



EUnetHTA Collaboration Organisational Structure 2009 - 2012 Governance Guiding Principles

0. Conditions for the development of Governance Guiding Principles

The EUnetHTA Collaboration was established in November 2008 by a group of 25 Founding Partner organisations from 13 EU Member States, Norway and Switzerland upon completion of the EUnetHTA project (2006-2008) responding to the need expressed by the EU Member States to establish a sustainable network for health technology assessment. The founding partners formed the EUnetHTA Collaboration to implement the EUnetHTA Collaboration Proposal of June 16, 2008, which was developed during the project and unanimously endorsed.

In December 2008 the DG SANCO of the EU Commission called upon the Member States to consider which public body would be best placed to represent their Member State in the Joint Action on HTA which is part of a DG SANCO Work Plan 2009 and which is aiming at "building on the expertise already developed in the field of HTA, ensuring the continuation and development of HTA in the EU, including work on relative effectiveness of drugs". A Joint Action for HTA preparatory meeting of appointed bodies and ministries of the EU Member States and EEA/EFTA states was held in Brussels on February 20, 2009. This meeting called upon EUnetHTA Collaboration to take a Joint Action process between Member States and the Commission forward, and National Board of Health of Denmark was appointed to be the coordinator.

On February 27, 2009 the formal call for proposals (including for Joint Actions) was issued by the Executive Agency for Health and Consumers.

The aim of these guiding principles is to constitute the self governance of EUnetHTA Collaboration to make structures, rights and duties of the network and its members transparent.

The purpose of the proposed organisational structure is to support and balance

- the functions/Work Packages of the EUnetHTA Collaboration and requirements and rules laid down for the Joint Action on HTA
- strong governance based on shared responsibility and timely and effective decision-making and implementation
- focus on rapid progress and practical orientation allowing cultural and contextual flexibility
- long-term viability, overall value and utility of the EUnetHTA Collaboration activities.

The Governance structures and principles are applied to the functioning of the EUnetHTA Collaboration in

- a) 2009, key activities of which will focus on coordinating the consolidation of the products, processes and the collaboration that has resulted from the EUnetHTA project, some activities extending from the EUnetHTA project work packages and preparation of the application to the Joint Action mechanism;
- b) 2010 – 2012, the timeframe of the Joint Action.

1. Aims and Governance Structures of EUnetHTA Collaboration

1.1 EUnetHTA Collaboration Mission

The mission of the EUnetHTA Collaboration is to support effective HTA collaboration in Europe that brings added value at the European, national and regional level

1.2 Aims

Work emerging from the EUnetHTA Collaboration aims to:

- assure quality through use of the best available evidence, common methodological and process standards and good review processes

- promote methodological and scientific independence thus contributing to high integrity of HTA products
- make analyses transparent and facilitate sharing of information
- be responsive to the needs of decision makers for timely, high quality HTAs on important health technologies
- maintain the independent role of each HTA Agency and institution in the production and use of assessments of evidence and conclusions
- promote information about frameworks for national stakeholder engagement in HTA, including with consumers
- be inclusive and share information to ensure that all relevant information is included in HTA
- support advancements both in research and in medical care.

The EUnetHTA Collaboration will recognise and facilitate solutions to overcome barriers caused by language and variations in perceptions of terminology and will facilitate national solutions to deliver context specific reporting in the most appropriate manner.

1.3 EUnetHTA Collaboration – Participants and Governance bodies

EUnetHTA Collaboration activities are carried out by the following participants and supported by governing structures of the network as described below.

1.3.1 Participants

a) EUnetHTA Collaboration Partners

- The Founding Partners¹ of the EUnetHTA Collaboration and
- Other publicly funded organisations from the EU Member States, EEA and EFTA countries that produce or contribute to HTA and are nominated by the respective Ministries of Health to participate in the Joint Action

can become EUnetHTA Collaboration Partners. For clarity and transparency, the mandate of each Partner organisation and a link to health policy in its country setting have to be described in detail. The official status of the organisation as being nominated by the Ministry of Health should be confirmed every 3 years.

The EUnetHTA Collaboration partner must follow the formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement). The formal requirements and limitations on the participation in the Joint Action are to be observed (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action).

b) EUnetHTA Collaboration Associates

Non-for-profit organisations that produce or contribute to HTA and are willing to be actively involved and provide scientific input in the activities of the EUnetHTA Collaboration. The expression of interest will be considered on their experience and competence. The status of the EUnetHTA Collaboration Associate is granted by the Executive Committee and confirmed yearly on the basis of the continuous active input of the organisation to the activities of the EUnetHTA Collaboration.

c) **Lead Partner Organisations:** Partners participate in the activities of the EUnetHTA Collaboration organised into functions/Work Packages (Figure 1). Each function/Work Package is led by one function/Work Package Lead Partner organisation. In exceptional cases approved by the Plenary Assembly, a function/Work Package can have a co-Lead Partner. The organisations interested in leading a function/Work Package have to ensure that their professional resources, competences and qualifications as well as financial resources are sufficient to perform the function/Work Package Lead responsibilities.²

The number of functions/Work Packages is subject to changing needs and priorities of the EUnetHTA Collaboration and is suggested by the Executive Committee for the decision by the Plenary Assembly.

¹ Organisations that sent to the EUnetHTA Secretariat by November 20 2008 a Declaration of Intent to establish the EUnetHTA Collaboration and that contributed financially to its operation in 2009 shall be deemed to have founded the EUnetHTA Collaboration and as such shall be Founding Partners.

² A process of identification, approval and dismissal of the Lead Partner organisations should be developed.

1.3.2 Governance bodies

- a) **The Plenary Assembly** is comprised of the head of each of the EUnetHTA Collaboration Partner organisations or a person appointed by the head (one representative per Partner organisation). The Chair of the Plenary Assembly is elected by the members of the Plenary Assembly.
- b) **The Executive Committee** is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat and elected representatives from three Partner organisations which do not have the function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Leader and the Secretariat Manager) and the Chair of the Plenary Assembly. The Chair of the Executive Committee is appointed by the members of the Executive Committee.
- c) **The Secretariat** is comprised of the Secretariat Director, Secretariat Manager and other staff members assisting with the administrative and financial management matters (administrative assistant, financial assistant, financial manager).
- d) **Stakeholder Forum** is formed to ensure the transparent engagement with stakeholders and comprised of but not limited to representatives from the European umbrella organisations representing interests of the following stakeholder groups:
1. Policymakers at regional/national/hospital level
 2. Patient organisations
 3. Healthcare professionals
 4. Payers (statutory health insurance)
 5. Industry
 6. Health related media

The specific composition of the Stakeholder Forum is suggested by the Executive Committee for discussion and approval by the Plenary Assembly. To maintain the effectiveness of the Stakeholder Forum, each stakeholder group should not be represented by more than 4 different European umbrella organisations. The participation in the EUnetHTA Stakeholder Forum is at the invitation of the EUnetHTA Executive Committee. The EUnetHTA Executive Committee develops and applies Stakeholder Forum Membership criteria to identify and invite organisations for participation in the Stakeholder Forum. Each stakeholder organisation holds a position in the Stakeholder Forum for 3 years.

The Plenary Assembly has the final decision-making power regarding issues of the stakeholder involvement in the EUnetHTA Collaboration.

2. Rights and obligations of the EUnetHTA Collaboration participants.

2.1 Rights and obligations of Partners

Each Partner shall actively participate in the EUnetHTA Collaboration activities and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time all of its agreed upon obligations. Partners shall

- promptly notify the function/Work Package Lead Partners and Secretariat of any significant problem and delay likely to affect the progress within the function/Work Package or the success of the EUnetHTA Collaboration and
- inform the Secretariat of relevant communications they receive from third parties in relation to the EUnetHTA Collaboration activities.

A Partner should designate an individual to be an official representative of the organisation who will have a right and obligation to represent an official position of this organisation in any policy- and decision-making process in the EUnetHTA Collaboration eg, at the Plenary Assembly meetings. In case of a Partner being involved in a number of distinct activities of the EUnetHTA Collaboration, a Partner has to indicate the official representative of the organisation for the general EUnetHTA Collaboration activities, and can designate several representatives to be involved in various specific activities of the EUnetHTA Collaboration.

Partners may use the title “EUnetHTA Partner” or “Partner of the European network for Health Technology Assessment (EUnetHTA)” and the official EUnetHTA logo for their websites or for specific correspondence, presentations and the like in relation to EUnetHTA .

Each Partner organisation shall endeavor to be represented at Plenary Assembly meetings, and shall have one voting member at each meeting.

Each Partner organisation shall have full access to the tools and information published within the EUnetHTA Information Management System. The degree of access to specific areas devoted to ongoing work (so-called Workrooms) is governed by the rules developed and agreed by the Executive Committee.

Any Partner may resign at any time (subject to formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement. The formal requirements and limitations on the participation in the Joint Action are to be observed (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action).

Any Partner may be required to resign by a vote of three-quarters of the Partnership (subject to consideration of the formal legal requirements of the Joint Action on HTA when applicable (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action). In case a Partner nominated by the Ministry of Health, the Plenary Assembly’s request for resignation of the Partner in question will be brought to the attention of the respective Ministry of Health to identify further appropriate procedural steps.

A Partner must follow the formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement) including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action.

2.1.1 Acting on behalf of EUnetHTA

Each Partner shall inform the Secretariat of any occasion if their representatives act as a EUnetHTA Partner or on behalf of EUnetHTA (e.g. when giving presentations, writing communications on EUnetHTA) for coordination and documentation purposes.

In cases when a EUnetHTA Partner is invited to participate in various projects or other activities “on behalf of EUnetHTA”, its role and responsibility as “EUnetHTA representative” would be limited to

- informing the EUnetHTA Secretariat of such involvements,
- providing information to EUnetHTA (through the EUnetHTA Secretariat) on the developments in the new project that the EUnetHTA Partner considers relevant and important for EUnetHTA,
- providing information about the developments within EUnetHTA

EUnetHTA Collaboration assumes no responsibility for the actions of the EUnetHTA Partners participating in the projects not directly initiated by the EUnetHTA Collaboration.

The EUnetHTA Partner cannot express views and take positions on issues “on behalf of EUnetHTA” unless a clear consent of the EUnetHTA Executive Committee is sought and received by the EUnetHTA Partner in advance.

The views and statements expressed by the EUnetHTA Partner without the prior consent of the EUnetHTA Executive Committee are the sole responsibilities of this EUnetHTA member and do not reflect the views of EUnetHTA. EUnetHTA assumes no responsibility for the contents of such views or statements.

2.2 Rights and obligations of Associates

Each Associate shall actively participate in the EUnetHTA Collaboration activities and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time all of its agreed upon obligations. Associates shall

- promptly notify the function/Work Package Lead Partners and Secretariat of any significant problem and delay likely to affect the progress within the function/Work Package or the success of the EUnetHTA Collaboration and
- inform the Secretariat of relevant communications they receive from third parties in relation to the EUnetHTA Collaboration activities.

An Associate should designate an individual to be an official representative of the organisation who will have a right and obligation to represent an official position of this organisation in general EUnetHTA Collaboration activities. In case of an Associate being involved in a number of distinct activities of the EUnetHTA Collaboration, an Associate has to indicate the official representative of the organisation for the general EUnetHTA Collaboration activities, and can designate several representatives to be involved in various specific activities of the EUnetHTA Collaboration.

Associates may use the title “EUnetHTA Associate” or “Associate of the European network for Health Technology Assessment (EUnetHTA)” and the official EUnetHTA logo for their websites or for specific correspondence, presentations and the like in relation to EUnetHTA.

Any Associate may resign at any time and maybe required to resign by a vote of here-quarters of the Partnership.

Each Associate can participate in the meetings of the Plenary Assembly and be represented by one member of its organisation, but shall have no voting rights.

Each Associate shall have access to the EUnetHTA Information Management System. The degree of access is governed by the rules developed and agreed by the Executive Committee.

2.3 Obligations of the Function/Work Package Lead Partners

Function/Work Package Lead Partners are responsible for the organisation of activities and management of their respective function/Work Package, including provision to the Secretariat of the information on the function/Work Package work plans, their implementation updates and results for inclusion in the annual report, participant organisations' lists and consultation with the Secretariat and other Lead Partners on major function/Work Package implementation issues that have implications for the overall functioning of the network. Any additional responsibilities of the Lead Partners are to be described in detail in the EUnetHTA Collaboration Standard Operating Procedures (SOP) Manual.

Lead Partner organisations are members of the Executive Committee. In cases of co-leadership of a function/Work package, the Lead Partner of the function/Work Package is the full member of the Executive Committee having 1 voting right. The Co-Lead Partner can act as an alternate and is allowed to attend the Executive Committee meetings without having voting rights, except when the “full member” is not present and delegated its voting right to the Co-Lead Partner.

2.3 Functions of the governance bodies³

2.3.1 Plenary Assembly

The Plenary Assembly is EUnetHTA's major governing and policy setting body. It is comprised of the head of each of the partner organisations or a person appointed by the head (one representative per organisation).

The Plenary Assembly takes a strategic overview of the work of the EUnetHTA Collaboration including functions such as:

- a. approving the composition of the Stakeholder Forum and its chair
- b. deciding by majority vote (1 voting right per partner) on strategic matters relevant to the development of the sustainable European network for HTA including changes in governance and organisational structure
- c. deciding on the Functions/Work Packages and their Lead Partners
- d. monitoring / supervising the progress of the network and performance of the Executive Committee and the Secretariat
- e. elect the non-function/Work Package members of the Executive Committee
- f. facilitating the Secretariat and the Executive Committee with the execution of its coordinating tasks
- g. approving strategy, work plans, an annual report, budgets
- h. advising on future developments
- i. admitting new partners / exclusion of partners

Delegates of the European Commission may additionally participate in the Plenary Assembly meetings but have no voting right. Observers can be invited to Plenary Assembly meetings to counsel the Plenary Assembly but have no voting rights.

³ See Appendix 2 Organisational Structure Grid

Decisions are taken by majority vote of Plenary Assembly members, in case of ties, the decision by the Plenary Assembly Chair prevails. Plenary Assembly chair exercise his/her voting rights only in case of ties.

The Plenary Assembly convenes once a year in a face-to-face meeting. Extraordinary meetings can be called subject to recommendation of the Executive Committee or on request from at least 1/3 of the Plenary Assembly members⁴..

The Plenary Assembly shall elect a Chair and a Deputy Chair from among its members by the absolute majority of its members on the basis of individual merits, and not as representatives of their respective organisations for the period of 2 years, not to serve for more than two terms in the same function, commencing the day following the annual Plenary Assembly meeting. Representatives of the Lead and Co-Lead Partner organisations are not eligible to run for the Plenary Assembly Chair/Deputy Chair position.

The Chair of the Plenary Assembly ensures an optimal liaison between the Plenary Assembly and the Executive Committee and is a non-voting member of the Executive Committee. Plenary Assembly Chair oversees that the Executive Committee and the Secretariat actually operate in such a way that the Plenary Assembly's opinion is sought whenever it should be sought and that the Plenary Assembly's decisions are taken into account and implemented by the Executive Committee and Secretariat. S/he has the internal task of motivating partners to participate in general and in the long term and facilitating efforts of seeking funding for the EUnetHTA Collaboration activities.

The procedure for the election of Chair shall be as follows:

The vote for the election of Chair shall be taken by an absolute majority of the Plenary Assembly voting members present and by secret ballot. Several rounds of election take place in case when more than 2 candidates are nominated for the same position and when no candidate receives an absolute majority of votes in the first round of election.

Nominations for Chair shall be submitted either by the candidates themselves or by other members of the Plenary Assembly to the secretariat no later than 3 weeks before the start of the Plenary Assembly meeting at which the election is to take place. The Secretariat shall send the nominations so received to the members of the Plenary Assembly no later than 10 working days before the Plenary Assembly meeting at which the election is to take place. Candidates shall submit a statement in support of their candidature at the time of the nomination. Two tellers shall be designated amongst the members, observers or the secretariat to assist in the counting of the vote.

An individual may be nominated for both Chair and Deputy Chair. If a nominated candidate is elected Chair, the nomination for Deputy of this individual will automatically become non-eligible.

If two or more candidates receive the same number of the majority votes for the same position, the next round of election takes place where the members cast votes only for the candidates that received the equal majority vote in the first round. Rounds will run until one of the remaining candidates receives simple majority of favourable votes of the Plenary Assembly members. In case of two remaining candidates receiving equal amount of votes, the election shall be suspended and the Plenary Assembly shall seek an agreement to enable new nominations and the process shall resume if possible during the same meeting of the Plenary Assembly. In such case, new nominations can be made during the meeting.

The Deputy Chair shall be elected following a procedure identical to that of the Chair.

The Deputy Chair shall automatically take the place of the Chair if he/she is prevented from attending to his/her duties.

2.3.2 Executive Committee

The Executive Committee is the major executive body responsible for coordinating the activities, implementing policy decisions and managing the affairs of the EUnetHTA Collaboration. It is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat and elected representatives from three Partner organisations which do not have the Function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Director and the Secretariat Manager) and the Chair of the Plenary Assembly.

⁴ considerations to be given to the funds availability to hold extraordinary meetings

The Executive Committee shall not contain more than 2 partners from one country. An organisation-member of the Executive Committee should designate an individual to be an official representative of an organisation on the Executive Committee who will represent an official position of an organisation in any decision-making process of the Executive Committee, and a substitute in cases of unavailability of the official representative.

The electable members of the Executive Committee are elected for the period of 1 year, not to serve for more than 2 consecutive terms in the same function. The function/Work Package Lead Partners serve 3-year terms.

The Executive Committee is responsible for supervising performance and monitoring the EUnetHTA Secretariat.

The Executive Committee is responsible for:

- a. appointing the chair of the Executive Committee
- b. supervising the Secretariat in implementing the work plan-
- c. develop strategy for approval by the Plenary Assembly
- d. preparing work plans and monitoring outcomes
- e. preparing suggestions for the changes in the governance and organisational structure for approval by the Plenary Assembly
- f. reviewing the performance of the Collaboration
- g. in charge of the information exchange with the Stakeholder Forum and other identified strategic external parties
- g. reviewing finances
- h. being accountable for the performance of the EUnetHTA Collaboration to the Plenary Assembly.

The representatives from the three Partner organisations which do not have the function/Work Packages lead responsibility and are willing to serve on the Executive Committee are elected by the Plenary Assembly at the Annual Meeting.

The procedure for the election of electable members of the Executive Committee shall be as follows:

The vote for the election Executive Committee member shall be taken by a simple majority of the Plenary Assembly voting members present at an annual meeting and by secret ballot. The election is EUnetHTA Collaboration partner organisation-based, ie each EUnetHTA Collaboration partner organisation has 3 votes to be cast for up to 3 organisations running for elections (1 vote only per 1 running organisation).

The declaration of interest to serve on the Executive Committee shall be submitted by the candidate organisations themselves to the Secretariat no later than 3 weeks before the start of the Plenary Assembly meeting at which the election is to take place. The Secretariat shall send the declarations so received to the members of the Plenary Assembly no later than 10 working days before the Plenary Assembly meeting at which the election is to take place. Candidate organisations shall submit a statement in support of their candidature at the time of the nomination which should present the organisation's ideas for networking, integration and collaboration along the cross-functional (Work Plan based) activities.

Two tellers shall be designated amongst the members, observers or the secretariat to assist in the counting of the vote.

The 3 organisations that receive the highest number of votes will be elected.

If two or more candidate organisations receive the same number of the majority votes, the next round of election takes place where the members cast votes only for the candidate organisations that received the equal majority vote in the first round. In each round, each EUnetHTA Collaboration Partner can cast 1 vote per running organisation (the total number of cast votes per EUnetHTA Collaboration Partner not to exceed the number of positions to be filled). Rounds will run until all the places on the Executive Board are filled.

The Chair of the Executive Committee is appointed by the members of the Executive Committee.

The regular meetings of the Executive Committee are convened monthly by the means of web-based conferencing solutions. There shall be at least one meeting per year with attendance of the members of the Executive Committee in person. The reports from the Executive Committee meetings are made available to the Plenary Assembly members.

Each member of the Executive Committee is authorized to exercise one (1) vote with respect to each matter to be decided upon by the Executive Committee (the Secretariat has one (1) vote (to be cast by the Director of the Secretariat (in case of absence, the Manager will have the vote); the Chair of the Plenary Assembly is a non-voting member of the Executive Committee).

2.3.3 Secretariat

The Secretariat is the executive body acting under the supervision of the Executive Committee and assisting the Executive Committee in implementing the policy decisions. It is comprised of the Secretariat Director, Secretariat Manager and other staff members assisting with the administrative and financial management matters (administrative assistant, financial assistant, financial manager).

The Secretariat supports partners in conducting the routine EUnetHTA management affairs and is responsible for:

- a. coordination function
- b. communication
- c. financial management
- d. development of strategy in coordination with the Executive Committee
- e. preparation of Work Plan
- f. Organising the Plenary Assembly and the Executive Committee meetings

The Secretariat must follow the formal legal requirements of the Joint Action on HTA when applicable.

The work of the Secretariat is led by the Director who works under the supervision of the Executive Committee and is co-responsible together with the Executive Committee for implementing the EUnetHTA Collaboration policy decisions. The Director acts as a facilitator of close coordination between functions/Work Packages with special emphasis on the HTA work content, is given the responsibility to facilitate the promotion of EUnetHTA in relation to a range of "external" entities, organisations and processes, and is expected to act on behalf of EUnetHTA with obligation to report and ensure approval of the Executive Committee on major strategic issues in situations when the Executive Committee cannot be directly involved.

The work of the secretariat is coordinated by the Secretariat Manager who works under the supervision of the Secretariat Director and in close cooperation with the Executive Committee members and EUnetHTA Collaboration partners. The Manager is responsible for managing the day-to-day activities and for operations management of the EUnetHTA Collaboration. The Manager is reporting to the Executive Committee and the Secretariat Director.

2.3.4 Stakeholder Forum

Stakeholder Forum is formed to ensure the transparent engagement with stakeholders and comprised of representatives of the identified stakeholder groups with broad and balanced representation including European umbrella interest organisations. The Stakeholder Forum receives information on Joint Action developments, globally and on every function/Work Package and provides comments on them to the Executive Committee.

A Stakeholder involvement policy is to be developed to support an effective EUnetHTA Collaboration information exchange with the Stakeholder Forum.

3. Governance Guiding Principles and Structure

- The Plenary Assembly is comprised of the head of each of the partner organisations or a person appointed by the head (one representative per organisation). It decides on the overall development of the EUnetHTA Collaboration based on input from the Secretariat and the Executive Committee. The Executive Committee is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat, elected representatives from three Partner organisations which do not have the function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Director and the Secretariat Manager) and the Chair of the Plenary Assembly. The Executive Committee shall not contain more than 2 partners from one country. The Executive Committee acts on behalf of, and is subordinate to the Plenary Assembly.
- The function/Work Package Lead Partners make decisions in daily network work in their functions/Work Packages.

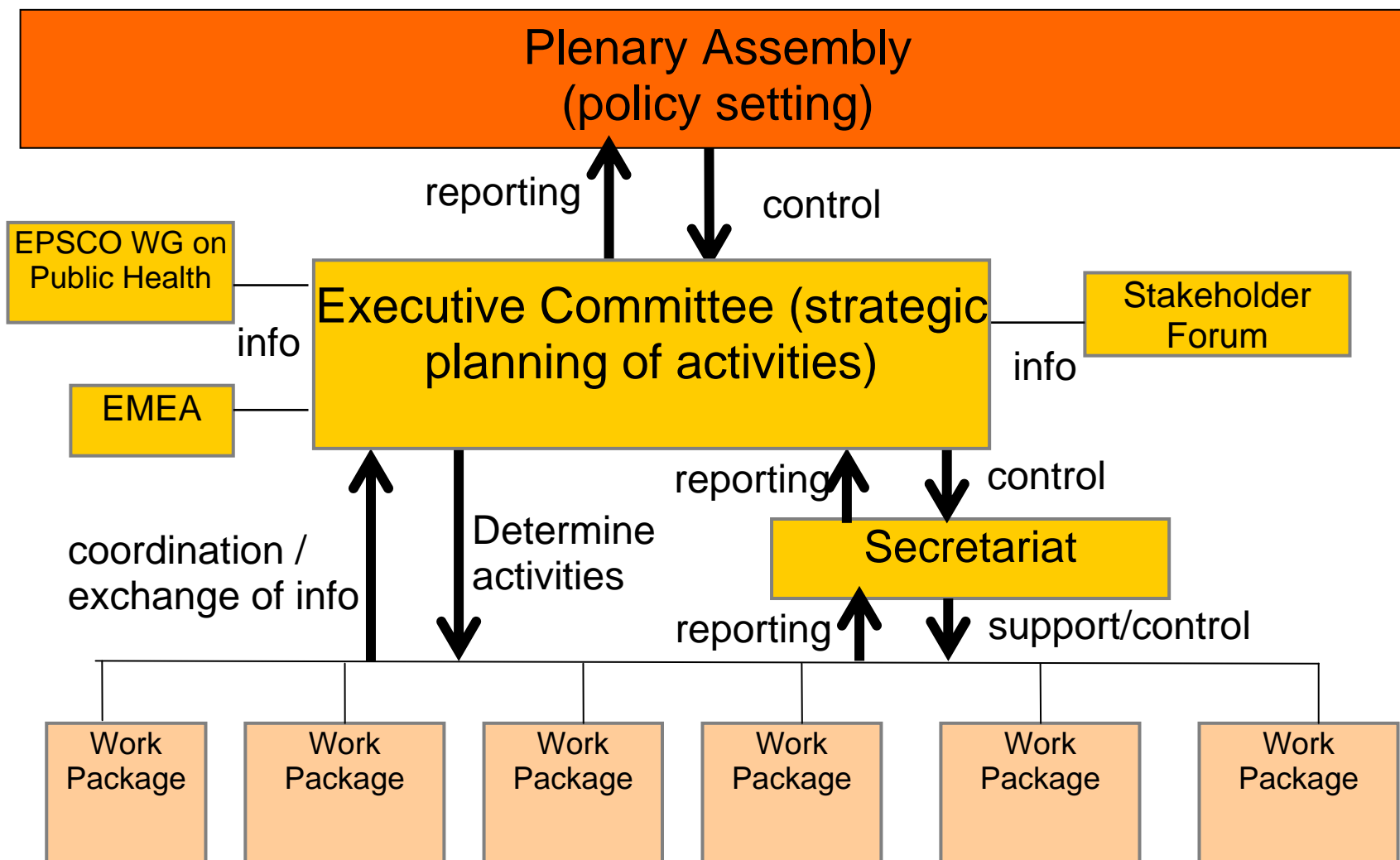
- The function/Work Package Coordination and the function/Work Package Communication/Dissemination⁵ are supporting functions facilitating effective operations of the whole of the EUnetHTA Collaboration
- When decisions within functions/Work Packages have significant implications for other functions/Work Packages, the Lead Partners of the functions/Work Packages affected and the Secretariat should be consulted. If the parties can't find a satisfactory agreement, the Secretariat should be involved and the Executive Committee should make a decision.
- When the Secretariat considers it necessary the Executive Committee should be consulted / make decision with the Secretariat
- When the Executive Committee cannot / should not make the decision, the Plenary Assembly should be involved
- The Executive Committee supervises the Secretariat on a continuing basis
- The Plenary Assembly receives regular updates in order to be able to guide the EUnetHTA Collaboration through transparent delegation
- Implementation is a responsibility of the appropriate decision maker with the partners involved

Figure 1 (next page)

⁵ Joint Action framework terminology (Dissemination Work Package)



Figure 1. EUnetHTA Collaboration Organisational Structure 2009-2012



Endorsed by the EUnetHTA Plenary Assembly
September 29, 2009, Seville, Spain

Appendix 1

Excerpt from the Grant Agreement for Joint Action – Article I.3 **ARTICLE I.3 – ROLE OF THE BENEFICIARIES**

I.3.1 The co-ordinator shall 'inter alia':

- a) have full responsibility for ensuring that the action is implemented in accordance with the agreement;
- b) be the intermediary for all communication between the co-beneficiaries and the Executive Agency in accordance with Article I.8. Any claims that the Executive Agency might have in respect of the agreement shall be addressed to, and answered by, the co-ordinator, save where specifically stated otherwise in the agreement;
- c) be responsible for supplying all documents and information to the Executive Agency which may be required under the agreement, in particular in relation to the requests for payment. The co-ordinator shall not delegate any part of this task to the co-beneficiaries or to any other party. Where information from the co-beneficiaries is required, the co-ordinator shall be responsible for obtaining and verifying this information and for passing it on to the Executive Agency;
- d) inform the co-beneficiaries of any event of which the co-ordinator is aware that is liable to substantially affect the implementation of the action;
- e) inform the Executive Agency of transfers between items of eligible costs, as provided in Article I.4.4;
- f) make the appropriate arrangements for providing the financial guarantee or the joint guarantee of the beneficiaries participating in the action, when requested, under the provisions of Article I.5;
- g) establish the payment requests on behalf of the beneficiaries, detailing the exact share and amount assigned to each beneficiary, in accordance with the agreement, and in particular the estimated eligible costs as foreseen in Annex II, and the actual costs incurred. All payments by the Executive Agency are made to the bank account(s) referred to in paragraph 1 of Article I.7;
- h) where designated the sole recipient of payments on behalf of all of the beneficiaries, ensure that all the appropriate payments are made to the co-beneficiaries without unjustified delay in accordance with paragraph 3 of Article I.7 and shall inform the Executive Agency of the distribution of the Community financial contribution between the co-beneficiaries and of the date of transfer;
- i) be responsible, in the event of audits, checks or evaluations, as described in Articles II.20 and II.6, for providing all the necessary documents, including the accounts of the co-beneficiaries, the original accounting documents and signed copies of sub-contracts, if any have been concluded by the beneficiaries in accordance with Article II.9.

I.3.2 The co-beneficiaries shall 'inter alia':

- a) agree upon appropriate arrangements between themselves for the proper performance of the action; *[The beneficiaries are deemed to have concluded an internal co-operation agreement regarding their internal operation and coordination. The co-operation agreement shall include all aspects necessary for the management of the beneficiaries and the implementation of the action;]*
- b) forward to the co-ordinator the data needed to draw up the reports, financial statements and other documents provided for in the agreement including its Annexes;
- c) ensure that all information to be provided to the Executive Agency is sent via the co-ordinator, save where the agreement specifically stipulates otherwise;
- d) inform the co-ordinator immediately of any event liable to substantially affect or delay the implementation of the action of which they are aware;
- e) inform the co-ordinator of transfers between items of eligible costs, as provided in Article I.4.4;
- f) provide the co-ordinator with all the necessary documents in the event of audits, checks or evaluations, as described in Articles II.20 and II.6.

Full text of the Grant Agreement for Joint Action :

http://ec.europa.eu/eahc/documents/health/calls/Model_Grant_Agreement_Joint_actions.pdf

Appendix 2 Organisational Structure Grid

	Main purpose	is comprised of	Positions	Main tasks / Responsibilities
Plenary Assembly	Principal policy setting body	head of each partner organisation (1 representative per partner organisation)	- Chair - Members	<ul style="list-style-type: none"> - Approving the composition of the Stakeholder Forum and its chair - deciding by majority vote (1 voting right per organisation) on strategic matters relevant to the development of the sustainable European network for HTA including changes in governance and organisational structure. - deciding on the functions/Work Package and their Lead Partners - monitoring / supervising the progress of the network and performance of the Executive Committee and the Secretariat - elect the non-function/Work Package members of the Executive Committee - facilitating the Secretariat and the Executive Committee with the execution of its coordinating tasks - approving strategy, work plans, an annual report, budgets - advising on future developments - approving changes in the governance and organisational structure - admitting new partners / exclusion of partners
Executive Committee	strategic leadership/main executive body	representatives of the function/Work Package Lead Partner organisations, the secretariat, 3 elected Partner organisations and chair of the Plenary Assembly (non-voting). Shall not contain more than 2 partners from one country.	- Chair - Members	<ul style="list-style-type: none"> - Appointing the chair of the Executive Committee - supervising the Secretariat in implementing the work plan- - develop strategy for approval by the Plenary Assembly - preparing work plans and monitoring outcomes - preparing suggestions for the changes in the governance and organisational structure for approval by the Plenary Assembly - reviewing the performance of the Collaboration - in charge of the information exchange with the Stakeholder Forum and other identified strategic external parties - reviewing finances - being accountable for the performance of the EUnetHTA Collaboration to the Plenary Assembly.
Secretariat	operational leadership	a director, a manager and staff members	- Director - Manager - Staff	<ul style="list-style-type: none"> - coordination function - communication - responsible for the financial management - develops strategy in coordination with the Executive Committee - prepares work plan - organisation of the Plenary Assembly and the Executive Committee meetings
Stakeholder Forum	information exchange	representatives of relevant stakeholder groups	- Chair - Members	<ul style="list-style-type: none"> - receives information on EUnetHTA Joint Action developments, globally and on every function/Work Package and provides comments on them to the Executive Committee