

## **Summaries of National Drug Coverage and Pharmaceutical Pricing Policies in 10 Countries:**

Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland and the U.K.

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# Australia

	2014 or closest year
<b>Population (millions)</b>	23.9
<b>GDP per capita</b>	US\$46,681
<b>Total health expenditure per capita</b>	US\$4,207
<b>Health expenditure as percentage of GDP</b>	9.0%
<b>Dominant source of health system financing (%)</b>	Public (68%)
<b>Total pharmaceutical expenditure per capita</b>	US\$626
<b>Dominant source of pharmaceutical financing (%)</b>	Public (49%)

Source: OECD Health Statistics 2016

## Health care system overview

Australia has a universal, largely tax-financed public insurance system for health care services. Australia's federal health system provides public subsidies for medical services and diagnostic tests through Medicare, and medicines through the Pharmaceutical Benefit Scheme (PBS). The federal government contributes to the cost of public hospitals and subsidizes ambulatory medical care and medicines. State governments administer public hospitals and a variety of other services. Private health insurance is commonly purchased by individuals to supplement Medicare coverage.

The PBS is a federal program that subsidizes the costs of prescription medicines dispensed in community pharmacies and private hospitals. The PBS also covers some medicines dispensed to public hospital outpatients and from public hospital emergency departments. Coverage of other medicines for inpatients in public hospitals is the responsibility of state and territory health departments.

## Drug regulation and licensing

The Australian government is responsible for drug regulation and licensing. A national agency called the Therapeutic Goods Administration licenses medical technologies and is responsible for ensuring their safety, quality, and efficacy.

Medicines may be reviewed for coverage decision-making while being assessed for market authorization by the Therapeutic Goods Administration.

## Drug coverage decision-making

The Pharmaceutical Benefits Advisory Committee (PBAC) is a statutory independent expert committee that makes recommendations to the Minister of Health regarding which medicines should be covered under the PBS and any additional conditions that should apply (e.g., restrictions to particular patient sub-groups). Final coverage decisions must be made by the Minister or Cabinet, depending on budget impact; however, a medicine cannot be added to the PBS without a positive recommendation from the PBAC.

As part of its assessment, the PBAC evaluates a medicine's cost-effectiveness and has the authority to withhold recommendation for positive listing if it believes the sponsor's proposed reimbursement price is too high. The PBAC uses an incremental cost-effectiveness ratio defined by the added cost per quality-adjusted life year (QALY) provided by a medicine. While the PBAC does not use a strict cost-effectiveness

threshold to guide recommendations, coverage of medicines with a cost per QALY ratio above US\$33,000 (AU\$45,000) are rare and limited to situations of significant unmet clinical need.

Conditional on a positive PBAC recommendation, the Minister of Health decides whether a medicine will be listed on one of two PBS formularies. In general, the first formulary (F1) is for single-source medicines that do not have therapeutic substitutes on the PBS. The second formulary (F2) is for multi-source medicines, or single-source medicines that are therapeutically interchangeable with multi-source medicines on the PBS. Medicines move to the second formulary as soon as a bioequivalent or biosimilar competitor is listed on the PBS.

## Reimbursement levels

For prescriptions filled in the community setting, Australians pay a co-payment of up to US\$28.59 (AU\$38.30) if the medicine is covered by the PBS. If the total cost of the prescription is lower than the fixed co-payment, the patient pays the lesser amount – the full cost of the prescription. Specific population subgroups (e.g., veterans, pensioners, and low-income workers) are eligible for concession cards that reduce co-payments under the PBS to US\$4.63 (AU\$6.20) per prescription.

For general beneficiaries of the PBS, co-payments for the balance of the year are reduced to the level of concession card holders when total annual household co-payments have reached US\$1,111 (AU\$1,475). For concession card holders, co-payments for the balance of the year are eliminated when total annual co-payments have reached US\$280 (AU\$372).

On the recommendation of the PBAC, the Minister of Health can define groups of therapeutically similar medicines that will be reimbursement at the price of the cheapest alternative. If a particular medicine from such a group is priced above the lowest cost alternative, patients are responsible for paying the price difference in addition to the mandatory PBS co-payment.

## Price controls

Pharmaceutical companies can set their prices in the non-PBS market without regulatory intervention. The prices of medicines reimbursed under the PBS are controlled through a combination of negotiation and statutory price disclosures and reductions.

For new medicines not subject to multi-source competition (F1 medicines not part of therapeutically interchangeable groups), prices are constrained by the cost-effectiveness considerations of formulary listing. As part of this process, risk-sharing agreements involving rebates paid directly to the government by the company are increasingly used to ensure cost-effectiveness of medicines at list prices and as used in clinical practice. After five years of coverage without multi-source competition, PBS listed medicines are subject to a mandatory 5% price reduction.

Medicines with bioequivalent or biosimilar competitors (F2 medicines) are subject to statutory price disclosure to the Department of Health. Manufacturers of these medicines must divulge the actual selling price of the medicines, including all rebates and incentives paid to wholesalers and pharmacies. If the difference between the PBS price and the disclosed selling price of a medicine is greater than 10%, the PBS price is reduced to the disclosed price.

In rare cases, special patient contribution arrangements can be made at the Minister's discretion whereby patients must pay a premium on top of the PBS reimbursement price, in addition to the applicable PBS co-payment.

## Distribution markups

The Australian government makes direct payments to pharmacists that dispense PBS-reimbursable medicines to the community. The remuneration of pharmacists and wholesalers is determined through negotiations with the Pharmacy Guild of Australia and wholesalers every five years. Under the current agreement, pharmacies are compensated through a fixed dispensation fee scheme that separates pharmacy remuneration from the price of medicines. Wholesalers continue to be reimbursed through a unit distribution fee plus a proportional markup, albeit one where the percentage markup decreases with the medicine's price.

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# Canada

	2014 or closest year
<b>Population (millions)</b>	35.9
<b>GDP per capita</b>	US\$45,025
<b>Total health expenditure per capita</b>	US\$4,496
<b>Health expenditure as percentage of GDP</b>	10.0%
<b>Dominant source of health system financing (%)</b>	Public (69%)
<b>Total pharmaceutical expenditure per capita</b>	US\$772
<b>Dominant source of pharmaceutical financing (%)</b>	Mixed*

\* Public payment, private insurance, and out-of-pocket charges are approximately equal (30–34%)

Source: OECD Health Statistics 2016

## Health care system overview

Canada has a universal public insurance system for specific health care services. All permanent residents have comprehensive public insurance for medically necessary physician services and hospital care, including medicines used in hospitals. The insurance is administered by 10 provincial and three territorial governments, with the federal government maintaining national standards through conditional cash transfers to provinces and territories.

There are no national standards for coverage of medicines used outside of hospitals in Canada. Consequently, eligibility for and terms of public drug coverage differ across the country. Most provincial drug plans offer targeted benefits for people on social assistance, people over age 65, and people with specific medical conditions (e.g., cancer and HIV). Voluntary private insurance is accessible to approximately two-thirds of Canadian workers, predominantly moderate- to high-income earners working for large employers.

Approximately 10% of Canadians have no public or private drug coverage. An additional 10% of Canadians are considered under-insured for prescription medicines, owing to high deductibles and/or co-insurance levels on coverage available to them.

## Drug regulation and licensing

The federal government is responsible for drug regulation and licensing in Canada. A federal department called Health Canada evaluates pre-market data on drug safety, efficacy, and quality. Health Canada also coordinates the federal government's post-approval safety surveillance and risk communications concerning licensed medicines.

Manufacturers must receive market authorization from Health Canada before submitting a medicine for public coverage decision-making.

## Drug coverage decision-making

Federal, provincial, and territorial drug plans in Canada operate independently. All public drug plans use positive formularies to delineate which medicines they cover for respective beneficiaries. To reduce duplication of efforts and harmonize the evidence base for decision-making, the Canadian Agency for

Drugs and Technologies in Health (CADTH) coordinates centralized assessments of new medicines for all public drug plans in Canada except those run by the province of Quebec. Quebec has independent but comparable processes of its own.

External, expert advisory committees develop CADTH's coverage recommendations for participating public drug plans based on critical analyses of clinical and economic data, along with input from patient representatives. CADTH's final recommendations concerning public coverage are only advisory; each participating public drug plan makes its own final decision as to whether to list a drug on its respective formulary. The timing and nature of final decisions can vary across public drug plans in Canada.

Private insurance plans operating in Canada may or may not operate with a formulary. Some adopt the public formulary that applies in the respective province or territory.

## Reimbursement levels

All inpatient medicines dispensed in hospitals are fully reimbursed under Canada's universal Medicare system. Terms of reimbursement for prescriptions in the community setting depend on the individual public or private drug plan that the patient may be covered by.

Almost all public and private drug plans in Canada use either fixed co-payments or percentage co-insurance on the cost of medicines for eligible beneficiaries. Public drug plans in Canada often apply generic reference pricing policies, under which they reimburse only the cost of generic versions of multi-source products, leaving patients the option to pay extra if they prefer the brand.

Therapeutic reference pricing has been applied, to a limited extent, in only one province: British Columbia. The British Columbia drug benefit plan will reimburse up to the reference price established by one or more low-cost medicines in each of eight therapeutic classes. Patients who prefer other medicines within the referenced therapeutic categories pay any price differential.

## Price controls

A combination of statutory regulations and voluntary price negotiations is used to control prices of medicines in Canada.

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial agency that enforces statutory limits on manufacturers' prices of patented medicines sold to hospitals, pharmacies, and wholesalers. The PMPRB uses a combination of internal and external reference pricing as a key determinant of its maximum allowable prices. The maximum price of a newly patented medicine is set at the median price of that product across seven official comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States) or at the equivalent maximum allowable price of patented comparators already on the Canadian market. Maximum allowable prices increase over time to account for general inflation; however, patented drug prices are never allowed to be the highest across the official comparator countries.

The PMPRB has authority to collect rebates from manufacturers who sell patented medicines at an average price above the maximum allowable level. Rebates are paid to the Government of Canada and are set in accordance with estimated surplus revenues stemming from the excessive pricing.

Patented medicines are typically priced below the maximum allowable by the PMPRB. This is in part a result of price negotiation by public drug plans in Canada. Private drug plans in Canada do little or no price negotiation of their own.

As cost-effectiveness is a key determinant of coverage decisions, manufacturers must price at levels that give their products a level of comparative cost-effectiveness. Increasingly, public drug plans are using negotiated price discounts (through what Canadians refer to as product listing agreements) to obtain prices that represent value for money for the government program. Product listing agreements involve confidential price discounts or rebates, paid directly to participating drug plans, in return for including the listed drug on the formulary.

There are no national regulations on the price of generic medicines in Canada. However, most public drug plans in Canada cap the maximum prices they will pay for generics at a percentage of the branded originator. These price caps vary by province and territory and range from 20% to 65% of the branded originator. Provinces have jointly set lower limits (at 18% of brand-name prices) on a small number of high-volume generic medicines.

Private drug plans do not generally negotiate drug prices with either brand-name or generic manufacturers. Some private drug plans use the local provincial government's allowable limits for generics, while some agree to pay higher prices than government plans will allow.

## Distribution markups

There is no formal regulation of drug distribution markups in Canada. Public drug plans use different and often complex methods of paying wholesalers and pharmacies. Some provincial drug plans set pre-defined limits on retail prices plus a fixed or cap fee for dispensing services. Others pay the pharmacy's acquisition price for the medicine plus fixed markups and dispensation fees.

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# France

	2014 or closest year
<b>Population (millions)</b>	64.4
<b>GDP per capita</b>	US\$39,301
<b>Total health expenditure per capita</b>	US\$4,367
<b>Health expenditure as percentage of GDP</b>	11.1%
<b>Dominant source of health system financing (%)</b>	Social Insurance (75%)
<b>Total pharmaceutical expenditure per capita</b>	US\$656
<b>Dominant source of pharmaceutical financing (%)</b>	Social Insurance (70%)

Source: OECD Health Statistics 2016

## Health care system overview

France has a social health insurance system that covers a range of health care services. Assurance Maladie is the statutory health insurance system, made up of three main health insurance funds, that subsidizes health services for the French population. It is influenced by state-led governance and increasingly relies on general tax-based financing.

Assurance Maladie subsidizes prescription medicines for residents in both inpatient and outpatient settings. Voluntary health insurance plays an important role in providing complementary coverage for pharmaceutical co-payments.

## Drug regulation and licensing

The government of France, operating through the National Agency for the Safety of Medicines and Health Products, is responsible for drug regulation and licensing. The National Agency for the Safety of Medicines and Health Products is responsible for ensuring the safety, efficacy, and quality of health products marketed in the country. Market authorization can also occur through the European Medicines Agency's centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

Medicines must receive market authorization prior to being evaluated for coverage provision by health insurers.

## Drug coverage decision-making

France's social health insurance system has two main formularies (positive lists): one for outpatient prescription medicines and one for inpatient medicines. The Ministry of Health is the ultimate authority regarding reimbursement eligibility and must sign off on all recommendations made by the various assessment agencies.

The reimbursement decision-making process starts with a dossier submission to the Transparency Committee, an expert advisory committee within the French National Authority for Health. The Transparency Committee appraises a medicine's therapeutic benefit in absolute and comparative terms as part of a two-stage process.

First, a medicine's absolute therapeutic benefit is assessed based on available scientific evidence concerning the severity of the targeted illness, efficacy, side effects, contribution to a therapeutic strategy, and public health interest. This value is assessed on a five-point rating scale (called the SMR), ranging from "major medical benefit" to "insufficient medical benefit," and is used to determine a medicine's reimbursement status.

Second, a medicine's added therapeutic benefit is assessed based on scientific evidence concerning comparative efficacy and tolerance in relation to existing treatment alternatives. This value is assessed on a five-point rating scale (called the ASMR), ranging from "major added benefit" to "no added benefit." It is used to determine acceptable pricing.

The Transparency Committee's recommendation is forwarded to the National Union of Health Insurance Funds, an organization of representatives from the three main health insurance schemes. The National Union of Health Insurance Funds decides on reimbursement status using the assessment of a medicine's absolute therapeutic benefit (SMR score). Reimbursement status is reassessed every five years.

Generic versions of originator products already listed for coverage can receive reimbursement status without assessment by the Transparency Committee, because it is presumed that they have the same absolute benefit as originators.

A subset of expensive hospital-only medicines are subject to price regulation and are excluded from standard hospital remuneration based on diagnosis-related groups. They are reimbursed separately by social health insurance to ensure equitable access to costly medicines without distorting the standard hospital payment system.

## Reimbursement levels

Medicines used in hospital are fully reimbursed through the hospital payment system, though patients may face co-insurance for the hospital care itself. Patients pay a combination of a fixed co-payment of US\$0.56 (€0.50) per prescription plus variable co-insurance rates for reimbursable prescription medicines dispensed in the community. Individuals with severe chronic conditions are exempt from these charges for medicines related to their illness. Private health insurance is often purchased to cover co-insurance rates.

The National Union of Health Insurance Funds sets co-insurance levels for reimbursed outpatient medicines based primarily on levels of absolute therapeutic benefit (SMR score). Co-insurance rates are generally as follows: (often through commentary private insurance) patients pay 35% of the cost of medicines providing major clinical benefit in treatment of serious diseases; 70% of the cost of medicines offering moderate clinical benefits in the treatment of serious disease; 70% of the cost of medicines providing either major or minor benefit in treatment of non-serious disease; and 85% of the cost of medicines with low clinical benefit. Patients pay no co-insurance on reimbursable medicines for treatment of severe chronic diseases (e.g., cancer).

France uses internal reference pricing within a limited number of generic groups. The reference price is set at the mean price of all generic medicines in the therapeutic cluster. Patients are responsible for paying the price difference if they elect to receive a medicine that is priced above the reference subsidy level.

## Price controls

Drug prices in France are controlled through a combination of negotiation, regulation, and statutory rebates. Medicines not listed for reimbursement under the social insurance system are priced freely.

Manufacturers of listed medicines negotiate prices with the Economic Committee for Health Products, an inter-ministerial government body with insurance sector representation. Negotiations are governed by a five-year framework agreement with the French Pharmaceutical Companies Association and take into consideration a medicine's comparative therapeutic benefit, sales volumes, foreign prices, and local comparator prices.

For medicines offering minor therapeutic benefits (ASMR score IV), prices above comparators are generally permitted only if the medicine is recommended for a restricted patient group. For medicines offering moderate to major added therapeutic benefit (ASMR scores I, II, and III), external reference pricing is applied: ex-factory prices must not be higher than the prices in Germany, the United Kingdom, Italy, and Spain.

For the majority of generic medicines, entry prices are set at 60% below the originator's on-patent price, while the originator's price is set at 20% below its on-patent price. Eighteen months after generic entry, the generic and originator prices are further discounted by 7% and 12.5%, respectively.

Prices of most inpatient medicines are directly negotiated by the hospital and the manufacturer or set through a hospital tendering processes. However, the price of medicines paid for through social insurance outside the standard hospital remuneration system is negotiated in the same way as outpatient medicines.

Price contracts with the Economic Committee for Health Products can involve price-volume agreements to further control drug expenditures. Contracts for new medicines with limited clinical evidence may also involve performance-based reimbursement schemes, under which the reimbursement price is conditional on health outcomes observed through post-marketing studies.

Finally, pharmaceutical firms are also subject to global price rebates. Each year, the government sets fixed annual growth rates for revenues from reimbursable medicines. Limits are set for the entire market and for therapeutic subclasses, and companies are collectively asked to pay rebates when revenues grow faster than allowable limits.

## Distribution markups

Distributor remuneration is regulated throughout the supply chain. Wholesale remuneration is based on proportional markups that decrease with drug costs. Pharmacy remuneration is based on proportional markups that decrease with drug costs plus fixed payments for pharmacists. To encourage uptake of generics, pharmacy remuneration for dispensing a generic is based on the price of the originator medicine.

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# Germany

	2014 or closest year
<b>Population (millions)</b>	80.7
<b>GDP per capita</b>	US\$46,394
<b>Total health expenditure per capita</b>	US\$5,119
<b>Health expenditure as percentage of GDP</b>	11.0%
<b>Dominant source of health system financing (%)</b>	Social Insurance (78%)
<b>Total pharmaceutical expenditure per capita</b>	US\$741
<b>Dominant source of pharmaceutical financing (%)</b>	Social Insurance (79%)

Source: OECD Health Statistics 2016

## Health care system overview

Germany's has a social health insurance scheme with substitutive private health insurance. Approximately 85% of Germany's population is covered by statutory health insurance through one of the 132 competing sickness funds; 11% of the population receives similar coverage through substitutive private health insurance. Self-regulated structures of sickness funds and health professionals operate the financing and delivery of benefits covered by Germany's social health insurance scheme.

Medicines used in hospital and in ambulatory settings are included in Germany's social health insurance scheme. Patients generally face co-payments for prescriptions filled in the community.

## Drug regulation and licensing

The German government is responsible for drug regulation and market authorization. The Federal Institute for Pharmaceuticals and Medical Devices regulates all medicines except blood, blood products, sera, and vaccines, which are regulated by the Paul Ehrlich Institute. Market authorization can also occur through the European Medicines Agency's centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

When a product enters the German market, the manufacturer is required to submit an application for benefit assessment.

## Drug coverage decision-making

Generally, authorized prescription medicines are reimbursed by sickness funds at market launch; however, a negative list defines the basket of medicines that are excluded from coverage, such as over-the-counter drugs, treatments for minor ailments, lifestyle medicines, and drugs deemed ineffective.

Appraisal of new medicines – primarily for subsequent price negotiations – is done by the Federal Joint Committee, which is composed of representatives from associations of physicians, dentists, hospitals, and sickness funds. In conducting assessments, the Federal Joint Committee usually requests that the Institute for Quality and Efficiency in Health Care (IQWiG) independently assesses the scientific evidence submitted by the manufacturer and conduct economic modeling.

Based on the IQWiG's report and its own consultations with relevant stakeholders, the Federal Joint Committee will categorize a medicine's relative benefit on a 6-point scale, ranging from "extensive benefit" over the chosen comparator to "less benefit" than the comparator. A single product can receive different ratings across different indications and sub-populations.

## Reimbursement levels

On prescriptions for reimbursed medicines, individuals make co-payments of US\$5.50–\$11.00 (€5–€10) per prescription. Additionally, Germany uses an extensive system of internal reference pricing to set reimbursement limits for groups of medicines that are deemed therapeutically comparable. Even a newly patented medicine will be included in the reference price system if the Federal Joint Committee deems that it provides no added benefit over comparators.

While the Federal Joint Committee determines which medicines are clustered together within a reference class, the Federal Association of Sickness Funds is responsible for setting the reference price within the class.

Patients are also responsible for any difference between the reference-based reimbursement level and a particular drug's higher market price. However, patients may be exempt from co-payments if they use a drug that is priced 30% below the reimbursement level for its reference cluster.

Medicines that show added clinical benefit over existing medicines or do not fit within existing therapeutic clusters go through a negotiation process with the National Association of Statutory Health Insurance Funds to determine a reimbursement level. Since manufacturers are initially free to set the market price, the negotiation process determines a price that will take effect one year after market launch. If a reimbursement level cannot be agreed upon, the decision is passed to an arbitration body that will set the reimbursement level based on the Federal Joint Committee's appraisal and the prices of comparator medicines.

## Price controls

Germany uses various forms of statutory rebates to indirectly control drug prices and spending by sickness funds. There are four ways in which rebates are used.

First, pharmacies are legally obligated to provide a flat US\$1.94 (€1.77) rebate per prescription sold to sickness funds.

Second, manufacturers are required to pay a percentage rebate to sickness funds for medicines outside the reference price scheme. These rebates are 7% for patented medicines and 6% to 16% for off-patent medicines.

Third, individual sickness funds can negotiate discount contracts with manufacturers for the exclusive use of a particular medicine. Pharmacies are compelled to dispense the contracted medicine if the physician has not explicitly stated that a particular brand must be dispensed.

Finally, Germany can impose an implicit price freeze through variable rebates that match any increases in the market price of medicines. Such a price freeze on reimbursed medicines has been in place since August 2009 and is expected to be lifted at the end 2022.

The system of reference-based reimbursement levels also has the effect of controlling drug prices in Germany. Medicines are generally priced within the reimbursement limit because, when selecting a medicine above a reference-based reimbursement level, physicians are legally obligated to inform patients of the added cost – a cost that the patients must pay.

Negotiations between the Federal Association of Sickness Funds and manufacturers of medicines not subject to the reference pricing system can also result in lower prices. These confidential price negotiations are based on the following criteria: cost of the therapy in comparison to its comparator; the Federal Joint Committee's appraisal; the number of patients in each targeted population; specific requirements to ensure appropriate use; and cost of therapy of other comparable medicines. In addition, the manufacturer must provide foreign ex-factory prices used in EU member states for the purpose of external reference pricing to facilitate fair price negotiations. The negotiated price does not take effect until after the first year of market entry; until then, the manufacturer is free to set the list price.

## Distribution markups

The German distribution chain is regulated and supply chain markups are fixed across the country. Wholesalers receive a markup on ex-factory prices of 3.15% plus a fixed fee of US\$0.77 (€0.70) per package or medicine distributed. Pharmacies receive a 3% markup on the wholesale price plus a US\$9.33 (€8.51) charge per item.

Germany encourages parallel imports of cheaper medicines from EU countries. Pharmacists are required to substitute parallel imports that are at least 15% cheaper or US\$16.48 (€15) less than their German-sourced version. However, this provision is no longer a substantive measure because of the now broad use of rebate contracts negotiated between individual sickness funds and manufacturers of multi-source medicines.

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# The Netherlands

	2014 or closest year
<b>Population (millions)</b>	16.9
<b>GDP per capita</b>	US\$48,253
<b>Total health expenditure per capita</b>	US\$5,277
<b>Health expenditure as percentage of GDP</b>	10.9%
<b>Dominant source of health system financing (%)</b>	Social Insurance (76%)
<b>Total pharmaceutical expenditure per capita</b>	US\$401
<b>Dominant source of pharmaceutical financing (%)</b>	Social Insurance (80%)

Source: OECD Health Statistics 2016

## Health care system overview

The Netherlands has a compulsory health insurance scheme that offers a package of health services and products to all residents. There is managed competition between the country's private health insurers and private health care providers. Residents pay a flat insurance premium to their chosen insurance fund and employers provide an additional income-related contribution.

A majority of outpatient prescription medicines are included in the bundle of insured products. The Ministry of Health, Welfare and Sport, advised by the National Health Care Institute (ZIN), determines reimbursement status and tariff rates for outpatient medicines. Access to inpatient medicines is determined by individual hospitals, which are reimbursed by insurance funds through a diagnosis-treatment tariff mechanism.

## Drug regulation and licensing

The government of the Netherlands is responsible for drug regulation and licensing. A national agency called the Medicines Evaluation Board assesses and monitors the safety, quality, and efficacy of all licensed medicines. Market authorization can also occur through the European Medicines Agency's centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

Medicines must receive market authorization prior to being evaluated for coverage provision by health insurers.

## Drug coverage decision-making

Medicines that have received market authorization can be submitted to the Ministry of Health for inclusion on the Drug Reimbursement System (GVS). The GVS is a national formulary outlining outpatient prescription medicines that are covered by insurance companies.

The ZIN is the government agency responsible for conducting the health technology assessments of medicines and recommending reimbursement status to the Ministry of Health. A committee of external experts (the Scientific Advisory Committee) provides the ZIN with advice and recommendations on issues of cost and effectiveness, and another external committee (the Insured Package Advisory Committee) provides advice on issues pertaining to social impact.



Access to inpatient medicines is decided by individual hospitals. Hospitals are generally reimbursed for care based on fixed fees that reflect the average cost of care, from diagnosis to discharge, including medications, for given diagnosis-treatment combinations. Under special conditions, the ZIN may advise that a medicine not be included within the normal diagnosis-related tariff system for hospital reimbursement.

## Reimbursement levels

The GVS has three distinct categories of medicines.

The first category (Annex 1A) includes off-patent originators and generics deemed therapeutically interchangeable within clusters of products that have equivalent indications, methods of administration, and clinical outcomes. These medicines are reimbursed through a reference pricing system.

The maximum coverage level for medicines within the therapeutically interchangeable clusters of the GVS (Annex 1A) is set at the mean pharmacy purchase price of all products in the cluster. For medicines that are priced above the reference, patients must pay the difference between the reference price and the medicine's retail price.

Individual health insurers are legally required to provide reimbursement for at least one medicine from within each therapeutically interchangeable cluster. Insurers may choose a preferred product within a cluster – a policy known as the “preference policy.” In such cases, patients are liable for the entire cost of non-preferred medicines unless the prescriber has indicated that a medical need requires a particular non-preferred product.

The second category of medicines (Annex 1B) includes originator products approved for full coverage on the GVS that do not fall into an existing therapeutic cluster. Such medicines ultimately move into therapeutic clusters – and are therefore reimbursed according to reference pricing schemes described above – when an interchangeable product enters the market.

The third category of medicines under the GVS (Annex 2) comprises medicines that are eligible for reimbursement only under special circumstances. This category of coverage is often used as a method of financial risk-sharing for high-cost medicines or coverage with evidence development for novel medicines.

## Price controls

Dutch drug prices are broadly controlled by the Medicinal Products Prices Act, the preference policy, and voluntary contractual agreements between insurers and suppliers.

Under the Medicinal Products Prices Act, the Ministry of Health uses external reference pricing to set the maximum allowable wholesale price of a product in the Netherlands at the average list price of the cheapest available comparable product (brand or generic) in four reference countries: Belgium, Germany, France, and the United Kingdom. External reference pricing is applied only when a product is qualified for reimbursement and when a comparable product is marketed in at least half of the reference countries.

The Medicinal Products Prices Act applies to both outpatient and inpatient medicines, but not over-the-counter drugs. Maximum prices are revised every six months to reflect fluctuations in the pricing of medicines in reference countries and the Euro-Pound exchange rate.

Prices are also limited, in part, by the national formulary listing process. For non-interchangeable medicines on the GVS (Annex 1B medicines), companies are free to propose a reimbursement price, recognizing that the proposed price may influence reimbursement eligibility. If the price is reasonable and within the bounds of the ZIN's economic eligibility criteria, the Ministry of Health will accept the manufacturer's recommended reimbursement level.

Health insurer preference policies play an important role in controlling prices of multi-source medicines. The purpose of the preference policy is to stimulate price competition among manufacturers of interchangeable medicines. Insurers attempt to select the medicines with the lowest pharmacy retail prices in their reference cluster.

## Distribution markups

Pharmacy remuneration is through a fixed dispensation fee that is separate from a medicine's price. This fee is set annually by the Dutch Healthcare Authority, an independent regulator of the health market, and is based on standard pharmacy practice costs and pharmacist income levels.

Health insurers may pay pharmacies greater fees in return for a higher standard of service. Further, health insurers may also receive discounts on pharmacy retail prices through voluntary agreements such as price-volume contracts, lowest price guarantees, and historical low price precedents. Wholesale mark-ups are not regulated.

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# New Zealand

	2014 or closest year
<b>Population (millions)</b>	4.5
<b>GDP per capita</b>	US\$37,712
<b>Total health expenditure per capita</b>	US\$3,537
<b>Health expenditure as percentage of GDP</b>	9.4%
<b>Dominant source of health system financing (%)</b>	Public (72%)
<b>Total pharmaceutical expenditure per capita</b>	US\$292
<b>Dominant source of pharmaceutical financing (%)</b>	Public (63%)

Source: OECD Health Statistics 2016

## Health care system overview

New Zealand has a universal, largely tax-financed public health care system. Funding and provision of health care is administered by regional organizations known as District Health Boards. There are no user charges for inpatient or outpatient services in publicly owned hospitals, and limited user charges for primary health care services.

All New Zealand residents receive full coverage for medicines dispensed at public hospitals. They also receive public subsidy for outpatient medicines, vaccines, and cancer drug treatments identified on a national formulary, the Pharmaceutical Schedule.

## Drug regulation and licensing

The New Zealand government is responsible for drug regulation and licensing. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) ensures safety, quality, and efficacy of medicines through market authorization and post-marketing surveillance of licensed medicines.

Generally, a medicine will be approved by Medsafe prior to a reimbursement application being made, but this is not a prerequisite.

## Drug coverage decision-making

The Pharmaceutical Management Agency (PHARMAC) is a Crown agent that manages health technology assessment and reimbursement for medicines on behalf of all District Health Boards and district hospitals. PHARMAC maintains the Pharmaceutical Schedule, a national formulary that outlines the outpatient medicines that are publicly subsidized by District Health Boards, the inpatient medicines that can be used in district hospitals, and criteria and eligibility for the provision of subsidies.

When assessing funding applications, PHARMAC has 15 Factors for Consideration for inpatient and outpatient medicines, including health needs, benefits and risks, and savings to patients, families, and the wider health system. A committee of senior medical practitioners (the Pharmacology and Therapeutics Advisory Committee) provides clinical advice to PHARMAC, with particular focus on critically appraising the clinical aspects of a medicine and the quality of evidence presented in the funding application. The committee will ultimately recommend that a medicine either be publicly funded with high, medium, or low priority, or not be funded at all.

PHARMAC conducts a thorough economic evaluation of all applications for funding of medicines. The primary economic evaluation method is cost-utility analysis, using the cost per quality-adjusted life year as a measure of cost-effectiveness. PHARMAC does not use a strict cost-effectiveness threshold, as the measure is meant only to aid in funding decisions. A medicine's prospective budget impact will influence its economic evaluation alongside other funding options available at the time and the total projected budget available.

## Reimbursement levels

All medicines dispensed by district hospital pharmacies are covered as part of inpatient care.

For medicines included on the Pharmaceutical Schedule and dispensed in the community, patients are required to pay a per-item co-payment of US\$3.50 (NZ\$5). Co-payments are not required for children under the age of 13 and can be reduced through the use of prescription subsidy cards, which are provided for eligible people whose families require more than 20 prescription items per year.

PHARMAC employs a form of reference pricing to set subsidy levels within therapeutic sub-groups of medicines that it deems produce "the same or similar effect in treating the same or similar conditions." PHARMAC may reimburse all medicines in such sub-groups at the level of the lowest-cost medicine. In cases where the price of a product is only partially subsidized by the reference-based subsidy, the patient must pay the price differential and the standard co-payment.

PHARMAC may arrange to provide patients with access to medicines not listed on the Pharmaceutical Schedule in special circumstances. Otherwise, patients must pay the full price of medicines not included on the Pharmaceutical Schedule.

## Price controls

Manufacturers are free to set drug prices without statutory restrictions in New Zealand. However, PHARMAC uses a number of voluntary price negotiations and supply contracts to control prices and expenditures.

For single-source products, PHARMAC negotiates pricing and supply agreements with suppliers. The contracts, which are generally confidential, may use fixed rebates, price-volume agreements, spending caps, or product bundling agreements to lower the net price and/or budget impact of a drug. These agreements leave the list price of the drug unchanged in all cases.

For multi-source medicines, PHARMAC employs tendering and sole supply contracts to procure secure supplies of competitively priced generic medicines.

## Distribution markups

Community pharmacies currently receive a 4%–5% margin on the subsidy level of a medicine, as well as a service fee. There is a proposal to change this to a system that includes a 2.5% margin and a small fixed dispensation fee (US\$.020 / NZ\$0.27) per package. Wholesaler markups are largely unregulated.

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# Norway

	2014 or closest year
<b>Population (millions)</b>	5.2
<b>GDP per capita</b>	US\$65,702
<b>Total health expenditure per capita</b>	US\$6,081
<b>Health expenditure as percentage of GDP</b>	9.3%
<b>Dominant source of health system financing (%)</b>	Public (74%)
<b>Total pharmaceutical expenditure per capita</b>	US\$457
<b>Dominant source of pharmaceutical financing (%)</b>	Public (57%)

Source: OECD Health Statistics 2016

## Health care system overview

Norway has an almost entirely national public health care system. The state-owned National Insurance Scheme provides health insurance coverage for all Norwegians. While health policy and funding is governed at the national level, provision of health care services is devolved to Norway's four Regional Health Authorities and many municipalities.

Medicines used within hospitals and approved medicines used in ambulatory settings are covered under Norway's publicly funded health care system. Patients face co-payments for various health services, including relatively high co-payments for covered outpatient medicines.

## Drug regulation and licensing

The Norwegian government, through the Norwegian Medicines Agency (NoMA), is responsible for drug regulation and licensing. NoMA is responsible for almost all aspects of the national pharmaceutical system, including market authorization, pricing, reimbursement eligibility, pharmacovigilance, clinical trial supervision, and supply chain administration.

Norway is part of the European Economic Area and therefore abides by EU regulations regarding European market authorization of medicines. NoMA can provide market authorization. Market authorization can also occur through the European Medicines Agency's centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

## Drug coverage decision-making

The National Insurance Scheme uses a national formulary (positive list) to define the outpatient prescription-only medicines that will be covered under the scheme. NoMA is responsible for the assessment and, generally, the approval of outpatient medicines for reimbursement under the National Insurance Scheme.

To be accepted for reimbursement, a medicine must meet four criteria. First, the medicine must treat a serious disease or risk factors leading to a serious disease. Second, the target condition must demand long-term therapy, as reimbursement is limited to long-term medicines treating serious chronic conditions requiring more than three months of treatment per year. The third criterion is that the medicine must

have proven clinical effectiveness in the target population. Finally, the medicine must be cost-effective in comparison to alternative therapies and meet budget restrictions.

A full pharmacoeconomic evaluation is conducted on all medicines seeking reimbursement except generic variants of medicines already reimbursed and new formulations with no change in health and economic outcomes compared with the alternative therapy. NoMA increasingly uses the cost per quality-adjusted life year (QALY) as a metric to gauge cost-effectiveness. A societal perspective is taken when calculating a medicine's cost per QALY; there is no strict cost-effectiveness threshold for determining reimbursement eligibility.

NoMA does not have the authority to grant reimbursement for new medicines or indications that are expected to have an initial five-year budget impact greater than US\$3 million (kr25 million) – equivalent to roughly US\$188 million for a population the size of the United States. In these cases, NoMA conducts a full health technology assessment with the aid of the National Advisory Committee for Drug Reimbursement. It then advises the Ministry of Health on reimbursement eligibility. If the Ministry supports approval, the reimbursement decision is put to a vote as a Budget Bill in Parliament. To date, Parliament has passed every drug reimbursement decision put forth by the Ministry of Health.

There is no national reimbursement formulary for inpatient medicines; however, hospital medicines committees in each of the Regional Health Authorities have advisory lists to guide hospitals in their procurement process. To aid in the hospital decision-making process, NoMA provides cost-effectiveness assessments, considers whether priority criteria are fulfilled, and calculates the expected budget impact of a new medicine.

## Reimbursement levels

There are four reimbursement categories: Schedule 2, 3a, 3b, and 4. For reimbursed medicines in the community setting, patients face co-insurance with annual out-of-pocket limits. Patients pay 38% of the cost of medicines preapproved for general reimbursement under the National Insurance Scheme (Schedule 2 of the national formulary). They also pay 38% co-insurance for medicines requiring case-by-case approval for reimbursement (schedule Schedule 3a and 3b drugs). Vaccines for communicable diseases and medicines to treat severe contagious diseases such as HIV/AIDS or tuberculosis (Schedule 4 drugs) are fully reimbursed.

Although there is co-insurance for most prescription medicines covered in the outpatient setting, these costs are included in an annual deductible system that limits patient total out-of-pocket costs for health services and products covered under the National Insurance Scheme. In 2016, individual annual expenses for covered health services were capped at US\$260 (kr2185), beyond which all costs are fully covered.

Inpatient medicines used in public hospitals are covered through individual hospital budgets. Thus, patients are not expected to pay any user fees for medicines administered in the hospital.

The funding of several groups of outpatient medicines has recently shifted from the National Insurance Scheme to individual hospitals. This has occurred with TNF-inhibitors (2006), multiple sclerosis medications (2008), and some cancer medicines (2014 and 2016). Even if these medicines are used and dispensed in the community, they are funded out of hospital budgets.

## Price controls

Prices in Norway are controlled through a combination of statutory price limits, supply contracts, and tendering. All market-authorized medicines must be submitted to NoMA for price-setting before they can enter the market.

NoMA sets the maximum pharmacy purchase price for outpatient prescription-only medicines using external reference pricing: the maximum price is set at the mean of the lowest three prices observed for comparator products (usually the same product) marketed in Austria, Belgium, Denmark, Finland, Germany, Ireland, Netherlands, Sweden, and the United Kingdom. NoMA updates the maximum prices for the top-selling 230 active ingredients annually to reflect price changes in reference countries. Maximum prices of other marketed medicines are also periodically updated.

Prices of multi-source, off-patent medicines are further limited using a stepped pricing model that applies when generic competition enters the market. The first price cut reduces the originator price by 35% and occurs when the first generic enters the market. The second cut occurs six months after initial generic entry and ranges from 59% to 81% of the originator's pre-competition price. The final cut is applicable a year after initial generic competition and ranges from 69% to 90% of the originator's pre-competition price. The size of the price cut depends on the size of the medicine's market; medicines with a smaller market receive lower price cuts.

Prices of inpatient medicines are determined through tendering or negotiations by the Health Agency Procurement Service and the drug supplier. The Health Agency Procurement Service is a joint procurement organization for the Regional Health Authorities and is responsible for attaining adequate drug supply for Norwegian public hospitals at cost-effective prices. As a monopsony purchaser, the Health Agency Procurement Service tenders supply contracts that lead to purchase prices below the maximum statutory price set by NoMA.

## Distribution markups

Wholesale markups are not regulated; however, as explained above, NoMA sets the maximum for pharmacy purchase prices.

NoMA also sets pharmacy markups, and thus effectively regulates maximum retail prices. Pharmacies are remunerated using a proportional markup that declines (from 7% to 2.5%) as the cost of the medicine increases. Pharmacies also receive a fixed dispensation fee of US\$2.98–\$4.76 (kr25–kr40).

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# Sweden

	2014 or closest year
<b>Population (millions)</b>	9.8
<b>GDP per capita</b>	US\$45,298
<b>Total health expenditure per capita</b>	US\$5,065
<b>Health expenditure as percentage of GDP</b>	11.2%
<b>Dominant source of health system financing (%)</b>	Public (83%)
<b>Total pharmaceutical expenditure per capita</b>	US\$489
<b>Dominant source of pharmaceutical financing (%)</b>	Public (52%)

Source: OECD Health Statistics 2016

## Health care system overview

Sweden has a universal, largely tax-financed public health care system. Sweden’s national government dictates national health policy, while its regional county councils are responsible for public provision of health services. County councils and municipalities provide 90% of health care to the public.

Sweden’s national Pharmaceutical Benefits Scheme (PBS) offers residents universal drug coverage. The PBS subsidizes a positive list of prescription medicines dispensed in the community.

## Drug regulation and licensing

The Medical Products Agency is the government institution responsible for drug regulation and licensing. In addition, the Medical Products Agency is charged with disseminating health product information, authorizing clinical trials, and regulating the use of medical products. Market authorization can also occur through the European Medicines Agency’s centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

A medicine must be have received market authorization prior to submitting an application for inclusion on the PBS.

## Drug coverage decision-making

The Dental and Pharmaceutical Benefits Agency (TLV) is an independent government agency that determines PBS coverage. The TLV makes reimbursement decisions on all new products and dosage forms. Most often, the TLV makes decisions about inclusion at the product level, but sometimes will limit coverage to particular indications.

The TLV makes decisions based on three principles: equal human value, needs solidarity, and cost-effectiveness. It can seek help in making a reimbursement decision from the Swedish Council on Technology Assessment in Health Care, which conducts scientific reviews of health products. Its final decisions are made by a Pharmaceutical Benefits Board composed of a Chair and six experts: a clinical pharmacologist, a health economist, a patient advocacy representative, and three health care planners from county councils. These members are appointed for their health care expertise and capacity to make drug coverage decisions.

Although the TLV often uses cost per quality-adjusted life year (QALY) as an incremental cost-effectiveness measure, it does not apply a strict cost-effectiveness threshold. Coverage decisions also take other factors into account, such as disease severity, social need, and availability of treatment options. Consequently, though cost-effectiveness ratios of reimbursed medicines have averaged approximately US\$40,000 per QALY, some medicines have been approved for PBS coverage at much higher cost per QALY ratios.

## Reimbursement levels

Medicines dispensed in inpatient settings are fully covered as part of standard hospital care. Medicines used in inpatient care are chosen and financed by city councils and municipalities; reimbursement is directly negotiated with the manufacturers.

Residents must pay the full price of outpatient medicines not included on the PBS. County councils pay the full cost of PBS medicines for children under age 18. Other residents pay the full cost of the first US\$128 (kr1100) of PBS prescriptions in a year and then decreasing proportions of additional PBS drug costs in the year. The maximum total annual out-of-pocket cost for medicines covered under the PBS is \$295 (kr2200) per patient.

County councils must accept the TLV's reimbursement coverage recommendations; however, the degree and rate of implementation of recommendations varies for some newly included PBS medicines because of differences in local factors, such as budgets and interpretations of TLV recommendations. Medicines that are not recommended by the TLV may receive public coverage from individual councils if they meet certain criteria (e.g., meet an unmet local need).

## Price controls

The prices of new medicines in Sweden are largely controlled through the TLV's cost-effectiveness assessments and reimbursement decisions. There are no price controls on non-PBS prescription medicines and over-the-counter drugs that are dispensed in the community.

Manufacturers are free to set prices on new medicines seeking PBS inclusion. The TLV does not negotiate on proposed prices; rather, it simply rejects PBS inclusion of medicines that are not deemed cost-effective at proposed prices. Manufacturers may resubmit new applications at lower prices in the hope that original decisions will be overturned.

If a manufacturer of a PBS-approved medicine wishes to raise its price, the TLV requires it to first de-list the medicine and then resubmit for complete reassessment at the higher price. Prices can be raised without full resubmission only when there is a genuine risk that the product may be discontinued in the Swedish market, thus threatening patients' health.

The TLV sets the maximum price of generic medicines based on the on-patent price of the originator product. The maximum price for all interchangeable versions of the medicine is set at 35% of the on-patent price of the originator product. This policy is applied when generic versions of a medicine have been on the market for four months and are priced below 70% of the originator's on-patent price.

This generic pricing policy is supported by mandatory generic substitution. Pharmacies are required to automatically substitute the cheaper interchangeable alternative, unless explicitly prohibited by the

prescribing physician. Patients who refuse the lower-cost version of a medicine must pay the difference in price.

Prices of inpatient hospital medicines are directly negotiated by manufacturers and county councils, which are responsible for hospital financing. Tendering is almost universally used to attain discounted prices on medicines used in the hospital setting. Patient access schemes are also commonly used at the county council level to improve accessibility to high-cost medicines that would not be cost-effective at posted prices.

## Distribution markups

The TLV sets both the wholesale list price and the pharmacy margin. Thus, the TLV in effect also sets pharmacy retail prices for PBS medicines. Pharmacies charge a regressive markup plus a flat dispensation fee. The pharmacy markup also depends on whether there is generic competition for the medicine. Parallel imports are allowed on medicines that can be purchased by pharmacies at prices lower than the price set by the TLV.

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# Switzerland

	2014 or closest year
<b>Population (millions)</b>	8.2
<b>GDP per capita</b>	US\$59,536
<b>Total health expenditure per capita</b>	US\$6,787
<b>Health expenditure as percentage of GDP</b>	11.4%
<b>Dominant source of health system financing (%)</b>	Social Insurance (47%)
<b>Total pharmaceutical expenditure per capita</b>	US\$730
<b>Dominant source of pharmaceutical financing (%)</b>	Social Insurance (65%)

Source: OECD Health Statistics 2016

## Health care system overview

Switzerland has a decentralized health care system that is financed through compulsory insurance. Responsibilities for health care funding and provision in Switzerland is shared by its federal government and its 26 cantons (relatively small but highly autonomous regional member states). All Swiss residents must purchase a basic package of health insurance that is defined by the federal government. They may purchase the basic package from one of approximately 60 private health insurance companies.

Prescription medicines are included in the basic insurance package that is mandatory for all Swiss residents. The federal government is responsible for deciding which medicines will be part of the basic insurance package and for ensuring that the prices of those medicines are reasonable.

## Drug regulation and licensing

The Swiss government, through Swissmedic (the Swiss Agency of Therapeutic Products), is responsible for drug regulation and licensing. Market authorizations are valid for five years in Switzerland, after which Swissmedic must reassess the medicine for continued market access.

A medicine must be approved by Swissmedic to be considered for inclusion under the mandatory basic health insurance package.

## Drug coverage decision-making

Switzerland's Federal Office of Public Health (FOPH) is responsible for determining which medicines are included in the mandatory basic insurance package. The main outpatient formulary for the mandatory insurance package is the List of Pharmaceutical Specialties.

The FOPH makes reimbursement decisions with the aid of an independent recommendation of the Federal Drug Commission, an external committee of health care stakeholders. Both the FOPH and the Federal Drug Commission assess medicines based on three criteria: effectiveness, appropriateness, and cost-effectiveness.

Switzerland does not have a formal health technology assessment body; therefore, the FOPH generally relies on information provided by developers and assessments conducted by other agencies, including

foreign health technology assessment bodies. Effectiveness and appropriateness, for example, are appraised, in part, using information submitted to Swissmedic as part of the market authorization process.

Cost-effectiveness is determined using a combination of internal and external price comparisons. Internally, the daily treatment cost of a new medicine is compared with the daily treatment costs of existing alternatives. The FOPH also looks at ex-factory prices in nine other European countries: Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Sweden, and the United Kingdom.

The FOPH re-evaluates list inclusion every three years, as well as when a medicine loses its patent or when there is a change in its indication and limitations. An abbreviated reimbursement assessment process without input from the Federal Drug Commission is applied to generic medicines. Generics are only included as a benefit under the mandatory insurance scheme if their ex-factory price is lower than the originator.

## Reimbursement levels

Patient cost-sharing of medicines is through a combination of deductibles and co-insurance. Deductible levels are chosen by individuals when they select their benefit package and associated premium level. A standard 10% co-payment is applied to most medicines covered under the basic benefit package.

A form of generic reference pricing is used in Switzerland. Patients pay a co-insurance rate of 20% for selecting an off-patent medicine (e.g., the originator brand) that is priced above levels established by low-cost versions with the same active substance and also approved for reimbursement. Co-insurance rates and conditions are reassessed annually.

Physicians can use medicines authorized by Swissmedic as part of regular inpatient treatment for patients in hospitals. Hospitals are reimbursed for the cost of inpatient medicines through a hospital payment scheme based on diagnosis-related groups.

## Price controls

Price regulation in Switzerland is based on pricing terms for medicines included for coverage in the mandatory basic health insurance package for all residents. Regulations do not apply to medicines not covered under the basic health insurance package.

The maximum allowable price for covered medicines is determined using a combination of external reference pricing and therapeutic price comparisons of alternatives already licensed in Switzerland. To achieve this, pharmaceutical manufacturers are required to supply their international pricing information (as reviewed by the drug pricing authority in the relevant country) as well as their “EU target price.”

The general formula used to determine allowable prices in Switzerland weights the average external reference price by two-thirds and the average therapeutic comparison price by one-third. The FOPH has some flexibility in its choice of comparator countries. For instance, an official reference country can be excluded from the pricing formula applied to a particular medicine if the medicine’s price in that country is an outlier.

Price premiums can be awarded to medicines that showcase innovation by being more effective, exhibiting fewer adverse side effects, or targeting a neglected disease. The premium will depend on the level of innovation and the cost of research and development. In practice, price premiums are usually

awarded to first or second entrants in a novel therapeutic class and amount to a price increase of 10%–20%.

Generics are priced using a discount system introduced in 2012 to encourage generic suppliers to enter the relatively small Swiss market. Generic price discounts range from 10% to 60% of the originator's price, with the larger discounts applied to generics entering markets with larger sales volumes.

Prices of medicines listed for coverage under the mandatory health insurance package are examined every three years and after a medicine's patent expiry or a change in its indications and limitations. The FOPH assesses whether the medicine's price still fulfills the criteria for cost-effectiveness and will calculate an updated maximum price using the same method as outlined above.

The FOPH can mandate a rebate on excess earnings accrued by a pharmaceutical company for pricing its medicine significantly above the new cost-effective price. Rebates occur when a drug's current price is found to be more than 3% above the allowable price and when such pricing has resulted in excess revenues greater than US\$20,500 (SF20,000) for the pharmaceutical company.

Although encouraged to do so, hospitals rarely procure inpatient medicines through public tenders.

## Distribution markups

The FOPH regulates distribution markups on ex-factory prices of listed medicines, thereby controlling retail prices.

Wholesalers and pharmacists share a combination of proportional margins and fixed distortion fees. The proportional distribution margins vary, regressively, from 12% for medicines with manufacturer prices below US\$895 (SF880) to 0% for medicines with manufacturer prices above US\$2,616 (SF2570). The fixed distribution margins vary, progressively, over the same price range, from US\$4 to \$243 (SF4 to SF240).

Swiss pharmacists also charge a fixed dispensation fee for their services.

Suppliers of unlisted, licensed medicines are free to set their own prices, although the Federal Department of Economic Affairs, Education, and Research monitors prices to ensure that they are reasonable.

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# United Kingdom

	2014 or closest year
<b>Population (millions)</b>	64.7
<b>GDP per capita</b>	US\$40,217
<b>Total health expenditure per capita</b>	US\$3,971
<b>Health expenditure as percentage of GDP</b>	9.9%
<b>Dominant source of health system financing (%)</b>	Public (79%)
<b>Total pharmaceutical expenditure per capita</b>	US\$485
<b>Dominant source of pharmaceutical financing (%)</b>	Public (66%)

Source: OECD Health Statistics 2016

## Health care system overview

The United Kingdom (UK) has a universal public health care system that provides access to health services throughout its four member countries: England, Scotland, Wales, and Northern Ireland. Health care is centrally financed through general taxes, but each member country is responsible for managing its own independent National Health Service (NHS).

Each NHS system in the UK provides access at the point of care to the majority of authorized prescription medicines. Patients in Scotland, Wales, and Northern Ireland face no user charges for covered prescriptions; patients in England may face co-payments for prescriptions filled in the community.

## Drug regulation and licensing

Manufacturing, market authorization, regulation, and pricing of medicines are all governed at the UK level. The Medicines and Healthcare Products Regulatory Agency within the UK Department of Health is responsible for the licensing of new medicines in the UK. Market authorization can also occur through the European Medicines Agency's centralized authorization procedure or by mutual recognition of licensing granted by another EU member state.

Medicines are not required to have market authorization prior to being appraised by a UK health technology assessment agency. However, it is mandatory that companies actively inform the health technology assessment agencies of their progress in attaining market authorization in the UK and EU.

## Drug coverage decision-making

Each country in the UK operates its own negative list of the licensed medicines that cannot be reimbursed through its NHS system. At a more local level, individual health authorities are in charge of the purchasing and provision of medicines, and thus of local formularies. The size of the health authorities differs among countries. In England, health administration is devolved to relatively small clinical commission groups; in Scotland, Wales, and Northern Ireland, administration is more consolidated.

The National Institute for Health and Care Excellence (NICE) is the primary health technology assessment body in the UK. NICE conducts drug appraisals that evaluate clinical benefit, cost-effectiveness, and social impact. While NICE recommendations are officially directed toward England, the agency also provides guidance for Scotland, Wales, and Northern Ireland. Scotland and Wales have established their own drug



assessment agencies that provide additional advice to their governments: the Scottish Medicines Consortium and the All Wales Medicines Strategy Group.

NICE appraisals use the incremental cost per quality-adjusted life year (QALY) as a measure of a technology's cost-effectiveness compared with an alternative. A cost per QALY in the range of US\$26,227–\$39,340 (£20,000–£30,000) is loosely recognized as the upper threshold for NICE considering a product to be cost-effective. Prices above this threshold have been accepted only in exceptional cases, such as medicines used for extremely rare conditions or for end-of-life care.

Local health authorities select medicines for use in their regions based on the health technology assessments provided by NICE and other health technology assessment bodies. Comparative cost-effectiveness is a key factor in determining local formulary inclusion.

There is now a separate process for appraisal and funding of cancer drugs in England.

## Reimbursement levels

In all countries of the UK, patients are not charged for pharmaceutical care in NHS hospitals.

With the exception of medicines on negative lists for each NHS system, any outpatient medicine prescribed by an NHS physician will be fully reimbursed at the listed price. Patients in Scotland, Wales, and Northern Ireland face no user charges for covered prescriptions.

In England, patients are charged a fixed co-payment of US\$10.82 (£8.20) per item for outpatient prescriptions. Some populations are exempt from the co-payment, including children aged 16 and under, adults aged 65 and older, and patients with certain chronic conditions. Co-payments are not levied for some drug categories, such as those used to treat sexually transmitted infections or cancer.

## Price controls

Drug prices in the UK are managed through a complex system of profit regulation, price rebate schemes, and formulary decision-making by local health authorities.

List prices of brand-name medicines are controlled at the UK level through the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary, non-statutory agreement negotiated every five years by the Department of Health and the Association of the British Pharmaceutical Industry. The current PPRS applies until the end of 2018. Companies that choose not to sign on to the PPRS must abide by statutory regulations, which use a methodology similar to that of the PPRS.

The PPRS is a complex agreement with many stipulations that ultimately aim to set a ceiling for profits earned on the sale of medicines to the NHS. The current targets for allowable profits from sales to the NHS are 6% return on sales or 21% return on capital. Earned profits beyond a tolerance of 50% above the target rate of return (on sales or capital) must be returned through future price cuts or a rebate paid to the UK government.

To better align prices with the value of a medicine, the PPRS allows for “flexible pricing” whereby companies can raise or lower the original list price of a medicine when new evidence alters the value of an existing indication or a new indication is added.

Patient-access schemes are also used to lower the effective price of new medicines to a point where they can be reimbursed under the NHS, even if they are not considered cost-effective by NICE at posted prices. The purpose of a patient-access scheme is to allow pharmaceutical companies to maintain high list prices, which are used by the external reference pricing systems of other countries, while meeting desired cost-effectiveness for the NHS.

In England and Wales, reimbursement prices of generic drugs are determined by the UK Department of Health. Each month, the Department of Health publishes the NHS Drug Tariff, which outlines reimbursement prices for generic medicines paid to contracted dispensers. The tariff includes the list price of the NHS prescription medicine and the remuneration fee for professional services. Scotland and Northern Ireland have their own drug tariff systems for generic medicines.

Tenders are used for inpatient medicines, establishing discounting arrangements between NHS trusts and manufacturers. These tendered contracts are usually confidential. Outpatient medicines are rarely tendered, with the exception of vaccines; however, local trusts have been pushing for the use of tenders for outpatient medicines.

## Distribution markups

There are no statutory regulations on distribution markups in the UK. Wholesaler and pharmacy remuneration is included in NHS medicine list prices determined through the PPRS or set out in the NHS Drug Tariff. List price discounts are negotiated by the various distributors in the supply chain.

In England, almost 85% of medicines dispensed in community pharmacies are supplied through wholesalers. Wholesalers generally receive a discount of approximately 12.5% on the list price from manufacturers. Most of this discount, approximately 10.5% of the list price, is passed on to pharmacies when the medicines are sold to them. Community pharmacies also receive additional remuneration per dispensation from the NHS for the provision of special services.

The Department of Health also sets a maximum profit margin that community pharmacies are permitted to retain through cost-effective purchasing of medicines. In 2014/2015, the retained profit margin was set at US\$1.04 billion (£800 million). Profits exceeding this cap are paid back to the government through future discounts on the reimbursement levels paid to pharmacies.

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