PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: France 2020

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

---

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: France 2020

Final version

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Author:
Sabine Vogler (PPRI Secretariat, Gesundheit Österreich / GÖG)

Project assistant:
Romana Landauer (PPRI Secretariat, Gesundheit Österreich / GÖG)

Review and translation of the Summary in French:
Jonathan Rodrigues (Comité économique des produits de santé / CEPS)

Vienna, October 2020
Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

Suggestion for citation: Vogler Sabine (2020): PPRI Pharma Brief: France 2020. Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series. Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna

P4/33/4493

Owner, editor and publisher: Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Stubenring 6, 1010 Vienna, Austria, Tel. +43 1 515 61, websites: www.goeg.at and https://ppri.goeg.at

This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in France is part of the series of PPRI Pharma Briefs launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 51 – mostly European – countries (as of August 2020) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and pharmaceutical policy analysis, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to cross-learn and benchmark as well as for researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

Well-established publications that offer pharmaceutical pricing and reimbursement information on a single PPRI country are the **PPRI Pharma Profiles** that are available as in-depth reports as well as short reports, see https://ppri.goeg.at/ppri_pharma_profiles. Furthermore, one-page graphical abstracts are provided in the **PPRI Posters**, see https://ppri.goeg.at/ppri_posters.

The new series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries.

The PPRI Pharma Briefs draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (1 January 2020)	67.064 million
Country size (1 January 2019)	632 734 km² (including oversea areas)
Gross domestic product / GDP (2019)	GDP per capita: € 35,960 (provisional data)
Health expenditure / HE (2019, estimated values)	HE per capita: € 4,037.7 / USD PPP 5,375.7 HE in % of GDP: 11.2% Public HE as % of total HE: 83.7%
Pharmaceutical expenditure / PE (2018)	PE per capita: € 569 / USD 671.4 PE in % of HE: 13.0%

GDP = gross domestic product, HE = health expenditure, PE = pharmaceutical expenditure, PPP = Purchasing Power Parities, USD = United States dollars
Pharmaceutical expenditure data relate to the outpatient sector only

Sources: population – INSEE Bilan démographique [1]; country size – INSEE Comparateur de territoire. France entière [2]; GDP – Eurostat [3], health expenditure – OECD Health Statistics [4], pharmaceutical expenditure: OECD pharmaceutical spending [5]

Provision of pharmaceuticals

Community pharmacies (1 January 2020)	20,736 community pharmacies
Wholesale (2019)	7 full-line wholesale companies 185 wholesale outlets
Pharmaceutical industry (2020)	250 companies

Sources: community pharmacies – Ordre National des Pharmaciens [6]; wholesale – CSRP [7]; pharmaceutical companies – LEEM [8]

Pharmaceutical market

Pharmaceutical market (2019)	€ 60 billion (at ex-factory prices, excluding taxes)
Medicines (1 April 2020)	16,822 medicines authorised (counted including different pharmaceutical forms and dosages) 13,023 medicines marketed (counted including different pharmaceutical forms and dosages)
Generic market shares (2018)	18.9% in value (outpatient sector) 37.3% in volume (outpatient sector)

Sources: pharmaceutical market – LEEM [8]; medicines – data retrieved from the ANMS [9]; generic market shares – data provided by CEPS

Pharmaceutical pricing (2020)

Price regulation	Yes, in place for outpatient and inpatient medicines included in the respective reimbursement lists (i.e. all reimbursed medicines except those in Diagnosis Related Group (DRG) funding)
Pricing authorities	**Outpatient**: Economic Committee for Health Care Products (Comité économique des produits de santé / CEPS) **Inpatient**: Economic Committee for Health Care Products (Comité économique des produits de santé / CEPS) except for inpatient medicines in Diagnosis Related Group (DRG) funding; procurement is done by the purchasers (hospitals, hospital owner associations, hospital purchasing groups)
Key pricing policies	**External price referencing**: yes, for outpatient and inpatient medicines in a reimbursement list limited to medicines considered as innovative (value score "Amélioration du service médical rendu" / ASMR of I, II or III). Basket countries are Germany, Italy, Spain and UK. List price in France cannot be lower than the lowest price among the reference countries. **Value-based pricing** elements: yes, pricing negotiations are mostly based on a value score for the additional benefit (ASMR), defined by the Health Technology Assessment (HTA) agency HAS. **Price negotiations**: for outpatient and inpatient medicines in a reimbursement list except for inpatient medicines in Diagnosis Related Group (DRG) funding **Managed-entry agreements**: used for some outpatient and inpatient medicines, mainly financially-based (as single discount or price-volume agreements) **Tendering**: for some inpatient medicines **Cost-plus pricing**: not used **Generic price link**: yes, for outpatient and inpatient medicines in a reimbursement list and not part of a Diagnosis Related Group (DRG) funding **Biosimilar price link**: yes, for outpatient and inpatient medicines in a reimbursement list and not part of a Diagnosis Related Group (DRG) funding
Pricing in the supply chain	**Wholesale**: regressive mark-up scheme for reimbursable medicines **Pharmacy**: regressive mark-up scheme and dispensing fees for reimbursable medicines **Value-added tax**: 2.1% on reimbursable and 10% on non-reimbursable medicines (standard VAT: 20%)

Source: overview provided by the PPRI Secretariat

Pharmaceutical reimbursement (2020)

Reimbursement authorities	**Outpatient:** Social health insurance **Inpatient:** Social health insurance
Reimbursement lists	**Outpatient:** a reimbursement list for outpatient medicines (positive list) at national level **Inpatient:** two reimbursement lists for hospital medicines (not included in the DRG funding) at national level; in addition, hospital pharmaceutical formularies
Reimbursement criteria	**Outpatient**: decision on inclusion into reimbursement list is based on the value score (SMR) of the clinical assessment and defined by Health Technology Assessment (HTA). The decision is taken by the National Statutory Health Insurance. **Inpatient:** decision on inclusion into one of the reimbursement lists is based on a ministerial decision.
Co-payments for medicines	**Outpatient:** a prescription fee & percentage co-payments of the medicine's price **Inpatient:** no co-payment
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** in place **Prescribing by International Non-Proprietary Name (INN):** obligatory **Generic substitution:** allowed **Biosimilar substitution:** not allowed

Source: overview provided by the PPRI Secretariat

Key technical terms are defined in the glossary in Annex 3.

Summary

Health care in France is based on a Bismarckian social health insurance system. With regard to pricing and reimbursement of medicines, key institutions are the Ministry of Solidarity and Health which hosts the Economic Committee for Health Care Products (CEPS), the National Union of Health Insurance Funds (UNCAM) and the High Authority of Health (HAS).

At HAS, the Transparency Committee performs the clinical evaluation while the Economic Evaluation and Public Health Committee is in charge of the economic assessment. The outcomes of the clinical assessment are a "medical value" (*Service médical rendu* / SMR) rating, which impacts the reimbursement rate of outpatient medicines and the "improvement in medical value" (*Amélioration du service médical rendu* / ASMR) rating which impacts the price of a medicine. The findings of the economic assessment provide an incremental cost-effectiveness ratio (ICER) and sometimes a budget impact analysis. Clinical assessment is mandatory for all medicines for which reimbursement is applied while eligibility to an economic assessment is based on specific criteria.

Medicines included in the outpatient or inpatient reimbursement lists are price-regulated. There is free pricing for non-reimbursed outpatient medicines, hospital medicines in the Diagnosis Related Groups (DRG) system and medicines included in an early access scheme (for the latter, however, with possible pay-backs once a regulated price is reached). Prices of medicines under price regulation are negotiated between the Economic Committee for Health Care Products (CEPS) and the pharmaceutical company. In case of high ASMR rating (ASMR I, II or III on a scale from I to V) and no methodological shortcomings in the economic assessment, prices in Germany, Italy, Spain and UK are considered as one element in the price negotiation (external price referencing). In this situation, the list price in France cannot be lower than the lowest price in the reference countries. Prices of reimbursable generics and biosimilar medicines are set based on the price of the originator or reference medicines, with different rates per sector (outpatient / inpatient) and medicine. Tendering is often applied for medicines procured by hospitals. Some hospitals collaborate in joint procurement initiatives.

In the outpatient sector, wholesalers and community pharmacies are remunerated through a regressive mark-up scheme for handling or dispensing reimbursable medicines, respectively. In addition, community pharmacies receive dispensing fees. The mark-up scheme for pharmacies provides incentives to dispense generics, and there are specific remuneration provisions for supplying three-month packs. Reimbursable medicines are charged a value-added tax of 2.1% compared to 10% for non-reimbursable medicines.

Depending on their SMR rating, outpatient reimbursable medicines are reimbursed at 65%, 30% or 15%; defined medicines for several and chronic diseases are always 100% reimbursed. Outpatients have to co-pay a prescription fee plus the percentage co-payments, which are frequently covered by a complementary "mutuelle" health insurance.

In the hospital sector, there are two reimbursement lists: the "liste en sus" for supplementary, usually high-priced or low-volume medicines, and the list of "retrocession medicines" dispensed

by hospital pharmacies to outpatients. For medicines included in these lists, health technology assessments (HTA), that have been performed by HAS, inform the price negotiations between CEPS and the pharmaceutical company. For some of them, CEPS may conclude a managed-entry agreement (MEA).

Hospital medicines not included in one of the two hospital reimbursement lists are funded through the DRG system. Hospitals may draw up their own pharmaceutical hospital formulary. Furthermore, hospitals or hospital groups also conclude individual MEA with companies.

In France a reference price system for clustering identical medicines is in place, and prescribing by the International Non-Proprietary Name (INN) and generic substitution are allowed. In addition, there are incentives targeted at prescribing doctors and pharmacists that aim to promote the uptake of generics.

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, France

Résumé

Le système de santé en France est basé sur un modèle assurantiel de type Bismarckien. Les institutions clés participant à la fixation du prix et du remboursement des médicaments sont le Ministère des Solidarités et de la Santé, le Comité économique des produits de santé (CEPS), l'Union nationale des caisses d'assurance maladie (UNCAM) et la Haute autorité de Santé (HAS).

La Commission de la Transparence de la HAS produit l'évaluation clinique alors que la Commission Évaluation Économique et de Santé Publique élabore l'avis d'efficience. L'avis de la Commission de la Transparence définit le niveau du Service médical rendu (SMR) servant de base à la fixation du taux de remboursement ainsi que l'Amélioration du service médical rendu (ASMR) qui sert de socle à la négociation du prix. L'avis d'efficience fournit le ratio différentiel coût-résultat (RDCR) et dans certains cas une analyse d'impact budgétaire. Alors que l'évaluation clinique est systématique pour tout médicament sollicitant une prise en charge, l'avis d'efficience est uniquement demandé sous certains critères.

Le prix des médicaments inscrits dans une liste de remboursement est administré. Le prix est librement fixé par les industriels pour les médicaments non-remboursés vendus en officine, les médicaments hospitaliers intra-GHS (groupe homogène de séjour) ainsi que les médicaments pris en charge en accès précoce (ATU) – concernant ce dernier un mécanisme de remise a posteriori s'applique. La régulation des prix s'effectue par négociation entre le CEPS et les laboratoires pharmaceutiques. Pour les médicaments considérés comme innovant (ASMR I à III) et en cas d'absence de réserve méthodologique majeure dans l'avis d'efficience, le médicament est éligible à une garantie de prix européen. Son prix facial ne peut être inférieur au prix le plus bas pratiqué dans les pays de référence constitué de l'Allemagne, l'Angleterre, l'Espagne et l'Italie. Le prix des médicaments génériques et biosimilaires remboursés est défini sur la base du médicament de référence. Des appels d'offres ont lieu pour les médicaments hospitaliers. Ils peuvent se faire au travers de groupements d'achat.

Dans le circuit ville, les grossistes-répartiteurs et les pharmacies d'officine sont rémunérées par une marge régressive en complément de quoi les pharmacies perçoivent des honoraires de dispensation. Des mesures incitatives favorisent la dispensation de génériques et de conditionnement trimestriels. La taxation de médicaments remboursés est de 2,1% ainsi que de 10% pour les médicaments non-remboursés.

En fonction du SMR octroyé, le taux de remboursement des médicaments « ville » varie de 15%, 30% et 65%. Le complément étant à la charge du patient. Cependant, cette part est souvent payée par des assurances complémentaires. Les médicaments traitant des affections dont la gravité et/ou le caractère chronique nécessitent un traitement prolongé et une thérapeutique particulièrement coûteuse sont pris en charge à 100%.

Dans le circuit hôpital, il existe deux listes de remboursement : la liste en sus pour les médicaments innovants, coûteux et associés à un faible volume et la liste de rétrocession correspondant aux médicaments dispensés à l'hôpital pour un usage ambulatoire. Pour les médicaments inclus

dans ces deux listes, un avis de la Commission de la Transparence est nécessaire et dans certains cas un avis d'efficience. Pour certains de ces traitements, le CEPS peut décider d'un accord de type « clause » aboutissant à une remise.

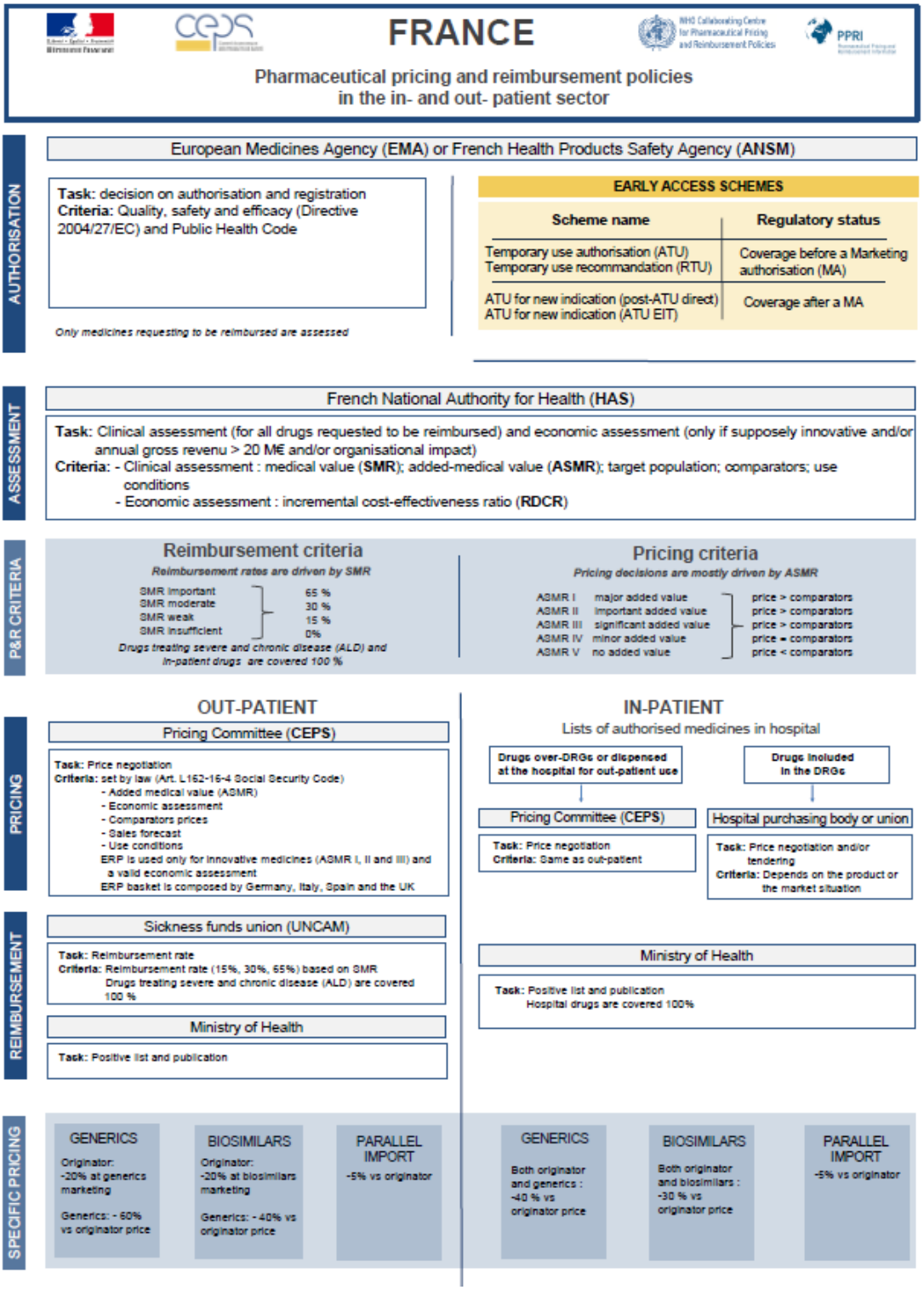
Les médicaments hospitaliers n'étant pas inclus dans l'une de ces deux listes sont financés par un GHS. Chaque hôpital constitue son propre formulaire thérapeutique. Les hôpitaux et les groupements d'achat hospitaliers peuvent en complément des accords obtenus par le CEPS, négocier des remises.

En France, un système de référencement par nom de molécule existe. La prescription se fait en dénomination commune internationale. La substitution par le pharmacien d'un princeps vers un générique est promue par des mesures incitatives.

Mots clés

Fixation des prix, remboursement, la politique de médicaments, les systèmes de médicaments, France

Graphical summary



Poster at the PPRI Conference, Vienna, 23 – 24 October 2019 [10], valid as 2020

1 Framework

The French health care and pharmaceutical system is based on the Bismarckian approach of a Social Health Insurance system, supplemented by complementary health insurances (so-called "mutuelles"). Thus, the Social Security Code (*Code de la sécurité sociale* / CSS) is a major **legal basis** of the pharmaceutical policy framework, adding to relevant provisions in the Public Health Code (*Code de la santé publique* / CSP). In addition, the French government and the health insurances, represented by the Economic Committee for Health Care Products (*Comité économique des produits de santé*, CEPS) and the pharmaceutical industry association (*Les Entreprises du medicament* / LEEM) have been concluding multi-annual framework agreements (*Accords Cadre*) which defined specificities of the price negotiation procedure (see also chapter 4 on "Developments").

The **competences** for regulatory and pharmaceutical policy matters (such as ➲ marketing authorisation, ➲ price negotiation and ➲ reimbursement; for terms labelled with the ➲ sign consult the glossary in Annex 3) are divided among public authorities. In principle, the same public institutions are responsible for policy implementation in the outpatient and inpatient sectors, however, processes differ. Linkage exists between pricing and reimbursement ➲ policies.

Key competent **authorities** for pricing and reimbursement in France are the Ministry of Solidarity and Health (*Ministère des Solidarités et de la Santé*) and the Ministry of Economy and Finance (*Ministère de l'Économie et des Finances*). The Economic Committee for Health Care Products, CEPS, affiliated to the Ministry of Solidarity and Health is in charge of pricing of medicines. The decision on the reimbursement level per medicine is taken by the National Union of Health Insurance Funds (*Union nationale des caisses d'assurance maladie*, UNCAM), and the sickness funds (health insurances) and the "mutuelles" offer reimbursement. The Social Health Insurance is also in charge of funding medicines in the inpatient sector. CEPS and UNCAM take their decisions based on ➲ Health Technology Assessment (HTA) provided by the Transparency Commission of the High Authority of Health (*Haute Autorité de Santé* / HAS). The Transparency Commission of HAS also advices the Ministry of Solidarity and Health if a medicine should be approved for use in the outpatient sector, in the inpatient sector or both. The French Medicines Agency (*Agence nationale de sécurité du médicament et des produits de santé* / ANSM) is not involved in pricing and reimbursement matters but it is in charge of marketing authorisation, pharmacovigilance and inspections and also early access authorisation (see Annex 1 for an overview of key stakeholders).

As a basis for pricing and reimbursement decisions, the Transparency Committee of the HTA institution HAS performs a clinical assessment while an economic assessment is performed by the Economic Evaluation and Public Health Committee, also affiliated to HAS. The clinical assessment defines two scores. The first is an assessment of the "medical value" (*Service médical rendu* / SMR). This is based on the criteria of efficacy and tolerance, the position of the medicine within the therapeutic area, the preventive, curative or symptomatic activity of the medicine and the public health interest, and it defines the reimbursement rate for outpatient medicines (see the section on "reimbursement"). The second score is an outcome indicator of "improvement in medical value" (*Amélioration du service médical rendu* / ASMR), and it informs about the value of the medicine compared to what is already available. The five scale AMSR rating impacts the price of the medicine

negotiated between the pharmaceutical industry and the CEPS Committee (see the section on "pricing").

Information presented in the PPRI Pharma Brief relates to the year 2020, unless indicated otherwise.

2 Pricing

Pricing at manufacturer price level

Prices of ➲ reimbursable medicines in the outpatient and inpatient sectors, apart from those that are included in the Diagnosis Related Groups (DRG) system, are regulated. Price control is done at the ex-factory price level and is achieved through ➲ price negotiation between CEPS and the pharmaceutical company.

For medicines with a rating of ASMPR I to III, i.e.

» ASMR I: major improvement (new therapeutic area, reduction of mortality),
» ASMR II: significant improvement in efficacy and/or reduction of side-effects,
» ASMR III: modest improvement in efficacy and/or reduction of side-effects,

➲ external price referencing (EPR) is applied as a supplementary pricing policy to inform the price negotiation. France applies a basket of four countries: Germany, Italy, Spain and UK. The list price must not be lower than the lowest price of that medicine in the reference countries. Prices in British pound are converted at the exchange rate at the time of the application of the EPR policy; price data are neither weighted by volume nor by economic data (such as purchasing power parities). Updates are possible at any time.

Pricing criteria are defined by law (Article L162-16-4 of the Social Security Code) [11]. The CEPS bases the price setting on the value score for the additional therapeutic benefit, the ASMR. In the price negotiation, it also takes prices of comparative medicines into consideration (internal reference pricing), alongside with the findings of the economic assessment, volume and sales forecasts and predictable and actual conditions of use. Production or other costs are not considered (no ➲ cost-plus pricing). For some medicines, ➲ managed-entry agreements (MEA) are concluded; they frequently take the form of a simple discount or a price-volume agreement (see below). Overall, CEPS based its pricing decisions on elements of ➲ value-based pricing.

Medicines with an ASMR I to III are priced at a higher level that the comparator medicine(s); ASMR IV are priced at the same level of a comparator medicine(s), and those with an ASMR V below the price of the comparator(s). France applies a ➲ price link policy for generics and biosimilar medicines that are included into reimbursement, as well as for the originator medicines and reference products, respectively, which have to lower their prices at the market entry of generic and biosimilar medicines: The reduction rates differ between outpatient and inpatient sectors as well as between generics / biosimilar medicines and their originator / reference medicines (no difference for parallel imported medicines).

Price reductions for medicines	Outpatient sector	Inpatient sector
Generic medicines market	Generic: – 60% of originator price Originator: – 20% of its own price	Generic: – 40% of originator price Originator: – 40% of its own price
Biosimilar medicines market	Biosimilar: – 40% of reference medicine price Reference medicine: – 20% of its own price	Biosimilar: – 30% of reference medicine price Reference medicine: – 30% of its own price
Parallel imported medicines	– 5% of the originator price	– 5% of the originator price

While inpatient medicines included in one of the reimbursement lists ("liste en sus" and "retrocession list") applied in hospitals are subject to ➲ price control, there is ➲ free pricing for medicines used in hospitals and funded through the DRG system as well as for non-reimbursable medicines. In addition, there is preliminary free pricing for the medicines in the early access scheme (*Autorisation temporaire d'utilisation* / ATU). For such ATU medicines which

» are intended to treat serious or rare diseases,
» in the absence of appropriate treatment and
» when the treatment cannot be postponed,

the manufacturer can freely set the price before any HTA and price negotiation. Should the set price exceed the HTA-based price negotiated with CEPS at a later stage, the company has to provide pay-backs.

Procurement

The policy of ➲ tendering plays a role for the ➲ procurement of medicines used in hospitals, in particular for high-value bids, in line with procurement requirements. Tendering or tender-like policies are not used for outpatient medicines.

Hospitals may procure on their own, and they can and do conclude MEA with the suppliers. In addition, several hospitals established joint procurement initiatives. Some are based on geography (collaboration in a region, e.g. *Réseau des acheteurs hospitaliers d'Ile de France*/ RESAH-IDF), while others relate to specialised care centres e.g. Regional Cancer Centers.

Pricing in the supply chain

Pharmaceutical ➲ wholesale for outpatient reimbursable medicines is remunerated via a two-scale statutory regressive mark-up scheme (for details including recent and planned changes see Annex 2).

In France, ➲ community pharmacies are remunerated via a statutory five-scale regressive ➲ mark-up scheme applicable to outpatient reimbursable originator medicines and generics included in the reference price system. For generics included in the reference price system, however, pharmacies receive the same amount of remuneration as if they dispensed the originator medicine – a measure to enhance generic uptake. Furthermore, specificities apply for three-month packs (pharmacy remuneration of 3 x 0.9 compared to one-month packs). In addition to the regressive mark-up scheme, pharmacies also receive a ➲ dispensing fee for supplying prescribed medication, with different rates (cf. Annex 2).

Remuneration for non-reimbursable medicines is not regulated; as a result, prices for these medicines can vary between community pharmacies.

In the supply chain, commercial ➲ discounts granted by wholesalers to community pharmacies are capped at 40% for reimbursed generic medicines and non-generics with prices aligned to their generic medicines and at 2.5% for reimbursed non-generic medicines.

If hospitals dispense medicines (so-called "retrocession medicines") to outpatients, they are allowed to charge a fee of € 22 per line of delivery.

The value-added tax (VAT) on medicines is 2.1% on reimbursable medicines and 10% on non-reimbursable medicines while the standard VAT rate is 20% in France.

3 Reimbursement

Reimbursement for outpatient medicines

Medicines classified for outpatient use are fully or partially reimbursed if they are included in the ➲ reimbursement list for the outpatient sector (positive list, no negative list is applied). The decision on their inclusion into reimbursement is based on an HTA report provided by the Transparency Committee of HAS.

In its clinical assessment, the "medical value" (*Service médical rendu* / SMR) of a medicine is evaluated based on the following criteria:

» Efficacy and tolerance
» Position within the therapeutic area
» Preventive, curative or symptomatic activity
» Public health interest

The assessed "medical value" impacts the reimbursement rate for outpatient medicines:

» Important SMR: 65% reimbursement
» Moderate SMR: 30% reimbursement
» Weak SMR: 15% reimbursement
» Insufficient SMR: 0% reimbursement

The National Union of Health Insurance Funds UNCAM decides on the reimbursement rate based on the SMR rating.

Patient-based reimbursement is possible in the cases of imported medicines with a marketing authorisation in another country (reimbursement of the price of the exporting country, at request of the physician) and "early access schemes" applied for medicines with a marketing authorisation in France *("ATU nominative"* for single patients and *"ATU cohort"* for patient group, at request of the manufacturer at a price freely set by the pharmaceutical company).

Medicines to treat severe and chronic diseases (*Affections de longue durée* / ALD) are always 100% reimbursed (around 30 diseases listed in this long duration diseases list).

Apart from patients with a severe and chronic disease, people in France have to pay **percentage** ➲ co-payments of 35%, 70% and 85%, depending on the reimbursement rate. These co-payments are usually reimbursed by their "mutuelle" insurance. In addition, adults above 18 years are charged a **prescription fee** of € 0.50 for each medicine pack (exemption for children), up to an annual cap of € 50 spent by patients on the prescription fee. People on low income and pregnant women and mothers of new born (six months after birth-giving) are exempt from co-payments (both the prescription fee as well as the percentage co-payments).

Reimbursement for inpatient medicines

Around 40% of the medicines used in hospitals are integrated in the performance-based costing system (*Tarification à l'activité* / T2A): they are included in the lump sums which are generated for reimbursement of Diagnosis Related Groups (DRG).

In addition, there are two reimbursement lists (positive lists) of medicines used in hospitals that are not included in the DRG system:

» **List of supplementary medicines** (so-called "*liste en sus*" or "*non T2A*" medicines), which contains mainly very expensive medicines or low volume medicines. It should be a transitional list, and after market entry of other new expensive medicines, medicines of the "liste en sus" are intended to return to the DRG system;
» **List of "retrocession" medicines** which are dispensed by hospital pharmacies to outpatients (since these medicines are not available in community pharmacies).

Medicines on these reimbursement lists are subject to an **HTA** performed by HAS and subsequent **price negotiations** (including the conclusion of a MEA) between CEPS and the pharmaceutical company. They are funded on an individual basis per product by the social health insurance – in contrast to the medicines in the DRG system.

In addition, at decentralised level, hospitals run their own lists (**pharmaceutical hospital formularies**). The Pharmaceutical and Therapeutic Committees in the hospitals decide on the inclusion on medicines in their formularies.

No co-payments of medicines are applied for inpatients.

Agreements

In recent years, **managed-entry agreements** (MEA) were concluded for new high-priced medicines for outpatient and inpatient use between the pharmaceutical company and CEPS. Common types are flat discounts ("discount on the first pack") and price-volume agreements. A few MEA are based on capping; performance-based MEA are rare. "Conditional pricing" (i.e. granting a higher price for medicine with limited evidence on their therapeutic benefit, under the condition that updated data are provided within 3-5 years) have no longer been concluded since 2016. Prices and content of the MEA are kept confidential, but CEPS published in its annual report the total amount of

discounts received per type of agreement. In 2019, 262 MEA were in place, thereof 185 led to a discount [12].

In addition, hospitals or hospital groups also conclude MEA with a pharmaceutical company.

The "**safeguard clause**" defines the contributions that pharmaceutical companies are obliged to pay to the social health insurance in case of excess of a defined threshold (➲ claw-back). Since 2019, the latter has been defined as the net annual turnover of a pharmaceutical company, and it has been fixed at 0.5% for the year 2020 (for changes in the design of the claw-back system, see chapter 4 "Developments").

In addition, the social health insurance receives "ATU" and "post-ATU" discounts which are pay-backs for medicines under the "early access scheme" ATU), see chapter 2 "Pricing".

No discounts or claw-backs to the social health insurance are requested from wholesalers or community pharmacies.

Demand-side measures

The sickness funds in France **monitor the prescription behaviour** of contract doctors with a view to their compliance to the prescribing guidelines. Representatives of the health insurance institutions (*Délégués de l'Assurance Maladie* / DAM) regularly visit prescribing doctors and also discuss their prescription behaviour. As part of performance-based remuneration (*Rémunération sur objectifs de santé publique* / ROSP), **objectives for a rational prescribing** (e.g. thresholds for generic prescribing for certain medicines groups) have been agreed, and are linked to financial incentives. As stated above in the section on "Pricing in the supply chain", the design of pharmacy remuneration provides incentives for pharmacists to dispense generics: i.e. the pharmacy receives the same amount of remuneration when a generic is dispensed as for the respective originator medicine and the discounts that wholesale is allowed to grant pharmacies are higher for generics than for originator medicines.

France has a ➲ reference price system (*Tarif forfaitaire de responsabilité* / TFR) in which identical medicines (of same active ingredient) are clustered and reimbursed at the same amount. Doctors are **obliged to prescribe by International Non-proprietary Name** (➲ INN prescribing), While ➲ **generic substitution** by a pharmacist is **allowed** (indicative, not obligatory), ➲ **biosimilar substitution** is not allowed.

4 Developments

The previous **Framework Agreement** between CEPS and the industry association LEEM, which provides specifications of the price negotiation procedure, was signed in December 2015 for a 3-year period. After a first extension of a year, another seven months of duration (till July 2020) were agreed [13]. In April 2019, CEPS and LEEM agreed on changes in the negotiation procedure (to be included in the new Framework Agreement): pharmaceutical companies have to update their price request based on the HTA report within two weeks upon its reception, and they have to justify

their price request. In July 2020, the Framework Agreement was extended until end of December 2020 [14].

In 2019, the **claw-back** system (i.e. payback for pharmaceutical companies to social health insurance) was changed to an application of the same rate for the outpatient and inpatient sectors, relating to the annual turnover of a pharmaceutical company (regardless of its growth, as in previous years, and removing exemptions for orphan medicines and generics).

France has seen changes in the **pharmacy remuneration**. Since 2015, dispensing fees have been granted to community pharmacies in return of lower mark-ups in the regressive scheme. In recent years, the pharmacy mark-up rates as well as the dispensing fees were regularly, de facto annually, modified. In September 2020, wholesale remuneration, which had been unchanged since 2012, was modified, with another adjustment scheduled for February 2021 [15] (see Annex 2).

From January 2020 on, patients who refuse generic **substitution** are reimbursed on the basis of the generic medicine price and no longer on the originator price. Since 2014, France awaited a decree to implement biosimilar substitution at pharmacy level following the 2014 Social Insurance law, which provided the legal basis for a possible introduction. However, the 2020 Social Insurance law abolished the possibility to introduce biosimilar substitution [16].

5 References

[1] INSEE. Bilan démographique 2019. Paris: Institut national de la statistique et des études économiques, 2020. Available from: https://www.insee.fr/fr/statistiques/4281618?sommaire=1912926 (accessed 27 April 2020).

[2] INSEE. Comparateur de territoire. France entière. Paris: Institut national de la statistique et des études économiques, 2019. Available from: https://www.insee.fr/fr/statistiques/1405599?geo=FE-1 (accessed 27 April 2020).

[3] Eurostat. Gross domestic product at market prices. 2020. Available from: https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tec00001&plugin=1 (accessed11 October 2020)

[4] Organisation for Economic Cooperation and Development (OECD). Health expenditure indicators. 2020. Available from: https://stats.oecd.org/BrandedView.aspx?oecd_bv_id=health-data-en&doi=data-00349-en# (accessed 11 October 2020).

[5] OECD. Pharmaceutical spending. Organisation for Economic Cooperation and Development, 2020. Available from: https://data.oecd.org/healthres/pharmaceutical-spending.htm (accessed11 October 2020).

[6] Ordre National des Pharmaciens. Démographie des pharmaciens. Panorama au 1er Janvier 2020. Paris, 2020. Available from: http://www.ordre.pharmacien.fr/content/download/506716/2312914/version/1/file/LA-DEMOGRAPHIE-2020.pdf (accessed 11 October 2020).

[7] CSRP. La répartition pharmaceutique. L'essentiel 2019. Paris: Chambre Syndicale de la Répartition Pharmaceutique, 2019. Available from: http://www.csrp.fr/sites/default/files/documentation/brochure_essentiel_csrp_2019_0.pdf (accessed 8 April 2020).

[8] LEEM. Bilan économique. Edition 2020. Paris: Les Entreprises du Médicament, 2020. Available from: https://www.leem.org/sites/default/files/2020-09/BilanEco2020correc.pdf (accessed 11 October 2020).

[9] ANMS. Répertoire des Spécialités Pharmaceutiques. Paris: Agence nationale de sécurité du médicament et des produits de santé, 2020. Available from: http://agence-prd.ansm.sante.fr/php/ecodex/telecharger/lirecis.php (accessed 8 April 2020).

[10] Comité économique des produits de santé (CEPS). Pharmaceutical pricing and reimbursement policies in the in- and out- patient sector. France. Country poster book. 4th PPRI Conference. Medicines access challenge - The value of pricing and reimbursement policy. 23 - 24 October 2019, Vienna, 2019. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/_Country_Poster_Book%20_final_V2.pdf (accessed 27 April 2020).

[11] République Française. Article L162-16-4 du Code de la sécurité sociale. Modifié par LOI n° 2019-1446 du 24 décembre 2019 - art. 42 (V). Paris, 2020. Available from: Accessible at: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025014102/2013-02-08 (accessed 28 September 2020).

[12] CEPS. Rapport d'activité 2019. Septembre 2020. Paris: Comité économique des produits de santé, 2020. Available from: https://solidarites-sante.gouv.fr/IMG/pdf/ceps_rapport_d_activite_2019_20201001.pdf (accessed 11 October 2020).

[13] LEEM. Médicament : prorogation de l'accord-cadre entre le Leem et le Comité économique des produits de santé jusqu'au 31 juillet 2020. Communiqué de presse. 20 decembre 2019. Paris: Les Entreprises du médicament, 2019. Available from: https://www.leem.org/sites/default/files/2019-12/CP20-12-2019-prorogation-accord-cadre-Leem-Ceps.pdf (accessed 8 April 2020).

[14] Avenant du 23 juillet 2020 prorogeant l'Accord cadre du 31 décembre 2015 entre le Comité économique des produits de santé et les Entreprises du médicament. . Paris, 2020. Available from: https://solidarites-sante.gouv.fr/IMG/pdf/avenant_du_2307020_a_l_accord_cadre_du_31-12-2015_entre_le_ceps_et_le_leem.pdf (accessed 11 October 2020).

[15] Le ministre de l'économie, des finances et de l'industrie, le ministre du travail, de l'emploi et de la santé et la ministre du budget, des comptes publics et de la réforme de l'Etat, porte-parole du Gouvernement. Arrêté du 14 septembre 2020 modifiant l'arrêté du 4 août 1987 relatif aux prix et aux marges des médicaments remboursables et des vaccins et des allergènes préparés spécialement pour un individu. Paris, 2020. Available from: https://www.legifrance.gouv.fr/download/pdf?id=x8h1GMsZOJg0LaYPl2_MCd2jrTMm77dcSXD8mIaldq8= (accessed 9 October 2020).

[16] Ordre National des Pharmaciens. Biosimilaires : la loi de financement de la Sécurité sociale pour 2020 supprime le droit de substitution. Paris, 2020. Available from: http://www.ordre.pharmacien.fr/Communications/Les-actualites/Biosimilaires-la-loi-de-financement-de-la-Securite-sociale-pour-2020-supprime-le-droit-de-substitution (accessed 20 October 2020).

[17] Galizzi MM, Ghislandi S, Miraldo M. Effects of reference pricing in pharmaceutical markets: a review. Pharmacoeconomics. 2011;29(1): 17-33.

[18] La ministre des solidarités et de la santé, le ministre de l'économie et des finances et le ministre de l'action et des comptes publics. Arrêté du 12 novembre 2018 modifiant l'arrêté du 4 août 1987 relatif aux prix et aux marges des médicaments remboursables et des vaccins et des allergènes préparés spécialement pour un individu. Paris, 2018. Available from: https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000037611571 (accessed 8 April 2020).

[19] Union nationale des caisses d'assurance maladie et Union des syndicats de pharmacie d'officine. Avis relatif à l'avenant n° 19 à la convention nationale du 4 avril 2012 organisant les rapports entre les pharmaciens titulaires d'officine et l'assurance maladie. JORF n°0029 du 4 février 2020. texte n° 113. 2020. Available from: https://www.legifrance.gouv.fr/affichTexte.do;jsessionid=041B7800636F41BDF8BFC187B81A37A3.tplgfr32s_2?cidTexte=JORFTEXT000041521799&dateTexte=&oldAction=rechJO&categorieLien=id&idJO=JORFCONT000041521116 (accessed 8 April 2020).

[20] USPO. Valorisation des honoraires de dispensation au 1er janvier 2020. Paris: Union des syndicats de pharmacie d'officine, 2020. Available from: https://uspo.fr/valorisation-des-honoraires-de-dispensation-au-1er-janvier-2020 (accessed 8 April 2020).

[21] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. Glossary of Pharmaceutical Terms. Vienna, 2020. Available from: https://ppri.goeg.at/ppri-glossary (accessed 8 April 2020).

6 Annex

Annex 1: Stakeholders

Role	Name in local language (French)	Website(s)
Competent authority for marketing authorisation of medicines	Agence nationale de sécurité du médicament et des produits de santé (ANSM)	www.ansm.sante.fr
Competent authority for pricing of medicines	Comité économique des produits de santé (CEPS), Ministère des Solidarités et de la Santé Publique	https://solidarites-sante.gouv.fr/ministere/acteurs/instances-rattachees/article/ceps-comite-economique-des-produits-de-sante
Competent authority for reimbursement of medicines (outpatient)	Union nationale des caisses d'assurance maladie	https://www.ameli.fr
Public payers for outpatient medicines	Caisses d'assurance maladie	www.ameli.fr
Public payers for inpatient medicines	Caisses d'assurance maladie	www.ameli.fr
Patients organisations	e.g. France Assos Santé, La Ligue contre le cancer	https://www.france-assos-sante.org https://ligue-contre-le-cancer.france-assos-sante.org
Consumers organisations	e.g. UFC-Que Choisir, Consommation Logement Cadre et Vie (CLCV)	e.g. www.quechoisir.org , httwww.clcv.org
Pharmacy associations	e.g. Fédération des Syndicats Pharmaceutiques de France (FSPF), Ordre National des Pharmaciens, Union des syndicats de pharmacie d'officine (USPO)	e.g. www.fspf.fr www.ordre.pharmacien.fr , https://uspo.fr
Industry associations	Les Entreprises du Médicament, GEnérique Même MEdicament (GEMME)	e.g. www.leem.org , www.medicamentsgeneriques.info
Wholesale association	Chambre Syndicale de la Répartition Pharmaceutique (CSRP)	www.csrp.fr

Source: overview provided by the PPRI Secretariat

Annex 2: Regulation of wholesale and pharmacy remuneration (as of 2020)

Wholesale remuneration

Wholesale mark-up scheme for outpatient reimbursable medicines (till 29 September 2020)

Part of the ex-factory price (excl. VAT)	Maximum mark-up referring to the respective part of the ex-factory price
€ 0.00 – € 450.00	6.68%, but at least € 0.3
€ 450.01 and above	0%

excl. = excluding, VAT = value-added tax

Source: Arrêté du 26 décembre 2011 modifiant l'arrêté du 4 août 1987 relatif aux prix et aux marges des médicaments remboursables et des vaccins et des allergènes préparés spécialement pour un individu [17]

Wholesale mark-up scheme for outpatient reimbursable medicines (from 30 September 2020 on)

Part of the ex-factory price (excl. VAT)	Maximum mark-up referring to the respective part of the ex-factory price
€ 0.00 – € 571.05	7.53%, but at least € 0.3 and not more than € 43
€ 571.05 and above	0%

excl. = excluding, VAT = value-added tax

Source: Arrêté du 14 septembre 2020 modifiant l'arrêté du 4 août 1987 relatif aux prix et aux marges des médicaments remboursables et des vaccins et des allergènes préparés spécialement pour un individu [15]

Pharmacy remuneration

Pharmacy mark-up scheme for outpatient reimbursable medicines except generics under the reference price system (2020)

Part of the ex-factory price (excl. VAT)	Maximum mark-up referring to the respective part of the ex-factory price
€ 0.00 – € 1.91	10.0%
€ 1.92 – € 22.90	7%
€ 22.91 – € 150,00	5.5%
€ 150.01 – € 1930.00	5%
€ 1930.00 and above	0%

excl. = excluding, VAT = value-added tax

Source: Arrêté du 12 novembre 2018 modifiant l'arrêté du 4 août 1987 relatif aux prix et aux marges des médicaments remboursables et des vaccins et des allergènes préparés spécialement pour un individu [18]

Dispensing fees for outpatient reimbursable medicines granted to community pharmacies (2020)

Remuneration	Service specification
€ 1.02 TTC	Remuneration per pack
€ 2.76 TTC	Remuneration for filling a prescription of a three-months pack
€ 0.31 TTC	Remuneration for filling a prescription of 5 and more lines
€ 0.51 TTC	Remuneration fee for filling a prescription
€ 1.58 TTC	Remuneration linked to age of the patient, for filling the prescription for patient younger than 3 years and older than 70 years
€ 3.57 TTC	Remuneration for filling a prescription of one or more medicines defined in the national pharmaceutical agreement between sickness funds and pharmacies

TTC = toutes taxes comprises / all taxes included

Source: Avis relatif à l'avenant n° 19 à la convention nationale du 4 avril 2012 organisant les rapports entre les pharmaciens titulaires d'officine et l'assurance maladie [19, 20]

Annex 3: Glossary

biosimilar substitution	Practice of dispensing a biosimilar medicine instead of another equivalent and interchangeable biosimilar or biotechnological originator medicine at the pharmacy level without consulting the prescriber.
claw-back	A policy where funds already paid by public payers to pharmaceutical companies, wholesalers or pharmacists have to be paid back to the third party payers under certain conditions (e.g. if a certain threshold is exceeded).
community pharmacies	Health care facilities which dispense medicines (prescription-only medicines and/or non-prescription medicines, reimbursable and/or non-reimbursable medicines) to outpatients.
co-payment	Insured patient's contribution towards the cost of a medical service covered by the health insurance. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered "reasonable".
discount	A price reduction granted to specified purchasers under specific conditions prior to purchase.
dispensing fee	A fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up.
external price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
free pricing	Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).
Health Technology Assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
INN prescribing	Requirement for prescribers (e.g. physicians) to prescribe a medicine by its International Non-Proprietary Name (INN), i.e. the active ingredient name instead of the trade name.
managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.

marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
mark-up	Percentage added on the purchasing price to get the selling price.
pharmaceutical expenditure	Total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives and other medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.
policies	Instruments, tools and approaches that allow policy-makers to achieve defined objectives.
price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
pricing (price setting)	Act of determining the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a public authority (price control).
price negotiation	A pricing procedure, in which medicine prices are discussed and agreed (e.g. between manufacturer and third party payer).
price regulation (price control)	Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement).
procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by a third party payer, or only partially (a specific percentage).
reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance / National Health Service).
reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).

tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.
value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies [21]