



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/CHMP/726358/2022
Human Medicines Division

Committee for medicinal products for human use (CHMP) PROM¹ minutes for the meeting on 5 September 2022

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

5 September 2022, 09:00–13:40, 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 the PROM agenda for 5 September 2022 meeting.

1.3. Adoption of the minutes

CHMP PROM Minutes of 5 September 2022 meeting will be adopted at the September CHMP plenary.

2. Quality Domain

2.1. Biologics Working Party (BWP)

Chairs: Sol Ruiz, Sean Barry

2.1.1. Agenda and minutes

- Draft agenda for BWP meeting to be held virtually on 5-7 September 2022
- Final minutes for BWP meeting held virtually on 13-15 June 2022

Action: For information

The CHMP noted the agenda and the minutes.

2.1.2. EDQM letters to BWP and CMDh requesting input on the limit for residual protein in monographs of unfractionated heparin (Heparin sodium (0333) and Heparin calcium (0332))

Proposal to continue scientific discussion at BWP and prepare a joint response from CMDh and CHMP (BWP) to EDQM, for requested deadline of 30 November 2022.

Action: For information

CHMP noted the proposal to continue scientific discussion at BWP to prepare a joint response from CMDh and CHMP (BWP) to EDQM.

2.1.3. PMF dossier requirements. Questions and Answers for PMF Holders

This Q&A supplements the data requirements in the published guidelines on Plasma Master File (PMF) Scientific requirements (EMA/CHMP/BWP/3794/03) and dossier requirements on PMF epidemiological data (EMA/CHMP/BWP/548524/2008) on topics related to inspection approval status, information on audits and epidemiology alert limits.

Action: For adoption

The CHMP adopted the Questions and Answers on PMF requirements for PMF Holders.

2.2. Quality Working Party (QWP)

Chair: Blanka Hirschlerova

2.2.1. Agenda and minutes

- Final agenda for QWP-CT meeting held virtually on 13 July 2022
- Final minutes for QWP-CT meeting held virtually on 13 July 2022

Action: For information

The CHMP noted the agenda and the minutes.

2.2.2. Guideline on the development and manufacture of synthetic peptides: concept paper for public consultation

The 3-year workplan of QWP foresees the preparation of a guideline (scope includes human and veterinary medicinal products) on the development and manufacture of synthetic peptides, and a guideline on the development and manufacture of synthetic oligonucleotides. In view of this, two concept papers were prepared by the drafting group, discussed in QWP and CVMP and are now proposed for adoption. A 3-month public consultation for the concept papers is proposed.

CHMP: Blanka Hirschlerova

Action: For adoption

The CHMP adopted the concept paper for public consultation on the future Guideline on the development and manufacture of synthetic peptides.

2.2.3. Guideline on the development and manufacture of synthetic oligonucleotides: concept paper for public consultation

See 2.2.2

A 3-month public consultation for the concept papers is proposed.

CHMP: Blanka Hirschlerova

Action: For adoption

The CHMP adopted the concept paper for public consultation on the future Guideline on the development and manufacture of synthetic oligonucleotides.

2.2.4. Nomination of new alternate to the QWP

Nomination of new QWP alternate to replace Ewa Wyzsecka-Kaszuba representing Poland.

Action: For endorsement

The CHMP endorsed the nomination of the new QWP alternate Natalia Wąsowicz to replace Ewa Wyzsecka-Kaszuba representing Poland.

2.2.5. Nomination of new member to the QWP

Nomination of new QWP member to replace Kim Notenboom representing the Netherlands.

Action: For endorsement

The CHMP endorsed the nomination of the new QWP member Peter Caspers to replace Kim Notenboom representing the Netherlands.

2.3. Biosimilar Medicinal Product Working Party (BMWP)

No topics

2.4. Quality Innovation Group (QIG)

No topics

2.5. Formulation Expert Group (FEG)

No topics

3. Non-Clinical Domain

3.1. Non-Clinical Working Party (NCWP)

Chairs: Susanne Brendler-Schwaab, Karen van Malderen

3.1.1. Agenda and minutes

- Draft minutes for NcWP meeting held virtually on 12-13 July 2022
- Draft agenda for NcWP meeting to be held virtually on 1 and 7 September 2022

Action: For information

The CHMP noted the agenda and the minutes.

3.1.2. CMDh questions to NcWP on new nitrosamines

CMDh requests that the NcWP determines the acceptable intake for the following nitrosamines based on lifetime daily exposure including information on the points of departure and methodology used.

- N-nitroso-moxifloxacin
- N-nitroso-fluoxetine
- N- nitroso-nebivolol
- N-nitroso-bisoprolol
- N-nitroso-biotin
- N-nitroso-diclofenac
- N-Nitroso-betahistine

- N-nitroso-Bupropion

Action: For adoption

The CHMP adopted the CMDh requests to NcWP to determine acceptable intakes for the above-mentioned nitrosamines.

3.1.3. Third party request for clarifications on the SWP response to CMDh on genotoxicity and contraception

In February 2020, based on a request from CMDh, the Safety working party (SWP) published advice on the duration of contraception in male and female patients after cessation of treatment with a genotoxic drug in the context both of clinical trial applications as well as marketing authorisation applications (EMA/CHMP/SWP/74077/2020). In July 2022, the CMDh and EMA have received questions from a third party for which NcWP view is sought.

Action: For adoption

The CHMP adopted the questions to NcWP for clarifications on the SWP response to CMDh on genotoxicity and contraception.

3.1.4. Creation of an excipients drafting group

The Non-clinical domain governance adopted the creation of an ad hoc excipients drafting group for finalising the excipients safety information documents which have been on hold due to the Business Contingency Plan. The following excipients will be covered:

- Lactose
- Dextrans
- Polysorbate
- Proline

A kick-off meeting will take place in September

Action: For information

The CHMP noted the creation of an excipients drafting group.

3.1.5. New nomination in the ERA drafting group

Following the stepping away from Caroline Moermond, nomination of a member of the ERA drafting group to finalise the revision of the Environmental Risk Assessment guideline.

Action: For endorsement

The CHMP endorsed the nomination of Melvin Faber (RIVM) as a member of the ERA drafting group.

3.1.6. Non-clinical software

EMA has acquired all non-clinical software packages on behalf of NCAs for an initial 5-year period. These tools are widely used for non-clinical and quality applications and include in

silico prediction software for toxicity, metabolic fate and chemical degradation of chemicals, chemical database software for chemical toxicity information management and software for the calculation of purge factors. In order to install the software in the NCAs and get credentials, every NCA should confirm to NCWP secretariat their interest in using the software. A training will be organised and made available via the EU NTC to all assessors.

Action: for information

The CHMP noted the update on Lhasa software.

3.2. Joint 3Rs Replacement, Reduction and Refinement Working Party (3Rs)

Chair(s): Sonja Beken, Sarah Adler-Flindt

3.2.1. Nomination of the J3RsWP Chair and Vice-chair

Upon constitution of the J3RsWP following the implementation of the new Working Parties Operating Model (WOM), a first meeting was held on 18 July 2022 to elect the Chair and Vice-Chair. During the meeting, it was agreed to select a Chair from the area of human medicinal products, while the Vice-Chair would represent the area of veterinary products. The following members were elected:

- Dr Sonja Beken (Belgian NCA) as Chair
- and Dr Sarah Adler-Flindt (German NCA) as Vice-chair.

Action: For endorsement

The CHMP endorsed Sonja Beken as Chair and Sarah Adler as Vice-chair of the J3RsWP.

4. Methodology Domain

4.1. Methodology Working Party (MWP)

Chairs: Kit Roes, Kristin Karlsson

4.1.1. Agenda and minutes

- Final agenda and minutes for MWP meetings held virtually on 14 and 28 July 2022

Action: For information

The CHMP noted the agenda and the minutes.

4.2. Biostatistics Operational Expert Group (BOEG)

No topics

4.3. Modelling and Simulation Operational Expert Group (MSOEG)

No topics

4.4. Real World Data Operational Expert Group (RWDOEG)

No topics

4.5. Pharmacokinetics Working Party (PKWP)

No topics

5. Clinical Domain

5.1. Central Nervous System Working Party (CNSWP)

Chair: Andre Elferink

5.1.1. Launch call for nomination for new member for CNSWP

The current CNS WP has only 7 members. It is proposed to add an additional member to bring the Working Party to full capacity. It is proposed to launch a call for nomination for a new member for CNSWP.

Nominations should be sent to the Agency by **9 September 2022**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Action: For information

The CHMP noted the launch of the call for nomination for a new member for CNSWP.

5.2. Cardiovascular Working Party (CVSWP)

Chairs: Alar Irs, Patrick Vrijlandt

5.2.1. CVSWP response to the PKWP LoQs regarding considerations for digoxin as NTI drug

The CVSWP input was requested by the PKWP (July 2022) on the qualification of digoxin as a drug of narrow therapeutic index (NTI).

CHMP: Alar Irs

Action: For adoption

The CHMP adopted the CVSWP response to the PKWP LoQs regarding considerations for digoxin as NTI drug.

5.3. Oncology Working Party (ONCWP)

Chair: Pierre Demolis

5.3.1. Nomination of Oncology ESEC experts

- Nomination by ONCWP of the experts to enter the Oncology European Specialised Expert Community (ESEC)

Action: For endorsement

The CHMP endorsed the nomination as ONCWP ESEC expert.

5.3.2. Update on the Oncology ESEC

Update on the start of projects and training/presentations.

Action: For information

The CHMP noted the projects and trainings/presentation of the Oncology ESEC.

5.3.3. Agenda and Minutes

- Agenda from the ONCWP meeting held on 13 July 2022
- Minutes from the ONCWP meeting held virtually on 20 May 2022

Action: For information

The CHMP noted the agenda and minutes.

5.4. Rheumatology and Immunology Working Party (RIWP)

No topics

5.5. Infectious Disease Working Party (IDWP)

No topics

5.6. Vaccines Working Party (VWP)

No topics

5.7. Haematology Working Party (HaemWP)

Chair: Daniela Philadelphia

5.7.1. Agenda

- Draft agenda of the HAEMWP to be held virtually on 9 September 2022

Action: For information

The CHMP noted the agenda.

5.7.2. Minutes Blood cluster TC

- Final minutes of the Blood cluster TC held virtually on 24 June 2022

Action: For information

The CHMP noted the minutes.

5.7.3. Minutes annual meeting with PPTA and IPFA

- Final minutes of the annual meeting with PPTA and IPFA held on 7 June 2022

Action: For information

The CHMP noted the minutes.

5.8. Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEG)

No topics

6. Patients, Healthcare Professionals and Consumers

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

No topics

7. Harmonisation and consistency groups

7.1. International Council on Harmonisation (ICH)

7.1.1. ICH E19 – A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials

Following the public consultation that closed in Q4 2019, the ICH E19 working group has been revising the draft guideline. The final version has now been agreed and is brought to CHMP for adoption. After this, implementation is foreseen (6 months from date of publication).

Action: For adoption

The CHMP adopted the final version of ICH E19 – A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials. This guideline will be implemented in the EU 6 months after publication on the EMA website.

7.1.2. ICH S1B(R1) – Revision of the guideline on testing for carcinogenicity of pharmaceuticals

Following the Non-Clinical WP endorsement of the final guideline version and the conclusion of the ICH process, this guideline is to be adopted by CHMP. Implementation will follow 6 months from publication.

Action: For adoption

The CHMP adopted the revision of the guideline ICH S1B(R1) on testing for carcinogenicity of pharmaceuticals. This guideline will be implemented in the EU 6 months after publication on the EMA website. CHMP supported also that a further presentation on how submissions following the novel S1B(R1) approach would be handled by SAWP in consultation with the NCWP.

7.2. Guideline Consistency Group (GCG)

No topics

7.3. Summary of product characteristics Advisory Group

No topics

8. Joint groups and collaboration with other Scientific committees

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

No topics

8.2. Collaboration with other Scientific committees

8.2.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 29 August-01 September 2022.

Action: For information

The CHMP noted the summary of recommendations and advice.

9. Regulatory/Organisational matters

9.1. Regulatory Issues/new legislation

No topics

9.2. CHMP organisation/templates

9.2.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

The CHMP endorsed the proposed learnings.

9.2.2. CHMP Rules of Procedure amendments

Following the entry into force of both EU Regulations on medical devices, i.e. Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), as well as the Regulation (EU) 2022/123 on a reinforced

role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, an update in the CHMP's Rules of Procedure (RoP) is required.

Action: For adoption

The CHMP adopted the CHMP Rules of Procedure amendments.

10. Product development support

10.1. Scientific Advice Working Party (SAWP)

Chair: Paolo Foggi Agenda and Table of Decisions

- Agenda from 29 August until 01 September 2022 SAWP meeting held face-to-face
- Draft Table of Decisions from 29 August until 01 September 2022 SAWP meeting held face-to-face

Action: For information

The CHMP noted the agenda and the table of decisions.

10.1.1. Appointment of CHMP peer review for SA

Action: For information

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

10.1.2. Nomination of new members and alternates to the Scientific Advice Working Party

Nomination of new SAWP members and alternates.

Required areas of expertise: Haematology/ onco-haematology, cardiology, biosimilars.

Action: For endorsement

The CHMP endorsed Nanna Borup Johansen as new SAWP member.

10.2. Innovation Task Force

10.2.1. ITF meeting

Meeting date: 7 September 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.2. ITF meeting

Meeting date: 15 September 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.3. ITF meeting

Meeting date: 29 September 2022

Action: For adoption

The CHMP endorsed the meeting.

10.2.4. ITF meeting

Meeting date: 23 September 2022 or 28 October 2022 tbc

Action: For adoption

The CHMP endorsed the meeting.

10.2.5. ITF meeting

Meeting date: 10 October 2022

Action: For adoption

The CHMP endorsed the meeting.

11. Product related topics

11.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

The CHMP Chair flagged some procedures on the agenda of the upcoming plenary.

11.2. 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

The CHMP noted the COVID-19 ongoing and upcoming procedures.

11.3. gefapixant - EMEA/H/C/005476 and EMEA/H/C/005884

Treatment of refractory or unexplained chronic cough

Scope: CHMP list of questions for consultation to the MWP

Action: For adoption

The CHMP agreed to consult the MWP and adopted a list of questions to this group.

11.4. teriparatide - EMEA/H/C/004932

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

Scope: Letter by the applicant dated 1 September 2022 requesting an extension to the clock stop to respond to the list of questions adopted in July 2022.

List of Outstanding Issues adopted on 21.07.2022, 16.12.2021. List of Questions adopted on 28.01.2021.

Action: For adoption

The CHMP agreed to the request by the applicant for an extension to the clock stop to respond to the list of outstanding issues.

12. Any Other Business

12.1. Rapporteurships

Action: For information

The CHMP noted list update.

12.2. PRIME implementation of 5-year review recommendations

Presentation of the proposals for implementation of the recommendations arising from the first 5 years' experience with the scheme (see also [PRIME 5-year report](#)), as discussed and agreed by the PRIME oversight group.

Action: For adoption

The CHMP adopted the PRIME implementation of 5-year review recommendations.

12.3. Update on the upcoming proof-of-concept raw data pilot

Update on the proof-of-concept raw data pilot. The pilot, which is expected to start in Q3 2022, will analyse individual patient data in electronic structured format (raw data) from selected marketing authorisation applications. The pilot aims at generating relevant learnings about accessing and analysing raw data during the assessment process. The proof-of-concept raw data pilot is part of EMA's Lifecycle Regulatory Submissions Raw Data project, which is focusing on utilising raw data to support regulatory decision-making and was listed as an action in CHMP's work plan for 2022.

Action: For information

CHMP noted the update on the upcoming proof-of-concept raw data pilot. CHMP requested clarification on the IT systems to support this initiative. Members enquired on the decision-making process for the decision to proceed with the pilot for selected products and it was clarified that the decision will be taken upon submission of the products by the rapporteurs. Members requested to capture the time spent for the process and assessment of raw data.

12.4. Real World Evidence pilot and DARWIN EU®

Update on the establishment of DARWIN EU® containing an update on the list of data partners selected for Year 1 and an update on the progress of studies. Additionally, update on the RWE pilot with CHMP, with a reminder to submit all research questions to the EMA RWE team.

Action: For discussion

CHMP noted the update on the establishment of DARWIN EU®.

12.5. Call to CHMP members to be part of the Immunisation and Vaccine Monitoring Board (IVMAB) of the ECDC/EMA Vaccine Monitoring Platform (VMP)

The vaccine monitoring platform (VMP), under the EMA and ECDC's extended mandates, has been established for the joint coordination of vaccine safety and effectiveness studies. The VMP will feature, as part of its governance, an EU Immunisation and Vaccine Monitoring Board (IVMAB) that will have a consultative and facilitative (non-binding) role, to help inform regulatory or public health action. Request to three CHMP members to join the IVMAB.

Interested members should express their interest by **8 September 2022**.

Action: For information

The CHMP noted the call to CHMP members to be part of the Immunisation and Vaccine Monitoring Board (IVMAB) of the ECDC/EMA Vaccine Monitoring Platform (VMP).

13. List of Participants

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Harald Enzmann	Chair	Germany	No interests declared	
Andrea Laslop	Member	Austria	No interests declared	
Daniela Philadelphia	Alternate	Austria	No interests declared	
Christophe Focke	Member	Belgium	No restrictions applicable to this meeting	
Karin Janssen van Doorn	Alternate	Belgium	No interests declared	
Margareta Bego	Member	Croatia	No interests declared	
Selma Arapovic Dzakula	Alternate	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	
Thalia Marie Estrup Blicher	Member	Denmark	No restrictions applicable to this meeting	
Aaron Sosa Mejia	Alternate	Denmark	No restrictions applicable to this meeting	
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 Lähtenvuo	Alternate	Finland	No interests declared	
Alexandre Moreau	Member	France	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	
Konstantina Alexopoulou	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Robert Porszasz	Member	Hungary	No interests declared	
Agnes Gyurasics	Alternate	Hungary	No interests declared	
Armando Genazzani	Member	Italy	No interests declared	
Maria Grazia Evandri	Alternate	Italy	No interests declared	
Elita Poplavska	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member	Lithuania	No participation in final deliberations and voting on	COVID-19 vaccines
Martine Trauffer	Member	Luxembourg	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Alexandra Branchu	Alternate	Luxembourg	No restrictions applicable to this meeting	
Johann Lodewijk Hillege	Member	Netherlands	No interests declared	
Paula Boudewina van Hennik	Alternate	Netherlands	No interests declared	
Eva Skovlund	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:	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 interests declared	
Nevenka Trsinar Brodt	Alternate	Slovenia	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 interests declared	
Jan Mueller-Berghaus	Co-opted member	Germany	No interests declared	
Blanka Hirschlerova	Co-opted member	Czechia	No interests declared	
Sabine Mayrhofer	Expert - via WebEx*	Germany	No interests declared	
Nora Cascante Estepa	Expert - via WebEx*	Germany	No interests declared	
Vincent Gazin	Expert - via WebEx*	France	No interests declared	
Finbarr Leacy	Expert - via WebEx*	Ireland	No interests declared	
Luca Santi	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Martina Perini	Expert - via WebEx*	Italy	No restrictions applicable to this meeting	
Mette Toftegaard Madsen	Expert - via WebEx*	Denmark	No interests declared	
Hinke Johanna Van der Woude	Expert - via WebEx*	Netherlands	No interests declared	
Laura Rodwell	Expert - via WebEx*	Netherlands	No interests declared	
Maria Grünwald	Expert - via WebEx*	Sweden	No interests declared	
Peter Mol	Expert - via WebEx*	Netherlands	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda and for which restrictions apply
Deirdre Mannion	Expert - via WebEx*	Denmark	No restrictions applicable to this meeting	
Mas Parra Paloma	Expert - via WebEx*	Spain	No restrictions applicable to this meeting	
Eva M. Lindberg	Expert - via WebEx*	Sweden	No interests declared	
Meeting run with support from relevant EMA staff.				

Experts were evaluated against the agenda topics or activities they participated in.