23 May 2016
EMA/CHMP/349943/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 23-26 May 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

23 May 2016, 13:00 – 19:30, room 2A

24 May 2016, 08:30 – 19:30, room 2A

25 May 2016, 08:30 – 19:30, room 2A

26 May 2016, 08:30 – 15:00, room 2A

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 23-26 May 2016. See May 2016 CHMP minutes (to be published post June 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 23-26 May 2016

1.3. Adoption of the minutes

CHMP minutes for 25-28 April 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - amikacin - Orphan - EMEA/H/C/003936

Insmed Limited; Treatment of Mycobacterium avium Complex (MAC) lung disease in adult patients who have persistent positive sputum cultures despite the use of medically appropriate first-line therapy

Scope: Oral explanation

Action: Oral explanation to be held on 24 May 2016 at 14.00.

List of Outstanding Issues adopted on 25.02.2016. List of Questions adopted on 25.06.2015.

2.1.2. - drisapersen - Orphan - EMEA/H/C/003846

BioMarin International Limited; treatment of Duchenne muscular dystrophy (DMD)

Scope: Oral explanation

Action: Possible oral explanation to be held on 24 May 2016 at 9.00.

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 22.10.2015.

Participation of patients' representatives

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

2.2. Re-examination procedure oral explanations

2.3. Post-authorisation procedure oral explanations

2.3.1. Arzerra - ofatumumab - Orphan - EMEA/H/C/001131/II/0041

Novartis Europharm Ltd

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Bjorg Bolstad, PRAC Rapporteur: Doris Stenver

Scope: Opinion / Request for Supplementary Information

"Extension of Indication to include maintenance therapy in Chronic Lymphocytic Leukemia (CLL).
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In accordance with the new QRD template version 9.1, the MAH is also taking the opportunity of this procedure to update the Annex II and combine the 2 SmPCs for the 100mg and 1,000mg vials."

Action: Possible oral explanation to be held on 24 May 2016 at 11.00.

Request for Supplementary Information adopted on 28.04.2016, 25.02.2016, 22.10.2015.

SAG Oncology meeting was held on 14 April 2016.

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - bortezomib - EMEA/H/C/004207

treatment of multiple myeloma

Scope: Opinion, Similarity assessment report

Action: For adoption

List of Questions adopted on 28.01.2016. List of Outstanding Issues adopted on 01.04.2016

3.1.2. - bortezomib - EMEA/H/C/004076

treatment of multiple myeloma

Scope: Opinion, Similarity assessment report

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016, 28.01.2016. List of Questions adopted on 23.07.2015.

3.1.3. - sofosbuvir / velpatasvir - EMEA/H/C/004210

Accelerated assessment

treatment of chronic hepatitis C virus

Scope: Opinion

Action: For adoption

List of Questions adopted on 01.04.2016.

3.1.4. - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016, 25.02.2016. List of Questions adopted on 17.12.2015. Oral explanation held on 26.0.4.2016.

3.1.5. - pemetrexed - EMEA/H/C/003895

treatment of malignant pleural mesothelioma and non-small cell lung cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 22.10.2015.

3.1.6. - saxagliptin / dapagliflozin - EMEA/H/C/004057

treatment of type 2 diabetes

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.04.2016, 25.02.2016. List of Questions adopted on 24.09.2015.

3.1.7. - grazoprevir / elbasvir - EMEA/H/C/004126

treatment of chronic hepatitis C (CHC) in adults

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016, 25.02.2016. List of Questions adopted on 19.11.2015.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - darunavir - EMEA/H/C/004068

treatment of HIV-1

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 17.12.2015.

3.2.2. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004050

treatment of HIV

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 19.11.2015.

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

APEIRON Biologics AG; treatment of neuroblastoma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

BWP Report

3.2.4. - tenofovir disoproxil - EMEA/H/C/004049

treatment of HIV-1 infection and hepatitis B infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 17.12.2015.

3.2.5. - tenofovir disoproxil - EMEA/H/C/004120

treatment of HIV-1 infection and hepatitis B infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

3.2.6. - eluxadoline - EMEA/H/C/004098

for the treatment of irritable bowel syndrome with diarrhoea

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

3.3. Initial applications; Day 120 list of questions

3.3.1. - cabozantinib - EMEA/H/C/004163

Accelerated assessment

treatment of advanced renal cell carcinoma (RCC)

Scope: Day 120 list of questions

Action: For adoption

3.3.2. - prasterone - EMEA/H/C/004138

treatment of vulvovaginal atrophy

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - lenvatinib - EMEA/H/C/004224

Accelerated assessment

in combination with everolimus for the treatment of unresectable advanced or metastatic renal cell carcinoma (RCC)

Scope: Day 120 list of questions

Action: For adoption

3.3.4. - nonacog beta pegol - Orphan - EMEA/H/C/004178

Novo Nordisk A/S; treatment of haemophilia B

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.5. - tadalafil - EMEA/H/C/004297

treatment of pulmonary arterial hypertension (PAH)

Scope: Day 120 list of questions

Action: For adoption

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

treatment of prostate cancer

Scope: Day 120 list of questions

Action: For adoption

3.3.7. - pegfilgrastim - EMEA/H/C/004211

treatment of neutropenia

Scope: Day 120 list of questions

Action: For adoption

BWP Report

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

3.4.1. - ertapenem - EMEA/H/C/004080

treatment of bacterial infections and prophylaxis of surgical site infection following elective colorectal surgery

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted in February 2016.

Action: For adoption

List of Questions adopted on 25.02.2016

3.4.2. - allogeneic t cells genetically modified to express suicide gene - Orphan - ATMP - EMEA/H/C/002801

MolMed SpA; treatment in haploidentical haematopoietic stem cell transplantation

Scope: Update on procedure, Oral Explanation held at CAT on 18.05.2016

Action: For information

List of Outstanding Issues adopted on 01.04.2016, 28.01.2016, 26.03.2015. List of Questions adopted on 24.07.2014.

BWP Report

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

Sunesis Europe Ltd; treatment acute myeloid leukaemia

Scope: Request for an extension to the clock stop to respond to the Day 120 List of questions adopted in April 2016.

Action: For adoption

List of Questions adopted on 28.04.2016.

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

3.5.1. Sialanar - glycopyrronium bromide - PUMA - EMEA/H/C/003883

Proveca Limited; treatment of sialorrhoea

Scope: Letter from the applicant dated May 2016 requesting a re-examination of the Opinion adopted on 28.04.2016. Appointment of re-examination Rapporteurs

Action: Appointment of re-examination Rapporteurs

The Committee appointed Kristina Dunder as Re-examination Rapporteur and Arantxa Sancho Lopez as the re-examination Co-Rapporteur by written procedure on 17 May 2016. The PRAC Rapporteur remains the same for the initial evaluation.

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Opsiria - sirolimus - Orphan - EMEA/H/C/003978

Santen Oy; treatment of chronic non-infectious uveitis

Scope: Letter from the applicant dated 20 May 2016 informing of the decision to withdraw the MAA.

Action: For information

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. Repatha - evolocumab - EMEA/H/C/003766/X/0002

Amgen Europe B.V.

Rapporteur: Pieter de Graeff, PRAC Rapporteur: Kimmo Jaakkola

Scope: "To add a new strength of 420 mg (120 mg/mL) for evolocumab solution for injection in cartridge, for subcutaneous (SC) administration by an automated mini-doser device."

Action: For adoption

List of Questions adopted on 25.02.2016.

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. Fycompa - perampanel - EMEA/H/C/002434/X/0025

Eisai Europe Ltd.

Scope: "To add a new pharmaceutical form, oral solution, to the one currently approved (EU/1/12/776/024).
To add a new strength of 0.5 mg/ml for Fycompa finished product (EU/1/12/776/024)."

Action: For adoption

List of Questions adopted on 17.12.2015.

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. Ruconest - conestat alfa - EMEA/H/C/001223/X/0034

Pharming Group N.V

Rapporteur: Nithyanandan Nagercoil, Scope: "Addition of a new pharmaceutical form "powder and solvent for solution for injection" with self-administration kit."

Action: For adoption

4.3.2. Tivicay - dolutegravir - EMEA/H/C/002753/X/0018/G

ViiV Healthcare UK Limited

Rapporteur: Filip Josephson, Co-Rapporteur: Joseph Emmerich, PRAC Rapporteur: Julie Williams

Scope: "An extension application to add two new strengths (10mg and 25mg tablets) to support the extension (variation type II C.I.6) of the target population covered by the authorised therapeutic indication for Tivicay to treat paediatric patients from 6 years of age infected with HIV. Data from cohort I and II A of the clinical trial ING112578 are presented in support of the new therapeutic indication."

Action: For adoption

4.3.3. Zytiga - abiraterone - EMEA/H/C/002321/X/0039

Janssen-Cilag International N.V.

Rapporteur: Arantxa Sancho-Lopez, Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (500mg film-coated tablets)."

Action: For adoption

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

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

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. Adcetris - brentuximab vedotin - Orphan - EMEA/H/C/002455/II/0025

Takeda Pharma A/S

Rapporteur: Pieter de Graeff, Co-Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Sabine Straus

Scope: "Extension of Indication to include new indication for Adcetris (for the treatment of adult patients at increased risk of relapse or progression following ASCT"), 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." Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004).

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016, 01.04.2016, 22.10.2015, 25.06.2015.

5.1.2. Humira - adalimumab - EMEA/H/C/000481/II/0146

AbbVie Ltd.

Rapporteur: Kristina Dunder, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include treatment of non-infectious intermediate, posterior and panuveitis in adult patients for Humira.
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 is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016, 17.12.2015.

5.1.3. Kyprolis - carfilzomib - Orphan - EMEA/H/C/003790/II/0001/G

Amgen Europe B.V.

Rapporteur: Arantxa Sancho-Lopez, Scope: "Extension of Indication to include new indication for Kyprolis to be used with either lenalidomide and dexamethasone or dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the Marketing authorisation holder (MAH) updated section 6.6 of the SmPC to include the option to administer Kyprolis in a 100 mL intravenous bag containing 5% glucose solution for injection in line with the extension of indication part of this variation. Furthermore the MAH took the opportunity to include some editorial changes and harmonisations in the PI."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016.

5.1.4. Lucentis - ranibizumab - EMEA/H/C/000715/II/0061

Novartis Europharm Ltd

Rapporteur: Kristina Dunder, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Ulla Wändel Liminga

Scope: "Extension of Indication to include treatment of visual impairment due to choroidal neovascularization (CNV) based on 6-month data from the pivotal study CRFB002G2301 (MINERVA). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.8 and 5.1 and the Package Leaflet is proposed to be updated accordingly.

The application included an updated RMP version 16.0."

Action: For adoption

5.1.5. Revestive - teduglutide - Orphan - EMEA/H/C/002345/II/0020

NPS Pharma Holdings Limited

Rapporteur: Sinan B. Sarac, PRAC Rapporteur: Torbjorn Callreus

Scope: "Extension of Indication to include paediatric population for Revestive.
As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated in order to update the safety information. The Package Leaflet is updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015.

5.1.6. Synjardy - empagliflozin / metformin - EMEA/H/C/003770/II/0015

Boehringer Ingelheim GmbH

Rapporteur: Pieter de Graeff, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Miguel-Angel Macia

Scope: "Extension of Indication to include treatment with Synjardy as adjunct to standard care therapy in adult patients with type 2 diabetes mellitus and high cardiovascular risk when treatment with empagliflozin and metformin is appropriate and empagliflozin is needed to reduce the risk of all-cause mortality by reducing cardiovascular death and cardiovascular death or hospitalization for heart failure. As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated based on the final CSR of study EMPA-REG OUTCOME. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes/corrections in the SmPC. Moreover, the updated RMP version 5.0 has been submitted."

Action: For adoption

5.1.7. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0012

PTC Therapeutics International Limited

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Sabine Straus

Scope: "Extension of indication for Translarna to include the treatment of cystic fibrosis resulting from a nonsense mutation in at least one allele of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Consequently, sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 5.1, 5.2 of the SmPC were updated. The Package leaflet and RMP are being updated accordingly.
The MAH took also the opportunity to implement the QRD template v9.1. and proposed combined SmPC for Translarna 125 mg, 250 mg and 1000 mg granules for oral suspension. Minor editorial changes have been introduced throughout the PI.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC)

726/2004)

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

5.1.8. Tysabri - natalizumab - EMEA/H/C/000603/II/0077

Biogen Idec Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include new indication for Tysabri.
As a consequence, sections 4.1 AND 4.4 of the SmPC are updated in order to provide physicians with more options for treating RRMS patients with high disease activity who fail an initial disease modifying therapy (DMT). Consequential changes to sections 4.2, 4.3, 5.1 and Package Leaflet in Sections 2 and 3 are also proposed."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015, 25.06.2015.

5.1.9. Xalkori - crizotinib - EMEA/H/C/002489/II/0039

Pfizer Limited

Rapporteur: Pierre Demolis, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Isabelle Robine

Scope: "Extension of Indication to include treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC) based on the results of Study A8081001 (a multinational, multicentre, open-label, single-arm study of the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of crizotinib in patients with advanced cancer). Consequential changes are proposed to SmPC sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Annex II. The application included an updated RMP version 7.0."

Action: For adoption

5.1.10. Trajenta Jentadueto - linagliptin - EMEA/H/C/WS0915

Boehringer Ingelheim International GmbH

Lead Rapporteur: Pieter de Graeff, PRAC Rapporteur: Menno van der Elst

Scope: "Extension of Indication to include use of Trajenta as combination therapy with metformin and an SGLT-2 inhibitor and use of Jentadueto as combination therapy with an SGLT-2 inhibitor. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated based on studies 1245.30, 1275.10 and 1275.1. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to make minor editorial changes in the SmPC for Jentadueto only. Moreover, the updated RMP version 10 (for Trajenta) and version 12 (for Jentadueto) have been submitted."

Action: For adoption

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

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

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

6.2. Update of Ancillary medicinal substances in medical devices

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)

8. Pre-submission issues

8.1. Pre-submission issue

8.1.1. - glibenclamide - Orphan - H0004379

AmmTek; Treatment of neonatal diabetes, paediatric formulation (ready to use oral suspension of glibenclamide) to be used in newborns, infants and children.

Scope: Letter from the company dated 30 March 2016 requesting an accelerated assessment

Action: For adoption

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

8.1.2. - etirinotecan Pegol - H0003874

indicated for the treatment of patients with locally recurrent or metastatic breast cancer (MBC). Prior therapy should have included an anthracycline, a taxane and capecitabine (ATC).

Scope: Letter from the company dated 3 May 2016 requesting an accelerated assessment

Action: For adoption

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

8.1.3. - midostaurin - Orphan - H0004095

Novartis Europharm Ltd; indicated as a combination therapy for the treatment of patients with newly diagnosed acute myeloid leukaemia who are FLT3 mutation-positive and who are eligible to receive standard induction and consolidation chemotherapy; indicated for the treatment of patients with aggressive systemic mastocytosis (ASM) or mast cell leukemia (MCL) with or without an associated hematologic non-mast cell lineage disorder (AHNMD).

Scope: Letter from the company dated 4 May 2016 requesting an accelerated assessment

Action: For adoption

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

8.2.2. Recommendation for PRIME eligibility

Action: For adoption

8.2.3. Fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector

Executive Director decision on fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector

Action: For adoption

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Simponi - golimumab - EMEA/H/C/000992/II/0063

MAH: Janssen Biologics B.V., Rapporteur: Kristina Dunder, PRAC Rapporteur: Ulla Wändel Liminga,

Scope: Opinion

"Update of the SmPC sections 4.2 and 5.1 in order to reflect the data from a multicentre, placebo-controlled, double-blind, randomised-withdrawal, parallel group study (GO KIDS) in children (2 to 17 years of age) with active polyarticular juvenile idiopathic arthritis (pJIA). The Package leaflet is proposed to be updated accordingly. This procedure includes also an update to the RMP."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015, 26.03.2015.

9.1.2. Revatio - sildenafil - EMEA/H/C/000638/II/0073

MAH: Pfizer Limited, Rapporteur: Pieter de Graeff,

Scope: Opinion

"Following the availability of powder for oral suspension formulation and following the request of CHMP, update of sections 4.2, 6.3, 6.4 and 6.6 of Revatio 20mg film-coated tablets SmPC and section 4.2 of Revatio 10mg powder for oral suspension to delete information related to the extemporaneously prepared oral suspension. The film-coated tablet PL is updated accordingly."

Action: For adoption

10. Referral procedures

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

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

10.2.1. Desloratadine-containing products

Rapporteur: Daniel Brasseur, Co-Rapporteur: Andrea Laslop

Scope: Opinion or List of Outstanding Issues

Prescription status of desloratadine-containing products

Action: For adoption

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

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

10.4.1. Diclofenac 50 mg Tablets - Diclofenac epolamine - EMEA/H/A-29/1434

Altergon Italia srl

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Joseph Emmerich,

RMS: UK, CMS: CZ, FR, SK

Decentralised Procedure number: UK/H/5906/001/DC

Scope: List of outstanding Issues / Opinion

Disagreements regarding the demonstration of bioequivalence in the fed state

Action: For adoption

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

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

10.6.1. Dienogest/Ethinylestradiol containing products indicated in acne - Dienogest / EMEA/H/A-31/ 1435

Rapporteur: Martina Weise, Co-Rapporteur: Nithyanandan Nagercoil,

Scope: Amended timetable

Action: For information, adopted via written procedure on 03.05.2016

The CHMP noted a 1-month extension to the timetable adopted by written procedure on 03.05.2016

Re-start of the procedure: 28.04.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 08.06.2016

Comments: 13.06.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 16.06.2016

CHMP list of outstanding issues or Opinion: June 2016 CHMP

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: Letter from the MAH dated 4 May 2016 requesting an extension of timeframe to submit responses to the List of Questions adopted on 1 April 2016.

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: Revised timetable adopted by written procedure

Submission of responses: 04.08.2016

Re-start of the procedure: 18.08.2016

Rapporteur/co-rapporteur assessment reports circulated to CHMP: 31.08.2016

Comments: 05.09.2016

Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP: 08.09.2016

CHMP LoOI/CHMP opinion: September 2016 CHMP

10.6.3. Semler Research Centre Private Ltd - EMEA/H/A-31/1443

Rapporteur: Pieter de Graeff, Co-Rapporteur: Concepcion Prieto-Yerro

Scope: Update on the procedure

Article 31 referral triggered by the UK, Germany, Spain, Denmark and the Netherlands in relation to findings of non-compliance with GCP at the Semler bioanalytical and clinical facilities in Bangalore, India

Action: For information

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

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

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

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

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. Levonelle 1500mcg tablets and associated names – Levonorgestrel - EMEA/H/A-13/1427

MAH: Gedeon Richter Plc Group of companies

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: Daniela Melchiorri RMS: UK, CMS: AT, BE, CZ, DE, EL, ES, FR, IE, ES, IS, IT, LT, LU, NL, NO, PL, PT, SE, Mutual recognition procedure: UK/H/0803/001/II/022

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25 February 2016. List of Questions adopted on 22 October 2015.

11. Pharmacovigilance issue

11.1. Early Notification System

May 2016 2016 Early Notification System on envisaged CHMP/CMDh outcome accompanied by communication to the general public

Action: For information

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

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

Scope: ITF Briefing Meeting

Meeting date: 22 June 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 1 June 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: TBD

Action: For adoption

Scope: ITF Briefing Meeting Meeting date: 17 June 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 4 July 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: TBD

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 25 May 2016

Action: For adoption

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

Request from EDQM for EMA scientific Opinion under Art. 57 (1)J of Regulation (EC) No 726/2004

Scope: Timetable

Action: For adoption

Request from the European Commission for an EMA scientific Opinion under Article 57

Scope: Timetable

Action: For adoption

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Confirmation of area of expertise of Co-opted Member

Action: For discussion

Mandate of Sol Ruiz and Jean-Louis Robert expires in July 2016. Sol Ruiz's area of expertise has been in Quality (biotech and biological), with expertise in advanced therapies (gene, cell and tissue therapies) and Jean-Louis Robert's in Quality (non-biologicals, synthetic chemicals).

Comment from Spanish delegation on area of expertise

14.1.2. Assessment Report templates for Generic products

Scope: Proposal to amend assessment report templates for Generic products.

Action: For discussion

14.1.3. Feedback from recent interactions on evaluation management

Action: For discussion

14.1.4. Confirmation of joint CHMP/PDCO membership for Hungary, Romania, Luxembourg

Hungary - Agnes Gyurasics and Melinda Sobor

Romania - Nela Vilceanu and Dana Gabriela Marin

Luxembourg - Jacqueline Genoux-Hames and Carola de Beaufort

Action: For adoption

14.1.5. Update on the "CHMP assessment report on the significant clinical benefit in comparison with existing therapies in accordance with Article 14(11) of Regulation (EC) No 726/2004" and "Practical guidance on elements required to grant an additional year of marketing protection due to significant clinical benefit"

Action: For information

14.2. Coordination with EMA Scientific Committees

14.2.1. Pharmacovigilance Risk Assessment Committee (PRAC)

Summary of recommendations and advice of PRAC meeting held on **10-13 May 2016**

Action: For information

List of Union Reference Dates and frequency of submission of Periodic Safety Update Reports (EURD list) for May 2016

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 19-20 May 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Not applicable this month

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at May 2016 PDCO

Action: For information

Report from the PDCO meeting held on 25-27 May 2016

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 17-19 May 2016
Action: For information

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 23-25 May 2016

Action: For information

Response from PKWP to question from the CMDh on bioequivalence for generic ibuprofen products

Action: For adoption

14.2.7. Committee for Medicinal Products for Veterinary Use (CVMP)

Scope: "Updated scientific advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health

Action: For adoption for public consultation until 2 June 2016

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 10-13 May 2016. Table of conclusions

Action: For information

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

Election of SAWP Vice Chair

Action: For adoption

14.3.2. Gastroenterology Drafting Group

Nomination of observer – Mari Thorn (DE)

Action: For adoption

14.3.3. Safety Working Party (SWP)

Pulegone and Menthofurane – SWP responses to HMPC/CHMP questions on the HMPC public statement (EMA/CHMP/SWP/305366/2016)

Action: For adoption

14.3.4. Radiopharmaceutical Drafting Group (RDG)

Chair: Patrick Salmon

Scope: Guideline on core SmPC and Package Leaflet for Fluorodopa (EMA/CHMP/337958/2016)

Action: For adoption for 4 months public consultation

Scope: Guideline on core SmPC and Package Leaflet for gadoteric acid (EMA/CHMP/337820/2016)

Action: For adoption for 4 months public consultation

Scope: Guideline on core SmPC and Package Leaflet for (68Ge/68Ga) generator (EMA/CHMP/337681/2016)

Action: For adoption for 4 months public consultation

14.4. Cooperation within the EU regulatory network

14.5. Cooperation with International Regulators

14.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Scope: ICH E11 (R) 1

Presentation by Daniel Brasseur

Action: For information

Scope: Appointment of Piotr Krauze as an Expert representing EU for ICH Q12, replacing David Cockburn in this role

Action: For adoption

Scope: S3A Q&A - Step 2 - Note for guidance on toxicokinetics the assessment of systemic exposure in toxicity studies - questions and answers (EMA/CHMP/ICH/320985/2016)

Action: For adoption

Scope: Guideline on enhancing the format and structure of benefit-risk information in ICH Efficacy - M4E(R2)

Action: For information

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

14.7. CHMP work plan

14.8. Planning and reporting

14.9. Others

15. Any other business

15.1. AOB topic

16. 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)*

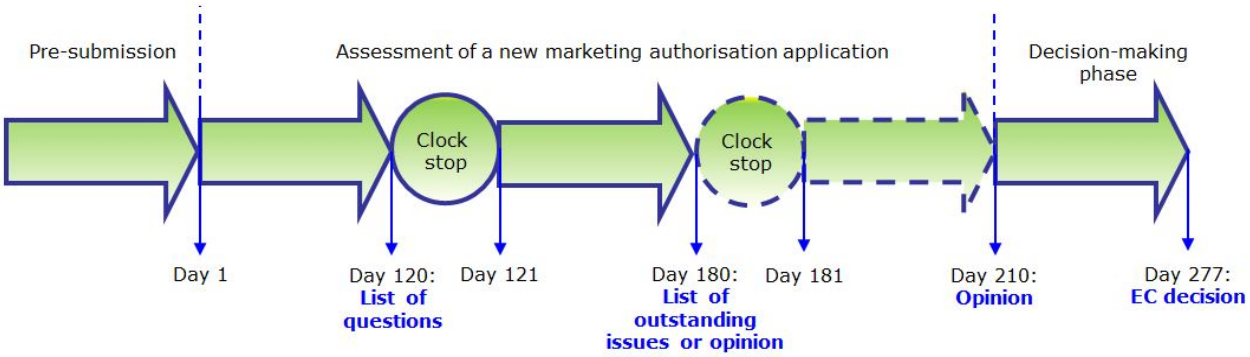
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures (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/