21 July 2017
EMA/CHMP/468845/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] minutes of the meeting on 10 July 2017

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

Health and safety information

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

Disclaimers

Some of the information contained in this document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this 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 minutes 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).

[1] The CHMP ORGAM is a meeting to discuss CHMP organisational matters. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some ORGAM topics can be discussed at the CHMP Plenary. Please note that the ORGAM meeting is not taking place every month.

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Table of contents

1. Agenda and Minutes

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

1.2. Adoption of agenda

CHMP ORGAM agenda for 10 July 2017 meeting

The CHMP adopted the ORGAM agenda.

1.3. Adoption of the minutes

CHMP Orgam Minutes of 10 July 2017 meeting were adopted at the July 2017 CHMP plenary.

2. Working Parties, Committees, SAGs and Drafting Groups

2.1. General

2.1.1. Safety Working Party (SWP)

Chair: Jan Willem Van der Laan

Concept paper on the development of a reflection paper on the non-clinical evaluation of radiopharmaceuticals (EMA/CHMP/SWP/545959/2016)

Action: For adoption for 3-month public consultation

In the framework of currently available guidelines (such as ICH M3(R2), ICH S6(R1), ICH S9 or the EMA Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products) the reflection paper will provide basic considerations for a non-clinical data package taking into account the specific features of radiopharmaceuticals. The Safety Working Party (SWP) of the CHMP recommends the issuing of a reflection paper on guiding principles for the non-clinical development of radiopharmaceuticals. The paper will be based on current guidelines and the scientific review of the different intended uses of radiopharmaceuticals including radiodiagnostics as well as radiotherapeutics. Focus will be on opportunities to targeted non-clinical programs according to specific development settings and product types.

The CHMP adopted the concept paper for 3-month public consultation.

Revised SWP Work plan 2017 (EMA/CHMP/SWP/615357/2016 Rev. 01)

Action: For adoption

The changes in work plan related to small changes in time management of deliverables and workshop on non-animal approaches in support of medicinal product development –

challenges and opportunities for use of Micro-physiological systems, to be held in 5th October 2017.

The CHMP adopted the revised work plan.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

Call for nomination of Vice-Chair

CHMP Members, and QWP Members and Alternates are eligible for the position of QWP Vice Chairperson. Eligible experts, who wish to apply for the Vice Chairperson position are requested to submit a brief resume in support of their candidature together with a brief resume, highlighting the expertise.

Nominations should be sent to the EMA **by 13 July 2017.**

The Vice Chair will be elected by CHMP at the July meeting.

Action: For information

The CHMP noted the call.

Minutes from QWP Core team January – June 2017

January (EMA/13259/2017); February (EMA/88667/2017); March (EMA/160002/2017); April (EMA/220423/2017); May (EMA/279850/2017); June (EMA/350856/2017)

Action: For information

The CHMP noted the minutes.

Joint GMP/GDP IWG & QWP letters to MAHs and Industry organisations regarding qualification of active substance manufacturers as required by Article 46 of Directive 2001/83 (as amended) and Article 50 of Directive 2001/82 (as amended)

Presentation by Jean-Louis Robert

Action: For adoption

Letter and questionnaire will be sent to selected MAHs. Feedback is expected on the practical experience of MAHs in working with import authorisation holders (MIAHs) to ensure active pharmaceutical ingredient (API) manufacturers are adequately qualified.

In order to gather information as broad as possible on this matter another letter will be sent to industry organisations to obtain the views of industry stakeholder groups. Industry organisations are therefore kindly requested to consult their membership if necessary and submit their views. The timelines were discussed. The documents will be sent after summer.

The CHMP adopted the letters to be sent out.

2.1.3. Scientific Advice Working Party (SAWP)

Chair: Robert Hemmings

No items

2.1.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)

Co-chair: Kaisa Immonen

Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting (EMA/182189/2017)

Action: For information

The CHMP noted the minutes.

2.1.5. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)

Co-chair: Gonzalo Calvo

See 2.1.4.

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

No items

2.1.7. Committees

CHMP 2017 Work Plan: mid-year update

Action: For information

The update will be given at the plenary.

2.1.8. International Council on Harmonisation (ICH)

ICH guideline E2B (R3) - questions and answers, step 5 (EMA/CHMP/ICH/3943/2003)

Action: For adoption

The CHMP adopted the ICH guideline E2B (R3) - questions and answers, step 5.

ICH guideline M7(R1) on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk, step 5 (EMA/CHMP/ICH/83812/2013)

Action: For adoption for 6 months public consultation

The CHMP adopted the guideline for 6 months public consultation.

ICH guideline E9(R1) on Statistical Principles for Clinical Trials, draft, Step 1 (CPMP/ICH/363/96)

Action: For adoption

The CHMP adopted the ICH guideline E9(R1), draft, Step 1.

ICH guideline S5(R3) on detection of toxicity to reproduction for human pharmaceuticals, draft, step 1 (CPMP/ICH/386/95)

Action: For adoption

The CHMP adopted the ICH guideline S5(R3), draft, Step 1.

Report of the meeting in Montreal – June 2017

- ICH Report (EMA/365808/2017)

Action: For discussion

The CHMP noted the report from ICH meeting in Montreal in June 2017.

2.1.9. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J3RsWG)

Chair: Ellen-Margrethe Vestergaard, Co-Chair: Susanne Brendler-Schwaab

Nomination of J3RsWG members by working parties and election of co-opted members by core-members. Election of Chairperson and Vice chairperson by J3RsWG members consisting of core-members and co-opted members for a 3-year mandate

Action: For adoption

Background information: J3RsWG's mandate (EMA/CHMP/CVMP/JEG-3Rs/442724/2012);

CV of co-opted members R. Woodland (EMA/273340/2017), K. Cussler (EMA/273339/2017), E.-M. Vestergaard (EMA/273338/2017), S. Beken (EMA/273341/2017)

The CHMP adopted the new co-opted members Klaus Cussler, Ellen-Margrethe Vestergaard, Ralph Woodland, Sonja Beken. Ellen-Margarethe Vestergaard was adopted as Chair and Susanne Brendler-Schwaab as Co-Chair.

2.1.10. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

Chair: Nienke Rodenhuis

No items

2.1.11. Joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG)

Chair: Gérard Moulin

No items

2.2. Biologicals

2.2.1. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz/Martina Weise

Call for nomination of a new member following the departure of Ann Johnsson (SE)

Nominations should be sent **by 01 September 2017**.
Candidates should submit a brief résumé in support of their candidature. The nomination is going to take place at the September 2017 CHMP Plenary meeting. Candidates can also express an interest to become Vice-Chair of BMWP as the election of the Vice-Chair is also scheduled at the September 2017 CHMP Plenary meeting.

Action: For information

The CHMP noted the call.

Nomination of Teresa Bazantova (CZ) and Kirstine Moll Harboe (DK) as observers to BMWP

- Current membership list

Action: For adoption

The CHMP nominated Teresa Bazantova (CZ) and Kirstine Moll Harboe (DK) as observers to BMWP.

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse

Final minutes from face-to-face meeting held 10-11 May 2017
(EMA/CHMP/BWP/294715/2017)

Action: For information

The CHMP noted the final minutes.

Draft agenda for BWP face-to-face meeting to be held 4-6 September 2017
(EMA/CHMP/BWP/405311/2017)

Action: For information

The CHMP noted the agenda.

Guideline on Influenza Vaccines – Quality Module

(EMA/CHMP/BWP/310834/2012)

Action: For adoption

The CHMP adopted the revised guideline. There were minor updates in the guideline related to review of the naming of pandemic/pre-pandemic vaccines. Specifically, pandemic vaccines which contain a strain with pandemic potential, which are authorised prior to the recognition of a pandemic situation (previously referred to as mock up vaccines) are now termed 'pandemic preparedness vaccines,' to highlight their role in preparation for future potential influenza pandemics. Pre-pandemic vaccines contain an emerging influenza virus strain of animal origin with pandemic potential (zoonotic virus; a zoonosis is an infectious disease that spreads from animals to humans). Consequently, pre-pandemic vaccines are now referred to as 'zoonotic influenza vaccines' throughout this module. Other minor editorial changes were made, also for consistency purposes and legal references were corrected. The revised guideline will be published.

Concept paper on the revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (EMA/CAT/424191/2017)
Rapporteur: M. Timon

Action: For adoption for 3 months public consultation

This concept paper proposes a revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (EMA/CAT/GTWP/671639/2008) that came into effect in 2012. The guideline covers all cases of genetically modified cells intended for use in humans, independent of whether the genetic modification has been carried out for clinical indication (i.e. gene therapy medicinal products), for manufacturing purposes or any other reason. The revision is intended to review the existing guideline text and update it, where needed, in light of new developments in the area of CAR-T cells and genome editing. The concept paper is proposed to be published for a three months public consultation phase.

The CHMP adopted the concept paper for 3 months public consultation.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell/Svein Rune Andersen

No items

2.2.4. Blood Products Working Party (BPWP)

Chair: Jacqueline Kerr

Presentation of the revised guideline on clinical investigation of recombinant and human plasma-derived factor VIII products (EMA/CHMP/BPWP/392490/2017)

Revised guideline (EMA/CHMP/BPWP/392489/2017)

Core SmPC (EMA/CHMP/BPWP/392488/2017)

Action: For discussion

The CHMP discussed the revised guideline. The scope of the revision was to reconsider the Previously Untreated Patients (PUPs) approach and to remove the requirement to perform studies in such population. Guidance on the core data parameters to be collected in Registries have been added in the guideline so that PUPs data can be obtained through Registries. The revised guideline has been presented to PDCO and PRAC which have agreed to remove this requirement to perform PUPs studies. The BPWP also suggest to not include guidance on non-replacement therapies (e.g. gene therapies, monoclonal antibodies) in this revision. It is envisaged to draft a separate reflection paper which is proposed in the BPWP work plan for 2018.

Further CHMP discussion planned for September/ October this year. If needed based on the comments received by the stakeholders, a workshop is planned for Q1-2018.

Revised Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) and related core SmPC

Action: For discussion

The revised guideline and the revised core summary of product characteristics for human normal immunoglobulin for intravenous administration (IVIg) were presented by Jacqueline Kerr. The revision relates to:

- The rewording of the secondary immunodeficiencies

- Add chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and multifocal motor neuropathy (MMN) (2 CNS indications) to the established indications of the core SmPC. This point has been a matter of debate for the past 10 years.

A workshop to discuss these two issues further before the finalisation of the guideline is planned in November 2017.

The CHMP was invited to provide their comments on the guideline by **8th September 2017.**

Final BPWP Agenda 29-30 June 2017

Action: For information

The CHMP noted the agenda.

Draft BPWP Minutes 29-30 June 2017

Action: For information

The CHMP noted the minutes.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

Concept paper on predictive biomarker-based assay development in the context of drug development and lifecycle (EMA/CHMP/240411/2017)

Rapporteurs: Joerg Engelbergs, Shirley Hopper

Action: For adoption for 3 months public consultation

Companion diagnostics and brief overview of new EU Regulation in context of concept paper on predictive biomarker-based assay development were presented. Definition of companion diagnostic and role of EMA in consultation on companion diagnostics was discussed. The role of CHMP is expected to increase. For companion diagnostics, notified body (NB), before issuing CE mark, shall consult competent authority (EMA). The topic is also in CHMP Work Plan and is led by CHMP Vice-Chair Harald Enzmann.

Shirley Hopper presented the concept paper, which will provide recommendations relating to the interface between predictive biomarker-based assays including compendium diagnostics, and the development and lifecycle of medicinal products.

The CHMP adopted the concept paper for 3 months public consultation.

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure (EMA/CHMP/760545/2016)

Rapporteurs: Giuseppe Rosano, Pieter de Graeff

Action: For adoption

- Overview of comments

Action: For information

The guideline was presented by Kristina Dunder. The guideline addresses the EU regulatory position on the clinical development of new medicinal products in the treatment of patients with chronic heart failure (CHF). The aim of this document is to replace the Note for guidance on clinical investigation of medicinal products for the treatment of cardiac failure (CPMP/EWP/235/95, Rev. 1). The principal changes from the previous document relate to:

(i) differentiation of types of heart failure between reduced and preserved ejection fraction;

(ii) inclusion of patients that are clinically stable early after hospitalisation for heart failure;

(iii) description of ways to measure worsening of heart failure;

(iv) reassessment of efficacy criteria and the need for morbidity and mortality trials.

The CHMP adopted the guideline and noted the overview of comments.

Guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome (CPMP/EWP/570/98) (EMA/CHMP/760125/2016)

Rapporteurs: Amany El Gazayerly, Joseph Emmerich

Action: For adoption

- Overview of comments

Action: For information

The aim of the guideline is to provide guidance when performing trials to develop medicinal products in the management of acute coronary syndrome (ACS). The present update includes the following changes:

1) guidance addressing both ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI), as well as unstable angina (UA), 2) update in their definitions, 3) risk stratification using different scoring systems, 4) to be investigated endpoints, and 5) clinical developments of new medicinal products beyond the acute stage, including agents other than antiplatelets and anticoagulants.

The CHMP adopted the guideline and noted the overview of comments.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Draft minutes of the F2F meeting on 17 March 2017 (EMA/CHMP/187515/2017)

Action: For information

The CHMP noted the minutes.

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/Maria Jesus Fernandez Cortizo

Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat pulmonary disease due to Mycobacterium tuberculosis

Rapporteur: Mair Powell

Action: For adoption

This addendum covers the evaluation of new agents for the treatment of pulmonary disease due to Mycobacterium tuberculosis, defined as disease affecting the lung parenchyma. The CHMP adopted the addendum to the guideline.

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

Nomination of Marcela Vostarkova (CZ) as an observer to ONCWP

- Current membership list

Action: For adoption

The CHMP nominated Marcela Vostarkova (CZ) as an observer to ONCWP.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

CMDh Question to PKWP - BE studies for oral solutions – Administration with or without water (EMA/CHMP/364793/2017): PKWP response

Rapporteur: Sotiris Michaleas

Action: For adoption

The CHMP discussed the PKWP response. It was concluded in the response that a possible effect of fluid intake during administration on the bioavailability of an oral solution/suspension cannot be excluded. The magnitude of this effect is expected in most cases to be maximal when administration takes place without water, which generally represents the worst-case scenario.

Product-specific bioequivalence guidelines:

1. Ibuprofen 200 - 800 mg oral use, immediate release formulations product-specific bioequivalence guidance (EMA/CHMP/356876/2017)

   Rapporteur: Susan Cole

2. Dimethyl fumarate gastro-resistant capsules 120 mg and 240 mg product-specific bioequivalence guidance (EMA/CHMP/421315/2017)

   Rapporteur: Henrike Potthast

3. Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance (EMA/CHMP/315234/2014)

   Rapporteur: Alfredo Garcia-Arieta

4. Prasugrel film-coated tablets 5 and 10 mg product-specific bioequivalence guidance (EMA/CHMP/158772/2016)

   Rapporteur: Christina Thygesen Eltorp

Action: For adoption for 3 months public consultation

The CHMP adopted the product**-**specific guidelines for 3 months public consultation.

Draft minutes of the F2F meeting on 25-26 April 2017 (EMA/271894/2017)

Action: For information

The CHMP noted the draft minutes.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Anja Schiel/Thomas Lang

Nomination of Ann-Kristin Leuchs (DE) as an observer to BSWP

- Current membership list

Action: For adoption

The CHMP nominated Ann-Kristin Leuchs (DE) as an observer to BSWP.

Minutes of BSWP virtual meeting held on 13 June 2017 (EMA/325842/2017)

Action: For information

The CHMP noted the minutes.

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

No items

2.3.8. Scientific Advisory Groups (SAGs)

No items

2.3.9. Drafting Groups (DGs)

2.3.9.1. Gastroenterology Drafting Group (GDG)

Chair: Elmer Schabel

No items

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No items

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Guideline on core SmPC and Package Leaflet for (68Ge-68Ga) generator (EMA/313282/2017)

Action: For adoption

- Overview of comments 'Guideline on core SmPC and Package Leaflet for (68Ge68Ga)' (EMA/313283/2017)

Action: For information

Postponed.

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Annex to the Guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'

Action: For adoption

The final revised Annex of the excipient labelling guideline containing 15 updated excipients labels (previously adopted by CHMP following a public consultation) was presented. The Annex will be now a separate document maintained by EMA (as a technical annex) while the main guideline remains under the European Commission (NTA group) responsibility. An explanatory text on the landing webpages of both EMA and European Commission will ensure the transition to this new process. The Annex has been translated by QRD in all EU languages (editorial work ongoing). Following endorsement by the European Commission both websites (EMA and EC) will be updated simultaneously after agreement on the date of publication. The CHMP adopted the annex.

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting

Action: For discussion and agreement

The CHMP agreed to the meeting.

2.3.10.2. Guideline Consistency Group (GCG)

Chair: Barbara van Zwieten-Boot

No items

2.3.10.3. IPRF Nano Working Group

Chair: Harald Enzmann/Jean Louis Robert

No items

3. Organisational, regulatory and methodological matters

3.1. Regulatory Issues / new legislation

3.1.1. EU-US Mutual Recognition Agreement on GMP Inspections

Draft Q&As on impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations

Presentation on MRA

Action: For information

There have been 3 questions and answers developed and EMA intends to publish as soon as possible so as to minimise disruption to planned submissions in the run up to, and after, the MRA becomes operational (November 2017). EMA proposed to publish these Q&As as part of a news item on the MRA in July 2017. CMDh will also be asked to agree to publish them on the HMA website.

Currently all marketing authorisation (or variation) applications that include a manufacturing site located in a third country with whom the European Union has a Mutual Recognition Agreement (MRA) or similar arrangement, must be accompanied by a GMP certificate issued by the authorities of the country in question. FDA do not issue GMP certificates but have confirmed that an export certificate will be issued. The US manufacturer(s) should apply to FDA for the Export Certificate and the EU marketing authorisation applicant or holder should ensure that a certificate is submitted for all US sites listed in the EU submission. Alternatively, if pre-existing valid GMP certificates issued by an EEA authority are available these can continue to be used. In case of any questions please send them during this week.

Further information is available.

The CHMP noted the information.

3.1.2. Change to CHMP Rapporteur and Co-Rapporteur AR due date in first phase of initial MAA

CHMP Rapporteurs' ARs in the first phase of MAA are due on D80 of the procedure which is a Saturday. The ARs are often circulated on Monday (D82) and this contributes to a reporting of an arterially high number of delayed ARs. It is proposed (based on an HMA proposal endorsed by EMA management) to formally move the CHMP Rapporteurs' ARs to D82 (Monday).

Action: For adoption

The CHMP agreed to the proposal.

3.2. Meeting organisation / templates

3.2.1. Pilot phase for abolition of signatures for divergent positions for referral procedures

The proposal is to start new process from September onwards.

Action: For information

The proposal is to start electronic process for the endorsement of divergent signatures, i.e. to abolish the physical signatures from the divergent position documents. The new process foresees that, following the trend vote on final outcome, the Procedure Manager asks, as per current practice, the divergent members to draft the wording for a divergent statement. Procedure assistant would copy the final agreed text in the template for divergent positions and once the final vote is taken, circulate an e-mail to divergent members stating that the enclosed document is circulated for a final endorsement and that it will be used as an appendix to the PRAC Recommendation or CHMP Opinion (deadline to confirm end of same day). Procedure Assistant will ensure that the e-mails of all the divergent committee members agreeing to the final wording are saved in the EMA system and considered a record (Core-Masterfiled). In case of any questions, please send email.

The CHMP noted the proposal. Further discussion will be held in July Plenary meeting.

3.2.2. Update to the CHMP templates on initial Marketing Authorisation

Update to the Rapporteurs' D80 AR overview guidance document to add guidance specific to biosimilars (including a revised Benefit/Risk balance section). When adopted, the changes will be implemented in all relevant templates on initial MA.

Action: For discussion and adoption

The CHMP discussed the templates. The changes proposed to the template were to include guidance specific to biosimilars: clarification when sections are not applicable; update on Quality aspects.

There were 2 options proposed for Benefit/Risk balance section. The CHMP agreed on option B - to develop a specific structure for biosimilar (preferred by assessors)

Extrapolation will be reflected: it should be clarified, how this should be addressed (see B/R). CHMP comments are awaited **by 17 July 2017** and further discussions will be held in July Plenary.

3.3. Pharmacovigilance

3.3.1. Re-examination of Art.31 Referral on Gadolinium containing contrast agents: Briefing CHMP on PRAC recommendations

Action: For discussion

TC with PRAC Chair June Raine

The CHMP was updated by the PRAC chair on the PRAC recommendation adopted during its July meeting. The PRAC rapporteurs of the re-examination will present the PRAC assessment and recommendation to the CHMP during July's plenary. In addition, MAH wishing to present their disagreement with any aspects of the PRAC recommendation as regards their own products will be invited to have oral explanations in front of CHMP. The SWP chair is invited to the plenary discussion as pre-clinical expert.

4. Any Other Business

No items

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP members:

Agnes Gyurasics

Alexandre Moreau

Concepcion Prieto Yerro

Eleftheria Nikolaidi

Ewa Balkowiec Iskra

Greg Markey

Harald Enzmann

Jan Mueller-Berghaus

Jean-Louis Robert

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Outi Mäki-Ikola

Robert James Hemmings

Svein Rune Andersen

CHMP alternate members:

Bjorg Bolstad

Dana Gabriela Marin

Fátima Ventura

Filip Josephson

Nithyanandan Nagercoil

Experts:

Anders Lignell

Jacqueline Kerr

Jan Willem van der Laan

Kristina Bech Jensen

Mair Powell

Maria Escudero Galindo

Maria Romero Guerra

Patricia Diaz Ramos

Shirley Hopper

Valerie Lescrainier

Meeting was run with support from the relevant EMA staff