HAUTE AUTORITÉ DE SANTÉ

Innovative health technologies: criteria and incentives in France

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HAS
France

HAS HTA Division

- Assessment of pharmaceuticals
- Assessment of medical devices
- Assessment of diagnostic and therapeutic procedures
- Assessment of public health programs and health-economics
- Methodological support Unit

➢ How to identify really innovative technologies?

Innovative health technologies: Actions

- **Aim: early access when appropriate**

- **Supportive measures**
  - Anticipated assessment (Fast track)
  - Coverage with evidence development
  - Under development: Scientific advice

Innovative health technology Criteria

- Therapeutic or diagnostic innovation

AND

- Clinical benefit for the patient

Therapeutic innovation

Pharmaceuticals

- **New treatment modality (one of the following)**
  - New therapeutic class
  - New mechanism of action
  - New target population
  - New formulation/modality of administration

Medical devices

New technology (« breakthrough »)

Therapeutic or diagnostic innovation

Medical or interventional procedures

Impact on the organisation or the structure of patient care, benefit for professionals (one of the following) :

Significant modification of:

- the carrying out of the procedure (technical skills, duration, mental effort)
- the technical environment and organisational aspects (staff, equipment, organisation of care delivery) necessary for the carrying out of the intervention
- staff training (theory and practice)

Clinical benefit for the patient

- HT that meets (in the context of use)
  - an unmet medical need, or
  - medical need for a serious, life-threatening and/or chronically debilitating disease, insufficiently covered by existing therapies
- Important « added therapeutic value » : improvement over existing methods in the treatment of target population in terms of safety, efficacy, or easier access to the technology
- Compensation of handicap/improvement of HRQoL

Innovation
Supportive measures

- Accelerated assessment (Fast Track)
- Coverage with evidence development (MDs, procedures, combined products)
- Scientific advice for potentially innovative HT

Accelerated assessment (fast track)

- **Assessment of technology (drug or MD) to start at an early stage**
  - Before granting of CE mark for devices, before CHMP opinion for drugs
  - Parallel assessment processes
  - Allows to publish HAS guidance simultaneously to marketing approval (CE mark or Marketing Authorisation)

CED in France

- New Law entered into force in March 2010
  - Concerns innovative MDs and interventional procedures
  - Temporary ad hoc coverage
  - Limited diffusion of the technology (list of centres)
  - Additional evidence generation
- Six HTs were considered innovative by HAS, CED proposed
  - Based on the definition of therapeutic innovation for MD and procedures
  - Based on limited data indicating potential clinical benefit and absence of an important risk shown on short-term surrogate and intermediate endpoints
- Decision pending.

Scientific advice

- Pilot phase currently ongoing at HAS for innovative HTs (drugs, MDs, procedures)
  - Influence the generation of more adequate and better quality data for future submission
- Role: review and advice on:
  - development program in general,
  - minimal data set for considering CED
  - design of confirmatory trial
- Pilot parallel scientific advice with HTA agencies and EMA (drugs)

Future challenges

- Scientific advice
  - Decision to be taken by HAS Board
  - Fees for service?
  - International coordination (EUnetHTA, EMA)
- Implementation of CED for innovative MDs and procedures
- International cooperation: EUnetTHA Joint Action 1 and 2

Thank you for your attention

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