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EURO-MED-STAT

Monitoring expenditure and utilization of medicinal products in the European Union countries: a Public Health approach

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Background: There is uncertainty about the level of utilization and expenditure for medicines in the European Union (EU), making assessment of their impact on public health difficult. Our aim is to develop indicators to monitor price, expenditure and utilization of medicinal products in the EU, so as to facilitate comparisons. Methods: There are four major tasks. Task 1: To catalogue data sources and available data in each EU Member State. Task 2: To assess the reliability and comparability of data among the EU Member States by ATC/DDD on country coverage, reimbursement, prescriptions, price category (e.g. wholesale, hospital, retail) and private versus public spending. Task 3: To develop Standard Operating Procedures for data management and to define clearly the proposed indicators in terms of objective, definition, description, rationale, and data collection. Task 4: To pool, compare and report the validated data according to the established indicators, using cardiovascular medicines as an example. Results: Preliminary results from Tasks 1 and 2 are available and demonstrate the methodological difficulties in comparing data from different countries. Multiple data sources must be used. These cover different populations, and refer to different prices or costs. Nevertheless, useful data can be derived, illustrated by the example of lipid lowering medicines. The data shows that only five products are commonly available in all countries. Even when a medicine is available in all countries, there may be substantial differences in packages, which can hinder comparison. Data on utilization of statins shows high usage in Scandinavian countries and least in Italy. Conclusion: The preliminary results of EURO-MED-STAT show wide differences in availability, and use of medicines across Europe that may have substantial implications for public health.

Keywords: ATC/DDD, cardiovascular medicines, medicinal products, utilization

More than 100,000 medicinal products are marketed in the European Union at a total cost of 100 billion Euro per year.[1] This large utilization of medicines and expenditure has a major impact on public health in the following ways:

- They bring benefits to patients through their intended therapeutic effects: i.e. improving or preventing diseases and relieving symptoms.
- They may cause adverse effects, accounting for as much as 10% of all hospital admissions in some surveys. There are also other associated adverse effects arising from poor use, including medication errors, poor quality of prescribing by doctors, and poor compliance with medicines by patients. These may be harmful directly, or indirectly by waste of money or other limited health care resources.
- Medicines account for a substantial portion of health expenditure (up to 20-21% in Spain and France), and although often valuable, there may be an opportunity cost if the expenditure could be used in other ways to improve public health to a greater extent. Furthermore, pharmaceutical expenditure is rising faster than any other area of health care and this is a source of concern to governments, which strive to maintain equitable access to medicines for the population at an affordable cost.
- Utilization of medicines has a large environmental impact because users excrete metabolites and/or unmodified medicines. As of 2000, more than 80 medicines from a wide array of therapeutic classes have been detected in the environment, at concentrations similar to that of pesticides. The risk to the environment or human health of this chronic exposure has never been assessed.[2]
- Europe is a major manufacturer and exporter of medicines (a positive trade balance of about 9.2 billion Euro in 1995),[3] with attendant benefits of employment and industrial and technology development.

The exact impact on public health of medicines use and the government expenditure on prescriptions (for branded, generic or even over-the-counter medicines) is difficult to assess, in part because of uncertainty about the extent of such utilization and expenditure. Although comparative figures are available from different sources (e.g. OECD, IMS) the methods by which these data were collected and exact definitions and limits of what was measured are not always clear. Our aim in establishing the EURO-MED-STAT project is to develop a set of indicators, to be integrated into the EU Public Health Information Network (EUPHIN), for monitoring price, state expenditure and utilization of medicinal products in

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the EU member states. The monitoring of price and utilization in a standardized manner could then be used by each EU member state, allowing better comparison between countries and allowing each country to benchmark its performance against others. This study follows on from a related study to evaluate availability of medicines across the EU.[4] The aim of this paper is to present the protocol of the EURO-MED-STAT project, to provide some preliminary data from the ongoing project and discuss some methodological problems in comparing national data.

METHODS

A collaboration of academics and government agencies was formed to undertake the project *(appendix)*. The project was broken into four different tasks.

- Task 1: To produce an inventory of data sources and a survey of available data in each EU Member State on medicine utilization in the community and in hospital, medicine expenditure and medicine prices.
- Task 2: To assess the reliability of the data and its comparability between countries: the data are to be collected by defined daily dose (DDD) and medicines classified by ATC code.[5]

Key questions on utilization are whether the data covers all the country or only regions, whether both community and hospital data are available, what the sources of such data were (wholesalers, pharmacies, prescribers), whether the data covers only reimbursed medicines or all products (including vitamins and herbal products), and whether they cover only medicines subject to prescription or also self-medication products; and an assessment of the quality of the data, its reliability and availability. Key questions on price and expenditure data are: definition of price (ex-factory, wholesaler, pharmacy, state reimbursed); retail pharmacy price and hospital price; and private spending versus public spending.

- Task 3: To develop Standard Operating Procedure (SOPs) for data management (collection, validation and comparison). SOPs are essential to overcome the difficulties arising from the differences among national health systems, in the classification of medicinal products and in recording utilization and expenditure.

We used the ATC/DDD methodology[5] to organise raw data and to structure the analyses by therapeutic classes. The European Standard for Medicinal product identification (ENV 12610)[6] by the European Committee for Standardization (CEN) will be used as a standard for describing medicinal products and their packages. A set of utilization, cost and expenditure indicators derived from the available validated data will then be produced for data comparison. A key point will be to establish the aims of each indicator and its intended audience/target group. Each indicator will therefore be clearly defined (objective, definition, description, rationale and data collection). The SOPs will also define the confidentiality and accessibility level of the data.

- Task 4: To pool and compare the validated data according to the established indicators.

We chose cardiovascular medicines as an example to test these systems and therefore also sought the corresponding utilization and expenditure data. These were selected because of the public health importance of cardiovascular disease and to parallel other EU public health projects on morbidity (EUROCISS[7]).

RESULTS

Preliminary results of tasks 1 and 2 are now available, and we illustrate them and the developing standard operating procedures (task 3) by applying the methods to an area of cardiovascular therapy (task 4). The major data sources used, selected after careful analysis from a list of 72, are shown in *table 1* and are mostly governmental, government funded, or major insurance fund sources. We display some illustrative data in relation to lipid lowering medicines, not as definitive results but only as examples of what the project might produce. Considerable cross-checking of data is still required, and not all countries are covered yet. The data also serve to illustrate some of the difficulties of this type of work.

The availability of all lipid lowering medicines (i.e. those classified as C10 by ATC) in June 2002 was reviewed in 14 EU countries (Luxembourg missing) and Norway (*table 2*). Of 37 products, only five are available in all countries while 18 are available in only one country. As a rule, more recent products tend to be present in more countries than older products. Germany, Italy and Spain are the most liberal countries, with 21 and 17 products licensed respectively, while Norway, Ireland and Denmark are most restrictive, with eight and nine products, respectively.

There are also differences within individual medicines. For example, the range of pack sizes of simvastatin 20 mg across the fifteen countries is shown in *table 3*. There are wide variations in the pack size available, from 10 tablets in four different countries up to 112 (in Norway and Denmark). Seven countries had a range of pack sizes available while in Austria, Belgium, France, Greece, Ireland, Italy Spain and the UK only one pack size is available, often different from country to country.

The data can also show differences in utilization (in DDDs/1000 patients covered/day) (*figure 1*). The data shown refers to the calendar year 2000 and covers 12 of the countries – data from Belgium, Luxembourg, Austria and Greece are not available at present. Utilization varies by the country: per capita, it is greatest in the Scandinavian countries and lowest in Italy. This data relates in most countries to the state or insurance fund reimbursed use only, and may cover different populations in different health services.

These data may therefore not be strictly comparable, as different national health services reimburse medicines to different segments of the country's population, and different countries can provide slightly different data. For instance, the Irish data refers only to the population covered by the General Medical Services Scheme (about one third of the population); the Swedish covers all statin prescriptions regardless of reimbursement; for Germany, the Netherlands, France and Portugal the data refer to the

population covered by Social Insurances (from 75% to 90% of the whole population, according to the country); Norwegian data covers total use (including hospital utilization); UK data refers to England only.

DISCUSSION

These preliminary results show wide variation in the availability of medicines across the surveyed countries. The newer medicines tend to be more widely available, and this may reflect the better evidence base for their use. It is difficult to compare medicines across Europe because of this variation in availability and also because of variation in the pack size, tablet strength and often manufacturer. So far, the European Medicines Evaluation Agency (EMEA) centralised regulatory procedure does not seem to have a major impact on this problem because of the limited number of medicines approved and because differences between countries in available strengths and packs persist even for medicines approved under a centralised procedure. The costs per tablet or per DDD vary substantially from country to country, sometimes giving rise to parallel importation from one country to another.

More importantly, the tables illustrate the range of data available and some of the practical difficulties faced in achieving such comparable data. These necessitate caution in interpreting even this preliminary data. For example, when considering utilization, we face a range of difficulties: our databases may cover all or only part of a population. And if only part, we must ask whether that part is representative of the whole (as we believe in the Netherlands and Germany) or not (as in Ireland where the data covers only the most poor and probably also most sick one third of the population). Few of our databases include over-the-counter medicines, which are of increasing importance in certain therapeutic areas, nor even all prescribed medicines, but only for the most part, medicines reimbursed within each national health service system. There is no hospital data readily available in most countries.

The DDD is a useful common measure for medicine utilization and was designed for that purpose but it does not reflect the actual dose prescribed in any country (e.g. DDD of pravastatin is 20 mg but the average daily quantity prescribed in England is 15 mg[8]). Nor does the

Table 1 Information sources for licensed medicines, prices and expenditure/utilization data

	Source of information for licensed medicines and prices	Source of information for state expenditure / utilization data
ATS	Österreichische Apotheker: Austria Codex und Warenverzeichnis (Austria Codex and List of commodities/products by the Austrian Association of Pharmacists)	Hauptverband der Österreichischen Sozialversicherungsträger (Federation of Austrian Social Insurance Institutions)
BEL	BCFI-Databank / Banque des Données CBIP (Belgian Centre for Pharmacotherapeutic Information Database)	Farmanet (RijksInstituut voor Ziekte en InvaliditeitsVerzekering / Institut National d' Assurance Invalidité) (National Institute for Health and Disability Insurance)
DNK	Lægemiddelstyrelsen (Danish Medicines Agency)	Lægemiddelstyrelsen (Danish Medicines Agency)
FIN	Suomen Apteekkariliiton Lääkevalmisteiden tiedosto (Register of Pharmaceutical Products on Sale in Finland)	Lääkemyyntirekisteri, Lääkelaitos (Drug Sales Register owned by the National Agency for Medicines)
FRA	Comité National Hospitalier d'Information Médicale (CNHIM) – Base de données Thériaque (National Hospital Committee of Medical Information – Theriaque database)	Caisse Nationale d'Assurance Maladie (CNAM) base de données Médicam (National Health Insurance- database Medicam)
GER	Classification file from the German Drug Index, Research Institute of the AOK (WIdo-German Social Insurance)	Database of the German Drug Index, Research Institute of the AOK (WIdo-German Social Insurance)
GRE	National Formulary of the National Organisation of Drugs (EOF)	No data identified
IRL	Reimbursement files from the General Medical Services Payments Board	Reimbursement files from the General Medical Services Payments Board
ITA	Ministero della Salute – Banca dati dei farmaci registrati (Ministry of Health-database of licensed medicines)	Ministero della Salute-Osservatorio Nazionale sull'Impiego dei Medicinali (OsMed) (Ministry of Health – Observatory on Utilization of Medicines)
NDL	Z-Index Den Haag / Ministerie van Volksgezondheid, Welzijn en Sport Den Haag (Z-Index The Hague / Ministry of Health, Welfare and Sport The Hague)	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)
NOR	Norwegian Pharmaceutical Association	Norwegian Institute of Public Health (data based on total sales from all Norwegian wholesalers)
PRT	INFARMED– National Institute of Pharmacy	INFARMED– National Institute of Pharmacy
SPA	Catalogue of Pharmaceuticals Specialities Consejo General de Colegios Oficiales de Farmacéuticos: Catálogo de Especialidades Farmacéuticas (Pharmaceuticals Association)	Agencia Española del Medicamento – Especialidades y consumo de medicamentos (Database ECOM) (Ministry of Health, Spanish Medicines Agency)
SWE	Apoteket – National Corporation of Swedish Pharmacies	Apoteket – National Corporation of Swedish Pharmacies
UK	British National Formulary no 43; 2002	Prescription Pricing Authority (PPA)

ATS= Austria, BEL= Belgium, DNK= Denmark, FIN= Finland, FRA= France, GER= Germany, GRE= Greece, IRL= Ireland, ITA= Italy, NDL= The Netherlands, NOR= Norway, PRT= Portugal, SPA= Spain, SWE= Sweden, UK= United Kingdom

Table 2 Licensed / available serum lipid reducing agents (C10) in the year 2002 in 15 European countries

ATC	Active ingredients	ATS	BEL	DNK	FIN	FRA	GER	GRE	IRL	ITA	NDL	NOR	PRT	SPA	SWE	UK	
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	•	•	•			•	•	a	•	•		•			•	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	Probucol												•	•			2
C10AX03	Tiadenol					•				•							2
C10	Dultosilato de piperazina													•			1
C10	Filicol													•			1
C10	Piricarbato													•			1
C10AA51	Simvastatin, combinations														•		1
C10AB	Binifibrate													•			1
C10AB	Fibrate	•															1
C10AC	Divistyramine									•							1
C10AD	Sorbinicate									•							1
C10AX	Phosphatidylcholine									•							1
C10AX05	Meglutol									•							1
C10	Xantol micotinate						•										1
C10	Garlic clove powder						•										1
C10	Soybean phospolipids						•										1
C10	Essential phospholipids						•										1
C10	Pectin						•										1
C10	Allium sativum						•										1
C10	Magnesium-pyroxidal-5-phosphate-glutamate						•										1
C10	Beta-sitosterol						•										1
Number of licensed active ingredients		14	10	9	10	11	21	13	8	17	10	8	15	17	11	13	37
		ATS	BEL	DNK	FIN	FRA	GER	GRE	IRL	ITA	NDL	NOR	PRT	SPA	SWE	UK	

Country abbreviations: ATS= Austria, BEL= Belgium, DNK= Denmark, FIN= Finland, FRA= France, GER= Germany, GRE= Greece, IRL= Ireland, ITA= Italy, NDL= The Netherlands, NOR= Norway, PRT= Portugal, SPA= Spain, SWE= Sweden, UK= United Kingdom.
For all the substances with an ATC 2nd or 4th level code, this code is unofficial.
Dultosilato de piperazina, filicol and piricarbato are the Spanish names for these ingredients.
a: Acipimox was a licensed product in Ireland in 2000 but not in 2002.

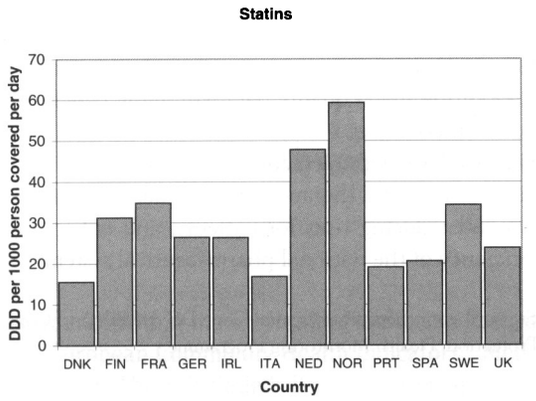

Figure 1 Statin utilization by DDD/1000inh/day in 12 European countries in 2000
See text for details and limitations. Country abbreviations as in *tables*

DDD imply clinical equivalence, and so to add up a total of DDDs for all statins as in *figure 1* may be excessively simplistic and must not be over-interpreted. Although we wish to classify medicines by ATC code, in practice different countries may use different versions of the code or may even have created their own codes, e.g. for panthetine which is classed in ATC code officially released by the Oslo Centre as A11HA32 (vitamins) but in Italy and Spain is reclassified based on its use as C10AX. The value for DDD may change between some versions of the code, although the WHO generally avoids this.

Finally, we must consider the implications of differences in utilization in the different countries. For instance in relation to statin prescribing, do the high levels in Scandinavian countries relate to morbidity or to the fact that doctors are more aware and informed on the benefits of statins because the landmark 4S study was carried out there? And do the low levels in Italy relate to the virtues of a Mediterranean diet and low morbidity, or to the use of low doses rather than to small numbers of patients treated or a higher discontinuation rate? Use of other lipid reducing medicines than the statins (listed in *table 2*) may also explain some of the differences. Our final data will not answer all these questions but will prompt a further examination in each country to question why these differences exist and what the optimal case in the interests of public health should be.

Another aim of the EUROMED-STAT project is to collect data on prices and this illustrates further difficulties. Comparing price is not simple. First there are issues of converting different currencies (less of a problem since the introduction of the euro). Second, there are widely recognized differences in purchasing power parity between countries both generally and more specifically for pharmaceuticals. Third, there are a number of prices which might be compared, e.g. ex factory, wholesaler, ex pharmacy or the price reimbursed by the state. All of these would have value to different stakeholders, though data on all are not readily available. Even to settle on pharmacy retail price, the most widely available, is problematic — in some countries this includes a mark up for the pharmacist, but not in others, or it may include value added tax at varying rates. The total cost of medicines to a third party payer may be less than the sum of the retail pharmacy costs since in some countries, e.g. the UK, the state pays only a discounted fee to the pharmacist.

Nevertheless if we aim to look at European differences pharmacy retail price has the advantage, as compared to ex-factory price, to represent all the components of the system, including differences in distribution costs. Finally, the 'price' may be a myth[9] – national policy may fix a reference price, or may control the price or the true cost in other, more indirect, ways, for instance by volume/price negotiations in France or by the Pharmaceutical Pricing Regulatory Scheme in the UK. An example of the effects of this last scheme relevant to the example shown here is the flat pricing structure of statins in the UK – i.e. simvastatin costs the same per tablet regardless of dose and as a result, costs 0.95 Euro/DDD if prescribed as 20 mg tablets, but only 0.25 Euro if prescribed as 80 mg tablets. In comparing price across countries, we may also be forced to view only those items which are mutually available

Table 3 Simvastatin 20 mg – the 13 available pack sizes in 15 European countries

Pack size	ATS	BEL	DNK	FIN	FRA	GER	GRE	IRL	ITA	NDL	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			•								•				

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across all EU countries – our previous work suggests that this is as low as 7% of all available active ingredients, and if we have to limit our study still further not just to active ingredients but to identical packs by the same manufacturer, and for instance exclude consideration of local generic products, the value of the data would be greatly diminished. These problems will limit our ability to meet our objective of comparing prices, but as with many health service research projects, the availability of data may force a change in the originally planned objectives.

Despite the limitations arising from these difficulties and uncertainties, we believe the data from this project, when complete, will be of value because of the information it will provide, the questions it will raise, and because of the insights it will give in a key area of health care and health care spending. Our data will also provide key denominators to help interpret adverse medicine reaction rates, or rates and trends in cardiovascular disease for instance. Our data will be of value because of the transparency in its collection, a factor often missed in data from other sources. Finally the project will be useful as it will explore methods and create standardized operating procedures that can be extended to other areas of pharmaceutical utilization and expenditure.

CONCLUSIONS

EURO-MED-STAT aims to produce a set of specific indicators for monitoring the use of medicines and related expenditure across the EU member states. The wide differences between national systems make this a difficult objective but the quality of our data, and the transparency in their collection, will be superior to any previously collect in this area. A standardized mean of monitoring medicine utilization and expenditure internationally offers several advantages from a public health perspective. 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 utilization which may lead to 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.

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