P. Folino-Gallo · T. Walley · J.C. Frolich · A. Carvajal · I.R. Edwards

**Availability of medicines in the European Union: results from the EURO-Medicines project**

Received: 3 May 2001 / Accepted in revised form: 26 June 2001 / Published online: 2 August 2001
© Springer-Verlag 2001

**Abstract** Objective: There is at present no comprehensive directory of medicines available in European countries. Such a directory would be valuable to policy analysts, clinicians, regulatory agencies, pharmaceutical companies and consumer groups. The aim of this project was to compile such a directory of all medicines marketed in each of the European Union member countries.

Methods: Lists of medicines for each country, compiled from several national sources, classified by Anatomical-Chemical-Therapeutic (ATC) code. Census date was late 1998.

Results: A comprehensive directory was created using data from 14 of the 15 European Union countries. Numbers of trade names and of active ingredients varied widely, from Germany with 18,554 and 1973, respectively, to Denmark with 1915 and 1016, respectively. In individual therapeutic areas, there were variations in the numbers of active ingredients available: the least variation between countries was in antineoplastic medicines (ATC code L, maximum number available in any country 101, minimum 60) and wider variation in alimentary (ATC code A, maximum 256, minimum 103) or cardiovascular (ATC code C, maximum 269, minimum 112). Only 7% of all the active ingredients were available in all the countries studied. The Scandinavian countries had the greatest proportion of active ingredients (60%) available in all other countries. Each country had a number of active ingredients available only in that country – Italy had the largest number of these.

Conclusions: The directory illustrates the wide variations in the availability of medicines across the European Union. The range of drugs available in each country represents differences in regulatory and market policies, as well as cultural and historic differences. This directory lends itself to many further analyses.

**Keywords** Medicines · Europe · Regulation

**Introduction**

The development of centralised drug licensing in the European Union is an example of the harmonisation of European institutions [1, 2]. This follows from a system of individual national licensing agencies acting independently that has not entirely disappeared but which is far less important than before. A result of this previous system is that many older drugs are available in only one or some of the European states but not in others, or that the doses and indications may vary between countries. Other discrepancies have existed and continue to exist in the patterns of drug use with relatively few drugs being widely used in more than one country [3, 4], in expenditure on medication and in drug prices. Some of the most widely used medicines in some countries have even been withdrawn or were never licensed in others. There is rarely any scientific rationale for these discrepancies.

A system of improved communication between national and pan-European regulatory agencies and the pharmaceutical industry was proposed in the early 1990s [5], particularly with regard to regulatory activity, pharmacovigilance and medicinal product authorisations. The general public was to have access to this information. Part of this was a directory of medicines,
the European Product Index (EPI), itself a by-product of the European Community Pharmaceutical Information project [6]. The aims of this project were to ensure market transparency [7], support pharmacovigilance and provide technical information by creating a repertory of drugs available in the European Union. Early trials suggested that the system would be of great value, but various difficulties have meant that the EPI has never been developed. European regulatory agencies depend on a drug dictionary produced by the World Health Organization (WHO) and on a commercial directory produced by a for-profit organisation. The former, although useful, does not contain dosage form and some other information. The latter is not available to other groups except at great expense.

Identifying the discrepancies in availability of medicines can therefore be difficult, since at present there exists no directory of all medicines available in each European state. Such a directory would be of value to regulatory agencies, to those agencies negotiating drug prices, to manufacturers and those charged with promoting good prescribing. Other potential users of such a directory would be those with direct responsibility for patient care who need to identify the medicines a patient is using and consumers. To fill this gap, we undertook the “EURO-Medicines” project, funded by the Commission of the European Communities under the IV Research programme (Biomed 2-Area 6, Public Health).

Its aims were to define drugs available in member states and, using these data, to compare the performance of each member state in regulating its drug market. The objectives (tasks) of this project were threefold:

- **Task 1** – to undertake a comprehensive survey of all medicines marketed in each of the 15 European Union members
- **Task 2** – to examine selected medicines identified from the list developed in task 1 as being available in most or all countries by reviewing the summary of product characteristics (SPC), since this represents the uses of the medicines approved in each state by the regulatory agencies
- **Task 3** – to list active ingredients withdrawn for reason of safety or ineffectiveness from any of the countries identified from official lists and from published data and to examine if these ingredients were still available in other countries

This paper describes task 1.

**Methods**

Each medicine was to be classified by the WHO Anatomical Therapeutic Chemical (ATC) code [8] and identified by international non-proprietary name of its active ingredients. Other information to be recorded was the proprietary name (with details such as pharmaceutical form, strength and pack size), the marketing authorisation holder, the year of approval, whether reimbursed by the health service, prescription status (hospital only, prescription only, over-the-counter) and any special restrictions on its use (e.g. for opiates or other controlled drugs). Unbranded or generic medicines were treated in the same way with the exception of the proprietary name. Utilisation data and prices were also recorded when available. The census period for these lists was the second half of 1998.

A number of methodological difficulties were anticipated. We expected difficulty in finding complete national databases of good quality, despite a European requirement to have such a list available in each state [9]. We therefore aimed to use a variety of agencies in each of the member states to compile a list of available medicines, largely national formularies and also data from Ministries of Health or other national organisations, public or commercial as necessary. We also expected the data from such diverse sources to be of varying quality, and for quality assurance and standardisation of the data we followed the European Prestandard ENV 12610 (Medical Informatics – Medicinal Product Identification) [10].

Further difficulties were the definitions of what constituted a medicine. For licensed drugs, this is clear but for many over-the-counter (OTC) preparations, the distinction may be difficult. For OTC preparations such as vitamins, we decided to include a preparation only if we considered that it was clearly used therapeutically, and not as a simple food supplement, based on listing in the British National Formulary or similar source. Similarly, we decided to exclude herbal and homeopathic preparations where the range of products available varies enormously across Europe. We generally accepted the ATC code assignment on a national list where available, but for some countries it was necessary to undertake the assignment. The data were analysed using commonly available software (MS Excel 97 and Access 97).

**Results**

Data were received from a variety of sources. For only one country (Greece) was it not possible to obtain data. No source had all the information required, and the sources ranged from national lists provided by state agencies to prescribing databases, compendia of summaries of product characteristics, as well commercial directories of available medicines (Table 1). There are no data available at present on dermatological preparations in Portugal. The data on trade names for Austria, Belgium and Germany include not only the proprietary name but also the formulation and strength; these data are therefore not directly comparable to the data for the other countries which include only the proprietary name.

**Numbers of medicines available**

The numbers of medicines available varied widely among countries, with Germany having the largest number of both active ingredients (by ATC codes) and trade names and the Scandinavian countries the least (Table 2). The average ratio between trade names and active ingredients is higher in Germany than in other countries. Details by ATC code (1st level) are shown in Table 3.

**Similarities and discrepancies between countries**

The similarities and discrepancies between countries were further explored. Table 4 shows what percentage of the ingredients licensed in each country is available in the other countries, for those countries for which complete data are available. More than 60% of the ingre-