

New medicine

**AUTHORISATION/
CLASSIFICATION**

EVALUATION

**PRICING &
REIMBURSEMENT**

DISTRIBUTION

**POST
AUTHORISATION**

VIGILANCE

**European Medicines Agency (EMA)
or
French Health Products Safety Agency / Agence nationale de sécurité du médicament et des produits de santé (ANSM)**

Task: Decision on authorization and registration
 Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Public Health Code

French Health Products Safety Agency / Agence nationale de sécurité du médicament et des produits de santé (ANSM)

Task: Decision on prescription, dispensing requirements and if a pharmaceutical fulfills the criteria of pharmaceuticals
 Criteria: Directive 92/56/EEC, law on prescription requirement, prescription requirement order etc.

ANSM is also in charge of
pharmacovigilance

French National Authority for Health / Haute Autorité de santé (HAS)

Task: Health technology assessment and medico-economic assessment (only for innovative drugs)
 Criteria: - HTA : Clinical benefit and therapeutic interest (SMR), level of improvement of clinical benefit (ASMR)
 - Medico-economic: incremental cost-effectiveness ratio (RDCR)

OUT-PATIENT

IN - PATIENT

PRICING

REIMBURSEMENT

REIMBURSEMENT

Pricing Committee (CEPS)

Task: Price negotiations
 Criteria: At ex-factory level, depending on ASMR +/- RDCR

Task: Publication of ex-factory and retail price (distribution mark-ups regulated)

Sickness funds union (UNCAM)

Task: Reimbursement rate
 Criteria: SMR, reimbursement rates (15%,35%, 65%)

List of authorised medicines in hospital

Drugs on the top of DRGs	Drugs included into the DRGs
---------------------------------	-------------------------------------

PRICING

Pricing Committee (CEPS)

Task: Price negotiations
 Criteria: At ex-factory level, depending on ASMR +/- RDCR

Hospital purchasing body or union

Task: Price negotiations or tendering of medicines
 Criteria: Depending on the product or on the market situation of the medicine

Ministry of Health and Ministry of Finance

Task: Distribution mark-ups regulation
 Criteria: Wholesalers, pharmacists margins

Ministry of Health

Task: List registration and publication
 100% reimbursement rate list of medicines on list of authorised medicines in hospitals

Pharmaceutical companies

Wholesalers

Pharmaceutical and Therapeutic Committee per hospital

Task: Decision on use of medicines

Pharmacies

Hospitals

French Health Products Safety Agency / Agence nationale de sécurité du médicament et des produits de santé (ANSM)

- Advertising control and distribution of Rational Drug Use Guidelines Commission
- Pharmacovigilance Commission

OUT-PATIENT

IN - PATIENT