VIGILANCE

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 Quality, safety, efficacy (Directive 2004/27/EC) and Public Health Code Criteria: 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** - PATIENT **PRICING** REIMBURSEMENT **PRICING** REIMBURSEMENT **Pricing Committee (CEPS)** Sickness funds union **Pricing Committee (CEPS)** Working group DRGs (UNCAM) Task: Task: List of medicines Reimbursement Price negotiations included in DRGs Task: Task: Reimbursement rate level for Criteria: At ex-factory level, Criteria: SMR, reimbursement supplementary list with free pricing depending on ASMR rates (15%,35%, 65%) and reassigned Criteria: Pharmacological, medicines medical therapeutic, Task: Publication of ex-Criteria: At ex-factory level pharmacoeconomic factory and retail price criteria (distribution mark-ups regulated)* *Prices available at http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php^pp_site Ministry of Health Task: List registration and publication 100% reimbursement rate list of medicines on list of authorised medicines in hospitals in cons. with **Pharmaceutical** Hospital Pharmaceutical companies and Therapeutic Task: Decision on use Committee per hospital (owner) of medicines Hospital purchasing body or union in cons. with Price negotiations or tendering Hospital pharmacy of medicines Wholesalers and/or Depending on the product or on teria: depot the market situation of the medicine Pharmaceutical formulary per hospital

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

Pharmacies

Hospitals