Pharmaceutical Expenditure Tracking, Budgeting and Forecasting in 23 OECD and EU countries

Country Notes

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The analytical report and country notes will be launched in April 2019.

The report and relevant work under this project, part of the EU agenda for effective, accessible and resilient health systems, are available here:

https://ec.europa.eu/health/policies/costeffective_medicines_en

http://www.oecd.org/health/health-systems/access-to-medicines.htm

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Introduction

To inform an OECD project looking at how countries can predict pharmaceutical spending, the OECD launched in the spring of 2018 a survey to collect information on country practices in pharmaceutical expenditure tracking and projections, and on budget and/or expenditure cap setting. Twenty-two of 40 countries responded to this survey.[1] The country notes presented in this report draw on country responses and desk research. The full text of the online questionnaire can be found in annex to the report "Improving Forecasting of Pharmaceutical Spending", as well as tables with responses from countries.

[1] A note on New Zealand was prepared from an interview.

Australia

Pharmaceutical expenditure and utilisation tracking

In Australia, most prescription medicines dispensed in the community, and certain medicines dispensed to hospital outpatients, are subsidised by the federal government via the Pharmaceutical Benefits Scheme (PBS).[2] Under the PBS the federal government reimburses pharmacies for the costs of dispensing medicines prescribed in accordance with a national formulary. Patients contribute to the costs of the subsidised medicines via two levels of fixed co-payments. PBS expenditure and utilisation are tracked on a monthly basis, with data from 1992 publicly available from Medicare Australia at http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp. Data may be disaggregated by region, beneficiary type, product, and at ATC level 5.

Pharmaceutical budgets

The PBS represents by far the largest share of public expenditure on medicines. Each year budgeted amounts for the current and subsequent 3 years are presented in the annual Portfolio Budget Statements.[3] In 2019-2020 the budgeted expenditure for the PBS is AUD 12.2 billion (approx. EUR 8.8 billion)[4] . Factors taken into account in determining the budget estimates are:

- Overall fiscal/government budget constraints and macroeconomic factors;
- Demographic and epidemiologic trends;
- Clinical guidelines involving pharmaceutical treatments;
- Past growth trends in pharmaceutical spending;
- Patent expiry dates for on-patent products, and potential generic or biosimilar entry and uptake;
- Anticipated market entry of new medicines;
- Recent market entry, coverage determinations and prices of new medicines;
- Amended listings, and legislated price changes.

[2] Medicines dispensed to inpatients are funded from public hospital budgets, which are the responsibility of the states and territories, albeit supported by federal funding. Medicines for certain rare conditions are also subsidised under the (federal) Life Saving Drugs Programme (LSDP), and for veterans under the Repatriation Pharmaceutical Benefits Scheme. These programmes are very small in comparison with the PBS.

[3] See http://www.health.gov.au/internet/budget/publishing.nsf/Content/2018-2019_Health_PBS_sup2/$File/2018-19_Health_PBS_2.04_Outcome_4.pdf

[4] In Australia, the financial year extends from 1 July until 30 June of the following year.

Pharmaceutical expenditure caps

The PBS is a demand-driven federal programme with an uncapped appropriation; thus Australia does not set a cap on overall pharmaceutical expenditure. However, for certain individual high-cost medicines (and in some cases medicine classes) confidential deeds of agreement with manufacturers provide for rebates where annual expenditure exceeds pre-determined levels.

Forecasts and projections

In Australia, for the vast majority of medicines covered by the PBS, modelling of expenditure is undertaken by the following process:

a) Preparation of prescription volume forecasts using statistical methods, based on historical utilisation of medicines. These forecasts are disaggregated by a number of categories such as drug, patient status, pharmacy type.

b) Development of scenarios that model current and future expenditure per prescription. A baseline scenario is created yearly as part of the Mid-Year Economic & Fiscal Outlook (MYEFO) to model current business rules and known future policy settings. New policies are modelled by applying variations to this baseline.

c) Evaluation of the prescription forecasts against a scenario. This process calculates expected expenditure by using scenario rules to determine the cost of each projected prescription.

For a few specialised medicines and programmes, different approaches may be used, such as tracking of patient numbers or of past aggregate expenditure. For that reason, Australia forecasts future expenditure based on currently subsidised medicines taking into account population growth and disease prevalence. The population growth and disease prevalence are drawn from historical PBS claims data rather than broader national or international sources. The additional net impacts of new medicine listings are added to the forecast as they occur. This takes into account that the inclusion of a new medicine in the reimbursement formulary cannot be assured.

The same forecasting database is used to model proposed changes to policy settings to ensure that the forecasts also factor in elements such as population growth and disease prevalence.

Horizon scanning

Horizon scanning takes the form of anticipating patent expiry dates for on-patent products, potential generic/biosimilar entry and uptake, and identification of new medicines expected to enter the market and/or be reimbursed by the PBS.

Austria

Pharmaceutical expenditure and utilisation tracking

Austria does not currently track pharmaceutical expenditure or utilisation at national or subnational level. However the Main Association of Austrian Social Security Institutions tracks expenditure and utilisation on reimbursed outpatient medicines, by individual product.

Electronic billing by pharmacies to the statutory sickness funds is the source of expenditure data. The Main Association of Austrian Social Security Institutions maintains a central database of all billing data, referred to as *automated billing of medicines* ("*Maschinelle Heilmittelabrechnung*").

The data are held by the Statutory Sickness Funds (SSF) and the Main Association of Austrian Social Security Institutions. Extracts can be made available upon specific requests to researchers, government agencies or independent bodies.

Pharmaceutical budgets

Sickness funds finance covered outpatient medicines dispensed by community pharmacies and state governments finance medicines used in and dispensed by hospitals.

The government does not set a budget for pharmaceutical spending at national or sub-national level as part of the budgetary process. However, since 2013, the SSFs and the federal and state governments agree on a cap on annual growth in SSF public health expenditure in national planning agreements. These are based on the federal constitution and referred to as *target-based governance agreements* ("*Zielsteuerungsverträge*"). The national cap is disaggregated at the level of each SSF and state government, but not by function of care.

Pharmaceutical expenditure caps

While target-based governance agreements effectively set a cap on total health expenditure by SSFs and state governments, no cap is defined specifically for pharmaceutical expenditure.

Forecasts and projections

The SSFs and the Main Association of Austrian Social Security Institutions routinely prepare aggregate projections of pharmaceutical spending. The projections have time horizons of up to 5 years and are updated quarterly. They draw extensively on expert opinion, are prepared as a standalone exercise, and are intended for internal purposes only. Results are not made public. While no periodic ex-post assessment is undertaken, forecasts are routinely re-evaluated and updated to address specific questions relating to reimbursement decisions.

Horizon scanning

Horizon scanning is undertaken in cooperation with the BeNeLuxA Network.

Belgium

Pharmaceutical expenditure and utilisation tracking

In Belgium, both pharmaceutical expenditure and utilisation have been tracked since 1996 for medicines covered by health insurance. Data are available at ATC level 5 and for individual products.

Data are collected from monthly invoices sent from community pharmacies to health insurers, and then sent quarterly to the National Institute for Health and Disability Insurance (NIHDI).

The Monitoring Of Reimbursement Significant Expenses ('MORSE') report has been published annually since 2008 by the National Institute of Health Insurance (INAMI). Based on reimbursement claims from community pharmacies and hospitals, the report tracks utilisation and expenditures of medicines by therapeutic class to understand trends, to evaluate the financial impact of policies and to forecast expenditures. All published reports are available online.[5] The last report was published in 2018, with time series for number of patients treated, volumes (DDD) and expenditures from 2007 to 2016 or 2017 (estimates), by dispensing entity (community pharmacy or hospital), by therapeutic class, and by active ingredients in some therapeutic classes (INAMI, 2018[1]).

The last report shows for example that medicines dispensed in hospitals accounted for 39% of social insurance pharmaceutical expenditures in 2016.

Pharmaceutical budgets

In Belgium, a budget is set for total health insurance expenditures of the next year. This overall budget is decomposed in subcategories of benefits, such as physicians, hospitals, pharmacy.[6]

The pharmaceutical budget covers spending on medicines dispensed in community pharmacies; administered in outpatient settings; dispensed or administered in hospitals and included in global budgets or DRG-payments; and those used in the treatment of specific conditions and paid on top of other hospital payments. The total amount budgeted for 2018 was EUR 4,135 billion. Budgets are also defined at sub-national level.

The preparation of the pharmaceutical budget involves the Ministries of Social Affairs and Budget, health care payers, and the pharmaceutical industry, with the final decision made by the King, after deliberation by the Council of Ministers (cf. Law of 14 July 1994 - art. 69 § 5).

According to the survey, the following survey influence pharmaceutical budget setting:

- Macro-economic factors
- Overall fiscal/government budget constraints

[5] https://www.riziv.fgov.be/fr/publications/Pages/rapport-morse.aspx

[6] http://www.coopami.org/fr/countries/countries/marocco/projects/2015/pdf/2015113006.pdf

- Demographic and epidemiologic trends
- Clinical guidelines involving pharmaceutical treatments
- Past growth trends in pharmaceutical spending
- Patent expiry dates for on-patent products
- Potential generic or biosimilar entry and uptake
- Anticipated market entry of new medicines
- Prices of new medicines
- Recent market entry and coverage determination of new medicines

Pharmaceutical expenditure caps

In 2015, the 'Pact for the Future',[7] signed between the Minister of Health and the association representing the pharmaceutical industry, set expenditure targets on a pluri-annual basis. The Pact anticipated an average annual growth of 0.5% of social health insurance expenditure on pharmaceuticals for the 2016-2018 period. This was based on hypotheses regarding the impact of new entrants, losses of market exclusivity, and some policy changes (De Block, 2015[6]).

The following factors are considered in defining the cap:

- Macro-economic factors
- Overall fiscal/government budget constraints
- Demographic & epidemiologic trends
- Past trends in pharmaceutical spending
- Predictable changes in medicines distribution costs
- Medicines in development pipelines
- Clinical guidelines involving pharmaceutical treatments
- Medicines in development (pipeline)
- Patent expiry dates and potential generic/biosimilar entry/uptake
- Predictable changes in medicines distribution costs

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared twice yearly by the National Institute for Health and Disability Insurance (NIHDI) together with the Ministry of Social Affairs and the pharmaceutical industry. Projections are developed separately for different sub-budgets (e.g. community pharmacy, outpatient setting, inpatient care, etc.)

[7] https://www.deblock.belgium.be/nl/maggie-de-block-en-farmasector-sluiten-uniek-toekomstpact

and embedded in a broader forecasting model. They are intended for internal use only and not made public.[8,9]

Inputs to the projections include:

- Demographic trends
- Population burden of disease
- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in medicine prices
- Changes in prescribing or treatment patterns
- Horizon scanning

There is no formal ex-post assessment of the predictive value of the projections, but they are compared to actual values and to simulations obtained from the PROMES Model, developed by the Federal Planning Bureau (FPB). The Federal Planning Bureau is a public agency that makes studies and projections on economic, social and environmental policy issues and on their integration within the context of sustainable development. For that purpose, the FPB collects and analyses data, explores plausible evolutions, identifies alternatives, evaluates the impact of policy measures, and formulates proposals. Government, parliament, social partners and national and international institutions appeal to the FPB's scientific expertise.

Horizon scanning

Until recently, there was no formal horizon scanning in Belgium. A proposal for collaboration in horizon scanning for BeNeLuxA was put forward in 2017.[10]

[8] http://www.coopami.org/fr/countries/countries/marocco/projects/2015/pdf/2015113006.pdf

[9] https://www.plan.be/press/event_det.php?lang=fr&KeyPub=40ects/2015/pdf/2015113006.pdf

[10] http://www.beneluxa.org/sites/beneluxa.org/files/201707/Horizon%20scanning_Scientific Report_full.pdf

Cyprus

Pharmaceutical expenditure and utilisation tracking

In Cyprus[11], pharmaceutical expenditure has been tracked for 10 years. Expenditure data are publicly available in Cyprus Government Gazette Online.

Public pharmaceutical utilisation has been tracked since 2014. The data are tracked by therapeutic area; care setting; and at ATC levels 4 and 5. They are not publicly available.

Pharmaceutical budgets

Cyprus sets an annual pharmaceutical budget, with the aims to control spending; prioritise expenditures according to health priorities, and allocate a fixed share of health expenditure to pharmaceuticals.

The budget is prepared jointly by the Ministry of Heath and the Ministry of Finance, and approved by the Ministry of Finance.

The budget is defined at central level and covers spending on medicines administered in outpatient settings; dispensed or administered in hospitals and included in global budgets or DRG-payments; and medicines used in the treatment of certain specific conditions – e.g. high-cost cancer medicines prescribed and administered in inpatient settings – and funded separately to other hospital payments.

According to responses to the survey, factors influencing pharmaceutical budget setting are:

- Overall fiscal/government budget constraints
- Clinical guidelines involving pharmaceutical treatments
- Past growth trends in pharmaceutical spending
- Patent expiry dates for on-patent products
- Potential generic or biosimilar entry and uptake
- Anticipated market entry of new medicines
- Prices of new medicines
- Recent market entry and coverage determination of new medicines

[11] 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. Turkey recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the "Cyprus issue". 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.

Pharmaceutical expenditure caps

The Ministry of Finance also sets a cap on overall pharmaceutical expenditure, taking into account the following:

- Overall fiscal/government budget constraints
- Past trends in pharmaceutical spending
- Potential generic or biosimilar entry and uptake
- Predictable changes in medicines distribution costs
- Clinical guidelines involving pharmaceutical treatments
- Patent expiry dates for on-patent products
- Medicines in development (pipeline)

Forecasts and projections

The Ministry of Health prepares short-term standalone projections of pharmaceutical expenditure annually, by sub-budget, which are informed by:

- Population burden of disease
- Changes in generic/biosimilar uptake
- Changes in prescribing or treatment patterns
- Past trends in pharmaceutical spending
- Changes in medicine prices
- Horizon scanning

The projections are for internal purposes only and are not made publicly available. There is no formal ex-post assessment of their predictive value.

Horizon scanning

There is no formal Horizon Scanning (HS) but EMA's reports are used to predict new entries of medicines.

Czech Republic

Pharmaceutical expenditure and utilisation tracking

In the Czech Republic, pharmaceutical expenditure and utilisation tracking only commenced in 2018, with data from 2015-2017 compiled thus far. Tracking is undertaken by region, therapeutic class, care setting, ATC code, and product, using the National Registry of Reimbursed Health Services (NRRHS), and thus is limited to tracking medicines reimbursed by one of the health insurance companies.

As it is a new data collection, the production and dissemination system is still being developed and the data are not publicly available.

Pharmaceutical budgets

The government does not set a budget for public pharmaceutical spending at national or sub-national level as part of the budgetary process.

Pharmaceutical expenditure caps

The Ministry of Health sets an annual cap for expenditures associated to medicines used in the treatment of selected conditions (i.e. high-cost cancer medicines prescribed and administered in inpatient settings) and paid for over and above other hospital payments.

The objective of the cap is to control spending, prioritise expenditures according to health priorities, and encourage the use of biosimilar drugs and generics. Factors in setting the cap in pharmaceutical spending are:

- Overall fiscal/government budget constraints
- Epidemiologic trends
- Past trends in pharmaceutical spending
- Medicines in development pipelines
- Potential generic/biosimilar entry/uptake
- Predictable changes in medicines distribution costs.

Each health fund negotiates individual caps with individual health care providers but the cap is not always binding (for example in case of unexpected expenditure growth). Individual health insurance funds set their own expenditure caps, but usually follow a template prepared by the Ministry of Health in the annual Reimbursement Directive. Individual caps for the Health Insurance Funds can be found on their respective webpages as part of their health-insurance plans for 2018 (budget item 2.1.5).[12] The Directive is binding only in cases where health insurance funds and health care providers fail to reach an agreement on the setting of individual caps.

[12] For the biggest fund (VZP), the link is: https://www.vzp.cz/o-nas/dokumenty/zdravotne-pojistne-plany

The Ministry of Health consults the Institute of Health Information and Statistics of the Czech Republic (responsible for epidemiological predictions and expenditure forecasts) and the State Institute for Drug Control (responsible for setting the reimbursement of pharmaceuticals and horizon scanning) when setting the cap in the Reimbursement Directive. In 2018, the total capped expenditure amount for high-cost pharmaceuticals was CZK 16 152 million across all health insurance funds.

Forecasts and projections

The Ministry of Health, in cooperation with the Institute of Health Information and Statistics of the Czech Republic, develops annual projections for health insurance funds' expenditure on particular groups of high cost medicines prescribed in special centres. The projections are standalone and short-term.

The modelling approach used may differ between groups of medicines, but generally includes regression modelling for extrapolation of past epidemiological and/or spending trends, with adjustments based on the expected budget impact of newly approved medicines. Some of the methodology has been published in the literature; however, the current reports are primarily for internal use and the outcomes are used for formulating the Reimbursement Decree.

According to survey responses, inputs to the projections include:

- Demographic trends
- Population burden of disease
- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Budget impact as estimated in applications / assessments for reimbursement or coverage
- Past trends in pharmaceutical spending

The modelling approach can differ for different groups of medicines, but generally includes regression modelling for extrapolation of past trends in epidemiology and/or spending, possibly corrected by clinical decision models; adjustments are made based on expected budget impact of newly approved medicines,

Thus far, comparisons of actual vs projected expenditure have only been undertaken as part of a pilot focusing on innovative medicines prescribed in special centres.

Horizon scanning

Horizon scanning is not done systematically, but ad hoc working groups look at selected medicines.

Estonia

Pharmaceutical expenditure and utilisation tracking

In Estonia, pharmaceutical expenditure and utilisation have been tracked since 2003.

Pharmaceutical expenditure has been tracked *via an e-prescription system* since 2010, with prior data from paper prescriptions also recorded in an electronic database. Expenditure is tracked by therapeutic class, ATC level 5 and by product.

Pharmaceutical utilisation is tracked via the same process, disaggregated by therapeutic area, ATC levels 3, 4 and 5, and individual product. The data are available on line.[13] at. Comparisons of actual vs expected utilisation are undertaken by ATC levels 2, 3, 4 and 5, but only aggregate data are publicly available (overall expenditure vs predicted)

Based on 2018 data, the Estonian Health Insurance Fund (EHIF) covers 73% of the costs of out-patient medicines; for in-patient medicines included in the health care service list, 100% is covered.

Pharmaceutical budgets

Estonia sets an annual pharmaceutical budget in order to control spending on pharmaceuticals and to prioritise expenditures according to health priorities. The budget is defined at central level.

The pharmaceutical budget covers spending on medicines:

- Dispensed in community pharmacies
- Dispensed or administered in outpatient settings
- Dispensed or administered in hospitals; and included in global budgets or DRG-payments
- Used in the treatment of specific conditions (eg high-cost cancer drugs used in inpatient settings) and funded separately to other hospital payments.

The preparation of the pharmaceutical budget involves the Ministries of Health and Finance and health care payers, with the final decision made by the Board of the Health Insurance Fund.

The total amount budgeted for 2018 was EUR 139 million for outpatient medicines and approximately EUR 60 million for inpatient medicines. However, the programme is demand driven, and is still funded if the budget is exceeded.

According to survey responses, factors influencing pharmaceutical budget setting:

- Overall fiscal/government budget constraints
- Past trends in pharmaceutical spending

[13] https://www.haigekassa.ee/haigekassa/aruanded-eelarve-ja-statistika/finantsnaitajad/soodusravimite-statistika

- Patent expiry dates
- Potential generic/biosimilar entry/uptake
- Anticipated market entry of new medicines
- Prices of new medicines

Pharmaceutical expenditure caps

Estonia sets a notional cap on annual expenditure on out-patient medicines**;** it should not exceed 20% of the amount allocated for health services benefits in the annual budget of health care expenses. The cap is set by the National Parliament and is driven by overall fiscal/government budget constraints. [14]

Forecasts and projections

The Health Insurance Fund prepares annually short-term projections of expenditure covering the pharmaceutical budget as a whole. These projections are embedded in a broader forecasting model. Projections are based on forecasting based on previous years. The projections are publicly available.[15] Ex-post assessment of real vs forecasted expenditure is undertaken quarterly.

According to survey responses, inputs to the projections include:

- Budget impact as estimated in applications/assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in medicine prices
- Changes in prescribing or treatment patterns
- (Limited) horizon scanning

Horizon scanning

Horizon scanning is not done systematically, but an effort is made to forecast the launch of generics and biosimilars and to take these into account in budget planning.

[14] See https://www.riigiteataja.ee/en/eli/511012018002/consolide

[15] See https://www.haigekassa.ee/haigekassa/majandusaruanded-ja-eelarve

Finland

Pharmaceutical expenditure and utilisation tracking

In Finland, the pharmaceutical expenditure for outpatient medicines is tracked at national level. The expenditure is disaggregated by ATC code (level 5). The data is compiled by Social Insurance Institution and has been tracked for decades, publicly available since 2008.[16] .

In Finland the pharmaceutical utilisation is tracked at national level by ATC level 5.

Finnish Statistics on Medicines lists drugs according to the ATC classification. These statistics include only preparations registered for human use. The sales figures of Finnish Statistics on Medicines are based on the sales of the three largest drug wholesalers in Finland, Oriola, Tamro and Magnum Medical, which together account for nearly 100% of total drug sales. The remainder (about 1%) is mainly comprised of hospital sales. VAT (10%) is not included in the wholesale figures. In Finnish Statistics on Medicines, drug consumption is expressed using Defined Daily Doses (DDDs). The calculations are based on the volume of sales to pharmacies and hospitals by wholesalers and on the assumed average dose per day for each drug. Consumption is usually expressed as a number of DDDs per 1,000 inhabitants and per day.

The Finnish Statistics on Medicines have been published since 1987 and are publicly available.[17]

Pharmaceutical budgets

Finland does not currently set a budget for pharmaceutical spending at national or sub-national level as part of the budgetary process.

Medicines are funded through two different channels. Outpatient prescription medicines are funded by the National Health Insurance Scheme while the municipalities are responsible for financing the medicines used in hospitals and in health centres. None of these institutions establishes a strict budget for pharmaceutical expenditures.

Pharmaceutical expenditure caps

Finland does not define a cap on pharmaceutical spending at national or sub-national level.

Forecasts and projections

Finland (Social Insurance Institution) prepares long-term forecasts for preparing budget framework on reimbursement expenditure of outpatient medicines.

Horizon scanning

Finland does not currently undertake pharmaceutical horizon scanning.

[16] http://raportit.kela.fi/ibi_apps/WFServlet

[17] https://www.kela.fi/web/en/statistical-publications_finnish-statistics-on-medicines

France

Pharmaceutical expenditure and utilisation tracking

In France, pharmaceutical expenditure and utilisation have been tracked for more than 10 years. The national claims database managed by the National Health Insurance Fund provides detailed product level information on expenditure on medicines dispensed in all community pharmacies and all expensive medicinal products in the hospital setting. Expenditure can be broken down by region, care setting, payer, prescriber, therapeutic area, ATC level 5 and product.

Raw data are publicly available online for medicines dispensed to outpatients, separated in two distinct databases for medicines prescribed by ambulatory providers and medicines prescribed by hospitals.[18]

The Healthcare products pricing committee (CEPS) produces annually some statistics on pharmaceutical expenditures, but not at a very disaggregated level.[19]

Pharmaceutical budgets

France does not set an annual budget for public pharmaceutical spending. However, the annual target set by the Parliament for total social health insurance expenditures includes pharmaceutical expenditures in broader sub-categories for which individual targets are defined (namely outpatient care and hospital care). Many mechanisms, including an alert system, have been put in place to make sure these expenditures targets are not over-run. If there is a risk, emergency measures might be introduced, including measures affecting pharmaceutical expenditures (e.g. price reductions).

Pharmaceutical expenditure caps

In France, the Parliament votes annually a cap for the growth of pharmaceutical companies' sales of reimbursable medicines. For 2017, two separate caps had been set for pharmaceuticals dispensed to oupatients (+0%) and for expensive pharmaceuticals dispensed in hospitals and paid to hospitals beyond and above DRG-like tarifs (+2%). Actual growth in 2017 was below the cap for medicines dispensed to outpatients but exceeded the cap for expensive hospital medicines. In reaction, a uniform 20% clawback applied to all companies selling these medicines. Due to a complex mechanism by which companies can accumulate "rebate credits" for different motives, this amount was reduced for some of them. The total amount of "macro-economic" clawback due for 2017 was thus EUR 52 million (CEPS, 2018[2]).

[18] http://open-data-assurance-maladie.ameli.fr/medicaments/index.php

[19] See activity reports here: https://solidarites-sante.gouv.fr/ministere/acteurs/instances-rattachees/article/rapports-d-activite-du-ceps

For 2018, the two caps have been set at +0% for medicines dispensed to outpatients and +3% for expensive medicines in hospitals.[20] According to France's response to the survey, the following factors are taken into account when defining this cap:

- Overall fiscal/government budget constraints
- Demographic & epidemiologic trends
- Clinical guidelines involving pharmaceutical treatments
- Past trends in pharmaceutical spending
- Patent expiry dates and potential generic/biosimilar entry/uptake
- Medicines in development pipelines
- Predictable changes in medicines distribution costs.

In 2018, the French government and health industries published a strategic plan to boost the development of health industries (CSIS, 2018[3]). The plan includes provisions aimed to increase the predictability of the revenues for the pharmaceutical industry. For the next three years, a minimum annual growth rate of 3% has been defined for revenues derived from reimbursed "innovative medicines", as well as 0.5% growth of the annual turnover, which corresponds to 1% growth for social health insurance expenditure (ibid.).

Forecasts and projections

Short term projections of pharmaceutical expenditure are prepared by the Ministry of Health and the Ministry of Finance. Projections are developed several times a year; cover the pharmaceutical budget as a whole, and are embedded in a broader forecasting model. They are intended for internal use only.

There is no formal ex-post assessment of the predictive value of the projections.

According to survey responses, Inputs to the projections include:

- Demographic trends
- Population burden of disease
- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Budget impact as estimated in applications/assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in medicine prices
- Changes in prescribing or treatment patterns
- Horizon scanning

[20] See http://www.senat.fr/rap/a17-068/a17-06819.html

Horizon scanning

Regular meetings take place between the Healthcare products pricing committee (CEPS) and representatives of the pharmaceutical industry and in bilateral meetings with companies, in which the R&D pipeline and the prospective entry of new products in the next few years are discussed. Teams in charge of prospective budgeting monitor the launch of new products, as well as reports in the trade press and via expert databases.

As a result of the CSIS, the French Haute Autorité de Sante (HAS) is about to create a horizon scanning process for medicines and biomarkers in cancer.

Ireland

Pharmaceutical expenditure and utilisation tracking

In Ireland, pharmaceutical expenditure and utilisation have been tracked since 1998. The Primary Care Reimbursement Service (PCRS) collects monthly pharmacy prescription claims data using an Oracle database, allowing for disaggregation of data from which analyses are undertaken and expenditure and utilisation tracked. Expenditure data are disaggregated by ATC level 5 and product. Utilisation data are tracked by ATC levels 3, 4 and 5, and by individual product. The data are not made publicly available.

Pharmaceutical budgets

Ireland sets an annual budget for public pharmaceutical spending in order to control spending; prioritise expenditures according to health priorities; and allocate a fixed share of health expenditure to pharmaceuticals.

The budget preparation involves the Ministries of Heath and Finance, and health care payers, with the final decision taken by the Ministry of Finance

The budget is defined at the central level and covers spending on medicines:

- Dispensed in community pharmacies
- Administered in outpatient settings
- Dispensed or administered in hospitals and included in global budgets or DRG-payments;
- Used in the treatment of specific conditions (e.g. high-cost cancer drugs used in inpatient settings) and funded separately to other hospital payments.

Budget data are available in the National Service Plan (NSP) 2018.[21] A budget line isolates the budget for drugs within the budget for primary care reimbursement services (p. 99); and two other lines related to reduction in prescription charges and thresholds to access the drug payment scheme. Expenditures for medicines used in hospitals and for high-tech medicines are not isolated in this budget document.

According to survey responses, the following factors taken into account in pharmaceutical in budget setting:

- Macroeconomic factors;
- Overall fiscal/government budget constraints;
- Demographic trends;
- Epidemiologic trends;
- Clinical guidelines involving pharmaceutical treatments;
- Past trends in pharmaceutical spending; patent expiry dates;

[21] https://www.hse.ie/eng/services/publications/serviceplans/national-service-plan-2018.pdf

- Potential generic/biosimilar entry/uptake; anticipated market entry of new medicines;
- Prices of new medicines; recent market entry and coverage determination of new medicines.

The NSP however mentions the provisions of the Framework Agreement on the Supply and Pricing of Medicines signed between the government and the pharmaceutical industry for 2016-2020, which are expected to keep the pharmaceutical budget under control, such as: price revisions, rebates, price setting of generic entrants and coverage conditions for biosimilars.

Pharmaceutical expenditure caps

Ireland sets an annual cap on pharmaceutical expenditure, which is determined by the Ministry of Finance. As with the pharmaceutical budget, the cap on pharmaceutical expenditure is not disaggregated but is captured in the NSP:

https://www.hse.ie/eng/services /publications/serviceplans/national-service-plan-2018.pdf

According to survey responses, factors considered when defining the cap in pharmaceutical spending include:

- Macroeconomic factors;
- Overall fiscal/government budget constraints;
- Demographic trends;
- Medicines in development pipelines;
- Clinical guidelines involving pharmaceutical treatments;
- Patent expiry dates and potential generic/biosimilar entry/uptake;
- Predictable changes in medicines distribution costs.

Forecasts and projections

Short term projections of pharmaceutical expenditure are prepared by the Ministries of Health and Finance and the Health Service Executive (HSE)

The projections cover the pharmaceutical budget as a whole, and are embedded in a broader forecasting model. They are updated on a monthly basis. The projections and the models used to develop them are published annually in the NSP. Ex-post assessments are used to evaluate the predictive value of the projections.

According to survey responses, inputs to the pharmaceutical expenditure projections include:

- Demographic trends
- Population burden of disease
- New medicines expected to receive marketing authorisation and/or to be reimbursed

- Budget impact as estimated in applications/assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in medicine prices

Horizon scanning

In accordance with the Irish Pharmaceutical Healthcare Association (IPHA) framework agreement, companies submit new medicine horizon scans by the end of July each year, indicating all new medicines for which they intend to seek reimbursement in the coming years. Medicines included in the horizon scan may be submitted for rapid review assessment and (as appropriate) to the National Centre for Pharmacoeconomics (NCPE) for health technology assessment in the following year. Examples of data sources include the *European Federation of Pharmaceutical Industries and Associations (EFPIA) Pipeline Review of Innovative Therapies* and the EMA/CHMP.

Italy

Pharmaceutical expenditure and utilisation tracking

Italy's pharmaceutical expenditure has been tracked since 1985, with publication of national reports since 2000. Data are disaggregated by region, therapeutic area, ATC level 5, care setting, and product. Public pharmaceutical utilisation is also tracked by therapeutic area; care setting; at ATC levels 3, 4 and 5; and by product.

The data are accessible through the website of the Italian Medicines Agency (AIFA).[22]

Pharmaceutical budgets

In Italy, a fixed proportion of the National Health System (NHS) budget is allocated to pharmaceutical expenditure. The budget act voted in 2016 for 2017 defined the following elements:

- The budget for pharmaceuticals is limited to 14.85% of all resources of the Italian NHS. This budget is further split in two budget caps:
- 6.89% of NHS spending is allocated to expenditures on pharmaceuticals directly purchased from manufacturers (mainly by hospitals)
- and 7.96% to regional expenditures on pharmaceuticals purchased in pharmacies (Aifa, 2018[4]).

If the "direct purchase budget" is overrun, then pharmaceutical companies and regions are requested to cover the deficit (50% each). If the "retail budget" is exceeded, the pharmaceutical industry and distributors must pay back the difference.

Since 2015, two special funds of EUR 500 million each have been allocated to the purchase of "innovative oncology medicines" and "innovative non-oncology medicines". The medicine agency AIFA establishes the list of "innovative medicines" eligible for this financing and not included in the budget cap defined above (Aifa, 2018[4]).

Italy's pharmaceutical budgets cover spending on medicines:

- Dispensed in community pharmacies
- Administered in outpatient settings
- Dispensed or administered in hospitals and included in global budgets or DRG-payments
- Medicines used in the treatment of certain specific conditions – e.g. high-cost cancer medicines prescribed and administered in inpatient settings – and funded separately to other hospital payments.

The objectives of setting a budget for pharmaceuticals are to control spending and allocate a fixed share of health expenditure to pharmaceuticals. Budgets are defined at both central

[22] http://www.aifa.gov.it/content/osservatorio-sull%E2%80%99impiego-dei-medicinali-osmed

and regional levels. Preparation of the pharmaceutical budget is undertaken jointly by the Ministries of Health and Finance and health care payers, with the final decision made by the two Ministries.

According to the survey, factors influencing pharmaceutical budget setting are:

- Macro-economic factors
- Overall fiscal/government budget constraints
- Demographic trends
- Epidemiologic trends
- Past trends in pharmaceutical spending
- Patent expiry dates
- Potential generic / biosimilar entry/ uptake
- Prices of new medicines
- Recent market entry and coverage determination of new medicines

Pharmaceutical expenditure caps

AIFA does not set a macro-economic cap on pharmaceutical expenditure. However, since 2007, AIFA allocates annual expenditure caps for each pharmaceutical company, based on current and forecast market shares. If the global budget is over-run, each company is requested to claw back an amount of money computed as a proportion of the difference between its actual revenue and its sales cap (Jommi and Minghetti, 2015[5])

Forecasts and projections

Italy currently prepares ad hoc projections of pharmaceutical spending only. Methods for the preparation of systematic projections are currently under development

Horizon scanning

Horizon Scanning (HS) is used to support the prioritisation of resource allocation in the pharmaceutical sector, by estimating the impact on the NHS of the authorisation of both new medicines and new indications for existing medicines. HS also promotes early access to promising medicines and enables the collection of effectiveness data in clinical practice.

HS activity regarding products already in development is focused on supporting Health Technology Assessment (HTA) activities through systematic collection of information on medicines that a) could receive marketing authorisation through the centralized procedure within 12-36 months and b) could have significant economic impact on the NHS. To support optimal resource allocation, AIFA uses predefined criteria to identify and prioritise those products of greatest interest to the NHS.

HS methods are re-evaluated yearly in order to optimize the HS activities.

Japan

Pharmaceutical expenditure and utilisation tracking

Pharmaceutical expenditures and utilisation have been tracked since 2011. The data are publicly available, and are disaggregated by region and therapeutic area. The Ministry of Health, Labour and Welfare collects information from health insurance claims review and from reimbursement services that act as intermediaries between medical services providers and insurers.

Pharmaceutical budgets

Japan does not define a budget for public pharmaceutical expenditures as part of its budgeting process since pharmaceuticals are mainly financed through health insurance schemes.

Pharmaceutical expenditure caps

No cap is defined for pharmaceutical expenditures.

Forecasts and projections

The Ministry of Health, Labour and Welfare performs short-term projections for pharmaceutical expenditures annually. These projections are embedded in a broader forecasting model. They take into account the budget impact estimated in applications provided or assessments performed to inform decision on medicine coverage.

Projections are not publicly available, and there is no formal ex-post assessment.

Horizon scanning

Japan does not perform horizon scanning.

Korea

Pharmaceutical expenditure and utilisation tracking

Pharmaceutical expenditure and utilisation has been tracked since 2001, at product level. Data can be presented by region, care setting and therapeutic class or according to patient characteristics. Some information might be available at http://opendata.hira.or.kr/home.do.

Pharmaceutical budgets

Korea does not set a budget for public pharmaceutical expenditure.

Pharmaceutical expenditure caps

No cap is set for pharmaceutical expenditure.

Forecasts and projections

Forecasts and projections are not performed as they are not perceived as useful in the Korean system.

Latvia

Pharmaceutical expenditure and utilisation tracking

In Latvia, pharmaceutical expenditure and utilisation have been tracked since 2004. Pharmaceutical expenditure is tracked by region, therapeutic area and product. Pharmaceutical utilisation is tracked by therapeutic area, care setting, prescriber and individual product. The NHS is custodian of databases of reimbursable medicines paid for by the state. The data are publicly available.[23]

Actual and projected utilisation are compared by therapeutic area, but these data are not in the public domain.

Pharmaceutical budgets

Latvia sets an annual pharmaceutical budget in order to control spending and to allocate a fixed share of health expenditure to pharmaceuticals. The pharmaceutical budget covers spending on medicines administered in outpatient settings. The budget is defined centrally, at the level of the financing system but also at prescriber level.

The preparation of the pharmaceutical budget involves the Ministries of Health and Finance, andthe final decision is voted by the national parliament.

The State budget for 2018 was of EUR 130 million for outpatient medicines and a further EUR 11.4 million for the centralized purchase of medicines. [24]

According to the survey, the following factors influence pharmaceutical budget setting: overall fiscal/government budget constraints; past trends in pharmaceutical spending; and prices of new medicines.

Pharmaceutical expenditure caps

An annual pharmaceutical expenditure cap is set by the Cabinet of Ministers.

If the National Health Service detects an annual increase of more than 10% in the sales volumes of particular reimbursed medicines or medical devices that have been listed for at least three years, a rebate is mandated (except where a sales volume contract has been previously signed or prescription conditions have changed).[25]

[23] See http://www.vmnvd.gov.lv/lv/503-ligumpartneriem/operativa-budzeta-informacija/valsts-budzeta-lidzeklu-izlietojums-valsts-kompensejamo-zalu-apmaksa

[24] See annex 4;29. Ministry of Health; programme No.33.03.00 Reimbursable pharmaceuticals at https://likumi.lv/ta/id/295569-par-valsts-budzetu-2018-gadam and at http://www.vm.gov.lv/images/userfiles/Bud%C5%BEets/VM_budzets_03.01.2018(1).pdf

[25] See https://likumi.lv/ta/en/en/id/147522-procedures-for-the-reimbursement-of-expenditures-for-the-acquisition-of-medicinal-products-and-medical-devices-intended-for-the-outpatient-medical-treatment

According to survey responses, factors taking into account when defining the cap in pharmaceutical spending include overall fiscal/government budget constraints and past trends in pharmaceutical spending.

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared annually by the Ministry of Health and the pharmaceutical industry. The projections cover the pharmaceutical budget as a whole and are embedded in a broader forecasting model of the health care budget. They are intended for internal use only. No ex-post assessment is undertaken of the predictive value of the projections.

Inputs to the projections include population, burden of disease, as well as past trends in pharmaceutical spending.

Horizon scanning

Latvia does not undertake horizon scanning at this time.

Lithuania

Pharmaceutical expenditure and utilisation tracking

In Lithuania, pharmaceutical expenditure has been tracked for 8 years. Data are disaggregated by region, payer, therapeutic class, ATC level 5, and product. The data are not publicly available.

Pharmaceutical utilisation is also tracked by therapeutic class, ATC levels 3, 4 and 5, and individual product. Drug consumption figures are usually presented as the number of DDDs/1000 inhabitants/day. Sales data presented in DDD/1000 inhabitants/day provide a rough estimate of the proportion of the population within a defined area treated daily with certain drugs. Utilisation data are available at http://www.vlk.lt/veikla/veiklos-sritys/kompensuojamieji-vaistai/Statistika.

Pharmaceutical budgets

Lithuania sets annual pharmaceutical budgets in order to control spending on pharmaceuticals. Budgets are defined at both central and financing system levels. The preparation of the pharmaceutical budget involves the Ministries of Health and Finance and health care payers, with the final decision made by the national parliament.

The pharmaceutical budget covers spending on medicines dispensed in community pharmacies. The total amount budgeted for 2018 was EUR 311 million.[26]

According to survey responses, factors influencing pharmaceutical budget setting include:

- Macro-economic factors
- Overall fiscal/government budget constraints
- Past trends in pharmaceutical spending
- Potential generic / biosimilar entry / uptake

Pharmaceutical expenditure caps

Lithuania does not set an annual cap on total or public pharmaceutical expenditure

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared twice yearly by the National Health Insurance Fund. The projections are developed for the Compulsory Health Insurance Fund (CHIF budget) and are standalone. They are published and available to the public.

There is no formal ex-post assessment of the predictive value of the projections.

[26] See https://www.e-tar.lt/portal/lt/legalAct/c68db830e58f11e7acd7ea182930b17f

According to the survey responses, inputs to the projections include:

- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Budget impact as estimated in applications/assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in medicine prices
- Changes in prescribing or treatment patterns

The methodology used for expenditure projections for the Compulsory Health Insurance Fund (CHIF) budget is approved by the director of the National Health Insurance Fund (date 23 June 2014; No 1K-152) and is not publicly available.

Horizon scanning

Lithuania does not currently undertake horizon scanning.

Luxembourg

Pharmaceutical expenditure and utilisation tracking

Pharmaceutical expenditure has been tracked for the last 10 years, by ATC level 5 and individual product; however, the data are not publicly available.

Pharmaceutical utilisation has also been tracked for the last 10 years, by ATC level 5 and individual product, using specially designed studies, with a summary published.[27]

Comparisons of actual vs expected utilisation are also undertaken, albeit in aggregate only, and are published. See http://cns.public.lu/fr/publications/decompte-annuel/budget-am-2018.html.

Pharmaceutical budgets

Luxembourg does not set an annual pharmaceutical budget.

Pharmaceutical expenditure caps

Luxembourg does not set a cap on total or public pharmaceutical expenditure.

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared by the National Health Insurance (CNS). Projections are developed separately for different sub-budgets, are limited to reimbursed medicines, and are embedded in a broader forecasting model. They are intended for internal use only and updated 2-3 times/year. There is no formal ex-post assessment of the predictive value of the projections. Inputs to the projections include:

- Demographic trends
- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Budget impact as estimated in applications/assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in medicine prices

Horizon scanning

A proposal for collaboration in horizon scanning for BeNeLuxA was put forward in 2017.[28]

[27] See https://cns.public.lu/dam-assets/publications/cahiers-cns/cns-cahier-etudes-01-2017-12pages-small-.pdf

[28] See: http://www.beneluxa.org/sites/beneluxa.org/files/2017- 07/Horizon%20scanning _ScientificReport_full.pdf

Malta

Pharmaceutical expenditure and utilisation tracking

In Malta, pharmaceutical expenditure has been tracked for the last 6 years. The data are not publicly available.

The Central Procurement & Supplies Unit (CPSU) of the Ministry of Health is allocated a yearly recurrent expenditure amount, and monthly forecasts are provided to the Ministry of Finance for audit purposes and to determine if further funding is required. CPSU is also allocated funding for new medicines (e.g. oncology) through the Chief Medical Officer.

Pharmaceutical utilisation is also tracked, disaggregated by care setting. These data are publicly available. Comparisons of actual vs projected utilisation are undertaken using unique national product codes and are publicly available at: https://deputyprimeminister.gov.mt/en/cpsu/Pages/CPSU%20Reports.aspx

Pharmaceutical budgets

Malta sets an annual, centrally-defined, pharmaceutical budget in order to allocate a fixed share of health expenditure to pharmaceuticals. This budget covers spending on medicines supplied to community pharmacies and the NHS.

In 2018 the amount budgeted for 'medicines and surgical materials' was EUR 104 million.

The preparation of the budget involves the Ministries of Health and Finance, with the final decision made by the National Parliament.

According to survey responses, factors influencing pharmaceutical budget setting include:

- Macro-economic factors
- Overall fiscal/government budget constraints
- Demographic and epidemiologic trends
- Clinical guidelines involving pharmaceutical treatments
- Past growth trends in pharmaceutical spending
- Patent expiry dates for on-patent products
- Potential generic or biosimilar entry and uptake
- Anticipated market entry of new medicines
- Prices of new medicines
- Recent market entry and coverage determination of new medicines.

Pharmaceutical expenditure caps

An annual pharmaceutical expenditure cap is assigned by the Ministry of Finance, based on the previous year's forecast. Additional allocations may be made following monthly forecast updates submitted to the Ministry of Finance.

Factors in defining the cap in pharmaceutical spending include: overall fiscal/government budget constraints, and past trends in pharmaceutical spending.

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared and updated monthly by the Ministry of Health. Projections cover the pharmaceutical budget as a whole, are based on past trends in pharmaceutical spending, and are standalone. They are intended for internal use only.

No ex-post assessment is undertaken of the predictive value of the projections.

Horizon scanning

Horizon scanning takes the form of market research into biosimilars and innovative medicines that may compete with currently approved medicines.

The Netherlands

Pharmaceutical expenditure and utilisation tracking

In the Netherlands, pharmaceutical expenditure and utilisation have been tracked for 15-20 years. Expenditure is tracked by region, payer, therapeutic class, care setting, ATC level 5, and individual product, using reimbursement data from pharmacies. Utilisation is tracked by therapeutic area; care setting; ACT levels 3, 4, and 5; and individual product.

Summary data are publicly available at ATC level 5 at www.gipdatabank.nl.

Actual utilisation is compared with predicted for new medicines at ATC level 5, but the data are not publicly available

Pharmaceutical budgets

The Netherlands sets an annual pharmaceutical budget in order to control spending on pharmaceuticals. The pharmaceutical budget covers spending on medicines dispensed in community pharmacies and administered in outpatient settings.

The budget is defined at central level. Its preparation involves the Ministries of Health and Finance, with the final decision made by Ministry of Health

Factors influencing pharmaceutical budget setting: overall fiscal/government budget constraints, past growth trends in pharmaceutical spending, anticipated market entry of new medicines. The total amount budgeted for pharmaceuticals used in extramural care in 2018 was EUR 4.7 billion.

Pharmaceutical expenditure caps

The Netherlands does not set a cap on total and/or public pharmaceutical expenditure.

Forecasts and projections

In the Netherlands, the Healthcare Institute has been forecasting pharmaceutical expenditures for 5 years, with the aim to inform the budget cycle of the Ministry of Health, Welfare and Sports. The Central Planning Board (CPB) is also using the results of this estimate, including for the annual Macro Economic Outlook. The GIP data collection allows decomposing past trends in volume trends (number of insured person, number of prescriptions and number of standard daily doses) and price trends (price per prescription and price per DDD).

The database also enables to distinguish off-patent multi-source medicines and on-patent single source ones. The modelling mainly draws on trends for different categories of medicines (e.g. inpatient, generics). Trends in volumes, prices and rates of substitution are taken into account (Zorginstituut Nederland, 2018[18]).

The most recent projections cover the period 2017-2021. For all years except 2017, the annual growth rate is projected to be 2.5%, which results from a 2.5% annual average increase of volume (measured in DDDs); and two opposite trends which offset each other: lower prices due to health insurance preference policies and price pressures resulting from

the Pharmaceuticals Prices Act on one hand, and inflow of new, often more expensive medicines on the other hand. The growth rate for 2017 was projected to be +0.8% (ibid.).[29]

Ex-post assessment is undertaken of the predictive value of the projections, mainly to understand predicted vs actual trends and to assess the financial impact of developments not included in the prediction model.

Inputs to the projections include:

- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Past trends in pharmaceutical spending
- Changes in medicine prices
- Horizon scanning

Horizon scanning

Horizon scanning is undertaken. See www.horizonscangeneesmiddelen.nl

In addition, a proposal for collaboration in horizon scanning for BeNeLuxA was put forward in 2017.[30]

[29] For further reference, see www.gipdatabank.nl
www.rijksbegroting.nl/2018/voorbereiding/begroting,kst236981_37.html
www.gipdatabank.nl/databank#/g/00-totaal/R_90_grafiek;
www.zorginstituutnederland.nl/publicaties/publicatie/2018/04/17/gipeilingen

[30] See: http://www.beneluxa.org/sites/beneluxa.org/files/2017-07/Horizon %20scanning_ ScientificReport_full.pdf

New Zealand

Pharmaceutical expenditure and utilisation tracking

New Zealand's Pharmaceutical Management Agency (PHARMAC) is responsible for the selection and procurement of medicines and vaccines publicly funded through NZ's District Health Boards (DHBs) - both products dispensed in the community and administered in DHB hospitals - and funded via the Combined Pharmaceutical Budget (CPB). PHARMAC is responsible for both expenditure and utilisation tracking. Disaggregated utilisation and expenditure data do not appear to be publicly available.

Pharmaceutical budgets

The CPB is set each year by the Minister of Health and in 2017-2018 budget was NZD 875.50 million for 'combined pharmaceuticals' (community pharmaceuticals, hospital pharmaceutical cancer treatments, vaccines and haemophilia treatments).

Pharmaceutical expenditure caps

There is no expenditure cap per se, as the CPB operates as a fixed budget constraint. DHBs hold the funds and PHARMAC works to ensure spending does not exceed the CPB, although PHARMAC holds a small discretionary budget to manage unanticipated overruns.

While the 2017-2018 budget was NZD 875.50, gross expenditure on community pharmaceuticals, hospital pharmaceuticals, cancer treatments, vaccines and haemophilia treatments was actually NZD 1321.10 million, with PHARMAC's commercial agreements with suppliers accounting for NZD 445.60 million in rebates and adjustments.[31] However, these represent ex-ante agreed rebates built into the calculation of the CPB, rather than 'clawback' arrangements to manage overspending.

Forecasts and projections

PHARMAC's ability to manage within its budget is critically dependent on its ability to forecast spending accurately. PHARMAC uses a custom-built database, aggregating all the necessary data from different sources. Volumes are forecast separately from transactions/expenditure. The forecast does not include estimates of expenditure on anticipated new investments, but is used to forecast expenditure 'headroom'.

Factors taken into account in the modelling exercise include: expert advice, drug uptake rates, seasonal and business days, price changes, rebates, policy changes, market changes, transactions, new listings. The model uses a combination of a linear and log linear volume forecasts, using a bottom-up approach involving estimating volume and expenditure at

[31] See PHARMAC's Annual Report for the year ended 30 June 2018 https://www.pharmac.govt.nz/assets/annual-report-2017-2018.pdf

product level. Macro adjustments are made as necessary for any changes that cannot be incorporated at the product level.

Forecasts are modelled over a 5-year horizon and fully reviewed on a quarterly basis, with 'light' reviews undertaken each month.

Horizon scanning

New Zealand does not undertake horizon scanning.

Norway

Pharmaceutical expenditure and utilisation tracking

Pharmaceutical expenditure financed by hospitals has been tracked by the Norwegian Directorate of Health since 2010, based on expenditure data obtained from hospitals. Reports are published on a yearly basis. Expenditure is also tracked by the Norwegian Hospital Procurement Trust (*Sykehusinnkjøp HF*) and by the Hospital Pharmacies (*Sykehusapotekene*). The data are publicly available.[32]

Pharmaceutical expenditure financed by the National Health Insurance scheme has been tracked by the Norwegian Directorate of Health since 2011, based on expenditure data obtained from pharmacies. The data are publicly available at https://helsedirektoratet.no/statistikk-og-analyse/legemidler-statistikk-folketrygden.

The Institute for Public Health receives anonymised information from pharmacies about all prescribed medicines which have been dispensed to patients. Utilisation and expenditure related to prescription drugs dispensed by all pharmacies have been tracked since 2004, for individual products. Information on utilization includes the number of patients treated and the number of DDDs. The data can also be presented by gender, age, and geography. The data are available at the Norwegian Prescription Database (NorPD)[33] as annual reports with detailed information on medicine utilisation by ATC class (up to level 5), gender, age group and region (Berg et al., 2018[6])). Users can also request tailored reports according to their needs from the website http://www.norpd.no. The Norwegian Directorate for Health also publishes an annual report on pharmaceutical expenditure in hospitals (Norwegian Directorate of Health, 2018[6]).

Pharmaceutical budgets

In Norway, medicines are financed through several channels. Regional Health Authorities finance specialised medicines for inpatient care or prescribed in hospitals and dispensed by any pharmacy (hospital or community)for outpatient care (known as “H-prescription medicines”). The National Health Insurance scheme covers medicines prescribed by primary care providers or specialists. Municipalities finance the costs of medicines dispensed in long term care and patients finance the costs of OTC products and non-covered prescription medicines (See Figure below).

Norway sets an annual pharmaceutical budget in order to control spending on medicines financed by the National Insurance Scheme. The Ministry of Health and Care Services (MHCS) develops the budget at central level and the Parliament makes the final decision. The budget for 2018 was set at NOK 10,162 billion (EUR 1.06 bln).[34]

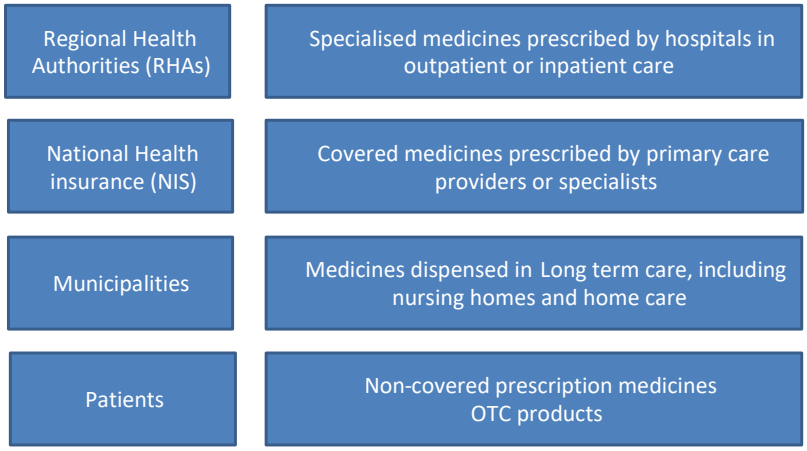
According to survey responses, factors influencing pharmaceutical budget setting are past growth trends in pharmaceutical spending; and potential generic entry and uptake.

[32] See https://helsedirektoratet.no/statistikk-og-analyse/samdata

[33] See https://www.fhi.no/en/hn/health-registries/norpd

[34] See https://www.regjeringen.no/no/dokumenter/prop.-1-s-20182019/id2613728/

Figure. Main financing sources for pharmaceuticals in Norway



Source: Authors' compilation from different sources

Pharmaceutical expenditure caps

Norway does not set caps on pharmaceutical expenditure.

Forecasts and projections

Projections of pharmaceutical expenditure covered by the National Insurance scheme are prepared quarterly by the Norwegian Directorate of Health, the Norwegian Ministry of Health and Care Services and the Norwegian Ministry of Finance. as part of the National budget setting. The projections cover the budget as a whole. These projections are a component of overall expenditure control of the National Insurance scheme, and are embedded in a broader forecasting model.

Modelling is based on assessing annual changes in expenditure from 2003, with projections for 0-5 years. The data are for internal purposes only and are not publicly available.

Ex-post assessment of the predictive value of the projections is not undertaken, but the projections are updated quarterly based on actual expenditure data from the past months and years.

Inputs to the projections include:

- Budget impact as estimated in applications / assessments for reimbursement or coverage
- Past trends in pharmaceutical spending
- Changes in generic uptake
- Changes in medicine prices

Horizon scanning

The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway was launched in 2013 and includes a component of

horizon scanning.[35] The purpose of the horizon scanning process is to ensure that new and important health technologies are identified and prioritized for health technology assessments.

The system for managed introduction of new technologies is based on a broad cooperation between the four regional health authorities (including all the hospitals), the Norwegian Hospital Procurement Trust, the Norwegian Institute of Public Health, the Norwegian Medicines Agency, the Norwegian Directorate of Health and the Norwegian Radiation Protection Authority. Its overall objective is to manage the introduction of new technologies in order to meet health needs and sustainability of health systems through managed introduction and prioritization.

Horizon scanning for pharmaceuticals is performed by the Norwegian Medicines Agency (NOMA), in collaboration with the Norwegian Institute of Public Health. Its main purpose is to notify the arrival of new medicines with a predictable impact on the health system. HS reports are not assessments but they provide information on the product, indication, target population, etc. They are available online.[36]

Practically, NOMA prepares short reports (early alerts) for all new active substances and extended indications that result in new patients, between 6 and 12 months prior to the marketing authorization (MA). The scope is to ensure that new and important drugs are identified and prioritized for health technology assessment (HTA).

Pipeline meetings with companies are organised as a supplement to the early alerts with a somewhat longer time perspective (24-36 months before MA). The Norwegian Hospital Procurement Trust and Division drug procurements (LIS) are represented at these meetings. Each meeting is limited to 60 minutes and aims to collect the following information for medicines in the pipeline:

- Active substance and expected mechanism of action
- Planned medical indication
- Medical value compared to current treatment
- Schedule for submission to regulatory authorities and expected approval

Participants to the meeting are also interested in:

- Results from registration studies;
- Patient population that may be relevant for the medicine in Norway;
- Upcoming patent expiry;
- Price and expected budget impact;
- New technology challenging existing regulations.

Companies are invited to provide relevant information in written form within one week after the meeting. Information is treated confidentially, unless companies decide otherwise. Participation to these meeting is voluntary. In 2019, four dates have been defined for these meetings.

[35] See: https://nyemetoder.no/English

[36] See: https://legemiddelverket.no/english/public-funding-and-pricing/horizon-scanning

Poland

Pharmaceutical expenditure and utilisation tracking

In Poland, both pharmaceutical expenditure and pharmaceutical utilisation are tracked, to inform budgeting and control expenditure of public funds.

The National Health Fund (NHF) collects data on prescriptions dispensed by pharmacies for reimbursed medicines. Pharmacies are obliged to send to the NHF reports on turnover of reimbursed products every two weeks. The NHF also collects data on drug programme expenditure. Tracking is based on dispensing data from pharmacies and reimbursement data from NHF.

Pharmaceutical budgets

Poland sets an annual pharmaceutical budget in order to control spending and allocate a fixed share of health expenditure to pharmaceuticals. The pharmaceutical budget covers pharmacy reimbursements, drug programmes and medicines used in chemotherapy.

The budget is defined at central level, and is fixed. The annual limit of pharmaceutical expenditure is 17% of the total budget for heatlh care services financed from public funds.

The preparation of the pharmaceutical budget involves the Ministries of Health and Finance, health care payers, and the pharmaceutical industry, with the final decision made by the Ministry of Finance.

Pharmaceutical expenditure caps

Poland's pharmaceutical reimbursement system includes a general clawback mechanism, under which 50% of pharmaceutical expenditure exceeding the budget limit (17% of public health care expenditure) must be rebated by pharmaceutical companies.

It is also possible to set clawbacks as a component of a managed entry agreement concluded during the process of reimbursement negotiations.

Forecasts and projections

Pharmaceutical expenditure projections are not considered necessary for budget setting.

Horizon scanning

Poland does not currently undertake horizon scanning.

Portugal

Pharmaceutical expenditure and utilisation tracking

In Portugal, pharmaceutical expenditure and utilisation have been tracked for the last 20 years. Pharmaceutical expenditure is tracked by region, care setting, therapeutic class, ATC level 5, and individual product. Pharmaceutical utilisation is tracked by therapeutic area; care setting; ATC levels 1 through 5; and by individual product.

Reimbursement claims are collected at patient level on a monthly basis in outpatient settings. Hospital consumption is also collected on a monthly basis.

Infarmed publishes monthly and annual reports monitoring medicines utilisation and consumption, with separate reports for the ambulatory and hospital sectors. The most recent annual report presents data for 2017,with use and expenditure by broad therapeutic class, and for some products with high expenditures or growth, change by comparison with 2016, and expenditure by hospital (Infarmed, 2018[7]; Infarmed, 2018[8]). Reports and benchmarking dashboards are available on the INFARMED website.[37]

Pharmaceutical budgets

Portugal does not set an annual pharmaceutical budget.

Pharmaceutical expenditure caps

Portugal does not set a cap on total and/or public pharmaceutical expenditure.

Forecasts and projections

Short-term projections of pharmaceutical expenditure are prepared by INFARMED and presented to the Ministry of Health. The projections cover the budget as a whole and are standalone. They are based on past trends in pharmaceutical spending. They are intended for internal use only and not publicly available. There is no formal ex-post assessment of the predictive value of the projections.

Horizon scanning

Horizon scanning is not yet used in forecasting expenditure models. Infarmed has in place a horizon scanning system to plan the introduction of new medicines but is not yet using this information in forecasting exercises.

[37] See http://www.infarmed.pt/web/infarmed/profissionais-de-saude/utilizacao-e-despesa/relatorios and http://www.infarmed.pt/web/infarmed/profissionais-de-saude/utilizacao-e-despesa/benchmarking-ambulatorio

Sweden

Pharmaceutical expenditure and utilisation tracking

In Sweden, pharmaceutical expenditure has been tracked since 2003, by payer, therapeutic class, and by ATC level 5. The data are not publicly available.

Pharmaceutical utilisation has been tracked since 2006, by therapeutic area, care setting, ATC levels 3, 4, and 5, and by individual product. The data are publicly available.[38]

Pharmaceutical budgets

Sweden sets an annual pharmaceutical budget in order to apportion expenditure according to health priorities and allocate a fixed share of health expenditure to pharmaceuticals. Budgets are defined at both central and sub-national levels.

The preparation of the central pharmaceutical budget involves the Ministries of Health and Finance, with the final decision made by the Ministry of Finance.

For 2018 the total amount was SEK 27 789 million (approximately EUR 2.7 billion).[39]

The central pharmaceutical budget covers spending on prescribed outpatient medicines assessed as cost-effective by the Dental and Pharmaceutical Benefits Agency (TLV) and subsidized by government.

- According to survey responses, factors influencing pharmaceutical budget setting include:
- Macro-economic factors
- Overall fiscal/government budget constraints
- Demographic and epidemiologic trends
- Clinical guidelines involving pharmaceutical treatments
- Patent expiry dates for on-patent products
- Potential generic or biosimilar entry and uptake
- Past growth trends in pharmaceutical spending
- Anticipated market entry of new medicines
- Prices of new medicines
- Recent market entry and coverage determination of new medicines

In addition, hospital medicines and some prescribed outpatient medicines that are not covered by the government are funded at the sub-national level by regions/ county councils.

[38] See at: http://www.socialstyrelsen.se/statistik/statistikdatabas/lakemedel

[39] See https://skl.se/download/18.2ec0a40816106217d5ceb22a/1516972923886/01-2018-WEBB-Kostnader%20for%20lakemedelsformanerna.pdf

In 2018, the sub-national level financed medicines for SEK 9 016 million (approximately EUR 880 million).

Pharmaceutical expenditure caps

Sweden does not set a cap on total or public pharmaceutical expenditure.

Forecasts and projections

The National Board of Health and Welfare (NBHW) prepares short-term projections of pharmaceutical expenditure twice yearly. The projections are a standalone exercise and cover the pharmaceutical budget as a whole.

The model used to project pharmaceutical expenditures in the next two years is built on a methodology taking into account linear and exponential projections as well as historical variations. Overall volume, product mix and price trends are projected separately. These three inputs constitute the baseline scenario, which is used to model and test the potential effects that different factors, e.g. the introduction of new medicines, patent expiries, changes in clinical guidelines and practice, will have on pharmaceutical spending. The projections presented in the report for 2018-2020 have been developed in collaboration with IQVIA and are based on data extracted from public sources and eHealth databases, and discussed in national expert groups. Furthermore, the projections are based on the assumption that the regulatory framework for reimbursement remains unchanged during the projection period. However some scenarios are not taken into account in the model, either because the effect on pharmaceutical spending cannot be quantified or it is little likelihood that the scenario will eventuate (The National Board of Health and Welfare, 2018[18]).

The predictive value of the projections is assessed ex-post. The NBHW's forecast for the cost of benefits (including VAT) in autumn 2017 was SEK 23.44 million, and the actual value was SEK 23.26 million, a 0.8% percent difference. The data are publicly available.[40]

Inputs to the projections include:

- Demographic trends
- Population burden of disease
- New medicines expected to receive marketing authorisation and/or be reimbursed by health coverage schemes
- Past trends in pharmaceutical spending
- Changes in generic/biosimilar uptake
- Changes in prescribing or treatment patterns
- Changes in medicine prices
- Horizon scanning

[40] See http://www.socialstyrelsen.se/publikationer2018/2018-4-21

Horizon scanning

A horizon scanning (HS) working group was established in 2009 by the four largest county councils in Sweden. It identifies new medicines and indications expected to gain marketing authorisation within a foreseeable timeframe, in three stages:

- Data collection, monitoring sources
- Filtration and compilation of collected data – about 1–2- years before expected marketing authorization (medicines in phase II or III or their development).
- Early assessment reports describing the current state of knowledge, about 6 months before marketing authorisation.

1) The initial step of the process consists in identifying new and emerging technologies before marketing authorization. The information comes from a variety of sources. It is primarily informed by "pipeline meetings" (three meetings are scheduled for 2019) and company reports but also by information from other horizon scanning initiatives, investors reports, press release. Scientific publications, conference proceedings, information from medicines agencies and registries of clinical trials are used as secondary sources of information (Eriksson et al., 2017[9]).

2) The filtration process takes into account the following set of criteria: the size of patient population; the severity of the disease; the potential to improve patient clinical outcomes; an innovative way of treating the disease; the potential to affect treatment costs; the potential to require reorganisation of the health care system; potential safety issues needing consideration; potentially high media/public interest; potential to influence treatment guidelines; non-optimal introduction rate following marketing authorization: and potential legal, ethical or political interest. The evaluators also consider whether the medicine/indication belongs to a growing class of medicines or therapy area; whether it represents a new form of treatment or a new class of medicines; whether it is relevant to Swedish conditions.[41]

3) Early assessment reports on products/indications typically include information on expected date for marketing authorisation, clinical benefits and risks; clinical need and patient population, other completed or ongoing clinical trials for the same active substance; other completed or ongoing clinical trials for other substances in the same indication; the status of marketing authorisation in other markets, costs and other consequences on healthcare system; as well as options for post-launch monitoring.

The horizon scanning system has several outputs: a database with all identified new medicines; a list of prioritized medicines and indications, with individual early assessment reports; as well as quarterly newsletters.[42]

[41] See https://www.janusinfo.se/nationelltordnatinforande/managedintroductionthisishowitworks/inenglish/horizonscanning.5.4771ab7716298ed82ba97406.html

[42] See https://www.janusinfo.se/nationelltordnatinforande/horizonscanning.4.728c0e316219da813569ab4.html

Switzerland

Pharmaceutical expenditure and utilisation tracking

Switzerland has tracked expenditures since 23 years but information is only disaggregated by regions. This information is publicly available and this is a national data collection.[43]

Pharmaceutical budgets

Switzerland does not set a budget for pharmaceutical expenditures.

Pharmaceutical expenditure caps

Switzerland does not set a cap for pharmaceutical expenditures.

Forecasts and projections

Switzerland does not undertake projections for pharmaceutical expenditure but is considering implementing projections in 2019-2020.

Horizon scanning

At the moment horizon scanning is not part of the evaluation process in Switzerland, but Switzerland is interested in horizon scanning and involved in the initiatives of BeNeLuxA.

[43] https://www.bag.admin.ch/bag/de/home/service/zahlen-fakten/statistiken-zur-krankenversicherung/statistik-der-obligatorischen-krankenversicherung.html

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