C 231/16 |
| • Suvaxyn PCV<br>• inactivated porcine cirovirus recombinant virus (cPCV) 1-2 | Fort Dodge United Kingdom | • Piglets<br>• Vaccine to reduce PCV-2 viraemia | • 20/05/2008<br>• 13/05/2008<br>• 184<br>• 147 | • 18/05/2009<br>• 24/07/2009<br>• 30/07/2009<br>• OJ C 231/16 |
| • Palladia<br>• toceranib | Pfizer United Kingdom | • Dogs<br>• Treatment of Patnaik grade II or III, recurrent, cutaneous tumours | • 20/05/2008<br>• 18/06/2009<br>• 174<br>• 157 | • 14/07/2009<br>• 23/09/2009<br>• 25/09/2009<br>• OJ C 260/13 |
| • Zolvix<br>• monepantel | Novartis Denmark | • Sheep<br>• Anthelmintic | • 16/09/2008<br>• 15/07/2009<br>• 119<br>• 92 | • 11/08/2009<br>• 04/11/2009 |
| • RESPIPORC FLU3<br>• Inactivated influenza A virus/ swine | IDT Biologiak GmhB Germany | • Pigs<br>• Immunisation against swine influenza | • 12/08/2008<br>• 11/11/2009<br>• 210<br>• 246 | • 06/11/2009<br>• 14/01/2010 |
| • Gripovac 3<br>• Inactivated influenza A virus/ swine | Mérial S.A.S. France | • Pigs<br>• Immunisation against swine influenza | • 09/03/2009<br>• 11/11/2009<br>• 156<br>• 92 | • 06/11/2009<br>• 14/01/2010 |
| • Zulvac 8 Bovis<br>• Inactivated blue | Fort Dodge Animal Health | • Cattle<br>• Prevention of | • 25/03/2008<br>• 11/11/2009 | • 09/12/2009<br>• 15/01/2010 |

| **Product**<br>• Invented name<br>• INN/Common name | **Marketing authorisation holder** | **Therapeutic area**<br>• Target species<br>• Summary of indication | **EMA/CVMP**<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| tongue virus, serotype 8 | United Kingdom | viraemia caused by Bluetongue Virus, serotype 8. | • 168<br>• 427 | |
| • Zulvac 8 Ovis<br>• inactivated blue tongue virus, serotype 8 | Fort Dodge Animal Health<br>United Kingdom | • Sheep<br>• Prevention of viraemia caused by Bluetongue Virus, serotype 8. | • 17/04/2008<br>• 11/11/2009<br>• 145<br>• 428 | • 09/12/2009<br>• 15/01/2010 |

## *CVMP Opinions in 2009 on establishment of MRLs for new substances*

### Positive Opinions

| **Substance INN** | **Therapeutic area**<br>• Target species | **EMA/CVMP**<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Date of regulation<br>• Official Journal |
|---|---|---|---|
| Gamithromycin | • Bovine | • Following provisional MRLs<br>• 14/01/2009<br>• 83<br>• - | • 29/01/2009<br>• 04/07/2009<br>• OJ L 175/3 |
| Diclofenac | • Bovine (milk) | • 13/11/2008<br>• 11/02/2009<br>• 90<br>• 0 | • 27/02/2009<br>• 04/07/2009<br>• OJ L 175/5 |
| Valnemulin | • Rabbit | • 16/01/2009<br>• 16/04/2009<br>• 90<br>• 0 | • 06/05/2009 |
| Methylprednisolone | • Bovine (milk) | • 16/04/2009<br>• 15/07/2009<br>• 90<br>• 0 | • 23/07/2009 |
| Tildipirosin | • Cattle<br>• Pigs | • 19/03/2009<br>• 10/12/2009<br>• 119<br>• 146 | • 22/12/2009 |

# Annex 12 – COMP opinions in 2009 on designation of orphan medicinal products

## *COMP positive designation opinions*

| **Product INN** | **Sponsor** | **Summary of indication** | **EMA/COMP**<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | **European Commission**<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| 2,2-dimethylbutyric acid, sodium salt | Isabelle Ramirez - Germany | Treatment of beta-thalassaemia intermedia and major | • 23.10.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells | Teva Pharma GmbH - Germany | Treatment of acute myeloid leukaemia | • 23.07.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| Tobramycin (inhalation use) | PARI Pharma GmbH - Germany | Treatment of Pseudomonas Aeruginosa lung infection in cystic fibrosis | • 17.10.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells | Teva Pharma GmbH - Germany | Treatment of acute lymphoblastic leukaemia | • 23.07.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| (6R)-4, 5, 6, 7-tetrahydro-N6-propyl-2, 6-benzothiazolediamine dihydrochloride monohydrate | Knopp Neurosciences Sub Ltd - UK | Treatment of amyotrophic lateral sclerosis | • 23.10.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| N-terminal hexaglutamine-tagged recombinant human N-acetylgalactosamine-6-sulfate sulfatase | Dr Gosse B. Bruinsma - The Netherlands | Treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome) | • 23.10.2008<br>• 07.11.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| Mifepristone | EXELGYN - France | Treatment of hypercortisolism (Cushing's syndrome) of endogenous origin | • 12.09.2008<br>• 05.12.2008<br>• 07.01.2009<br>• 61 days | • 27.01.2009<br>• 27.02.2009 |
| 2,2-dimethylbutyric acid, sodium salt | Isabelle Ramirez - Germany | Treatment of sickle cell disease | • 20.11.2008<br>• 05.12.2008<br>• 09.02.2009<br>• 66 days | • 23.02.2009<br>• 18.03.2009 |
| N-(5-tert-Butylisoxazol-3-yl)-N'-{4-[7-(2-(morpholin-4-yl)ethoxy) imidazo[2,1-b][1,3]benzothiazol-2-yl]phenyl}urea di-hydrochloride salt | Ambit Europe Limited - UK | Treatment of acute myeloid leukaemia | • 20.11.2008<br>• 05.12.2008<br>• 09.02.2009<br>• 66 days | • 23.02.2009<br>• 23.03.2009 |
| (R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile phosphate | Incyte Corporation Ltd - UK | Treatment of myelofibrosis secondary to polycythemia vera or essential thrombocythemia | • 20.11.2008<br>• 05.12.2008<br>• 09.02.2009<br>• 66 days | • 23.02.2009<br>• 03.04.2009 |
| Autologous tumor-derived gp96 heat shock protein-peptide complex | Antigenics Therapeutics Limited - Ireland | Treatment of glioma | • 20.11.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |
| Talampanel | Teva Pharma GmbH - Germany | Treatment of glioma | • 09.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |

| **Product INN** | **Sponsor** | **Summary of indication** | **EMA/COMP**<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | **European Commission**<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Autologous haematopoietic stem cells transduced with lentiviral vector encoding the human beta-globin gene | EGT San Rocco Italia SRL - Italy | Treatment of beta-thalassaemia intermedia and major | • 09.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |
| Lintuzumab | Seattle Genetics UK, Limited - UK | Treatment of myelodysplastic syndrome | • 11.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |
| Guanabenz | Acure Pharma AB - Sweden | Treatment of traumatic spinal cord injury | • 12.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |
| Adeno-associated viral vector containing porphobilinogen deaminase gene | Amsterdam Molecular Therapeutics BV - The Netherlands | Treatment of acute intermittent porphyria | • 20.11.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 29.04.2009 |
| Skin equivalent graft genetically corrected with a COL7A1-encoding SIN retroviral vector | Prof. Alain Hovnanian - France | Treatment of dystrophic epidermolysis bullosa | • 27.10.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 30.04.2009 |
| Nanobody directed towards the human A1 domain of von Willebrand factor | Ablynx NV - Belgium | Treatment of thrombotic thrombocytopenic purpura | • 09.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 30.04.2009 |
| Mercaptopurine (oral suspension) | Nova Laboratories Limited - UK | Treatment of acute lymphoblastic leukaemia | • 09.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 30.04.2009 |
| Lintuzumab | Seattle Genetics UK, Limited - UK | Treatment of acute myeloid leukaemia | • 11.12.2008<br>• 05.01.2009<br>• 04.03.2009<br>• 58 days | • 24.03.2009<br>• 30.04.2009 |
| Treprostinil diethanolamine | United Therapeutics Europe Ltd - UK | Treatment of systemic sclerosis | • 20.11.2008<br>• 06.02.2009<br>• 02.04.2009<br>• 55 days | • 21.04.2009<br>• 15.05.2009 |
| Alicaforsen | Atlantic Healthcare Limited - UK | Treatment of pouchitis | • 27.01.2009<br>• 06.02.2009<br>• 02.04.2009<br>• 55 days | • 21.04.2009<br>• 15.05.2009 |
| 2',3',5'-tri-O-acetyluridine | Wellstat Therapeutics EU Limited - UK | Treatment of 5-fluorouracil overdose | • 11.12.2008<br>• 05.01.2009<br>• 02.04.2009<br>• 87 days | • 21.04.2009<br>• 15.05.2009 |
| Humanised IgG4 monoclonal antibody to the human toll-like receptor type 2 | Opsona Therapeutics - Ireland | Prevention of the ischaemia/reperfusion injury associated with solid organ transplantation | • 11.12.2008<br>• 05.01.2009<br>• 02.04.2009<br>• 87 days | • 21.04.2009<br>• 15.05.2009 |
| Pegylated recombinant human factor IX | Novo Nordisk A/S - Denmark | Treatment of haemophilia B | • 21.01.2009<br>• 06.02.2009<br>• 02.04.2009<br>• 55 days | • 21.04.2009<br>• 15.05.2009 |
| Dexamethasone phosphate (iontophoretic solution, ocular use) | Voisin Consulting S.A.R.L. - France | Treatment of corneal graft rejection | • 09.12.2008<br>• 05.01.2009<br>• 02.04.2009<br>• 87 days | • 21.04.2009<br>• 15.05.2009 |
| L-asparaginase encapsulated in erythrocytes | ERYtech Pharma S.A. - France | Treatment of pancreatic cancer | • 17.11.2008<br>• 06.02.2009<br>• 02.04.2009<br>• 55 days | • 21.04.2009<br>• 15.05.2009 |
| S-[2,3-bispalmitoyloxy-(2R)-propyl]-cysteinyl-GNNDESNISFKEK | Mbiotec GmbH - Germany | Treatment of pancreatic cancer | • 20.11.2008<br>• 05.01.2009<br>• 02.04.2009<br>• 87 days | • 21.04.2009<br>• 15.05.2009 |

| Product INN | Sponsor | Summary of indication | EMA/COMP<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | European Commission<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| 4,6,8-trihydroxy-10-(3,7,11-trimethyldodeca-2,6,10-trienyl)-5,10-dihydrodibenzo[b,e][1,4] diazepin-11-one | Albany Regulatory Consulting Ltd - UK | Treatment of glioma | • 20.01.2009<br>• 06.02.2009<br>• 02.04.2009<br>• 55 days | • 21.04.2009<br>• 15.05.2009 |
| Murine monoclonal antibody to GD2 | United Therapeutics Europe Ltd - UK | Treatment of neuroblastoma | • 20.02.2009<br>• 09.03.2009<br>• 05.05.2009<br>• 57 days | • 20.05.2009<br>• 12.06.2009 |
| Chimeric-anti-interleukin-6 monoclonal antibody | Centocor, B.V. - The Netherlands | Treatment of multiple myeloma | • 16.01.2009<br>• 06.02.2009<br>• 05.05.2009<br>• 88 days | • 20.05.2009<br>• 12.06.2009 |
| Talampanel | Teva Pharma GmbH - Germany | Treatment of amyotrophic lateral sclerosis | • 20.02.2009<br>• 09.03.2009<br>• 05.05.2009<br>• 57 days | • 20.05.2009<br>• 12.06.2009 |
| Octreotide chloride (lipid depot solution) | Camurus AB - Sweden | Treatment of acromegaly | • 19.02.2009<br>• 09.03.2009<br>• 05.05.2009<br>• 57 days | • 20.05.2009<br>• 12.06.2009 |
| Desipramine chlorhydrate | Targeon SAS - France | Treatment of Rett syndrome | • 22.01.2009<br>• 09.03.2009<br>• 05.05.2009<br>• 57 days | • 20.05.2009<br>• 12.06.2009 |
| Octocog alpha (liposomal) | Bayer Schering Pharma AG - Germany | Treatment of haemophilia A | • 23.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Blinatumomab | Micromet AG - Germany | Treatment of acute lymphoblastic leukaemia | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Recombinant human N-acetylgalactosamine-6-sulfatase | BioMarin Europe Ltd. - United Kingdom | Treatment of mucopolysaccharidosis, type IVA (Morquio A syndrome) | • 23.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Recombinant hisitidine-tagged idiotype immunoglobulin Fab fragment of clonal B-cell receptors | CellGenix Technologie Transfer GmbH - Germany | Treatment of diffuse large B-cell lymphoma | • 22.10.2008<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells | Teva Pharma GmbH - Germany | Treatment of Hodgkin lymphoma | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Afamelanotide | Clinuvel UK Limited (record 2) - UK | Treatment of solar urticaria | • 23.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Eculizumab | Alexion Europe SAS | Treatment of atypical hemolytic uremic syndrome | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Trabedersen | Antisense Pharma GmbH - Germany | Treatment of pancreatic cancer | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Ciclosporin (eye drops, solution) | Allergan Pharmaceuticals Ireland - Ireland | Treatment of atopic keratoconjunctivitis | • 23.02.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |

| Product INN | Sponsor | Summary of indication | EMA/COMP<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | European Commission<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Ciprofloxacin (liposomal) | Interface International Consultancy Ltd - United Kingdom | Treatment of cystic fibrosis | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| (S)-3'-(OH)-desazadesferrithiocin-polyether, magnesium salt | FerroKin BioSciences Ltd - UK | Treatment of chronic iron overload requiring chelation therapy | • 16.02.2009<br>• 09.03.2009<br>• 04.06.2009<br>• 87 days | • 30.06.2009<br>• 24.07.2009 |
| Tamibarotene | Eudax S.R.L. - Italy | Treatment of acute promyelocytic leukaemia | • 14.01.2009<br>• 09.03.2009<br>• 04.06.2009<br>• 87 days | • 30.06.2009<br>• 24.07.2009 |
| Tosedostat | Chroma Therapeutics Ltd - UK | Treatment of acute myeloid leukaemia | • 25.03.2009<br>• 14.04.2009<br>• 04.06.2009<br>• 51 days | • 30.06.2009<br>• 24.07.2009 |
| Hypothiocyanite / lactoferrin | Alaxia - France | Treatment of cystic fibrosis | • 17.02.2009<br>• 09.03.2009<br>• 04.06.2009<br>• 87 days | • 30.06.2009<br>• 24.07.2009 |
| 26 base single stranded phosphodiester DNA oligonucleotide | Antisoma Research Limited - United Kingdom | Treatment of acute myeloid leukaemia | • 16.03.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Human C1 inhibitor | ViroPharma SPRL - Belgium | Treatment of angioedema caused by C1 inhibitor deficiency | • 25.03.2009<br>• 14.04.2009<br>• 08.07.2009<br>• 85 days | • 24.07.2009<br>• 08.10.2009 |
| Adeno-associated viral vector containing modified U1 snRNA | Amsterdam Molecular Therapeutics BV - The Netherlands | Treatment of Duchenne muscular dystrophy | • 15.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Pomalidomide | Celgene Europe Limited - UK | Treatment of multiple myeloma | • 18.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Pasireotide | Novartis Europharm Limited - UK | Treatment of acromegaly | • 18.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells | Teva Pharma GmbH - Germany | Treatment of myelodysplastic syndrome | • 25.03.2009<br>• 14.04.2009<br>• 08.07.2009<br>• 85 days | • 24.07.2009<br>• 08.10.2009 |
| (-)-trans-3-(5,6-dihydro-4H-pyrrolo [3,2,1-ij] quinolin-1yl)-4(1H-indol-3-yl) pyrrolidine-2, 5-dione | Gregory Fryer Associates Ltd - United Kingdom | Treatment of soft tissue sarcomas | • 25.03.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 11.09.2009<br>• 08.10.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells | Teva Pharma GmbH - Germany | Treatment of chronic myeloid leukaemia | • 25.03.2009<br>• 14.04.2009<br>• 08.07.2009<br>• 85 days | • 24.07.2009<br>• 08.10.2009 |
| Sequence modified human recombinant factor VIIa | Bayer Schering Pharma AG - Germany | Treatment of haemophilia B | • 29.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 11.09.2009<br>• 08.10.2009 |
| Eicosapentaenoic acid | SLA Pharma (UK) Ltd - UK | Treatment of familial adenomatous polyposis | • 28.04.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| (S)-ethyl 2-amino-3-(4-(2-amino-6((R)-1-(4-chloro-2-(3-methyl-1H-pyrazol-1-yl)phenyl)-2,2,2-trifluoroethoxy)pyrimidin-4-yl)phenyl)propanoate | Lexicon Celtic Ltd - UK | Treatment of carcinoid tumours | • 15.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |

| **Product INN** | **Sponsor** | **Summary of indication** | **EMA/COMP**<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | **European Commission**<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Pasireotide | Novartis Europharm Limited - UK | Treatment of Cushing's disease | • 18.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue (eASCs, adipose derived stem cells) | Cellerix S.A. - Spain | Treatment of anal fistula | • 18.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.07.2009<br>• 08.10.2009 |
| Human tumour necrosis factor alpha-derived peptide Cys-Gly-Gln-Arg-Glu-Thr-Pro-Glu-Gly-Ala-Glu-Ala-Lys-Pro-Trp-Tyr-Cys | Apeptico Forschung und Entwicklung GmbH - Austria | Treatment of acute lung injury | • 12.03.2009<br>• 14.04.2009<br>• 08.07.2009<br>• 85 days | • 11.09.2009<br>• 08.10.2009 |
| Sequence-modified recombinant human factor VIIa | Bayer Schering Pharma AG - Germany | Treatment of hemophilia A | • 25.03.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 11.09.2009<br>• 09.10.2009 |
| Recombinant human serum amyloid P | RegPak BioPharma Consulting - The Netherlands | Prevention of scarring post glaucoma filtration surgery (trabeculectomy) | • 26.03.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 11.09.2009<br>• 09.10.2009 |
| Recombinant antibody construct against human CD30 and CD16A | Affimed Therapeutics AG - Germany | Treatment of Hodgkin lymphoma | • 14.05.2009<br>• 05.06.2009<br>• 08.07.2009<br>• 33 days | • 24.09.2009<br>• 09.10.2009 |
| Low molecular weight dextran sulfate | TikoMed AB - Sweden | To prevent graft rejection during pancreatic islet transplantation | • 25.03.2009<br>• 14.04.2009<br>• 08.07.2009<br>• 85 days | • 24.07.2009<br>• 09.10.2009 |
| Masitinib mesilate | AB Science - France | Treatment of pancreatic cancer | • 26.05.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| 4-benzyl-2-naphtalen-1-yl-1,2,4-thiadiazolidine-3,5-dione | NOSCIRA, S.A. - Spain | Treatment of progressive supranuclear palsy | • 25.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| Cholic Acid | Special Products Ltd. - United Kingdom | Treatment of inborn errors of primary bile acid synthesis responsive to treatment with cholic acid | • 25.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| 5'-O-(trans-9''-octadecenoyl)-1-beta-D-2'deoxy-2',2'-difluorocytidine | Clavis Pharma ASA - Norway | Treatment of pancreatic cancer | • 22.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| Anti-EphA2 monoclonal antibody conjugated to maleimidocaproyl monomethylauristatin phenylalanine | MedImmune Ltd - UK | Treatment of ovarian cancer | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| 6-chloro-2,3,4,9-tetrahydro-1H-carbazole-1-carboxamide | Siena Biotech SpA - Italy | Treatment of Huntington's disease | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 28.10.2009 |
| Human anthrax immunoglobulin | Emergent Sales and Marketing Germany GmbH - Germany | Treatment on inhalation anthrax disease | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 28.09.2009<br>• 05.11.2009 |

| Product INN | Sponsor | Summary of indication | EMA/COMP<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | European Commission<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Patupilone | Novartis Europharm Limited - UK | Treatment of fallopian tube cancer | • 18.05.2009<br>• 05.06.2009<br>• 02.09.2009<br>• 89 days | • 23.09.2009<br>• 05.11.2009 |
| Patupilone | Novartis Europharm Limited - UK | Treatment of primary peritoneal cancer | • 18.05.2009<br>• 05.06.2009<br>• 02.09.2009<br>• 89 days | • 23.09.2009<br>• 05.11.2009 |
| Human anthrax immunoglobulin | Emergent Sales and Marketing Germany GmbH - Germany | Post-exposure prophylaxis of inhalation anthrax disease | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 28.09.2009<br>• 09.11.2009 |
| N-[(2S)-2,3-dihydroxypropyl]-3-[(2-fluoro-4-iodophenyl)amino]isonicotinamide hydrochloride | Merck KGaA - Germany | Treatment of pancreatic cancer | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 09.11.2009 |
| Peptides mimicking antigen receptors on autoimmune B cells and autoimmune T cells associated with myasthenia gravis | CuraVac Europe SPRL - Belgium | Treatment of myasthenia gravis | • 25.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 09.11.2009 |
| NGR-human Tumor Necrosis Factor | MolMed S.p.A. - Italy | Treatment of hepatocellular carcinoma | • 24.06.2009<br>• 10.07.2009<br>• 02.09.2009<br>• 54 days | • 23.09.2009<br>• 09.11.2009 |
| 16-base single-stranded PNA oligonucleotide linked to a 7-aminoacid peptide | Biogenera srl - Italy | Treatment of neuroblastoma | • 23.07.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 25.11.2009 |
| N-[6-(cis-2,6-Dimethylmorpholin-4-yl)pyridine-3-yl]-2-methyl-4'-(trifluoromethoxy)[1,1'-biphenyl]-3-carboxamide | Novartis Europharm Limited - UK | Treatment of naevoid basal cell carcinoma syndrome (Gorlin syndrome) | • 15.05.2009<br>• 10.07.2009<br>• 07.10.2009<br>• 89 days | • 21.10.2009<br>• 25.11.2009 |
| Pegylated carboxyhaemoglobin | Voisin Consulting S.A.R.L. - France | Treatment of sickle cell disease | • 25.06.2009<br>• 10.07.2009<br>• 07.10.2009<br>• 89 days | • 21.10.2009<br>• 26.11.2009 |
| 1-Cyclopropyl-3-[3-(5-morpholin-4-ylmethyl-1H-benzoimidazol-2-yl)-1H-pyrazol-4-yl]-urea | Astex Therapeutics Ltd - United Kingdom | Treatment of acute myeloid leukaemia | • 24.07.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 26.11.2009 |
| 6-thioguanine (oral liquid) | Only For Children Pharmaceuticals - France | Treatment of acute lymphoblastic leukaemia | • 24.07.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 26.11.2009 |
| Recombinant chimeric monoclonal antibody against CD20 | LFB-Biotechnologies - France | Treatment of chronic lymphocytic leukaemia | • 24.07.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 26.11.2009 |
| Vaccinia GM-CSF/TK-deactivated virus | Sirius Regulatory Consulting Limited - UK | Treatment of hepatocellular carcinoma | • 25.06.2009<br>• 10.07.2009<br>• 07.10.2009<br>• 89 days | • 21.10.2009<br>• 26.11.2009 |
| 8-[4-(1-aminocyclobutyl)phenyl]-9-phenyl-1,2,4-triazolo[3,4-f][1,6]naphthyridin-3(2H)-one mono-hydrochloride | Merck Sharp & Dohme Limited - UK | Treatment of ovarian cancer | • 23.07.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 30.11.2009 |
| Human MHC non-restricted cytotoxic T-cell line | Abiogen Pharma S.p.A. - Italy | Treatment of ovarian cancer | • 23.01.2009<br>• 10.08.2009<br>• 07.10.2009<br>• 58 days | • 21.10.2009<br>• 30.11.2009 |

| Product INN | Sponsor | Summary of indication | EMA/COMP<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | European Commission<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Veltuzumab | Immunomedics GmbH - Germany | Treatment of chronic lymphocytic leukaemia | • 07.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 29.01.2010 |
| Human monoclonal antibody against Pseudomonas aeruginosa IATS-O1 | Envestia Limited - United Kingdom | Treatment of pneumonia caused by serotype O1 Pseudomonas aeruginosa | • 28.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Recombinant kallikrein inhibitor | Voisin Consulting S.A.R.L. - France | Treatment of Netherton syndrome | • 26.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 29.01.2010 |
| Lithium citrate tetrahydrate (in reverse-micelle formulation) | Medesis Pharma - France | Treatment of Huntington's disease | • 24.07.2009<br>• 10.08.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Recombinant fusion protein consisting of the extracellular portion of CD95 fused to the Fc part of a human IgG1 molecule | Apogenix GmbH - Germany | Treatment of glioma | • 29.07.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Pegylated recombinant phenylalanine ammonia lyase | BioMarin Europe Ltd. - United Kingdom | Treatment of hyperphenylalaninaemia | • 28.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Givinostat | Italfarmaco S.p.A. - Italy | Treatment of systemic-onset juvenile idiopathic arthritis | • 24.07.2009<br>• 10.08.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Streptococcus pyogenes Su strain cells treated with benzylpenicillin | Theradex (Europe) Ltd. - United Kingdom | Treatment of congenital lymphatic malformations | • 18.05.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 29.01.2010 |
| Beta-artemether / lumefantrine (powder for oral suspension) | Dafra Pharma International NV - Belgium | Treatment of malaria | • 28.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Recombinant human vascular endothelial growth factor | NeuroNova AB - Sweden | Treatment of amyotrophic lateral sclerosis | • 27.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 29.01.2010 |
| Macitentan | Actelion Registration Limited - United Kingdom | Treatment of idiopathic pulmonary fibrosis | • 19.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Brivudine | RESprotect GmbH - Germany | Treatment of pancreatic cancer | • 26.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Recombinant human elafin | Proteo Biotech AG - Germany | Treatment of oesophagus carcinoma | • 14.05.2009<br>• 10.08.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| 2-iminobiotin | Neurophyxia B.V. - The Netherlands | Treatment of perinatal asphyxia | • 27.08.2009<br>• 15.09.2009<br>• 05.11.2009<br>• 51 days | • 27.11.2009<br>• 28.01.2010 |
| Ecopipam | Dr Alain Munoz - France | Treatment of Lesch-Nyhan disease | • 13.08.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 03.02.2010 |
| Pixantrone dimaleate | CTI Life Sciences Ltd - UK | Treatment of diffuse large B-cell lymphoma | • 24.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |

| **Product INN** | **Sponsor** | **Summary of indication** | **EMA/COMP**<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | **European Commission**<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Panobinostat | Novartis Europharm Limited - UK | Treatment of Hodgkin's lymphoma | • 24.07.2009<br>• 15.09.2009<br>• 03.12.2009<br>• 79 days | • 23.12.2009<br>• 02.02.2010 |
| Recombinant human monoclonal antibody to human interleukin (IL)-17A of the IgG1/k class | Novartis Europharm Limited - UK | Treatment of chronic non-infectious uveitis | • 19.05.2009<br>• 15.09.2009<br>• 03.12.2009<br>• 79 days | • 23.12.2009<br>• 02.02.2010 |
| Benzamide, 3-(2-imidazo[1,2-b]pyridazin-3-ylethynyl)-4-methyl-N-[4-[(4-methyl-1-piperazinyl)methyl]-3-(trifluoromethyl)phenyl] | ARIAD Pharma Ltd - UK | Treatment of acute lymphoblastic leukemia | • 23.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |
| Givinostat | Italfarmaco S.p.A. - Italy | Treatment of polycythaemia vera | • 24.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 03.02.2010 |
| Fingolimod | Novartis Europharm Limited - UK | Treatment of chronic inflammatory demyelinating polyneuropathy | • 27.08.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |
| Lentiviral vector containing the human *ABCA4* gene | Oxford Biomedica (UK) Ltd - UK | Treatment of Stargardt's disease | • 24.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |
| RNA, [P-deoxy-P-(dimethylamino)] (2',3'-dideoxy-2',3'-imino-2',3'-seco) (2'a→5') (C-m5U-m5U-A-C-A-G-G-C-m5U-C-C-A-A-m5U-A-G-m5U-G-G-m5U-C-A-G-m5U), 5' [P-[4-[[2-[2-(2-hydroxyethoxy)ethoxy]ethoxy]carbonyl]-1-piperazinyl]-N,N-dimethylaminophosphonamidate], 3'-[2'a-[N2-acetyl-L-arginyl-6-aminohexanoyl-L-arginyl-L-arginyl-β-alanyl-L-arginyl-L-arginyl-6-aminohexanoyl-L-arginyl-L-arginyl-β-alanyl-L-arginyl-6-aminohexanoyl-β-alanyl], octahydrochloride | AVI BioPharma International Ltd - UK | Treatment of Duchenne muscular dystrophy | • 13.07.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |
| Recombinant fusion protein linking human coagulation factor IX with human albumin | CSL Behring GmbH - Germany | Treatment of haemophilia B | • 23.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 04.02.2010 |
| Benzamide, 3-(2-imidazo[1,2-b]pyridazin-3-ylethynyl)-4-methyl-N-[4-[(4-methyl-1-piperazinyl)methyl]-3-(trifluoromethyl)phenyl]- | ARIAD Pharma Ltd - UK | Treatment of chronic myeloid leukemia | • 23.09.2009<br>• 09.10.2009<br>• 03.12.2009<br>• 55 days | • 23.12.2009<br>• 02.02.2010 |

## *Negative COMP designation opinions*

| **Product INN** | **Sponsor** | **Summary of indication** | **EMA/COMP**<br>• Submission<br>• Start date<br>• Opinion<br>• Active time | **European Commission**<br>• Opinion received<br>• Date of decision |
|---|---|---|---|---|
| Molgramostim | Drugrecure Aps - Denmark | Treatment of cystic fibrosis | • 08.07.2009<br>• 10.08.2009<br>• 05.11.2009<br>• | • Decision awaited |

# Annex 13 – HMPC Community herbal monographs and entries into list of herbal substances in 2009

## *Community herbal monographs*

| Reference number | Document title | Status |
|---|---|---|
| EMEA/HMPC/591648/2007 | Community herbal monograph on Boldi folium | Adopted January 2009 |
| EMEA/HMPC/295338/2007 | Community herbal monograph on Salicis cortex | Adopted January 2009 |
| EMEA/HMPC/105536/2008 | Community herbal monograph on Centaurii herba | Adopted March 2009 |
| EMEA/HMPC/98717/2008 | Community herbal monograph on Althaeae radix | Adopted May 2009 |
| EMEA/HMPC/234463/2008 | Community herbal monograph on Absinthii herba | Adopted July 2009 |
| EMEA/HMPC/332350/2008 | Community herbal monograph on Echinaceae pallidae radix | Adopted July 2009 |
| EMEA/HMPC/225319/2008 | Community herbal monograph on Hippocastani semen | Adopted July 2009 |
| EMEA/HMPC/456845/2008 | Community herbal monograph on Curcumae longae rhizoma | Adopted November 2009 |
| EMEA/HMPC/114586/2008 | Community herbal monograph on Hamamelidis folium | Adopted November 2009 |
| EMEA/HMPC/114583/2008 | Community herbal monograph on Hamamelidis cortex | Adopted November 2009 |
| EMEA/HMPC/114584/2008 | Community herbal monograph on Hamamelidis folium et cortex aut ramunculus destillatum | Adopted November 2009 |
| EMEA/HMPC/101304/2008 | Community herbal Monograph on Hyperici herba | Adopted November 2009 |
| EMEA/HMPC/441929/2008 | Community herbal monograph on Juniperi pseudo-fructus | Released for public consultation January 2009<br>Adopted November 2009 |
| EMEA/HMPC/331653/2008 | Community herbal monograph on Salviae folium | Released for public consultation January 2009<br>Adopted November 2009 |
| EMEA/HMPC/212895/2008 | Community herbal monograph on Taraxaci radix cum herba | Released for public consultation January 2009<br>Adopted November 2009 |
| EMEA/HMPC/579636/2008 | Community herbal monograph on Taraxaci folium | Released for public consultation January 2009<br>Adopted November 2009 |
| EMEA/HMPC/578324/2008 | Community herbal monograph on Gentianae radix | Released for public consultation March 2009<br>Adopted November 2009 |
| EMEA/HMPC/131901/2009 | Community herbal monograph on Thymi aetheroleum | Released for public consultation May 2009 |
| EMEA/HMPC/585558/2007 | Community herbal monograph on Valerianae radix/Lupuli flos | Released for public consultation May 2009 |
| EMEA/HMPC/577784/2008 | Community herbal monograph on Echinaceae purpureae radix | Released for public consultation July 2009 |
| EMEA/HMPC/580539/2008 | Community herbal monograph on Mate folium | Released for public consultation July 2009 |
| EMEA/HMPC/281496/2009 | Community herbal monograph on Orthosiphonis folium | Released for public consultation July 2009 |

| Reference number | Document title | Status |
|---|---|---|
| EMEA/HMPC/142986/2009 | Community herbal monograph on Ribis nigri folium | Released for public consultation July 2009 |
| EMEA/HMPC/13633/2009 | Community herbal monograph on Rosmarini folium | Released for public consultation July 2009 |
| EMEA/HMPC/235453/2009 | Community herbal monograph on Rosmarini aetheroleum | Released for public consultation July 2009 |
| EMEA/HMPC/508015/2007 | Public statement on Urticae folium | Released for public consultation July 2009 |
| EMEA/HMPC/144006/2009 | Community herbal monograph on Agni casti fructus | Released for public consultation September 2009 |
| EMEA/HMPC/600717/2007 | Community herbal monograph on Cimicifugae rhizoma | Released for public consultation September 2009 |
| EMEA/HMPC/579663/2009 | Public statement on Centellae herba | Released for public consultation September 2009 |
| EMEA/HMPC/16635/2009 | Community herbal monograph on Vitis viniferae folium | Released for public consultation November 2009 |
| EMEA/HMPC/726698/2009 | Public statement on Echinaceae angustifolia radix | Released for public consultation November 2009 |
| EMEA/HMPC/727465/2009 | Public statement on Euphrasiae herba | Released for public consultation November 2009 |
| EMEA/HMPC/41843/2009 | Public statement on Salviae aetheroleum | Released for public consultation November 2009 |

## *Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products*

| Reference number | Document title | Status |
|---|---|---|
| EMEA/HMPC/704562/2009 | Community list entry on Hamamelidis folium et cortex aut ramunculus destillatum | Released for public consultation November 2009 |

# Annex 14 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2009

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| velaglucerase alfa | Shire Human Genetic Therapies AB | Endocrinology-Gynaecology-Fertility-Metabolism | W (negative) withdrawn before decision | • 13.11.208<br>• 09.01.2009 | n/a |
| Aliskiren hemifumarate / valsartan | Novartis Europharm Ltd | Cardiovascular diseases | W | • 13.11.2008<br>• 09.01.2009 | P/31/2009 23.02.2009 |
| Aliskiren hemifumarate / valsartan | Novartis Europharm Ltd | Cardiovascular diseases | W | • 13.11.2008<br>• 09.01.2009 | P/32/2009 23.02.2009 |
| Lapatinib ditosylate monohydrate (Tyverb) | Glaxo Group Limited | Oncology | W | • 13.11.2008<br>• 09.01.2009 | P/36/2009 24.02.2009 |
| Pemetrexed (Alimta) | Eli Lilly & Company | Oncology | W | • 13.03.2008<br>• 09.01.2009 | P/34/2009 24.02.2009 |
| Anastrozole (ARIMIDEX and associated names | AstraZeneca AB | Endocrinology-Gynaecology-Fertility-Metabolism / Oncology | P | • 01.07.2008<br>• 09.01.2009 | P/20/2009 08.01.2009 |
| Antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells (VEPACELL) | Baxter Innovations GmbH | Vaccines | P | • 10.04.2009<br>• 09.01.2009 | P/25/09 23.02.2009 |
| asenapine maleate | N.V. Organon | Psychiatry | P | • 08.05.2008<br>• 09.01.2009 | P/29/09 23.02.2009 |
| Iron, aqua carbonate hydroxy oxo starch sucrose complex | Novartis Europharm Limited | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 08.05.2008<br>• 09.01.2009 | P/23/2009 23.02.2009 |
| methoxy polyethylene glycol - epoetin beta (Mircera) | Roche Registration Limited | Uro-nephrology | P | • 08.05.2008<br>• 09.01.2009 | P/26/09 23.02.2009 |
| Modified Grass Pollen Extract | Allergy Therapeutics (UK) Ltd | Pneumology-Allergology | P | • 01.07.2008<br>• 09.01.2009 | P/18/2009 04.02.2009 |
| N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4- oxoquinoline-3-carboxamide | Vertex Pharmaceuticals Incorporated | Pneumology-Allergology | P | • 27.08.2008<br>• 09.01.2009 | P/30/2009 23.02.2009 |
| PEGylated recombinant Factor VIIa | Novo Nordisk A/S | Haematology-Hemostaseology | P | • 08.05.2008<br>• 09.01.2009 | P/28/2009 23.02.2009 |
| Plerixafor (Mozobil)) | Genzyme Europe B.V. | Oncology | P | • 14.02.2008<br>• 09.01.2009 | P/27/09 23.02.2009 |
| Sunitinib malate (Sutent) | Pfizer Limited | Oncology | P | • 31.07.2008<br>• 09.01.2009 | P/35/2009 24.02.2009 |
| Ustekinumab (STELARA)) | Janssen-Cilag International NV | Dermatology | P | • 31.07.2008<br>• 09.01.2009 | P/19/2009 04.02.2009 |
| Drospirenone/Ethinylestradiol (as bethadex clathrate) (YAZ and associated names) | Bayer Schering Pharma AG | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 13.03.2008<br>• 09.01.2009 | P/24/2009 23.02.2009 |
| Latanoprost (Xalatan) | Dr Steven Hall | Ophthalmology | PM | • 13.11.2008<br>• 09.01.2009 | P/33/2009 24.02.2009 |
| Glucose monohydrate | Cblaya & Mhuguet S.L. | Pain | P | • 08.05.2009<br>• 06.02.2009 | P/45/2009 24.03.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H1N1 / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H3N2 /influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Fluad and associated names) | Novartis Vaccines and Diagnostics S.r.l. | Vaccines | P | • 10.04.2008<br>• 06.02.2009 | P/40/2009 23.03.2009 |
| Bisoprolol fumarate | ASA Pharma Plc | Cardiovascular diseases | W | • 11.12.2008<br>• 06.02.2009 | P/50/2009 24.03.2009 |
| Bisoprolol fumarate | ASA Pharma Plc | Cardiovascular diseases | W | • 11.12.2008<br>• 06.02.2009 | P/51/2009 24.03.2009 |
| Bisoprolol fumarate | ASA Pharma Plc | Cardiovascular diseases | W | • 11.12.2008<br>• 06.02.2009 | P/52/2009 24.03.2009 |
| Bisoprolol fumarate | ASA Pharma Plc | Cardiovascular diseases | W | • 11.12.2008<br>• 06.02.2009 | P/53/2009 24.03.2009 |
| Bisoprolol fumarate | ASA Pharma Plc | Cardiovascular diseases | W | • 11.12.2008<br>• 06.02.2009 | P/54/2009 24.03.2009 |
| Dexamethasone (Posurdex) | Allergan Pharmaceuticals Ireland | Ophthalmology | W | • 11.12.2009<br>• 06.02.2009 | P/44/2009 23.03.2009 |
| Nilotinib (Tasigna) | Novartis Europharm Limited | Oncology | P | • 01.07.2008<br>• 06.02.2009 | P/60/2009 23.03.2009 |
| Maribavir | ViroPharma SPRL | Infectious Diseases | P | • 31.07.2007<br>• 06.02.2009 | P/42/2009 23.03.2009 |
| Melatonin (Circadin) | RAD Neurim Pharmaceuticals EEC Ltd | Neurology | W | • 11.12.2008<br>• 06.02.2009 | P/49/2009 24.03.2009 |
| Tapentadol hydrochloride | Grünenthal GmbH | Pain | P | • 31.07.2008<br>• 06.02.2009 | P/48/2009 24.03.2009 |
| Tapentadol hydrochloride | Grünenthal GmbH | Pain | P | • 11.12.2008<br>• 06.02.2009 | P/54/2009 24.03.2009 |
| Tapentadol hydrochloride | Grünenthal GmbH | Pain | P | • 11.12.2008<br>• 06.02.2009 | P/56/2009 24.03.2009 |
| Golimumab (Simponi) | Centocor B.V. | Immunology-Rheumatology-Transplantation | P | • 31.07.2009<br>• 06.02.2009 | P/59/2009 28.03.2009 |
| 17-allylamino-17-demethoxygeldanamycin hydroquinone, hydrochloride | Voisin Consulting SARL | Oncology | W | • 11.12.2008<br>• 06.02.2009 | P/38/2009 04.03.2009 |
| Toclimizumab (Tocilizumab Roche) | Roche Registration Limited | Immunology–Rheumatology-Transplantation | P | • 27.08.2008<br>• 06.02.2009 | P/57/2009 25.03.2009 |
| Candesartan cilexetil (Blopress and associated names) | Takeda Global Research and Development Centre (Europe) Ltd | Cardiovascular diseases | P | • 30.08.2009<br>• 06.02.2009 | P/22/2009 20.02.2009 |
| (2S)-N-{4-[(Z)-amino(methoxyimino)methyl]benzyl}-1-{(2R)-2-[3-chloro-5-(difluoromethoxy) phenyl]-2-hydroxyethanoyl}-azetidine-2-carboxamide, benzenesulfonic acid salt | AstraZeneca AB | Cardiovascular diseases | W (negative) withdrawn before decision | • 11.12.2008<br>• 06.02.2009 | n/a |
| Cannabidiol, delta-9-tetrahydrocannabinol | GW Pharma Ltd | Neurology | P | • 31.07.2008<br>• 06.02.2009 | P/41/2009 23.03.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Candesartan cilexetil (Atacand and associated name) | AstraZeneca AB | Cardiovascular diseases | P | • 30.08.2007<br>• 06.02.2009 | P/21/2009 20.02.2009 |
| 3-[5-(2-fluoro-phenyl)-[1, 2, 4]oxadiazole-3-yl]- benzoic acid | PTC Therapeutics Inc, | Neurology | P | • 14.02.2008<br>• 06.02.2009 | P/83/2009 15.05.2009 |
| fluticasone propionate / formoterol fumarate | Mundipharma Research Ltd | Pneumology-Allergology | P | • 14.02.2008<br>• 06.02.2009 | P/39/2009 20.03.2009 |
| Clevidipine butyrate (CleviprexTM (clevidipine butyrate injectable emulsion)) | The Medicines Company | Cardiovascular diseases | P | • 01.07.2008<br>• 06.02.2009 | P/37/2009 23.02.2009 |
| Cysteamine hydrochloride (CYSTADROPS) | Orphan Europe SARL | Ophthalmology | P | • 01.07.2008<br>• 06.02.2009 | P/47/2009 24.03.2009 |
| Dirucotide acetate | Eli Lilly and Company Limited | Neurology | W | • 11.12.2008<br>• 06.02.2009 | P/43/2009 23.03.2009 |
| Tobramycin | Novartis Europharm Limited | Pneumology-Allergology | P | • 01.07.2008<br>• 06.02.2009 | P/58/2009 28.03.2009 |
| Nomegestrol acetate and 17beta - estradiol | N.V. Organon (part of Schering Plough) | Endocrinology-Gynaecology-Fertility-Metabolism | PM | • 11.12.2008<br>• 06.02.2009 | P/46/2009 24.03.2009 |
| Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1) | GSK Biologicals | Vaccines | P | • 14.02.2008<br>• 06.03.2009 | P/81/2009 24.04.2009 |
| Pasireotide | Novartis Europharm Ltd | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 08.01.2009<br>• 06.03.2009 | P/75/2009 20.04.2009 |
| Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1) | GlaxoSmithKline Biologicals S.A. | Vaccines | P | • 14.08.2008<br>• 06.03.2009 | P/79/2009 24.04.2009 |
| Sitagliptin (phosphate monohydrate) (Januvia) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | P | • 08.01.2009<br>• 06.03.2009 | P/61/2009 27.03.2009 |
| Sitagliptin (phosphate monohydrate) (Xelevia) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | P | • 08.01.2009<br>• 06.03.2009 | P/62/2009 27.03.2009 |
| Sitagliptin (phosphate monohydrate) (Tesavel) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | P | • 08.01.2009<br>• 06.03.2009 | P/63/2009 27.03.2009 |
| Telcagepant | Merck Sharp & Dohme (Europe), Inc | Pain and neurology | P | • 01.07.2008<br>• 06.03.2009 | P/68/2009 20.04.2009 |
| Recombinant human monoclonal antibody of the IgG1 class to insulin-like growth factor-1 receptor (RO4858696) | Roche Registration Limited | Oncology | P | • 01.07.2008<br>• 06.03.2009 | P/70/2009 20.04.2009 |
| Purified antigen fractions of inactivated split virion Influenza A/VietNam/1194/2004(H5N1)( Pandemrix, Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) (referring to Informed Consent for Prepandrix), Prepandrix | GlaxoSmithKline Biologicals S.A | Vaccines | P | • 13.03.2008<br>• 06.03.2009 | P/80/2009 24.04.2009 |
| Ulpristal (Ellaone) | Laboratoire HRA Pharma | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 27.08.2009<br>• 06.03.2009 | P/71/2009 20.04.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Bismuth subcitrate potassium / Metronidazole / Tetracycline hydrochloride (Pylera) | Axcan Pharma SA | Gastroenterology-hepatology | W | • 08.01.2009<br>• 06.03.2009 | P/74/2009 20.04.2009 |
| Sieved freeze-dried allergen extract of Dermatophagoides farinae / sieved freeze-dried allergen extractof Dermatophagoides pteronyssinus (Oralair sublingual tablet of house dust mites) | STALLERGENES | Pneumology-Allergology | P | • 27.08.2008<br>• 06.03.2009 | P/72/2009 20.04.2009 |
| Dihydroartemisinin / piperaquine phosphate anhydride (Eurartesim) | Sigma-Tau SpA | Infectious diseases | P | • 13.03.2009<br>• 06.03.2009 | P/67/2009 20.04.2009 |
| Mercaptopurine monohydrate | Nova Laboratories Limited | Oncology | P | • 25.09.2008<br>• 06.03.2009 | P/73/2009 20.04.2009 |
| Calcipotriol hydrate / hydrocortisone | LEO Pharma A/S | Dermatology | P | • 01.07.2008<br>• 06.03.2009 | P/69/2009 20.04.2009 |
| 13 valent pneumococcal polysaccharide conjugate vaccine: 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 | Wyeth Lederle Vaccines SA | Vaccines | PM | • 08.01.2009<br>• 06.03.2009 | P/66/2009 20.04.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Conjugate Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate | | | | | |
| Purified diphtheria toxoid, Purified tetanus toxoid, Five component acellular pertussis [Purified Pertussis Toxoid, Purified Filamentous Haemagglutinin, Purified Fimbriae Types 2 and 3, and Purified Pertactin], Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 and Type 3 (Saukett), Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PEDIACEL) | Sanofi Pasteur MSD SNC | Vaccines | PM | • 05.02.2009<br>• 06.03.2009 | P/64/2009 31.03.2009 |
| Rolofylline | Merck Sharp & Dohme (Europe), Inc. | Cardiovascular diseases | P | • 27.08.2008<br>• 03.04.2009 | P/87/2009 18.05.2009 |
| Moxifloxacin hydrochloride (Avalox" and associated names) | Bayer Schering Pharma AG | Infectious Diseases | P | • 27.08.2008<br>• 03.04.2009 | P/96/2009 19.05.2009 |
| Moxifloxacin hydrochloride (Octegra" and associated names) | Bayer Schering Pharma AG | Infectious Diseases | P | • 05.02.2009<br>• 03.04.2009 | P/97/2009 19.05.2009 |
| Moxifloxacin hydrochloride (Actimax" and associated names) | Bayer Schering Pharma AG | Infectious Diseases | P | • 05.02.2009<br>• 03.04.2009 | P/98/2009 19.05.2009 |
| Moxifloxacin hydrochloride (Actira" and associated names) | Bayer Schering Pharma AG | Infectious Diseases | P | • 05.02.2009<br>• 03.04.2009 | P/99/2009 19.05.2009 |
| Drospirenone / ethinylestradiol, betadex clathrate) / L-5-methyltetrahydrofolic acid, calcium salt (YAZ + Metafolin) | Bayer Schering Pharma AG | Endocrinology–Gynaecology–Fertility-Metabolism | W | • 05.02.2009<br>• 03.04.2009 | P/89/2009 18.05.2009 |
| Drospirenone / ethinylestradiol, betadex clathrate) / L-5-methyltetrahydrofolic acid, calcium salt | Bayer Schering Pharma AG | Endocrinology–Gynaecology–Fertility-Metabolism | W | • 05.02.2009<br>• 03.04.2009 | P/90/2009 08.05.2009 |
| Regadenoson | CV Therapeutics Europe Ltd | Diagnostic / Cardiovascular Diseases | P | • 16.10.2008<br>• 03.04.2009 | P/82/2009 24.04.2009 |
| Aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis | Allergopharma J. Ganzer KG | Pneumology-Allergology | P | • 27.08.2009<br>• 03.04.2009 | P/147/2009 20.06.2009 |
| Simvastatin/fenofibrate | FOURNIER Laboratories Ireland Ltd | Cardiovascular diseases | W | • 50.02.2009<br>• 03.04.2009 | P/92/2009 18.05.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Raltegravir (Isentress) | Merck Sharp & Dohme (Europe), Inc. | Infectious Diseases | P | • 01.07.2008<br>• 03.04.2009 | P/95/2009 19.05.2009 |
| Alogliptin benzoate | Takeda Global Research and Development Centre (Europe) Ltd. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 05.02.2009<br>• 03.04.2009 | P/93/2009 16.06.2009 |
| Rubidium-82 (CardioGen-82) (Advanced Accelerator Applications) | Advanced Accelerator Applications | Diagnostic | P | • 05.02.2009<br>• 03.04.2009 | P/91/2009 18.05.2009 |
| Bilastine (Bilaxten) | FAES FARMA, S.A. | Oto-rhino-laryngology Pneumology – Allergology Dermatology | P | • 27.08.2008<br>• 03.04.2009 | P/88/2009 18.05.2009 |
| Tigecycline (Tygacil) | Wyeth Europa Limited | Infectious diseases | PM | • 05.02.2009<br>• 03.04.2009 | P/85/2009 08.05.2009 |
| Mepolizumab (Bosatria) | Glaxo Group Limited | Gastroenterology-Hepatology/ Immunology | PM | • 05.02.2009<br>• 03.04.2009 | P/94/2009 19.05.2009 |
| Rosuvastatin (CRESTOR and associated names) | AstraZeneca AB | Cardiovascular Diseases | PM | • 05.03.2009<br>• 03.04.2009 | P/76/2009 20.04.2009 |
| Bromfenac sodium sesquihydrate | Croma Pharma GmbH | Ophthalmology | W | • 25.09.2008<br>• 30.04.2009 | P/84/2009 15.05.2009 |
| Pravastatin sodium/ Fenofibrate (PRAVAFEN (decision of NRG awaited) | Laboratoires SMB s.a. | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 05.03.2009<br>• 30.04.2009 | P/115/2009 15.06.2009 |
| Aliskiren hemifumarate / amlodipine besilate | Novartis Europharm Ltd. | Cardiovascular diseases | W | • 05.03.2009<br>• 30.04.2009 | P/118/2009 15.06.2009 |
| Aliskiren hemifumarate / amlodipine besilate | Novartis Europharm Ltd. | Cardiovascular diseases | W | • 05.03.2009<br>• 30.04.2009 | P/119/2009 15.06.2009 |
| Aliskiren hemifumarate / amlodipine besilate | Novartis Europharm Ltd. | Cardiovascular diseases | W | • 05.03.2009<br>• 30.04.2009 | P/120/2009 15.06.2009 |
| Azilsartan medoxomil | Takeda Global Research and Development Centre (Europe) Ltd | cardiovascular diseases | P | • 08.05.2008<br>• 30.04.2009 | P/105/2009 15.06.2009 |
| Recombinant human anti-Rhesus D monoclonal antibody (LFB-R593) | LFB Biotechnologies | Immunology-Rheumatology-Transplantation | W | • 05.03.2009<br>• 30.04.2009 | P/117/2009 16.06.2009 |
| Dienogest / ethinylestradiol / L-5-methyltetrahydrofolic acid, calcium salt (Valette + Metafolin) | Bayer Schering Pharma AG | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 05.03.2009<br>• 30.04.2009 | P/121/2009 16.06.2009 |
| Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein | Sanofi Pasteur MSD SNC | Vaccines | P | • 16.10.2008<br>• 30.04.2009 | P/110/2009 16.06.2009 |
| Human Papillomavirus1 Type 6 L1 protein / Human Papillomavirus1 Type 11 L1 protein / Human Papillomavirus1 Type 16 L1 protein / Human Papillomavirus1 Type 18 L1 | Merck Sharp & Dohme (Europe) Inc | Vaccines | P | • 16.10.2008<br>• 30.04.2009 | P/111/2009 16.06.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Clazosentan (Pivlaz) | Actelion Registration Ltd | Neurology | W | • 25.09.2008<br>• 30.04.2009 | P/109/2009 16.06.2009 |
| Triamcinolone acetonide (TRIESENCE) | Alcon Pharma GmbH | Ophthalmology | W | • 05.03.2009<br>• 30.04.2009 | P/113/2009 15.06.2009 |
| Human autologous mesenchymal adult stem cells extracted from adipose tissue (Ontaril) | CELLERIX, S.A | Gastroenterology-Hepatology | W | • 05.03.2009<br>• 30.04.2009 | P/122/2009 15.06.2009 |
| Linagliptin (Ondero) | Boehringer Ingelheim International | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 05.03.2009<br>• 30.04.2009 | P/114/2009 15.06.2009 |
| Etanercept | Wyeth Europa Limited | Immunology-rheumatology-transplantation | P | • 25.09.2008<br>• 30.04.2009 | P/106/2009 16.06.2009 |
| Carisbamate (Comfyde) | Janssen Cilag NV International | Neurology | P | • 25.09.2008<br>• 30.04.2009 | P/108/2009 09.06.2009 |
| Cladribine (MOVECTRO (proposal submitted to the NRG on November 10, 2008)) | Merck KGaA | Neorology | P | • 16.10.2008<br>• 30.04.2009 | P/101/2009 19.05.2009 |
| Nε141-[2-(2-(2,3-(mPeg(20000)yloxy) propyloxycarbonylamino)ethyloximino)ethyl] hGH | Novo Nordisk A/S | Endocrinology-Gynaecology-Fertility-Metabolism | W, company withdrew before Decision | • 25.09.2008<br>• 30.04.2009 | n/a |
| Dexamethasone/ciprofloxacin hydrochloride | Alcon Pharma GmbH | Oto-rhino-laryngology | P | • 11.12.2008<br>• 30.04.2009 | P/112/2009 15.06.2009 |
| Adalimumab (Humira) | Abbott Laboratories Ltd. | Gastroenterology-Hepatology Dermatology Immunology–Rheumatology-Transplantation | P | • 25.09.2008<br>• 30.04.2009 | P/102/2009 18.05.2009 |
| Esomeprazole sodium, esomeprazole magnesium trihydrate (Nexium and associated names) | AstraZeneca AB | Gastroenterology-hepatology | P | • 31.07.2008<br>• 30.04.2009 | P/107/2009 19.06.2009 |
| Human plasma proteins (uniplasLG) | Octapharma Pharmazeutika | Haematology-hemostaseology | W | • 05.03.2009<br>• 30.04.2009 | P/116/2009 16.06.2009 |
| Abatacept (ORENCIA) | Bristol-Myers Squibb Pharma EEIG | Immunology rheumatology/ transplantation | PM | • 30.04.2009<br>• 30.04.2009 | P/100/2009 19.05.2009 |
| Insulin glaring (Lantus) | Sanofi-Aventis Deutschland GmbH | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 13.11.2008<br>• 29.05.2009 | P/133/2009 15.07.2009 |
| Insulin glaring (Optisulin) | Sanofi-Aventis Deutschland GmbH | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 13.11.2008<br>• 29.05.2009 | P/136/2009 15.07.2009 |
| clostridium collagenase | Pfizer Limited | Uro-nephrology Musculo-skeletal diseases | W | • 02.04.2009<br>• 29.05.2009 | P/139/2009 15.07.2009 |
| Brivaracetam | UCB Pharma SA | Neurology | P | • 31.07.2008<br>• 29.05.2009 | P/126/2009 13.07.2009 |
| Canakinumab (Ilaris) | Novartis Europharm Limited | Immunology rheumatology/ transplantation | P | • 16.10.2008<br>• 29.05.2009 | P/131/2009 15.07.2009 |
| Omacetaxine mepesuccinate | ChemGenex Europe S.A.S. | Oncology | W | • 05.02.2009<br>• 29.05.2009 | P/138/2009 15.07.2009 |
| Colesevelam (Cholestagel) | Genzyme Europe B.V. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/124/2009 19.06.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Telavancin hydrochloride (VIBATIV) | Astellas Pharma Europe B.V. | Infectious Diseases | P | • 31.07.2008<br>• 29.05.2009 | P/127/2009 14.07.2009 |
| Rituximab (MabThera) | Roche Products Ltd | Immunology–Rheumatology-Transplantation Oncology | P | • 31.08.2008<br>• 29.05.2009 | P/128/2009 14.07.2009 |
| Rilpivirine | Janssen-Cilag International N.V. | Infectious dieseases | P | • 16.10.2008<br>• 29.05.2009 | P/144/2009 17.07.2009 |
| Dienogest, Estradiol valerate (Qlaira) | Bayer Schering Pharma AG | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/140/2009 15.07.2009 |
| Nevirapine (Viramune) | Boehringer Ingelheim International GmbH | Infectious diseases | P | • 13.11.2008<br>• 29.05.2009 | P/134/2009 15.07.2009 |
| Recombinant human C1 inhibitor | Pharming Group N.V. | Immunology–Rheumatology-Transplantation Dermatology | P | • 16.10.2008 | P/132/2009 17.07.2009 |
| Recombinant human C1 inhibitor (Rhucin) | Pharming Group N.V. | Immunology–Rheumatology-Transplantation Dermatology | P | • 16.10.2008<br>• 29.05.2009 | P/132/2009 17.07.2009 |
| Drospirenone / ethinylestradiol, betadex clathrate / L-5-methyltetrahydrofolic acid, calcium salt (Yasmin + Metafolin)q | Bayer Schering Pharma AG | Endocrinology-gynaecology-fertility-metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/130/2009 14.07.2009 |
| fosaprepitant dimeglumine (IVEMEND) | Merck Sharp & Dohme Ltd. | Obcology | P | • 13.11.2008<br>• 29.05.2009 | P/137/2009 15.07.2009 |
| Simvastatin / sitagliptin phosphate monohydrate | Merck Sharp & Dohme (Europe), Inc. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/169/2009 28.08.2009 |
| Simvastatin / sitagliptin phosphate monohydrate | Merck Sharp & Dohme (Europe), Inc. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/170/2009 28.08.2009 |
| Simvastatin / sitagliptin phosphate monohydrate | Merck Sharp & Dohme (Europe), Inc. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/171/2009 28.08.2009 |
| Simvastatin / sitagliptin phosphate monohydrate | Merck Sharp & Dohme (Europe), Inc. | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 02.04.2009<br>• 29.05.2009 | P/172/2009 28.08.2009 |
| N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea | Abbott Laboratories | Oncology | P | • 16.10.2008<br>• 29.05.2009 | P/135/2009 15.07.2009 |
| Valsartan (Diovan) | Novartis Europharm Limited | Cardiovascular diseases | PM | • 02.04.2009<br>• 29.05.2009 | P/125/2009 26.06.2009 |
| Rosuvastatin calcium (Crestor and associated names) | AstraZeneca AB | Cardiovascular diseases | PM | • 22.05.2009<br>• 29.05.2009 | P/123/2009 12.06.2009 |
| Tocilizumab (RoActemra) | Roche Registration Limited | Immunology–Rheumatology-Transplantation | PM | • 02.04.2009<br>• 29.05.2009 | P/129/2009 14.07.2009 |
| Mifeprestone, Misoprostol (Medabon) | Sun Pharmaceutical Industries Europe B.V. | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 13.11.2008<br>• 26.06.2009 | P/156/2009 11.08.2009 |
| Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class | Novartis Europharm Ltd | Dermatology | P | • 16.10.2008<br>• 26.06.2009 | P/154/2009 11.08.2009 |
| Testosterone (Intrisa) | Procter & Gamble Pharmaceuticals UK Ltd | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 30.04.2009<br>• 26.06.2009 | P/160/2009 11.08.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Testosterone (Livensa) | Procter & Gamble Pharmaceuticals UK Ltd | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 30.04.2009<br>• 26.06.2009 | P/161/2009 11.08.2009 |
| Human coagulation Factor VIII/von Willebrand Factor (complex) (Biostate) | CSL Behring | Haematology-Hemostaseology | P | • 27.08.2008<br>• 26.06.2009 | P/164/2009 14.08.2009 |
| 5-Aminolevulinic acid, hydrochloride | Biofrontera Bioscience GmbH | Dermatology | W | • 30.04.2009<br>• 26.06.2009 | P/157/2009 11.08.2009 |
| A/Viet Nam/1194/2004 (H5N1) virus surface inactivated antigen (Aflunov and associated names, Focetria and associated names.) | Novartis Vaccines and Diagnostics S.r.l. | Vaccines | P | • 30.04.2009<br>• 26.06.2009 | P/150/2009 05.08.2009 |
| Dirucotide acetate | Eli Lilly and Company Limited | Neurology | W | • 30.04.2009<br>• 26.06.2009 | P/203/2009 15.10.2009 |
| Live bacterium B. thetaiotaomicron | GT Biologics | Gastroenterology-Hepatology | P | • 30.04.2009<br>• 26.06.2009 | P/166/2009 21.08.2009 |
| Desvenlafaxine succinate monohydrate | Laboratorios Almirall S.A. | Psychiatry | W | • 30.04.2009<br>• 26.06.2009 | P/158/2009 11.08.2009 |
| Human normal immunoglobulin (Gammagen) | Orfagen | Dermatology | P | • 11.12.2008<br>• 26.06.2009 | P/165/2009 14.08.2009 |
| Patupilone | Novartis Europharm Ltd | Oncology | W | • 30.04.2009<br>• 26.06.2009 | P/163/2009 12.08.2009 |
| Midazolam hydrochloride | Auralis Limited | Neurology | P | • 13.11.2009<br>• 26.06.2009 | P/155/2009 11.08.2009 |
| Paliperidone (Invega) | Janssen-Cilag International NV | Psychiatry | PM | • 30.04.2009<br>• 26.06.2009 | P/149/2009 07.08.2009 |
| Doripenem monohydrate | Johnson & Johnson PRD | Ibfectious diseases | PM | • 30.04.2009<br>• 26.06.2009 | P/151/2009 07.08.2009 |
| Latanoprost (Xalatan) | Pfizer Global Research & Development | Ophthalmology | PM | • 30.04.2009<br>• 26.06.2009 | P/162/2009 12.08.2009 |
| Denosumab (Prolia, Amgiva) | Amgen Europe B.V. | Oncology<br>Endocrinology-Gynaecology-Fertility-Metabolism<br>Immunology–Rheumatology-Transplantation | PM | • 30.04.2009<br>• 26.06.2009 | P/148/2009 15.07.2009 |
| Cinacalcet (Mimparat) | Amgen Europe B.V | Uro-Nephrology | P | • 31.07.2009<br>• 24.07.2009 | P/167/2009 14.08.2009 |
| Sodium-X-5-hydroxy-X-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572) | GlaxoSmithKline Trading Services Ltd. | Infectious diseases | P | • 11.12.2009<br>• 24.07.2009 | P/178/2009 07.09.2009 |
| 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 | GlaxoSmithKline Biologicals s.a | Vaccines | P | • 08.01.2009<br>• 24.07.2009 | P/186/2009 08.09.2009 |
| Motavizumab | Abbott Laboratories Limited | Neonatology - paediatric intensive | P | • 25.09.2008 | P/152/2009 07.08.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| | | ca | | • 24.07.2009 | |
| Purified Diphteria Toxoid / Purified Tetanus Toxoid / Purified Pertussis Toxoid (PT) / Purified Filamentous Haemagglutinin (FHA) / Purified Fimbriae Types 2 and 3 (FIM) / Purified Pertactin (PRN) / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Polyribosylribitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC / Hepatitis B Surface Antigen, recombinant (HBsAg) | Sanofi Pasteur MSD SNC | Vaccines | P | • 30.04.2009<br>• 24.07.2009 | P/168/2009 09.10.2009 |
| Human normal immunoglobulin | Kedrion S.p.A. | Immunology-Rheumatology-Transplantation / | P | • 08.01.2009<br>• 24.07.2009 | P/187/2009 08.09.2009 |
| Saxagliptin (Onglyza) | Bristol-Myers Squibb/AstraZeneca EEIG | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 10.04.2008<br>• 24.07.2009 | P/176/2009 07.09.2009 |
| Paracetamol / Opium (LAMALINE) | Solvay Pharma | Pain | W | • 28.05.2009 | P/181/2009 07.09.2009 |
| Paracetamol / Opium (DIAGYNE) | Solvay Pharma | Pain | W | • 28.05.2009 | P/182/2009 07.09.2009 |
| Human normal immunoglobulin | LFB Biotechnologies | Immunology–Rheumatology-Transplantation | P | • 28.05.2009<br>• 24.07.2009 | P/184/2009 07.09.2009 |
| Ranibizumab (Lucentis) | Novartis Europharm Limited | Opthalmology | W | • 02.04.2009<br>• 24.07.2009 | P/183/2009 07.09.2009 |
| tramadol / paracetamol | TEVA Pharma B.V. | Pain | W | • 25.06.2009<br>• 24.07.2009 | P/185/2009 08.09.2009 |
| 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative | Novartis Europharm Ltd. | Cardiovascular diseases | P | • 31.07.2008<br>• 24.07.2009 | P/177/2009 07.09.2009 |
| Tapentadol hydrochloride (Palexia) | Grünenthal GmbH | Pain | PM | • 25.06.2009<br>• 24.07.2009 | P/174/2009 07.09.2009 |
| Tapentadol hydrochloride (Ixarto) | Grünenthal GmbH | Pain | PM | • 25.06.2009<br>• 24.07.2009 | P/179/2009 07.09.2009 |
| Tapentadol hydrochloride (Tapentadol GRT) | Grünenthal GmbH | Pain | PM | • 25.06.2009<br>• 24.07.2009 | P/180/2009 07.09.2009 |
| N-Acetyl-L-Cysteine (corresponds to L-Cysteine), L-Alanine, L-Alanyl-L-Glutamine (corresponds to to L-Alanine and L-Glutamine), L-Arginine, Glycine, Glycyl-L-Tyrosine (corresponds to Glycine and L-Tyrosine), L-Histidine, L-Isoleucine, L-Leucine, L-Lysine acetate (corresponds to L-Lysine), L-Methionine, L-Phenylalanine, L-Proline, L-Serine, Taurine, L-Threonine, L-Tryptophan, L-Valine (Neoven) | Fresenius Kabi Deutschland GmbH | Nutrition | PM | • 28.05.2008<br>• 24.07.2009 | P/175/2009 07.09.2009 |
| Montelukas (Singulair) | Merck Sharp & Dohme Ltd | Pneumology-Allergology | PM | • 28.05.2009<br>• 24.07.2009 | P/200/2009 01.10.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Vicriviroc maleate (Envold, Incincra, Vicincra, Celcrive) | Schering-Plough Europe | Infectious diseases | PM | • 28.05.2009<br>• 24.07.2009 | P/188/2009 11.09.2009 |
| Retigabine (Keppra, Koptas) | Glaxo Group Limited | Neurology | PM | • 28.05.2009<br>• 24.07.2009 | P/153/2009 09.10.2009 |
| Propranolol hydrochloride | Pierre Fabre Dermatologie | Dermatology | P | • 02.04.2009<br>• 21.08.2009 | P/194/2009 07.10.2009 |
| split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), non-adjuvanted | Sanofi Pasteur SA | Vaccines | P | • 20.08.2009<br>• 21.08.2009 | P/196/2009 07.10.2009 |
| split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), non-adjuvanted | Sanofi Pasteur SA | Vaccines | P | • 20.08.2009<br>• 21.08.2009 | P/197/2009 07.10.2009 |
| Clopidogrel (Clopidogrel Winthrop) | Sanofi Pharma Bristol-Myers Squibb SNC | Cardiovascular diseases | P | • 25.06.2009<br>• 21.08.2009 | P/189/2009 22.09.2009 |
| Clopidogrel (Clopidogrel BMS) | Sanofi Pharma Bristol-Myers Squibb SNC | Cardiovascular diseases | P | • 25.06.2009<br>• 21.08.2009 | P/190/2009 22.09.2009 |
| A/California/7/2009 influenza-like virus strain | Novartis Vaccines & Diagnostics GmbH & Co. KG | Vaccines | P | • 20.08.2009<br>• 21.08.2009 | P/198/2009 09.10.2009 |
| Pegaptanib sodium (Macugen) | Pfizer Global Research & Development | Ophthalmology | W | • 25.06.2009<br>• 21.08.2009 | P/195/2009 07.10.2009 |
| Oseltamivir phosphate (Tamiflu) | Roche Registration Ltd | Infectious dieases | P | • 27.08.2009<br>• 01.09.2009 | P/192/2009 02.10.2009 |
| Fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1) | Glaxo Group Limited | Pneumology-Alllergology | P | • 11.12.2008<br>• 18.09.2009 | P/202/2009 12.10.2009 |
| C1 Inhibitor (Cinryze) | ViroPharma SPRL | Immunology–rheumatology-transplantation | P | • 30.04.2009<br>• 18.09.2009 | P/193/2009 02.10.2009 |
| Soluble yeast beta-1,3/1,6-glucan | Biotec Pharmacon ASA | Endocrinology-gynaecology-fertility-metabolism | W | • 23.07.2009<br>• 18.09.2009 | P/221/2009 03.11.2009 |
| Mannitol (Bronchitol) | Pharmaxis Pharmaceuticals Limited | Pneumology – allergology | P | • 05.02.2009<br>• 18.09.2009 | P/204/2009 21.10.2009 |
| Ticagrelor | AstraZeneca AB | Cardiovascular diseases | P | • 05.03.2009<br>• 18.09.2009 | P/199/2009 02.10.2009 |
| Bromocriptine mesylate (Cycloset) | VeroScience EU Ltd | Endocrinology-gynaecology-fertility-metabolism | P | • 05.02.2009<br>• 18.09.2009 | P/214/2009 30.10.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at GlaxoSmithKline Biologicals Dresden manufacturing site) (Pandemrix H1N1 (Invented Name under review by NRG) | GlaxoSmithKline Biologicals S.A. | Vaccines | P | • 17.09.2009<br>• 18.09.2009 | P/205/2009 03.11.2009 |
| Ambrisentan (Volibris) | Glaxo Group Limited | Cardiovascular diseases | P | • 23.07.2009<br>• 18.09.2009 | P/209/2009 30.10.2009 |
| Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at GlaxoSmithKline Biologicals Quebec manufacturing site) | GlaxoSmithKline Biologicals S.A. | Vaccines | P | • 20.08.2009<br>• 18.09.2009 | P/219/2009 30.10.2009 |
| Ulipristal acetate (Myonova) | PregLem SA | Endocrinology-gynaecology-fertility-metabolism | W | • 23.07.2009<br>• 18.09.2009 | P/215/2009 30.10.2009 |
| Icatibant acetate (Firazyr) | Jerini AG | Immunology-rheumatology-transplantation | P | • 11.12.2009<br>• 18.09.2009 | P/222/2009 04.11.2009 |
| Rivaroxaban (Xarelto) | Bayer Schering Pharma AG, | Cardiovascular diseases | P | • 11.12.2009<br>• 18.09.2009 | P/223/2009 04.11.2009 |
| Ibuprofen / Famotidine | Horizon Therapeutics Inc. | Pain | W | • 23.07.2009<br>• 18.09.2009 | P/201/2009 09.10.2009 |
| Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerized, allergenic extract of birch, alder and hazel pollen (Depigoid Bäume-Mix) | LETI Pharma GmbH | Pneumology – allergology | RW | • 23.07.2009<br>• 18.09.2009 | P/218/2009 30.10.2009 |
| Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerized allergic extract of birch pollen (Depigoid Birke) | LETI Pharma GmbH | Pneumology-Allergology | RW | • 23.07.2009<br>• 18.09.2009 | P/216/2009 30.10.2009 |
| Chloroprocaine hydrochloride | Sintetica Italia S.r.l | Anaesthesiology | RW | • 23.07.2009<br>• 18.09.2009 | P/217/2009 30.10.2009 |
| Latanoprost (Xalatan) | Pfizer Global Research & Development | Ophthalmology | PM | • 20.08.2009<br>• 18.09.2009 | P/220/2009 03.11.2009 |
| Skimmed cow's milk powder (Diallertest) | DBV Technologies | Diagnostic and other | PM | • 20.08.2009<br>• 18.09.2009 | P/208/09 30.10.2009 |
| Sitagliptin (phosphate monohydrate) (Januvia) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | PM | • 20.08.2009<br>• 18.09.2009 | P/211/2009 30.10.2009 |
| Sitagliptin (phosphate monohydrate) (Xelevia) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | PM | • 20.08.2009<br>• 18.09.2009 | P/212/2009 30.10.2009 |
| Sitagliptin (phosphate monohydrate) (Tesavel) | Merck Sharp and Dohme (Europe), Inc. | Endocrinology-gynaecology-fertility-metabolism | PM | • 20.08.2009<br>• 18.09.2009 | P/213/2009 30.10.2009 |
| Eltrombopag (REVOLADE) | GlaxoSmithKline Trading Services Limited | Haematology-haemostaseology | PM | • 23.07.2009<br>• 18.09.2009 | P/207/2009 30.10.2009 |
| Alanine / arginine / aspartic acid / cysteine glutamic acid | Baxter World Trade SPRL | Nutrition | PM | • 20.08.2009 | P/191/2009 02.10.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| / glycine / histidine / isoleucine / leucine / lysine monohydrate methionine / ornithine HCl phenylalanine / praline / serine / taurine / threonine / tryptophan / tyrosine / valine / sodium chloride / potassium acetate / calcium chloride dehydrate / magnesium acetate tetrahydrate / sodium glycerophosphate / hydrated / glucose monohydrate / olive oil / soya-bean oil (Numeta) | | | | • 18.09.2009 | |
| Zoledronic acid anhydrous (Aclasta) | Novartis Europharm Limited | Endocrinology-Gynaecology-Fertility-Metabolism | PM withdrawn before Decision | • 23.07.2009<br>• 18.09.2009 | n/a |
| Rosuvastatin calcium (RESTOR and associated names, CIRANTAN, PROVISACOR, ROSUVASTATIN ASTRAZENECA) | AstraZeneca AB | Endocrinology-Gynaecology-Fertility-Metabolism/ AstraZeneca AB | PM | • 23.07.2009<br>• 18.09.2009 | P/206/2009 30.10.2009 |
| Esomeprazole sodium, esomeprazole magnesium trihydrate (Nexium and associated names) | AstraZeneca AB | Gastroenterology-hepatology | PM | • 23.07.2009<br>• 18.09.2009 | P/209/2009 30.10.2009 |
| Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide | Daiichi Sankyo Europe GmbH | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/226/2009 04.11.2009 |
| Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide | Daiichi Sankyo Europe GmbH | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/227/2009 04.11.2009 |
| Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide | Daiichi Sankyo Europe GmbH | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/228/2009 04.11.2009 |
| Sildenafil citrate (Revatio) | Pfizer Limited | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/244/2009 02.11.2009 |
| Diphtheria toxoid, tetanus toxoid, inactivated poliovirus: type 2 (MEF-1 strain), inactivated poliovirus: type 3 (Saukett strain), inactivated poliovirus: type 1 (Mahoney strain), Bordetella pertussis antigens: filamentous haemagglutinin, pertactin, pertussis toxoid (Boostrix Polio and associated names) | GlaxoSmithKline Biologicals S.A | Vaccines | P | • 05.03.2009<br>• 16.10.2009 | P/239/2009 01.12.2009 |
| Imatinib (Glivec) | Novartis Europharm Limited | Oncology | P | • 05.03.2009<br>• 16.10.2009 | P/243/2009 02.12.2009 |
| Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide | Daiichi Sankyo Europe GmbH | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/228/2009 04.11.2009 |
| Aliskiren hemifumarate / amlodipine besilate / hydrochlorothiazide | Novartis Europharm Ltd. | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/236/2009 27.11.2009 |
| Dasatinib (Sprycel) | Bristol-Myers Squibb Pharma EEIG | Oncology | P | • 30.04.2009<br>• 16.10.2009 | P/225/2009 03.11.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Exenatide (Byetta) | Eli Lilly and Company | Endocrinology-gynaecology-fertility-metabolism | P | • 20.08.2009<br>• 16.10.2009 | P/237/2009 30.11.2009 |
| Nomegestrol acetate and 17beta - estradiol | NV Organon (part of Schering Plough) | Endocrinology-gynaecology-fertility-metabolism | P | • 20.08.2009<br>• 16.10.2009 | P/230/2009 13.11.2009 |
| Saxagliptin / metformin | Bristol-Myers Squibb / AstraZeneca EEIG | Endocrinology-gynaecology-fertility-metabolism | W | • 20.08.2009<br>• 16.10.2009 | P/240/2009 01.12.2009 |
| Simvastatin / ramipril / acetyl salicylic acid | Ferrer Internacional, S.A | Cardiovascular diseases | W | • 20.08.2009<br>• 16.10.2009 | P/235/2009 27.11.2009 |
| Fluorouracil / salicylic acid | Almirall Hermal GmbH | Dermatology | W | • 20.08.2009<br>• 16.10.2009 | P/241/2009 01.12.2009 |
| Recombinant human monoclonal antibody of the IgG1 class to insulin-like growth factor-1 receptor (RO4858696) | Roche Registration Limited | Oncology | PM | • 20.08.2009<br>• 16.10.2009 | P/242/2009 02.12.2009 |
| Plerixafor (Mozobil) | Genzyme Europe B.V. | Oncology | PM | • 17.09.2009<br>• 16.10.2009 | P/2322009 27.11.2009 |
| Canakinumab (Ilairs) | Novartis Europharm Limited | Immunology–Rheumatology-Transplantation | PM | • 20.08.2009<br>• 16.10.2009 | P/238/2009 01.12.2009 |
| Paliperidone / paliperidone palmitate | Janssen-Cilag International NV | Psychiatry | PM | • 17.09.2009<br>• 16.10.2009 | P/229/2009 04.11.2009 |
| Asenapine maleate | N.V. Organon | Psychiatry | PM | • 20.08.2009<br>• 16.10.2009 | P/233/2009 27.11.2009 |
| Azilsartan medoxomil | Takeda Global Research and Development Centre (Europe) Ltd | Cardiovascular diseases | PM | • 20.08.2009<br>• 16.10.2009 | P/234/2009 27.11.2009 |
| Belimumab (BENLYSTA) | Glaxo Group Limited | Immunology–rheumatology-transplantation | P | • 05.03.2009<br>• 13.11.2009 | P/254/2009 22.12.2009 |
| Velaglucerase alfa | Shire Pharmaceuticals Ireland Limited | Endocrinology-gynaecology-fertility-metabolism | P | • 30.04.2009<br>• 13.11.2009 | P/245/2009 24.11.2009 |
| Bevacizumab (Avastin) | Roche Registration Ltd | Oncology | P withdrawn before Decision | • 02.04.2009<br>• 13.11.2009 | n/a |
| Nitric oxide (INOmax) | INO Therapeutics AB | Cardiovascular Diseases | W | • 25.06.2009<br>• 13.11.2009 | P/256/2009 22.12.2009 |
| Tramadol hydrochloride / paracetamol | Labopharm Europe Limited | Pain | W | • 17.09.2009<br>• 13.11.2009 | P/260/2009 23.12.2009 |
| Tramadol hydrochloride / paracetamol | Labopharm Europe Limited | Pain | W | • 17.09.2009<br>• 13.11.2009 | P/261/2009 23.12.2009 |
| Briakinumab | Abbott Laboratories Ltd | Dermatology | P | • 30.04.2009<br>• 13.11.2009 | Not available yet |
| Paracetamol / ibuprofen (Maxigesic, Maxigesic Junior, Duo-power) | Vale Pharmaceuticals Limited | Pain | P | • 17.09.2009<br>• 13.11.2009 | P/259/2009 23.12.2009 |
| Fampridine | Acorda Therapeutics, Inc. | Neurology | P | • 25.06.2009<br>• 13.11.2009 | P/247/2009 04.12.2009 |
| Ferumoxytol | AMAG Pharmaceuticals, Inc. | Haematology-Hemostaseology | P | • 17.09.2009<br>• 13.11.2009 | P/248/2009 10.12.2009 |
| Allogeneic ex vivo expanded umbilical cord blood cells (StemEx) | Teva Pharma GmbH | haematology-haemostaseology / oncology | W | • 17.09.2009<br>• 13.11.2009 | ?255/2009 22.12.2009 |
| Amlodipine besilate / bisoprolol fumarate (Cardiprol) | EGIS Pharmaceuticals PLC | Cardiovascular diseases | W | • 17.09.2009<br>• 13.11.2009 | P/251/2009 18.12.2009 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| Aliskiren (Rasilez) | Novartis Europharm Ltd. | Cardiovascular diseases | P | • 25.09.2008<br>• 13.11.2009 | P/253/2009 22.12.2009 |
| Benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl]-hydrochloride(1:2) (ABT-263) | Abbott Laboratories | Oncology | P | • 05.02.2009<br>• 13.11.2009 | P/249/2009 14.12.2009 |
| Fentanyl citrate (Instanyl) | Nycomed Danmark ApS | Pain | RP | • 05.03.2009<br>• 13.11.2009 | P/258/2009 23.12.2009 |
| Etravirine (Intelence) | Janssen-Cilag International NV | Infectious diseases | PM | • 17.09.2009<br>• 13.11.2009 | P/257/2009 23.12.2009 |
| Dabigatran etexilate mesylate | Boehringer Ingelheim International GmbH | Haematology-Haemostaseology | PM | • 15.10.2009<br>• 13.11.2009 | P/246/2009 27.11.2009 |
| House dust mites allergen extract | Stallergenes | Pneumology-Allergology | PM | • 17.09.2009<br>• 13.11.2009 | P/252/2009 22.12.2009 |
| N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide | Vertex Pharmaceuticals Incorporated | Pneumology – Allergology | PM | • 17.09.2009<br>• 13.11.2009 | P/250/2009 18.12.2009 |
| Paliperidone / paliperidone palmitate (Invega) | Janssen-Cilag International NV | Psychiatry | PM | • 06.11.2009<br>• 13.11.2009 | P/231/2009 27.11.2009 |
| Teplizumab | Eli Lilly and Company Limited | Endocrinology-Gynaecology-Fertility-Metabolism | P | • 30.04.2009<br>• 11.12.2009 | P/8/2010 29.01.2010 |
| Givinostat | Italfarmaco SpA | Immunology-Rheumatology-Transplantation | P | • 30.04.2009<br>• 11.12.2009 | P/9/2010 29.01.2010 |
| Japanese encephalitis virus (strain SA14-14-2 (inactivated)) (Ixiaro) | Intercell AG | Vaccines | P | • 02.04.2009<br>• 11.12.2009 | P/10/2010 29.01.2010 |
| linagliptin, metformin | Boehringer Ingelheim International GmbH | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 15.10.2009<br>• 11.12.2009 | Not available yet |
| (D-6-n-propyl-8β-ergolinylmethylthioacetyl)-DLys(D-6-n-propyl-8β-ergolinylmethylthioacetyl)-Cys-Tyr-DTrp-Lys-Abu-Cys-Thr-NH2 | Ipsen Pharma | Endocrinology-Gynaecology-Fertility-Metabolism | W | • 15.10.2009<br>• 11.12.2009 | P/11/2010 29.01.2010 |
| Larvae of Lucilia sericata (BioFOAM Dressing) | ZooBiotic Limited | Other | W | • 15.10.2009<br>• 11.12.2009 | P/4/2010 25.01.2010 |
| Amlodipine besylate, valsartan, hydrochlorothiazide | Novartis Europharm Ltd. | Cardiovascular diseases | W | • 15.10.2009<br>• 11.12.2009 | P/6/2010 25.01.2010 |

| Product INN/ Invented Name | Applicant | Therapeutic Area | PIP (P) / PIP Modification (PM) / Full Waiver (W) | PDCO<br>• Start date<br>• Opinion | EMA Decision |
|---|---|---|---|---|---|
| (1R,2R,4S)-4-{(2R)-2-[(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,27-dihydroxy-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-1,5,11,28,29-pentaoxo-1,4,5,6,9,10,11,12,13,14,21,22,23,24,25,26,27,28,29,31,32,33,34,34a-tetracosahydro-3H-23,27-epoxypyrido[2,1-c][1,4]oxazacyclohentriacontin-3-yl]propyl}-2-methoxycyclohexyldimethyl-phosphinate (also known as: MK-8669 and AP23573 and ridaforolimus) | Merck Sharp and Dohme (Europe), Inc. | Oncology | P | • 30.04.2009<br>• 11.12.2009 | P/2/2010<br>25.01.2010 |
| Amlodipine besilate, Atorvastatin (L-lysine salt) | Gedeon Richter Plc. | Cardiovascular Diseases | W | • 15.10.2009<br>• 11.12.2009 | P/5/2010<br>25.01.2010 |
| Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein (Gardasil) | Sanofi Pasteur MSD SNC | Vaccines | PM | • 19.11.2009<br>• 11.12.2009 | Not available yet |
| Moxifloxacin hydrochloride (Avalox and associated names) | Bayer Schering Pharma AG | Infectious Diseases | PM | • 15.10.2009<br>• 11.12.2009 | P/262/2009<br>23.12.2009 |
| Moxifloxacin hydrochloride (Octegra and associated names) | Bayer Schering Pharma AG | Infectious Diseases | PM | • 15.10.2009<br>• 11.12.2009 | P/263/2009<br>23.12.2009 |
| Moxifloxacin hydrochloride (Actimax and associated names) | Bayer Schering Pharma AG | Infectious Diseases | PM | • 15.10.2009<br>• 11.12.2009 | P/264/2009<br>23.12.2009 |
| Moxifloxacin hydrochloride (Actira and associated names) | Bayer Schering Pharma AG | Infectious Diseases | PM | • 15.10.2009<br>• 11.12.2009 | P/265/2009<br>23.12.2009 |
| Ulipristal acetate (Ellaone) | Laboratoire HRA Pharma | Endocrinology-Gynaecology-Fertility-Metabolism | PM | • 19.11.2009<br>• 11.12.2009 | P/1/2010<br>25.01.2010 |
| Voclosporine (LUVENIQ) | Lux Biosciences GmbH | Ophthalmology | PM | • 19.11.2009<br>• 11.12.2009 | P/7/2010<br>26.01.2010 |

# Annex 15 – Guidelines and working documents in 2009

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

| **Working Party/Group** | **Total number of adopted guidelines/ documents for which working party/group is responsible** | **Number of concept papers/ guidelines/ documents initiated during 2009** | **Number of concept papers/ guidelines/ documents in progress during 2009** | **Number of guidelines/ documents adopted during 2009** |
|---|---|---|---|---|
| CHMP Biologics Working Party | … | … | … | … |
| CHMP Blood Products Working Party | … | … | … | … |
| CHMP Efficacy Working Party | … | … | … | … |
| CHMP Gene Therapy Working Party | … | … | … | … |
| CHMP Pharmacogenomics Working Party | … | … | | … |
| CHMP Pharmacovigilance Working Party | 31 | 5 | 8 | 7 |
| CHMP Safety Working Party | … | … | … | … |
| CHMP Scientific Advice Working Party | … | … | … | … |
| CHMP Similar Biological (Biosimilar) Medicinal Products Working Party | … | … | … | … |
| CHMP Vaccine Working Party | … | … | … | … |
| CHMP Working Party on Cell-based Products | … | … | … | … |
| CHMP Invented Name Review Group | 0 | 1 | 1 | 1 |
| EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) | 10 | 5 | NA | 7 |
| EMA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) | 3 | 2 | NA | 3 |
| CHMP Ad-Hoc SmPC Group | … | … | … | … |

| Working Party/Group | Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest |
|---|---|
| CHMP Biologics Working Party | • Emergent novel H1N1 pandemic influenza vaccine: composition, quality criteria for the production and release of vaccine batches (EU recommendation)<br>• Creutzfeldt-Jakob Disease (CJD) risk and urine-derived medicinal products (report of expert workshop) |
| CHMP Blood Products Working Party | • Intravenous immunoglobulins (revised guidelines for public consultation)<br>• Factor VIII and IX products, with focus on paediatric studies (revised guidelines for second public consultation) |
| CHMP Efficacy Working Party | • Direct-acting antiviral agents intended for treatment of chronic hepatitis C (guideline)<br>• Medicinal products for the treatment of pulmonary arterial hypertension (guideline)<br>• Medicinal products for the treatment of ankylosing spondylitis (guideline)<br>• Medicinal products for the treatment of cystic fibrosis (guideline)<br>• Extrapolation of results from clinical studies conducted outside the EU to the EU-population (reflection paper) |
| CHMP Gene Therapy Working Party | • Follow-up of patients administered with gene therapy medicinal products (guideline)<br>• Virus and vector shedding (considerations on general principles)<br>• Quality, pre-clinical and clinical aspects of gene transfer medicinal products (concept paper on revision of guideline) |
| CHMP Pharmacogenomics Working Party | • Use of genetic testing in pharmacokinetic studies; recommending why and when genetic testing should be considered, as well as safety and efficacy results in future clinical studies and pharmacovigilance (draft guideline)<br>• Use of genomic biomarkers for population selection in clinical trials; to ensure that biomarkers to be used in clinical trials to select or de-select patients for treatment are appropriate (reflection paper) |
| CHMP Pharmacovigilance Working Party | • Publication Policy for PhVWP Monthly Reports (finalised and agreed)<br>• CHMP Guideline on the Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis against Infectious Diseases (finalised and agreed)<br>• European Pharmacovigilance Strategy for (A) H1N1 Vaccines Benefit-Risk Surveillance (finalised and agreed)<br>• CHMP Recommendations CHMP Recommendations for the Pharmacovigilance Plan as part of the Risk Management Plan to be submitted with the Marketing Authorisation Application for a Pandemic Influenza Vaccine (contribution finalised and agreed)<br>• European Pharmacovigilance Strategy for Pandemic Influenza Antivirals (finalised and agreed)<br>• Best Practice Guide for Member States on PSUR assessment worksharing (revision agreed)<br>• Guidance for Marketing Authorisation Holders on PSUR assessment worksharing (revision agreed)<br>• Volume 9A – Ch I.7 on Post-Authorisation Safety Studies (Rev 2008 finalised post-consultation at PhVWP/CHMP level, finalisation at EC level ongoing)<br>• Volume 9A – various Ch's for clarifications re EudraVigilance (Rev 2008 finalised post-consultation at PhVWP/CHMP level, finalisation at EC level ongoing)<br>• CHMP Guideline on the Preparation of Assessment Reports on Periodic Safety Update Reports (revision finalised for pilot use, to be publicly consulted in |

| Working Party/Group | Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest |
|---|---|
| | 2010)<br>• Best Practice Guide for Member States on Communication and Implementation of Safety Information (revision by CMD(h) and PhVWP ongoing)<br>• ICH-M1/MedDRA (contribution to ongoing maintenance at ICH and MSSO level)<br>• ICH-M5/IS IDMP on Identification of Medicinal Products (contribution to ongoing development)<br>• ICH-E2B(R3) on Individual Case Safety Reports (contribution to ongoing development into IS ICSR)<br>• ICH-E2F on Development Safety Update Reports (contribution to ongoing development)<br>• PhVWP Business Continuity Plan (drafting initiated)<br>• Volume 9A – Ch I.3 on Risk Management Plans (discussion on revision initiated)<br>• Volume 9A – Ch I.4 on Individual Case Safety Reports re screening of MAH websites (discussion on revised recommendation initiated)<br>• Volume 9A – Ch IV.2 on Direct Healthcare Professional Communications (discussion on revision initiated)<br>• ICH-E2C(R1) on Periodic Safety Update Reports (drafting of Concept Paper for revision initiated) |
| CHMP Similar Biological (Biosimilar) Medicinal Products Working Party | • Similar biological medicinal products containing monoclonal antibodies (draft guideline) |
| CHMP Vaccine Working Party | • Quality, non-clinical and clinical aspects of live recombinant viral vectored vaccines (draft guideline) |
| CHMP Working Party on Cell-based Products | • Risk-based approach of advanced therapy medicinal products (ATMPs) according to revised Annex I, part IV of Directive 2001/83/EC (concept paper and guideline)<br>• Stem cell medicinal products (reflection paper)<br>• Clinical aspects related to regenerative medicine (reflection paper)<br>• Cell-based products (question and answer document) |
| CHMP Invented Name Review Group | • NRG Position Paper - Criteria for NRG objections based on potential risk to confusion with names of suspended or withdrawn/revoked Marketing Authorisations (MA) (EMEA/531570/2008)<br>• NRG Position Paper (DRAFT) - Re-use of invented names of medicinal products (draft document) |
| EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) | • Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (EMEA/40926/2009)<br>• Second report on the progress of the interaction with Patients' and Consumers' Organisations and analysis of the degree of satisfaction of patients/consumers involved in EMEA activities during 2008 (EMEA/259449/09)<br>• Reflection paper on the further involvement of patients and consumers in the agency's activities (EMA/10723/2009)<br>• Report from experience acquired from pilot phase participation of patients/consumers representatives in PHVWP and proposal for participation of patients'/consumers' representatives as observer to the PHVWP (EMA/355206/2009)<br>• Framework on the interaction between the EMEA and patients' and consumers' organisations (EMEA/354515/2005-Final) |

| Working Party/Group | Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest |
|---|---|
| | • Rules of Involvement of Members of Patients' / Consumers' and Healthcare Professionals' Organisations in Committees related activities (EMEA/483439/2008 rev. 1)<br>• Criteria to be fulfilled by patients' and consumers' organisations involved in the European Medicines Agency activities (EMEA/14610/04/Final) |
| EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) | • HCP WG: Final Recommendations and Proposals for Action (EMEA/185036/2008)<br>• Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (EMEA/40926/2009)<br>• Rules of Involvement of Members of Patients' / Consumers' and Healthcare Professionals' Organisations in Committees related activities (EMEA/483439/2008 rev. 1) |

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

### CVMP Efficacy

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/016/00-Rev.1-CONSULTATION | Guideline on the conduct of bioequivalence studies for veterinary medicinal products | Adopted for consultation, March 2009 (End of consultation: September 2009) |
| EMEA/CVMP/EWP/82829/2009 | Question and Answer document in relation to CVMP Guideline on "Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats" | Adopted, March 2009 |
| EMEA/CVMP/28510/2008 | Guideline on dossier requirements for anticancer medicinal products for dogs and cats | Adopted, April 2009 |
| EMEA/CVMP/EWP/37388/2009-CONSULTATION | Concept paper on the revision of the guideline on statistical principles for veterinary clinical trials | Adopted for consultation, June 2009 (End of consultation: September 2009) |
| EMEA/CVMP/EWP/459868/2008-CONSULTATION | (Revised) guideline on demonstration of target animal safety and efficacy of veterinary medicinal products for use in farmed fish | Adopted for consultation, October 2009 (End of consultation: April 2009) |
| EMEA/CVMP/EWP/459883/2008-CONSULTATION | Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees | Adopted for consultation, October 2009 (End of consultation: April 2009) |

### CVMP Environmental Risk Assessment (ERA)

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/ERA/10043/2009-CONSULTATION | Concept paper on the fate of veterinary medicinal products in manure | Adopted, April 2009 |

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/ERA/172074/2008-Rev.1 | Update of Question & Answer document on the implementation of the CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in Support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II) | Adopted, September 2009 |
| EMEA/CVMP/ERA/12254/2009-CONSULTATION | Concept paper on higher tier testing of antiparasitics to dung organisms | Adopted for consultation, (End of consultation: November 2009) |

**CVMP Immunologicals**

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/IWP/105506/2007-CONSULTATION | Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease | Adopted for consultation, March 2009 (End of consultation: September 2009) |
| EMEA/CVMP/IWP/439467/2007-CONSULTATION | Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals | Adopted for consultation, March 2009 (End of consultation: September 2009) |
| EMEA/CVMP/IWP/250147/2008-CONSULTATION | Guideline on data requirements to support in-use stability claims for veterinary vaccines | Adopted for consultation, March 2009 (End of consultation: September 2009) |
| EMEA/CVMP/IWP/123243/2006-Rev.1-CONSULTATION | Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets | Adopted for consultation, March 2009 (End of consultation: June 2009) |
| EMEA/CVMP/340494/2009 | Question and Answer document on inactivation kinetics studies | Adopted, June 2009 |
| EMEA/CVMP/IWP/105504/2007 | Guideline on the requirements for the replacement of established Master Seeds (MS) already used in authorised immunological veterinary medicinal products | Adopted, July 2009 |

**CVMP Pharmacovigilance**

| Reference number | Document title | Status |
|---|---|---|
| SOP-EMEA/599270/2007 | SOP on Handling of pharmacovigilance Rapid Alerts (RAs) and Non Urgent Information (NUI)for veterinary use | Endorsed, January 2009 |
| EMEA/CVMP/10418/2009 | Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products | Adopted, February 2009 |
| SOP/V/4023-Rev.1 | Management of Period Safety Update | Adopted, April 2009 |

| Reference number | Document title | Status |
|---|---|---|
| | Reports (PSURs) for Centrally Authorised Products (CAPs) and Annex I – Contact details of national competent authorities for PSUR submission | |
| EMEA/CVMP/PhVWP/133883/2004-Rev.2 | Mandate, Objectives and Rules of Procedure For The CVMP Pharmacovigilance Working Party (PhVWP-V) | Adopted, April 2009 |
| EMEA/INS/PhV/85061/2008 | Procedure for Reporting of Pharmacovigilance Inspections Requested by the CVMP | Adopted, April 2009 |
| EMEA/CVMP/10418/2009-Rev.1 | Combined VeDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals and Humans | Adopted, June 2009 |
| EMEA/CVMP/553/03-Rev.4 | Revised List of Species and Breeds for Electronic Reporting of Suspected Adverse Reactions in Veterinary Pharmacovigilance | Adopted, June 2009 |
| EMEA/CVMP/353015/2009 | Deprecated Veddra Recoded Term List for Implementation of the Combined VeDDRA List | Adopted, June 2009 |
| SOP/V/4052 | SOP on procedure for Management of 15-day Suspected Adverse Reaction (SAR) reports to a centrally authorised veterinary medicinal product | Endorsed, July 2009 |
| EMEA/CVMP/126726/2007-CONSULTATION | Reflection paper on Risk Management Plans for Centrally Authorised Veterinary Medicinal Products | Adopted for consultation, November 2009 (End of consultation: March 2010) |

**Joint CHMP/CVMP Quality**

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/QWP/544461/2007 | Guideline on the quality aspects of single-dose veterinary spot-on products | Adopted, January 2009 |
| EMEA/CHMP/CVMP/QWP/663093/2008 | Question and Answer document on Plastic Immediate Packaging Materials | Adopted, January 2009 |
| EMEA/CHMP/CVMP/QWP/17760/2009-Rev.1-CONSULTATION | Revised Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations | Adopted for consultation, February 2009 (End of consultation: August 2009) |
| EMEA/555991/2007 | New Question and Answers which aim to clarify several issues associated with the use of Process Analytical Technology (PAT), | Adopted, February 2009 |
| EMEA/CHMP/CVMP/QWP/160263/2009 | Question and Answer documents on endotoxin/sterility testing during and at | Adopted, April 2009 |

| Reference number | Document title | Status |
|---|---|---|
| | the end of shelf-life | |
| EMEA/CHMP/CVMP/QWP/450653/2006 | Recommendation on the Assessment of the quality of medicinal products containing existing/ known active substances | Adopted, April 2009 |
| EMEA/HMPC/CHMP/CVMP/287539/2005-Rev.1 | Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/ traditional herbal medicinal products | Adopted, December 2009 |

**CVMP Safety**

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/SWP/322484/2008-Rev.1-CONSULTATION | Guideline on user safety for pharmaceutical veterinary medicinal products | Adopted for consultation, April 2009 (End of consultation, August 2009) |
| EMEA/CVMP/VICH/486/02-Rev.2 | VICH Guideline on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing | Adopted, April 2009 |
| EMEA/CVMP/516817/2009-CONSULTATION | Guideline on data to be provided in support of a request to include substance in the list of substances considered as not falling within the scope of regulation (EC) No. 470/2009 | Adopted for consultation, November 2009 (End of consultation, May 2010) |
| EMEA/CVMP/VICH/463072/2009 | VICH GL46: Metabolism study to determine the quantity and identify the nature of residues | Adopted for consultation, December 2009 (End of consultation, May 2010) |
| EMEA/CVMP/VICH/463104/2009 | VICH GL47: Comparative metabolism studies in laboratory animals | Adopted for consultation, December 2009 (End of consultation, May 2010) |
| EMEA/CVMP/VICH/463199/2009 | VICH GL48: Marker residue depletion studies to establish product withdrawal periods | Adopted for consultation, December 2009 (End of consultation, May 2010) |
| EMEA/CVMP/VICH/463202/2009 | VICH GL49: Validation of analytical methods used in residue depletion studies | Adopted for consultation, December 2009 (End of consultation, May 2010) |

**CVMP Scientific Advisory Group on Antimicrobials**

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/SAGAM/81730/2006 | Revised Reflection Paper on the use of 3rd and 4th generation cephalosporins in food producing animals in the European Union: development of resistance and impact on human and animal health, including | Adopted, March 2009 |

| Reference number | Document title | Status |
|---|---|---|
| | recommendations | |
| EMEA/CVMP/SAGAM/68290/2009 | Reflection paper on MRSA in food producing and companion animals in the European Union: epidemiology and control options for human and animal health | Adopted, March 2009 |
| EMEA/CVMP/SAGAM/113420/2009-CONSULTATION | Concept paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health | Adopted for consultation, June 2009 (End of consultation, August 2009) |
| EMEA/CVMP/SAGAM/386369/2009-CONSULTATION | Concept paper on meticillin-resistant Staphylococcus (pseud)intermedius | Adopted for consultation, July 2009 (End of consultation, March 2010) |

**CVMP General**

| Reference number | Document title | Status |
|---|---|---|
| EMEA/INS/GCP/390778/2008 | Procedure for the preparation of a risk-based programme for routine PhV Inspections of MAHs connected with Veterinary Centrally Authorised Products (CAPs) | Adopted, January 2009 |
| EMEA/INS/GCP/85059/2008 | Procedure for coordination of pharmacovigilance inspections requests by the CVMP | Adopted, January 2009 |
| EMEA/INS/S&T/75010/2009 | Sampling and Testing of Centrally Authorised products | Adopted, April 2009 |
| EMEA/CVMP/248499/2007-Rev.1 | Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products | Adopted, April 2009 |
| EMEA/CVMP/425558/2006-Rev.1 | Reflection paper on publication of withdrawals of Marketing Authorisation applications for veterinary medicinal products | Adopted, June 2009 |
| EMEA/CVMP/430509/2009-CONSULTATION | Guideline on the change in classification of veterinary medicinal products authorised by the Community | Adopted for consultation, September 2009 (End of consultation, March 2010) |
| EMEA/CVMP/468877/2009 | Appointment and responsibilities of rapporteur and co-rapporteur for procedures regarding veterinary medicinal products | Adopted, September 2009 |
| EMEA/CVMP/2128/2007-Rev.1-CONSULTATION | Revised procedural advice on the re-examination of CVMP opinions | Adopted for consultation, September 2009 (End of consultation, November 2009) |

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/626480/2009-CONSULTATION | Concept paper for the revision of the assessor guideline | Adopted for consultation, October 2009 (End of consultation, December 2009) |

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

| Scientific Committee | Total number of adopted guidelines/ documents for which committee is responsible | Number of concept papers/ guidelines/ documents initiated in 2009 | Number of concept papers/ guidelines/ documents in progress during 2009 | Number of guidelines/ documents adopted in 2009 |
|---|---|---|---|---|
| Committee for Orphan Medicinal Products | 5 | 0 | 1 | 0 |

| Scientific Committee | Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest |
|---|---|
| Committee for Orphan Medicinal Products | Elements required to support the medical plausibility and the assumption of significant benefit for orphan medicinal product designation (recommendation). Adopted November 2008 and released for consultation January 2009. Comments discussed and implemented in 2009. |

## *Committee on Herbal Medicines (HMPC)*

| Reference number | Document title | Status |
|---|---|---|
| EMEA/HMPC/574496/08 Rev. 1 | Recommended format for a list of references | Adopted July 2009 |
| EMEA/HMPC/67644/2009 | Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products | Released for public consultation March 2009<br>Adopted November 2009 |
| EMEA/HMPC/644241/2009 | Mandate, objectives and composition for the HMPC Organisational matters drafting group (ORGAM DG) | Adopted November 2009 |
| EMEA/HMPC/3626/2009 | Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products | Released for public consultation January 2009 |
| EMEA/HMPC/328575/07 Rev. 1 | Procedure on management of proposals from interested parties for Community list entries or Community herbal monographs | Released for public consultation March 2009<br>Adopted November 2009 |

| | | |
|---|---|---|
| EMEA/HMPC/108877/05 Rev. 1 | Procedure for the appointment by the HMPC of a Rapporteur responsible for<br>- a scientific evaluation or<br>- the establishment of a Community herbal monograph and/or Community list entry | Adopted March 2009 |
| EMEA/HMPC/1004/2006 Rev. 2 | Procedure for calls for scientific data for use in HMPC assessment work | Adopted March 2009 |
| EMEA/HMPC/107436/05 Rev. 4 | Template for a Community herbal monograph | Adopted July 2009 |

## *Paediatric Committee (PDCO)*

| Reference number | Document title | Status |
|---|---|---|
| EMEA/536810/2008 | PDCO/CHMP guideline on the investigation of medicinal products in the term and preterm neonate | Adopted 25/06/09<br>Into effect 01/01/10 |
| EMEA/405779/2009 | EMEA/PDCO standard paediatric investigation plan for non-adjuvanted or adjuvanted pandemic influenza vaccines during a pandemic | Adopted 26/06/09 |
| EMA/737605/2009 | Draft EMEA/PDCO standard paediatric investigation plan for allergen products for specific immunotherapy | Adopted 23/11/09 |
| EMEA/414936/2009 | Revised priority list for studies into off-patent paediatric medicinal products | Adopted (with revisions) 11/09/09 |

## *Committee for Advanced Therapies (CAT)*

| Scientific Committee | Total number of adopted guidelines/ documents for which committee is responsible | Number of concept papers/ guidelines/ documents initiated in 2009 | Number of concept papers/ guidelines/ documents in progress during 2009 | Number of guidelines/ documents adopted in 2009 |
|---|---|---|---|---|
| Committee for Advanced Therapies | 0 | 2 | 2 | 0 |

| Scientific Committee | Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest |
|---|---|
| Committee for Advanced Therapies | • Scientific Guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products<br>• Reflection paper on in-vitro cultured chondrocyte containing products for cartilage repair of the knee |

# Annex 16 – Arbitration and Community referrals overview 2009

## *Referrals made to the CHMP*

### Procedures started

| Type of referral | Date of CHMP start of procedure | International non-proprietary name (INN) |
|---|---|---|
| Article 29(4) of Directive 2001/83/EC | 22/01/2009 | tolperison hydrochloride |
| Article 29(4) of Directive 2001/83/EC | 22/01/2009 | trimetazidine |
| Article 29(4) of Directive 2001/83/EC | 22/01/2009 | trimetazidine |
| Article 29(4) of Directive 2001/83/EC | 19/02/2009 | fludeoxyglucose (18F) |
| Article 29(4) of Directive 2001/83/EC | 29/05/2009 | fentanyl |
| Article 29(4) of Directive 2001/83/EC | 29/05/2009 | pantoprazole |
| Article 29(4) of Directive 2001/83/EC | 29/05/2009 | pantoprazole |
| Article 29(4) of Directive 2001/83/EC | 22/10/2009 | bendamustin |
| Article 29(4) of Directive 2001/83/EC | 28/10/2009 | pantoprazole sodium sesquihydrate |
| Article 29(4) of Directive 2001/83/EC | 17/12/2009 | chlorhexidine |
| Article 29(4) of Directive 2001/83/EC | 18/12/2009 | clopidogrel |
| Article 29(4) of Directive 2001/83/EC | 18/12/2009 | clopidogrel |
| Article 29(4) of Directive 2001/83/EC | 19/11/2009 | morphine sulphate |
| Article 30 of Directive 2001/83/EC | 19/02/2009 | fluvastatin |
| Article 30 of Directive 2001/83/EC | 23/04/2009 | ceftazidime |
| Article 30 of Directive 2001/83/EC | 29/05/2009 | imipenem/cilastatin |
| Article 30 of Directive 2001/83/EC | 25/06/2009 | piperacillin/tazobactam |
| Article 30 of Directive 2001/83/EC | 23/07/2009 | candesartan |
| Article 30 of Directive 2001/83/EC | 24/09/2009 | cilazapril |
| Article 30 of Directive 2001/83/EC | 24/09/2009 | escitalopram |
| Article 30 of Directive 2001/83/EC | 24/09/2009 | escitalopram |
| Article 30 of Directive 2001/83/EC | 17/12/2009 | cilazapril |
| Article 30 of Directive 2001/83/EC | 18/12/2009 | atorvastatin |
| Article 31 of Directive 2001/83/EC | 23/04/2009 | valproic acid/valproate |
| Article 31 of Directive 2001/83/EC | 29/05/2009 | modafinil |
| Article 31 of Directive 2001/83/EC | 22/10/2009 | morphine, oxycodone, fentanyl, hydromorphone |
| Article 31 of Directive 2001/83/EC | 22/10/2009 | fenofibrate, bezafibrate, ciprofibrate, gemfibrozil |
| Article 29 of Regulation (EC) No 1901/2006 | 29/05/2009 | anastrozole |
| Article 29 of Regulation (EC) No 1901/2006 | 24/09/2009 | valsartan |
| Article 29 of Regulation (EC) No 1901/2006 | 24/09/2009 | valsartan |
| Article 29 of Regulation (EC) No 1901/2006 | 17/11/2009 | atorvastatin calcium |
| Article 29 of Regulation (EC) No 1901/2006 | 17/11/2009 | atorvastatin calcium |
| Article 29 of Regulation (EC) No 1901/2006 | 17/11/2009 | atorvastatin calcium |
| Article 107 of Directive 2004/27/EC | 24/09/2009 | iodocasein/thiamine |
| Article 107 of Directive 2004/27/EC | 24/09/2009 | propacetamol |
| Article 107 of Directive 2004/27/EC | 02/12/2009 | benfluorex |
| Article 107 of Directive 2004/27/EC | 17/12/2009 | ketoprofene |
| Article 107(2) of Directive 2001/83/EC | 18/12/2009 | sibutramine hydrochloride monohydrate |
| Article 5(3) procedure of Regulation (EC) 726/2004 | 19/02/2009 | bisphosphonates |
| Article 5(3) procedure of Regulation (EC) 726/2004 | 30/04/2009 | oseltamivir/zanamivir |

| Type of referral | Date of CHMP start of procedure | International non-proprietary name (INN) |
|---|---|---|
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 19/03/2009 | valproic acid |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 23/07/2009 | icodextrin |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 23/07/2009 | ethinylestradiol/drospirenone |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 23/07/2009 | ethinylestradiol/drospirenone |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 19/11/2009 | somatropin |
| Article 6(13) Of Commission Regulation (EC) N. 1084/2003 | 29/05/2009 | quetiapine |

**Procedures finalised**

| Type of referral | Date of CHMP opinion | International non-proprietary name (INN) |
|---|---|---|
| Article 29(4) of Directive 2001/83/EC | 22/01/2009 | trimetazidine |
| Article 29(4) of Directive 2001/83/EC | 22/01/2009 | trimetazidine |
| Article 29(4) of Directive 2001/83/EC | 19/02/2009 | budesonide |
| Article 29(4) of Directive 2001/83/EC | 19/03/2009 | betahistine dihydrochloride |
| Article 29(4) of Directive 2001/83/EC | 19/03/2009 | fludeoxyglucose (18F) |
| Article 29(4) of Directive 2001/83/EC | 23/04/2009 | itraconazole |
| Article 29(4) of Directive 2001/83/EC | 29/05/2009 | loratadine |
| Article 29(4) of Directive 2001/83/EC | 25/06/2009 | moxifloxacin hydrochloride |
| Article 29(4) of Directive 2001/83/EC | 25/06/2009 | moxifloxacin hydrochloride |
| Article 29(4) of Directive 2001/83/EC | 25/06/2009 | teicoplanin |
| Article 29(4) of Directive 2001/83/EC | 25/06/2009 | fentanyl |
| Article 29(4) of Directive 2001/83/EC | 23/07/2009 | ciclosporin |
| Article 29(4) of Directive 2001/83/EC | 22/10/2009 | tolperison hydrochloride |
| Article 29(4) of Directive 2001/83/EC | 19/11/2009 | pantoprazole |
| Article 29(4) of Directive 2001/83/EC | 19/11/2009 | pantoprazole |
| Article 29(4) of Directive 2001/83/EC | 19/11/2009 | pantoprazole sodium sesquihydrate |
| Article 30 of Directive 2001/83/EC | 19/03/2009 | valsartan |
| Article 30 of Directive 2001/83/EC | 25/06/2009 | amoxicilin/clavulanic acid |
| Article 30 of Directive 2001/83/EC | 25/06/2009 | topiramate |
| Article 30 of Directive 2001/83/EC | 25/06/2009 | topiramate |
| Article 30 of Directive 2001/83/EC | 23/07/2009 | meropenem |
| Article 30 of Directive 2001/83/EC | 19/11/2009 | fluvastatin |
| Article 30 of Directive 2001/83/EC | 17/12/2009 | pantoprazole |
| Article 31 of Directive 2001/83/EC | 22/01/2009 | methylphenidate |
| Article 31 of Directive 2001/83/EC | 25/06/2009 | dextropropoxyphene and paracetamol |
| Article 31 of Directive 2001/83/EC | 19/11/2009 | gadodiamide, gadopentetic acid, gadobenic acid, gadoxetic acid, gadoteridol, gadobutrol and gadoteric acid |
| Article 31 of Directive 2001/83/EC | 17/12/2009 | valproic acid/valproate |
| Article 36 of Directive 2001/83/EC | 22/01/2009 | formoterol fumarate dehydrate |
| Article 36 of Directive 2001/83/EC | 22/01/2009 | formoterol fumarate dehydrate |
| Article 29 of Regulation (EC) No 1901/2006 | 23/07/2009 | anastrozole |
| Article 29 of Regulation (EC) No 1901/2006 | 17/12/2009 | valsartan |
| Article 29 of Regulation (EC) No 1901/2006 | 17/12/2009 | valsartan |
| Article 107 of Directive 2004/27/EC | 22/10/2009 | iodocasein/thiamine |

| Type of referral | Date of CHMP opinion | International non-proprietary name (INN) |
|---|---|---|
| Article 107 of Directive 2004/27/EC | 17/12/2009 | benfluorex |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 19/11/2009 | icodextrin |
| Article 6(12) Of Commission Regulation (EC) N. 1084/2003 | 17/12/2009 | valproic acid |
| Article 5(3) procedure of Regulation (EC) 726/2004 | 23/07/2009 | oseltamivir/zanamivir |
| Article 5(3) procedure of Regulation (EC) 726/2004 | 24/09/2009 | bisphosphonates |

## *Referrals made to the CVMP*

| Type of referral | • Date of clock start<br>• CVMP opinion | • Product name<br>• INN |
|---|---|---|
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 13/05/2008<br>15/01/2009 | • ENRO-K 10% oral solution<br>• Enrofloxacin |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 13/05/2008<br>15/01/2009 | • Unisol (avifox) 10% oral solution<br>• Enrofloxacin |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 14/08/2008<br>11/03/2009<br>(after re-examination) | • Pharmasin 100% w/w water soluble granules<br>• Tylosine tartrate |
| Referral under Art. 35 of Directive 2001/82/EC | 15/04/2009<br>05/06/2009<br>(after re-examination) | • Injectable veterinary medicinal products containing ivermectin indicated for use in cattle<br>• Ivermectin |
| Referral under Art. 35 of Directive 2001/82/EC | 11/02/2009 | • All strengths of water soluble powders and oral solutions containing doxycycline hyclate<br>• Doxycycline hyclate |
| Referral under Art. 35 of Directive 2001/82/EC | 16/04/2009 | • Veterinary medicinal formulations containing colistin at 2 MIU/ml and intended for administration in drinking water to any food producing species<br>• Colistin sulfate |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 16/09/2008<br>16/09/2009<br>(after re-examination) | • Clavobay Lactating Cow<br>• Amoxicillin and clavulanic acid |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 16/09/2008<br>13/05/2009 | • Shotaflor 300 mg/ml<br>• Florfenicol |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 16/09/2008<br>13/05/2009 | • Fenflor 300 mg/ml<br>• Florfenicol |
| Referral for arbitration – Art. 34(1) Directive 2001/82/EC | 16/09/2008<br>13/05/2009 | • Pulmotil AC and associated names<br>• Tilmicosin |
| Referral for arbitration – Art. 34(1) Directive 2001/82/EC | 16/07/2008<br>13/05/2009 | • Pulmotil 40/100/200 VET Premix<br>• Tilmicosin |
| Referral under Art. 35 of Directive 2001/82/EC | 13/05/2009<br>11/11/2009<br>(under re-examination) | • Veterinary medicinal products containing quinolones or fluoroquinolones for all food-producing species<br>• Quinolones / fluoroquinolones |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 12/05/2009<br>09/12/2009 | • Cevazuril 50 mg/ml oral suspension for piglets<br>• Toltrazuril |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 15/10/2008<br>11/11/2009<br>(after re-examination) | • APPM Respipharm<br>• Strains of Actinobacillus pleuropneumoniae |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 12/11/2008<br>11/11/2009<br>(under re-examination) | • Tildren 500 mg<br>• Tiludronic acid (as disodium salt) |

| Type of referral | • Date of clock start<br>• CVMP opinion | • Product name<br>• INN |
|---|---|---|
| Referral for arbitration – Art. 6(12) of Commission Regulation 2001/82/EC | 14/07/2009<br>08/12/2009 | • Vasotop (1.25, 2.5 and 0.625 mg)<br>• Ramipril |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 14/07/2009<br>14/10/2009 | • Poulvac Bursa Plus<br>• Live infectious Bursal Disease Virus, strain V877 |
| Referral for arbitration – Art. 6(12) of Regulation (EC) No 1084/2003 | 14/10/2009 | • Porcilis PRRS<br>• Live attenuated PRRS virus strain DV |
| Referral for arbitration – Art. 6(12) of Regulation (EC) No 1084/2003 | 14/10/2009 | • Porcilis M Hyo<br>• Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11 |
| Referral for arbitration – Art. 34 of Directive 2001/82/EC | 11/11/2009 | • Fortekor vet and associated names<br>• Benazepril hydrochloride |

# Annex 17 – Publications by EMA staff member and experts in 2009

**Bauer P., Koenig F., Brannath W., Posch M.:**
Selection and bias-two hostile brothers. Statistics In Medicine. 2010 Jan 15;29(1):1-13. (Published online 2009)

**Borg J.J., Robert J-L., Wade G., Aislaitner D., Pirożynski M., Abadie E., Salmonson T., Vella Bonanno P.:**
Where is Industry Getting it Wrong? A Review of Quality Concerns Raised at Day 120 by the Committee for Medicinal Products for Human Use during European Centralised Marketing Authorisation Submissions for Chemical Entity Medicinal Products. J Pharm Pharmaceut Sci (www.cspsCanada.org) 12(2):181-198, 2009. Published, August 6, 2009

**Brasseur D., Pons G., coll. Saint-Raymond A. (2009):**
Le Règlement européen de "Meilleurs médicaments pour les enfants en Europe" Une chance pour la recherche et les soins en pédiatrie? In: Delfosse ML, Parizeau MH, Amman JP La recherche clinique avec les enfants: à la croisée de l'éthique et du droit. Belgique, France, Québec: Editions Anthemis

**Broich K.:**
Committee for Medicinal Products for Human Use (CHMP) assessment on efficacy of antidepressants. Eur Neuropsychopharmacol. 2009 May; 19(5):305-8. Epub 2009 Mar 9

**Jekerle V., Schröder C., Pedone E.:**
Legal basis of the Advanced Therapies Regulation. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2010 Jan;53(1):4-8 (Published online 2009)

**Celis P., Miglicacio G., Pedone E., Petracek J., Pinheiro M-H., Salmikangas P., Schneider C.K.:**
Advanced therapies: Regulatory principles and practise. Regulatory Rapporteur 2009; 6, 12-16

**Celis P., Pedone E.:**
The Committee for Advanced Therapies at the European Medicines Agency and the Advanced Therapies Certification Procedure. Drug Development 2009; 4, 64-67

**Eichler H-G., Abadie E., Raine J.M., Salmonson T.:**
Safe Drugs and the Cost of Good Intentions. New England Journal of Medicine 2009; 360: 14, 1378-1380

**Eichler I., Saint-Raymond A.:**
The EU Paediatric Regulation: The way forward or a Barrier to Progress? The Regulatory Affairs Journal 2009, 20: 347-348

**Fanciulli G., Tomasi P.A., Delitala A.P., Delitala G.:**
Activation of alpha1-adrenoceptors inhibits growth hormone secretion in humans. Exp Clin Endocrinol Diabetes. 2009 Oct;117(9): 460-2

**Giezen T.J., Mantel-Teeuwisse A.K., Strauss S.M.J.M., Egberts T.C.G., Blackburn S., Persson I., Leufkens H.G.M.:**
Evaluation of Post-Authorization Safety Studies in the First Cohort of EU Risk Management Plans at Time of Regulatory Approval. Drug Safety, Volume 32, Number 12, 1 December 2009, pp. 1175-1187(13)

**Goedecke T., Brosch S., Arlett P.:**
EudraVigilance - the common EU database to support pharmacovigilance activities. Regulatory Rapporteur 2009; 6(2), 6 -11

**Grein K.:**
Pharmacovigilance and the European Medicines Agency: conduct of pharmacovigilance activities. In: Woodward, KN. Veterinary Pharmacovigilance: Adverse Reactions to Veterinary Medicinal Products. Wiley-Blackwell Publishing. (2009)

**Ludolph A.C., Kassubek J., Landwehrmeyer B.G., Mandelkow E., Mandelkow E.M., Burn D.J., Caparros-Lefebvre D., Frey K.A., de Yebenes J.G., Gasser T., Heutink P., Höglinger G., Jamrozik Z., Jellinger K.A., Kazantsev A., Kretzschmar H., Lang A.E., Litvan I., Lucas J.J., McGeer P.L., Melquist S., Oertel W., Otto M., Paviour D., Reum T., Saint-Raymond A., Steele J.C., Tolnay M., Tumani H., van Swieten J.C., Vanier M.T., Vonsattel J.P., Wagner S., Wszolek Z.K.:**
Reisensburg Working Group for Tauopathies With Parkinsonism: Tauopathies with parkinsonism: clinical spectrum, neuropathologic basis, biological markers, and treatment options. Eur J Neurol. 2009 Mar;16(3):297-309

**Manolis E., Pons G.:**
Proposals for model-based paediatric medicinal development within the current European Union regulatory framework. British Journal of Clinical Pharmacology, Volume 68 Issue 4, Pages 493–501. Published Online: 26 Jun 2009

**Novelli G., Borgiani P., Ciccacci C., Di Daniele N., Sirugo G., Papaluca Amati M.:**
Pharmacogenomics: Role in Medicines Approval and Clinical Use. Public Health Genomics. Published online: October 6, 2009

**Regnstrom J., Koenig F., Aronsson B., Reimer T., Svendsen K., Tsigkos S., Flamion B., Eichler H.G., Vamvakas S.:**
Factors associated with success of market authorisation applications for pharmaceutical drugs submitted to the European Medicines Agency. Eur J Clin Pharmacol. 2010 Jan;66(1):39-48. (Published online 2009)

**Saint-Raymond A., Seigneuret N.:**
The European paediatric initiative: 1 year of experience. Paediatr Drugs 2009; 11(1):9-10

**Saint-Raymond A. (2009):**
Médicaments pédiatriques et recherche : un équilibre fragile à trouver entre risques et bénéfices In: Delfosse ML, Parizeau MH, Amman JP La recherche clinique avec les enfants: à la croisée de l'éthique et du droit. Belgique, France, Québec: Editions Anthemis

**Schneider C.K., Papaluca M., Kurki P.:**
A European perspective on immunogenicity evaluation. Nature Biotechnology, volume 27 number 6 june 2009, 507-508

**Shah R.R., Saint Raymond A. (2009):**
Regulation of Human Medicinal Products in the European Union. In: Griffin, JP The Textbook of Pharmaceutical Medicine. 6th ed. BMJ Books: 444-499

**Shivji R., Purves J., Celis P.:**
European Medicines Agency: influenza pandemic preparedness. Risk Wise Epidemics ISBN: 0-9536140-6-9 Page 36-39

**Tomasi P.A., Fanciulli G., Casti T., Delitala G.:**
Persistent hyperprolactinemia and bilateral galactocele in a male infant. Int J Pediatr Endocrinol. 2009; 2009:578610

# Annex 18 – Agency contact points

## *Pharmacovigilance and product quality defect reporting*

The constant monitoring of the safety of medicines after authorisation ('pharmacovigilance') is an important part of the work of the national competent authorities and the European Medicines Agency. The Agency receives safety reports and product quality defect reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use

Peter ARLETT
Direct telephone: +44 (0)20 7523 7108
E-mail: pharmacovigilance@ema.europa.eu

For matters relating to pharmacovigilance for medicinal products for veterinary use

Jos OLAERTS
Direct telephone: +44 (0)20 7418 8624
E-mail: vet-phv@ema.europa.eu

For product quality defects and recalls see www.ema.europa.eu/inspections/defectinstruction.html

For instructions and contact points

E-mail: qdefect@ema.europa.eu
Direct telephone: +44 (0)20 7523 7676 (for use as stated in the relevant instructions only)
Fax: +44 (0)20 7418 8590
Out of hours telephone: +44 (0)7880 550 697

## *SME Office*

The SME office has been set up within the Agency to address the particular needs of smaller companies. The office aims to facilitate communication with SMEs through dedicated personnel within the Agency who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs.

SME office contact point:

Melanie CARR
Direct telephone: +44 (0)20 7418 8575/8463
Fax: +44 (0)20 7523 7040
E-mail: smeoffice@ema.europa.eu

## *Certificates of a medicinal product*

The EMA issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health Organisation. These certify the marketing authorisation and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorisation applications in and export to non-EU countries.

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use:

E-mail: certificate@ema.europa.eu
Direct telephone: +44 (0)20 7523 7107
Fax: +44 (0)20 7418 8595

### *PMF/VAMF EMA certificates*

The Agency issues plasma master file (PMF) and vaccine antigen master file (VAMF) certificates of a medicinal product in conformity with the arrangements laid down by Community legislation. The Agency PMF/VAMF certification process is an assessment of the PMF/VAMF application dossier. The certificate of compliance is valid throughout the European Community.

For enquiries concerning PMF certificates

Silvia DOMINGO ROIGÉ
Direct telephone: +44 (0)20 7418 8552
Fax: +44 (0)20 7418 8545
E-mail: PMF@ema.europa.eu

For enquiries concerning VAMF certificates

Ragini SHIVJI
Direct telephone: +44 (0)20 7418 8698
Fax: +44 (0)20 7418 8545
E-mail: VAMF@ema.europa.eu

### *Documentation services*

A wide range of documents are published by the Agency, including press releases, general information documents, annual reports and work programmes.

These and other documents are available:

- on the Internet at www.ema.europa.eu
- by email request to info@ema.europa.eu
- by fax to +44 (0)20 7418 8670
- by writing to:

  EMA Documentation service
  European Medicines Agency
  7 Westferry Circus
  Canary Wharf
  London E14 4HB, UK

### *European experts list*

Over 4 000 experts are used by the Agency in its scientific evaluation work. The list of these European experts is available for examination on request at the Agency's offices.

Requests should be sent in writing to the European Medicines Agency or to

E-mail: europeanexperts@ema.europa.eu

## *Press office*

For press enquiries please contact:

Martin HARVEY ALLCHURCH or Monika BENSTETTER
Telephone +44 (0)20 7418 8427
E-mail: press@ema.europa.eu