EURO-MED-STAT

**Working Group on Recommendations for National Registers of Medicinal Products
with validated ATC codes and DDD values**
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THE LIBRARY OF EUROPEAN UNION PHARMACEUTICAL INDICATORS

Recommendations for national registers of medicinal products

with validated ATC codes and DDD values

These Recommendations have been produced by the: *"EURO-MED-STAT Working Group on Recommendations for National Registers of Medicinal Products with validated ATC codes and DDD values"* and have been approved by all the members of the EURO-MED-STAT Group.

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Recommendations for national registers of medicinal products

The EURO-MED-STAT Group

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1- Rationale for national registers of medicinal products with validated ATC codes and DDD values

More than 100,000 pharmaceutical packages are licensed in the European Union countries and tons of medicines are daily used with a yearly expenditure wider than 100 billion euro.

This very large amount of medicines is a challenge to public health for several reasons:
- Medicines can positively influence public health by their intended therapeutic effect
- Medicines can adversely affect public health because of medicine related problems; medicines related problems are an important cause of mortality and most of them can be prevented
- There is an important economic burden of medicines on healthcare systems
- Medicines are able, via the wastewater, to pollute the environment, including drinking water. Several medicines have endocrine-disrupters or carcinogenic properties.
- There are wide discrepancies between European countries in licensed medicines and in their price, utilisation and expenditure

Because of these challenges of medicines on public health there is a need
- to increase awareness and spread knowledge on the impact of medicine utilisation on public health
- to promote European harmonised data collection about licensed medicines, their prices, utilisation and expenditure
- to develop indicators for monitoring price, utilisation and expenditure of medicines at a European level
- to promote benchmarking exercise on utilisation of medicines at national and regional level
- to assess the outcome of medicine utilisation, linking pharmacoepidemiological data to morbidity-mortality data
- to develop a public health-oriented European database of the licensed medicines with relevant information about their best use

For all these purposes it is essential to have an internationally valid classification system of medicines and a measurement system of their utilisation.

Since 1981, the WHO Regional Office for Europe has recommended the ATC (Anatomical Therapeutic Chemical) classification system and the DDD (Defined Daily Dose) as the standard for medicine classification and drug utilisation studies, respectively.

Since 1996 the ATC/DDD methodology has been adopted and proposed by the WHO Headquarters for global use.

The EURO-MED-STAT project has inventoried more than 72 different registers of medicinal products in the European Union Member States and Norway. These registers strongly differ in both their content and structure.

For monitoring and comparing the medicines available in the European Union, their prices, utilisation, expenditure and licensed clinical properties, it is necessary that national data can be compared by national registers with similar structure and content. For this purpose it is needed that the ATC/DDD system is implemented in a valid and transparent way in all the countries and that national registers of medicinal products are able to link each pharmaceutical pack to its ATC code and DDD value.

2- Aim of the Recommendations for national registers of medicinal products with validated ATC codes and DDD values

The aim of these Recommendations is to define the criteria for the production, validation, and maintenance of national registers of medicinal products with validated ATC codes and DDD values in the Member States of the European Union. This will allow validated comparisons at a European level of licensed medicines, their price, expenditure, utilisation and licensed clinical properties.

3- Content of the National Registers

The register should contain information on all medicine packages licensed and available on the national market for human use.

The full list of fields for each record is given in section 5 – EURO-MED-STAT Minimal Data Set for national Registers of medicinal products (page 9).

The register should be updated on a regular basis (e.g. monthly or every second week), and the date of the latest update should always be included in the register.

If the register contains packages, licensed but not available on the market, a mechanism to identify these records should be in place. Utilisation data will normally only cover packages available on the market, and this may be one way of separating licensed medicine packages from licensed and marketed medicine packages. If date of marketing is included in the register (as recommended), this data element will be the best way of separating these records.

Registers of Medicinal Products produced by Medicine Agencies will normally include all licensed medicines.

Historical versions of the register with packages no longer licensed or available should be kept. This is of importance for updating of ATC codes and DDD values of historical utilisation and expenditure data.

When producing and presenting trends in utilisation and expenditure data over years, it is important that the data for the different years are presented by using the same ATC/DDD version.

4- Structure of the National Registers

The structure of the National Register should be in compliance with the following standards.

European PreStandard ENV 12610 for the Identification of medicinal products

European PreStandard ENV 12610 (Medical Informatics – Medicinal product identification by the European Committee for Standardization; Brussels 1997) is aimed to define the language to be used to structure coding systems for the identification of medicinal products. The PreStandard contains the definition of the concepts and the description of the characteristics and the relationship needed to identify each of these unambiguously, particularly for the purpose of exchange of information between information systems.

European Pharmacopoeia of the Council of Europe for the pharmaceutical forms

The pharmaceutical form is the combination of the form in which a medicinal product is presented by the manufacturer (form of presentation) and the form in which it is administered including the physical form (form of administration).

The List of pharmaceutical forms by the European Pharmacopoeia of the Council of Europe-European Directorate for the Quality of Medicines (List of Standard Term, Introduction and Guidance for use - 2002 Edition) presents the basic terms needed to characterise the pharmaceutical form of a medicinal product. It contains the translation in 21 different languages and can be ordered to:

http://www.coe.int
http://www.pheur.org

It is based on the following principles:
- Terminology is to be used consistently thorough the list
- Each term should be as short as possible, commensurate with providing the necessary information
- Each term need to convey several "elements" of information. The number of elements will vary from one product type to another.

A complete list of the official English terms for pharmaceutical forms is given in Annexe 7 – Council of Europe. Standard terms. List of pharmaceutical forms (page 77).

Council Directive 92/26/EEC and Council of Europe for the Legal categories of medicines

EEC Directive 92/26 [Council Directive 92/26/EEC concerning the classification for the supply of medicinal products for human use: OJ L 113, 30.4.1992; Bull. 3-1992, point 1.2.19]

Council of Europe-Committee of Ministers. Resolution (AP 2000)1 on the classification of medicines, which are obtainable only on medical prescription. Adopted by the Committee of Ministers on 15 March 2000 at the 702nd Meeting of the Ministers' Deputies.

WHO International Non-proprietary names for the Name of the active ingredients

International Non-proprietary Names (INN) for active ingredients assigned by WHO
http://www.who.int/medicines/organization/qsm/activities/qualityassurance/inn/orginn.shtml

ATC Index and Guidelines for ATC Classification and DDD assignment for ATC codes and DDD values

ATC index and Guidelines for ATC classification and DDD assignment are released annually by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo.

For further information, see paragraph 6 - ATC and DDD linkage process (page 16).

5- EURO-MED-STAT - Minimal Data Set for National Register of Medicinal Products with Validated ATC Codes and DDD Values

The Register should contain at least the following elements (in separate fields):
1. **Registration number or other unique identifier**
2. **ATC code**
3. **Active ingredient(s)**
4. **Medicinal Product Name with its specifiers**
5. **Trade Name**
6. **Pharmaceutical Form**
7. **Strength**
8. **Pack size**
9. **Legal category**
10. **Reimbursement**
11. **Pharmacy retail price**
12. **Date of approval**
13. **Date of first marketing**
14. **Date of removal from the market**
15. **Holder of marketing authorisation**
16. **Generic**
17. **Parallel import**
18. **Value of the DDD**
19. **Route of administration**
20. **Number of DDDs in the pack**

5.1- Registration (Marketing authorisation) number or other unique identifier

Allowed format: letter, number or alphanumeric code [text]. Length: >6
Definition. The registration number can be defined as a code representing the market authorisation act within a given marketing authorisation territory. No definition of registration number is given in the rules governing medicinal products for human use in the European Union.

A code must be used once and it cannot be repeated in the file.

If a pack is withdrawn from the market the number cannot be used for a new licensed product.

It can be an advantage when more national registers use the same number [i.e. the Nordic number] for the same package.

5.2- ATC code

Allowed format: alphanumeric code [text]. Length: max 7 characters
Definition. See separate description in paragraph 6 - ATC and DDD linkage process.
Examples: C09AA01; C03AA01; B01AC06

5.3- Active ingredient 1

Allowed format: text
Definition. Ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicinal product.

Nomenclature. International non-proprietary names (INN) should be used. If INN names are not assigned, USAN (United States Adopted Name) or BAN (British Approved Name) names should be used. If the product contains more than one active ingredient it is recommended that the description stops to the first three ingredients. In this case the names of the active ingredients should be given in the same order of the "ATC INDEX with DDD"

5.3a- Active ingredient 2

For a second active ingredient in the case the medicinal products contains more than one active ingredient

5.3b- Active ingredient 3

For a third active ingredient in the case the medicinal products contains more than one active ingredient

5.3c- Further active ingredients

Allowed format: yes/no
If the package contains more than the three active ingredients given in the fields above, this should be indicated in this field, without further description of these additional active ingredients

5.4- Medicinal Product Name with its specifiers

Allowed format: Text
Definition. Medicinal Product Name Specifiers are the additional elements added to the medicinal product name in order to distinguish medicinal products with the same medicinal product name. The additional elements can be based on:

- the galenic properties (enteric coated, slow release, CR)
- a strength related property (by means of an imprecise term (Forte, Mitis) or by means of an indication related to the amount of active ingredient (Transderm Nitro 5, Humelin 60/40)
- an intended user group (paediatric, geriatric)
- the ingredients, mainly the reference active ingredient (Rubella live vaccine)
- the physical nature of the product
- the route of administration (Oral gel; Oral Tablets; Intravenous solution)
- the pack size (28 tablets;

These elements should be treated as an integral part of the medicinal product name for identification purposes.
Directive 92/27 EEC indicates specifiers to add to the medicinal product name e.g. strength and pharmaceutical form

Examples: Capoten tablet 50 mg 28-tab pack
Lasix injectable solution 10 mg/mL ampoule 2 mL
Canesten cream 1% tube 50 g

5.5- Trade Name

Allowed format: text
Definition. Name given for marketing purposes to any ready-prepared medicinal product placed on the market under a special name and in a special pack. A trade name may be a protected trademark. (Synonyms: Brand name; Innovator's name; Fantasy name; Proprietary product name; Pharmaceutical speciality product name; Medicinal speciality product name)
Examples: Lasix, Canesten, Berotec, Captopril GNR, etc.

5.6- Pharmaceutical Form

Allowed format: text
Definition. The Pharmaceutical Form is the combination of the form in which a medicinal product is presented by the manufacturer (*form of presentation*) and the form in which it is administered including the physical form (*form of administration*).

The pharmaceutical forms included in the register should be present in the "List of pharmaceutical forms by the European Pharmacopoeia of the Council of Europe - European Directorate for the Quality of Medicines (List of Standard Term, Introduction and Guidance for use - 2002 Edition)". An English version of this list is given in Annexe 7 - Council of Europe. Standard terms. List of pharmaceutical forms (page 77).

5.7a- Strength 1 (value)

Allowed format: number; two decimal digits.
Definition. Designation based on the composition of one or more pharmaceutical products in a medicinal product. The strength of a medicinal product is simply an expression of an identifying characteristic based on its composition.

Strength will not normally be given for multiple ingredient medicinal products with more than three ingredients. Non-standardised expressions of strength are often used in addition to a trade name or a generic name (forte, paediatric, super, plus) but this should be avoided.

The strength should refer to the declared content of the active ingredient according to the pharmaceutical form in a single dose unit such as:
1 tablet or capsule
1 suppository
1 unit dose powder
1 unit dose spray (nasal or inhalation)
1 enema
1 vial

For medicinal products not available in single dose units, the strength normally would refer to:
1 ml solution
1 gram or 100 gram of powder or cream
For plasters, the strength normally would refer to the daily delivered dose
Non numerical value of strength (forte, mild, paediatric, etc) must be avoided.

5.7b- Strength 1 (unit)

Allowed format: text
Should refer to the declared unit of the strength.

Examples of suggested units (suggested abbreviations):
Gram (g)
Milligram (mg)
Microgram (mcg)
International unit (U)
Thousand international units (TU)
Million international units (MU)
Gram per millilitre (g/mL)
Milligram per millilitre (mg/mL)
Microgram per millilitre (mcg/mL)

Strength 2 (value)

For a second active ingredient. According to the same rule of 5.7a - Strength 1 (value).

Strength 2 (unit)

For a second active ingredient. According to the same rule of 5.7b - Strength 1 (unit).

Strength 3 (value)

For a third active ingredient. According to the same rule of 5.7a - Strength 1 (value) and 5.7b - Strength 2 (value)

Strength 3 (unit)

For a third active ingredient. According to the same rule of 5.7b - Strength 1 (unit) and 5.7b - Strength 2 (unit).

5.8a- Pack size (value)

Allowed format: number (the values more commonly ranges from 1 to 200)

For medicinal products available in single dose units, the pack size is defined as:
number of tablets or capsules
number of suppositories
number of dose powders
number of dose sprays
number of enemas
number of plasters
number of vials

For medicinal products not available in single dose units, the pack size is defined as:
Number of ml solution
Number of grams of powder or cream
See also definition of package in the Annex 1 – Glossary & List of Abrreviations (page 18).

5.8b- Pack size (unit)

Allowed format: text

Examples of units:
Tablets
Capsules
Suppositories
Dose powders
Dose sprays
Enemas
Plasters
Vials
Millilitre (mL)
Gram (g)

5.9- Legal Category

Allowed format: text
Definition. The legal category of a medicine establishes the conditions or restrictions that could be imposed on its supply or use, including the conditions under which the medicines may be made available to patients. The two main categories are: product subject and not subject to medical pre-scription.
Neither Legal Categories nor their identification are harmonised at a European level.
A full list of the Legal Categories of Medicinal Products used in the European Union countries and Norway together with their explanation is given in Annex 5-Legal classification of medicines in the European Union countries and Norway (page 57).

5.10- Reimbursement

Allowed format. text

Definition. All the European Member States support the cost of pharmaceutical therapy to patients. This can differ according to medicine, disease and patient (reimbursement per pack, reimbursement per disease, reimbursement per budget and/or expenditure, reimbursement per category of patient, etc). The reimbursement of a medicine can range from 0% to 100% of its price.

Because of the differences in pharmaceutical care systems there is no harmonisation at a European level.

A full list of the Legal Categories of Medicinal Products used in the European Union countries and Norway together with their explanation is given in Annex 6-Reimbursement categories of medicines in the European Union countries and Norway (page 65).

5.11- Pharmacy Retail Price

Allowed format. number, two decimal digits.

Currency. euro (€) or local currency for non-euro zone.

Definition. It is the price charged by retail pharmacist to the general public. It is discussed in the section 2.2.3-Pharmacy retail prices of the related document The Library of EU Pharmaceutical indicators-Price Indicators.

The pharmacy retail price, according to the official price list, should be given here, i.e. the price without any discount, including dispensing fee and VAT (for the countries where VAT is added to medicines)

5.12- Date of approval

Suggested format. date (MM-YYYY)

The date when the medicinal product is licensed (i.e. it receives its authorisation)

For medicinal products approved under the EMEA centralised procedure the date of centralised approval should be given.

5.13- Date of first marketing

Suggested format: date (MM-YYYY)

The date when the medicinal package is firstly marketed

5.14- Date of removal from the market

Suggested format: date (MM-YYYY)

The date when the medicinal package is no longer available on the market

5.15- Holder of Marketing Authorisation

Allowed format. text

Definition. Natural or legal person in possession of the licence or marketing authorisation for a medicinal product within a given territory.

5.16- Generic

Allowed format. GNR (=generic), PMP (proprietary medicinal products).
Definition. Medicine identical in chemical composition to a brand name pharmaceutical preparation, but produced by a different company after the firm's patent expires. In some cases generic companies are subsidiaries of the companies producing the proprietary product.

5.17- Parallel import

Allowed format: yes/no
Definition. Parallel import is based on a medicine from one producer having different prices in different countries. The price differences make it profitable to buy medicines in low price countries and subsequently sell it in high price countries.

The competition element from parallel import is however limited because the producer controls the access both in export and import countries. In some cases the importers in each country are subsidiaries of the producers.

5.18a- DDD (value)

Allowed format: number; three decimal digits.
From the latest version of the "ATC INDEX with DDDs" which is updated annually and released in January by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo.

5.18b- DDD (unit)

Allowed format: text
Allowed units (according to the ATC INDEX with DDDs):
g = gram
mg = milligram
mcg = microgram
U = International unit
TU = Thousand international units
MU = Million international units
mmol = millimole
mL = millilitre
UD = unit dose (used for DDDs for multingredient products)

5.19- Route of administration

Allowed format: text
Definition. The route of administration indicates the part of the body on which, trough which or into which the product is to be introduced and relates in this context to the DDD value.

Allowed terms (according to the ATC INDEX with DDDs):
Inhal = inhalation
N   = nasal
O   = oral
P   = parenteral
R   = rectal
SL   = sublingual/buccal
TD   = transdermal
V   = vaginal

5.20- Number of DDDs in the pack

If the strength unit and the DDD unit is the same, the number of DDDs in a pack can be calculated by the following formula:

Strength (value) x pack size/value of DDD

For some packages, e.g. multiingredient products, the number of DDDs in a package must be calculated by using additional information about the product (see separate comment in the paragraph 6 - ATC/DDD linkage process).

6 - ATC and DDD linkage process

The purpose of this process is to link the correct and valid ATC 5th level code to each medicinal product package.

This will allow to link the correct Defined Daily Dose (sometimes in function of the route of administration or the chemical salt) and finally, to calculate the number of DDDs per package (adequate information about the product is necessary in order to calculate this number properly).

It is recommended to have strict control routines for adding and changing the ATC/DDD information in the National Registers of Medicines, as this is the basis for calculating utilisation data in a correct and comparable way.

The team responsible for the National Registers of Medicines should be properly trained in the ATC/DDD methodology and collaborate closely with the WHO Collaborating Centre for Drug Statistics Methodology in Oslo.

When a new substance is introduced on the market for which no official ATC code or DDD yet has been assigned (the latest assignments are available on the website of the Centre), a request for a new ATC/DDD should immediately be sent to the WHO Collaborating Centre. Application form for new ATC codes and DDDs are available on the website of the Centre (www.whocc.no) and the Centre normally assigns a preliminary ATC code within 4-6 weeks.

New DDDs are assigned twice annually.

Early December each year, the annual update to the next version of the ATC INDEX is made available by the WHO-Collaborating Centre. Updates of the ATC codes and DDD values in the National Registers of Medicines should be made early the following year.

7- Production of utilisation and expenditure data

Sales figures (from companies, wholesalers, pharmacies or other sources) in number of packages of medicinal products can be easily linked to each record of the national registers and the following recommended utilisation and expenditure indicators can be produced.

1- The indicator **Utilisation in DDDs** can be calculated by multiplying the number of packages sold with the number of DDDs in the package.

Number of packages sold x Number of DDD in the pack

2- The indicator **DDDs/1000 inhabitants/day**, can be calculated as follows:

$$\frac{\textit{Total consumption measured in DDDs}}{\textit{Number of days in the period of data collection x number of inhabitants}} \; x\; 1000$$

The number of inhabitants in the denominator should refer to the total population covered by the data collected. If the coverage of the consumption is not 100%, then the population size should be corrected accordingly and described.

3- The indicator **expenditure per DDD** can be calculated as follows:

$$\frac{\textit{Number of packages sold x Pharmacy Retail Price}}{\textit{Consumption in DDDs}}$$

A full description of these indicators is given in the related document: The Library of European Union Pharmaceutical Indicators. Expenditure and Utilisation Indicators.

ANNEX 1 - GLOSSARY & LIST OF ABBREVIATIONS

Ambulatory Care: All types of health services provided to patients who are not confined to an institutional bed as inpatients during the time services are rendered. Ambulatory care delivered in institutions that also deliver inpatient care is usually called "outpatient care."

ATC: Anatomical, Therapeuthical, Chemical. A classification system of medicines where the active substances are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Active Ingredient: Ingredient   that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicinal product

ATC / DDD System   see ATC; DDD

Centralised Procedure: A way of approval of medicinal products in the European Union. Under the centralised procedure a new medicine is evaluated by the European Medicines Evaluation Agency (EMEA) and if the evaluation is positive the Commission grants an approval valid in all the Member States.

DDD: Daily Defined Dose. The assumed average maintenance dose per day for a medicine used for its main indication in adults

ENV 12610:   A European Prestandard (ENV) approved by the European Committee for Standardization (CEN) on 1997-03-11 regarding Medical informatics - Medicinal product identification

Excipient Ingredient: Ingredient that is inert in relation to the intended activity of the medicinal product

Generic Medicines (Generic):   Medicines which are identical in chemical composition to a brand name pharmaceutical preparation, but produced by a different company after the firm's patent expires

Generic Name: Medicinal product name based on the active ingredient (generic)

name(s). A synonym is non-proprietary name. The short term "generic" is frequently used for this kind of medicinal product

Ingredient: Substance included as a component in a product (see: Active ingredient; Excipient ingredient)

Ingredient Name: Ingredient designation in the form of a name (ex amoxicillin, salicylic acid)

Inpatient, (see also Ambulatory Care; Outpatient):   A patient who is formally admitted (or "hospitalised") for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing inpatient care. (OECD, 2000)

Legal category of medicines establishes the conditions or restrictions that could be imposed on the supply or the use of a medicinal product, including the conditions under which the medicinal product may be made available to patients. The two main categories are: product subject and not subject to medical prescription.

Manufacturer   Natural or legal person with responsibility for the manufacturing of a product

Marketing Authorisation   Legal licence for marketing a medicinal product within a given territory

Marketing Authorisation Holder   Natural or legal person in possession of the licence or marketing authorisation for a medicinal product within a given territory

Marketing Authorisation Number Designation in the form of a number representing the market authorisation act within a given marketing authorisation territory

Medicinal product   Product intended to be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions (Directive 65/65 EEC)

Medicinal Product Name   Medicinal product designation in the form of a name (see: Trade name and Generic name)

Medicinal Product Name Specifiers Additional element(s) added to the medicinal product name in order to distinguish medicinal products with the same medicinal product name. The additional elements can be based on:

- the pharmacokinetic properties (enteric coated, slow release, CR)
- a strength related property (by means of an imprecise term (Forte, Mitis) or by means of an indication related to the amount of active ingredient (Transderm Nitro 5, Humelin 60/40)
- an intended user group (paediatric, geriatric)
- the ingredients, mainly the reference active ingredient (Rubella live vaccine)
- the physical nature of the product
- the route of administration (Oral gel; Oral Tablets; Intravenous solution)

These elements should be treated as an integral part of the medicinal product name for identification purposes. Directive 92/27 EEC indicates specifiers to add to the medicinal product name e.g. strength and pharmaceutical form

Medicinal Product Package   See Package

Non-proprietary Name   See Generic Name

Outpatient: (see also Inpatient)   Medical and paramedical services delivered to patients who are not formally admitted to the facility (physician's private office, hospital outpatient centre or ambulatory-care centre) and do not stay overnight (OECD, 2000)

Package   Delivery unit of a medicinal product in an outer container as identified by the registration number or other unique identifier (Synonym to be avoided: presentation)

Parallel Import Marketing of a medicine package from a country with cheaper price to a country with more expensive price. The competition element from parallel import is however limited because the producer controls the access both in export and import countries. In some cases the importers in each country are subsidiaries of the producers.

Pharmaceutical Form   Form in which a pharmaceutical product is presented in a medicinal product (ex. tablet, syrup, suspension, cream). Synonym: galenic form.

Pharmaceutical Product   Product consisting of one or more ingredients. A pharmaceutical product may have a different pharmaceutical form from the final intended medicinal product (ex. an amount of powder of penicillin and physiologic solution to be mixed together are both pharmaceutical products. They are both part of a medicinal product)

Reimbursement categories of medicines. All the European Member States support the cost of pharmaceutical therapy to patients. This can different according to medicine, disease and patient. The reimbursement can range from 0% to 100%.

Strength; Unit Dose   Designation based on the composition of one or more pharmaceutical products in a medicinal product. The strength of a medicinal product is simply an expression of an identifying characteristic based on its composition.

Strength will not normally be given for multiple ingredient medicinal products. Non-standardised expressions of strength are often used in addition to a trade name or a generic name (forte, paediatric, super, plus)

Trade Name   Name given for marketing purposes to any ready-prepared medicinal product placed on the market under a special name and in a special pack. A trade name may be a protected trademark. (Synonyms: Brand name; Innovator's name; Fantasy name; Proprietary product name; Pharmaceutical speciality product name; Medicinal speciality product name)

ANNEXE 2 - LIST OF NATIONAL REGISTERS OF MEDICINAL PRODUCTS and UTILISATION / EXPENDITURE DATA BY COUNTRY

Austria – List of national registers of medicinal products and expenditure / utilisation data

Pharmazeutisches Informationssystem (Pharmaceutical Information System) by the Bundesministerium für Soziale Sicherheit und Generationen -BMSG (Federal Ministry of Social Security and Generations)

This register contains information about price (out of hospital) for all the licensed medicines (Prescription Only Medicines and OTC), reimbursed and not reimbursed.
It includes:
- Ex-factory price (Reported price of the marketing authorization holder, without VAT)
- Wholesale price (Calculated price based on the official regulated margin scheme for wholesalers).
- There is no information about pharmacy retail price.

The information is not publicly available but it is planned to publish some information of the database (name of product, name of substance, authorisation holder, date of approval, pack size, ATC code) on the website of the Ministry of Social Security and Generations.
No periodical report is produced.
The information, updated regularly, is originated by the Bundesministerium für Soziale Sicherheit und Generationen, marketing authorisation applicants.

Austria Codex by the Österreichische Apotheker-Verlagsgesellschaft m.b.H. (Austrian Chamber of Pharmacists)

This register contains information about price (out of hospital) for all the licensed medicines (Prescription Only Medicines and OTC), reimbursed and not reimbursed.
It includes:
- Pharmacy retail price (Official pharmacy selling price without VAT).

The information is originated by pharmacies, it is available on payment and is updated monthly.

Heilmittelverzeichnis (List of Pharmaceuticals) by Hauptverband der Österreichischen Sozialversicherungsträger (Federation of Austrian Social Insurance Institutions)

This register contains information about price (out of hospital) for all the licensed (Prescription Only Medicines and OTC) and reimbursed medicines.
It includes:
- Reimbursement price (Official price without VAT).

The "Heilmittelverzeichnis" is a register, listing all pharmaceuticals that can be prescribed at the expense of the Social Insurance. The register is based on the approval procedure of the Federation of Austrian Social Insurance Institutions that decides whether a pharmaceutical should be included in this list.
The information is restricted to special users because the periodical report "Heilmittelverzeichnis" is, after being up-dated (twice per year), automatically sent to the "contract doctor" (physicians who have a contract with the Social Insurance). For others, it is difficult to get a copy.

Pegasus by the Hauptverband der Österreichischen Sozialversicherungsträger (Federation of the Austrian Social Insurance Institutions)

This register contains information about utilisation, expenditure and price.
It includes:
- Reimbursement price
- Utilisation data (out of hospital data reported in number of packs prescribed)
- Expenditure data (out-of-hospital data)

The information, updated twice a year, is originated by sickness funds. The information is not publicly available and no periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to the geographic definition, this database contains information at national level.

The expenditure data refers to out of hospital. The utilisation data refers to out of hospital and the data are habitually reported in number of packs sold.

Foko by the Hauptverband der Österreichischen Sozialversicherungsträger (Federation of Austrian Social Insurance Institutions)

This register contains information about utilisation, expenditure and price.
It includes:
- Reimbursement price
- Utilisation data (out of hospital data reported in number of packs prescribed)
- Expenditure data (out-of-hospital data)

The information, updated quarterly, is originated by sickness funds. The information is not publicly available and no periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about reimbursed medicines.

With regard to the geographic definition, this database contains information at regional level (some of the nine provinces of Austria, planned to cover all provinces)

The expenditure data refers to out of hospital. The utilisation data refers to out of hospital and the data are habitually reported in number of packs sold.

Warenverzeichnis (List of commodities / products)

This register contains information about price.
It includes:
- Pharmacy price
- Reimbursement price

The information, updated monthly, is originated by pharmacies.

The information is on payment. The Warenverzeichnis is a database that is used in the pharmacy. A hard copy is published regularly.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines (reimbursed and not-reimbursed).

Institut für Medizinische Statistik (IMS) data

These data contain information about utilisation.
They includes:
- Pharmacy price
- Ex factory price
- Utilisation data (pooled data from out of hospital and hospital)

The information is available on payment and several reports are produced.

The information is updated regularly: sales data are up-dated weekly, data on prescriptions quarterly. The information is originated by physicians (prescribing data), wholesalers (sales data) and pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not-reimbursed).

With regard to the geographic definition, this database contains information at national level.

This database contains information at a representative sample level. The utilisation data are reported in number of packs sold and number of patients treated.

Krankenanstalten – Kostenstellenstatistik (Statistic Cost Accounts in Hospitals) by Bundesministerium für Soziale Sicherheit und Generationen (BMSG)/Federal Ministry of Social Security and Generations

This register contains information about expenditure.

It includes:
- Expenditure data in hospital

The information is restricted to special users. No periodical report is produced.

The information, updated yearly, is originated by hospitals.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

Mikrozensus-Erhebung, Sonderprogramm „Fragen zur Gesundheit" (Mikrozensus Survey, Special Program „Questions concerning Health") by Statistik Austria (National Statistics Institution)

This register contains information about utilisation of medicines at out-of-the hospital level.

There is no detailed information, neither on pharmaceuticals (trade names) nor on the amount consumed. In the survey, people are asked two questions concerning pharmaceutical consumption: 1) "Did you take pharmaceuticals prescribed by a physician in the course of the last 4 weeks? Against which diseases and illnesses?"

The person interviewed is shown as a list of 18 groups of general remedies (e.g. remedies against cardiac diseases, against high blood pressure, against low blood pressure, against asthma, against alimentary problems, problems to sleep, head aches, nervousness, etc.)

2) "Did you take pharmaceuticals not prescribed by a physician, namely circulation remedies, laxatives, remedies against in case of a cold, analgesics, in the course of the last 4 weeks?"

The information is on payment. A periodical report is produced.

The information, updated about every 10 years, is originated by patient surveys.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about human use. With regard to the geographic definition, this database contains information at national level.

This database contains information at a representative sample level.

Pharma Preisinformation - PPI (Pharma Price Information) by ÖBIG Österreichisches Bundesinstitut für Gesundheitswesen (Austrian Health Institute)

This register contains information about price.

PPI is an Austrian data source, i.e. available in Austria and held by an Austrian institution. However, it covers not only data on Austria, but also for the other EU Member States.

It includes:
- Ex factory price (Official price without VAT)
- Wholesale price (Official price without VAT)
- Pharmacy price (Official price with and without VAT)

The information is on payment. No periodical report is produced.

The information, updated every two weeks is originated by different originators.

With regard to the geographic definition, this database contains information at national level.

Belgium - List of national registers of medicinal products and expenditure / utilisation data

Belgian Centre for Pharmacotherapeutic Information BCFI-Databank / Banque des Données CBIP

This register contains information about price.
It includes:
- Pharmacy price
- Reimbursement price

The information is publicly available and is updated monthly. The information is originated from the Health Department. Market availability is checked with wholesalers and community pharmacists.

With regard to legal classification this database contains information about all medicines for human use (restricted to medicinal packages available in ambulatory care and hospital care). There is no information about uni-dose distribution unit in hospital care.

With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not-reimbursed)

Database of medicines at the Directorate-General for Medicinal Products of the Federal Public Service Public Health, Food Chain Security and Environment

This register contains information related to medicines.
The information is updated weekly.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not-reimbursed).

With regard to the geographic definition, this database contains information at national level.

The Directorate-General for Medicinal Products of the Federal Public Service Public Health, Food Chain Security and Environment share this database with the the following institutions: FPS Economy, SMEs, Self-employed and Energy, which add the following data:
- the size of the packages
- the national number (CNK)
- the date of marketing
- the reimbursement (yes or no)
- the public price
- the number of packages sold every year (ex-factory).

Compendium des Medicaments (Medicine list) by the Association Générale de l'Industrie du Mèdicament-AGIM (General Association of Pharmaceutical Industries)

This register contains information about price.
It includes:
- Pharmacy price

The information is originated by the pharmaceutical companies.

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not-reimbursed).

Farmanet / Pharmanet by RijksInstituut voor Ziekte en Invaliditeits Voorziening (RIZIV)

This register contains information about utilisation, expenditure and price.
It includes:
- Number of patients treated
- Number of packs sold
- Number of DDDs
- DDD/ 1000inh /day

Fields referring to the patients:
- Sex; age (in cohorts of five years); number of packs received; number of DDD received; social status (normal insured or underprivileged)

Fields referring to the prescribers:
- Unique identifier including local area of activity, Sex, age, specialisation

Fields referring to the dispensers:
- No information is available

The information, updated yearly, is restricted to special users (data are available to researchers on a per protocol base)

A periodical report is produced (Farmaceutische Kengetallen).

With regard to legal classification this database contains information about prescription only medicines. With regard to reimbursement status this database contains information about reimbursed medicines.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at complete coverage level.

The expenditure data refers to out of hospital. The utilisation data refers to out of hospital and the data are habitually reported in DDD, DDD/1000inh/day, Number of packs sold and number of patients treated.

Institute of Pharmacoepdiemiology of Belgium IFEB / IPHEB

This register contains information about utilisation (out-of-hospital), expenditure (out-of-hospital) and price.
It includes:
- Pharmacy price
- Reimbursement price
- Number of packs sold
- DDDs
- DDD/1000inh/day

The information is available on payment. A periodical report is produced and the information is updated regularly on a monthly basis. The information is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about prescription only medicines. With regard to reimbursement status this database contains information about all reimbursed medicines.

With regard to the geographic definition, this database contains information at national level (extrapolation of 65% of the community pharmacies to population data).

Denmark - List of national registers of medicinal products and expenditure / utilisation data

Specialitetstaksten (Pricelist)

This register contains information about price.
It includes:
- Wholesale price (without VAT)
- Pharmacy price (with VAT)
- Reimbursement price (with VAT)
- European average price (from 13 countries reported by the manufacturers to the Danish Medicines Agency.

The information (in a book and electronic) is on payment and is primarily used by the pharmacies and doctors.

A periodical report (Specialitetstaksten) is produced and updated every two weeks. The information about prices is originated by the companies, which report the price to the Danish Medicines Agency if they want to change their prices.

With regard to legal classification this database contains information about all medicines for human use (Only the OTC also allowed to be sold outside pharmacies do not have a fixed Pharmacy Retail Price). With regard to reimbursement status this database contains information about all medicines for human use.

Lægemiddelkataloget

This register contains information about most licensed medicines including their price, posology, indications and adverse effects.

The information is publicly available on payment.

The information is originated by a Special Committee of Royal Pharmaceutical Society & British Medical Association.

With regard to legal classification this source contains information about prescription only medicines and over the counter medicines. This does not necessarily include all prescription only medicines, as unlicensed medicines may also be prescribed and reimbursed in the UK.

It does not include General Sale (GSL) medicines.

Lægemiddelstyrelsen Lægemiddelstatistikregister (The Register of Medicinal Products Statistics)

This register contains information about utilisation (out of hospital and hospital), expenditure (out of hospital and hospital), and price.
It includes:
- Wholesale price (without VAT), which is identical for all pharmacies in the primary health care sector
- Pharmacy retail price (with VAT)
- Reimbursement price (with VAT)
- Sales in terms of Pharmacy retail price
- Number of persons in treatment
- Number of packs sold
- DDD
- DDD/1000inh/day

Fields referring to the patients:
- Unique identifier, Sex; birth date; age; number of packs received; medical condition for the prescription (planned)

Fields referring to the prescribers:
- Unique identifier, specialisation

Fields referring to the dispensers:
- Unique identifier, local area, date of dispensing, time of dispensing

The information, updated monthly, is originated by pharmacies plus information/data from hospital pharmacies, The National Central Laboratory of the Danish Health System and other non prescription stores and places of retail allowed to sell a list of OTC products.

The information from this register is publicly available. Raw data in the database is only available to the Danish Medicines Agency.

Several periodic reports are produced:

Quarterly statistics (sales, person in treatment and volume at 1st ATC level and for selected groups of medicines and medicinal products

5-year statistics for the whole country (sales, volume, persons in treatment, share of women and median age at 5th ATC level, updated yearly.

With regard to legal classification this database contains information about all medicines for human use (Prescribed Only Medicines and OTC). With regard to reimbursement status this database contains information about all medicines for human use. With regard to the geographic definition, this database contains information at national and regional level.

Finland - List of national registers of medicinal products and expenditure / utilisation data

Lääkemyyntirekisteri (Drug Sales Register) by the Lääkelaitos (National Agency for Medicines)

This register contains information about utilisation (out of hospital and hospital) and expenditure (out of hospital and hospital) of pharmaceutical products
.
It includes:
Fields referring to medicinal product:
- ATC code
- Nordic commodity number, trade name, pharmaceutical form, strength, pack size, number of DDDs per package, legal category, marketing authorisation holder
- Wholesale expenditure
- DDD/1000inh/day
Fields referring to dispensers:
- unique identifier
- local area

Information about expenditure and utilisation at ATC group level is published quarterly in the Internet (www.nam.fi) and annually in the Finnish Statistics on Medicines (book).
Information at product level is restricted to special users and on payment.

Information, updated monthly, is originated by wholesalers.

With regard to legal classification this database contains information about all medicines for human use.
With regard to the geographic definition, this database contains information at national and regional level.

Lääkevalmisteiden perusrekisteri (List of Registered Medicines) by the Lääkelaitos (National Agency for Medicines)

This register contains information about registered medicinal products.

It includes:
- ATC code
- Nordic commodity number, trade name, pharmaceutical form, strength, pack size, marketing authorisation holder, number of DDDs per package, legal category
- Date of approval, date of first marketing (from year 1997)

Information is publicly available and on payment.

No periodical report is produced.

Paradox 7, HILA 2000 (Register of fixed wholesale prices) by the Lääkkeiden hintalautakunta (Pharmaceuticals Pricing Board)

This register contains information about price (out of hospital) of reimbursable medicinal products.

It includes :
- ATC code
- Nordic commodity number, trade name, pharmaceutical form, strength, pack size, marketing authorisation holder
- Wholesale price (official price without VAT)

Information is publicly available.

A periodical report (Pharmaceuticals Pricing Board's Info) is produced monthly.

With regard to legal classification this database contains information about all medicines for human use that have fixed wholesale price.
With regard to reimbursement status this database contains information about reimbursed medicines.

Reseptirekisteri (Prescription Register) at Kansaneläkelaitos (Social Insurance Institution)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital) of reimbursed medicines.

It includes:
Fields referring to the medicinal product:
- Nordic commodity number; trade name, pharmaceutical form, strength, pack size, ATC code, expenditure, reimbursement
Fields referring to the patients:
- Unique identifier, local area; sex, birth date, age, number of packs received, medical condition for the prescription (when belongs to the Special Reimbursement Category).
Fields referring to the prescribers:
- Unique identifier, living area, sex, age, specialisation
Fields referring to the dispensers:
- Unique identifier, local area, date of dispensing

Information at ATC group or patient group level is publicly available on payment. More detailed information is restricted to special users and on payment.

Information is published annually in the Internet (www.kela.fi/research) and in the Finnish Statistics on Medicines (book).

Information, updated monthly, is originated from pharmacies (dispensing data).

With regard to reimbursement status this database contains information about reimbursed medicines.
With regard to the geographic definition, this database contains information at national and regional level.

Suomen Apteekkariliiton Lääkevalmisteiden tiedosto (Register of Pharmaceutical Products on Sale in Finland) by the Suomen Apteekkariliitto (Association of Finnish Pharmacies)

This register contains information about pharmaceutical products (human and veterinary) available in Finnish pharmacies. Besides products with marketing authorisation, the database includes also products with special licences in case the licence is national or the product is reimbursable.

It includes:
- Nordic commodity number, brand name, pharmaceutical form, strength, pack size,
- Wholesale price (without VAT).
- Pharmacy price (with and without VAT)
- Reimbursement status, narcotic code and codes indicating eligibility for special reimbursement rates
- ATC code
- Active ingredients
- Generic substitution code (pack size level) and price corridor levels
- Special demands for prescribing (attached to the marketing authorisation)
- EAN code
- Wholesaler and ordering code

In addition to the previous, the database consists specific information about the expiry dates of fixed wholesale prices etc.

Information is collected from pharmaceutical companies, the Pharmaceuticals Pricing Board, the Social Insurance Institution and the National Agency for Medicines.

Information is updated every other week (24 times a year) and delivered to users electronically or by diskettes

Information is publicly available and on payment.

The database is used by pharmacies, authorities, the Social Insurance Institution, pharmaceutical companies and IT-companies offering patient record systems including prescribing for health care units. It is a reference database for pharmaceuticals in the national e-prescription pilot project run by the Ministry of Social Welfare and Health.

Public can find information from web address http://www.apteekkariliitto.fi/geneerinen or http://kelaapp.kela.fi:8080/laakekys_app/LaakekysApplication.

France - List of national registers of medicinal products and expenditure / utilisation data

Database at the Agence Française de Sécurité Sanitaire des Produits de Santé-AFSSAPS (French Agency of Sanitary Security of Health Products)

This register contains information about expenditure [out of hospital and hospital (pooled data)]
It includes:
- Fields referring to patients, prescribers and dispensers (aggregated by ATC code).

The information is publicly available, updated yearly and a periodical report is produced.

The information is originated by companies.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

Database of reimbursed medicines expenditures by the Caisse nationale d'Assurance Maladie des Travailleurs Salariés –CNAMTS (National Health Insurance for Working People)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Number of packages sold
- Fields referring to patients, prescribers and dispensers (aggregated by French CIP code)

The information is publicly available and a periodical report (MEDICAM) is produced yearly.

The information is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about prescription only medicines.

With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at the following level: 70% of global expenditure by the CNAMTS and other related health insurance systems.

Guide des Equivalents Thérapeutiques (Guide of Therapeutic Equivalents) from the Caisse Nationale d'Assurance Maladie des Travailleurs Salariés –CNAMTS (The National Health Insurance for Working People)

This register contains information about price (out of hospital).

It includes:
- Pharmacy price

The information, updated yearly, is publicly available but no periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

Database of sold medicines by the Groupement pour l'Elaboration et la Réalisation de Statistiques –GERS (Organisation for the Working-out and the Fulfilment of Statistics)

This register contains information about utilisation [out of hospital and hospital (pooled data)] and expenditure [out of hospital and hospital (pooled data)] and price.

It includes:
- Ex factory price
- Wholesale price
- Pharmacy price
- Number of items (in packs for pharmacies and in units for hospitals)
- Fields referring to patients, prescribers and dispensers (aggregated by EPhMRA and French CIP codes)

The information is on payment. No periodical report is produced.

The information, updated monthly is originated by companies and wholesalers (sales data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

The expenditure data refers to out of hospital and hospital (pooled data).

Dictionnaire Vidal

This register contains information about price.

It includes:
- Pharmacy retail price

The information is on payment. A periodical report is produced.

The information, updated yearly is originated by official information from the CEPS and AFSSAPS and the companies).

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines for human use.

Germany - List of national registers of medicinal products and expenditure / utilisation data

Rote Liste

This register contains information about most licensed medicines including their price, posology, indications and adverse effects.

It includes:
- Pharmacy price (Official price with VAT)

The information is publicly available on payment.

The information is updated yearly and a periodical report is produced.

With regard to legal classification this source contains information about prescription only medicines and over the counter medicines.

GKV – Arzneimittelindex (German Drug Index) by Wissenschaftliches Institut der AOK –WidO (Research Institute of the Statutory Health Insurance)

This register contains information about utilisation (out of hospital), expenditure (out of hospital) and price (out of hospital).

It includes:
- Pharmacy retail prices
- Number of packs sold
- DDD
- Fields referring to patients (local area, sex and birth date)
- Fields referring to Prescribers (Unique identifier, local area of activity, specialisation.

The information is restricted to special users. A periodical report is produced (Arzneiverord-nungs-Report (Drug Prescription Report), Springer-Verlag, Berlin, Heidelberg, yearly edition, approx. 900 pages).

The information, updated yearly and quarterly is originated by physicians (prescribing data) and Lauer-Taxe (a price list of all pharmacy products in Germany, which is updated every two weeks).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Greece - List of national registers of medicinal products and expenditure / utilisation data

National Organisation for Medicines

It includes:
- Wholesale price
- Pharmacy price
- Hospital price

The information is restricted to special users.

No periodical report is produced. The information is updated daily.

With regard to legal classification this database contains information about all medicines for human use.

GREDIS II

This register contains information about expenditure and price.

It includes:
- Pharmacy price

The information is not publicly available.

A periodical report is produced.

The information, updated monthly is originated by companies (sales data).

With regard to legal classification this database contains information about all medicines for human use. With regard to reimbursement status this database contains information about all medicines for human use. With regard to the geographic definition, this database contains information at national level. With regard to the representativity, this database contains information at complete coverage (>95%) level.

The expenditure data refers to out of hospital and hospital (pooled data).

The utilisation data is habitually reported in DDD, DDD/1000inh/day, number of packs sold and sales data.

Ireland - List of national registers of medicinal products and expenditure / utilisation data

GMS (General Medical Services) database

This database contains information about utilisation, expenditure and price. The raw data in the database is restricted to special users (permission must be requested from the GMS (Payments) Board). An annual report is produced by the GMS (Payments) Board and this is available on their website: www.gmspb.ie.

The data is updated monthly. It originates in pharmacies and is then transmitted to the GMS (Payments) Board where it is used to process claims for payments to pharmacists. The database contains information at national and regional level.

The database contains information on all medicines reimbursed on the GMS scheme. The GMS scheme provides free health services to approximately 29.8% of the Irish population, including provision of medicines without charge. Eligibility for this service is means tested and therefore such groups as the elderly and the socially disadvantaged are over represented with respect to the general population. The GMS covers 1.17 million people and it accounts for approximately 70% of all medicines prescribed in primary care in Ireland.

The GMS database does not provide data for the other Community Drug Schemes or for hospitals.

It includes information about the ex-wholesale and the reimbursement price (this includes ex-wholesale price, dispensing fee and VAT).

The utilisation data are reported in DDDs but the database does not provide complete population coverage; therefore we report DDDs / 1000 GMS population / day.

Monthly Index of Medical Specialities (MIMS)

This register contains information about the ex-wholesale price of prescription only medicines and over the counter medicines. It is an independently written publication designed as a prescribing guide for general practitioners.

The information is publicly available on payment and is updated on a monthly basis. This source contains information about legal classification and reimbursement status of medicines.

Italy - List of national registers of medicinal products and expenditure / utilisation data

Database sui Farmaci del Ministero della Salute (Medicines Directory at the Ministry of Health)

This register contains information about price.

It includes:

- Pharmacy retail prices (with VAT)

The information is publicly available and can be downloaded by internet in MS excel format.

The information, updated regularly, is originated by the Administration, according to the new authorisations and changes and withdrawals of authorisation.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about reimbursed and not-reimbursed medicines.

Database interno sui prezzi presso il Ministero del Tesoro, Bilancio e della Programmazione Economica (Price Directory at the Ministry of Economics)

This register contains information about price.

It includes:

- Ex-factory prices (requested by the company and approved)
- Pharmacy retail prices
- Lower European price
- Higher European price
- Average European price
- Number of countries used for the calculation of the average price
- Market share during the first, the second and the third year of marketing

The information is generally restricted to the Administration for monitoring and negotiates prices.

No periodical report is produced.

The information, updated regularly, is originated by companies.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about reimbursed and not-reimbursed medicines.

Informatore farmaceutico

This register contains information about price.

It includes:

- Pharmacy price (with VAT)

The information is available on payment. A periodical report is produced. This directory is mainly addressed to pharmacists but a version for physicians is available too. It is on sale by mail and in the bookshop.

The information, updated monthly and often daily is originated by the legal notices (Official Journal).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

Repertorio Farmaceutico Italiano-REFI (Medicine list) by the Associazione Nazionale dell'Industria Farmaceutica – Farmindustria (National Association of Pharmaceutical Industries)

This register contains information about price.

It includes:
- Pharmacy price (with VAT)
- Summary of Product Characteristics

The information is publicly available. A periodical report (REFI) is produced.

The information, is originated by pharmaceutical companies.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

Osservatorio sull'Utilizzo dei Medicinali presso il Ministero della Salute (Observatory on Utilisation of Medicines at the Italian Ministry of Health)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Pharmacy price
- Number of packs sold
- DDDs
- DDD/1000inh/day (from the first to the fifth ATC level at national and regional level. Regional data are weighted for age classes).

The information is publicly available.

Periodical reports, with aggregated data, are produced: the first one refers to the first quarter of the year; the second refers to the first three quarters and the last to the whole year.

The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about Prescription medicines only.

With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage.

La Spesa Farmaceutica convenzionata SSN (Pharmaceutical Expenditure within the National Health Service) by the Agenzia per i Servizi Sanitari Regionali (Agency for Regional Health Services)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Number of packs sold
- Fields referring to patients (unique identifier, local area, birth date, number of packs received)
- Fields referring to prescribers (unique identifier, local area of activity)
- Fields referring to dispensers (unique identifier, local area, date of dispensing)

The information is publicly available at aggregated level and restricted to special users to lower level. A periodical report ("La spesa farmaceutica convenzionata") is produced.

The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about prescription medicines only.

With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to the geographic definition, this database contains information at national and regional level. With regard to the representativity, this database contains information at complete coverage (>95%) level.

Appropriatezza delle Prescrizioni Farmaceutiche (Appropriateness of Pharmaceutical Prescribing) by the Agenzia per i Servizi Sanitari Regionali (Agency for Regional Health Services) (in progress)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:

- Fields referring to patients: unique identifier, local area, birth date, sex, reason (disease) for prescribing
- Fields referring to medicine prescribed: unique identifier (AIC code, linkable to ATC code, Trade name and its specifiers, Holder of Marketing Authorisation) and quantiy prescribed
- Fields referring to prescribers (unique identifier, local area of activity)

The information, is originated by GPs (prescribing data).

With regard to legal classification this database contains information about prescription medicines only. With regard to reimbursement status this database contains information about reimbursed medicines and not reimbursed medicines.

The Netherlands - List of national registers of medicinal products and expenditure / utilisation data

Algemeen Gegevens Beheer Zorgverleners - AGB-z (General Data Controle-medical persons) by Vektis BV

This register contains information about expenditure and price of medicines used by medical persons in health care.

It includes:
- Fields referring to prescriber (Unique identifier, sex, age, specialisation)

The information is restricted to special users and on payment.

A periodical report is produced and the information, updated weekly, is provided by the Health Insurances.

With regard to geographic definition this database contains information at the national level.

BIOS by the Medicines Evaluation Board

This register contains information related to medicines.

Parts of the information concerning registered products are made available on internet and a periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use.

With regard to the representativity this database contains information about complete coverage.

Pharmacy Information System by Vektis BV

This register contains information about utilisation (out of hospital), expenditure (out of hospital) and price.

It includes:
- Pharmacy price (with VAT)
- Number of packs sold
- DDDs
- Fields related to patient (unique identifier, local area, sex, birth year, number of packs received, number of DDDs received, insurance)
- Fields referring to prescriber (type of specialist
- Fields referring to dispenser (date of dispensing)

The information is restricted to special users and on payment.

A standard periodical report ("FIS-Terugkoppeling") is produced twice a year, strictly available to the participating health insurance companies. This consists of a management report, an in-depth software-application with mirror-information and an ASCII-file for researchers. The Vektis publication "Zorgthermometer", containing some interesting information based on the Pharmacy Information System is publicly available.

The information, updated monthly is originated by health care insurance.

With regard to legal classification this database contains information about prescription only medicines.

With regard to reimbursement status this database contains information about reimbursed and not-reimbursed medicines.

With regard to geographic definition this database contains information at national and regional level.

Dutch Drug Information Project- GIP by Healthcare Insurance Council

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Pharmacy price (without VAT)
- Reimbursement price (actual price withou VAT)

- Number of patients treated
- Number of prescriptions
- Number of users
- Number of packs sold
- DDDs
- DDD/1000inh/day

The information is publicly available and aggregated data are published twice per year in the periodical report "GIPelingen"

The information, updated monthly is originated by pharmacies (dispensing data) and Health insurance companies.

With regard to legal classification this database contains information about Prescription medicines only.

With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information of a representative sample (about 55%).

Informatiesysteem Farmaceutische Middelen (Information System Pharmaceutical Products) by Vektis BV

This register contains information about utilisation, expenditure and price.
It includes:
- Wholesale price (official)
- Pharmacy price (official)
- Reimbursement price

The information is restricted to special users and on payment. No periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use (prescription only medicines and oTC).

With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not reimbursed)

With regard to the geographic definition, this database contains information at national level.

Multiple database by IMS Health

This register contains information about utilisation out of hospital), expenditure (hospital and out of hospital) and price.

It includes:
- Ex factory price
- Wholesale price
- Pharmacy price
- Number of packs sold
- Number of patients treated
- DDDs (PDDs available)
- DDD/1000inh/day
- Fields referring to patient (unique identifier, local area, sex, age, number of packs received, numbe rof DDDs received, medical conditions for the prescription, insurance)
- Fields referring to prescriber (specialisation)
- Fields referring to dispenser (no information)

The information is restricted to special users and on payment.

A periodical report is produced.

The information, updated weekly is originated by wholesalers (sales data), pharmacies (dispensing data) and Physicians (prescribing data).

With regard to legal classification this database contains information about all medicines for human use (prescription only mediicnes and OTCs)

With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not reimbursed)

 With regard to geographic definition this database contains information at national and regional level (66 regions).

With regard to the representativity this database contains information about a representative sample.

Landelijk Informatie Netwerk Huisartsenzorg – LINH (National Information Network in General Practice) byDutch Association of General Practitioners, Dutch College of General Practitioners, Centre for Quality of Care Research, Netherlands Institute for Health Services Research (NIVEL)

This register contains information about utilisation (out of hospital)

It includes:
- Ex factory price
- Reimbursement price
- Number of prescriptions
- Number of patients treated
- DDDs
- DDD/1000inh/day

The information is restricted to special users and on payment (data is accessible for independent research projects that agree to publish the research results)

A periodical report is produced yearly.

The information, updated quarterly is originated by physicians (prescribing data).

With regard to legal classification this database contains information about Prescription medicines only.

With regard to reimbursement status this database contains information about reimbursed medicines only.

With regard to geographic definition this database contains information at national level (representative sample).

PHARMO Database by he PHARMO Institute

This register contains information about utilisation (hospital and out of hospital), expenditure (hospital and out of hospital) and price.

It includes:
- Ex factory price
- Wholesale price
- Pharmacy price
- Reimbursement price
- Number of packs sold
- Number of patients treated
- DDDs
- Fields referring to patient (unique identifier, sex, birth date, age, number of packs received, number of DDD received, medical condition for the prescription, insurance, family relationship, hospital admission/discharges, complete medical history
- Fields referring to prescriber (unique identifier, local area of activity, sex, age, specialisation, graduation date)
- Fields referring to dispenser (unique identifier, local area, date of dispensing)

The information is publicly available for research questions and on payment.

No periodical report is produced.

The information, updated quarterly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use , prescription medicines only, and over the counter medicines.

With regard to reimbursement status this database contains information about all medicines for human use, reimbursed medicines only and not-reimbursed medicines.

With regard to the representativity this database contains information about a representative sample of about one million patients)

SFK Database by SFK (Foundation for Pharmaceutical Statistics)

This register contains information about utilisation [hospital since 2002) and out of hospital], expenditure [hospital (since 2002) and out of hospital] and price.

It includes:
- Ex factory price (official price without VAT)
- Wholesale price (official price without VAT)
- Pharmacy price (official price without VAT)

- Reimbursement price (official price without VAT)
- Number of patients treated
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to patient (unique identifier, local area, sex, birth date, age, number of packs received, number of DDD received, insurance)
- Fields referring to prescriber (unique identifier, specialisation)
- Fields referring to dispenser (unique identifier, local area, date of dispensing)

The information is restricted to special users.

A periodical report (Facts and figures) is produced yearly.

The information, updated quarterly and monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use (prescription medicines only and over the counter medicines).

With regard to reimbursement status this database contains information about all medicines for human use (reimbursed medicines only and not-reimbursed medicines).

With regard to geographic definition this database contains information at national, regional and area code level.

With regard to the representativity this database contains information about 85% of the population.

Norway - List of national registers of medicinal products and expenditure / utilisation data

The National Drug Register

This register contains information about price.

It includes:

- Wholesale price
- Pharmacy price

The information is restricted to special users and on payment.

A periodical report is produced.

The information, updated yearly, is originated by wholesaler (sales data) companies (sales data) and others.

With regard to legal classification this database contains information about all medicines for human use, prescription only medicines and over the counter medicines.

With regard to reimbursement status this database contains information about all medicines for human use. With regard to the geographic definition, this database contains information at national level.

Norwegian Database on Wholesale Statistics

This register contains information about utilisation [out of hospital and hospital (pooled data)] and expenditure [out of hospital and hospital (pooled data)].

It includes:

- Wholesale price
- Ex-factory- price
- Pharmacy price
- DDD/1000inh/day

The information is publicly available.

A periodical report is produced. The information, updated monthly and yearly is originated by wholesaler (sales data).

With regard to legal classification this database contains information about all medicines for human use, prescription only medicines and over the counter medicines.

With regard to the geographic definition, this database contains information at national and regional.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Portugal - List of national registers of medicinal products and expenditure /utilisation data

National Drug Expenditure Database at the Observatorio do medicamento – INFARMED (National Institute of Drugs and Pharmacy)

This register contains information about expenditure ([out of hospital and hospital (ambulatory data) and price.

It includes:
- Pharmacy price (official price and actual price)
- Reimbursement price (official price and actual price)
- Number of packs sold

The information is restricted to special users.

A periodical report is produced. The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about prescription only medicines.

With regard to reimbursement status this database contains information about reimbursed medicines.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information about comment 100% of reimbursed medicines.

IMS Health Database

This register contains information about utilisation (out of hospital and hospital), expenditure (out of hospital and hospital) and price.

It includes:
- Pharmacy price
- Number of packs sold

The information is restricted to special users on payment.

A periodical report is produced.

The information, updated monthly is originated by pharmacies (dispensing data), physicians (prescribing data) and wholesaler (sales data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

Spain - List of national registers of medicinal products and expenditure /utilisation data

Especialidades Consumo de Medicamentos-ECOM database (Consumption of Medicines) by the Ministerio de Sanidad y Consumo (Ministry of Health)

This register contains information about utilisation (out of hospital), expenditure (out of hospital) and doesn't include prices.

It includes:
- Number of packs sold (which can be converted in DDD)

The information is restricted to special users.

The information, updated yearly is originated by pharmacies (dispensing data) and a periodical report is produced.

With regard to legal classification this database contains information about prescription only medicines.

With regard to reimbursement status this database contains information about reimbursed medicines.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Vademecum Internacional (International Vademecum) by Medicom

This register contains information about price.

It includes:
- Pharmacy price (Actual price with VAT)

The information is publicly available. A periodical report is produced.

The information, updated yearly is originated by companies.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

Catálogo de Especialidades Farmacéuticas (Catalogue of Pharmaceuticals Specialities) by the Consejo General de Colegios Oficiales de Farmacéuticos

This register contains information about price.

It includes:
- Pharmacy price (official price with VAT)

The information is publicly available. A periodical report is produced.

The information, updated yearly is originated by the National Pharmacists Association.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

IMS Database

This register contains information about utilisation, expenditure and price.

It includes:
-

The information is restricted to special users and on payment.

The information, updated yearly is originated by pharmacies (dispensing data), companies, wholesalers, physicians and others.

With regard to legal classification this database contains information about prescription only medicines.

With regard to reimbursement status this database contains information about reimbursed medicines.

With regard to the geographic definition, this database contains information at national and regional level.

Sweden - List of national registers of medicinal products and expenditure / utilisation data

Inleveransstatistik (Wholesale statistics) by Wholesalers, KD and Tamro (available through Apoteket AB and Läkemedelsstatistik)

This register contains information about utilisation [out of hospital and hospital (pooled data)] and expenditure [out of hospital and hospital (pooled data)].

It includes:
- Wholesale price (Actual price without VAT)
- Pharmacy price (Actual price without VAT)
- Number of packs sold
- Number of DDD
- DDD/1000inh/day

The information is publicly available and on payment.

A periodical report is produced. The information, updated daily at wholesale level and monthly at Apoteket level, is originated by wholesalers (sales data)

With regard to legal classification and reimbursement this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Oppenvard-forskrivning (Prescription sales) by Apoteket

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Wholesale price (Actual price without VAT)
- Reimbursement price (Actual price without VAT)
- Pharmacy price (Actual price without VAT)
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to patients (Local area, sex and age); prescribers (local area of activity) and dispensers (Unique identifier, local area, date of dispensing)

The information is publicly available and on payment.

A periodical report is produced. The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification and reimbursement this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Slutenvårdsförsäljning (Hospital sales) by Apoteket

This register contains information about utilisation (hospital) and expenditure (hospital).

It includes:
- Wholesale price (Actual price without VAT)
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to prescriber (hospital ward) and fields referring to dispenser ((unique identifier, local area, date of dispensing)

The information is publicly available and on payment.

No periodical report is produced.

The information, updated monthly is originated by hospital pharmacies (dispensing data).

With regard to legal classification and reimbursement this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage

Egenvårdsförsäljning (OTC sales) by Apoteket

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Wholesale price (Actual price without VAT)
- Pharmacy price (Actual price with and without VAT)
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to the dispenser (unique identifier, local area, date of dispensing)

The information is publicly available and on payment.

No periodical report is produced.

The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about over the counter medicines (OTC). With regard to reimbursement status this database contains information about all medicines for human use (reimbursed and not-reimbursed).

With regard to the geographic definition, this database contains information at national and regional level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Diagnos Receptundersokningen (DRU) (Diagnosis and prescription survey) (available by Apoteket)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Wholesale price (actual price without VAT)
- Pharmacy price (actual price without VAT)
- Reimbursement price ((actual price without VAT)
- Number of patients treated
- Number of packs sold
- DDD
- DDD/1000inh/day

The information is publicly available and on payment.

A periodical report is produced. The information, updated twice a year is originated by Physicians (prescribing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database includes about 1/8 sample of prescribers in Sweden and it is possible to estimate the value to the whole Swedish population.

Jämtlandsstudien (The Jämtland Study) by the County Council of Jämtland and Apoteket

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Wholesale price (actual price without VAT)
- Pharmacy price (actual price without VAT)
- Reimbursement price ((actual price without VAT)
- Number of prescriptions
- Number of patients treated
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to patient (unique identifier, sex, birth date, age, number of packs received, number of DDD received)
- Fields referring to prescriber (no information is available)
- Fields referring to dispenser (unique identifier, local area, date of dispensing)

The information is publicly available and restricted to special users.

A periodical report is produced.

The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at county level.

With regard to the representativity, this database contains information at a representative sample level (Persons born on selected days per month. In all cohort of approximately 17,000 persons since mid seventies).

Tierpsprojektet (Tierp project) by Institutionen för folkhälso och vårdvetenskap

This register contains information about utilisation (out of hospital).

It includes:
- Pharmacy price (Actual price without VAT)
- Reimbursement price ((Actual price without VAT)
- Number of patients treated
- Number of prescriptions
- Number of packs sold
- DDD
- DDD/1000inh/day
- Fields referring to patient (unique identifier, sex, birth date, age, number of DDD received)
- Fields referring to prescriber and dispenser (no information is available)

The information is restricted to special users. A periodical report is produced.

The information, updated continuously with a long lag time is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at regional level.

With regard to the representativity, this database contains information at complete coverage (all inhabitants, about 20,000 persons, in the community of Tierp, since mid seventies)

United Kingdom - List of national registers of medicinal products and expenditure / utilisation data

Prescriptions dispensed in the community by the Statistic Division of the Department of Health

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Number of packs sold
- Number of prescription items (i.e. number of prescriptions written for a particular medicine, which is not quite the same as number of packs)

A periodical report is produced and is publicly available by website.

The information, updated yearly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about reimbursement medicines only.

With regard to the geographic definition, this database contains information at national (England only) level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

British National Formulary by the Joint Formulary Committee of the Royal Pharmaceutical Society and the British Medical Association

This register contains information about most licensed medicines including their price, posology, indications and adverse effects.

It includes:
- Pharmacy price (Official price without VAT)

The information is publicly available on payment.

The information is updated twice a year and a periodical report is produced.

The information is originated by a Special Committee of Royal Pharmaceutical Society & British Medical Association.

With regard to legal classification this source contains information about prescription only medicines and over the counter medicines. This does not necessarily include all prescription only medicines, as unlicensed medicines may also be prescribed and reimbursed in the UK.

It does not include General Sale (GSL) medicines.

Hospital database at the Department of Health

This register contains information about utilisation (hospital) and expenditure (hospital), based on data bought from IMS by the Department of Health.

The information is restricted to special users.

A periodical report is produced.

The exact source of data is unclear; typically it originates from wholesalers (sales data) but there is collection of actual levels of use of medicines from hospital pharmacies also.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Prescribing Pricing Authority Database by the Prescribing Pricing Authority

This register contains information about utilisation (out of hospital) and expenditure (out of hospital). It contains information about all reimbursed medicines and has no information on private use at all.

It includes:
- Number of items
- Number of average daily quantities
- (DDD may be available)
- Fields referring to patient [local area, age (over or under 65), number of packs received]
- Fields referred to prescriber (unique identifier, local area of activity)
- Fields referring to dispenser (unique identifier, local area, date of dispensing)

The information is restricted to special users but a periodical report is produced and made publicly available.

The information, updated monthly is originated by pharmacies (dispensing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about reimbursement medicines with a volume greater than 50 items in the year.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Chemist and Druggist by the National Pharmaceutical Association

This register contains information about price. This is essentially a catalogue for pharmacists to purchase from. It is the single most complete list of medicines available. It includes a range of other products, apart from medicines, e.g. perfumes, cosmetics etc.

It includes:
- Wholesaler price

The information is publicly available. A periodical report is produced.

The information, updated monthly is originated by companies.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

Mediplus by Intercontinental Medical Services (IMS)

This register contains information about utilisation (out of hospital). It is specifically a primary care database

It includes:
- Number of patients treated
- Number of packs prescribed
- Size of the receiving population is also known so data per head of population is available

The information is on payment and no periodical report is produced.

The information, updated quarterly is originated by Physicians (prescribing data).

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level. With regard to the representativity, this database contains information at representative sample level (based on data from 100 practices spread around the country).

General Practice Research Database (GPRD) at the Medicines and Health Care Related Products Agency (MHRA) (formerly Medicines Control Agency)

This register contains information about utilisation (out of hospital) and expenditure (out of hospital).

It includes:
- Number of patients treated
- Number of packs sold
- Fields referring to patient (unique identifier, local area, sex, birth date, age, number of packs received, medical condition for the prescription)
- Fields referring to prescriber (unique identifier, local area activity)
- Fields referring to dispenser (no information)
- The information is publicly available and on payment.

A periodical report is produced.

The information, updated quarterly is originated by Physicians (prescribing data).

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at representative sample.

Doctors Independent Network

This register contains information about utilisation (out of hospital).

It includes:
- Number of patients treated
- Number of prescriptions
- Number of packs sold
- Fields referring to patient (unique identifier, local area, sex, birth date, age, number of packs received, medical condition for the prescription)
- Fields referring to prescriber (unique identifier, local area activity, specialisation)
- Fields referring to dispenser (no information)

The information is on payment. No periodical report is produced.

The information, updated quarterly is originated by Physicians (prescribing data).

With regard to legal classification this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at representative sample.

IMS Database Intercontinental Medical Statistics

This register contains information about utilisation (out of hospital and hospital) and expenditure (out of hospital and hospital).

It includes:
- Wholesaler price
- Number of packs sold
- Fields referring to dispenser (unique identifier, local area)

The information is on payment (data collected and sold to pharmaceutical industry).

The information, updated quarterly is originated by wholesalers (sales data)

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

With regard to the geographic definition, this database contains information at national level.

With regard to the representativity, this database contains information at complete coverage (>95%) level.

Datasheet Compendium by the Association of the British Pharmaceutical Industries (ABPI)

This database is produced by the manufacturers of medicines, it consists of their summary of product characteristics. Its main value is that it is source of marketing authorisation dates review etc.

The information about licensed clinical properties of medicines is publicly available.

The information, updated yearly, is originated by companies (sales data). It only contains those mediicnes produced by companies who are members of the ABPI, hence no generics and some of the smaller branded companies are not included either.

With regard to legal classification this database contains information about prescription only medicines.

Database of licensed medicines at the at the Medicines and Health Care Related Products Agency (MHRA) (formerly Medicines Control Agency)

This is an internal document, parts of its are publicly available but full availability is only possible on special request.

It contains a list of licensed medicines in UK.

A periodical report is produced.

With regard to legal classification this database contains information about all medicines for human use.

With regard to reimbursement status this database contains information about all medicines for human use.

ANNEXE 3 - SELECTED SOURCES OF INFORMATION FOR LICENSED MEDICINES, THEIR PRICES AND STATE EXPENDITURE / UTILISATION DATA

1. Source of information for licensed medicines and prices
2. Source of information for state expenditure / utilization data

AUSTRIA
1. Österreichische Apothekerkammer: Austria Codex und Warenverzeichnis (Austria Codex and List of commodities/products by the Austrian Association of Pharmacists)
2. Hauptverband der Österreichischen Sozialversicherungsträger (Federation of Austrian Social Insurance Institutions)

BELGIUM
1. BCFI-Databank / Banque des Données CBIP (Belgian Centre for Pharmacotherapeutic Information Database)
2. Farmanet (RijksInstituut voor Ziekte en InvaliditeitsVerzekering / Institut National d' Assurance Invalidité) (National Institute for Health and Disability Insurance)

DENMARK
1. – 2 Lægemiddelstyrelsen (Danish Medicines Agency)   Lægemiddelstyrelsen (Danish Medicines Agency)

FINLAND
1. Suomen Apteekkariliiton Lääkevalmisteiden tiedosto (Register of Pharmaceutical Products on Sale in Finland) owned by the Association of Finnish Pharmacies
2. Lääkemyyntirekisteri, Lääkelaitos (Medicine Sales Register owned by the National Agency for Medicines)

FRANCE
1. Comité National Hospitalier d'Information Médicale (CNHIM) - Base de données Thériaque - (National Hospital Committee of Medical Information – Theriaque database)
2. Caisse Nationale d'Assurance Maladie (CNAM) base de données Médicam (National Health Insurance- database Medicam) –

GERMANY
1. Classification file from the German Medicine Index, Research Institute of the AOK (WIdO)
2. Database of the German Medicine Index, Research Institute of the AOK (WIdO)

GREECE
1. National Formulary of the National Organisation of Medicines (EOF)
2. No data identified

IRELAND
1. Reimbursement files from the General Medical Services Payments Board
2. Reimbursement files from the General Medical Services Payments Board

ITALY
1. Ministero della Salute- Banca dati dei farmaci registrati (Ministry of Health-database of licensed medicines)
2. Ministero della Salute-Osservatorio Nazionale sull'Impiego dei Medicinali (OsMed) (Ministry of Health – Observatory on Utilization of Medicines)

1. Source of information for licensed medicines and prices
2. Source of information for state expenditure / utilization data

THE NETHERLANDS
1. Z-Index Den Haag / Ministerie van Volksgezondheid, Welzijn en Sport Den Haag (Z-Index The Hague / Ministry of Health, Welfare and Sport The Hague)
2. College voor Zorgverzekeringen, Geneesmiddelen Informatie Project Amstelveen / Stichting Farmaceutische Kengetallen Den Haag (Health Care Insurance Board, Pharmaceutical Products Information Project Amstelveen / Foundation for Pharmaceutical Statistics The Hague)

NORWAY
1. Norwegian Pharmacy Association
2. Norwegian Institute of Public Health (data based on total sales from all Norwegian wholesalers)

PORTUGAL
1. INFARMED- National Institute of Pharmacy
2. INFARMED- National Institute of Pharmacy

SPAIN
1. Catalogue of Pharmaceuticals Specialities Consejo General de Colegios Oficiales de Farmacéuticos: Catálogo de Especialidades Farmacéuticas (Pharmaceuticals Association)
2. Agencia Española del Medicamento - Especialidades y consumo de medicamentos (Database ECOM) (Ministry of Health, Spanish Medicines Agency-)

SWEDEN
1. Apoteket – National Corporation of Swedish Pharmacies
2. Apoteket - National Corporation of Swedish Pharmacies

UNITED KINGDOM
1. British National Formulary
2. Prescription Pricing Authority (PPA)

ANNEXE 4 - EXAMPLES

Example 1 (referring to a package licensed in UK):

Hygroton 50 mg tablets (containing one active ingredient, i.e. Chlorthalidone (INN name)) in packages of 28 tablets from Alliance. The DDD for oral formulations of Chlorthalidone is 25 mg. The example below shows how the data elements (that would be the same in all countries in the minimal dataset) should be filled in for this product:

Registration number	xxxxxxx
ATC code	C03BA04
Active ingredient	Chlorthalidone
Active ingredient 2	
Active ingredient 3	
Further active ingredients	No
Medicinal Product name with its specifiers	Hygroton 50 mg tablets
Trade name	Hygroton
Pharmaceutical form	tablets
Strength (value)	50
Strength unit	mg
Strength (value) 2	
Strength unit 2	
Strength (value) 3	
Strength unit 3	
Pack size	28
Pack size unit	tablets
Legal Category	POM
Reimbursement	Y
Pharmacy retail price	£ 1.68
Date of approval	mm/yyyy
Date of first marketing	mm/yyyy
Date of removal from the market	
Holder of marketing authorisation	Alliance
Generic	NO
Parallel import	NO
Value of the DDD	25
Unit of the DDD	mg
Route of administration	O
Number of DDDs in the pack	56

Example 2 (referring to a package licensed in France):

Moduretic 50 mg tablets (containing two active ingredients, i.e. Hydrochlorothiazide and Amiloride (INN names)) in packages of 28 tablets from Du Pont Pharma.

This product should be given once daily and the DDD for this combination product is then one tablet according to the publication "*Guidelines for ATC classification and DDD assignment*".

The example below shows how the data elements (that would be the same in all countries in the minimal dataset) should be filled in for this product:

Registration number	314 924.0
ATC code	C03EA01
Active ingredient	Hydrochlorothiazide
Active ingredient 2	Amiloride
Active ingredient 3	
Further active ingredients	No
Medicinal Product name with its specifiers	Moduretic 50 mg tablets
Trade name	Moduretic
Pharmaceutical form	tablets
Strength (value)	50
Strength unit	mg
Strength (value) 2	5
Strength unit 2	mg
Strength (value) 3	
Strength unit 3	
Pack size	30
Pack size unit	tablets
Legal Category	POM
Reimbursement	Y
Pharmacy retail price	€ 6.25
Date of approval	06/1972
Date of first marketing	mm/yyyy
Date of removal from the market	
Holder of marketing authorisation	Du Pont Pharma
Generic	NO
Parallel import	NO
Value of the DDD	1
Unit of the DDD	UD
Route of administration	O
Number of DDDs in the pack	30

Annexe 5 - Legal Classification of medicines in the European Union Member States and Norway

Austria

Rezeptpflichtig and verschreibungspflichtig

Prescription only" pharmaceuticals (in need of medical prescription).

Rezeptfrei and nicht-verschreibungspflichtig

mean OTCs (no need for a medical prescription).

Legal basis: The Pharmaceutical Act (Arzneimittelgesetz) talks of "Arzneispezialitäten, die […] nur auf Rezept abgegeben werden dürfen" (pharmaceutical specialities which […] may only be dispensed on the basis of a prescription". The Prescription Act (Rezeptpflichtgesetz) states: "Arzneimittel, die auch bei bestimmungsgemäßen Gebrauch das Leben oder die Gesundheit von Menschen […] gefährden können, dürfen […] nur auf Grund ärztlicher Verschreibung (Rezept eines Arztes […]) abgegeben werden" (Pharmaceuticals that, even with correct use, may constitute a risk for life or health of human beings […] , may only be dispensed on the basis of a medical prescription). These are so-called "rezeptpflichtige Arzneimittel" (prescription-only pharmaceuticals). The other terms ("rezeptfrei", "verschreibungspflichtig", "nicht-verschreibungspflichtig") are not used in legal texts.

There are no legal abbreviations of the terms "rezeptpflichtig" / "rezeptfrei"and "verschreibungspflichtig" / „nicht-verschreibungspflichtig".

Belgium

Rx.

Prescription Only

OTC.

Over the Counter, freely deliverable by the pharmacists
Note: there are controlled substances, such as the narcotic analgesics that need special prescribing instructions.

Some medicinal products are only available in the hospital. However, there is no legal category or reimbursement status that makes this factual situation explicit (Important for neuromuscular blockers, potentially used in euthanasia in ambulatory care).

Medicinal product packages where the ingestion of the entire content could provoke (sub)lethal overdose, are marked with a special label (Death skull).

There is more and more pressure on the delivery of non-reimbursed, but POM medicines.

Denmark

A.

Prescription only medicines. Only one delivery from the same prescription.

AP4.

Prescription only medicines. Only one delivery from the same prescription. The prescription is subjected to a special surveillance (fx euphoriant medicine).

B.

Prescription only medicines. Only one delivery from the same prescription unless the prescriber has indicated more than one delivery at the prescription.

BEGR.

The medicine may only be delivered to the hospitals.

HA.

OTC's only allowed to be sold from pharmacies.

HF/HX.

OTC's allowed to be sold from pharmacies and other non-prescription stores and places of retail that are authorised by the Danish Medicines Agency.

NBS.

Only a specialist may prescribe the medicinal product.

SSI.

The medicinal product can directly be delivered to doctors, dentists, veterinary surgeons, pharmacies and hospitals from the National Central Laboratory of the Danish Health System.

SVS.

The medicinal product can directly be delivered to pharmacies and veterinary surgeons from the Danish Veterinary Laboratory.

Finland

Reseptilääke.

Prescription only medicines

Itsehoitolääke.

Over-the-counter products

France

Liste I.

Reimbursable pharmaceuticals for sales by pharmacies

Liste II.

Reimbursable pharmaceuticals dispensed by hospitals

Stupefiants

Need of special prescription limited to 7, 14 or 28 days

OTC

Medicines withou need of a medical prescription

Germany

Verschreibungspflichtig.

Need of medical prescription equivalent to the UK "prescription only medicines"

Apothekenpflichtig.

A medicinal product can only be supplied by a pharmacy

Freiverkäuflich.

These medicines can be sold in drugstores and supermarkets

Betäubungsmittel (Btm).

Controlled substances (opioids, amphetamines, etc.) are under special legal control, if they can induce drug dependence

Greece

1. Prescription only medicines

A prescription is obligatory to purchase the medicines under this category. Each prescription may only be used once.

2. Medicines for hospital use

The list contains medicines that are dispensed to hospitals only.

3. Special medicines

Dispensing come under special law arrangements according to Directives issued by the Ministries of Health and Commerce.

4. OTC

Medicines freely available from the chemists without prescription.

The above-mentioned categories are not the actual classification used in the database. There are 32 categories, which can band together, in the above 4 general groups.

Ireland

Prescription only medicines

The Medicinal Products (Prescription and Control of Supply) Regulations, 1996 set out the classes of medicines that must be supplied on prescription.

There are three classes of prescription only medicines:

S1A - An S1A medicine may be dispensed on one occasion only.

S1B - An S1B medicine may be repeated for six months at appropriate intervals, unless the prescriber directs otherwise.

S1C - An S1C medicine may only be dispensed in a hospital.

Misuse of Drugs Regulations, 1988 and 1993

Some prescription only medicines are "controlled medicines" and are classified into five schedules with different controls applying to each – these include opiates, amphetamines and other potential medicines of abuse.

Pharmacist supervised sale (PS)

Certain medicinal preparations, which are exempt from prescription control, may only be supplied by or under the personal supervision of a pharmacist.

A number of substances are specifically exempted from this pharmacist-supervised sale requirement, for example aspirin, paracetamol and certain vitamins. These substances may be supplied in non-pharmacy outlets when contained in OTC preparations.

Italy

RMS (Ricetta Medica Speciale).

This refers to the prescription of narcotic medicines. It is a special formulary, in triplicate (one copy for the doctor, one for the dispensing pharmacy and one for the administration). The pharmacist must hold it for 5 years after dispensation. (D.P.R. 309/90)

RNR (Ricetta Non Ripetibile).

This receipt can be used once only.

RR (Ricetta Ripetibile).

This receipt can be used several times, during a period of max 6 months.

RL (Ricetta Limitativa).

This refers to medicines whose prescribing is limited to special settings (hospital and universities) and/or specialists (oncologist, endocrinologist, etc)

OTC.

Over the counter medicines; it can be sold in pharmacy without a written receipt

SP (senza prescrizione).

As for OTC, but the medicines included in this category can be advertised (TV, radio, press) to the public

OSP (Farmaci Ospedalieri).

Medicinal product for hospital and nursing home use only, not for sale to the patients. Twenty-six subcategories are included in this class (radiopharmaceuticals, dialysis, ophtalmics, intensive care departments, etc).

The Netherlands

UR; uitsluitend recept, WTG-product, receptplichtig.

Need of medical prescription

Niet-UR; OTC, receptvrij, vrije verkoop, handverkoop buiten-WTG-product.

No need of medical prescription

Artikel 4 homeopathische producten.

No need of medical prescription. Homeopathic products , very diluted: at least 1 to 10.000

Artikel 6 homeopathische producten.

No need of medical prescription. Homeopathic products, not very diluted. May have indication for use.

Norway

A

Mainly substances classified as narcotics according to international conventions.   Some substances from the psychotropic convention (P II) are also included here.

B

Mainly tranquillisers and hypnotics - psychotropic medicines (P II)

C

All other POM

F

OTC

Portugal

Medicamentos de Receita Médica Renovável

Renewal prescriptions – for the chronic diseases and for some special diseases medicines that have a safe profile can be dispensed without the need for a new prescription (the patient does not need to be consulted by a physician).

Medicamentos Sujeitos a Receita Médica Especial

Special Prescription – These include psycothropics and medicines that have the potential for abuse and dependence.

Medicamentos de Receita Médica Restrita

Restrict Prescription – reserved for very specialised hospitals or that can be used in ambulatory care but which have a high probability for serious adverse reactions

Medicamentos de Receita Médica Não Renovável

Non-renewal prescription – medicines that don't comply with the characteristics above mentioned

Medicamentos não Sujeitos a receita médica

OTC. According to European Union norms and legislation, namely Directive 92/26/EEC

Autorização de Utilização Especial

In absolutely exceptional cases for medicines that don't have MA in our country and in some clinical situations (vg : orphan drugs, rare diseases) and for investigational medicinal products.

Spain

Especialidades dispensables con receta médica

They need a prescription. This category includes most of the medicines. They can or cannot be reimbursed by The National Health Service.

Especialidades dispensables sin receta médica

They do not need prescription. The National Health Service does not reimburse them. They can be advertised.

Especialidades Farmacéuticas Publicitarias (EFP)

They do not need prescription. The National Health Service does not reimburse them. They are all advertised.

Especilidades Farmacéuticas Genéricas (EFG)

Generics. They can or cannot need prescription. If they have prescription the National Health Service reimburses them.

Especialidades farmaceúticas de uso hospitalario

Prescription and dispensation only into the Hospital. All are reimbursed.

Especialidades de diagnóstico hospitalario (DH)

They need prescription for a specialist and can be purchased at the community pharmacy. They are reimbursed after supervision.

Especialidades farmacéuticas de especial control médico (ECM)

They are subjected to a special control. They need prescription for a specialist and supervision. They are all reimbursed. (Examples: clozapine; isotretinoine; …)

Especialidades con aportación reducida

They are some medicines such as those very expensive or those intended for chronic treatments that are in a list. Patients have to pay only a 10% of the price up to an amount of 2,64 €.

Tratamiento de larga duración

Medicines for long treatments. They are all reimbursed in the usual way or as the medicines in the above group (10% up to 2,64 €.)

Medicamentos extranjeros

They come from abroad and obviously they are not available in Spain. They need a special authorisation. They are all reimbursed.

Psicotropos y estupefacientes

Psychotropics: The pharmacist has to register all the prescriptions of this type (medicine and doctor who prescribes).

Narcotics

They need a special prescription form (i.e. morphine). Not all opioids need a special prescription form (tramadol does not need it).

Tratamientos compasivos

Compassionate treatments. Must be authorised by the Ministry of Health Dispensation at the Hospital otherwise by the pharmaceutical company. Reimbursed.

Vacunas

Vaccines. They are all reimbursed.

Sweden

Receptbelagda läkemedel

Prescription Only Medicines

Receptfria läkemedel

OTC medicines

United Kingdom

POM

Prescription only medicine, available only on prescription of a doctor (although increasingly also on prescription of nurses or pharmacists). These are only available through pharmacies. Some POMs are recommended only for prescription by certain groups, e.g. hospital consultants or in certain settings. Other restrictions may be imposed, for instance, a requirement that clozapine can only be prescribed as part of a monitored system.

CD

Some POMs are "controlled medicines" and have special prescription writing restrictions around them – these include opiates, amphetamines and other potential medicines of abuse. Some benzodiazepines, e.g. temazepam, although not strictly a CD, also have similar prescription restrictions placed around them.

P

Pharmacy. These are medicines that can be sold by a pharmacist without prescription. It includes a number of medicines that are POM but provided in lower dose, e.g. ranitidine, nizatidine. The Pharmacist is professionally required to advise the patient on the use of the medicine and to ensure that the condition for which it is being used is appropriate.

GSL-General Sale List

This consists of medicines available for general sale in supermarkets, grocery stores etc. It includes either small quantities or low doses of widely used analgesics and symptomatic remedies. There is no check on the condition for which it is used, nor is any specific advice given to the customer.

Annexe 6 – Reimbursement categories of medicines in the European Union Member States and Norway

Austria

According to the General Social Insurance Act (ASVG), in Austria all pharmaceuticals are reimbursable, if they are "required for effective and sufficient medical treatment which does not exceed the necessary level"

However, two different types of reimbursement are distinguished: the "Heilmittelverzeichnis" (Pharmaceutical List) and the "chefärztliche Bewilligung" (approval by the "head doctor").

Heilmittelverzeichnis.

Pharmaceuticals listed on the "Heilmittelverzeichnis" (Pharmaceutical List) qualify for automatic reimbursement (100%).

Chefärztliche Bewilligung.

Pharmaceuticals which are not listed on the "Heilmittelverzeichnis" (Pharmaceutical List) are only funded (100%) by the social insurance if they are approved by the health insurance fund (though a so-called "head doctor" of the health insurance fund).

According to the ASVG-based guidelines by the Federation of Austrian Social Insurance Institutions for economic prescribing, some remedies must never get an approval by the "head doctor": medicinal wines, mineral waters, tonics, bath oils without proven therapeutic effects, cosmetics, remedies for the cessation of nicotine dependence and for the stimulation and/or intensification of the sex drive. As they are not listed in the "Heilmittelverzeichnis", they are thus exempted from the general reimbursement scheme (negative list).

* The social insurance scheme in Austria is based on the General Social Insurance Act (ASVG – Allgemeines Sozialversicherungsgesetz), which covers the majority of employed persons and pensioners. Apart from the ASVG scheme, there are specific laws for civil servants, persons active in a craft or trade, self-employed persons, farmers and notaries.

Belgium

Category A.

Vital Medicines: (e.g. against Diabetes, Cancer, AIDS)
100% reimbursement (Represent 14.6% of the state expenditures)

Category B.

Important medicines, for non-life-threatening diseases:
75% reimbursement for normal insures (with a maximum per package 9.79 EUR:
85% reimbursement for underprivileged insured (orphans, widows, invalidated persons), with a maximum per package 6.57 EUR)
(represent 83,3 % of state expenditures)

Category C.

(C; Cx;Cs) Medicines more likely to be comfort medicines
Normal insured: 50% Reimbursement (Max 12,24 EUR)
Underprivileged: 50% Reimbursement (Max 9,79 EUR)
40% Reimbursement (no max.)
20% Reimbursement (no max.)
(represent 2.1 % of state expenditures)

Denmark

The reimbursement system in Denmark

Health Insurance provides reimbursement for the majority of medicinal products (general reimbursement). The majority of prescription-only medicinal products are entitled to general reimbursement. Some medicinal products only receive general reimbursement in particular cases, e.g. for the treatment of certain diseases. Some OTCs are entitled to general reimbursement if the product is prescribed by the GP and the patient is a pensioner or has a permanent disorder. When the Danish Medicines Agency evaluates whether general reimbursement should be given to a medicinal product, the effect of the medicinal products is evaluated in relation to the price.

The size of reimbursement depends on the patient's total annual expenses on reimbursement-entitled medicinal products, before the reimbursement is subtracted. The larger expenses within a one-year period, the more the patient receives in reimbursement.

Within groups of the same medicinal products a reimbursement price is calculated, i.e. the European average price or the price for the cheapest medicinal product in the group, if the group doesn't have a European average price. When a medicinal product doesn't belong to a group of generic products, the reimbursement price will be the European average price or, if the product isn't on the market in the rest of Europe, the Danish price. The European average price is calculated against a background of the prices in 13 European countries: Iceland, Norway, Sweden, Finland, Germany, Netherlands, Belgium, Austria, France, Italy, UK, Ireland and Liechtenstein. If the medicinal product is only on the market in Denmark and fx Sweden, the European average price will be the price in Sweden.

The reimbursement constitutes 50%, 75%, 85% or 100% of the price of the reimbursement price. How large a percent the patient receives in reimbursement is dependent on the amount of expenses the patient has had within one year on medicinal products entitled to reimbursement, see the table given below.

If the prescribed medicinal product is more expensive than the reimbursement price, the patient only receives reimbursement for the reimbursement price. This means the patient has to pay the extra expense by him- or herself, which is the difference between the price of the medicinal product and the reimbursement price. The reimbursement can therefore amount to less than the above-mentioned percentages. The pharmacy can - instead of the medicinal product prescribed - dispense a generic or parallel imported medicinal product. The pharmacy must dispense a cheaper medicinal product, unless the doctor has decided against substitution by writing it on the prescription. If both the patient and the doctor agree on substitution, the patient will receive the cheapest medicinal product and obtain reimbursement to the total price.

If the patient spends large amounts of money annually on reimbursement-entitled medicinal products (at present over 2,556 Euro for adults and 2,784 Euro for children under 18 years), the patient can, via the doctor, apply for chronic reimbursement, and whereby obtain 100 % in reimbursement for all expenses greater than this amount. Some patients get further reimbursement from the local authority (the municipality) if they are a pensioner or have financial problems.

Reimbursement for persons older than 18 years

0 %	0 - 68.60 Euro
50 %	68.60 - 165.40 Euro
75 %	165.40 – 386.60 Euro
85 %	Over 386.60 Euro

Reimbursement for persons younger than 18 years

50 %	0 - 68.60 Euro
50 %	68.60 - 165.40 Euro
75 %	165.40 – 386.60 Euro
85 %	Over 386.60 Euro

Finland

Peruskorvausluokka.

Basic Refund Category: Patient pays EUR 10.00 plus 50% of the remaining costs of preparations purchased on one occasion. When the Pharmaceuticals Pricing Board accepts a reasonable wholesale price for a medicine, it is automatically reimbursed in the basic refund category.

Merkittävät ja kalliit lääkkeet.

Significant and Expensive Medicines: Sub-group of the Basic Refund Category. To qualify for a refund of a medicine belonging to this group, the patient has to prove his/her need for such medication by providing a separate statement. The statement can either be in the form of doctor's certificate or as an addendum to the prescription sheet. Without this statement, the medicine can not be reimbursed. The sub-group includes, for example, certain medicines used in the treatment of MS, erectile dysfunction and obesity. Council of State determines which medicines belong to this sub-group.

Alempi erityiskorvausluokka.

Lower Special Refund Category: Patient pays EUR 5.00 plus 25% of the remaining costs of preparations purchased on one occasion. Includes medicines for chronic conditions such as asthma, hypercholesterolemia, hypertension and ulcerative colitis. Council of State determines diseases and the Pharmaceuticals Pricing Board individual medicinal products belonging to this Category. The patient has to prove his/her need for this medication by providing a doctor's certificate. Without this certificate, the medicine is reimbursed in the Basic Refund Category.

Ylempi erityiskorvausluokka.

Higher Special Refund Category: Patient pays EUR 5.00 of the costs of preparations purchased on one occasion. Includes medicines for the treatment of life threatening and severe chronic diseases, including cancer, diabetes and some psychotic disorders. Council of State determines diseases and the Pharmaceuticals Pricing Board individual medicinal products belonging to this Category. The patient has to prove his/her need for this medication by providing a doctor's certificate. Without this certificate, the medicine is reimbursed in the Basic Refund Category.

Lisäkorvaus.

Additional Refund: If person's annual medicine costs exceed a certain limit (EUR 601 in 2003 and € 605 in 2004), the remainder is refunded entirety.

France

100%.

Medicines used in life threatening conditions (diabetes, AIDS, cancer)

65%.

Reimbursed medicines different from the group 100% or to the group 35%

35%.

Medicines used mainly for non-serious conditions (acute conditions)

0%.

OTC medicines

Germany

Verordnungsfähig.

Reimbursed: These medicines are reimbursed. In 2004 all medicines will be reimbursed which are "verschreibungspflichtig".

Nicht verordnungsfähig.

Not reimbursed: These medicines are not reimbursed. In 2004 medicines which are not "verschreibungspflichtig" will be not reimbursed.

Greece

Συνταγογραφούμενα φάρμακα (Syntagografoumena farmaka).

A list of prescription medicines includes all reimbursed medicines. The list is updated periodically by the Ministry of Health.

Μη συνταγογραφούμενα φάρμακα. (Mi syntagografoumena farmaka)

Medicines for which no prescription is required are Not Reimbursed medicines.

Ireland

General Medical Service (GMS) Scheme – 100% reimbursement.

The GMS scheme is a means tested scheme and is dependant upon factors such as age, marital status, living alone or with family and allowances e.g. for children under sixteen years. Since July 1st 2001 all residents over the age of 70 years are eligible for the GMS scheme regardless of means. Those who are covered by the GMS scheme are entitled to free prescription medicines. The number of eligible persons under the GMS scheme at the end of the year 2002 was 1,168,745 i.e. 29.8% of the population. Over 77% of eligible persons availed of the scheme in 2002.

Long Term Illness (LTI) Scheme – 100% reimbursement

The LTI Scheme entitles patients suffering from any one of fifteen specified chronic conditions to full medicine reimbursement irrespective of income.

Drugs Payment (DP) Scheme

The DP scheme, introduced on 1/7/1999, applies to Irish residents who are not eligible for the GMS scheme. Under the DP scheme no individual or family is required to pay more than €78 in any calendar month for approved prescribed medicines for use by that person or his/her family in that month.

European Economic Area (EEA) Scheme and High Tech Drugs (HTD) Scheme

The European Economic Area (EEA) scheme provides visitors from other member states, with established eligibility, emergency general practitioner services while on a temporary visit. In 2002, prescription items dispensed under the EEA scheme cost €1.5 million.

The High Tech Drugs (HTD) scheme facilitates the supply by community pharmacies of certain high cost medicines e.g. those used in conjunction with chemotherapy, beta-interferon etc. which had previously been supplied primarily in the hospital setting. The cost of medicines dispensed under the HTD scheme is paid directly to the wholesalers and pharmacists are paid a standard patient care fee of €49.64 per month to cover dispensing.

Italy

Classe A.

This class includes "essential medicines and medicines for chronic diseases".

All the medicines included in this category are fully reimbursed (100% of their price) by the National Health Service.

This means that the patient receives by the pharmacist the prescribed medicine paying only a ticket (around 1-2 €, according to the local area) .

Lower income subjects are ticket-free.

Patients with specific social diseases (diabetes, hypertension and other CV diseases, epilepsies, cancer, etc) are ticket-free for all the medicines needed to treat the disease. (i.e. an epileptic patient is ticket-free for his/her antiepileptic medicine, but he/she must pay the ticket for an antibiotic).

Classe A con nota CUF.

The medicines included in this category are fully reimbursed (100% of their price) by the National Health Service for some specific diseases only.

If the medicine is prescribed for a disease not included in the Nota CUF (list) it will be not reimbursed.

The aim of this system, hardly criticised by pharmaceutical companies, is to limit both expenditure and inappropriate utilisation. Note CUF could be defined as guidelines for the appropriate use of medicines and they are an important effort of rationalising GP prescriptions.

A full list of the "Note CUF" is available at www.ministerosalute.it   (formerly www.sanita.it)

Classe C.

The National Health System does not reimburse the medicines included in this class.

This class includes: medicines for minor ailments (cold, cough, vitamins, etc); poor value medicines without a well established activity; medicines which use is discouraged (benzodiazepines); single trade names with a very higher price as compared with lower price competitor.

Basically, all the non-prescribed medicines are not reimbursed. Some prescribed medicines can be not reimbursed.

The Netherlands

Explanation about the current system:

Only products that have marketing authorisation are eligible to be reimbursed. All reimbursed products are on a positive list (Medicinal Product Reimbursement System (Geneesmiddelen ver-goedingssysteem.

Following explanation and categories are legal only for public health insurers, but there is a convenant with the private insurers to act the same way. Mostly they do.

Annex 1a (WTG-producten).

For those products, which are therapeutically interchangeable, a reference price system exists. This so called "clustering" is based on the following criteria:

Range of indications;

Route of administration;

Absence of clinically relevant differences in efficacy and side effects to:

Whole patient group;

Different patient age groups;

To be used in the same age groups.

Within a cluster of comparable products a reimbursement limit is calculated, based on the prices of 1998/IV. In contrast to the above mentioned Medicinal Products Prices Act the price of a pharmaceutical product can exceed this reimbursement limit. The difference has to be paid by the patient. In reality most products are priced on or below this limit, so although theoretically possible co-payment is almost non-existing. 96% of prescriptions are totally reimbursed.

Clusterable products are published on the positive annex 1A.

Annex 1b (WTG-producten).

Products that cannot be clustered, but are reimbursed, are published on 1B. This annex 1B has no reimbursement limits. Conditions for placement on annex 1B are:

Therapeutic value: the new product is compared with the present standard therapy for that indication with respect to:

Effectiveness and/or efficacy;

Side effects;

Less important items are:

Applicability;

User-convenience

Experience;

Quality of Life.

A lower therapeutic value leads to a negative reimbursement decision.

Cost / efficiency: A this moment only direct medical costs of the new product is compared to present standard therapy for that indication. At this moment the system is in transition to include pharmaco-economic data into the comparison.

If costs are lower or comparable a positive decision is taken. If costs are higher in combination with a higher therapeutic value, the Minister of Health will decide based on the interest of public health.

Annex 2 (WTG-producten).

In some cases extra constrains on reimbursement are necessary. These extra conditions are published on annex 2. Examples of conditions are:

Limitation in patient population;

Strict treatment protocol;

Prior authorisation by health care insurer;

Limited prescriber groups.

Buiten-WTG-producten;

OTC, Not chronisch. No reimbursement

Buiten-WTG-producten; OTC, chronisch.

When an OTC product can be used for chronic treatment, the prescriber writes this aim down on the prescription, and it is not the first prescription, the product will be reimbursed.

Homeopathische geneesmiddelen .

No reimbursement

Medicinal products dispensed to inpatients in hospitals.

Reimbursed

Norway

Blue prescription.

Reimbursement not connected only to the medicine, but based on indication – main rule: Medicine expenses in chronic diseases with long-term treatment are reimbursed. Usually 64 % reimbursed. All expenses over 48 Euro/3 months are covered. 100% reimbursement for children<7 years old.

White prescription.

Usually not reimbursed. For some specified indications and when expenses are over 160 Euro/year: 67% of the expenses can be reimbursed.
For a few indications: 100 %.

Portugal

Escalões de Comparticipação.

There are four normal levels of reimbursement:

Level A

100%

Level B

70%

Level C:

40%

Level D:

20%

The classification of the medicinal products in the different reimbursement categories depends on their therapeutic classification, considering that therapeutic groups and sub-groups have been previously integrated in the different categories.

Level D (20%) is a temporary reimbursement period and should be reserved for the medicinal products that for public health reasons need to be in the market to benefit patients but are still under assessment (pharmacoeconomic study).

The criteria for reimbursement eligibility is based on the medicinal product characteristics of a product, namely:

- Innovative medicinal products that are supposed to fill a therapeutic group gap: Need to demonstrate higher efficacy and/or tolerance compared to existing similar products
- New form, dosage or package of a product already in the reimbursement list: Need to demonstrate therapeutic advantage and economic benefit
- Products not characterised as significant therapeutic innovation and not identical to products already in the list: Need to demonstrate therapeutic advantage and economic benefit
- Products with more than one active substance, one of them existing as a separated product in the market: Need to demonstrate the therapeutic benefit of the combined product compared to the active substances administered separately. The price of combined product cannot be higher than those of the products having the isolate composite substances.

Products having more than one substance, no one existing as separate products in the market: Need to demonstrate therapeutic advantage.

Regimes Especiais de Comparticipação.

In the case of pensioners whose income is not higher than the national minimum wage, an extra 15% is reimbursed in the case of the non fully reimbursement categories, reaching a level of 85, 55 and 35 per cent respectively.

Comparticipação dos Genéricos.

For generic medicines there is an extra 10% added to the different reimbursement levels.

The reimbursement rates for generics are therefore 100%; 80%, 50% and 30% for the general system, and 100%, 95%, 65% and 45% for the pensioner whose income is not higher than the national minimum wage.

Spain

Pensionistas (receta roja).

This category includes people > 65 years old, retired and handicapped people. They do not pay for medicines.

Activos (receta verde).

This category includes active workers. They pay 40% of medicine price.

Enfermedad laboral o accidente de trabajo (receta azul).

Here are included people who suffer an industrial accident or occupational diseases. They do not pay for medicines.

MUFACE (Mutualidad General de Funcionarios Civiles del Estado).

MUFACE is a mutuality that includes civil servants; they pay 30% of the medicines prices.

ISFAS (Instituto Social de las Fuerzas Armadas).

ISFAS is a special regimen that includes military personnel; they pay 30% of the medicines prices.

MUGEJU (Mutualidad General Judicial).

MUGEJU is a mutuality that includes civil servant from the Justice Administration; they pay 30% of the medicines prices.

Síndrome Tóxico.

People who was affected by the toxic syndrome in Spain. They do not pay for the medicines.

Campaña Sanitaria.

It refers to particular health interventions. People pay 10% of the medicines price up to 2,64 €.

Sweden

Since October 2003, an active decision regarding reimbursement status is made by the Pharmaceutical Benefits Board for all new medicines. A process has also been started to go through the reimbursement status for all products already registered in Sweden. More information is available at www.lfn.se

Inom läkemedelsförmånen (Reimbursed)

The majority of medicinal products prescribed in Sweden are reimbursed. A product can be included in the Pharmaceutical Benefit Scheme with special terms and conditions, for instance that the drug is included only for a particular use. To be included in the Pharmaceutical Benefit Scheme, the cost of the product must be reasonable from a medical, humanitarian and economic aspect and no other available drugs or treatments should be significantly more suitable for the purpose. Some non-prescription drugs are also included in the Scheme but only if they are prescribed.

Utom läkemedelsförmånen (Not reimbursed)

This category include all medicinal products that does not meet the criteria for inclusion in the Pharmaceutical Benefit Scheme mentioned above as well as most Medicinal products with a price set by the company without a negotiation with the Pharmaceutical Benefits Board.

United Kingdom

Reimbursed.

This covers the vast number of medicines in the UK. It includes POM and P, and OTC medicines if prescribed, it also includes homeopathic medicines or even medicines that are not licensed in the UK but which are legally imported. It also includes items such as, for instance, gluten free bread for celiac disease. The default is that all new medicines are reimbursed. A decision not to reimburse may be made by a specific Department of Health Committee, but this has been relatively inactive in recent times. There is also an Advisory Committee on Borderline Substances which make recommendations on "nutriceuticals" and other substances, which might or might not be regarded as medicines. There is a facility for the Minister of Health to decide that a particular medicine can be reimbursed only in certain circumstances, e.g. gluten free bread is only available for patients with a clear diagnosis of celiac disease or sildenafil can only be provided for patients with defined physical or psychosexual disorders. The doctor is required to annotate the prescription that the patient fits into one of these categories.

Not reimbursed.

This includes medicines specifically excluded by Department of Health Committee. They are annotated in the British National Formulary as NHS. There was a major expansion of this list in 1984 and a slight expansion in 1993. A manufacturer may specifically request that a medicine be included on this, for instance, minoxidil for hair loss. An example of a medicine that has recently been delisted from this list are nicotine replacement products.

Annexe 7 - Council of Europe. STANDARD TERMS. LIST OF PHARMACEUTICAL FORMS.

Oral preparations – liquid and semi-solid forms

1. Oral drops, solution
2. Oral drops, suspension,
3. Oral drops, emulsion
4. Oral liquid
5. Oral solution
6. Oral suspension
7. Oral emulsion
8. Powder for oral solution
9. Powder for oral suspension
10. Granules for oral solution
11. Granules for oral suspension
12. Powder and solvent for oral solution
13. Powder and solvent for oral suspension
14. Syrup
15. Powder for syrup
16. Granules for syrup
17. Soluble tablet
18. Dispersible tablet
19. Herbal tea
20. Oral gel
21. Oral paste

Oral preparation - solid forms

1. Instant herbal tea
2. Oral powder
3. Effervescent powder
4. Granules
5. Effervescent granules
6. Gastro-resistant granules
7. Prolonged-release granules
8. Modified-release granules
9. Cachet
10. Capsule, hard
11. Capsule, soft
12. Gastro-resistant capsule, hard
13. Gastro-resistant capsule, soft
14. Prolonged-release capsule, hard
15. Prolonged-release capsule, soft
16. Modified-release capsule, hard
17. Modified-release capsule, soft
18. Tablet
19. Coated tablet
20. Film-coated tablet
21. Effervescent tablet
22. Orodispersible tablet
23. Oral lyophilisate
24. Gastro-resistant tablet
25. Prolonged-release tablet
26. Modified-release tablet
27. Chewable tablet
28. Medicated chewing-gum

29. Oral gum
30. Pillules
31. Lick block
32. Premix for medicated feeding stuff
33. Medicated pellets

Oromucosal preparations

1. Gargle
2. Concentrate for gargle
3. Gargle, powder for solution
4. Gargle, tablet for solution
5. Oromucosal solution
6. Oromucosal suspension
7. Oromucosal drops
8. Oromucosal spray
9. Sublingual spray
10. Mouth wash
11. Mouth wash, tablet for solution
12. Gingival solution
13. Oromucosal gel
14. Oromucosal paste
15. Gingival gel
16. Gingival paste
17. Oromucosal capsule
18. Sublingual tablet
19. Muco-adhesive buccal tablet
20. Buccal tablet
21. Lozenge
22. Compressed lozenge
23. Pastille

Preparation for dental use

1. Dental gel
2. Dental stick
3. Dental insert
4. Dental-powder
5. Dental solution
6. Dental suspension
7. Dental emulsion
8. Toothpaste

Cutaneous and transdermal preparations

1. Bath additive
2. Cream
3. Gel
4. Ointment
5. Cutaneous paste
6. Medicated plaster
7. Cutaneous foam
8. Shampoo
9. Cutaneous spray, solution
10. Cutaneous spray, suspension
11. Cutaneous spray, powder
12. Cutaneous liquid
13. Cutaneous solution
14. Concentrate for cutaneous solution
15. Cutaneous suspension
16. Cutaneous emulsion

17. Cutaneous powder
18. Solution for iontophoresis
19. Transdermal patch
20. Collodion
21. Medicated nail lacquer
22. Poultice
23. Cutaneous stick
24. Cutaneous sponge
25. Impregnated dressing
26. Collar
27. Medicated pendant
28. Ear tag
29. Dip solution
30. Dip suspension
31. Dip emulsion
32. Concentrate for dip solution
33. Concentrate for dip suspension
34. Concentrate for dip emulsion
35. Concentrate for solution for fish treatment
36. Powder for solution for fish treatment
37. Pour-on solution
    1. Pour-on suspension
38. Pour-on emulsion
39. Spot-on solution
40. Spot-on suspension
41. Spot-on emulsion
42. Teat dip solution
43. Teat dip suspension
44. Teat dip emulsion
45. Teat spray solution

Eye preparations

1. Eye cream
2. Eye gel
3. Eye ointment
4. Eye drops, solution
5. Eye drops, suspension
6. Eye drops, powder and solvent for solution
7. Eye drops, powder and solvent for sospension
8. Eye drops, solvent for reconstitution
9. Eye drops, prolonged release
10. Eye lotion
11. Eye lotion, solvent for reconstitution
12. Ophthalmic insert

Ear preparations

1. Ear cream
2. Ear gel
3. Ear ointment
4. Ear drops, solution
5. Ear drops, suspension
6. Ear drops, emulsion
7. Ear powder
8. Ear spray
9. Ear spray, suspension
10. Ear spray, emulsion
11. Ear wash, solution
12. Ear wash, emulsion
13. Ear tampon

14. Ear stick

Nasal preparations

1. Nasal cream
2. Nasal gel
3. Nasal ointment
4. Nasal drops, solution
5. Nasal drops, suspension
6. Nasal drops, emulsion
7. Nasal powder
8. Nasal spray, solution
9. Nasal spray, suspension
10. Nasal spray, emulsion
11. Nasal wash
12. Nasal stick

Vaginal preparations

1. Vaginal cream
2. Vaginal gel
3. Vaginal ointment
4. Vaginal foam
5. Vaginal solution
6. Vaginal suspension
7. Vaginal emulsion
8. Tablet for vaginal solution
9. Pessary
10. Vaginal capsule, hard
11. Vaginal capsule, soft
12. Vaginal tablet
13. Effervescent vaginal tablet
14. Medicated vaginal tampon
15. Vaginal delivery system
16. Vaginal sponge

Rectal preparations

1. Rectal cream
2. Rectal gel
3. Rectal ointment
4. Rectal foam
5. Rectal solution
6. Rectal suspension
7. Rectal emulsion
8. Concentrate for rectal solution
9. Powder for rectal solution
10. Powder for rectal suspension
11. Tablet for rectal solution
12. Tablet for rectal suspension
13. Suppository
14. Rectal capsule
15. Rectal tampon

Preparations for inhalation

1. Nebuliser solution
2. Nebuliser suspension
3. Powder for nebuliser suspension
4. Powder for nebuliser solution
5. Nebuliser emulsion

6. Pressurised inhalation, solution
7. Pressurised inhalation, suspension
8. Pressurised inhalation, emulsion
9. Inhalation powder
10. Inhalation powder, hard capsule
11. Inhalation powder, hard capsule
12. Inhalation powder, pre-dispensed
13. Inhalation vapour, powder
14. Inhalation vapour, capsule
15. Inhalation vapour, solution
16. Inhalation vapour, tablet
17. Inhalation vapour, ointment
18. Inhalation vapour, liquid
19. Inhalation gas

Parenteral preparations

1. Gel for injection
2. Solution for injection
3. Suspension for injection
4. Emulsion for injection
5. Powder for solution for injection
6. Powder for suspension for injection
7. Powder and solvent for solution for injection
8. Powder and solvent for suspension for injection
9. Concentrate for solution for injection
10. Solution for infusion
11. Emulsion for infusion
12. Powder for solution for infusion
13. Concentrate for solution for infusion
14. Powder and solvent for solution for infusion
15. Solvent for parenteral use

Implants

1. Implant
2. Implantation tablet
3. Implantation chain

Preparation for dialysis

1. Solution for peritoneal dialysis
2. Solution for haemofiltration
3. Solution for haemodiafiltration
4. Solution for haemodialysis
5. Concentrate for haemodialysis solution

Preparation for intravesical and urethral use

1. Solution for intravesical use
2. Bladder irrigation
3. Powder for bladder irrigation
4. Urethral gel
5. Urethral stick

Tracheopulmonary preparations

1. Endotracheopulmanary instillation, solution
2. Endotracheopulmanary instillation, powder for solution
3. Endotracheopulmanary instillation, suspension
4. Endotracheopulmanary instillation, powder and solvent for solution

Endocervical preparations

1. Endocervical gel
2. Powder and solvent for endocervical gel

Intramammary preparations

1. Endotracheopulmanary instillation, powder for solution

Intrauterine preparations

1. Intrauterine delivery system

Environmental preparations

Miscellaneous

Denture lacquer
Anticoagulant and preservative solution for blood
Solution for blood fraction modification
Wound stick
Radiopharmaceutical precursor
Radionuclide generator
Kit for radiopharmaceutical preparation
Gastroenteral solution
Dispersion
Gastroenteral suspension
Gastroenteral emulsion
Solution for organ preservation
Irrigation solution
Stomach irrigation
Sealant
Powder and solvent for sealant
Impregnated pad
Living tissue equivalent