



HAUTE AUTORITÉ DE SANTÉ

Keeping track of rapidly developing technologies

The French experience

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Haute Autorité de santé (HAS)

Introducing new technologies: what is at stake?

=> Making Price and Reimbursement (P&R) decisions in a context of:

- greater uncertainty and incomplete information (both on medical and economic dimensions)
- greater pressure from manufacturers and patient-groups to rapidly introduce new technologies into the healthcare system ...

Introducing new technologies: what is at stake?

... **While measuring the risks of inappropriate decisions :**

- Excessively delaying potential benefits to patients
- Introducing technologies that will turn out to be inefficient, not cost-effective or with a low benefit-risk ratio

The two main trade-offs facing decision-makers

- Reducing risk of inappropriate decisions,
... without unduly delaying access.
- Rewarding truly innovative technologies,
... while keeping within the Nation's health care budget

Flexibility and responsiveness

- Evaluate the technology over the whole life-cycle rather than focus on pre-market assessment
- Recognise need for 'extraordinary need technology' without lowering assessment standards
- Early dialogue with industry on research needs and data collection

Monitoring

- Ensure availability of information at all stages to allow evidence based decision-making
- Introduction of innovations under conditions with agreement by all stake-holders
- Exchange of information with other countries in view of the global nature of the market and its regulation

Background on the French health care system

- General coverage of health products and services for all
 - Freedom of choice (patients and professionals)
 - Fee for service payment
- Coverage decision is the most important lever for introduction and generalization of new technologies in France since prices are increasingly set internationally

A four step procedure for new technologies

- Marketing authorization (drugs) – EC marking (medical devices)
- Assessment of expected and actual clinical benefits (HAS) with cost-effectiveness studies for some technologies
- Price negotiation
- Coverage decision

1. Temporary authorization for use (ATU) for :

- An innovative drug for a severe disease
- for which there is no effective treatment
- in public and private hospitals,
- even before a market authorization has been granted

Condition: a clinical trial must be under way

=> Example : Protease inhibitors for HIV patients in 1996:
introduction nearly one year before other countries

Potential risks

- No clinical and cost effectiveness assessment by HAS
- P&R revisions at end of temporary period are made more difficult since technology already in use!
=> recent legal provision allows such revisions

- Reimbursement granted temporarily for a drug with MA
- but with evidence of benefit in a new indication

Condition : use within protocol in hospitals.

=> Example: Herceptin ® as adjuvant therapy for breast cancer

Potential risks

- Introduction without assessment in the new indication
- but within a well defined protocol of limited duration and with data requirements
- Final decision based on the collected data when available

- Coverage for potentially innovative procedures conditioned on prospective data collection
- Strict monitoring of use (within a limited number of institutions) before generalisation
- May influence end of product development phase
- Mechanism defined jointly by HTA producer (HAS) and payer

- Can be requested from manufacturers at the time of expected benefit assessment
 - Aim: to provide data on use in real-life conditions including efficiency and equity of access
 - Request included in the contract signed between firms and CEPS after price negotiation
 - 112 requests – 41 drug companies since 1997
 - Results analysed at the time of re-assessment of *actual* clinical benefits (coverage decision every 5 years for drugs)
- Allows confirmation or modification of decision initially based on the *expected* clinical benefits

- Provides manufacturers guidance on the type of data needed for the coverage decision (advice on development plan)
 - Increases quality of data submitted for coverage and price decisions
 - May be determinant for a future technology's market and socially useful in identifying relevant gaps
- Risk : Some risk-sharing could be implicitly assumed by firms although scientific advice from HAS bears no commitment value

- **In general, these mechanisms were first developed for drugs**
- **They are currently being adapted for medical devices and for new diagnostic and therapeutic procedures**
- **In addition to these measures, there are :**
 - research programs to finance development stages of selected innovations
 - Volume control mechanisms based on contracts either between hospital and regional hospital agencies (ARH) or between health professionals and national health insurance funds.

Decision makers are pushed to take decisions increasingly early

- Yet unconditional introduction is costly for society (see initial trade-offs)

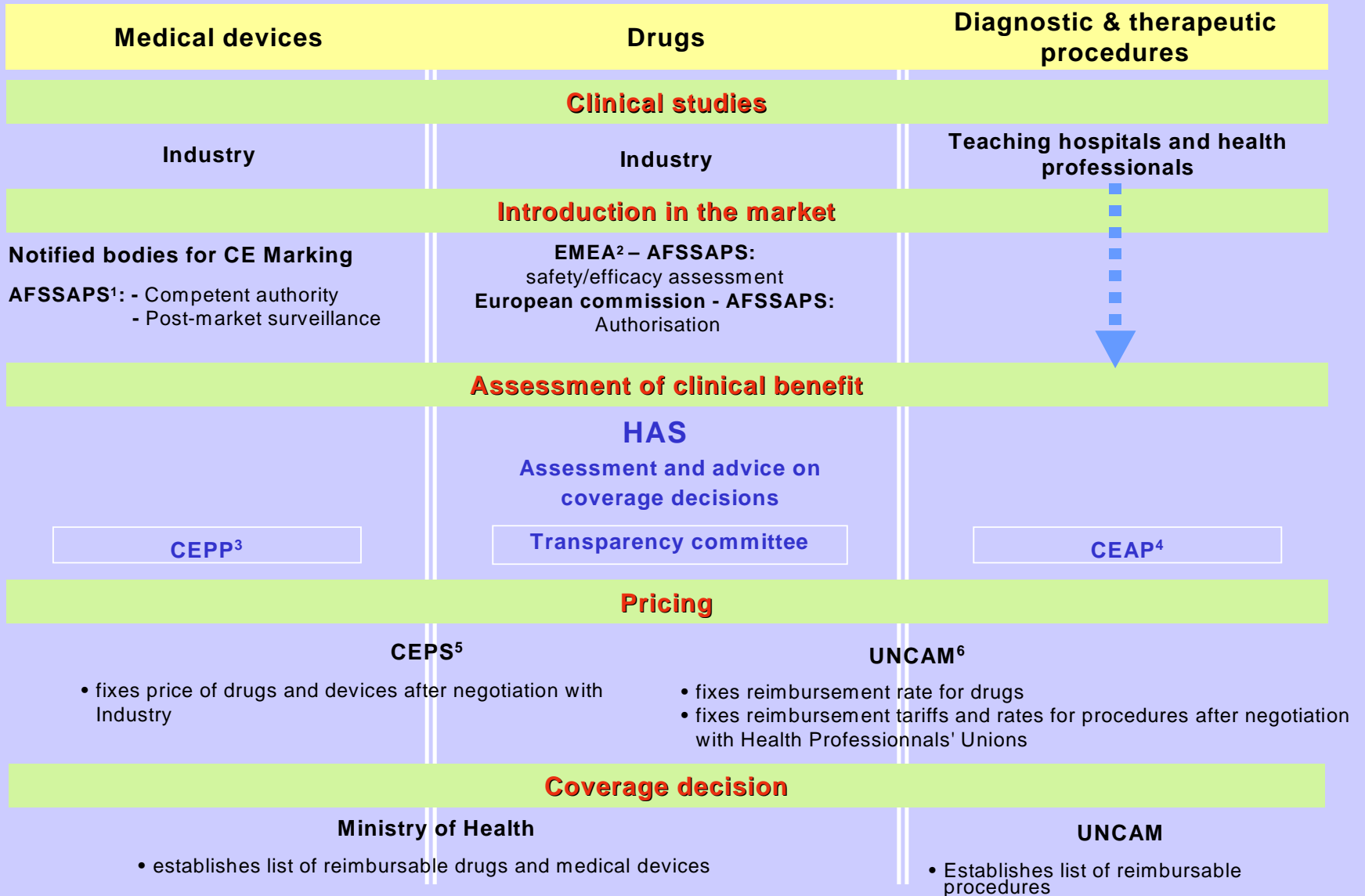
Response

- Various facilitating and conditional mechanisms set up to deal with uncertainty

Conditions for success:

- Involvement of all stakeholders and agreement on conditions
- Clear definition of responsibilities between agencies involved in the marketing, pricing and coverage decisions
- High quality HTA at all stages of the decision making process

- 1. Contribute towards harmonizing HTA methodologies and assessment tools (EUNetHTA project) and help define high performance instruments for data collection**
- 2. Help in the definition of truly innovative technologies**
- 3. Encourage use of HTA by decision-makers of all Member States**
- 4. Enhance experience sharing among MS to avoid waste of time and resources in assessment process**



1. AFSSAPS: French Health Products Safety Agency; 2. EMA: European Medicines Agency; 3. CEPP: Committee for the assessment of medical devices; 4. CEAP: Committee for the assessment of diagnostic and therapeutic procedures; 5. CEPS: Committee for pricing and reimbursement of healthcare products (reports to the Ministry of Health, Industry and Finances); 6. UNCAM: Association of National Health Insurance funds