



# **Working with health in DG Sanco**

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# Presentation outline

- DG Sanco and health in the EU
  - Unit C5 tasks
  - Health technology assessment
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# DG Sanco – Health and Consumers

- One of appx. 25 Directorate-Generals
- DG Sanco “serves” Commissioner John Dalli (MT)
- Responsible for consumers, food safety and health

# Health in the EU

Treaty on the Functioning of the European Union Article 168, 7:

Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care... [included] the management of health services and medical care and the allocation of the resources to them.

# Still EU legislation on...

- Medicinal products
- Medicinal products
- Quality and safety of blood, tissue and cells
- Patient rights in cross-border healthcare (under negotiation)

## Unit C5 – a coordination unit

- Appx. 25 staff, including 3 national experts
- Coordination of media work in the field of health
- Coordination of cross-unit requests (briefings to Commissioner etc.)
- Coordination of the Health Strategy

## C5 – Policy areas (i)

- Patient safety and quality of care
  - Support Member State cooperation to improve quality of health services and increase patient safety
- Health workforce
  - Mobility of health personnel
  - Ensuring sufficient workforce for the future

## C5 – policy areas (ii)

### ■ Regional cooperation

- Ensure a holistic health aspect in EU regional policies (e.g. structural funds)

### ■ eHealth

- Make our ICT systems interact better
- Make eHealth solutions contribute to cost-effectiveness and patient safety

### ■ Health technology assessment (HTA)

- (More later)

## C5 – policy areas (iii)

- Directive on patient rights in cross-border healthcare
  - 2nd reading in Council and Parliament
  - Purpose: Codify rulings in the Court
  - Systems for reimbursement of costs from treatment in other EU countries
  - Regulating what kind of treatment entitles to reimbursement

# Health technology assessment

- Healthcare technology is defined as, i.e:
  - prevention and rehabilitation
  - vaccines
  - pharmaceuticals and medical devices
  - medical and surgical procedures
  - the systems within which health is protected and maintained
- Health technology assessment (HTA) is an approach to evaluate the relative effect a given health technology has on a medical condition:
  - Is the technology effective?
  - For whom does it work?
  - What costs are entailed?
  - How well does it work compared to alternative technologies?

## HTA is used for...

- **Pharmaceuticals:** 15-20% of overall health care budgets but 80% of all HTA's produced. HTA methodologies are rather well elaborated.
- **Medical devices:** the efficacy depends not only on the device itself, but on how it is used. HTA methods are complex
- **Other health interventions:** only ad-hoc HTA methods

# European cooperation on HTA

- HTA cooperation supported by the EU since 2006
- Based on voluntary involvement of Member States
- Norway active in this cooperation through Kunnskapssenteret for helsetjenesten

# The status for HTA in Europe

- Difference in knowledge: From advanced use (such as UK) to non- or re-use (such as small MS)
- Overlap: A number of HTA's in MS concern the same technologies, but efforts are not coordinated
- Duplication of efforts: Could not measuring relative efficacy and effectiveness be done jointly?

# Commission's overall goals on HTA

- HTA= patients' satisfaction, costs containment, reward for innovation
- All health technologies should be covered – not just "products"

## Overall goals (2)

- Provide decision makers, health professionals and managers, patients with robust scientific evidence on technologies
- Reduce duplication of work for MS
- Reduce the national hurdles to market access faced after licensing
- Support MS with little HTA capacity

# Specific goals on HTA

- Develop core HTA methodologies, focusing on the clinical parts
- Facilitate and accelerate the decision-making processes on pricing and reimbursement/ uptake/ access (relative efficacy of technologies)
- Collect long-term and cross-border data on effectiveness of health technologies

## Specific goals (2)

- Promote the early dialogue (scient. advice) between sponsors and HTA bodies/ payers during the tech. development process
- Increase the stakeholders' capacity to contribute to HTA's
- Establish clear and transparent stakeholders' involvement rules

## Specific goals (3)

- What is not a primary objective of the HTA cooperation:
  - Consider costs/ societal perspectives
  - Effective market access all over the EU
  - Developing clinical guidelines

# 1st Joint Action EC/MS EUnetHTA

- Period: 2010-2012, 24 MS
- Budget: 6 Mio € (50 % supported by EU)
- EUnetHTA's objectives:
  - To further develop the "core HTA" methods
  - To develop specific methods on relative effectiveness assessment of pharmaceuticals + improvement of EPAR's
  - To conduct horizon scanning of new tech.
  - To set up an information management system + long term business model
  - To set up a policy on stakeholder's involvement

## 2nd Joint Action 2012/ 2014?

- Overall objective: need for better knowledge/ feedback on opportunities and limitations to joint HTA production
- Production of joint HTA's + core HTA's (early assessments of pharma + MD)
- Increase capacities of stakeholders
- Test real life governance of the cooperation + collect info on costs and organisational matters
- Total budget: up to 7 Mio €

# The proposed directive on cross-border health care (CBHC)

- Art. 14 □ From project-based to permanent cooperation on HTA
- “The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States.
- The members of the network shall participate and contribute to the network’s activities according to the legislation of the Member State where they are established”.

# State of play of the directive

- First reading finished in EP and Council;  
2nd reading autumn 2010
- The issues at stake on HTA cooperation
  - Scope of the work: relative efficacy versus effectiveness?
  - How binding should the conclusions be?
  - How much money are MS/ industry ready to contribute? Impact on the HTA production?
  - Degree of stakeholders' involvement?
  - Decision making process

# Governance of the cooperation

## ■ What is taken for granted is:

- MS HTA bodies will do the work
- HTA process should remain separate from the regulatory process

## ■ Reflection process on the structure:

- EC/ MS coordination and hosting
- Decision making process/ CAVOD may help
- Capacity to cover all and cross technologies
- Build on existing synergies, expertise and other regulatory requirements (PRAC)
- Cost/ efficiency of the structure itself

# Conclusions

- HTA part of the overall EU strategy on innovation
- There is a strong added value in considering HTA at EU level:
  - Pooling of expertise
  - Minimised duplication of efforts
- Final objective is not harmonisation of the decisions. But some standardisation may be agreed between MS.

## Conclusions (2)

- Stakeholders' involvement is a key success factor of cooperation at EU level
- All actors involved need to explore new ways of working together. Defragmentation is needed.
- A sustainable cooperation is needed. Long term solutions are currently being evaluated.