



HAUTE AUTORITÉ DE SANTÉ

Haute Autorité de Santé and the evolution and impact of HTA in France

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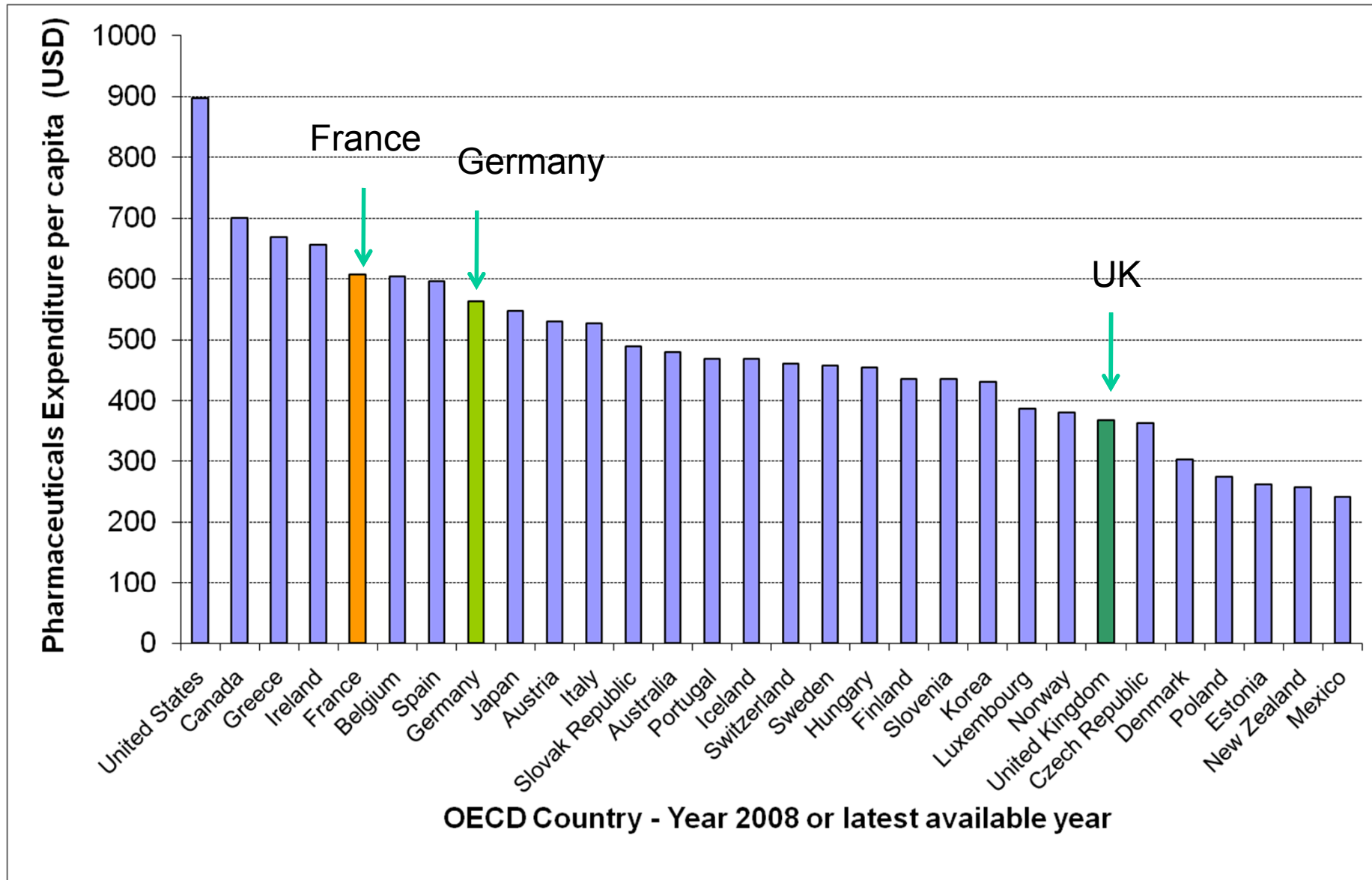
The French Healthcare system in a nutshell

- **Unitary centralized state**
- **NHI**
 - Mandatory, coverage (up to 65%) for the entire population
- **Supplementary Health Insurance:**
 - 90 percent of the population subscribe to supplementary health insurance
- **Pharmaceuticals :**
 - Positive list of reimbursed products
 - Supplementary insurance : 100% reimbursement rate for all listed drugs, no money to be paid to pharmacist in most cases
 - Possible off-label use in rare or chronic severe diseases

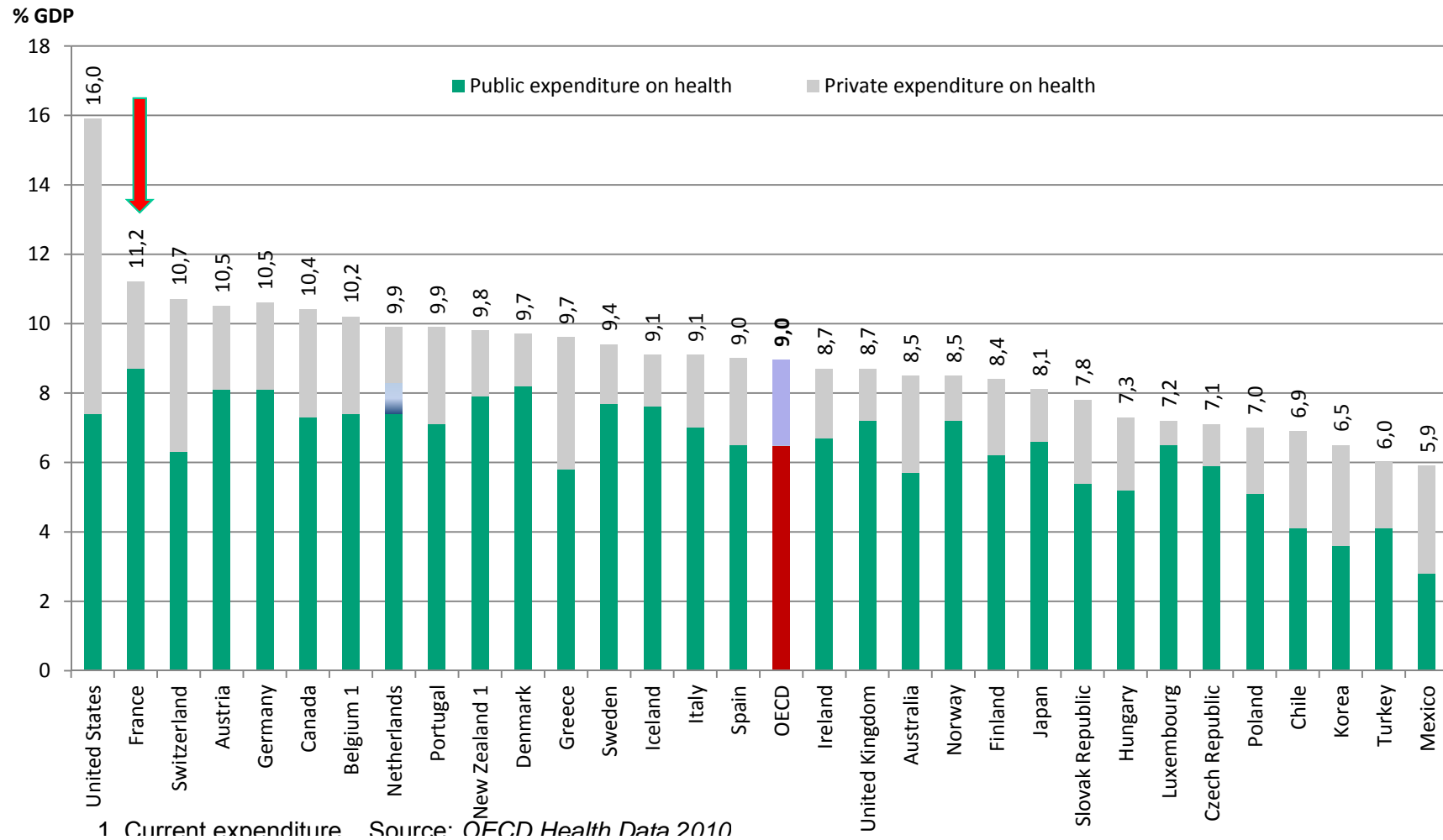
French healthcare system (Cont.)

- **French healthcare organization**
 - Ambulatory care : dominated by solo-based, fee-for-service private practice
 - Mix of public and proprietary hospitals for acute institutional care
 - Patients free to navigate and be reimbursed under NHI.
- **Pharmaceutical expenditure**
 - Per capita drug expenditure
From number 1 to number 3 in Europe

Pharma expenditure per capita (USD)



Health expenditure as a share of GDP, 2008 (or latest year available)



HAS : an independent scientific public body

Broad scope of missions and an integrated global approach to improve quality and safety of healthcare:

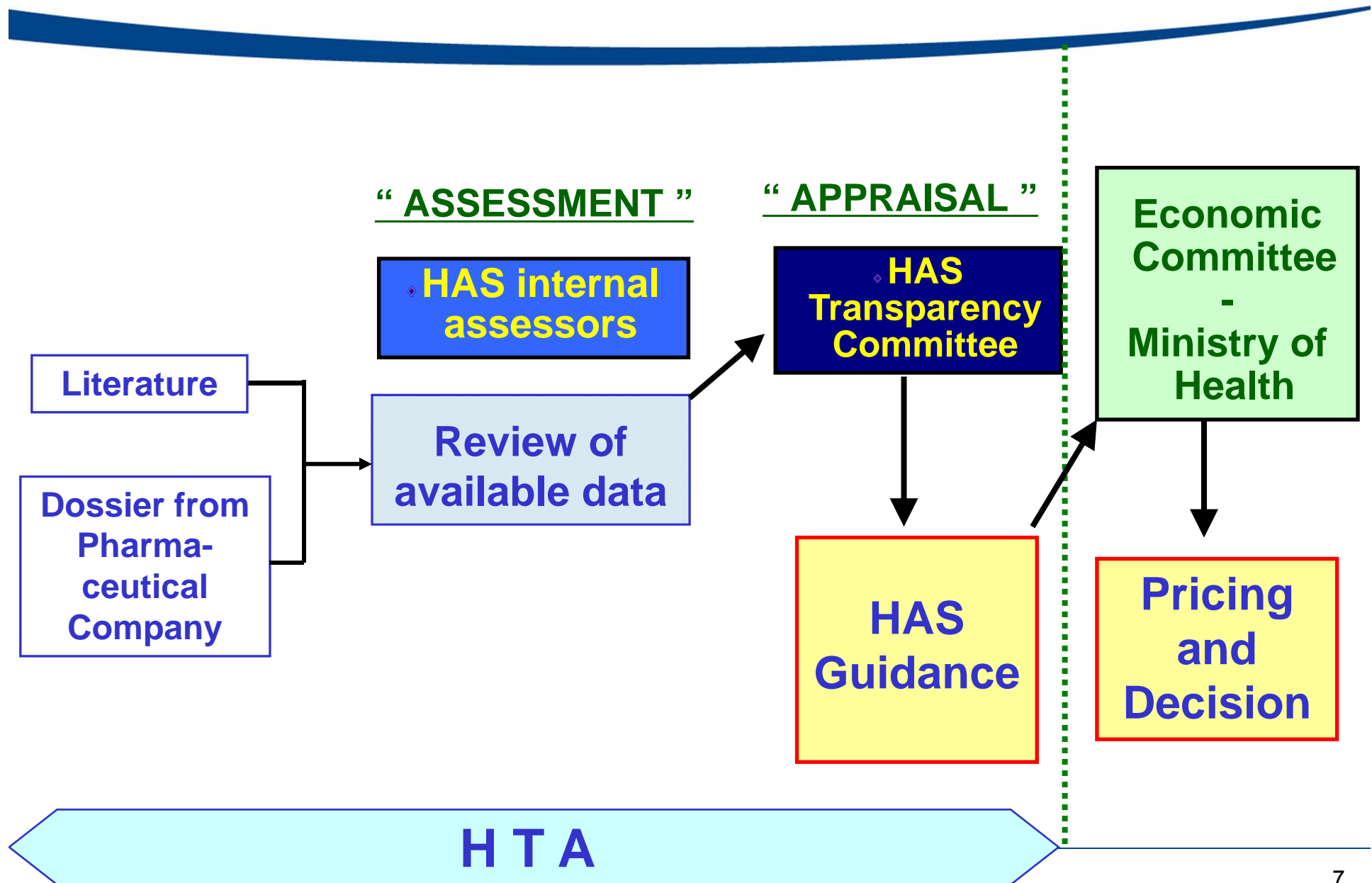
1) Health Technology Assessment

(drugs, devices, diagnostic and interventional procedures)
for pricing and reimbursement,

2) Quality of care and patients safety

- clinical practice guidelines,
- public health guidance,
- chronic disease management models and guidance,
- guidance and recommendations on the most effective strategies (prescriptions, care pathways...)
- Certification and continuous professional development,
- hospital accreditation,

STAs and Decision Making for Drugs



Two questions, two criteria

- **Is the drug eligible for reimbursement ?**
 - ▶ *SMR (Service Médical Rendu) Medical benefit*
 - Severity of the disease
 - Clinical effectiveness (magnitude of effect)
 - Impact on public health and healthcare organisation
 - Insufficient : no reimbursement
 - Sufficient : graded from poor to important : eligible for price negotiation
- **Does the drug bring some progress over existing therapies?**
 - ▶ *ASMR (Amélioration du Service Médical Rendu) Therapeutic added value*
 - Graded from none (level 5) to major (Level 1)

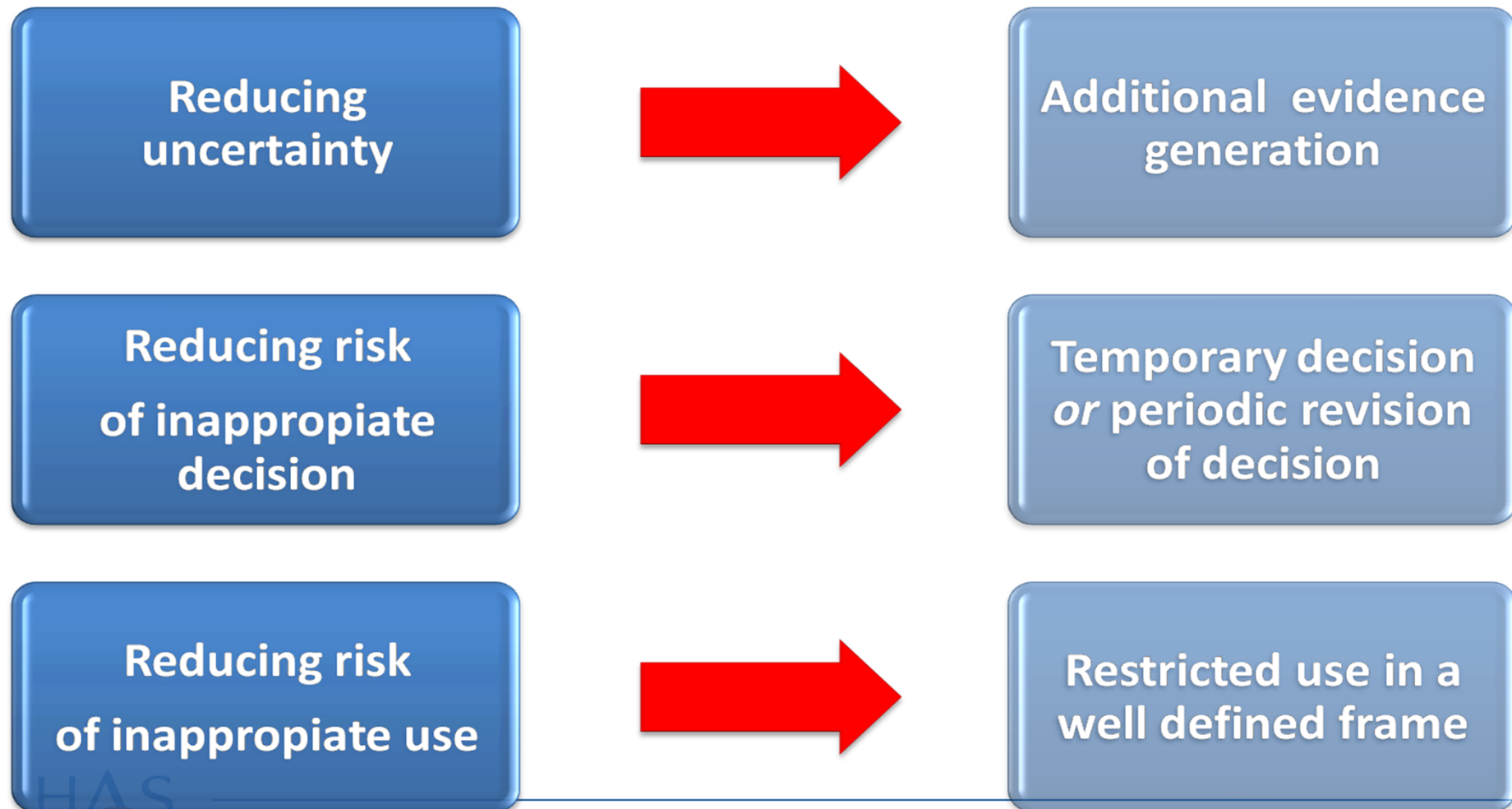
Some figures

- **> 600 Drugs STAs reports per year**
- **> 100 “important” ones :**
 - for new drugs, new indications or important changes in the conditions of reimbursement
- **84 days: average time for issuing guidance**
- **Actual benefit (SMR) judged sufficient : > 90%**
- **No clinical added value for > 60% of new drugs/new indications**
 - Decreased proportion of drugs with “significant” added value (ASMR: moderate to major, I to III)

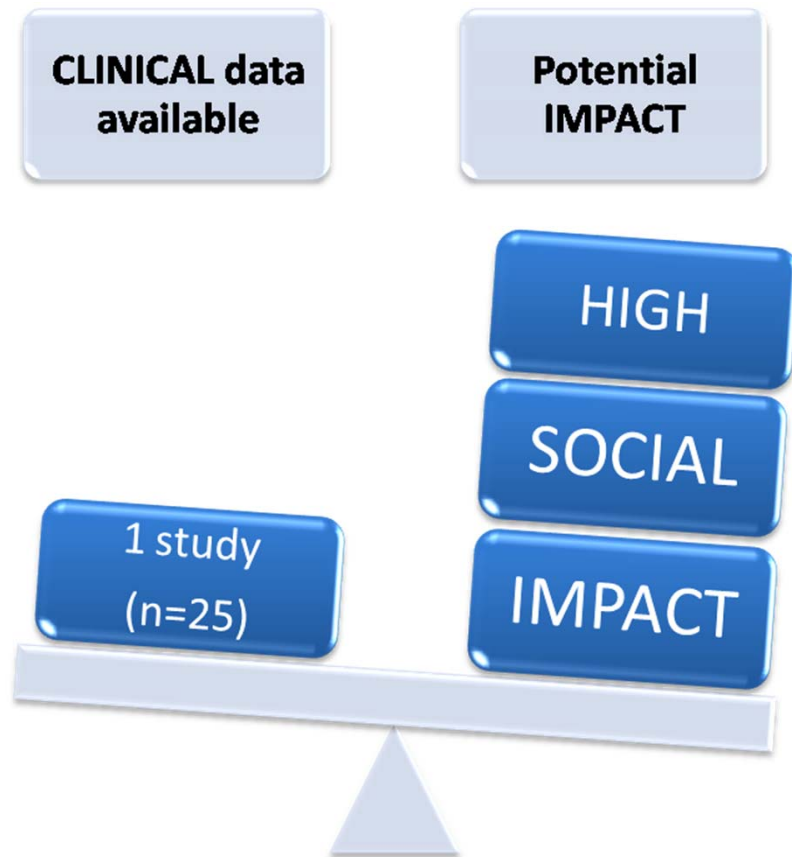
STAs for Medical devices and procedures

- **HTA guidance by HAS particularly important :**
 - Clinical data are much more limited than for drugs
 - HAS guidance important to indicate how to deal with uncertainty (managed entry schemes, further data generation...)
 - Actions needed to improve the quality and adequacy of the data produced by technologies sponsors
- **Innovative devices and procedures**
 - Potential important gain in health, but questions remain on long term efficacy/safety and impact on healthcare organisation
 - Managed entry schemes particularly needed

Coverage with evidence development for innovative MDs and procedures



Percutaneous aortic valve replacement



→ HAS in favor of reimbursement provided that:

- It is granted for a limited period (3 years)
- its prescription is restricted to multidisciplinary teams
- A study to confirm the benefit is initiated straightaway with an annual feed-back to HAS

→ temporary reimbursement decision by Ministry of Health





Economic evaluation and Multiple Technology Appraisals ("Full HTA")

Economic evaluation at HAS

- **New remit (2008), increasing activity**
- **Multiple Technology Appraisals**
 - At the time of re-assessment
 - To date : Main objective = promote proper use
 - Evaluation of statins: Prices hierarchy among products/dosages does not reflect differences in efficacy
 - Drug eluting stents: clinically slightly better than Bare Metal Stents, significant price differences
- **Prices of new drugs**
 - High prices for some new drugs despite no added value was recognised (no ASMR) by Transparency Committee

Full HTA: assessment of public health actions

- **Screening programmes**

 - **Economic aspects**

 - Have to be assessed to support decision making

 - **Ethical aspects:**

 - Down's syndrome screening
 - Hearing defects in neonates

 - **Societal aspects**

 - HIV screening policy

- **Debate on possible evolution with increasing economic assessment at HAS**



HAS 2010 annual activity report

- **795** single technology assessment on medicines
- **159** single technology assessment on MD
- **20** HTA reports on procedures (diagnostic or therapeutic)
- **13** health economic assessments
- **6** public health programs recommendations
- **20** proper use leaflets (4 drugs, 5 MDs, 11 procedures)

Moving from informing policy decisions to influencing professional practices

Various actors (MoH, NHI funds, others) identify sources of unjustified healthcare expenditures

- variations in the use of HT
 - heterogeneity of practices
 - inappropriate use of HT.
- **Need to control volumes of activities based on evidence and on standards of best practice and quality in healthcare**

Appropriateness

- **Assessment of the appropriateness of healthcare**
 - not only assessing the safety, effectiveness and efficiency of HT
 - but also recommending how to best use a technology for the right medical condition, at the right moment in the clinical pathway, at the right place in the care strategy, in the right healthcare setting, at the right cost.
- **Implication of : HTA, clinical guidelines production, promotion of actions by health professionals through CPD**

First assessments to promote appropriateness of care

- **Indications and non-indications of partly obsolete imaging techniques**
 - chest, skull, abdomen X-rays
- **biological tests**
 - for the diagnosis of acute cardiac disease or acute pancreatitis
- **New requests from Health Insurance and MoH :**
 - appendectomy, tonsillectomy
 - planned caesarian delivery ...

Proper Use Leaflets



Diagnostic biologique de pancréatite aiguë :



Devant un tableau clinique évocateur de pancréatite aiguë, **le seul dosage biologique à visée diagnostique à réaliser est celui de la lipasémie**. Une évaluation de la HAS* a confirmé la supériorité de ce dosage sur celui de l'amylasémie, qui n'a plus d'intérêt dans cette indication. Cette fiche revient sur les quatre principales conclusions de cette évaluation.

Le diagnostic biologique d'une pancréatite aiguë doit être réalisé le plus tôt possible, au mieux dans les 48 heures après le début des signes cliniques (*douleur abdominale aiguë intense épigastrique, le plus souvent accompagnée de nausées et vomissements*).

La lipasémie a une efficacité diagnostique supérieure à celle de l'amylasémie pour le diagnostic de la pancréatite aiguë.

Le diagnostic d'une pancréatite aiguë est établi en présence d'un tableau clinique évocateur et d'une élévation de la lipasémie d'au moins 3 fois la normale du laboratoire (3N).

En cas de lipasémie inférieure à 3N, il faut tenir compte du temps écoulé entre le début des signes cliniques et le dosage de la lipase.

* Cette évaluation a été réalisée par la HAS à partir d'une revue de la littérature et de la consultation d'un groupe de 17 experts désignés par les sociétés savantes concernées.



Quand NE PAS prescrire une radio du thorax



Un examen d'imagerie, quel qu'il soit, n'est indiqué qu'après un bilan clinique permettant une prise de décision argumentée.

La radio du thorax est très largement utilisée dans l'exploration de nombreuses pathologies touchant le thorax et son contenu. Sa place dans la stratégie diagnostique a cependant diminué avec l'évolution des techniques d'imagerie. La Haute Autorité de Santé (HAS) a évalué et mis à jour ses anciennes indications. Ce faisant, un certain nombre de « non-indications » sont apparues.

Seules ont été retenues ici les principales situations cliniques explicitement documentées dans la littérature comme des non-indications et qui font encore l'objet de prescriptions fréquentes.

Pathologie respiratoire non tumorale



- Infections des voies aériennes hautes
- Bronchite aiguë
- Bronchiolite de l'enfant (premier épisode non compliqué)
- Douleur thoracique non spécifique (hors contexte d'urgence)

■ Aucune imagerie alternative n'est recommandée.

Pathologie cardiovasculaire (hors péri-opératoire)



- Hypertension artérielle (HTA)

■ L'échocardiographie-Doppler est recommandée dans des cas particuliers.

- Insuffisance cardiaque congestive chronique et cardiomyopathies (suivi périodique)

■ L'échocardiographie-Doppler est recommandée.

Pathologie tumorale



■ Dans ce domaine, la radio du thorax ne garde que quelques indications dans certains cancers, précisées dans le rapport complet « Principales indications et non indications de la radiographie du thorax » (disponible sur www.has-sante.fr).

HAS : Meeting future challenges

- **HAS strengths :**
 - well established independent scientific body with recognised legitimacy
 - All HTA activities under a single roof
 - Broad scope of consolidated missions
- **Challenges :**
 - Timeliness
 - 18 months necessary to produce a full HTA report, or a clinical guideline
 - Coordination with other Actors
 - French Medicines agency, French CDC
 - Information to the public
 - Further develop economic assessment of drugs and devices
 - Coordination between the various missions of HAS to ensure synergistic effect



European Joint Action on HTA 2010 – 2012

- **HAS appointed by French government to participate in EUnetHTA Joint Action**
- **Active involvement, particularly in 2 work packages :**

WP5: Relative Effectiveness Assessment (REA) of Pharmaceuticals (Lead: CVZ, co-lead: HAS)

WP7 New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments (Lead: HAS, Co-lead: LBI)



Impact of the Benfluorex case

- **Consequences of the Benfluorex scandal**
 - Drugs and their evaluation process are under scrutiny
 - Current debate on drug evaluation at every stage: licensing, pharmacovigilance, HTA...
- **Several reports transmitted to the MoH**
 - by Parliament (3 reports), Administrative inspectorate (3 reports)
- **Multistakeholder debate organised by Minister of Health (Assises du Medicament)**
 - 6 working groups (Licensing, pharmacovigilance, Off -label use, Information, Organisational aspects, Medical Devices)
- **Legislative changes to be presented to Parliament by mid 2011**

Conclusions: Future context for drug assessment/appraisal?

- **French context:**
 - Importance of the future changes yet unknown
 - organisational aspects,
 - evolution of the French model of ASMR-based pricing ?
- **European Context**
 - Definition of realistic objectives for the Joint Action 2
 - EMA – HTA working together :
 - Scientific Advice
 - Post marketing data collection
 - Other areas
 - What's next : Governance of the future permanent cooperation (CBHC Directive)