VIGILANCE

AUTHORISATION/ CLASSIFICATION

EVALUATION

REIMBURSEMENT

New medicine

European Medicines Agency (EMA) or French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)

Task: Decision on authorization and registration

Criteria: Quality, safety, efficacy (Directive 2004/27/EC) and Public Health Code

French Health Products Safety Agency /

Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)

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.

AFSSAPS is also in charge of pharmacovigilance

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

Transparency commission évaluation (CT)

Clinical benefit and therapeutic interest (SMR), level of improvement of clinical benefit (ASMR) Criteria:

OUT-PATIENT IN - PATIENT PRICING REIMBURSEMENT **PRICING** REIMBURSEMENT

Task:

Pricing Committee (CEPS)

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

Task: Publication of exfactory and retail price (distribution mark-ups regulated)*

Sickness funds union (UNCAM)

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

Pricing Committee (CEPS)

Reimbursement level for supplementary list and reassigned medicines Criteria: At ex-factory level

Working group DRGs

Task:

Criteria:

List of medicines included in DRGs with free pricing Pharmacological, medical therapeutic,

pharmacoeconomic criteria

Prices available at http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php^{}p_site

Ministry of Health and Ministry of Finance

Task: Distribution mark-ups

regulation Wholesalers

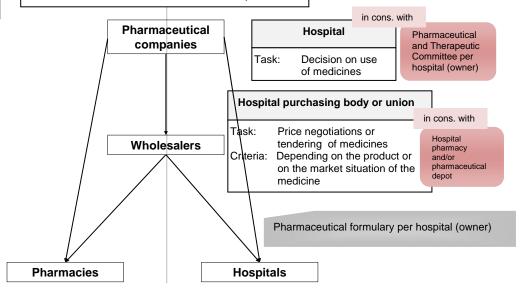
Criteria:

pharmacists margins

Ministry of Health

Task: List registration and publication

100% reimbursement rate list of medicines on list of authorised medicines in hospitals



French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé AFSSAPS)

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