

# **French pharmaceutical system**

## ***Focus on pricing and reimbursement***

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Sophie DELCROIX-LOPES  
CNAMTS



### **Conflict of interest disclosure**

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**The author declares that she has no competing interests.**

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## Agenda

1. **Health care system and expenditure**
2. **Pharmaceutical system and expenditure**
3. **Pricing & reimbursement**
  - » Process
  - » Pricing
  - » Reimbursement



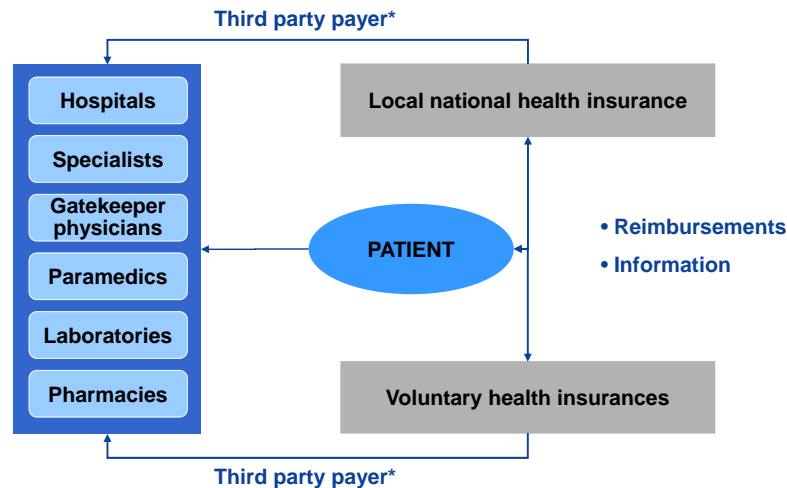
## Health care system

- **National health insurance: from employment to resident status criteria**
  - Occupation-based system for historical reasons : social protection originally provided by employers (bismarck)
  - covers almost 100% of the resident population
    - including the Universal Health Insurance Coverage (CMU Act) : 2,3% in 2006
  - also covers sickness, maternity and work injury leaves
- **Health insurance system divided into 3 main schemes:**
  - general scheme for salaried workers (85% of population)
  - agricultural scheme (6%)
  - free-lance workers (5%)
  - the industry-specific funds



## French system viewed from the patient

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\* direct payment by the health insurance fund to the provider

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## Private/complementary health insurance

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- **94% of the population with private insurance**
  - complementary health insurance : subscription on a usually voluntary basis (collective contracts by employers)
  - including 6% covered by the free Complementary Universal Health Insurance Coverage (CMUC) for people with low incomes
- **Patients' co-payments on fees, drugs, hospital per diem stays can be covered by private insurance**

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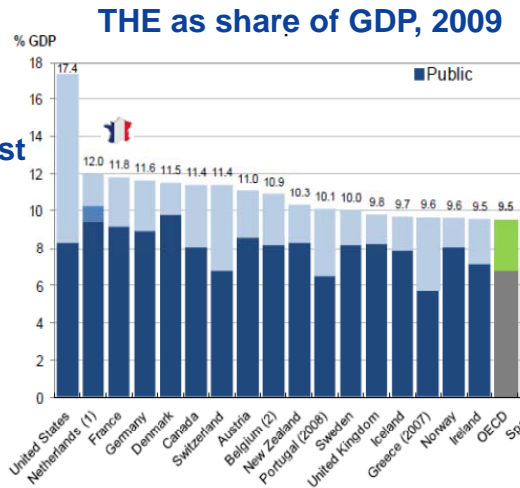
## Total health expenditure (THE) 7

→ 11.8 % of GDP (2009)

→ 3rd highest rate amongst OECD countries

→ 77.9% share of public funding, remaining 22% from private expenditure:

- 3% of private insurance
- 9% of out-of-pocket payments (OPP)



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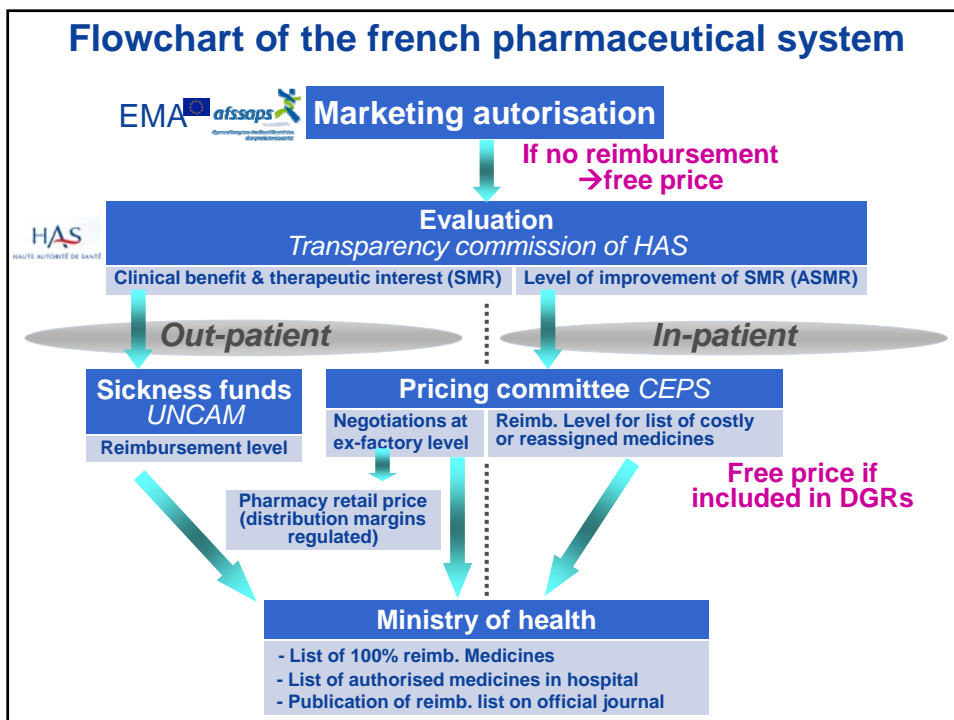
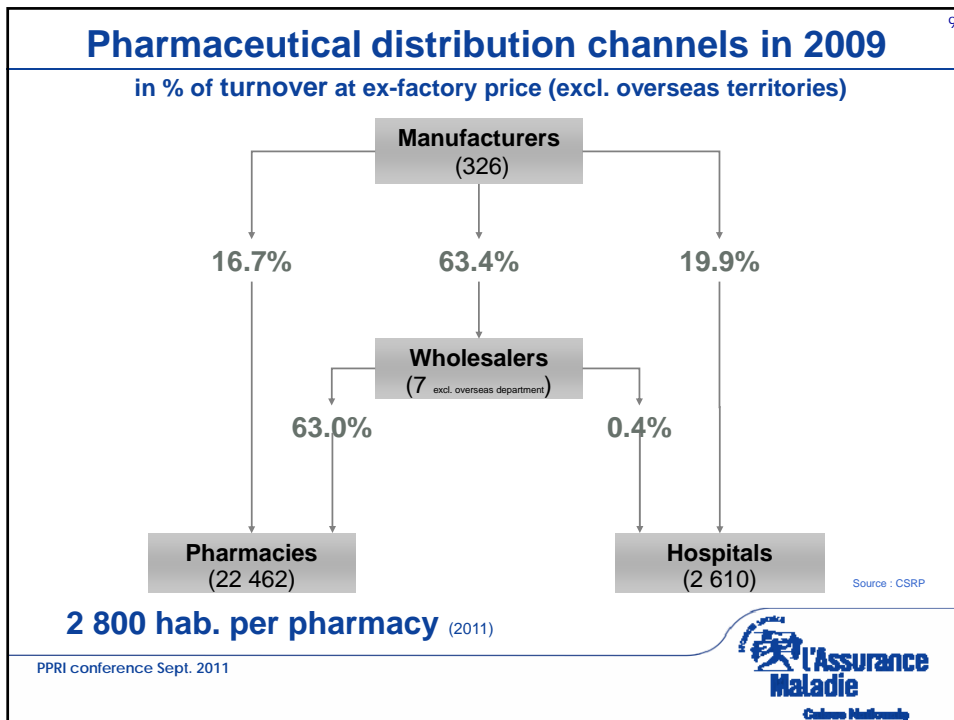


## Pharmaceutical expenditure (PE) 8

- **Out-patient PE, excluding bandages** (OECD; 2009)
  - 15,8% of THE
  - 550€ per capita, 460€ of prescription medicines
  - 66% of public out-patient PE (national health accounts 2009)
- **Inpatient PE = 23% of PE (at ex-factory price)** (2009, CEPS)
- **Self-medication = 6.5% of pharmaceutical sales** (2009, AFIPA)

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## Price based on improvement of clinical benefit level<sup>11</sup>

- Only pharmaceuticals with improvement in medical service (ASMR) or savings eligible for reimbursement
- ASMR “*Amélioration du service médical rendu*” levels:
  - I: major (new therapeutic area, reduction of mortality)
  - II: significant in efficacy and/or reduction of side-effects
  - III: modest in efficacy and/or reduction of side-effects
  - IV: minor improvement
  - V: no improvement
- Price of highly innovative pharmaceuticals = ASMR levels I to III must be consistent with the prices of similar pharmaceuticals in other European countries

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## Pricing regulatory framework<sup>12</sup>

- Framework : 3-year agreement “accord cadre” between the Economic Committee for Health Care Products (CEPS) and pharmaceutical manufacturers
- Clawback system
  - the “safeguard contribution” : payment by companies if their turnover exceeds the “K rate” threshold if not in “accord cadre” agreement
  - by products otherwise as % of turnover increase : either price decrease or rebate
- Prices set at ex-factory level ...
- ... but pharmacy retail prices (PRP) for reimbursable pharmaceuticals also regulated since distributors’ margins are regulated as well

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## Price regulation for out-patient

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- **Free pricing for non-reimbursable pharmaceuticals**
- **Pricing negotiation for reimb. products at ex-factory price**
  - Price-volume and risk-sharing agreements: the CEPS conducts price-volume agreements or contracts based on posologies or treatment durations
- **External price referencing (EPR) :**
  - Basket of 4 countries : UK, Germany, Spain and Italy
  - Applies to products with a level of improvement of clinical benefit (ASMR) I, II or III for the major indication
- **Fast-track application : 1 application accepted among 3 in 2009**

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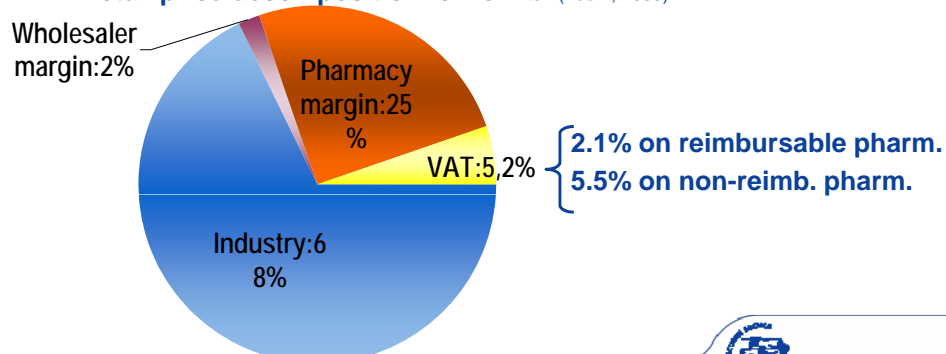


## Distribution mark-ups for out-patient

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- **Non-reimbursable pharmaceuticals : free distribution margin**
- **Reimb. pharm. : regressive mark up + flat fee (€0.53 per pack)**
  - Incentive for pharmacists to **substitute with generics**: margin calculation based on the originator product price

**Retail price decomposition for reimb.** (Leem; 2009)



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## Discounts / rebates

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- **Discounts and rebates of the pharmacy purchasing prices (PPP) negotiated between supplier and pharmacist**
- **REGULATED : maximum level of rebates/discounts granted to pharmacists for reimb. pharmaceuticals**
  - Pharmacists maximum discount for reimb. products=2.5%
  - With one exception for reimbursable generics :
    - 17% maximum discount/rebate for reimbursable generics of the ex-factory price
    - Pharmacist can also benefit from the wholesale margin

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## Price regulation for in-patient

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- **Set up of a basis of reimbursement “cession price” or “responsibility price” for costly medicines on the supplementary list “liste en sus”**
  - Supplementary list = 44% of in-patient pharma. exp.
- **Free pricing for most pharmaceuticals approved for hospital use otherwise**

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## Hospital tendering for pharmaceuticals

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- **Hospitals carry out their own procurement**
- **Bulk-buying organisations to negotiate cheaper purchase prices**
  - All Regional University Hospitals and largest General Hospitals share a common structure “Union des Hôpitaux pour les Achats” (UNI.H.A) which negotiates various products and services from medicines to laundry
  - Several other group of hospital purchasing do exist :
    - for a region (e.g.: RESAH-IDF)
    - or specialised care centers (e.g.: regional cancer centers)

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## Generics

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- **Market authorisation simplified procedure for generics : bioequivalence with the original product proof**
- **A generic group is defined**
  - Generic group list “*le répertoire*” registered by *Afssaps*
  - For all molecules of the same Anatomic Therapeutic Chemical (ATC) classification level 5
  - With the same dosage and the same packaging.
- **Market shares (2009) : 24% in volume and 14% in value**
  - Substitution rate: 71.2 % in packs and 62.2 % in value (excluding VAT)

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## Generic pricing policies

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- **At patent expiry :**
  - Ex-factory price regulation
    - Original product : -15%
    - Generics = 45% of original product before the 15% cut
  - Pharmacy margin based on original product price
- **After 18 months :**
  - if penetration rate  $\geq 60\%$ : ex-factory prices reviewed
    - -12,5% for the original product and -7% for the generics
  - otherwise eligible to reference price system

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## Reference price system

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- “*Tarif Forfaitaire de Responsabilité*”, TFR
- **All pharmaceuticals in a generic group have the same level of reimbursement**
- **In 2010, 195 generic groups were under TFR among the 939 generic groups**
- **The reference price level is defined by the CEPS**
- **Groups under the TFR account for 4% in value and 7% in volume of the out-patient reimb. Market** (Leem)

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## Reimbursement rate process

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- **The National Union of Health Insurance Funds (UNCAM) in charge of setting the reimbursement rate**
  - after assessment of medical service and improvement of medical service by the Transparency Commission (HAS) and evaluation of clinical added value
  - and simultaneously of the pricing procedure CEPS

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## Reimbursement scheme: product & disease specific<sup>22</sup>

- **Product specific**
- **Patient specific**
  - For patients with **long-term illnesses** from a specific list 'ALD - *affections longue durée*'
  - For **socially disadvantaged** patients
    - free of charge Universal Health Insurance Coverage (CMU) for low-income patients : allows access to care from doctors and nurses, as well as paying for pharmaceuticals, hospital charges
    - State Medical Aid for foreigners

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## 2 lists of reimbursable medicines

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- **2 lists of reimbursable medicines, i.e. positive lists:**
  - list for out-patient care and for sales by pharmacies
  - list of hospital medicines for the hospital sector
    - Supplementary list of costly medicines
    - Reassigned medicines: hospital pharmacy delivery to out-patients (e.g. HIV)
- **Average reimbursement rate for pharmaceuticals = 75.7% (2009; general scheme only)**

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## Reimbursement rates

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Clinical benefit (SMR)	Non-serious disease	Serious disease
Major	30%	65%
Moderate	30%	
Weak	15%	
Insufficient	Not listed for reimbursement	

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**Thank you !**  
*sophie.lopes@cnamts.fr*

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