EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

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MULTIANNUAL WORK PROGRAMME 2014-2015

ADOPTED AT THE 1ST HTA NETWORK MEETING, 16 OCTOBER 2013

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1. OVERALL OBJECTIVE OF THE HTA NETWORK

The overall objective of the HTA Network is spelled out in Article 15(2) of Directive 2011/24.

- *Support cooperation between national authorities or bodies responsible for HTA*
- *Support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;*
- *Support the analysis of the nature and type of information that can be exchanged;*
- *Avoid duplication of assessments*

In line with Art 15(7) of Directive 2011/24, measures adopted to implement this MWP shall not interfere with Member States' competence in deciding on the implementation of Health Technology Assessment conclusions and shall fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care.

2. STRATEGIC WORK PLAN 2014-2015

2.1. Overall aim for the programming period

Develop a vision on the long-term provisions for HTA cooperation in the EU

Rationale: The EU has been supporting cooperation at scientific level between national authorities responsible for HTA since the 1990s. Such support has enabled HTA Agencies to build trust about respective working methods, to create a common framework of work (common ICT tools and common framework e.g. the HTA core model) and start doing joint work.

In its last phase of EU-funded cooperation the focus of scientific cooperation is on implementing the common framework and increasing piloting joint work.

To build on results achieved so far and to develop a longer term vision, the HTA network should notably:

1. Agree on the scope of EU cooperation both on the technologies (e.g. pharmaceuticals, medical devices, diagnostics, screening, complex interventions) and the HTA domains to be addressed (clinical domains only or to include other domains such as economic evaluation and organisational aspects [1]).

[1] as defined by the HTA Core Model

2. Agree on how a permanent cooperation mechanism at EU level, consisting in both a strategic and scientific level can be implemented, and address its financial sustainability after the EU funding from the forthcoming health programme is ending.

3. Reflect on new ways of delivering existing and innovative health technologies and health care services that contribute to value.

2.2. Specific tasks

a) Adoption of a position paper on long term provisions of EU cooperation on HTA, including recommendations for priority areas to be addressed by the scientific and technical cooperation mechanism (post 2015)

Timing: first draft 1st half 2014, adoption 2nd half 2014

Rationale: to bring further EU cooperation on HTA it is essential to define and agree on the strategic directions including the scope and ambition of EU cooperation. Such strategic directions should also provide recommendations on priority areas to be addressed by the scientific and technical cooperation in the development of a possible third Joint Action. The possible new JA should continue to facilitate cooperation at scientific and technical level between HTA authorities and other relevant players after the EUnetHTA contract ends.

b) Adoption of a reflection paper on the conditions to facilitate take up and re-use at national level of joint HTA production including information and joint assessments

Timing: 1st half 2015

Rationale: EU cooperation on HTA has shown that joint work is not used at national and regional level as much as it could be. This issue has to be addressed both at strategic level and at scientific and technical level. The objective of such activities would be to provide recommendations to the scientific and technical cooperation on what is necessary to enable competent authorities to increase re-use of joint HTA work at national/regional level.

In addition, to increase the number of joint pilots, specifically in the domain of pharmaceutical rapid assessments, it is necessary to encourage industries to take part in joint work and to encourage national authorities to promote such joint work.

c) Adoption of a reflection paper on the interaction between regulatory and HTA issues

Timing: 2nd half 2015

Rationale: Currently the different phases enabling patients to access new technologies, from research to regulatory approval, and pricing/reimbursement are carried out independently and are not sufficiently coordinated.

This often results in different requirements from different regulatory authorities (EU or national) and HTA bodies, and may delay access to treatment. While specificity must be maintained to meet the objectives of each phase, more synergy and de-fragmentation should be achieved. This would not only speed patient access to potentially innovative technologies, but also contribute to increase the business predictability and the reduction of administrative hurdles, both for public regulators and technology developers, while safeguarding the criteria applied for placing technologies on the EU market. Activities in this direction are on-going, the reflection paper will take these into account.

2.3. Possible other tasks

Discuss the involvement of all interested working parties in the HTA process, notably patients, health professionals, managers, and payers.

Discuss or provide input on research needs for HTA, under and outside the H2020 EU research programme. Facilitate, as appropriate, take-up and dissemination of results of EU and non EU initiatives in the area of HTA, including from international organisations.

Provide input on HTA issues in relation to the EU Semester Agenda.[2]

[2] The EU Semester Agenda is a yearly cycle of economic policy coordination lead by the EU Institutions to support Member States in their efforts to meet Europe 2020 targets and implement growth-enhancing policies. AS part of this process the each year the European Commission undertakes a detailed analysis of EU Member States' programmes of economic and structural reforms and provides them with recommendations for the next 12-18 months. Health care is part of the European Semester.