MedtecHTA Final Conference
Bocconi University
November 13°, 2015

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Why do we need HTA?

- Technological innovation in healthcare is a key determinant of **better health outcomes** but also a driver of **healthcare expenditure**.
- Governments struggle to keep a fair balance between patients' **access to modern care** and **economic sustainability** of healthcare systems.
- **Health Technology Assessment** (HTA) provides policy-makers with **evidence-based information** that help formulating health policies that are **safe**, **effective**, **patient-focused** and **cost-effective**, balancing access to innovation and cost containment.

The European context

- In the European Union there is a diffused and growing awareness that **governing the introduction of new technologies** is key to **improve citizens' health**.
- The European Union supported and facilitated **cooperation on HTA** through the Directive 2011/24 (article 15), which established the **HTA Network**, a voluntary network gathering all **Member States** and several **stakeholders** (industry, payers, providers and patients)
- The HTAN has already worked on the adoption of:
  - a position paper on Strategy for EU Cooperation on Health Technology Assessment (October 2014)
  - a reflection paper on Reuse of joint work in national HTA activities (April 2015)
  - a reflection paper on the interaction between regulatory and HTA issues (in second half of 2015).

HTA in Italy today

The future of HTA in Italy

- National Health Pact 2014-2016 (art. 26), «Creation of an institutional model for HTA of medical devices» aimed to:
  - Promote the use of cost-effective medical devices that generate value for the system.
  - Coordinate different government levels (i.e., national, regional and hospital) in order to keep system's unity and equal access to all patients through the:
    - Definition of priorities, establishment of a "Cabina di regia" (Steering Committee) chaired by the Ministry of Health, involvement of stakeholders (e.g., patients, citizens, clinicians, industry).
    - Provision of information supporting tenders for medical devices procurement.
    - Promotion of a National Programme of HTA for medical devices

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"'s 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

The Innovation Working Group

- An informal technical group has been established called **"Tavolo Innovazione"** (Innovation Working Group)
- It is composed of stakeholders representatives of regions, universities and research centers, scientific and patient associations as well as the industry
- 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 Plan for HTA

Cabina di Regia (MoH)

- Policy
- Priority setting
- Final recommendations

- MoH
- Italian HTA Agency

Advisor

Tavolo Innovazione

- Technical skills
- Methodological guidelines
- Procedural guidelines

- Regions
- Patients
- Clinicians
- Industry
- academia

Conclusions

- The Italian Ministry of Health has a strong will to promote an effective HTA national programme, that guarantees fast access to innovation, appropriateness in the use of resources and equity across the nation.
- It's time to give to HTA a central role and to overcome the current fragmented situation*
- The establishment of such a programme requires the implementation of the most advanced methods, that must be uniformly shared among all actors involved in HTA.
- MedtecHTA is the «perfect fit» and comes timely
- Therefore, I welcome this valuable initiative, whose results and recommendations will certainly inspire us.

*Ciani, Tarricone, Torbica. Health Policy 2012

Thank you!