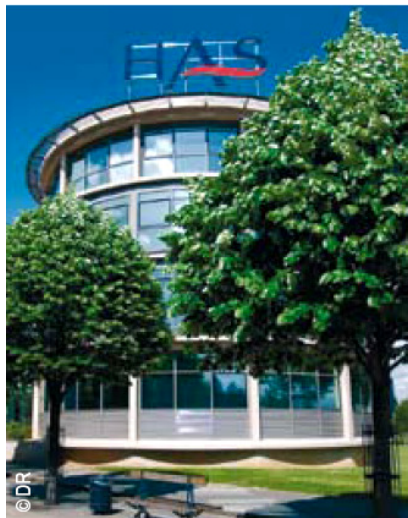




HAUTE AUTORITÉ DE SANTÉ

Effectiveness of current medicines policies: From policy to practice and how policies work in practice



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Declaration of interests



No conflicts of interest

Perspective



- Both academic and from an advisory body (Haute Autorité de Santé) to health decision-makers (price fixing authority, CEPS and national health insurance for reimbursement decisions)

Issues to be addressed in this session

«Medicines policy effectiveness and efficiency in resource allocation: improving policies to address societal health need ... »

1 - Which aspects of medicines policies are relevant here ? Safety vs P&R vs good use?

=> choice of P&R and good use according to HAS remit

2 – What does ‘medicines policy effectiveness’ mean?

=> literally: ‘the extent to which a policy does more good than harm in real life’ ... but good or harm to whom ?

=> Proposal: moving to public policy evaluation framework: ie whether a policy attains its initially stated objective

What is at stake for P&R decision-makers?

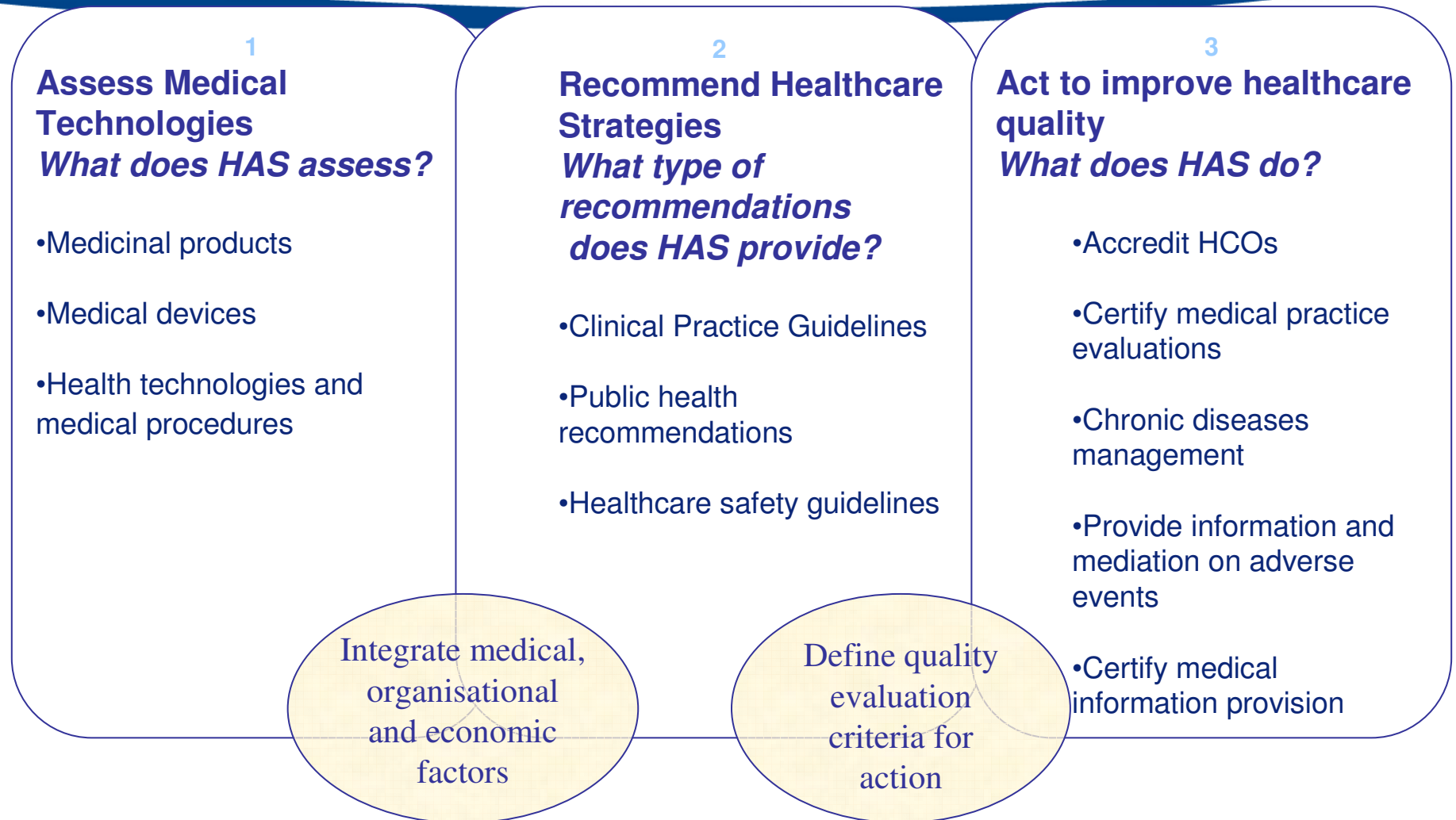
- rewarding truly innovative technologies
- reducing the risks of inappropriate decisions :
 - 1 - *Excessively delaying potential benefits to patients, and in some cases, denying access to treatment*
 - 2 - *Introducing technologies that will turn out to be inefficient, not cost-effective or with a low benefit-risk ratio*
- while keeping within the Nation's health care budget



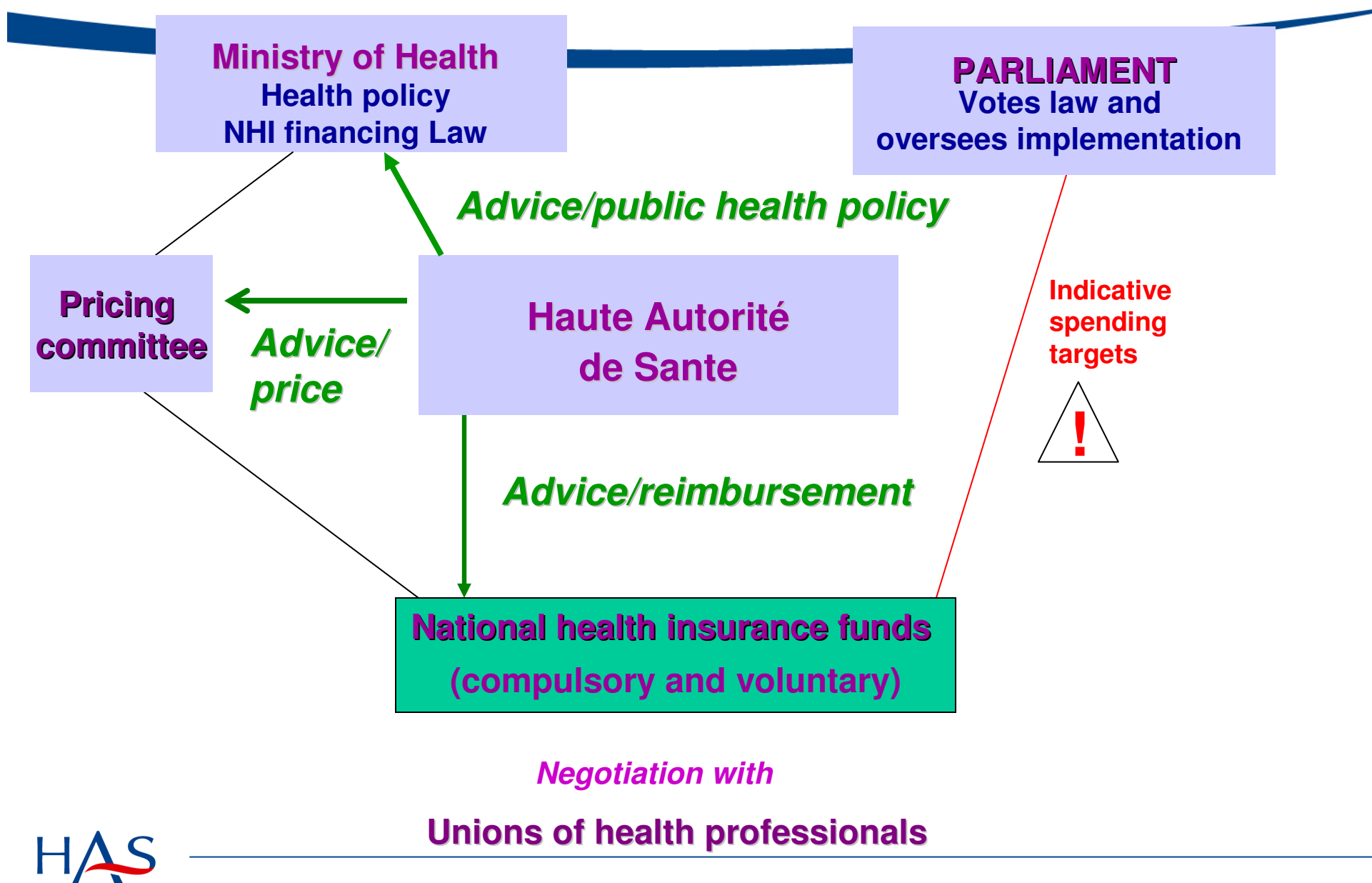
01

**Short background
on HAS in France**

HAS: towards an integrated approach



HAS strikes to ensure high-quality healthcare for all





02

Drug reimbursement and pricing in France

General rules for drug reimbursement

1. All drugs have to be assessed by HAS

- ✓ before inclusion on the **positive list** of reimbursed products

2. Regulated prices.

- ✓ Negotiating committee = CEPS (Economic Committee for Health Products) CEPS and HAS are separate entities.

3. Link between HAS opinion and drug prices

- ✓ Assessment of clinical added value

4. Review every 5 year

- ✓ or when significant new information is available.
Assessment of added value can be revised

Single technology assessments (STA)

Question : *Should the drug be reimbursed?*

Criterion : « *AB* » *Actual Benefit*

« *SMR* » *Service médical rendu*

Actual benefit takes into account:

- The indication : disease characteristics (severity)
- The drug characteristics :
 - Clinical effectiveness (Level of efficacy in CT, generalisability)
 - Impact on public health (Health Status, healthcare organization..)

Consequences

- No reimbursement if SMR considered as Insufficient
- Product eligible for reimbursement in other cases

Single technology assessments (STA)

Question: *Does the drug improve patients clinical situation, as compared to existing therapies ?*

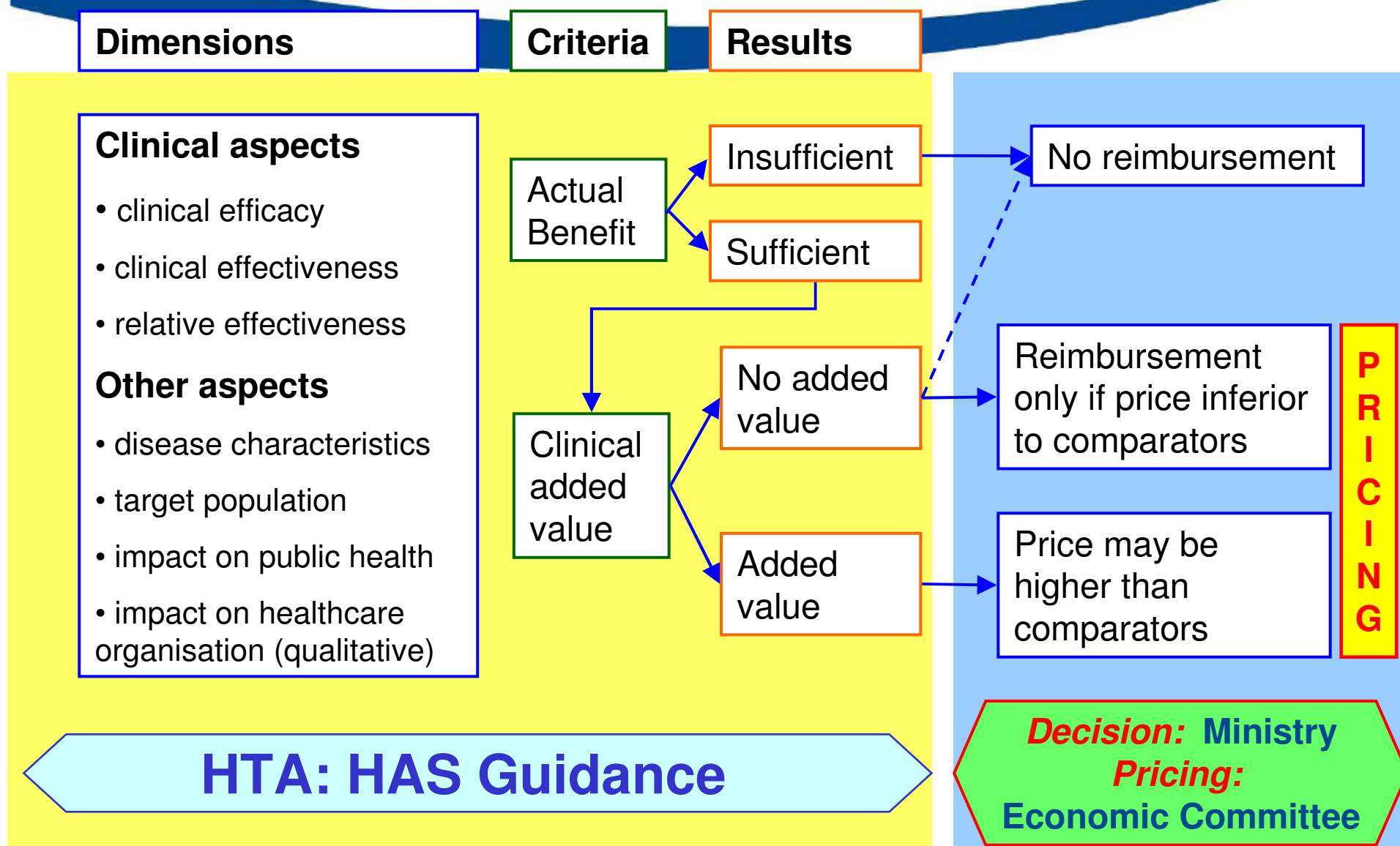
Criterion: « *Clinical added value* »
« *ASMR* » (*Amélioration du SMR*)

Clinical improvement:	Major	ASMR I
	Important	ASMR II
	Moderate	ASMR III
	Minor	ASMR IV
No clinical improvement▶	ASMR V

Consequences:

- Price negotiation
- Information ▶ Health Professionals and the Public

Initial assessment: From HTA to decision making on price and reimbursement



Drug pricing rules in France

- **Sale Price :**
 - Set by the Economic Committee for Health Products after negotiation with the company.
- **Account is primarily taken of:**
 - the 'ASMR' (**clinical added value**) of the medicine,
 - the prices of medicines serving the same therapeutic purpose,
 - forecast or recorded **sales volumes**
 - foreseeable and actual conditions of use of the medicine.
- **ASMR and price**
 - No added value(Level V) : only listed if it brings savings
 - Most innovative drugs (Level I, II and III) eligible for faster access at a european price (Price notification instead of negotiation)



02

**Integrating clinical
health and
community benefits**

The steps towards full HTA at HAS

HAS task force on community benefit (2007):

Main conclusions

- Supplementing individual medical benefit with community benefit in the assessment of healthcare technologies,
- Community benefit refers to the economic notion of opportunity cost (alternative uses of the funding must be considered when assessing a technology)
- Involving other disciplines than medicine and economics, such as sociology, philosophy, public health
- Being transparent about values / assessment processes
- Developing stakeholders' consultation

Introducing economics into assessments

- **New law, Dec. 2007: « As part of its missions, HAS produces guidance and recommendations on the most effective strategies (prescriptions, care pathways...) »**
- **This new economic remit does not cover Single Technology Assessments (STAs) that are performed at the time of initial listing of a medicinal product.**
- **STA is carried out within a short time period and mostly based on the assessment of comparative clinical effectiveness.**
- **Cost-effectiveness and other non-clinical considerations (societal, ethical...) will now supplement the clinical effectiveness data in case of multiple technology assessments (MTA), when reassessing health products.**

From Initial Assessment (STA) to Reassessment (MTA)

Initial Assessment

- Single TA
- All products
- Timeframe: < 90 days
- Evaluation: mainly clinical

GUIDANCE:

- ▶ Positive or Negative opinion
- ▶ Clinical Added Value
- ▶ Target population
- ▶ Recommendation on best use
- ▶ Request for post marketing study

Reassessment

- Multiple TA
- Prioritization ▶ Work Program
- Timeframe: variable
- Evaluation: clinical, ethical, economic, societal aspects

OUTCOME:

- ▶ Recommendation on most effective strategies
- ▶ Consequences on price - reimbursement

Introducing economics into assessments

Economic and Public Health Specialist Committee (CEESP), set up in July 2008

- Complementing medical opinions issued by the HAS committees for drugs and for medical devices and procedures with community benefit assessment
- Multidisciplinary approach: 25 members, various profiles (economics, ethics/philosophy, social sciences, patient representatives, GPs and specialists)...
- In charge of Multiple Technology Appraisals (MTAs), at reassessment phase, and Public Health Guidance (Scoping, validation, methods)

HAS' methods guide for economic assessments

- This guide is aimed at those who:
 - submit economic assessments to HAS' specialist committees
 - produce economic literature reviews and/or models for HAS (whether external consultants or internally)
- CEESP is in charge of scoping and validating this guide
- It aims at identifying the options preferred by HAS on a number of technical issues (perspective, discounting, costs, outcomes, ...)
- The first draft has been released in December 2010 and is currently under revision after stakeholders' consultation

Some of the principles put forward



- Being transparent about assumptions and methodological choices
- Being explicit about the level of uncertainty and the robustness of the results to different assumptions (sensitivity analysis)
- Justifying divergence from ‘standard case’ and being explicit about implications of such departure
- Reconsidering result when more evidence is available
- ...

Conclusion



From both an academic and policy-adviser point of view :

- It is important to assess the benefits to society of carrying out HTAs and whether they are being used for decision-making ...**
- It is equally important to analyse the impact on society at large of P&R decisions (both in terms of efficiency and equity)**
- The long term equilibrium properties of the current and alternative (value based) international pricing system should also be carefully analysed**

Thank you for your attention

<http://www.has-sante.fr>



The screenshot shows the HAS (Haute Autorité de Santé) website. The header includes the HAS logo, navigation links (English, Plan du site, FAQ, RSS, Aide, Contact, Mentions légales), a search bar, and a link to 'Recherche avancée'. The main navigation bar lists: Accueil, Présentation de la HAS, Événements, Toutes nos publications, Ressources humaines, Marchés publics, and Liens. The main content area features a large banner for 'Certification des établissements de santé : la HAS recherche des experts-visiteurs' with a photo of three healthcare professionals. Below this is a section for 'ACTUALITÉS' with three items: 1. 'Appel d'offres relatif à l'analyse de la littérature et la participation à la rédaction d'un rapport sur la révision de descriptions génériques' (dated 19 juin 2009). 2. 'La revue de mortalité et de morbidité (RMM) : une démarche d'amélioration de la qualité et de la sécurité des soins' (dated 18 mai 2009). 3. 'La HAS publie son programme de travail' (dated 18 mai 2009). 4. 'IPAQSS 2008 : la généralisation sur le champ MCO - contexte et résultats' (dated 13 mars 2009). On the left sidebar, there are links for 'Professionnels de santé', 'Grand public', 'Presse', and 'Programmes Thématiques'. At the bottom left, there is a section for 'ÉVÉNEMENTS' with a photo of a medical procedure and links to 'Rencontres HAS 2008' and 'La HAS au Congrès de la médecine générale du 25 au 27 juin 2009'. On the right sidebar, there is a section for 'OUTILS' with links to 'ABC', 'Glossaire', and 'Alerte'. Below that is a section for 'Lettres d'information' with links to 'HAS Actualités & Pratiques n°10 - Juin 2009' and 'Lettre d'information de la HAS n°17 - Mai / Juin 2009'. At the bottom right, there is a link to 'EPP infos n°36 - Juin'.

HAUTE AUTORITÉ DE SANTÉ

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Certification des établissements de santé : la HAS recherche des experts-visiteurs

En savoir plus

ACTUALITÉS

- ⊗ **Appel d'offres relatif à l'analyse de la littérature et la participation à la rédaction d'un rapport sur la révision de descriptions génériques**
Afin de satisfaire les besoins croissants en termes d'évaluation tout en maintenant un haut niveau de qualité, le service d'évaluation des dispositifs médicaux de la HAS a choisi d'externaliser une partie de la rédaction du rapport sur la révision des descriptions génériques des implants pour plastie endocanalaire dit «stent» (lot 1) et une partie de la rédaction du rapport sur la révision des des...19 juin 2009
- ⊗ **La revue de mortalité et de morbidité (RMM) : une démarche d'amélioration de la qualité et de la sécurité des soins**
La Haute Autorité de Santé propose à l'attention des équipes médico-soignantes un guide leur permettant de mettre en place des revues de morbidité et de mortalité (RMM). L'objectif de la HAS est d'améliorer la qualité et la sécurité des soins tout en favorisant le déploiement de cette démarche dans le cadre du développement des différents dispositifs existants : évaluation des pratiques profession...18 mai 2009
- ⊗ **La HAS publie son programme de travail**
Le programme de travail de la Haute Autorité de Santé a été actualisé récemment après la mise en œuvre d'une procédure annuelle d'identification et de sélection des thèmes de travail.18 mai 2009
- ⊗ **IPAQSS 2008 : la généralisation sur le champ MCO - contexte et résultats**
La clôture des 3 thèmes d'indicateurs recueillis en 2008 a été réalisée le 13 mars 2009. Jusqu'alors, les établissements MCO avaient accès à leurs résultats individuels dès la validation de la saisie. Ils peuvent

OUTILS

ABC | Glossaire | @ Alerte

LETTRES D'INFORMATION

HAS Actualités & Pratiques n°10 - Juin 2009
Lettre aux professionnels de santé. Rendez-vous chaque 1er jeudi du mois.

Lettre d'information de la HAS n°17 - Mai / Juin 2009
Lettre institutionnelle bimestrielle

EPP infos n°36 - Juin

ÉVÉNEMENTS

- Rencontres HAS 2008 : synthèses des sessions disponibles
- La HAS au Congrès de la médecine générale du 25 au 27 juin 2009
- EPP - Bilan et perspectives - Voir la retransmission des débats en

HAS