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Monitoring expenditure and utilisation of medicines in the European Union. A public health approach.

The EURO-MED-STAT Group*

* For the list of the participants to the EURO-MED-STAT and EURO-MED-STAT (db) projects see annexe 1

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Abstract

Background

Thousands of medicinal products are licensed in the European Union Member States. This large quantity of medicines has an important impact on individual and public health but the information available on the licensed medicines, their clinical properties, prices, utilisation and expenditure is difficult to retrieve.
Thus there is a need for monitoring the price, expenditure and utilisation of medicines and their impact on the population's health. For these reasons the European Commission funded a project to define a set of indicators and to build a European database of medicines.

Methods

A collaboration of academics and government agencies was formed to undertake the project which aims to fill the information gap on medicines in Europe by identifying the available data sources, defining a set of EU pharmaceutical indicators, and building a European database of medicines available on the internet.

Results

The project has formed a Library of European Union Pharmaceutical Indicators. This includes recommendations for national registers (to produce valid and comparable data), and a set of indicators (price, expenditure, utilisation) for monitoring pharmaceutical policies.
Moreover, the project has built a (beta version) database of licensed medicines in Europe, which can be freely accessed on the internet. The database provides, in a simple manner, useful information difficult to retrieve by other sources.

Conclusions

The EURO-MED-STAT project has defined a set of indicators to monitor the utilisation and expenditure of medicines from a public health perspective.
It has also proven that a European database of medicines is feasible and can provide useful information to stakeholders.

Key words: medicines, utilisation, ATC/DDD, public health

Introduction

More than one hundred thousands different pharmaceutical products are licensed in the European Union countries. This large quantity of medicines has an important impact on individual and public health, however, the information available on the number of medicines licensed, their prices, utilisation and expenditure is difficult to retrieve. As a consequence it is difficult to study and define the impact of medicines on public health in Europe. [1,2]

Occasional reports have shown that medicines licensed in a country can be unavailable or they can be withdrawn from the market in others, while licensed clinical properties (indications, posology, contraindications, warnings, list of adverse effects) can substantially differ from country to country.

Moreover, price, expenditure and utilisation of medicines are different across European countries and medicines sold most often in one country may not be licensed or used in others.

Thus it is important to have a set of indicators for monitoring these different elements and one (or more) data source(s) for studying, according to the established indicators, the performance of the pharmaceutical systems in the European Union countries and their impact on the population's health.

The exact impact of the use of medicines and expenditure on public health is difficult to assess, in part because of the uncertainty about the extent of such utilisation and expenditure.

Our aim in establishing the EURO-MED-STAT project was to develop a set of indicators, to be used for monitoring price, expenditure and

utilisation of medicinal products in the EU member states and building a data source (the EURO-MED-STAT database) able to provide the data needed for calculating the indicators.

The monitoring of price and utilisation in a standardised manner could then be used by each EU member state, allowing for better comparison between countries and allowing each country to benchmark its performance against others.

Methods

A collaboration of academics and government agencies (appendix 1) was formed to undertake the project. [3]

The EURO-MED-STAT (European Medicines Statistics) project aims to fill the medicines information gap in Europe by the:

- identification and evaluation of the data sources in the EU countries
- comparison of existing data and suggestions for a minimal data set for European registers for medicinal products
- production of a Library of EU Pharmaceutical Indicators
- feasibility analysis of a European database for medicinal products with information on licensed clinical properties, legal classification, reim-bursement category, price, expenditure and utilisation.

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 [4,5] has been adopted and proposed by the WHO Headquarters for global use.

The EURO-MED-STAT project has inventoried, in the European Union Member States and Norway, more than 72 different registers of medicinal products, which differ greatly in both their content and structure. By comparing the different registers and the existing standard the EURO-MED-STAT project has identified and suggested a minimal data set and recommendations for national registers of medicines, with validated ATC codes and DDD values.

Moreover, two *ad hoc* working groups have defined a set of indicators on price and expenditure/utilization of medicines by an intensive analysis of the experience in Europe, Canada, the US and Australia and several discussions by the expert groups.

Finally, according to the suggested minimal data set the project is building a database, whose beta version is available on the project's website, and is able to provide the data needed for calculating the indicators for the library.

Results

1. The Library of European Union Pharmaceutical Indicators

A library of European Union Pharmaceutical Indicators was built by the project and is currently available on the internet (www.euromedstat.cnr.it/indicators/indicators.asp).

Such a library includes three different sections:

- recommendations for national registers of medicinal products with validated ATC codes and DDD values [6]
- price Indicators [7]
- expenditure and Utilisation Indicators. [8]

Recommendations for national registers of medicinal products with validated ATC codes and DDD values

The EURO-MED-STAT project has inventoried more than 72 different registers of medicinal products in the participating countries. These registers strongly differ in both their content and structure.

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

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.

A minimal data set was defined by the project and this is discussed in details elsewhere in this issue of the journal. [9]

Price, Utilisation and Expenditure Indicators

Prices of medicines differ widely across countries but it is very difficult to compare them due to a series of methodological problems. First of all it is

very difficult to build a common basket to be used for comparison (Price Index) [10] because some top selling medicines from one country may not be used or licensed in others. Moreover, when a medicine is licensed in more countries differences may exist in the licensed packages (pharmaceutical form, strength, and number of units). Finally, distribution cost (wholesale and pharmacist) and taxation can vary widely (VAT is 0% in UK and 25% in Denmark).[7] As a result it is very difficult to perform wide international comparisons which take in account a large basket of medicines across a wide number of countries. Furthermore, the information available for hospital prices is limited.

To partly overcome some of these difficulties it was suggested that EURO-MED-STAT used the indicator Price per Daily Defined Dose (DDD) as it can be usefully cross-compared with the expenditure per DDD (an "actual" price) [7,8]. This Price per Daily Defined Dose together with other indicators (Ratio of highest to lowest price; Expenditure per DDD; Market Efficiency Index and Potential Savings) are described in details elsewhere in this journal. [11]

2.The EURO-MED-STAT database

The EURO-MED-STAT database, whose beta version is available on the internet, contains information on the medicines licensed in the European Union countries.

According to the main problems identified by the project the database will have in its final version several search functions.

The first search option called "Licensed Medicines" [12] will permit the study of the structure of the pharmaceutical market on a national and international basis. This means that it will allow a search if a specific ingredient or trade name is licensed in one or more countries, with detailed information on its marketing authorisation holder, strengths, number of units in the pack, price, legal category and reimbursement.

Within this "Licensed Medicines" option it is also possible to compare the number of licensed medicines by the different ATC groups (cardiovascular, respiratory, neurological, etc) and finally, it is possible to study the structure of the pharmaceutical system in terms of mutual availability of medicines (how many medicines licensed in a country are mutually available in one or more other countries).

A second section (in progress) called "Utilisation / Expenditure" will provide data on utilisation (in DDDs and in DDD/1000inh/day) and expenditure (in million € and in € per DDD).[12]

The wide differences and the usefulness of the database in identifying these difference are illustrated in the following examples.

Table 1 shows the list of the different eighteen trade names used in the first eight countries whose data were loaded in the database. Most of these names (13/18) are used in only one country, contributing to the high level of system entropy.

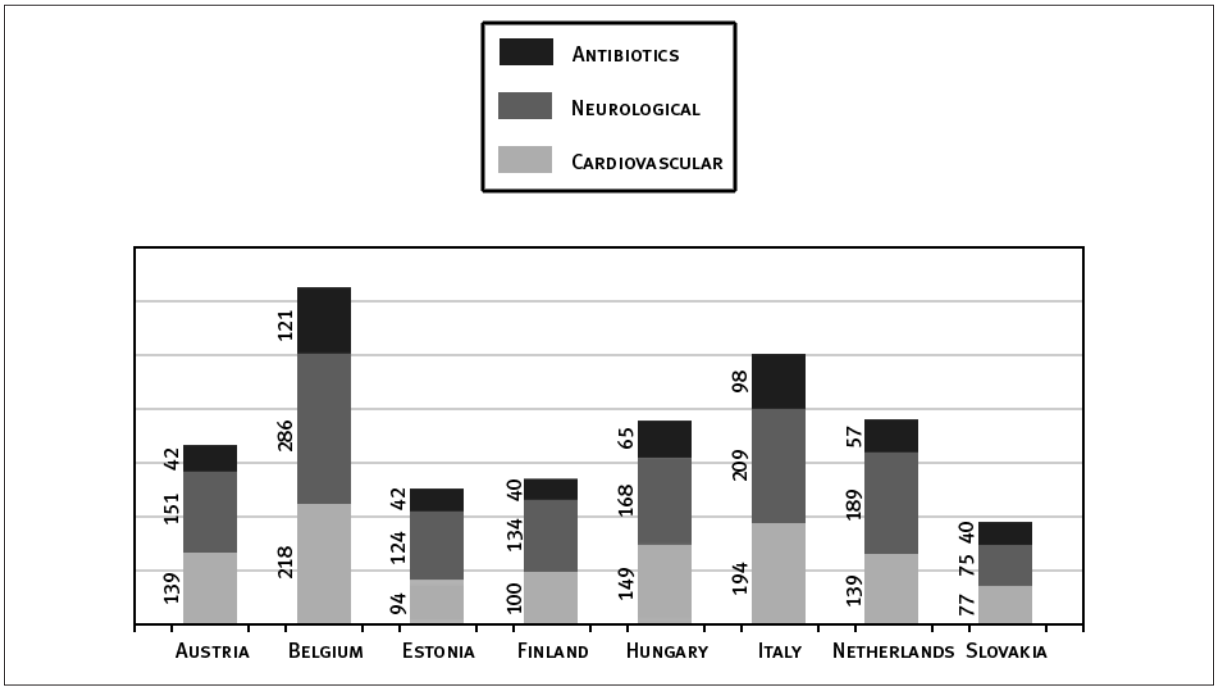
Graph 1 shows the number of licensed active ingredients in the same countries for the cardiovascular group, the neurological group and antibiotics. Belgium is the country with the highest number of licensed ingredients (121

Table 1. List of the eighteen different names in eight countries for enalapril-containing products

Trade name	country
ACEPRIL	Hungary
ALAPRIL	Austria
BERLIPRIL	Estonia, Hungary, Slovakia
CONVERTEN	Italy
DOCENALA	Belgium
EDNYT	Estonia, Hungary, Slovakia
ENAC	Austria
ENALOC	Finland
ENAP	Estonia, Hungary, Slovakia
ENAPREN	Italy
ENAPRIL	Austria
INVORIL	Estonia, Hungary
LINATIL	Finland
MEPRIL	Austria
NAPRILENE	Italy
RENAPRIL	Hungary
RENISTAD	Austria
RENITEC	Austria, Belgium, Estonia, Finland, Hungary, The Netherlands

Source: the EURO-MED-STAT database (accessed on April 2006)

Graph 1. Number of active ingredients licensed in eight EU countries within the following therapeutic groups: cardiovascular, neurologicals, antibiotics



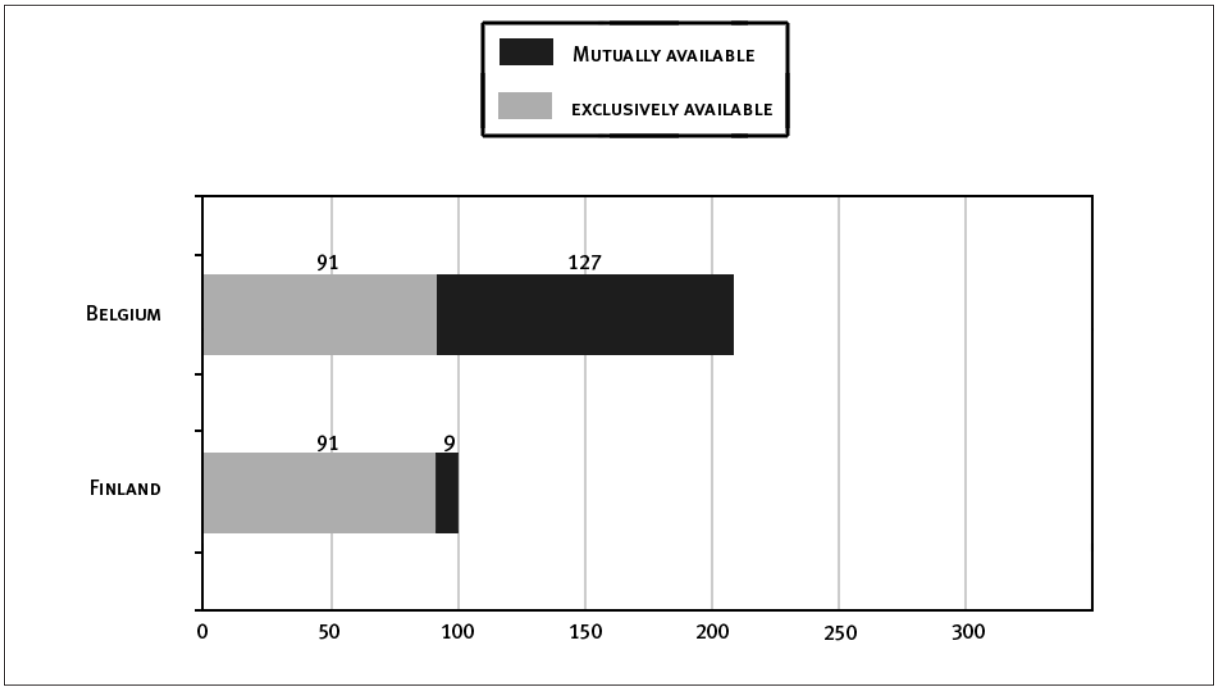
Source: the EURO-MED-STAT database (accessed on April 2006)

antibiotics), which is twice greater that of their neighbour the Netherlands and three times greater than Slovakia.

Graph 2 shows the number of cardiovascular active ingredients licensed in Finland (100) and Belgium (218). Ninety-one ingredients are mutually available in both of the countries; nine of the ingredients licensed in Finland are not licensed in Belgium, while 127 of the ingredients licensed in Belgium are exclusively available in that country and are not licensed in Finland.

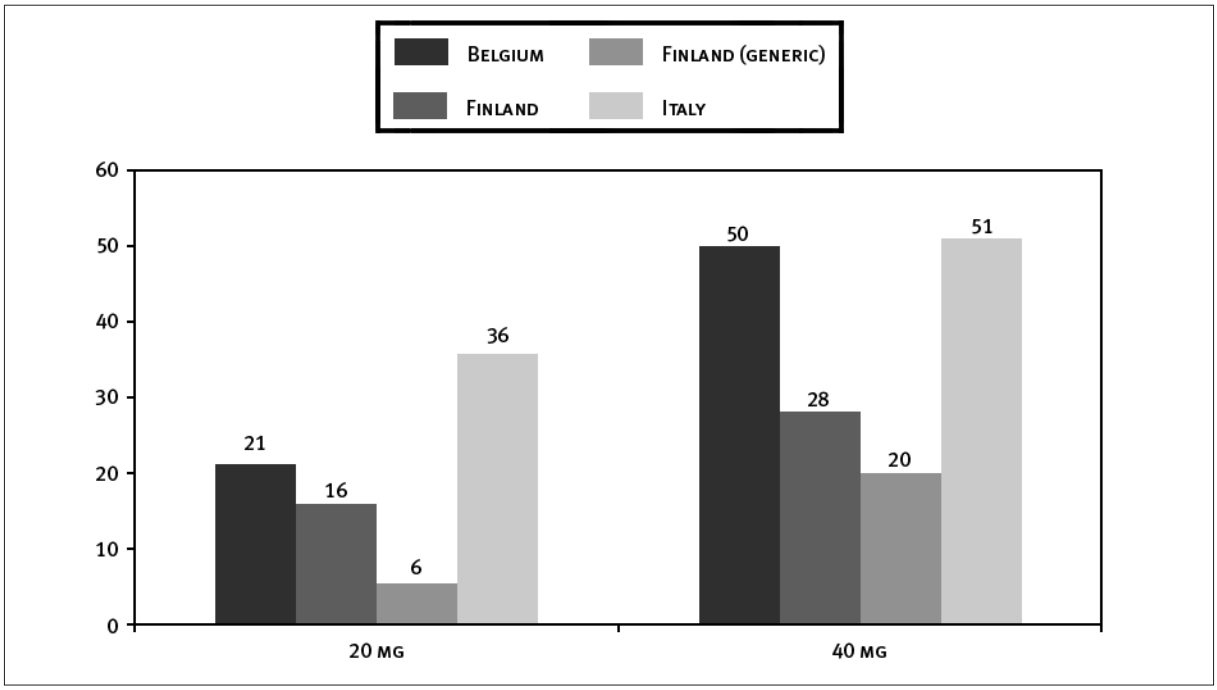
Graph 3 gives a price comparison of a top selling medicine (simvastatin) in Belgium, Finland and Italy.

Graph 2. Mutually available and exclusively available cardiovascular medicines in Finland and Belgium



Source: the EURO-MED-STAT database (accessed on April 2006)

Graph 3. Differences in pharmacy retail price in euro for the product ZOCOR (simvastatin) 28tbs



Source: the EURO-MED-STAT database (accessed on April 2006)

Discussion

In a public health perspective there are several reasons to measure medicine utilisation and expenditure [1]:

- prescription of a medicine is the most common therapeutic intervention and one of the most common medical acts (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 the 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
- there are wide discrepancies between European countries in both licensed medicines and in their utilisation and expenditure.

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

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

For all of these reasons it is relevant to have information that facilitates the comparison and monitoring of medicine utilisation and expenditure at a European level.

Health policy and pharmaceutical decisions are not included in the Maastricht Treaty, this means that decisions regarding these topic are exclusively the responsibility of the Member States.

For this reason, the exchange of information between countries and an increased transparency in this sector have become vital. A system of improved pan-European communication in the pharmaceutical field was proposed in the early 1990s, this included a European directory of medicines (the European Product Index, EPI), aimed at ensuring market transparency and providing technical information that would also be available for patients.[13]

Such a directory has proved to be useful for a number of activities.[14] However, various difficulties have meant that such a European directory of medicines, which has been in the planning since the early 1990s, had not been developed. Further efforts, such as the MINE project [15], by other European or national Institutions, including the European Medicines

Agency (EMEA) have been stopped or have not yet produced available results.

With our results we have proven that a European database of medicines is feasible and that it can provide useful information enabling the comparison of the pharmaceutical policies of the member states, in terms of licensing, pricing and reimbursement of medicines.

The need to bring together data from different Member States requires a process of harmonization of the different national registers with a European standard, partly defined by the EURO-MED-STAT Project.

The availability of one (or more) European database of medicines will facilitate the obtainment, in a simple manner, of information that is otherwise difficult and time-consuming to obtain.

Conclusions

A European database of medicines is feasible and it can provide, in an uncomplicated manner, useful information to patients, health professionals and regulators.

Such a database can contribute to a better harmonisation of the different pharmaceutical systems in Europe and allow the monitoring of prices, expenditure and the utilisation of medicines according to the established indicators.

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Annexe 1 – List of participants to the EURO-MED-STAT and EURO-MED-STAT (db) projects

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