



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 January 2021  
EMA/CHMP/34231/2021  
Human Medicines Division

## Committee for medicinal products for human use (CHMP) ORGAM<sup>1</sup> minutes for the meeting on 18 January 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

18 January 2021, 09:30–14:30, virtual meeting/ room 09-A

### Disclaimers

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

Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

### Note on access to documents

Some documents mentioned in the agenda/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).

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<sup>1</sup> 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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## 1. Agenda and Minutes

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

### 1.2. Adoption of agenda

The CHMP adopted ORGAM agenda for 18 January 2021 meeting.

### 1.3. Adoption of the minutes

CHMP ORGAM Minutes of January 2021 meeting will be adopted at the January 2021 CHMP plenary.

## 2. Regulatory and organisational matters

### 2.1. Regulatory Issues / new legislation

No topics

### 2.2. CHMP organisation / templates

#### 2.2.1. CHMP learnings

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Process to collect and record CHMP learnings.

CHMP: Outi Mäki-Ikola

**Action:** For discussion

CHMP endorsed learnings.

#### 2.2.2. CHMP Co-opted membership

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The 3-year mandate for the CHMP co-opted member Blanka Hirschlerova ends on 18 March 2021. The CHMP should discuss and agree on area of expertise needed at their January CHMP ORGAM.

**Action:** For discussion

The CHMP should discuss and agree of area of expertise needed with regards to the vacant seat at their January CHMP Plenary.

The members were asked to send suggestions on the required area of expertise for discussion in January plenary by 25 January 2021.

#### 2.2.3. Organisational information on January 2021 plenary meeting

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CHMP plenary meeting in January 2021 being extended for an additional day to Friday 29 January. Organisation implication on the time-schedule being explained to the committee.

**Action:** For information

The CHMP was informed about the extension of the January 2021 plenary meeting to Friday.

#### 2.2.4. Revision of Accelerated Assessment Request/Briefing Note template

The revision of the AA briefing note template discussed at the January 2020 CHMP ORGAM has now been finalised and is ready for release.

CHMP: Jan Müller-Berghaus

**Action:** For information

CHMP was informed about the finalisation of the AA briefing note template discussed at the January 2020 CHMP ORGAM. CHMP noted the changes introduced to the guideline during the 2020 revision.

### **3. Harmonisation and consistency groups**

#### **3.1. International Council on Harmonisation (ICH)**

No topics

#### **3.2. Guideline Consistency Group (GCG)**

Chair: Aranzazu Sancho-Lopez

No topics

#### **3.3. Summary of product characteristics Advisory Group**

No topics

### **4. Non therapeutic-area-specific working parties**

#### **4.1. Biologics Working Party (BWP)**

Chairs: Sol Ruiz/Nanna Aaby Kruse

##### 4.1.1. Agenda(s) and minutes

- Final minutes for BWP meeting held by teleconference on 3-5 November 2020
- Draft agenda for BWP meeting to be held by teleconference on 18-20 January 2021

**Action:** For information

CHMP noted the Agenda and Minutes.

##### 4.1.2. Joint BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications

This toolbox guidance follows on from the Workshop with stakeholders on support to quality development in early access approaches (i.e. PRIME, Breakthrough Therapies) held jointly with the US Food and Drug Administration (FDA) in November 2018.

**Action:** For adoption

The CHMP noted the Joint BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications with no further comments.

## 4.2. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

No topics

## 4.3. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

### 4.3.1. WHO plan to revise the General GL on SBP (Similar Biologic Products)

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Introduction of WHO initiative to review its General GL on SBP (Similar Biologic Products) in line with the current scientific evidence and experience.

**Action:** For information

The BMWP Chair introduced the WHO initiative to review its General GL on SBP (Similar Biologic Products) from 2009 and update it such that it is in line with the current scientific evidence and experience. The CHMP acknowledged the feedback and expressed the wish to be kept informed of the developments in this field.

## 4.4. Biostatistics Working Party (BSWP)

Chairs: Kit Roes/Jörg Zinserling

### 4.4.1. Question and Answer on Data Monitoring Committee issues – Stakeholder comments and responses

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BSWP is seeking CHMP adoption for the responses to the stakeholder comments received during the public consultation phase. The final Q&A accounting for these comments was adopted by CHMP on 17 September 2020 and published on the EMA website on 8 October 2020. For completeness, the stakeholder comments and responses should also be published on the dedicated website.

**Action:** For adoption

CHMP adopted responses to the stakeholder comments received during the public consultation on the Question and Answer on Data Monitoring Committee issues guideline phase with no further comments.

## 4.5. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

No topics

## 4.6. Pharmacogenomics Working Party (PGWP)

Chair: Markus Paulmichl

No topics

## 4.7. Pharmacokinetics Working Party (PKWP)

Chair: Carolien Versantvoort

### 4.7.1. Product-specific guidelines

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#### Revision of product-specific guidelines

- Sorafenib product-specific bioequivalence guidance (EMA/CHMP/315232/2014) Revision 1 (text amendments, no change in requirements, not for public consultation)

Rapporteur: Erika Fredriksson

**Action:** For adoption

The CHMP adopted for Sorafenib product-specific bioequivalence guidance with no additional comments.

### 4.7.2. PKWP response to CHMP on splitting modified-release tablets

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PKWP response to CHMP question on use of bioequivalence studies to support splitting modified-release (MR) tablets.

Rapporteur: Paulo Paixao/Iva Klarica Domjanović

**Action:** For adoption

CHMP adopted PKWP response to CHMP question on use of bioequivalence studies to support splitting modified-release (MR) tablets with no further comments.

### 4.7.3. Change(s) to PKWP composition

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Nomination by BfArM (DE) of Katalina Mettke as an additional assessor to the PKWP.

**Action:** For endorsement

CHMP endorsed nomination of Katalina Mettke as an additional assessor to the PKWP.

### 4.7.4. 15<sup>th</sup> Workshop on Recent Issues in Bioanalysis (WRIB)

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Proposal to have PKWP member Jan Welink representing CHMP/EMA at the workshop to be held 27 September – 1 October 2021 in Orlando, FL, USA.

**Action:** For endorsement

CHMP endorsed participation of PKWP member Jan Welink representing CHMP/EMA at the workshop to be held 27 September – 1 October 2021 in Orlando, FL, USA.

## 5. Therapeutic-area-specific working parties and SAGs

### 5.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

No topics

### 5.2. Central Nervous System Working Party (CNSWP)

Chair(s): Vacant

No topics

### 5.3. Cardiovascular Working Party (CVSWP)

Chair: Alar Irs

No topics

### 5.4. Infectious Diseases Working Party (IDWP)

Chair(s): Vacant

No topics

### 5.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

#### 5.5.1. Agenda(s) and minutes

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- Final minutes for ONCWP meeting held by Adobe Connect on 16 December 2020
- Final agenda for ONCWP meeting held by Adobe Connect on 13 January 2021

**Action:** For information

CHMP noted agenda and minutes.

### 5.6. Rheumatology/Immunology Working Party (RIWP)

Chair: Romaldas Mačiulaitis

No topics

### 5.7. Vaccines Working Party (VWP)

Chair: Mair Powell



### 5.7.1. VWP report on influenza vaccines effectiveness

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VWP report on the influenza effectiveness data from the DRIVE consortium covering the 2019-2020 season endorsed by CHMP following written procedure ending on 18 December 2020.

**Action:** For information

CHMP noted VWP report on the influenza effectiveness data from the DRIVE consortium covering the 2019-2020 season with no further comments.

## 5.8. Scientific Advisory Groups (SAGs)

No topics

## 6. Drafting groups

### 6.1. Excipients Drafting Group

Chair(s): Vacant

No topics

### 6.2. Gastroenterology Drafting Group (GDG)

Chair(s): Vacant

No topics

### 6.3. Geriatric Expert Group (GEG)

Chair(s): Vacant

No topics

### 6.4. Radiopharmaceuticals Drafting Group (RadDG)

Chair(s): Vacant

No topics

### 6.5. Respiratory Drafting Group (RDG)

Chair: Karolina Törneke

No topics

## 7. Joint groups and collaboration with other committees

### 7.1. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova/Laivi Saaremäel

### 7.1.1. Agenda(s) and minutes

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Minutes from September QWP plenary meeting held 16-18 September 2020.

**Action:** For information

CHMP noted the Minutes.

### 7.1.2. QWP Core Team

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Minutes from December QWP CT meeting held 2 December 2020.

**Action:** For information

CHMP noted the Minutes.

### 7.1.3. Change(s) to QWP composition

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Nomination received for a new member and alternate from Sweden.

- Kristofer Olofsson (member) replacing Sven-Erik Hillver
- Annika Ridell (alternate)

**Action:** For endorsement

CHMP endorsed nomination of QWP member for Sweden Kristofer Olofsson replacing Sven-Erik Hillver and appointment of Annika Ridell as QWP alternate for Sweden.

### 7.1.4. QWP response to CMDh on referral

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Feedback on acceptability on an alternative shortened (121°C / ≥ 8 min) sterilization cycle.

**Action:** For adoption

CHMP adopted QWP response to CMDh on referral with no further comments.

### 7.1.5. QWP response to CMDh on extrapolation of stability data

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Following receipt of the letter from CMDh EMA/575938/2020, dated 30 October 2020, the QWP discussed their question on the extension of shelf-life/re-test period in variation applications using extrapolation at the December 2020 QWP plenary meeting.

**Action:** For adoption

CHMP adopted response to CMDh on extrapolation of stability data.

## 7.2. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

PCWP: Co-chair: Kaisa Immonen Co-chair: Juan Garcia Burgos (EMA)

HCPWP: Co-chair: Ulrich Jaeger Co-chair: Juan Garcia Burgos (EMA)

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

Chair(s): Ellen-Margrethe Vestergaard/Susanne Brendler-Schwaab

No topics

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

Chair: Nienke Rodenhuis

No topics

### 7.5. Collaboration with other committees

#### 7.5.1. PRAC report to CHMP

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Summary of recommendations and advice of PRAC meeting held on 11-14 January 2021.

**Action:** For information

The CHMP noted the Summary of recommendations and advice.

## 8. Product development support

### 8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

#### 8.1.1. Appointment of CHMP peer review for SA

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**Action:** For information

The CHMP noted the information.

### 8.2. Innovation Task Force

#### 8.2.1. ITF meeting

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Meeting date: 08 January 2021 at 15:00 – 16:30 CET

**Action:** For adoption

The meeting was endorsed.

#### 8.2.2. ITF meeting

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Meeting date: 20 January 2021 at 11:00 – 12:30 CET

**Action:** For adoption

The meeting was endorsed.

## 9. Any Other Business

### 9.1.1. Proposal to update ORGAM meeting structure

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CHMP: Harald Enzmann

**Action:** For information

CHMP was informed on the proposal to update ORGAM meeting structure.

### 9.1.2. Cross-Committee Task Force on Registries

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Call for interest of a new CHMP representative.

**Action:** For information

CHMP was informed on the need to nominate a CHMP representative for Cross-Committee Task Force on Registries. Cross-Committee Task Force on Registries is a joint effort for developing a Guidance on Registry-based studies following the public consultation of a draft version. Nominations to be sent as soon as possible or at the latest by 1 February 2021.

### 9.1.3. Update on Aplidin Court Case

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Update on the status on Aplidin following Court Case *T-594/18, Pharma Mar v Commission E*.

**Action:** For information

CHMP was updated on court case *T-594/18, Pharma Mar vs Commission*.

### 9.1.4. CHMP Work Plan 2021

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Discussion on draft CHMP Work Plan 2021

**Action:** For discussion

Draft CHMP Work Plan 2021 document intended for publication. CHMP members are invited to volunteer as contributors in individual activities or send comments on the wording of the document by 27 January 2021.

### 9.1.5. Preview CHMP Plenary

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CHMP: Harald Enzmann

**Action:** For information

### 9.1.6. GCP IWG justification paper for the need to update the CHMP guideline on Data Monitoring Committees (DMCs)

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Need for CHMP guideline on Data Monitoring Committees (DMCs) to be harmonised with current legal and regulatory framework as well as the necessity for additional guidance.

**Action:** For endorsement

CHMP was presented with GCP IWG justification paper for the need to update the CHMP guideline on Data Monitoring Committees (DMCs) and endorsed the need for this update. A multidisciplinary drafting team will be set up.

#### 9.1.7. Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified) - H0005735

BioNTech Manufacturing GmbH; active immunisation against COVID-19 disease.

Rapporteur: Filip Josephson, Co-Rapporteur: Jean-Michel Race, PRAC Rapporteur: Menno van der Elst

Scope: Update on upcoming post-authorisation submission.

**Action:** For discussion

## 10. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphy	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Selma Arapovic Dzakula	Alternate	Croatia	No interests declared	
Tomas Radimersky	Alternate	Czech Republic	No interests declared	
Sinan B. Sarac	Member	Denmark	No interests declared	
Kirstine Moll Harboe	Alternate	Denmark	No interests declared	
Alar Irs	Member	Estonia	No restrictions applicable to this meeting	
Edward Laane	Alternate	Estonia	No restrictions applicable to this meeting	
Outi Mäki-Ikola	Member	Finland	No restrictions applicable to this meeting	
Alexandre Moreau	Member	France	No interests declared	
Martina Weise	Member	Germany	No restrictions applicable to this meeting	
Janet Koenig	Alternate	Germany	No interests declared	
Konstantinos Markopoulos	Member	Greece	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Martine Trauffer	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Bjorg Bolstad	Member	Norway	No restrictions applicable to this meeting	
Ingrid Wang	Alternate	Norway	No interests declared	
Ewa Balkowiec Iskra	Member	Poland	No interests declared	
Bruno Sepodes	Member (Vice-Chair)	Portugal	No interests declared	
Fatima Ventura	Alternate	Portugal	No participation in final deliberations and voting on	any COVID-19 vaccines under EU Advance Purchase Agreement
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Frantisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No participation in discussions, final deliberations and voting on	Tysabri - natalizumab - EMEA/H/C/000603/X/0116
Nevenka Trsinar Brodt	Alternate	Slovenia	No interests declared	
Maria Concepcion Prieto Yerro	Member	Spain	No interests declared	
Blanca Garcia-Ochoa	Alternate	Spain	No interests declared	
Kristina Dunder	Member	Sweden	No interests declared	
Filip Josephson	Alternate	Sweden	No interests declared	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czech Republic	No interests declared	
Dagmar Stará	EC Representative	European Commission		
Elena Wolff-Holz	BMWP Chair	Germany	No interests declared	
Violeta Stoyanova-Beninska	COMP Chair	The Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Koenraad Norga	Expert - via Adobe*	Belgium	No restrictions applicable to this meeting	
Ilko Getov	Expert - via Adobe*	Bulgaria	No interests declared	
Iva Klarica Domjanovic	Expert - via Adobe*	Croatia	No interests declared	
Deirdre Mannion	Expert - via Adobe*	Denmark	No restrictions applicable to this meeting	
Mette Toftegaard Madsen	Expert - via Adobe*	Denmark	No interests declared	
Martina Schussler-Lenz	Expert - via Adobe*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via Adobe*	Germany	No interests declared	
Sabine Mayrhofer	Expert - via Adobe*	Germany	No interests declared	
Johanna Lahteenvujo	Expert - via Adobe*	Finland	No interests declared	
Niklas Ekman	Expert - via Adobe*	Finland	No interests declared	
Giuseppa Pistrutto	Expert - via Adobe*	Italy	No interests declared	
Kora Doorduyn - van der Stoep	Expert - via Adobe*	The Netherlands	No interests declared	
Anja Schiel	Expert - via Adobe*	Norway	No interests declared	
Paulo Paixão	Expert - via Adobe*	Portugal	No interests declared	
Concepcion Gimenez Rebollo	Expert - via Adobe*	Spain	No interests declared	
Maria Victoria Tudanca Pacios	Expert - via Adobe*	Spain	No interests declared	
Milena Peraita Ezcurra	Expert - via Adobe*	Spain	No interest declared	
A representative from the European Commission attended the meeting.				
Meeting run with the help of EMA staff				