Strategy for

EU cooperation on Health Technology Assessment (HTA)

The HTA Network is a voluntary network, set up by Directive2011/24 (article 15) gathering all Member States, Norway and Iceland*. It also associates, as observers, stakeholders representing industry, payers, providers and patients. The Joint Action EUnetHTA provides the scientific and technical support to the Network.

** Application submitted to the Network in October 2014*

Adopted unanimously by the HTA Network, Rome, 29 October 2014

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1. INTRODUCTION

The HTA Network (The Network) aims at supporting cooperation between national authorities or bodies responsible for Health Technology Assessments[1]. It is a voluntary network, set up by Directive 2011/24 (article 15) and it gathers all Member States, Norway and Iceland[2]. Stakeholders' representatives are also associated to the Network as observers[3]. The Joint Action EUnetHTA provides scientific and technical support to the Network[4].

This paper has been drafted by the Network, having consulted observers. Its objective is twofold:

- Set out its strategic vision, including its long term sustainability.
- Identify priority areas to be addressed through the Network and to be potentially co-funded by the EU (e.g. through a possible JA3 on HTA under the next Health Programme).

The activities proposed in this strategy paper will build on, amongst other things, the outcome of the existing cooperation between national and regional bodies within EUnetHTA, and the results of other relevant EU funded initiatives[5].

In line with Art 15(7) of Directive 2011/24, and article 168 of the Treaty of the EU, measures adopted to implement the HTA Network Multiannual Work Programme (MWP), including this strategy paper, shall aim at strengthening cooperation and shall not interfere with areas of Member States' competence in deciding on the implementation of HTA conclusions and shall not harmonise national laws or regulations of the Member States. Cooperation at EU level shall fully respect their responsibilities to organise and deliver health services and medical care. Individual Member States are free to decide the level at which they are willing to participate in cooperation efforts.

Within three years of the adoption of this Strategy, the Network shall review progress in its implementation.

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1 Article 15(2) Directive 2011/24/EU on the applications of patients' rights in cross-border healthcare http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

2 Application submitted to the Network in October 2014

3 Article 8 Rules of Procedures http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

4 Article 8 Rules of Procedures of the HTA Network http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

5 Projects cofounded by the EU under the 7th Research Framework Programme relevant to HTA includes: AdhopHTA (www.adhophta.eu); MedtecHTA (www.medtechta.eu); INTEGRATE-HTA (www.integrate-hta.eu) and ADVANCE-HTA (www.advance-hta.eu).

2. THE VISION – EVIDENCE IS GLOBAL, DECISION IS LOCAL

HTA can be instrumental in promoting innovation that delivers better outcomes for patients and society as a whole. It provides evidence-based information and analysis which is useful in making decisions on how to allocate resources. It is also a useful tool to help decision-makers achieve sustainable healthcare systems, in the best interest of European patients.

The goal of European cooperation is to increase use, quality and efficiency[6] of HTA production in Europe and to promote HTA in decision-making, in accordance with national practices and legislative frameworks.

With this overall goal, the Network acknowledges that European cooperation in HTA can:

- Promote more consistent approaches to HTA as a health policy tool to support evidence-based, sustainable, equitable choices in healthcare and health technologies;
- Increase efficiency, optimize use of resources and avoid duplication when performing HTAs;
- Further develop national "know-how" and capacities on HTA and developing "shared know-how" among national bodies working together to produce and apply shared methodologies;
- Facilitate joint work[7] in HTA, and enhance the exchange of experience and good practices.

The Network recognises that:

- Trust is a precondition for a successful cooperation and that such trust can only be achieved through a true commitment of all actors, access to expertise, development of capacities, and high quality output
- Cooperation is based on the principle of good governance, including: transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder involvement
- Cooperation should respond to the needs of different target audiences (e.g. health policy-makers, professionals and patients, payers, regulators and

[6] http://ec.europa.eu/health/technology_assessment/docs/study_ecorys_european_cooperation_hta_en.pdf

[7] See Annex 5- Glossary

developers of health technologies) and provide support for decision-making in health care

- There are challenges in engaging in activities across national boundaries and in joint work. However, the benefits of such activities are expected to largely outweigh the challenges[8].

The Network aims at implementing a vision which reflects that methodologies and evidence used to assess technologies are often global and can and should be shared, as appropriate, while decisions made on the basis of the assessments are local and within the responsibility of national and regional authorities.

In view of the above, the Network aims at designing and implementing a model of collaboration which could enable HTA bodies willing to do so:

- to rely more extensively on each other's work to perform national HTA reports,
- to engage in joint work, for further national consideration and adaptation
- to cooperate more efficiently in defining evidence requirements through the life cycle of technologies from scientific advice (during development and scientific evaluation - pre licencing) to surveillance after introduction to healthcare practice.

The principles and actions agreed in this strategy document should be further developed in the work plan of any forthcoming scientific and technical mechanism of cooperation between Members States on HTA.

To implement the principles outlined above the HTA Network:

- **Calls upon all actors including national authorities, HTA bodies, stakeholders and the European Commission, to play an active part in shaping the next phase of EU cooperation and actively engage in EU activities on HTA.**

[8] Challenges may include: the need to use additional resources to perform start up work, adapt well established working practices, translation costs etc…

2.1. Broad scope of EU cooperation in HTA

The Network considers that cooperation at EU level can encompass:

1) The full life cycle of health technologies. Cooperation on HTA can play a role in the horizon scanning phase and in the early stages of development, for example in early dialogue and scientific advice. It can also play a role in early (rapid) assessment when a technology is new and at a later stage (full assessment) when a technology has become more established. Finally, when a technology becomes obsolete and inappropriate, HTA can help in decision-making on disinvestment.

Within the life cycle of health technologies, synergies both upstream with regulatory (or notified) bodies and downstream with payers and healthcare providers, can better serve patients' interests, by enabling quicker access to innovative effective technology within sustainable healthcare systems.

2) The whole range of health technologies. Cooperation on HTA will go beyond pharmaceuticals and medical devices. It shall also embrace interventions such as companion diagnostics, surgical procedures, preventive and health promotion programmes, Information and Communication Technology (ICT) tools and integrated care processes. The requirements for assessing different technologies vary depending on their specific characteristics. Nevertheless there should be a consistent, fit for purpose HTA approach to these various technologies. It should be noted that in specific areas, for example treatments for rare conditions, paediatric medicines or advanced therapies, the added value of EU cooperation is likely to be even greater. This should be taken into account in priority setting.

3) All different aspects ("Domains") of HTA. To date and in the short term, the primary focus of EU cooperation is on the clinical domains of HTA, particularly important for the so-called HTA Core Model for Rapid Relative Effectiveness Assessment (REA). This model for rapid REA has been developed as a priority to respond to the time limits defined by the Transparency Directive[9]. The Network considers that cooperation on other aspects which are more context-specific, such as economic, organisational or societal perspectives should also be further explored, taking into account existing activities within the mechanism of cooperation at scientific and technical level.

[9] Council Directive 89/105/EEC lays down harmonised provisions to ensure the transparency of national provisions regulating the pricing and reimbursement of medicinal products. It is commonly referred to as the "Transparency Directive".

4) Providing support and input to a wide-range of decision-makers in health care. HTA cooperation at EU level will facilitate joint HTA activities and enhance the exchange of experience and good practices. The HTA cooperation should address the needs of different audiences, like health policy makers, providers, payers, regulators, developers of innovative health technologies and, importantly, patients.

5) A clear framework for priority setting. Considering the ambitious and broad scope of cooperation, the Network aims at defining and implementing a clear and transparent framework for priority setting, reflecting the added value of the cooperation, synergies with national activities and the level of commitment of relevant actors. The framework for priority setting will need to be in line with the work programme set out by the Network and this Strategy. The Network will also set out specific priorities regarding the development of proposals for future cooperation between Member States on HTA at the scientific and technical level.

To implement the principles outlined above, the HTA Network:

- **Calls on the Commission to facilitate interaction and synergies between the Network and other relevant European networks and bodies, which could contribute to the activities of the Network and facilitate a full life cycle approach to health technologies.**
- **Commits to involve relevant national and regional actors in line with national and regional priorities and responsibilities, to facilitate synergies in all stages of the lifecycle of health technologies. They include HTA statutory bodies, regulators (or notified bodies for Medical Devices), authorities responsible for pricing and reimbursement, healthcare providers, payers, patient representatives and research institutes.**
- **Calls upon any possible future cooperation mechanism at the scientific and technical level (e.g. Joint Action) to further develop opportunities for European cooperation spanning the whole range of technologies and to further explore non-clinical domains, as appropriate.**

2.2. Synergies and complementarity of European activities with national activities

To implement the overall vision, in line with the priorities and capacities of participating Member States, the Network calls for:

- the strengthening and further development of joint work
- the re-use, including increasing uptake, of joint work in national and regional activities, where relevant and in line with national and regional legislation.
- joint work to minimise potential duplication, for example by contributing filling gaps of activities not performed at national level.
- the vision outlined in this strategy paper to be reflected in national and regional strategies.

In order to achieve these goals, national authorities and the Network should address facilitating factors listed below in line with respective roles and responsibilities.

Authorities responsible for HTA should aim at

- Improving awareness of and access to information on relevant HTA-related joint work between and within national HTA bodies and other relevant competent authorities;
- Encouraging wider use of HTA and uptake of recognised tools and methodologies including those developed by / for the European cooperation;
- Increasing the quality and consistency of HTAs produced at all levels, which may involve aligning methodologies, to facilitate re-use, as appropriate;
- Avoiding duplication of efforts when performing national assessments, by exchanging information, and using available evidence, including evidence generated by national authorities or by joint work. For example, national/relevant authorities should avoid requesting additional HTA evidence generation from health technologies developers, when the evidence required has already been collected through joint work, unless this is to address important gaps in existing evidence, to overcome methodological shortcomings or to respond to specific national requirements not addressed by joint work.
- Reviewing any structural/administrative/legal provisions preventing collaboration on joint work, as relevant;
- Promoting best practice in HTA processes by fostering the inclusion of stakeholders' contributions in HTA processes;
- Ensuring that HTAs are electronically accessible, including a summary in English, and understandable to stakeholders.

The Network shall set up scientific and technical capacity to:

- Support and develop fit for purpose, professional and robust network coordination including project management and relevant joint project management tools.
- Improve and integrate existing ICT tools[10] and where necessary, develop new ones, to facilitate sharing of structured HTA information, re-use of national work and development of joint work. For example a dedicated internet-portal to share work done and evidences collected at national level. The latter would build on existing EU and national initiatives (e.g. the POP and EVIDENT databases, HTA Core Model® online[11]) and serve as a working tool for HTA cooperation, as well as facilitate national work.
- Develop, maintain and refine shared scientific standards including methodologies and tools for all relevant HTA steps;
- Organize external scientific validation of HTA joint work, to contribute to the aim of producing outputs of the highest quality.

To implement the principles outlined above the HTA Network:

- **Calls upon HTA bodies to reuse joint work, where relevant, in their national activities**
- **Calls upon stakeholders, particularly health technology developers to engage in European activities in HTA e.g. by taking part in EU joint pilots.**
- **Commits to address the facilitating factors outlined above, in line with the relevant competences, responsibilities and opportunities.**
- **Acknowledges the importance of stakeholders' involvement in HTA processes at European, national and regional level.**

[10] ICT tools aiming at supporting European cooperation should be interoperable, as much as possible, with national/regional tools and applications.

[11] See Annex 3 "Glossary"

2.3. Synergies between HTA and regulatory[12] issues

The Network acknowledges that stronger synergies and closer interaction between developers of health technologies, regulators, HTA bodies and decision makers can improve timely and comprehensive access to information and data through the life cycle of health technology. Provided that the different remits and aims of the different processes and players are maintained, stronger synergies can contribute to:

- Facilitating patients' safe, sustainable and timely access to innovative, effective technologies;
- Reducing duplication of efforts for clinical studies, data generation and analysis, faced by all actors along the pathway;
- Improving business predictability for developers of health technologies;
- Providing for a more seamless transition of technologies from development to regulatory and implementation stages.

For pharmaceuticals, synergies shall be explored both, in the pre-marketing phase and in the post marketing phase by, for example:

- Conducting parallel early dialogues/scientific advice with developers of technologies (pre-marketing phase);
- Timely exchange of information between regulatory and HTA bodies both in the pre-marketing phase and post marketing phase;
- Cooperation on defining phase IV studies and observational data collection and research (post-marketing phase);
- Supporting initiatives for more transparency of scientific data generated in the regulatory sector.

For medical devices, synergies should be explored in relation to the Medical Devices legislation. This may include:

- Supporting initiatives for more transparency of scientific data, including clinical data, generated in the regulatory sector,

[12] In this context "regulatory" should be understood as covering also the conformity assessment procedures with Notified Bodies necessary for placing medical devices on the market.

- Assisting medical device conformity assessments, including development of relevant guidance for clinical evaluation of specific types of medical device and in vitro diagnostics (IVD).
- Conducting early dialogues/scientific advice with developers of technologies (pre-market access).
- Designing studies that could meet requirements for post market clinical follow-up, including evaluation of registries and coverage with evidence schemes.

For other types of technologies, potential synergies shall be identified and explored on an ad hoc basis.

To implement the principles outlined above the Network:

- **Calls upon HTA bodies to take part in parallel early dialogue with technologies developers.**
- **Calls upon technology developers (both pharmaceuticals and other medical technologies) to engage in early dialogue and scientific advice processes involving both regulators and HTA bodies.**
- **Commits to further strengthen interaction between HTA bodies and the EMA, building on ongoing cooperation within the EUnetHTA Joint Action.**
- **Commits to developing further links with bodies responsible for conformity assessment of Medical Devices, within the framework of relevant legislation and relevant working/expert groups at EU and international level.**
- **Calls on the Commission to facilitate exchange of information with the Network, as appropriate. For example, when implementing relevant legislative and non-legislative measures which can contribute to strengthening synergies between regulators and HTA bodies. Such synergies may be found in the pharmaceutical sector in the area of pharmacovigilance and evidence generation, clinical trials; for medical devices in clinical investigations and evaluation and post-marketing clinical follow up.**

2.4. EU cooperation on HTA in the broader European and global context

The Network recognises that HTA is a research and policy area in continuous development. In this context several initiatives and collaborations on HTA are ongoing at different levels including regional, national, European and global (see Annex 2).

In the specific area of research, cooperation at European and global level could contribute to generate evidence through independent clinical research. It could help in sharing costs of research and to access patients and medical expertise.

With the overall goal of increasing use, quality, and efficiency of HTA production in Europe, the Network considers that EU cooperation both at policy and scientific levels is well positioned to make an important contribution to global cooperation on HTA.

While its activities are focused to the EU, the Network:

- **Welcomes the WHO Resolution on "Health intervention and technology assessment in support of universal health coverage".**
- **Acknowledges the importance of collaboration initiatives at global level and aims at promoting synergies, where relevant.**
- **Calls for national authorities and HTA bodies, when acting as individual members in national or international initiatives on HTA, to build upon European level developments, to avoid duplication of efforts and to foster synergies, where relevant.**
- **Calls for the European Commission to include HTA as part of the "EU Health strategy for Developing Countries".**
- **Calls for cooperation between national, European and international research programmes, to align, when possible, and create synergies between their respective work programmes and research priorities.**

3. IMPLEMENTATION OF HTA COOPERATION AT EU LEVEL

In order to translate the strategic vision into useful activities, it is necessary to address operational issues - including governance and long term sustainability - when funding currently granted by the Health Programme ends.

In doing so a number of principles shall be considered.

- The benefits of EU cooperation on HTA result from a combination of different activities, ranging from sharing information, developing common methodological approaches, developing and using common tools, to cooperation on early dialogues and rapid or full HTAs. In this respect, in line with the provision of the EU Treaty (Article 168), and article 15(7) of Directive 2011/24, it should be clarified that joint work does not include recommendations for reimbursement purposes or interfere with Member States' competences in deciding on the implementation of Health Technology Assessment and the organisation of healthcare services.
- Member States may approach cooperation from different angles, depending on their willingness and capacity to take part in the activities. For example, while some countries may focus on sharing national data, developing guidelines for common methodologies and conducting early dialogues, others may prioritise joint work on structured HTA information for rapid or full HTAs.
- Because of the voluntary nature of European cooperation and Member States varying approaches to cooperation, joint work may not involve all Member States. Several activities, following different timeframes and with different participants can be pursued. However, once engaged in specific activities, relevant bodies seek to fulfil the commitments they have made and to reuse the output of joint work in their national HTA activities, as appropriate and in line with national legislation or requirements.

3.1. Governance

The governance of the cooperation is based on a two layer system, one strategic (the HTA Network) and one scientific-technical. Currently scientific-technical cooperation is provided by EUnetHTA Joint Action 2. Once EUnetHTA ends in October 2015, a new Joint Action on HTA could support the activities. No later than 2020 a suitable sustainable mechanism shall be identified to continue to support the scientific-technical cooperation.

The HTA Network[13] defines long-term-strategies, discusses general policies of cooperation and gives guidance and priorities on the work programme of the scientific and technical level. The scientific-technical cooperation[14] coordinates the exchange and the production of HTA information, including work on methodologies; it defines procedures and discusses scientific and technical aspects of HTA.

The governance system currently in place enables the strategic level to provide guidance, including in relation to prioritisation, to the scientific-technical level, without undermining its scientific independence. The HTA Network defines the strategic long term vision of the European collaboration and agrees on its work programme[15]. The technical-scientific level agrees upon its own work plan, in line with the strategic guidance received from the Network. A regular reporting mechanism shall be a key tool for ensuring synergies and consistency on the two levels of activities.

Stakeholders are associated with both the strategic and the scientific-technical level, with the appropriate modalities. The role of stakeholders' representatives shall be further defined to ensure that their involvement is fit for purpose and can efficiently and effectively contribute to the specific activities and the overall objective.

3.2. Financial sustainability

A successful European cooperation on HTA depends on demonstrating its benefits at national, regional and local level. It is expected that those Member States who do not yet have substantial HTA capacity and expertise as well as those who can within their national processes engage in joint work, would benefit from significant gains by systematically sharing know-how and feeding joint work into national HTA activities. Benefits may include reducing potential duplication of scientific work done individually by national or regional HTA bodies, increasing expertise through collaboration, increasing quality and production of national (and regional) HTA work, and maximisation of the benefits realised from invested resources.

To facilitate this it is necessary in the immediate term to continue to provide financial support for 'start up' costs, and to refine the process for joint work. This includes, for example, further development of IT tools, infrastructure and training

[13] Members of the HTA Network are the national authorities or bodies responsible for HTA nominated by the Member States.

[14] Members of the scientific-technical cooperation are the organisations or bodies performing HTA or using HTA to inform decision making with an explicit mandate at national or regional level. Members of the scientific-technical cooperation are also nominated by the Member States.

[15] Article 1, "Rules of procedure of the HTA Network" http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

activities. The funding could be provided under the Health Programme 2014-2020. The EC is planning to propose to Member States a new (third) Joint Action on HTA to enable this.

However, EU financial support cannot be taken for granted. It will only be useful if Member States will commit to joint work in a future Joint Action (in the areas of interest to them) and agree on a proposal for a sustainable model for the next phase of cooperation, once the Health Programme funding ends. According to the EU Financial Regulations[16], the Health Programme cannot fund recurring activities. Its support will be limited in time and cannot be extended beyond 2020. Other funding sources to support future cooperation at scientific-technical level shall be identified, for example the EU research funding under H2020 could provide opportunities to develop specific research challenges, however the best way to place this work on a long term sustainable footing is for the outputs to be useful and relevant to the Member States.

In the longer term scenario (after 2020) it is expected that scientific activities necessary to deliver joint work will continue to be carried out by national and regional HTA agencies or bodies. Administrative coordination and other supporting functions may be performed within suitable structures and possibly be supported by the EU budget.

The HTA Network shall reflect on and identify possible funding models and funding opportunities after 2020. The following shall be taken into account:

- The results and the experience gained by national and regional HTA bodies as a result of the current and a possible future Joint Action on HTA.
- The willingness of Member States to plan, budget and invest resources in specific activities of the cooperation, in kind or in cash.
- Scientific synergies and any efficiency gain which may be generated within different models (including consideration of reusing existing structures) to support and take forward the cooperation.
- The possibility of relying on different funding mechanisms for different activities and output of the cooperation, involving different players, as appropriate.

To implement the principles outlined above the HTA Network:

- **Commits to explore models for long term sustainability of the cooperation by considering relevant funding opportunities and by including joint work in national (and regional) HTA activities, as appropriate and in line with national requirements.**
- **Commits to be actively involved in preparing the proposed new Joint Action on HTA to strengthen the process leading to joint work and maximise the benefit of European cooperation.**
- **Calls upon the Commission to explore:**
    - **how to secure support for activities necessary to facilitate joint work at EU level on a permanent basis; and**
    - **how a range of models, including existing structures, could facilitate cooperation between HTA Bodies and create efficiency gains, scientific synergies as well as safeguard the scientific independence of the process.**

ANNEX 1: BACKGROUND

Health Technology Assessment (HTA) has become an important tool to aid decisions which involve difficult trade-offs and responses to innovation and sustainability of the health care system. Most national and local governments already use HTA to some extent for decision making for example, in the reimbursement and funding or guidance on the use of new and already existing medical technologies. However, this growing interest in HTA does not always seem in line with the limited HTA capacity available at the national and local government level. Moreover, there are indications that some of these initiatives at a national/local level show significant overlap, e.g. in terms of the topics looked at, on an international level. Therefore, there is a growing interest in international collaboration on HTA projects, in which sharing the experience, skills, tools and methodology, is an efficient way to improve quality and reduce duplication of HTA products. Additionally, this international collaboration may increase capacity to produce comprehensive high quality HTA information and the number of timely high quality national HTA reports, respecting the independence of national decision-making.

In Europe, collaboration in HTA has been ongoing for more than twenty years by EU co-funded projects which started to facilitate cooperation at scientific and technical level. Today, up to 2015, cooperation between national and regional HTA bodies is supported by the Joint Action EUnetHTA. EUnetHTA is active in producing and testing common tools for HTA and is placing significant priority in developing joint work that is expected to be taken up and used by interested national or regional bodies for their national decision-making.

To further strengthen the cooperation between Member States on HTA, the European Commission, in line with provision of article 15 of the Directive on Cross border care (2011/24/EU), set up the HTA Network. The HTA Network gathers national authorities responsible for HTA designated by the Member States and focus its scope of cooperation on strategic issues relevant to HTA.

The strategic level (HTA Network) and the scientific and technical level (JA) are synergistic c and complementary and shall continue to work in close cooperation to implement the vision outlined in this strategy paper.

ANNEX 2: NON EXHAUSTIVE OVERVIEW OF HTA COOPERATION INITIATIVES IN THE EUROPEAN AND GLOBAL CONTEXT

Considering the relevance of HTA as policy and scientific area of interest for decision makers and stakeholders, a number of cooperation and parallel initiatives are ongoing at regional, national European and global level. Here below is given a non-exhaustive overview of networks and initiatives which appear to be relevant for the activities of the HTA Network and can be characterized as:

Networks. An example is the Network of Competent Authorities on Pricing and Reimbursement, whose members are government organisations that are responsible for pricing and reimbursement of medicines. Some of their members are also partners in EUnetHTA and/or Members of the HTA Network. Another example is MEDEV, an informal network group under the umbrella of the European Social Insurance Platform (ESIP) whose members are HTA organisations and payers. This group is also involved in discussions on pricing and reimbursement of pharmaceuticals and many of their members are also partners in EUnetHTA. A further example is INAHTA, which is the international network of HTA in which members are HTA organizations from around the globe.

Scientific societies. The two most relevant international societies are HTA international (HTAi) and the International Society of Pharmacoeconomics and Outcomes Research (ISPOR). While the first society mostly focuses on HTA policy and ethical, social and organizational aspects of HTA, the focus of the latter is mostly around health economics and outcomes research, predominantly in the pharmaceutical domain. There is a memorandum of understanding between HTAi and EUnetHTA and collaboration is ongoing in a similar field as the collaboration with INAHTA.

Projects. Although there are many HTA projects that are nationally or internationally funded, some are of special interest for European collaboration on HTA. Firstly, there are four FP7 projects that deal with HTA on different levels (AdHopHTA, Advance_HTA, Integrate-HTA and MedTecHTA) and these already have some links to EUnetHTA. These projects address specific aspects of HTA, such as HTA for hospitals or medical devices. Another example is the MoCA project that addresses the life cycle of orphan drugs in which, amongst others, members of MEDEV participate. A third example is a project called GetReal that is funded by the innovative medicines initiative (IMI), which addresses the incorporation of real-life clinical data into drug development. This project focuses on the development of methodology for using data from daily practice for decision making in different phases of the drug life cycle.

Another initiative relevant to the HTA cooperation is the EU co-funded JA on patient registries (PARENT), as registries are known to be a useful tool to collecting patient data which can be used for HTAs activities.

ANNEX 3: GLOSSARY

AdHopHTA	FP7 project (http://www.adhophta.eu) that aims to strengthen the use and impact of excellent quality HTA results in hospital settings, making available pragmatic knowledge and tools to facilitate adoption of hospital based HTA initiatives.
Advance_HTA	FP7 project (http://www.advance-hta.eu) that comprises several complementary streams of research that aim to advance and strengthen the methodological tools and practices relating to the application and implementation of HTA.
Clinical domains	The first four domains of the HTA core model®: Health problem, description of the technology, safety and effectiveness
CSR	Clinical Study Summary Reports
Domains	The HTA core model® consist of nine domains indicating the different areas of assessments such as safety and effectiveness but also areas like organizational aspects, social and ethical aspects
Duplication of assessments	The POP database has clearly indicated that for many technologies, similar assessments are being performed within congruent time frames. Joint assessment work could for instance, help to decrease this duplication of assessments by the preparation of joint reports that may used in the interested Member States.
ECORYS study	Study providing an economic and governance analysis of the establishment of a permanent secretariat for the European Cooperation on Health Technology Assessment (http://ec.europa.eu/health/technology_assessment/docs/study_ecorys_european_cooperation_hta_en.pdf)
EHP	European Health Program (2008-2013). The Second Programme of Community Action in the Field of Health 2008-2013 came into force from 1 January,

	2008. The objectives are to improve citizens' health security; to promote health, including the reduction of health inequalities and to generate and disseminate health information and knowledge.
EMA	European Medicines Agency (http://www.ema.europa.eu/ema/)
ESIP	European Social Insurance Platform (http://www.esip.org)
EUnetHTA	European Network for Health Technology Assessment. It is a Joint Action, co –funded by the Health Programme of the European Commissions (DG SANCO) and participating organisations. It gathers mainly national and regional HTA bodies. Its scope of activities is on scientific and technical issues. www.EUnetHTA.eu
EUR-ASSESS	European project aimed at developing a coordinated approach to health care technology assessment in Europe (1994-1997)
EVIDENT database	The Evidence database on new technologies (EVIDENT Database) (http://www.eunethta.eu/evident-database) allows sharing and storage of information on reimbursement/coverage and assessment status of promising technologies and on additional studies requested or recommended further to a HTA.
FP7	EU's Seventh Framework Programme for Research (http://ec.europa.eu/research/fp7/)
GetReal	This IMI funded project aims to improve the incorporation of real-life clinical data into drug development
HTA	Health Technology Assessment (HTA Network) and referred to as such.
HTA Core Model®	The HTA Core Model® (http://www.eunethta.eu/hta-core-model) is a methodological framework for shared production and sharing of HTA Information.
HTAi	Health Technology Assessment International (www.htai.org) is the global scientific and professional society for all those who produce, use,

	or encounter HTA.
HTA Network	The Health Technology Assessment Network. It is a voluntary Network set up under Article 15 of Directive 2011/24. It gathers mainly Ministries of Health or competent authorities responsible for HTA, appointed by Member States. Its scope of activities is on strategic issues. http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm
HTA report	An HTA report is an independent, objective, and transparent collection of HTA information to inform policy. Depending on the specific context, it may address all aspects (domains) within the HTA process.
IMI	The Innovative Medicines Initiative (www.imi.europe.eu) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.
INAHTA	The International Network of Agencies for Health Technology Assessment (http://www.inahta.org/) is a non-profit organization that was established in 1993 and has now grown to 57 member agencies from 32 countries including North and Latin America, Europe, Africa, Asia, Australia, and New Zealand.
INTEGRATE-HTA	FP7 project on Integrated health technology assessment (http://www.integrate-hta.eu). This project aims to develop concepts and methods that enable a patient-centred, comprehensive assessment of complex health technologies.
ISPOR	The International Society for Pharmacoeconomics and Outcomes Research (www.ispor.org) promotes worldwide the science of pharmacoeconomics (health economics) and outcomes research
IVD	in vitro diagnostics
JA	Joint Action. A Joint Action consists of activities carried out by the European Union and one or more Member States or by the EU and the competent

	authorities of other countries participating in the Health Programme together.
Joint work	Activities in which countries and/or organisations work together in order to prepare shared products or agreed outcomes. These may include, for example, literature reviews, structured information for rapid or full HTAs, early dialogues or scientific advice on R&D planning and study design. Joint work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enable an effective exchange of this information.
MEDEV	The Medicine Evaluation Committee (http://www.esip.org/files/pb51_0_0.pdf). This is informal network group under the umbrella of ESIP which members are HTA organisations and payers. This group is also involved in discussions on pricing and reimbursement of pharmaceuticals
MedTecHTA	FP7 project (http://www.medtechta.eu/) that aims to improve the existing methodological framework within the paradigm of HTA for the assessment of medical devices, and to develop this framework into a tool that provides structured, evidence-based input into health policies
MoCA	Mechanism of Coordinated Access to Orphan Medicinal products (http://www.eurordis.org/content/moca). This project seeks collaborative ways to identify and assess the added value of orphan medicinal products.
MWP	Multi-annual Work Programme
PAES	post-authorization efficacy studies
PARENT	The objective of the PAtient REgistries iNitiaTive (http://www.patientregistries.eu) is to support EU Member States in developing comparable and interoperable patient registries in clinical fields of identified importance (e.g. chronic diseases, medical technology). The aim is to rationalize the development and governance of interoperable

	patient registries, thus enabling the use of secondary data for public health and research purposes in cross-organizational and cross-border setting.
Parallel early dialogue/scientific advise	At the same timepoint/location, but not necessarily together, scientific advise of regulators and HTA organisations on the prerequisites for phase III trials that are going to be initiated by the manufacturer for market registration and reimbursement
Pre-marketing and post-marketing phase	Before (pre-) and after (post-) the market authorisation of a new pharmaceutical
POP database	The EUnetHTA Planned and Ongoing Projects (POP) database (http://www.eunethta.eu/pop-database) allows HTA agencies to share information with each other on planned and on-going projects conducted at the individual agency. The aim of the database is to reduce duplication and facilitate collaboration among HTA agencies.
SAG	Stakeholder Advisory Groups. Advisory groups of experts from different stakeholders providing advice on different activities in EUnetHTA. These groups are always active before public consultation
Stakeholder Forum	Forum of stakeholders that provide structural input in EUnetHTA. The stakeholder forum has members from four important groups: patient and healthcare consumers, healthcare providers, payers and industry
Scientific/operational level	In the paper this concept is represented by European Network for Health Technology Assessment (EUnetHTA) and any possible future Joint Action and referred to as such.
Strategic level on HTA	In the paper this concept is represented by the Health Technology Assessment Network