16 December 2016
EMA/CHMP/858237/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for medicinal products for human use (CHMP)

ORGAM[1] Minutes of the meeting on 05 December 2016

Chair: Tomas Salmonson – Vice-Chair: Harald Enzmann

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 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. Agenda and Minutes

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

1.2. Adoption of agenda

CHMP Orgam Agenda for December 2016 meeting was adopted

1.3. Adoption of the minutes

CHMP Orgam Minutes of December 2016 meeting will be adopted at the December 2016 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

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

Action: For adoption

The CHMP adopted the revised SWP Work plan 2017.

Final minutes from face-to-face meeting held 4-5 October 2016 (EMA/CHMP/SWP/662977/2016)

Action: For information

The CHMP noted the minutes.

Jan Willem Van der Laan representing the EMA at the EC conference on “Non-Animal Approaches – The Way Forward” to be held in Brussels on 6-7 December 2016

Action: For information

- Presentation - Conference Brussels 5th version 28-11-2016 (EXT/800590/2016)

Action: For information

The CHMP noted the presentation and agreed that Jan Willem Van der Laan will represent EMA at the EC conference.

Question and Answers on Implementation of risk based prevention of cross contamination in production and ‘Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities’ (EMA/CHMP/SWP/169430/2012)

Action: For adoption for 3 months public consultation

A group of inspectors representing BE, DE, IE, FR-h, FR-v and UK, some of whom were previously involved in drafting recent revisions to chapters 3 and 5 of the EU GMP guide, have discussed concerns with implementation of the guide to setting health based limits for cross contamination control. Experience from inspections conducted since publication of these documents has identified difficulties in interpretation and application of applying the requirements guide with appropriate prioritization, organizational and technical controls using a quality risk management approach.

The CHMP adopted the Question and Answers for 3 months public consultation.

2.1.2. Quality Working Party (QWP)

Chair: Jean-Louis Robert

No items

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

PCWP Work plan 2017 (EMA/540720/2016)

Action: For adoption

The CHMP adopted the PCWP Work plan 2017.

Report from the PCWP/HCPWP workshop on social media held on 19 September 2016 (EMA/625077/2016)

Action: For information

The CHMP noted the report. The workshop was the first in a series of meetings that will cover linked topics related to advances in digital health including social media, 'big data' analysis and IMI (Innovative Medicines Initiatives) projects such as WEB-RADR, where EMA will provide a platform for discussion and an opportunity for mutual learning.

Agenda for the training session for patients and consumers interested in EMA activities on 29 November 2016 (EMA/636824/2016)

Action: For information

The CHMP noted the agenda.

Agenda for the PCWP meeting with all eligible organisations on 30 November 2016 (EMA/668397/2016)

Action: For information

The CHMP noted the agenda.

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

Co-chair: Gonzalo Calvo

HCPWP Work plan 2017 (EMA/493549/2016)

Action: For adoption

The CHMP adopted the HCPWP Work plan 2017.

Report from the PCWP/HCPWP workshop on social media held on 19 September 2016 (EMA/625077/2016)

Action: For information

The CHMP noted the report. The workshop was the first in a series of meetings that will cover linked topics related to advances in digital health including social media, 'big data' analysis and IMI (Innovative Medicines Initiatives) projects such as WEB-RADR, where EMA will provide a platform for discussion and an opportunity for mutual learning.

2.1.6. Geriatric Expert Group (GEG)

Chair: Niccolo Marchionni

No items

2.1.7. Committees

Committee for Advanced Therapies (CAT): Draft Minutes of the November 2016 meeting (EMA/CAT/707323/2016)

Action: For information

The CHMP noted the draft minutes.

CHMP Draft Work plan 2017 (EMA/CHMP/474618/2016)

Action: For discussion

The CHMP members were invited to comment high level topics for 2017 work plan. The draft work plan will be sent to members for further comments. The CHMP noted the information.

2.1.8. International Council on Harmonisation (ICH)

ICH guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological / biological entities) – questions and answers, step 2b ((EMEA/CHMP/ICH/809509/206)

Action: For adoption for 3 months public consultation

The CHMP adopted the guideline for 3 months public consultation. This Q&A document is intended to provide additional clarification and to promote convergence on the considerations for the selection and justification of starting materials and on the information that should be provided in marketing authorisation applications and/or Master Files. The focus of the Q&A document is on chemical entity drug substances.

Q3C (R6): Impurities: guideline for residual solvents, step 5 (EMA/CHMP/ICH/82260/2006)

Action: For adoption

The CHMP adopted the guideline. The objective of the guideline is to recommend acceptable amounts for residual solvents in pharmaceuticals for the safety of the patient. The guideline recommends use of less toxic solvents and describes levels considered to be toxicologically acceptable for some residual solvents.

Guideline for good clinical practice E6(R2), step 5, Integrated Addendum (EMEA/CPMP/ICH/135/95)

Action: For adoption

The CHMP adopted the guideline. The objective of this ICH GCP Guideline is to provide a unified standard in the ICH regions to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

Report on meeting in Osaka – November 2016

- ICH report (EMA/807597/2016)

Action: For discussion

- ICH report (presentation)

Action: For information

The CHMP noted the report from ICH meeting in Osaka in November 2016.

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 (JEG 3Rs)

Acting Chair: Ellen-Margrethe Vestergaard

Revised mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG) (EMA/CHMP/CVMP/JEG-3Rs/442724/2012)

- Background note (EMA/624150/2016)

- JEG 3Rs progress report 2011-2016 (EMA/CHMP/CVMP/JEG-3Rs/498328/2016)

Action: For adoption

In 2016 a review of the work of JEG 3Rs identified a number of initiatives that are expected to be largely complete by the end of its current mandate. As no new significant projects have been proposed, but recognising the continued importance of developments in 3Rs, it is proposed to maintain JEG 3Rs but in a revised form with the creation of a Working Group.

The new joint CVMP/CHMP working group on the application of the 3Rs (J3RsWG) would be a smaller group more focused on reacting to requests from CHMP/CVMP, responding to public consultations of published guidance and reflection papers and continuing the scientific review of batch release tests for human and veterinary vaccines/biologicals for alignment with best practice in 3Rs.

For the period of 2017 to 2019 the objectives of J3RsWG would focus in the following areas:

(1) Finalisation and adoption of reflection papers and guidelines under development on 3Rs.

(2) 3Rs issues related to batch release testing for veterinary IVMPs and human vaccines & biologicals.

(3) Supporting implementation of Directive 2010/63/EU

The CHMP adopted the revised mandate.

JEG 3Rs Work plan 2017 (EMA/CHMP/CVMP/JEG-3Rs/647540/2016)

Action: For adoption

The CHMP adopted the JEG 3Rs Work plan 2017.

Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)

- Background note (EMA/756897/2016)

Action: For adoption

The guideline aims to encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches. Following the consultation two reflection papers (one human and one veterinary) were developed as a follow up to that draft guideline and provides an overview of the main animal tests required for the regulatory testing of veterinary medicinal products. These reflection papers progressed more quickly than the guideline and have been adopted by both CVMP and CHMP. This Guideline aims to encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches.

The CHMP adopted the guideline.

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

BMWP Work plan 2017 (EMA/627104/2016)

Action: For adoption

The CHMP adopted the BMWP Work plan 2017.

Final minutes of BMWP meeting held on 02 September 2016 (EMA/687226/2016)

Action: For information

The CHMP noted the minutes.

Final minutes of BMWP meeting held on 18 October 2016 (EMA/690775/2016)

Action: For information

The CHMP noted the minutes.

2.2.2. Biologicals Working Party (BWP)

Chair: Sol Ruiz/Nanna Aaby Kruse/Ilona Reischl

Draft agenda for BWP face-to-face meeting to be held 16-18 January 2017 (EMA/CHMP/BWP/754304/2016)

Action: For information

The CHMP noted the agenda.

Final minutes from face-to-face meeting held 3-5 October 2016 (EMA/CHMP/BWP/661858/2016)

Action: For information

The CHMP noted the minutes.

BWP Work Plan 2017 (EMA/CHMP/BWP/612761/2016)

Action: For adoption

The CHMP adopted the BWP Work Plan 2017.

Update on Triton X-100 and REACH Regulation

Action: For information

The CHMP noted the update from BWP on Triton X-100 and REACH Regulation and respective correspondence between ECHA and the other stakeholders.

Alan Fauconnier to represent BWP at IABS conference (International Alliance for Biological Standardization) on deep sequencing to take place on 27-28 October 2017 at the US Pharmacopeia, Rockville, MD

Action: For information

The CHMP agreed that Alan Fauconnier will represent BWP at IABS conference.

2.2.3. Vaccines Working Party (VWP)

Chair: Mair Powell

VWP Work plan 2017 (EMA/654970/2016)

Action: For adoption

The CHMP adopted the VWP Work plan 2017.

Final agenda of VWP held on 22-23 November 2016 (EMA/649282/2016)

Action: For information

The CHMP noted the agenda.

Final minutes of VWP held via teleconference on 17 June 2016 (EMA/427229/2016)

Action: For information

The CHMP noted the minutes.

Nomination of Květoslava Mlčochová (CZ) as an observer to VWP

- Current membership list

Action: For adoption

The CHMP nominated Květoslava Mlčochová (CZ) as an observer to VWP.

2.2.4. Blood Products Working Party (BPWP)

Chair: Anneliese Hilger

BPWP Work plan 2017 (EMA/CHMP/BPWP/583702/2016)

Action: For adoption

The CHMP adopted the BPWP Work plan 2017.

Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) (EMA/CHMP/BPWP/94033/2007 rev. 3) and related core SmPC (EMA/CHMP/BPWP/94038/2007 Rev. 5)

Action: For adoption for 3-months public consultation

The CHMP adopted both guidelines for 3-months public consultation. The guideline for intravenous administration describes the information to be documented when an application for a marketing authorisation for IVIg is made, including biological data, pharmacokinetics, clinical trials and patient follow-up. This core SmPC guideline covers human normal immunoglobulin for intravenous administration defined by the European Pharmacopoeia monograph 0918. It does not apply to products intentionally prepared to contain fragments or chemically modified IgG.

Final Minutes of BPWP face-to-face meeting held on 16-17 November 2016 (EMA/CHMP/BPWP/753658/2016)

Action: For information

The CHMP noted the minutes.

2.2.5. Pharmacogenomics Working Party (PGWP)

Chair: Krishna Prasad/Markus Paulmichl

PGWP Work plan 2017 (EMA/CHMP/389037/2016)

Action: For adoption

Postponed to December Plenary

2.3. Therapeutics

2.3.1. Cardiovascular Working Party (CVSWP)

Chair: Pieter de Graeff/Kristina Dunder

Draft agenda of CVSWP meeting to be held face-to-face on 23 November 2016 (EMA/703661/2016)

Action: For information

The CHMP noted the agenda.

CVSWP Work plan 2017 (EMA/CHMP/639699/2016)

Action: For adoption

The CHMP adopted the CVSWP Work plan 2017.

2.3.2. Central Nervous System Working Party (CNSWP)

Chair: Karl Broich

Draft agenda of CNSWP meeting to be held face-to-face on 2 December 2016 (EMA/731153/2016)

Action: For information

The CHMP noted the agenda.

2.3.3. Infectious Diseases Working Party (IDWP)

Chair: Anders Lignell/ Maria Jesus Fernandez Cortizo

IDWP Work plan 2017 (EMA/662804/2016)

Action: For adoption

The CHMP adopted the IDWP Work plan 2017.

Final agenda for IDWP held on 24 November 2016 (EMA/644649/2016)

Action: For information

The CHMP noted the agenda.

Nomination of Shiva Ramroop (UK) as an observer to IDWP (EMA/828382/2010)

- Current membership list

Action: For adoption

The CHMP nominated Shiva Ramroop (UK) as an observer to IDWP.

2.3.4. Oncology Working Party

Chair: Pierre Demolis/Paolo Foggi

ONCWP Work plan 2017 (EMA/633841/2016)

Action: For adoption

The CHMP adopted the ONCWP Work plan 2017.

Final agenda for ONCWP held on 17 November 2016 (EMA/740268/2016)

Action: For information

The CHMP noted the agenda.

Final minutes of ONCWP held on 05 October 2016 (EMA/754341/2016)

Action: For information

The CHMP noted the minutes.

2.3.5. Pharmacokinetics Working Party (PKWP)

Chair: Jan Welink/Alfredo Garcia-Arieta

Jan Welink representing CHMP at the 11th WRIB conference in California 3-7 April 2017

Action: For information

The CHMP agreed that Jan Welink will represent CHMP at the 11th WRIB conference.

Appointment of Gustav Ahlin (SE) as additional expert to the PKWP

Action: For adoption

The CHMP appointed Gustav Ahlin (SE) as additional expert to the PKWP.

PKWP Work plan 2017 (EMA/CHMP/643117/2016)

Action: For adoption

Postponed to December Plenary

Q&A CHMP request to PKWP for clarification on demonstrating bioequivalence of low dose acetylsalicylic acid gastro-resistant formulations in fixed dose combinations with substitution indication (EMA/CHMP/754380/2016)

Action: For adoption

The CHMP adopted the PKWP response.

Q&A Question on requirements for bioequivalence studies under fasting and fed conditions (general) (EMA/CHMP/805455/2016)

Action: For discussion

Postponed to December Plenary

Q & A PKWP clarification on Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**); Appendix II section on oral solutions

Action: For adoption

Postponed to December Plenary

Product-specific bioequivalence guidance Batch 4 – Final guidance

- Everolimus tablets 0.25, 0.5, 0.75 and 1mg; 2.5, 5 and 4 10mg, dispersible tablets 0.1 and 0.25mg; 2, 3 and 5mg 5 product-specific bioequivalence guidance (EMA/CHMP/154772/2016)
- Pazopanib film-coated tablet 200mg and 400mg product-specific bioequivalence guidance (EMA/CHMP/154805/2016)
- Levodopa/Carbidopa/Entacapone film-coated tablet 4 200mg/50mg/200mg, 175mg/43.75mg/200mg, 5 150mg/37.5mg/200mg, 125mg/31.25mg/200mg, 6 100mg/25mg/200mg, 75mg/18.75mg/200mg and 7 50mg/12.5mg/200mg product-specific bioequivalence 8 guidance (EMA/CHMP/162889/2016)
- Fingolimod capsules 0.5mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016)

- Paliperidone prolonged-release tablets 1.5mg, 3mg, 6mg, 9mg and 12mg product-specific bioequivalence guidance (EMA/CHMP/154812/2016)

Action: For adoption

The CHMP adopted the final guidance.

Product-specific bioequivalence guidance Batch 6:

- Crizotinib hard capsules 200 and 250 mg product-specific bioequivalence guidance
- Dabigatran etexilate hard capsules 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance
- Elvitegravir, 85 and 150 mg product-specific bioequivalence guidance
- Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil, film-coated tablets, 150 mg/150 mg/200 mg/245 mg product-specific bioequivalence guidance
- Emtricitabine/rilpivirine/tenofovir disoproxil, film-coated tablets, 200 mg/25 mg/245 mg product-specific bioequivalence guidance (EMA/CHMP/805532/2016)
- Vortioxetine - hydrobromide, 5, 10, 15, and 20 mg immediate release tablets; vortioxetine lactate, oral drops solution 20 mg/ml product-specific bioequivalence guidance (EMA/CHMP/474974/2016)

Action: For adoption for 3 months public consultation

The CHMP adopted the guidance for 3 months public consultation.

Draft agenda for PKWP meeting to be held by Adobe on 5 December 2016 (EMA/747053/2016)

Action: For information

The CHMP noted the agenda.

Final programme of the EMA workshop on qualification and reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation (EMA/128306/2016) held on 21 November 2016 (EMA/128306/2016)

Action: For information

The CHMP noted the programme.

2.3.6. Biostatistics Working Party (BSWP)

Chair: Vacant/Thomas Lang

BSWP Work plan 2017 (EMA/626873/2016)

Action: For adoption

The CHMP adopted the BSWP Work plan 2017.

Final minutes of BSWP meeting held on 29-30 September 2016 (EMA/646364/2016)

Action: For information

The CHMP noted the minutes.

Draft Agenda for BSWP meeting to be held on 06 December 2016 (EMA/792259/2016)

Action: For information

The CHMP noted the agenda.

Guideline on multiplicity issues in clinical trials (EMA/CHMP/720718/2016)

Action: For adoption for a 3-month public consultation

- Presentation on multiplicity issues in clinical trials (EMA/813056/2016)

Action: For information

Postponed to December plenary

2.3.7. Rheumatology/Immunology Working Party (RIWP)

Chair: Jan Mueller-Berghaus

RIWP Work plan 2017 (EMA/646364/2016)

Action: For adoption

Postponed to December Plenary

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

Call for nomination of a new Chairperson following end of mandate in February 2017

Action: For information

Nominations to be sent by 31 January 2017

Candidates should submit a brief résumé in support of their candidature.

The CHMP noted the information.

Gastroenterology Drafting Group Work plan 2017 (EMA/CHMP/653568/2016)

Action: For adoption

The CHMP adopted the Gastroenterology Drafting Group Work plan 2017.

2.3.9.2. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

RDG Work plan 2017 (EMA/CHMP/571474/2016)

Action: For adoption

The CHMP adopted the RDG Work plan 2017.

2.3.9.3. Radiopharmaceutical Drafting Group (RadDG)

Chair: Anabel Cortes

Core SmPC and PL for nanocolloidal technetium (99mTc) albumin (EMA/CHMP/337958/2016)

Action: For adoption

- Overview of consultation with OncWP and of comments received by EMA Paediatric team

Action: For information

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

Core SmPC and PL for iopamidol 300 (EMA/25459/2016)

Action: For adoption for 4-months public consultation

The CHMP adopted the guideline for 4-months public consultation. The purpose of this core SmPC and package leaflet is to provide applicants and regulators with harmonised guidance on the information to be included in the Summary of product characteristics (SmPC) for iopamidol 300. This guideline should be read in conjunction with the QRD product information templates and the guideline on Summary of Product Characteristics.

Core SmPC and PL for iopamidol 370 (EMA/25460/2016)

Action: For adoption for 4-months public consultation

The CHMP adopted the guideline for 4-months public consultation. The purpose of this core SmPC and package leaflet is to provide applicants and regulators with harmonised guidance on the information to be included in the Summary of product characteristics (SmPC) for iopamidol 370. This guideline should be read in conjunction with the QRD product information templates and the guideline on Summary of Product Characteristics.

Core SmPC and PL for fluorodopa (18F) (EMA/CHMP/337958/2016)

Action: For adoption

- Overview of comments received (EMA/CHMP/758629/2016)

Action: For information

The CHMP adopted the guideline and noted the overview of comments. The purpose of this core SmPC and Package Leaflet is to provide applicants and regulators with harmonised guidance on the information to be included in the Summary of product characteristics

(SmPC) for fluorodopa (18F). This guideline should be read in conjunction with the core SmPC and Package Leaflet for Radiopharmaceuticals, the QRD product information templates and the guideline on Summary of Product Characteristics.

RadDG Work plan 2017 (EMA/CHMP/633868/2016)

Action: For adoption

The CHMP adopted the RadDG Work plan 2017.

2.3.9.4. Excipients Drafting Group

Chair: Dominique Masset

Excipients drafting group Work plan 2017 (EMA/CHMP/750448/2016)

Action: For adoption

The CHMP adopted the Excipients drafting group Work plan 2017.

Final minutes of the Excipients DG held via teleconference on 28 September 2016 (EMA/655812/2016)

Action: For information

The CHMP noted the minutes.

Information in the package leaflet for aspartame in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/134648/2015)

Action: For adoption

- Overview of comments received (EMA/CHMP/581993/2016)

Action: For information

The CHMP adopted the guideline and noted the overview of comments. The main reason for re-assessing the information on the package leaflet was to review its use as sweetener in paediatrics. Simultaneously, EFSA was starting a re-evaluation of the safety of aspartame as a food additive in the EU (E951) which was published in December 2013. The EFSA assessment served as the basis for the present evaluation of aspartame as excipient in medicinal products.

Information in the package leaflet for fructose and sorbitol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/460886/2014)

Action: For adoption

- Overview of comments received (EMA/CHMP/581887/2016)

Action: For information

The CHMP adopted the guideline and noted the overview of comments. It is proposed to strengthen the warning for medicinal products containing fructose/sorbitol and given intravenously with regard to the risk for very young children or unconscious patients.

Information in the package leaflet for phosphates in eye drops in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/632775/2016)

Action: For adoption

Document prepared in reference to the 'Questions and answers on the use of phosphates in eye drops' (EMA/CHMP/753373/2012)

The CHMP adopted the guideline. In order to make healthcare professionals and patients aware of the evidence suggesting that patients who already had severe damage to the cornea might develop calcification during treatment with phosphate-containing eye drops, it was recommended that the information for the package leaflet of eye medicines containing phosphates should be updated, as well as the Summary of Product Characteristics.

Information in the package leaflet for fragrance allergens in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/273718/2014)

Action: For adoption

- Overview of comments received (EMA/CHMP/579645/2016)

Action: For information
The CHMP adopted the guideline and noted the overview of comments.

Questions and answers on propylene glycol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (EMA/CHMP/704195/2013)

Action: For adoption

- Overview of comments received (EMA/CHMP/157147/2015)

Action: For information

- Background report (EMA/CHMP/334655/2013)

Action: For information

The CHMP adopted the Questions and answers and noted the overview of comments and background report. The main reason for updating the information in the package leaflet are to update the thresholds and toxicological profile following a review of the published safety data and to adjust them in relation to different age groups.

2.3.10. Additional agenda points

2.3.10.1. Innovation Task Force

ITF Briefing Meeting
Meeting date: 13 December 2016

Action: For discussion and agreement

The CHMP agreed to the meeting.

ITF briefing meeting
Meeting date: 13 December 2016

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. Update of the procedural documentation on Article 58 applications

Revision of the procedural guideline on Article 58 applications and related application forms

- Application forms (EMA/619738/2016), (EMA/619737/2016)
- Presentation (EMA/747762/2016)
- Pre and Post "Article 58" scientific opinions procedural advice for users (EMA/534107/2008)

Action: For discussion

The CHMP members were asked to send comments no later than **6th of January 2017**. A wider diffusion to other stakeholders (WHO, EC) will follow.

The CHMP noted the information.

3.1.2. Best practice guide on measures improving predictability of submissions and adherence to communicated submission deadlines (EMA/760652/2016)

Action: For discussion

Postponed to December Plenary

3.1.3. ATMP guideline on safety and efficacy follow-up and risk management

Follow-up from April ORGAM meeting, where the CHMP agreed on the guideline revision

Action: For discussion

Postponed

3.2. Meeting organisation / templates

No items

3.3. Pharmacovigilance

No items

4. Any Other Business

No items

5. List of participants

CHMP Chairman:

Tomas Salmonson

CHMP Members:

Agnes Gyurasics

Andrea Laslop

Daniela Melchiorri

George Aislaitner

Greg Markey

Harald Enzmann

Johann Lodewijk Hillege

Katarina Vučić

Kristina Dunder

Natalja Karpova

Nela Vilceanu

Outi Mäki-Ikola

Pierre Demolis

Robert James Hemmings

CHMP Alternate Members:

Dana Gabriela Marin

Milena Stain

Nithyanandan Nagercoil

Selma Arapovic Dzakula

Experts:

Anabel Cortés Blanco

Anneliese Hilger

Carolien Versantvoort

Christophe Focke

Elena Wolff-Holz

Elmer Schabel

Henrike Potthast

Mette Tranholm

A representative from the European Commission participated in the meeting

Meeting was run with support from the relevant EMA staff