
EURO-MED-STAT

Working Group on Medicine Utilisation and Expenditure Indicators

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Utilisation / Expenditure Indicators

These Recommendations have been produced by the: “EURO-MED-STAT Working Group on Expenditure and Utilisation Indicators” and have been approved by all the members of the EURO-MED-STAT Group.

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Expenditure and Utilisation Indicators

The Library of European Union Pharmaceutical Indicators

The EURO-MED-STAT Group

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1- Introduction

Impact of medicine utilisation and expenditure on public health

More than 100,000 medicinal products are presently licensed and marketed in the European Union countries. The overall use of active ingredients is in the order of tons per day and the expenditure higher than €100 billion per year (2/3 of which are paid by national health care systems).

This wide utilisation of medicines has an important impact on public health and exerts its influence by four different ways:

1. Medicines cause intended therapeutic effects: i.e. improving or preventing diseases and relieving symptoms;
2. Medicines may cause medication errors and other medicine-related problems: patients taking a medicine for no medically valid indication, patients receiving a wrong medicine or the right medicine in the wrong way, patients failing to receive the medicine they need, patients experiencing adverse drug reactions.
3. Medicines pose an economic burden and impose an opportunity cost: pharmaceutical expenditure accounts for a large proportion of health care spending and it is rising faster than any other area of health care.
4. The use of pharmaceuticals has an ecotoxicological impact by releasing in the environment, via the wastewater, pharmacologically active substances (including endocrine disrupters and carcinogens) able to pollute drinking water, rivers, seas and soil.

Thus in a public health perspective there are several reasons to measure medicine utilisation and expenditure:

- Prescription of a medicine is the most common therapeutic intervention and one of the most common medical act (up to 95% of all doctor-patient contacts result in a prescription for a medicinal product)
- Most prescriptions are repeat prescriptions for medicines used for chronic conditions, especially in elderly
- for the reasons described above medicines have a wide impact on public health
- medicines can adversely affect public health because of medicine related problems
- medicines related problems are an important cause of mortality and most problems can be prevented
- utilisation data can be a useful denominator for pharmacovigilance analyses
- there is an important economic burden of medicines on health systems
- medicines are able, via the wastewater, to pollute the environment, including drinking water and several medicines have endocrine-disrupters or carcinogenic properties.
- there are wide discrepancies between European countries in both licensed medicines and in their utilisation and expenditure

Making comparable information publicly available and so increasing transparency in this sector where wide financial interests play an important role, is in itself useful.

In addition, good quality data will allow benchmarking between countries in expenditure and utilisation. This can be useful to measure quality of care and to identify areas for improvements in the quality of pharmaceutical care and therapeutic outcome, increasing benefits and reducing risks for patients, and enhancing the efficiency of the national pharmaceutical systems.

For all these reasons is relevant to have information able to compare and monitor medicine utilisation and expenditure at a European level.

To do this there are two different aspects and problems to be solved:

- 1- data sources on medicine utilisation and expenditure
- 2- pharmaceutical indicators for monitoring medicine utilisation and expenditure

2- Data sources on medicine utilisation and expenditure in the European Union Member States and Norway

Table 1 outlines the results of our surveys about data sources whose details (including information provided and coverage) are given in the document *The Library of European Union Pharmaceutical Indicators-Recommendations for national registers of medicinal products with validated ATC codes and DDD values* (Annex 2- List of national registers of medicinal products and utilisation expenditure data by country; page 19).

In table 1 we separated hospital from out-of-hospital data. Information on hospital utilisation, like information on price of medicines in hospital, is available in only few countries (in France hospital data are pooled with out-of-hospital data).

Moreover, hospital utilisation of medicines strongly depends on the case-mix of the hospital: i.e. a hospital whose patients have mainly infectious diseases will have a greater utilisation of antimicrobial agents than a hospital whose patients are mainly affected by cardiac diseases. Finally the largest amount of medicines is used out-of-hospital and there is an important trend to shift care from hospital to general practice. For all these reasons we decided to concentrate our efforts on out-of-hospital utilisation (primary care).

Table 1. Number of data sources of medicine utilisation/expenditure at different points in the distribution chain across European Union Member States and Norway

	HOSPITAL DATA	OUT-OF-HOSPITAL DATA		
		Selling Data (Pharmaceutical Companies or Wholesalers)	Dispensing data (Pharmacy) and/or Reimbursement data (Sickness funds)	Prescribing data (Physicians)
Austria	1	1	3	—
Belgium	—	1	2	—
Denmark	1	1	1	—
Finland	1	1	1	—
France	(pooled hospital and out-of-hospital data)		1	—
Germany	—	1	1	—
Greece	—	1	1	—
Ireland	—	1	1	—
Italy	—	1	2	1 (ongoing project)
Netherlands	—	1	3	1
Norway	(pooled hospital and out-of-hospital data)		1*	—
Portugal	—	1	2	—
Spain	—	1	2	—
Sweden	1	1	4	1
UK	1	1	3	3
TOTAL	5	15	27	6

* National prescription database established in January 2004
Source: EUROMEDSTAT project

Data of medicine utilisation and expenditure in primary care can originate from all the different levels of the distribution chain:

- selling data from pharmaceutical companies and/or wholesalers
- dispensing data from pharmacies
- reimbursement data from National Health Service, social insurances or other third payers
- prescribing data from general practitioners or other prescribers.

These different sources can provide different type of information.

- From selling data (originated by pharmaceutical companies and/or wholesaler) it is possible to calculate the aggregated data of medicine utilisation and expenditure.
- From dispensing data (originated by pharmacies) it is possible to calculate the aggregated data of medicine utilisation and expenditure. Although summarised dispensing data do not contain any clinical information they can identify variations in prescribing. Moreover in some countries the dispensed package can be linked to some information on prescriber and user (usually sex and age) or to the individual patient and prescriber and this allows better analysis of utilisation, for instance for age classes, as shown in figure 1 for Sweden. Recording data on medicine use on an individual basis gives the possibility of investigating the prevalence and incidence of medicine use. Performing record-linkage studies by using prescription data from pharmacies with other health information registers may give valuable information on outcome.
- From reimbursement data (originated by pharmacies and managed by the public institution responsible for reimbursement) it is possible to obtain the same kind of information generated by dispensing data. They have the same limitations and in some cases it is possible to disaggregate for age classes as shown in figure 2 for Germany.
- From prescribing data (originated by general practitioners or other prescribers) it is possible to obtain more detailed information allowing to link the prescribed medicine to the individual patient and often to reason for prescribing. Unfortunately, as shown in table 1, the number of these prescribing database is limited to few countries and often the data are confined to a restricted sample of population. It is of interest that in some countries these prescribing data are used for GPs remuneration (last GPs contract in UK or in Slovak Republic) and they are becoming “*administrative*” data. This will allow in the future the availability of prescribing data on wider populations.
- Patient Health Interview Survey (HIS) can provide some information about utilisation but the quality is thought to be poor and it is often difficult or impossible to link the patient to a specific medicine. For these reasons HIS is not further discussed.

Despite the wide amount of utilisation, the large expenditure and the number of existing data sources the information about utilisation and expenditure of medicines available at a European level is occasional, limited to few countries and/or few medicines and no periodical report from European or other international institutions comparing medicine utilisation and expenditure is available. For the Nordic countries, the Nordic Medico Statistical Committee (NOMESCO) includes comparable data of use of a number of medicines groups in their annual publication (www.nom-nos.dk).

This lack of information is mainly due to the lack of reliable and comparable publicly available data collected in a standardised way from different countries.

In the scientific literature three main papers compared utilisation of medicines across EU Member States:

-the first one is a paper about utilisation of antibiotics published on the Lancet in 2001 with data referring to 1997 (Cars et al. Variation in antibiotic use in the European Union. Lancet. 2001 Jun 9; 357:1851-3);

-the second is also a paper about utilisation of antibacterials with focus also on the challenges in collecting true comparable national drug use data in Europe (Rønning et al. Problems in collecting comparable national drug use data in Europe: the example of antibacterials. Eur J Clin Pharmacol (2003) 58: 843-849).

- the third one is the EURO-MED-STAT paper on statin utilisation published in the British Medical Journal in 2004 with data referring to the year 2000 (Walley et al. Variations and increase in use of statins across Europe: data from administrative databases. BMJ. 2004 Feb 14; 328:385-6).

These papers used different data sources. Because of the lack of other publicly available data, the Swedish authors of The Lancet paper bought data on antibiotic utilisation by a private, for-

profit company (IMS) at an expensive price and with limitations in their use and disclosure and a special approach was used to recalculate the utilisation data in DDD and make this data comparable between countries. This makes very difficult to repeat the research or to enlarge it to other therapeutic classes.

For the other two papers it was possible to use administrative data, which are routinely collected by public institutions in the Member States. Advantages and limitations of the EURO-MED-STAT data sources are described in detail in the next section 3.

3- The EURO-MED-STAT administrative data sources for utilisation and expenditure data of pharmaceutical products

3.1 Advantages of the EURO-MED-STAT data sources

Within the sources identified by the EURO-MED-STAT project listed in Table 1 and discussed in Chapter 2- *Data sources on medicine utilisation and expenditure in the European Union Member States and Norway* (page 00) we identified and selected a list of possible data sources useful for collecting data at a European level.

For brevity in this report these registers are called EURO-MED-STAT administrative data sources or shortly EURO-MED-STAT data sources.

The criteria used to include a national register in the list of the EURO-MED-STAT data sources were: utilisation of the ATC / DDD system (or possibility to use the ATC/DDD system), data reliability and coverage of the population.

A list of the sources identified by this project as reliable data sources for medicine utilisation and expenditure is given in Annex 2-*Selected EURO-MED-STAT data sources for utilisation and expenditure data of pharmaceutical products in the EU countries and Norway* (page 00).

The EURO-MED-STAT data sources are all publicly supported sources, mostly governmental or major insurance/sickness funds. These systems cover usually the publicly funded use in the community.

We checked the possibility to organise a European data collection by using these sources and cardiovascular medicines (with particular reference to statins) as a test case.

We were able to collect data on the main cardiovascular classes of the ATC system (C01 Cardiac therapy; C03 Diuretics; C07 Beta blocking Agents; C08 Calcium channel blockers; C09 Agents acting on the renin-angiotensin system and C10 Serum lipid reducing agents).

Data on statins were published in 2004 (Walley et al Variations and increase in use of statins across Europe: data from administrative databases. *BMJ* 2004; 328:385-6).

However, in order to compare data from different national databases, it is very important to check if the data are produced in a similar way and whether the methodology is applied similarly in the different countries (see also “Validity and Limits” in chapter 5). Our work proved that quality of administrative data is high and national administrative databases can be used as a basis for a European collection of utilisation and expenditure data.

Differently from other commercial sources this is feasible, not expensive and it can be repeated on several years allowing comparison on time.

Assuming that the costs of data collection and processing continue to be borne by the reimbursement process, they could be made available to all governments at a relatively small cost if there were agreement on the format of data collection and reporting.

The European data collection of utilisation and expenditure data would be facilitated if the relevant registries in each country can be standardised according to the WHO suggested ATC/DDD standard and the Minimal Data Set identified in the related EURO-MED-STAT document *Recommendations for national registers with validated ATC codes and DDD values*.

3.2 Comparability of the EURO-MED-STAT data sources between countries

Table 2 outlines the results of the EURO-MED-STAT data sources in terms of origin of the data and coverage of the population.

For most sources data are originated by the pharmacies and they can be dispensing data or reimbursement data.

The coverage of the population is 100% in about half of the countries. In the other countries the coverage is higher than $\frac{2}{3}$ with the exception of Ireland where the coverage is less than $\frac{1}{3}$ (29%) of the general population. These differences in coverage, with the exception of Ireland, don't seem to be a major problem because it is possible to calculate most of the indicators using the covered

population. Ireland can be a problem because the population covered under the GSM scheme is probably the poorer and sicker third of the Irish population.

Table 2. Origin of the data and coverage of the population of the EURO-MED-STAT data sources.

Country	Origin of the data	Total population X 10 ⁶	Covered population X 10 ⁶	Coverage of the population %
Austria	Pharmacy	8.1	8.1	100
Belgium	Pharmacy	10.3	9.2	90
Denmark	Pharmacy	5.4	5.4	100
Finland	Pharmacy	5.2	5.2	100
France	Pharmacy	59.3	41.6	70
Germany	Pharmacy	82.4	70.7	86
Greece	No data source was identified			
Ireland	Pharmacy	3.9	1.15	29
Italy	Pharmacy	56.3	56.3	100
Netherlands	Pharmacy	16.1	14.9	93
Norway	Wholesale*	4.5	4.5	100
Portugal	Pharmacy	10.3	7.3	71
Spain	Pharmacy	40.4	40.4	100
Sweden	Pharmacy	8.9	8.9	100
UK (England only)	Pharmacy	50.18	50.2	100

Source: EUROMEDSTAT project and Eurostat-Health statistics: Key data on health 2002 for total population

3.3 Comparability of the EURO-MED-STAT data sources with other commercial sources

Since the EURO-MED-STAT data sources have not been widely used for such international comparison before, we thought of interest to compare data on utilisation and costs from these databases with similar IMS (International Medical Service) commercial data, which provides on payment selling data to pharmaceutical companies using wholesale data (Walley et al. Comparison of national administrative and commercial database to monitor expenditure and cost of statins across Europe. *Eur J Clin Pharmacol* 2004 in press). Medicines studied were simvastatin, lovastatin, pravastatin, fluvastatin, atorvastatin and cerivastatin (withdrawn for safety reasons in August 2001).

Data on utilisation was by total Defined Daily Doses (DDD), and subsequently calculated per 1000 population covered by each national database per day. Expenditure in EURO-MED-STAT data is that stated by each national system covered and may not exactly reflect actual costs because of discounts or additional fees. IMS data was provided at ex-factory prices. "Cost" per DDD, and DDD/1000 inhabitants (covered by the database) per day were derived from these main outcomes.

Of the 14 countries for which EURO-MED-STAT data were available, IMS data were not available for Denmark or Sweden as these are provided to IMS under license and no comparison could be made.

Variance in DDD/1000 inhabitants/day (median -1%) was small in most countries (Finland, France, Germany, Netherlands, Norway, Portugal and UK), but some countries showed wider variance. This may be due to limitations in state coverage for prescribed medicines, so that the IMS figure includes extensive private use. Limited coverage of the population in both databases may also be a factor in France.

These results demonstrate still further the value of our approach and the advantages of the EURO-MED-STAT data sources.

4- Problems in defining pharmaceutical indicators for monitoring medicine utilisation and expenditure

4.1 Differences in availability of medicines between European Union countries and Norway

The pharmaceutical market in the European Union countries and Norway is widely different and not homogenous. One of the main differences is related to the different licensed active ingredients: medicines available in a country can be not licensed or withdrawn from the market in others.

Table 00 shows a list of licensed serum lipid reducing agents in fifteen European countries: only five ingredients are licensed in all the fifteen countries and a number of ingredients is licensed in one or two countries only.

Tab 3. Licensed serum lipid reducing agents (C10) in 15 European countries. Year 2002

ATC	active ingredients	ATS	BEL	DNK	FIN	FRA	GER	GRE	IRL	ITA	NLD	NOR	PRT	SPA	SWE	UK	TOT
C10AA01	Simvastatin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
C10AA03	Pravastatin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
C10AA04	Fluvastatin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
C10AA05	Atorvastatin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
C10AC01	Cholestyramine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	15
C10AB04	Gemfibrozil	✓		✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	13
C10AB02	Bezafibrate	✓	✓		✓	✓	✓		✓	✓			✓	✓	✓	✓	12
C10AB05	Fenofibrate	✓	✓		✓	✓	✓	✓	✓				✓	✓	✓	✓	12
C10AC02	Colestipol	✓	✓	✓	✓		✓		✓		✓	✓	✓	✓	✓	✓	11
C10AD06	Acipimox	✓	✓	✓			✓	✓		✓			✓			✓	9
C10AA02	Lovastatin	✓		✓	✓		✓	✓				✓	✓	✓			8
C10AB08	Ciprofibrate		✓			✓		✓			✓		✓			✓	6
C10AX06	Omega-3-triglycerides	✓						✓		✓		✓				✓	5
C10AD02	Nicotinic acid						✓	✓							✓	✓	4
C10AX04	Benfluorex					✓				✓			✓	✓			4
C10AB09	Etofibrate	✓					✓						✓				3
C10AC03	Detaxtran									✓				✓			2
C10AX02	Probucof												✓	✓			2
C10AX03	Tiadenol					✓				✓							2
C10	Dultosil. de piperazina													✓			1
C10	Filicol													✓			1
C10	Piricarbate													✓			1
C10AA51	Simvastatin, combinat.														✓		1
C10AB	Binifibrate													✓			1
C10AB	Fibrate	✓															1
C10AC	Divistyramine									✓							1
C10AD	Sorbinate									✓							1
C10AX	Phosphatidylcholine									✓							1
C10AX05	Meglutol									✓							1

Source: modified from The EURO-MED-STAT Group: Monitoring expenditure and utilisation of medicinal products in the European Union countries: a public health approach. Eur J Public Health 2003; 3:95-100

Table 00 gives a clear idea of the difficulties in organising comparative data on medicines utilisation at a European level. About half of the ingredients listed in table 00 are confined to one or few countries, they are often old products with limited therapeutic value and each individual country can have experienced problems in linking an official ATC code released by the Oslo Centre to the active ingredient.

As shown in Table 00 the differences between countries are not limited to the licensed ingredients but they also regard, for a same ingredient, the licensed packages (number of units and strengths). This makes difficult or impossible to compare directly the utilisation and the expenditure of a same active ingredient and/or of the same packages.

Table 4. Simvastatin 20 mg - The 13 available pack sizes in 15 European countries. Year 2002

PACK SIZE	ATS	BEL	DNK	FIN	FRA	GER	GRE	IRL	ITA	NLD	NOR	PRT	SPA	SWE	UK
10 tabs							✓		✓	✓		✓			
12 tabs											✓				
20 tabs												✓			
28 tabs		✓	✓	✓	✓			✓		✓	✓		✓	✓	✓
30 tabs	✓			✓		✓				✓	✓	✓			
49 tabs											✓			✓	
50 tabs						✓									
56 tabs			✓												
60 tabs												✓			
84 tabs			✓												
98 tabs			✓	✓							✓			✓	
100 tabs			✓	✓		✓					✓			✓	
112 tabs			✓								✓				

Source: EURO-MED-STAT project

4.2 The ATC / DDD system

An internationally valid classification system of medicines and a measurement system of utilisation are thus necessary to make utilisation and expenditure data comparable between different geographic areas that can use different active ingredients and different packages.

The ATC/DDD system has proven useful in overcoming these differences and it has been suggested as a standard by WHO-Europe since 1981 and by WHO Headquarter since 1996 for global use.

The ATC system is a classification system that divides the medicines into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties. Each ingredient is identified by a specific alpha-numeric code and it is possible to cluster ingredients in groups with similar characteristics according to the different ATC levels.

The DDD is defined as “the assumed average maintenance dose per day for a medicine used for its main indication in adults”. The DDD is thus a unit of measurement, which allows measurements of utilisation independent from the differences in package size, in strength and pharmaceutical form.

The system has still some limitations (DDDs are not established for some classes of medicines) but its advantages largely overcome its limits and it is recommended as a standard also by the EURO-MED-STAT Group for calculating indicators of utilisation and expenditure.

We have also produced *Recommendations for national registers of medicinal products with validated ATC codes and DDD values* that are aimed to make the implementation of ATC/DDD system valid and transparent in all the countries and make the registers of medicines able to link each pharmaceutical pack to its ATC code and DDD value.

4.3 Utilisation of medicines, epidemiology and impact on population health

Studying medicines utilisation like the consumption of other health care resources is a complex task, which must take in account several variables.

These include:

- Relationship between age and utilisation of medicines
- Relationship between prevalence of diseases and utilisation of medicines
- Relationship between medicine utilisation and expenditure
- Relationship between utilisation of medicines and consumption of other health care resources
- Outcome of medicine utilisation and population health.

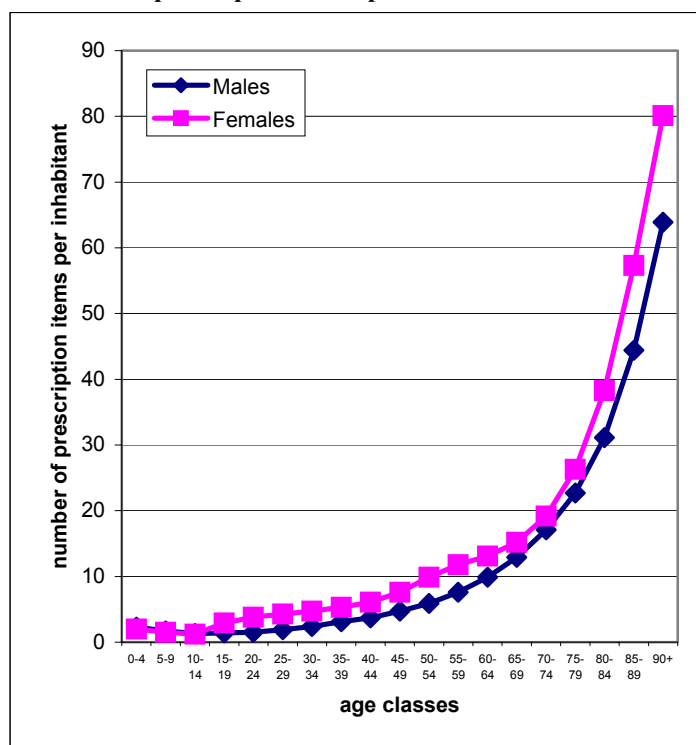
It is thus relevant to try to define in more details these factors and take them in account when interpreting data from different countries.

4.3.1 Relationship between age and utilisation of medicines and adjustment for population structure (age and sex)

A strong relation exists between age and utilisation of medicines (figures 1-2). This age-utilisation relationship is important when we compare utilisation data across countries because the population structure of the European countries is not similar (table 3) and thus some of the differences found can be related to differences in the population structure: at parity of other conditions a country with older population will use a wider amount of medicines than a country with younger population.

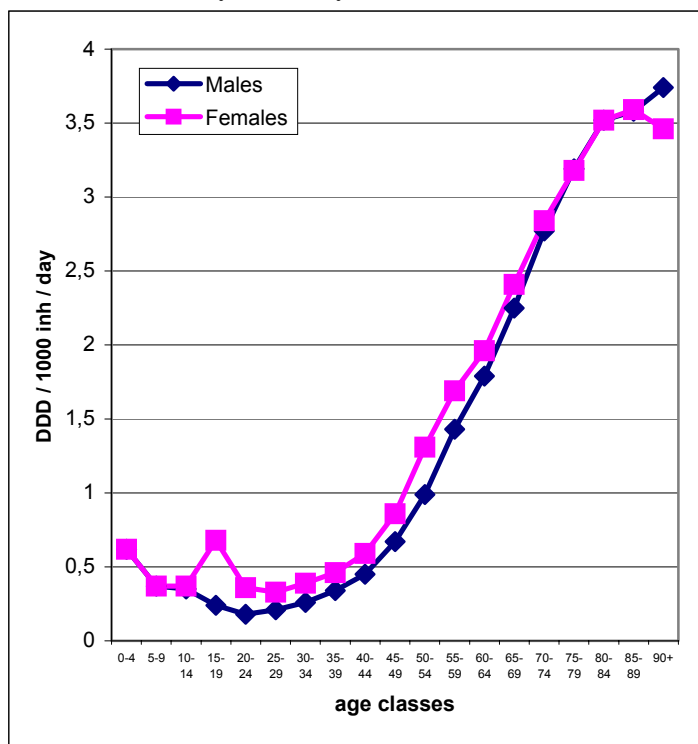
Ideally, aggregated data of utilisation and expenditure should be standardised for the population structure to remove the effects of differences in age. This is not always possible because in some national registers there is no information about the recipient (user).

Figure 1. Relationship between age and utilisation of medicines in number of prescription items per inhabitants-Sweden 2000



Source: Apoteket: Svensk Läkemedels-Statistik

Figure 2. Relationship between age and utilisation of medicines in DDD/1000inh/day-Germany 2001



Source: Schwabe U., Paffrath D. (eds.): Arzneiverordnungs-Report 2002. Springer-Verlag, Berlin Heidelberg (2002)

Table 5. Percentage of people older than 65 years and aged 0-14 years in the EU Member States and Norway. Year 2001

Country	Total population X 10 ⁶	% population older than 65 years	% population aged 0-14 years
Austria	8.1	15.54	16.53
Belgium	10.3	16.25*	17.81*
Denmark	5.4	14.86**	18.31**
Finland	5.2	15.08	18.00
France	59.5	16.08***	18.83***
Germany	82.4	16.85	15.42
Greece	10.6	17.86	14.63
Ireland	3.8	11.17	21.51
Italy	57.0	18.68	14.22
Netherlands	16.0	13.58***	18.60***
Norway	4.5	15.01	20.04
Portugal	10.3	16.45	15.94
Spain	40.6	16.96	14.60
Sweden	8.9	17.22	18.27
UK	59.1	15.85	18.79

* data refers to 1997; ** data refers to 1999; *** data refers to 2000
Source: European Health for All database (updated June 2004)

4.3.2 Relationship between utilisation of medicines and incidence/prevalence of diseases

Medicines should be used to treat specific diseases and thus a relation can be expected between medicine utilisation and the epidemiology of the disease for which the medicine is thought to be effective. A very weak relationship ($r = 0.02$) exists between utilisation of statins (in DDD /1000 inh /day) and prevalence of hypercholesterolemia (assessed by Health Examination Survey in a representative sample of the population) in the Italian regions suggesting that prevalence of the disease can not be the major determinant of utilisation of this class of medicines in Italy. Using the same data sources a closer relationship ($r = 0.52$) was found between utilisation of antidiabetic agents and prevalence of diabetes mellitus. The study of these relations can suggest useful fields of further analysis. Unfortunately epidemiological data on incidence/prevalence of the diseases are not common at a European level.

In some countries the utilisation of statins has been studied in relation to cardiovascular mortality but this relation is too much biased to be thought useful.

Figure 3a. Relationship between utilisation of statins (C10AA) and prevalence of hypercholesterolemia in the Italian Regions. Year 2002. (Each point represents the values of one region)

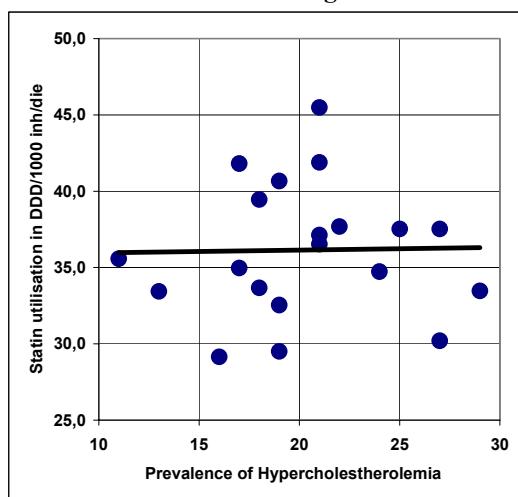
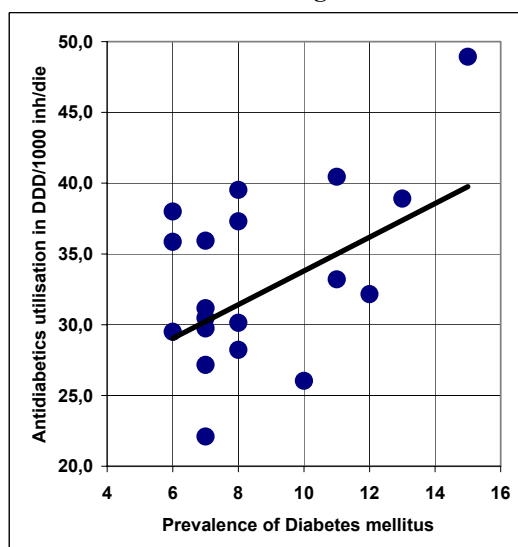


Figure 3b. Relationship between utilisation of antidiabetics (A10A) and prevalence of diabetes mellitus in the Italian Regions. Year 2002. (Each point represents the values of one region)



4.3.3 Relationship between utilisation of medicines and utilisation of other health care resources

An important objective is to link the utilisation of medicines to the utilisation of other health care resources (i.e. hospital care).

This is relevant because:

- Most medicines are used in primary care for chronic conditions (hypertension, asthma, diabetes, heart failure, etc). Linking hospitalisation rate for these conditions with utilisation of medicines can provide useful information on quality of primary care. (AHRQ Quality indicators-Guide to Prevention Quality Indicators: Hospital Admission for Ambulatory Care Sensitive Conditions-2001. AHRQPub No. 02-R0203)
- there may be an opportunity cost if the expenditure for medicines could be used in other ways to improve public health to a greater extent

At present time there are no comparable international data on this subject but this should be a priority in developing international comparative data.

4.3.4 Outcome of medicine utilisation and impact on population health

The utilisation of most medicines shows large geographic variations at both national and international level (i.e. utilisation of statins in 2000 in Norway was fourfold wider than in Denmark) and this can suggest the possibility of over- or under-treatment.

Moreover most medicines are used for chronic conditions, mainly for cardiovascular diseases with an important economic burden. The EURO-MED-STAT data estimated that utilisation of statins in 2000 accounted for four billion €.

Thus it is of interest to assess if this important economic investment in medicines has a result on population health (for instance decrease of cardiovascular mortality) and how it is possible to quantify this.

On the other hand it could be of interest to know if the relative low use of medicines in some areas, as compared to other areas, has a negative influence on mortality.

Linking utilisation of medicines to their impact on population health is a very complex and challenging perspective and the methods to assess this impact are not yet well developed. But the first step in this analysis is the availability of reliable and comparable utilisation data.

5- Indicators

Utilisation indicators

- Utilisation in Daily Defined Doses (DDDs)
- Utilisation in DDD/1000inh/die
- *Ratio* indicators
- Medicine Utilisation 90%

Expenditure indicators

- Pharmaceutical Expenditure on Total Health Expenditure
- Pharmaceutical Expenditure per capita
- Expenditure in € per DDD
- Expenditure for Generics on Total Pharmaceutical Expenditure; Utilisation of Generics on Total Utilisation of Medicines
- Expenditure for New Medicines on Total Pharmaceutical Expenditure; Utilisation of New Medicines on Total Utilisation of Medicines
- Top Ten Pharmacological Classes by 2nd Level of ATC
- Top Ten Ingredients by 5th Level of ATC

5.1 Utilisation in Daily Defined Doses (DDDs)

Significance

Utilisation in Daily Defined Doses (DDD) provides information on the extent of a single medicine or a basket of medicines used in a specific geographic area (nation or region).

Public health objective

The Utilisation in Daily Defined Doses (DDDs) data are useful to study the extent of medicine utilisation in a defined area and its changes on time.

The Utilisation in DDDs is also the basis for the calculation of “*ratio*” indicators, which can provide some information on the appropriateness and quality of medicine utilisation (see 5.3 *Ratio indicators* page 00)

Operational definition

Number of packages sold x DDD of the package

Benchmark

A benchmark value cannot be given because of the several different components that can influence this indicator.

Data source

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Relevant institutions using this indicator

The ATC/DDD system is suggested as a standard by the World Health Organisation. Some European countries (as the *Arzneiverordnungs Report* published yearly in Germany) report their utilisation data according to this standard, alone or in conjunction with DDD/1000inh/die

Validity and Limits

The indicator is able to overcome the difficulty in providing statistic data on medicine utilisation that can be originated from the differences in packages (different strength, different size) available on the market.

It also allows a comparison of the utilisation of different medicines within a same therapeutic group (for instance the utilisation of simvastatin, lovastatin, pravastatin, fluvastatin and atorvastatin into the statin group) or the utilisation of medicines of different therapeutic groups (for instance utilisation of diuretics and beta-blockers).

Differences between countries in the value of this indicator can be related to:

- 1) Differences in the population covered, differences the number of treated patients, differences in the epidemiology (prevalence / incidence) of the disease, differences in medical approach (pharmacological or non-pharmacological treatment)
- 2) Differences in the quantity of medicine used that can be related to the duration of treatment, differences in the dosage regimens and (for chronic therapy) patient’s compliance to the treatment
- 3) Differences (mistakes) in linking the DDD value assigned by the Oslo Centre to the individual package; thus the need of transparency and quality assurance in this linkage process.

Levels of aggregation

Data can be aggregated for different ATC levels from 1st to 5th.

At the ATC 5th level data can be presented by names (proprietary or generic), by packages and by Holder of marketing authorisation.

Identified bias (es)

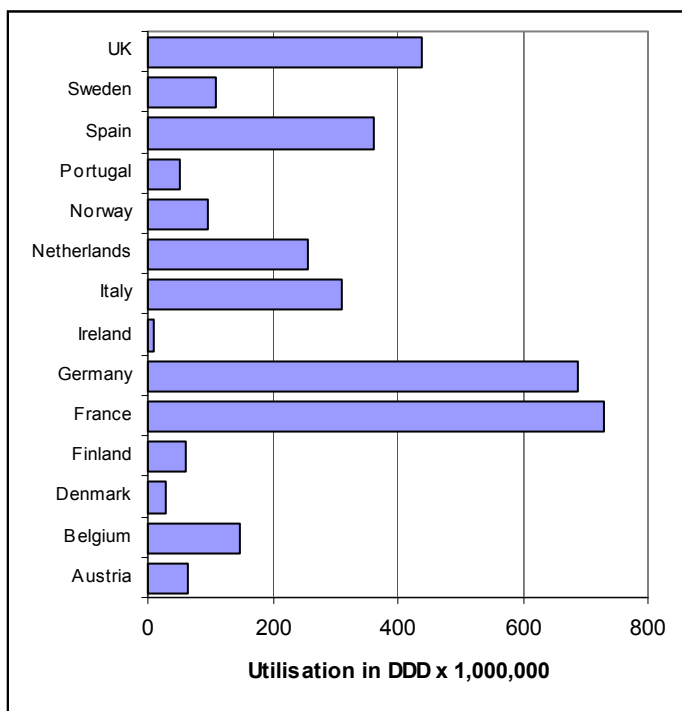
See paragraph 4-*Problems in defining pharmaceutical indicators for monitoring medicine utilisation and expenditure* (page 00)

Expected difficulties in calculating the indicator

The indicator can be calculated for the ingredients with an official DDD released by the WHO-Oslo Centre. Some product groups do not have official DDD. Thus utilisation in DDDs can be calculated for most but not all medicines.

Example.

Utilisation of statins in DDDs in the European Union countries and Norway
Year 2000



Source: EURO-MED-STAT project

5.2 Utilisation in DDD / 1000inh / day

Significance

Utilisation in DDD / 1000inh / day gives an estimate of the utilisation of medicines in a given area (nation, region etc), which is independent of the dimensions of the population and makes possible comparisons between areas with different number of population.

Public health objective

The Utilisation in DDD / 1000inh / day is useful to study the extent of medicine utilisation in a defined area and its changes on time. It is useful for national and international comparisons especially when the areas to be compared have a different number of inhabitants.

Operational definition

$$\frac{\text{Total consumption in DDDs}}{\text{Covered inhabitants x Days in the period of data collection}} \times 1000$$

Benchmark

A benchmark value cannot be given because of the several different components that can influence this indicator.

Data source

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Relevant institutions using this indicator

The ATC/DDD system is suggested as a standard by the World Health Organisation. Most European countries report their utilisation data according to this standard.

Validity and Limits

This indicator is able to standardise utilisation data for the differences in the number of inhabitants in different countries or geographic areas and makes comparable data originating from areas with different number of population or data collected for different periods of time.

Because of the direct relationship between age and utilisation of medicines it could be useful to standardise for age classes or to present age-specific data (for instance utilisation in people > 65 yrs or > 75 yrs).

Differences between countries in the value of this indicator can be related to:

- 1) Differences in the number of treated patients (per 1,000 population) that can be due to demographic differences (particularly % of older people), differences in the epidemiology (prevalence / incidence) of the disease, differences in medical approach (pharmacological or non-pharmacological treatment)
- 2) Differences in the quantity of medicine used that can be related to the duration of treatment, differences in the dosage regimens and (for chronic therapy) patient's compliance to the treatment
- 3) Differences (mistakes) in linking the DDD value assigned by the Oslo Centre to the individual package; thus the need of transparency and quality assurance in this linkage process..

Levels of aggregation

Data can be aggregated for different ATC levels from 1st to 5th.

At the ATC 5th level data can be presented by names (proprietary or generic), by packages and by Holder of marketing authorisation.

Identified bias (es)

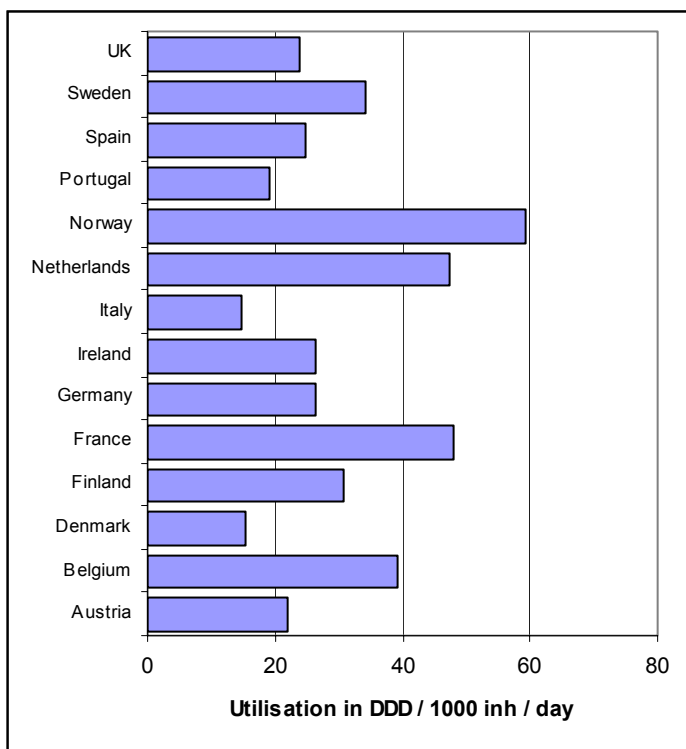
See paragraph 4-*Problems in defining pharmaceutical indicators for monitoring medicine utilisation and expenditure* (page 00)

Expected difficulties in calculating the indicator

The indicator can be calculated for the ingredients with an official DDD released by the WHO-Oslo Centre. Some product groups do not have official DDD. Thus utilisation in DDD/1000inh/day can be calculated for most but not all medicines.

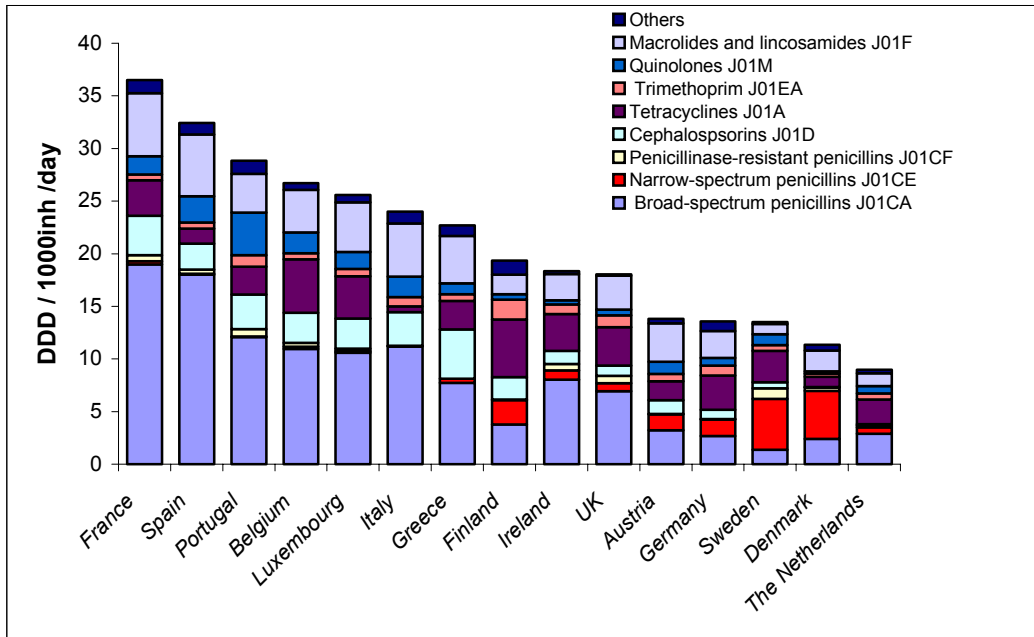
Example.

Utilisation of statins in DDD/1000inh/day in the European Union countries and Norway.
Year 2000



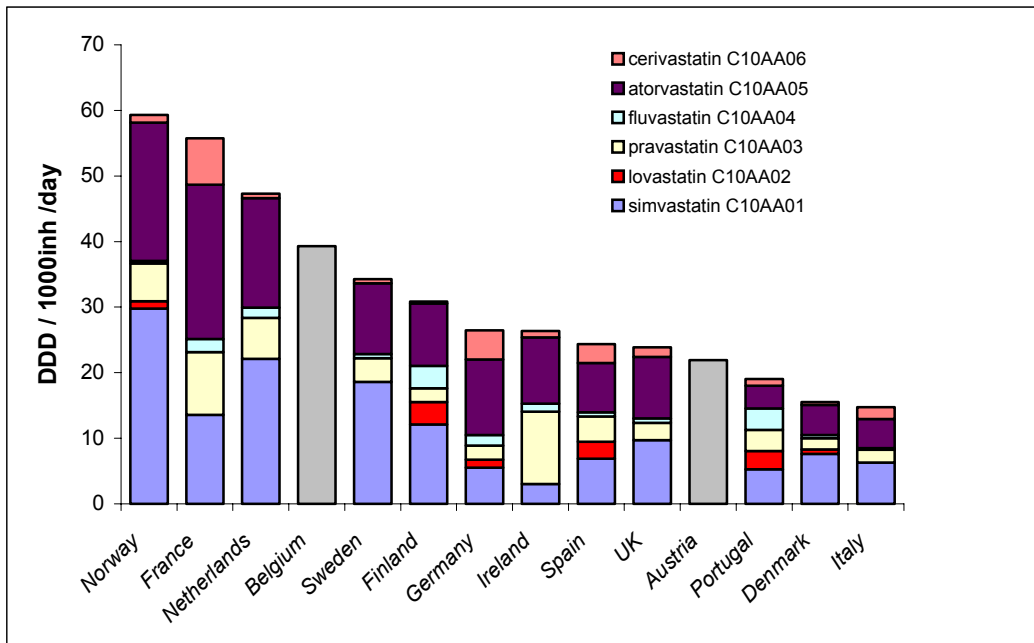
Source: EURO-MED-STAT project

Use and pattern of utilisation of antibiotics in the European Union countries. Year 1997



Source: Cars et al. Variation in antibiotic use in the European Union. The Lancet 2001; 357:1851-3

Use and pattern of utilisation of statins in the European Union countries and Norway. Year 2000



Source: The EURO-MED-STAT project. (Walley et al. Variations and increase in use of statins across Europe: data from administrative databases. BMJ, Feb 2004; 328: 385-6)

5.3 Ratio indicators

Several institutions have developed *ratio* indicators, starting from DDDs utilisation data.

These indicators calculate the ratio between some ingredients and /or therapeutic classes. They have not been validated but they are thought to provide some information on quality and cost of prescribing.

A list of Agencies that have proposed “*ratio*” indicators includes: the UK-National Health System, Audit Scotland, Australian NHS, Institut Català de la Salut.

We report in this paragraph some of these indicators just as an example, but much more work is needed before these *ratio* indicators can be used in an extensive way.

5.3.1 Medicines considered to be of limited value and/or less suitable for prescribing

Prescribing of medicines of limited value

Rationale

There are several reasons for which a medicine or a group of medicines can be considered of limited value and/or less suitable for prescribing

. They include:

- absence of a clear documentation of the efficacy (for example peripheral vasodilators or topical non steroidal anti-inflammatory drugs)
- a lower safety as compared to other medicines with comparable efficacy
- established medicines for which clinical trials have proved a negative outcome on primary end points (for example Hormone Replacement Therapy following the results of the Women Health Initiative Trial or doxazosin following the results of the ALLHAT study)
- medicines withdrawn from one or more countries and still available in others (trimetazidine withdrawn from the UK market and still available in other countries)
- old medicines licensed in a country and that never obtained a license in other countries (tiadenol, binifibrate and other medicines listed in Tab 00)
- some new medicines (new chemical entities or modified release formulations) with higher cost and no therapeutic advantage as compared to established medicines

Lists of medicines of limited value and/or less suitable for prescribing have been developed in several countries (France: Analysis of the “service medical rendu”; UK-British National Formulary: List of medicines less suitable for prescribing; Spain-Catalona List of medicines of low level by the Committee for Evaluation of Medicines, etc). Some of these, according to the national system, can be reimbursed medicines or not reimbursed medicines.

5.3.2 Utilisation of cephalosporins as a percentage of total antibiotic utilisation

Rationale

Cephalosporins are a first-line therapy in a limited amount of infections in general practice. To limit the development of resistance their use should mainly reserved to severe infections (i.e. Acute pyelonephritis, Peritonitis, Meningitis by Haemophilus influenzae or pneumococci, Septicaemia, etc), which are mainly treated in hospital.

Operational definition

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{J01DA consumption in DDDs}}{\text{J01 consumption in DDDs}} \times 100$$

J01DA = Cephalosporins and related substances

J01 = Antibacterials for systemic use

5.3.3 Utilisation of quinolones as a percentage of total antibiotic utilisation

Rationale

Quinolones are a first-line therapy in a limited amount of infections in general practice. The British National Formulary suggests the use of quinolones in few types of infections as for example Acute prostatitis. To limit the development of resistance their use should be limited and mainly reserved to the above mentioned infections.

Operational definition

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{J01M consumption in DDDs}}{\text{J01 consumption in DDDs}} \times 100$$

J01M = Quinolone antibacterials

J01 = Antibacterials for systemic use

5.3.4 Utilisation of penicillins as a percentage of total antibiotic utilisation

Rationale

A penicillin is a first line therapy in many infections in general practice (i.e. non viral infections of the upper respiratory tract). Their use is effective and limit the utilisation of other classes of antibiotics (cephalosporins and quinolones)

Operational definition

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{J01C consumption in DDDs}}{\text{J01 consumption in DDDs}} \times 100$$

J01C = Beta-lactam antibacterials, penicillins

J01 = Antibacterials for systemic use

5.3.5 *Utilisation of amoxicillin as a percentage of utilisation of amoxicillin and amoxicillin and enzyme inhibitor*

Rationale

The association of amoxicillin and clavulanic acid is indicated in infections due to beta-lactamase-producing strains, where amoxicillin alone is not appropriate. This therapeutic advantage is counterbalanced by an increased risk of liver toxicity, which is six times greater with the association than with amoxicillin alone. In some countries the association is much more expensive than amoxicillin alone.

Operational definition

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{J01CA04 consumption in DDDs}}{\text{J01CA04 and J01CR02 consumption in DDDs}} \times 100$$

J01CA04 = Amoxicillin

J01CR02 = Amoxicillin and enzyme inhibitor

5.3.8 *ACE-Inhibitors as a percentage of angiotensin II receptor antagonists and ACE inhibitors*

Rationale

[to be described]

Operational definition

$$\frac{\text{Numerator}}{\text{Denominator}} = \frac{\text{C09AA consumption in DDDs}}{\text{C09AA + C09CA consumption in DDDs}} \times 100$$

C09AA = ACE inhibitors, plain

C09CA = Angiotensin II antagonists, plain

5.4 Drug Utilisation 90% (DU90%)

Significance

The DU90% focuses on the number of ingredients that account for 90% of the use, measured in Daily Defined Doses (DDDs), within a therapeutic group.

It assumes that prescribing a limited range of medicines within one group is preferable.

Using the DU 90% individual agents within a medicine group are ranked by prescribing volume, and the number of different agents comprising the upper 90% determined. The number of agents prescribed can then be compared between prescribers or geographic areas or with therapeutic guidelines.

Public health objective

This method may give an estimate of the adherence to guidelines (or local recommendations) in a simple and inexpensive way using sales data.

Operational definition

$$\frac{\text{Total utilisation in DDDs}}{100} \times 90$$

Numerator
Denominator

Benchmark

The highest number of ingredients of the DU90% included into guidelines or local recommendations.

Data source

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Relevant institutions using this indicator

This indicators has been proposed by : Bergman U, Popa C, Tomson Y et al. *Drug utilization 90% - a simple method for assessing the quality of drug prescribing*. Eur J Clin Pharmacol 1998; 54:113-18.

It has been used for geographic comparisons between several European countries.

Validity and Limits

DU90% can be considered as an inexpensive and simple method for assessing the general quality of prescribing. The method can be applied to individual agents of selected therapeutic classes (ATC groups) or to all the medicines. It may identify problem areas where further analyses are required. This method cannot examine the appropriateness of use and does not provide outcome data. It may be of utility where access to patient specific data on medicine use is limited.

Identified bias (es)

See paragraph 4-Indicators (page 00)

Expected difficulties in calculating the indicator

DU90% can be calculated for the ingredients with an official DDD released by the WHO-Oslo Centre. Some product groups do not have official DDD and this can be a difficulty in calculating this indicator.

5.5 Pharmaceutical Expenditure / Total Health Expenditure

Significance

This indicator gives an estimate of the economic burden of medicine utilisation on healthcare systems.

Public health objective

The growth in pharmaceutical expenditure raises concerns in terms of affordability and on the financing of health care systems.

Because of the increasing utilisation of some expensive medicines pharmaceutical expenditure is expected to grow in the next years.

Operational definition

$$\frac{\text{Pharmaceutical Expenditure}}{\text{Total Health Expenditure}} \times 100$$

Benchmark

It is not possible to define a benchmark value. International comparisons can provide useful data.

Data source

OECD (Health data)

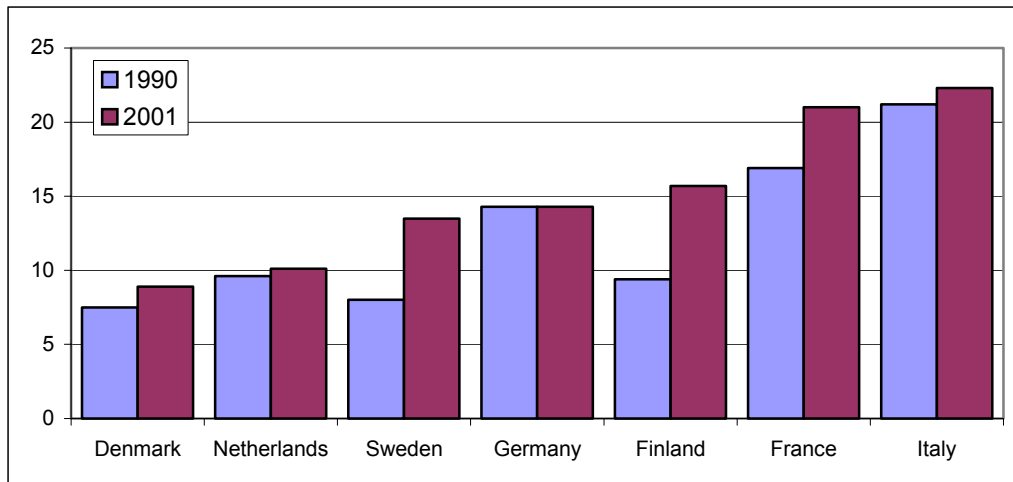
Relevant institutions using this indicator

This indicator is used in many international comparisons to have an estimate of the burden of pharmaceutical expenditure on total health expenditure.

Identified bias (es)

The extent of the denominator (Total health expenditure) can substantially vary from country to country. For this reason is useful to associate this indicator with the indicator Pharmaceutical Expenditure per capita

Pharmaceutical expenditure as a percentage of total public health expenditure. Years 1990 and 2001



Source: Health at a Glance – OECD Indicators 2003

5.6 Pharmaceutical Expenditure per capita

Significance

This indicator gives an estimate of the economic burden of medicine utilisation on healthcare systems.

Public health objective

The growth in pharmaceutical expenditure raises concerns in terms of affordability and on the financing of health care systems.

Because of the increasing utilisation of some expensive medicines pharmaceutical expenditure is expected to grow in the next years.

Operational definition

Numerator	Pharmaceutical Expenditure
Denominator	Covered Population

Benchmark

It is not possible to define a benchmark value. International comparisons can provide useful data.

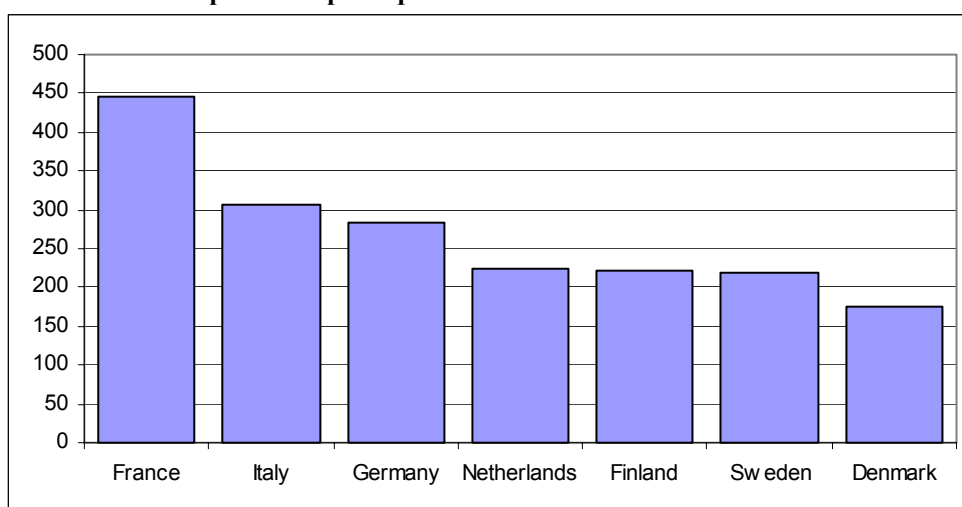
Data source

OECD (Health data)

Relevant institutions using this indicator

This indicator is used in many international comparisons to have an estimate of the burden of pharmaceutical expenditure on total health expenditure

Pharmaceutical expenditure per capita in €. Year 2001



Source: Health at a Glance – OECD Indicators 2003

5.7 Expenditure in € per DDD

Significance

The expenditure per DDD represents the actual cost paid by a health system to provide specific medicines.

Public health objective

This indicator provides information on the actual cost paid for a medicine and allows comparisons between countries (international differences in the expenditure for a same medicine).

It also allows comparisons between medicines with comparable licensed clinical properties allowing to calculate exact differentials within a country or between countries.

This indicator is used in the document *Price Indicators* section 5.2.2 Market Efficiency Index; section 5.2.3 Potential savings and section 5.2.4 Ratio of highest to lowest price.

Operational definition

Numerator	Expenditure in €
Denominator	Number of DDDs

Benchmark

The lowest value.

Data source

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Relevant institutions using this indicator

This indicator is used by several institutions. It has been extensively used late 2002 by the Italian Ministry of Health to operate substantial price cuttings where the differentials in cost per DDD were thought to be too high.

Validity and Limits

This is a very useful indicators because it allows comparisons between countries independently from the different packages (often with different prices) available in the EU countries.

Identified bias (es)

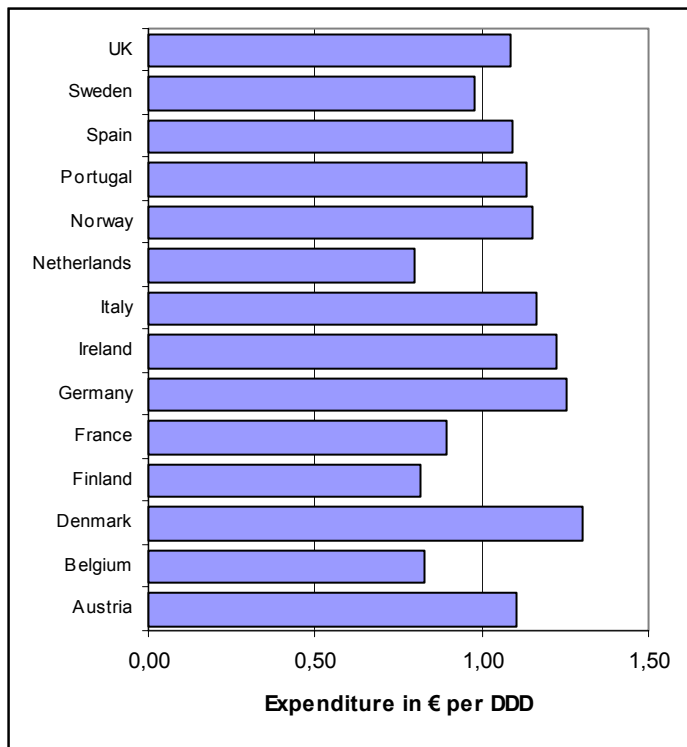
See paragraph 4-Indicators (page 00). See also the document *Library of EU Pharmaceutical Indicators. Price indicators*. Chapter 3 Data availability of pharmaceutical prices in the European Union Member States and Norway (page 10) and Chapter 4-Data comparability (page 13)

Expected difficulties in calculating the indicator

The indicator can be calculated for the ingredients with an official DDD released by the WHO-Oslo Centre. Some product groups do not have official DDD. Thus Expenditure in € per DDD can be calculated for most but not all medicines.

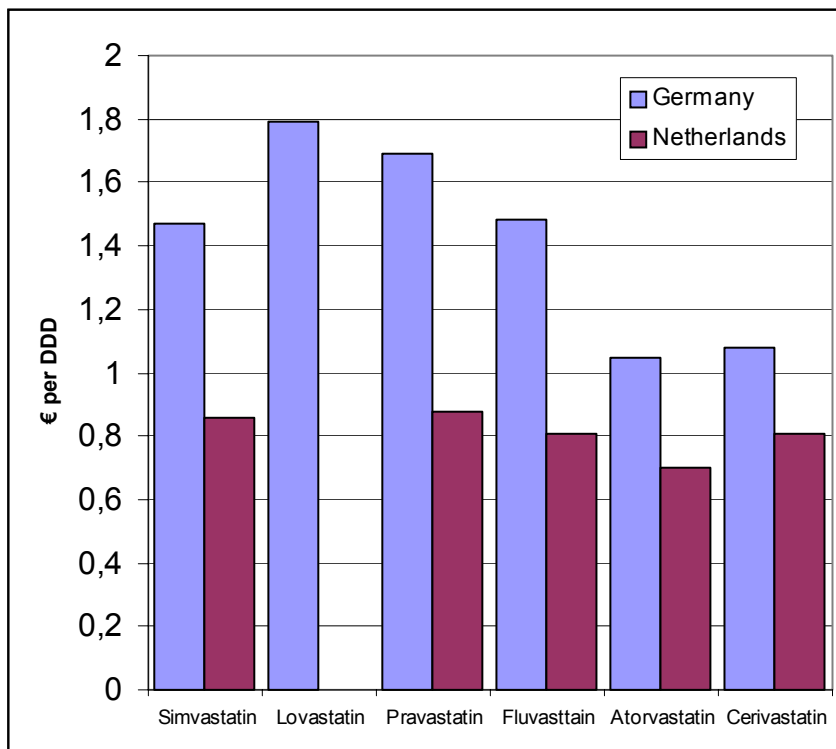
Examples.

Expenditure per DDD for statins in the European Union countries and Norway



Source: EURO-MED-STAT project

Expenditure per DDD for statins in Germany and The Netherlands in the year 2000



Source: EURO-MED-STAT project

5.8a Expenditure for generics / total pharmaceutical expenditure

5.8b Utilisation of generics / total medicine utilisation

Significance

A generic medicine is a medicine identical in chemical composition to a brand name pharmaceutical preparation, produced by a different company, after the firm's patent expires. Price of generic compounds is lower than brand names.

Public health objective

A greater utilisation of generic compounds is a way to obtain a cost minimisation and thus contain pharmaceutical expenditure.

Operational definitions

$$\frac{\text{Pharmaceutical Expenditure for generic products}}{\text{Total Pharmaceutical Expenditure}} \times 100$$

$$\frac{\text{Utilisation of generic products in DDDs}}{\text{Total Utilisation in DDDs}} \times 100$$

Benchmark

The optimal value can differ from country to country.

In Scotland (UK) in 2002 this value attained 76% and the optimum rate is considered to be around 80%; in Catalonia (Spain) the best value is indicated as equal to or greater than 15%.

Data sources

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Relevant institutions using this indicator

Most countries use this indicator to estimate the possibility of cost minimisation.

Identified bias (es)

See paragraph 4-Indicators (page 00)

Expected difficulties in calculating the indicator

There may be difficulties in identifying the generic products in the national registers. For this reason the document *Library of EU pharmaceutical indicators-Recommendations for national registers of medicinal products with validated ATC codes and DDD values* suggests to have a specific field for an easy identification of generic products.

5.9a Expenditure for new medicines per total expenditure

5.9b Utilisation of new medicines per total utilisation

Significance

In most European countries price of pharmaceutical products is relatively stable on time and for pharmaceutical companies the introduction of new products is a way to obtain higher prices.

Public health objective

Often new products are me-too medicines or modified release formulations of old medicines without an innovative value. For this reason is relevant to know how much money is spent in the utilisation of new products.

Operational definitions

Numerator	Pharmaceutical Expenditure for new products	x 100
Denominator	Total Pharmaceutical Expenditure	

Numerator	Utilisation of new products in DDDs	x 100
Denominator	Total Utilisation in DDDs	

Benchmark

It is not possible to give a benchmark but international and local comparisons (especially by ATC groups) can provide useful information

Data sources

See Annex 2 – Selected data sources for utilisation and expenditure data of pharmaceutical products in the European Union countries and Norway (page 00)

Validity and Limits

Some new medicines can represent an important therapeutic progress and their use, as compared to older medicines, could be justified.

Identified bias (es)

See paragraph 4-Indicators (page 00)

Expected difficulties in calculating the indicator

It could be difficult to identify the new products. For this reason the document Library of EU pharmaceutical indicators-Recommendations for national registers of medicinal products with validated ATC codes and DDD values suggests to have two specific fields (Date of approval; Date of first marketing) for an easy identification of new products.

Annex 1- Selected EURO-MED-STAT data sources for utilisation and expenditure data of pharmaceutical products in the EU countries and Norway

Austria

Hauptverband der Österreichischen Sozialversicherungsträger/PEGASUS (Federation of Austrian Social Insurance Institutions)

Belgium

Farmanet (Rijksinstituut voor Ziekte en InvaliditeitsVerzekering/Institut National d'Assurance Invalidité) (National Institute for Health and Disability Insurance)

Denmark

Lægemiddelstyrelsen (Danish Medicines Agency)

Finland

Lääkemyyntirekisteri, Lääkelaitos (drug sales register owned by the National Agency for Medicines)

France

Caisse Nationale d'Assurance Maladie (CNAM) base de données Médicam (National Health Insurance—database Medicam)

Germany

Database of the German Drug Index, Research Institute of the AOK (WiDO)

Ireland

Reimbursement files from the General Medical Services Payments Board

Italy

Ministero della Salute-Osservatorio Nazionale sull'Impiego dei Medicinali (OsMed) (Ministry of Health-Observatory on Utilisation of Medicines)

Netherlands

College voor Zorgverzekeringen, Geneesmiddelen Informatie Project Diemen/Stichting Farmaceutische Kengetallen Den Haag (Health Care Insurance Board, Pharmaceutical Products Information Project Diemen/Foundation for Pharmaceutical Statistics, The Hague)

Norway

Norwegian Institute of Public Health (data based on total sales from all Norwegian wholesalers)

Portugal

INFARMED-National Institute of Pharmacy

Spain

Agencia Española del Medicamento, Especialidades y consumo de medicamentos (database ECOM) (Ministry of Health, Spanish Medicines Agency)

Sweden

Apoteket, National Corporation of Swedish Pharmacies

United Kingdom

Prescription Pricing Authority (PPA)

Example of reporting utilisation and expenditure data

Table 00. Utilisation and expenditure for statins (C10) in the European Union countries and Norway. Year 2000

Country	Utilisation in million DDD	Utilisation in DDD/1000inh/day	Expenditure in million €	Expenditure per DDD
Austria	64.96	21.94	71.71	1.10
Belgium	146.9	39.32	121.2	0.82
Finland	59.30	31.25	48.82	0.82
France	730.46	48.11	653.67	0.89
Germany	688.40	26.47	864.74	1.26
Ireland	11.06	26.47	13.55	1.22
Italy	309.72	14.74	360.72	1.16
Netherlands	256.29	47.28	204.31	0.80
Norway	96.92	59.29	111.78	1.15
Portugal	50.94	19.06	57.74	1.13
Spain	370.30	20.58	393.43	1.06
UK (England)	437.05	23.86	474.87	1.09

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