EU HTA cooperation answering national needs

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Key points

- Governance of medical devices expenditures: what we have learnt
- The new Italian HTA organization and the relationship with the HTA Network and EUnetHTA
- Conclusions

It has been a long road …

The starting point

Governance of medical devices expenditures (1/3)

In Italy, the medical device sector represents **0,7% of GDP** and it is a relevant expenditure in the public health.

In this framework for several years, the Ministry of Health has been conducting a regulatory pathway aimed at delivering timely verification tools for monitoring and control of expenditure.

Governance of medical devices expenditures (2/3)

The Financial Law 2003 established the Committee for Medical Devices (CUD) with the following task:

- create a national database
- design a national classification of medical devices (CND) in order to establish reference prices for medical devices

Governance of medical devices expenditures (3/3)

The 2006 Financial Law

- defines the procedure for manufacturers to register medical devices into the national database
- establishes procedures for the National Health System to communicate medical devices consumptions

The 2007 Financial Law

- empowers the CUD to elaborate a list of MDs whose expenditure represents more than 50% of the global expenditure for MDs;
- based on this list, the Ministry of health is set in charge of defining NHS contracts
- the CUD was empowered to set up studies of appropriateness of use of specific MD categories, as well in terms of cost-comparison vs. adequate alternatives. The results of these studies were to be published in the Ministry of health website

Reference prices Ministerial decrees

- D.M. 11/10/2007
- D.M. 25/01/2008
- D.M. 15/04/2008
- D.M. 17/02/2009

They establish reference prices to be used by the NHS as baseline of call for tender for procurement of defined categories of medical devices

A lesson learnt…

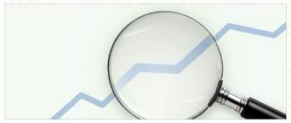
Reference prices

- are difficult to determine, if we take the several variables (training, maintainance, timeframe of payment, etc.) into consideration
- become obsolete soon
- do not allow to discriminate between high and low quality medical devices
- do not support innovation

The next step

A useful tool has been set up

THE FRAMEWORK



The medical device sector represents **0,7% of italian GDP**

THE TARGET

To provide the tools for monitoring and governing of the public expenditure on medical devices

THE TOOLS

- Repertory on Medical Devices
- Information Flow on consumption of medical devices which are directly purchased by NHS
- Income Statement

THE RESULTS ACHIEVED

At the moment Italy, is one of the few Countries which can count on structured information about procurements and expenditure for medical devices used by the NHS

A new direction

Going towards a national HTA programme

- The National Health Plan (PSN) 2006-2008 recognizes the value of HTA for medical devices
- In 2009 a Technical committee for the governance of medical devices expenditures was established. The Committee foresees the participation of representatives of the Ministry of Health, the Ministry of Economic Development and of the stakeholders in order to
  - elaborate proposals to overtake reference prices
  - present medium and long-term solutions such as a procurement observatory and implementation of HTA

In 2009 the first HTA and HS reports are published in the MoH website

- HTA reports are elaborated by AGENAS
- They are the results of the work of different actors
- The primary aim is to provide NHS with solid evidences for an appropriate resources allocation

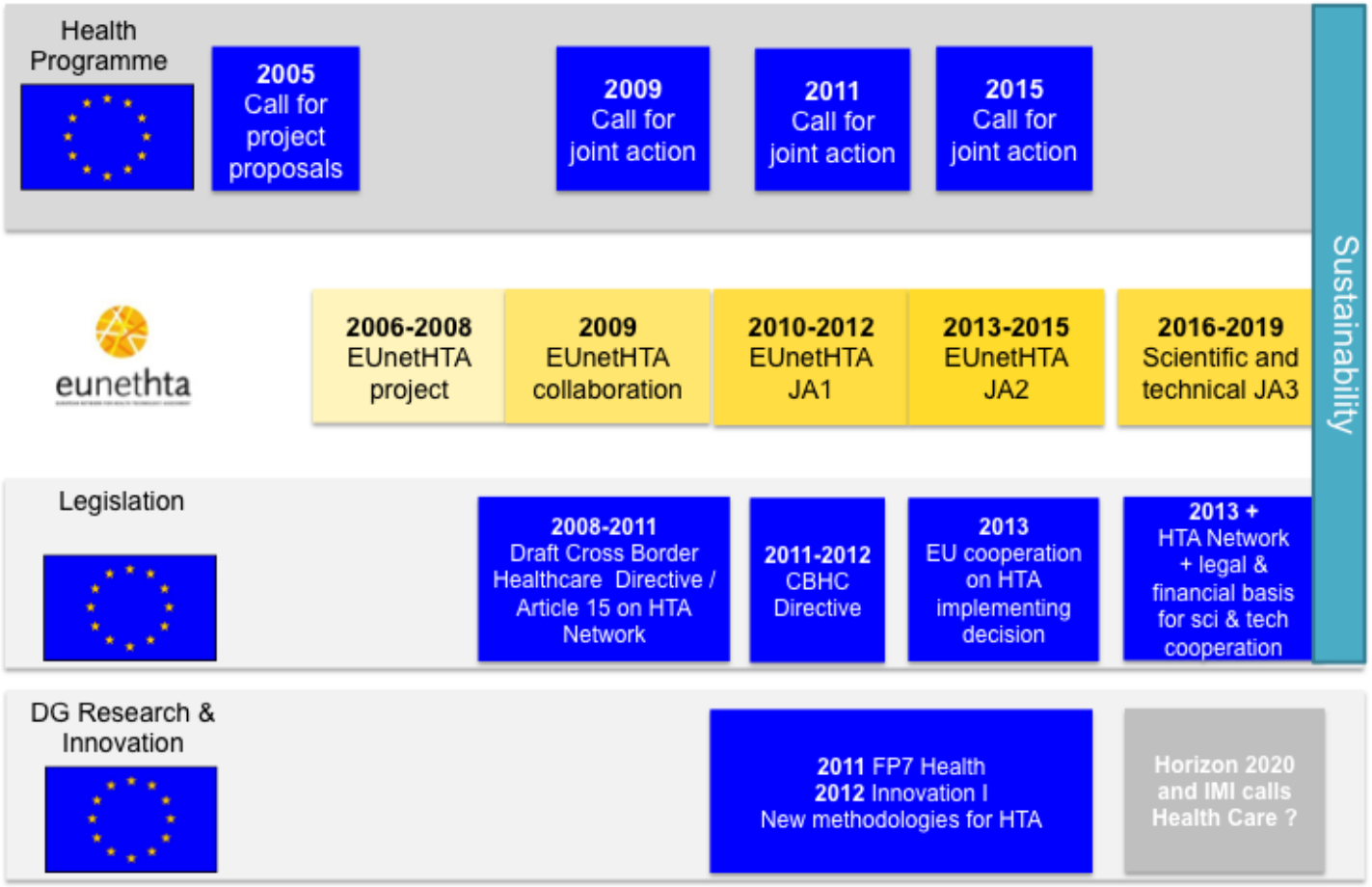
HTA: the Ministry of Health website

Publications

- ✓ 17 HTA (Full, Rapid, Adapted)
- ✓ 4 Systematic reviews
- ✓ 17 Horizon Scanning Reports
- ✓ 1 Finding investigation

The new Italian HTA organization and the relationship with the HTA Network and EUnetHTA

10 years of HTA collaboration in EU



In 2013 in Europe…

The HTA Network is established

…while in Italy

Health Pact (Patto per la salute) 2014-2016

- Article 26 foresees the establishment of an institutional model of HTA for medical devices in order to implement article 15 of Directive 2011/24/EU and to foster the use of cost-effective medical devices

- foresees the establishment of «Cabina di Regia» (a control room) a sort of national Steering Committee

Ministerial Decree March 12, 2015

- The *Cabina di Regia* is established at the Ministry of Health
- It is composed of:
  - Director General of medical devices and pharmaceutical services with the role of Chair
  - Director General of health planning
  - Director General of digital development, health IT systems and statistics
  - 1 representative of the Agency for the relationships State-Regions (AGENAS)
  - 1 representative of the Italian Medicines Agency (AIFA)
  - 8 representatives from Regions
  - Secretariat

The Cabina di Regia tasks

The Ministry of health plays a "strategic" role at central level for medical devices governance in:

- managing relationships with stakeholders both at European and at national level, with associations representing patients, citizens, manufacturers and clinicians
- defining a uniform methodology
- defining priorities
- evaluating the evidence gathered to formulate policies, guidelines, recommendations on medical devices
- monitoring the effects of recommendations implementation, using tools developed in recent years such as the flow of medical devices procurements at local level

… last but not least

The Innovation Working Group

- An informal technical group has been established
- It is composed of **stakeholders** (representatives of regions, universities and research centers, scientific and patient associations as well as representatives of manufacturers)
- The Innovation Working Group has an advisory role and participates in the preliminary phases of the discussion, supporting the definition of methodological and procedural guidelines and, when the system will be fully operational, taking part in the appraisal phase or elaboration of recommendations.

The National HTA Programme

The Cabina di Regia and the Innovation Working Group have the role of setting the strategic-political orientation of national HTA and of supporting the National HTA Programme through concrete proposals, on the basis of skills, knowledge and experience of its members respectively.

2016 Financial Law - Article 31

The *Cabina di regia* will:

a) define priorities for multi-dimensional medical devices assessment based on relevance of health problem as well as safety, effectiveness, economic and organizational impact of medical devices, in line with European guidelines (EUnetHTA);

b) promote and coordinate the activities of multidimensional assessment performed by Age.Na.S.

c) validate methodological criteria to be used for the production of multidimensional reports in the National Programme of HTA

d) manage publication, dissemination and evaluation of impacts at national level of outcomes referred to in point b) according to validated methods referred to in point c) in order to promote their use by the regions and health agencies to inform decisions on the adoption and introduction of medical devices and the divestment.

Conclusions

- In Italy the governance of medical devices has been so far a long and a tortuous pathway.
- A new organization providing the Ministry of health with a central and strategic role has been established.
- In this framework the relationship of the *Cabina di Regia* with the HTA Network and EUnetHTA will be crucial.
- The goal is to have sustainable national health systems within Europe.

The secret of getting ahead is getting started

Mark Twain

Thank you for your attention!