Department of Registers and Statistics
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Statistical register's production and quality

National Prescribed Drug Register

What follows is a description of the register of all withdrawals of prescription drugs and certain prescription commodities.

Reference period

From July 2005 onwards. The Register is updated on a monthly basis.

Table of contents

Production of the statistical register

F1 Context of the statistical register

The National Board of Health and Welfare maintains a number of personal ID number-based registers that are used as a basis for statistics and research on health care and social services. The National Prescribed Drug Register is one of the National Board of Health and Welfare's health data registers. The National Prescribed Drug Register is an individual register that covers all pharmacy dispensing of prescription drugs and prescription-only commodities.

F2 Design

F2.1 Outline of register content

The National Prescribed Drug Register includes all withdrawals of drugs dispensed on prescription and all eligible consumables and foodstuffs dispensed on prescription in pharmacies from July 2005 onwards. Around 100 million withdrawals are made annually. Thus, the Register does not include non-prescription sales of drugs, or inpatient medication orders administered in the health care sector.

F2.2 Data sources

Sales transactions for prescription drugs are continuously collected from pharmacies and forwarded to the Swedish eHealth Agency's sales transaction register, *FOTA*. Data collection is automated through connection to the pharmacy's administrative system and is instantaneous. Additional information is linked to each transaction through automated cross-checks with the following registers also held by the Swedish eHealth Agency:

- The *EXPO* register of dispensaries contains information about pharmacies in Sweden that are authorised by the Swedish Medical Products Agency to operate an outpatient pharmacy.
- The *FOLK* register of power-of-attorney documentation collects the information that pharmacies record about customers/healthcare entities when processing power of attorney.
- The *FORS* register of licenses collects information on licensed prescribers, specialist qualifications and restricted prescribing rights.
- The *ARKO* register of workplace codes contains information on healthcare workplace codes.

The national *VARA* register of articles and products contains information on pharmaceutical products.

F2.3 Time frame

The Register is updated every month with data from the Swedish eHealth Agency. Updates are made approx. one week into the subsequent month.

F2.4 Collection procedure

F2.4.1 Data collection methods and providers

Data on prescription drugs are collected with a process that is largely automated, with data regularly extracted directly from administrative systems. All those who are authorised to sell medicines to consumers are obliged to provide the Swedish eHealth Agency with the information necessary for the Agency to keep statistics on retail trade, as stated in *Lagen om handel med läkemedel* (2009:366) (Act on trade in pharmaceuticals). The Swedish eHealth Agency, in turn, submits data on prescription dispensing to the National Board of Health and Welfare, as stated in *Lagen om nationell läkemedelslista* (2018:1212) (National Medication List Act).

Once the Swedish eHealth Agency has submitted the data to the National Board of Health and Welfare, the eHealth Agency is obliged to delete personal data within three months. The eHealth Agency is not allowed by law to store personal ID numbers.

F2.4.2 Measurement

The sales transactions are created in the pharmacy's POS systems and sent instantly to the Swedish eHealth Agency. The data reported by pharmacies are linked to the benefit system and forms the basis for the reimbursement of benefit amounts.

F2.4.3 Defective deliveries

Variable EDATUM 2005: a delay in the recording of EDATUM for the year 2005 means that 25 to 35 per cent of the records in this year have EDATUM equal to the last date of the month.

Variables OTYP and TRANSTYP 2017: Around 2.4 million entries with an invoicing period of March-May 2017 have incorrect values. This represents about eight per cent of the total number of entries in the Register for these three months. The error means that records that should have had the value 'R' or 'L' have been given the value '3' for the variable OTYP, and that entries that should have had the value '*Vanlig förskrivning*' have been given the value '*Förskrivning till dospatienter*' for the variable TRANSTYP.

F2.5 Processing with review

F2.5.1 Coding

The product number of the received medicinal product is stored in the National Prescribed Drug Register and is used as a key to retrieve updated information on the product from the product register. The ATC code or DDD value of a medicinal product may change. Detailed information on the medicinal product dispensed (e.g., ATC, DDD, strength) can be found in a separate register that is updated daily by the eHealth Agency. The medicines in the Register are categorised by the ATC codes defined by the WHO. ATC codes classify medicines according to their use and chemical substance. ATC codes have initial letters A-V. Consumables instead have product-grouping codes (assigned by the Swedish Dental and Pharmaceutical Benefits Agency, TLV) and begin with Y (these codes are also included in the variable ATC).

F2.5.2 Duplicate check

See F2.5.3 below.

F2.5.3 Reasonableness check

The Swedish eHealth Agency performs quality control of the statistics in the form of validations and checks for unauthorised values and combinations of values (see Annex 1).

F2.5.4 Imputations

No imputations are made.

F2.5.5 Model-based calculations

No model-based calculations are made.

F2.5.6 Comparisons with other registers and data sources

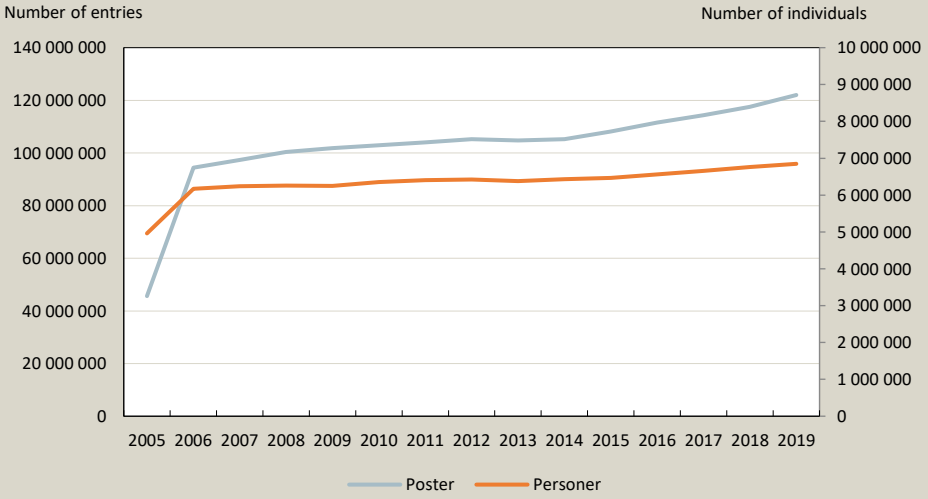
The Swedish eHealth Agency has sales data on the entire Swedish pharmaceutical market broken down by prescription, inpatient medication order and self-care. These data can be used to calculate the proportion of medicine use that is dispensed on prescription and thus included in the National Prescribed Drug Register (e.g., as a proportion of the total number of DDDs sold for a particular ATC code).

F3 Implementation

F3.1 Quantitative information

The number of registered dispensations (entries) has increased from just under 100 million to 120 million per year since the establishment of the Register. The number of entries has increased slightly faster than the unique number of individuals retrieved, reflecting an increase in drug use over the period.

Figure 1: Number of entries and individuals per year



Source: The National Prescribed Drug Register, National Board of Health and Welfare

F3.2 Deviations from the design

No significant deviations from the design have been made.

Statistical register quality

K1 Relevance

K1.1 Objectives and information needs

K1.1.1 Register objective

The purpose of the Register is to provide a basis for the production of statistics, monitoring, evaluation and quality assurance of health care, and research into drug use, safety and efficacy.

K1.1.2 Information needs of register users

The Register is used to describe the use of prescription medicines as well as the distribution of drug use at the population and national level. Statistics based on the Register are used by numerous public authorities and representatives from the pharmaceutical industry, in research and journalism, for quality assurance and monitoring and as a basis for public debate.

K1.2 Register content

K1.2.1 Object and population

The target and observation object of the Register is all withdrawals of prescription drugs (as well as eligible consumables and food) dispensed at pharmacies in Sweden. The target population is everyone who collects prescriptions medicines (and eligible consumables and food) from pharmacies in Sweden.

Coordination numbers are not collected, but enter the Register as invalid personal ID numbers.

K1.2.2 Variables

The National Prescribed Drug Register contains data on:

- Patient - sex, age, place of registration, personal ID number,
- Dispensed product - e.g., prescription and dispensing date, prescription type, product number, dosage text, costs and county code of the dispensing pharmacy. More detailed information on the product, e.g., name of the medicine, ATC code can be obtained via a separate product register, and
- Prescriber - profession (midwife, dentist, doctor, etc.), specialisation (e.g., surgery), administrative details of the workplace (e.g. county, form of ownership, field of activity).

A complete list of variables is available on the Register's website.

K1.2.3 Reference times

The National Prescribed Drug Register contains data as of July 2005. The Register is updated on a monthly basis.

K2 Reliability

K2.1 Overall reliability

The statistics are based on a comprehensive survey where there is a legal obligation for pharmacies to provide information. Data collection is made through a process that is automated and occurs instantaneously at the point of sale in pharmacies. Reliability is considered very good, with no known major non-response or measurement errors. The data reported by pharmacies are linked to the benefit system and forms the basis for the reimbursement of benefit amounts.

K2.2 Sources of uncertainty

K2.2.1 Coverage

The Register is a comprehensive data collection where the provision of information is regulated by law and where the information is used as a basis for the reimbursement of benefits, thus providing strong incentives to provide information. The Swedish eHealth Agency monitors newly established pharmacies in particular. Coverage should therefore be very high, and there is no known object non-response. However, the Swedish eHealth Agency has thus far not made any systematic non-response measurements and therefore cannot comment with full certainty on the size of any non-response.

The Register does not cover inpatient medication orders. Depending on how the supply of medicines is organised in the regions, a medicine may be given as an inpatient medication order or prescribed through a pharmacy, and therefore the treatments covered by the Register may be different. This is mainly due to the following:

- Some regions choose to administer certain medicines more extensively in day hospital rather than prescribing them. In these cases, the data will be categorised under inpatient medication orders and not under prescription medicines. Other regions take the opposite approach, and even medicines administered intravenously (and thus almost exclusively by healthcare professionals) can in some cases be dispensed on prescription. These are mainly expensive drugs, such as anti-cancer drugs and biologics for the treatment of rheumatoid arthritis and other autoimmune diseases.
- Some nursing homes/specialised housing have their own drug stores that provide patients with their prescription medicines, rather than dispensing them in pharmacies. In these cases as well, the data will be categorised under inpatient medication orders and not under prescription medicines.
- Vaccines are usually not prescribed but ordered directly from the vaccination centre. Again, the data will be categorised under inpatient medication orders and not under prescription medicines.

K2.2.2 Measurement

The risk of measurement errors in the Register is low because the collection process is based on administrative systems. The Swedish eHealth Agency carries out quality-control checks on the data in the form of validations and checks for unauthorised values and combinations of values. These checks are summarised

in Annex 1. The Swedish eHealth Agency has not received any indications of significant measurement errors during the year.

In the National Prescribed Drug Register, negative values may occur for the variables *antal*, *tkost*, *patkost*, *lankost* and/or *fddd*. This may be because a medicine has been registered in the system but then not collected, or because a pharmacy has accepted a return of a medicine (e.g., in case of product failure). There may also be misreported transactions that need to be corrected for some reason. Whatever the information to be changed, a whole entry/row (the original row) is credited and a new row is sent. For example, in 2019 about 0.09 per cent of the rows had a negative value for the variable number.

In the event that the FOTA sales-transaction register or the pharmacy reporting system is down, pharmacies may store the transactions on their premises and report retrospectively, creating a backlog.

Transactions are recorded at the time of invoicing, which may be later than the time of dispensing. The Register is divided into years and months based on the pharmacy's billing months and not the month of dispensing. This means that between 10,000 and 50,000 entries each year, corresponding to 0.01-0.05 per cent of the entire year's entries, lag behind the next annual file. The backlog may be slightly larger between months. If exact dates are important, selection by year or month from the variable *edatum* may be needed.

K2.2.3 Non-response

As all pharmacies must report using an automated process, the coverage is assumed to be very good (see above, K2.2.1 Coverage), and non-response at the variable level is very low.

Coordination numbers are not collected for the National Prescribed Drug Register, but are instead registered as invalid personal ID numbers. For invalid or missing personal ID numbers and reserve numbers, information on age, sex and place of civil registration is not recorded. This also applies when a date of birth is recorded instead of a personal ID number.

However, this non-response may differ for different groups of drugs. For certain groups of drugs, such as drugs for infectious diseases and parasitic diseases, the loss of personal ID number, sex, age and place of registration is slightly higher than the average, up to about 2.5 per cent, compared with about 0.3 per cent for all groups of medicines in an average year. In the current collection, it is not possible to distinguish between observations concerning persons who do not have a personal ID number and observations where personal ID numbers are recorded incorrectly. All drug groups have a peak for this non-response in 2016. The non-response rate for personal ID number, sex, age and place of registration for commodities is slightly higher than for drugs.

Some groups of drugs, such as dermatologicals, artificial blood and intravenous fluids, lack comparable defined daily doses and therefore have no value for this variable. This is also the case for some other groups of medicines, such as chemotherapy and vaccines, which have no fixed daily doses. 'Off-label' drugs have also lacked daily doses since autumn 2013. Off-label drugs are drugs that are not authorised for sale on the Swedish market, but for which the Medical Products Agency has granted a special marketing authorisation. These structurally missing values should be addressed in the production of statistics and comparisons of drug volumes based on defined daily doses.

K2.2.4 Data processing

The sales transactions are reported automatically and instantaneously from the pharmacies to the FOTA register of the Swedish eHealth Agency. FOTA is interfaced with a number of other registers (see F2.2) to link additional information to each transaction. This synchronisation is also automated.

Reported transactions that are subsequently found to be incorrect can be corrected. This can be done directly at the pharmacy operator by crediting the existing erroneous transaction and possibly loading a new correct transaction. It can also be done by the eHealth Agency by deleting erroneous transactions.

Information on the product itself, e.g., the ATC code, product name and pack size, can be found in a separate product register. The product information must be linked to the drug data at each new withdrawal from the Register, using the key-variable product number. The aim is to get up-to-date information on the product without having to update the entire National Prescribed Drug Register every time a change occurs (e.g., when a product number changes ATC code). Instead, only the product register itself is updated once a month.

K2.2.5 Modelling assumptions

No modelling assumptions are made.

K2.3 Provisional register compared to final register

There are no provisional versions of the Register.

K3 Timeliness and punctuality

K3.1 Preparation time

Preparation time for the eHealth Agency is three business days.

K3.2 Frequency

The National Prescribed Drug Register is updated on a monthly basis.

K3.3 Punctuality

The Register has been updated as planned since 2005.

K4 Accessibility and clarity

K4.1 Access to the register

National Prescribed Drug Register data may be disclosed for research and statistical purposes. Each request for disclosure is subject to a confidentiality assessment. The National Board of Health and Welfare's statistical registers are subject to statistical confidentiality according to Chapter 24 Section 8 of the Public Access to Information and Secrecy Act (2009:400).

Aggregated data from the Register are also available through our commissioning activities, in the National Board of Health and Welfare's statistics database, and in the official statistics published annually in the form of a fact sheet and an Excel appendix with time series.

K4.2 Dissemination of information

Updated Information about the Register can be found at socialstyrelsen.se. The official statistics are published once a year and the date is indicated in the publication calendar of the National Board of Health and Welfare. The Register is further documented on socialstyrelsen.se, including detailed descriptions of variables and value sets:

K5 Comparability and interoperability

K5.1 Comparability over time

In general, there are good opportunities for comparison over time. There are some changes in variable content over time. Information on parish in the variable *LKF* (County, municipality and parish) is only available until 2015.

The National Prescribed Drug Register may differ slightly between different withdrawals. This may be due to a change in the ATC code of a medicinal substance or a change in the DDD value (the latest version of the ATC classification and the latest DDD values are always used when submitting data - even for older data). However, these differences do not significantly affect comparability over time.

The extent to which certain drugs are ordered via inpatient medication orders in day hospital, instead of being prescribed (see 2.2.4 Non-response), may vary over time. If one or more regions begin ordering a certain medicine through inpatient medication orders, it may appear that the use of that medicine has decreased. Similarly, if regions move to more widespread prescribing of the drug, a false increase may occur.

K5.2 Interoperability with other registers

Since its inception in July 2005, the National Prescribed Drug Register contains individual-based data, which enables cross-referencing with, e.g., other health data registers, the National Cause of Death Register and the Register on Participation in Education.

Note that the National Patient Register covers medication orders, including during outpatient doctor visits, but the quality of these variables is judged to be poor (for more information see the documentation for the current register).

General information

U1 Confidentiality and personal data processing

In the special activities of public agencies for the production of statistics, confidentiality applies in accordance with Chapter 24, Section 8 of the Public Access to Information and Secrecy Act (2009:400). However, information needed for research and statistical purposes, we well as information that is not directly attributable to an individual through his or her name, other identity code or similar relationship, may be disclosed if it is clear that the information can be disclosed without causing damage or harm to the individual or someone close to him or her.

When processing personal data, i.e., information that can be directly or indirectly attributed to a living person, the General Data Protection Regulation

2016/679[1] and the Regulation (2018:218) containing supplementary provisions to the EU General Data Protection Regulation apply.

In addition, the Act regarding official statistics (2001:99) (*Lagen om den officiella statistiken*), the Ordinance regarding official statistics (2001:100) (*Förordningen om den officiella statistiken*) and the Act regarding the health data register (1998:543), as well as the Ordinance on drug registers at the National Board of Health and Welfare (2005:363), apply to the processing of personal data.

U2 Retention and data erasure

The National Prescribed Drug Register is a register where personal data must be exempt from data erasure. The Register is covered by the Swedish National Archives' Regulations regarding exemptions from data erasure at the National Board of Health and Welfare (RA-MS 2020:22). Primary data, i.e., the basis for the register, may be erased five years after the basis has been received by the public agency.

The Register is a so-called living register, which means that continuous updates can change data even historically. Immediate erasure of incorrect data is permitted under RA-MS 2020:22, which means that earlier versions of the register are generally not saved by the National Board of Health and Welfare.

U3 Obligation to give information

The Swedish National Board of Health and Welfare is obliged to provide information to the Swedish National Agency for Health and Welfare in accordance with *Lagen om nationell läkemedelslista* (National Medication List Act) (2018:1212).

U4 EU regulation and international reporting

The National Board of Health and Welfare reports extracts from the Register to OECD and NOMESCO annually.

U5 History

Statistics on pharmaceutical sales have been collected since at least the 1970s, but apart from a study on one-seventh of the population of Jämtland, it was initially not an individual-based register, but anonymised data and volume statistics. Such data, in a complete form, were collected by the National Board of Health and Welfare between 1995-2005, based on data from Apoteket AB. In the early 2000s, two government inquiries were made into the possibility of introducing an individual-based data register. The inquiries were followed by the ratification of a government bill in 2004[2], which resulted in the establishment of the National Prescribed Drug Register on 1 July 2005. Initially managed by Apoteket AB, collection was transferred to Apotekens Service AB (which is a state-owned company established in 2008 and not to be confused with the private company of the same name established in 2020) after the deregulation of

[1] Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[2] Govt. Bill 2004/05:70 *Om ökad patientsäkerhet på läkemedelsområdet* (On improving patient safety in the field of medicines).

the Swedish pharmacy market in 2009. Subsequently, Apotekens Service AB was reorganised in 2014 as the Swedish eHealth Agency.

U6 Contact details

Questions regarding the National Prescribed Drug Register can be sent to the functional mailbox of the *Reproduktion och läkemedel* team:
Unit: Statistik 1
E-mail: rela@socialstyrelsen.se
Telephone: 075 247 3000

Version history

Version	Change	Date
1.0	The document is new	30/06/2021

Annex 1:

Validation rules

No.	Term	Obtained from a register other than FOTA	Validation upon reporting to FOTA
1	County (pharmacy)	EXPO via expoid	The value must exist in Micro/Basic Data and be active on the pick-up date
2	Dispensation date		Pick-up date must be syntactically correct <= Today's date >= Prescription issue date
3	Date of issue		No more than 15 months before pick-up date Date of issue<=pick-up date Mandatory for out-patient prescribing
4	The patient's personal ID number		If personal ID number exists and lookup against FOLK failed, transaction is stored in warning table
5	County (patient)	FOLK via personal ID number	Mandatory if a valid PERSONNUMMER (=hit in FOLK) exists, except for individuals with classified personal data, otherwise NULL
6	Municipality (patient)	FOLK via personal ID number	Mandatory if a valid PERSONNUMMER (=hit in FOLK) exists, except for individuals with classified personal data, otherwise NULL
7	Parish (patient)		Not used
8	Mode of sale		Must be available in Micro/Basic Data For EEA-country prescribing, mode of sale must be R, 2 or 3. Must not be E for commodity type RX
9	Operator's dispensary ID		
10	Order number		
11	Benefit type		The value must be in Micro/Basic Data Mandatory for in-patient prescriptions For prescriptions in EEA countries, benefit type = U Commodities cannot be reported as a benefit type S
12	Profession	FORS via prescriber code	Mandatory for prescriptions for drugs (not applicable to UTFKAT: VET)
13	Education code	FORS via prescriber code	
14	Specialisation code 1	FORS via prescriber code	
15	Specialisation code 2	FORS via prescriber code	
16	Specialisation code 3	FORS via prescriber code	
17	Specialisation code 4	FORS via prescriber code	
18	Specialisation code 5	FORS via prescriber code	
19	Specialisation code 6	FORS via prescriber code	
20	Specialisation code 7	FORS via prescriber code	
21	Workplace code		Must be valid on the date of issue Mandatory for benefit types R and F Mandatory for benefit type S if County is missing

No.	Term	Obtained from a register other than FOTA	Validation upon reporting to FOTA
22	Form of ownership	ARKO via work-place code	
23	Type of care	ARKO via work-place code	
24	Field of activity	ARKO via work-place code	
25	Category of issuer		The value must exist in Micro/Basic Data and be active Mandatory for Outpatient Prescription (Warning (not reject) for Outpatient Medication Order)
26	Origin		The value must be available in Micro/Basic Data Mandatory for outpatient prescription
27	Trial pack		Must be 1 or 0
28	Exchange permitted		The value must be in Micro/Basic Data
29	Product ID prescribed		No longer used
30	NPLpackId prescribed		The field is used if a change has taken place If filled in - must not be the same as NPLPackID The value must be in Micro/Basic Data For medicines, it must correspond to the specified prescribed product number
31	Product number prescribed		The field is used if a change has taken place If filled in - must not be the same as VARUNR The value must be in Micro/Basic Data For medicines, it must correspond to the specified prescribed nplPackID
32	GTIN prescribed		If filled in - must not be the same as GTIN The value must be in Micro/Basic Data
33	VaruID		No longer used
34	NPLpackId		Mandatory for transactions relating to drugs otherwise NULL The value must be present in Micro/Basic Data For drugs it must correspond to the specified product number
35	Product number		The value must be present in Micro/Basic Data. For drugs, it must correspond to the specified NPLPackID
36	GTIN		The value must be present in Micro/Basic Data
37	Product type		Value must be in Micro/Basic Data Cannot be RX if sales mode=E
38	Number of packages		
39	Total product sale price, excluding VAT		
40	VAT rate		The value must exist in Micro/Basic Data and be active Can only be zero for prescribed drugs (benefit type R and S)
41	Benefit excluding VAT		Benefit excluding VAT may only appear if benefit type = R, F, L or Z, otherwise NULL
42	Surplus cost excluding VAT		
43	Start date		
44	Entered out-of-pocket expense		
45	Dosage text		Mandatory for Mode of sale = R, 0, 1, 2 and 3 and Benefit type = R, U, F or S
46	PDD total strength		
47	PDD strength unit		

No.	Term	Obtained from a register other than FOTA	Validation upon reporting to FOTA
48	PDD code		

Source: The Swedish eHealth Agency