14 June 2021
EMA/CHMP/336435/2021 Rev.0
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] minutes for the meeting on 14th June 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

14 June 2021, 09:00–16:00, virtual meeting / room 08-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).

[1] The CHMP PReparatory and Organisational Matters (PROM) is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. 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 PROM topics can be discussed at the CHMP Plenary.

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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 PROM Agenda for 10 May 2021 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of June 2021 meeting will be adopted at the June 2021 CHMP plenary.

2. Non therapeutic-area-specific working parties

2.1. 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)

2.1.1. Agenda and minutes

- Draft agenda for PCWP-HCPWP Joint meeting held virtually on 01-02 June 2021
- Minutes from PCWP-HCPWP Joint meeting held virtually on 03-04 June 2021

Action: For information

CHMP noted the agenda and minutes.

2.2. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Adobe Connect on 12-14 April 2021
- Draft agenda for BWP meeting to be held by WebEx on 14-16 June 2021

Action: For information

CHMP noted the agenda and minutes.

2.2.2. Nomination of new alternate to the BWP

Nomination of new BWP alternate representing Italy.

Action: For endorsement

CHMP endorsed the nomination of new BWP alternate Sonia Russo representing Italy.

2.2.3. Revision of the Guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/BWP/534898/2008

Request from European Commission related to Clinical Trial Regulation. QWP working in parallel on the guideline for chemical IMPs (see 2.3.3).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 6).

Draft guideline proposal to be published by CHMP in June for a targeted 2-month public consultation (i.e. chapter 6 only).

Action: For adoption

CHMP adopted draft on the revision of the guideline on the requirements for quality documentation concerning biological investigational medicinal products (IMPs) in clinical trials with no further comments.

2.3. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 12 May 2021
- Final minutes for QWP meeting held by Adobe Connect on 1-2 March 2021

Action: For information

CHMP noted the minutes.

2.3.2. Nomination of new Lithuanian member to the QWP

Nomination of new QWP member replacing Valdemaras Brusokas representing Lithuania.

Action: For endorsement

CHMP endorsed the nomination of new QWP member Indre Sveikauskaite replacing Valdemaras Brusokas representing Lithuania.

2.3.3. Revision of the Guideline on requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMPs) in clinical trials - EMA/CHMP/QWP/545525/2017

Request from European Commission related to Clinical Trial Regulation. BWP working in parallel on the guideline for biological IMPs (see 2.2.2).

Updates are proposed to the classification of changes to IMPs which require substantial modification of the IMPD (guideline chapter 9).

Draft guideline proposal to be published by CHMP in June for a targeted 2-month public consultation (i.e. chapter 9 only).

Action: For adoption

CHMP adopted draft on the revision of the guideline on the requirements for quality documentation concerning chemical investigational medicinal products (IMPs) in clinical trials with no further comments.

2.4. Safety Working Party (SWP)

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

2.4.1. Agenda and minutes

- Final minutes for SWP meeting held by teleconference on 19 April 2021
- Draft agenda for EMA/FDA non-clinical oncology cluster meeting to be held by teleconference on 8 June 2021

Action: For information

CHMP noted the agenda and minutes.

2.4.2. SWP response to CMDh request on the AI for N-nitrosovarenicline

The SWP has finalised a position on the acceptable intake of N-nitrosovarenicline, a nitrosamine impurity found to be present in some varenicline products. This position has been harmonised with international regulators in the nitrosamine international technical working group.

Action: For adoption

CHMP adopted SWP response to CMDh request on the AI for N-nitrosovarenicline in varenicline.

2.4.3. SWP response to CMDh request on 4-nitrosomorpholine (NMOR) in molsidomine

The SWP has finalised a position on the acceptable intake of N-nitrosomorpholine, a nitrosamine impurity known to be present in some molsidomine products.

Action: For adoption

CHMP adopted CMDh request on 4-nitrosomorpholine (NMOR) in molsidomine.

2.4.4. Diethanolamine – SWP opinion for publication

SWP addressed CMDh questions on Diethanolamine and coconut oil diethanolamine condensate as excipients in 2018 and 2020. It is proposed to publish on EMA external website a position combining both opinions adopted by the CHMP in November 2018 and November 2020.

Action: For adoption

CHMP adopted publication of SWP opinion on Diethanolamine and coconut diethanolamine condensate as excipients with no further comments.

2.4.5. Change in nomination between Croatian SWP member and alternate

Nikolina Tori, current SWP alternate, to become member, and Jasenka Mrsic-Pelcic, current member, to become alternate.

Action: For endorsement

CHMP endorsed the nomination of Nikolina Tori, current SWP alternate, to become member, and Jasenka Mrsic-Pelcic, current member, to become alternate representing Croatia.

2.4.6. Call for nomination for the election of the SWP chair

Jan Willem van der Laan's second term will expire on 18 October 2021. Nominations have to be sent together with a CV and a brief motivation letter.

Action: For information

CHMP noted the call for nomination for the election of the SWP chair. Nominations should be sent together with a CV and a brief motivation letter by 27th September. Elections will take place at the October CHMP plenary.

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chair: Elena Wolff-Holz

2.5.1. Agenda and minutes

- Agenda of BMWP meetings held virtually on 28 April 2021 and 26 May 2021
- Final minutes for BMWP meetings held on 31 March and 28 April 2021

Action: For information

CHMP noted the agenda and minutes.

2.6. Biostatistics Working Party (BSWP)

Chair: Kit Roes

2.6.1. Reflection Paper on Statistical Methodology for the Comparative Assessment of Quality Attributes in Drug Development - EMA/CHMP/138502/2017

Reflection paper on the topic of "Statistical Issues in Quality Assessment" and high-level overview of how the comments received were taken into consideration.

Action: For adoption

CHMP discussed the reflection paper on the topic of "Statistical Issues in Quality Assessment" and high-level overview of how the comments received were taken into consideration. CHMP concluded that more time to analyse the topic was needed and requested re-discussion in July PROM.

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda

- Draft agenda of MSWP meeting held virtually via Webex on 02 June 2021

Action: For information

CHMP noted the agenda.

2.7.2. Nomination of new member to the Modelling and simulation Working Party

Nomination of new MSWP member representing France.

Action: For endorsement

CHMP endorsed the nomination of new MSWP member Anke-Katrin Volz representing France.

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair (ad interim): Carolien Versantvoort

2.9.1. Questions from Committees, other Working Parties

- CMDh request for CHMP (PKWP) input regarding procedure Megestrol acetate 40 mg/ml oral suspension and bioequivalence study requirements for micronised suspension generic applications.
- PKWP (CHMP) response to CMDh request for input regarding procedure Tapentadol prolonged release capsules

Action: For adoption

- CHMP adopted request for CHMP (PKWP) input regarding procedure Megestrol acetate 40 mg/ml oral suspension and bioequivalence study requirements for micronised suspension generic applications with no further comments.
- CHMP adopted PKWP (CHMP) response to CMDh request for input regarding procedure Tapentadol prolonged release capsules

2.9.2. PKWP Q&A on biowaivers for additional strengths of immediate release fixed combinations

Issue identified in a Scientific Advice procedure including request for information on how large can the deviations from proportionality in composition be in the case of fixed combinations with highly soluble active substances in an application with multiple strengths. PKWP have developed a new proposed Q&A in response (complementing current existing PKWP Q&A 6.4).

Action: For adoption

CHMP adopted the PKWP Q&A on biowaivers for additional strengths of immediate release fixed combinations with no further comments.

2.9.3. PKWP request to CHMP to draft a Q&A on alternatives to rifampicin in drug-drug interaction (DDI) studies in healthy volunteers

CHMP previously adopted (CHMP plenary minutes April 2021) the Nitrosamine Implementation Oversight Group (NIOG) response (10 March 2021) to a question from PKWP on use of rifampicin in DDI studies in healthy volunteers. PKWP is now requesting agreement from CHMP to develop a Q&A for alternatives to rifampicin in such studies.

Action: For adoption

CHMP adopted the PKWP request to CHMP to draft a Q&A on alternatives to rifampicin in drug-drug interaction (DDI) studies in healthy volunteers with no further comments.

2.9.4. Change in composition to PKWP

Addition of a new expert.

Action: For adoption

CHMP endorsed the nomination of Sigurrós Sigmarsdóttir (IS) as an additional expert.

2.9.5. Minutes

- Final minutes of PKWP meeting held via Webex on 19 May 2021

Action: For information

CHMP noted the minutes.

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Agendas

- Final agenda of the annual EMA/PPTA-IPFA meeting held by teleconference on 10 June 2021
- Draft agenda for the Blood cluster meeting held by teleconference on 04 June 2021

Action: For information

CHMP noted the agendas.

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

No topics

3.5. Oncology Working Party (ONCWP)

Chairs: Sinan B. Sarac/Paolo Foggi

3.5.1. Agenda and minutes

- Final minutes for ONCWP meeting held by Adobe Connect on 06 May 2021
- Final agenda for ONCWP meeting held by Adobe Connect on 11 June 2021

Action: For information

CHMP noted the agenda and minutes.

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Nomination of experts for ICH groups

- ICH Guideline Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
- ICH Guideline Q3E Guideline for Extractables and Leachables (E&L) **Action:** For endorsement

CHMP endorsed nomination of expert Mats Jernberg (SE) for ICH Guideline Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin.

CHMP endorsed nomination of expert Katrin Buss (DE) for ICH Guideline Q3E Guideline for Extractables and Leachables (E&L).

5.1.2. ICH E6 GCP principles

In the context of the ICH E6 (GCP) revision process, a new document – named draft "ICH E6 Principles" – has been published.

Action: For discussion

CHMP noted broader plans for renovation of GCP ICH E6 (GCP) revision process with no further comments.

5.1.3. ICH S12 Biodistribution Studies for Gene Therapy Products

Step2b- New draft guidance ICH S12 Biodistribution Studies for Gene Therapy Products to be adopted for 4-month public consultation.

Action: For adoption

CHMP was presented with proposal for new draft guidance ICH S12 Biodistribution Studies for Gene Therapy Products for 4-month public consultation. Public consultation expected to finalise in 2022. CHMP members adopted New draft guidance ICH S12 Biodistribution Studies for Gene Therapy Products for 4-month public consultation.

5.2. Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. 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)

No topics

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

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 07-10 June 2021

Action: For information

The CHMP noted the Summary of recommendations and advice.

6.3.2. RMP safety specification assessment responsibilities for generic products – transfer from the CHMP to PRAC

Transfer of the safety specification assessment responsibilities for generic products from the CHMP to PRAC has been agreed in 2020, however due to COVID-19 BCP the transfer had not taken place. Proposal by EMA on a pragmatic way forward to enable the agreed transfer.

Action: For endorsement

CHMP endorsed the proposal for transfer of RMP safety specification assessment responsibilities for generic products from the CHMP to PRAC with no further comments. The start date applies to all MAAs for Article 10.1 (generics) submitted as of 01 September 2021.

7. Regulatory / Organisational matters

7.1. Regulatory Issues / new legislation

No topics

7.2. CHMP organisation / templates

7.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

CHMP endorsed learnings.

8. Product development support

8.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

8.1.1. Appointment of CHMP peer review for SA

Action: For information

CHMP noted the appointment of CHMP peer review for Scientific Advice.

8.2. Innovation Task Force

8.2.1. ITF meeting

Meeting date: 04 June 2021

Action: For adoption

CHMP endorsed the meeting.

8.2.2. ITF meeting

Meeting date: 30 June 2021

Action: For adoption

CHMP endorsed the meeting.

9. Product related topics

9.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP noted the update. CHMP chair flagged some procedures for adoption in the upcoming plenary for which different views from committee members indicate possibly extended discussion. CHMP members involved or particularly interested in these procedures were encouraged to discuss in advance before the plenary meeting. Sending comments prior to the plenary meeting was encouraged as this will facilitate a structured discussion.

9.1.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

Action: For information

CHMP noted the list of currently COVID-19 ongoing and upcoming procedures.

9.1.3. Comirnaty – COVID-19 mRNA Vaccine (nucleoside modified) - EMEA/H/C/005735/X/0001

BioNTech Manufacturing GmbH

Rapporteur: Filip Josephson, PRAC Rapporteur: Menno van der Elst

Update on upcoming post-authorisation activities

Proposed procedure timetable

Action: For adoption

CHMP was updated on the status of post-authorisation activities for this medicinal product. CHMP adopted the proposed procedure timetable.

9.1.4. pralsetinib - EMEA/H/C/005413

treatment of non-small cell lung cancer (NSCLC)

Scope: Update on the status of this application

Action: For discussion

List of Outstanding Issues adopted on 28.01.2021. List of Questions adopted on 17.09.2020.

CHMP was updated with the status of this application.

10. Any Other Business

10.1.1. Update from Research and Innovation workstream

Summary of recent activities in the workstream's areas of Innovation Task Force, Horizon Scanning and Business Pipeline/Forecasting and is looking to open opportunities for Committee members to contribute to upcoming activities.

Action: For discussion

CHMP noted the update of recent activities in the workstream's areas of Innovation Task Force, Horizon Scanning and Business Pipeline/Forecasting.

10.1.2. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus Drafting Group

Proposal to establish a Drafting Group to revise the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus and call for nominations. Nominations to be sent by 12 July 2021.

Action: For endorsement

CHMP endorsed the proposal to establish a Drafting Group to revise the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus and noted the call for nominations.

10.1.3. CHMP strategic, review and learning meeting under the Slovenian presidency of the Council of the European Union

Presentation on the SRLM under the Slovenian presidency for the 2nd part of 2021 to be introduced by SI CHMP member.

CHMP: Nevenka Tsinar

Action: For information

CHMP noted and welcomed upcoming strategic, review and learning meeting under the Slovenian presidency of the Council of the European Union expected for the 2nd part of 2021.

10.1.4. Future of presential plenary meetings

Discussion on the return to presential plenary meetings.

CHMP: Harald Enzmann

Action: For discussion

CHMP discussed the future of presential plenary meeting and advantages of virtual and presential meetings.

10.1.5. Lisboa criteria for comprehensiveness

Criteria to be added to the AR templates for assessor to consider during evaluation.

CHMP: Harald Enzmann

Action: For discussion

CHMP was presented with the final criteria agreed at the Strategic Review and Learning Meeting under the Portuguese Presidency that took place on 27th May 2021. CHMP requested that the criteria is added to the AR templates for assessor to consider during evaluation.

10.1.6. Media reports over the weekend 11th-13th June with misinformation about EMA's scientific considerations on AstraZeneca's COVID-19 vaccine

Discussion over Media reports following article published in La Stampa, in which Marco Cavaleri was misquoted regarding AstraZeneca's COVID-19 vaccine.

Action: For information

CHMP was informed about media reports following article published in La Stampa, in which Marco Cavaleri was misquoted regarding AstraZeneca's COVID-19 vaccine. EMA's regulatory position in respect to AstraZeneca's COVID-19 vaccine as adopted by EMA scientific Committees is unchanged. The benefit-risk balance is positive, and the vaccine remains authorised in all populations.

EMA has taken actions to set the record straight; La Stampa published a correction of their original article, EMA provided statements to ANSA and Reuters to address the misinformation and clarify EMA's regulatory position which have been taken into consideration and published, a letter has been sent to the Editor of La Stampa and EMA update press contacts to inform them of the misinformation circulating in the media and to request that they update already published stories. In addition, EMA's regulatory position was also clarified via a widely seen Twitter post published on Sunday. EMA is committed to review procedures on how interviews are conducted to ensure factually correct reporting in the interest of public health.

11. 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	
Ilko Getov	Member	Bulgaria	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Helena Panayiotopoulou	Member	Cyprus	No interests declared	
Ondřej Slanař	Member	Czechia	No restrictions applicable to this meeting	
Tomas Radimersky	Alternate	Czechia	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	
Johanna Lähteenvuo	Alternate	Finland	No interests declared	
Jean-Michel Race	Alternate	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	
Hrefna Gudmundsdottir	Alternate	Iceland	No interests declared	
Jayne Crowe	Member	Ireland	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No interests declared	Covid-19 vaccines
Martine Trauffler	Member	Luxembourg	No interests declared	
John Joseph Borg	Member	Malta	No interests declared	
Johann Lodewijk Hillege	Member	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 restrictions applicable to this meeting	Covid-19 vaccines
Simona Badoi	Member	Romania	No interests declared	
Dana Gabriela Marin	Alternate	Romania	No interests declared	
Francisek Drafi	Member	Slovakia	No interests declared	
Dorota Distlerova	Alternate	Slovakia	No participation in discussions, final deliberations and voting	Nuwiq - simoctocog alfa - EMEA/H/C/002813/X/0042
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	
Christian Gartner	Co-opted member	Austria	No restrictions applicable to this meeting	
Carla Torre	Co-opted member	Portugal	No interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Vincent Gazin	Expert - via Webex*	France	No interests declared	
Irene Bachmann	Expert - via Webex*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via Webex*	Germany	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sabine Mayrhofer	Expert - via Webex*	Germany	No interests declared	
Alfredo García-Arieta	Expert - via Webex*	Spain	No interests declared	
Jan Welink	Expert - via Webex*	Netherlands	No interests declared	
Deirdre Mannion	Expert - via Webex*	Denmark	No restrictions applicable to this meeting	
Anne Hasle Buur	Expert - via Webex*	Denmark	No interests declared	
Carolien Versantvoort	Expert - via Webex*	Netherlands	No interests declared	
Sabine Straus	Expert - via Webex*	Netherlands	No interests declared	
Louise Frederikke Swaffield Bang-Lauritsen	Expert - via Webex*	Denmark	No interests declared	
Ira Koval	Expert - via Webex*	Netherlands	No restrictions applicable to this meeting	
Christian B. (Kit) Roes	Expert - via Webex*	Netherlands	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company	WS1953 Segluromet - ertugliflozin / metformin hydrochloride - EMEA/H/C/004314/WS1953/0012 Steglatro - ertugliflozin - EMEA/H/C/004315/WS1953/0013 Zepatier - elbasvir / grazoprevir - EMEA/H/C/004126/II/0029 Keytruda - pembrolizumab - EMEA/H/C/003820/II/99 - 104 - 105
Martina Schuessler-Lenz	Expert - via Webex*	Germany	No interests declared	
Thomas Lang	Expert - via Webex*	Austria	No interests declared	
Meeting run with the help of EMA staff				

*Experts were evaluated against the product(s) they have been invited to talk about