25 April 2016
EMA/CHMP/287724/2016
Procedure Management and Committees Support Division

Committee for medicinal products for human use (CHMP)

Draft agenda for the meeting on 25-28 April 2016

Chair: Tomas Salmonson – Vice-Chair: Pierre Demolis

25 April 2016, 13:00 – 19:30, room 2A

26 April 2016, 08:30 – 19:30, room 2A

27 April 2016, 08:30 – 19:30, room 2A

28 April 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).

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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 25-28 April 2016. See April 2016 CHMP minutes (to be published post May 2016 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for 25-28 April 2016.

1.3. Adoption of the minutes

CHMP minutes for 29 March - 1 April 2016.

2. Oral Explanations

2.1. Pre-authorisation procedure oral explanations

2.1.1. - sirolimus - Orphan - EMEA/H/C/003978

Santen Oy; treatment of chronic non-infectious uveitis

Scope: Oral explanation, Report from Ad-hoc expert group meeting held on 5 April 2016.

Action: Possible oral explanation to be held on Tuesday 26 April 2016 at 14.00. Report from ad-hoc expert meeting held on 5 April 2016.

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 25.06.2015.

Minutes of ad-hoc experts' group meeting held on 5 April 2016.

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

treatment of type 2 diabetes

Scope: Oral explanation

Action: Possible oral explanation to be held on Tuesday 26 April 2016 at 16.00.

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

2.2. Re-examination procedure oral explanations

2.3. Post-authorisation procedure oral explanations

2.3.1. 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: Oral explanation, report by Prof Jonas Bergh from SAG Oncology meeting held on 14th April 2016

Action: Possible oral explanation to be held on Tuesday 26 April 2016 at 11.00.

"Extension of Indication to include new indication for Adcetris (Adcetris is indicated 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 01.04.2016, 22.10.2015, 25.06.2015.

See also 5.1.1

2.4. Referral procedure oral explanations

2.4.1. Otipax 1% (11 mg/ml) ear drops, solution – lidocaine hydrochloride - EMEA/H/A-29/1426

Biocodex Benelux SA/NV

Rapporteur: Daniel Brasseur, Co-Rapporteur: Martina Weise, ,

RMS: BE, CMS: AT, CY, DE, DK, EL, ES, FI, IT, NO, PL, PT, SE, Mutual recognition procedure number: BE/H/0213/001/MR

Scope: Possible oral explanation and Opinion

Disagreement regarding efficacy and the evidence of well-established use.

Action: Possible oral explanation to be held on Tuesday 26 April 2016 at 9.00.

List of Questions adopted on 22 October 2015. List of outstanding issues adopted on 25.02.2016.

See also 10.4.1

3. Initial applications

3.1. Initial applications; Opinions

3.1.1. - atazanavir - EMEA/H/C/004048

treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 28.01.2016, 22.10.2015. List of Questions adopted on 21.05.2015.

3.1.2. - lutetium (177 lu) chloride - EMEA/H/C/003999

radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide

Scope: Opinion

Action: For adoption

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

3.1.3. - pancreas powder - EMEA/H/C/002070

treatment in exocrine pancreatic insufficiency

Scope: Opinion

Action: For adoption

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

BWP Report

3.1.4. - emtricitabine / rilpivirine / tenofovir alafenamide - EMEA/H/C/004156

treatment of HIV-1

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 01.04.2016. List of Questions adopted on 17.12.2015.

3.1.5. - opicapone - EMEA/H/C/002790

Parkinson's disease and motor fluctuations

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 25.02.2016, 19.11.2015, 24.09.2015. List of Questions adopted on 23.04.2015.

3.1.6. - glycopyrronium bromide - PUMA - EMEA/H/C/003883

treatment of sialorrhoea

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 25.06.2015.

3.1.7. - chlorhexidine - Article 58 - EMEA/H/W/003799

Accelerated assessment

prophylaxis of omphalitis

Scope: Opinion

Action: For adoption

List of Questions adopted on 25.02.2016.

3.1.8. - ceftazidime / avibactam - EMEA/H/C/004027

treatment of complicated Intra-Abdominal Infection (cIAI), complicated Urinary Tract Infection (cUTI), including pyelonephritis, nosocomial pneumonia, including ventilator associated pneumonia (VAP), infections due to aerobic Gram-negative organisms in patients with limited treatment options

Scope: Opinion

Action: For adoption

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

3.1.9. - daclizumab - EMEA/H/C/003862

treatment of multiple sclerosis (RMS)

Scope: Opinion

Action: For adoption

List of Outstanding Issues adopted on 17.12.2015. List of Questions adopted on 23.07.2015.

3.2. Initial applications; Day 180 list of outstanding issues

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

treatment of multiple myeloma

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 28.01.2016.

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

Accelerated assessment

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

Scope: Day 150 List of Outstanding Issues

Action: For adoption

List of Questions adopted on 25.02.2016.

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

NPS Pharma Holdings Limited; treatment of hypoparathyroidism

Scope: 2nd Day 180 list of outstanding issue, Report from ad hoc expert group meeting held on 20 January 2016.

Action: For adoption

List of Outstanding Issues adopted on 24.09.2015. List of Questions adopted on 26.03.2015. BWP Report

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

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

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 19.11.2015.

3.2.5. - methotrexate - EMEA/H/C/003983

treatment of active rheumatoid arthritis; severe, active juvenile idiopathic arthritis; severe recalcitrant disabling psoriasis

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 17.12.2015.

3.2.6. - reslizumab - EMEA/H/C/003912

treatment of asthma and elevated blood eosinophils who are inadequately controlled on inhaled corticosteroids

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 19.11.2015.

BWP Report

3.2.7. - enoxaparin sodium - EMEA/H/C/004264

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

BWP Report.

3.2.8. - enoxaparin sodium - EMEA/H/C/003795

prophylaxis of thromboembolic disorders of venous origin

Scope: Day 180 list of outstanding issue

Action: For adoption

List of Questions adopted on 23.07.2015.

BWP Report.

3.3. Initial applications; Day 120 list of questions

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

treatment of haemophilia A

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.2. - 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 120 list of questions

Action: For adoption

BWP Report

3.3.3. - 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 120 list of questions

Action: For adoption

BWP Report

3.3.4. - fluciclovine (18f) - EMEA/H/C/004197

diagnostic agent for prostate cancer

Scope: Day 120 list of questions

Action: For adoption

3.3.5. - trientine tetrahydrochloride - Orphan - EMEA/H/C/004005

GMP-Orphan SA; Wilson’s disease

Scope: Day 120 list of questions

Action: For adoption

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

treatment of HIV-1 infection

Scope: Day 120 list of questions,

Action: For adoption

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

treatment of schizophrenia

Scope: Day 120 list of questions

Action: For adoption

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

treatment of diabetes mellitus in adults

Scope: Day 120 list of questions

Action: For adoption

BWP Report

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

treatment of diabetes mellitus

Scope: Day 120 list of questions

Action: For adoption

BWP Report

3.3.10. - sodium zirconium cyclosilicate - EMEA/H/C/004029

for the treatment of hyperkalaemia

Scope: Day 120 list of questions

Action: For adoption

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

treatment of osteoporosis

Scope: Day 120 list of questions

Action: For adoption

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

Sunesis Europe Ltd; treatment acute myeloid leukaemia

Scope: Day 120 list of questions

Action: For adoption

3.3.13. - dimethyl fumarate - EMEA/H/C/002157

treatment of moderate to severe plaque psoriasis in adults in need of systemic drug therapy, treatment of plaque psoriasis

Scope: Day 120 list of questions

Action: For adoption

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

treatment of osteoporosis

Scope: Day 120 list of questions

Action: For adoption

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

3.4.1. lenvatinib - EMEA/H/C/004224

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

Scope: Assessment Report on similarity

Action: For adoption

3.4.2. - alendronic acid / colecalciferol - EMEA/H/C/004172

treatment of postmenopausal osteoporosis

Scope: Letter from the applicant dated 11 April 2016 requesting a extension of clock stop to submit responses to Day 120 List of Questions adopted in February 2016.

Action: For information

List of Questions adopted on 25.02.2016.

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

treatment of chronic hepatitis C (CHC) in adults

Action: For discussion

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

3.4.4. - irinotecan - Orphan - EMEA/H/C/004125

Baxter Innovations GmbH; treatment of pancreatic cancer

Scope: Letter from the applicant dated 15 April 2016 requesting extension of clock stop to respond to the Day 180 list of outstanding issues adopted on 25.02.2016

Action: For adoption by written procedure

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

3.4.5. - miglustat - EMEA/H/C/004016

treatment of Gaucher disease

Scope: Response from PKWP on CHMP question

Action: For adoption

List of outstanding issues adopted on 01.04.2016. List of Questions adopted on 23.07.2015.

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

3.6. Initial applications in the decision-making phase

3.7. Withdrawals of initial marketing authorisation application

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

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

4.1.1. Reyataz - atazanavir / atazanavir sulfate - EMEA/H/C/000494/X/0094/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Joseph Emmerich, Co-Rapporteur: Nithyanandan Nagercoil, PRAC Rapporteur: Arnaud Batz

Scope: “An extension application covering a new pharmaceutical form (oral powder), a new strength for the oral powder presentation (50mg), and a new paediatric indication (patients from 3 months of age and weighing at least 5kg); a type II variation (C.1.6) to updated Reyataz capsules in light of new paediatric data; a type IB (C.I.11) variation to make minor revisions to the RMP with regards to nephrolithiasis, folllowing PRAC's assesment of RMP version 7.3.”

Action: For adoption

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

4.1.2. Daklinza - daclatasvir - EMEA/H/C/003768/X/0013

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Filip Josephson,

Scope: “To add a new strength of 90 mg for Daklinza with the same pharmaceutical form (film-coated tablets) and route of administration (oral administration) as the currently approved Daklinza 30 mg and 60 mg film-coated tablets.”

Action: For adoption

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. 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

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 (Adcetris is indicated 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 01.04.2016, 22.10.2015, 25.06.2015.

See also 2.3.1

5.1.2. Afinitor - everolimus - EMEA/H/C/001038/II/0048

Novartis Europharm Ltd

Rapporteur: Harald Enzmann, Co-Rapporteur: Filip Josephson, PRAC Rapporteur: Martin Huber

Scope: "Extension of Indication to include a new indication for the treatment of unresectable or metastatic, well-differentiated non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease for Afinitor.
As a consequence, sections 4.1, 4.4, 4.8 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 9.1."

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016, 19.11.2015.

5.1.3. 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, Report by Prof Jonas Bergh from SAG Oncology meeting held on 14 April 2016

Scope: "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 an 1,000mg vials."

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016, 22.10.2015.

5.1.4. Avastin - bevacizumab - EMEA/H/C/000582/II/0086

Roche Registration Limited

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

Scope: "Extension of indication to extend the use of Avastin in combination with erlotinib for the first line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous NSCLC with EGFR activating mutations. As a consequence sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are proposed to be updated. The Package Leaflet and RMP are updated in accordance."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 22.10.2015.

5.1.5. Ferriprox - deferiprone - EMEA/H/C/000236/II/0103

Apotex Europe BV

Rapporteur: Pierre Demolis, Co-Rapporteur: Concepcion Prieto Yerro

Scope: "Extension of Indication to include a new indication for Ferriprox in combination with another chelator.
As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance.
In addition, the MAH took the opportunity of this procedure to update the Product Information in compliance with the QRD template version 9.1 and combine the SmPC for the 500mg and 1000mg tablets. The contact details of France and Portugal have been updated in the PL."

Action: For adoption

Request for Supplementary Information adopted on 25.02.2016, 17.12.2015.

5.1.6. Gazyvaro - obinutuzumab - Orphan - EMEA/H/C/002799/II/0007

Roche Registration Limited

Rapporteur: Sinan B. Sarac, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams

Scope: "Extension of indication to add the treatment of patients with follicular lymphoma based on the results of the pivotal study GAO4753g. Consequently, updates to sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 of the SmPC, the Package Leaflet and RMP have been proposed. Furthermore, the MAH took the opportunity to make minor editorial changes to sections 4.4, 4.6, 5.3 and 6.6 of the SmPC."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015.

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

AbbVie Ltd.

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

Scope: Request for Supplementary Information / Opinion, report from ad-hoc expert group meeting held on 5 April 2016

"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 17.12.2015.

5.1.8. HyQvia - human normal immunoglobulin - EMEA/H/C/002491/II/0021

Baxalta Innovations GmbH

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Andrea Laslop,

Scope: "Extension of Indication to include paediatric population for HyQvia.
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."

Action: For adoption

Request for Supplementary Information adopted on 28.01.2016.

5.1.9. Imbruvica - ibrutinib - Orphan - EMEA/H/C/003791/II/0016

Janssen-Cilag International NV

Rapporteur: Filip Josephson, PRAC Rapporteur: Julie Williams

Scope: "Extension of Indication to broaden the existing indication for chronic lymphocytic leukaemia (CLL) to include all previously untreated patients including those with 17p deletion or TP53 mutation based on the results from the final CSR of study PCYC-1115-CA (MEA 021) for Imbruvica. As a consequence, sections 4.1, 4.6, 4.8, 5.1 and 5.3 of the SmPC are being updated. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes to the SmPC and to bring Annex II in line with the latest QRD template version 9.1. Moreover, the updated RMP version 5.0 has been submitted."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 28.01.2016.

5.1.10. Keytruda - pembrolizumab - EMEA/H/C/003820/II/0007

Merck Sharp & Dohme Limited

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

Scope: "Extension of Indication to include a new indication for Keytruda in second line Non-Small Cell Lung Cancer (NSCLC). 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."

Action: For adoption

5.1.11. 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

5.1.12. Ryzodeg - insulin degludec / insulin aspart - EMEA/H/C/002499/II/0017

Novo Nordisk A/S

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

Scope: "Extension of Indication to include paediatric population from 1 to 18 year of age for Ryzodeg. 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. Furthermore, the PI is brought in line with the latest QRD template version 9.1."

Action: For adoption

Request for Supplementary Information adopted on 28.01.2016.

5.1.13. Truvada - emtricitabine / tenofovir disoproxil - EMEA/H/C/000594/II/0126

Gilead Sciences International Ltd

Rapporteur: Greg Markey, Co-Rapporteur: Pierre Demolis, PRAC Rapporteur: Julie Williams

Scope: "Extension of the indication to add Pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in adults at high risk. As a consequence, sections 4.1, 4.2, 4.3, 4.4, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance."

Action: For adoption

5.1.14. Victoza - liraglutide - EMEA/H/C/001026/II/0038

Novo Nordisk A/S

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

Scope: "Extension of Indication to include second-line monotherapy in type II diabetes for Victoza. Additionally, the MAH updated information related to hepatic and renal impairment. As a consequence, sections 4.1, 4.2, 5.1 and 5.2 of the SmPC are updated with new efficacy and safety information. The Package Leaflet is updated in accordance.
Furthermore, the Marketing authorisation holder (MAH) took the opportunity to align the PI with the latest QRD template version 9.1."

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016.

5.1.15. 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.
In addition, the applicant took the opportunity to update the PI in line with the latest QRD template."

Action: For adoption

5.1.16. Zinforo - ceftaroline fosamil - EMEA/H/C/002252/II/0022

AstraZeneca AB

Rapporteur: Greg Markey

Scope: "Extension of Indication to include new population, children over the age of 2 months and adolescents, for Zinforo. As a consequence, sections 4.1, 4.2, 5.2, 5.3 and 6.6 of the SmPC are updated with new information on dosing, PK and pre-clinical safety. The Package Leaflet is updated in accordance. In addition, the Marketing Authorisation Holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet."

Action: For adoption

Request for Supplementary Information adopted on 17.12.2015, 24.09.2015.

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

5.2.1. Caprelsa - vandetanib - EMEA/H/C/002315/II/0016

AstraZeneca AB

Rapporteur: Pierre Demolis,

Scope: "Extension of Indication to include paediatric indication population for Caprelsa.
As a consequence, sections 4.1, 4.2, 4.6, 4.8, 5.1 and 5.2 of the SmPC are updated in update the safety information. The Package Leaflet is updated in accordance."

Scope: Letter from the MAH dated 11 April 2016 requesting an extension of timeframe to respond to the Request for Supplementary Information adopted on 01.04.2016.

Action: For adoption

Request for Supplementary Information adopted on 01.04.2016, 19.11.2015.

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. - 177Lu-DOTA0-Tyr3-Octreotate - Orphan - H0004123

Advanced Accelerator Applications - Saint Genis Pouilly; treatment of metastatic or unresectable, well differentiated, midgut (jejunum, ileum, appendix and ascending colon) neuroendocrine tumours, which overexpresssomatostatin receptors

Scope: Letter from the company dated 12 April 2016 requesting an accelerated assessment

Action: For adoption

Intended submission date: 26 April 2016

Rapporteur's briefing note

8.1.1. - Cerliponase alfa - Orphan - H0004065

BioMarin International Limited; Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

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

Action: For adoption

Rapporteur's briefing note

8.1.2. - Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli),Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) - H0004051

Prevention of invasive meningococcal disease caused by Neisseria meningitidis (IMD) serogroup B in individuals 10 years and older.

Scope: Letter from the company dated 12 April 2016 requesting an accelerated assessment

Action: For adoption

Rapporteur's briefing note

8.2. Priority Medicines (PRIME)

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

Scope: List of applications received

Action: For information

9. Post-authorisation issues

9.1. Post-authorisation issues

9.1.1. Translarna - ataluren – Orphan - EMEA/H/C/002720/R/0022

MAH: PTC Therapeutics International Limited, treatment of Duchenne muscular dystrophy

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

Scope: Request for supplementary information / Opinion

Renewal of Conditional Marketing Authorisations

Action: For discussion

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

10.1.1. Invokana - canagliflozin - EMEA/H/C/002649/A20/0018

Janssen-Cilag International N.V.; treatment of type 2 diabetes mellitus

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder

Scope: Article 20 procedure to PRAC was triggered by European Commission on 15 April 2016, Signal of potential increased risk of lower limb amputations

Action: For information

DHPC and communication plan recommended by the PRAC for the signal adopted by written procedure on 15 April 2016.

10.1.2. Vokanamet - canagliflozin / metformin - EMEA/H/C/002656/A20/0014

Janssen-Cilag International N.V.; treatment of type 2 diabetes mellitus

Rapporteur: Martina Weise, Co-Rapporteur: Kristina Dunder

Scope: Article 20 procedure to PRAC was triggered by European Commission on 15 April 2016, Signal of potential increased risk of lower limb amputations

Action: For information

DHPC and communication plan recommended by the PRAC for the signal adopted by written procedure on 15 April 2016.

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

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. Otipax 1% (11 mg/ml) ear drops, solution – lidocaine hydrochloride - EMEA/H/A-29/1426

Biocodex Benelux SA/NV

Rapporteur: Daniel Brasseur, Co-Rapporteur: Martina Weise, ,

RMS: BE, CMS: AT, CY, DE, DK, EL, ES, FI, IT, NO, PL, PT, SE, Mutual recognition procedure number: BE/H/0213/001/MR

Scope: Possible oral explanation and Opinion

Disagreement regarding efficacy and the evidence of well-established use.

Action: For adoption

List of Questions adopted on 22 October 2015. List of outstanding issues adopted on 25.02.2016.

See also 2.4.1

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

10.5.1. Durogesic transdermal patches – fentanyl - EMEA/H/A-30/1413

Janssen-Cilag group of companies and associated companies

Rapporteur: Johann Lodewijk Hillege, Co-Rapporteur: Martina Weise,

Scope: List of outstanding Issues

Action: For adoption

List of outstanding Issues adopted 28 January 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 Questions to SAG, Letter from the MAH dated 14 April 2016 requesting an extension of time frame to respond to the List of outstanding issues adopted 1 April 2016.

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: Letter from the MAH dated 14 April 2016 requesting an extension of time frame to respond to the List of outstanding issues adopted 1 April 2016.

Action: For adoption

10.5.4. Lovenox and associated names – enoxaparin - EMEA/H/A-30/1429

Sanofi Aventis group of companies and associated companies

Rapporteur: Joseph Emmerich, Co-Rapporteur: Pieter de Graeff,

Scope: List of outstanding Issues

Harmonisation exercise for Lovenox and associated names. The review was triggered by France, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

List of Questions adopted on 19.11.2015.

Action: For adoption

10.5.5. Novantrone and associated names - mitoxantrone - EMEA/H/A-30/1399

MEDA group of companies and associated companies

Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert Hemmings,

Scope: Opinion

Harmonisation exercise for Novantrone and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

Action: For adoption

Scientific Advisory Group meeting held on 06.11.2015. List of outstanding issues adopted on 28.01.2016, 19.11.2015, 23.07.2015, 26.03.2015.

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

10.6.1. Inhaled corticosteroids (ICS)-containing medicinal products indicated in the treatment of chronic obstructive pulmonary disease: beclomethasone (NAP); beclomethasone, formoterol (NAP); budesonide (NAP); budesonide, formoterol – BIRESP SPIROMAX (CAP); BUDESONIDE FORMOTEROL TEVA (CAP); DUORESP SPIROMAX (CAP); VYALER SPIROMAX (CAP); flunisolide, salbutamol (NAP); fluticasone (NAP); fluticasone, salmeterol (NAP); fluticasone, vilanterol – RELVAR ELLIPTA (CAP); REVINTY ELLIPTA (CAP) – EMEA/H/A-31/1415

Applicant: Glaxo Group Ltd, Teva Pharma B.V., Teva Pharmaceuticals Europe, various

PRAC Rapporteur: Rafe Suvarna; PRAC Co-rapporteur: Jan Neuhauser

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

A referral procedure under Article 31 of Directive 2001/83/EC for inhaled corticosteroids (ICS)-containing products (beclomethasone; budesonide; flunisolide; fluticasone proprionate; fluticasone furoate) reviewing the risk of pneumonia in patients with chronic obstructive pulmonary disease (COPD) is to be concluded.

Scope: Opinion

Action: For adoption

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

April 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: 13th May 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 10th May 2016

Action: For adoption

Scope: ITF Briefing Meeting

Meeting date: 28th June 2016

Action: For adoption

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. Discussion on area of expertise of Co-opted Member

Scope : 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).

14.1.2. Joint CHMP and COMP strategic review and learning meeting to be held in Utrecht on 31 May-1 June 2016

CHMP: Pieter De Graeff

Scope: Agenda

Action: For information

14.1.3. Best Practice Guide for CHMP plenaries

Action: For adoption

14.1.4. New procedure for assessing imposed PASS final study results for CAPs and NAPs under Art 107q of Directive 2010/84/EU

Scope: Appointment of CHMP sponsor

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 **11-14 April 2016**

Action: For information

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

Action: For adoption

14.2.2. Committee for Advanced Therapies (CAT)

CAT draft minutes of meeting held on 21-22 April 2016
Action: For information

14.2.3. Committee for Herbal Medicinal Products (HMPC)

Report from the HMPC meeting held on 4-7 April 2016

Action: For information

14.2.4. Paediatric Committee (PDCO)

PIPs reaching D30 at April 2016 PDCO

Action: For information

Report from the PDCO meeting held on 27-29 April 2016

Action: For information

14.2.5. Committee for Orphan Medicinal Products (COMP)

Report from the COMP meeting held on 19-21 April 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 25-27 April 2016

Action: For information

Scope: Letter from CHMh dated 21 April 2016 regarding regarding administration of crushed/disintegrated tablets, List of questions to PKWP

Action: For adoption

Letter from the CMDh dated 22 April 2016 regarding low dose acetylsalicylic acid gastro-resistant formulations in fixed dose combinations with substitution indication, List of questions to the PKWP

Action: For adoption

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 11-14 April 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. Vaccines Working Party (VWP)

Chair: Daniel Brasseur,

Scope: Nomination of new core members

- Current membership list

Action: For adoption

14.3.3. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad

Scope: Guideline on good pharmacogenomic practice (EMA/CHMP/268544/2016)

Action: For adoption for 5-month public consultation

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

14.8. Planning and reporting

14.9. Others

15. Any other business

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)*

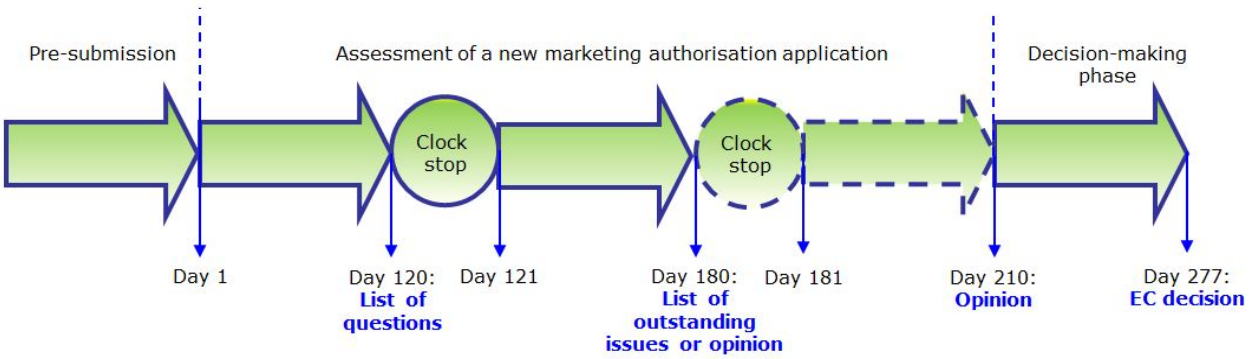
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 3, 4 and 5) or referral procedures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

PRIME

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier

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/