

Pharmaceutical pricing and reimbursement policies in the in- and out- patient sector

European Medicines Agency (**EMA**) or French Health Products Safety Agency (**ANSM**)

AUTHORISATION

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

Only medicines requesting to be reimbursed are assessed

EARLY ACCESS SCHEMES

Scheme name	Regulatory status
Temporary use authorisation (ATU) Temporary use recommendation (RTU)	Coverage before a Marketing authorisation (MA)
ATU for new indication (post-ATU direct) ATU for new indication (ATU EIT)	Coverage after a MA

ASSESSMENT

French National Authority for Health (**HAS**)

Task: Clinical assessment (for all drugs requested to be reimbursed) and economic assessment (only if supposedly innovative and/or annual gross revenue > 20 M€ and/or organisational impact)
Criteria: - Clinical assessment : medical value (**SMR**); added-medical value (**ASMR**); target population; comparators; use conditions
 - Economic assessment : incremental cost-effectiveness ratio (**RDCR**)

P&R CRITERIA

Reimbursement criteria

Reimbursement rates are driven by SMR

SMR important	}	65 %
SMR moderate		35 %
SMR weak		15 %
SMR insufficient		0%

Drugs treating severe and chronic disease (ALD) and in-patient drugs are covered 100 %

Pricing criteria

Pricing decisions are mostly driven by ASMR

ASMR I	major added value	}	price > comparators
ASMR II	important added value		price > comparators
ASMR III	significant added value		price > comparators
ASMR IV	minor added value		price = comparators
ASMR V	no added value		price < comparators

OUT-PATIENT

Pricing Committee (**CEPS**)

Task: Price negotiation
Criteria: set by law (Art. L162-16-4 Social Security Code)
 - Added medical value (ASMR)
 - Economic assessment
 - Comparators prices
 - Sales forecast
 - Use conditions
 ERP is used only for innovative medicines (ASMR I, II and III) and a valid economic assessment
 ERP basket is composed by Germany, Italy, Spain and the UK

Sickness funds union (**UNCAM**)

Task: Reimbursement rate
Criteria: Reimbursement rate (15%, 35%, 65%) based on SMR
 Drugs treating severe and chronic disease (ALD) are covered 100 %

Ministry of Health

Task: Positive list and publication

IN-PATIENT

Lists of authorised medicines in hospital

Drugs over-DRGs or dispensed at the hospital for out-patient use

Drugs included in the DRGs

Pricing Committee (**CEPS**)

Hospital purchasing body or union

Task: Price negotiation
Criteria: Same as out-patient

Task: Price negotiation and/or tendering
Criteria: Depends on the product or the market situation

Ministry of Health

Task: Positive list and publication
 Hospital drugs are covered 100%

SPECIFIC PRICING

GENERICS

Originator:
-20% at generics marketing

Generics: - 60% vs originator price

BIOSIMILARS

Originator:
-20% at biosimilars marketing

Generics: - 40% vs originator price

PARALLEL IMPORT

-5% vs originator

GENERICS

Both originator and generics :
-40 % vs originator price

BIOSIMILARS

Both originator and biosimilars :
-30 % vs originator price

PARALLEL IMPORT

-5% vs originator