

# Using Routinely Collected Data to Inform Pharmaceutical Policies

| EU/EEA Country Notes





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# Introduction

Routinely collected data on prescribed and dispensed medicines reflect a key component of patients' interaction with the healthcare system. When medicines are prescribed by healthcare providers or dispensed to patients, routine data are collected through pharmaceutical records, personal health records or reimbursement claims. Routinely collected data offer opportunities to generate evidence from clinical practice, and to assess and monitor the effectiveness and safety, benefit and costs of health care interventions. However, OECD and EU countries are unevenly prepared to harness the potential of routinely collected data.

To assess countries' capacities to generate evidence from clinical practice and their impact on pharmaceutical policy development, the OECD - with support from the European Commission - investigated countries' collection, uptake and use of routine data on prescribed and dispensed medicines. For that purpose, a survey was distributed to all OECD and EU member countries in the Spring of 2018.

Nineteen EU/EEA countries fully completed the survey and their responses created the basis for these EU/EEA Country Notes.

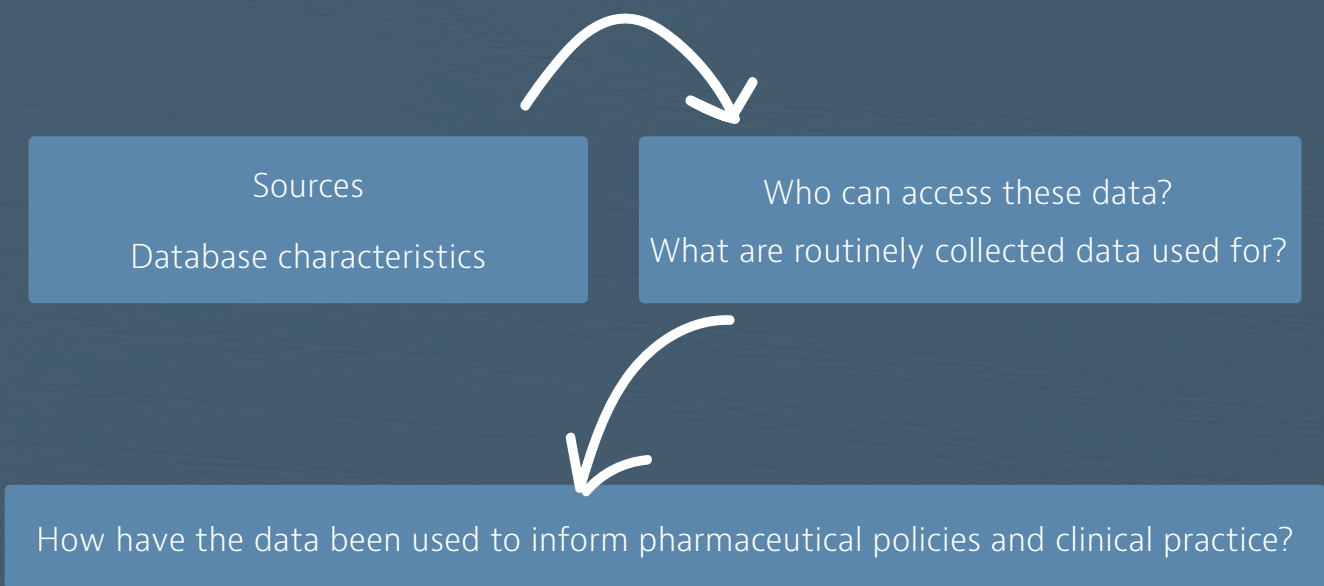
Findings from the survey also informed an analytical OECD report - Using Routinely Collected Data to Inform Pharmaceutical Policies - exploring the use of these data both in OECD and EU member countries.

The EU/EEA Country Notes and the analytical report were launched in February 2019.

# Reading the *EU/EEA Country Notes*

All *EU/EEA Country Notes* have the same structure.

They start with an opening paragraph and then, following the same pattern, present information on routinely collected data in countries:





Patient-level data on prescribed and dispensed medicines are routinely collected in Austria. These data include information on medicines that are prescribed by physicians, dispensed by pharmacists and reimbursed by the Statutory Sickness Fund.

## Sources

Reimbursement claims are the main sources of routinely collected data in Austria. The data are collected and made available at the national level covering 100% of the Austrian population that is covered by the Statutory Sickness Fund.

### Database characteristics

Routinely collected data on prescribed, dispensed and reimbursed medicines are held in the database Maschinelle Heilmittelabrechnung, with the Main Association of Austrian Social Security Institutions serving as the data custodian. The database contains patient-level information on prescribed, dispensed and reimbursed medicines between 2013 and 2017 as the latest year available.

Although the database cannot be linked with other databases containing patient-level information, it does include other patient-level data beyond prescribed and dispensed medicines, such as:

- Demographic characteristics
- Specialist group and region of the prescribing doctor and dispensing pharmacy

### Who can access these data?

- The Ministry of Health
- The Medicine Regulatory Agency
- The Statutory Sickness Funds
- HTA bodies and other agencies responsible for developing clinical guidelines
- Non-profit research units and universities

### What are routinely collected data used for?

Routinely collected data are used to monitor trends in medicine consumption and pharmaceutical spending at the national level. These data may be used to respond to specific enquiries from reimbursement authorities.

## How have the data been used to inform pharmaceutical policies and clinical practice?

In Austria, routinely collected data on dispensed medicines have been used in pharmaco-epidemiological studies. For example, Zebenholzer<sup>1</sup> et al extracted claims data from the Maschinelle Heilmittelabrechnung, in order to evaluate the use and potential overuse of pain medication (triptan) in the treatment of migraine. The study concluded that the overall triptan use and consequently overuse of triptan was low in Austria, but the risk of overuse varied between different patient groups.

While the Medicine Regulatory Agency and those in charge of health technology assessments do not consider routinely collected data in their assessments and decision-making processes, such data may provide guidance for reimbursement decisions in Austria.

1. Zebenholzer et al. (2018). Use and overuse of triptans in Austria – a survey based on nationwide healthcare claims data. *The Journal of Headache and Pain* 19:34

# Belgium



Patient-level data on prescribed and dispensed medicines are routinely collected in Belgium. These data include information on medicines that are dispensed in hospitals, ambulatory care clinics and long-term care institutions. Also patient-level information on physician - prescribed medicines are included, as long as they have been dispensed by pharmacists.

## Sources

Community pharmacy records and insurance claims are the main sources of routinely collected data in Belgium.

## Database characteristics

Routine data are collected from all the seven Belgian Sickness Funds, aggregated and made available in the Common Sickness Funds Agency's database, InterMutualistisch Agentschap - Agence InterMutualiste (IMA-AIM).

The IMA-AIM database covers 100% of the population, containing data from 2006 to 2017. The data are kept available and accessible indefinitely, IMA-AIM serving as the data custodian.

Beyond routinely collected data on prescribed and dispensed medicines, IMA-AIM database includes patient-level information on patients' demographic characteristics, mortality and information related to utilisation of other healthcare services covered and reimbursed by the sickness funds.

IMA-AIM can be linked to other databases containing patient-level information, but this is not routinely done.

## Who can access these data?

- The Ministry of Health
- Health care payers
- The Belgian Knowledge Centre (KCE)
- Non-profit research units and universities
- Other stakeholders can under certain conditions request access to aggregated data

## What are routinely collected data used for?

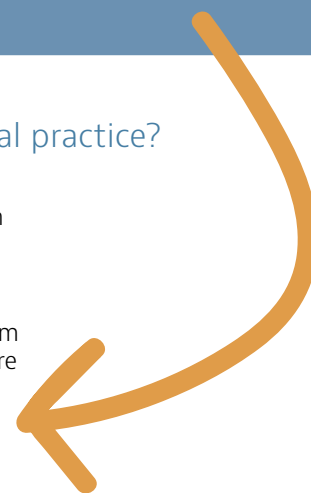
- Monitoring trends in medicine consumption
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Evaluating safety of medicines
- Evaluating effectiveness and cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Routinely collected data from the IMA-AIM databases are frequently used in published pharmaco-epidemiological studies assessing safety and effectiveness of medicines and to identify prescription patterns.

Regulatory agencies and the health technology assessment body (KCE) may take into account routinely collected data in their assessments and decision-making processes, however, evidence from observational studies are given less weight than data derived from randomised-control trials and are rarely central to decision-making.

Routinely-collected data are not used to inform price-setting or reimbursement levels in Belgium.





Patient-level data on prescribed and dispensed medicines are routinely collected in Cyprus. These data include information on medicines prescribed by physicians, dispensed by pharmacists in hospitals, ambulatory care clinics and long-term care facilities and paid by health coverage schemes.

## Sources

Hospital pharmacy records and pharmaceutical wholesalers' records are the main sources of patient-level routinely collected data on prescribed and dispensed medicines.

## Database characteristics

Routine data on prescribed and dispensed medicines are collected and made available in the Pharmaceutical Services Database at the national level covering 80% of the Cypriot population. The data custodian is the Ministry of Health. Routine data were collected for the first time in 2014 and are kept accessible for a period of 5 years.

The Pharmaceutical Services Database does not include any other types of patient-level information beyond prescription/dispensing of medicines and cannot be linked to other types of databases that do.

## Who can access these data?

- The Ministry of Health

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Research, evaluation and authorisation of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

There is no health technology assessment body in Cyprus and routinely collected data on prescribed and dispensed medicines have not been used to inform decisions on reimbursement or coverage.



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.

# Czech Republic

Patient-level data on prescribed and dispensed medicines are routinely collected in the Czech Republic. These data include information on medicines reimbursed by the health coverage scheme.

## Sources

Insurance claims are the main sources of routinely collected data.

## Database characteristics

Routine data are collected nationally and made available in the National Registry of Reimbursed Health Services (NRRHS) database at the national level, covering 100% of the Czech population.

The NRRHS has been operational since January 2018 within the National Health Information System of the Czech Republic. Institute of Health Information and Statistics of the Czech Republic serves as the data custodian.

Beyond information on prescribed and dispensed medicines, the NRRHS includes patient-level data on demographic characteristics, patients' medical history and utilisation of all types of reimbursed health services.

The NRRHS can be linked to other databases of the National Health Information System including patient-level information, which makes it possible to obtain information on selected diagnoses and mortality.

## Who can access these data?

- Employees of the data custodian (Institute of Health Information and Statistics)
- Other stakeholders through aggregated data files or analyses requests

## What are routinely collected data used for?

Since the NRRHS database has only been operational since January 2018, it is still open to identify areas in which routinely collected data will be used.

## How have the data been used to inform pharmaceutical policies and clinical practice?

Routinely collected data from the NRRHS have been used for the production of annual projections for Health insurance Funds' expenditure on particular groups of high cost medicines prescribed in special centres.





# Estonia

Patient-level data on prescribed and dispensed medicines are routinely collected in Estonia. These data include information on medicines that are prescribed by physicians, dispensed by pharmacists and reimbursed by the Estonian Health Insurance Fund.

## Sources

Community pharmacy records completed by pharmacists along with ePrescriptions are the main sources of routinely collected data in Estonia.

## Database characteristics

Routine data are collected nationally covering 100% of the population and accessible in the Prescription Center (SAP SEM platform) database with the Estonian Health Insurance Fund as the data custodian. Data are available from 2010 to 2018 and are kept available for research purposes indefinitely.

Beyond information on prescribed and dispensed medicines, the SAP SEM platform contains patient-level information on demographic characteristics of patients and diagnoses associated with every pharmaceutical prescription.

The SAP SEM platform can also be linked to other databases containing patient-level information, including diagnostic information that is not associated with prescriptions, and patients' medical history, mortality and utilisation of other health services.

## Who can access these data?

- The Ministry of Health
- The Medicine Regulatory Agency
- The Estonian Health Insurance Fund
- The Estonian Centre for Health Technology Assessment
- Non-profit research units and universities

## What are routinely collected data used for?


- Monitoring trends in medicines consumption and spending at national level
- Informing/changing clinical practice
- Monitoring provider compliance with guidelines and prescribing quality and behaviour
- Evaluating the safety of medicines
- Evaluating the effectiveness of medicines
- Evaluating the cost-effectiveness and comparative effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Routinely collected data on prescribed and dispensed medicines are not considered by regulatory bodies in charge of issuing market approvals in Estonia. Nevertheless, routinely collected data serve many purposes in other areas of pharmaceutical coverage policies and practice.

Routinely collected data from the SAP SEM Platform are used to inform clinical practice and assess the quality of care delivered in the Estonian healthcare system. For example, in 2018 routinely collected data on prescribed medicines from were used in a study assessing the appropriateness of medicines' prescribing and the quality of care provided to asthma patients.

The Estonian Centre for Health Technology Assessment includes routinely collected data from the SAP SEM Platform in their analyses, which in turn are used to inform the Estonian Health Insurance Fund's decisions on whether to include new technologies to the range of benefits publicly covered, conducting cost-effectiveness and budget impact analyses. The results of the analyses are publicly available on the Centre's website: <https://tervis.ut.ee/et/tth/raportid-0>







# Finland

Patient-level data on prescribed and dispensed medicines are routinely collected in Finland. These data include information on medicines that are prescribed by physicians, dispensed by pharmacists and reimbursed by the National Health Insurance.

## Sources

Community pharmacy records completed by pharmacists and ePrescriptions along with personalised health records completed by providers working in general practice, ambulatory care clinics or hospitals are the main sources of routinely collected data in Finland.

### Database characteristics

Routine data on prescribed and dispensed medicines are nationally aggregated covering 100% of the Finnish population.

Data on dispensed and reimbursed prescriptions are kept in the Finnish Prescription Registry (Reseptitiedosto). Data are available from 1993 to 2017 (latest year available) and the data custodian is the Social Insurance Institution (Kela).

Data on all reimbursed and non-reimbursed ePrescribed medicines are kept in the Prescription Centre database (Reseptikeskus). Data are stored in the Centre of Health and Welfare (Kanta) services and accessible upon request. Data are available from 2010 with full national coverage since 2017.

Beyond routinely collected data on prescribed and dispensed medicines, Reseptitiedosto and Reseptikeskus include data on demographic characteristics of patients.

The databases can be linked to other databases including other types of patient-level information: diagnoses not associated with prescriptions, disease registries, birth registry, mortality, and utilisation of social services and other health care services such as hospital discharges and primary care consultations.

### Who can access these data?

- The Ministry of Health
- The Medicine Regulatory Agency
- The National Health Insurance
- HTA bodies
- Non-profit research units and/or universities
- Researchers with appropriately defined research plan
- The legislation on secondary use of health and social data is currently being reformed

### What are routinely collected data used for?

- Monitoring trends in medicines consumption and/or spending at the national level
- Informing/changing clinical practice
- Monitoring provider compliance with guidelines and prescribing quality and behaviour
- Evaluating the safety and effectiveness of medicines
- Evaluating the cost-effectiveness and comparative effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

In Finland, routinely collected data may be taken into account by the medicine regulatory agency and health technology assessment body, but analyses based on observational data are graded lower than evidence derived from randomised controlled trials and are rarely central to decision-making. However, microsimulation methods based on routinely collected data are used in the policy making process to produce prospective and retrospective evaluations of planned and implemented changes of pricing and reimbursement policies.

Furthermore, routinely collected data are often used in published pharmacoepidemiological studies evaluating medicine use and prescribing quality. Finally, they inform economic and policy analyses evaluating the impact of reimbursement and pricing policies, generic substitution and the reference price system, among others. These studies have had direct impact on pharmaceutical policies in Finland and notably led to increased focus on medication safety for elderly, efforts to tackle increases of prices for generics and the establishment of a working group on rational drug use among polypharmacy patients.

Finnish Statistics on Medicines reports yearly basic figures on medicine use based on routinely collected data: <http://www.kela.fi/web/en/statistical-publications/finnish-statistics-on-medicines>



# France



Patient-level data on dispensed medicines are routinely collected in France. These data include information on medicines that are dispensed by pharmacists and reimbursed by the National Health Insurance (Assurance Maladie).

## Sources

Insurance claims are the main sources of routinely collected data on dispensed and reimbursed medicines in France.

### Database characteristics

Routine data on prescribed and dispensed medicines are collected nationally covering 99% of the population. The data are kept in the SNIIRAM database with the National Health Insurance Fund (CNAM) as the data custodian. Data are available from 1999 to 2017 (latest year available) and kept accessible for research purposes indefinitely.

Beyond routinely collected data on dispensed and reimbursed medicines, SNIIRAM includes patient-level information on mortality and utilisation of other types of healthcare services such as: doctors' consultations, procedures performed by ambulatory care physicians, laboratory and imaging tests, medical devices purchased directly by patients, and consultations with physiotherapists, nurses, midwives and orthoptists.

Additionally, information on high cost medicines/medical devices paid on top of DRG payments is collected in the SNIIRAM database.

SNIIRAM can also be linked to other databases including patient-level information on hospitalisations (diagnostics, surgical procedures, length of stay etc.), mortality and patients' demographic characteristics.

### Who can access these data?

- The Ministry of Health
- The Medicine Regulatory Agency
- Health care payers
- HTA bodies or other agencies responsible for developing clinical guidelines
- Non-profit research units and/or universities
- Everyone with a research project of public interest, with authorisation from Institut National des Données de Santé (National Institute for Health Data)

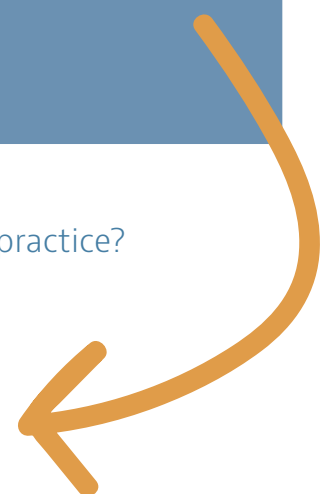
### What are routinely collected data used for?

- Monitoring trends in medicines consumption and/or spending at the national level
- Monitoring patient adherence to treatment
- Monitoring provider compliance with guidelines
- Evaluating the safety of medicines
- Evaluating the effectiveness and cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Routinely collected data on prescribed and dispensed medicines are used to inform decisions made by regulatory agency in charge of issuing market approvals.

Health technology assessment bodies take into account routinely collected data in their assessments and decision-making processes and these data have also been used to inform price setting and coverage policies. For example, routinely collected data have been used to assess specific risks associated with some products benfluorex (withdrawn from the market), pioglitazone (suspension of marketing authorisation and delisting), olmesartan (delisting), 3rd generation combined hormonal contraceptives (delisting); or to monitor prescription and use of clorazepate dipotassium (change in packaging required to limit overuse). In other cases, assessments confirmed the safety profiles of products and did not lead to any change in marketing authorisation or coverage (e.g. HPV vaccines).



# Ireland

Patient-level data on prescribed and dispensed medicines are routinely collected in Ireland. These data include information on medicines that are prescribed by physicians and dispensed by pharmacists in community pharmacies as well as in ambulatory care clinics and long-term care institutions.

## Sources

Community pharmacy records, either completed by pharmacists or ePrescriptions, are the main sources of routinely collected data in Ireland.

## Database characteristics

Routinely data on prescribed and dispensed medicines are nationally aggregated and kept in the National Shared Services Primary Care Reimbursement Service of the Health Service Executive in Ireland (HSE-PCRS) database.

The HSE-PCRS database provides details on monthly dispensed medications for each individual within the general medical services scheme. Data are available from 1998 to 2018.

Beyond routinely collected data on dispensed and reimbursed medicines, the HSE-PCRS database includes patient-level information on demographic characteristics as well as on mortality. The HSE-PCRS database cannot be linked to other databases containing patient-level information.

## Who can access these data?

- Health Information and Quality Authority (HIQA) in charge of conducting health technology assessments
- Non-profit research units and universities

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Evaluating the cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

In Ireland, regulatory authorities do not take into account routinely collected data in their decision-making processes. However, several examples exist where routinely collected data have informed health technology assessments. In 2017, for example, Health Information and Quality Authority (HIQA) based its assessment of smoking cessation treatments on HSE-PCRS data and recommended that the uptake of varenicline should be maximised, alone or in combination with nicotine replacement therapy, among smokers wishing to use some type of pharmacological support in their attempt to quit smoking. When concerns regarding over-prescriptions were raised, HSE-PCRS data were used to monitor prescribing behaviour and prescribers' compliance with guidelines. The analysis further identified opportunities for substantial cost savings if generic substitution were implemented at the national level.

HSE-PCRS data have further been used to inform clinical practice and influence prescribing behaviour of antidepressants. The Irish Medicines Management Programme on Preferred Drugs reviewed the prescription data from the HSE-PCRS database antidepressants in order to guide prescribers towards prescribing the antidepressant of proven safety, efficacy and cost-effectiveness in the management of patients diagnosed with depression.



Patient-level data on prescribed and dispensed medicines are routinely collected in Italy. These data include information on medicines prescribed by physicians, dispensed by pharmacists (including over-the-counter drugs) and reimbursed by national health insurance. The Italian Medicines Agency (AIFA) Monitoring Registries include data on a subset of medicines dispensed in hospitals.

## Sources

Routinely collected data are extracted from personal health records, including electronic health records completed by physicians or other providers working in hospitals, general practice or ambulatory care clinics.

### Database characteristics

Routine data are collected regionally and aggregated nationally covering 100% of the Italian population. Data have been available from 2012 and are accessible and available indefinitely.

Routinely collected data on prescribed and dispensed medicines are available in the AIFA Monitoring Registries, for which AIFA serves as the data custodian, and Tessa Sanitaria, with the Ministry of Finance and Economics serve as the custodian.

Beyond data on prescribed and dispensed medicines, these data also include information on patients' demographics. Through the AIFA Monitoring Registries, information on patient characteristics and clinical outcomes are collected.

The AIFA Monitoring Registries and the Tessa Sanitaria cannot be linked to other databases containing patient-level information.

### Who can access these data?

- The Ministry of Health and other Governmental Ministries
- The Italian Medicines Agency (AIFA)
- Health technology assessment bodies responsible for developing clinical guidelines
- For AIFA Monitoring Registries, market authorisation holders may only access data on their own products

### What are routinely collected data used for?

- Monitoring and describing trends in medicine consumption and spending at the national level
- AIFA Monitoring Registries can be used to monitor patients' adherence to treatment and evaluate effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

AIFA's National Observatory on the Use of Medicines (OsMED) publishes annual reports containing the latest available data on consumption trends and prescription patterns in addition to pharmaceutical spending by sector and region.

Regulatory bodies use routinely collected data in their assessments and decision-making processes. Routinely collected data and data from the AIFA Monitoring Registries have been used in post-marketing evaluations of authorised medicinal products in Italy.

Agencies in charge of health technology assessment take into account routinely collected data on prescribed and dispensed medicines in their assessments. Alongside data on utilisation, treatment duration and other clinical information, routinely collected data are used in reassessments of prices and reimbursement conditions of pharmaceuticals that are included in the range of benefits publicly covered.



# Latvia

Patient-level data on prescribed and dispensed medicines are routinely collected in Latvia. These data include information on medicines that are dispensed by pharmacists and reimbursed by the National Health Insurance.

## Sources

Community pharmacy records, either completed by pharmacists or ePrescriptions, are the main sources of routinely collected data in Latvia.

## Database characteristics

Routinely collected data on dispensed and reimbursed medicines are kept in the national database BMANS with the National Health Service as data custodian covering 100% of the population. Data are available from 2004 to 2017 and kept accessible indefinitely.

Beyond routinely collected data on dispensed and reimbursed medicines, the BMANS database include patient-level information on demographic characteristics, diagnoses associated with every pharmaceutical prescription as well as on mortality.

The BMANS database can also be linked to other databases containing patient-level information in addition to the ones above, notably diagnoses unrelated to prescriptions, doctors' consultations and hospitalisations.

## Who can access these data?

- Employees of the data custodians

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level

## How have the data been used to inform pharmaceutical policies and clinical practice?

Regulatory bodies in charge of issuing market approval do not take into account routinely collected data in their assessments and decision-making processes. Neither have such data been routinely used in health technology assessments or to inform price setting or coverage decisions in Latvia.



# Lithuania



Patient-level data on prescribed and dispensed medicines are routinely collected in Lithuania. These data include information on medicines that are prescribed by physicians, dispensed by pharmacists and reimbursed by the National Health Insurance Fund.

## Sources

Insurance claims, community pharmacy records completed by pharmacists and ePrescriptions along with personalised health records completed by providers working in general practice, ambulatory care clinics or hospitals are the main sources of routinely collected data.

## Database characteristics

Routinely collected data on prescribed and dispensed medicines are kept in the national database SVEIDRA with the National Health Insurance Fund as data custodian covering 96% of the population. Data are available from 2013 to 2018 and kept accessible for 5 years.

Beyond routinely collected data on dispensed, prescribed and reimbursed medicines, the SVEIDRA database include patient-level information on demographic characteristics and diagnoses associated with every pharmaceutical prescription.

In addition to the information above, the SVEIDRA database can be linked to other databases containing patient-level information on other diagnoses not associated with prescriptions, patients' medical history and data extracted from different national disease registries.

## Who can access these data?

- The Ministry of Health

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour

## How have the data been used to inform pharmaceutical policies and clinical practice?

Regulatory bodies in charge of issuing market approval do not take into account routinely collected data in their post-marketing assessments and decision-making processes.

Health technology assessment bodies may take into account routinely collected data in their analyses, but analyses based on observational data are graded lower than evidence derived from randomised controlled trials.

Data from the SVEIDRA database have, for example, been used to influence coverage conditions for antibiotics in Lithuania. The National Health Insurance Fund collected and analysed data on the consumption of antibiotics and presented the findings to the National Reimbursement Committee. As a result, the Ministry of Health and National Doctors' Association are currently revising the prescription and reimbursement guidelines aiming to restrict the indications for which antibiotics can be prescribed and reimbursed and reduce the overall consumption of antibiotics. The revised list of indications has yet to be presented to the Reimbursement Committee.



# Luxembourg

Patient-level data on prescribed and dispensed medicines are routinely collected in Luxembourg. These data include information on medicines reimbursed by the National Health Insurance (Caisse Nationale de Santé, CNS).

## Sources

Personal medical records completed by providers, including those working in general practice and hospitals are the main sources of routinely collected data.

## Database characteristics

Routinely collected data on reimbursed medicines are integrated in the CNS data warehouse and kept in the database CNS Prestations. The data are collected at the health insurance level and nationally aggregated covering 100% of the insured population with the CNS serving as the data custodian. The data are available from 1994 to 2017 (latest year available) and are accessible indefinitely.

Beyond routinely collected data on reimbursed medicines the CNS Prestations include information on prescribing physicians as well as a unique patient identifier that allows linking of the patient-level information in CNS Prestations to other databases including information such as;

- Demographic characteristics
- Other diagnoses not associated with prescriptions
- Patients' medical history
- Mortality
- Utilisation of health care and social care services

## Who can access these data?

- The Ministry of Social Security

## What are routinely collected data used for?

- Monitoring trends in medicines consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines and prescribing quality and behaviour
- Evaluating the safety and effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

CNS uses routinely collected data on reimbursed medicines in analyses of clinical practice, to monitor pharmaceutical prescription patterns and to identify drivers of growing pharmaceutical spending. For example, the Conseil Scientifique provided recommendations on antibiotics prophylaxis prior to surgery and evaluated the clinical guidelines for insomnia treatment in general practice using routinely collected data from the CNS Prestations database. CNS published in 2017 an analysis of pharmaceutical spending between 2011-2015 which found that medicines used in the treatment of hepatitis C were the main driver of spending growth in Luxembourg.

When it comes to coverage decisions and health technology assessments, evidence from randomised clinical trials is graded higher compared to analyses based exclusively on observational data. Regulatory bodies and health technology assessment agencies may therefore consider routinely collected data in their assessments, but these data are rarely central to decision-making. Nevertheless, routinely collected data have been used to inform decisions on price-setting and inclusion/exclusion from public coverage schemes.



# Malta



Patient-level data on prescribed and dispensed medicines are routinely collected in Malta. These data include information on medicines prescribed by physicians, dispensed by pharmacists in hospitals, ambulatory care clinics, and long-term care institutions as well as reimbursed by national health insurance.

## Sources

Personal medical records completed by providers, including those working in general practice, ambulatory care clinics and hospitals are the main sources of routinely collected data.

## Database characteristics

Routinely collected data on medicines are kept in separate databases in Malta. The entitlement databases, Schedule V, and the Medicines Approval Section both have the Pharmacy of your Choice (POYC) as the data custodian. The dispensing databases are also kept separate and managed by the pharmacist of the dispensing entity.

Although the data are not aggregated to the national level, the databases cover 100% of the Maltese population. Data are available from 2000 to 2018 and can be accessed indefinitely.

The databases cannot be linked to other databases containing patient-level information. Beyond routinely collected data on prescribed, dispensed and reimbursed medicines, the databases include patient-level information on:

- Demographic characteristics
- Diagnoses associated with every pharmaceutical prescription
- Other diagnoses not associated with prescriptions
- Patients' medical history
- Results of laboratory tests
- Results of medical imaging
- Mortality

## Who can access these data?

- The Ministry of Health
- HTA bodies or other agencies responsible for developing clinical guidelines
- Non-profit research units and/or universities
- Consultants

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Evaluating the safety and effectiveness of medicines
- Evaluating comparative effectiveness and cost-effectiveness of medicines
- To raise orders and support procurement processes

## How have the data been used to inform pharmaceutical policies and clinical practice?

In Malta, routinely collected data are used in daily practice to support and improve procurement processes and ensure sustainability of access to medicines. Most of these studies are not made public to ensure confidentiality of patient details and pharmaceutical prices. The Medicine Regulatory Agency in charge of issuing market approvals and health technology assessment body do not take into account routinely collected data in their assessments and decision-making processes.

Nevertheless, routinely collected data have been used to inform decisions on price-setting and inclusion/exclusion from public coverage, for example by estimating the potential budget impact of including a specific treatment to the range of health benefits publicly covered.





# Netherlands

Patient-level data on prescribed and dispensed medicines are routinely collected in the Netherlands. These data include information on medicines that are dispensed by pharmacists.

## Sources

Pharmaceutical records completed by pharmacists are the main sources of routinely collected data.

## Database characteristics

Routinely collected data on dispensed medicines are kept in the database of the Sticthing Farmaceutische Kengetallen (SFK), who serve as the data custodian.

The data are aggregated nationally and cover 95% of the Dutch population. Data are available from 2008 to 2018 and can be accessed for a period of 10 years.

While the SFK database cannot be linked to other databases containing other types of patient-level information, SFK database includes information on patients' demographic characteristics, the geographical region where the medicine was dispensed and over-the-counter medicines dispensed to patients.

## Who can access these data?

- The Ministry of Health, Welfare and Sports
- The Medicine Regulatory Agency
- Organisations linked to the Ministry of Health, Welfare and Sports
- General practitioners
- Academic researchers

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Evaluating cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Health technology assessment bodies do not take into account routinely collected data in their assessments and decision-making, but cost-effectiveness analyses based on routinely collected data are used to inform coverage decisions on whether medicines should be included or excluded from the range of benefits covered.

Analyses conducted using routinely collected data on dispensed medicines in the Netherlands are available on the websites of the National Institute for Public Health and Environment [www.rivm.nl](http://www.rivm.nl)



Patient-level data on prescribed and dispensed medicines are routinely collected in Norway. These data include medicines that are prescribed by physicians, dispensed by pharmacists either in pharmacies or in ambulatory care clinics and long-term institutions and reimbursed by health coverage schemes.

## Sources

Community pharmacy records and personal health records are the main sources of routinely collected data. The data are available from 2004 onwards and cover 100% of the Norwegian population.

### Database characteristics

Routine data on prescribed medicines are kept in the Norwegian Prescription Registry with the Norwegian Institute of Public Health serving as the data custodian. All data are kept accessible indefinitely.

Beyond routinely collected data on prescribed medicines, the Norwegian Prescription Registry contains information on patients' demographic characteristics and mortality.

The Prescription Registry can further be linked to other databases including patient-level information (for ex. health surveys, registries, population cohorts) containing information beyond data on prescribed and dispensed medicines. These databases include information on:

- Demographic characteristics
- Diagnostic information
- Medical history
- Lifestyle and health status
- Genetic information
- Mortality
- Health service consumption

### Who can access these data?

- The Ministry of Health and Care Services
- The Medicine Regulatory Agency
- Health care payers
- HTA bodies or other agencies responsible for developing clinical guidelines
- Non-profit research units and/or universities

### What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring patients' adherence to treatment
- Monitoring providers' compliance with guidelines, prescribing quality and behaviour
- Evaluating the safety and effectiveness of medicines
- Evaluating comparative effectiveness and cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Routinely collected data on prescribed and dispensed medicines are not used to inform coverage decisions in Norway. Nevertheless, data from the Norwegian Prescription Registry are often used in research and have been used in published studies, for example in the assessment of cancer risk in diabetes patients, research on attention deficit hyperactivity disorder (ADHD) and trends in use of anticoagulants.

Studies carried out using the routine data on prescribed medicines are publicly available.

<https://www.fhi.no/hn/helseregistre-og-registre/reseptregisteret/publikasjonsliste-for-reseptregisteret/>





# Portugal

Patient-level data on prescribed and dispensed medicines are routinely collected in Portugal. These data include information on and medicines prescribed by physicians and reimbursed by the health coverage scheme.

## Sources

Reimbursement claims data and personal medical records completed by providers, including those working in general practice, ambulatory care clinics and hospitals, are the main sources of routinely collected data.

## Database characteristics

Routine data on prescribed medicines are kept in the PEM database, while routine extracted from reimbursement claims are kept in the CCF database.

The data are collected and made available at the national level covering 100% of the Portuguese population. The data are available from 2014 to 2018.

The Portuguese Shared Services in the Ministry of Health (SPMS) is in charge of aggregating data, while the National Authority of Medicines and Health Products (INFARMED) manages the data and produces analytical reports.

Beyond routinely collected data on prescribed and reimbursed medicines, the databases do not contain other types of patient-level information.

The databases cannot be linked to other databases containing patient-level information.

## Who can access these data?

- The Ministry of Health

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Informing and changing clinical practice
- Monitoring provider compliance with guidelines, prescribing quality and behaviour

## How have the data been used to inform pharmaceutical policies and clinical practice?

Regulatory agencies and health technology assessment bodies take into account routinely collected data in their assessments and decision-making processes.

Routinely collected data have been used in the negotiations of expenditure caps in managed entry agreements. Furthermore, routinely-collected data are also used to define who is eligible for coverage and to inform decisions on price-setting and inclusion/exclusion from public coverage schemes.




 A banner image showing the word "Romania" in white text on a blue, brush-stroke-like background. To the right, there is a photograph of several white capsules and a blister pack of pills on a wooden surface.
 

# Romania

Patient-level data on prescribed and dispensed medicines are routinely collected in Romania. These data include information on medicines prescribed by physicians, dispensed by pharmacists and in hospitals as well as medicines reimbursed by national health insurance.

## Sources

Hospital pharmacy records completed by pharmacists and ePrescriptions along with personalised health records completed by providers working in general practice, ambulatory care clinics or hospitals are the main sources of routinely collected data in Romania.

## Database characteristics

Routinely collected data on prescribed and dispensed medicines are collected and analysed by District Health Insurance Houses at the regional level before being aggregated and administrated at the national level. Data are made available in the SIUI SIPE database at the national level covering the insured Romanian population, with the National Health Insurance House (CNAS) serving as the data custodian. Routinely collected data are available from 2012 to 2018 and can be accessed indefinitely.

Beyond data on prescribed and dispensed medicines, the SIUI SIPE database includes patient-level information on demographic characteristics and diagnoses associated with every pharmaceutical prescription.

SIUI SIPE can also be linked to other databases including patient-level information on other diagnoses not associated with prescriptions, patients' medical history, genetic information, lifestyle-related factors and utilisation of health-care services.

## Who can access these data?

- The Ministry of Health

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Monitoring provider compliance with guidelines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Regulatory bodies and health technology assessment agencies do not consider routinely collected data in their assessments and decision-making processes.

Neither have routinely collected data on prescribed and reimbursed medicines been used to inform price-setting or coverage decisions.

Studies based on routinely collected data on prescribed and dispensed medicines are published on the CNAS website: [www.cnas.ro//page/consum-medicamente.html](http://www.cnas.ro//page/consum-medicamente.html)

# Sweden

Patient-level data on prescribed and dispensed medicines are routinely collected in Sweden. These data include information on reimbursed medicines dispensed by pharmacists.

## Sources

Community pharmacy records completed by pharmacists and ePrescriptions are the main sources of routinely collected data.

## Database characteristics

Routinely collected data on prescribed, dispensed and reimbursed medicines are made available in the Swedish Prescribed Drug Register with the National Board of Health and Welfare serving as the data custodian.

The data are collected nationally and cover 100% of the Swedish population. In the Swedish Prescribed Drug Register, data are available from 2005 to 2018 and can be accessed indefinitely.

Beyond information on prescribed and dispensed medicines, the Swedish Prescribed Drug Register includes patient-level information on patients' demographic characteristics.

In addition, the Swedish Prescribed Drug Register can be linked to other databases including patient-level information on:

- Physiologic characteristics of patients
- Diagnoses associated with every pharmaceutical prescription
- Patients' medical history
- Other information extracted from disease-specific registries
- Results of laboratory tests and medical imaging
- Genetic information
- Mortality
- Other measures of health status
- Life-style-related factors
- Utilisation of social care services
- Inpatient and outpatient visits

## Who can access these data?

Non-profit research units and/or universities

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and national spending
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Informing and changing clinical practice
- Evaluating safety and effectiveness of medicines
- Evaluating comparative effectiveness and cost-effectiveness of medicines

## How have the data been used to inform pharmaceutical policies and clinical practice?

Regulatory bodies and health technology assessment agencies may consider routinely collected data in their assessments, but these data are rarely central to decision-making. Analyses based on observational data are graded lower than evidence derived from randomised controlled trials. In the past, routinely-collected data have been used to inform decisions on price-setting and inclusion/exclusion from public coverage schemes.

Routinely collected data on prescribed and dispensed medicines from the Swedish Prescribed Drug Register have been used in several studies and analyses looking at effectiveness and safety of medicines. In the Swedish National Board on Health and Welfare's annual publication on the Quality and Effectiveness of the Swedish healthcare system, routinely collected data on prescribed medicines are used to monitor medicine consumption and prescription patterns of anticoagulants and antibiotics.

# United Kingdom

Patient-level data on prescribed and dispensed medicines are routinely collected in the United Kingdom. These data include information on reimbursed medicines, prescribed by physicians and dispensed by pharmacists.

## Sources

Community pharmacy records completed by pharmacists and ePrescriptions and personalised health records completed by providers working in general practice, ambulatory care clinics or hospitals are the main sources of routinely collected data.

## Database characteristics

Individual patient level data from community pharmacies and individual general practices are pooled to create a national database by different organisations for various purposes including healthcare planning, payments and research. Data are available from 2014 to 2018, cover 100% of the population and can be accessed for 60 months.

Prescription data are accessible to authorised users via the online application ePACT2 for which the NHS Business Services Authority serves as the data custodian. Patient-level data from a network of general practices across the UK are collected by and accessible via the Clinical Practice Research Datalink (CPRD) with the Medicines and Health Care Products Regulatory Agency serving as the data custodian.

Beyond information on prescribed and dispensed medicines, the CPRD include patient-level information on patients' demographic characteristics, diagnostics, medical history, test results, lifestyle-related factors, mortality and consumption of other health care services. In addition, the CPRD can be linked to disease-specific registries.

## Who can access these data?

- The Department of Health and Social Care
- NHS
- Clinical Commissioning groups (local NHS payers)
- National level data are available to organisations that can provide a valid reason for requiring access

## What are routinely collected data used for?

- Monitoring trends in medicine consumption and spending at the national level
- Monitoring provider compliance with guidelines, prescribing quality and behaviour
- Informing and changing clinical practice
- Evaluating safety and effectiveness of medicines
- Evaluating cost-effectiveness of medicines
- Measuring the impact and effectiveness of regulatory actions and guidance, assessing vaccines safety and effectiveness surveillance (CPRD)

## How have the data been used to inform pharmaceutical policies and clinical practice?

For more than 30 years, research using CPRD data and services have informed clinical guidance and best practice, resulting in over 2,000 peer-reviewed publications investigating drug safety, use of medicines, effectiveness of health policy, health care delivery and disease risk factors.

Regulatory bodies grade evidence from observational studies lower than evidence derived from randomised controlled trials. Routinely collected data used to inform health technology assessments of pharmaceuticals normally have a supporting character only and rarely play a central role in decision-making.

The current situation may change in the future because of managed access for certain treatments, which will normally be in either highly specialised technologies used in treatment of ultra-rare conditions where it may not be feasible to conduct randomised controlled trials. The new operating model of the Cancer Drugs Fund permits access to promising cancer treatments, despite significant clinical uncertainty. When NICE recommends a treatment for use in the Cancer Drugs Fund, there is managed access while further data are collected and the guidance is subsequently reviewed. The additional data may come from a clinical trial or other sources such as routinely collected data and Public Health England's datasets.

## Contact

Health Division, OECD

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<http://www.oecd.org/els/health-systems/routinely-collected-data-to-inform-pharmaceutical-policies.htm>

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](https://ec.europa.eu/health/policies/costeffective_medicines_en)

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