Ten country case studies

Enhancing competition in on-patent markets

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Tables

List of acronyms / abbreviations

ABPI	Association of the British Pharmaceutical Industry
ACOSS	Agence Centrale des Organismes de Sécurité Social
ACP	Alternative Commercial Proposals
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AIFA	Agenzia Italiana del Fármaco
AMNOG	Arzneimittelmarktneuordnungsgesetz
AOK	Allgemeine Ortskrankenkassen
ATC code	Anatomical Therapeutic Chemical code
CCG	Clinical Commissioning Groups
CDF	Cancer Drugs Fund
CEPS	Comité Économique des Produits de Santé
CIPE	Inter-ministerial Committee for Economic Planning
CIPM	Comisión Interministerial de Precios de los Medicamentos
CMU	Commercial Medicines Unit
CNAMTS	Caisse Nationale d'Assurance Maladie des Travailleurs Salariés
CNPMDM	National Commission on Drug and Medical Device Prices
CPB	Combined Pharmaceutical Budget
CPR	Pricing and Reimbursement Committee
CSE	Commissione Scientifica ed Economica del Farmaco
CTS	Technical Scientific Committee
DDD	Defined Daily Dose
DHS	Department of Health and Social Care
DNP	Director of the National Planning Department
DPS	Dynamic purchasing system
DRCBT	Directorate for the Regulation of Benefits, Costs, Tariffs and Conditions of Insurance
EC	European Commission
ECPC	European Cancer Patient Coalition
EEA	European Economic Area
EMA	European Medicines Agency

EPS	Health Promoting Entity
ERP	External reference pricing
EU	European Union
G-BA	Gemeinsamer Bundesausschuss
GKV-SV	Gesetzliche Krankenversicherung - Spitzenverband
HELFO	Helseøkonomiforvaltningen
HMO	Health Maintenance Organisation
HPF	Hospital pharmaceutical formularies
HST	Highly Specialised Technologies
HTA	Health Technology Assessment
ICER	Incremental cost-effectiveness ratio
IETS	Instituto de Evaluación Tecnologica en Salud
INGESA	Instituto Nacional de Gestión Sanitaria
INVIMA	Colombian National Food & Drug Surveillance Institute
IPS	Health Service Provider Institutions
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
LIS	Norwegian Drug Procurement Cooperation
MAH	Marketing authorisation holder
MEA	Managed entry agreements
MEAT	Most economically advantageous tender
MI4A	Market Information for Access to Vaccines Initiative
NCPE	Irish National Centre for Pharmacoeconomics
NIS	National Insurance Scheme
NHS	National Health System
NICE	National Institute for Health and Clinical Excellence
NIPH	Norwegian Institute of Public Health
NoMA	Norwegian Medicines Agency
OECD	Organisation for Economic Co-operation and Development
PAHO	Pan American Health Organisation
PFN	Prontuario Farmaceutico Nazionale
PHARMAC	Pharmaceutical Management Agency
PHI	Private health insurance
POM	Prescription-only Medicines
POS	Plan de Beneficios en Salud
PPP	Pharmacy purchase price

PPRI	Pharmaceutical Pricing and Reimbursement Information
PRP	Retail price level
PTC	Pharmaceutical and Therapeutic Committees
RHA	Regional health authorities
RIPS	Individual Health Services Report
SALAR	Swedish Association of Local Authorities and Regions
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services
SGSSS	Sistema General de Seguridad Social en Salud
SHI	Statutory health insurance
SIC	Superintendence of Industry and Commerce
SISMED	Sistema de Información de Precios de Medicamentos
SMPA	Swedish Medical Products Agency
SMR	Service médical rendu
SNS	Sistema Nacional de Salud
SSN	Servizio Sanitario Nazionale
TLV	Tandvårds- och läkemedelsförmånsverket
TRP	Therapeutic Positioning Report
TVCG	Therapeutic Value Coordination Group
UNCAM	Union nationale des caisses d'assurance maladie
VAT	Value Added Tax
VPAS	Voluntary Scheme for Branded Medicines Pricing and Access
WHA	World Health Assembly
WHO	World Health Organisation

1 Ten case studies

France

Context

France's health system is mainly based on a social health insurance (SHI) system. The SHI system offers coverage to the whole population based on residence through various compulsory schemes. The main fund (*Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* (CNAMTS)) covers 92% of the population; the agricultural fund covers another 7%. Other small funds (specific to certain professional categories) cover the remaining 1%. Coverage by the SHI is complemented by a system of private health insurance arrangements, which became compulsory under certain employment conditions in 2016 (OECD, 2021[1]). Nearly all the population (95 %) has complementary health insurance, mainly to cover co-payments and to attain better coverage for medical goods and services poorly covered by the SHI, such as dental and optical care. In 2015, the French parliament adopted a law that aimed to increase the universality of health coverage and the uniformity of protection across sickness funds. In 2019, public and private compulsory health insurance schemes funded 83.7 % of all health spending in France – higher than the OECD average of 74% (European Observatory on Health Systems and Policies, 2021[2]).

Coverage and pricing

Pricing and reimbursement decisions are the responsibility of three institutions: 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 (*Haute Autorité de Santé,* HAS). Decisions on reimbursement and pricing are informed by clinical and economic evaluations undertaken by two committees that are part of HAS - the Transparency Committee (TC) and the Economic Evaluation and Public Health Committee (Parlement français, 2019[3]). Clinical evaluation is mandatory for all medicines reimbursed by SHI while a health economic assessment is only performed for products claimed to be innovative and associated with a potentially significant impact on health spending (Haute Autorité de Santé, 2019[4]).

Reimbursement lists exist for both outpatient medicines and hospital medicines. The decision for inclusion into the outpatient reimbursement list is taken by the National Union of Health Insurance Funds (UNCAM), based on the value score (SMR) of the clinical evaluation by HAS. The final decision for inclusion in the reimbursement list is taken by the Ministry of Solidarity and Health (Rahman, 2019[5]; Impact HTA, 2019[6]; Vogler, 2020[7]).

For certain innovative and expensive medicines, a derogation mechanism exists, known as the *'liste en sus'*, which allows reimbursement despite the high costs (Ministère de la Santé et de

la Prévention, 2022[8]). This list can include medicines such as immunotherapies and cancer therapies.

Principles of assessment

The clinical evaluation assigns two ratings to each medicine: a first rating reflecting the 'medical value' of the medicine (*Service médical rendu*, SMR), impacting the reimbursement rate; and a second rating reflecting the 'improvement in medical value' (*Amélioration du service médical rendu*), affecting the medicine price (i.e. whether to assign a price premium or requiring a discount) (Impact HTA, 2019[6]; Haute Autorité de Santé, 2021[9]). From 2009 through 2016, the TC evaluated on average 85 new medications per year. On average, only 1.4 were ranked ASMR I; 3.3 were ranked ASMR II; and 8 were ranked ASMR III. Most had low added value: 22 were ranked ASMR IV and 51 were ranked ASMR V (Rodwin, 2019[10]). The economic assessment results in an estimated incremental cost-effectiveness ratio (ICER) and often a budget impact analysis to estimate the annual financial impact of the adoption of a medicine (Impact HTA, 2019[6]; Haute Autorité de Santé, 2021[9]).

France sets its reimbursement rate based on the "absolute clinical value of the medicine". SMR rating is qualified as major or important, moderate, weak or insufficient and takes into account a number of factors, namely: the severity of the condition to be treated; whether the product is of public interest and performing a preventive, curative, or symptomatic function; as well as its effectiveness and adverse effects, and the existence of therapeutic alternatives (Haute Autorité de Santé, 2021[9]).

Pricing mechanisms

Reimbursed medicines: budget caps, price-volume agreements and rebates, value-based pricing, external reference pricing and internal reference pricing

Prices of medicines in the reimbursement list are regulated. The parliament enacts annual laws that **cap companies' turnover** on reimbursed medicines and introduce **clawbacks** after the threshold is surpassed. Manufacturers may have to repay 50% to 70% of their above-the-cap sales revenue in the form of **rebates** (up to 10% of revenues).

Prices are set in accordance with the added therapeutic value (i.e. **value-based pricing**) using the ASMR rating. The CEPS may negotiate with manufacturers two prices: a list price, which may reflect a price premium for higher ASMR ratings, and a confidential discount paid as a rebate to the Central Agency for Social Security Organisations (ACOSS). Industry observers report secret discounts ranging from 10 to more than 50 percent of the list price (Rodwin, 2021[11]; CEPS, 2021[12]). Medicines with ASMR scores I through III (i.e., with major or important or moderate scores and certain medicines within ASMR IV i.e. minor score) are assigned a higher price than the lowest-priced comparator (price premium) (Impact HTA, 2019[6]). Since 2003, CEPS grants such medicines a list price in France consistent with four reference price countries (i.e. **external reference pricing**) - the UK, Germany, Italy and Spain – aiming for a negotiated price near the lowest-priced country. For medicines with ASMR IV, CEPS sets prices no higher than the least costly comparator. Prices of ASMR V (i.e., no added therapeutic value) medicines are set 5 to 10% below the price of their lowest-priced comparator (Parlement français, 2022[13]). The CEPS can negotiate market entry agreements such as price-volume agreements, rebates or performance-based models for certain medicines. It may review existing agreements negotiated with manufacturers if new marketing authorisations for new indications come into effect (Rodwin, 2021[11]).

Medicines are clustered by molecule and reimbursed at the same amount (i.e. **internal reference pricing**[1]). Additionally, prices of reimbursable generics and biosimilar medicines are set based on the price of the originator or reference medicines (minus a discount), with different reduction rates per sector (outpatient/inpatient) and medicine. Moreover, originator and reference medicines have to lower their prices when generic or biosimilar medicines enter the market (Vogler, 2020[7]).

Non-reimbursed medicines: free pricing and managed entry agreements

There is **free pricing** for non-reimbursed outpatient medicines and hospital medicines not included in the reimbursement list. Hospitals negotiate prices directly with manufacturers for low-cost medicines that are funded through prospective payment (i.e. using the Diagnosis Related Groups (DRG) system) so the discounts on these are fully captured by the hospitals. However, since SHI reimburses high-cost medicines separately from hospital treatment, hospitals and SHI share equal discounts negotiated on these drugs (Rodwin, 2019[14]).

Moreover, CEPS often negotiates **managed entry agreements** (MEA) with manufacturers to contract the payment schedule to be conditional on clinical outcomes, resulting in refunds to the Social Security in case the medicines do not produce the contracted clinical results (Parlement français, 2022[13]). Recent proposals for outcomes-based agreements with instalment payments for ATMPs are presented in the new Social Security Bill 2023 (see Box 1.1) to regulate expenditure on certain products. Price cuts are expected to save €900 million in 2023, with a further €200 million of projected savings from safeguard clauses that require paybacks if spending limits are breached (Ministère des Finances, 2022[15]).

Pricing in the supply chain

Wholesalers and community pharmacies are remunerated through a regressive mark-up scheme for dispensing reimbursable medicines (i.e. wholesaler mark-up: capped linear mark-up to 6.86% of the manufacturer price, with a minimum of 0.30€ and a maximum of 30.03€; pharmacists' remuneration: paid based on a mixed system with a calculated fee of 1.02€ per medicine dispensed (+ 0.51€ per complex prescription)) (European Observatory on Health Systems and Policies, 2015[16]). 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. There are discounts for both wholesalers and pharmacists. Commercial discounts given by wholesalers to community pharmacies are capped at 40% for reimbursed generic medicines and non-generics and at 2.5% for reimbursed non-generic medicines (Vogler, 2020[7]).

Patient co-payments

In France, cost-sharing levels are determined based on demonstrated benefit. Depending on their SMR rating, outpatient reimbursable medicines are reimbursed at 65%, 30% or 15% for high-value, moderate value and low-value medicines, respectively; medicines for certain life-threatening conditions and chronic diseases are always fully reimbursed. Patients must pay a

[1] The practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or therapeutically equivalent therapies in a country to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country. Generic and biosimilar price links and reference price systems are variants of internal price referencing (Pharmaceutical Pricing and Reimbursement Network, 2023[178]).

prescription fee plus the percentage co-payments, which are frequently covered by complementary health insurance. Hospital medicines are fully covered by SHI (Rahman, 2019[5]; Impact HTA, 2019[6]; Vogler, 2020[7]).

Since January 2020, patients who refuse generic substitution are reimbursed based on the generic medicine price and no longer on the originator price (Vogler, 2020[7]).

Procurement and tendering

Types of procurement procedures

France uses the following procedures to procure medicines:

- **Tendering**[2] **of off-patent inpatient medicines** and medicines in certain therapeutic classes used in hospitals. Some recent tenders targeted the purchase of vaccines (hepatitis A and B; tuberculosis; diphtheria; tetanus; pertussis; polio; measles, mumps, rubella, Japanese encephalitis; yellow fever; influenza, etc.), medicines for the central nervous system, human polyvalent intravenous immune globulin, and human albumin (Vogler, Salcher-Konrad and Habimana, 2022[17]; TED, 2022[18]).Tendering is designed at indication level (data from OECD survey on On-patent Competition, 2022);
- **Facility-based procurement** used by the hospital sector, and **joint procurement** by groups of hospitals or facilities in both the **inpatient** and **outpatient** sectors at regional level. Joint procurement and facility-based procurement may be used by the same institutions but for different products. Hospitals or hospital groups may join a regional or a national central procurement body depending on the type of medicines required (Vogler, Salcher-Konrad and Habimana, 2022[17]);
- **Both single- and multiple-winner awards procedures** are applied for tendering. Multi-winner award procedures are the default for some types of medicines, namely supply-critical products (Vogler, Salcher-Konrad and Habimana, 2022[17]). The traditional 'winner takes all' approach has been criticised to lead to shortages and product withdrawals from the market. To maintain competition and avoid shortages, France now partly implements a 'two winners' approach in national tenders. Recent examples include tenders for *trastuzumab* with two suppliers accounting each for 50% of the total market in France (EFPIA, 2022[19]); and
- **Open procedures** (meaning any supplier may submit a full tender) for tendering applied in all forms of hospital procurement, including national, regional, group-based and facility-level procurement; as well as competitive bidding (Rodwin, 2019[14]) and dynamic purchasing systems (DPS)[3] to allow suppliers to join the system on an ongoing basis (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Only public hospitals are required by law to acquire medicines through public procurement procedures. Some hospitals collaborate in joint procurement initiatives by voluntarily joining centralised procurement bodies. At a national level, two main procurement bodies were designated as national procurement bodies for medicines in the inpatient sector in 2019: (1) the

[2] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

[3] Dynamic Purchasing Systems (DPS) allow recurring purchasing from a supplier while allowing new suppliers to join the system on an ongoing basis (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Réseau des Acheteurs Hospitaliers (Resah)[4] and (2) the *Union des Hôpitaux pour les Achats* (UniHA)[5]. *UNICANCER Achats* also serves as a national procurement body, but only for Cancer Centers. At a regional level, several group purchasing organisations are involved in the procurement of medicines, including the *Groupement de Coopération Sanitaire Achats du Centre, Agence Générale des Equipements et Produits de Santé* (AGEPS), and the *l'Assistance Publique – Hôpitaux de Paris*.

Tendering award criteria

According to the EU Directive 2014/24 (European Parliament, 2014[20]), contracts should be awarded to the most economically advantageous tender (MEAT), using a range of criteria including price (often the dominant criteria), security of supply (stock levels serve as criterion for major therapeutic classes), quality of the product (including solubility, packaging, differentiation in the strengths, unit dose, etc), and environmental criteria in relation to logistics. Local production can be used as an award criterion for hospital tenders in France to address the security of supply issues in upcoming tenders (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

In France, demand-side measures, such as prescribing by the International Non-Proprietary Name (INN), are in place to enhance the uptake of off-patent medicines. In addition, there are incentives targeted at prescribing doctors and community pharmacies that aim to promote the uptake of generics.

- **Generic substitution**. To enhance the uptake of off-patent medicines, generic substitution by a pharmacist is allowed in France (this is indicative, not obligatory), although certain exceptions may apply (Vogler, 2020[7]).
- **Biosimilar substitution**. The French Social Security Financing Bill for 2022 allowed biosimilar substitution at pharmacy level (Parlement français, 2021[21]). In addition, the prescription of biosimilars rather than originator drugs is incentivised at regional level. There is also an incentive scheme in place for private doctors to encourage the prescription of certain biosimilar medicines, however, no national indicator currently tracks biosimilar prescriptions.
- **Prescribing by International Non-Proprietary Name** (INN) is mandatory in France (Vogler, 2020[7]).
- **Rational use, pay-for-performance and prescribing monitoring**. France' sickness funds 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*) regularly visit prescribing doctors and discuss their prescription behaviour. As part of performance-based remuneration (*Rémunération sur objectifs de santé publique*, ROSP), objectives for rational prescribing (e.g. thresholds for generic prescribing for certain medicines groups) have

[4] Resah is a regional CPB for the metropolitan region of Paris but designated in 2019 by the Direction Générale de l'Offre des Soins (DGOS) as a national procurer for hospital procurement.

[5] UniHA is a regional CPB for the Lyon region but designated in 2019 by Direction Générale de l'Offre des Soins (DGOS)as a national procurer for hospital procurement.

been agreed upon, and are linked to financial incentives. Pharmacists are remunerated on a basis that incentivises generic substitution (Vogler, 2020[7]).

Box 1.1. The French Social Security Financing Bill for 2023

In September 2022, the French Social Security Financing Bill (PLFSS) for 2023 was presented (Ministère de l'Économie et des Finances, 2022[22]).

The proposed PLFSS presents a new funding model for advanced therapy medicinal products (ATMPs) - it introduces a derogatory financing mechanism for ATMPs registered on the reimbursement list. A threshold will be defined by ministerial order to cap the maximum purchase price for the hospital. If the price charged by the manufacturer exceeds that threshold, the treatment cost will be determined by agreement or, if no agreement can be reached, by decision of CEPS. This treatment cost will recover the amount paid by the health care facility and, if applicable, the amount paid by the health insurance (GD Avocats, 2022[23]; Ministère de l'Économie et des Finances, 2022[22]).

Furthermore, the PLFSS proposes outcomes-based agreements with instalment payments for ATMPs. The funding model entails that if the treatment cost exceeds the amount paid by the health care institution, additional annual payments will be made by the health insurance. The number, amount and terms of these payments shall be determined by agreement or, failing that, by decision of CEPS. However, the payments by the health insurance will be conditioned on the observed effectiveness of the treatment. The payments must reflect the efficacy data of the medicine, and, in case of treatment failure, the manufacturer may be obliged to reimburse the health insurer for part of the amounts received (GD Avocats, 2022[23]; Ministère de l'Économie et des Finances, 2022[22]).

This new funding model for ATMPs aims to help alleviate the financial burden on health institutions and allows to share the financial risk with the manufacturer (GD Avocats, 2022[23]; Ministère de l'Économie et des Finances, 2022[22]).

Italy

Context

Italy's National Health Service (*Servizio Sanitario Nazionale, SSN*) is decentralised and regionally based. The central government channels general tax revenues for publicly financed health care, defines the benefits package, and exercises overall stewardship. Each region is responsible for the organisation and delivery of health services through local health units and via public and accredited private hospitals. The basic benefits package must be guaranteed uniformly across the country. Funds are assigned to the regions which are intended to cover the provision of a minimum of health care services (Essential Care Levels (LEA)) uniformly guaranteed throughout the country and provided by the government. Regions can enlarge the benefits package if they have sufficient resources, while regional drug commissions are responsible for identifying and monitoring access and availability to medicines in hospitals (Tikkanen et al., 2020[24]; OECD/European Observatory on Health Systems and Policies, 2021[25]).

Coverage and pricing

The SSN covers reimbursement of medicines included in a national positive list (*Prontuario Farmaceutico Nazionale*, PFN) after being evaluated by the Italian Medicines Agency (AIFA). AIFA is responsible for all matters regarding medicines for human use including market authorisation, pharmacovigilance, monitoring of spending, and pricing and reimbursement of medicines. AIFA performs health technology assessments (HTA) to support the Technical Scientific Committee (*Commissione Tecnico Scientifica*, CTS), in the evaluation of the added value of medicines and to determine the reimbursement status. The Pricing and Reimbursement Committee (*Comitato Prezzi e Rimborso*, CPR) offers technical advisory support for the price negotiation with manufacturers. A reorganisation of AIFA is set for 2023 (see Box 1.2). Reimbursed medicines are included in PFN either in the reimbursement list 'class A' (medicines for outpatient use) or in the list 'class H' (medicines for inpatient use). While medicines for outpatient use are reimbursed per product, medicines used in hospitals are funded through the diagnosis-related group (DRG) system. Funding on top of these tariffs may be granted by regions for high-cost drugs, through inclusion on the so-called 'File F' list. Each region has its own 'File F' list, resulting in substantial variation between regions regarding the treatments that are included on these lists. Non-reimbursed medicines are allocated to 'class C' (i.e. a negative reimbursement list) and can be dispensed to citizens with or without a medical prescription (respectively 'Class C' with prescriptions and 'C' without obligation of prescription (C - SOP/OTC)). The price of non-reimbursed medicines is not regulated; it is suggested by the MAH and monitored by AIFA. (Panteli et al., 2016[26]; Vogler, 2021[27]). Moreover, Decree No. 158/ 2012 introduced the 'class C-NN' including medicines awaiting negotiation, which can be purchased by public health facilities (Repubblica Italiana, 2012[28]).

In addition to the national reimbursement list, hospitals have their own hospital pharmaceutical formulary[6] to select from. Purchasing of medicines for inpatient use is done by hospitals and sometimes by regions through tender procedures. Hospital pharmacies are entitled to a 50% discount on the retail price of 'class C' medicines. To further contain costs and enable closer monitoring, hospital pharmacies became legally authorised to purchase medicines for direct dispensing to patients for outpatient use ('distribuzione diretta') or for dispensing, by community

[6] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

pharmacies, under specific regional agreements ('distribuzione per conto') (AIFA, 2021[29]). Additionally, Italy introduced two 'innovation funds' in 2017, one for innovative oncology medicines and one for innovative non-oncology medicines. The funds reimburse innovative medicines at the regional level under specific conditions, as established by the 2017 Budget law (No. 232/2016) (Repubblica Italiana, 2016[30]). Each fund is allocated EUR 500 million to be available for the regions for 36 months. AIFA identified the criteria for assessing the innovative status of medicines, with reference to one or more indications (Fortinguerra et al., 2019[31]). Only medicines with 'full' innovative status can access the special funds.

Pricing and reimbursement decision-making does not differ between outpatient and inpatient sectors (Panteli et al., 2016[32]; Vogler, 2021[27]; Tavella et al., 2014[33]; Villa et al., 2022[34]). For orphan medicines and other medicines of exceptional relevance for the SSN, there is a fast-track procedure, which must be completed within 100 days of submission of the reimbursement application.

Principles of assessment

The decision to grant reimbursement to a medicine is conditional on the joint price and reimbursement negotiation performed by AIFA with the manufacturer (Law No. 326 of 24 November 2003), in accordance with methods and criteria identified by the Ministerial Decree of 2 August 2019 (OJ No. 185 of 24 July 2020) and the AIFA guideline for pricing and reimbursement submissions released in December 2020 (AIFIA, 2020[35]). The new Pricing and Reimbursement Decree replaces the Resolution No. 3/2001 of the Inter-ministerial Committee for Economic Planning (CIPE), which governed medicine pricing in Italy for 19 years. To support reimbursement decisions and inform price negotiations, the new Decree requests manufacturers to demonstrate the added therapeutic value of the product in relation to available alternatives (or best supportive care in case these are not present). If an added value cannot be proven, the company is requested to provide further elements of interest, in terms of economic benefits for the SSN. Moreover, the reimbursement application must also include information on the launch of a medicine, and its consumption and reimbursement status in other countries, following the resolution on 'Improving the transparency of markets for medicines, vaccines, and other health products' of the World Health Assembly (Panteli et al., 2016[32]; Vogler, 2021[27]; World Health Assembly, 2019[36]; AIFIA, 2020[35])

The AIFA guideline further details the type of information required from manufacturers in the reimbursement application, including the specific cases where cost-effectiveness and budget impact analyses are formally requested and for which their results are expected to be useful for setting the price of medicines (Russo et al., 2022[37]). The price negotiated by AIFA with the pharmaceutical company represents the maximum sale price for the SSN, which is the same throughout Italy, and does not include margins for wholesalers and pharmacists, which are added in the retail channel. In many cases, for on-patent medicines the negotiated price, net of discounts or other commercial agreements, remains confidential to the public following a non-disclosure agreement between the parties (Russo et al., 2021[38]). Reimbursement of innovative medicines under the two 'innovation funds' is also assessed by AIFA against three criteria, namely: unmet therapeutic need, the therapeutic added value of the innovative medicine as well as the quality of evidence (Xoxi et al., 2022[39]; Vogler, 2021[27]; Fortinguerra et al., 2019[31]).

Pricing mechanisms

Reimbursed medicines: national budget caps, paybacks, internal reference pricing, external reference pricing and managed entry agreements

In Italy, overspending is regulated through **national budget caps**, which are defined on an annual basis. The national pharmaceutical expenditure ceiling is stated ex-ante at the national level by law, corresponding to 14.85% of the National Health Fund (Budget Law No. 178/2020). Two distinct ceilings are in force for medicines procured and dispensed by community pharmacies and for those procured by public health facilities (respectively 7% and 7.85% of the National Health Fund). Exceeding the ceiling results in the application of the payback procedure. In case the ceiling is exceeded for medicines purchased by public health facilities, payback is paid equally by manufacturers and regions. Several additional measures have been introduced to reduce costs and ensure compliance with the budget target, including monitoring of biosimilars use and expenditure (AIFA, 2022[40]), price renegotiations, AIFA Notes, Transparency list for generic medicines (see below), regional therapeutic handbooks at local level consisting of a list of medicines to be used by public entities during patients' hospitalisation, and the promotion of tendering (Selletti, Putignano and Tiboni, 2022[41]; Vogler, 2021[27]).

Prices of reimbursable medicines are negotiated between AIFA and manufacturers conditional on the principles of assessment outlined above. Central negotiations, that usually result in a discount on the list price proposed by the companies, are aimed at setting medicine prices in line with the added value they bring to patients and guaranteeing the affordability of medicines for the SSN. The use of other commercial agreements (e.g. Managed Entry Agreements (MEAs)) is considered an additional negotiation option to grant a positive reimbursement status and reduce medicine costs from a public payer perspective (Russo et al., 2021[42]). Other special regulatory instruments apply for reimbursable medicines covered by the SSN in outpatient and inpatient sectors, namely internal reference pricing, external reference pricing, and mandatory discounts:

- **Internal reference pricing.** Reimbursed medicines in 'class A' (i.e. medicines for outpatient use) not covered by a patent are subject to reference pricing (at ATC-5 level) and the maximum amount reimbursed is equal to the price of the cheapest generic or biosimilar medicine within a reference cluster of medicines with similar active substances. The purchase of more expensive equivalent medicines is only possible at the request of a patient and is subject to additional co-payment. In principle, generics and biosimilars must be priced at least 20% lower than the originator or reference medicine (Repubblica Italiana, 2012[43]). AIFA publishes a 'Transparency List' with the reference prices for the reimbursement list. Biosimilars are excluded from the 'Transparency List', however there are additional rules for tendering of biosimilar medicines (see below the section 'procurement and tendering') (Panteli et al., 2016[32]; Vogler, 2021[27]; Selletti, Putignano and Tiboni, 2022[41]).
- **External reference pricing.** AIFA uses data on prices of the same medicine in other European countries to inform the price and reimbursement negotiation, though there is no specific formula for determining a benchmark price. Currently, Italy considers 24

European reference countries: Austria, Belgium, Croatia, Cyprus[78], Czech Republic, Denmark, Estonia, Greece, Finland, France, Hungary, Iceland, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia and the UK (Vogler, 2021[44]).

- **Mandatory discounts**. Manufacturers are obliged to grant the SSN a cumulative 5% + 5% mandatory manufacturer discount on the ex-factory price of reimbursed medicines (Vogler, 2021[44]). The 5% discount is given to the SSN at the time of procurement plus an additional 5% that the MAH can decide to give either at the procurement or later in the form of a rebate.

There is also increasing use of **managed-entry agreements (MEAs)**, usually for reimbursable medicines with high budget impact in outpatient and inpatient sectors. AIFA negotiates with manufacturers either financial MEAs (such as price-capping, price-volume agreements, cost sharing, or confidential discounts), performance-based MEAs (such as payment-by-results or risk-sharing agreements) or 'appropriateness agreements' to monitor appropriate prescribing through AIFA Monitoring Registries (Panteli et al., 2016[32]).

Non-reimbursed medicines: free pricing and price caps

There is **free pricing** for non-reimbursed medicines, however, a price increase is only allowed every second year and must not exceed the expected inflation rate. To ensure compliance with these rules, AIFA monitors the prices of non-reimbursed prescription-only medicines, while manufacturers are obliged to communicate price variations of non-reimbursed non-prescription medicines to AIFA (Vogler, 2021[44]).

Pricing in supply chain

In the outpatient sector, prices of reimbursable medicines are regulated throughout the supply chain, with **statutory linear mark-ups** being applied for wholesalers and community pharmacies. For reimbursable originator and biosimilar medicines, wholesale linear mark-ups are set to 3% of the pharmacy retail price while pharmacy linear mark-ups are set with progressive discounts ranging 11.35–26.6% of the pharmacy retail price (net of VAT). Mark-ups for reimbursable on-patent and biosimilar medicines differ from those for reimbursable generic medicines. Moreover, community pharmacies are requested to grant a statutory discount to the SSN, based on their location (urban or rural pharmacies) and the annual sales of the pharmacy. For non-reimbursable medicines, wholesale and pharmacy margins are not regulated (Panteli et al., 2016[32]).

Patient co-payments

Co-payments can vary with condition and income and are set at national and regional level.

[7] Note by Turkey: the information in this document with reference to "Cyprus" relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Türkiye recognizes the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of United Nations, Türkiye shall preserve its position concerning the 'Cyprus issue'.

[8] Note by all the European Union Member States of the OECD and the European Union: The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus.

Fixed co-payment (generally €2 per item) amounts and exemptions are regionally determined. Prices of medicines included in the PFN are fully covered by the SSN. However, patients pay a fixed prescription fee (that varies across regions) for medicines for outpatient use in several regions. There are exemptions from the prescription fees (e.g. for vulnerable social groups, pregnant women) but the exemptions differ between the regions. No co-payments are applicable for medicines in inpatient use (Panteli et al., 2016[32]).

Procurement and tendering

Types of procurement procedures

Italy uses the following procurement procedures:

- Tendering[9] designed at the **therapeutic class level** used to obtain discounts based on the evidence of comparative effectiveness of multiple therapeutic alternatives with different active substances. AIFA is responsible for therapeutic equivalence determinations (Selletti, Putignano and Tiboni, 2022[41]);
- **Facility-based procurement** and **joint procurement** by groups of hospitals or facilities used for both hospital and outpatient medicine procedures (Vogler, Salcher-Konrad and Habimana, 2022[17]). Many novel medicines used by inpatients and dispensed to outpatients at hospitals (e.g. for hepatitis C and diabetes) are procured by hospitals and regions. In 2015, medicines procured by health authorities accounted for 33% of the total pharmaceutical market and 49% of medicines covered by the SSN (Jommi and Minghetti, 2015[45]);
- **Centralised procurement at the national and regional level** used in both outpatient and hospital sectors. The main route for procuring inpatient medicines is centralised procurement at regional level. However, facility-based procurement is also used as an additional route for procurement for hospital medicines (both on- and off-patent);
- Both **single- and multiple-winner awards** procedures are applied for tendering. Moreover, since 2017 **multi-award procedures are the default for biosimilars** used both in outpatient and hospital sectors if three or more medicines of an active substance have been marketed. All bidders are granted a defined share (Repubblica Italiana, 2016[30]; Vogler, Salcher-Konrad and Habimana, 2022[17]);
- Centralised procurement uses **open procedures** for tendering (off-patent) medicines through an e-procurement platform using the so-called 'dynamic purchasing system' (DPS) methodology (*Sistema dinamico di acquisto,* Sdapa) as a major procurement technique. In addition, regions and hospitals also perform their own procurements of medicines through their own DPS[10] systems. The use of DPS in Italy arrived with the translation into national law of the EU Procurement Directive (European Parliament, 2014[20]). The Italian Budget Law 2020 (Repubblica Italiana, 2019[46])allowed application of the DPS for the call of single and multi-award open procedures.
- Italy is involved in the cross-country collaboration '**Valletta Declaration**', established in May 2017, which aims to improve access to medicines, through collaboration in HTA and joint procurement (Vogler et al., 2020[47]).

[9] For definitions on tendering, please see Box 1.2 in the Health Working Paper.

[10] Dynamic Purchasing Systems (DPS) allow recurring purchasing from a supplier while allowing new suppliers to join the system on an ongoing basis (Vogler, Salcher-Konrad and Habimana, 2022[17]).

At national level, public procurement of medicines by hospitals and regions are supported centrally by the national procurement body Consip[11], part of the Ministry of Economy and Finance. Hospitals can call negotiated procedures through the DPS provided by Consip or they can also join on-going procurement procedures at regional level. At a regional level, public procurement of medicines for inpatient and outpatient use involves the various regional central procurement bodies *Centrali di Committenza Regionali*.

Tendering award criteria

Price is the dominant criterion for awarding tenders in Italy. Moreover, Italy applies criteria regarding the quality and safety for centralised procurement procedures at the regional level. In some rare cases the regional body awards tenders which also considered qualitative elements, such as the number of dosages available and the quality of customer service (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

Italy has implemented a series of mechanisms to encourage the use of certain products over others, namely:

- **Prescribing by International Non-Proprietary Name** (INN) recommended.
- **Generic substitution,** mandating pharmacies to substitute originators with generics (unless indicated by prescribing doctor or preferred by the patient bearing the cost difference). Italy also uses prescribing software to monitor price differences to select the cheapest alternative by default. Between 2005 and 2019, the generics market share in Italy increased from 7% to 28% in volume, however it remains 20 percentage points below the EU average, which shows the uptake of generics is constrained by a pharmacy remuneration system linked to the sales price (OECD/European Observatory on Health Systems and Policies, 2021[25]) (Panteli et al., 2016[32]).
- **Biosimilar substitution**. Regions have adopted guidelines to encourage the substitution of reference products with biosimilars where appropriate, however, biosimilar substitution at pharmacy level is not allowed. Moreover, a physician must justify the clinical reason why he wants to prescribe a more expensive medicine to his/her patient (Vogler, 2021[27]; Caputi et al., 2016[48]).
- **Hospital formularies**[12]. Regional 'therapeutic handbooks' consist of a list of medicines to be used by public entities during patients' hospitalisation. Hospitals develop their own formularies using several criteria including efficacy, safety and cost-benefit ratio. These lists are applied at a regional level and may thus differ between regions (Selletti, Putignano and Tiboni, 2022[41]; Prada et al., 2020[49]; Vogler, 2021[27]).
- **Prescription targets.** Some regional governments and local health authorities define specified prescribing targets to limit spending (Vogler, 2021[27]; Caputi et al., 2016[48]).

[11] Home | Consip

[12] For definitions on formulary management mechanisms, please see Box 1.3 in the Health Working Paper.

Box 1.2. Reorganisation of AIFA to happen in 2023

New legislation introduces the merger of the Technical Scientific Committee (CTS) and the Pricing and Reimbursement Committee (CPR) into a new Scientific and Economic Commission for Pharmaceuticals (*Commissione Scientifica ed Economica del Farmaco*; CSE). The CSE will oversee the current tasks and responsibilities of both the CTS and CPR but will only have half the number of its current members (Repubblica Italiana, 2022[50]).

The reorganisation means that the role of Director General will be terminated, and two new roles will be established in its place (i.e. the Scientific Director and the Administrative Director). The AIFA's President will become the sole legal representative of AIFA (Repubblica Italiana, 2022[50]).

The merger of the CTS and CPR into the new CSE will not take place until the terms of the current committees expire at the end of February 2023. The CSE will have ten members, who will be appointed within 60 days from the date of entry into force of the legislation (Rodriquez, 2022[51]; Repubblica Italiana, 2022[50]).

The Board of Directors of AIFA will remain made up of 5 members: the president, two representatives indicated by the Ministry of Health and two representatives indicated by the State Regions Conference (Rodriquez, 2022[51]; Repubblica Italiana, 2022[50]).

The creation of the CSE is expected to help accelerate the evaluation and approval of new medicines in Italy (AboutPharma, 2022[52]). According to the EFPIA Patients WAIT Survey 2021 (EFPIA, 2022[53]), the average time from EU marketing authorisation to public reimbursement in Italy is 429 days.

Germany

Context

Germany has a multi-payer health system that provides nearly universal health coverage. Health insurance is compulsory, but people with an income above a fixed threshold or belonging to a particular professional group can opt out of statutory health insurance (SHI) coverage and take up private health insurance (PHI). In 2019, about 11 % of the population was covered by PHI; 89 % by SHI. In 2019, SHI covered 82% of the total spending of all licensed prescription pharmaceuticals in Germany. Currently, there are 103 sickness funds and 41 PHI companies, with the three largest sickness funds covering more than one-third of the population (OECD/European Observatory on Health Systems and Policies, 2021[54]).

Coverage and pricing

All licensed prescription medicines are reimbursed. All medicines entering the market are reimbursed by sickness funds unless they are excluded by federal law (e.g. over-the-counter medicines (OTC)) or by a decision of the Federal Joint Committee (*Gemeinsamer Bundesausschuss* - G-BA). Unlike many other countries, the basket of pharmaceuticals reimbursed by SHI in Germany is not defined through a positive list. The decision-making is decentralised and divided between the federal and state level, as well as self-governance bodies that are part of G-BA. The federal government defines only the legal framework, while regulatory details are specified in directives issued by the G-BA. The G-BA is composed of representatives of associations of sickness funds, physicians, dentists and hospitals, as well as three independent members (plus patient representatives without voting rights) and takes decisions on SHI benefits, reimbursement systems and quality assurance (Wenzl and Paris, 2018[55]).

To support decision-making by the *G-BA*, the Institute for Quality and Efficiency (IQWiG) commissions Health Technology Assessments (HTA) and makes recommendations for the in- or exclusion of health technologies into the SHI benefit basket. The IQWiG is an independent body in charge of evaluating the quality and efficiency of health services and health products. The G-BA reserves the right to exclude or limit the reimbursement of products through guidelines or treatment recommendations. In particular, the G-BA may limit reimbursement for a drug if its therapeutic effect, medical necessity, or cost-effectiveness cannot be demonstrated, or if there are more cost-effective treatments with comparable therapeutic effects (Blümel et al., 2020[56]).

Principles of assessment

Germany adopted a law reforming the pharmaceutical market (*ArzneimittelmarktNeuordnungsgesetz* – AMNOG) in 2011 that rules the principle of free pricing when medicines are authorised to be marketed but imposes a systematic and formal assessment of the 'added therapeutic benefit' of new medicines to negotiate the price according to the therapeutic value of the medicine within twelve months after market launch. In 2022, changes to AMNOG were adopted to make the negotiated reimbursement price effective seven months after market launch (see Box 1.3).

The 'added therapeutic benefit' of each new product is assessed against a standard treatment (an appropriate comparator) and ranked on a 6-point scale. The top 4 ranks indicate the new product has major, considerable, or minor added benefit or that added benefit is not quantifiable. The bottom 2 ranks indicate added benefit is not proven. The rules for the

assessment of new medicines are defined in § 35a of the Fifth Social Security Code (*Fünftes Sozialgesetzbuch* - SGB V) (Deutscher Bundestag, 1988[57]). The 'added therapeutic benefit' is assessed considering improvements in health status, reductions in the duration of the disease, survival gains, the reduction of side effects, or an improvement in quality of life. The G-BA requires the highest possible level of evidence and prefers direct comparisons and relevant endpoints but may be flexible where needed, for example when the company can justify that evidence based on randomised controlled trials is not available (Blümel et al., 2020[56]; Wenzl and Paris, 2018[55]).

The AMNOG process applies to all new patented products introduced to the German market, except for those with an annual SHI spend of less than 1 million euros (Wenzl and Paris, 2018[55]). For orphan drugs, 'added therapeutic benefit' is assumed by virtue of marketing authorisation without reference to an appropriate comparator provided that the annual SHI expenditure remains below EUR 30 million. Nonetheless, the G-BA assesses the magnitude of the additional therapeutic benefit for relevant patient groups to create the basis for price negotiations. Once the EUR 30 million threshold is exceeded, manufacturers are required to submit data on additional therapeutic benefits and orphan drugs are evaluated, and prices renegotiated, in the same manner as for all other drugs. There are no special arrangements for other expensive drugs, such as those used in oncology. However, the price negotiation process following G-BA appraisal leaves broad leeway for the negotiating parties to agree on discounts and rebates or other mechanisms that can lower prices for SHI (Wenzl and Paris, 2018[55]). New AMNOG rules adopted in October 2022 will impose stricter price regulation that strongly impact pricing and negotiation (Deutscher Bundestag, 2022[58]).

Pricing mechanisms

Pricing mechanisms differ between the hospital and the outpatient sector, and between OTC and prescription-only pharmaceuticals.

Free pricing and price negotiations for hospital medicines

Prices of medicines used in hospitals are not regulated (**free pricing**) and are the result of confidential transactions between manufacturers and hospitals, hospital chains, or group purchasing organisations. However, the prices negotiated for retail products under the AMNOG process are the ceiling prices for the purchase of medicines by hospitals since 2017 (Bundestag, 2016[59]). Moreover, the cost of medicines used by hospitals is included in the payments by diagnosis-related group (DRG) for the entire treatment episode. In 2019, pharmaceutical spending covered by SHI and PHI on medicines dispensed in hospitals amounted to 28.1% of total pharmaceutical spending, while spending on retail covered 18.5% of health spending (OECD, 2022[60]).

Reference prices, mandatory rebates and statutory prices for outpatient medicines

Special regulatory instruments apply for prescription drugs covered by SHI benefit packages and paid by sickness funds, namely reference prices, mandatory rebates and statutory prices/price freezes:

- Prices are set conditional on the added therapeutic value (i.e. **value-based pricing**) For on-patent medicines showing added therapeutic benefit, a reimbursement price is negotiated between the national association of SHI funds (GKV-SV) and the manufacturer based on the prices of appropriate comparators both in Germany and

internationally[13] as well as a premium for the additional benefit of the new product if the additional benefit is major or considerable. If parties cannot reach an agreement, the reimbursement price is set by arbitration. If no incremental therapeutic benefit is found, medicines are included in a reference price group subject to a reference price (as detailed below).

- **Internal reference prices.** If no incremental therapeutic benefit is found, medicines are included in a reference price group subject to a **reference price** (i.e. the maximum reimbursement amount) (Blümel et al., 2020[56]; Wenzl and Paris, 2018[55]). Once the G-BA establishes the reference price group, the GKV-SV determines a reference price for all products in the same reference group. Generally, the reference price is calculated so that about one-third of the products are available at or below the reference price (Dietz and Baumann, 2008[61]).
- **Mandatory rebates**. Pharmaceutical manufacturers and wholesalers are obliged by law to grant discounts (*Herstellerrabatt*) to the sickness funds (§130a SGB V) (Deutscher Bundestag, 1988[57]): some rebates are mandatory for all products covered under SHI (e.g. the pharmacy rebate of EUR 2.30 per package), others depend on the existence of contractual agreements (e.g. rebates to an individual sickness fund) or special product characteristics. For example, manufacturers must grant a 7% discount off ex-factory price to sickness funds and other PHI on patented pharmaceuticals that are not clustered in reference price groups (SGB V, § 130a) (Wenzl and Paris, 2018[55]; Deutscher Bundestag, 1988[57]).
- **Price freezes and statutory pricing**. Since 2010, a statutory price freeze has been in place in Germany that prevents pharmaceutical companies from increasing prices of reimbursable prescription-only drugs that are not subject to fixed prices. Only adjustments for inflation may be claimed retroactively. This price freeze was formerly planned to expire on 31 December 2022. However, the German parliament has accepted the draft for the law on the financial stabilization of the German statutory health insurance system ('GKV-FinStG') in October 2022. This act extends the price freeze until the end of 2026 and sets forth a new potential exemption from the price freeze for medicines that receive a new marketing authorisation for either a new indication or a new patient group and promise an improvement of the medical care (Deutscher Bundestag, 2022[58]).

Pricing in supply chain

Prices of medicines dispensed in pharmacies are regulated through the Pharmaceutical Price Ordinance which stipulates **fixed mark-ups** on manufacturers' selling prices and thereby guarantees identical prices for prescription drugs in all German pharmacies. In addition, it enables manufacturers to determine the ex-wholesaler and the ex-pharmacy price of the

[13] Benchmarking against European countries that are selected based on three criteria: (i) they are member states of the European Economic Area (EEA); (ii) together account for at least 80% of the population of the EEA (excluding Germany); and (iii) countries perform economically similarly to Germany. The list of benchmark countries is reviewed annually and revised as necessary; as of 2012, the list includes 15 EU countries: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, the Netherlands, Portugal, Sweden, the Slovak Republic, Spain and the United Kingdom. For the purposes of the negotiation, the pharmaceutical company must provide information on foreign benchmark prices (Wenzl and Paris, 2018[62]).

product by setting the ex-factory price. Also, discounts can be negotiated between manufacturers, wholesalers and pharmacies (Wenzl and Paris, 2018[55]; Panteli et al., 2016[26]).

The sickness funds pay pharmacists for prescription-only medicines a flat-rate payment of EUR 8.35 plus EUR 0.21 for the Pharmacy Emergency Service plus a fixed margin of 3% (from the manufacturer's price). Sickness funds receive a discount (*Apothekenabschlag*) of EUR 1.77 per dispensed prescription-only drug from the pharmacies if the sickness funds pay the respective pharmacy within 10 days. Manufacturers can submit new market prices up to twice a month for products covered by the reference price system. The GKV-SV is required to update the reference group on a quarterly basis and to update the reimbursement limit at least once a year (Blümel et al., 2020[56]; Wenzl and Paris, 2018[55]).

Pharmaceutical companies must grant a **7% discount** to sickness funds and other health insurers on on-patent medicines that are not clustered in reference price groups. For outpatient medicines in the generic form not clustered in reference price groups**, a 6% discount applies plus an additional discount not exceeding 10%.** Legislation also prohibits price increases; in that it requires manufacturers to grant a rebate equalling any price increase versus prices on 1 August 2009. The later regulation, referred to as 'price moratorium' was extended through 2022, subject to an adjustment for inflation as of 2018, in the 2017 law strengthening the pharmaceutical supply (*Gesetz zur Stärkung der Arzneimittelversorgung* – AMVSG) (Wenzl and Paris, 2018[62]; Deutscher Bundestag, 1988[57]).

Patient co-payments

The 2004 SHI Modernization Act (Deutscher Bundestag, 2004[63])) sets a co-insurance rate of 10% for prescribed drugs (with a minimum co-payment of EUR 5 and a maximum EUR 10 per prescription). For non-prescription pharmaceuticals, pharmacies can freely determine prices. Moreover, patients must pay any difference between the market price and the maximum reimbursement amount for those medicines price referenced. Consequently, in most cases, manufacturers reduce the market price to the reference price in order to avoid competing products being preferred (Robinson, Panteli and Ex, 2019[64]). Products that are at least 30% below the reference price are exempted from co-payments. Compulsory health insurance (statutory and private) covers 84% of the expenditure for retail medicines and patients pay the rest through co-insurance payments or consumption of OTC medicines. Hospital medicines are fully covered by health insurance (Wenzl and Paris, 2018[55]).

Procurement and tendering

Types of procurement procedures

Germany uses the following procedures to procure medicines:

- Most of the tenders[14] are organised in two ways: (1) at **active substance level** (molecule); and (2) **bundle or portfolio contracts**, whereby products are grouped and manufacturers are assessed by the level of rebate offered for that group of products (Kanavos, Seeley and Vandoros, 2014[65]). For example, two sickness funds (the *Deutsche Angestellten Krankenkasse.* DAK and the *Techniker Krankenkasse,* TK) have used bundle contracts (Kanavos, Seeley and Vandoros, 2014[65]);
- Tendering applied in the **outpatient and hospital sectors**. Public hospitals are required by law to acquire medicines (either **off- or on-patent**) through public procurement

[14] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

procedures if spending is over a certain threshold (i.e. value net of value-added tax (VAT) estimated to be equal to or greater than EUR 140 000) in accordance with European public procurement law (European Parliament and Council of the European Union, 2014[66]). For higher value contracts, these rules are based on general EU public procurement rules (Your Europe, 2022[67]). For contracts with a value below that threshold, national budgetary laws are the main source of public procurement rules. Calls for tendering are mostly, but not only, for generics (Wenzl and Paris, 2018[62]);

- **Facility-based procurement** is the main route for procurement of medicines for **hospital** use by the hospital sector, but some hospitals cooperate by **jointly procuring** via groups of hospitals or facilities. Joint procurement and facility-based procurement may be used by the same institutions but for different products (Vogler, Salcher-Konrad and Habimana, 2022[17]);
- Use of centralised procurement at the national level used both in the outpatient and hospital sectors. Use of centralised procurement at the regional level is used only by the outpatient sector, where not only regional and municipal health authorities participate, but also not-for-profit associations and regionally operating health insurances (Vogler, Salcher-Konrad and Habimana, 2022[17])*;*
- Both **single- and multiple-winner awards procedures** are applied for tendering designed at active substance level to award a place on the reimbursement list (Vogler, Salcher-Konrad and Habimana, 2022[17]); and
- '**Open house contracts**' in which sickness funds bid 'discount contracts'[15] in which interested suppliers agree to grant the requested discount, without any further negotiations (Vogler, Salcher-Konrad and Habimana, 2022[17]). 'Discount contracts' are considered tendering procedures according to European jurisprudence (Vogler et al., 2021[68]). This type of procedure concerns mostly generics, but also some branded drugs. In 2014, while most of the sickness funds sign contracts for generic products, some of them have ventured into rebate contracts on patent-protected brands, which accounted for 2.9% of total rebate sales volume. *Allgemeine Ortskrankenkassen* (AOK) tenders are held for >90 molecules. These tenders can be regionalized for AOK, one of the largest sickness funds that accounts for a significant (40%) part of the pharmaceutical (tender) market (Vogler, Salcher-Konrad and Habimana, 2022[17]).

At a national level, the following procurement bodies are involved in the public procurement of medicines in Germany (Vogler, Salcher-Konrad and Habimana, 2022[17]):

- The '*Bundesministerium für Gesundheit*' (BMG; Ministry of Health) nationally responsible for centralised procurement of vaccines for the outpatient sector in case of a public health emergency;
- The '*Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr*' (BAAINBw; Federal Office of Bundeswehr Equipment, Information, Technology and In-Service Support) nationally responsible for centralised procurement of medicines used in the outpatient sector;

[15] Tendering is viewed as a cost containment measure for sickness funds to control rising levels of pharmaceutical expenditure. These procedures work based on the response of manufacturers to an 'invitation' to reduce the offered list price by providing a price (rebate) upfront. Although the lowest possible price is a key factor to win a contract, other factors are also considered for awarding the tender, including the capacity to deliver a complete range of a product's portfolio (i.e. the number of product presentations based on dosage). A large number of companies have contracts generally based on price-volume agreements.

- The '*Bundesinstitut für Arzneimittel und Medizinprodukte'* (BfArM; Federal Institute for Medicines and Medical Devices) nationally responsible for coordinating the needs for both the inpatient and outpatient sectors;
- The '*Zentrum für Pandemie-Impfstoffe und –Therapeutika* (ZEPAI)' (Center for Pandemic Vaccines and Therapeutics) is operationally involved in the procurement of vaccines and therapeutics for both the inpatient and outpatient sector to enhance pandemic preparedness; and,
- Sickness funds which are involved in the tendering-like system for pricing outpatient medicines in the outpatient sector.

At a regional level, the following regional centralised procurement bodies are also involved in public procurement of medicines: first, *AGKAMED*, which is a group procurement organisation involved in the public procurement of medicines for member hospitals and rehabilitation clinics in the hospital sector; and, second, the *Dienstleistungs- und Einkaufsgemeinschaft Kommunaler Krankenhäuser eG im Deutschen Städtetag* (GDEKK), which is a group procurement organisation for district hospitals in the hospital sector (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Tendering award criteria

According to the EU Directive 2014/24 (European Parliament, 2014[20]), contracts in Germany are awarded to the most economically advantageous tender (MEAT), using a range of criteria defined by each contracting authority including price (often the dominant criteria), but also quality and safety of the product (no further detail about how this is defined), or the best price-quality ratio. Moreover, the German hospital setting uses, non-systematically, the 'added therapeutic value' as an award criteria for tenders (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

The G-BA issues guidelines on prescribing pharmaceuticals and excludes certain medicines from SHI coverage for certain indications. Physicians who disregard these guidelines are informed of the alternative cost-effective treatment options and ultimately held liable for compensation. Other mechanisms are in place to encourage the use of certain products over others, ensuring cost containment or efficiency gains through quality assurance, namely (IGES Institute, 2020[69]):

- **Generic substitution**. The aut-idem ('or the same') provision introduced in 2002 through the Pharmaceutical Expenditure Limitation Act (*Arzneimittelausgaben*-Germany 57 *Begrenzungsgesetz* (Deutscher Bundestag, 2002[70]) imposes upon pharmacies the obligation to sell a cheaper generic product of a given active substance. For each active substance, products with a negotiated discount contract between the patient's sickness fund and the manufacturer have priority; should such products not be available, cheaper options need to be considered, including parallel imports with a price at least 15% lower than the originator (net of the legally imposed general rebate) (Blümel et al., 2020[56]; Wenzl and Paris, 2018[55]; Panteli et al., 2016[26]).
- **Prescribing budgets and target volumes** ('*Richtgrößenvolumen')* are instruments used to control the spending limit of prescribers within a given timeframe. Regional pharmaceutical budgets were replaced by practice-specific target volumes in 2001. Since then, associations of sickness funds and SHI physicians at state level are mandated to determine an annual expenditure volume and derive target volumes for individual practices. Exceeding predefined benchmarks can lead to retrospective

requests for justification and potential paybacks to sickness funds (Panteli et al., 2016[26]). There are quotas to prescribe specific active substances. For example, in the State of Berlin, 70% of all prescribed SSRIs must either be citalopram or sertraline. The physicians can prescribe other SSRIs for the remaining 30%. Individual physicians are sometimes given the incentive to achieve specific quotas. Non-compliant physicians could face fee reductions and may also have to attend professional training on prescribing economically (IGES Institute, 2020[69]).

- **Prescription guidelines:** G-BA can issue guidelines for the prescription of costly pharmaceuticals and exclude specific pharmaceuticals from GKV coverage for certain indications. Physicians ignoring these guidelines are informed about therapeutic alternatives by the GKV funds, and ultimately made liable for compensation. The Medicinal Products Directive (*Arzneimittel*-Richtlinie/AM-RL (Gemeinsamer Bundesausschuss, 2022[71])) lays down the general principles for the prescription of medicines stating that if multiple options are available across therapeutic classes, the physician must prescribe the most cost-effective alternative.

Box 1.3. New AMNOG rules adopted in 2022

On 20 October 2022, the German Parliament approved new AMNOG rules ('GKV-FinStG') that strongly impact pricing and negotiations (Deutscher Bundestag, 2022[58]), namely:

- The price freeze that has been in effect since 2010 has been extended again until the end of 2026 (see above). Additionally, the new rules present a potential new exemption from the price freeze for medicines that receive a new marketing authorisation for either a new indication or a new patient group and that promise an improvement of the medical care;
- The process for negotiating AMNOG rebates has been modified to give the GKV increased powers. Medicines that offer minor or non-quantifiable additional benefit are priced in line with patent-protected comparators. Medicines showing no additional benefit have a lower rebated price than their comparators if the comparators are patent protected. Medicines with considerable or major additional benefit are exempt from these guidelines. In addition, a discount formula is applied to patent-protected comparator therapies that have not yet undergone a benefit assessment (i.e., launched before 2011);
- AMNOG rebates are backdated to take effect from the seventh month after launch (instead of the previous 12-month free pricing period). The mandatory rebate on patent-protected drugs outside the reference pricing system is increased from 7% to 12% for one year. A new 20% discount applies to certain combination therapies (excluding drugs that have major or considerable additional benefits). Moreover, for the first time, AMNOG rebate negotiations require volume-related elements, i.e. price-volume agreements or annual prescription volume caps;
- The new rules provide the health insurances with more powers and flexibility during the price negotiations. In accordance with GKV-FinStG, the reimbursement price negotiations could consider price-volume components or prescription volume caps;
- The mandatory 'pharmacy discount' that pharmacies are obliged to pay to the health insurance funds have been increased from €1.77 to €2.00 per prescription package for a period of two years;
- Under GKV-FinStG, combination therapies are subject to the new AMNOG rules as well as subject to a new combination markdown. When the GBA determines the additional benefit of a

new medicine, it lists the pharmaceuticals that can be used in combination with the new drug. For all drugs with new active substances that are used in a combination as listed by the GBA, the health insurance funds receive a markdown payment of 20% of the pharmaceutical company's sales price. A possible exemption of this mandatory markup payment is foreseen under the new rules if the actual combination has been subject to an AMNOG benefit assessment by the GBA and came out at least with a significant benefit;

- The sales threshold at which orphan drugs become subject to the standard AMNOG evaluation process is reduced from €50 million per year to €30 million per year. If the revenue of an orphan drug remains below this threshold, the AMNOG procedure continues to deem the additional benefit of an orphan drug to be recognised at the time of its marketing authorisation.

In December 2022, the German Health Minister Karl Lauterbach announced legislation to be published in 2023 setting out a number of policy changes on off-patent market including changes to the reference price system and generic substitution, new rules for rebate and tendering agreements for certain off-patent medicines (initially to be applied to cancer drugs and antibiotics), supply guarantees of essential paediatric medicines, as well as early detection of medicine shortages for critical medicines.

Source: (Deutscher Bundestag, 2022[72]).

Norway

Context

The Norwegian healthcare system offers universal coverage to all legal residents, as well as EU and EEA residents and Australians, through bilateral agreements, and is financed by general taxation and out-of-pocket payments while financing through private medical insurance is limited. All residents are covered by the National Insurance Scheme (*Folketrygden*, NIS) which is managed by the Norwegian Health Economics Administration (*Helseøkonomiforvaltningen*, HELFO) (OECD/European Observatory on Health Systems and Policies, 2021[73]; Saunes, Karanikolos and Sagan, 2020[74]).

The system has a semi-decentralised governance. At the national level, the government decides on national priorities and the parliament adopts the annual national budget, proposed by the Ministry of Finance. The central government is responsible for hospital and specialist care services, with delivery ensured by four regional health authorities (RHAs). Municipalities, on the other hand, are responsible for primary and public health care, including services provided by family doctors, maternity and child health centres, school health services and immunisation centres, as well as long-term care and social services (Helsedirektoratet, 2021[75]). Financing of RHAs consists of two parts: an ex-ante fixed budget and a diagnosis-related group (DRG) system for somatic care/services. In 2022, each part made up around 50% of the total financing (Helsedirektoratet, 2021[75]).

Coverage and pricing

The Norwegian Medicines Agency (NoMA) is responsible for reimbursement decisions on behalf of the NIS while the Norwegian Directorate of Health (*Helsedirektoratet*) decides which pharmaceuticals should be funded by the NIS or the RHAs. HELFO, the Norwegian Health Economics Administration, is responsible for the actual reimbursement of all pharmaceuticals that are covered by the NIS, and the reimbursement payments to pharmacies and patients.

Reimbursement is based on positive lists. NIS only covers reimbursement for severe diseases or 'long-term' treatments, defined as more than three months of medication per year. There are three reimbursement schemes covered by the NIS as detailed in Table 0.1 (Weise, 2018[76]; Saunes, Karanikolos and Sagan, 2020[74]; Henning Aure and Festøy, 2022[77]). Medicines intended for short-term therapy (e.g. antibiotics for pneumonia) and those not covered by the schemes below are paid for by the patient up to a maximum yearly threshold amount, after which expenses are reimbursed by the NIS. In 2021 the threshold was set at NOK 2460. Some short-term treatments are covered by NIS (e.g. medicines for infertility treatment and contraceptives).

Table 1.1. Reimbursement categories covered by the National Insurance Scheme in Norway

Reimbursement schemes	Reimbursement rate (%)	Description
Schedule 2	61	Pre-approved medicines for reimbursement under the condition that the patient has a severe disease and need for long-term treatment (>3 months). This list is updated by the Norwegian Medicines Agency (NoMA) once a month and it is a prerequisite that the product has obtained marketing authorisation in Norway.
Schedule 3	61	For medicines other than those under Schedules 2 and 4. Reimbursement can be granted upon submission of an individual application and only for long-term treatment (>3 months) including for products that have not obtained marketing authorisation. Confidential discounts are often negotiated under managed entry

		agreements. This implies that some medicines may achieve significant reimbursed sales before marketing authorisation in Norway, with no statutory maximum pharmacy purchasing price.
Schedule 4	100	For medicines used to treat serious contagious diseases such as tuberculosis, HIV or hepatitis C. Financing responsibility was moved from the NIS to the Regional Health Authorities in 2018.

Source: Authors based on (Weise, 2018[76]; Saunes, Karanikolos and Sagan, 2020[74]; Henning Aure and Festøy, 2022[77]).

All new medicines (including new indications) seeking reimbursement must undergo a health technology assessment (HTA) at national level[16]. HTA is the responsibility of the Norwegian Institute of Public Health (NIPH) since 2016 and NoMA is responsible for identifying the relevant products in a horizon scanning document. The horizon scanning document supports the marketing authorisation holder (MAH) to prepare all the necessary analyses and documentation for the HTA. The process is open to input from specialist care, patients and patient organisations, industry, and the general public to submit proposals for HTAs.

Moreover, in 2013 the National System for the Managed Introduction of New Health Technologies, established the so-called 'New Methods' system (Helsedirektoratet, 2021[78]) applied at both national and local levels: at national level, decisions are made by the four RHAs by mutual agreement; and, at local level, decisions are made based on the mini-HTA performed at hospital level. The system is based on a broad cooperation between the four RHAs including all the hospitals, the Procurement services for Health Enterprises Ltd, NIPH, NoMA, the Norwegian Directorate of Health, and the Norwegian Radiation Protection Authority. An Ordering Forum, *Bestillerforum* RHF, consisting of the four medical directors (one for each RHA) and two delegates from the Norwegian Directorate of Health, has the mandate to prioritise the HTAs to be conducted on the basis of submitted proposals and horizon scanning reports (Norwegian Ministry of Health and Care Services, 2017[79]; Helsedirektoratet, 2021[78]).

Principles of assessment

New products are assessed based on three priority-setting criteria as follows:

- The **benefit criteria** measured in terms of healthy life years and quality-adjusted life-years (QALYs), assessing whether the product will extend the patient's life and/or enhance quality of life by increasing the likelihood of survival or reduced loss of function, improvement of physical or mental function, reduction of pain, physical or mental distress;
- The **resource criteria** measured in terms of the estimated relevant uses of resources connected to treatment with the new medicinal product; and,
- The **severity criteria** measured as the number of healthy life years lost (in QALYs) as a result of not using the product in question, assessing the severity of the condition on the basis of risk of death or loss of function, the degree of loss of physical and mental function, pain, physical or mental distress.

HTA reports a cost effectiveness ratio (cost per QALY ratio) compared to a threshold fixed at NOK 275 000 per QALY gained. For severe conditions, a higher cost effectiveness ratio may be accepted. Severity is measured as absolute QALY shortfall. If the reimbursement decision is estimated to have an annual incremental fiscal impact above NOK 100M by the fifth year after

[16] HTA is performed in three different formats including mini-HTA, single technology assessments (STA) and full HTA reports. Since 2015, STA have been conducted for all new drugs and indications and HTA reports are available soon after a marketing authorisation.

approval, NoMA is not authorised to grant reimbursement and will pass its appraisal on to the Ministry of Health and Care Services before the case can be brought before Parliament in the form of a budget bill (Saunes, Karanikolos and Sagan, 2020[74]; PharmaBoardroom, 2021[80]; Norwegian Ministry of Health and Care Services, 2017[79]; Henning Aure and Festøy, 2022[77]).

Pricing mechanisms

Norway has a statutory pricing policy for prescription-only medicines based on maximum price regulation and stepped pricing for generics (*Trinnpris*) regulation. HTA performed on all new medicines seeking reimbursement influences price negotiations with manufacturers. Pay-backs are usually not used in Norway, while the Directorate of Health is authorised to enter into managed-entry agreements (MEA) with MAH for medicines reimbursed by the NIS (Helse- og omsorgsdepartementet, 2010[81]; Weise, 2018[76]; Henning Aure and Festøy, 2022[77]).

Cost-effectiveness assessment, maximum prices, external reference pricing and stepped generic pricing for prescription-only reimbursed medicines

- **Cost effectiveness assessment**. Assessment of the cost effectiveness ratio compares the cost of a new medicine per QALY against the fixed threshold of NOK 275 000 per QALY gained. Price is therefore a decisive factor in the reimbursement decision, leading to negotiation of a lower price than the statutory maximum price to ensure that a medicine becomes cost-effective. The reimbursement status may be affected by new evidence, price changes or market entry of a more cost-effective competitor (Norwegian Ministry of Health and Care Services, 2016[82]).
- **Maximum prices and external reference pricing**. Since 2002, all registered prescription-only medicines are assigned a maximum price by NoMA, even before marketing authorisation is granted in Norway and regardless of request for reimbursement. The maximum price consists of two elements: the maximum pharmacy purchase price and the maximum pharmacy retail price, adding a maximum mark-up for pharmacies (see in more detail in section *Prescribing and Dispensing*). The pharmacy purchase price is decided based on external reference pricing considering the average price of the three lowest prices of the reference countries (currently Sweden, Finland, Denmark, Germany, the UK, Netherlands, Austria, Belgium, and Ireland) converted to NOK[17]. Price comparisons with other countries consider differences in prices at unit level (i.e. pack size, tablet, dose, etc.), various types of modes of administration, and different product names (Helse- og omsorgsdepartementet, 2010[81]; Saunes, Karanikolos and Sagan, 2020[74]; Henning Aure and Festøy, 2022[77]).
- **Stepped pricing for generics**. A stepped price scheme for generics was implemented in 2005 which sets a maximum reimbursement amount for both branded and generic pharmaceuticals. NoMA publishes a 'substitution list', updated monthly, with a list of products considered interchangeable. The maximum reimbursement amount is automatically reduced (in steps) following patent expiry. The size of these reductions depends on annual sales prior to the establishment of generic competition and time since competition was established (Weise, 2018[76]; Saunes, Karanikolos and Sagan, 2020[74]; PharmaBoardroom, 2021[80]; Henning Aure and Festøy, 2022[77]).

[17] Price comparison is based on the price in the local currency, converted to NOK. The mean exchange rate of the last six whole months, as presented by the Central Bank of Norway, is used for the conversion. For medicines that require obligatory emergency stock for wholesalers, NoMA adds an additional 1% to the PPP. An example are ready-to-use adrenaline injections.

Tendering, price negotiations and MEAs for hospital medicines

- **Tendering and price negotiations for hospital medicines**. The main pricing policy in Norwegian hospitals is tendering[18]. The Norwegian Drug Procurement Cooperation (LIS) negotiates prices mainly on behalf of the RHAs, hospitals, and in some circumstances for the NIS. Prices are the same for all hospitals and are often confidential. Other discounts or product bundling are not common in the tendering process. Suppliers are required to grant minimum discounts, typically in the range 5%-17%, in order to participate in some tenders. In 2018, LIS tenders gave a price reduction of 40% on average for the Norwegian hospitals, compared to the statutory maximum prices (EY, 2019[83]; Norwegian Ministry of Health and Care Services, 2017[79]; Helsedirektoratet, 2021[78]; Henning Aure and Festøy, 2022[77]).
- **MEAs.** The Directorate of Health is authorised to enter into MEAs with MAH for medicines reimbursed by the NIS. The first MEAs were entered in 2017, consisting of reimbursement agreements with two MAH to access the PCSK9 inhibitors Repatha® and Praluent®. The criteria for entering into this agreement were that the treatment was addressing a highly unmet need, there was a defined patient group, treatment proved to be cost-effective with the confidential discount given, and the total budget impact did not exceed NOK 100 million a year. The MEAs include an agreed and confidential discount per sold package, which is paid back by MAH every month. For a patient to access these medicines, the doctor must apply for individual reimbursement (Schedule 3) and fulfil a defined set of terms (Weise, 2018[76]; Henning Aure and Festøy, 2022[77]).

Pricing in supply chain

Wholesalers are free to negotiate mark-ups with the manufacturers however medicines can only be sold at or below a maximum retail price level (as discussed in the section *Pricing Mechanisms*). The MAH and NoMA can initiate a re-evaluation of the maximum prices, but adjustments can only take place once per year. The maximum retail price level is decided by adding the maximum pharmacy purchase price to a maximum mark-up for pharmacies. The maximum mark-up for pharmacies for prescription-only medicines are based on the following criteria: 2.0% add-on from the maximum pharmacy purchase price; NOK 29.00 add-on per package; 0.5% add-on from the maximum pharmacy purchase price if the prescription medicine requires cooling; and, NOK 19.00 add-on per package for A/B-preparations[19].

Additionally, there is no regulation of pharmacy mark-ups in the scheme of the stepped pricing for generics, with pharmacies holding a financial incentive to dispense generics instead of branded products (Weise, 2018[76]; Saunes, Karanikolos and Sagan, 2020[74]; Henning Aure and Festøy, 2022[77]).

Patient co-payments

Medicines in publicly funded hospitals are fully covered by the hospital budgets and ultimately the RHAs. In 2006, the H-prescription (hospital financed) scheme was established for products prescribed in the hospital but administered by the patients themselves in outpatient setting. These do not involve any co-payment and the expenses are covered by the RHAs. These are

[18] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

[19] A and B preparations are medicines that are addictive, and thus require specific prescriptions and personal ID prior to issuing. A preparations are the strongest and include morphine and other opiates while B preparations are addictive and include e.g. diazepam and sleeping pills.

usually expensive medicines intended for long term treatment (H-prescriptions), e.g. products for Crohn's Disease, Bechterew's disorder and some types of cancer treatments.

Medicines intended for short-term treatment and those not covered by the schemes described above are paid for by the patient up to a maximum reimbursement amount, after which they are reimbursed by the NIS. In 2021 the threshold of maximum cost was set at NOK 2460. Other short-term treatments covered by NIS include medicines and expenses related to infertility treatment (IVF) and contraceptives for young women (Weise, 2018[76]; PPRI, 2019[84]).

Procurement and tendering

Types of procurement procedures

Norway uses the following procedures to procure medicines:

- Tenders[20] based on **active substance** for an assortment of essential medicines used in **hospital care**;
- **Tenders per indication for both in- and outpatient care**. Based on the offers from suppliers, a specialist group – consisting of doctors, nurses, representatives from patient organisations, NoMA and LIS - prepares a recommendation for the disease/indication in question with those medicines considered to be therapeutically equivalent (LIS recommendation);
- **Facility-based procurement** used in the hospital sector. **Centralised procurement at the national level** used in both outpatient and hospital sector. The main route for procuring inpatient medicines is centralised procurement at the national level, but hospitals may also procure medicines on their own, at different prices than the ones negotiated by LIS. Framework agreements are applied for medicines in the inpatient sector (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Use of **multiple-winner awards procedures** are applied for tendering and all suppliers who are qualified will receive an agreement. Medicines are ranked by price by the specialist group. This ranking is the basis for the prescribing recommendations that are distributed to the providers and suppliers;
- In Norway, tendering is used centrally by the four regional health authorities (RHAs) to procure medicines on behalf of the funded hospitals.
- **Open procedures** are applied in both facility-based and centralised procurement. It is mostly used for procurement of medicines used in specialist care, and typically conducted at central national level. Facility-based procurement is rarely used, but when individual hospitals conduct their own procurement, they use open procedure tenders (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Norway is part of the cross-country collaboration '**Nordic Pharmaceutical Forum**', which aims to increase purchasing power and to ensure security of supply through horizon scanning, manufacturing, logistics, security of supply, and joint procurement and negotiations.

The Norwegian Drug Procurement Cooperation (LIS), hospital pharmacies, hospital pharmacists, hospitals with pharmaceutical and therapeutic committees (PTC) and hospital departments are involved in the procurement process for medicines for use in hospitals (EY, 2019[83]; PPRI, 2019[84]; Højgaard et al., 2017[85]; Henning Aure and Festøy, 2022[77]). The

[20] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

tenders are published in the Doffin[21] and TED[22] database, due to legal provision (EY, 2019[83]; PPRI, 2019[84]; Højgaard et al., 2017[85]; Henning Aure and Festøy, 2022[77]).

Tendering award criteria

In Norway, tenders are awarded using a range of criteria, including price; security of continuous supply; product characteristics (e.g. administration form, packaging unit formulation and strength varieties, and labelling); generic name (according to European Pharmacopoeia); delivery reliability and service such as training and medical enquiries; and environmental criteria (Weise, 2018[76]; Vogler, Salcher-Konrad and Habimana, 2022[17]). Moreover, added therapeutic value has been applied as a criterion for selected tenders (Vogler, Salcher-Konrad and Habimana, 2022[17]).

In addition, Norway together with Denmark, Iceland, and Sweden (and Finland as an observer) are cooperating under the Nordic Pharmaceuticals Forum in jointly procuring and awarding framework tendering agreements to ensure the security of medicine supply (Barrenho and Lopert, 2022[86]).

Prescribing and dispensing

- **Prescribing by International Non-Proprietary Name** (INN) recommended. Doctors are allowed, but not obliged, to prescribe by International Non-proprietary Names (INN). There is no systematic evaluation of provider prescribing behaviour (Saunes, Karanikolos and Sagan, 2020[74]).
- **Generic substitution**. Generic substitution has been allowed in Norway since 2001 however pharmacies are not allowed to dispense a medicine with equal therapeutic benefits and a different active substance nor to substitute biological medicinal products with biosimilar products (Saunes, Karanikolos and Sagan, 2020[74]).
- **Prescribing guidelines**. For outpatient medicines, doctors in the primary sector are expected to prescribe the cheapest equivalent product unless there are serious medical reasons for prescribing a more expensive alternative.
- **Hospital formularies**[23]. For hospital medicines, the pharmaceutical and therapeutical committees (PCTs) in each RHAs and together with LIS define a list of recommended products/suppliers on the advisory list of medicines; deviations from the LIS recommendations must be documented. The lists are indicative for internal use in the hospital and are not published externally. They are updated on a yearly basis (EY, 2019[83]; Weise, 2018[76]; PPRI, 2019[84]; Højgaard et al., 2017[85]; Henning Aure and Festøy, 2022[77]).

[21] Doffin

[22] Place of performance (Map) - TED Tenders Electronic Daily (europa.eu)

[23] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

Spain

Context

The Spanish national health system (Sistema Nacional de Salud, SNS) provides universal coverage and is financed mainly by taxes. Spain's 17 autonomous regions have their own health services. National planning and regulation are the responsibility of the Ministry of Health, but the primary jurisdiction over operational planning at the regional level, including resource allocation, procurement and provision, has been delegated to the 17 regional health authorities (OECD/European Observatory on Health Systems and Policies, 2021[87]).

Key institutions in Spain's health system are the Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS), which is responsible for marketing authorisation and clinical assessments of medicines, and the Ministry of Health (MoH), which performs HTA and prepares pricing and reimbursement decisions. The final pricing and reimbursement decision is taken by the Inter-Ministerial Pricing and Reimbursement Committee (Comisión Interministerial de Precios de los Medicamentos, CIPM), affiliated to the MoH and involving national public authorities and the regions. CIPM decisions apply to all medicines used in the Spanish SNS (both outpatient and inpatient sector). The regions pay for medicines and have some discretion to conduct some follow-up measures regarding the pricing and reimbursement decision (Vogler, 2020[88]).

Coverage and pricing

Spain regulates the prices of reimbursed medicines used in the inpatient and outpatient sector. Given the combined procedure for pricing and reimbursement decisions, the same institutions play a role in each decision process, namely the MoH, CIPM, AEMPS to provide a clinical assessment, the regions, and possibly regional HTA institutions (Vogler, 2020[88]).

The pricing and reimbursement decision is informed by an HTA process, which consists of a clinical and economic assessment. The clinical assessment is conducted by AEMPS, which produces a Therapeutic Positioning Report (Informe de Posicionamiento Terapéutico), and the economic assessment is performed by the MoH. The HTA considers the findings of the clinical assessment as well as the added value of the medicine (cost-effectiveness analysis), medicine prices in other countries, estimated manufacturing costs, and the estimated budget. Informed by the HTA, the MoH subsequently conducts price and reimbursement negotiations with the marketing authorisation holder (MAH) (Vogler, 2020[88]).

Spain uses a combination of a national positive list and negative list. These national lists are supplemented by hospital pharmaceutical formularies[24] (HPF) used by hospitals. There are individual HPF per hospital and joint HPF in some regions, but there is no national HPF. The decision on the inclusion of a medicine into a HPF is taken at hospital level by its Pharmaceutical and Therapeutic Committee, which is responsible for setting, developing, and updating the HPF (Vogler, 2020[88]).

Principles of assessment

The AEMPS produces a Therapeutic Positioning Report (TRP), presenting the clinical assessment results (Ministry of Health, 2019[89]). This report is prepared by the Therapeutic

[24] For definitions on formulary management mechanisms, please see Box 1.3 in the Health Working Paper.

Value Coordination Group (TVCG) led by AEMPS. The TVCG also involves members of the MoH and the regional governments. The purpose of the TPR is to inform about the therapeutic value of a medicine based on evidence of its effectiveness, safety, and comparative effectiveness compared to existing medicines for the same indication. The health gains identified are not mapped to a generic scale (e.g. QALYS), as in other countries. AEMPS prepares a draft TPR before producing the final report based on comments of the TVCG, experts and stakeholders (Vogler, 2020[88]).

Based on the TPR, the MoH performs the full HTA including an economic evaluation and a budget impact analysis. The following components are investigated:

- the added value of the medicine compared to equivalent alternatives (cost-effectiveness analysis),
- the place of the medicine in the treatment of the indication as indicated in the TPR,
- the price requested by the MAH and the prices in other countries,
- the estimated manufacturing costs, and
- the estimated budget.

Hence, Spain's pharmaceutical pricing policy framework for new medicines considers value elements, although value-based pricing is not a primary pricing policy (Vogler, 2020[88]).

Pricing mechanisms

Reimbursed medicines: price negotiations, internal and external reference pricing, MEAs, mandatory discounts and tendering

- **Price negotiations** form a key pricing policy to set the price of new on-patent medicines. These negotiations take place between the MAH and MoH. According to the Medicines Act (Spanish parliament, 2006[90]), the severity of the disease, medical need, therapeutic benefit, degree of innovation, cost-effectiveness and budgetary impact are among the criteria informing the pricing and reimbursement decision (Vogler, 2020[88]).
- **Internal reference price system** clusters medicines at active substance level and imposes the same reference price per cluster. The price is determined based on the lowest-priced medicine, expressed in lowest daily treatment costs per defined daily doses (DDD). The Directorate General for Common NHS Services Portfolio and Pharmacy of the MoH establishes the reference groups and determines the references prices, which are annually updated by a ministerial order[25] (Ministerio de Sanidad, 2015[91]). Additionally, prices of generic and biosimilar medicines are linked to the prices of the originator and reference medicines. The first generic must have a price that is 40% lower than the originator medicine's price. As soon as a reference group has been created, the price of the generic must be lowered to the price of the lowest generic in that group. If the price is not reduced, the medicine will be substituted by the lowest priced generic at the pharmacy level. For biosimilar medicines, the price reduction is not mandatory, nevertheless, biosimilars tend to be priced around 30% lower than the reference product. Moreover, originator and reference medicines must lower their prices when the first generic or biosimilar medicine enters the market respectively. (Vogler, 2020[88]).

[25] In 2022, Spain updated the reference price system of medicines of the SNS. The reference prices of 17.097 product presentations will be altered, which will result in in a saving of €271 million (Gomez, 2022[177]).

- **External reference pricing**. Medicine prices in other countries are considered as supportive information to inform price negotiations. It is applied on a case-by-case basis and mainly used for new medicines without a therapeutic equivalent. Spain considers 14 European reference countries: Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Slovenia, Sweden, Slovakia, and UK. The Spanish price should not be higher than the lowest price of that medicine in the reference countries (Vogler, 2020[88]).
- For new, high-priced medicines (outpatient and inpatient use), **managed-entry agreements** (MEA) may be concluded between the MAH and the MoH. Usage of both financial and performance-based MEAs has been reported (Vogler, 2020[88]).
- In accordance with the Royal Decree Law 8/2020 (Spanish parliament, 2020[92]), Spain implements a **mandatory discount** (claw-back) applicable to all medicines sold to the SNS (outpatient and inpatient) that are not included in the reference price system. The discounts amount to 7.5% for new medicines, 4% for orphan medicines, and 15% for medicines older than 10 years without a generic or biosimilar alternative. The 7.5%, and 4% discounts are levied on the pharmacy retail price, but equally impact the wholesale price and the ex-factory price.
- **Tendering procedures** at therapeutic indication level are in place for outpatient and inpatient medicines, in addition to price setting at national level (Vogler, Salcher-Konrad and Habimana, 2022[17]). See more detail in section *Procurement and tendering*.

Non-reimbursed medicines: free pricing

For non-reimbursable medicines (i.e. medicines not included in the SNS) there is **free pricing**. Manufacturers may set the price at their own discretion (Vogler, 2020[88]).

Pricing in supply chain

The wholesale price and pharmacy retail price of all outpatient medicines are regulated based on **statutory regressive margin schemes** (Ministerio de Sanidad y Consumo, 2008[93]; Spanish parliament, 2010[94]). The wholesale and pharmacy margin schemes are applied to all medicines used in the outpatient sector, independently of whether they are reimbursed. For medicines used in the inpatient sector, prices are set at the ex-factory price level; no mark-ups are applied (Vogler, 2020[88]).

Spain applies two **claw-back systems**. Since 2010, a mandatory discount of 7.5% for new medicines and 4% for orphan medicines is levied on the retail price of reimbursed medicines for both outpatient and inpatient use. The discount equally impacts manufacturers, wholesalers, and pharmacies (Vogler, 2020[88]). In another claw-back system, community pharmacies must make payments to the SNS based on their annual sales of SNS medicines at ex-factory price level (Vogler, 2020[88]; Ministerio de Sanidad y Consumo, 2008[93]).

The **value-added tax** (VAT) is 4% on medicines, while the VAT on medical devices is 10% and the standard VAT is 21% (Vogler, 2020[88]).

Patient co-payments

Reimbursable outpatient medicines are not fully covered by the SNS. Patients must pay **percentage co-payments (i.e. co-insurance)**, which are generally linked to socio-economic status. Figures for 2020 were the following:

- For the working population, co-payment rates of 40%, 50% or 60%, depending on the income of the patient are applied (yearly income of < € 18,000; € 18,000 – € 100,000 and > € 100,000, respectively).
- Pensioners have to co-pay 10% of the pharmacy retail price with a ceiling of € 8.23 per month (yearly income of < € 18,000), of 10% of the pharmacy retail price with a ceiling of € 18.52 per month (yearly income of € 18,000 – € 100,000) or 60% of the pharmacy retail price with a ceiling of € 61.75 per month (yearly income of > € 100,000).
- Medicines for chronic diseases always carry a co-payment of 10% of the pharmacy retail price, independent from the income of the patient and with a maximum of € 4.24 per pack.
- Exemptions: low-income pensioners, long-term unemployed without unemployment benefits, and people involved in work accidents or suffering from occupational diseases (Vogler, 2020[88]).

No co-payments are charged on medicines for **inpatient use** (Vogler, 2020[88]).

Procurement and tendering

Types of procurement procedures

Spain uses the following procedures to procure medicines:

- Tendering [26] for inpatient and outpatient medicines, designed at **indication level** (OECD Survey on On-patent Competition, 2022).
- **Facility-based procurement** and **joint procurement** used for hospital medicines. Centralised procurement at regional level is the main route for procurement, but facility-based procurement and joint procurement by hospitals provide an additional route for procuring inpatient medicines (Vogler, Salcher-Konrad and Habimana, 2022[17]). Medicines of high budget impact are purchased jointly by hospitals of the same region. For these regional procurement activities, regional procurement committees have been established, and all hospitals that are members of the joint purchasing group must use the medicine that wins the tender. Key actors on behalf of the purchasing body are the purchasing committee, the hospital pharmacy, the main doctor in the field and hospital administration (Vogler, 2020[88]; Vogler, Salcher-Konrad and Habimana, 2022[17]).
- **Centralised procurement** in the **inpatient** and **outpatient** sector at both national and regional level. At the national level, procurement is performed by the Instituto Nacional de Gestión Sanitaria (INGESA), which functions as the national procurement agency and performs framework agreements and further procurement procedures (Vogler, 2020[88]; Vogler, Salcher-Konrad and Habimana, 2022[17]). Framework agreements are generally used for off-patent medicines in the inpatient setting (Vogler, Salcher-Konrad and Habimana, 2022[17]). At the regional level, Consorci de Salut i Social de Catalunya is among the centralised procurement bodies used for inpatient and outpatient procurement (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- In the outpatient sector, a common procurement model is direct acquisition from pharmaceutical companies by pharmacies. Some pharmacies have joined groups called ‘procurement centres’ that have been created to strengthen purchasing power (Vogler, 2020[88]).

[26] For definitions on tendering, please see Box 1.2 in the Health Working Paper.

- Some regions apply **tendering-like systems** in the outpatient sector, in addition to the price setting at national level. For instance, the region of Andalusia used to apply an auction-like system for the procurement of off-patent outpatient medicines (no longer in place) (Casanova-Juanes, Mestre-Ferrandiz and Espín-Balbino, 2018[95]). The (ceiling) prices are still determined by the CIPM, but the tender with the lowest price will be selected for reimbursement (Vogler, 2020[88]; Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Use of dynamic purchasing systems to a limited extent, and only certain contracting authorities may use it (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Spain is involved in the cross-country collaboration '**Valletta Declaration**', established in May 2017, which aims to improve access to medicines, through collaboration in HTA and joint procurement (Vogler, 2020[88]; Vogler et al., 2020[47]).

Tendering award criteria

According to the EU Directive 2014/24 (European Parliament, 2014[20]), contracts are awarded to the most economically advantageous tender (MEAT, dominant criterion to award contracts for inpatient medicines), using a range of criteria, including price (often the dominant criteria), security of supply, added therapeutic value, and product quality and safety. Moreover, tenders launched by the national procurement agency have included environmental criteria (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

- **Generic substitution** is mandatory at community pharmacy level. The lowest-priced alternative medicine is always dispensed. Patients cannot obtain a higher-priced brand even if they would be willing to pay the price difference (Vogler, 2020[88]).
- **Biosimilar substitution** is not allowed. However, in contrast to substitution (at pharmacy level), **switching** (from the reference medicine to a biosimilar, and between biosimilar medicines) by a doctor is possible (Vogler, 2020[88]; Vogler, Salcher-Konrad and Habimana, 2022[17]).
- **Prescribing by INN (International Non-Proprietary Name)** is mandatory. It is possible to prescribe by trade name for chronic care patients whose prescription corresponds to the continuity of treatment, only if the prescribed medicine is included in the reference price system or it has the lowest price within the reference group (Vogler, 2020[88]; Vogler, Salcher-Konrad and Habimana, 2022[17]).
- **Hospital formularies** [27] **:** There are individual formularies per hospital and joint formularies in some regions, but there is no national formulary. The decision on the inclusion of a medicine into a formulary is taken at hospital level by its Pharmaceutical and Therapeutic Committee, which is responsible for setting, developing, and updating the formulary (Vogler, 2020[88]).

[27] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

Sweden

Context

Sweden's National Health Service (NHS) system is primarily funded by taxes covering all residents and is highly decentralised with three independent governmental levels: the national government, 21 regions, and 290 municipalities. The principal health policy objectives and frameworks are determined by the government at the national level, but the actual provision of services is done by the regions and local authorities (Björvang, Ponén and Rönholm, 2023[96]). The regions are responsible for financing (through government subsidies and co-payments), procuring, and providing health services in primary, specialist and psychiatric care, while the National Board of Health and Welfare acts as the government's central advisory and supervisory agency for health and social services over the regions. Finally, the municipalities are responsible for delivering school health care and social care for children and adults as well as home care and rehabilitation services for older people and those living with disabilities (OECD/European Observatory on Health Systems and Policies, 2021[97]).

Coverage and pricing

The NHS covers reimbursement of outpatient medicines included in a national positive list (Pharmaceutical Benefits Scheme). Decisions on pricing and reimbursement are undertaken simultaneously and result in a joint decision informed by the health technology assessments (HTA) performed by the Dental and Pharmaceutical Benefits Agency (TLV). TLV is responsible for pricing and reimbursement decisions on outpatient medicines. Decisions for new outpatient medicines are made by the Pharmaceutical Benefits Board (expert board within TLV). The Board is responsible for decisions concerning new: original brand products, dosage forms of medicines already granted reimbursement status, and off-patent medicines. The Board consists of seven members, which represent the regions, universities, and patient organisations (TLV Dental and Pharmaceutical Benefits Agency, 2022[98]; Björvang, Ponén and Rönholm, 2023[96]). The Board consists of seven members, which represent the regions, universities, and patient organisations (Pontén; Johan, Rönnholm and Skiöld, 2017[99]; TLV Dental and Pharmaceutical Benefits Agency, 2022[98]).

Outpatient medicines are usually granted reimbursement status for all indications (general reimbursement). However, some products may be reimbursed for a limited area of use or indication or only to a specified patient group (restricted reimbursement), for example, if a medicine is only cost-effective for one limited and specific group of patients (TLV Dental and Pharmaceutical Benefits Agency, 2022[98]). TLV can review the reimbursement status of medicines at any point in time (TLV Dental and Pharmaceutical Benefits Agency, 2022[98]).

Outpatient medicines are funded by the regions, who are granted a pharmaceutical budget from the government to cover reimbursed medicines under the benefits scheme. On an annual basis, the government and the Swedish Association of Local Authorities and Regions (SALAR) negotiate an agreement on the conditions (including the amount) of the funding for reimbursed medicines. Inpatient medicines are not covered by the national benefits scheme and regions are solely responsible for their funding and procurement. The regions have Pharmaceutical and Therapeutics Committees responsible for publishing hospital formularies[28] recommending

[28] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

medicines as the first-choice treatment to support physicians in their choice of medicines (Björvang, Ponén and Rönholm, 2023[96]).

Principles of assessment

Cost-effectiveness analysis is used by TLV to inform decisions on pricing and reimbursement by comparing the medicine candidate for reimbursement against two or more alternative products. Results are presented as a cost per quality-adjusted life year (QALY) gained. If the cost per QALY gained is considered reasonable in relation to the severity of the condition, the new treatment is deemed cost effective (TLV Dental and Pharmaceutical Benefits Agency, 2022[100]). TLV analyses both direct and indirect costs and benefits in their HTA process. Regarding direct costs, all costs related to the use of the medicine are evaluated including physician visits, cost of a standard course of treatment, health care costs related to subsequent interventions as well as costs of side-effects. The direct benefits include any improvements in health status (measured as QALYs), any cost savings, in terms of foregone medical treatments, and gains in worker productivity due to less sick days taken. The results of the cost-effectiveness analysis act as a go/no-go decision point; if the drug is deemed not to be cost-effective at the proposed price, then it will normally not be placed on the positive list.

Eligibility to reimburse outpatient medicines is based on three principles (SFS 2002:160 (Riksdag, 2002[101])): (1) human dignity to ensure equal access; (2) need and solidarity to ensure patients with more severe diseases are prioritised over patients with less severe conditions; and (3) cost-effectiveness favouring reimbursement of medicines delivering improved health and quality of life at the lowest cost. Provided that the first two principles are met, reimbursement is granted if TLV finds that the requested price is justified in terms of improved health and cost savings (i.e. cost-effective) (TLV Dental and Pharmaceutical Benefits Agency, 2022[98]; Björvang, Ponén and Rönholm, 2023[96]). The existence of a managed entry agreement (MEA) between the regions and manufacturers may also affect the reimbursement decision (TLV Dental and Pharmaceutical Benefits Agency, 2022[98]; Björvang, Ponén and Rönholm, 2023[96]).cost-effective) (Pontén; Johan, Rönnholm and Skiöld, 2017[99]; TLV Dental and Pharmaceutical Benefits Agency, 2022[98]). The existence of a managed entry agreement (MEA) between the regions and manufacturers may also affect the reimbursement decision (Pontén; Johan, Rönnholm and Skiöld, 2017[99]; TLV Dental and Pharmaceutical Benefits Agency, 2022[98]).

Reimbursement decisions of medicines used in specialised inpatient care are based upon the results of the HTA performed by TLV after the Council for New Therapies (NT-Council) selection of medicines to be evaluated. TLV produces HTA analysis of the product at different price levels and supports the NT-council in making recommendations at a national level on the preferred treatment. The recommendations and information provided will support the regions when deciding on choice of treatment (see below) (Björvang, Ponén and Rönholm, 2023[96]).

Pricing mechanisms

Reimbursed medicines: statutory pricing, internal reference pricing, MEAs and mandatory price reductions

- **Statutory pricing** applies to outpatient medicines. The price needs to be justified based on the value that the medicine delivers in light of the three principles discussed above (see *Principles of assessment*).
- Generic substitution leads to lower prices, and, subsequently, significant price differences between generic substitutes can arise. In this situation, TLV will lower the

maximum accepted selling price within the benefits scheme by setting a **lower ceiling price for substitutable medicines** (most relevant for branded original products that lost patent protection). Each month, TLV analyses prices and sales volumes to find groups where the criteria for setting a ceiling price are met. When the prices of a group of substitutable medicines have fallen by at least 70 per cent of the price that the medicines had before generic competition arose, and when generic competition has been ongoing for at least six months, TLV sets a ceiling price. The new fixed ceiling price is 35 per cent of the price of the pharmaceuticals before generic competition emerged (Björvang, Ponén and Rönholm, 2023[96]).

- **Managed entry agreements (MEAs)**. MEAs are used in Sweden for high-priced novel medicines as well as to negotiate significant price reductions between the regions and manufacturers and subsequent pricing and reimbursement decisions (Vogler, Salcher-Konrad and Habimana, 2022[17]). In addition, Sweden uses risk-sharing agreements to allow access to novel medicines that reveal uncertain clinical effectiveness.
- **Mandatory price reductions (15-year rule)**. In a law enacted in 2015 (TLV, 2014[102]), pricing arrangements for reimbursed medicines older than 15 years (or that have no (or weak) generic competition) impose a price reduction of 7.5%. The 15-year threshold is based on the date of first marketing authorisation in each substance group, meaning that TLV can reduce prices of recently approved medicines if the first marketing authorisation in the same substance group is older than 15 years (Björvang, Ponén and Rönholm, 2023[96]). In 2019, the TLV announced that 111 products (with different substance and form) will have their prices cut by 7.5% in accordance with the 15-year rule - where prices are cut on substances whose patent expires but do not yet face generic competition (PPRI, 2019[103]).

External reference pricing, cost-plus pricing, price-volume agreements, clawbacks and internal reference pricing are **not** used in Sweden (Björvang, Ponén and Rönholm, 2023[96]).

Free pricing for non-reimbursed medicines

Medicines outside the benefits scheme (i.e. non-reimbursed prescription-only medicines and most OTC medicines) are unregulated and subject to **free pricing**. There is no regulation of prices for medicines used in hospitals. If the same product is reimbursed for outpatient use, there is a price set for the prescribed medicine. That price acts as an informal 'reference price for hospital use' (Pontén; Johan, Rönnholm and Skiöld, 2017[99]).

The regions are responsible for procuring inpatient medicines in their respective area. The regions have lists of preferred medicines which are supposed to be first choice for treatment. Prices of hospital medicines used by public providers are determined by the region's procurement process (see section 'Procurement and tendering' below) regulated by the Public Procurement Act (2016:1145 (Swedish Competition Authority, 2022[104])). Prices of medicines used in private providers will vary according to whether the provider has jointly procured medicines with regions or procured them independently (Pontén; Johan, Rönnholm and Skiöld, 2017[99]).

Pricing in supply chain

Wholesalers are free to negotiate their **mark-up** directly with the manufacturer however the pharmacy **retail mark-up** is regulated following a regressive mark-up up to a ceiling set by TLV for those medicines covered by the benefits scheme. Pharmacies receive an extra SEK 12.75 (~€1.1) when dispensing a product with competition from generics i.e., within the 'Product-of-the-month' system (see below) (Björvang, Ponén and Rönholm, 2023[96]).

The **standard VAT rate** is 25% and is applied to OTC-medicines and medical devices. There is no VAT on prescribed medicines (Björvang, Ponén and Rönholm, 2023[96]).

Patient co-payments

Co-payments for outpatient reimbursed medicines are calculated according to a 'high-cost threshold' that incrementally reduces patient costs for prescription medicines and applies for a 12-month period from the first purchase up to a maximum 2 600 SEK (€~240) per year, as follows (TLV Dental and Pharmaceutical Benefits Agency, 2022[105]; Riksdag, 2002[101]; Björvang, Ponén and Rönholm, 2023[96]):

- Between 0 SEK and 1,300 SEK the patient pays 100% of the cost of the medicine
- Between 1,301 SEK and 2,481 SEK the patient pays 50% of the cost of the medicine
- Between 2,482 SEK and 4,610 SEK patient pays 25% of the cost of the medicine
- Between 4,611 SEK and 6,381 SEK patient pays 10% of the cost of the medicine

Medicines for vulnerable groups[29] and those used for infectious diseases prescribed under the Swedish Communicable Diseases Act are exemptions (Björvang, Ponén and Rönholm, 2023[96]).

Non-reimbursed medicines and prescription free medicines (OTC) are generally not subsidised, and therefore the prices for these product segments are unregulated (Björvang, Ponén and Rönholm, 2023[96]).

Procurement and tendering

Types of procurement procedures

Sweden uses the following procedures to procure medicines:

- **Centralised procurement at the national level** used in the outpatient sector. Framework agreements have been applied for outpatient medicines (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- **Centralised procurement at the regional level** and **joint procurement** used in the hospital sector. The main route for procuring inpatient medicines is centralised procurement at regional level, performed by the regions. However, joint procurement between individual hospitals is also used as a supplementary route (de facto no facility-based procurement) (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Both **single- and multiple-winner awards procedures** are applied for tendering[30]. Some regions use multi-winner awards for inpatient medicines, but each region has its own processes, including whether to use single- or multiple-winner awards (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- Centralised and joint procurement regularly use **open tenders** for inpatient medicines. At regional level, tendering is done for all inpatient medicines. Tenders can be active substance-based or therapeutic indication-based and are typically conducted every 1-2 years. Dynamic purchasing systems are used in some capacity, but their use is limited

[29] Vulnerable groups include children under 18 years old, insulins, pharmaceuticals prescribed for preventing contamination of certain communicable diseases (i.e. HIV), and medicines for persons lacking perception of their own state of illness; medicines in these situations are always subsidized at 100 %.

[30] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

with only some contracting authorities allowed to use it (Vogler, Salcher-Konrad and Habimana, 2022[17]).

- **'Product-of-the-month'** is a tendering-like system for off-patent outpatient medicines. For defined active substances, the generic with the lowest price is considered as the preferred product for the respective month and will be dispensed in the pharmacies due to the mandatory generic substitution. The product of the month is set by TLV and the company responsible for the product of the month must provide it to all pharmacies (TLV Dental and Pharmaceutical Benefits Agency, 2022[106]).
- Sweden is part of the cross-country collaboration '**Nordic Pharmaceutical Forum**', which aims to increase purchasing power and to ensure security of supply through horizon scanning, manufacturing, logistics, security of supply, and joint procurement and negotiations.

At a national level, the following procurement bodies are involved in the public procurement of (outpatient) medicines in Sweden:

- *'Adda'* nationally responsible for conducting procurement for some outpatient medicines (e.g. vaccines). This centralised procurement body is operated by the association of local authorities.
- *'Dental and Pharmaceutical Benefits Agency'* (TLV) nationally responsible for the tendering-like system for off-patent outpatient medicines. TLV indicates the 'product-of-the-month' based on the lowest price submitted by manufacturers (Vogler, Salcher-Konrad and Habimana, 2022[17]).

At a regional level, the regions are responsible for procuring medicines for inpatient use. In practice, procurement is, to an increasing degree, coordinated among the regions. In some cases, other informal groupings of regions can make joint procurements. Also, national procurement takes place in some circumstances. The participating regions give power of attorney to the purchasing region and will later individually make an allocation decision (Pontén; Johan, Rönnholm and Skiöld, 2017[99]).

The regions have lists of preferred medicines for treatment. Hospital pharmacies are expected to dispense and stock other medicines as well. The decision concerning which medicines should be primarily used in the inpatient sector is made at two levels: at the regional level, where regions decide which medicine to procure, and at the local level, provided that each hospital decides on which medicines are required to be procured (Björvang, Ponén and Rönholm, 2023[96]).

Tendering award criteria

According to the EU Directive 2014/24 (European Parliament, 2014[20]), contracts should be awarded to the most economically advantageous tender (MEAT), using a range of criteria, including price (often the main criterion), security of supply, environmental criterion (legal required criterion in publicly awarded contracts), quality and safety of the product (applied only for outpatient medicines) and added therapeutic value (non-systematically, used for inpatient medicines). At regional level, the decision to accept a tender is based on a set of criteria that the regions laid down. Since most regions group together with other regions to get volumes large enough for discounts, the criteria tend to be uniform across the country. Usually, priority is given to quality aspects of the tender (i.e. the medical and pharmaceutical value) although price also features (Pontén; Johan, Rönnholm and Skiöld, 2017[99]; Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

- **Generic substitution** is mandatory since October 2002 (TLV Dental and Pharmaceutical Benefits Agency, 2022[107]). Pharmacies are obliged to offer the therapeutic alternative with the lowest price (per unit) however the prescriber or the pharmacist may refuse substitution on medical grounds. The Medical Products Agency[31] decides on which pharmaceuticals are considered therapeutic alternatives. Each month, TLV informs which product in each package-size group has the lowest retail price per unit and that should be dispensed at the pharmacies that month (this system is referred to as the **product-of-the-month**). TLV also appoints two other product alternatives in case of shortage of the cheapest product (Pontén; Johan, Rönnholm and Skiöld, 2017[99]; TLV Dental and Pharmaceutical Benefits Agency, 2022[106]).
- **Clinical and treatment guidelines**: The National Board of Health and Welfare, in collaboration with other actors, such as the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services), SMPA (Swedish Medical Products Agency) and TLV, provides evidence-based guidelines for the care and treatment of patients. The guidelines include recommendations for decisions on priority setting and provide national support to assist health care providers in establishing disease-management programmes. Different versions of these guidelines are available for decision-makers, health care professionals, and patients and their relatives (Björvang, Ponén and Rönholm, 2023[96]).
- **Target regional 'Wise Lists' for rational prescribing**: Regional 'Wise Lists' (the Stockholm region developed the so-called 'Kloka Lista' but other regions have similar lists (Janusinfo Region Stockholm, 2023[108])), updated on an annual basis, recommend a list of medicines in outpatient and hospital care eligible for reimbursement that physicians are encouraged to prescribe for treating common diseases and an additional 100 medicines for specialised care. For example, to ensure rational use of prescribing, the Stockholm region developed the so-called 'Kloka Lista' (translated as 'Wise List'). The 'Wise List' is also actively communicated to the patients (Vogler, Salcher-Konrad and Habimana, 2022[17]).
- **Hospital formularies** [32] : Regions are required to have a Pharmaceutical and Therapeutics Committees. The committees support physicians in their choice of medicines through publishing an annual list of medicines recommended as the first-choice treatment for a range of common diseases and through various types of training and development initiatives (Björvang, Ponén and Rönholm, 2023[96]).
- Prescription by International Non-proprietary Name (INN) is not allowed. Instead, prescribers must indicate a brand name of either an original or a generic product (Björvang, Ponén and Rönholm, 2023[96]).

[31] The Swedish Medical Products Agency (SMPA) is the national authority responsible for the regulation and surveillance of medicines and provides recommendations for medical treatment in several therapeutic areas

[32] For definitions on formulary management mechanisms, please see Box 1.3 in the Health Working Paper.

United Kingdom

Context

The National Health System (NHS) is almost entirely state-funded and mostly free to patients at the point of need. The UK comprises four constituent nations: England, Wales, Scotland, and Northern Ireland. Since 1999, health care has become a devolved responsibility in the four nations, namely on how services are organised and paid for. Even so, they all follow the tax-funded NHS model, and many key concepts are similar across nations.

The United Kingdom Government allocates a set budget for health care in England, whereas Scotland, Wales, and Northern Ireland have received a general block grant for public spending decided separately by each devolved administration. The health ministers of Scotland, Wales, and Northern Ireland are responsible for setting the strategic direction and policy for the NHS in their respective countries. In England, this function is shared between the health minister and NHS England. Clinical Commissioning Groups (CCGs) in England (replaced by Integrated Care Systems in July 2022), Health Boards in Scotland and Wales, and the Health and Social Care Board in Northern Ireland, are responsible for commissioning or planning services in their respective areas. The manufacturing, licensing and regulation of medicines as well as price control is all done at United Kingdom level (OECD/European Observatory on Health Systems and Policies, 2019[109]; European Observatory on Health Systems and Policies, 2022[110]).

Coverage and pricing

The Human Medicines Regulations 2012 (Department of Health & Social Care, 2012[111]) defines three broad classes of medicines that are eligible for reimbursement by the UK NHS: (1) 'Prescription-only Medicines' ('POMs'); (2) 'General Sale Medicines', which do not require a prescription; and (3) 'Pharmacy Medicines', which can be purchased without a prescription but only from a pharmacy. In principle, NHS reimbursement is available to all three classes of medicines, but expenditure is increasingly focused on POMs.

Coverage and reimbursement by the NHS differ between primary care/outpatient medicines and hospital medicines. Most outpatient/primary care medicines are eligible for reimbursement except those products 'blacklisted' in the Drug Tariff or those with conditional reimbursement (i.e. 'Selected List'[33] in the Drug Tariff). Funding is ensured centrally by the NHS under the Community Pharmacy Contractual Framework and products are reimbursed as follows (Castle, Kelly and Gathani, 2021[112]):

(i) at the Drug Tariff which lists the reimbursement amount for commonly used, mostly generic products;

(ii) at the 'NHS list price' which applies mainly to branded products specifying the price at which medicines are reimbursed by the NHS (as explained below); or

(iii) otherwise, at the net price at which the dispensing pharmacy purchased the product.

For hospital medicines, coverage and reimbursement decisions were effectively the responsibility of approximately 100 local Clinical Commissioning Groups ('CCGs'). CCGs and

[33] Prescription of some drugs is restricted in certain circumstances. Prescriptions must follow the Selected List Scheme (SLS) if the patient and purpose of treatment comply with that specified in the list. An example of such is where specific patient criteria are set. (NHS website https://formularymk.mediafury.net/6-Selective-List-Scheme-(SLS)/index.html)

Hospital Trusts followed local formularies[34] and were given financial autonomy to incentivise value-based spending. In 2022, CCGs were replaced by approximately 42 local Integrated Care Systems (ICS) (Department of Health and Social Care, 2022[113]). Moreover, hospitals may be able to purchase medicines under contract at a discount to the 'NHS list price' (Kullman et al., 2010[114]; Panteli et al., 2016[26]).

Once a medicine is granted marketing authorisation and pricing approval, it will most likely be granted automatic full reimbursement by the NHS England. In practice, reimbursement decisions are determined by the National Institute for Health & Care (NICE)[35]. NICE is the independent agency responsible for making recommendations on the clinical and cost-effectiveness of new medicines and treatments to the NHS (in England and Wales). A positive recommendation for a medicine forces reimbursement by the NHS. However, a negative recommendation does not necessarily prevent a product from being reimbursed, but it delays or challenges funding and may lead to further negotiations between the NHS and manufacturers (Kullman et al., 2010[114]; Panteli et al., 2016[26]; PPRI, 2019[115]).

Principles of assessment

Incremental cost-effectiveness ratio

NICE assesses the incremental cost-effectiveness ratio ('ICER') of a medicine against an existing appropriate reference comparator based on the incremental costs and health benefits, measured as quality-adjusted life year ('QALY'). For most medicines, NICE issues a positive recommendation if the ICER is less than £20,000. NICE may apply its discretion to recommend technologies with ICERs between £20,000 and £30,000, where justified on certain grounds, such as the innovative nature of a medicine. Under its standard methodology, NICE rarely awards positive recommendations to medicines whose ICER exceeds £30,000. However, discretion has been used for products considered 'life extending' in end-of-life (e.g., many oncology products) with ICERs of up to £50,000. NICE's cost-per-QALY thresholds have remained fixed for several years (National Institute for Health and Care Excellence, 2023[116]).

Assessment of high-cost medicines differs from NICE's standard methodology. For example, cancer drugs and 'Highly Specialised Technologies' ('HST'), which treat rare and specialist conditions, follow a specific assessment pathway. NICE will usually recommend HSTs that have an ICER of less than £100,000 but it has discretion in certain circumstances to recommend products above that threshold, usually up to ICERs of £300,000 (National Institute for Health and Care Excellence, 2023[117]). Another instance in which NICE deviates from its standard methodology is when making use of the Cancer Drugs Fund ('CDF') under which NICE may

[34] For definitions on formulary management mechanisms, please see Box 1.3 in the Health Working Paper.

[35] Similar bodies assess health technologies in other parts of the United Kingdom, most notably the Scottish Medicines Consortium (SMC) and Scottish Health Technologies Group (SHTG), both part of NHS Healthcare Improvement Scotland, in Scotland. SMC assesses medicines and SHTG assesses non-medicine devices. The All Wales Medicines Strategy Group (AWMSG) in Wales, assesses pharmaceuticals. The remit of AWMSG is complementary to that of NICE, only including the assessment of new pharmaceuticals that are not on the 12-month work programme of NICE. Moreover, NICE guidance can supersede AWMSG recommendations. In contrast, the scope of SMC and SHTG are not complementary to NICE, and each organisation issues separate recommendations on new pharmaceuticals and devices. Northern Ireland does not have an equivalent body; instead, the Northern Ireland Department of Health endorses NICE guidance, unless it is not found to be locally applicable.

recommend NHS reimbursement for several high-cost oncology technologies, including CAR-T and certain immuno-oncology therapies for which clinical uncertainty needs further investigation or budget impact is high. NICE will recommend a product to receive funding from the CDF, at a negotiated price, if it has the potential to satisfy the criteria for routine commissioning, but there is clinical uncertainty that needs further investigation (i.e., through data collection in the NHS or clinical studies). The drug will remain available within the CDF while more evidence becomes available, at which point NICE will subject it to one of its standard technology appraisal processes. The CDF has provided a route to NHS funding for a number of highly innovative, high-cost oncology technologies, including CAR-T and certain immuno-oncology therapies (Castle, Kelly and Gathani, 2021[112]).

Pricing mechanisms

Cost-effectiveness assessment and elements of value-based pricing for specific medicines

Assessment of the cost effectiveness ratio compares the cost of a new medicine per QALY against the fixed threshold of £20,000 per QALY gained, which dictates reimbursement by the NHS, however, there is discretion in the reimbursement decision if thresholds are higher, as discussion in the previous section (Panteli et al., 2016[26]).

Profit caps and price control schemes for branded medicines reimbursed by the NHS

Branded medicines supplied to the NHS are subject to one of two price control schemes: the Voluntary Scheme for Branded Medicines Pricing and Access ('VPAS') (Department of Health and Social Care, 2019[118]); or the so-called 'Statutory Scheme' (Department of Health and Social Care, 2018[119]) defining net sales caps for branded medicines as detailed in Box 1.4 (Panteli et al., 2016[26]; Department of Health and Social Care and ABPI, 2018[120]; Rodwin, 2021[121]).

Free pricing for generics

Generic manufacturers and suppliers have freedom of pricing in the UK, with the Government relying on competition to keep prices low. The Government only intervenes in pricing if there are concerns competition has not been encouraged (Castle, Kelly and Gathani, 2021[112]).

Box 1.4. Price control schemes for branded medicines reimbursed by the UK NHS

The Voluntary Scheme for Branded Medicines Pricing and Access ('VPAS')

VPAS is a voluntary agreement between the Department of Health and Social Care ('DHSC'), NHS England, the Association of the British Pharmaceutical Industry ('ABPI') and manufacturers of branded medicines. The current scheme dates from 1 January 2019 runs for five years with key features such as:

- Cap increases in the amount the NHS spends on branded medicines to 2% growth per annum. To stay within this cap, manufacturers must pay the Department of Health a fixed percentage of their net sales of branded medicines ('Scheme Payments') supplied to the NHS, subject to certain exceptions.

- Percentages are fixed for one calendar year and depend on the difference between the agreed and projected growth in sales. Scheme Payments were set at 26.5% of net sales for 2023.
- Medicines containing new active substances sold to the NHS within 36 months of their marketing authorisation are excluded from paying scheme payments.
- Medicine list prices cannot increase without the prior approval of the Department of Health.

The 'Statutory Scheme' applies to those manufacturers not joining VPAS

Currently, the Statutory Scheme includes the following features:

- Manufacturers must pay a percentage of their net sales of branded products to the NHS on a quarterly basis. The percentage payable was 24.4% for 2023.
- The maximum price of a product that was on the market on 1 December 2013 is capped to the price at that date, subject to any agreed increases.
- Price increases and the price of new presentations require the agreement of the Secretary of State, who must consider factors including: (i) the clinical need for the product; (ii) the cost of therapeutically equivalent or comparable products (including in other European Economic Area countries); (iii) if the product contains a new active substance; and (iv) estimated profits and other financial parameters, etc.
- Unless the VPAS applies, the Statutory Scheme will encompass all biologic medicines supplied to the NHS, including biosimilars.

Source: (Department of Health and Social Care, 2019[118]) (Department of Health and Social Care, 2018[119])

Price negotiations and managed entry agreements

Additionally, NICE assesses the budget impact of cost-effective medicines likely to cost the NHS more than £20 million in any of the first three years of its use. Such cases may be subject to further price negotiations between the manufacturer and the NHS through the use of Patient Access Schemes or Managed Access Agreements (MEAs). Where the clinical data supporting a NICE application are uncertain, NICE may recommend a product subject to a Managed Access Agreement. These agreements enable NHS patients to access treatment, while allowing the company to collect real-world data for a NICE reappraisal. The commercial terms of these agreements are usually confidential and include formal pricing agreements including discounts, rebates, free-stock or outcome-based pricing (National Institute for Health and Care Excellence, 2023[116]; Panteli et al., 2016[26]; Rodwin, 2021[121]).

Pricing in supply chain

There are no regulated or set margins in the UK for wholesalers or pharmacies – these are negotiated by the parties in the supply chain. The Drug Tariff outlines the fees to be paid to pharmacists for dispensing NHS prescriptions. Prescription-only medicines are VAT-free, while over-the-counter (OTC) medicines are taxed at standard rates (Panteli et al., 2016[26])

Patient co-payments

Patients are not charged for pharmaceuticals used in inpatient care. Patients in England are however charged for prescriptions in the community at a fixed flat rate of £9.35 per item as of 2022. Exemptions cover a broad range of people, including individuals under 16 and over 60

years of age, those with low incomes, during pregnancy, and for chronic diseases such as diabetes or epilepsy, so that about 90% of all prescriptions are distributed free of charge (OECD/European Observatory on Health Systems and Policies, 2019[109]; European Observatory on Health Systems and Policies, 2022[110]). Wales, Northern Ireland, and Scotland have abolished the prescription charge.

Procurement and tendering

Types of procurement procedures

Historically, tendering[36] for pharmaceuticals was focused on hospital medicines often at the end of patent life but it is now used much more widely to procure medicines earlier in their patent protected period (Rodwin, 2021[121]). The United Kingdom uses the following procedures to procure medicines:

- Tendering for **generics** and **some on-patented medicines for hospital use**. Separate tenders for each medication, forms of administration and doses. The decision to purchase a branded drug is ordinarily informed by relevant NICE guidelines;
- Procurement can be either at **local level** (e.g. directly with hospital), a **regional framework agreement** (e.g. through collective procurement hubs) or a **national framework agreement** (e.g. through NHS supply chain). The NHS purchases certain medicines nationally, including most medicines for oncology, retroviral treatment of HIV, treatment of Hepatitis C, vaccines, and other high-cost medicines. Group hospital associations and individual hospitals tend to purchase individually when this is not done through national purchasing (Rodwin, 2021[121]);
- Tenders in England are managed across pharmacy purchasing groups. The groups are configured to present sufficiently high usage volumes to attract the best prices for both branded and generic medicines. The configurations are designed to maintain continuity of supply and avoid monopolies.
- Both **single- and multiple-winner awards procedures** are applied for tendering. Single winner awards are used for products that just came off-patent (Vogler, Salcher-Konrad and Habimana, 2022[17]). NHS England seeks 2 or 3 suppliers nationally to serve distinct regions and contracts require sellers to supply as much medication needed for 2 years.
- **Open procedure tenders** are used for medicines with no or limited competition (Vogler, Salcher-Konrad and Habimana, 2022[17]).

The Commercial Medicines Unit (CMU) is responsible for tendering, awarding, and managing frameworks for licensed medicines for the regional purchasing groups. CMU works on behalf of both the DHSC and the NHS. The NHS increasingly uses Framework Agreements (structured agreements in which a consortium of NHS 'buyers' can purchase products for centrally contracted prices).

Tendering award criteria

'Framework Agreements' are regulated under the UK Public Contracts Regulations 2015 (UK Parliament, 2015[122]). Moreover, the Public Contracts Regulations 2015 (UK Parliament, 2015[122])) establishes that contracts must be awarded based on the 'Most Economically

[36] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

Advantageous Tender (MEAT)'. The United Kingdom often focuses on cost to award tender contract, although other criteria also feature, including product training. In the hospital sector, price and quality are applied as the main award criteria (Vogler, Salcher-Konrad and Habimana, 2022[17]).

Prescribing and dispensing

- **Generic/biosimilar substitution.** In general, pharmacy-level generic or biosimilar substitution is prohibited for a brand-name prescription however is lawful if provided for under a 'Serious Shortage Protocol' (which is a statutory mechanism that amends pharmacy dispensing rules if the Department of Health considers there is a serious shortage of one or many medicines in the UK). In any case, clinicians are encouraged to prescribe most products by their International Non-proprietary Name ('INN') to encourage generic prescribing and dispensing. In addition, CCGs and Hospital Trusts also run programmes to switch patients from innovative to generic or biosimilar products (Panteli et al., 2016[26]).
- **Prescribing guidelines:** In principle doctors can prescribe any outpatient medicine, except those that are blacklisted or have their use restricted via the grey list (both lists are very limited in scope). However, prescribing is also constrained by:
    - **NICE guidelines** (and professional guidance) indicating that certain conditions should be managed through the prescribing of certain medicines in a given specialty;
    - **Local formularies** [37] listing those medicines approved by the local commissioning organisations[38].

  In principle, prescribers can decide which hospital medicine to prescribe if this is reimbursed. However, in practice prescription is constrained in several ways namely by:
    - **NICE technology appraisals** and recommendations;
    - **Early access agreements** and the **Cancer Drugs Fund**, which establish the circumstances under which a given high-priced drug can be prescribed; and
    - **Regional drug formularies**, which set out those drugs which will automatically be reimbursed (PPRI, 2019[123]).

[37] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

[38] Where a doctor wishes to prescribe a medicine which is not approved for reimbursement, they can submit an individual funding request (IFR) to the local commissioning body. In doing so, they must set out the case why the medicine is necessary, e.g. on compassionate grounds on the basis that all other approved treatments have failed.

Colombia

Context

Colombia has a Social Security System (*Sistema General de Seguridad Social en Salud* (SGSSS)) with universal healthcare coverage which is regulated by the National Government through the Ministry of Health. Colombian citizens benefit from the healthcare system being affiliated either under the Contributory[39] (private) or Subsidised[40] (public) Regimes. Each affiliate is free to choose a Health Promoting Entity (EPS) freely and voluntarily. In the case of employees, the company should not influence this decision. EPS operate in a similar way to an insurance company and are in charge of ensuring the provision of all health services included in the health care benefits (POS) and also for enrolment, collection of payments and registration with the health system. By 2020, 46.4% of all affiliates belonged to the Contributory Regime, 49.2% were affiliated through the Subsidised Regime, and the remaining affiliates belonged to exceptional regimes (SIC, 2020[124]).

Coverage and pricing

The SGSSS covers an explicit list of health care benefits (POS). The POS includes services, technologies and medicines for health promotion, prevention, diagnosis, treatment and rehabilitation services. In addition, all citizens have access to technologies and social services excluded from POS by a judicial mandate that orders the State to pay directly for the new technology in protection to the individual's constitutional right to health. In this case, prescribers must fill-in an electronic form to get direct approval by the government. New and current technologies and services not included in the POS are then paid for by the government under a reimbursement scheme. Following a legal change in 2015, Colombia is shifting from an explicitly defined benefits package to an implicitly defined package with a negative list (Giedion et al., 2018[125]).

Jurisdiction over marketing authorisation for medicines, biologicals and medical devices is centralised at the Colombian National Food & Drug Surveillance Institute, better known as INVIMA[41]. This is a decentralised agency of the Ministry of Health, created in 1993. The POS only covers the indications approved by the INVIMA for each medicine (Castro, 2017[126]; Prada et al., 2018[127]). The Directorate for the Regulation of Benefits, Costs, Tariffs and Conditions of Insurance (DRCBT) is responsible for making technical proposals to update the benefit plan (POS) taking into account the recommendations from the Institute of Health Technology Assessment (*Instituto de Evaluación Tecnologica en Salud*, IETS). The Advisory Commission on Benefits, Costs, Fees and Operating Conditions of Health Insurance is in charge of deciding on the updates to the POS based on the technical proposal of the DRCBT and ensuring that the proposal respects the fiscal space allocated by the Ministry of Finance and Public Credit.

[39] The Contributory Regime refers to all affiliates paying or contributing to the system through a legal fixed monthly fee (as employees or self-employees). Relatives in the first degree of consanguinity of the contributor may be enrolled as beneficiaries (e.g. wife/husband and children under 18) and in some special cases people economically dependent on the contributor (inc. children, parents, and relatives up to the third degree of consanguinity) may be included.

[40] Subsidised Regime include all citizens who are unemployed and/or belong to levels 1 and 2 of the Sisben (a census/survey classifying the poverty levels of affiliates). The subsidized regime includes the affiliates' families.

[41] More information available at invima.gov.co

The Advisory Commission is composed exclusively of members of the Executive: a delegate of the President of the Republic, the Minister of Health, the Minister of Finance, the Director of the National Planning Department (DNP) and the Director of the IETS. The directors of INVIMA and the National Institute of Health may attend the sessions as guests. The technical secretariat of the commission is provided by the Benefits Regulation Directorate (*Dirección de Regulación de Beneficios*) (Giedion et al., 2018[125]).

The National Government, through the National Commission on Drug and Medical Device Prices (CNPMDM), is responsible for regulating the prices of drugs and active substances, based on external reference pricing. The CNPMDM is a tripartite entity formed by a delegate of the Presidency of the Republic of Colombia, the Minister of Commerce, Industry and Tourism, and the Minister of Health and Social Protection (Escobar et al., 2021[128]).

Additionally, according to Article 132 of Law 1438/2011, the Superintendence of Industry and Commerce (SIC) is the entity in charge of investigating and sanctioning infringements against the price control regulations of medicines and medical devices. The same authority is competent regarding the omission, reluctance to, or inaccuracy in the provision of price information to the Medicines Price Information System – SISMED (Escobar et al., 2021[128]).

Principles of assessment

As of 2022, the CNPMDM had drafted some changes to the methodology established in the Circular 03 of 2013 (CNPMDM, 2013[129]). More specifically, the CNPMDM proposed incorporating cost-effectiveness assessments undertaken by the IETS to inform pricing and reimbursement decisions namely to set maximum prices under the direct control regime (see below) (CNPMDM, 2022[130]). Currently, when updating the medicines and technologies covered by the POS (see Box 1.5), the analyses carried out by the IETS are important inputs for the Advisory Commission on Benefits, Costs, Fees and Operating Conditions of Health Insurance, although their consultation is not mandatory (Giedion et al., 2018[125]).

The IETS was created in 2011, by the MoH as a health technology assessment agency with the aim of producing evidence-based information to support pricing decisions (Bardey, Harker and Zuluaga, 2021[131]). The services provided by IETS include the production of systematic literature reviews, clinical practice guidelines, horizon scanning, budget impact analyses, comparative effectiveness assessments and economic evaluations.

Box 1.5. Brief overview of the POS update process and principles of assessment

2013 POS update

Most of the medicines currently included in the POS can be traced back to the POS update from 2013. For this update, the Ministry of Health's DRBCT identified all authorised technologies in Colombia, both medicines and procedures, regardless of whether they were in the POS or not. At the same time, they determined which pathologies had the greatest impact on the health of Colombians in terms of years of healthy life potentially lost. Based on this information, the technologies to be included were listed by therapeutic group. After a process of exclusion justified for various reasons, it was decided which technologies would be submitted for evaluation according to the criteria of burden of disease, recovery by value and recovery by frequency. The Ministry of Health then contracted the IETS for the development of these technology assessments. The list of technologies that were positively evaluated by the IETS were published on the Ministry of Health's website, and citizens, organised civil society and health professionals could then vote. The voting consisted of rating from one to five each of the following

five aspects of the technology (Ministerio de Salud y Protección Social, 2013[132]; Ministerio de Salud y Protección Social, 2018[133]).

- severity of the disease
- improvement of efficacy compared to treatments already included
- type of clinical benefit, improvement of safety and tolerance
- differential health need (chronicity and palliation)

The prioritised technologies were presented to the Advisory Commission, which subsequently deliberated on the inclusion of 63 technologies in the POS, taking into account the country's health priorities and fiscal availability. Of these technologies, 56 were medicines, 5 procedures and 2 devices (Ministry of Health and Social Protection, 2013[134]). In addition to the inclusion process, it was determined which technologies could be excluded from the POS, listing those that had not been used in the last four years, according to the Individual Health Services Report (RIPS). In this way, the aim was to identify those technologies that were obsolete or had been replaced. This list was submitted for comments to specialists from medical societies and academia.

2015 POS update

For medicines, this update started with the nomination of technologies, submitted by different stakeholders, to define candidates for evaluation by the Advisory Commission on Benefits, Costs, Fees and Operating Conditions of Health Insurance. The following criteria were defined ex ante for the nomination of technologies (Ministerio de Salud y Protección Social, 2013[132]; Ministerio de Salud y Protección Social, 2018[133]):

- respond to the main health needs of the population;
- show clinical effectiveness;
- a technology not already included in the POS; and,
- focus primarily on technologies for first line of care or treatment of daily use.

Nominated medicines that complied with the established requirements were grouped according to generic name and indication. It was then determined which groups required an HTA, which only required budget impact analysis, and which should not be considered because they did not have a sanitary registration or had previously been assessed with a negative recommendation. The recommended technologies were available on the MOH's website and citizens were invited to comment before the Advisory Committee's deliberation.

The 2015 POS update process was an important step from the point of view of the evolution of prioritisation mechanisms in Colombia. It meant that a methodology was consolidated to define inclusions in a broad manner, and established that for a given therapeutic grouping, everything available on the market could be included, as long as its effectiveness had been demonstrated and its cost was equal to or lower than its POS equivalent. Currently, the POS is updated every 2 years and this process follows the same methodology used in 2015.

Under the 2015 Statutory Law (Colombian Congress, 2015[135]), the explicit POS is expected to disappear and the benefit plan will change from a plan explicitly defined as a set of services and technologies to one defined by exclusions. The new POS will inform patients about the services and medicines to which they will not be entitled, unlike the previous one that only determined the treatments to which they could have access without restrictions.

Source: (Giedion et al., 2018[125]).

Pricing mechanisms

There are two price control modalities for regulating medicine prices in Colombia, namely:

- **Free pricing or controlled freedom regime** under which wholesalers can freely determine their price with the only obligation to inform the Ministry of Health of their commercial operations in accordance with the regulations in force. This includes all drugs marketed nationwide, with the exception of those that enter the direct control regime by order of the CNPMDM.
- **Maximum sales prices and external reference pricing** through a direct control regime set by the CNPMDM at one or more levels of the supply chain and focus mainly on high-priced medicines whose sales price in the Colombian market are higher than the international reference price calculated by the CNPMDM. Prices are set using external reference pricing of 17 OECD countries used as reference countries[42] (Escobar et al., 2021[128]; CNPMDM, 2019[136]). Both POS and No-POS medicines can be regulated, and the regulation can apply to both institutional and commercial prices (see *Pricing in supply chain*). There are three cases in which a medicine can be moved to the direct control regime:
    1) When the medicine is of public health interest, or because it has a high impact on the sustainability of the General Social Security Health System;
    2) When the price is raised in an unjustified manner; or
    3) When the national reference price is considerably higher than the international reference price.

Pricing in supply chain

There are two main distribution and marketing channels for medicines in Colombia:

- The institutional channel which corresponds to the supply of medicines for SGSSS affiliates. The Health Promotion Entities (EPS) acquire products from manufacturers through SGSSS and these products are distributed through the dispensaries contracted by the Health Service Provider Institutions (IPS) (Escobar et al., 2021[128]).
- The commercial channel which corresponds to the supply of medicines for other purchasers. In this channel, medicines are distributed through pharmacies and retail stores which offer medicines at prices that include transportation costs and a markup on the manufacturers' sales price that remunerates the distribution activity carried out by these stores (Escobar et al., 2021[128]).

[42] Based on criteria of trade integration, geographic proximity to Colombia, similarity in the degree of general economic intervention, membership in the OECD and availability of information, the reference countries will be Argentina, Brazil, Chile, Ecuador, Mexico, Panama, Peru, Uruguay, Spain, the United States, the United Kingdom, Australia, Canada, France, Norway, Germany and Portugal. The PRI is calculated by taking information from all these countries, when available. If it is not available, only those countries on the list for which information is available are used as reference countries. This methodology is based on the provisions of Circular 03 of 2013. of the CNPMDM and it has four steps namely: (i) definition of the relevant market; (ii) measurement of its concentration level; (iii) calculation of reference price; and (iv) administrative fixation, if applicable (CNPMDM, 2013[129]).

Price regulation under the direct control regime diverges between the institutional channel and the commercial channel:

- In the institutional channel, the maximum sales price can be raised only by the same amount as the logistics costs for these medicines; which corresponds to up to 7% for drugs with a maximum sales price less than or equal to $1,000,000 Colombian Pesos (COP); or up to 3.5% for drugs with a maximum sales price greater than COP $1,000,000.
- For commercial prices, prices are regulated through imposing a mark-up between the ex-factory price and the distributor price of no larger than 7%, approximately. For these regulated medicines, manufacturers, wholesalers and/or importers cannot set a higher price than the regulated one (Escobar et al., 2021[128]; CNPMDM, 2019[136]).
- The readjustment of the maximum sale prices set by the CNPMDM is equivalent to the proportion of the variation of the Consumer Price Index (CPI) of the previous year.

Patient co-payments

Agreement 260 of the National Council of Social Security in Health (Consejo Nacional de Seguridad Social en Salud, 2004[137]) establishes that co-payments must be applied to all the services contained in the benefits plan except for promotion and prevention services, maternal and infant care, disease management of communicable diseases, catastrophic or high-cost diseases or initial emergency care.

Procurement and tendering

Types of procurement procedures

Colombia uses the following procedures to procure medicines:

- Use of **centralised procurement**. In July 2017, the Ministry of Health incorporated the centralised procurement mechanism of PAHO for the treatment of Hepatitis C. Two treatments were included in the negotiation. One was the medicine commercially known as Harvoni® (combination of the molecules sofosbuvir and ledispavir), produced by Gilead Pharmaceuticals. The other treatment was the combination of Daklinza® (daclatasvir) and Sovaldi® (sofosbuvir), produced by Bristol-Myers Squibb and Gilead, respectively. The mechanism consisted of a wholesale purchase made by the Government, through PAHO, based on demand estimates for the entire country. In this sense, it was no longer the EPS that negotiated limited quantities and alone with the manufacturers (Pérez et al., 2019[138]);
- Colombia uses **tendering**[43] and **price negotiations** for the procurement of medicines (PPRI, 2015[139]). Tendering is designed at therapeutic class level to encourage competition between therapeutic alternatives (OECD survey on On-patent Competition, 2022).

Tendering award criteria

- The award criteria for tendering depend on the product or on the market situation of the medicine (PPRI, 2015[139]).

[43] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

Prescribing and dispensing

- **Generic substitution**: Physicians must prescribe medicines using the International Non-proprietary Name (INN, i.e. the generic name). On the other hand the EPS must guarantee its affiliates timely access to the medicines included in the benefits plan, regardless of their commercial name (whether its generic or brand name) (CNPMDM, 2019[136]).
- Use of **formulary management mechanisms** [44] (OECD survey on On-patent Competition, 2022).
- **Prescribing guidelines** in which medicines are ranked according to cost or cost-effectiveness. Prescribers have financial incentives to favour off-patent or multi-source medicines (OECD survey on On-patent Competition, 2022).

[44] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

Israel

Context

Israel provides universal health coverage to its citizens and permanent residents through four Health Maintenance Organisations (HMOs) (Ministry of Health, 2023[140]). Under the National Health Insurance Law, individuals are obliged to register in one of the four HMOs that cover a basic basket of services (Healthcare Basket) (Kol Z'Chut, 2021[141]). HMOs may also offer their members additional health care plans, known as 'supplementary insurance', which most citizens purchase to cover services not included in the Healthcare Basket (Tikkanen et al., 2020[142]). Only 63% percent of Israel's health spending is publicly financed – one of the lowest proportions among OECD countries - and most citizens purchase supplementary insurance to cover services not insured by the basic basket (Tikkanen et al., 2020[142]).

Coverage and pricing

The National Health Insurance Law foresees the 'updating, expanding and changing of the Healthcare Basket' through the following mechanism: the Ministry of Health (MoH) launches an annual call to different stakeholders in the health sector (e.g., hospital directors, HMOs) to submit applications for the inclusion of new medicines and technologies in the Basket. Patients and patient associations as well as manufacturers are also encouraged to submit applications. The *Division for Assessment of Technology in the Health Basket* assesses (with the support of other entities in the MoH, such as the *Medical Technology Policy Division* that carries out the health technology assessments) those medicines and technologies, which are then transferred for deliberation to the Public Committee for the Expansion of the Basket ('Basket Committee'[45]) (Ministry of Health, 2022[143]; Ministry of Health, 2023[144]; Ministry of Health, 2023[145]).

The Law establishes that expansion of the Basket requires budgetary considerations and joint approval by the MoH, the Minister of Finance, and the Health Council (Ministry of Health, 2022[143]) (Tikkanen et al., 2020[142]). The annual budget is allocated to HMOs based on a formula that considers factors like the age, gender, and place of residence of the individuals being insured (Brammli-Greenberg et al., 2015[146]). Aside the medicines included in the Basket, HMOs are legally required to cover all medicines and technologies listed in their additional insurance, which may be free-of-charge for the patient or available via a regulated co-payment (Brammli-Greenberg et al., 2015[146]; PPRI, 2019[147]; Kol Zchut, 2022[148]). HMOs are not required to cover treatments not included in the list (PPRI, 2019[147]; Kol Zchut, 2022[148])[46]. Hospitals operate outside of the *Healthcare Basket* – they 'must provide the health treatment and the necessary drugs whether included in the basket or not' (PPRI, 2019[147]).

[45] The 'Basket Committee' is composed of physicians, HMOs, MoH, Ministry of Finance and public representatives.

[46] Patients can apply for the reimbursement of medicines not included in the Basket or their HMO's additional health care plans by appealing to their HMO's exceptions committee (PPRI, 2019[147]).The purpose of the committee is to consider requests for assistance beyond that which is required by law, and it has the authority to consider and decide regarding the coverage of medicines not included in the basket (Kol Z'Chut, 2021[176]).

Principles of assessment

The *Division for Assessment of Technology in the Basket* conducts a multitude of analyses to inform the decision of the Basket Committee, namely:

- Clinical assessment of the safety and effectiveness of the new medicine;
- Assessment of the epidemiology, needs assessment and expected patients' volumes;
- A review of the existing experience in the use of the new medicine;
- Budgetary impact of the inclusion in the Basket of the medicine;
- Economic evaluation of the additional costs and benefits of the new medicine;
- Eventual evaluation of the social and legal impact of inclusion of the new medicine in the Basket and reference opinions of senior experts from various fields (Ministry of Health, 2022[143]).

The Basket Committee ranks applications in order of priority (from high importance to low importance) using the following criteria (non-exhaustive) (Ministry of Health, 2022[143]):

- The effectiveness of medicine (or technology) in the treatment of the disease;
- Evidence of the impact of the medicine or technology on mortality as well as the evidence on prolonging life and improving of expected life quality of life;
- The existence of a therapeutic alternative and its effectiveness;
- The economic cost (at the individual and national levels) of the inclusion of the medicine in the Basket;
- The expected incremental health benefit delivered by the inclusion of the medicine in the Basket in the short and long term.

Decisions on coverage and reimbursement are conditional on HTA and made on the level of the active substance (molecule) and medical indication (PPRI, 2019[147]).

Pricing mechanisms

Maximum prices, external reference pricing and managed entry agreements

- **Maximum prices**. The Ministry of Health sets and publicly discloses **maximum prices** for outpatient and inpatient medicines, whether reimbursed or not (State of Israel Ministry of Health, 2018[149]). Prices of medicines used in the hospital sector are additionally subject to a **price capping system**, which mandates discounts that range from 18.5% to 80% of the regulated maximum prices set by the MOH. However, HMOs are also free to negotiate special arrangements with hospitals for medicines that do not necessarily follow this price regulation. This is often the case for oncology medicines (PPRI, 2017[150]; PPRI, 2019[147]).
- **External Reference Pricing** is used to establish the maximum price for novel and biosimilar medicines. The maximum price is calculated at the average of the three lowest wholesale prices across seven reference countries[47]. To encourage supply of medicines with multiple indications, in 2019 the government adopted a new method that includes the highest-price product alternative. In the case of generic drugs or novel medicines with product alternatives in generic form, prices are adjusted to the price level

[47] The reference countries are Belgium, England, France, Germany, Hungary, Netherlands, and Spain.

on a fixed day of the previous year. Price increases can be considered if they do not exceed 5%, because of currency fluctuations above/under 3% against the EURO, and these increases require the approval of the MoH (PPRI, 2019[115]).

- **Managed entry agreements.** The actual purchase prices of medicines included in the Basket (and in the additional insurance plans) are negotiated confidentially between the HMOs and the manufacturers. Around 30% of new therapies enter the Basket after negotiations (Brammli-Greenberg et al., 2015[146]; PPRI, 2019[115]).

Pricing in supply chain

In Israel, a **regressive mark-up** is applied to pharmacy retail prices, ranging from 37% for medicines that cost up to 38 NIS per package to a 10% margin for medicines that cost more than 1750 NIS per package. This margin was previously 15% and dropped to 10% following a reform in 2019 (PPRI, 2019[115]). A standard VAT of 17% is applied to all medicines (PPRI, 2019[115]).

Patient co-payments

All medicines listed in the Healthcare Basket are fully covered. Patients pay a percentage co-payment of up to 10% for generic medicines and 15% for patented medicines used in the outpatient sector (PPRI, 2019[115]). Holocaust survivors and individuals with severe diseases are exempt, while other groups (people with a certain condition) benefit from discounts on coinsurance or monthly coinsurance caps. Medicines administered in the inpatient sector are free-of-charge (Tikkanen et al., 2020[142]).

Procurement and tendering

Types of procurement procedures:

- In Israel, health care providers fall into three categories: (i) government-owned providers, (ii) providers owned and integrated with HMOs and (iii) privately-owned providers. Both government- and HMO-owned providers undertake **joint procurement** procedures, while private providers may procure and contract together with HMOs. Government-owned medical facilities procure medicines through the MoH's group purchasing organisation (SAREL) (Brammli-Greenberg et al., 2015[146]; PPRI, 2017[150]; SAREL, 2018[151]).
- **Single-winner tender**[48]. Suppliers usually compete for the right to be the sole supplier (*'Sole Supply Status'*), although HMOs have manoeuvres to negotiate different types of agreements (Sax, 2014[152]; PPRI, 2017[150])
- Tendering is designed at **therapeutic class** level to encourage price competition between treatment alternatives (OECD survey on On-patent Competition, 2022).

[48] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

Tendering award criteria (information not available)

Prescribing and dispensing

- **Generic substitution**. Pharmacists may substitute brand name with cheaper generic versions, but only if the substitute has the same active substance, form, and medical effect as the initially prescribed medication (Siegel-Itzkovich, 1999[153]).
- **Formularies and prescribing guidelines**[49]. HMOs determine their own formularies within the framework of the basket. HMOs use a prescription software to this end. In many cases, HMOs recommend the use of generics or lower-cost branded products. Hospitals have their own preferred medicines list (PPRI, 2012[154]).

[49] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

New Zealand

Context

New Zealand's universal health coverage is financed mostly through general taxes and reimburses a variety of services and products for those eligible. Although co-payment is required in some cases, and varies across settings (e.g. public hospital, GP, dentist), New Zealand has low out-of-pocket spending compared to the OECD average (New Zealand – 2.1%, OECD average – 3.1%). While the government subsidises out-of-pocket payment for higher-risk groups and low-income earners, one third of the population purchases private health insurance to cover co-payments and non-reimbursed services or products (Tikkanen et al., 2020[155]; New Zealand Government, 2022[156]; OECD, 2021[1]). In 2022, New Zealand consolidated the 20 former District Health Boards who were charged with planning, purchasing, and providing health services at the local level, into a single national agency, Health New Zealand (New Zealand Government, 2022[157]).

Coverage and pricing

The Pharmaceutical Management Agency (Pharmac) is New Zealand's coverage and reimbursement institution that decides which medicines are part of the Pharmaceutical Schedule – the positive reimbursement list for medicines dispensed in the community and hospitals. The medicines on the Pharmaceutical Schedule are funded by the Combined Pharmaceutical Budget (CPB), which gets approved annually by the Minister of Health (Pharmac, 2022[158]). Prior to the reform in 2022, Pharmac only managed but did not actually hold the CPB – it was top sliced of the individual budgets of the twenty District Health Boards (DHBs) (Tikkanen et al., 2020[155]). Hospitals were funded for their purchases directly by the DHBs while community pharmacies got reimbursed through a centralised procedure by the MoH (Pharmac, 2021[159]). At the present, the CPB is directly allocated to Pharmac by the New Zealand government. Prior to 2022, Pharmac had a risk fund which could be used to manage over or under spending of the CPB (Pharmac, 2022[158]).

Suppliers can only apply to be included on the Pharmaceutical Schedule if their medicine has been approved by the Medicines and Medical Devices Authority (MEDSAFE), with the exception of cancer medicines and medicines for rare disorders whose application can be submitted even before marketing approval is granted (Pharmac, 2022[160]). The price of reimbursed medicines (i.e. listed on the Pharmaceutical Schedule) is negotiated between Pharmac and manufacturers confidentially (Foster and Preval, 2011[161]). Apart from vaccines and some contraceptives, Pharmac does not directly purchase from suppliers (Pharmac, 2021[159]). The Pharmaceutical Schedule indicates which products have prescribing restrictions attached to them – either requiring prescribing by (or on the recommendation of) a particular specialist type and/or only using it in specified clinical circumstances. (Pharmac, 2022[162]).

Principles of assessment

Pharmac decides which medicines to include in the Pharmaceutical Schedule in a process called 'prioritisation': Medicines are assessed according to several criteria (*Factors for Consideration*) to assess their impact on the individual patient, their family, community and society, and the health system, across four dimensions: (i) need, (ii) health benefits, (iii) cost and savings, and (iv) suitability. For (ii) and (iii) Pharmac performs a cost-utility analysis. However, the decision whether to include a medicine ultimately depends on the amount of

funding available, which is fixed by the CPB (Pharmac, 2022[163]). Specifically, for on-patent medicines, Pharmac considers the length of the patent and the time until a generic pharmaceutical is likely to become available, on top of the cost of the medicine in comparison to product alternatives from the same or different therapeutic class (Pharmac, 2015[164]).

Pricing mechanisms

Reimbursed medicines: managed entry agreements and confidential rebates, expenditure caps, internal reference pricing and multi-product tendering

Pharmac uses a variety of mechanisms to ensure spending remains within the budget such as:

- **Managed entry agreements**: Pharmac directly negotiates and agrees funding terms with pharmaceutical suppliers for inclusion on the Pharmaceutical Schedule, which covers both hospital and community markets (Pharmac, 2021[165]; Pharmac, 2022[166]).
- **Rebates**: Pharmac and the supplier may agree for a portion of expenditure to be rebated back to Pharmac by the supplier, which may be based on a maximum level of expenditure per year, a volume-based discount or a flat unit-based discount (Pharmac, 2021[165]; Pharmac, 2022[166]).
- **Multi-product tendering** and **price renegotiations**: Pharmac achieves most of its budget savings through open competition for near-exclusive supply of off-patent products. Savings are also sometimes negotiated with suppliers in return for protection from tendering, widening access criteria or funding new treatments. (Pharmac, 2022[166]).
- **External reference pricing** is used informally to inform pricing decisions. Medicine prices in Australia, Canada and the United Kingdom are taken into account as supportive information during price negotiations (Holtorf et al., 2019[167]).

Non-reimbursed medicines: free pricing

In the case of non-reimbursed medicines, manufacturers can set freely their own prices. Patients bear the cost of the wholesale mark-up and a pharmacy mark-up (Pharmac, 2020[168]).

Pricing in supply chain

For reimbursed products used in outpatient care, the Government (through Health New Zealand, a separate agency to Pharmac) covers the pharmacy's handling and services fees, as well as the pharmacy's mark-up and pack fees. The handling fee of NZD 1.01 is paid for the dispensing of a medicine, while the service fee is calculated using a multiplier (depending on type of service[50]) that is applied to the base handling fee. The pharmacy mark-up is regulated as a percentage[51] of the reimbursement amount (subsidy), while the pack fee is volume-based (0.25 NZD per pack).There are no pharmacy fees or regulation on mark-ups on cancer treatments or hospital pharmaceuticals (provided by the hospital pharmacy) (Pharmac, 2020[168]; Health New Zealand, 2018[169]).

[50] For example, multiplier of 7.95 for ECP (extemporaneously compounded preparations) services, 5.30 for Special Foods services (Health New Zealand, 2018[169]).

[51] For medicines with a reimbursement amount lower than 150 NZD, the mark-up percentage applied to the reimbursement amount is 3%; for medicines with a higher reimbursement amount, 4% respectively (Health New Zealand, 2018[169]).

It is worth noting that historically partial funding resulted during the transition from one brand to another as Pharmac would fund both brands at the lowest rate for a period of time. At present, Pharmac does not follow this transition procedure – medicines are either fully-funded or not reimbursed.

Patient co-payments

In New Zealand, the co-payment for fully reimbursed medicines is 5 NZD. Prescriptions from a public hospital, a midwife or a Family Planning Clinic also fall under this category, even if the medicine is not fully funded by PHARMAC. The subsidy is only granted in the case that the prescriber has an agreement with Health New Zealand. Co-payments are capped at 20 prescriptions per family per year – in this case, the family will receive a prescription subsidy card and will not have to pay any prescription charges until the 1st February of the following year. Additionally, the New Zealand government subsidises out-of-pocket payments for higher-risk groups through the High Use Health Cards, and for low-income earners through the Community Services Card (CSCs) (Health New Zealand, 2022[170]).

Procurement and tendering

Types of procurement procedures

New Zealand uses the following procurement procedures:

- **Procurement at the national level (managed through Pharmac) with facility-based purchasing** for both the **inpatient** and **outpatient** sectors. Community pharmacies purchase medicines from wholesalers or directly from pharmaceutical companies, and are then reimbursed based on the amount of the subsidy set by Pharmac. Hospitals are under the obligation to only use medicines listed in Section H of the Pharmaceutical Schedule (Pharmac, 2020[171]). Most hospital items are reimbursed by Pharmac on a bulk-basis, while more expensive items, such as cancer treatments, are claimed.
- **'Principal Supply Status':** Until recently, Pharmac used a procurement model centred on sole-supply agreements where the manufacturers were invited to submit a bid to supply the whole market for a given medication. If successful, manufacturers of outpatient medicines could be awarded what is referred to as the '*Sole Supply Status'*. Hospital medicines could be awarded the '*Hospital Supply Status'*, under which hospitals were obliged to purchase from the contracted manufacturer (Pharmac, 2020[171]). In 2020, Pharmac replaced the use of *'Sole Supply Status'* and *'Hospital Supply Status'* with '*Principal Supply Status*' (PSS). The supplier who is awarded the '*Principal Supply Status*' is guaranteed up to 95% of the total funded market for about 3 years (Pharmac, 2022[172]). Hospitals still remain under the obligation to purchase medicines with PSS. This procurement procedure gives Pharmac more flexibility to fund small volumes of products from alternative brands (Pharmac, 2022[172]).
- Pharmac applies **tendering by active substance** to encourage price competition between treatment alternatives (OECD survey on On-patent Competition, 2022). For certain lung cancer medicines, tendering[52] by indication has been applied.
- **Requests for Proposals and Alternative Commercial Proposals**: In some cases, tendering might not be appropriate (e.g. on-patent medicines), and Pharmac invites suppliers to submit proposals for specific indications. This scheme is called Request for

[52] For definitions on tendering, please see Box 1.2. in the Health Working Paper.

Proposals (RFPs) and allows suppliers to put in pricing for 1st line and 2nd line access (preferential listing). Similarly, Pharmac can also invite suppliers to submit Alternative Commercial Proposals (ACPs) for the products they would like to include in the annual multi-product tender. Pharmac can then decide between the ACP and launching an official tender for those products (Pharmac, 2022[166]).

Tendering award criteria

PHARMAC's Tender Evaluation Committee evaluates bids using the *Factors for Consideration* framework (see section on Principles of Assessment) (Pharmac, 2022[173]). The *Factors for Consideration* framework stresses the impact of the fixed budget on funding decisions, meaning that price is likely to be an important criterion for evaluation (Pharmac, 2022[163]).

Prescribing and dispensing

The Pharmaceutical Schedule regulates which prescribing and dispensing activity will be funded, although it does not offer prescribing advice. The following prescribing and dispensing initiatives are in place:

- **Prescribing by International Non-Proprietary Name** (INN) is recommended (Pharmac, 2016[174]).
- **Dispensing variation:** Pharmacists may switch the prescribed product that has no subsidy or has a manufacturer's price higher than the subsidy to the fully subsidised alternative listed in the Schedule and claim the subsidy (substitution). Pharmacists may also alter the presentation of a subsidised pharmaceutical to another presentation without altering the dose, the frequency and/or the total daily dose dispensed (Pharmac, 2022[162]). Following a molecule switch, pharmacists are required to advise patients on the first changed dispensing. The fees are covered by the government (Pharmac, 2020[168]).
- **Hospital formularies**[53]. Hospitals can only prescribe a treatment to a patient with the exact clinical circumstances indicated in the Schedule (Hospital Indication Restrictions) (Pharmac, 2022[175]).

[53] For definitions on formulary management mechanisms, please see Box 1.3. in the Health Working Paper.

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