04 May 2017
EMA/254538/2017 Corr.
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Minutes of the meeting on 20-23 March 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

Corr. – deletion of product cessation under 9.1

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified as included in the list of participants and restrictions. See (current) March 2017 CHMP minutes for the list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session held 20-23 March 2017. See (current) March 2017 CHMP minutes (to be published post April 2017 CHMP meeting).

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The CHMP welcomed Norwegian new member Stein Rune Andersen replacing Karsten Bruins Slot. The Committee also noted new member from Cyprus Emilia Mavrokordatou, replacing alternate member Georgios Savva, and the current member Panayiotis Triantafyllis was moved to alternate member position.

1.2. Adoption of agenda

CHMP agenda for 20-23 March 2017.

The CHMP adopted the agenda.

1.3. Adoption of the minutes

CHMP minutes for 20-23 February 2017.

The CHMP adopted the minutes.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - dinutuximab beta - Orphan - EMEA/H/C/003918

APEIRON Biologics AG; treatment of neuroblastoma

Scope: Oral explanation

Action: Possible oral explanation to be held on 21 March 2017 at time 09:00

List of Outstanding Issues adopted on 23.02.2017, 13.10.2016, 26.05.2016. List of Questions adopted on 24.09.2015.

An oral explanation was held on 21 March 2017 at 09:00.

See 3.1.2

2.1.2. - nusinersen - Orphan - EMEA/H/C/004312

Accelerated assessment

Biogen Idec Ltd; for the treatment of Spinal Muscular Atrophy (SMA)

Scope: Oral explanation/Day 180 list of outstanding issue

Action: Possible oral explanation to be held on 22 March 2017 at time 11:00

List of Questions adopted on 24.01.2017.

An oral explanation was held on 22 March 2017 at 12:00.

See 3.2.7

2.2. Re-examination procedure oral explanations

No items

2.3. Post-authorisation procedure oral explanations

No items

2.4. Referral procedure oral explanations

No items

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. Axumin - fluciclovine (^{18}F) - EMEA/H/C/004197

Blue Earth Diagnostics Ltd; diagnostic agent for Positron Emission Tomography (PET) of adult men with suspected recurrence of prostate cancer

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 15.12.2016. List of Questions adopted on 28.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that fluciclovine (18F) is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

3.1.2. Dinutuximab beta Apeiron - dinutuximab beta - Orphan - EMEA/H/C/003918

APEIRON Biologics AG; treatment of neuroblastoma

Scope: Opinion

Action: For adoption

Known active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 23.02.2017, 13.10.2016, 26.05.2016. List of Questions adopted on 24.09.2015.

See 2.1

An oral explanation was held on 21 March 2017 at 09:00.

The applicant presented at the oral explanation data in support of their new active substance claim and clinical superiority to Unituxin.

The CHMP discussed the data presented by the applicant in support of their claims.

The CHMP was informed about the withdrawal of Unituxin – see 9.1. Post-authorisation issues.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that dinutuximab beta is not a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

3.1.3. Ivabradine Accord - ivabradine - EMEA/H/C/004241

Accord Healthcare Ltd; treatment of angina pectoris

Scope: Opinion

Action: For adoption

Generic application (Article 10(1) of Directive No 2001/83/EC), Generic of Procoralan

List of Outstanding Issues adopted on 15.12.2016. List of Questions adopted on 01.04.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The CHMP noted the letter of recommendation dated 21 March 2017.

The summary of opinion was circulated for information.

3.1.4. Elmiron - pentosan polysulfate sodium - Orphan - EMEA/H/C/004246

bene-Arzneimittel GmbH; treatment of Interstitial Cystitis (IC)

Scope: Opinion

Action: For adoption

Well-established use application (Article 10a of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 23.02.2017, 10.11.2016. List of Questions adopted on 23.06.2016.

The Committee confirmed that all issues previously identified in this application had been

addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

3.1.5. Refixia - nonacog beta pegol - Orphan - EMEA/H/C/004178

Novo Nordisk A/S; treatment of haemophilia B

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

Oral explanation held on 15.09.2016. List of Outstanding Issues adopted on 15.09.2016. List of Questions adopted on 26.05.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by majority (25 positive out of 31 votes) together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that nonacog beta pegol is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The divergent positions (Katarina Vucic) and (Alexandre Moreau, Daniela Melchiorri, Harald Enzmann, Jan Mueller-Berghaus, Koenraad Norga) were appended to the opinion.

The legal status was agreed as medicinal product subject to restricted medical prescription.

The summary of opinion was circulated for information.

The CHMP adopted the similarity assessment report.

The CHMP adopted the BWP report.

3.1.6. Trumenba - meningococcal group B vaccine (recombinant, component, adsorbed) - EMEA/H/C/004051

Pfizer Limited; prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B

Scope: Opinion

Action: For adoption

New active substance (Article 8(3) of Directive No 2001/83/EC)

List of Outstanding Issues adopted on 26.01.2017. List of Questions adopted on 15.09.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus together with the CHMP assessment report and translation timetable.

Furthermore, the CHMP considered that *Neisseria meningitidis* serogroup B bivalent lipoprotein (recombinant lipidated fHbp (factor H binding protein) subfamily A and B) is a new active substance, as claimed by the applicant.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The legal status was agreed as medicinal product subject to medical prescription.

The summary of opinion was circulated for information.

The CHMP noted the letter of recommendation dated 23 March 2017.

The CHMP adopted the BWP report.

3.2. Initial applications; List of outstanding issues (Day 180; Day 120 for procedures with accelerated assessment timetable)

3.2.1. - dengue tetravalent vaccine (live, attenuated) - EMEA/H/C/004171

indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.07.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues. The CHMP agreed to consult a SAG and adopted a list of questions to this group.

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.2. - efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004250

treatment of HIV-1 infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 10.11.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

3.2.3. - alpha-1-antitrypsin - Orphan - EMEA/H/C/003934

Kamada BioPharma Limited at Fieldfisher LLP; treatment and maintenance therapy of adult patients with congenital deficiency of alpha-1 antitrypsin and lung disease with clinical evidence of emphysema and airway obstruction (FEV1/SVC<70%)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 21.07.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.4. - nitisinone - EMEA/H/C/004281

treatment of hepatorenal tyrosinemia type 1

Scope: Day 180 list of outstanding issue
Letter from the applicant dated 15 March 2017 requesting an extension of clock stop to respond to the List of Outstanding Issue

Action: For adoption

List of Questions adopted on 21.07.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues with a specific timetable.

3.2.5. - ocrelizumab - EMEA/H/C/004043

treatment of multiple sclerosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 15.09.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues.

The Committee adopted a list of outstanding issues with a specific timetable.

The Committee agreed to consult the SAG Neurology and adopted a list of question to this group.

The CHMP adopted the BWP report.

3.2.6. - etirinotecan pegol - EMEA/H/C/003874

treatment of breast cancer with brain metastases

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 10.11.2016.

The Committee was reminded of the status of this application and its remaining outstanding issues

The Committee adopted a list of outstanding issues with a specific timetable.

The CHMP adopted the BWP report.

3.2.7. - nusinersen - Orphan - EMEA/H/C/004312

Accelerated assessment

Biogen Idec Ltd; for the treatment of Spinal Muscular Atrophy (SMA)

Scope: Possible oral explanation to be held on 22 March 2017 at time 11:00.

Action: For adoption

List of Questions adopted on 24.01.2017.

See 2.1.2

An oral explanation was held on 22 March 2017 at 12:00.

The Committee discussed the presented data.

The Committee adopted a list of outstanding issues with a specific timetable.

3.3. Initial applications; List of questions (Day 120; Day 90 for procedures with accelerated assessment timetable)

3.3.1. - adalimumab - EMEA/H/C/004319

treatment of rheumatoid arthritis, axial spondyloarthritis, psoriasis, hidradenitis suppurativa (HS), Crohn's disease, ulcerative colitis and uveitis.

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP adopted the BWP report.

3.3.2. - darunavir - EMEA/H/C/004273

treatment of HIV-1 infection

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.3. - dupilumab - EMEA/H/C/004390

treatment of moderate-to-severe atopic dermatitis

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP adopted the BWP report.

3.3.4. - naloxone - EMEA/H/C/004325

for emergency use for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.5. - ciclosporin - EMEA/H/C/004229

for the treatment of moderate dry eye disease in adults

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.6. - rucaparib - Orphan - EMEA/H/C/004272

Clovis Oncology UK Ltd; treatment of ovarian cancer

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

3.3.7. - pegfilgrastim - EMEA/H/C/004413

treatment of neutropenia

Scope: Day 120 list of questions

Action: For adoption

The Committee discussed the issues identified in this application.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

The CHMP adopted the BWP report.

3.4. Update on on-going initial applications for Centralised procedure

3.4.1. - cerliponase alfa - Orphan - EMEA/H/C/004065

Accelerated assessment

BioMarin International Limited; treatment of neuronal ceroid lipofuscinosis type 2

Scope: Report from ad-hoc expert group held on 7 March 2017

Action: For information

List of outstanding issue adopted on 23.02.2017, List of Questions adopted on 13.12.2016.

The CHMP noted the report from the ad-hoc expert group.

3.4.2. - entecavir - EMEA/H/C/004458

treatment of chronic hepatitis B virus infection

Scope: Request by the applicant for extension to the clock stop to respond to the day 120 list of questions adopted on 15 December 2016.

Adopted by written procedure on 9 March 2017.

Action: For information

List of questions adopted on 15.12.2016.

The CHMP agreed to the request by the applicant for extension to the clock stop to respond to the day 120 list of questions adopted on 15 December 2016, by written procedure on 9 March 2017.

3.4.3. - iloperidone - EMEA/H/C/004149

treatment of schizophrenia

Scope: Letter from the applicant dated 8 March 2017 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 23 February 2017.

Action: For adoption

List of outstanding issue adopted on 23.02.2017, List of Questions adopted on 28.04.2016.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the List of Outstanding Issues adopted on 23 February 2017.

3.4.4. - brodalumab - EMEA/H/C/003959

moderate to severe plaque psoriasis

Scope: PRAC advice

Action: For discussion

List of Outstanding Issues adopted on 26.01.2017, 10.11.2016, 15.09.2016. List of Questions adopted on 01.04.2016.

The CHMP noted the advice from the PRAC.

3.4.5. - masitinib - Orphan - EMEA/H/C/004398

AB Science; treatment of amyotrophic lateral sclerosis

Scope: Letter from the applicant dated 16 March 2017 requesting an extension of clock-stop to respond to the List of Questions adopted on 26 January 2017

Action: For adoption

List of Questions adopted on 26.01.2017

The CHMP agreed to the request by the applicant for an extension of clock-stop to respond to the List of Questions adopted on 26 January 2017.

3.4.6. - binimetinib - EMEA/H/C/004052

treatment of unresectable or metastatic melanoma
Treatment of unresectable melanoma, with NRA Q61 mutation.

Scope: Request by the applicant for an extension to the clock stop to respond to the day 120 list of questions adopted on 26 January 2017.

Action: For adoption

List of Questions adopted on 26.01.2017

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the day 120 list of questions adopted on 26 January 2017.

3.4.7. - d-biotin - EMEA/H/C/004153

treatment of progressive multiple sclerosis (primary or secondary)

Scope: Letter from the applicant dated 28 February 2017 requesting an extension of clock stop to respond to the List of Questions adopted on 15 December 2016

Action: For adoption

List of Questions adopted on 15.12.2016.

The CHMP agreed to the request by the applicant for an extension of clock stop to respond to the List of Questions adopted on 15 December 2016.

3.4.8. - cariprazine - EMEA/H/C/002770

treatment of schizophrenia

Scope: Letter from the applicant dated 14 March 2017 requesting an extension of clock stop to respond to the List of Outstanding Issues adopted on 23 February 2017.

Action: For adoption

List of Outstanding Issues adopted on 23.02.2017. List of Questions adopted on 21.07.2016.

The CHMP agreed to the request by the applicant for an extension of clock stop to respond to the List of Outstanding Issues adopted on 23 February 2017.

3.4.9. - abaloparatide - EMEA/H/C/004157

treatment of osteoporosis

Scope: extension of the clock stop to respond to the List of Outstanding Issues adopted on 15 December 2016.

Action: For adoption

List of Outstanding Issues adopted on 15.12.2016. List of Questions adopted on 01.04.2016.

The CHMP noted the request by the applicant for a clock stop extension to respond to the List of Outstanding Issues adopted on 15 December 2016.

The CHMP adopted a revised list of outstanding issues with a specific timetable.

3.4.10. - human IgG1 monoclonal antibody specific for human interleukin-1 alpha - EMEA/H/C/004388

treatment of metastatic colorectal cancer

Scope: Letter from the applicant

Action: For information

List of Outstanding Issues adopted on 15.12.2016, List of Questions adopted on 21.07.2016

The CHMP noted the letter form the applicant

3.4.11. - padeliporfin - EMEA/H/C/004182

treatment of prostate cancer

Scope: List of experts for the SAG

Action: For adoption

List of Questions adopted on 26.05.2016. List of Outstanding Issue adopted on 15.12.2016.

The CHMP adopted the list of experts for the SAG Oncology.

3.4.12. - vosaroxin - Orphan - EMEA/H/C/004118

Sunesis Europe Ltd; treatment acute myeloid leukaemia

Scope: List of experts for the SAG

Action: For adoption

List of Outstanding Issues adopted on 15.12.2016. List of Questions adopted on 28.04.2016.

The CHMP adopted the list of experts for the SAG Oncology.

3.4.13. - trastuzumab - EMEA/H/C/004323

treatment of breast cancer and metastatic gastric cancer

Scope: Letter from the applicant dated 23 March 2017 requesting an extension of clock stop to respond to the List of Questions adopted on 26 January 2017.

Action: For adoption

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of questions adopted on 26 January 2017

3.5. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

No items

3.6. Initial applications in the decision-making phase

No items

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Blectifor - caffeine citrate - Orphan - EMEA/H/C/004100

Viridian Pharma Ltd; indicated in preterm neonates for the prevention of bronchopulmonary dysplasia

Rapporteur: Milena Stain, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: Withdrawal of initial marketing authorisation application

Action: For information

The CHMP noted the letter from the applicant informing about the withdrawal of the initial marketing authorisation application.

3.7.2. Enpaxiq - pacritinib - Orphan - EMEA/H/C/004193

CTI Life Sciences Limited; treatment of myelofibrosis

Scope: Withdrawal of initial marketing authorisation application

Action: For information

List of Questions adopted on 15.09.2016.

The CHMP noted the letter from the applicant informing about the withdrawal of the initial marketing authorisation application.

4. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Opinion

4.1.1. Benepali - etanercept - EMEA/H/C/004007/X/0016

Samsung Bioepis UK Limited (SBUK)

Rapporteur: Andrea Laslop, PRAC Rapporteur: Patrick Batty

Scope: “To add a new strength of 25 mg solution for injection in pre-filled syringe.”

Action: For adoption

List of Questions adopted on 15.12.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

4.1.2. Brilique - ticagrelor - EMEA/H/C/001241/X/0034

AstraZeneca AB

Rapporteur: Johann Lodewijk Hillege

Scope: “To add new pharmaceutical form (orodispersible tablets 90 mg) to the currently approved presentations for Brilique.”

Action: For adoption

List of Outstanding Issues adopted on 26.01.2017. List of Questions adopted on 15.09.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

4.2. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues

4.2.1. Mimpara - cinacalcet - EMEA/H/C/000570/X/0055/G

Amgen Europe B.V.

Rapporteur: Kristina Dunder, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Ulla Wändel Liminga

Scope: “Extension application to introduce a new pharmaceutical form associated with new strengths (1 mg, 2.5 mg and 5 mg hard capsules) grouped with a type II variation (C.1.6.a) to include paediatric use in the approved indication.

As a consequence, sections 4.2 and 4.4 of the SmPC are updated to detail posology in paediatric patients and to update the safety information, respectively.

The Package Leaflet and Labelling are updated in accordance.

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.

Furthermore, the PI is brought in line with the latest QRD template version 10."

Action: For adoption

List of Questions adopted on 13.10.2016.

The Committee discussed the issues identified in this application, which were related to pharmacokinetics, clinical and quality aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of outstanding issues and a specific timetable.

4.3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question

4.3.1. Tasigna - nilotinib - Orphan - EMEA/H/C/000798/X/0088/G

Novartis Europharm Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Doris Stenver

Scope: "Extension of Indication to include treatment of paediatric patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase (Ph+ CML-CP), or with Ph+ CML-CP resistant or intolerant to prior therapy including imatinib, based on results from two clinical studies in paediatric patients conducted in accordance with the approved Tasigna Paediatric Investigation Plan (PIP), the Phase I PK study CAMN107A2120 and the Phase II safety and efficacy study CAMN107A2203. An updated RMP version 18.0 was provided as part of the application.
Extension application to add a new strength of 50mg hard capsules.
In addition, the applicant proposes to merge the SmPCs for the 50 mg and 200 mg strengths."

Action: For adoption

The Committee discussed the issues identified in this application. The main outstanding issues were related to quality and clinical aspects.

The Committee adopted the CHMP recommendation and scientific discussion together with the list of questions.

4.4. Update on on-going extension application according to Annex I of Commission Regulation (EC) No 1234/2008

No items

4.5. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

No items

5. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

5.1. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008; Opinions or Requests for supplementary information

5.1.1. Bydureon - exenatide - EMEA/H/C/002020/II/0041

AstraZeneca AB

Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue

Scope: "Update of section 4.1 of the SmPC in order to align with more recently approved glucose-lowering agents and with "Reflection paper on the wording of indication for medicinal products for treatment of type 2 diabetes" and update of section 5.1 based on the study D5553C00003 (Duration 8 study) which evaluated concomitant add-on treatment with the combination of exenatide once weekly 2 mg and dapagliflozin 10 mg once daily in patients with type 2 diabetes mellitus who have inadequate glycaemic control on metformin. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes in the SmPC and Package Leaflet. Furthermore, the updated RMP version 24 has been submitted."

Action: For adoption

The Committee noted the issues identified in this application, which were related to efficacy and safety aspects. The applicant should further clarify the data provided.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.2. Genvoya - elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004042/II/0026

Gilead Sciences International Ltd

Rapporteur: Robert James Hemmings, PRAC Rapporteur: Amelia Cupelli

Scope: "Extension of Indication to include paediatric patients from 6 of age to less than 12

years of age, with body weight of at least 25kg, infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir, for Genvoya.

As a consequence, sections 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated based on the analysis of the paediatric study GS-US-292-0106 (Cohort 2) "A Phase 2/3, Open-Label Study of the Pharmacokinetics, Safety, and Antiviral Activity of the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) in HIV-1 Infected Antiretroviral Treatment Naive Adolescents and Virologically Suppressed Children".

The Package Leaflet and the Risk Management Plan (v. 3) are updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application and noted that there are questions related to non-clinical and clinical part.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.3. Humira - adalimumab - EMEA/H/C/000481/II/0163

AbbVie Ltd.

Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include new indication for treatment of chronic non-infectious uveitis in paediatric patients for Humira. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and the RMP are updated in accordance.
In addition, the Marketing authorisation holder (MAH) took the opportunity to implement an alternative format statement for blind/partially sighted patients into the Package Leaflet as it was introduced with procedure EMEA/H/C/000481/N/0155.
Furthermore, the MAH has made some editorial changes to the Package leaflet."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to extrapolation to all subsets of uveitis and the proposed posology.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.4. Izba - travoprost - EMEA/H/C/002738/II/0005

Alcon Laboratories (UK) Ltd

Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Almath Spooner

Scope: "Extension of Indication to include treatment of paediatric patients aged 2 months to < 18 years with ocular hypertension or paediatric glaucoma in order to decrease of elevated intraocular pressure. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet has been updated accordingly. In addition, the

marketing authorisation holder took the opportunity to introduce minor corrections in the SmPC and to update the list of local representatives in the PL. The RMP has updated to version 9.0"

Action: For adoption

Request for Supplementary Information adopted on 15.12.2016.

The Committee discussed the issues identified in this application. The Committee noted the modelling approach with the existing clinical data to support the paediatric indication.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.5. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0014

Merck Sharp & Dohme Limited

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include monotherapy treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are transplant-ineligible and have failed BV, based on the results from study KEYNOTE-087, an open-label Phase II trial of pembrolizumab in subjects with relapsed or refractory cHL and study KEYNOTE-013, a Phase Ib multi-cohort trial of pembrolizumab in subjects with hematologic malignancies. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated and the Package Leaflet is updated accordingly. Annex II has been updated to include changes to the 'additional risk minimisation measures' and the 'obligation to conduct post-authorisation measures'. An updated RMP version 5.3 was agreed during the procedure."

Action: For adoption

Request for Supplementary Information adopted on 26.01.2017.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.6. Nplate - romiplostim - Orphan - EMEA/H/C/000942/II/0060/G

Amgen Europe B.V.

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Eva A. Segovia

Scope: "C.I.6.a - Extension of Indication to include paediatric population for Nplate: to register Nplate for the use in the paediatric chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients: 1 year of age and older.

As a consequence Product information has been updated accordingly.
The RMP version 18 has also been submitted.
Furthermore, the PI is brought in line with the latest QRD templare version 10.

B.II.e.5.c – To add a low-dose romiplostim 125 microgram vial presentation for powder for solution for injection (4 vials pack).

B.II.e.5.a.1 – To add a 1 vial pack size of a low-dose romiplostim 125 microgram presentation."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to clinical and quality part.

The Committee adopted a request for supplementary information.

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the RSI.

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0017

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include treatment of recurrent or metastatic squamous cell cancer of the head and neck (SCCHN) after platinum-based therapy in adults for OPDIVO.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, of the SmPC are updated in order to add the proposed new indication, add a warning that patients with a baseline performance score ≥ 2, untreated brain metastasis, active autoimmune disease, or medical conditions requiring systemic immunosuppression were excluded from the SCCHN clinical trial and update the undesirable effect and safety information. Labelling is updated in accordance. Moreover, the updated RMP version 6.0 has been submitted"

Action: For adoption

Request for Supplementary Information adopted on 26.01.2017, 13.10.2016.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.8. Opdivo - nivolumab - EMEA/H/C/003985/II/0019

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy for OPDIVO.
As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated in order to add the proposed indication, add a warning about the patient populations excluded from the clinical trial, and update the safety information. The Package Leaflet is updated in accordance.
Moreover, the updated RMP version 7.0 has been submitted"

Action: For adoption

Request for Supplementary Information adopted on 15.12.2016.

The Committee discussed the issues identified in this application, relating to the wording of the indication. Further data in patients with low PD-L1 expression was considered required to substantiate the broad indication.

The Committee adopted a 2nd request for supplementary information with a specific timetable.

5.1.9. Opdivo - nivolumab - EMEA/H/C/003985/II/0029

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include the treatment of hepatocellular carcinoma after prior sorafenib therapy in adults for OPDIVO.
As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
Moreover, the updated RMP version 8.0 has been submitted."

Action: For adoption

The Committee discussed the issues identified in this application. The Committee noted one clinical issue, highlighting the main drawbacks identified: the exploratory, non-comparative design of the single trial, the uncertainty whether the primary endpoint results represent clinical benefit, the immature OS data, the selection bias for relatively indolent tumours, and uncertainties regarding patients that could benefit to a greater/lesser extent based on subgroups. Justification of study design as well as the possibility to generate confirmatory data should also be provided by the applicant.

The Committee adopted a request for supplementary information with a specific timetable.

The CHMP adopted the assessment report on similarity.

5.1.10. Opdivo - nivolumab - EMEA/H/C/003985/II/0030

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include treatment of adults with mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) metastatic colorectal cancer after prior fluoropyrimidine based therapy for OPDIVO.
As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated in order to add the new indication and update the safety information. The Package Leaflet is updated in accordance.
RMP version 9.0 is submitted with this application"

Action: For adoption

The Committee discussed the issues identified in this application. The Committee noted the remaining issues related to efficacy and indication wording. An update and more mature study results should be provided. In the light of these results, a sound justification is required to support the claimed indication, which at present includes ⩾2lines of treatment as well as sporadic vs germline MSI forms.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.11. RoActemra - tocilizumab - EMEA/H/C/000955/II/0066

Roche Registration Limited

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Agnes Gyurasics, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of indication to include an indication in adult patients for the treatment of giant cell arteritis for the subcutaneous formulation of RoActemra. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated to reflect information relevant to this indication. The Package Leaflet is updated in accordance."

Action: For adoption

The Committee discussed the issues identified in this application, which were related to indication statement and pharmacology, efficacy and safety aspects. The MAH should propose a wording for the indication which reflects the study design and endpoints.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.12. Soliris - eculizumab - Orphan - EMEA/H/C/000791/II/0090

Alexion Europe SAS

Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia

Scope: "Extension of Indication of Soliris to include the 'treatment of Refractory generalized Myasthenia Gravis (gMG) patients who are antiacetylcholine receptor (AChR) antibody-

positive'.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated to include information on the new indication and to include the new methodology to calculate the Adverse Drug Reaction frequencies (section 4.8).
The RMP is updated accordingly (version 14.0)."

Action: For adoption

The Committee discussed the issues identified in this application. The Committee noted important doubts on the clinical relevance of the observed differences between eculizumab and placebo-treated patients, particularly since the magnitude of the differences are in the verge of those considered clinically relevant by available medical literature in the field. Further discussion is required to justify the clinical relevance of the observed effect for the broad intended target population and further data should be provided to demonstrate the maintenance of the effect over time.

The Committee discussed the need for a SAG and considered involvement of SAG relevant.

The Committee adopted a request for supplementary information with a specific timetable.

5.1.13. Zebinix - eslicarbazepine acetate - EMEA/H/C/000988/II/0053

Bial - Portela & Cª, S.A.

Rapporteur: Martina Weise, Co-Rapporteur: Ondřej Slanař, PRAC Rapporteur: Martin Huber

Scope: "Extension of indication for the tablet formulation to include the use of Zebinix as monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy, in addition to the previously authorised indication as adjunctive therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.8, and 5.1 of the SmPC have been updated. The Package Leaflet was updated in accordance. Furthermore, the product information is being brought in line with the latest QRD template version."

Action: For adoption

Request for Supplementary Information adopted on 15.12.2016, 21.07.2016.

The Committee noted that the application for extension of market exclusivity of Zebinix has been withdrawn.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

5.1.14. Zykadia - ceritinib - EMEA/H/C/003819/II/0012

Novartis Europharm Ltd

Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include new indication/population for Zykadia as first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC are updated to update the information based primarily on the supporting study, CLDK378A2301 (ASCEND-4). The Package Leaflet is updated in accordance.

An updated Risk Management Plan (Version 6) is also included in the application."

Action: For adoption

The Committee discussed the issues identified in this application. The members were reminded of the clinical data and considered seeking further clarifications on some safety and efficacy aspects, as well as the environmental risk assessment.

The Committee adopted a request for supplementary information with a specific timetable.

5.2. Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

5.2.1. Tasigna - nilotinib - Orphan - EMEA/H/C/000798/II/0084/G

Novartis Europharm Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Doris Stenver

Scope: List of experts for the SAG

Action: For adoption

Request for Supplementary Information adopted on 13.10.2016.

The CHMP adopted a list of experts for the SAG Oncology.

5.3. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

No items

6. Ancillary medicinal substances in medical devices

6.1. Ancillary medicinal substances in medical devices; Opinions/ Day 180 list of outstanding issues / Day 120 list of questions

No items

6.2. Update of Ancillary medicinal substances in medical devices

No items

7. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

7.1. Procedure under Article 83(1) of Regulation (EC) 726/2004 (Compassionate Use)

No items

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. – letermovir – Orphan - H0004536

Merck Sharp & Dohme Limited,

Indicated for prophylaxis of cytomegalovirus (CMV) infection or disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)

Scope: Briefing note and Rapporteurs' recommendation on the request for accelerated assessment

Action: For adoption

The CHMP agreed to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.1.2. – erenumab - H0004447

Prophylaxis of migraine in adults

Scope: Briefing note and Rapporteurs' recommendation on the request for accelerated assessment

Action: For adoption

The CHMP did not agree to the request for accelerated assessment and adopted the briefing note and Rapporteurs' recommendation on the Request for Accelerated Assessment.

8.2. Priority Medicines (PRIME)

Disclosure of information related to priority medicines cannot be released at present time as these contain commercially confidential information

8.2.1. List of applications received

Action: For information

Note: Products requesting eligibility under PRIME scheme are listed in the Annex G.

The CHMP noted the list of applications received.

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

The CHMP adopted the recommendation for PRIME eligibility. The CHMP reviewed 4 recommendations for eligibility to PRIME: 4 were denied. The individual outcomes are listed in PRIME Monthly Report on EMA website.

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Mozobil - plerixafor – Orphan - EMEA/H/C/001030/II/0030/G

Genzyme Europe BV

Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus,

Scope: "Submission of the final report from study ARD12858 (MOZ23510) "A pilot, exploratory, randomized, phase 2 safety study evaluating tumor cell (plasma cell) mobilization and apheresis product contamination in plerixafor plus non-pegylated G-CSF mobilized patients and in non pegylated G-CSF alone mobilized patients" listed as a category 3 study in the RMP.

Submission of the final report from study OBS13611 (MOZ18009), a multicenter, noninterventional registry designed to evaluate the long-term outcomes for patients who received plerixafor for stem cell mobilization and completed hematopoietic stem cell transplantation (HSCT) compared with patients who received other mobilization methods and completed HSCT, listed as a category 3 study in the RMP.

Submission of the final report from study OBS13612 (MOZ19310), monitoring the plerixafor off-label transplant use, in patients and donors in EBMT centers performing autologous transplants and/or allogeneic transplants, listed as a category 3 study in the RMP."

Action: For discussion

The Committee discussed the issues identified in this application related to the data provided in study OBS13611 and the different outcomes for patients with multiple myeloma compared to lymphoma patients. It was agreed to seek clarification from the MAH.

The Committee adopted a request for supplementary information with a specific timetable.

9.1.2. Fampyra - fampridine - EMEA/H/C/002097/II/0036/G

MAH: Biogen Idec Ltd

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus

Scope: "This is a grouped variation proposing updates to the SmPC sections 4.2, 4.8, 5.1, Annex II and Package Leaflet based on the clinical study ENHANCE and to the SmPC section 4.6 based on the data from the FOLLOW pregnancy registry. The RMP (version 11) has been updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0. Finally, the CHMP recommends the granting of a marketing authorisation no longer subject to specific obligations."
Action: For discussion

Request for Supplementary Information adopted on 26.01.2017.

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report and translation timetable.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

The summary of opinion was circulated for information.

See also B. 5.3 annex to minutes

9.1.3. Epclusa - sofosbuvir/velpatasvir - EMEA/H/C/004210/WS1075/0006 Harvoni - ledipasvir/sofosbuvir - EMEA/H/C/003850/WS1075/0043 Sovaldi – sofosbuvir - EMEA/H/C/002798/WS1075/0037 - WS1075

MAH: Gilead Sciences International Ltd

Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ana Sofia Diniz Martins

Scope: "Submission of the final non-clinical study report PC-334-2035 assessing the potential for a pharmacokinetic interaction via transporter or enzyme based inhibition when sofosbuvir and other Direct Acting Antivirals (DAAs) are used concomitantly with amiodarone. The RMPs

(Epclusa – RMP version 1.0, Harvoni – RMP version 2.0, Sovaldi – RMP version 5.0) have been updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 26.01.2017

See also B. 5.3 annex to minutes

The Committee confirmed that all issues previously identified in this application had been addressed.

The Committee adopted a positive opinion by consensus together with the CHMP Assessment Report.

The Icelandic and Norwegian CHMP members were in agreement with the CHMP recommendations.

9.1.4. Hemoprostol - misoprostol - Article 58 - EMEA/H/W/002652

Linepharma International Limited; treatment and prevention of Post Partum Haemorrhage

Rapporteur: Paula Boudewina van Hennik, Co-Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Alexandre Moreau

Scope: Intention to withdraw Article 58 scientific opinion

Action: For information

Article 58 of Regulation (EC) No 726/2004

The medicinal product Hemoprostol (200 µg, tablet) was exclusively intended for markets outside the European Union.

The CHMP noted the request for withdrawal.

9.1.5. Unituxin - dinutuximab - Orphan - EMEA/H/C/002800

United Therapeutics Europe Ltd

Rapporteurs: Robert James Hemmings, Co-Rapporteur: Alexandre Moreau

Scope: Withdrawal of marketing authorisation

Action: For information

The CHMP noted the withdrawal of the marketing authorisation.

10. Referral procedures

10.1. Procedure for Centrally Authorised products under Article 20 Council Regulation (EC) No 726/2004

No items

10.2. Requests for CHMP Opinion under Article 5(3) of Regulation (EC) No 726/2004

No items

10.3. Procedure under Articles 5(2) and 10 of the Regulation (EC) No 726/2004

No items

10.4. Disagreement between Member States on application for medicinal product (potential serious risk to public health) –under Article 29(4) of Directive 2001/83/EC

No items

10.5. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

No items

10.6. Community Interests - Referral under Article 31 of Directive 2001/83/EC

10.6.1. Micro Therapeutics Research Labs, India - EMEA/H/A-31/1450

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Milena Stain

Scope: Opinion

Action: For adoption

Reliability of the data of bioequivalence studies.

The CHMP adopted an opinion by consensus recommending the suspension of the national marketing authorisations of medicinal products without established bioequivalence. In Member States where the medicinal product is considered critical, the suspension can be deferred up to 24 months. The suspensions can be lifted once alternative data establishing bioequivalence are provided.

For some medicinal products the CHMP concluded that bioequivalence has been demonstrated vis-à-vis the EU reference medicinal product and recommended the maintenance of these marketing authorisations.

The CHMP also recommended that medicines not yet authorised but which are being evaluated on the basis of bioequivalence studies from these sites should not be authorised until bioequivalence is demonstrated using alternative data.

The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.

The CHMP noted the public health communication.

10.6.2. Symbioflor 2, Escherichia Coli bacteria (cells and autolysate) - EMEA/H/A-31/1441

Symbiopharm GmbH,

Rapporteur: Harald Enzmann, Co-rapporteur: Milena Stain

Scope: Opinion

Article 31 triggered by the BfArM in Germany in March 2016 requesting the review of the benefit-risk balance for Symbioflor 2 and associated names following concerns that the effectiveness of the medicine(s) has not been adequately demonstrated.

Action: For adoption

The CHMP adopted a list of outstanding issues with a specific timetable.

Second CHMP list of outstanding issues: March 2017 CHMP

Submission of responses: 11.05.2017

Re-start of the procedure: 25.05.2017

Rapporteur/co-rapporteur joint assessment report circulated to CHMP: 07.06.2017

Comments: 12.06.2017

Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP: 15.06.2017

CHMP opinion: June 2017 CHMP

10.7. Re-examination Procedure under Article 32(4) of Directive 2001/83/EC

No items

10.8. Procedure under Article 107(2) of Directive 2001/83/EC

No items

10.9. Disagreement between Member States on Type II variation– Arbitration procedure initiated by MAH under Article 6(13) (EC) No 1084/2003

No items

10.10. Procedure under Article 29 Regulation (EC) 1901/2006

No items

10.11. Referral under Article 13 Disagreement between Member States on Type II variation– Arbitration procedure initiated by Member State under Article 13 (EC) No 1234/2008)

10.11.1. Cardioxane - Dexrazoxane - EMEA/H/A-13/1453

Clinigen Group

Rapporteur: Alexandre Moreau, Co-Rapporteur: Greg Markey

RMS: FR, CMS: CZ, DE, ES, IT, NL, PL & UK

Decentralised Procedure numbers: FR/H/283/01/II/27G

Scope: List of Questions/Opinion

Article 13 triggered by the ANSM in France in January 2017 requesting the CHMP's opinion whether the proposed lifting of the contraindication for a subset of anthracycline treated children is justified.

Action: For adoption

The CHMP discussed the need to collect further safety data from the patient populations discussed. A PASS as well as the use of targeted follow up questionnaires, scheduled annual PSURs and the use of existing registries were considered.

The CHMP adopted a list of questions with a specific timetable.

List of Questions: 23.03.2017

Submission of responses: 06.04.2017

Re-start of the procedure: 20.04.2017

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 03.05.2017

Comments: 08.05.2017

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 11.05.2017

CHMP opinion: May 2017 CHMP

11. Pharmacovigilance issue

11.1. Early Notification System

March 2017 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public.

Action: For information

The CHMP noted the ENS.

12. Inspections

12.1. GMP inspections

Disclosure of information related to GMP inspections will not be published as it undermines the purpose of such inspections

12.2. GCP inspections

Disclosure of information related to GCP inspections will not be published as it undermines the purpose of such inspections

12.3. Pharmacovigilance inspections

Disclosure of information related to Pharmacovigilance inspections will not be published as it undermines the purpose of such inspections

12.4. GLP inspections

Disclosure of information related to GLP inspections will not be published as it undermines the purpose of such inspections

13. Innovation Task Force

13.1. Minutes of Innovation Task Force

Action: For information

The CHMP noted the minutes.

13.2. Innovation Task Force briefing meetings

Disclosure of information related to briefing meetings taking place with applicants cannot be released at present time as deemed to contain commercially confidential information

13.2.1. Briefing meeting

Meeting date: 22 March 2017

Action: For information

The CHMP noted the briefing meeting

13.3. Requests for CHMP Opinion under Article 57(1)J and (1)P of Regulation (EC) No 726/2004

No items

13.4. Nanomedicines activities

No items

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Review of experience with the revised RMP assessment process for new marketing authorisations

Action: For information

A revised RMP review process was implemented for MAAs starting in May 2015 based on Management Board agreed principles for a collaborative approach PRAC/CHMP. More than 80 MAAs were included in the review allowing for reasonable data set, data was more robust for phases 1 and 2. Assessment teams from CHMP and PRAC performed their dedicated review tasks across all three phases in almost all cases (not more than 5% outliers). The correct templates were used in most cases (87-95% across the three phases). PRAC plenary discussions occurred where necessary for applications (the 9% of exceptional discussions are justified). On average the assessment reports were circulated on time in accordance with the timetable (mean delta between -1.59 days and +1.33 days). Overall the results were encouraging and the data suggest that the recently established process is workable. Concrete proposals have been made by some PRAC members for continuous improvement and these should be reviewed by the sponsor group. As next steps workshops and a survey were proposed. The Committee agreed to the workshop, however the survey was considered more suitable if it is broader.

The CHMP noted the information.

14.1.2. ATMP guideline on safety and efficacy follow-up and risk management (EMA/CHMP/65416/2016)

Scope: Comments received by CAT and PRAC before the consultation of GCG

Action: For information

The CHMP noted the update on guideline. The guideline will be sent to GCG.

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice from PRAC meeting held on 6-9 March 2017

Action: For information

The CHMP noted the report and Summary of recommendations and advice from PRAC.

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for March 2017

Action: For adoption

The CHMP noted the list.

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 15-17 March 2017
Action: For information

The CHMP noted the minutes.

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting

Action: For information

The CHMP noted the report.

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at March 2017 PDCO

Action: For information

The CHMP noted the information.

Report from the PDCO meeting held on 21-24 March 2017

Action: For information

The CHMP noted the report.

Joint CHMP/PDCO session

Agenda for joint session

Action: For information

The CHMP/PDCO Joint session took place on Wednesday 22 March from 8:30 – 9:30 in room 3A

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 14-15 March 2017
Action: For information

The CHMP noted the report.

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

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 20-22 March 2017

Action: For information

The CHMP noted the report.

14.3. Coordination with EMA Working Parties / Working Groups / Drafting Groups

14.3.1. Scientific Advice Working Party (SAWP)

Report from the SAWP meeting held on 6-9 March 2017. Table of conclusions

Action: For information

Scientific advice letters: See Annex GDisclosure of information related to scientific advice letters cannot be released at present time as these contain commercially confidential information.

The CHMP noted the report.

14.3.2. Scientific Advice Working Party (SAWP)

Appointment of a replacement SAWP member and alternate following resignation of Thomas Lang. The required area of expertise is statistics.

Action: For adoption

The CHMP appointed Christian Gartner (AT) and Stefan Lehr (AT) as new member and alternate to the SAWP.

14.3.3. Blood Products Working Party (BPWP)

Vice-Chair: Karri Penttilä,

Scope: Election of a new Chairperson of the Blood Products Working Party (BPWP).

Action: For adoption

The CHMP elected Jacqueline Kerr from Paul-Ehrlich-Institut (Germany) as new chair to the BPWP.

Nomination of new observer Marie Louise Schougaard Christiansen (DK) to the BPWP

Action: For adoption

CHMP nominated Marie Louise Schougaard Christiansen (DK) as new observer to the BPWP.

14.3.4. Ad-hoc Influenza Working Group

Scope: EU Strain selection for the Influenza Vaccines for the Season 2017/2018

Action: For adoption

The CHMP adopted the EU Strain selection report.

Scope: EU Recommendation for the Seasonal Influenza Vaccine Composition for the Season 2017/2018

Action: For adoption

Report from the Ad Hoc Influenza working group to the BWP

The CHMP adopted the EU recommendation.

14.3.5. CHMP ad-hoc drafting group

Scope: Revision of the Guideline on clinical development of fixed combination medicinal products

Action: For adoption

The guideline provides guidance on the clinical development strategy for a fixed combination medicinal product irrespective of the chosen legal basis for the marketing authorisation application. The guidance applies primarily to small molecules irrespective of route of administration and dosage form (immediate versus modified release), but the general principles also apply to biological products. The scientific principles are also applicable to a substance designed to dissociate in vivo into two or more active substances that form its principal therapeutic moieties. The guideline does not apply to a single molecule active substance that affects multiple pharmacological targets (i.e. has affinity to multiple receptors involved in the desired therapeutic outcome).

The guideline primarily discusses the development of fixed combination medicinal products with two active substances. However, it is expected that the same principles would generally apply to fixed combination medicinal products containing three or more active substances.

The guideline does not address the requirements for combination packs, i.e. where active substances are included in separate pharmaceutical forms marketed in the same package.

The clinical development of herbal fixed combinations as well as those composed of vitamins, oligo-elements and minerals are also outside of the scope of this guideline.

The CHMP adopted the guideline. The guideline will come into effect from 1st October 2017 onwards.

14.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Scope: Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development

Action: For adoption for 6-months public consultation

The reflection paper identifies three areas of interest from the regulatory perspective, where the comparative evaluation of drug product's quality characteristics plays an important role, either during drug development, during drug lifecycle, or during decision-making processes potentially leading to marketing authorisation. The document focusses on methodological aspects in relation to statistical data-comparison approaches for the settings of: pre- and post-manufacturing change, biosimilar developments as well as generics' development. For all these settings defined, the reflection paper raises open issues from a statistical perspective addressing questions related to comparison objectives, sampling strategies, sources of variability, options for statistical inference and acceptance ranges.

This document is targeted to both, experts from industry and regulatory assessors. The paper tries to connect to other available regulatory guidance where the issue of comparative data assessment concerning quality attributes is discussed for certain contexts, but where more detailed guidance of how to actually carry out the comparison task (based on empirical sample data) is lacking.

From the methodological perspective, the reflection paper is supposed to establish a common language and to improve understanding among all experts concerned with quality characteristics' data comparison. It is also supposed to trigger further discussion of realistic requirements to demonstrate 'similarity on the quality level' in the different contexts mentioned above. The paper however also discusses likely limitations hampering statistical inference, pointing towards meaningful – but expectedly less stringent – alternatives.

The CHMP discussed the disclaimer positioned on the cover page of the RP emphasising the aim to trigger further discussions and the proposal to extend the public consultation period. The CHMP agreed to have longer public consultation period.

The CHMP adopted the reflection paper for 12 months public consultation.

14.3.7. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Scope: Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied locally acting in the gastrointestinal tract as addendum to the guideline on the clinical requirements for locally applied, locally acting products containing known constituents (CPMP/EWP/239/95 Rev. 1)

Action: For adoption for 6 months public consultation

The CHMP adopted the guideline for 6 months public consultation. The guideline focuses on the choice of in vitro equivalence tests and PK bioequivalence studies as suitable models for the demonstration of therapeutic equivalence for locally applied, locally acting GI products with immediate or modified release containing the same chemical entity. The choice has to be fully justified.

The design of PD studies and therapeutic equivalence clinical trials depends on the respective therapeutic field. The corresponding guidelines should be taken into consideration and these types of studies and trials are outside of the scope of this guideline.

The scope is limited to chemical entities. Recommendations for biologicals can be found in guidelines on similar biological medicinal products.

14.3.8. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl,

Draft agenda for the F2F meeting on 27-28 March 2017 (Doc. Ref. EMA/75533/2017)

Action: For information

The CHMP noted the draft agenda.

Nomination of new expert Wilko Weichert (DE) to the PGWP

Action: For adoption

The CHMP nominated Wilko Weichert (DE) as expert to the PGWP.

14.3.9. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

Nomination of new observer Doris J. Hovgaard (DK) to the ONCWP

Action: For adoption

The CHMP nominated Doris J. Hovgaard (DK) as new observer to the ONCWP.

14.3.10. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Call for nomination of CVSWP core member following resignation of Karsten Bruins Slot

Nominations should be sent by 29th March 2017.

Action: For information

The CHMP noted the information.

14.3.11. Biologics Working Party (BWP)

Chair: Sol Ruiz,

Call for nomination of BWP Vice-Chair, the term current Vice Chair ending in April 2017.

Nominations should be sent by 6 April 2017.

Action: For information

The CHMP noted the information.

14.3.12. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich,

Nomination of new observer Eskild Colding-Jørgensen (DK) to the CNSWP

Action: For adoption

The CHMP nominated Eskild Colding-Jørgensen (DK) as new observer to the CNS WP.

14.4. Cooperation within the EU regulatory network

14.4.1. Joint EMA-European Commission Information guide for Healthcare professionals on biosimilars

Action: For information

The CHMP discussed the joint EMA-EC Information guide.

14.4.2. Revision of the Commission Regulation (EC) No 847/2000 of April 2000 laying down the provisions for implementation of the Criteria for designation of a medicinal product as an orphan medicinal product and definitions of the Concept 'similar medicinal product and 'clinical superiority'

Action: For information

The CHMP noted the revision of the Commission Regulation (EC) No 847/2000.

14.5. Cooperation with International Regulators

No items

14.6. Contacts of the CHMP with external parties and interaction with the Interested Parties to the Committee

No items

14.7. CHMP work plan

No items

14.8. Planning and reporting

No items

14.9. Others

No items

15. Any other business

15.1. AOB topic

15.1.1. Preparedness of the system and capacity increase

Action: For discussion

The CHMP noted the update.

15.1.2. Revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products'

CHMP Rapporteur: Harald Enzmann

Scope: update on the revision, workshop to be held 28 March 2017 (draft programme)

Action: For information

Between July and end of September 2016, EMA released for public consultation a concept paper which outlined the major areas for revision. Subsequently, a draft revised guideline was published for public consultation on 22 November 2016. The period of consultation for this ended 28 February 2017.

This workshop is one step in finalising the guidance with further involvement of stakeholders, including from other regulatory agencies, pharmaceutical industry, contract research organisations (CROs) and academia. The focus of the workshop will be on discussing comments received during the public consultations.

The day will begin with presentations on the key issues identified from the comments received. These key issues will be discussed further in breakout sessions. Options on how to take forward the issues will be consolidated from these sessions. Orientation will be sought on which options are preferred in a subsequent plenary discussion. The speakers and the moderators of the breakout sessions are members of the drafting group and will be responsible for the finalisation of the guideline.

The output of the workshop will be taken into account for the final guideline and also in the overviews of comments that will be published.

The CHMP noted update on the revision of guideline and draft agenda for the workshop.

16. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 20 – 23 March 2017 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Tomas Salmonson	Chair	Sweden	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Milena Stain	Alternate	Austria	No interests declared	
Bart Van der Schueren	Member	Belgium	No interests declared	
Mila Vlaskovska	Member	Bulgaria	No interests declared	
Katarina Vučić	Member	Croatia	No interests declared	
Panayiotis Triantafyllis	Alternate	Cyprus	No interests declared	
Radka Montoniová	Alternate	Czech Republic	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Hanne Lomholt Larsen	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Tuomo Lapveteläinen	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	No interests declared	
Joseph Emmerich	Alternate	France	No interests declared	
Harald Enzmann	Member (Vice-Chair)	Germany	No interests declared	
Martina Weise	Alternate	Germany	No restrictions applicable to this meeting	
Eleftheria Nikolaidi	Member	Greece	No interests declared	
Maria-Dimokleia Ziotopoulou	Alternate	Greece	No interests declared	
Agnes Gyurasics	Member	Hungary	No interests declared	
Hrefna Gudmundsdottir	Alternate	Iceland	No interests declared	
David Lyons	Member	Ireland	No restrictions applicable to this meeting	
Patrick Salmon	Alternate	Ireland	No interests declared	
Daniela Melchiorri	Member	Italy	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Juris Pokrotnieks	Member	Latvia	No restrictions applicable to this meeting	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on:	3.2.5. - ocrelizumab - EMEA/H/C/004043 5.1.11. - tocilizumab - EMEA/H/C/000955 /II/0066
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Svein Rune Andersen	Member	Norway	No interests declared	
Bjorg Bolstad	Alternate	Norway	No restrictions applicable to this meeting	
Piotr Fiedor	Member	Poland	No interests declared	
Aldona Paluchowska	Alternate	Poland	No interests declared	
Bruno Sepodes	Member	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on:	3.4.7. - d-biotin EMEA/H/C/004153
Nela Vilceanu	Member	Romania	No interests declared	
Eva Malikova	Alternate	Slovakia	No interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Concepcion Prieto Yerro	Member	Spain	No interests declared	
Arantxa Sancho-Lopez	Alternate	Spain	No restrictions applicable to this meeting	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Greg Markey	Member	United Kingdom	No interests declared	
Nithyanandan Nagercoil	Alternate	United Kingdom	No restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Robert James Hemmings	Co-opted member	United Kingdom	No restrictions applicable to this meeting	
Koenraad Norga	Co-opted member	Belgium	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Jean-Louis Robert	Co-opted member	Luxembourg	No interests declared	
Sol Ruiz	Co-opted member	Spain	No interests declared	
Sabine Mayrhofer	Expert - via telephone*	Germany	No interests declared	
Jorge Camarero Jiménez	Expert - in person*	Spain	No restrictions applicable to this meeting	
Patricia Diaz Ramos	Expert - in person*	Spain	No interests declared	
Agustin Portela Moreira	Expert - in person*	Spain	No interests declared	
Nele Berthels	Expert - in person*	Belgium	No interests declared	
Theis Moeslund Jensen	Expert - in person*	Denmark	No restrictions applicable to this meeting	
Valerie Lescrainier	Expert - in person*	Belgium	No interests declared	
Barbara Spruce	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Vincent Gazin	Expert - in person*	France	No interests declared	
Ghania Kerouani-Lafaye	Expert - in person*	France	No interests declared	
Marie-Christine Bielsky	Expert - in person*	UK	No restrictions applicable to this meeting	
Andrew Exley	Expert - in person*	UK	No restrictions applicable to this meeting	
Anabel Cortés Blanco	Expert - via	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	telephone*			
Barbara van Zwieten-Boot	Expert - via telephone*	Netherlands	No interests declared	
Thomas Lang	Expert - via telephone*	Austria	No interests declared	
Alan Fauconnier	Expert - via telephone*	Belgium	No interests declared	
Mario Miguel Rosa	Expert - via telephone*	Portugal	No interests declared	
Johannes Pohly	Expert - via telephone*	Germany	No interests declared	
Natalja Karpova	Member - via telephone*	Latvia	No interests declared	
Cecilia Chisholm	Expert - via telephone*	UK	No interests declared	
Peter Mol	Expert - via telephone*	Netherlands	No interests declared	
Alfredo Garcia Arieta	Expert - via telephone*	Spain	No interests declared	
Peter Kiely	Expert - via telephone*	Ireland	No interests declared	
Anja Schiel	Expert - via Adobe	Norway	No interests declared	
Miki Hew	Expert – via Adobe	Netherlands	No restrictions applicable to this meeting	
Bertil Jonsson	Expert - via Adobe	Sweden	No interests declared	
Sigrid Klaar	Expert - via Adobe	Sweden	No restrictions applicable to this meeting	
Elena Wolff-Holz	Expert - via Adobe	Germany	No interests declared	
Leon van Aerts	Expert - via Adobe	Netherlands	No interests declared	
Representative from the European Commission attended the meeting				

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.

17. Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CHMP agenda and should be read in conjunction with the agenda or the minutes.

Oral explanations *(section 2)*

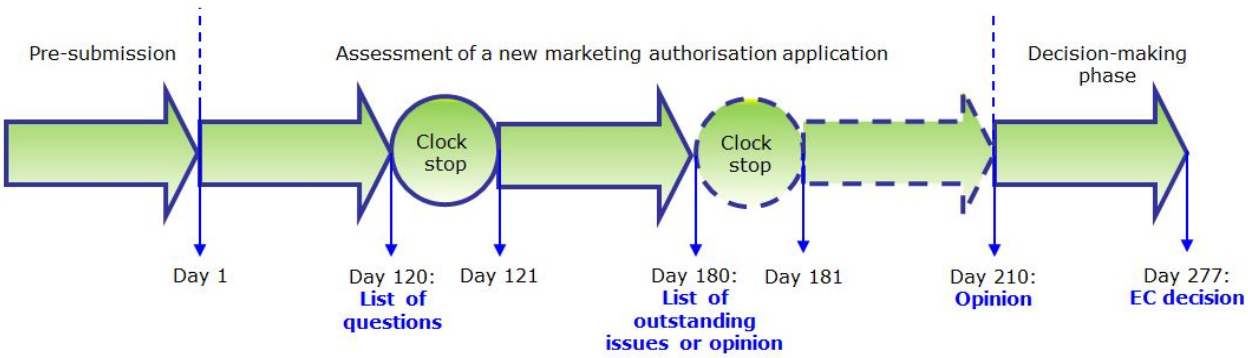
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (section 10) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

Initial applications *(section 3)*

This section lists applications for marketing authorisations of new medicines that are to be discussed by the Committee.

Section 3.1 is for medicinal products nearing the end of the evaluation and for which the CHMP is expected to adopt an **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CHMP. The clock stop happens after day 120 and may also happen after day 180, when the CHMP has adopted a list of questions or outstanding issues to be addressed by the company. Related discussions are listed in the agenda under sections 3.2 (**Day 180 List of outstanding issues**) and 3.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 3.4, **update on ongoing new applications for centralised procedures**.

The assessment leads to an opinion from the CHMP by day 210. Following a CHMP opinion the European Commission takes usually 67 days to issue a legally binding decision (i.e. by day 277 of the procedure). CHMP discussions on products that have received a CHMP opinion and are awaiting a decision are listed under section 3.6, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 4)*

Extensions of marketing authorisations are applications for the change or addition of new strengths,

formulations or routes of administration to existing marketing authorisations. Extension applications follow a 210-day evaluation process, similarly to applications for new medicines (see figure above).

Type II variations - Extension of indication procedures *(section 5)*

Type II variations are applications for a change to the marketing authorisation which requires an update of the product information and which is not covered in section 4. Type II variations include applications for a new use of the medicine (extension of indication), for which the assessment takes up to 90 days. For the applications listed in this section, the CHMP may adopt an opinion or request supplementary information from the applicant.

Ancillary medicinal substances in medical devices *(section 6)*

Although the EMA does not regulate medical devices it can be asked by the relevant authorities (the so-called Notified Bodies) that are responsible for regulating these devices to give a scientific opinion on a medicinal substance contained in a medical device.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 *(section 3.5)*

This section lists applications for new marketing authorisation for which the applicant has requested a re-examination of the opinion previously issued by the CHMP.

Re-examination procedures *(section5.3)*

This section lists applications for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP.

Withdrawal of application *(section 3.7)*

Applicants may decide to withdraw applications at any stage during the assessment and a CHMP opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Procedure under article 83(1) of regulation (EC) 726/2004 (compassionate use) *(section 7)*

Compassionate use is a way of making available to patients with an unmet medical need a promising medicine which has not yet been authorised (licensed) for their condition. Upon request, the CHMP provides recommendations to all EU Member States on how to administer, distribute and use certain medicines for compassionate use.

Pre-submission issues *(section 8)*

In some cases the CHMP may discuss a medicine before a formal application for marketing authorisation is submitted. These cases generally refer to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation. In case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

Post-authorisation issues *(section 9)*

This section lists other issues concerning authorised medicines that are not covered elsewhere in the agenda. Issues include supply shortages, quality defects, some annual reassessments or renewals or type II variations to marketing authorisations that would require specific discussion at the plenary.

Referral procedures *(section 10)*

This section lists referrals that are ongoing or due to be started at the plenary meeting. A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a

particular medicine or class of medicines on behalf of the EU. Further information on such procedures can be found here.

Pharmacovigilance issues *(section 11)*

This section lists issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines. Feedback is provided by the PRAC. This section also refers to the early notification system, a system used to notify the European regulatory network on proposed EMA communication on safety of medicines.

Inspections Issues *(section 12)*

This section lists inspections that are undertaken for some medicinal products. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Innovation task force *(section 13)*

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes from the last ITF meeting as well as any related issue that requires discussion with the CHMP are listed in this section of the agenda. Further information on the ITF can be found here.

Scientific advice working party (SAWP) *(section 14.3.1)*

This section refers to the monthly report from the CHMP's Scientific Advice Working Party (SAWP) on scientific advice given to companies during the development of medicines. Further general information on SAWP can be found here.

Satellite groups / other committees *(section 14.2)*

This section refers to the reports from groups and committees making decisions relating to human medicines: the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), the Committee for Orphan Medicinal Products (COMP), the Committee for Herbal Medicinal Products (HMPC), Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmamacovigilance Risk Assessment Committee (PRAC).

Invented name issues *(section 14.3)*

This section list issues related to invented names proposed by applicants for new medicines. The CHMP has established the Name Review Group (NRG) to perform reviews of the invented names. The group's main role is to consider whether the proposed names could create a public-health concern or potential safety risk. Further information can be found here.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 April 2017
EMA/254613/2017

Annex to March 2017 CHMP Minutes

Pre submission and post authorisations issues

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Send a question via our website www.ema.europa.eu/contact

A. PRE SUBMISSION ISSUES

A.1. ELIGIBILITY REQUESTS

Report on Eligibility to Centralised Procedure for March 2017: **For adoption**	Adopted.

A.2. Appointment of Rapporteur / Co-Rapporteur Full Applications

Final Outcome of Rapporteurship allocation for March 2017: **For adoption**	Adopted.

A.3. PRE-SUBMISSION ISSUES FOR INFORMATION

Disclosure of information related to pre-submission of initial applications cannot be released at present time as these contain commercially confidential information.

B. POST-AUTHORISATION PROCEDURES OUTCOMES

B.1. Annual re-assessment outcomes

B.1.1. Annual reassessment for products authorised under exceptional circumstances

Ceplene - histamine dihydrochloride - EMEA/H/C/000796/S/0030, Orphan MAH: Meda AB, Rapporteur: David Lyons, PRAC Rapporteur: Almath Spooner	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP opinion.
Kolbam - cholic acid - EMEA/H/C/002081/S/0020, Orphan MAH: Retrophin Europe Ltd, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Patrick Batty Request for Supplementary Information adopted on 23.03.2017.	Request for Supplementary Information adopted
Lojuxta - lomitapide - EMEA/H/C/002578/S/0023 MAH: Aegerion Pharmaceuticals Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst Request for Supplementary Information adopted on 23.02.2017, 10.11.2016.	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP opinion
Raxone - idebenone -	2nd Request for Supplementary Information

EMEA/H/C/003834/S/0005, Orphan MAH: Santhera Pharmaceuticals (Deutschland) GmbH, Rapporteur: John Joseph Borg, PRAC Rapporteur: Carmela Macchiarulo Request for Supplementary Information adopted on 23.03.2017, 26.01.2017.	adopted
Vedrop - tocofersolan - EMEA/H/C/000920/S/0019 MAH: Orphan Europe S.A.R.L., Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams Request for Supplementary Information adopted on 26.01.2017.	The Committee confirmed that all issues previously identified in this application had been addressed. The Committee adopted a positive opinion recommending the granting of a marketing authorisation by consensus, together with the CHMP assessment report. The Icelandic and Norwegian Members were in agreement with the CHMP recommendation.
Vyndaqel - tafamidis - EMEA/H/C/002294/S/0036, Orphan MAH: Pfizer Limited, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Caroline Laborde	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP opinion.
Xagrid - anagrelide - EMEA/H/C/000480/S/0077 MAH: Shire Pharmaceutical Contracts Ltd., Rapporteur: Alexandre Moreau, Co-Rapporteur: Koenraad Norga, PRAC Rapporteur: Caroline Laborde	Positive Opinion adopted by consensus together with the CHMP assessment report. The Marketing Authorisation remains under exceptional circumstances. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP opinion.

B.2. RENEWALS OF MARKETING AUTHORISATIONS OUTCOMES

B.2.1. Renewals of Marketing Authorisations requiring 2nd Renewal

Rasilez - aliskiren - EMEA/H/C/000780/R/0112 MAH: Novartis Europharm Ltd, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Carmela Macchiarulo Request for Supplementary Information adopted on 23.02.2017.	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information the CHMP was of the opinion that an additional five-year renewal was required. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.2.2. Renewals of Marketing Authorisations for unlimited validity

Cuprymina - copper (64Cu) chloride - EMEA/H/C/002136/R/0014	Request for Supplementary Information adopted

MAH: Sparkle S.r.l., Rapporteur: Greg Markey, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Patrick Batty Request for Supplementary Information adopted on 23.03.2017.	
Dacogen - decitabine - EMEA/H/C/002221/R/0030, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Alexandre Moreau, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Caroline Laborde	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Enurev Breezhaler - glycopyrronium bromide - EMEA/H/C/002691/R/0020 MAH: Novartis Europharm Ltd, Duplicate, Duplicate of Seebri Breezhaler, Rapporteur: Hanne Lomholt Larsen, Co-Rapporteur: David Lyons, PRAC Rapporteur: Torbjorn Callreus Request for Supplementary Information adopted on 23.03.2017.	Request for Supplementary Information adopted
Inlyta - axitinib - EMEA/H/C/002406/R/0021 MAH: Pfizer Limited, Rapporteur: Bjorg Bolstad, Co-Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Helga Haugom Olsen	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
NovoThirteen - catridecacog - EMEA/H/C/002284/R/0020 MAH: Novo Nordisk A/S, Rapporteur: Joseph Emmerich, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Caroline Laborde	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Revestive - teduglutide - EMEA/H/C/002345/R/0038, Orphan MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac, Co-Rapporteur: Harald Enzmann, PRAC Rapporteur: Torbjorn Callreus	Request for Supplementary Information adopted

Request for Supplementary Information adopted on 23.03.2017.	
Seebri Breezhaler - glycopyrronium - EMEA/H/C/002430/R/0020 MAH: Novartis Europharm Ltd, Rapporteur: Hanne Lomholt Larsen, Co-Rapporteur: David Lyons, PRAC Rapporteur: Torbjorn Callreus Request for Supplementary Information adopted on 23.03.2017.	Request for Supplementary Information adopted
Torisel - temsirolimus - EMEA/H/C/000799/R/0065, Orphan MAH: Pfizer Limited, Rapporteur: Harald Enzmann, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Martin Huber Request for Supplementary Information adopted on 23.03.2017.	Request for Supplementary Information adopted
Tovanor Breezhaler - glycopyrronium - EMEA/H/C/002690/R/0022 MAH: Novartis Europharm Ltd, Duplicate, Duplicate of Seebri Breezhaler, Rapporteur: Hanne Lomholt Larsen, Co-Rapporteur: David Lyons, PRAC Rapporteur: Torbjorn Callreus Request for Supplementary Information adopted on 23.03.2017.	Request for Supplementary Information adopted
Zoledronic acid Mylan - zoledronic acid - EMEA/H/C/002482/R/0013 MAH: Mylan S.A.S, Generic, Generic of Zometa, Rapporteur: Milena Stain, PRAC Rapporteur: Doris Stenver	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Zoledronic acid Teva - zoledronic acid - EMEA/H/C/002439/R/0018 MAH: Teva B.V., Generic, Generic of Zometa, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
Zoledronic acid Teva Pharma - zoledronic acid - EMEA/H/C/002437/R/0014 MAH: Teva B.V., Generic, Generic of Aclasta, Rapporteur: Filip Josephson, PRAC Rapporteur: Doris Stenver	Positive Opinion adopted by consensus together with the CHMP assessment report. Based on the review of the available information, the CHMP was of the opinion that the renewal of the marketing authorisation can

	be granted with unlimited validity. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.2.3. Renewals of Conditional Marketing Authorisations

Fampyra - fampridine - EMEA/H/C/002097/R/0037 MAH: Biogen Idec Ltd, Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Martina Weise, PRAC Rapporteur: Sabine Straus	Positive Opinion adopted by consensus together with the CHMP assessment. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.

B.3. POST-AUTHORISATION PHARMACOVIGILANCE OUTCOMES

Signal detection PRAC recommendations on signals adopted at the PRAC meeting held on 6-9 March 2017 PRAC:	
Signal of transplant rejection Keytruda-pembrolizumab- EMEA/H/C/003820 Merck Sharp & Dohme Limited, Rapporteur: Daniela Melchiorri, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus, PM: Daniel Gustafsson, EPL: Silvy Da Rocha Dias **OPDIVO - nivolumab - EMEA/H/C/003985** Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aranzazu Sancho-Lopez, Co-Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski, PM: Caroline Blanc, EPL: Silvy Da Rocha Dias	Adopted.
PSUR procedures for which PRAC adopted a recommendation for variation of the terms of the MA at its March 2017 meeting:	
EMEA/H/C/PSUSA/00000464/201607 (busulfan) CAPS: **Busilvex** (EMEA/H/C/000472) (busulfan), MAH: Pierre Fabre Medicament, Rapporteur: Aranzazu Sancho-Lopez	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends

NAPS:
Busulfan 2mg tablets PL 39699/0042 UK - ASPEN PHARMA TRADING LIMITED
BUSULFANO ASPEN 2 mg comprimidos recubiertos 33.323 ES - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg Compresse rivestite con film 024787018 IT - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg comprimés pelliculés 26/05/09/8259 LU - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg comprimés pelliculés BE 058615 BE - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg film-coated tablets PA 1691/008/001 IE - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg filmdragerade tabletter 5013 SE - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg filmom obalené tablety 44/0239/89-C/S SK - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg filmomhulde tabletten 260/05/09/8259 LU - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg filmomhulde tabletten BE 058615 BE - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg filmomhulde tabletten RVG 00262 NL - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg Filmtabletten 6101936.00.00 DE - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg filmuhúðaðar töflur 772142 IS - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg plėvele dengtos tabletės LT/1/94/2445/001 LT - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg, comprimé pelliculé 369 231-7 FR - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg, potahované tablety 44/239/89-C CZ - ASPEN PHARMA TRADING LIMITED
Myleran 2 mg, tabletki powlekane R/2779 PL - ASPEN PHARMA TRADING LIMITED
MYLERAN 2 mg-Filmtabletten 10.775 AT - ASPEN PHARMA TRADING LIMITED
MYLERAN, 2 mg õhukese polümeerikattega tabletid 101095 EE - ASPEN PHARMA TRADING LIMITED
Myleran, comprimate filmate, 2 mg

by consensus the variation to the terms of the marketing authorisations for the medicinal products containing the above referred active substance, concerning the following change(s):

Update of sections 4.4 and 4.5 of the SmPC to include the interaction with metronidazole and update of section 4.8 of the SmPC to add the adverse reaction 'Tooth hypoplasia'. Sections 2 and 4 of the Package leaflet are updated accordingly.

In addition, for the I.V. formulation only, update of section 4.4 of the SmPC to include a warning of thrombotic microangiopathy after hematopoietic cell transplantation. Section 2 of the Package leaflet is updated accordingly.

The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

546/2008/01 RO - ASPEN PHARMA TRADING LIMITED **Myleran, comprimate filmate, 2 mg** **546/2008/02 RO** - ASPEN PHARMA TRADING LIMITED **MYLERAN® 2 mg comprimidos 8144212 PT** - ASPEN PHARMA TRADING LIMITED **MILEPAN 2 mg filmirani tabletki 20000508 BG** - ASPEN PHARMA TRADING LIMITED , PRAC Rapporteur: Eva A. Segovia, "9 July 2013 to 8 July 2016: Update of sections 4.4 and 4.5 of the SmPC to include the interaction with metronidazole and update of section 4.8 of the SmPC to add the adverse reaction 'Tooth hypoplasia'. Sections 2 and 4 of the Package leaflet are updated accordingly. In addition, for the I.V. formulation only, update of section 4.4 of the SmPC to include a warning of thrombotic microangiopathy after hematopoietic cell transplantation. Section 2 of the Package leaflet is updated accordingly."	
EMEA/H/C/PSUSA/00000940/201608 (deferiprone) CAPS: **Ferriprox** (EMEA/H/C/000236) (deferiprone), MAH: Apotex Europe BV, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Caroline Laborde, "01/09/2015 - 31/08/2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended recommends by consensus, the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.4 and 4.8 of the SmPC to add a statement on the risk of neurological disorders which can occur in children. Section 4 of the Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00000962/201607 (desloratadine) CAPS: **Aerius** (EMEA/H/C/000313) (desloratadine), MAH: Merck Sharp & Dohme Limited, Rapporteur: Koenraad Norga **Azomyr** (EMEA/H/C/000310) (desloratadine), MAH: Merck Sharp & Dohme Limited, Rapporteur: Koenraad Norga **Dasselta** (EMEA/H/C/002310) (desloratadine), MAH: KRKA, d.d., Novo mesto, Rapporteur: Melinda Sobor **Desloratadine Actavis** (EMEA/H/C/002435) (desloratadine), MAH: Actavis Group PTC ehf, Rapporteur: Melinda Sobor **Desloratadine ratiopharm** (EMEA/H/C/002404) (desloratadine), MAH:	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 and Article 107g(3) of Directive 2001/83/EC the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the medicinal products containing the above referred active substance(s), concerning the following change(s): Update of section 4.8 of the SmPC and section 4 of the Package Leaflet: - to add the adverse reaction "abnormal behaviour" and "aggression" with a frequency unknown - to add the adverse reaction "QT prolongation" with a frequency unknown

ratiopharm GmbH, Rapporteur: Koenraad Norga
Desloratadine Teva (EMEA/H/C/002419) (desloratadine), MAH: Teva B.V., Rapporteur: Melinda Sobor
Neoclarityn (EMEA/H/C/000314) (desloratadine), MAH: Merck Sharp & Dohme Limited, Rapporteur: Koenraad Norga
NAPS:
Alerdes, 0,5 mg/ml, roztwór doustny 20454 PL - SYMPHAR SP. Z O.O.
Alerdes, 5 mg, tabletki powlekane 20067 PL - SYMPHAR SP. Z O.O.
ALERDIN 0,5 mg/ml oralna otopina UP/I-530-09/11-01/368 HR - BELUPO D.D.
ALERDIN 2,5 mg raspadljive tablete za usta UP/I-530-09/11-01/369 HR - BELUPO D.D.
ALERDIN 5 mg raspadljive tablete za usta UP/I-530-09/11-01/370 HR - BELUPO D.D.
Aleric Deslo Active, 2,5 mg, tabletki ulegające rozpadowi w jamie ustnej 20562 PL - US PHARMACIA SP. Z O.O.
Aleric Deslo Active, 5 mg, tabletki ulegające rozpadowi w jamie ustnej 20564 PL - US PHARMACIA SP. Z O.O.
Aleric Deslo, 0,5 mg/ml, roztwór doustny 20561 PL - US PHARMACIA SP. Z O.O.
Aleric Deslo, 5 mg, tabletki powlekane 20563 PL - US PHARMACIA SP. Z O.O.
Alvotadin 5 mg filmtabletta OGYI-T-22014/25 HU - ALVOGEN IPCO S.AR.L
Clarderin, 0,5 mg/ml, roztwór doustny 21102 PL - PHARMASWISS ČESKÁ REPUBLIKA S.R.O.
Clarderin, 5 mg, tabletki ulegające rozpadowi w jamie ustnej 21037 PL - PHARMASWISS ČESKÁ REPUBLIKA S.R.O.
Clarus 0,5 mg/ml solução oral 5634019 PT - LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.
Dareq 0,5 mg/ml Oral solution 21528 CY - DELORBIS PHARMACEUTICALS LTD
Dareq 5 mg Film-coated tablets 21529 CY - DELORBIS PHARMACEUTICALS LTD
Dehistar, 0,5 mg/ml, roztwór doustny 19985 PL - FARMACEUTYCZNA SPOLDZIELNIA PRACY GALENA
Dehistar, 5 mg, tabletki powlekane 19992 PL - FARMACEUTYCZNA SPOLDZIELNIA PRACY GALENA
DELESIT 5 mg filmom obalené tablety 24/0417/12-S SK - CIPLA (UK) LIMITED

Update of section 4.4 of the SmPC and section 2 of the Package Leaflet:
- to add a warning regarding convulsions.
The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

DELESIT 5 mg potahované tablety 24/682/12-C CZ - CIPLA (UK) LIMITED
Delortan Allergy, 5 mg, tabletki powlekane 22669 PL - WARSZAWSKIE ZAKLADY FARMACEUTYCZNE POLFA S.A.
Delortan, 0,5 mg/ml, roztwór doustny 20061 PL - WARSZAWSKIE ZAKLADY FARMACEUTYCZNE POLFA S.A.
Delortan, 5 mg, tabletki powlekane 20059 PL - WARSZAWSKIE ZAKLADY FARMACEUTYCZNE POLFA S.A.
Deslix, 0,5 mg/ml, roztwór doustny 20415 PL - MEDANA PHARMA SPOLKA AKCYJNA
Deslix, 5 mg, tabletki powlekane 20414 PL - MEDANA PHARMA SPOLKA AKCYJNA
DESLODYNA pro, 5 mg, tabletki ulegajace rozpadowi w jamie ustnej 19963 PL - HASCO-LEK
Deslodyna pro, smeltetabletter 5 mg 48300 DK - HASCO-LEK
Deslodyna, 0,5 mg/ml, roztwór doustny 19960 PL - HASCO-LEK
Deslodyna, 2,5 mg, tabletki ulegające rozpadowi w jamie ustnej 19962 PL - HASCO-LEK
Deslodyna, 5 mg, tabletki powlekane 19961 PL - HASCO-LEK
Deslodyna, filmovertrukne tabletter 48298 DK - HASCO-LEK
Deslodyna, oral opløsning 48314 DK - HASCO-LEK
Deslodyna, smeltetabletter 2,5 mg 48299 DK - HASCO-LEK
Deslomed 5 mg filmom obalené tablety 24/0748/11-S SK - CANDE S.R.O.
Deslor 0.5 mg/ml Oral Solution PA0711/202/002 IE - ROWEX LTD
Deslor 48335 DK - ROWEX LTD
Deslor 48336 DK - ROWEX LTD
Deslor 5 mg Film-Coated Tablets PA0711/202/001 IE - ROWEX LTD
Deslora-Denk 5 mg Filmtabletten 90185.00.00 DE - DENK PHARMA GMBH & CO. KG
Desloraderm 0,5 mg/ml Lösung zum Einnehmen 1-31334 AT - DERMAPHARM GMBH
Desloraderm 0,5 mg/ml Lösung zum Einnehmen 84588.00.00 DE - DERMAPHARM AG
Desloraderm 5 mg Filmtabletten 1-31333

AT - DERMAPHARM GMBH
Desloraderm 5 mg Filmtabletten 84587.00.00 DE - DERMAPHARM AG
Desloradia 5 mg Filmtabletten 2192095 DE - M.R. PHARMA, DE
Desloratadin +pharma 5 mg Filmtabletten 1-31178 AT - +PHARMA ARZNEIMITTEL GMBH
Desloratadin +pharma 5 mg potahované tablety 24/331/12-C CZ - +PHARMA ARZNEIMITTEL GMBH
Desloratadin - 1 A Pharma 5 mg Filmtabletten 84359.00.00 DE - 1 A PHARMA GMBH
DESLORATADIN ACTAVIS 0,5 MG/ML BELSŐLEGES OLDAT OGYI-T-22197/04 HU - ACTAVIS GROUP PTC EHF.
Desloratadin AL 5 mg Filmtabletten 84536.00.00 DE - ALIUD PHARMA GMBH
Desloratadin AL, filmovertrukne tabletter 48325 DK - ALIUD PHARMA GMBH
Desloratadin Apofri 5 mg filmdragerade tabletter 52183 SE - APOFRI AB
Desloratadin Apotex 0,5 mg/ml perorální roztok 24/406/12 C CZ - APOTEX EUROPE B.V.
Desloratadin Apotex 5 mg potahované tablety 24/209/13-C CZ - APOTEX EUROPE BV
Desloratadin Aristo 0,5 mg/ml Lösung zum Einnehmen 1-31628 AT - ARISTO PHARMA GMBH (ART 57)
Desloratadin Aristo 0,5 mg/ml Lösung zum Einnehmen 84989.00.00 DE - ARISTO PHARMA GMBH (ART 57)
Desloratadin Aristo® 5 mg Filmtabletten 1-31618 AT - ARISTO PHARMA GMBH (ART 57)
Desloratadin Aristo® 5 mg Filmtabletten 84988.00.00 DE - ARISTO PHARMA GMBH (ART 57)
Desloratadin axcount 0,5 mg/ml Lösung zum Einnehmen 94143.00.00 DE - AXCOUNT GENERIKA GMBH
Desloratadin axcount 2,5 mg Schmelztabletten 93355.00.00 DE - AXCOUNT GENERIKA GMBH
Desloratadin axcount 5 mg Filmtabletten 93357.00.00 DE - AXCOUNT GENERIKA GMBH
Desloratadin axcount 5 mg Schmelztabletten 93356.00.00 DE - AXCOUNT GENERIKA GMBH
Desloratadin Cipla 5 mg filmom obložene

tablete HR-H-302001390 HR - CIPLA EUROPE NV
Desloratadin Cipla 5 mg Filmtabletten 94826.00.00 DE - CIPLA EUROPE NV
Desloratadin Cipla, filmovertrukne tabletter 55618 DK - CIPLA EUROPE NV
DESLORATADIN DR.MAX 5 MG POTAHOVANÉ TABLETY 24/489/12-C CZ - DR. MAX
Desloratadin Genericon 5 mg Filmtabletten 1-31147 AT - GENERICON PHARMA GESELLSCHAFT M.B.H.
Desloratadin Glenmark 5 mg Tabletten 84037.00.00 DE - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadin Glenmark 5mg tabletter 48522 DK - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadin HCS® 5 mg Filmtabletten 90865.00.00 DE - TAD PHARMA GMBH
Desloratadin HEXAL 0,5 mg/ml Lösung zum Einnehmen 84366.00.00 DE - HEXAL AG
Desloratadin HEXAL 5 mg Filmtabletten 84365.00.00 DE - HEXAL AG
Desloratadin IBERMEDGEN 0.5 mg/ml peroralen raztvor II-21146 BG - IBERMEDGEN, S.A.
Desloratadin IBERMEDGEN 5 mg filmirani tabletki II-21147 BG - IBERMEDGEN, S.A.
Desloratadin Krka 5 mg potahované tablety 24/213/14-C CZ - KRKA, D.D., NOVO MESTO
Desloratadin M.R. Pharma 0,5 mg/ml Lösung zum Einnehmen 2192096 DE - M.R. PHARMA, DE
Desloratadin M.R. Pharma 5 mg Filmtabletten 2192094 DE - M.R. PHARMA, DE
Desloratadin Mylan 5 mg filmdragerade tabletter 46075 SE - MYLAN AB
Desloratadin Mylan 5 mg kalvopäällysteiset tabletit 29741 FI - MYLAN AB
Desloratadin Mylan 5 mg potahované tablety 24/683/12-C CZ - GENERICS [UK] LIMITED
Desloratadin Mylan, oral opløsning 48308 DK - MYLAN AB
Desloratadin Ranbaxy, filmovertrukne tabletter 48284 DK - RANBAXY PHARMACIE GENERIQUES
Desloratadin ratiopharm 2,5 mg Schmelztabletten 1-31313 AT - RATIOPHARM

ARZNEIMITTEL VERTRIEBS-GMBH
Desloratadin ratiopharm 5 mg Schmelztabletten 1-31314 AT - RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH
Desloratadin Sandoz 0,5 mg/ml drank BE420034 BE - SANDOZ N.V.
Desloratadin Sandoz 5 mg - Filmtabletten 1-31302 AT - SANDOZ GMBH
Desloratadin Sandoz 5 mg comprimés pelliculés 2013010011 LU - SANDOZ N.V.
Desloratadin Sandoz 5 mg filmomhulde tabletten BE420016 BE - SANDOZ N.V.
Desloratadin Sandoz 5 mg filmomhulde tabletten BE420025 BE - SANDOZ N.V.
Desloratadin Saneca 5 mg tablety 24/0318/12-S SK - SANECA PHARMACEUTICALS
Desloratadin Saneca 5 mg tablety 24/628/12-C CZ - SANECA PHARMACEUTICALS
Desloratadin Sipla 5 mg filmirani tabletki 20130159 BG - CIPLA (UK) LIMITED
Desloratadin Sofarma 0,5 mg/ml peroralen raztvorp 20150207 BG - SOPHARMA AD
Desloratadin Sofarma 5 mg filmirani tabletki 20160045 BG - SOPHARMA AD
Desloratadin Specifar 2.5mg smeltetabletter 48293 DK - SPECIFAR S.A.
Desloratadin Specifar 5mg filmovertrukne tabletter 48292 DK - SPECIFAR S.A.
Desloratadin STADA 0,5 mg/ml Lösung zum Einnehmen 84537.00.00 DE - STADAPHARM GMBH
Desloratadin Stada 0,5 mg/ml oraaliliuos 29571 FI - STADA ARZNEIMITTEL AG
Desloratadin Stada 5 mg 24/335/15-C CZ - STADA ARZNEIMITTEL AG
Desloratadin STADA 5 mg filmdragerade tabletter 45771 SE - STADA ARZNEIMITTEL AG
Desloratadin STADA 5 mg filmdragerade tabletter 45775 SE - STADA ARZNEIMITTEL AG
Desloratadin STADA 5 mg Filmtabletten 1-31291 AT - STADA ARZNEIMITTEL GMBH
Desloratadin Stada 5 mg kalvopäällysteinen tabletti 29570 FI - STADA ARZNEIMITTEL AG
Desloratadin Stada, filmovertrukne tabletter 48321 DK - STADA ARZNEIMITTEL AG
Desloratadin STADA® 5 mg Filmtabletten

84535.00.00 DE - STADAPHARM GMBH
Desloratadin Stadfa 0,5 mg/ml peroralen raztvorp 20120244 BG - STADA ARZNEIMITTEL AG
Desloratadin Teva 0,5 mg/ml belsőleges oldat OGYI-T-22096/05 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 0,5 mg/ml belsőleges oldat OGYI-T-22096/06 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 0,5 mg/ml belsőleges oldat OGYI-T-22096/07 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 0,5 mg/ml belsőleges oldat OGYI-T-22096/08 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 0,5 mg/ml belsőleges oldat OGYI-T-22096/09 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 2,5 mg szájban diszpergálódó tabletta OGYI-T-22096/01 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 2,5 mg szájban diszpergálódó tabletta OGYI-T-22096/02 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 5 mg szájban diszpergálódó tabletta OGYI-T-22096/03 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Teva 5 mg szájban diszpergálódó tabletta OGYI-T-22096/04 HU - TEVA GYÓGYSZERGYÁR ZRT
Desloratadin Zentiva 0,5 mg/ml perorální roztok 24/326/12-C CZ - ZENTIVA, K.S.
DESLORATADIN ZENTIVA 0,5 mg/ml perorálny roztok 24/0010/12-S SK - ZENTIVA, K.S.
Desloratadin Zentiva 5 mg filmirani tabletki 20120167 BG - ZENTIVA, K.S.
DESLORATADIN ZENTIVA 5 mg filmom obalené tablety 24/0008/12-S SK - ZENTIVA, K.S.
Desloratadin Zentiva 5 mg potahované tablety 24/324/12-C CZ - ZENTIVA, K.S.
Desloratadin Алвоген 0,5 mg/ml peroralen raztvorp II-18062 BG - ALVOGEN IPCO S.AR.L
Desloratadin Алвоген 5 mg filmirani tabletki II-18059 BG - ALVOGEN IPCO S.AR.L
Desloratadin Софарма 5 mg filmirani tabletki 20160045 BG - SOPHARMA AD
Desloratadin "Actavis PTC", oral opløsning 49155 DK - ACTAVIS GROUP PTC EHF.

Desloratadin "Stada Arzneimittel", filmovertrukne tabletter 54011 DK - STADA ARZNEIMITTEL AG
Desloratadin "Stada Arzneimittel", oral opløsning 48324 DK - STADA ARZNEIMITTEL AG
Desloratadin "Stada", oral opløsning 48323 DK - STADA ARZNEIMITTEL AG
Desloratadin-Hormosan 5 mg Filmtabletten 84742.00.00 DE - HORMOSAN PHARMA GMBH
Desloratadina Actavis 2.5 mg orodispersible tablets 5462502 PT - ACTAVIS GROUP PTC EHF.
Desloratadina Actavis 5 mg orodispersible tablets 5462825, 2510 PT - ACTAVIS GROUP PTC EHF.
Desloratadina Almus 5 mg comprimidos recubiertos con película EFG 76305 ES - ALMUS FARMACEUTICA S.A
Desloratadina Alter 5 mg comprimidos bucodispersables EFG 77984 ES - LABORATORIOS ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos orodispersíveis 5580436 PT - ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos orodispersíveis 5580444 PT - ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos orodispersíveis 5580451 PT - ALTER, S.A.
Desloratadina Alter 5 mg comprimidos recubiertos con película 77557 ES - LABORATORIOS ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos revestidos por película 5580469 PT - ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos revestidos por película 5580477 PT - ALTER, S.A.
Desloratadina ALTER 5 mg comprimidos revestidos por película 5580501 PT - ALTER, S.A.
Desloratadina Apotex 5 mg comprimidos recubiertos con película EFG 75985 ES - APOTEX EUROPE BV
Desloratadina Apotex AG 5 mg comprimidos recubiertos con película EFG 77669 ES - APOTEX EUROPE BV
Desloratadina Aristo 0,5 mg/ml solución oral EFG 76599 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 0,5mg/ml solução oral 5568936 PT - ARISTO PHARMA IBERIA, S.L.

Desloratadina Aristo 0,5mg/ml solução oral 5568944 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 0,5mg/ml solução oral 5568951 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 0,5mg/ml solução oral 5568969 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 0,5mg/ml solução oral 5568977 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 0,5mg/ml solução oral 5569009 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5 mg comprimidos bucodispersables EFG 77277 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568779 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568803 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568811 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568829 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568837 PT - ARISTO PHARMA IBERIA, S.L.
Desloratadina Aristo 5mg comprimidos revestidos por película 5568845 PT - ARISTO PHARMA IBERIA, S.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570019 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570021 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570033 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570045 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570058 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570060 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570072 IT - AUROBINDO

PHARMA (ITALIA) S.R.L.
DESLORATADINA AUROBINDO 0,5 mg/ml soluzione orale 041570084 IT - AUROBINDO PHARMA (ITALIA) S.R.L.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634274 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634308 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634316 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634324 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634332 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Azevedos 0,5 mg/ml solução oral 5634340 PT - LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Basi 5 mg comprimidos revestidos por película 5459433 PT - LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Basi 5 mg comprimidos revestidos por película 5459441 PT - LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Basi 5 mg comprimidos revestidos por película 5459458 PT - LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Basi 5 mg comprimidos revestidos por película 5459466 PT - LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.
Desloratadina Bluelife 0,5 mg Solução oral 14/H/0084/004 PT - BLUELIFE, SOCIEDADE UNIPESSOAL LDA.
Desloratadina Bluelife 2.5 mg Comprimido orodispersível 14/H/0084/002 PT - BLUELIFE, SOCIEDADE UNIPESSOAL LDA.
Desloratadina Bluelife 5 mg Comprimido orodispersível 14/H/0084/003 PT - BLUELIFE, SOCIEDADE UNIPESSOAL LDA.
Desloratadina Bluelife 5 mg Comprimido revestido por película 14/H/0084/001 PT - BLUELIFE, SOCIEDADE UNIPESSOAL LDA.
Desloratadina Bluepharma 5 mg

comprimidos revestidos por película 5428578 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428602 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428610 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428628 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428636 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428644 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Bluepharma 5 mg comprimidos revestidos por película 5428651 PT - BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.
Desloratadina Ciclum 0,5 mg/ml solução oral 5477740 PT - CICLUM FARMA UNIPESSOAL, LDA
Desloratadina Ciclum 0,5 mg/ml solução oral 5477757 PT - CICLUM FARMA UNIPESSOAL, LDA
Desloratadina Ciclum 0,5 mg/ml solução oral DK/H/2065/001 PT - CICLUM FARMA UNIPESSOAL, LDA
Desloratadina Ciclum 5 mg comprimidos revestidos por película 5477732 PT - CICLUM FARMA UNIPESSOAL, LDA
Desloratadina Ciclum 5 mg comprimidos revestidos por película DK/H/2050/001 PT - CICLUM FARMA UNIPESSOAL, LDA
desloratadina cinfa 5 mg comprimidos bucodispersables EFG. 78370 ES - LABORATORIOS CINFA, S.A.
desloratadina cinfa 5 mg comprimidos recubiertos con película EFG 75335 ES - LABORATORIOS CINFA, S.A.
Desloratadina Cinfa 5 mg comprimidos revestidos por película 5458906 PT - CINFA PORTUGAL, LDA.

Desloratadina Cipla 5 mg compresse rivestite con film 044367011 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg compresse rivestite con film 044367023 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg compresse rivestite con film 044367035 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg compresse rivestite con film 044367047 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg compresse rivestite con film 044367050 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg compresse rivestite con film 044367062 IT - CIPLA EUROPE NV
Desloratadina Cipla 5 mg comprimate filmate 8741/2016/06 RO - CIPLA EUROPE NV
Desloratadina Cipla 5 mg comprimidos recubiertos con película EFG 80568 ES - CIPLA EUROPE NV
Desloratadina Combix 5 mg comprimidos recubiertos con película EFG 76.043 ES - LABORATORIOS COMBIX, S.L.U.
DESLORATADINA DOC 5 mg compresse rivestite con film 040718013 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC 5 mg compresse rivestite con film 040718025 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC 5 mg compresse rivestite con film 040718037 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC 5 mg compresse rivestite con film 040718049 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC 5 mg compresse rivestite con film 040718052 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC Generici 2.5 mg compresse orodispersibili 040810057 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC Generici 5 mg compresse orodispersibili 040810 IT - DOC GENERICI S.R.L.
DESLORATADINA DOC Generici 5 mg compresse rivestite con film 040810 IT - DOC GENERICI S.R.L.

DESLORATADINA EG 5 mg compresse rivestite con film 040733014 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733026 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733038 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733040 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733053 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733065 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733077 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733089 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733091 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733103 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733115 IT - EG SPA
DESLORATADINA EG 5 mg compresse rivestite con film 040733127 IT - EG SPA
Desloratadina Farmoz 0,5 mg/ml solução oral 5451059 PT - FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.
Desloratadina Farmoz 5 mg comprimidos revestidos por película 5451067 PT - FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.
Desloratadina Farmoz 5 mg comprimidos revestidos por película 5451075 PT - FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.
Desloratadina Flas Combix 5 mg comprimidos bucodispersables EFG 76.037 ES - LABORATORIOS COMBIX, S.L.U.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657028 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657036 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657044 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657051 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657077 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657101 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml

solução oral 5657119 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657127 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657135 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657143 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657150 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657168 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657169 PT - GENEPHARM S.A.
Desloratadina Genepharm 0,5 mg/ml solução oral 5657176 PT - GENEPHARM S.A.
Desloratadina Genepharm 2,5 mg comprimidos orodispersíveis 5582077 PT - GENEPHARM S.A.
Desloratadina Genepharm 5 mg comprimidos orodispersíveis 5582101 PT - GENEPHARM S.A.
Desloratadina Genepharm 5 mg comprimidos revestidos por película 5582069 PT - GENEPHARM S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5415351 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5415369 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5415377 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5415401 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5415419 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5417522 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5417530 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5417548 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 0,5 mg/ml solucao oral 5417555 PT - GENERIS FARMACÊUTICA, S.A.

Desloratadina Generis 0,5 mg/ml solucao oral 5418215 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 2,5 mg comprimidos orodispersíveis 5413315 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 2,5 mg comprimidos orodispersíveis 5442504 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 5 mg comprimidos orodispersíveis 5413323 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Generis 5 mg comprimidos revestidos por película 5413331 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Germed 0,5 mg/ml solución oral EFG 75521 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 0,5 mg/ml solución oral EFG 75521 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 0,5 mg/ml solução oral 5469606 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 0,5 mg/ml solução oral 5469614 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 0,5 mg/ml solução oral 5469622 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 0,5 mg/ml soluzione orale 040983088 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 0,5 mg/ml soluzione orale 040983090 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 0,5 mg/ml soluzione orale 040983102 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 2,5 mg compresse orodispersibili 040983049 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 2,5 mg compresse orodispersibili 040983052 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 2,5 mg compresse orodispersibili 040983064 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 2,5 mg comprimidos orodispersíveis 5469549 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 2,5 mg comprimidos orodispersíveis 5469556 PT - GERMED FARMACÊUTICA, LDA.

Desloratadina Germed 2,5 mg comprimidos orodispersíveis 5469564 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 5 mg compresse orodispersibili 040983076 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 5 mg compresse rivestite con film 040983013 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 5 mg compresse rivestite con film 040983025 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 5 mg compresse rivestite con film 040983037 IT - GERMED PHARMA S.R.L.
Desloratadina Germed 5 mg comprimidos bucodispersables EFG 75523 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 5 mg comprimidos bucodispersables EFG 75523 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 5 mg comprimidos orodispersíveis 5469572 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 5 mg comprimidos recubiertos con pelicula EFG 75522 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 5 mg comprimidos recubiertos con pelicula EFG 75522 ES - ARISTO PHARMA IBERIA, S.L.
Desloratadina Germed 5 mg comprimidos revestidos por película 5469515 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 5 mg comprimidos revestidos por película 5469523 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Germed 5 mg comprimidos revestidos por película 5469531 PT - GERMED FARMACÊUTICA, LDA.
Desloratadina Glenmark 5 mg Comprimidos 5643200 PT - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadina Kern Pharma 0,5 mg/ml solución oral EFG 77592 ES - KERN PHARMA, S.L.
Desloratadina KERN PHARMA 5 mg comprimidos recubiertos con película EFG 75.304 ES - KERN PHARMA, S.L.
Desloratadina Krka 5 mg Comprimido revestido por película 5398953 PT - KRKA FARMACÊUTICA, UNIPESSOAL LDA.

Desloratadina Krka 5 mg Comprimido revestido por película 5398961 PT - KRKA FARMACÊUTICA, UNIPESSOAL LDA.
Desloratadina Krka 5 mg Comprimido revestido por película 5399233 PT - KRKA FARMACÊUTICA, UNIPESSOAL LDA.
Desloratadina Labesfal 0,5 mg/ml Solução oral 5472857 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 0,5 mg/ml Solução oral 5472865 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428412 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428420 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428438 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428446 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428453 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428461 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal 5 mg comprimidos revestidos por película 5428479 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal OD 2,5 mg Comprimido orodispersível 5472873 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal OD 2,5 mg Comprimido orodispersível 5472907 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Labesfal OD 5 mg Comprimidos orodispersíveis 5472915 PT - GENERIS FARMACÊUTICA, S.A.
Desloratadina Lesvi 5 mg comprimidos recubiertos con película EFG 75529 ES - LABORATORIOS LESVI, S.L.
Desloratadina Lupin 5 mg compresse rivestite con film 040827014 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827026 IT - LUPIN (EUROPE) LIMITED

Desloratadina Lupin 5 mg compresse rivestite con film 040827038 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827040 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827053 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827065 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827077 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827089 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827091 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827103 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827115 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827127 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827139 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827141 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827154 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827166 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827178 IT - LUPIN (EUROPE) LIMITED
Desloratadina Lupin 5 mg compresse rivestite con film 040827180 IT - LUPIN (EUROPE) LIMITED
Desloratadina Mepha, 0,5 mg/ml, solução oral 5415427 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO

FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5415435 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5415443 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5415450 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5415468 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5418223 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5418231 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5418249 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5418256 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 0,5 mg/ml, solução oral 5418264 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina Mepha, 5 mg, comprimidos revestidos por película 5413307 PT - MEPHA-INVESTIGACAO DESENVOLVIMENTO E FABRICACAO FARMACEUTICA, LDA.
Desloratadina MYLAN 0,5 mg/ml solución oral EFG 76343 ES - MYLAN PHARMACEUTICALS S.L.
Desloratadina Mylan 0,5 mg/ml solução oral 5439872 PT - MYLAN, LDA
Desloratadina MYLAN 5 mg comprimidos recubiertos con película EFG 76625 ES - MYLAN PHARMACEUTICALS S.L.
Desloratadina Mylan 5 mg comprimidos revestidos por película 5415476 PT - MYLAN,

LDA
Desloratadina Mylan 5 mg comprimidos revestidos por película 5415500 PT - MYLAN, LDA
Desloratadina Mylan 5 mg comprimidos revestidos por película 5415518 PT - MYLAN, LDA
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081011/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081023/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081035/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081047/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081050/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081062/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081074/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081086/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081098/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081100/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081112/M IT - MYLAN S.P.A.
Desloratadina Mylan Generics 5 mg compresse rivestite con film 041081124/M IT - MYLAN S.P.A.
Desloratadina NORMON 0,5 mg/ml solución oral EFG 75842 ES - LABORATORIOS NORMON, S.A.
Desloratadina Normon 0,5 mg/ml solução oral 5664933 PT - LABORATÓRIOS NORMON, S.A.
Desloratadina NORMON 5 mg comprimidos recubiertos con película EFG 75840 ES -

LABORATORIOS NORMON, S.A.
Desloratadina Normon 5 mg comprimidos revestidos por película 5664925 PT - LABORATÓRIOS NORMON, S.A.
Desloratadina Pharmakern 0,5 mg/ml solução oral 5558150 PT - PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.
Desloratadina Pharmakern 0,5 mg/ml solução oral 5558168 PT - PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.
Desloratadina Pharmakern 5 mg comprimidos revestidos por película 5450721 PT - PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.
Desloratadina Pharmakern 5 mg comprimidos revestidos por película 5450739 PT - PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.
Desloratadina Qualigen 0.5 mg/ml solución oral EFG 76.761 ES - QUALIGEN, S.L.
Desloratadina Qualigen 5 mg comprimidos recubiertos con película EFG 75542 ES - QUALIGEN, S.L.
Desloratadina ratiopharm 0,5 mg/ml solución oral EFG 77664 ES - RATIOPHARM ESPANA SA
Desloratadina ratiopharm 0,5 mg/ml Solução Oral 5580253 PT - RATIOPHARM-COMERCIO E INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA
Desloratadina ratiopharm 2,5 mg comprimidos orodispersíveis 5492137 PT - RATIOPHARM-COMERCIO E INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA
Desloratadina ratiopharm 5 mg comprimidos orodispersíveis 5492145 PT - RATIOPHARM-COMERCIO E INDUSTRIA DE PRODUTOS FARMACEUTICOS LDA
Desloratadina Sandoz 0,5mg/ml solución oral EFG 76283 ES - SANDOZ FARMACÉUTICA, S.A.
DESLORATADINA SANDOZ 040722011 IT - SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722023 IT - SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722035 IT - SANDOZ S.P.A.

DESLORATADINA SANDOZ 040722047 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722050 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722062 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722074 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722086 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722098 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722100 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722112 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722124 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722136 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722148 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722151 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722163 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722175 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722187 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722199 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722201 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722213 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722225 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722237 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722249 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722252 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722264 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722276 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722288 IT -
SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722290/M-

040722340 IT - SANDOZ S.P.A.
DESLORATADINA SANDOZ 040722326/M-040722377 IT - SANDOZ S.P.A.
Desloratadina Sandoz 5 mg comprimidos recubiertos EFG 76284 ES - SANDOZ FARMACÉUTICA, S.A.
Desloratadina Sandoz 5461348 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461355 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461363 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461371 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461405 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461413 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Sandoz 5461421 PT - SANDOZ FARMACÊUTICA LDA.
Desloratadina Specifar 5 mg comprimidos recubiertos con película EFG 76.344 ES - SPECIFAR S.A.
Desloratadina STADA 0,5 mg/ml solución oral EFG 75.387 ES - LABORATORIO STADA, S.L.
Desloratadina STADA 5 mg comprimidos recubiertos con película EFG 75.528 ES - LABORATORIO STADA, S.L.
Desloratadina Tarbis 0,5 mg/ml solución oral EFG 76340 ES - TARBIS FARMA, S.L.
Desloratadina Tarbis 5 mg comprimidos recubiertos con película EFG 76174 ES - TARBIS FARMA, S.L.
Desloratadina Tecnigen 0,5 mg/ml solución oral EFG 76.331 ES - TECNIMEDE ESPAÑA, INDUSTRIA FARMACÉUTICA, S.A.
Desloratadina TecniGen 5 mg comprimidos recubiertos con película EFG 76.332 ES - TECNIMEDE ESPAÑA IND. FCA., S.A.
Desloratadina TecniGen 5 mg comprimidos recubiertos con película EFG 76.332 ES - TECNIMEDE ESPAÑA, INDUSTRIA FARMACÉUTICA, S.A.
Desloratadina Teva 0,5 mg/ml solución oral EFG 77666 ES - TEVA PHARMA S.L.U
Desloratadina Teva 5 mg comprimidos bucodispersables EFG 76005 ES - TEVA PHARMA S.L.U
Desloratadina Teva 5 mg comprimidos orodispersíveis 5458609 PT - TEVA PHARMA

– PRODUTOS FARMACÊUTICOS LDA
Desloratadina toLife 2,5 mg comprimidos orodispersíveis 5413265 PT - TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.
Desloratadina toLife 2,5 mg comprimidos orodispersíveis 5442512 PT - TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.
Desloratadina toLife 5 mg comprimidos orodispersíveis 5413273 PT - TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.
Desloratadina toLife 5 mg comprimidos revestidos por película 5443320 PT - TOLIFE - PRODUTOS FARMACÊUTICOS, S.A.
Desloratadina Viso Farmacéutica 5 mg comprimidos EFG 76148 ES - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadina Worldrugs 0,5 mg/ml solução oral 5646328 PT - WORLDRUGS, LDA.
Desloratadina Zentiva 5 mg compresse rivestite con film 040872018 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872020 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872032 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872044 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872057 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872069 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872071 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872083 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872095 IT - ZENTIVA ITALIA SRL
Desloratadina Zentiva 5 mg compresse rivestite con film 040872107 IT - ZENTIVA ITALIA SRL
Desloratadină Alvogen 0,5 mg/ ml soluţie orală 4535/2012/01-08 RO - ALVOGEN IPCO

S.AR.L

Desloratadină Alvogen 5 mg comprimate filmate 4534/2012/01-28 RO - ALVOGEN IPCO S.AR.L

DESLORATADINĂ SANDOZ 0.5 mg soluţie orală 4660/2012/01 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 0.5 mg soluţie orală 4660/2012/02 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 0.5 mg soluţie orală 4660/2012/03 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 0.5 mg soluţie orală 4660/2012/04 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 0.5 mg soluţie orală 4660/2012/05 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/01 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/02 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/03 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/04 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/05 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/06 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/07 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/08 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/09 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/10 RO - S.C. SANDOZ S.R.L.

DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/11 RO -

S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/12 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/13 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/14 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/15 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/16 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/17 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/18 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/19 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/20 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/21 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/22 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/23 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/24 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/25 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/26 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/27 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/28 RO -

S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/29 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/30 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/31 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/32 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/33 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/34 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/35 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/36 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/37 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/38 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/39 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/40 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/41 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/42 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/43 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/44 RO -
S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/45 RO -

S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/46 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/47 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/48 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/49 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/50 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/51 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/52 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/53 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/54 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/55 RO - S.C. SANDOZ S.R.L.
DESLORATADINĂ SANDOZ 5 mg comprimate filmate 4659/2012/56 RO - S.C. SANDOZ S.R.L.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/01 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/02 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/03 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/04 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/05 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/06 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/07 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/08 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate

filmate 4481/2012/09 RO - TERAPIA S.A.
Desloratadină Terapia 5 mg comprimate filmate 4481/2012/10 RO - TERAPIA S.A.
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/01 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/02 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/03 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/04 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/05 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/06 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/07 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/08 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadină Teva 5 mg comprimate orodispersabile 4575/2012/09 RO - TEVA PHARMACEUTICALS S.R.L
Desloratadine +pharma, 5 mg, tabletki powlekane 20082 PL - +PHARMA ARZNEIMITTEL GMBH
Desloratadine 0.5 mg/ml oral solution PL 17907/0502 UK - BRISTOL LABORATORIES LTD (BERKHAMSTED)
Desloratadine 0.5 mg/ml Oral Solution PL 20416/0242 UK - CRESCENT PHARMA LIMITED
Desloratadine 0.5mg/ml Oral Solution PL24668/0162 UK - CADUCEUS PHARMA LIMITED
Desloratadine 1A Farma 48333 DK - 1A FARMA A/S
Desloratadine 1A Farma 48334 DK - 1A FARMA A/S
Desloratadine 2.5 mg orodispersible tablets PL 17907/0499 UK - BRISTOL LABORATORIES LTD (BERKHAMSTED)
Desloratadine 5 mg film-coated tablets PL 17907/0501 UK - BRISTOL LABORATORIES LTD (BERKHAMSTED)

Desloratadine 5 mg Film-Coated Tablets PL 20416/0241 UK - CRESCENT PHARMA LIMITED
Desloratadine 5 mg orodispersible tablets PL 17907/0500 UK - BRISTOL LABORATORIES LTD (BERKHAMSTED)
Desloratadine 5 mg tablets PL 25258/0052 UK - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadine 5mg Film-coated Tablets PL 35507/0035 UK - LUPIN (EUROPE) LIMITED
DESLORATADINE ACTAVIS 0,5 MG/ML ORAALILIUOS 30005 FI - ACTAVIS GROUP PTC EHF.
DESLORATADINE ACTAVIS, 0,5 MG/ML, ROZTWÓR DOUSTNY 20518 PL - ACTAVIS GROUP PTC EHF.
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 269 410-7 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 269 411-3 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 269 413-6 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 269 414-2 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 584 394-4 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 584 395-0 FR - ALMUS FRANCE
DESLORATADINE ALMUS 5 mg, comprimé pelliculé 584 396-7 FR - ALMUS FRANCE
Desloratadine Apotex 0.5 mg/ml oral solution 48309 DK - APOTEX EUROPE B.V.
Desloratadine Apotex 5 mg comprimidos revestidos por película NOT YET KNOWN PT - APOTEX EUROPE B.V.
Desloratadine Apotex 5 mg filmomhulde tabletten RVG 110966 NL - APOTEX EUROPE BV
DESLORATADINE ARROW 0,5 mg/ml, solution buvable 50638 FR - ARROW GENERIQUES
DESLORATADINE ARROW 5mg, comprimé pelliculé 50454 FR - ARROW GENERIQUES
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963070 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963131 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963360 FR -

BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963421 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963599 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963650 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963711 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963889 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941963940 FR - BIOGARAN
DESLORATADINE BIOGARAN 0,5 mg/ml, solution buvable 3400941964022 FR - BIOGARAN
DESLORATADINE BIOGARAN® 5 mg, comprimé pelliculé 3400930021149 FR - BIOGARAN
DESLORATADINE BIOGARAN® 5 mg, comprimé pelliculé 3400941999031 FR - BIOGARAN
DESLORATADINE BIOGARAN® 5 mg, comprimé pelliculé 3400941999499 FR - BIOGARAN
Desloratadine CF 0,5 mg/ml, drank RVG 109205 NL - CENTRAFARM B.V.
Desloratadine CF 5 mg, filmomhulde tabletten RVG 109204 NL - CENTRAFARM B.V.
Desloratadine Cipla 5 mg film-coated tablets MA1059/00401 MT - CIPLA EUROPE NV
Desloratadine Cipla 5 mg film-coated tablets PA1963/006/001 IE - CIPLA EUROPE NV
Desloratadine Cipla 5 mg film-coated tablets PL 43362/0015 UK - CIPLA EUROPE NV
Desloratadine Cipla 5 mg filmdragerade tabletter 45973 SE - CIPLA (UK) LIMITED
Desloratadine Cipla 5 mg filmomhulde tabletten BE489253 BE - CIPLA EUROPE NV
Desloratadine Cipla 5 mg filmtabletta OGYI-T-22321/01 HU - CIPLA (UK) LIMITED
Desloratadine Cipla 5 mg tabletter,

filmdrasjerte 15-10584 NO - CIPLA EUROPE NV

Desloratadine Clonmel 0.5 mg/ml oral solution PA0126/241/001 IE - CLONMEL HEALTHCARE LTD.

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 658 9 0 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 659 5 1 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 662 6 2 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 663 2 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 665 5 2 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 666 1 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 668 4 2 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 669 0 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 671 5 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 672 1 4 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 674 4 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 680 4 4 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 681 0 5 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 682 7 3 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 683 3 4 FR - CRISTERS

DESLORATADINE CRISTERS 5 mg,

comprimé pelliculé 34009 419 685 6 3 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 686 2 4 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 687 9 2 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 688 5 3 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 689 1 4 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 691 6 4 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 419 692 2 5 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 449 9 1 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 451 3 4 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 453 6 3 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 457 1 4 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 458 8 2 FR - CRISTERS
DESLORATADINE CRISTERS 5 mg, comprimé pelliculé 34009 580 459 4 3 FR - CRISTERS
Desloratadine Dr. Max, 5 mg, tabletki powlekane 20897 PL - DR. MAX
Desloratadine EG 0,5 mg/ml drank BE409735 BE - EUROGENERICS SA
Desloratadine EG 0,5 mg/ml Lösung zum Einnehmen BE409735 BE - EUROGENERICS SA
Desloratadine EG 0,5 mg/ml solution buvable 2013120609 LU - EUROGENERICS SA
Desloratadine EG 0,5 mg/ml solution buvable BE409735 BE - EUROGENERICS SA
DESLORATADINE EG 0,5 mg/ml, solution buvable NL50636 FR - EG LABO -

LABORATOIRES EUROGENERICS
Desloratadine EG 5 mg comprimés pelliculés 2013120608 LU - EUROGENERICS SA
Desloratadine EG 5 mg comprimés pelliculés BE412921 BE - EUROGENERICS SA
Desloratadine EG 5 mg filmomhulde tabletten BE412921 BE - EUROGENERICS SA
Desloratadine EG 5 mg Filmtabletten BE412921 BE - EUROGENERICS SA
DESLORATADINE EG 5 mg, comprimé pelliculé NL40899 FR - EG LABO - LABORATOIRES EUROGENERICS
Desloratadine ESP Pharma 0,5 mg/ml oral solution 20130245 BG - ACTAVIS GROUP PTC EHF.
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 101 7 3 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 102 3 4 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 104 6 3 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 105 2 4 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 106 9 2 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 107 5 3 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 279 108 1 4 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 864 8 1 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 865 4 2 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 866 0 3 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 867 7 1 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 868 3 2 FR -

EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009 586 870 8 2 FR - EVOLUPHARM
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé 34009279 109 8 2 FR - EVOLUPHARM
Desloratadine Gedeon Richter 5 mg film-coated tablets PL 04854-0125 UK - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/01 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/02 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/03 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/04 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/05 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/06 HU - GEDEON RICHTER PLC.
Desloratadine Gedeon Richter 5 mg filmtabletta OGYI-T-22039/07 HU - GEDEON RICHTER PLC.
Desloratadine Genoptim, 0,5 mg/ml, roztwór doustny 20574 PL - SYNOPTIS PHARMA SP Z O O
Desloratadine Genoptim, 5 mg, tabletki powlekane 20573 PL - SYNOPTIS PHARMA SP Z O O
Desloratadine Glenmark 5 mg tabletit 29566 FI - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadine Glenmark 5 mg tablets PA1462/007/001 IE - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadine Glenmark 5 mg tabletter 29566 FI - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadine Glenmark 5mg tabletten RVG 109194 NL - GLENMARK PHARMACEUTICALS EUROPE LIMITED
Desloratadine Glenmark 5mg tabletter 45749 SE - GLENMARK PHARMACEUTICALS

EUROPE LIMITED
DESLORATADINE MYLAN 0,5 mg/ml, solution buvable NL 50409 FR - MYLAN S.A.S
Desloratadine Mylan 5 mg film-coated tablets PL 04569/1302 UK - GENERICS [UK] LIMITED
DESLORATADINE MYLAN 5 mg, comprimé pelliculé NL 41140 FR - MYLAN S.A.S
Desloratadine Mylan 5 mg, filmomhulde tabletten RVG 109515 NL - MYLAN B.V.
DESLORATADINE MYLAN GENERIQUES 5 mg, comprimé pelliculé NL 50494 FR - MYLAN S.A.S
DESLORATADINE MYLAN PHARMA 5 mg, comprimé pelliculé NL50396 FR - MYLAN S.A.S
Desloratadine Mylan, 0,5 mg/ml, roztwór doustny 20785 PL - MYLAN S.A.S
Desloratadine Mylan, 5 mg, tabletki powlekane 20846 PL - MYLAN S.A.S
Desloratadine Peseri, 0,5 mg/ml, roztwór doustny 20479 PL - BIO PROFIL POLSKA SP Z OO
Desloratadine Peseri, 2,5 mg, tabletki u1egajce rozpadowi wjamie ustnej 20491 PL - PESERI TRADING LIMITED
Desloratadine Peseri, 5 mg, tabletki u1egajace rozpadowi wjamie ustnej 20492 PL - PESERI TRADING LIMITED
DESLORATADINE RANBAXY 5 mg, comprimé pelliculé NL 40918 FR - RANBAXY PHARMACIE GENERIQUES
Desloratadine ratiopharm 0,5 mg/ml oraaliliuos 30284 FI - RATIOPHARM GMBH
Desloratadine ratiopharm 0,5 mg/ml oral lösning 30284 FI - RATIOPHARM GMBH
Desloratadine ratiopharm 2,5 mg munsönderfallande tabletter 29581 FI - RATIOPHARM GMBH
Desloratadine ratiopharm 2,5 mg smeltetabletter 11-8180 NO - RATIOPHARM GMBH
Desloratadine ratiopharm 2,5 mg tabletti, suussa hajoava 29581 FI - RATIOPHARM GMBH
Desloratadine ratiopharm 5 mg munndreifitöflur IS/1/13/079/01 IS - RATIOPHARM GMBH
Desloratadine ratiopharm 5 mg munsönderfallande tabletter 29582 FI - RATIOPHARM GMBH

Desloratadine ratiopharm 5 mg smeltetabletter 11-8181 NO - RATIOPHARM GMBH
Desloratadine ratiopharm 5 mg tabletti, suussa hajoava 29582 FI - RATIOPHARM GMBH
Desloratadine ratiopharm, 0,5 mg/ml, roztwór doustny 21410 PL - RATIOPHARM GMBH
Desloratadine Sandoz 0,5 mg/ml, drank RVG 109202 NL - SANDOZ B.V.
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 167-6 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 168-2 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 169-9 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 170-7 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 171-3 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 173-6 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 174-2 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 175-9 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 176-5 FR - SANDOZ
DESLORATADINE SANDOZ 0,5 mg/ml, solution buvable 273 177-1 FR - SANDOZ
Desloratadine Sandoz 022141 CY - SANDOZ GMBH
Desloratadine Sandoz 022142 CY - SANDOZ GMBH
Desloratadine Sandoz 48329 DK - SANDOZ A/S
Desloratadine Sandoz 48330 DK - SANDOZ A/S
DESLORATADINE SANDOZ 5 mg comprimé pelliculé 275 897-1 FR - SANDOZ
DESLORATADINE SANDOZ 5 mg comprimé pelliculé 275 898-8 FR - SANDOZ
DESLORATADINE SANDOZ 5 mg comprimé pelliculé 275 899-4 FR - SANDOZ
DESLORATADINE SANDOZ 5 mg comprimé pelliculé 275 900-2 FR - SANDOZ
Desloratadine Sandoz 5 mg filmdragerade tabletter 45779 SE - SANDOZ A/S
Desloratadine Sandoz 5 mg filmuhúðaðar töflur IS/1/12/053/01 IS - SANDOZ A/S

Desloratadine Sandoz 5 mg kalvopäällysteinen tabletti 29573 FI - SANDOZ A/S
Desloratadine Sandoz 5 mg, filmomhulde tabletten RVG 109201 NL - SANDOZ B.V.
Desloratadine Smelttablet 2,5 mg Teva, orodispergeerbare tabletten RVG 109206 NL - TEVA NEDERLAND B.V.
Desloratadine Smelttablet 5 mg Teva, orodispergeerbare tabletten RVG 109207 BE - TEVA NEDERLAND B.V.
Desloratadine Sopharma 0,5 mg/ml geriamasis tirpalas LT/1/15/3736/001 LT - SOPHARMA AD
Desloratadine Sopharma 0,5 mg/ml oraaliliuos 32430 FI - SOPHARMA AD
Desloratadine Sopharma 0,5 mg/ml oral lösning 51396 SE - SOPHARMA AD
Desloratadine Sopharma 0,5 mg/ml roztwór doustny 22747 PL - SOPHARMA AD
Desloratadine Sopharma 0,5 mg/ml suukaudne lahus 874615 EE - SOPHARMA AD
Desloratadine Sopharma 0,5 mg/ml šķīdums iekšķīgai lietošanai 15-0132 LV - SOPHARMA AD
Desloratadine Sopharma 5 mg apvalkotās tabletes 16-0008 LV - SOPHARMA AD
Desloratadine Sopharma 5 mg apvalkotās tabletes 16-0008 LV - SOPHARMA AD
Desloratadine Sopharma 5 mg film-coated tablets 33349 FI - SOPHARMA AD
Desloratadine Sopharma 5 mg film-coated tablets 33349 FI - SOPHARMA AD
Desloratadine Sopharma 5 mg filmdragerade tabletter 52877 SE - SOPHARMA AD
Desloratadine Sopharma 5 mg filmdragerade tabletter 52877 SE - SOPHARMA AD
Desloratadine Sopharma 5 mg õhukese polümeerikattega tabletid 901016 EE - SOPHARMA AD
Desloratadine Sopharma 5 mg õhukese polümeerikattega tabletid 901016 EE - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/002 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/002 LT - SOPHARMA AD

Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/003 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/003 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/004 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/004 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/005 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/005 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/006 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/006 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/007 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plevele dengtos tabletes LT/1/16/3873/007 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plėvele dengtos tabletės LT/1/16/3873/001 LT - SOPHARMA AD
Desloratadine Sopharma 5 mg plėvele dengtos tabletės LT/1/16/3873/001 LT - SOPHARMA AD
Desloratadine Sopharma, 5 mg, tabletki powlekane 23119 PL - SOPHARMA AD
Desloratadine Sopharma, 5 mg, tabletki powlekane 23119 PL - SOPHARMA AD
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/13 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/14 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/15 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/16 HU - STADA

ARZNEIMITTEL AG
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/17 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 0,5 mg/ml belsőleges oldat OGYI-T-22041/18 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/01 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/02 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/03 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/04 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/05 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/06 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/07 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/08 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/09 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/10 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/11 HU - STADA ARZNEIMITTEL AG
Desloratadine Stada 5 mg filmtabletta OGYI-T-22041/12 HU - STADA ARZNEIMITTEL AG
Desloratadine Teva 0,5 mg/ml drank BE437342 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva 0,5 mg/ml perorální roztok 24/250/13-C CZ - TEVA PHARMACEUTICALS CR, S.R.O.
Desloratadine Teva 0,5 mg/ml, drank RVG 110902 NL - TEVA NEDERLAND B.V.

Desloratadine Teva 0,5 mg/ml, drank RVG 110903 NL - TEVA NEDERLAND B.V.
Desloratadine Teva 0,5 mg/ml, solution buvable BE437342 BE - TEVA PHARMA BELGIUM N.V./S.A
DESLORATADINE TEVA 0,5mg/ml LÖSUNG ZUM EINNEHMEN BE437342 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva 0.5 mg/ml peroralen raztvor 20130221 BG - TEVA PHARMACEUTICALS BULGARIA EOOD
Desloratadine Teva 2,5 mg comprimés orodispersibles BE419596 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva 2,5 mg Schmelztabletten BE419596 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva 5 mg orodispergeerbare tabletten BE419605 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva 5 mg Schmelztabletten BE419605 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratadine Teva Oral Solution 0.5 mg/ml PL 00289/1699 UK - TEVA UK LIMITED
Desloratadine Teva Pharma B.V. 0,5 mg/ml posimo dialyma 21782 CY - TEVA PHARMA B.V.
Desloratadine Teva Pharma B.V. 0,5 mg/ml posimo dialyma 49652/13-6-2014 GR - TEVA PHARMA B.V.
DESLORATADINE TEVA SANTE 5 mg, comprimé pelliculé NL50684 FR - TEVA SANTÉ
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 263 5 6 FR - LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 264 1 7 FR - LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 265 8 5 FR - LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 266 4 6 FR - LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 267 0 7 FR - LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé

pelliculé 34009 273 268 7 5 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 269 3 6 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 270 1 8 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 271 8 6 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 272 4 7 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 273 273 0 8 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 584 801 9 5 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 584 802 5 6 FR -
LABORATOIRES URGO
DESLORATADINE URGO 5 mg, comprimé pelliculé 34009 584 803 1 7 FR -
LABORATOIRES URGO
Desloratadine Zentiva 0,5 mg/ml geriamasis tirpalas LT/1/12/2847/001 LT -
ZENTIVA, K.S.
Desloratadine Zentiva 0,5 mg/ml geriamasis tirpalas LT/1/12/2847/002 LT -
ZENTIVA, K.S.
Desloratadine Zentiva 0,5 mg/ml geriamasis tirpalas LT/1/12/2847/003 LT -
ZENTIVA, K.S.
Desloratadine Zentiva 0,5 mg/ml geriamasis tirpalas LT/1/12/2847/004 LT -
ZENTIVA, K.S.
Desloratadine Zentiva 0,5 mg/ml geriamasis tirpalas LT/1/12/2847/005 LT -
ZENTIVA, K.S.
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 616 3 4 FR -
SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 618 6 3 FR -
SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 619 2 4 FR -
SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml,

solution buvable 34009 217 620 0 6 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 621 7 4 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 622 3 5 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 624 6 4 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 625 2 5 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217 626 9 3 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 0,5 mg/ml, solution buvable 34009 217615 7 3 FR - SANOFI-AVENTIS FRANCE
Desloratadine Zentiva 0,5 mg/ml, suukaudne lahus 774512 EE - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/006 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/007 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/008 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/009 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/010 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/011 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/012 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/013 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/014 LT - ZENTIVA, K.S.
Desloratadine Zentiva 5 mg plėvele dengtos tabletės LT/1/12/2847/015 LT - ZENTIVA,

K.S.
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 480 4 8 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 481 0 9 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 482 7 7 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 486 2 8 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 487 9 6 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 217 488 5 7 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 580 922 6 8 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 580 923 2 9 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 34009 580 924 9 7 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 340092 17 48338 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 340092 17 489 1 8 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 340092 17 4922 9 **FR** - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 340092 174 8567 FR - SANOFI-AVENTIS FRANCE
DESLORATADINE ZENTIVA 5 MG, COMPRIME PELLICULE 340092 174 916 8 **FR** - SANOFI-AVENTIS FRANCE
Desloratadine Zentiva 5 mg, õhukese polümeerikattega tabletid 774612 EE - ZENTIVA, K.S.
DESLORATADINE ZYDUS 5 mg, comprimé pelliculé 34009 268 610 2 5 FR - ZYDUS FRANCE
DESLORATADINE ZYDUS 5 mg, comprimé pelliculé 34009 268 611 9 3 FR - ZYDUS

FRANCE
DESLORATADINE ZYDUS 5 mg, comprimé pelliculé 34009 268 612 5 4 FR - ZYDUS FRANCE
DESLORATADINE ZYDUS 5 mg, comprimé pelliculé 34009 268 613 1 5 FR - ZYDUS FRANCE
Desloratadine "Hexal" 48331 DK - HEXAL A/S
Desloratadine "Hexal" 48332 DK - HEXAL A/S
Desloratadine/Genepharm 0.5 mg/ml posimo dialyma 31215 GR - GENEPHARM S.A.
Desloratadine/Genepharm 2.5 mg diskia diaspeiromena sto stoma 31212 GR - GENEPHARM S.A.
Desloratadine/Genepharm 5 mg diskia diaspeiromena sto stoma 31214 GR - GENEPHARM S.A.
Desloratadine/Genepharm 5 mg diskia epikalimena me lepto ymenio 31213 GR - GENEPHARM S.A.
Desloratadyna Apotex, 5 mg, tabletki powlekane 21023 PL - APOTEX EUROPE BV
Desloratatine Teva 2,5 mg orodispergeerbare tabletten BE419596 BE - TEVA PHARMA BELGIUM N.V./S.A
Desloratatine Teva 5 mg orodispergeerbare tabletten BE419605 BE - TEVA PHARMA BELGIUM N.V./S.A
Deslordis 5 mg filmom obložene tablete HR-H-465680296 HR - PLIVA HRVATSKA D.O.O.
Deslorius 0,5 mg/ml posimo dialyma 67125/11-9-13 GR - ALET PHARMACEUTICALS SA
Deslorius 2,5 mg diskia diaspeiromena sto stoma 67123/11-9-13 GR - ALET PHARMACEUTICALS SA
Deslorius 5 mg diskia diaspeiromena sto stoma 67124/11-9-13 GR - ALET PHARMACEUTICALS SA
Deslorius 5 mg diskia epikalimena me lepto ymenio 67122/11-9-13 GR - ALET PHARMACEUTICALS SA
Dynid 0,5 mg/ml soluție orală 4507/2012/01 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală 4507/2012/02 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală

4507/2012/03 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală
4507/2012/04 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală
4507/2012/05 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală
4507/2012/06 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală
4507/2012/07 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 0,5 mg/ml soluție orală
4507/2012/08 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/01 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/02 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/03 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/04 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/05 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/06 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/07 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/08 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/09 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg comprimate 4684/2012/10 RO - GLENMARK PHARMACEUTICALS S.R.O.
Dynid 5 mg Tablets PL 33882/0021 UK - GLENMARK PHARMACEUTICALS S.R.O.
Dynid, 0,5 mg/ml, roztwór doustny 20075 PL - GLENMARK PHARMACEUTICALS S.R.O.
Dynid, 5 mg, tabletki 20191 PL - GLENMARK PHARMACEUTICALS S.R.O.
EFESTAD 5 mg compresse rivestite con film 040855013 IT - CRINOS S.P.A.
EFESTAD 5 mg compresse rivestite con film 040855025 IT - CRINOS S.P.A.
EFESTAD 5 mg compresse rivestite con film 040855037 IT - CRINOS S.P.A.
EFESTAD 5 mg compresse rivestite con film 040855049 IT - CRINOS S.P.A.

Efestad 5 mg film-coated tablets PA0126/223/001 IE - CLONMEL HEALTHCARE LTD.
Efestad 5 mg filmirani tabletki 20120172 BG - STADA ARZNEIMITTEL AG
Esradin 5 mg filmom obalené tablety 24/0111/15-S SK - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmsko obložene tablete 5363-I-488/13 SI - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmsko obložene tablete 5363-I-489/13 SI - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/01 HU - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/02 HU - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/03 HU - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/04 HU - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/05 HU - KRKA, D.D., NOVO MESTO
Esradin 5 mg filmtabletta OGYI-T-21941/06 HU - KRKA, D.D., NOVO MESTO
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/001 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/002 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/003 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/004 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/005 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/006 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/007 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/008 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/009 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos

tabletės LT/1/15/3700/010 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/011 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/012 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg burnoje disperguojamos tabletės LT/1/15/3700/013 LT - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg muté dispergéjamás tabletes 15-0072 LV - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg mutē disperģējamās tabletes 15-0071 LV - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg suus dispergeeruvad tabletid 867115 EE - ACTAVIS GROUP PTC EHF.
Flynise 2,5 mg szájban diszpergálódó tabletta OGYI-T-22796/01-09 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/014 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/015 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/016 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/017 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/018 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/019 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/020 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/021 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/022 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos

tabletės LT/1/15/3700/023 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/024 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/025 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg burnoje disperguojamos tabletės LT/1/15/3700/026 LT - ACTAVIS GROUP PTC EHF.
Flynise 5 mg film-coated tablets 201500363 BG - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmdragerade tabletter 50926 SE - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmdrasjerte tabletter 14-10010 NO - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/01 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/02 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/03 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/04 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/05 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/06 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/07 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/08 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/09 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmtabletta OGYI-T-22794/10 HU - ACTAVIS GROUP PTC EHF.
Flynise 5 mg filmuhúðaðar töflur IS/1/15/022/01 IS - ACTAVIS GROUP PTC EHF.
Flynise 5 mg kalvopäällysteiset tabletit 32142 FI - ACTAVIS GROUP PTC EHF.
Flynise 5 mg muté dispergéjamás tabletes 15-0074 LV - ACTAVIS GROUP PTC EHF.
Flynise 5 mg mutē dispergējamās tabletes 15-0073 LV - ACTAVIS GROUP PTC EHF.
Flynise 5 mg Orodispersible Tablets PA 1380.162.1 IE - ACTAVIS GROUP PTC EHF.
Flynise 5 mg suus dispergeeruvad tabletid 867215 EE - ACTAVIS GROUP PTC EHF.
Flynise 5 mg szájban diszpergálódó tabletta

OGYI-T-22796/10-18 HU - ACTAVIS GROUP PTC EHF.
Flynise 53724 DK - ACTAVIS GROUP PTC EHF.
Flynise 53725 DK - ACTAVIS GROUP PTC EHF.
Flynise 53752 DK - ACTAVIS GROUP PTC EHF.
Flynise 5mg, tabletki pwolekane 22440 PL - ACTAVIS GROUP PTC EHF.
Flynise MA 628/12401 MT - ACTAVIS GROUP PTC EHF.
Flynise MA 628/12402 MT - ACTAVIS GROUP PTC EHF.
GOLDESIN 20338 PL - TACTICA PHARMACEUTICAL SP. Z O.O.
GOLDESIN, oral solution, 0,5mg/ml 20339 PL - TACTICA PHARMACEUTICAL SP. Z O.O.
Hitaxa fast, 2,5 mg, tabletki ulegajace rozpadowi w jamie ustnej 20223 PL - ADAMED
Hitaxa fast, 5 mg, tabletki ulegające rozpadowi w jamie ustnej 20224 PL - ADAMED
Hitaxa, 0,5 mg/ml, roztwór doustny 20360 PL - ADAMED
Hitaxa, 2,5 mg, tabletki ulegające rozpadowi w jamie ustnej 20256 PL - ADAMED
Hitaxa, 5 mg, tabletki ulegające rozpadowi w jamie ustnej 20257 PL - ADAMED
Jovesto 0,5 MG/ML peroralen raztvor 20120370 BG - SANDOZ PHARMACEUTICALS D.D.
JOVESTO 0,5 MG/ML PERORÁLNÍ ROZTOK 24/411/12-C CZ - SANDOZ S.R.O.
JOVESTO 0,5 mg/ml perorálny roztok 24/0203/12-S SK - SANDOZ PHARMACEUTICALS D.D.
Jovesto 20358 PL - SANDOZ GMBH
Jovesto 48337 DK - SANDOZ A/S
Jovesto 48338 DK - SANDOZ A/S
Jovesto 5 mg film-coated tablets 20120371 BG - SANDOZ PHARMACEUTICALS D.D.
JOVESTO 5 mg filmom obalené tablety 24/0202/12-S SK - SANDOZ PHARMACEUTICALS D.D.
JOVESTO 5 MG POTAHOVANÉ TABLETY 24/410/12-C CZ - SANDOZ S.R.O.
JOVESTO, 0,5 MG/ML, ROZTWÓR DOUSTNY 20359 PL - SANDOZ GMBH
Laboratoria PolfaŁódź ALERGO MAX 20478 PL - BIO PROFIL POLSKA SP Z OO
Lentrica 48341 DK - SANDOZ A/S

Lentrica 5 mg filmsko obložene tablete **5363-I-939/12 SI** - LEK PHARMACEUTICALS D.D. LJUBLJANA
Lorabel 0,5 mg/ml peroralna raztopina **5363-I-74/14 SI** - BELUPO D.O.O.
Lordestin 0,5 mg/ml belsöleges oldat **OGYI-T-22038/06 HU** - GEDEON RICHTER PLC.
Lordestin 0,5 mg/ml belsöleges oldat **OGYI-T-22038/07 HU** - GEDEON RICHTER PLC.
Lordestin 0,5 mg/ml belsöleges oldat **OGYI-T-22038/08 HU** - GEDEON RICHTER PLC.
Lordestin 0,5 mg/ml soluţie orală **6327/2014/01 RO** - GEDEON RICHTER ROMÂNIA S.A.
Lordestin 0,5 mg/ml soluţie orală **6327/2014/02 RO** - GEDEON RICHTER ROMÂNIA S.A.
Lordestin 0,5 mg/ml soluţie orală **6327/2014/03 RO** - GEDEON RICHTER ROMÂNIA S.A.
LORDESTIN 5 mg comprimate filmate **8182/2015/01 RO** - GEDEON RICHTER ROMÂNIA S.A.
LORDESTIN 5 mg comprimate filmate **8182/2015/02 RO** - GEDEON RICHTER ROMÂNIA S.A.
LORDESTIN 5 mg comprimate filmate **8182/2015/03 RO** - GEDEON RICHTER ROMÂNIA S.A.
LORDESTIN 5 mg comprimate filmate **8182/2015/04 RO** - GEDEON RICHTER ROMÂNIA S.A.
LORDESTIN 5 mg comprimate filmate **8182/2015/05 RO** - GEDEON RICHTER ROMÂNIA S.A.
Lordestin 5 mg filmtabletta OGYI-T-22038/01 HU - GEDEON RICHTER PLC.
Lordestin 5 mg filmtabletta OGYI-T-22038/02 HU - GEDEON RICHTER PLC.
Lordestin 5 mg filmtabletta OGYI-T-22038/03 HU - GEDEON RICHTER PLC.
Lordestin 5 mg filmtabletta OGYI-T-22038/04 HU - GEDEON RICHTER PLC.
Lordestin 5 mg filmtabletta OGYI-T-22038/05 HU - GEDEON RICHTER PLC.
Lordestin, 0,5 mg/ml, roztwór doustny **22110 PL** - GEDEON RICHTER POLSKA SP. Z. O.O.

Lordestin, 5 mg, tabletki powlekane 20074 PL - GEDEON RICHTER POLSKA SP. Z. O.O.
LOTERA 0000 PT - SVUS PHARMA A.S.
LOTERA 5 mg filmom obalené tablety 24/0038/12-S SK - SVUS PHARMA A.S.
LOTERA 5 mg potahované tablety 24/506/12-C CZ - SVUS PHARMA A.S.
RHINOHELP 2,5 mg diskia diaspeiromena sto stoma 24569/03-12-2015 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
RHINOHELP 2,5 mg diskia diaspeiromena sto stoma 24569/03-12-2015 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
RHINOHELP 5 mg diskia diaspeiromena sto stoma 24569/03-12-2015 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
RHINOHELP 5 mg diskia diaspeiromena sto stoma 24569/03-12-2015 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
RHINOHELP 5 mg diskia epikalimena me lepto ymenio 25654/15/11-03-2016 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
RHINOHELP 5 mg diskia epikalimena me lepto ymenio 25654/15/11-03-2016 GR - SPECIAL MEDICINES PHARMACEUTICAL PRODUCTS SINGLE-MEMBER PRIVATE COMPANY (PC)
Rinispes 0,5 mg/ml posimo dialyma 67134/11-09-2013 GR - SPECIFAR S.A.
Rinispes 5 mg diskia epikalimena me lepto ymenio 69066/11-9-13 GR - SPECIFAR S.A.
Suprodeslon, 0,5 mg/ml, roztwór doustny 20196 PL - S-LAB SP.ZO.O.
Suprodeslon, 5 mg, tabletki powlekane 20193 PL - S-LAB SP.ZO.O.
Teslor, 5 mg, tabletki powlekane 21598 PL - AFLOFARM FARMACJA POLSKA SP. Z O.O.
Valora, filmovertrukne tabletter 48322 DK - STADA ARZNEIMITTEL AG
Yosqiero 48339 DK - SANDOZ A/S
Yosqiero 48340 DK - SANDOZ A/S
Yosqiero 5 mg filmtabletta OGYI-T-22413/01 HU - SANDOZ HUNGÁRIA KFT
Yosqiero 5 mg filmtabletta OGYI-T-22413/02 HU - SANDOZ HUNGÁRIA KFT

Yosqiero 5 mg filmtabletta OGYI-T-22413/03 HU - SANDOZ HUNGÁRIA KFT **Yosqiero 5 mg filmtabletta OGYI-T-22413/04 HU** - SANDOZ HUNGÁRIA KFT **Yosqiero 5 mg õhukese polümeerikattega tabletid 786212 EE** - SANDOZ PHARMACEUTICALS D.D. **Yosqiero 5 mg õhukese polümeerkattega tabletid 786212 EE** - SANDOZ PHARMACEUTICALS D.D. , PRAC Rapporteur: Jean-Michel Dogné, "DLP 15/07/2016; 5 years"	
EMEA/H/C/PSUSA/00000963/201607 (desloratadine / pseudoephedrine) CAPS: **Aerinaze** (EMEA/H/C/000772) (desloratadine / pseudoephedrine sulphate), MAH: Merck Sharp & Dohme Limited, Rapporteur: Koenraad Norga, PRAC Rapporteur: Jean-Michel Dogné, "16 July 2012 to 15 July 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.8 of the SmPC and section 4 of the Package Leaflet: - to add the adverse reaction "abnormal behaviour" and "aggression" with a frequency unknown; - to add the adverse reaction "QT prolongation" in the table 'Other adverse reactions reported for desloratadine during the post-marketing period' with a frequency unknown. Update of section 4.4 of the SmPC and section 2 of the Package Leaflet: - to add a warning regarding convulsions. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00009329/201608 (vemurafenib) CAPS: **Zelboraf** (EMEA/H/C/002409) (vemurafenib), MAH: Roche Registration Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "7 August 2015 to 16 August 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus, the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): "Update of section 4.4 and 4.8 of the SmPC to add the adverse reactions Dupuytren's contracture and plantar fascial fibromatosis with common and uncommon frequency respectively. The Package leaflet is updated accordingly."

	The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010084/201608 (dabrafenib) CAPS: **Tafinlar** (EMEA/H/C/002604) (dabrafenib), MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "27 August 2015 to 26 August 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.4 of the SmPC to add a new warning on colitis and gastrointestinal perforation, update of section 4.8 of the SmPC to include as new adverse drug reactions 'photosensitivity reaction' with a 'common' frequency, 'colitis' and 'gastrointestinal perforation' with a 'common' frequency and 'myocarditis' with a 'not known' frequency. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010093/201608 (brimonidine (centrally authorised product only)) CAPS: **Mirvaso** (EMEA/H/C/002642) (brimonidine), MAH: GALDERMA INTERNATIONAL, Rapporteur: Filip Josephson, PRAC Rapporteur: Patrick Batty, "22/02/2016 to 21/08/2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation(s) for the above mentioned medicinal product(s), concerning the following change(s): Update of section 4.4 to add a warning on the risk of haemodynamic effects following laser therapy and update of 4.8 of the SmPC to add the adverse reactions 'bradycardia' with a frequency 'rare' and 'dizziness 'with frequency 'uncommon'. The Package leaflet is updated accordingly.
EMEA/H/C/PSUSA/00010409/201608 (panobinostat) CAPS: **Farydak** (EMEA/H/C/003725) (panobinostat), MAH: Novartis Europharm Ltd, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Julie Williams, "Changes to SmPC are needed in section 4.8 as follows: ADRs with a difference in frequency <1% between active arm and panobinostat arm are not listed (e.g. peripheral neuropathy and constipation known side effects of bortezomib treatment). (period: 23/02/2016 - 22/08/2016)"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Summary of Product Characteristics, Section 4.8 (Undesirable effects): New text is underlined and in bold, deleted text strike through: "Table 7 includes adverse drug reactions that occur due to the addition of panobinostat to the

	bortezomib and dexamethasone combination. The frequency category is reflecting the combination of all the agents i.e. panabinostat+bortezomib+dexamethasone. For adverse drug reactions that are related to bortezomib or dexamethasone treatment, please refer to their respective SmPC. Table 7 Panobinostat Aadverse drug reactions observed in multiple myeloma patients in the phase III study" The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.
EMEA/H/C/PSUSA/00010420/201608 (dinutuximab) CAPS: **Unituxin (SRD)** (EMEA/H/C/002800) (dinutuximab), MAH: United Therapeutics Europe Ltd, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Sabine Straus, "Update of section 4.4 of the SmPC to add a warning on the occurrence of transverse myelitis. Transverse myelitis is also added as an adverse drug reaction with the frequency "uncommon" in section 4.8 of the SmPC. The Package Leaflet is updated accordingly. In order to improve clarity of section 4 of the PL, it was also recommended to list the Posterior Reversible Encephalopathy Syndrome (PRES) at the beginning of the section and include the frequency of muscle weakness or inability to control urine as very common."	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.4 of the SmPC to add a warning on the occurrence of transverse myelitis. Transverse myelitis is also added as an adverse drug reaction with the frequency "uncommon" in section 4.8 of the SmPC. The Package Leaflet is updated accordingly. In order to improve clarity of section 4 of the PL, it was also recommended to list the Posterior Reversible Encephalopathy Syndrome (PRES) at the beginning of the section and include the frequency of muscle weakness or inability to control urine as very common. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP. The CHMP noted that the European Commission adopted the withdrawal of Unituxin on 20 March 2017.
EMEA/H/C/PSUSA/00010450/201608 (cobimetinib) CAPS: **Cotellic** (EMEA/H/C/003960) (cobimetinib), MAH: Roche Registration Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Sabine Straus, "24 February 2016 to 23 August 2016"	The CHMP, having considered in accordance with Article 28 of Regulation (EC) No 726/2004 the PSUR on the basis of the PRAC recommendation and the PRAC assessment report as appended, recommends by consensus the variation to the terms of the marketing authorisation for the above mentioned medicinal product, concerning the following change: Update of section 4.2, 4.4 and 4.8 of the SmPC to add the risks of Haemorrhage and

	Rhabdomyolysis/ CPK elevations, warnings and dose recommendations. The Package leaflet is updated accordingly. The Icelandic and the Norwegian CHMP members agree with the above-mentioned recommendation of the CHMP.

B.4. EPARs / WPARs

LifeGlobal Media - human serum albumin - EMEA/H/D/004287 Applicant: BSI Group, Human serum albumin as ancillary substance in media and solutions used in the area of human assisted reproductive procedures, Ancillary medicinal substance/blood derivative substance (Article 1(4)/1(4a) of both Directives No 93/42/EEC and 90/385/EEC)	adopted.
Emtricitabine/tenofovir disoproxil Krka d.d. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004686 Applicant: KRKA, d.d., Novo mesto, treatment of HIV-1 infection, Generic, Duplicate, Duplicate of Emtricitabine/Tenofovir disoproxil Krka, Generic application (Article 10(1) of Directive No 2001/83/EC)	adopted.
Natpar - parathyroid hormone - EMEA/H/C/003861, Orphan Applicant: Shire Pharmaceuticals Ireland Ltd, treatment of hypoparathyroidism, Known active substance (Article 8(3) of Directive No 2001/83/EC)	adopted.
Pemetrexed Hospira UK Limited - pemetrexed - EMEA/H/C/004488 Applicant: Hospira UK Limited, treatment of malignant pleural mesothelioma and non-small cell lung cancer, Generic, Duplicate, Generic of Alimta, Duplicate of Pemetrexed ditromethamine Hospira (WD), Generic application (Article 10(1) of Directive No 2001/83/EC)	adopted.
Roteas - edoxaban - EMEA/H/C/004339 Applicant: Daiichi Sankyo Europe GmbH, prevention of stroke; embolism and treatment of venous thromboembolism, Informed consent application (Article 10c of Directive No 2001/83/EC)	adopted.
Varuby - rolapitant - EMEA/H/C/004196 Applicant: Tesaro UK Limited, prevention of	adopted.

nausea and vomiting, New active substance (Article 8(3) of Directive No 2001/83/EC)	

B.5. TYPE II VARIATION, WORKSHARING PROCEDURE OUTCOMES

Disclosure of scopes related to Chemistry, Manufacturing, and Controls cannot be released at present time as these contain commercially confidential information.

B.5.1. CHMP assessed procedures scope: Pharmaceutical aspects

Armisarte - pemetrexed - EMEA/H/C/004109/II/0008/G MAH: Actavis Group PTC ehf, Rapporteur: Alar Irs Request for Supplementary Information adopted on 09.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Azarga - brinzolamide / timolol - EMEA/H/C/000960/II/0035/G MAH: Alcon Laboratories (UK) Ltd, Rapporteur: Hanne Lomholt Larsen Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Bexsero - meningococcal group B vaccine (rDNA, component, adsorbed) - EMEA/H/C/002333/II/0048 MAH: GSK Vaccines S.r.l, Rapporteur: Kristina Dunder Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Biopoin - epoetin theta - EMEA/H/C/001036/II/0036/G MAH: TEVA GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 23.03.2017, 19.01.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Envarsus - tacrolimus - EMEA/H/C/002655/II/0008/G MAH: Chiesi Farmaceutici S.p.A., Rapporteur: John Joseph Borg Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Eporatio - epoetin theta - EMEA/H/C/001033/II/0035/G MAH: ratiopharm GmbH, Rapporteur: Alexandre Moreau Request for Supplementary Information adopted	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

on 23.03.2017, 19.01.2017.	
Firazyr - icatibant - EMEA/H/C/000899/II/0036/G, Orphan MAH: Shire Orphan Therapies GmbH, Rapporteur: Kristina Dunder Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Fortacin - lidocaine / prilocaine - EMEA/H/C/002693/II/0015 MAH: Plethora Solutions Ltd., Rapporteur: Concepcion Prieto Yerro Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Hizentra - human normal immunoglobulin - EMEA/H/C/002127/II/0075 MAH: CSL Behring GmbH, Rapporteur: Jan Mueller-Berghaus Request for Supplementary Information adopted on 23.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0033/G MAH: Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Inhixa - enoxaparin sodium - EMEA/H/C/004264/II/0004/G MAH: Techdow Europe AB, Duplicate, Duplicate of Thorinane, Rapporteur: Andrea Laslop Opinion adopted on 02.03.2017.	Positive Opinion adopted by consensus on 02.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kalydeco - ivacaftor - EMEA/H/C/002494/II/0053/G, Orphan MAH: Vertex Pharmaceuticals (Europe) Ltd., Rapporteur: Concepcion Prieto Yerro Opinion adopted on 09.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Keytruda - pembrolizumab - EMEA/H/C/003820/II/0020/G MAH: Merck Sharp & Dohme Limited, Rapporteur: Daniela Melchiorri Opinion adopted on 09.03.2017.	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lonquex - lipegfilgrastim - EMEA/H/C/002556/II/0030/G MAH: Sicor Biotech UAB, Rapporteur: Greg Markey Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

MabThera - rituximab - EMEA/H/C/000165/II/0129/G MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 02.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
MabThera - rituximab - EMEA/H/C/000165/II/0130/G MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac Request for Supplementary Information adopted on 02.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Nucala - mepolizumab - EMEA/H/C/003860/II/0007 MAH: GlaxoSmithKline Trading Services, Rapporteur: Nithyanandan Nagercoil Request for Supplementary Information adopted on 23.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Nuwiq - simoctocog alfa - EMEA/H/C/002813/II/0012/G MAH: Octapharma AB, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2017. Request for Supplementary Information adopted on 19.01.2017, 13.10.2016, 14.07.2016.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Omnitrope - somatropin - EMEA/H/C/000607/II/0045 MAH: SANDOZ GmbH, Rapporteur: Johann Lodewijk Hillege Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Orencia - abatacept - EMEA/H/C/000701/II/0106/G MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola Opinion adopted on 16.03.2017. Request for Supplementary Information adopted on 02.02.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Ratiograstim - filgrastim - EMEA/H/C/000825/II/0053/G MAH: ratiopharm GmbH, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
ReFacto AF - moroctocog alfa - EMEA/H/C/000232/II/0139 MAH: Pfizer Limited, Rapporteur: Hanne Lomholt Larsen	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

Request for Supplementary Information adopted on 23.03.2017.	
Revestive - teduglutide - EMEA/H/C/002345/II/0035, Orphan MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Senshio - ospemifene - EMEA/H/C/002780/II/0010 MAH: Shionogi Limited, Rapporteur: Paula Boudewina van Hennik Opinion adopted on 02.03.2017. Request for Supplementary Information adopted on 10.11.2016, 04.08.2016.	Positive Opinion adopted by consensus on 02.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Siklos - hydroxycarbamide - EMEA/H/C/000689/II/0031/G, Orphan MAH: Addmedica, Rapporteur: Koenraad Norga Request for Supplementary Information adopted on 23.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Tevagrastim - filgrastim - EMEA/H/C/000827/II/0063/G MAH: TEVA GmbH, Duplicate, Duplicate of Biograstim, Rapporteur: Outi Mäki-Ikola Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Trisenox - arsenic trioxide - EMEA/H/C/000388/II/0063/G MAH: Teva B.V., Rapporteur: Alexandre Moreau Request for Supplementary Information adopted on 23.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Umbipro (TM) - chlorhexidine - EMEA/H/W/003799/II/0002/G MAH: GlaxoSmithKline Trading Services, Rapporteur: Patrick Salmon Request for Supplementary Information adopted on 23.03.2017, 26.01.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Zostavax - shingles (herpes zoster) vaccine (live) - EMEA/H/C/000674/II/0109/G MAH: MSD Vaccins, Rapporteur: Jan Mueller-Berghaus Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1099/G **Neulasta-** **EMEA/H/C/000420/WS1099/0092/G**	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

Ristempa- **EMEA/H/C/003910/WS1099/0009/G** MAH: Amgen Europe B.V., Lead Rapporteur: Robert James Hemmings Request for Supplementary Information adopted on 16.03.2017.	
WS1125/G **Helixate NexGen-** **EMEA/H/C/000276/WS1125/0187/G** **KOGENATE Bayer-** **EMEA/H/C/000275/WS1125/0195/G** MAH: Bayer Pharma AG, Lead Rapporteur: Jan Mueller-Berghaus Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.2. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Aclasta - zoledronic acid - **EMEA/H/C/000595/II/0068** MAH: Novartis Europharm Ltd, Rapporteur: Kristina Dunder, "Update of section 4.8 of the SmPC in order to add the adverse reaction hypophosphataemia with a frequency 'rare' based on post-marketing spontaneous reports and internal databases. The package leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to remove the lower level term 'shoulder pain' in the SmPC which is covered by the corresponding preferred term 'musculosketal pain', to update the list of local representatives in the Package Leaflet and to bring the product information in line with the latest QRD template version 10." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Afinitor - everolimus - **EMEA/H/C/001038/II/0051/G** MAH: Novartis Europharm Ltd, Rapporteur: Harald Enzmann, "C.I.13 Submission of the final clinical study report of study RAD001J2301: A randomized phase-III, double-blind, placebo-controlled multicenter trial of everolimus in combination with trastuzumab and paclitaxel, as first line therapy in women with HER2 positive locally advanced or metastatic breast cancer C.I.13 Submission of the final clinical study report of study RAD001W2301: A randomized Phase III, double-blind, placebo-controlled multicenter trial of everolimus in combination	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

with trastuzumab and vinorelbine, in pretreated women with HER2/neu over-expressing locally advanced or metastatic breast cancer In addition, the MAH included a report on exposure-response relationship combining data from these two trials." Opinion adopted on 16.03.2017.	
Cerdelga - eliglustat - EMEA/H/C/003724/II/0010, Orphan MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege, "Update of section 5.1 of the SmPC in order to update the safety and efficacy of eliglustat from studies in the GD1 patient population (studies ENGAGE & EDGE). In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet for Bulgaria and Romania." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0081 MAH: GSK Biologicals SA, Rapporteur: Bart Van der Schueren, "To submit the final effectiveness results of clinical study HPV-040, a community randomized study conducted in Finland to evaluate the effectiveness of two vaccination strategies for 12 -15 year old early adolescents using Cervarix, i.e., to vaccinate female adolescents only, or to vaccinate female and male adolescents." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 15.12.2016, 15.09.2016.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Effentora - fentanyl - EMEA/H/C/000833/II/0045 MAH: Teva B.V., Rapporteur: Martina Weise, "Update of sections 4.4 and 4.5 of the SmPC in order to add a warning on increased risk of increased depressant effects with the concomitant use of alcohol and possibility of a fatal outcome with concomitant use of other CNS depressants following a cumulative review on spontaneous reporting and literature review of these risks. The package leaflet has been updated accordingly.	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

In addition, the marketing authorisation holder took the opportunity to introduce editorial clarifications in Annex I and Annex IIIB and changes in accordance to QRD template 10." Opinion adopted on 09.03.2017.	
Enbrel - etanercept - EMEA/H/C/000262/II/0204 MAH: Pfizer Limited, Rapporteur: Robert James Hemmings, "Update of section 4.8 of the SmPC in order to change the frequency category of the ADR 'elevated liver enzymes' from rare to uncommon and to add some further details on the frequency of elevated liver enzymes reported ADRs with etanercept in double-blind controlled trials with or without concomitant methotrexate use, following the assessment of Enbrel (etanercept) PSUSA/00001295/201602.). The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.4 of the SmPC on traceability of biological medicinal products as requested by the CHMP, to make a small correction in section 6 of the 50 mg solution for injection in a pre-filled pen Package Leaflet and to bring the PI in line with the latest QRD template version 10." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
EVOTAZ - atazanavir / cobicistat - EMEA/H/C/003904/II/0010 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Bruno Sepodes, "Update of section 5.1 of the SmPC with Week 144 resistance data of study GS-US-216-0114 submitted in the context of the MAA. In addition, for clarification purposes, the MAH proposed to use the specific designation of tenofovir disoproxil fumarate throughout the EVOTAZ Product Information (PI) to differentiate this pharmaceutical entity from the tenofovir alafenamide (for which no studies with EVOTAZ have been conducted). Consequently section 4.5 of the SmPC was updated to reflect the expected pharmacokinetic effects of the concomitant administration of tenofovir alafenamide and EVOTAZ. Finally, the MAH took this opportunity to implement QRD version 10." Opinion adopted on 16.03.2017. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 19.01.2017, 29.09.2016.	
EVRA - ethinylestradiol / norelgestromin - EMEA/H/C/000410/II/0041 MAH: Janssen-Cilag International NV, Rapporteur: Paula Boudewina van Hennik, "Update of sections 4.3 and 4.5 of the SmPC in order to add a contraindication for patients receiving drug combinations with Direct-acting antiviral (DAA) agents that contain paritaprevir/ritonavir, ombitasvir, and/or dasabuvir as these DAAs have the potential for a drug-drug interaction with ethinyl estradiol (EE)-containing combined hormonal contraceptives resulting in ALT elevations. The Package Leaflet has been updated accordingly." Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Hetlioz - tasimelteon - EMEA/H/C/003870/II/0007, Orphan MAH: Vanda Pharmaceuticals Ltd., Rapporteur: Greg Markey, PRAC Rapporteur: Adam Przybylkowski, "Submission of the final report from Study VEC-162-3T3 NRU-PT, listed as a category 3 study in the Risk Management Plan. The Marketing Authorisation Holder has evaluated the phototoxicity potential of tasimelteon and its main metabolites (post authorisation measure; MEA 004), by conducting programme of three studies: Study VCR-TMI-121012 was conducted to determine the molar extinction coefficient for tasimelteon and its main metabolites. Studies TAJ0044 and TAJ0045 were conducted to assess the phototoxic potential of Tasimelteon metabolites M12 and M14 and Tasimelteon-phenol (M3 without the glucuronidation) and M3, respectively, in an in vitro neutral red uptake test using balb/c 3T3, clone 31, fibroblast cells." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0032 MAH: Baxalta Innovations GmbH, Rapporteur: Jan Mueller-Berghaus, "Update of section 4.2 and 4.8 of the SmPC in order to add information on infusion site leakage. The Package Leaflet is updated accordingly.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	
Invokana - canagliflozin - EMEA/H/C/002649/II/0026 MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, "Update of section 4.4 of the SmPC in order to update the safety information: the term 'and fatal' is added when describing the Diabetic Ketoacidosis cases that have been reported. The Package Leaflet is updated accordingly: term 'rare but serious, sometimes life-threatening and fatal' is added when describing Diabetic Ketoacidosis. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kuvan - sapropterin - EMEA/H/C/000943/II/0046, Orphan MAH: BioMarin International Limited, Rapporteur: Patrick Salmon, "Update of section 4.5 to delete the statement that no interaction studies have been performed and section 5.2 to reflect the relevant results of in vitro pharmacokinetic drug interactions studies BMN162-14-021, 022, 023, BMN162-15-036 and 101. In addition, the MAH took the opportunity of this procedure to improve the wording of section 4.2 and implement minor administrative changes in the SmPC." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Kuvan - sapropterin - EMEA/H/C/000943/II/0048/G, Orphan MAH: BioMarin International Limited, Rapporteur: Patrick Salmon, "Update of section 4.9 to add information regarding shortening of QT interval at high doses following review of	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

data of study QTC-001. Submission of the clinical study report EMR700773-004 (pilot study assessing the effect of sapropterin on cognitive abilities, study prematurely terminated due to enrolment issues) In addition, the MAH took the opportunity of this procedure to clarify the wording of section 4.2 and section 3 of the PL." Request for Supplementary Information adopted on 09.03.2017.	
Kyprolis - carfilzomib - EMEA/H/C/003790/II/0010, Orphan MAH: Amgen Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, "Submission of the final report from the physiologically-based pharmacokinetic (PBPK) model predicting the potential effect of carfilzomib at doses of 56 and 70 mg/m2 on the pharmacokinetics of CYP3A substrate midazolam, in order to fulfil the post-approval commitment (REC) issued during the review of variation EMEA/H/C/003790/II/01." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897/II/0003 MAH: Les Laboratoires Servier, Rapporteur: Paula Boudewina van Hennik, "Submission of the final report from the pharmacogenomics study (NP35044) of TAS-102 in patients with metastatic colorectal cancer refractory to standard chemotherapy (10040080) in order to fulfil a Recommendation made at the time of the initial MA." Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Lumigan - bimatoprost - EMEA/H/C/000391/II/0052 MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Hanne Lomholt Larsen, "Update of section 4.8 to add 4 adverse events in the Eye disorders SOC in line with the Company Core Data Sheet. The Package Leaflet has been updated accordingly. Section 3 of the PL was also amended to improve clarity of instructions. In addition, the MAH took the opportunity to update the Product Information in line with the QRD template version 10 and implement the	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.

unique identifier 2D barcode." Request for Supplementary Information adopted on 16.03.2017.	
NovoThirteen - catridecacog - EMEA/H/C/002284/II/0018 MAH: Novo Nordisk A/S, Rapporteur: Joseph Emmerich, "Update of sections 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to consolidate the outcome of the clinical development programme (studies F13CD-3720 and F13CD-3835) submitted in procedures P46/014 and P46/016. Section 4.4 was updated to reflect that on-demand treatment was used in the extension study F13CD-3720, section 4.8 was updated to reflect the data on number of patients/paediatric patients and exposures, in section 5.1 the bleeding rate was updated, in section 5.2 minor amendments were made to the half-life of NovoThirteen. In addition, the Marketing authorisation holder (MAH) took the opportunity to update Annex II with minor administrative amendments in line with QRD template 9.1 and Annex III in line with QRD template version 10.0." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Prevenar 13 - pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) - EMEA/H/C/001104/II/0149 MAH: Pfizer Limited, Rapporteur: Kristina Dunder, "Submission of the final clinical study report (CSR) of study B1851018, a Phase 4 study evaluating the impact of 13vPnC in reducing acute otitis media (AOM) and nasopharyngeal (NP) colonisation caused by S. pneumoniae in healthy children, in accordance with the Pharmacovigilance plan outlined in the EU RMP (version 11.0)." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 23.02.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Revestive - teduglutide - EMEA/H/C/002345/II/0032, Orphan MAH: Shire Pharmaceuticals Ireland Ltd, Rapporteur: Sinan B. Sarac, "Update of sections 4.3, 4.4, and 4.8 of the SmPC in order to update the safety information in line with	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

updated CCDS following review of the MAH's safety database. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes in section 5.1 of the SmPC." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 15.12.2016.	
Revolade - eltrombopag / eltrombopag olamine - EMEA/H/C/001110/II/0042 MAH: Novartis Europharm Ltd, Rapporteur: Aranzazu Sancho-Lopez, "Submission of the ASPIRE (TRC114968) final study report, a Three-Part Study of Eltrombopag in Thrombocytopenic Subjects with Myelodysplastic Syndromes or Acute Myeloid Leukemia (Part 1: Open-Label, Part 2: Randomized, Double-Blind, Part 3: Extension) assessing the potential risk of haematological changes, optimal dose escalation scheme and eltrombopag pharmacokinetics." Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Rotarix - human rotavirus, live attenuated - EMEA/H/C/000639/II/0089 MAH: GlaxoSmithKline Biologicals S.A., Rapporteur: Bart Van der Schueren, "Update of section 5.1 to introduce effectiveness data following completion of ecological observational study EPI-ROTA-025 VE AU DB (114910) - An ecological study to assess impact of rotavirus vaccination on hospitalisations for rotavirus gastroenteritis (RV GE) in children <5 years of age in Australia. In addition, the marketing authorisation holder took the opportunity to introduce clarifications in the SmPC." Opinion adopted on 02.03.2017. Request for Supplementary Information adopted on 27.10.2016.	Positive Opinion adopted by consensus on 02.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Rotarix - human rotavirus, live attenuated - EMEA/H/C/000639/II/0094 MAH: GlaxoSmithKline Biologicals S.A., Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Jean-Michel Dogné, "Submission of the final study report for EPI-ROTA-007 VS US DB (A phase IV, open, observational study of the safety of Rotarix, administered to a birth	Weekly start timetable.

cohort in US States health insurance plans) which is listed in the section III.4.3 of the Risk Management Plan (RMP) version 16. Consequently a revised RMP (version 17) is submitted in order to update information in relation to: the EPI-ROTA-007 VS US DB study; the EPI-ROTA-052 BOD EU SUPP as agreed during variation EMEA/H/C/0639/II/0086. In addition, the MAH took this opportinity to further update the RMP with the new due date for submission of the final study report for ROTA-085 PMS." Request for Supplementary Information adopted on 09.03.2017.	
Teysuno - tegafur / gimeracil / oteracil - EMEA/H/C/001242/II/0029 MAH: Nordic Group B.V., Rapporteur: Paula Boudewina van Hennik, "Submission of the final clinical study report for SALTO - A phase III randomized, multicentre study comparing the safety of Teysuno versus capecitabine, as monotherapy or in combination with bevacizumab, as first line treatment in patients with metastatic colorectal cancer." Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Torisel - temsirolimus - EMEA/H/C/000799/II/0066, Orphan MAH: Pfizer Limited, Rapporteur: Harald Enzmann, "Submission of the further analysis of a possible association of corticosteroid (pre-)treatment and frequency and severity of hypersensitivity/infusion reactions in study 3066K1-4438-WW (B1771007), as requested by the CHMP during procedures EMEA/H/C/799/MEA 023.1 and EMEA/H/C/799/MEA 024.1. No changes to the PI are proposed." Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Torisel - temsirolimus - EMEA/H/C/000799/II/0067, Orphan MAH: Pfizer Limited, Rapporteur: Harald Enzmann, "Submission of the final report from the Japanese post marketing surveillance (PMS) studies 3066K5-4406 and B1771016 together with the response to the questions raised by the CHMP on the interim report within procedure LEG 031.4." Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Translarna - ataluren - EMEA/H/C/002720/II/0031, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, “Update of section 4.5 of the SmPC in order to update information on interaction with other medicinal products adding adefovir as a medicinal product that is a substrate of OAT1 based on results from study “Safety and PK study of co-administration of ataluren and a sensitive probe substrate of organic anion transporter 1 (OAT1)” (MEA014). The MAH took the occasion to correct a minor typographical error in the SmPC.” Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Uptravi - selexipag - EMEA/H/C/003774/II/0007 MAH: Actelion Registration Ltd., Rapporteur: Martina Weise, “Update of sections 4.4 and 4.5 of the SmPC in order to add information on pharmacokinetic interactions with gemfibrozil and rifampicin in healthy subjects, based on the final clinical study report of the completed clinical pharmacology drug-drug interaction study AC-065-113. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update information on the hydrolysis of selexipag based on data from the previously submitted absolute bioavailability study AC-065-110, make minor amendments to sections 5.1 and 5.2 of the SmPC and to bring the PI in line with the latest QRD template version 10.” Request for Supplementary Information adopted on 23.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/II/0023 MAH: Janssen-Cilag International NV, Rapporteur: Martina Weise, “Update of section 4.4 of the SmPC in order to update the safety information: the term 'and fatal' is added when describing the Diabetic Ketoacidosis cases that have been reported. The Package Leaflet is updated accordingly: term 'rare but serious, sometimes life-threatening and fatal' is added when describing Diabetic Ketoacidosis. In addition, the Marketing authorisation holder	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

(MAH) took the opportunity to update the list of local representatives in the Package Leaflet." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	
Zepatier - elbasvir / grazoprevir - EMEA/H/C/004126/II/0006 MAH: Merck Sharp & Dohme Limited, Rapporteur: Greg Markey, "Update of section 5.2 of the SmPC in order to update the information on absolute bioavailability of elbasvir and grazoprevir following recent Company Core Data Sheet (CCDS) safety information update." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1041 **CONTROLOC Control- EMEA/H/C/001097/WS1041/0025** **PANTOLOC Control- EMEA/H/C/001100/WS1041/0029** **PANTOZOL Control- EMEA/H/C/001013/WS1041/0027** **SOMAC Control- EMEA/H/C/001098/WS1041/0026** MAH: Takeda GmbH, Lead Rapporteur: Greg Markey, "Update of sections 4.3, 4.4, 4.5, 4.6 and 4.8 of the SmPC to reflect that co-administration with HIV protease inhibitors in contraindicated (not only atazanavir), to include a warning about the reduction of the absorption of vitamin B12, and a warning about the increased risk of bone fractures and hypomagnesemia, to include drug interactions with HIV protease inhibitors in section 4.5 of the SmPC, to include that animal studies have shown excretion of pantoprazole in breast milk, and to include fracture of wrist, hip and spine as undesirable effects with unknown frequency. The package leaflet is updated accordingly." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1066 **Adcirca-EMEA/H/C/001021/WS1066/0026** **Cialis-EMEA/H/C/000436/WS1066/0086** MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Concepcion Prieto Yerro, "Update of sections 4.2 and 5.1 of the SmPC in order to reflect the results of study H6D-MC-LVJJ, a randomized,	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

double-blind, placebo-controlled phase 3 trial of tadalafil in the treatment of Duchenne Muscular Dystrophy (DMD), to fulfil Adcirca P46 019.1 and Cialis P46 045.1. Update of sections 4.2 and 5.1 of the Adcirca SmPC and update of section 5.1 of the Cialis SmPC in order to reflect the results of study H6D-MC-LVJJ, a randomized, double-blind, placebo-controlled phase 3 trial of tadalafil in the treatment of Duchenne Muscular Dystrophy (DMD), to fulfil Adcirca P46 019.1 and Cialis P46 045.1. In addition the MAH took the opportunity to update section 6.6 of the SmPC to remove the statement 'no special requirements' for Adcirca and Cialis and to add the standard statement about disposal of any unused or waste material for Cialis, and to align annex II.C with the latest QRD template version 10." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	
WS1079 **Exviera-EMEA/H/C/003837/WS1079/0023** **Viekirax-EMEA/H/C/003839/WS1079/0028** MAH: AbbVie Ltd., Lead Rapporteur: Filip Josephson, "Update of sections 4.4 and 4.5 of the SmPC to include a warning on the concomitant use of sirolimus and everolimus with dasabuvir and ombitasvir/paritaprevir/ritonavir and to update the information on the drug-drug interaction with sirolimus and everolimus. The Package Leaflet is updated accordingly." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 19.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1092 **Ebymect-EMEA/H/C/004162/WS1092/0017** **Edistride-EMEA/H/C/004161/WS1092/0013** **Forxiga-EMEA/H/C/002322/WS1092/0032** **Xigduo-EMEA/H/C/002672/WS1092/0028** MAH: AstraZeneca AB, Lead Rapporteur: Kristina Dunder, "Update of sections 4.4 and 5.1 of the SmPC in order to reflect the results of the Phase 3 study D5553C00003: 28-week safety	The Committee adopted a Request for Supplementary information together with a specific timetable.

and efficacy, randomised, double-blind comparison of simultaneous administration of exenatide once weekly 2 mg an dapagliflozin once daily 10 mg to exenatide once weekly 2 mg alone and dapagliflozin once daily 10 mg alone in patients with type 2 diabetes with inadequate glycaemic control on metformin. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to update the list of local representatives in the Package Leaflets for Ebymect and Edistride and to introduce minor editorial changes throughout the Product Informations." Request for Supplementary Information adopted on 23.03.2017.	
WS1106 **Exviera-EMEA/H/C/003837/WS1106/0027** **Viekirax-EMEA/H/C/003839/WS1106/0031** MAH: AbbVie Ltd., Lead Rapporteur: Filip Josephson, "Update of sections 4.4 and 4.5 of the SmPC in order to add a warning stating that concomitant use of tacrolimus with dasabuvir and ombitasvir/paritaprevir/ritonavir should be avoided unless the benefit outweigh the risks." Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1113 **Stribild-EMEA/H/C/002574/WS1113/0078** **Tybost-EMEA/H/C/002572/WS1113/0035** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James Hemmings, "Submission of the final report from Study GS-US-236-0128 listed as a category 3 study in the RMP. This is a randomized, double-blind phase 3B study to evaluate the safety and efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate versus Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 infected, antiretroviral treatment-naive women." Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
WS1123 **Kisplyx-EMEA/H/C/004224/WS1123/0003** **Lenvima-EMEA/H/C/003727/WS1123/0007**	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

MAH: Eisai Europe Ltd., Lead Rapporteur: Bart Van der Schueren, “Update of section 4.8 of the SmPC to add the adverse events “cholecystitis” with frequency common, and the adverse events “pancreatitis”, “amylase Increased” and “lipase increased” with frequencies uncommon, common and common, respectively. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to implement a correction to section 5.2 of the SmPC for both products and to combine the Kisplyx SmPC.” Opinion adopted on 23.03.2017.	

B.5.3. CHMP-PRAC assessed procedures

Benlysta - belimumab - EMEA/H/C/002015/II/0047 MAH: Glaxo Group Ltd, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, “Submission of the final report from study LBSL99/BEL112626 listed as a category 3 study in the RMP (MEA010). This is “A Multi-Center, Open Label, Continuation Trial of Monoclonal Anti-Blys Antibody in Subjects with SLE who completed the phase 2 Protocol LBSL02”. As a result, an updated RMP (version 20) was submitted.” Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Cinqaero - reslizumab - EMEA/H/C/003912/II/0005/G MAH: Teva Pharmaceuticals Limited, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Brigitte Keller-Stanislawski“Update of section 4.2 of the SmPC in order to include a revised dosing regimen as a result of the new 25mg vial presentation. Consequential B.II.e.5c variation to change the pack size of the finished product and update sections 6.5 and 6.6 of the SmPC. The Annex II, Package Leaflet, Labelling and Risk Management Plan v. 2.0 are updated accordingly.” Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Emtricitabine/Tenofovir disoproxil Mylan - emtricitabine / tenofovir disoproxil -	The Committee adopted a Request for Supplementary information together with a

EMEA/H/C/004050/II/0001 MAH: Mylan S.A.S, Generic, Generic of Truvada, Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Patrick Batty, "Update of the SmPC following the assessment of the extension of indication for the reference product, Truvada, for pre-exposure prophylaxis. The Package Leaflet, Annex II and Labelling are updated in accordance." Request for Supplementary Information adopted on 23.03.2017.	specific timetable.
Fampyra - fampridine - EMEA/H/C/002097/II/0036/G MAH: Biogen Idec Ltd, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus, "This is a grouped variation proposing updates to the SmPC sections 4.2, 4.8, 5.1, Annex II and Package Leaflet based on the clinical study ENHANCE and to the SmPC section 4.6 based on the data from the FOLLOW pregnancy registry. The RMP (version 11) has been updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0. Finally, the CHMP recommends the granting of a marketing authorisation no longer subject to specific obligations." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Firdapse - amifampridine - EMEA/H/C/001032/II/0043, Orphan MAH: BioMarin Europe Ltd, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, "Update of sections 4.4 and 5.3 of the SmPC respectively in order to delete the statements that amifampridine has not been fully tested in carcinogenicity models and to provide the findings from the carcinogenicity reports required for the completion of SOB 004. The RMP (v.9) is proposed to be updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to request the removal of the requirement to complete carcinogenicity testing in an appropriate model in section E of the Annex II." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Request for Supplementary Information adopted on 26.01.2017, 10.11.2016, 15.09.2016.	
Fluenz Tetra - influenza vaccine (live attenuated, nasal) - EMEA/H/C/002617/II/0064 MAH: AstraZeneca AB, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Jean-Michel Dogné, "C.I.13: Submission of the final Clinical Study Report for the study number MI-MA194: A Postmarketing Observational Evaluation of the Safety of Fluenz in Children and Adolescents with High-risk Conditions." Request for Supplementary Information adopted on 09.03.2017.	Weekly start timetable.
Imbruvica - ibrutinib - EMEA/H/C/003791/II/0029, Orphan MAH: Janssen-Cilag International NV, Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams, "Update of sections 4.5 of the SmPC to remove the statement that an interaction between products increasing stomach pH and ibrutinib have not been studied and section 5.2 to include the findings from study CLL1005. The Package Leaflet is not impacted by these changes. In addition, the RMP is updated to version 6.3 to reflect this new safety information." Request for Supplementary Information adopted on 23.03.2017, 15.12.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Lonsurf - trifluridine / tipiracil - EMEA/H/C/003897/II/0002/G MAH: Les Laboratoires Servier, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Ulla Wändel Liminga, "1) C.I.4 (type II) - Update of sections 4.2, 4.4 and 5.2 of the SmPC following availability of the final clinical study report for the study TO-TAS-102-106, A phase I, open-label study evaluating the safety, tolerability, and pharmacokinetics of TAS-102 in patients with advanced solid tumours and varying degrees of hepatic impairment (requested in MEA 002). As a consequence of TO-TAS-102-106 study results, the RMP (ver. 5.0) is updated to remove the missing information "Use in patients with moderate to severe hepatic impairment", and to add "Hyperbilirubinaemia in patients with baseline moderate to severe hepatic impairment" as important potential risk.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

2) C.I.4 (type II) - Update of sections 4.5 and 5.2 of the SmPC following availability of the results of the in vitro CYP induction study of tipiracil hydrochloride (TPI) using the appropriate concentration of TPI (requested in a recommendation). Section SVII.4 of the RMP is updated accordingly. 3) C.I.4 (type II) - Update of section 4.2 of the SmPC in order to correct inconsistencies in the dose calculation according to body surface area. The package leaflet is updated to add 'interstitial lung disease' in the serious side effects part of section 4. In addition, the MAH took the opportunity to update Annex IIIA in accordance with the latest QRD template." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	
Mozobil - plerixafor - EMEA/H/C/001030/II/0030/G, Orphan MAH: Genzyme Europe BV, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "Submission of the final report from study ARD12858 (MOZ23510) "A pilot, exploratory, randomized, phase 2 safety study evaluating tumor cell (plasma cell) mobilization and apheresis product contamination in plerixafor plus non-pegylated G-CSF mobilized patients and in non pegylated G-CSF alone mobilized patients" listed as a category 3 study in the RMP . Submission of the final report from study OBS13611 (MOZ18009), a multicenter, noninterventional registry designed to evaluate the long-term outcomes for patients who received plerixafor for stem cell mobilization and completed hematopoietic stem cell transplantation (HSCT) compared with patients who received other mobilization methods and completed HSCT, listed as a category 3 study in the RMP. Submission of the final report from study OBS13612 (MOZ19310), monitoring the plerixafor off-label transplant use, in patients and donors in EBMT centers performing autologous transplants and/or allogeneic transplants, listed as a category 3 study in the RMP." Request for Supplementary Information adopted	The Committee adopted a Request for Supplementary information together with a specific timetable.

on 23.03.2017.	
OPDIVO - nivolumab - EMEA/H/C/003985/II/0024 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Brigitte Keller-Stanislawski, "Update of section 5.1 of the SmPC in order to reflect the final overall survival and response data, including duration of response with longer follow-up, following completion of PAES CA209037 (Randomized, Open-Label, Phase 3 Trial of nivolumab vs Investigator's Choice in Advanced (Unresectable or Metastatic) Melanoma Patients Progressing Post Anti-CTLA-4 Therapy) and its addendum on predictability of efficacy with biomarkers. This application fulfils ANX 001 and 003.1. Annex II has been updated accordingly. RMP version 5.5 has been submitted within this application." Request for Supplementary Information adopted on 23.03.2017, 26.01.2017.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Orencia - abatacept - EMEA/H/C/000701/II/0107 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, "Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information following the MAH's initiative to update its clinical trials safety database to include all currently completed Orencia clinical trials for both the IV and SC formulations. The adverse reactions table in section 4.8, as well as the description of selected adverse reactions of special interest is being amended. Section 4.4 is being brought in line with the updated section 4.8. The package leaflet is being revised accordingly. An updated Risk Management Plan (Version 22) is also being submitted within this variation." Request for Supplementary Information adopted on 09.03.2017.	Weekly start timetable.
Rekovelle - follitropin delta - EMEA/H/C/003994/II/0003/G MAH: Ferring Pharmaceuticals A/S, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Menno van der Elst"Introduction of a pre-filled cartridge as a new presentation for Rekovelle strength 12 µg/0.36ml (variation B.IV.1.c type II)	The Committee adopted a Request for Supplementary information together with a specific timetable.

Addition of new pack size for the strength 36 µg/1.08ml and to add a new pack size for the strength 72 µg/2.16ml (2 variations B.II.e.5.a.1 type IAin) The Product Information and an updated RMP version 4.0 is proposed accordingly." Request for Supplementary Information adopted on 23.03.2017.	
Remicade - infliximab - EMEA/H/C/000240/II/0204 MAH: Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, "Submission of the final registry report from the C0168T71 study (a review and analysis of birth outcomes from Swedish, Danish and Finish medical birth registers) and an evaluation of pregnancy data from multiple sources. Section 4.6 of the SmPC, relevant section of the PL and the RMP version 13.2 has been updated to reflect the study results. The MAH has also taken the opportunity to bring the product in line with the QRD template and update the local representative section of the PL." Request for Supplementary Information adopted on 23.03.2017.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Soliris - eculizumab - EMEA/H/C/000791/II/0086/G, Orphan MAH: Alexion Europe SAS, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, "Type II (C.I.4): Update of section 4.8 of the SmPC with the ADR frequencies to reflect overall exposure to eculizumab in clinical trials. The Package Leaflet (section 4) is updated accordingly. Type II (C.I.3.b): update of section 4.4 of the SmPC with warning and precautions on meningococcal vaccination timing as recommended by PRAC. The Package Leaflet (sections 2 and 3) Annex II.D and the RMP (ver. 13) are updated accordingly. In addition, the MAH took the opportunity of this RMP update to implement the PRAC recommendation suggesting to remove the off label use from the missing information, to provide the exposure data from PSUR 13 and to update the epidemiology sections with more complete and recent scientific literature data. Moreover, the MAH took the opportunity of this	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

submission to add editorial changes and to bring the PI in line with the latest QRD template." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 15.12.2016, 15.09.2016.	
Tresiba - insulin degludec - EMEA/H/C/002498/II/0024/G MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, "Grouping of two variations to update sections 4.2 and 5.1 of the SmPC in order to include updated information on the use of Tresiba in terms of transfer from other basal insulin regimens and the effects of Tresiba on hypoglycaemia. The Package Leaflet and Labelling are proposed to be updated accordingly. An updated RMP (version 7.0) is being submitted. The proposed changes reflect the findings from two studies submitted: NN1250-3995 (SWITCH 1) and NN1250-3998 (SWITCH 2), comparing the safety and efficacy of Tresiba and insulin glargine U-100, mainly to document the hypoglycaemia profile in type 1 diabetes and type 2 diabetes, respectively. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0. Finally, minor changes have been made to the SmPC section 4.2 and the corresponding section of the Package Leaflet to clarify the correct use of Tresiba." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Tyverb - lapatinib - EMEA/H/C/000795/II/0048/G MAH: Novartis Europharm Ltd, Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga, "1) C.I.4 (type II): Update of sections 4.4, 4.8, and 5.1 of the SmPC in order to add a warning on QTc prolongation and update safety information following the submission of study report EGF114271 (A Phase IV placebo controlled single sequence crossover study to evaluate the effect of repeat oral doses of lapatinib on cardiac repolarization in patients with advanced cancer). The Package Leaflet is updated accordingly.	The Committee adopted a Request for Supplementary information together with a specific timetable.

2) C.I.4 (type II): Update of section 4.8 of the SmPC in order to further elaborate on the undesirable effect 'serious cutaneous reactions' based on the review of the Novartis safety database. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10. Moreover, the MAH took the opportunity to update Annex II to delete an Annex II condition which has been fulfilled with procedure ANX. 28.2. The RMP (version 32) is updated accordingly to the scopes presented above and also to introduce template-related changes, study milestones updates, and to upgrade 'food effect' to an important identified risk (from procedure EMEA/H/C/000795/II/0024)." Request for Supplementary Information adopted on 23.03.2017, 10.11.2016.	
Voncento - human coagulation factor VIII / human von willebrand factor - EMEA/H/C/002493/II/0017/G MAH: CSL Behring GmbH, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus, "C.I.4 (type II): Update of section 4.8 of the SmPC in order to update the frequencies of undesirable effects to reflect the final clinical study data from study CSLCT-BIO-08-53 in haemophilia A paediatric patients. The Package Leaflet is updated accordingly. The submission of the final CSR CSLCT-BIO-08-53 also leads to changes to the RMP (ver. 6.1) in order update the Company Core Safety Information (CCSI). C.I.11.z (type IB): Submission of a revised RMP in order to remove the commitment to conduct a post-marketing study for haemophilia A patients (CSLCT-BIO-12-78) for Voncento as consequence of new data from study CSLCT-BIO-08-53. In addition, the Marketing authorisation holder (MAH) took the opportunity to combine different strengths in the SmPC and Package Leaflet." Request for Supplementary Information adopted on 23.03.2017, 10.11.2016, 01.04.2016, 19.11.2015.	The Committee adopted a Request for Supplementary information together with a specific timetable.
Wakix - pitolisant - EMEA/H/C/002616/II/0004/G, Orphan	The Committee adopted a Request for Supplementary information together with a

MAH: BIOPROJET PHARMA, Rapporteur: Joseph Emmerich, PRAC Rapporteur: Kirsti Villikka, "Update of sections 4.4, 4.5, 4.6 and 5.2 of the SmPC based on the final CSR of study P15-02 (to assess the mass balance recovery, metabolite profile and metabolite identification of 14C-pitolisant at steady state conditions, in healthy CYP2D6 phenotyped subjects), P14-07 (to evaluate pharmacokinetic interaction of pitolisant with sodium oxybate and modafinil in healthy male volunteers) and P15-15 (to evaluate pharmacokinetic interaction of pitolisant with CYP3A4 substrates (midazolam), CYP2B6 substrates (bupropion), UGT2B7 inhibotors (probenecide)) in fulfilment of PAM (MEA 02, 03 and 04). The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial change in section 4.8 of the SmPC. Moreover, updated RMP version 5.0 has been submitted as part of this application." Request for Supplementary Information adopted on 23.03.2017.	specific timetable.
Xtandi - enzalutamide - EMEA/H/C/002639/II/0034 MAH: Astellas Pharma Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, "Update of section 5.1 of the SmPC in order to reflect the final results of the post authorisation efficacy study (PAES) CL-9785-0410 which was a study of enzalutaimide in patients with progressive mCRPC previously treated with abiraterone Acetate, listed as a category 3 in the RMP. The RMP version 11.0 has also been submitted."	Weekly start timetable.
Xtandi - enzalutamide - EMEA/H/C/002639/II/0035 MAH: Astellas Pharma Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.4 and 4.8 of the SmPC to reflect the final results of the post authorisation safety study (PASS) CL-9785-0403 which evaluated the risk of seizure among subjects with mCRPC treated with enzalutamide who were at potential increased risk of seizure (UPWARD) and was listed as a category 3 in the RMP. The RMP version 11.0 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to make a	Weekly start timetable.

correction in section 5.1 of the SmPC." Request for Supplementary Information adopted on 09.03.2017.	
Xtandi - enzalutamide - EMEA/H/C/002639/II/0036 MAH: Astellas Pharma Europe B.V., Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia, "Update of sections 4.6 and 5.3 of the SmPC to reflect the final results of study AE-7592-G, "Transfer of Radioactivity into Fetuses and Breast Milk in Rats after a Single Oral Administration of [14C] MDV3100- ISN: 9785-ME-0046". The Package Leaflet is updated accordingly. The RMP version 11.0 has also been submitted." Opinion adopted on 09.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
Xultophy - insulin degludec / liraglutide - EMEA/H/C/002647/II/0017 MAH: Novo Nordisk A/S, Rapporteur: Kristina Dunder, PRAC Rapporteur: Menno van der Elst, "Update of section 4.2 of the SmPC in order to update the information on use of Xultophy in patients with hepatic impairment, based on clinical trial NN2211-1328, the LEAD 1-6 meta-analysis as well as other liraglutide trials. In addition, 'fatigue' has been added to the tabulated list of adverse reactions in Section 4.8 of the SmPC. The Package Leaflet is updated accordingly. RMP version 6.0 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10." Request for Supplementary Information adopted on 23.03.2017.	The Committee adopted a Request for Supplementary information together with a specific timetable.
WS1075 **Epclusa-EMEA/H/C/004210/WS1075/0006** **Harvoni-EMEA/H/C/003850/WS1075/0043** **Sovaldi-EMEA/H/C/002798/WS1075/0037** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Ana Sofia Diniz Martins, "Submission of the final non-clinical study report PC-334-2035 assessing the potential for a pharmacokinetic interaction via transporter or enzyme based inhibition when sofosbuvir and other Direct Acting Antivirals (DAAs) are used	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

concomitantly with amiodarone The RMPs (Epclusa – RMP version 1.0, Harvoni – RMP version 2.0, Sovaldi – RMP version 5.0) have been updated accordingly." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	
WS1086 **Stribild-EMEA/H/C/002574/WS1086/0077** **Tybost-EMEA/H/C/002572/WS1086/0034** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Patrick Batty, "Submission of the final report from Study GS-US-236-0140. This is a randomized, open-label, phase 4 study evaluating the renal effect of Elvitegravir/ Cobicistat/ Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine /Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir-boosted Atazanavir plus Abacavir/ Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR ≥70 mL/min." Request for Supplementary Information adopted on 23.03.2017.	The Committee adopted a Request for Supplementary information together with a specific timetable.
WS1089/G **Prezista-** **EMEA/H/C/000707/WS1089/0086/G** **Rezolsta-** **EMEA/H/C/002819/WS1089/0018/G** MAH: Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, "Submission of the final report from Study GS-US-236-0140 listed as a category 3 study in the RMP. This is a randomized, open-label, phase 4 study evaluating the renal effect of Elvitegravir/ Cobicistat/ Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine /Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir-boosted Atazanavir plus Abacavir/ Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR ≥70 mL/min. The RMP has been updated accordingly and the important potential risks of renal toxicity removed. Based on cumulative review of the available	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

data, the Prezista and Rezolsta RMPs are updated to remove the important risks of 'pancreatis', 'convulsions' and 'cardiac conduction abnormalities' . The MAH took the opportunity of this procedure to include the Annex 7 in the Prezista RMP. The consolidated updated RMPs version 25.1 for Prezista and version 4.2 for Rezolsta are agreed." Opinion adopted on 23.03.2017.	
WS1103 **Ebymect-EMEA/H/C/004162/WS1103/0018** **Xigduo-EMEA/H/C/002672/WS1103/0029** MAH: AstraZeneca AB, Lead PRAC Rapporteur: Julie Williams, "The Applicant submitted a Type IB worksharing to update the RMP of Xigduo and its duplicate Ebymect. The proposed changes are in line with the outcome of the article 31 referral on metformin and metformin-containing medicines regarding the use in patients with moderate renal impairment (EMEA/H/A-31/1432). The Commission Decision for this article 31 referral was adopted on 12th December 2016." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1128 **Gardasil-EMEA/H/C/000703/WS1128/0071** **Silgard-EMEA/H/C/000732/WS1128/0062** MAH: MSD Vaccins, Lead Rapporteur: Kristina Dunder, Lead PRAC Rapporteur: Qun-Ying Yue, "Update of section 5.1 of the SmPC in order to following/based on the final report for Study P019-21 (Gardasil MEA 060.2 and Silgard MEA 059.2) and fourth interim report for Study P015-21 (Gardasil/Silgard MEA 019.7). Study P019-21 is a long-term Follow-up Study of Safety, Immunogenicity, and Effectiveness of Gardasil (Human Papillomavirus [Types 6, 11, 16, 18] Recombinant Vaccine) in Mid-Adult Women - The FUTURE III (Females United to Unilaterally Reduce Endo/Ecto Cervical Cancer). Study P015-21 is a registry-based Study of Protocol V501-015 Subjects, and Recipients of Gardasil recombinant vaccine in Countries with centralized cervical cancer screening infrastructures to evaluate the long-term effectiveness, immunogenicity, and safety of Gardasil.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

The RMP version 11 has also been submitted." Opinion adopted on 23.03.2017.	

B.5.4. PRAC assessed procedures

PRAC Led **Cervarix - human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed) - EMEA/H/C/000721/II/0086** MAH: GSK Biologicals SA, Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Jean-Michel Dogné, PRAC-CHMP liaison: Bart Van der Schueren, "Submission of the final report from study HPV-039, listed in the RMP as one of the measures to bring additional information on the theoretical risk of acquiring vaccine-induced autoimmune diseases and on pregnancy outcomes after vaccination. With this submission the MAH fulfils post-authorisation measure MEA 081." Opinion adopted on 09.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Corbilta - levodopa / carbidopa / entacapone - EMEA/H/C/002785/II/0009** MAH: Orion Corporation PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final report of pharmacoepidemiological registry study CCOM998A2001, as requested in PRAC PSUR Assessment report EMEA/H/C/PSUSA/00000547/201510. The study is listed as a category III study in the Risk Management plan (RMP) of Corbilta. The RMP of Corbilta is updated accordingly from version 1.1 to version 2.0. The MA holder does not propose any changes to the Product Information of Corbilta as a consequence of this Type II variation. The requested variation proposed amendments to the Risk Management Plan (RMP)." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Corbilta - levodopa / carbidopa / entacapone - EMEA/H/C/002785/II/0010** MAH: Orion Corporation, Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Kirsti Villikka, PRAC-CHMP liaison: Outi Mäki-Ikola, "Submission of the final report of pharmacoepidemiological registry study ER11-9411 was requested in	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

PRAC PSUR assessment report EMEA/H/C/PSUSA/00000547/201510. The study is listed as category III study in the Risk Management Plan (RMP) and the summary results indicate that treatment with entacapone does not increase the risk of prostate cancer in patients with Parkinson´s disease. The RMP of Corbilta is updated accordingly from version 1.1 to version 2.0. MA holder does not propose any changes to the Product Information of Corbilta as a consequence of this Type II variation." Opinion adopted on 23.03.2017.	
PRAC Led **Humira - adalimumab - EMEA/H/C/000481/II/0159** MAH: AbbVie Ltd., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder, "Submission of study P06-134: "A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of Humira in Subjects with Moderately to Severely Active Crohn's Disease" in fulfilment fo MEA 056.9. The study includes also some paediatric patients and fulfils article 46 paediatric obligations." Request for Supplementary Information adopted on 23.03.2017, 10.11.2016.	The Committee adopted a Request for Supplementary information together with a specific timetable.
PRAC Led **Orencia - abatacept - EMEA/H/C/000701/II/0108/G** MAH: Bristol-Myers Squibb Pharma EEIG, PRAC Rapporteur: Kirsti Villikka, "This grouping of two type II variations (category C.I.13) covers the submission of the final clinical study reports from epidemiological studies IM101045A & IM101045B, listed as category 3 studies in the RMP. IM101045A & IM101045B are both observational studies, sharing overlapping safety objectives (e.g.: to assess the risk of infections, infusion-related reactions, autoimmune disorders, injection reactions and combination use)." Request for Supplementary Information adopted on 09.03.2017.	Weekly start timetable.
PRAC Led **Ozurdex - dexamethasone - EMEA/H/C/001140/II/0025**	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP

MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, PRAC-CHMP liaison: Greg Markey, “In line with the RMP commitment, submission of the final report for the Post-Authorisation Safety Study 206207-025 (A Prospective Observational Study to Evaluate Long-Term Safety in Real-World Clinical Practice.)” Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	recommendation.
PRAC Led **Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0100** MAH: Boehringer Ingelheim International GmbH, Rapporteur: Hanne Lomholt Larsen, PRAC Rapporteur: Torbjorn Callreus, PRAC-CHMP liaison: Sinan B. Sarac, “Submission of the final report for study 1160.144, which evaluated the potential off-label use of dabigatran etexilate in Europe: A drug utilisation study in Cegedim France, Denmark, and CPRD UK.” Request for Supplementary Information adopted on 09.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
PRAC Led **Pradaxa - dabigatran etexilate - EMEA/H/C/000829/II/0101** MAH: Boehringer Ingelheim International GmbH, Rapporteur: Hanne Lomholt Larsen, PRAC Rapporteur: Torbjorn Callreus, PRAC-CHMP liaison: Sinan B. Sarac, “Submission of the final report of study 1160.162, an observational study assessing the management of gastrointestinal and urogenital bleeding events in patients with non valvular atrial fibrillation treated with dabigatran etexilate.” Opinion adopted on 09.03.2017.	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **Suboxone - buprenorphine / naloxone - EMEA/H/C/000697/II/0035** MAH: Indivior UK Limited, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison: Martina Weise, “Submission of the final study report for PEUS004 , a retrospective observational survey on Suboxone use in France. Consequently, the RMP (RMP 12.1) has been updated.”	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

Opinion adopted on 09.03.2017.	
PRAC Led **WS1059** **Prezista-EMEA/H/C/000707/WS1059/0084** **Rezolsta-EMEA/H/C/002819/WS1059/0015** MAH: Janssen-Cilag International NV, Lead Rapporteur: Johann Lodewijk Hillege, Lead PRAC Rapporteur: Menno van der Elst, PRAC-CHMP liaison: Johann Lodewijk Hillege, "Updated RMP (consolidated Prezista RMP version 25.1 and Rezolsta version 4.2) in order to delete the cat 3 study TMC114HIV3015 in HIV-1 infected pregnant women and replace the commitment by the assessment of the pharmacokinetics data in HIV-1 pregnant women." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 26.01.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
PRAC Led **WS1063** **Exviera-EMEA/H/C/003837/WS1063/0022** **Viekirax-EMEA/H/C/003839/WS1063/0027** MAH: AbbVie Ltd., Lead Rapporteur: Filip Josephson, Lead PRAC Rapporteur: Dolores Montero Corominas, PRAC-CHMP liaison: Concepcion Prieto Yerro, "To update the RMP for Exviera and Viekirax with the following changes: 1. Addition of information on cases of hepatic decompensation observed in patients with Child-Pugh B hepatic impairment, and the revision of the SmPC to change the dose recommendation of these patients to "not recommended", as well as the addition of statements recommending the monitoring of hepatic function in these patients as approved on 25 January 2016 ((Ref: EMEA/H/C/WS/0873). 2. Addition of a reference to nine drug-drug interaction studies as approved on 28 April 2016 (Ref: EMEA/H/C/WS0896/G). 3. Addition to the reference to the completion of rat 2 year carcinogenicity studies on dasabuvir (Exviera) and ombitasvir (Viekirax) as approved on 24 September 2015 (Ref:	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

EMEA/H/C/003837/II/0006 and EMEA/H/C/003839/II/0004). 4. Update of section 4.2 of SmPC for Virkirax to recommend a decrease in treatment duration of 12 weeks in GT4 cirrhotic patients, with a consequential change to sections 4.4 and 5.1 as approved on 18 August 2016 (Ref: EMEA/H/C/003839/II/0022/G). 5. Removal of the nonclinical PAMS 1-3 in the initial RMP, (Ref: EMEA/H/C/03837/MEA/003, EMEA/H/C/038397/MEA/002, EMEA/H/C/03839/MEA/003)." Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 15.12.2016.	

B.5.5. CHMP-CAT assessed procedures

B.5.6. CHMP-PRAC-CAT assessed procedures

B.5.7. PRAC assessed ATMP procedures

B.5.8. Unclassified procedures and worksharing procedures of type I variations

WS0934/G **Suboxone-** **EMEA/H/C/000697/WS0934/0034/G** MAH: Indivior UK Limited, Lead Rapporteur: Martina Weise Opinion adopted on 23.03.2017. Request for Supplementary Information adopted on 16.02.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS0972/G **Infanrix hexa-** **EMEA/H/C/000296/WS0972/0211/G** MAH: GSK Biologicals SA, Lead Rapporteur: Bart Van der Schueren Opinion adopted on 09.03.2017.	Positive Opinion adopted by consensus on 09.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1048/G **Infanrix hexa-** **EMEA/H/C/000296/WS1048/0212/G** MAH: GSK Biologicals SA, Lead Rapporteur: Bart Van der Schueren Opinion adopted on 23.03.2017. Request for Supplementary Information adopted	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

on 26.01.2017.	
WS1111 **Entresto-** **EMEA/H/C/004062/WS1111/0011** **Neparvis-** **EMEA/H/C/004343/WS1111/0009** MAH: Novartis Europharm Ltd, Lead Rapporteur: Johann Lodewijk Hillege"To extend the shelf-life of the finished product packaged in blisters (PVC/PVDC) from 30 months to 3 years." Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1121 **Lyrica-EMEA/H/C/000546/WS1121/0086** **Pregabalin Pfizer-** **EMEA/H/C/003880/WS1121/0016** MAH: Pfizer Limited, Lead Rapporteur: Johann Lodewijk Hillege"To add a new-pack of size 200 capsules in bottle (HDPE) for Lyrica 25mg hard capsules (EU/1/04/279/046) To add a new-pack of size 200 capsules in bottle (HDPE) for Pregabalin Pfizer 25mg hard capsules (EU/1/14/916/044)" Opinion adopted on 16.03.2017.	Positive Opinion adopted by consensus on 16.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.
WS1126 **Gardasil-** **EMEA/H/C/000703/WS1126/0070** **Silgard-EMEA/H/C/000732/WS1126/0061** MAH: MSD Vaccins, Lead Rapporteur: Kristina Dunder Request for Supplementary Information adopted on 16.03.2017.	Weekly start timetable. The Committee adopted a Request for Supplementary information together with a specific timetable.
WS1140 **Glyxambi-** **EMEA/H/C/003833/WS1140/0002** **Jentadueto-** **EMEA/H/C/002279/WS1140/0037** **Trajenta-** **EMEA/H/C/002110/WS1140/0027** MAH: Boehringer Ingelheim International GmbH, Lead Rapporteur: Johann Lodewijk Hillege"To add the ADR bullous pemphigoid to the Warnings and Precautions sections in the SmPC (section 4.4) and in the package leaflet (section 2)." Opinion adopted on 23.03.2017.	Positive Opinion adopted by consensus on 23.03.2017. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP recommendation.

B.5.9. Information on withdrawn type II variation / WS procedure

Translarna - ataluren - EMEA/H/C/002720/II/0012, Orphan MAH: PTC Therapeutics International Limited, Rapporteur: Johann Lodewijk Hillege, Withdrawal request submitted on 06.03.2017	The MAH withdrew the procedure on 06.03.2017

B.5.10. Information on type II variation / WS procedure with revised timetable

Saxenda - liraglutide - EMEA/H/C/003780/II/0011 MAH: Novo Nordisk A/S, Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Menno van der Elst, "Based on submission of the LEADER clinical study results (EX2211-3748: liraglutide effect on and action in diabetes, evaluation of cardiovascular outcome results), changes to sections 4.4, and 5.1 of the SmPC are being proposed in order to update the safety information and include a description of the clinical study outcomes. The Package Leaflet and Labelling are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to implement minor editorial changes throughout the product information. The LEADER study was included in the liraglutide RMP as a required pharmacovigilance activity (category 3) to specifically address the important potential risk of cardiovascular disorders in patients with Type 2 Diabetes Mellitus. Updates to the liraglutide RMP based on the study results are also proposed: this variation application fulfils two post-approval commitments in relation to the cardiovascular outcomes trial (MEA 002), as well as to provide additional information on the breast cancer cases found in LEADER (MEA 005). RMP Version 27 was submitted with the application. These liraglutide RMP modifications are in line with the proposed updates to the Saxenda Product Information described above." Request for Supplementary Information adopted on 23.02.2017. Request for clock stop extension.	The CHMP agreed with the request for clock stop extension.

B.6. START OF THE PROCEDURES TIMETABLES FOR INFORMATION

B.6.1. Start of procedure for New Applications: timetables for information

- rituximab - EMEA/H/C/004723
, treatment of Non-Hodgkin's lymphoma (NHL) and Chronic lymphocytic leukaemia (CLL)

- tildrakizumab - EMEA/H/C/004514
, treatment of adults with moderate-to-severe plaque psoriasis

- trastuzumab - EMEA/H/C/004361
, Metastatic breast cancer, early breast cancer, metastatic gastric cancer

- naldemedine - EMEA/H/C/004256
, treatment of opioid-induced constipation (OIC) in adult patients.

- brexpiprazole - EMEA/H/C/003841
, treatment of schizophrenia

- sufentanil - EMEA/H/C/004335
, management of acute moderate to severe pain

- rituximab - EMEA/H/C/004724
, treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis

- rituximab - EMEA/H/C/004725
, treatment of Non-Hodgkin's lymphoma (NHL), Granulomatosis with polyangiitis and microscopic polyangiitis

B.6.2. Start of procedure for Extension application according to Annex I of Reg. 1234/2008): timetables for information

Bortezomib Accord - bortezomib - EMEA/H/C/003984/X/0008
MAH: Accord Healthcare Ltd, Generic, Generic of VELCADE“Extension application to add a new strength of powder for solution for injection (1 mg) to the currently approved strength (3.5 mg) of Bortezomib Accord.”

Daliresp - roflumilast - EMEA/H/C/002398/X/0031
MAH: AstraZeneca AB, Informed Consent of Daxas“Extension application to add a new strength of 250 µg in a PVC/PVDC/Alu blister of 28 tablets.”

Daxas - roflumilast -

EMEA/H/C/001179/X/0035
MAH: AstraZeneca AB“Extension application to add a new strength of 250 µg in a PVC/PVDC/Alu blister of 28 tablets.”

Humira - adalimumab - EMEA/H/C/000481/X/0164/G
MAH: AbbVie Ltd., “Extension application to add a new strength/potency of 20 mg for adalimumab solution for injection in pre-filled syringe, grouped with a type II variation (C.I.4.z) to update of sections 4.2 of the SmPC in order to introduce new fixed dose regimen (posology) for the paediatric indications of JIA and Ps. The Package Leaflet and Labelling are updated accordingly.

In addition, the marketing authorisation holder took the opportunity to:
- introduce editorial changes to align wording and layout of the Product Information
- to amend the statement relating to anti-adalimumab antibody development in JIA patients, which will reside in section 5.1 of the Humira SmPCs (20 mg and 40 mg presentations).”

Libertek - roflumilast - EMEA/H/C/002399/X/0032
MAH: AstraZeneca AB, Informed Consent of DaxasExtension application to add a new strength of 250 µg in a PVC/PVDC/Alu blister of 28 tablets.”

Oncaspar - pegaspargase - EMEA/H/C/003789/X/0008
MAH: Baxalta Innovations GmbH,Extension application to add a new pharmaceutical form, powder for solution for injection/infusion (750 U/ml).”

Orkambi - lumacaftor / ivacaftor - EMEA/H/C/003954/X/0020
MAH: Vertex Pharmaceuticals (Europe) Ltd., “Extension application to add a new strength of film-coated tablets (100 mg Lumacaftor / 125 mg Ivacaftor) for paediatric use (6 to 11 years).”
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

B.6.3. Restart of procedure - responses received to Day 120 List of Questions timetables: for information

- paclitaxel - EMEA/H/C/004154, Orphan
treatment of ovarian cancer
List of Questions adopted on 23.06.2016.

- darunavir / cobicistat / emtricitabine / tenofovir alafenamide - EMEA/H/C/004391
, treatment of human immunodeficiency virus type 1 (HIV-1)
List of Questions adopted on 26.01.2017.

- efavirenz / emtricitabine / tenofovir disoproxil - EMEA/H/C/004240
, treatment of HIV-1 infection, Generic, Generic of Atripla
List of Questions adopted on 15.12.2016.

- entecavir - EMEA/H/C/004377
, treatment of chronic hepatitis B virus infection, Generic, Generic of Baraclude
List of Questions adopted on 15.12.2016.

- raltegravir - EMEA/H/C/000860/X/0059
"Extension application to add a new strength of 600mg film coated tablets."
List of Questions adopted on 13.10.2016.

Kuvan - sapropterin - EMEA/H/C/000943/X/0047, Orphan
MAH: BioMarin International Limited, "Extension application to introduce a new pharmaceutical form associated with new strength (100 mg and 500 mg powder for oral solution)."
List of Questions adopted on 23.02.2017.

- lutetium (177 Lu) dotatate - EMEA/H/C/004123, Orphan
, treatment of gastro-entero-pancreatic neuroendocrine tumours
List of Questions adopted on 15.09.2016.

- trastuzumab - EMEA/H/C/004346
, treatment of metastatic and early breast cancer and metastatic gastric cancer (MGC)
List of Questions adopted on 15.12.2016.

- denosumab - EMEA/H/C/001120/X/0059/G
MAH: Amgen Europe B.V.
List of Questions adopted on 26.01.2017.

- beclometasone dipropionate anhydrous / formoterol fumarate dihydrate /

glycopyrronium bromide -
EMEA/H/C/004257
, for the symptomatic treatment and reduction of exacerbations in adult patients with chronic obstructive pulmonary disease (COPD) with airflow limitation and who are at risk of exacerbations
List of Questions adopted on 23.02.2017.

- denosumab -
EMEA/H/C/002173/X/0048/G
MAH: Amgen Europe B.V.,
List of Questions adopted on 26.01.2017.

B.6.4. Annual Re-assessments: timetables for adoption

B.6.5. Renewals of Marketing Authorisations: timetables for adoption provided only if the validation has been completed

B.6.6. VARIATIONS – START OF THE PROCEDURE

Timetables for adoption provided that the validation has been completed.

B.6.7. Type II Variations scope of the Variations: Extension of indication

B.6.8. CHMP assessed procedures scope: Pharmaceutical aspects

Bexsero - meningococcal group B vaccine (rDNA, component, adsorbed) -
EMEA/H/C/002333/II/0051
MAH: GSK Vaccines S.r.l,

Cetrotide - cetrorelix acetate -
EMEA/H/C/000233/II/0058
MAH: Merck Serono Europe Limited,

Darunavir Mylan - darunavir -
EMEA/H/C/004068/II/0001/G
MAH: Mylan S.A.S, Generic, Generic of Prezista

Enbrel - etanercept -
EMEA/H/C/000262/II/0207/G
MAH: Pfizer Limited

Imatinib Teva - imatinib -
EMEA/H/C/002585/II/0026
MAH: Teva B.V., Generic, Generic of Glivec

Inflectra - infliximab -
EMEA/H/C/002778/II/0050/G
MAH: Hospira UK Limited, Duplicate, Duplicate of Remsima

Kalydeco - ivacaftor -
EMEA/H/C/002494/II/0057, Orphan
MAH: Vertex Pharmaceuticals (Europe) Ltd.

Menveo - meningococcal group A, C, W135 and Y conjugate vaccine -
EMEA/H/C/001095/II/0065
MAH: GSK Vaccines S.r.l

Nplate - romiplostim -
EMEA/H/C/000942/II/0062/G, Orphan
MAH: Amgen Europe B.V.

Omnitrope - somatropin -
EMEA/H/C/000607/II/0047
MAH: SANDOZ

Praluent - alirocumab -
EMEA/H/C/003882/II/0021/G
MAH: sanofi-aventis groupe

Privigen - human normal immunoglobulin -
EMEA/H/C/000831/II/0114/G
MAH: CSL Behring GmbH

Remsima - infliximab -
EMEA/H/C/002576/II/0042/G
MAH: Celltrion Healthcare Hungary Kft.,

Simponi - golimumab -
EMEA/H/C/000992/II/0075/G
MAH: Janssen Biologics B.V.,

Soliris - eculizumab -
EMEA/H/C/000791/II/0093, Orphan
MAH: Alexion Europe SAS

Synflorix - pneumococcal polysaccharide conjugate vaccine (adsorbed) -
EMEA/H/C/000973/II/0116/G

WS1132
Fiasp-EMEA/H/C/004046/WS1132/0002
NovoMix-
EMEA/H/C/000308/WS1132/0089
NovoRapid-
EMEA/H/C/000258/WS1132/0117
Ryzodeg-
EMEA/H/C/002499/WS1132/0022
MAH: Novo Nordisk A/S, Lead Rapporteur: Kristina Dunder

WS1143
Aflunov-

EMEA/H/C/002094/WS1143/0033
Foclivia-
EMEA/H/C/001208/WS1143/0028
MAH: Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri

WS1145/G
Aflunov-
EMEA/H/C/002094/WS1145/0034/G
Foclivia-
EMEA/H/C/001208/WS1145/0029/G
MAH: Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri

WS1155
Abseamed-
EMEA/H/C/000727/WS1155/0063
Binocrit-
EMEA/H/C/000725/WS1155/0063
Epoetin alfa Hexal-
EMEA/H/C/000726/WS1155/0062
MAH: Medice Arzneimittel Pütter GmbH & Co. KG, Duplicate, Duplicate of Epoetin alfa Hexal, Lead Rapporteur: Alexandre Moreau

B.6.9. CHMP assessed procedures scope: Non-Clinical and Clinical aspects

Cerdelga - eliglustat -
EMEA/H/C/003724/II/0011, Orphan
MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk HillegeUpdate of section 5.1 of the SmPC in order to reflect the final study results from study GZGD00304 (“A Phase 2, Open-Label, Multi-Center Study Evaluating the Efficacy, Safety and Pharmacokinetics of Genz-112638 in Gaucher Type 1 Patients”) listed as a category 3 study in the RMP (MEA 007).

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.”

Cyanokit - hydroxocobalamin -
EMEA/H/C/000806/II/0031
MAH: SERB SA, Rapporteur: Alexandre MoreauUpdate of sections 4.4 and 4.8 of the SmPC in order to add a warning on renal disorders and to update the safety information on skin and subcutaneous tissue disorders, renal and urinary disorders following a safety signal on renal disorders. The package leaflet is

updated accordingly."

Docetaxel Winthrop - docetaxel - EMEA/H/C/000808/II/0051

MAH: Aventis Pharma S.A., Informed Consent of Taxotere, Rapporteur: Alexandre Moreau, Update of section 4.8 of the SmPC to update the safety information related to electrolyte imbalance. The Package Leaflet is updated accordingly.

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Bulgaria and introduce minor corrections in the Package Leaflet."

Edurant - rilpivirine - EMEA/H/C/002264/II/0025

MAH: Janssen-Cilag International NV, Rapporteur: Johann Lodewijk HillegeUpdate of section 4.5 of the SmPC in order to include Pharmacokinetics data of drug-drug interactions between simeprevir and rilpivirine, based on final result from study TMC435-TiDP16-C114; this is a Phase I, 2-panel, open-label, randomized, cross-over study in healthy subjects to investigate the potential drug-drug interaction between simeprevir and RPV.

In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10."

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0033

MAH: Merck Sharp & Dohme Limited, Rapporteur: Paula Boudewina van Hennik, "Update of section 4.8 of the SmPC to add the new ADR 'hypersensitivity reactions (both local and generalized, including rash)' identified through post-marketing surveillance. The Package Leaflet has been updated accordingly."

Elonva - corifollitropin alfa - EMEA/H/C/001106/II/0034

MAH: Merck Sharp & Dohme Limited, Rapporteur: Paula Boudewina van Hennik, "Update of section 4.5 of the SmPC to add information pertaining to potential hCG cross-reactivity resulting in a false positive pregnancy test.
In addition, the MAH is taking the opportunity to implement changes in the annexes in line with

the QRD templates (versions 9.1 and 10) and to propose combined versions of the SmPCs and Package Leaflets for the different strengths."

Eperzan - albiglutide - EMEA/H/C/002735/II/0032

MAH: GlaxoSmithKline Trading Services, "Submission of the final clinical study report of the study 201834: A randomized, double-blind, single-dose, placebo controlled, 2-way cross-over study evaluating effect of albiglutide on cholecystokinin-induced gallbladder emptying in fasting healthy subjects, listed as a category 3 study in the RMP."

Epivir - lamivudine - EMEA/H/C/000107/II/0104

MAH: ViiV Healthcare UK Limited,"Update of section 4.5 of the SmPC of both Epivir tablets and oral solution, and section 4.4 of the SmPC for Epivir Oral solution only, to add information regarding the potential for interaction between lamivudine and sorbitol based on the results of Study 204857. Further, a minor amendment has been implemented throughout the SmPC to update the clinical terminology for 'Pneumocystis carinii pneumonia' to 'Pneumocystis jiroveci pneumonia'. In addition, the MAH has taken the opportunity to align the product information with the QRD template version 10, to make minor editorial changes in the annexes and to update the contact details of the local representative in Norway in the Package Leaflet."

Fabrazyme - agalsidase beta - EMEA/H/C/000370/II/0098

MAH: Genzyme Europe BV, Rapporteur: Johann Lodewijk Hillege"Update of section 4.8 of the SmPC in order to add membranous glomerulonephritis as a new Adverse event with a not known frequency following periodic cumulative review of adverse event data from the MAH adverse event (AE) database which resulted in the decision to update the company core data sheet. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Portugal in the Package Leaflet."

Galafold - migalastat - EMEA/H/C/004059/II/0009, Orphan

MAH: Amicus Therapeutics UK Ltd, Rapporteur: Johann Lodewijk Hillege, “Update of section 5.1 of the SmPC to add new mutations in Table 2: Galafold (migalastat) amenability table and to Table 3: Mutations not amenable to Galafold (migalastat).
In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce some minor editorial changes to the tables and to update the list of local representatives in the Package Leaflet.”

Harvoni - ledipasvir / sofosbuvir - EMEA/H/C/003850/II/0049
MAH: Gilead Sciences International Ltd, Rapporteur: Filip Josephson,Update of section 4.8 of the SmPC in order to add angioedema with frequency ‘unknown’. The Package Leaflet is updated accordingly.”

Kadcyla - trastuzumab emtansine - EMEA/H/C/002389/II/0031
MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac,To update the SmPC section 4.4 Special Warning and Precautions for use and section 4.8 Undesirable Effects to include haemorrhage under its own heading. The package leaflet is amended accordingly.”

Kisplyx - lenvatinib - EMEA/H/C/004224/II/0004
MAH: Eisai Europe Ltd., Rapporteur: Bart Van der Schueren“Submission of full report in regards to PD (secondary endpoint) from Study E7080-G000-205.”

Lixiana - edoxaban - EMEA/H/C/002629/II/0012
MAH: Daiichi Sankyo Europe GmbH, Rapporteur: Concepcion Prieto Yerro“Update of sections 4.2 and 5.1 of the SmPC in order to add information deriving from new clinical data for the use of edoxaban as anticoagulant therapy for patients with non-valvular atrial fibrillation undergoing cardioversion. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Portugal in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.0.”

Pyramax - pyronaridine / artesunate -

EMEA/H/W/002319/II/0015
MAH: Shin Poong Pharmaceutical Co., Ltd., Rapporteur: Joseph Emmerich"Submission of the final report from study SP-C-013-11 listed as a category 3 study in the RMP. This is a phase IIIb/IV comparative, randomised, multi-centre, open label, parallel 3-arm clinical study to assess the safety and efficacy of repeated administration of pyronaridine-artesunate, dihydroartemisinin-piperaquine or artemether-lumefantrine or artesunate-amodiaquine over a 2-year period in children and adult patients with acute uncomplicated Plasmodium sp. malaria."

Taxotere - docetaxel -
EMEA/H/C/000073/II/0125
MAH: Aventis Pharma S.A., Rapporteur: Alexandre Moreau,"Update of section 4.8 of the SmPC to update the safety information related to electrolyte imbalance. The Package Leaflet is updated accordingly.

In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Bulgaria and introduce minor corrections in the Package Leaflet."

Tybost - cobicistat -
EMEA/H/C/002572/II/0036
MAH: Gilead Sciences International Ltd, Rapporteur: Robert James Hemmings"Submission of the integrated resistance analysis (PC-236-2016) of the genotypic changes in the protease gene for all HIV-1 infected subjects participating in Phase 3 clinical trials of Stribild (GS-US-236-0102, GS-US-236-0103, GS-US-236-0128, GS-US-264-0110, GS-US-236-0121 and GS-US-236-0123) listed as category 3 studies in the RMP."

Wakix - pitolisant -
EMEA/H/C/002616/II/0007, Orphan
MAH: BIOPROJET PHARMA, Rapporteur: Joseph Emmerich,Submission of the final CSR for Study P11-11; a multi-centre, single dose trial to evaluate the pharmacokinetics of pitolisant in children from 6 to less than 18 years with narcolepsy (Measure 3 of the agreed PIP)."

Zeffix - lamivudine -
EMEA/H/C/000242/II/0069
MAH: Glaxo Group Ltd, Duplicate, Duplicate of Epivir, "Update of section 4.5 of the SmPC to

add information regarding a potential interaction with sorbitol-containing medicines. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement a minor change in the labelling in line with the QRD template version 10."

WS1136
Descovy-
EMEA/H/C/004094/WS1136/0017
Genvoya-
EMEA/H/C/004042/WS1136/0031
Odefsey-
EMEA/H/C/004156/WS1136/0013
MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James HemmingsUpdate of sections 4.4, 4.8. 5.1 and 5.2 of the SmPC in order to provide 48 weeks data from Study GS-US-292-1249; this is a Phase 3b open-label study of the efficacy and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide single-tablet regimen in HIV-1/Hepatitis B co-infected adults.
The Package Leaflet is updated accordingly.

In addition, the Worksharing applicant (WSA) took the opportunity to make minor administrative changes in the SmPC and the Package Leaflet."

WS1137
Lyrica-EMEA/H/C/000546/WS1137/0087
Pregabalin Pfizer-
EMEA/H/C/003880/WS1137/0017
MAH: Pfizer Limited, Lead Rapporteur: Johann Lodewijk Hillege"Update of sections 4.8 and 5.1 of the SmPC in order to reflect final results from paediatric study A0081041: "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of Pregabalin as Adjunctive Therapy in Children 4-16 Years of Age with Partial Onset Seizures"."

WS1144/G
Afinitor-
EMEA/H/C/001038/WS1144/0052/G
Votubia-
EMEA/H/C/002311/WS1144/0042/G
MAH: Novartis Europharm Ltd, Lead Rapporteur: Harald EnzmannUpdate of sections 4.4 and 4.8 of the SmPC in order to include new safety information on stomatitis and its

management based on final results from study CRAD001JUS226: a phase II, single arm study of the use of steroid-based mouthwash to prevent stomatitis in postmenopausal women with advanced or metastatic hormone receptor positive breast cancer being treated with everolimus plus exemestane Update of section 4.6 of the SmPC in order to add new information on breast-feeding The Package Leaflets are updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to bring the Afinitor PI in line with the latest QRD template version 10."	
WS1152 **Descovy-** **EMEA/H/C/004094/WS1152/0016** **Genvoya-** **EMEA/H/C/004042/WS1152/0030** **Odefsey-** **EMEA/H/C/004156/WS1152/0012** MAH: Gilead Sciences International Ltd, Lead Rapporteur: Robert James Hemmings, "Update of sections 4.8 and 5.1 of the SmPC in order to amend the information regarding undesirable effects and pharmacodynamic properties of Genvoya, Descovy and Odefsey following Week 144 efficacy and safety data from Study GS-US-292-0112, listed as a category 4 study in the RMP; this is a phase 3 open-label safety study of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide single-tablet regimen in HIV-1 positive patients with mild to moderate renal impairment. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity make administrative updated to the Genvoya SmPC."	
WS1156 **Combivir-** **EMEA/H/C/000190/WS1156/0090** **Kivexa-EMEA/H/C/000581/WS1156/0072** **Triumeq-** **EMEA/H/C/002754/WS1156/0042** **Trizivir-EMEA/H/C/000338/WS1156/0104** MAH: ViiV Healthcare UK Limited, Lead Rapporteur: Joseph Emmerich"Update of section	

4.5 of the SmPC to add information regarding the potential interaction between lamivudine and sorbitol based on the results of Study 204857. The Package Leaflet has been updated accordingly. Further, a minor amendment has been implemented throughout the SmPC in order to update the clinical terminology of Pneumocystis carinii pneumonia to Pneumocystis jiroveci pneumonia. In addition, the MAH takes the opportunity to make minor editorial changes , to align the annexes with the QRD template version 10 and to update the contact details of the local representative in Norway in the Package Leaflet."

B.6.10. CHMP-PRAC assessed procedures

Dificlir - fidaxomicin - EMEA/H/C/002087/II/0028

MAH: Astellas Pharma Europe B.V., Rapporteur: Filip Josephson, PRAC Rapporteur: Qun-Ying Yue,"C.I.11: Submission of an updated RMP version 7 in order to remove the post-authorization measure (PAM) MEA003 (concerning clinical study 2819-CL-2001 in patients with Clostridium difficile Infection who will receive a second course offidaxomicin) due to the non-feasibility of the study."

Jinarc - tolvaptan - EMEA/H/C/002788/II/0006

MAH: Otsuka Pharmaceutical Europe Ltd, Rapporteur: Greg Markey, PRAC Rapporteur: Julie Williams, Update of section 5.1 of the SmPC based on final results from study 156-08-271 (TEMPO 4:4) listed as a PAES in Annex II. This study is a Multicenter, Open-label, Extension Study (Extension of Trial 156-04-251) to Evaluate the Long-term Safety and Efficacy of Oral Tolvaptan Tablet Regimens in Patients With Autosomal Dominant Polycystic. It provides data for Jinarc treatment of autosomal dominant polcystic kidney disease (ADPKD) over 5 years. Reference to submission of this study is being deleted from Annex II.

In addition, the Marketing authorisation holder (MAH) took the opportunity to add the current ATC code applicable for tolvaptan as it has been assigned by by WHO.

The RMP version 13.1 has also been submitted to reflect the completion of the 156-08-271 study."

NINLARO - ixazomib - EMEA/H/C/003844/II/0002, Orphan

MAH: Takeda Pharma A/S, Rapporteur: Greg Markey, PRAC Rapporteur: Ulla Wändel Liminga, "Update of sections 4.8 and 5.1 of the SmPC to reflect the final overall survival analysis of C16010 China continuation study, a phase III study comparing ixazomib plus lenalidomide and dexamethasone versus placebo plus lenalidomide in patients with relapsed and/or refractory multiple myeloma, in order to fulfil SOB (Specific Obligation) 002. Annex II.E and the RMP (version 2.0) are updated accordingly. In addition the Marketing Authorisation Holder (MAH) took the opportunity to make a small correction in sections 4.7 and 9 of the SmPC and to the German translations."

OLYSIO - simeprevir - EMEA/H/C/002777/II/0031

MAH: Janssen-Cilag International NV, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Julie Williams"Update of section 5.1 of the SmPC in order to update the efficacy information following results from study HPC3002 A Prospective 3-year Follow-up Study in Subjects Previously Treated in a Phase IIb or Phase III Study with a TMC435-containing Regimen for the Treatment of Hepatitis C Virus (HCV) Infection listed as a category 3 study in the RMP and in fulfilment of MEA005. The RMP version 4.0 has also been submitted which includes updates of changes already agreed in procedures EMEA/H/C/002777/II/0021,EMEA/H/C/002777/II/0027 and EMEA/H/A-20/1438/C/2777/0019."

Pegasys - peginterferon alfa-2a - EMEA/H/C/000395/II/0092

MAH: Roche Registration Limited, Rapporteur: Filip Josephson, PRAC Rapporteur: Qun-Ying Yue,"Submission of the final report from a systematic review and individual patient data meta-analysis of PEG-IFN studies to identify optimal stopping rules in order to provide the final outcome related to the assessment of a Response Guided Therapy (RGT) for Pegasys in HBV-infected patients."

TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0036/G

MAH: Biogen Idec Ltd, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, "C.I.13: Submission of a Clinical Study Report for study 109HV321: A Randomized, Double-Blind, Phase 3b Study to Evaluate the Safety and Tolerability of BG00012 when Administered as 240 mg BID (twice daily) Dose Regimen with and without Aspirin Compared to Placebo or Following a Slow Titration (Category 3)

C.I.13: Submission of a Clinical Study Report for study 109MS406 (ASSURE): A Phase 4, Randomized, Double-Blind Study with a Safety Extension Period to Evaluate the Effect of Aspirin on Flushing Events in Subjects with Relapsing-Remitting Multiple Sclerosis Treated with Tecfidera (Dimethyl Fumarate) Delayed-release Capsules (Category 4)"

TECFIDERA - dimethyl fumarate - EMEA/H/C/002601/II/0037

MAH: Biogen Idec Ltd, Rapporteur: Martina Weise, PRAC Rapporteur: Martin Huber, C.I.4: Submission of a Clinical Study Report for study 109MS307: An Open-Label Study to Assess the Immune Response to Vaccination in Tecfidera-Treated Versus Interferon-Treated Subjects With Relapsing Forms of Multiple Sclerosis (Category 3). Consequently, this variation includes an update to section 4.5 (Interaction with other medicinal products and other forms of interaction) of the Summary of Product Characteristics (SmPC) and section 2 of the package leaflet."

Truxima - rituximab - EMEA/H/C/004112/II/0002/G

MAH: Celltrion Healthcare Hungary Kft., Rapporteur: Sol Ruiz, PRAC Rapporteur: Doris Stenver,

Xarelto - rivaroxaban - EMEA/H/C/000944/II/0052/G

MAH: Bayer Pharma AG, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue,
1) C.1.4. To add the authorised indications "Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults" to Xarelto 10 mg based on Einstein Choice trial (A randomised

phase III clinical study to evaluate efficacy and safety of Reduced-dosed rivaroxaban and standard-dosed rivaroxaban versus ASA in the long-term prevention of recurrent symptomatic venous thromboembolism in patients with symptomatic deep-vein thrombosis and/or pulmonary embolism) in section 4.1 of the SmPC 10 mg. Consequently: - Changes in sections 4.2, 4.8 and 5.1 for Xarelto 10mg, 15mg and 20 mg are made in order to update the posology, efficacy and safety information. - Annex III is updated to include Xarelto 10 mg into Patient alert card to support management of bleeding when the 10 mg is treated for long-term prevention of recurrent VTE - RMP (version 10) is updated 2) B.II.e.5.a.1- to add a new pack size of 14 film coated tablets in blister (PP/alu) for Xarelto 10 mg 3) B.II.e.5.a.1- to add a new pack size of 28 film coated tablets in blister (PP/alu) for Xarelto 10 mg 4) B.II.e.5.a.1- to add a new pack size of 98 film coated tablets in blister (PP/alu) for Xarelto 10 mg	
Yervoy - ipilimumab - EMEA/H/C/002213/II/0042 MAH: Bristol-Myers Squibb Pharma EEIG, Rapporteur: Paula Boudewina van Hennik, PRAC Rapporteur: Sabine Straus“Update of sections 4.4, 4.8 and 5.1 of the SmPC to reflect the final results of study CA184-169, a randomized double-blind phase III study of ipilimumab administered at 3 mg/kg versus at 10 mg/kg in subjects previously treated or untreated with unresectable or metastatic melanoma, in order to fulfil ANX 014.1. Annex II.D and the RMP (version 14.0) are updated accordingly. In addition the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet, to include some editorial changes and correct some typos throughout the product information, and to bring the product information in line with the latest QRD template version 10.”	
Zinbryta - daclizumab - EMEA/H/C/003862/II/0007 MAH: Biogen Idec Ltd, Rapporteur: Bruno	

Sepodes, PRAC Rapporteur: Eva A. Segovia, Update of sections 4.4 and 4.8 of the SmPC in order to add autoimmune haemolytic anaemia with frequency 'uncommon' and to include a warning concerning symptoms of this adverse drug reaction.
The Package Leaflet is updated accordingly.
In addition, the Marketing authorisation holder took the opportunity to implement minor editorial amendments throughout the Product Information.
The RMP version 5.0 has also been submitted."

WS1158/G
Humalog-
EMEA/H/C/000088/WS1158/0154/G
Liprolog-
EMEA/H/C/000393/WS1158/0117/G
MAH: Eli Lilly Nederland B.V., Lead Rapporteur: Robert James Hemmings, Lead PRAC Rapporteur: Julie Williams

B.6.11. PRAC assessed procedures

PRAC Led
Avastin - bevacizumab -
EMEA/H/C/000582/II/0095
MAH: Roche Registration Limited, Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Doris Stenver, PRAC-CHMP liaison: Sinan B. SaracSubmission of an updated RMP version 28.0 in order to remove the post-authorisation measure outlined in section III.4.3 of the RMP consisting of the submission of an extension protocol in order to obtain additional long-term follow-up (LTFU) information from the paediatric population after patients complete the minimum 5.5 year follow-up period as defined in the BO20924 (BERNIE) paediatric study protocol and to amend the date of submission of the final report (addendum CSR) for the BO20924 (BERNIE) study."

PRAC Led
Benlysta - belimumab -
EMEA/H/C/002015/II/0049
MAH: Glaxo Group Ltd, Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga, PRAC-CHMP liaison: Kristina Dunder"Submission of an updated RMP version 23 in order to amend the CSR available time line, patient number and

the primary and secondary endpoints listed in the EU Risk Management Plan, with regards to study HGS1006-C1121/BEL114054."

PRAC Led

Inovelon - rufinamide -

EMEA/H/C/000660/II/0041, Orphan

MAH: Eisai Ltd, Rapporteur: Alexandre Moreau, PRAC Rapporteur: Claire Ferard, PRAC-CHMP liaison: Pierre Demolis"Submission of the final clinical study report for study E2080-E044-401, the European registry of anti-epileptic drug use in patients with Lennox-Gastaut Syndrome (LAG), listed as a category 3 study in the RMP, in order to fulfil MEA 002.1. This is a non-interventional EU registry study entering patients (aged ≥4 years) with LGS who required a modification in anti-epileptic therapy (either the addition of another AED or the change of one drug to another) to evaluate the long-term safety of rufinamide."

PRAC Led

Plenadren - hydrocortisone -

EMEA/H/C/002185/II/0024, Orphan

MAH: Shire Services BVBA, Rapporteur: Kristina Dunder, PRAC Rapporteur: Qun-Ying Yue, PRAC-CHMP liaison: Kristina Dunder"Submission of an updated RMP (version 3.1) in order to submit protocol amendments of SHP 617-400 (EU-AIR) study – A European multicentre, multi-country, post-authorisation, observation study (registry) of patients with chronic adrenal insufficiency (category 3).

Additionally, the opportunity is being taken to implement a change agreed by the PRAC/CHMP as part of the assessment of MEA 005.3 in July 2016 and remove from the RMP reference to study SHP617-404 (SWE-DUS), a Category 3 study to monitor off-label use of Plenadren to evaluate physician prescribing patterns."

PRAC Led

WS1160

Afinitor-

EMEA/H/C/001038/WS1160/0053

Votubia-

EMEA/H/C/002311/WS1160/0043

MAH: Novartis Europharm Ltd, Lead Rapporteur: Harald Enzmann, Lead PRAC Rapporteur: Martin Huber, PRAC-CHMP liaison:

Harald Enzmann“To extend the due date of CRAD001Y2201 in the Oncology setting (Afinitor) from 3Q 2017 to 1Q 2018 in risk management plan and annex II and to for Study CRAD001MIC03 in the TSC setting (Votubia) from December 2017 to 2Q 2018. Furthermore the MAH align the RMP by introduced some administrative changes.”

B.6.12. CHMP-CAT assessed procedures

Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells -
EMEA/H/C/002450/II/0012/G, Orphan, ATMP
MAH: Chiesi Farmaceutici S.p.A., Rapporteur: Egbert Flory

B.6.13. CHMP-PRAC-CAT assessed procedures

B.6.14. PRAC assessed ATMP procedures

B.6.15. Unclassified procedures and worksharing procedures of type I variations

WS1115/G
Ambirix-
EMEA/H/C/000426/WS1115/0084/G
Twinrix Adult-
EMEA/H/C/000112/WS1115/0118/G
Twinrix Paediatric-
EMEA/H/C/000129/WS1115/0119/G
MAH: GSK Biologicals SA, Lead Rapporteur: Robert James Hemmings

WS1116
Infanrix hexa-
EMEA/H/C/000296/WS1116/0217
MAH: GSK Biologicals SA, Lead Rapporteur: Bart Van der Schueren

WS1122/G
Hexacima-
EMEA/H/C/002702/WS1122/0060/G
Hexaxim-
EMEA/H/W/002495/WS1122/0066/G
Hexyon-
EMEA/H/C/002796/WS1122/0064/G
MAH: Sanofi Pasteur SA, Lead Rapporteur: Jan Mueller-Berghaus

WS1129/G
Hexacima-
EMEA/H/C/002702/WS1129/0061/G
Hexaxim-
EMEA/H/W/002495/WS1129/0067/G
Hexyon-
EMEA/H/C/002796/WS1129/0065/G
MAH: Sanofi Pasteur SA, Lead Rapporteur: Jan Mueller-Berghaus

WS1138
Actos-EMEA/H/C/000285/WS1138/0077
Competact-
EMEA/H/C/000655/WS1138/0065
Glubrava-
EMEA/H/C/000893/WS1138/0051
Glustin-EMEA/H/C/000286/WS1138/0076
Tandemact-
EMEA/H/C/000680/WS1138/0055
MAH: Takeda Pharma A/S, Lead Rapporteur: Patrick Salmon

WS1139/G
Rivastigmine 1A Pharma-
EMEA/H/C/001181/WS1139/0023/G
Rivastigmine Hexal-
EMEA/H/C/001182/WS1139/0024/G
Rivastigmine Sandoz-
EMEA/H/C/001183/WS1139/0025/G
MAH: 1 A Pharma GmbH, Informed Consent of Exelon, Lead Rapporteur: Alexandre Moreau

WS1157
Relvar Ellipta-
EMEA/H/C/002673/WS1157/0030
Revinty Ellipta-
EMEA/H/C/002745/WS1157/0026
MAH: Glaxo Group Ltd, Lead Rapporteur: Concepcion Prieto Yerro “To update section 4.5 of the SmPC and section 2 of the package leaflet following the release of the PRAC recommendation on signals (EMA/PRAC/700146/2016) on 21st November 2016. The MAH is also proposing a new wording in the `Systemic corticosteroid effects' section of Section 4.4 related to `Cushing's syndrome or adrenal syppression'.”

WS1165

Aflunov-
EMEA/H/C/002094/WS1165/0035
Foclivia-
EMEA/H/C/001208/WS1165/0030
MAH: Seqirus S.r.l, Lead Rapporteur: Daniela Melchiorri

B.7. DOCUMENTS TABLED IN MMD AFTER THE CHMP PLENARY

B.7.1. Line listing for Variation Type I and Variation Type II (MMD only) post authorisation procedures from the beginning of the year.

B.7.2. Line listing overview of all applications under the centralised procedure (MMD only). line listing - products - authorised, under evaluation, suspended.xls

B.7.3. Opinion on Marketing Authorisation transfer (MMD only).

B.7.4. Notifications in accordance with Article 61(3) of Council Directive 2001/83/EC (MMD only).

B.7.5. Request for supplementary information relating to Notification of Type I variation (MMD only).

B.7.6. Notifications of Type I Variations (MMD only).

C. Annex C - Post-Authorisation Measures (PAMs), (Line listing of Post authorisation measures with a description of the PAM. Procedures starting in that given month with assessment timetabled)

D. Annex D - Post-Authorisation Measures (PAMs), (Details on PAMs including description and conclusion, for adoption by CHMP in that given month, or finalised ones with PRAC recommendation and no adoption by CHMP needed)

E. Annex E - EMEA CERTIFICATION OF PLASMA MASTER FILES

Disclosure of information related to plasma master files cannot be released at present time as these contain commercially confidential information.

E.1. PMF Certification Dossiers:

E.1.1. Annual Update

E.1.2. Variations:

E.1.3. Initial PMF Certification:

E.2. Time Tables – starting & ongoing procedures: For information

PMF timetables starting and ongoing procedures	Tabled in MMD and sent by post mail (folder E).

F. ANNEX F - Decision of the Granting of a Fee Reduction/Fee Waiver

F.1. Parallel Distribution - Pursuant to Article 9 of Council Regulation (EC) No. 2743/98 of 14 December 1998, as amended

F.2. Request for scientific opinion on justification of exceptional circumstance and for imperative grounds of public health

G. ANNEX G

G.1. Final Scientific Advice (Reports and Scientific Advice letters):

Disclosure of information related to Scientific Advice cannot be released at present time as these contain commercially confidential information.

Qualification of Biomarkers

HTA

G.2. Ongoing procedures

G.3. PRIME

Disclosure of some information related to PRIME cannot be released at present time as these contain commercially confidential information.

G.3.1. List of procedures concluding at 20-23 March 2017 CHMP plenary:

Haematology-haemostaseology		
1.	ATMP; Treatment of Fanconi anaemia type A	The CHMP denied eligibility to PRIME and adopted the critical summary report.
Oncology		
2.	Treatment of metastatic breast cancer	The CHMP denied eligibility to PRIME and adopted the critical summary report.
3.	Treatment of Ovarian Cancer	The CHMP denied eligibility to PRIME and adopted the critical summary report.
4.	Treatment of locally advanced or metastatic HER2+ breast carcinoma	The CHMP denied eligibility to PRIME and adopted the critical summary report.

G.3.2. List of procedures starting in March 2017 for April 2017 CHMP adoption of outcomes

H. ANNEX H - Product Shared Mailboxes – e-mail address