# France Pricing & Reimbursement Market-System Overview

Updated October 2021

# French pharmaceutical pricing & reimbursement is a largely nationalized process based predominantly on demonstrated clinical value

## General Overview

| Aspect | Key Considerations |
|---|---|
| **Payer Evaluation** | ▪ The Transparency Commission (TC) evaluates the medical benefit (SMR) and level of therapeutic improvement versus a defined standard of care (ASMR) for all new drugs and line extensions<br>▪ The output of the TC review heavily influences the reimbursement rate set by UNCAM and the price subsequently negotiated with the CEPS |
| **Price Setting** | ▪ Price setting is conducted by the Economic Committee (CEPS)<br>▪ The outcomes of the TC evaluation (ASMR level), cost of SoC and defined patient population are key inputs in decision making<br>– The CEPS often negotiate a price-volume agreement (PVA) with manufacturers<br>▪ A health-economics (HE) analysis is made by the Health Economic Committee (CEESP) when cumulative conditions are met* |
| **Reimbursement/ Funding** | ▪ UNCAM determines the reimbursement level for a drug based on the TC's SMR level<br>▪ While there are multiple level of reimbursement rates, the majority of drugs are 100% reimbursed through a combination of Social Security (taxes) and Complimentary Insurance |
| **Cost Containment** | ▪ As a nationalized system, most cost containment associated with novel drugs is managed through price-volume agreements<br>– However, the CEPS may negotiate different contracts at times, such as risk-sharing agreements<br>▪ Once reimbursed, physicians are relatively free to prescribe according to guidance from the TC |

*Notes: *If likely significant budget impact and manufacturer seeking ASMR I-III (exceptions for conducting evaluation with ASMR IV are for orphan drugs with large anticipated budget impact), SMR = Medical Benefit, ASMR = Improvement of the Medical Benefit versus a comparator (not an absolute rating), UNCAM = Union Nationale des Caisses d'Assurance Maladie (National Association of Health Insurance Funds)*

# The MoH is responsible for public health at the national level, with the TC playing a key role in the HTA process (1/2)

## Description of Key Stakeholders

| | Stakeholder | Level | Description |
|---|---|---|---|
| Market Authorization | **ANSM – L'Agence nationale de sécurité du medicament et des produits de santé** (National Agency for the Safety of Medicines and Health Products) | **National** | ▪ Drug regulatory agency, grants marketing authorisation<br>▪ Responsible for inclusion of drugs in lists such as the compassionate access program, or the retrocession list |
| Payer Evaluation | **HAS** - **Haute Autorite de Sante** (French National Authority for Health) | **National** | ▪ The HAS is the main HTA body in France; it is an independent public body with financial autonomy aimed at improving the quality and efficiency of healthcare<br>▪ HAS is responsible for the assessment of drugs, medical devices and procedures<br>▪ In addition, HAS is accredits healthcare organizations and healthcare professionals |
| | **TC - Commission de la Transparence** (Transparency Commission) | **National** | ▪ A body within HAS whose role is to conduct technical clinical appraisals<br>▪ Awards SMR (which assess the efficacy of a drug) and ASMR (the incremental benefit over comparators) ratings, defines eligible population and submits recommendations to CEPS |
| | **CTV - Commission Technique des Vaccinations** (Vaccine Technical Committee) | **National** | ▪ Updates the National Immunization Program including providing recommendations and vaccination schedules<br>▪ Co-ordinates with the TC and CEESP |
| | **CEESP - Commission d'Évaluation Économique et de Santé Publique** (Economic Evaluation and Public Health Committee ) | **National** | ▪ Conducts health economic assessment for innovative products (ASMR I-III and likely to have a significant budget impact)<br>▪ Recommendations feed into CEPS' negotiation |

# The MoH is responsible for public health at the national level, with the TC playing a key role in the HTA process (2/2)

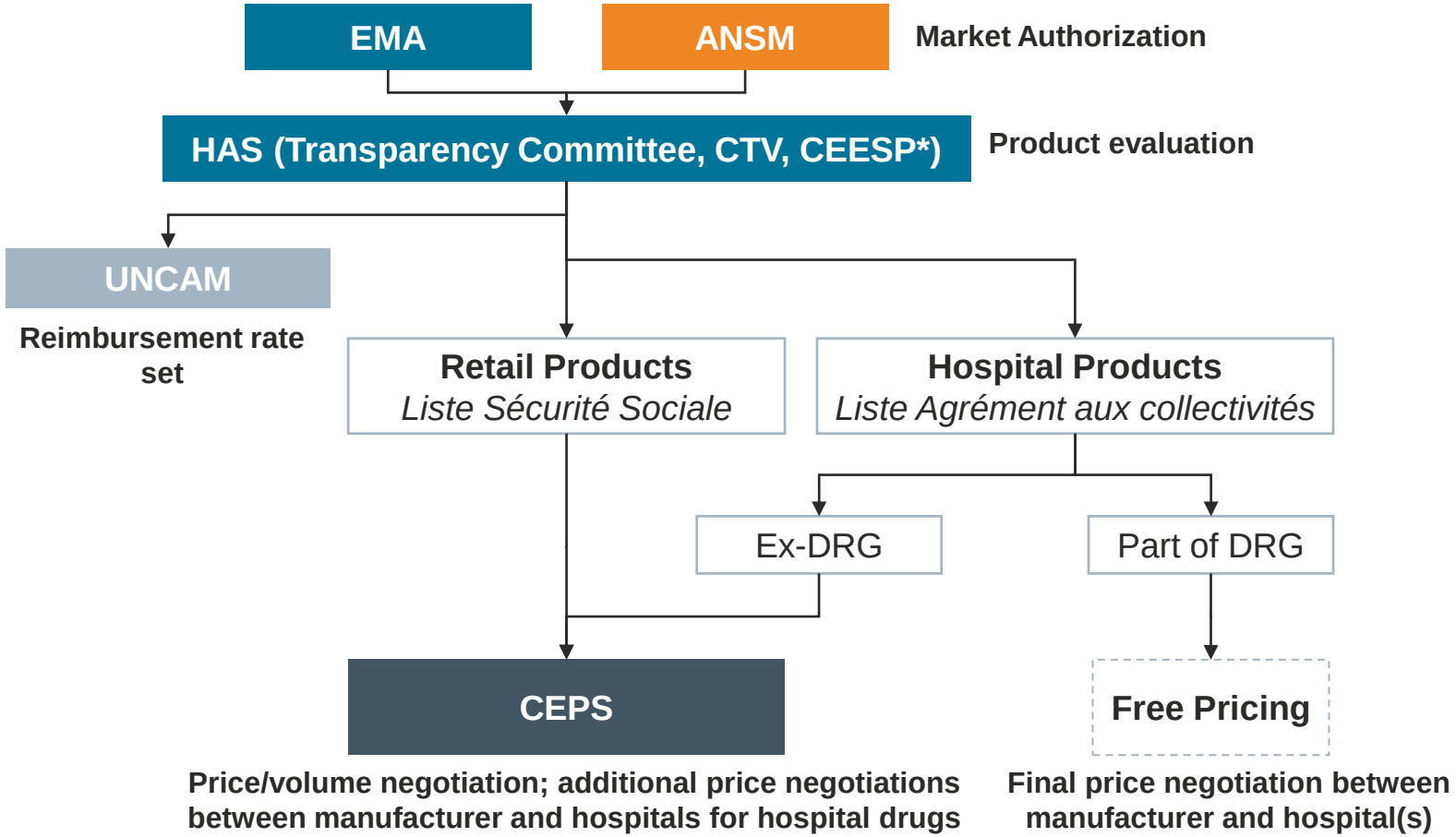
## Description of Key Stakeholders

| | Stakeholder | Level | Description |
|---|---|---|---|
| Price Setting | **CEPS - Comité Economique des Produits de Santé** (Economic committee for health products) | **National** | ▪ Negotiates price-volume agreements for drugs and medical devices with manufacturers based on the recommendations from the TC and CEESP<br>▪ Sets prices for reimbursable retail medicines, hospital products and reference prices |
| Funding / Reimbursement | **UNCAM – Union Nationale des Caisses d'"Assurance Maladie** (National Association of Health Insurance Funds) | **National** | ▪ Sets the reimbursement rates based on HAS recommendation of the Clinical Benefit Assessment (SMR) as well as the seriousness of the disease; there are 5 reimbursement categories 0, 15%, 30%, 65% and 100%<br>▪ UNCAM also decides on healthcare policies and defines services eligible for reimbursement |
| | **CH - Conseil de l'Hospitalisation** (Hospitalization Council) | **National** | ▪ Develops policies for the funding of healthcare institutions and determines the objectives of health insurance expenditure regarding hospitalisation (e.g. liste en sus GHS for expensive medicines) |
| | **CME- Commission Medicale D'Etablissement** (Medical establishment committee) | **Local** | ▪ Defines the therapeutic priorities of the hospital and organizes and delivers care<br>▪ Defines hospital formulary depending on therapeutic priorities, cost effectiveness and resource optimization, and advises on medicine prescriptions |
| | **Mutuelles** (Complementary health insurance) | **National** | ▪ Mutuelles are employer or union funded, and provide complementary health insurance in addition to the statutory health insurance offered by the MoH<br>▪ Retail drugs are reimbursed by statutory health insurance at a level defined by UNCAM; mutuelles then reimburse the remainder of these costs to the patient |

# The TC evaluates retail and hospital products which influences price, access and reimbursement rates

## France P&MA Overview

*Hierarchy of influence from market authorization to reimbursement*




- Public financing of health care in France is among the highest in Europe and out-of-pocket spending among the lowest; 70% of the total healthcare expenditure is publicly funded, mostly through SHI
- The Ministry of Health (MoH) sets and implements government policy in public health and organizes and finances the health care system; it defines the benefit package, sets provider fees and evaluates and prices drugs
- The HAS is the MoH body responsible for conducting HTAs; after market authorization, drugs are evaluated by the TC and additionally the CEESP when conditions are met*, followed by price negotiation with CEPS

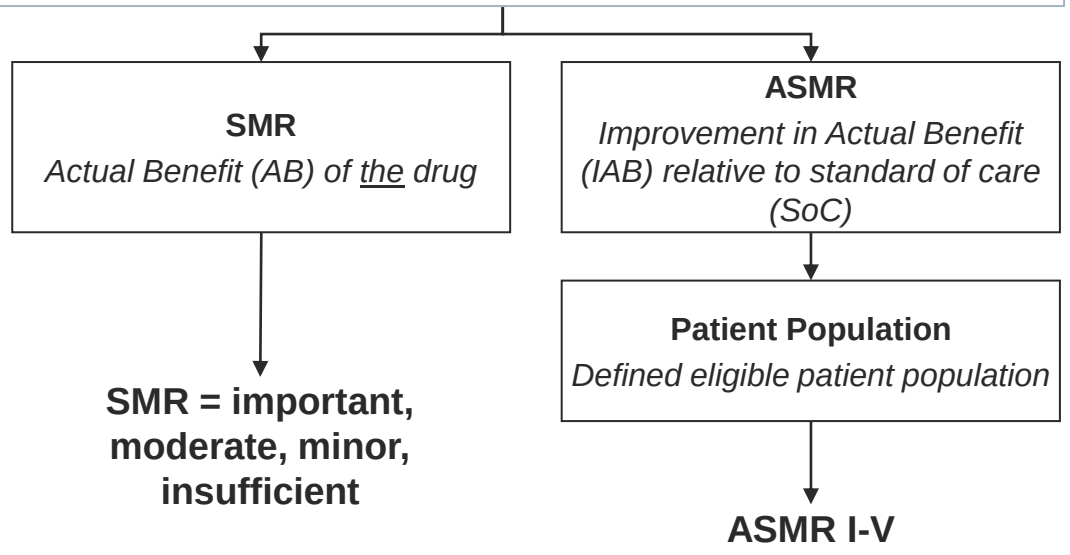
*Notes: *CEESP performs health economic evaluation for ASMR I-III and drugs with likely high budget impact, Liste Sécurité Sociale is a list of reimbursable retail products, Liste Agrément aux collectivités is the list of medicines for use by communities and public services, EMA = European medicines agency, SHI = Statutory health insurance, HTA = Health technology appraisal*

# As such, the TC is the main stakeholder in the HTA process and is predominantly driven by clinical value; it awards SMR and ASMR

## Overview of National HTA in FR

### Transparency Commission

The TC conducts a technical assessment giving an opinion on Medical Benefit (SMR) based on five criteria; efficacy & safety; therapeutic strategy/alternatives; disease severity; treatment type; public health impact




***Drugs are re-assessed at the request of the TC****

### SMR - Service Medical Rendu

- The SMR is mainly based on the clinical efficacy and safety of the technology. It also considers other parameters such as the severity of the disease and the public health relevance of the technology
- Drugs are given a SMR rating: Insufficient, Low, Moderate or Important

### ASMR - Amélioration du Service Médical Rendu

- The ASMR indicates the improvement in the medical benefit of the technology relative to similar available treatments
  - Standard of care is defined based on local guidelines and utilization
- ASMR is rated on a scale from I for major improvement, most likely life-saving technologies, to V for no improvement and has implications on subsequent price negotiations with CEPS

*Notes: *For one of the following 4 reasons: 1. entry of a new drug with a significant improvement in ASMR that could change the treatment paradigm, 2. new data submission 3. reports of safety concerns 4. request of social security for drugs perceived particularly expensive. SMR = Medical Benefit; ASMR = Improvement of the Medical Benefit versus a comparator (not an absolute rating). Source: https://www.lmtavocats.com/media/files/telecharger_lmt-avocats-publie-dans-hospitalia-09-2020.pdf*

# Clinical effectiveness relative to the defined standard of care is a key driver of reimbursement decisions in France

## Factors Influencing HTA Decisions

**KEY:** *Low* ○ → ◑ → ● *High*

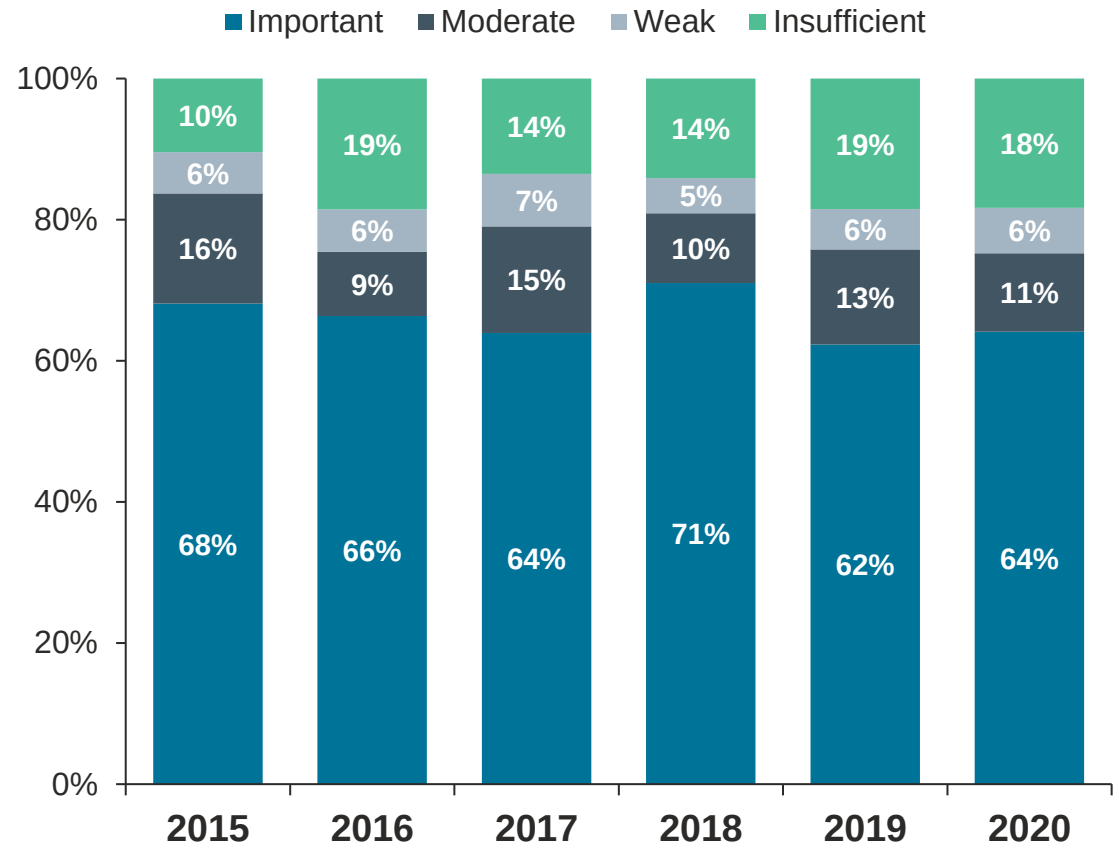
| Factor | Level of Influence on Reimbursement | Key Considerations |
|---|---|---|
| **Unmet Need** | ◔ | ▪ Disease severity, morbidity, mortality, socio-economic burden, and availability and effectiveness of therapeutic alternatives are all considered |
| **Population Size** | ◑ | ▪ Size of patient population and therapeutic positioning in relation to other available treatments are important in the French HTA |
| **Therapeutic Improvement** | ◔ | ▪ ASMR determined based on the drug's clinical value relative to its comparator which typically forms the price reference; efficacy (emphasis on 'hard outcomes'), tolerability, administration etc. are all taken into consideration |
| **Medico Economic Evaluation*** | ○ *(CEESP evaluation influences price)* | ▪ CEESP performs cost-effectiveness analyses on drugs which are submitted to receive ASMR I-III and have a high budget impact**, although there is no defined ICER threshold<br>▪ Drugs which receive ASMR I-III and orphan drugs with ASMR IV are eligible for a minimum price in line with the rest of Europe<br>▪ CEESP evaluation informs price negotiations with CEPS but has no implication on reimbursement |
| **Budget Impact** | ◔ | ▪ Eligible population, as determined by the Transparency Commission, forms the basis of the price-volume agreement negotiated with CEPS |
| **Quality of Evidence** | ◔ | ▪ Strength of clinical trials (head-to-head vs. standard of care preferred) |

**Usually a cost-effectiveness or cost-utility analysis, **and under some conditions drugs with ASMR IV (e.g. orphan drugs). Source: https://www.has-sante.fr/upload/docs/application/pdf/2020-11/methodological_guidance_2020_-choices_in_methods_for_economic_evaluation.pdf, https://solidarites-sante.gouv.fr/IMG/pdf/accord_cadre_21-24_signe.pdf*

# Most drugs receive SMR “important” which determines reimbursement rates

## SMR Outcomes in France

*SMR ratings between 2015 and 2020*



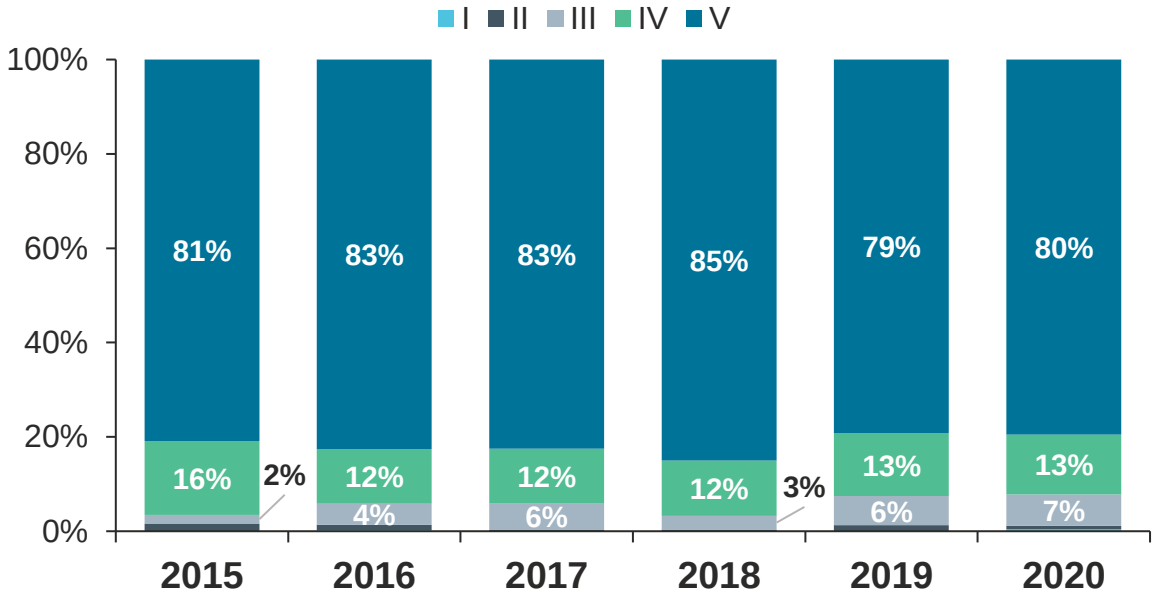

- SMR ratings inform whether a drug will be reimbursed, and what level reimbursement will be covered by SHI
- The SMR rating is a measure of the “Actual Benefit”; based on the product’s medical benefit
- SMR is awarded based on five criteria:
  1. Efficacy and safety
  2. Position of the drug in the therapeutic algorithm
  3. Severity of disease
  4. Type of treatment; preventative, curative or symptomatic
  5. Public health impact
- The majority of drugs receive SMR “important”; however, there has been a gradual increase in the proportion of “insufficient” ratings over the past few years
- This impacts the level at which retail drugs are reimbursed through social security funds*

*Notes: *See slide 11 for reimbursement rates. Source: https://www.data.gouv.fr/en/organizations/haute-autorite-de-sante-has/*

# ASMR levels influences the price setting process; ASMR V is the most common rating

## ASMR Outcomes in France

*ASMR ratings between 2015 and 2020*




## Rationale for ASMR Ratings

*Improvement in Actual Benefit is categorized based on assessment of the product's value relative to SoC*

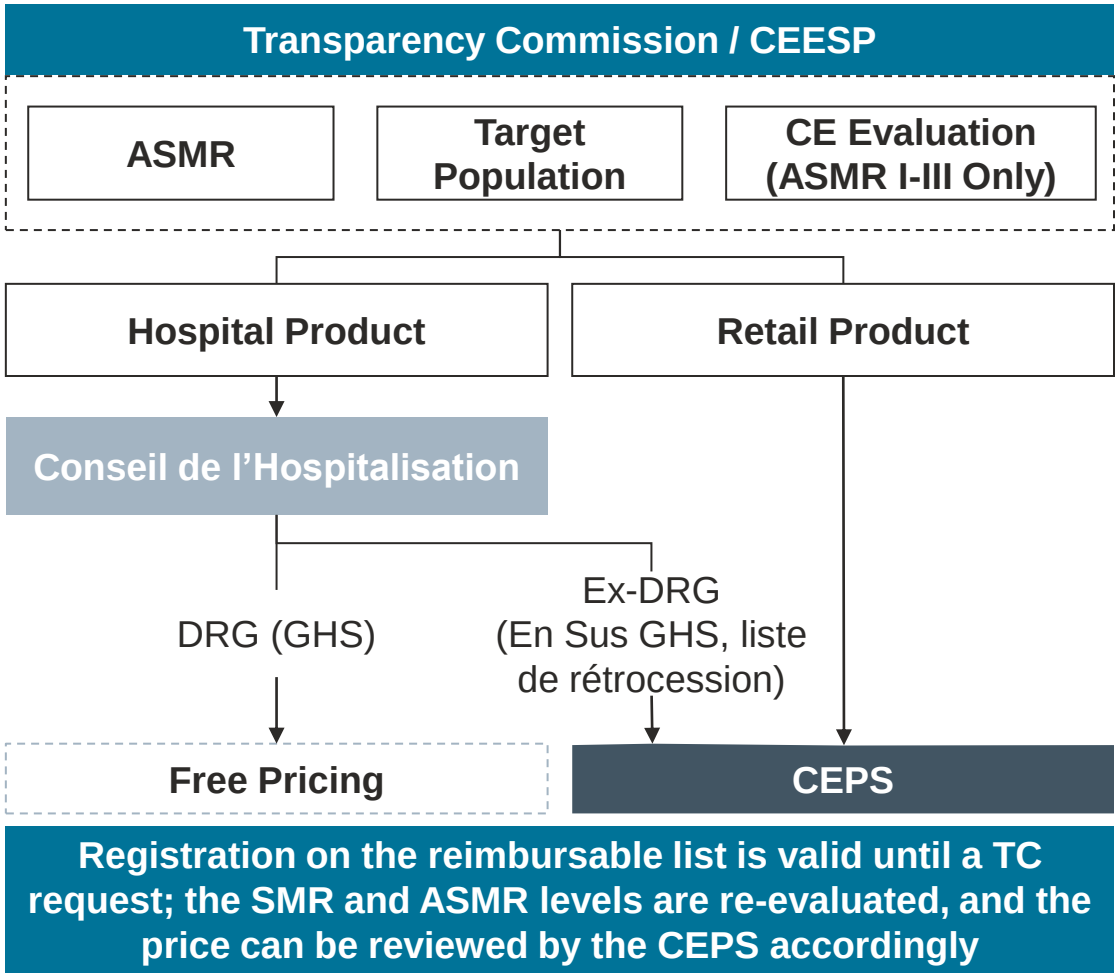
| Score | Rationale | Price Implications |
|---|---|---|
| I | Major therapeutic advance | Premium vs price comparator likely |
| II | Important improvement in terms of efficacy / reduced side effects | |
| III | Moderate improvement in terms of efficacy / reduced side effects | |
| IV | Minor improvements in terms of efficacy, ease of use, justified extension of product range, improved pharmacokinetics or lower risk of drug interactions | Parity to price comparator possible, risk of price discount |
| V | No improvement, but may be reimbursed | Likely price discount |

- ASMR reflects the improvement in the medical benefit of the technology in comparison with similar available treatments; ~80% of therapies are rated ASMR V
- If ASMR I-III, the price will not be lower than the price in any of the 4 comparator European markets (DE, UK, IT and ES), but requires significant differentiation and demonstration of cost effectiveness
  - Manufacturer can set price 'freely' (depot de prix), in line with prices in other EU3 + UK, and have the price monitored by CEPS over time to ensure a price in line with EU3 + UK; the price is guaranteed for 6 years
- ASMR IV-V are far more common and denote no or minimal actual benefit; they typically result in prices lower than the comparator and/or additional restrictions beyond the label indication

*Source: https://www.data.gouv.fr/en/organizations/haute-autorite-de-sante-has/, https://solidarites-sante.gouv.fr/IMG/pdf/accord_cadre_21-24_signe.pdf*

# Price-volume agreements are negotiated with CEPS and are highly confidential in nature

## Price Setting in France

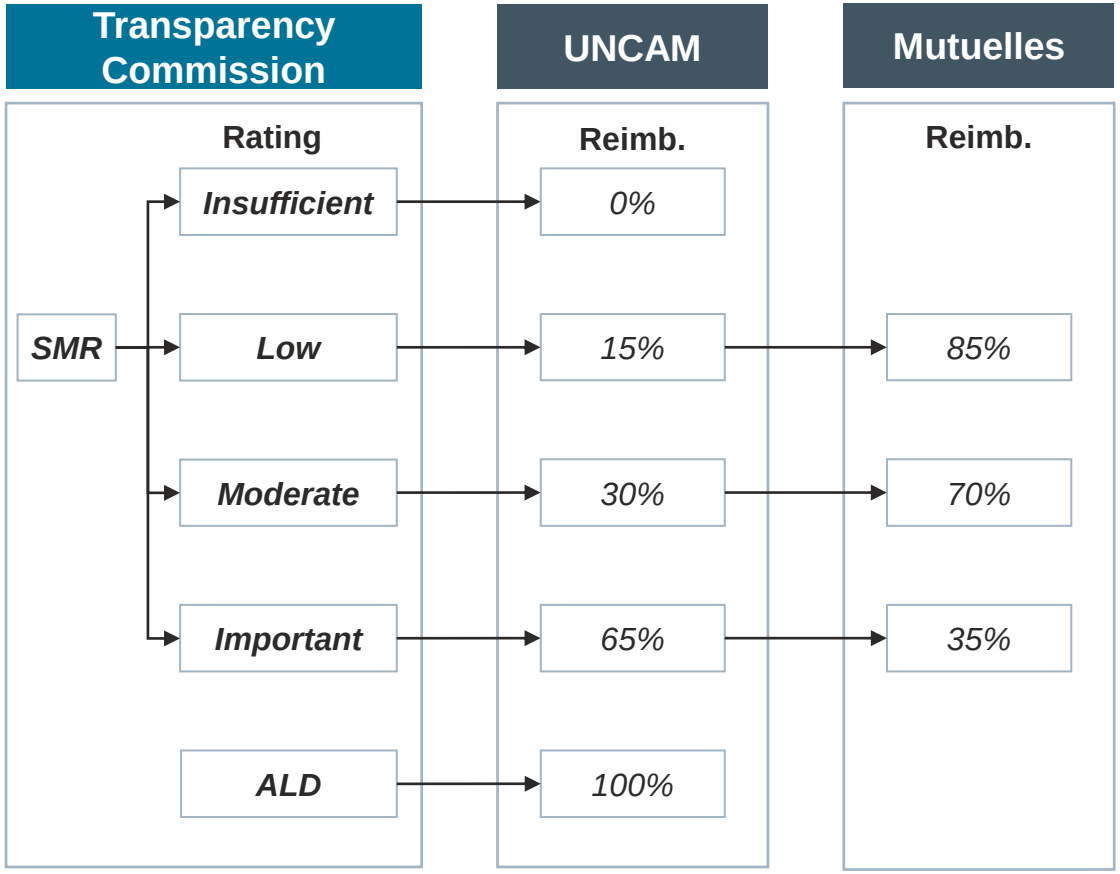



- CEPS set prices for reimbursable retail medicines, hospital products and reference prices based on outcomes of the TC and, where applicable, CEESP evaluations
  - The TC defines the eligible population, and the ASMR rating, which forms the basis of the price-volume agreement negotiated with CEPS
  - CEESP performs cost-effectiveness analyses on drugs which are submitted to receive ASMR I-III, although there is no ICER threshold
  - In general, the price depends upon; ASMR level, price of comparators in FR, price of the product in the EU5, three-year sales forecast, size of target population and conditions for use
- Drugs which receive ASMR I-III and orphan drugs with ASMR IV are eligible for a minimum price in line with the rest of Europe
- Hospital drugs, which do not require extra-funding and are funded via the DRG mechanism are freely priced and negotiations take place between the hospital and the manufacturer
  - Prices can then be negotiated down though hospital buying groups
  - Tendering is possible, especially for inpatient drugs; for more expensive drugs, CEPS oversees the price negotiation

*Notes: GHS = Groupes homogènes de séjours, DRG = Diagnosis Related Group*

# The SMR rating correlates with the level of SHI reimbursement in the retail setting; UNCAM and Mutuelles share the cost of retail products

## Funding & Reimbursement of Retail Products

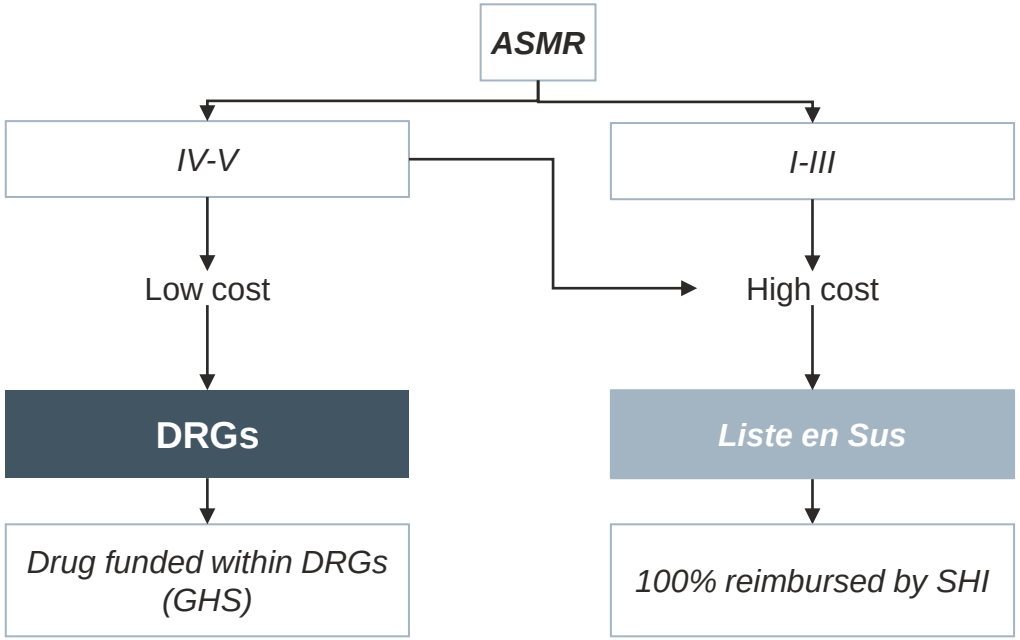



- Retail drugs are funded predominantly by Social Security (Assurance Maladie) and priced at the drug price negotiated with CEPS at a national level
  - Reimbursement rates are set by UNCAM and heavily influenced by SMR (range from 0-65% reimbursement)
  - The remainder of drug cost is covered by complementary insurers (Mutuelles) which are largely employer or union funded
- Typically, the manufacturer suggests a price in accordance with prices in the EU3 + UK; price volume agreements are often decided for the first 4 years
- The ALD (Affection de Longue Durée) covers chronic illnesses (e.g., diabetes, HIV), which reimburses products and services at 100%

*Notes: ALD = Affection de Longue Durée*

# Hospital products are funded through DRG budgets; high-cost drugs with ASMR I-III ratings can be reimbursed through the Liste en Sus

## Funding & Reimbursement of Hospital Products




- Hospital treatment is 100% reimbursed by SHI
- Hospital drugs are predominantly funded through a diagnosis-related groups (DRG/GHS) system, also known as T2A; this is a bundle price to cover the cost of the treated patient during their stay and price may be negotiated by hospitals
  - T2A tariffs are set based on average costs across several hospitals
- Innovative and expensive products are often excluded from the DRG system and funded by social security to ensure they remain affordable for hospitals; these products are placed on the Liste en Sus
- In addition, drugs that are only sold in hospital pharmacies due to safety concerns* are put on the retrocession list (Liste de Rétrocession) and are funded by the SHI

### Criteria for Inclusion on the *Liste en Sus*

- SMR important, ASMR I-III, although it is possible for a drug with ASMR IV to be on the list if there is no other therapeutic alternative available on the market
- Estimated cost 30% above the DRG
- If drug has ASMR IV or V and its comparator is on the List en Sus, then it is automatically included

**This also includes drugs subject to an early access program, SHI = Statutory Health Insurance*

# As a highly nationalized market, France controls price and budget impact more than they control market access

## Market Access and Cost Containment Considerations

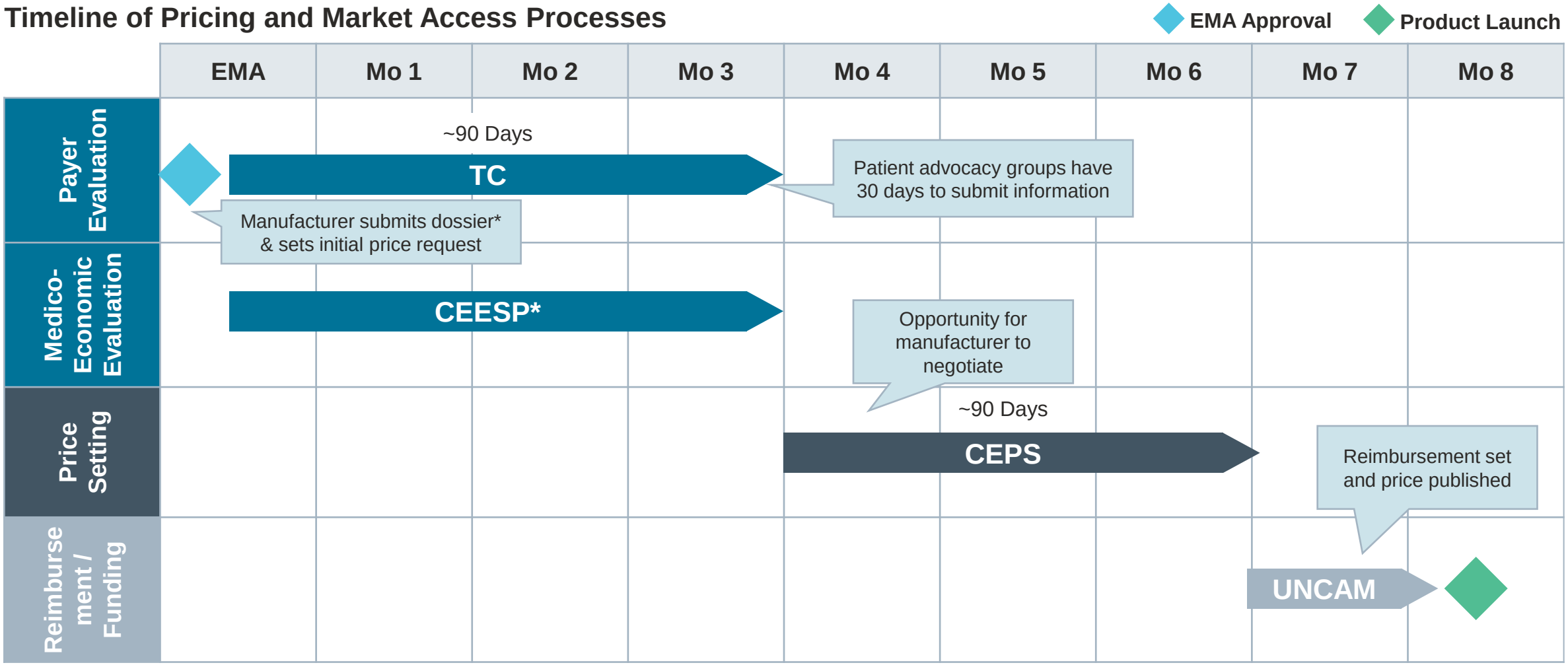
**KEY:** *Low* ○ → ◑ → ● *High*

| Mechanism | | Level Applied | Frequency of Use | Commentary |
|---|---|---|---|---|
| **Net Pricing** | **Confidential Discounts** | National | ● | Confidential discounts are very common in France as part of price-volume agreements; except for generics, where the list and net price are the same |
| **Managed Entry Agreements** | **Financial Based** | National | ● | Price-volume agreement commonplace, price often tiered based on volume; rebate agreements based on revenue can also be negotiated for high cost drugs (i.e. orphan medicines) |
| | **Performance Based** | National | ◔ | Rarely used, only for innovative gene therapies; particularly, risk sharing agreements and coverage with evidence development |
| **Population Restrictions** | **Patient Subset** | National | ◑ | The TC defines the appropriate population for reimbursement for clinical/economic reasons, and this can include restrictions to specific subpopulations of patients |
| | **Site of Care/ Prescriber** | National | ◕ | Common for TC to define the site of care and the prescriber for the drug to be administered |
| | **Formulary Exclusion** | Hospital | ◔ | Uncommon, but possible for hospital drugs* where only a few drugs will be placed on formulary for each therapeutic class; hospital formularies are reassessed every year or two |
| **Other** | **Prescription Budgets/ Quotas** | Prescriber | ◑ | There are soft targets for generic prescriptions, and GPs can be rewarded for savings to the health system (monitored through reduced prescriptions, generic prescribing and vaccination) |
| | **Generic Substitution** | Pharmacy | ● | Pharmacy-level substitution permitted for drugs on the liste en sus of drugs where substitution is authorized |

*Note: *Hospital drug status includes: DRG (GHS), liste en sus, or T2A exclusion list (high-cost drugs which require extra funding), liste de retrocession (retail drugs that can only be purchased in hospital pharmacies)*

# On average, it takes ~210 days for a product following marketing authorization to be reimbursed; however, the target for completion of price negotiation is 180 days

## Timeline of Pricing and Market Access Processes




*2-part submission, technical and economic file evaluated by TC and CEESP/CEPS respectively, **if likely significant budget impact and manufacturer seeking ASMR I-III. Sources: https://www.has-sante.fr/upload/docs/application/pdf/2017-11/principes_devaluation_de_la_cnedimts-v4-161117.pdf ; https://drugdevelopment.labcorp.com/content/dam/covance/assetLibrary/salessheets/Pricing-Reimbursement-France-SSCMA053.pdf

## For Further Information:

**Matt Storer**
**Managing Partner**
**matt.storer@windrosecg.com**

**Website**: www.windrosecg.com
**General Contact**: info@windrosecg.com

Eight Tower Bridge
161 Washington Street, Suite 330
Conshohocken, PA 19428

20 Old Bailey
Suite 501
London, EC4M 7AN

Hertensteinstrasse 51
6004 Lucerne
Switzerland