EUnetHTA Joint Action 2
Plenary Assembly

Madrid, Spain
April 10 2014, 09:00-17:30
April 11 2014, 09:00-15:00

Address of the meeting venue:
Hotel Melia Galgos, c/Calle de Claudio Coello, 139 - Madrid 28006.
Tel: +34 91 5626 600

Summary Report

April 10, 2014

1. Opening remarks	**09:00 – 09:15**
2. First half of EUnetHTA JA2 – report from the Coordinator	**09:15 – 10:15**
3. EUnetHTA Elections 2014 • Presentation of candidates and procedure	**10:15 – 10:45**
Coffee break – and voting	*10:45 – 11:15*
4. Approval of amended SOP and EUnetHTA Conflict of Interest Policy	**11:15 – 12:00**
5. Short- (2014-15), mid- (2016-20) and long-term (post-2020) strategic development of EUnetHTA • Introduction by EUnetHTA and HTA Network	**12:00 – 12:30**
Lunch	*12:30 – 13:30*
6. Results of the elections	**13:30 – 13:40**
7. Short-term (2014-15) strategic development of EUnetHTA	**13:40 –14:45**
Coffee break	*14:45 – 15:15*
8. Mid-term (2016-20) strategic development of EUnetHTA - I • Introduction and Group work	**15:15 – 17:30**

April 11, 2014

1. Reports from Group discussions	**09:00 – 10:15**
Coffee break	*10:15 – 10:45*
2. Mid-term (2016-20) strategic development of EUnetHTA – II • Plenary discussion	**10:45 – 12:00**
Lunch	*12:00 – 13:00*
3. Long term (post-2020) strategic development of EUnetHTA	**13:00 – 14:00**
4. HTA 2.0 Europe – teaming up for value, Rome Oct. 30-31 2014	**14:00 – 14:30**
5. Other issues and Conclusion	**14:30 – 15:00**

April 10, 2014

1. Opening remarks and adoption of agenda

Mirjana Huic (AAZ, PA Chair), Antonio Sarria-Santamera (Director HTA Department ISCIII) and Finn Børlum Kristensen (DHMA, EUnetHTA Exec Comm Chair) addressed the audience welcoming the participants and underlining the importance of the current Plenary Assembly (PA) meeting in shaping the future of the European cooperation on HTA. The agenda was adopted as is.

2. First half of EUnetHTA JA2 – report from the Coordinator

Julia Chamova (DHMA, EUnetHTA Secretariat) presented a report from the JA2 Coordinator on results, achievements and lessons learned from the activities in the first half of JA2 *(Appendix A, slides 5-25).*

Key comments from the plenary discussion on experiences from the first half of JA2[1]:

- Joint work on methodological guidelines/guidance is a strong facilitating factor in promoting EU collaboration and application of its results nationally (in national processes)
- Engagement in joint work on HTA at the EU-level brings about acceleration and real-time information exchange between HTA agencies in Europe on relevant topics in areas of common interest such as reimbursement status updates in different countries, regulatory activities, stakeholder involvement practices “know-how”, etc
- Particularly for new/”young” HTA agencies participation in and contribution to joint work in a EU-wide cooperation brings benefits of improving
  a) local competence and capacity in HTA
  b) national awareness and political recognition of concrete benefits of HTA for the national/regional healthcare systems
  c) methodologies and professionalism in local HTA processes
  d) effective communication and cooperation with relevant national/regional policy- and decision-makers (eg, higher standing of HTA with the national policy makers through eg, recognition of improved efficiency via national leveraging of the HTA work done somewhere else, contribution to the quality improvement of the national work, etc)

[1] Representatives from a total of 16 EU countries expressed their views, 2 stakeholder groups (providers and industry) and the Commission. Both small/big, established/new HTA organisations expressed their views.

- Development of consistent and coherent stakeholder involvement practice in EUnetHTA assists the development of national stakeholder involvement processes and communication with stakeholders
- Principles of transparency employed in EUnetHTA practices has a strong potential to contribute positively to developing similar national practices, however, it is a process that requires time, initiative and consistent effort on national level
- Important to maintain involvement of those who are willing and ready to collaborate in the design and development of tools for collaboration (it is challenging at times as there might be a lack of capacity to provide input into these activities due to other work commitments)
- Development and strengthening of the EU cooperation on HTA has brought about an actual change in
  a) using English as the publication language for the HTA reports (while local languages are used to publish the summaries of the reports), eg, in Norway, Austria, Finland, Italy
  b) the local HTA production processes, ie, a new project is not started without checking the POP database and identifying work already done by others or identifying potential partners for a joint work or at least information exchange on the topic, eg, Finland (THL, FIMEA), Belgium (KCE), Austria (LBI), Croatia (AZZ)[2] already widely practiced this approach.
- Project management support in EUnetHTA and an expected professionalisation of the EU cooperation management practices are positive developments supporting overall improvement of EU cooperation on HTA and strengthening engagement of individual organisations in the EU cooperation efforts
- Being engaged in the joint work on an EU-level directly contributes to standardisation of the HTA methodologies and indirectly influences the HTA production routines in various HTA agencies towards more consistent/coherent approaches across borders due to the staff being constantly "exposed" to different working methods and solutions in the partner HTA organisations. Adjustment of the administrative rules of the EU financing of the European cooperation that facilitate retaining of the staff (and not project-based/short-term employment of the staff members to be engaged in the EU cooperation) would further support the retention of "corporate memory" of the knowledge and skills gained via the involvement in sharing of work across HTA organisations.
- Mentioned barriers to /challenges with European cooperation on HTA:
  - Administrative burdens associated with the current joint action mechanism formalities
  - Topic selection for joint assessment work needs to be improved to achieve increased relevance and impact at national level. Expectation of the EU-wide relevance of specific topics for HTA should be realistically managed (eg, identifying those that are relevant to a higher number of HTA agencies) while also taking on the task nationally to inform relevant national decision-making players on the topics that are coming up for prioritisation in EUnetHTA – many times local decision-makers are not aware of what is relevant in other European countries in order to anticipate and be proactive to the emergence of the technologies (and the need for their assessment) in their country. The "economy of scale" of the joint assessment topics with time will bring about the critical number of topics that will eventually be relevant to greater numbers of countries.
  - Changes in the political environment of participating countries that influence the level of interest in being engaged in the EU cooperation activities or adapting the results of the EU cooperation on the national/local level
  - While the content of, and methodologies used in, the EUnetHTA output is broadly accepted across countries, the format of EUnetHTA outputs makes it still difficult to transfer the results into the national practice– more work needs to be done to improve the overall user-friendliness and flexibility of the EUnetHTA output formats to fit varying national/local circumstances of the HTA processes in various European countries
  - Managing tight timelines for delivering a jointly produced output and simultaneously ensuring its high quality – joint work requires an efficient and professional management effort to ensure delivery on both accounts (timing and quality)

[2] The EUnetHTA Secretariat will review the HTA production routines of the rest of the EUnetHTA partnership to identify how widely the mentioned approach is spread among the Partners and Associates

- Clear, explicit commitment of applying the EUnetHTA outputs on the national/regional level, eg, results of the pilot assessments (Core HTAs/ rapid REAs) will be a clear signal of the concrete value of EUnetHTA activities to a range of stakeholders
- The industry stakeholder group highlighted the operational challenges of engaging with EUnetHTA (perceived lack of (or not clarified) "end-user" involvement, inconvenient timelines and their extension for additional input, the concepts (eg, HTA Core Model) that are difficult to grasp and implement in internal company processes, lack of cooperation between EUnetHTA and FP7 projects[3], WP SAG input is limited to reviewing and responding to the requests for input via e-mail (i.e., no more direct contact with the project team), more direct involvement of manufacturers is needed in the pilots in reviewing the methodologies including the template for submissions.
- The provider stakeholder group input:
    - highlighted the necessity for the stakeholders to provide input when offered an opportunity to do so rather than abstaining from getting engaged;
    - fair, affordable innovation is needed by patients and providers irrespective of the country where the treatment is offered ;
    - discrepancies or uneven degree of implementation of HTA with the application of common methods done on a common basis between EU countries would be counterproductive in supporting the access to innovation; involving provider representatives early enough in the planning and discussions of EUnetHTA process and tools developments is important;
    - limited structural and financial resources for providing input should be recognised and effective ways of involvement in EUnetHTA work are therefore even more important
- The diversity of participants and activity areas in the EU cooperation is a strength of EUnetHTA to build and capitalise on as well as to manage appropriately to allow further growth and development. Managing diversity also allows meeting the future needs of the European HTA cooperation and the common challenges that the healthcare systems of the European countries are facing.

3. EUnetHTA Elections 2014

Julia Chamova (DHMA, EUnetHTA Secretariat) presented the election procedure.
(Appendix A, slide 27-32)

Presentation of candidates and procedure

Luciana Ballini, Head of Research Unit – 'Regional Observatory for Health Innovation', Agenzia Sanitaria e Sociale Regionale (ASSR), Italy (Chair of the Plenary Assemby).

Mairin Ryan, Director HTA, Health Information and Quality Authority (HIQA), Ireland. (Deputy Chair of the Plenary Assemby).

Galician Agency for Health Technology Assessment (Avalia-T), representing the Spanish Network of HTA Agencies and Services of the National Health System,, Spain (Represented by Marisa López Garcia) (Executive Committee member)

National Institute for Health and Care Excellence (NICE), UK (Represented by Elisabeth George) (Executive Committee member)

State Health Care Accreditation Agency (VASPVT), Lithuania (Represented by Gintaré Miksiené) (Executive Committee member)

Swiss Network for Health Technology Assessment (SNHTA), Switzerland (Represented by Christoph Künzli from the Swiss Federal Office of Public Health) (Executive Committee member)

[3] EUnetHTA Secretariat comment: EUnetHTA has an ongoing collaboration with all 4 FP7-funded projects on HTA since the start of EUnetHTA JA2.

The Chair (Luciana Ballini) and Deputy Chair (Mairin Ryan) were elected by acclamation.

4. Approval of amended SOP and EUnetHTA Conflict of Interest Policy

Julia Chamova (DHMA, EUnetHTA Secretariat) presented the background and details of the proposal for standardising the procedures for handling conflict of interest (CoI) and confidentiality issues.*(Appendix A, slide 33-37)*

Clarifications and suggested adjustments to the proposal from the plenary discussion:

- A Declaration of Interest and Confidentiality Undertaking (DOICU) form must be completed by authors, co-authors, dedicated reviewers, and other reviewers as well
- A Task Force will be formed to develop standard criteria for assessing presence of conflict of interest; representatives of WP4, 5 and 7 LP and Co-LP organisations will be specifically asked to participate in the Task Force. A proposal of the criteria is to be developed and presented for approval no later than the next PA meeting in May 2015
- With regards to the responsibility/liability for the issues of CoI and confidentiality of staff members employed part-time/temporarily in one of the EUnetHTA partner and associate organisations, it is the responsibility of the individual or the institution that employs them. Neither the EUnetHTA Secretariat nor the EUnetHTA partner agencies responsible for coordination of specific activities in EUnetHTA are to be held responsible. It is the responsibility of the institution participating in EUnetHTA to ensure that the EUnetHTA requirements are met.
- Item 9 of the DOICU form will allow non-provision of specific details on the third persons relevant to the individual in cases when it is prohibited by national legislation in the country to provide such information. The reason for not providing this information will need to be explicitly stated in the form
- Definition of “commercial confidentiality” need to be further explored in each concrete case with the entity that holds such information and identifies it to be “commercially confidential”
- Concept of “shared confidentiality” (ie, when an expert needs to consult with other experts) needs to be accommodated along the lines that is now handled in SAGs, ie, those who expert wants to share confidential information with should sign confidentiality undertaking prior to any information sharing takes place
- During the work on specific EUnetHTA projects where DOICU issues are pertinent and relevant, individuals should be regularly reminded that they need to inform the EUnetHTA Secretariat and relevant WP LPs/Co-LPs on any changes in their personal situation with regards to CoI
- The completed and signed DOICU forms will be kept confidential - further exploring of how to appropriately handle the information received with regards to simultaneously adhering to the principles of transparency should be done
- DOICU form, footnote 1 will be changed from 5 years to 3 years
- DOICU form, item 10 will be rephrased to read “I have another interest to declare”

With the comments given and adjustments proposed the procedure and new DOICU form were approved.

Julia Chamova (DHMA, EUnetHTA Secretariat) presented the background to the proposed adjustments in the EUnetHTA SOP manual. It was clarified that the changes can be suggested by any EUnetHTA Partner/associate organisation throughout the year, and the proposed changes are to be approved by the Plenary Assembly. All changes will be visible in the next issue of the SOP Manual.

The changes in the SOP were approved.

5. Short- (2014-15), mid- (2016-20) and long-term (post-2020) strategic development of EUnetHTA

Introduction by EUnetHTA and HTA Network

Flora Giorgio (European Commission, HTA Network Secretariat) presented views and considerations from the HTA Network Secretariat of the European Commission, DG SANCO *(Appendix B)*

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) presented views and considerations from the EUnetHTA Executive Committee (*Appendix A, slide 40)*

Clarifying comments:

- There is a wealth of indications of positive progress, value and integration results across borders in EUnetHTA, the scientific and technical cooperation on HTA -, however, the articulation of the tangible benefits can be improved in order to effectively reach and accordingly have impact on the Commission and MS (political decision making level) audiences
- Legal challenges on national (MS) level in some countries that hinder moving cross-border HTA cooperation results into a mainstream of national/regional HTA processes need to be effectively analysed and addressed
- Activities associated with development and maintenance of tools that support cross-border cooperation on HTA can be defined as coordination service functions eligible for EU financial support

6. Results of elections

National Institute for Health and Care Excellence (NICE), UK (Represented by Elisabeth George), State Health Care Accreditation Agency (VASPVT), Lithuania (Represented by Gintaré Miksiené) and Swiss Network for Health Technology Assessment (SNHTA), Switzerland (Represented by Christoph Künzli) were elected to the EUnetHTA Executive Committee (with the respective vote distribution as 30, 28 and 31 votes).

7. Short-term (2014-15) strategic development of EUnetHTA

Mirjana Huic (AAZ, PA Chair) introduced the agenda item *(Appendix A, slide 43-52).*

Key comments from the plenary discussion on the short-term (2014-15):

- Knowledge and insight into the value of the cross-border cooperation activities for the production of HTA at the national level has been gathered within EUnetHTA. The scientific and technical mechanism (EUnetHTA) should continue informing the strategic level (HTA Network) deliberations to define strategic priorities for the European cooperation on HTA.
- Develop a definition/description of the term “joint assessment report” that
    - takes into account a particular context of cross-border cooperation on HTA,
    - includes the description of the format of reporting (ie, focusing on its utility in representing the results of the joint assessment work meeting the needs of the end user being the HTA doers in the national/regional HTA organisations),
    - describes its status with regards the national HTA reports (competency of MS in organization and delivery of health care (i.e., subsidiarity) must be observed),
    - clarifies how it contributed to meeting the purpose of measuring the output of the JA2 activities in WP4 and WP5 (described as indicators in the JA2 grant agreement)
- Use the suggested criteria to identify the indications of the national uptake of the EUnetHTA output as presented at the PA meeting in Madrid
    - The measuring of national uptake should focus on the national/regional use of the EUnetHTA-produced scientific output in the national/regional HTA production (ie, scientific) processes (eg, in the form of adaptation of the scientific results). It is not a requirement to show the impact on the national *decision-making* of the national reports based on the EUnetHTA output. It is important to uphold a differentiation between the two levels of impact (1- adaptation and usage of the joint scientific work results to/in the national production of the scientific HTA information for decision-making, 2 – national uptake of information that impacts policy-/ decision-making)

  - Recording of “cooperation clusters” and production of specific scientific output by these clusters based on the common interest areas identified through POP Database. Such cooperation was time and again mentioned by many PA members as an important specific indicator of value of the EU cooperation for national HTA production processes.
- More attention to the timing, processes and needs in the national/regional HTA production processes – better insight into these processes will allow the proactive management of the common usage of EUnetHTA output
  - Different local characteristics, needs and state of development of HTA within healthcare systems must be taken into account when considering readiness to use specific EUnetHTA output - not all EUnetHTA output would be interesting/useful to the same degree/in equal measure “across the board” to all EUnetHTA partners. As preparation for a possible JA3, local needs and how they are connected to different type of EUnetHTA outputs should be addressed
- Describe various participation levels (3 levels as per the EUnetHTA strategy), ie, what does it concretely mean to participate at each level: conditions of participation, what exactly each EUnetHTA partner organisation would be committed to do/provide during a given period of time
- Industry stakeholders: national legal constraints in implementing the results of joint work needs to be made explicit; pilots evaluation and tracking of national implementation of the joint work results; metrics to measure impact on the national level needs to be developed; a joint assessment report as an output format is generally more acceptable when it is focuses on the first 4 domains of the HTA Core Model
- Accelerate/improve efforts in EUnetHTA partner organisations to overcome “resistance to change” in their routine working processes– both by informing and working with the top management as well as by expanding the “exposure” of as many staff members as possible to the results and tools of EUnetHTA
  - Systematic searches in the POP Database should be introduced into the working processes at the start of each new project (doing so will offer a concrete approach tofinding an opportunity to capitalise on the work done by others)
  - Informing the national/regional decision makers who commission topics to the HTA agencies (where a mechanism of commissioning is used to fund HTAs) on the available results of the EUnetHTA joint work (REA pilots, Core HTAs) might proactively move the topics that can be common to a larger number of countries to the top of the list
- Monitoring the resource use for joint work and the subsequent adaptation of it to the national/regional setting would be very useful when promoting the joint work to the decision-makers who will be those that decide if the joint work should be incorporated in national/regional processes
- External collaborations: EMA work on pharmacovigilance and post-authorisation efficacy studies might provide a useful vehicle for advancing concrete cooperation in HTA and regulators
- Value added by the EUnetHTA activities should be looked at and evaluated by putting together benefits offered and experienced through participating in various EUnetHTA activities – realisation of positive effects of eg, economy of scale will be possible (and should be looked at) not only via assessing its achievement through single, stand-alone EUnetHTA activities, e.g. REA pilots and implementation of their results nationally, but also via bringing forward a cumulative positive effect of all the activities performed by EUnetHTA that bring value to varying degree to different HTA agencies in various EU countries.

8. Mid-term (2016-20) strategic development of EUnetHTA – I

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) introduced the topics for the group discussion *(Appendix A, slide 53-56)*

Introduction and Group work

Julia Chamova (DHMA, EUnetHTA Secretariat) introduced the group work practicalities *(Appendix A, slide 57-58).* The Plenary Assembly were divided into 6 groups *(Appendix C)*.

April 11, 2014

1. Reports from Group discussions

Jürgen Hohmann (CEM) presented the group work from the Green *group (Appendix D)*

Francois Meyer (HAS) presented the group work from the Orange group *(Appendix E)*

Gro Jamtvedt (NOKC) presented the group work from the Blue group *(Appendix F)*

Claudia Wild (LBI) presented the group work from the Pink group *(Appendix G)*

- Comments from the industry stakeholder group representative on the report from Pink group:
    - The summary was presented without an endorsement from the industry representative who did not participate in the entire group's work; the requested better communication entails not limiting the industry input to reviewing documents and responding to e-mails; industry has no intention in slowing down the processes.

Mairin Ryan (HIQA) presented the group work from the Beige group:

- Objectives:
    - Support production of HTAs that inform decision-making on effective treatments of patients. In doing so it is important
        - To allow participation at different levels of engagement in the cooperation
        - To increase the level of participation across the countries
        - To increase the quality, quantity and the utility of the output over time so that the improvements and commitment is ensured continuously in order to demonstrate sustainable and sustained added value as the cooperation continues and goes from one phase to another
    - Outputs to be more user-friendly to facilitate uptake
- Comprehensive suite of guidelines by the end of JA3
- Further integration of the EUnetHTA tools and activities into the day-to-day activities of participating organisations
- More flexible ways of working together to meet the demands "real-time"
- JA3 need to make more effort in promoting the utility of HTA to inform decision-making
- New areas for cooperation are HTA to support clinical practice guidelines and multi-technology assessment (or HTA on complex technologies)
- Priorities:
    - EUnetHTA needs to continuously demonstrate that it adds value – working towards improving and increasing joint work; plus capacity building and methodology development to support joint work should be continued. The HTA network should provide input w to priorities on areas of cooperation, but EUnetHTA needs to have a voice to influence the research priorities at the European level (through cooperation with and informing Horizon 2020 process)
- Current limitations:
    - The distance in perception of the utility of HTA between the decision-makers and HTA doers – there should be more use of the EU Commission and EUnetHTA input to address this gap
    - Recognition of the language barriers and ways to overcome them (eg, some members of the staffs who still do not have sufficient proficiency in English – some of the EUnetHTA output should be translated into local languages to facilitate local marketing of the benefits and utility of the international work to meet the local needs)
    - The challenge lying in the relative priority of the international activities vs. acute priorities of the national work

  - HTA Core Model should become more user-friendly
  - 3-year work plans are developed and all resources are allocated up-front and no resources are available for flexible real-time re-allocation of resources to allow adaptation of the plans and joint work
- Modes of operation:
  - In order to do more and faster work: activity centres that specialize in some areas
  - Support functions and IT functions should be assigned to the permanent Secretariat
  - Currently there are a number of organisations that were not officially nominated to the JA. They do a sizeable amount of work in EUnetHTA but are not compensated for their work from the funds, thus, allocation of funds that respect fair recognition and reward of real input to the work (connected to this – more flexibility in engaging with academic institutions is needed to enable flexible subcontracting)
- The relationship between the HTA Network and EUnetHTA/scientific and technical cooperation mechanism:
  - Clear division of tasks
  - Open communication channels for exchanging of ideas
  - Prioritisation of topics with input from the strategic level of the European cooperation on HTA
  - Transparency of decision-making by the HTA network should be ensured
  - Pragmatic, effective connection to other EU networks, eg E-health network or network on rare disease would be welcome
- Improvement in specific processes:
  - Prioritization and selection of topics for joint work should be improved: important to facilitate that the outputs of the joint work are useful for concrete decision-making (somehow contributing to maximising the utility of the national reports to support timely decision-making to allow patient access to effective technologies in national/regional healthcare). The number of countries that are willing to commit to joint work on a topic should influence the choice of the topic for joint work
  - Stakeholder engagement: The differences and range and intensity of engagement across the stakeholder groups should be recognised and should be effectively addressed
  - For the “newer” HTA agencies: facilitate exchange internships with more experienced HTA agencies
- EMA as a host of the coordination secretariat function:
  - There is a general recognition of the experience and professionalism of EMA in providing such service within their current remit, however, there is a concern that the work of EMA is (informing) regulatory decision-making and for that purpose the approach is highly standardised and the outputs are not flexible for other purposes. The culture and nature of EUnetHTA is different: It is inclusive and flexible (with regards to levels of participation, the utility of EUnetHTA outputs being different at national level recognizing and adjusting to differences in national healthcare systems). Additionally, the scope of EMA’s work and competence is pharmaceuticals – while EUnetHTA’s scope is wider including “other” (than drugs) technologies (including different types of interventions e.g., even social care interventions for some HTA agencies).

Julia Chamova (DHMA, EUnetHTA Secretariat) presented the group work from the Yellow group:

- Objectives:
  - Move from pilots to real life: Incorporate EUnetHTA processes, use of its tools into the daily practices of HTA production in participating organisations
  - Improve the mechanism of rapid, effective response to the need of bringing people from different HTA agencies together in collaborative efforts on specific topics “real time”
    - The EUnetHTA liaison function is very important for working together effectively in various constellations

        - Continuous informing and appropriate involvement of top management in the participating organisations in EUnetHTA activities is crucial in ensuring adoption of new ways of working together
    - Involvement mechanism should be adjusted to effectively engage technology producers in assessment processes
    - Test and deliver a final workable business model for the permanent European cooperation on HTA
        - The mapping of the needs of the agencies and decision-makers in the EU countries would potentially be useful in order to find effective ways to ensure timeliness of collaborative efforts to fit into the national processes
    - Clarify and agree the scope, tasks and modes of interaction between the strategic and scientific and technical levels of the European cooperation on HTA
- Priorities:
    - It is necessary to distinguish between objectives for the methodology improvement and for real-life HTA production
    - Needs of the "customers"/funders of the European cooperation on HTA activities at the MS level and the EU level (Commission) need to be known and taken into account when prioritising specific activities
    - Those activities that have greater potential to
        - facilitate concrete collaborative work
        - support "division of labour" among participating agencies and increase their individual production capacity

      should be prioritized
    - generic management tools/processes to bring staffs together to produce HTA output
- Limitations:
    - Capacity at the organsations' level to carry out and engage into many different cooperation activities
    - Currently the joint work makes the production more complex and burdensome as the participation in the EUnetHTA activities are still parallel to the local production work – adjustments need to be done at the local (i.e., national/regional) level through explicit requirements of adjusting local internal work processes to incorporate European cooperation as an integral part of the local HTA production process. This should not to be considered to be "external"/"extracurricular" activity but rather a recognised integral part of the organisation's HTA production process
    - Translation of EUnetHTA output: It is suggested to make local HTA reports in English and translate the summaries into local languages for decision-makers
    - Methodology still differ – commonly agreed methodologies and development of methodological guidance in EUnetHTA are very important and useful
    - There is still some lack of trust – this can be overcome through continuing to work together
- Modes of operations:
    - A central secretariat function ensuring the consistency, coherence and progress of work across various lines of activity is important but not sufficient
    - Activity centers specialising in certain type of content production activity should provide coordination and facilitation in that specialized area of cooperation
        - E.g., an Activity Center on Rapid HTAs: A) constant reviewing of POP database for potential cooperation topics in rapid HTAs, B) finding partners and bringing them together for collaborative work on the topic, C) providing professional skills in project management, looking after issues of authorship, liabilities, etc., providing certain training activities that support more effective engagement in rapid HTA production; possibly playing a role in prioritizing subjects for coordinated, joint work in rapid HTA production (NB! Clarifications need to be made of such role in connection with the remit and scope of the HTA Network task of topic (area) prioritisation)

- Relationship between HTA Network and EUnetHTA/scientific and technical cooperation mechanism:
    - The HTA Network has its focus on high-level objectives of the European cooperation on HTA while the scientific and technical cooperation level is in charge of and define how the objectives are implemented into scientific and technical work
    - The share of high level decision-makers from MS as members of the HTA Network should be increased to facilitate greater coherence between the role, tasks of the strategic level and its membership
    - Consistency in the time horizons between the two levels for priority setting and implementation of the priorities (allowing sensible time horizons for implementation by the scientific level before the strategic level introduces the next change in priorities)
- Improvements of specific processes:
    - Stakeholder involvement should be further developed to provide higher value to the processes at the strategic, and at the scientific and technical cooperation levels respectively
    - Improvement of the topic identification process should be more responsive to the emerging national needs of the national/regional HTA production process
    - Training is important not only to the currently prioritized stakeholder groups (patients and providers) – the needs of the "ultimate customers" of HTA, ie, decisions-makers might be another target group for training efforts
    - Capacity building with new members of the network to improve skills to effectively engage in joint work in order to serve the national needs
- Other issues:
    - Individual HTA agencies/EUnetHTA partners should explicitly commit to the production of joint reports and be held responsible to act on the commitment – level of funding/financing should correspond to the commitment level

Comment from the payer stakeholder group representative with a wish to add to the report from the Yellow group:

- It is important for the payers to be represented at the strategic level; it is equally important to continue engagement at the scientific and technical cooperation level especially in the prioritisation of the topics and to continuously be informed about the progress at the scientific level. The current practice of being involved in the revision of the scientific deliverables seems not to bring the highest value to the process.

2. Mid-term (2016-20) strategic development of EUnetHTA – II

Key comments from the plenary discussion after group presentations on the mid-term (2016-20):

- There is a growing common high-level understanding and convergence of view on the challenges and the way forward
- A growing recognition of, respect for and pragmatic approaches to the work with the national processes by the cross-border cooperation will assist in diminishing the national barriers to accept, actively participate in the cooperation and support its credibility with the Member States
- Need to define the role, function and specific tasks of the coordinator/coordinating facility to support the permanent cooperation in order to identify the most suitable solution for hosting the coordination function.
- Stakeholder view (providers): There should be a recognition of the different speeds in implementing HTA in various European countries. However, this is not a welcome approach in the long run as it creates inequality and diminishes fairness between the European countries in terms of access to certain technologies and benefits to providers and patients in different European countries. Efficiency as the primary goal should be balanced against the equality and fairness considerations when talking about benefits of the cross-border cooperation on HTA
- Current organisations representing stakeholder views are political organizations by nature and do not have an immediate access to the right technical competence to be provided to the scientific and technical processes of the European cooperation on HTA – sufficient time needs to be given

to the stakeholder organisations to locate appropriate competence in the network of their member organisations

- Stakeholder groups appreciate and support the value of working in an open environment welcoming input of each stakeholder group – splitting the stakeholders apart or actions that contribute to opposing stakeholder groups vis-à-vis each other are not constructive and do not bring value to the process. Would be usefull to have eg, EUnetHTA Charter on values addressing issues of mutual respect and value of various groups contributions to the HTA process, spirit for the collaboration so that all relevant parties see the value and opportunity to be engaged and involved appropriately
- HTA of "old" technologies with a purpose of "freeing" resources for true effective innovations might prove to be a strategically important perspective to explore practically in the scientific and technical mechanism of cross-border cooperation on HTA
- Links to clinical practice guidelines development is an important avenue of development to explore, i.e., how HTA work can feed into the guideline development work
- The development of joint work processes is done though a step-wise approach; it recognises existing differences and respects current and changing nature of readiness to get engaged in various types of joint work – some countries are more ready immediately to get engaged at a higher level in a certain activity, while other countries might follow suit (in this particular activity) at a later stage; this approach should be further strengthened in JA3 via offering concrete tools and mechanism of engagement that do not offer "one-size-fits-all" solutions only, certain adjustments of joint work mechanisms to meet national/regional needs must be further explored while realizing that individual "tailor-made" solutions for each and every participating country cannot be an option either
- With the emergence of the strategic level and scientific/technical cooperation level the role and tasks of stakeholder groups in the European cooperation on HTA are changing. Their future role and tasks should be adjusted to best serve the purpose of an appropriate and more effective stakeholder involvement approaches in each of the levels (e.g., involvement of stakeholders in the form of SAGs are more targeted to the needs of the scientific/technical level i.e., closer to methodologies, science and tapping into expertise of stakeholders in these aspects of HTA cooperation, while SF involvement would be more oriented towards the policy level, i.e. the HTA Network)
- Stakeholders: There should be a dialogue with each stakeholder group in expressing their preferences of which role each group would like to play. There are different interests and different ways to be involved (e.g., in the scoping phase – it is very difficult to find patient representatives or healthcare professionals. Perhaps a face-to-face meeting with the local HTA agency participating in a joint work so that language barriers are not creating problems and insights are gathered this way). Disease specific HTA methodology guidelines development in EUnetHTA would greatly benefit from patient and healthcare professionals input. Communication plan to address the needs of target groups other than HTA researchers eg, clinicians, patients, to understand the HTA output.
- The main objective of JA3 should be to shape and test the potential permanent model of cooperation on HTA in Europe post 2020. Assessment of the needs of different countries should be performed in order to put in place more effective procedures supporting joint work. Possibly attempts should be made during the 5-year period to align assessment of technologies based on their pathways to market in countries where these pathways are similar – the information on the technologies pathways to market may support understanding of the value of joint assessment work and improve acceptance of joint work – appropriate topic section procedure for joint work would be crucial here (insight into the local (national/regional) topic prioritization for HTA by decision-makers would be helpful).
- Pharmaceuticals, devices and complex interventions should be among topics for the joint work in the next period
- HTA needs to be linked not only to reimbursement and market access in Member States, but to overall health planning and general allocation of resources in systems

- New, innovative approaches to applying the HTA Core Model concept in HTA production processes – not only for joint work – should be explored, eg, using the model's structure for different stages of the local (national/regional) HTA production process
- Continuous attention to and improvement of the process and project management in the next phase is crucial to ensure professionalism in coordination of joint work, work with the stakeholders, external parties, specific technology developers, etc
- Identification of a location for hosting the coordination function post-2020 should start early in the next period and constructive, appropriate ways of involving or working together with tsuch an entity should be a part of activities in the mid-term to ensure a timely transition to the phase after 2020. Partnership with such an entity should clearly have an objective of exploring feasibility and viability of its hosting function for the European cooperation on HTA post-2020; all necessary changes in the mandate, structure, operations, etc of such an entity need to be secured and be in place for it to be ready to start hosting in 2020. Recognition – on many levels (political, administrative, practical, etc) – and respect of the diversity of the HTA agencies and of their place in the healthcare systems of different Member States must be explicit and ensured.
- Focus on and choice of specific activities to be pursued as part of JA3 should be based on the consideration of those with the highest sustainability potential for the permanent structure after 2020
- An official organisational structure that has all the legal, governance, etc tools to effectively manage the cooperation in a permanent stage must be proposed sufficiently early during JA3 and put in place by the end of JA3 – otherwise sustainability and permanency is threatened and cannot be ensured if there is no tangible, concrete support structure
- Link and cooperation between EUnetHTA and the medical device competent and notifying bodies (issuing CE-mark) should be practically explored in JA3 to support timely access of HTA bodies in Europe to the information on medical device CE-mark certification. This information can help in topic prioritization procedure
- More effective ways of integrating new staff (that would be joining HTA agencies during the 5 years of JA3) into the joint work processes of the European cooperation on HTA should be explored
- It is a prerequisite and an absolute necessity to know as soon as possible the formal conditions of Joint Action 3, timelines, how much paper work needs to be done – as again the formalities and administrative work – not to speak about the specific content development for JA3 proposal – will coincide with the work to still be done in JA2 doubling and tripling the workload on the JA2 participating agencies
    - There is a high probability that the formal mechanism of financing JA3 will offer only the project-based financing solutions to support permanence-oriented activities to be developed in JA3. Nevertheless, the long-term "way of thinking" and approaching tasks in JA3 by the participating organisations should be as if they were participating in the permanent scientific and technical European cooperation on HTA that already has a permanent structure for operations and permanent support mechanisms
    - The dilemma between the objective of shaping and testing the permanent solution while being given only project-based management and financing tools to implement the objectives has a high potential for eventually creating implementation problems that very likely will be outside of the control and influence of the EUnetHTA partners (or whichever consortium might take up the task of implementing JA3)
- Five years are a long time period in 21st century. As far as possible JA3 should allow much flexibility and offer opportunities for being adaptive to changes in the external environment (as well as to the changes that might take place in the eg, organizational structures, mandates of the participating organisations) during the course of its implementation – new, disruptive technologies and complex solutions might be entering healthcare markets, changes in legislature and remits of internal and external partners, etc.
- More effective communication – and communication strategy and plan – should be developed to reach target audiences of national decision-makers, patients, providers, payers
- High-level focus points from the discussion:

- From piloting to real life work
- Clear explicit commitment on the national level to participate in and implement the results of joint work
- Activity centers are emerging as means for facilitation and for coordination in specialised area of cooperation activities in addition to a general coordination hub (e.g., coordinating secretariat)
- Professional project and operations management must be ensured
- Topic selection and prioritization process needs to be improved and further developed to be better aligned with and meeting the needs of national HTA processes
- The content of capacity building and training should expand to include methodology; the target groups for the training activities should include decision-makers and offer appropriate content and effective training approaches
- More effective ways of stakeholder involvement should be found

Julia Chamova (DHMA, EUnetHTA Secretariat) presented a proposed timeline and next steps in developing the Recommendations (Deliverable 1 of JA2) to advise on the content and form of JA3 (*Appendix 1, slide 63*)

Flora Giorgio, European Commission, commented on a necessity to be aligned with the timelines for the formal processes of the approval and implementation of the Work Programme for the next year of the Health Programme, preliminary late autumn 2014 is a target time for the 2015 Work Programme to be published. Call for negotiation will be issued shortly thereafter. A formal call to the Member States (contacted through permanent representations in Brussels) to nominate participants in the next joint actions is a mechanism that is not to be changed. There are no guarantees that the group to be negotiated with will be identical to EUnetHTA's current partnership.

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) emphasized the importance and necessity of continuous cooperation and communication between individual EUnetHTA organisations and their respective country Ministries of Health and health attaches in Brussels to stay relevant in the upcoming process. Coordination and communication within EUnetHTA on the matter is facilitated by the JA2 Coordinator through the EUnetHTA Secretariat. Flexibilities of the Commission's current mechanism of joint action must be further explored to ensure best possible conditions for achieving the objectives for the permanent cooperation to be an attainable reality.

3. Long term (post-2020) strategic development of EUnetHTA

Finn Børlum Kristensen (DHMA, EUnetHTA Secretariat) introduced the agenda item *(Appendix A, slide 65-80).*

Key comments from the plenary discussion on the long-term (post-2020):

- Requirements to be met /criteria for selecting any of the potential entities that might host a coordination function of the scientific and technical mechanism of the permanent European HTA cooperation after 2020 must be defined and clearly stated as early as possible in the 2016-2020 period
- Focus on clearly articulating the conditions for the permanent European cooperation on HTA for it to be sustainable (with financing issues being just a part of the range of factors affecting sustainability) and assessment of realistic options to support and host coordinating function for the cooperation should guide discussions leading to a final choice to be made in the later part of JA3. Developments/changes in the external environment affecting EUnetHTA developments should constantly be taken into considerations
    - Identification and clear articulation of the specifics of the coordination functions for the European cooperation on HTA shall guide the assessment of appropriateness of and "best value offered" by each potential hosting option
- The range of options for hosting function of the coordination services for the European cooperation on HTA (no hierarchy in order of presentation) were mentioned: The Joint Research

Centre (the European Commission's in-house science service), EMA, ECDC, the Commission services themselves (in Brussels/Luxembourg), an EU Member State entity still to be identified
    - Close attention to and analysis of current way of organising and working in each of these options need to be done to identify opportunities and threats as well as strengths and weaknesses with regards to their potential hosting function for the European cooperation on HTA.
- Concerns raised re: post-2020 period:
    - Ensuring a clear understanding of the separation of remits and mandates of regulatory and HTA agencies
    - Ensuring dynamic and flexible connection points for different activity pathways of a network might be problematic if formal mechanisms and structures do not provide appropriate tools and solutions (administrative, management and financing) to support the flexibility and dynamism of a network. The nature of network interaction and developments differs from the ways a single institution or organisation develops ("a network is neither an agency nor a company nor a corporation")
    - Completion of formal processes in time (including legislative – at the European level mainly, but potentially also at national level) to bring the necessary changes into the current mandates and remits of a potential hosting organisation so that the coordination function of the European cooperation on HTA can be entrusted to a hosting organisation that will also be found appropriate and acceptable by all stakeholders. It might simply take much longer than 5 years to put in place formal legal provisions and practical arrangements for a certain agency to host the European cooperation on HTA – work on that must start as soon as possible
    - Irrespective of an assumption that a hosting organisation would not be performing any scientific work in the post-2020 organisational model, the role and associated coordination tasks for the whole of the European cooperation on HTA opens for a lot of influence on how things are to be done in the network. The future organisational and governance model needs to ensure "balance of interests and influences" between the elements in the governance structure to allow effective management and strategic development of the network as a whole. The EUnetHTA Secretariat provides scientific input to the coordination of the scientific activities (besides facilitating overall coordination) which allows ensuring overall coherence across various scientific activities – a function which is important and valuable to receive from a coordinating secretariat.
- Close cooperation with EMA (as one of the alternatives to provide a hosting function for coordination activities) in JA2 and JA3 will further advance both parties' understanding of how each party works to lay a foundation for practical solutions respecting remits and boundaries a guarantee non-interference in certain work processes
- Understanding of the Commission's preferences for a certain hosting option would help in finding an appropriate and acceptable solution to both the European Commission and the Member States that jointly support the European cooperation on HTA
    - The Joint Research Center (JRC) is a DG of the Commission, i.e., a Commission service. JRC does not have an experience in networking and supporting networks. It will not have financial capacity to support the coordination function (as a Commission service budget cuts are projected in the years to come, about 5% yearly cuts in budget in all of the Commission services)
    - EMA is an independent (from the Commission) EU agency governed by a Management Board with representation from the Member States. It has experience in supporting networking and a long-standing experience in working with the national medicines agencies. The scientific work is done by national agencies, EMA performs administrative and facilitation functions to support the work done by the scientific committees. These committees consist of experts designated by the Member States' agencies (e.g. CHMP, PRAC). EMA's budget is not directly influenced by the budgetary cuts if compared to eg, JRC's budget.

- If the partners are getting value from the cooperation, then gains received from the cooperation will contribute to balancing out the need for additional resources for the partners to participate in the cooperation activities. There will be a kind of "disinvestment" from old ways of working substituted by new ways of working (involving cross-border cooperation which brings value to local processes). This would contribute to the sustainability of the European cooperation on HTA
- Industry stakeholder perspective: the mid-term should be used to ensure that methodologies and activities performed are fit-for-purpose to meet the goals that are to be set by the HTA Network and the goals set by the national healthcare systems. The work, results and lessons learned from the years of EUnetHTA activities should be integrated and inform the establishment of the permanent European cooperation on HTA. The kind of involvement and set up for working with stakeholders in EUnetHTA is highly appreciated and should inform the approaches of stakeholder involvement in the permanent structure; the focus of scientific and technical cooperation should not be lost with the emergence of a strategic level. There is a concern of the medical device industry regarding a possible hosting by EMA which arises from EMA being the regulatory agency for pharmaceuticals – and thus does not possess competence and knowledge regarding evaluation of medical devices
- Preliminary legal analysis regarding hosting by a European agency indicate that a legal basis for such hosting needs to be in place through certain adjustments in relevant European legislative acts – a process that takes time and needs to be put in motion in 2016-2017 (latest) in order to have solutions in place by 2020. JA3 should start work early on developing a scenario that describes what will be coordinated in the permanent European cooperation on HTA, including how and by whom in order to support the process of having the final solution ready for implementation from 2020, and not risk having a disruptive gap after JA3.

4. HTA 2.0 Europe – teaming up for value, Rome Oct. 30-31 2014

Julia Chamova (DHMA, EUnetHTA Secretariat) presented the conference *(Appendix A, slide 81-89)*

5. Other issues and Conclusion

- WP3 encouraged the PA meeting participants to complete the yearly WP3 survey and ask their colleagues back home to do the same
- Additionally WP3 reminded to fill in the EUnetHTA timesheets at the end of each project year in order to have data to analyse costs and cost-efficiency of joint work.
- The participants thanked ISCIII and the EUnetHTA Secretariat team for a great work in preparing and holding the PA meeting. Mirjana Huic was warmly thanked for her contribution as a Plenary Assembly Chair during her term 2012-2014.

EUnetHTA Joint Action 2
Plenary Assembly
Madrid, Spain
April 10, 2014 09:00 – 17:30
April 11, 2014 09:00 – 15:00

Organised by: EUnetHTA Secretariat, DHMA, Danish Health and Medicines Authority and ISCIII,Instituto de Salud Carlos III, Spain
Address of the meeting venue: HOTEL MELIA GALGOS, Calle de Claudio Coello, 139, Madrid

Participants List

EUnetHTA Partners:

Member	Organisation	Country
Ingrid Rosian-Schikuta	**GÖG-Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen**	Austria
Sonja Scheffel	**HVB, Hauptverband der Österreichischen Sozialversicherungsträger**	Austria
Claudia Wild	**LBI-HTA (Ludwig Boltzmann Institute of Health Technology Assessment)**	Austria
Raf Mertens	**KCE, Belgian Health Care Knowledge Centre**	Belgium
Rossitsa Vassileva	**NCPRMP, National Council for Pricing and Reimbursement**	Bulgaria
Mirjana Huic	**AAZ, Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment**	Croatia
Pavel Vepřek	**Ministry of Health of the Czech Republic**	Czech Republic
Finn Børlum Kristensen **Julia Chamova** **Anne Raahauge** **Johannes Tvilling**	**DHMA, Danish Health and Medicines Authority (EUnetHTA Secretariat)**	Denmark

Ulla Væggemose	**CR.DK, HTA and Health Services Research, Public Health and Quality Improvement, Central Denmark Region**	Denmark
Raul Allan Kiivet	**UTA, Department of Public Health, University of Tartu**	Estonia
Pertti Happonen	**FIMEA, Finnish Medicines Agency**	Finland
Kristian Lampe	**THL, National Institute for Health and Welfare**	Finland
François Meyer	**HAS, Haute Autorité de Santé**	France
Dietrich Kaiser	**DIMDI, Deutsches Institut für Medizinische Dokumentation und Information**	Germany
Alric Rüther	**IQWIG, Institute for Quality and Efficiency in Health Care**	Germany
Bertalan Nemeth	**GYEMSZI, National Institute for Quality and Organisational Development in Healthcare and Medicine**	Hungary
Mairin Ryan	**HIQA, Health Information and Quality Authority**	Ireland
Marina Cerbo	**Agena's, Agenzia Nazionale per i Servizi Sanitari Regionali**	Italy
Agnese Cangini	**AIFA, Italian Medicines Agency**	Italy
Luciana Ballini	**ASSR, Agenzia Sanitaria e Sociale Regionale. Regione Emilia Romagna**	Italy
Anna Gelisio	**Regione del Veneto**	Italy
Inese Kaupere	**NHS, National Health Service**	Latvia
Gintaré Miksiene	**VASPVT, State Health Care Accreditation Agency**	Lithuania
Jürgen Hohmann	**CEM, Cellule d'Expertise Médicale,**	Luxembourg

Isabelle Zahra-Pulis	**DPA/MHEC, Directorate for Pharmaceutical Affairs, Ministry for Health, the Elderly and Community Care**	Malta
Wim Goettsch	**ZIN, National Health Care Institute**	Netherlands
Gro Jamtvedt	**NOKC, Norwegian Knowledge Centre for the Health Services**	Norway
Anna Zawada	**AHTAPol, Agency for Health Technology Assessment**	Poland
João Martins	**INFARMED, National Authority of Medicines and Health Products**	Portugal
Cristian Vladescu	**NSPH MPD, National School of Public Health, Management and Professional Development**	Romania
Tomas Tesar	**MoH Slovakia**	Slovak Republic
Boris Majcen	**IER, Institute of Economic Research**	Republic of Slovenia
Marjetka Jelenc	**NIJZ, National Institute of Public Health**	Republic of Slovenia
Teresa Molina Lopez	**AETSA, Andalusian HTA Agency**	Spain
Marisa López García	**AVALIA-t, Galician Agency for HTA Assessment**	Spain
Antonio Sarría-Santamera **Iñaki Imaz** **Setefilla Luengo** **Almudena Albertos**	**ISC lll, Instituto De Salud Carlos lll**	Spain
José Asua	**OSTEBA, Basque Agency for HTA, Department of Health and Consumers Affairs**	Spain

Sophie Werkö	**SBU, Swedish Council on Technology Assessment in Health Care**	Sweden
Christoph Künzli	**SNHTA, Swiss Network for Health Technology Assessment** ***(JA2 CP – Founding Partner)***	Switzerland
Andrew Cook	**NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre**	United Kingdom
Elisabeth George	**NICE,** **National Institute for Health and Care Excellence**	United Kingdom

EUnetHTA Associates:

Peter Kolominsky-Rabas	peter.kolominsky@uk-erlangen.de	**Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health, University of Erlangen-Nuremberg**	Germany
Celia Juárez	cjuarez@msssi.es	**MSSSI, Spanish Ministry of Health, Social Policy and Equality**	Spain
		MSSSI, Spanish Ministry of Health, Social Policy and Equality	Spain
Lisa Landerholm	lisa.landerholm@tlv.se	**TLV, Dental and Pharmaceutical Benefits Agency**	Sweden
Bilgehan Karadayi	Bilgehan.karadayi@saglik.gov.tr	**SAGLIK, Health Technology Assessment Department**	Turkey

EU Institutions:

Flora Giorgio	**DG Sanco, European Commission**	EU

EUnetHTA Stakeholder Forum representatives:

François Houÿez	**EURORDIS, European Rare Diseases Organisation**	Co—Chair of the Stakeholder Forum
Nicole Denjoy	**COCIR, European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry**	INDUSTRY
Irina Odnoletkova	**AIM, Association Internationale de la Mutualité**	PAYERS
Jacques De Haller	**CPME, Comité Permanent des Médecins Européens**	PROVIDERS

Apologies:

Cari Almazán	**AQuAS, Agency for Health Quality and Assessment of Catalonia (JA2 CP)**	Spain
Liuska Sanna	**EPF, European Patients' Forum**	PATIENTS / CONSUMERS
Plamen Dimitrov	**NCPHP, National Center of Public Health Protection**	Bulgaria
Elpida Pavi	**NSPH, National School of Public Health**	Greece

Appendix A: General Presentation

Appendix B: HTA Network Presentation

Appendix C: Group members (6 groups)

Appendix D: Green group report

Appendix E: Orange group report

Appendix F: Blue group report

Appendix G: Pink group report