EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2014
EMA/CHMP/312497/2014
Procedure Management and Business Support Division

Committee for medicinal products for human use (CHMP)

Agenda of meeting to be held on 23-26 June 2014

Chair: Tomas Salmonson – Vice-chair: Pierre Demolis

23 June 2014, 13:00 – 19:30, room 3A

24 June 2014, 08:30 – 19:30, room 3A

25 June 2014, 08:30 – 19:30, room 3A

26 June 2014, 08:30 – 16:00, room 3A

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under 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).

Health & 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 and therefore not disclosed. With regards to therapeutic indications 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. The procedures discussed by the CHMP are on-going and therefore are considered confidential. 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. For orphan medicinal products the applicant details are published as this information is

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already publicly available. Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.
Further information with relevant explanatory notes can be found at the end of this document.

For adoption

AGENDA (EMA/CHMP/312497/2014) and Annex to CHMP agenda of the CHMP plenary session to be held 23-26 June 2014	
TIMESCHEDULE of the CHMP plenary session to be held 23-26 June 2014	
MINUTES of the CHMP plenary session held 19-22 May 2014(EMA/CHMP/329259/2014)	
MINUTES of the June 2014 CHMP ORGAM meeting held on 16 June 2014 (EMA/CHMP/359130/2014)	

For information

PRE-MEETING LIST of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP plenary session to be held 23-26 June 2014.	*See June 2014 minutes (to be published post July 2014 CHMP meeting)*
Draft Agenda of July 2014 CHMP meeting	

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1. ORAL EXPLANATIONS

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(EMEA/H/C/002314), (bazedoxifene / estrogens conjugated), (treatment of oestrogen deficiency and osteoporosis) List of Outstanding Issues adopted in March 2014. List of Questions adopted in November 2012.	Possible oral explanation to be held on Tuesday 24 June 2014 at 9.00. Opinion in July 2014.
(EMEA/H/C/002418), Orphan (dexamethasone acetate), (treatment of symptomatic multiple myeloma) List of Outstanding Issues adopted in September 2013 and February and April 2014. List of Questions adopted in May 2013	Possible oral explanation to be held on Tuesday 24 June 2014 at 11.30.

(EMEA/H/C/002647), (insulin degludec / liraglutide), (treatment of type 2 diabetes mellitus) List of Outstanding Issues adopted on 20.03.2014. List of Questions adopted on 24.10.2013. • List of experts for the SAG Diabetes/Endocrinology adopted via written procedure on 4 June 2014: **For information** • Report from SAG Diabetes/Endocrinology held on 5 June 2014: **For discussion** • BWP Report: **For adoption**	Possible oral explanation to be held on Tuesday 24 June 2014 at 14.00.

1.2. Re-examination Procedure Oral Explanation

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Ozurdex (EMEA/H/C/001140/II/0015), (dexamethasone), MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Julie Williams, "Update of section 4.1 of the SmPC to add a new indication for treatment of adult patients with diabetic macular oedema. The MAH also used this opportunity to implement QRD version 9.0." Request for Supplementary Information adopted on 20.02.2014, 24.10.2013.	Possible oral explanation to be held on Wednesday 25 June 2014 at 9.00. See also 4.1 Opinions or Requests for Supplementary information - – Type II variation; Extension of indication

1.4. Community Procedure Oral Explanations

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2. NEW APPLICATIONS

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(EMEA/H/C/002835)
(insulin glargine), (treatment of diabetes mellitus)
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List of Questions adopted on 10.10.2013.

- BWP Report: **For adoption**

(EMEA/H/C/002272), (clopidogrel / acetylsalicylic acid), (indicated for the prevention of atherothrombotic events)
List of Outstanding Issues adopted on 25.04.2014.
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(EMEA/H/C/003768)
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(EMEA/H/C/002705), (mixture of polynuclear iron(iii)-oxyhydroxide, sucrose and starches), (indicated for the control of serum phosphorus levels in patients with end-stage renal disease (ESRD))
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(EMEA/H/C/002557), (flutemetamol f-18), (indicated for the visual detection of amyloid-beta neuritic plaques in the brain)
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List of Questions adopted on 25.04.2013.

2.2. Day 180 List of outstanding issues – New full applications

(EMEA/H/C/002829), Orphan,
(ramucirumab), Applicant: Eli Lilly Nederland B.V., (treatment of gastric cancer)
List of Questions adopted on 23.01.2014.

- BWP Report: **For adoption**

(EMEA/H/C/003791), Orphan
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(EMEA/H/C/002810), (naloxegol)
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List of Questions adopted on 23.01.2014.

(EMEA/H/C/003726), Orphan
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List of Questions adopted on 23.01.2014.

(EMEA/H/C/002819), (darunavir / cobicistat), (treatment of patients with human immunodeficiency virus (HIV-1) in antiretroviral therapy (ART) naïve adults and ART-experienced adults with no darunavir resistance associated mutations and
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List of Questions adopted on 20.02.2014.

(EMEA/H/C/002754), (dolutegravir / abacavir / lamivudine), (treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age who are antiretroviral treatment-naïve or are infected with HIV without documented or clinically suspected resistance to any of the three antiretroviral agents)
List of Questions adopted on 20.03.2014.

(EMEA/H/C/002825), (dulaglutide),
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List of Questions adopted on 20.02.2014.

- BWP Report: **For adoption**

(EMEA/H/C/003843), (idelalisib), (treatment of patients with relapsed chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL))
List of Questions adopted on 20.03.2014.

- List of experts for the SAG Oncology adopted by written procedure on 9 June 2014: **For information**
- Report from SAG Oncology held on 10 June 2014: **For discussion**

2.3. Day 120 List of questions – New full applications

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(EMEA/H/C/002629), (edoxaban), (prevention of stroke and systemic embolism and treatment of venous thromboembolism)

(EMEA/H/C/002749), (lutetium, isotope of mass 177), (used only for the radiolabelling of carrier molecules)

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- Request from the applicant requesting an extension of clock stop to respond to the Day 180 List of Outstanding Issues adopted in January 2014: **For adoption**

(EMEA/H/C/002772) Orphan (dasiprotimut-t), Applicant: Biovest Europe Ltd, (treatment of non-Hodgkin's lymphoma)

- Letter from the applicant dated 13 June 2014 requesting an extension of clock stop to respond to the Day 120 List of Questions: **For information**

(EMEA/H/C/002830), Orphan (mifepristone), Applicant: FGK Representative Service GmbH, (treatment of signs and symptoms of endogenous Cushing's syndrome in adults)
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- Letter from the applicant dated 18 June 2014 requesting extension of clock stop to respond to the Day 120 List of Questions **For information**

(EMEA/H/C/002347), (perflubutane), (ultrasound imaging agent indicated for the detection of coronary artery disease (CAD))
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- List of experts for SAG CVS: **For adoption**

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Oral explanation held in March 2014. List of Outstanding Issues adopted on 22.03.2014, 19.12.2013 and 24.10.2013. List of Questions adopted in 30.05.2013.

- List of experts for SAG Oncology: **For adoption**

(EMEA/H/C/002807), (human fibrinogen / human thrombin), (fibrocaps (human plasma-derived fibrinogen and thrombin) is used as an adjunct to haemostasis)
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- Letter from the applicant dated 18 June 2014 requesting an extension clock stop to respond to the Day 120 List of Questions : **For information**

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(EMEA/H/C/000860/X/0044/G),
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List of Questions adopted on 20.02.2014.

3.3. Extension of marketing authorisation according to Annex I of Reg. 1234/2008; Day 120 List of Questions

Ibandronic acid Accord (EMEA/H/C/002638/X/0006), (ibandronic acid), MAH: Accord Healthcare Limited, Generic, Rapporteur: Alar Irs, "To add a new strength/potency and a new pharmaceutical form 3 mg solution for injection."

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Request for Supplementary Information adopted on 22.05.2014, 19.12.2013.

ECALTA (EMEA/H/C/000788/II/0026), (anidulafungin), MAH: Pfizer Limited, Rapporteur: Pieter de Graeff, Co-Rapporteur: Jens Ersbøll, PRAC Rapporteur: Sabine Straus, "Extension of indication for treatment of neutropenic patients with invasive candidiasis and non-neutropenic patients with Cancida deep tissue infection"
Request for Supplementary Information adopted on 20.03.2014.

Eliquis (EMEA/H/C/002148/II/0014/G), (apixaban), MAH: Bristol-Myers Squibb / Pfizer EEIG, Rapporteur: Pieter de Graeff, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Sabine Straus, "Extension of indication to include treatment of DVT and PE and prevention of recurrent deep vein thrombosis and pulmonary embolism in adults and a type IA to add a new pack size of 28 film coated tablets for Eliquis 5mg strength."
Request for Supplementary Information adopted on 20.02.2014.

Enbrel (EMEA/H/C/000262/II/0167), (etanercept), MAH: Pfizer Limited, Rapporteur: Robert James Hemmings, PRAC Rapporteur: Rafe Suvarna, "Extension of indication for treatment of adults with severe non-radiographic axial spondyloarthritis (nr-AxSpA")
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Eylea (EMEA/H/C/002392/II/0009), (aflibercept), MAH: Bayer Pharma AG, Rapporteur: Pierre Demolis, Co-Rapporteur: Robert James Hemmings, PRAC Rapporteur: Evelyne Falip, "Extension of indication for treatment of adult patients with diabetic macular oedema"
Request for Supplementary Information adopted on 22.05.2014, 20.02.2014.
Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004).

Kalydeco (EMEA/H/C/002494/II/0009), Orphan, (ivacaftor), MAH: Vertex Pharmaceuticals (U.K.) Ltd., Rapporteur: Concepcion Prieto Yerro, Co-Rapporteur: Melinda Sobor, PRAC Rapporteur: Miguel-Angel Macia, "Update of sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC to extend the indication of Kalydeco in the treatment of cystic fibrosis to patients aged 6 years and older who have other gating (class III) mutation in the CFTR gene G551D.
Request for Supplementary Information adopted on 25.04.2014, 23.01.2014.

Ozurdex (EMEA/H/C/001140/II/0015), (dexamethasone), MAH: Allergan Pharmaceuticals Ireland, Rapporteur: Greg Markey, Co-Rapporteur: Concepcion Prieto Yerro, PRAC Rapporteur: Julie Williams, "Update of section 4.1 of the SmPC to add a new indication for treatment of adult patients with diabetic macular oedema. The MAH also used this opportunity to implement QRD version 9.0." Request for Supplementary Information adopted on 20.02.2014, 24.10.2013.	Possible oral explanation and Opinion to be held on Wednesday 25 June 2014 at 9.00. See also I.3 Post-authorisation procedure Oral explanations
Pandemrix (EMEA/H/C/000832/II/0069), (pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted) a/california/7/2009 (h1n1)v like strain (x-179a)), MAH: GlaxoSmithKline Biologicals, Rapporteur: Rafe Suvarna, PRAC Rapporteur: Julie Williams, "Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC to reflect data currently available on H1N1 influenza disease burden, effectiveness and safety of Pandemrix and epidemiology of narcolepsy." Request for Supplementary Information adopted on 20.03.2014.	
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Rienso (EMEA/H/C/002215/II/0008), (ferumoxytol), MAH: Takeda Pharma A/S, Rapporteur: Harald Enzmann, Co-Rapporteur: Romaldas Mačiulaitis, PRAC Rapporteur: Martin Huber, "Extension of indication: all cause iron deficiency anaemia when oral therapy is ineffective or inappropriate or where there is a need for rapid iron repletion"
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Stivarga (EMEA/H/C/002573/II/0001)
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Request for Supplementary information adopted on 22.05.2014, 19.12.2013.

4.2. Update on on-going Type II variation - Extension of indications

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- Similarity assessment report : **For adoption**

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- Day 180 List of Outstanding Issues: **For adoption**
- BWP Report: **For adoption**

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- Letter from the applicant dated 5 June 2014 requesting re-examination of the Opinion adopted in May 2014: **For information**
- Appointment of re-examination (Co)Rapporteurs: **For discussion**

8. WITHDRAWAL OF APPLICATION

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- Letter from the applicant dated 9 May 2014 requesting accelerated assessment: **For information**
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Procoralan (EMEA/H/C/000597/II/0030), (ivabradine), MAH: Les Laboratoires Servier, Rapporteur: Pieter de Graeff, "C.I.13 Submission of the report of the clinical study CL3-16257-068." Request for Supplementary Information adopted on 25.04.2014.	
Corlentor (EMEA/H/C/000598/II/0029), (ivabradine), MAH: Les Laboratoires Servier, Rapporteur: Pieter de Graeff, "C.I.13 Submission of the report of the clinical study CL3-16257-068" Request for Supplementary Information adopted on 25.04.2014.	See Procoralan II/30

WS0492 **M-M-RVAXPRO-** **EMEA/H/C/000604/WS0492/0059** **Proquad-** **EMEA/H/C/000622/WS0492/0077**	(measles, mumps and rubella vaccine (live)measles, mumps, rubella and varicella vaccine (live)), MAH: Sanofi Pasteur MSD SNC, Rapporteur: Jan Mueller-Berghaus, Procedure "To update section 4.8 of the SmPC to include acute disseminated encephalomyelitis (ADEM) in section 4.8 of the SmPC based on a review of reports of cases of encephalopathy consistent with ADEM for measles, mumps and rubella virus vaccine live (M-M-R II / M-M-RVaxpro) and measles, mumps, rubella and varicella (Oka/Merck) virus vaccine live (ProQuad). Request for Supplementary Information adopted on 20.03.2014.

12. REFERRAL PROCEDURES

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Article 29(4) triggered due to disagreement with regard to the demonstration of contraceptive effectiveness and treatment compliance.
List of Questions adopted on 20 February 2014.

- List of Outstanding Issues / Opinion: **For adoption**

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(octreotide acetate) Novartis Pharma AG group of companies and associated companies
Rapporteur: Agnes Gyurasics, Co-Rapporteur: Robert James Hemmings,
List of Outstanding Issues adopted in November 2014. List of Questions adopted in May 2013.

- Opinion: **For adoption**

Sandostatin (EMA/H/A-30/1354)
(octreotide acetate) Novartis Pharma AG Group of companies and associated companies
Rapporteur: Agnes Gyurasics, Co-Rapporteur: Robert James Hemmings,
List of Outstanding Issues adopted in November 2014. List of Questions adopted in May 2013.

- Opinion: **For adoption**

Haldol (haloperidol), Janssen-Cilag Group of companies and associated companies
Rapporteur: Martina Weise, Co-Rapporteur: Ivana Mikacic

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Rapporteur: Rafe Suvarna, Co-Rapporteur: Pieter de Graeff,

- FUM related to the 3rd annual cumulative safety reviews on nephrogenic systemic fibrosis (NSF): Omniscan (GE HealthCare) fifth monthly update and interim analysis report submission as requested by CHMP in November 2013 and assessment report: **For adoption**

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14.2. GCP Inspections

Request for GCP Inspections: **For adoption**	*Disclosure of information relating to GCP inspections will not be published as undermining the purpose of such inspections.*

14.3. Pharmacovigilance Inspections

Request for Pharmacovigilance Inspections: **For adoption**	*Disclosure of information relating to Pharmacovigilance inspections will not be published as undermining the purpose of such inspections.*

14.4. GLP Inspections

Request for GLP Inspections: **For adoption**	*Disclosure of information relating to GLP inspections will not be published as undermining the purpose of such inspections.*

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Update from CVMP on the evaluation of the potential the risk for the consumer resulting from the use of lidocaine in food producing species: **For information**	Article 30(3) procedure started at CVMP in January 2013.

18.2. Committee for Orphan Medicinal Products (COMP)

Press release of the COMP meeting held on 10-12 June 2014: **for information**	To be sent in the Post-mail.

18.3. Committee for Herbal Medicinal Products (HMPC)

HMPC request to PRAC and SWP on toxicological assessment of pulegone/menthofuran and consequences for medicinal products containing menthae piperitae aetheroleum: **For information**	

18.4. Paediatric Committee (PDCO)

PIPs reaching D30 at June 2014 PDCO: **For information**	To be sent in the Post-mail.
Report from the PDCO meeting held on 18-20 June 2014: **For information**	
Request form the PDCO for the input regarding the draft Paediatric Investigation Plan for DTaP-containing combination vaccine: **For discussion**	

18.5. Committee for Advanced Therapies (CAT)

Table of Decisions of CAT meeting held on 19-20 June 2014: **For information**	

19. INVENTED NAME ISSUES

Table of Decisions of the NRG meeting held on 15 May 2014: **For adoption**	

20. ANY OTHER BUSINESS

Election of QWP Chair in June 2014: **For adoption**	
Presentation on move to 30 Churchill Place: **For information**	
Follow up action plan on Quality of Opinions: **For information**	
Action Plan from the CHMP informal meeting under the Greek presidency held in Uppsala on 26 – 28 May 2014: **For adoption**	
Feedback from informal CHMP meeting held in Uppsala on 26 – 28 May 2014 on the pilot phase to involve patients at CHMP oral explanations: **For discussion** Pilot phase to involve patients in benefit/risk discussions at CHMP meetings: **For adoption**	

Overview of comments received on 'Guideline on stability testing for applications for variations to a marketing authorisation' (EMA/CHMP/CVMP/QWP/441071/2011): **For information**	
Call for assessor's interest to attend the Regulatory session on the 'latest developments in Alzheimer's disease' during the ECNP congress on Monday 20 October 2014: **For information**	This open session was organised in collaboration between ECNP and EMA/CNSWP and will include speakers from EMA, industry and academia: http://www.ecnp-congress.eu/Highlights/Regulatory%20update%20session.aspx The registration for this session is free. The CNSWP members/observers have been informed directly in parallel.
Questions & answers on practical implementation of Article 20 Pharmacovigilance Procedure, revised version: **For information**	Follow up from June CHMP ORGAM. The Q&A was revised following comments received during the ORGAM meeting.
August CHMP plenary to be replaced by CHMP written procedure: **For adoption** Timetable for August 2014 written procedure: **For adoption**	
CHMP Work Plan 2015: **For discussion**	
Mandate, objectives and rules of procedure for a new Ethics Advisory Group (EAG): **For discussion**	

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 1)*

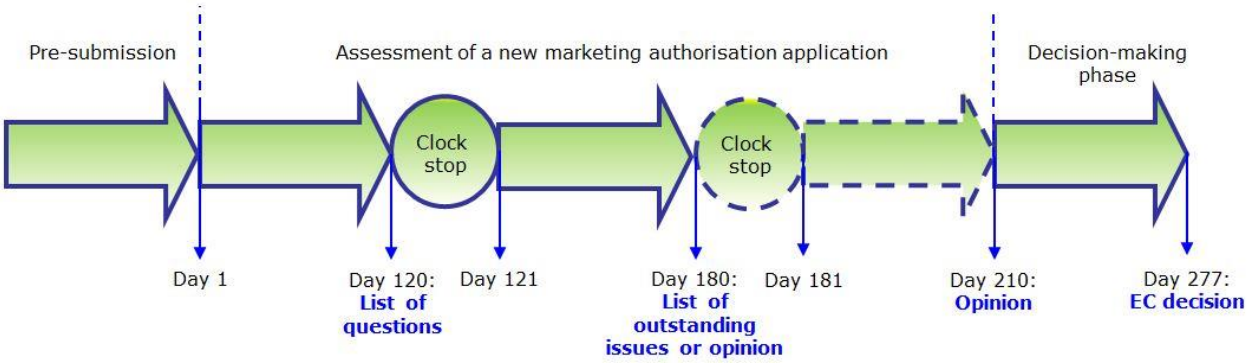
The items listed in this section are those for which marketing authorisation holders (MAHs) or applicants have been invited to the CHMP plenary meeting to address questions raised by the Committee. Oral explanations normally relate to on-going applications (section 2 and 3) or referral procedures (section 12) but can relate to any other issue for which the CHMP would like to discuss with company representatives in person.

New applications *(section 2)*

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

Section 2.1 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 a 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 2.2 (**Day 180 List of outstanding issues**) and 2.3 (**Day 120 list of questions**).

CHMP discussions may also occur at any other stage of the evaluation, and these are listed under section 2.4, **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 2.5, **products in the decision making phase**.

Extension of marketing authorisations according to Annex I of Reg. 1234/2008 *(section 3)*

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 4)*

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 3. 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 5)*

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 6)*

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 *(section 7)*

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

Withdrawal of application *(section 8)*

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 9)*

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 10)*

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 11)*

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 12)*

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 13)*

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 14)*

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 15)*

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 16)*

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 17)*

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 18)*

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.