

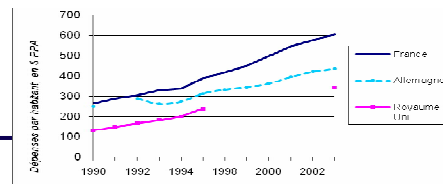
## Governance of effectiveness assessment in France

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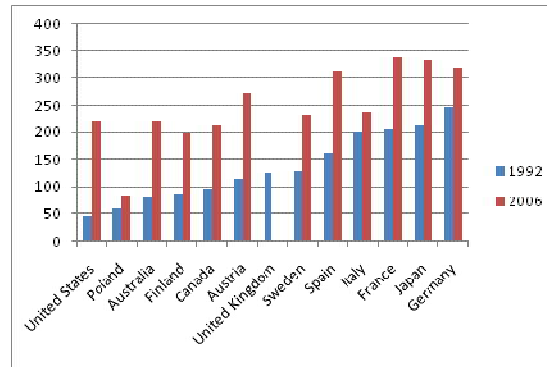
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## French Context



- *Bismarck-type system combining compulsory and voluntary complementary insurance*
- *Rapid growth of health expenditure following a slowdown in the 90s (annual rate of increase 3.5% since 2000)*
- *Public pharmaceutical expenditure per head is among the highest in OECD (15% public expenditure) and was increasing more rapidly than other countries*
- *Use of a positive list to define what is paid by public insurance (and complementary insurance)*
- *Reimbursement rates (for drugs) depend on drug effectiveness and are fixed : 35%, 65%, 100%*
- *Pharmaceutical industry (production) is very important*

## Public expenditure on pharmaceuticals /capita, US\$ 2000 PPP



## French National Authority for Health: HAS

- Set up in 2004 as an independent public body to bring under a single roof a number of activities and institutions to improve the quality of patient care
- Mission includes:
  - Assessment of drugs, medical devices, procedures, health strategies
  - Publication of clinical guidelines
  - Accreditation of healthcare organisations
  - Certification of doctors
- Annual budget of 60m Euros comes from:
  - taxes on promotional spending by drug companies (33%), National Health Insurance (31%), state funding (14%), HCO accreditation fees (14.6%), fees for assessing applications for inclusion on reimbursement lists (7%)

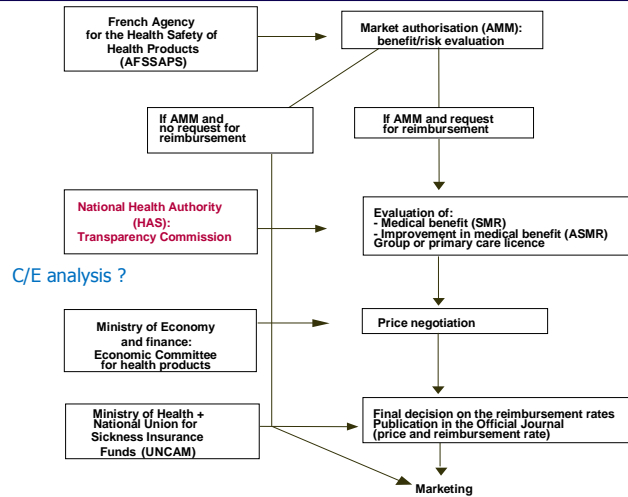
## Advisory role for reimbursement decisions

- **Opinion on the clinical effectiveness (SMR) and relative benefit (ASMR) of drugs, medical devices, and diagnostic and therapeutic procedures**
  - **SMR** (effectiveness) takes into account clinical impact + importance for public health (four levels: none, low, moderate, important)
  - Determines the reimbursement rates (0, 35%, 65%, 100%)
  - **ASMR** (improvement in effectiveness/ indirect cost analysis) compares the contribution of the new drug/diagnostic, etc. compared with existing ones
  - Determines the price (levels 1 to 5)
- **Opinion on targeted practice agreements**  
HAS vets all quality targets for practitioners (*ACBUS, CAPI*), which are set out in agreements between NHI and health professionals, if concern the quality, safety, and efficacy of practice
- **Opinion on chronic (long-term) conditions**  
definition of conditions that require lengthy and expensive treatment (establishing the eligibility criteria for 100% NHI cover for 30 chronic conditions and the treatments required)
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## Place of cost-effectiveness analysis

- In 2008 HAS was given a new mission to carry out medico-economic evaluation of health technologies (drugs, procedures, health strategies ...)
- What is medico-economic evaluation for HAS?
  - (in best case) A tool for better using available health resources
  - Understand better the global cost implications of health interventions/technologies that have been adopted
- What it is not ?
  - A tool for rationing health care
  - Establishing criteria for deciding what to include in the health basket
- Still on shaky ground
  - Separate from medical effectiveness evaluation
  - *Expost* rather than *exante* evaluation
  - Limited analysis of opportunity costs of different strategies
  - Little political power

## Key stages in HTA process (Drug reimbursement)



## Market share of drugs by their reimbursement rates

	Market share
Médicaments remboursés à 0%	11 %
Médicaments remboursés à 35%	17 %
Médicaments remboursés à 65%	70 %
Médicaments remboursés à 100%	2 %

Source: Briand et Chambaretaud, 2001

## In practice...

- 1999 to 2001 the Transparency Commission evaluated the therapeutic value of 4490 reimbursable specialties
- Recommended that 835 should be removed from the list because their SMR is inadequate
- Only 72 removed, and vigorous contestations from the industry
- HAS asked to re-evaluate these drugs in 2004
- Almost all of the specialties reevaluated by September 2005 were again judged inadequate
- The Minister decided not to reimburse them after March 2006 with the exception of veinotoniques which are reimbursed 15% until 2008

## A comparison of molecules reimbursed in three countries: example of benzodiazepines

- Benzodiazepines are used in the treatment of insomnia, anxiety and epilepsy
- They are addictive and susceptible to misuse and abuse (supply is regulated for public health /security reasons in England, France and Germany)
- Of 20 products reimbursed in France (17 at 65%) half are either not reimbursed or not on the market in UK
- In UK only reimbursed in generic form
- In Germany they are all subject to reference pricing (in France only one)
- The reimbursement rates comply with the recommendations of HAS in France (SMR "important" to "moderate")
- Cost in 2002 (per 1000 habitant):
  - more than 2600€ in France; 1200€ in Germany; 1100€ in England

## Comparison of drug baskets in three therapeutic classes, 2002

	France	Germany	England
<b>Number of molecules reimbursed</b>			
Benzodiazépines	20	18	10
Vasodilatateurs	15	14	9
Dysfonctionnement érec tiles	1	1	9
Anti -obésités	0	0	5
Anti -tabagiques	0	0	2
<b>Public expenditure , euros/1000 habitants</b>			
Benzodiazépines	2615	1185	1108
Vasodilatateurs	3829	1440	181
Dysfonctionnement érectiles	50	182	1027
Anti -obésités	0	0	1108
Anti -tabagiques	0	0	906

## Concluding remarks

- There is a high margin for improving resource use with CEA
- There are different approaches to "effectiveness assessment"
- Solutions need to fit with system design
- To make CEA programs work, you need political will, stakeholders agreement, incentive scheme ...)
- Effectiveness analysis is not forcibly a scientific process

## Questions

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- How much can we “mutualize” knowledge on effectiveness assessment?
- Is it possible to set a gold standard for conducting effectiveness assessment?