12 September 2016
EMA/CHMP/603605/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 12-15 September 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

12 September 2016, 13:00 – 19:30, room 2A

13 September 2016, 08:30 – 19:30, room 2A

14 September 2016, 08:30 – 19:30, room 2A

15 September 2016, 08:30 – 16:00, 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).

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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 12-15 September 2016. See September 2016 CHMP minutes (to be published post October 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 12-15 September 2016

1.3. Adoption of the minutes

CHMP minutes for 18-21 July 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - venetoclax - Orphan - EMEA/H/C/004106

AbbVie Ltd.; treatment of patients with CLL who have failed a B-cell receptor inhibitor due to intolerance or progression

Scope: Oral explanation

Action: Oral explanation to be held on Tuesday 13 September 2016 at 9:00

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 01.04.2016.

2.1.2. - cediranib - Orphan - EMEA/H/C/004003

AstraZeneca AB; treatment of platinum sensitive relapsed (PSR) ovarian cancer relapsed (PSR) ovarian cancer

Scope: Oral explanation

Action: Oral explanation to be held on Wednesday 14 September 2016 at 11:00

List of Outstanding Issues adopted on 28.04.2016. List of Questions adopted on 19.11.2015.

2.2. Re-examination procedure oral explanations

2.2.1. Ninlaro - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: possible oral explanation, opinion, Report from SAG Oncology meeting held on 5 September 2016

Action: Oral explanation to be held on Tuesday 13 September 2016 at 14:00

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

Opinion adopted on 26 May 2016.

See also 3.5.1

2.3. Post-authorisation procedure oral explanations

2.3.1. Jardiance - empagliflozin - EMEA/H/C/002677/II/0014

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Dolores Montero Corominas

Scope: Possible oral explanation to be held on Wednesday 14 September 2016 at 09:00

"Extension of indication to include a new indication on prevention of cardiovascular events, based on the final data of the cardiovascular safety phase III clinical trial EMPA-REG OUTCOME. As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is also updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make some editorial changes."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016.

See also 5.1.4

2.4. Referral procedure oral explanations

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - chenodeoxycholic acid - Orphan - EMEA/H/C/004061

Sigma-tau Arzneimittel GmbH; treatment of inborn errors of primary bile acid synthesis

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016, 28.04.2016. List of Questions adopted on 25.02.2016.

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

treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 26.05.2016. List of Questions adopted on 17.12.2015.

3.1.3. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004137

treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 25.02.2016.

3.1.4. - empagliflozin / linagliptin - EMEA/H/C/003833

treatment of type 2 diabetes mellitus

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 25.02.2016.

3.1.5. - sildenafil - EMEA/H/C/004289

treatment of patients with pulmonary arterial hypertension

Scope: Opinion

Action: For adoption

List of Questions adopted on 01.04.2016.

3.1.6. - palbociclib - EMEA/H/C/003853

treatment of breast cancer

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 17.12.2015.

3.1.7. - ivabradine - EMEA/H/C/004217

treatment of angina pectoris

Scope: Opinion

Action: For adoption

List of Questions adopted on 01.04.2016.

3.1.8. - ivabradine - EMEA/H/C/004117

treatment of angina pectoris

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 01.04.2016.

3.1.9. - olaratumab - Orphan - EMEA/H/C/004216

Accelerated assessment

Eli Lilly Nederland B.V.; treatment of soft tissue sarcoma

Scope: Opinion

Action: For adoption

List of Questions adopted on 23.06.2016.

BWP report

3.1.10. - etelcalcetide - EMEA/H/C/003995

treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy, treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 23.06.2016. List of Questions adopted on 28.01.2016.

3.1.11. - edotreotide - Orphan - EMEA/H/C/004140

Advanced Accelerator Applications; Diagnosis of gastro-entero-pancreatic neuroendocrine tumours

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 25.02.2016.

3.2. Initial applications; Day 180 list of outstanding issues

3.2.1. - aceneuramic acid - Orphan - EMEA/H/C/004176

Ultragenyx UK Limited; treatment of Hereditary Inclusion Body Myopathy (HIBM)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

3.2.2. - lonoctocog alfa - EMEA/H/C/004075

treatment of haemophilia A

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.2.3. - alectinib - EMEA/H/C/004164

indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive.

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

3.2.4. - adalimumab - EMEA/H/C/004212

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatri Crohn's disease and Ulcerative colitis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.2.5. - adalimumab - EMEA/H/C/004373

treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease,

paediatri Crohn's disease and Ulcerative colitis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

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

moderate to severe plaque psoriasis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 01.04.2016.

BWP report

3.2.7. - emtricitabine / tenofovir disoproxil - EMEA/H/C/004215

treatment of HIV-1 infection

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

3.2.8. - insulin aspart - EMEA/H/C/004046

Treatment of diabetes mellitus in adults

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.2.9. - eryaspase - Orphan - EMEA/H/C/004055

ERYTECH Pharma S.A.; treatment of leukaemia

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

BWP report

3.2.10. - insulin glargine - EMEA/H/C/004101

treatment of diabetes mellitus

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.2.11. - chlormethine - Orphan - EMEA/H/C/002826

Actelion Registration Ltd.; treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 24.09.2015.

3.2.12. - teriparatide - EMEA/H/C/004368

treatment of osteoporosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.2.13. - parathyroid hormone - Orphan - EMEA/H/C/003861

NPS Pharma Holdings Limited; treatment of hypoparathyroidism

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016, 28.04.2016, 24.09.2015. List of Questions adopted on 26.03.2015.

BWP report

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

Novo Nordisk A/S; treatment of haemophilia B

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.05.2016.

BWP report

3.2.15. - obeticholic acid - Orphan - EMEA/H/C/004093

Intercept Pharma Ltd; treatment of primary biliary cirrhosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 22.10.2015.

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

treatment of pulmonary arterial hypertension (PAH)

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 26.05.2016.

3.2.17. - tenofovir alafenamide - EMEA/H/C/004169

chronic hepatitis B in adults

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.06.2016.

3.2.18. - teriparatide - EMEA/H/C/003916

treatment of osteoporosis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.04.2016.

BWP report

3.3. Initial applications; Day 120 list of questions

3.3.1. - inotuzumab ozogamicin - Orphan - EMEA/H/C/004119

Pfizer Limited; Treatment of ALL

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.2. - pacritinib - Orphan - EMEA/H/C/004193

Baxalta Innovations GmbH; treatment of myelofibrosis

Scope: Day 120 list of questions

Action: For adoption

3.3.3. - febuxostat - EMEA/H/C/004374

treatment of hyperuricaemia

Scope: Day 120 list of questions

Action: For adoption

3.3.4. - lutetium (177 Lu) dotatate - Orphan - EMEA/H/C/004123

Accelerated assessment

Advanced Accelerator Applications; Treatment of gastro-entero-pancreatic neuroendocrine tumours

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - masitinib - Orphan - EMEA/H/C/004159

AB Science; treatment of mastocytosis

Scope: Day 120 list of questions

Action: For adoption

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

treatment of adult patients with multiple sclerosis
treatment of multiple sclerosis

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.7. - rituximab - EMEA/H/C/003903

treatment of Non-Hodgkin's lymphoma (NHL), Chronic lymphocytic leukaemia (CLL), Rheumatoid arthritis and Granulomatosis with polyangiitis and microscopic polyangiitis

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.8. - atezolizumab - EMEA/H/C/004143

treatment of metastatic urothelial
treatment of urothelial carcinoma and non-small cell lung cancer (NSCLC)

Scope: Day 120 list of questions

Action: For adoption

BWP report

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

prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B.

Scope: Day 120 list of questions

Action: For adoption

BWP report

3.3.10. - carglumic acid - EMEA/H/C/004019

treatment of hyperammoniemia

Scope: Day 120 list of questions

Action: For adoption

3.3.11. - patiromer sorbitex calcium - EMEA/H/C/004180

treatment of hyperkalaemia

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. - bezlotoxumab - EMEA/H/C/004136

indicated for the prevention of Clostridium difficile infection (CDI) recurrence

Scope: amended timetable

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016, List of Questions adopted on 01.04.2016.

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

3.5.1. Ninlaro - ixazomib - Orphan - EMEA/H/C/003844

Takeda Pharma A/S; multiple myeloma

Scope: possible oral explanation, opinion, Report from SAG Oncology meeting held on 5 September 2016

Action: For discussion

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

Opinion adopted on 26 May 2016.

List of experts for the SAG Oncology as well as the list of questions to this group was adopted via written procedure on 02.09.2016.

See also 2.2.1

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

3.7.1. Cokiera - dasabuvir / ombitasvir / paritaprevir / ritonavir - EMEA/H/C/004235

AbbVie Ltd.; treatment of hepatitis C

Rapporteur: Kristina Dunder, Co-Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Margarida Guimarães

Scope: Withdrawal of initial marketing authorisation application

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. 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

List of Questions adopted on 26.05.2016.

4.1.2. Stelara - ustekinumab - EMEA/H/C/000958/X/0049/G

Janssen-Cilag International N.V.

Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams

Scope: "An extension application covering a new pharmaceutical form (concentrate for solution for infusion), a new strength (130mg) and a new route of administration (intravenous use); a type II variation (C.1.6.a) to add a new indication (Crohn`s Disease)."

Action: For adoption

List of Outstanding Issues adopted on 21.07.2016. List of Questions adopted on 28.04.2016.

4.1.3. 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

List of Questions adopted on 26.05.2016.

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

Janssen-Cilag International N.V.

Rapporteur: Aranzazu Sancho-Lopez,

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

Action: For adoption

List of Questions adopted on 26.05.2016.

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

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

4.3.1. 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

4.3.2. Esbriet - pirfenidone - Orphan - EMEA/H/C/002154/X/0035/G

Roche Registration Limited

Rapporteur: Greg Markey, Co-Rapporteur: David Lyons, PRAC Rapporteur: Julie Williams

Scope: "Extension application to introduce a new pharmaceutical form associated with 3 new strengths (267mg, 534mg and 801mg film-coated tablets).
In addition, the following manufacturing sites are also introduced for the currently approved 267mg hard capsules presentations (EU/1/11/667/001-003):
B.I.b.1.f - To add an alternative site responsible for quality control of the active substance.
B.I.b.1.f - To add an alternative site responsible for quality control of the active substance."

Action: For adoption

4.3.3. Ilaris - canakinumab - EMEA/H/C/001109/X/0045/G

Novartis Europharm Ltd

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Outi Mäki-Ikola, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Grouped application comprising an extension application covering an additional formulation (150 mg/ml solution for injection) and a type II variation (C.I.6.a) to add a new indication.
The proposed new indication is based on the results of the pivotal phase 3 study CACZ885N2301 and covers the treatment of adults and children of 2 years of age and older with one of the following Periodic Fever Syndromes:
- Tumour Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS);
- Hyperimmunoglobulin D Syndrome (HIDS) / Mevalonate Kinase Deficiency (MKD);
- Familial Mediterranean Fever (FMF) in patients in whom colchicine is contraindicated, is not tolerated, or does not provide an adequate response.
As a consequence sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the annexes have been aligned with the latest QRD template v.10. A revised RMP version 11 was provided as part of the application."

Action: For adoption

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

4.4.1. Xtandi - enzalutamide - EMEA/H/C/002639/X/0029

Astellas Pharma Europe B.V.

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

Scope: "To add new pharmaceutical form and strenghts (film-coated tablets 40 mg and 80 mg) to the currently approved presentations for Xtandi."

Clockstop extension requested to respond to LoQ,

Action: For adoption

List of Questions adopted on 21.07.2016.

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. Abilify - aripiprazole - EMEA/H/C/000471/II/0110

Otsuka Pharmaceutical Europe Ltd

Rapporteur: Bruno Sepodes, Scope: "Extension of Indication to include treatment of schizophrenia in adolescents between 13 – 15 years of age based on paediatric studies 31-09-266 and 31-09-267 submitted according to Article 46 of the paediatric regulation. As a consequence sections 4.1, 4.2 and 4.8 of the SmPC have been updated and the Package Leaflet has been updated accordingly."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016, 24.09.2015.

5.1.2. Cinryze - C1-esterase inhibitor, human - EMEA/H/C/001207/II/0045

Shire Services BVBA

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: "Extension of Indication to include children with hereditary angioedema (HAE) in the treatment and pre-procedure prevention of angioedema attacks.
As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2, 6.5 and 6.5 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance.
In addition, an update of regional information in module 3.2.R due to the proposed dose recommendation for children is submitted."

Action: For adoption

5.1.3. Inovelon - rufinamide - Orphan - EMEA/H/C/000660/II/0037

Eisai Ltd

Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard

Scope: "Extension of Indication to include treatment of seizures associated with Lennox-Gastaut Syndrome in paediatric patients 1 year of age and older, based on the results of study E2080-G000-303 (Study 303); a randomized, controlled, open-label study to evaluate the cognitive development effects and safety, and pharmacokinetics of adjunctive rufinamide treatment in paediatric subjects 1 to less than 4 years of age with inadequately controlled Lennox-Gastaut Syndrome. This study was conducted to fulfil the long-term (2

years) safety and efficacy objectives required as part of the Paediatric Investigation Plan (PIP) EMEA-000709-PIP01-09. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are proposed to be updated and the Package Leaflet is proposed to be updated accordingly. In addition, the MAH took the opportunity to make minor editorial changes in the annexes, to implement changes in line with the latest QRD template and to combine the SmPCs, labelling and Package Leaflets for the three authorised strengths of the tablet formulation in line with the current version of the QRD template. The application included an updated RMP version 9.0."

Action: For adoption

5.1.4. Jardiance - empagliflozin - EMEA/H/C/002677/II/0014

Boehringer Ingelheim International GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Dolores Montero Corominas

Scope: Possible oral explanation to be held on Wednesday 14 September 2016 at 09:00

"Extension of indication to include a new indication on prevention of cardiovascular events, based on the final data of the cardiovascular safety phase III clinical trial EMPA-REG OUTCOME. As a consequence, section 4.1 of the SmPC is updated. The Package Leaflet is also updated accordingly.
In addition, the Marketing authorisation holder (MAH) took the opportunity to make some editorial changes."

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016, 25.02.2016.

See also 2.3.1

5.1.5. Nimenrix - meningococcal group A, C, W135 and Y conjugate vaccine - EMEA/H/C/002226/II/0049

Pfizer Limited

Rapporteur: Greg Markey, Co-Rapporteur: Karsten Bruins Slot, PRAC Rapporteur: Rafe Suvarna

Scope: "Extension of Indication to include a wider paediatric population starting from 6 weeks of age for Nimenrix. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and the RMP are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016.

5.1.6. NovoRapid - insulin aspart - EMEA/H/C/000258/II/0112

Novo Nordisk A/S

Rapporteur: Kristina Dunder

Scope: “Extension of Indication to include the use of NovoRapid in children from 1 to 2 years of age.
As a consequence, sections 4.1, 4.2, 4.4 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
Furthermore, the PI is brought in line with the latest QRD template version 10.”

Action: For adoption

5.1.7. Opdivo - nivolumab - EMEA/H/C/003985/II/0012

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 adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL):
- after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin, or
- after at least two prior therapies in patients who are not candidates for ASCT,
for OPDIVO as monotherapy.
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 new indication, add a warning that patients with active autoimmune disease and symptomatic interstitial lung disease were excluded from clinical trials of cHL, and update the safety and pharmacodynamic information. The Package Leaflet is updated in accordance.
Furthermore, the PI is brought in line with the latest QRD template version 10.0.
Moreover, the updated RMP version 5.0 has been submitted”

Action: For adoption

Request for Supplementary Information adopted on 23.06.2016.

5.1.8. Raxone - idebenone - Orphan - EMEA/H/C/003834/II/0003

Santhera Pharmaceuticals (Deutschland) GmbH

Rapporteur: John Joseph Borg, Co-Rapporteur: Andrea Laslop, PRAC Rapporteur: Carmela Macchiarulo

Scope: “Extension of indication to include treatment of patients with Duchenne muscular dystrophy in whom respiratory function has started to decline and who are currently not taking concomitant glucocorticoids. Raxone can be used in patients previously treated with glucocorticoids or in patients in whom glucocorticoid treatment is not desired, not tolerated or is contraindicated.”

Action: For adoption

5.1.9. Revlimid - lenalidomide - Orphan - EMEA/H/C/000717/II/0089/G

Celgene Europe Limited

Rapporteur: Pierre Demolis, PRAC Rapporteur: Claire Ferard

Scope: “Extension of indication to add treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who have undergone autologous stem cell transplantation (ASCT). Consequently SmPC sections 4.1, 4.2, 4.4, 4.8 and 5.1 have been updated with the efficacy

and safety data. The Package Leaflet and the RMP have been updated accordingly. Furthermore, the MAH introduced 7-day pack sizes for the 10 mg and 15 mg strengths with subsequent changes to the Product Information."

Action: For adoption

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

Boehringer Ingelheim GmbH

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Daniela Melchiorri, PRAC Rapporteur: Dolores Montero Corominas

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

Request for Supplementary Information adopted on 26.05.2016.

5.1.11. Vimpat - lacosamide - EMEA/H/C/000863/II/0060/G

UCB Pharma S.A.

Rapporteur: Filip Josephson, Co-Rapporteur: Luca Pani, PRAC Rapporteur: Qun-Ying Yue

Scope: "C.I.6.a - Extension of Indication to add a new indication as monotherapy in the treatment of partial-onset seizures . As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly.
B.I.b.1.b – To tighten the specification limit for heavy metals in the specifications for the active substance lacosamide from 'NMT 20 ppm' to 'NMT 10 ppm'.
B.I.b.2.a – Minor change to the test procedure for heavy metals for the active substance lacosamide to replace water in the dilution of the lead standard solution with water:methanol (1:1). In addition, 2.0 mg of lacosamide is weighed for the sample solution instead of 1.0 mg.
B.II.d.1.a – To tighten the specification limit for bacterial endotoxins in the specifications for the finished product Vimpat 10mg/ml solution for infusion (EU/1/08/470/016-17) from 'NMT 17.5 EU/ml' to 'NMT 11.7 EU/ml'.
B.I.b.1.b – To tighten the specification limit for bacterial endotoxins in the specifications for the active substance lacosamide from 'NMT 1.75 EU/mg' to 'NMT 1.17 EU/mg'. The change applies only to the parenteral presentations.
In addition, the applicant took the opportunity to update the PI in line with the latest QRD template."

Action: For adoption

Request for Supplementary Information adopted on 28.04.2016.

5.1.12. Votubia - everolimus - Orphan - EMEA/H/C/002311/II/0041

Novartis Europharm Ltd

Rapporteur: Harald Enzmann, Co-Rapporteur: Greg Markey, PRAC Rapporteur: Martin Huber

Scope: “Extension of Indication to include adjunctive treatment of patients aged 2 years and older with refractory seizures associated with tuberous sclerosis complex (TSC) for Votubia 2 mg, 3 mg and 5 mg dispersible tablets.
Sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated in parallel based on the results from the pivotal study. In addition, sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 are also updated for the 2.5 mg, 5 mg and 10 mg tablets to reflect on data relevant to these formulations.
The Package Leaflet is updated in accordance.
Furthermore, the PI is brought in line with the latest QRD template version 10.”

Action: For adoption

5.1.13. Renvela Sevelamer carbonate Zentiva - sevelamer sevelamer - EMEA/H/C/WS0965

Genzyme Europe BV

Lead Rapporteur: Bart Van der Schueren, PRAC Rapporteur: Veerle Verlinden

Scope: “Extension of indication for Renvela and Sevelamer carbonate Zentiva to include the control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area (BSA) of >0.75 m2) with chronic kidney disease.
As a consequence, section 4.2 of the SmPC is updated to detail posology in the paediatric patients.
The Package Leaflet is updated in accordance.”

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. Ribociclib - H0004213

Treatment of breast cancer,

Scope: Letter from the company dated 29.07.2016 requesting an accelerated assessment.

Action: For adoption

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

8.1.2. nusinersen - Orphan - H0004312

Biogen Idec Ltd, Treatment of Spinal Muscular Atrophy (SMA),

Scope: Letter from the company dated 05.08.2016 requesting an accelerated assessment.

Action: For adoption

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

8.1.3. Naloxone HCl Dihydrate – H0004325

Emergency use for the complete or partial reversal of respiratory depression induced by natural or synthetic opioids,

Scope: Letter from the company dated 07.07.2016 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

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Helicobacter Test INFAI - 13C-urea - EMEA/H/C/000140/II/0019

MAH: INFAI GmbH, Rapporteur: Andrea Laslop,

Scope: Request for Supplementary Information / Opinion

"Update of the SmPC section 4.2, 4.3, 5.1 and 6.5 in order to add information on use of Refex test meal prior to the Helicobacter Test INFAI administration. The Package leaflet has been updated accordingly. Additionally, the MAH has taken the opportunity to align the PI with the latest QRD template version 9.1."

Request for Supplementary Information adopted on 21.07.2016, 23.06.2016, 01.04.2016, 28.01.2016.

Action: For adoption

9.1.2. Soliris - eculizumab - Orphan - EMEA/H/C/000791/II/0086/G

MAH: Alexion Europe SAS, Rapporteur: Aranzazu Sancho-Lopez, PRAC Rapporteur: Eva A. Segovia

Scope: Request for Supplementary Information / Opinion

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 submission to add editorial changes and to bring the PI in line with the latest QRD template."

Action: For adoption

9.1.3. Iressa - Gefitinib - EMEA/H/C/001016/LEG 021 & EMEA/H/C/001016/LEG 022

MAH: AstraZeneca AB

Rapporteur: Filip Josephson, PRAC Rapporteur: Ulla Wändel Liminga

Scope: PRAC advice

(LEG/21): Submission of a detailed literature review on resistance mechanism to gefitinib by transformation of non-small cell lung cancer (NSCLC) and lung adenocarcinoma to small cell carcinoma as requested in the conclusions of PSUSA/00001518/201507 procedure adopted by PRAC and CHMP in January 2016

(LEG/22): Submission of a detailed analysis on a safety meta-analysis reporting a higher frequency of gefitinib-related hepatotoxicity of grade ≥ 3 in Asians compared to non-Asians (Takeda et al, Lung Cancer. 2015, Apr;88(1):74-9) as requested in the conclusions of PSUSA/00001518/201507 procedure adopted by PRAC and CHMP in January 2016

Action: For adoption

9.1.4. Translarna - ataluren - Orphan - EMEA/H/C/002720/II/0020 & EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited,

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Sabine Straus,

Scope: List of experts to the SAG

Type II variation

"Update of sections 4.4, 4.6, 4.7, 4.8, and 5.1 of the SmPC and Annex II in order to reflect the result from the submitted study TC124-GD-020-DMD object of SOB 001. The Package Leaflet and the RMP are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to include some minor editorial changes throughout the Product information."
Request for Supplementary Information adopted on 21.07.2016, 01.04.2016.

Renewal of Marketing Authorisation

Scope: List of experts to the SAG
Request for Supplementary Information adopted on 21.07.2016, 28.04.2016.

Action: For adoption

9.1.5. Cresemba – Isavuconazole - EMEA/H/C/002734/MEA/004

MAH: Basilea Medical Ltd

Rapporteur: Johann Lodewijk Hillege, PRAC Rapporteur: Adam Przybylkowski

Scope: Updated assessment report

Action: For adoption

10. Referral procedures

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

10.1.1. Direct-acting antivirals (DAAV) indicated for the treatment of hepatitis C (interferon free - EMEA/H/A-20/1438

PRAC Rapporteur: Margarida Guimarães; PRAC Co-rapporteur: Dolores Montero Corominas

Scope: List of experts to the SAG HIV/viral meeting

Action: For adoption

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

10.2.1. Desloratadine-containing products - desloratadine - EMEA/H/A-5(3)/1431

Rapporteur: Koen Norga, Co-Rapporteur: Andrea Laslop,

Scope: List of Outstanding Issues, amended timetable

Prescription status of desloratadine-containing products

Action: For adoption

List of outstanding issues adopted on 26 May 2016

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

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

10.5.1. Clenil and associated names - Beclometasone dipropionate - EMEA/H/A-30/1418

Chiesi group of companies and associated companies

Rapporteur: Daniela Melchiorri, Co-Rapporteur: Martina Weise

Scope: Possible oral explanation to be held on 13 September 2016 at 11:00, Opinion

Harmonisation exercise for Clenil and associated names (beclometasone dipropionate). The review was triggered by Italy due to the need to harmonise the product information across all Member States, including the therapeutic indication, the target populations and the posology recommendations.

Action: For adoption

List of Questions adopted on 25.06.2015. List of outstanding issues adopted 19 November 2015, 1 April 2016 and 21 July 2016.

10.5.2. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol),

Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: List of expert to the SAG Psychiatry meeting

Action: For adoption

10.5.3. Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić,

Scope: List of expert to the SAG Psychiatry meeting

Action: For adoption

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

10.6.1. Pharmaceutics International – EMEA/H/A-31/1444

Rapporteur: Nithyanandan Nagercoil, Co-Rapporteur: David Lyons,

Scope: Opinion or List of outstanding issues

Article 31 triggered by the European Commission

Action: For adoption

List of Questions adopted on 23.06.2016. List of Outstanding Issues adopted on 21 July 2016.

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

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

Scope: Opinion or List of outstanding issues

Action: For adoption

List of Outstanding Issues adopted on 23 June 2016.

10.6.3. Metformin and metformin containing fixed-dose combinations – metformin containing products – EMEA/H/A-31/1432

Rapporteur: Kristina Dunder, Co-Rapporteur: Johann Lodewijk Hillege, Scope: Opinion

Review of use in patients with renal impairment and precautions regarding lactic acidosis

Action: For adoption

List of Questions adopted 28 January 2016. List of Outstanding Issues adopted on 23 June 2016

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

Symbiopharm GmbH,

Rapporteur: Harald Enzmann, Co-rapporteur: Milena Stain;

Scope: List of outstanding issues

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.

Answer from EMA to the section ‘historical and legal background’ concerning the marketing authorisation for Symbioflor and MAH’s conclusion from a legal perspective presented in the response to the list of questions.

Action: For adoption

List of Questions adopted on 1 April 2016.

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)

11. Pharmacovigilance issue

11.1. Early Notification System

September 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

ITF Briefing Meeting

Meeting date: 14 September 2016

Action: For discussion and agreement

ITF Briefing Meeting

Meeting date: 19 September 2016

Action: For discussion and agreement

ITF briefing meeting

Meeting date: 30 September 2016

Action: For discussion and agreement

ITF Briefing Meeting

Meeting date: 12 September 2016

Action: For discussion and agreement

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

13.4. Nanomedicines activities

14. Organisational, regulatory and methodological matters

14.1. Mandate and organisation of the CHMP

14.1.1. Review of experience with the Early Background Summary

Scope: An Outcome of a review of experience with the Early Background Summaries. A survey amongst CAT/CHMP/PRAC assessors was conducted following the pilot starting at the end of 2014. The data collection and analysis are completed based on a total 121 responses for the 21 products in scope of the exercise.

Action: For discussion

Postponed from July 2016 Plenary

14.1.2. Update on data gathering

Scope: The project started in March 2014 to gather evidence needed by the European Commission in drafting future legislative proposal on fees. The goal was to assemble evidence about the time spent on procedures at EMA and NCA's. An update will be given on the progress.

Action: For information

14.1.3. Joint CHMP-PDCO Strategic Review & Learning Meeting to be held in Brussels, 19-21 October 2016 under the Slovakian Presidency of the Council of the European Union

Scope: Agenda topics of the upcoming Strategic Review and Learning meeting

Action: For discussion

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 **30-02 September 2016**

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 08-09 September 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 19-20 September 2016

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at September 2016 PDCO

Action: For information

Report from the PDCO meeting held on 14-16 September 2016

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 06-08 September 2016

Action: For information

14.2.6. CMDh

Report from the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) on the meeting held on 12-14 September 2016

Action: For information

Letter from the CMDh dated 5th July 2016 to the PGWP on applicability of Art. 31 referral outcome on codeine-containing medicinal products to medicinal products containing morphine derivatives

Action: For information

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 30 August - 02 September 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.

14.3.2. Name Review Group (NRG)

PRAC advice on potential name-related issue

Potential for name-related confusion identified post-authorisation with 2 CAPs and 1 NAP

Action: For discussion

14.3.3. Central Nervous System Working Party (CNSWP)

Scope: Election of a chair of the CNSWP

Action: For adoption

14.3.4. Biosimilar Medicinal Product Working Party (BMWP)

Scope: The election of a chair of the BMWP is postponed. It was agreed to first appoint a 10th member and then continue with the chair election procedure.

Action: For information

Scope: Call for nomination of a 10th BMWP member in light of expiry of the mandate of Christian Schneider as chair in September 2016 and his intention to become an observer of BMWP.

Action: For information

Nominations for a BMWP member should be sent by 30 September 2016.

Scope: Nomination of Christian Schneider as observer after expiry of his chairmanship

Action: For adoption

14.3.5. Vaccines Working Party (VWP)

Scope: Extension of deadline for call for nomination of new VWP chair person

Please send nominations by 30 September 2016. Candidates should submit a brief résumé in support of their candidature. Election of the chair is foreseen for the October CHMP plenary.

Action: For information

VWP response to the PDCO letter and questions on the PIP

Scope: Responses to PDCO

Action: For information

14.3.6. Infectious Diseases Working Party (IDWP)

Scope: Election of a chair of the IDWP

Action: For adoption

14.3.7. Oncology Working Party (ONCWP)

Scope: Election of a chair of the ONCWP

Action: For adoption

14.3.8. Biostatistics Working Party (BSWP)

Scope: Extension of deadline for call for nomination of new BSWP chair.

Expertise sought: Candidates for the position should be professionally qualified senior assessors within the European regulatory network, with relevant expertise in the field of biostatistics. Experience in co-operation with EMA Committees, Working Parties and Working Groups would be of advantage.

Please send nominations by 31 October 2016.

Candidates should submit a brief résumé in support of their candidature. Election of the chair is foreseen for the November CHMP plenary.

Action: For information

14.3.9. Radiopharmaceutical Drafting Group (RadDG)

Scope: Election of a chair of the RadDG

Action: For adoption

14.3.10. Biologics Working Party (BWP)

CHMP: Sol Ruiz,

Scope: BWP report: Viral safety of plasma-derived and urine-derived medicinal products with respect to Zika virus

Action: For adoption

14.3.11. Quality working party (QWP)

Chair: Jean-Louis Robert

Scope: Q/A on deletion of a non-significant specification parameter

Action: For adoption

14.3.12. Safety Working Party (SWP)

Chair: Jan Willem van der Laan

Scope: Nomination of new member Jasenka Mršić Pelčić to replace Blaženka Jurišić (HR)

Action: For adoption

14.4. Cooperation within the EU regulatory network

14.5. Cooperation with International Regulators

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

14.7. CHMP work plan

CHMP 2017 Work Plan: draft list of proposed topics

Action: For discussion

14.8. Planning and reporting

14.8.1. New marketing authorisation applications for 2016 with appointed rapporteurs

Action: For information

14.9. Others

15. Any other business

15.1. AOB topic

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

Scope: Update. The concept paper was adopted at the July 2016 CHMP Plenary for 2 months public consultation.

Action: For information

15.1.2. EMA - internal organisational adjustments

Scope: Update on the internal organisational adjustments

Action: For information

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)*

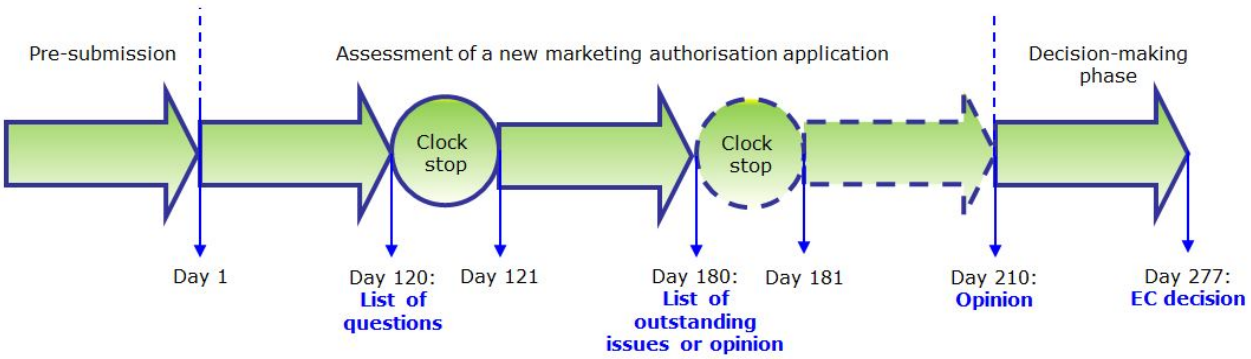
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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