EURO-MED-STAT (European Medicines Statistics)

I. TECHNICAL INFORMATION

1. AREA OF ACTIVITIES / WORKING PARTY Pharmaceuticals / Working Party on Health Systems	
2. TITLE OF PROJECT **EURO-MED-STAT. Monitoring expenditure and utilisation of medicinal products in the European Union countries. A public health approach.**	
3. START DATE OF THE PROJECT February 2002	
4. DURATION OF THE PROJECT 24 months	
6. PROJECT LEADER / ORGANISATION Pietro Folino-Gallo, M.D. / IRPPS – National Research Council	
7. PROJECT NUMBER **SI2.327499 (2001CVG3-511)**	
8. SANCO REPRESENTATIVE Zinta Podniece	
9. COUNTRIES INVOLVED	
MEMBER STATES: [x] A (Austria) [x] B (Belgium) [ ] CY (Cyprus) [ ] CZ (the Czech Republic) [x] D (Germany) [x] DK (Denmark) [x] E (Spain) [ ] EE (Estonia) [x] EL (Greece)	CANDIDATE COUNTRIES: [ ] BG (Bulgaria) [ ] TR (Turkey) [ ] RO (Romania) EFTA/EEA COUNTRIES: [ ] (IS) Iceland [ ] (LI) Liechtenstein [x] (NO) Norway

[x] F (France) [x] FIN (Finland) [ ] HU (Hungary) [x] I (Italy) [x] IRL (Ireland) [ ] L (Luxembourg) [ ] LT (Lithuania) [ ] LV (Latvia) [ ] MT (Malta) [x] NL (Netherlands) [x] P (Portugal) [ ] PL (Poland) [x] S (Sweden) [ ] SI (Slovenia) [ ] SK (the Slovak Republic) [x] UK (United Kingdom)	OTHERS: World Health Organisation – Regional Office for Europe
10. REPORT STATUS (INTERIM OR FINAL) Final report	

II. CONTENT RELATED INFORMATION

11. CONTEXT/INTRODUCTION

Several thousand medicinal products are licensed in the European countries and tons of medicines are daily used with a yearly expenditure wider than 100 billion euro (attaining in some countries more than 20% of the health expenditure).

Wide discrepancies do exist across the European Union countries in:

- the number, pack size and strength of licensed medicines,
- the legal classification and reimbursement categories
- the price, expenditure and utilisation.

At present, there is in Europe a general lack of information on several aspects related to pharmaceutical products and their utilisation. There is no up to date European registry of licensed medicines, and information on medicines, their licensed clinical properties (indications, contraindications, warnings and side effects), their price, expenditure and utilisation can be retrieved and compared internationally only with great difficulty.
Standard sources such as WHO, OECD or EUROSTAT do not collect or publish information on price, expenditure and utilisation of medicines in a systematic way and data collected by industry and market research agencies are not publicly available.
The result is that there is no systematic information on price, expenditure and utilisation of medicines at a European level, nor even an established data flow to facilitate this.

12. AIM AND OBJECTIVES OF THE PROJECT

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

- Identification and evaluation of the data sources in the EU countries
- Comparison of the existing data and suggestion for a minimal data set for European registers of medicinal products
- Production of a Library of EU Pharmaceutical Indicators
- Feasibility analysis of a European database of medicinal products with information on licensed clinical properties, legal classification, reimbursement category, price, expenditure and utilisation.

13. PERFORMANCE PROCESS (ACTIVITIES / DESIGN / INSTRUMENTS)

TASK 1: performing an inventory of data sources and a survey of available data on medicines in the EU Member States
Listing Bodies/Institutions collecting utilisation, price and expenditure data;
Listing the collected data and the methods used for their collection

TASK 2: assessing data reliability and comparability between countries
Utilisation Data: Covering of the country (nation-wide or regional); Community or hospital utilisation data; Reimbursed medicines or all the products; Prescribed Only Medicines and/or OTC products; Data Source (Wholesalers, Pharmacies, Prescribers); Users and indications; Units of measurement used (ATC/DDD, number of items, costs, etc.); When ATC/DDD is not used possibility to convert the data in this system; When ATC is used quality control of ATC and DDD assignment; Electronic format and compatibility.
Price and Expenditure Data: Kind of price (ex-factory, wholesaler, pharmacy); Community Price and Hospital Price; Reimbursed medicines or all medicines; Prescribed Only Medicines and/or OTC products; Private spending versus public spending; Expenditure data by ATC groups; Breakdown by kind of approval ("centralised", "mutual recognition", national); Electronic format and compatibility.

TASK 3: developing a set of Recommendations for national registers of medicinal products with validated ATC codes and DDD values
Recommendations are needed to overcome the difficulties arising from the national discrepancies in health systems and in the classification of medicinal products and to harmonise the available sources.
The ATC/DDD methodology, suggested as a standard from the World Health Organisation, will be used for organising raw data and for structuring the analyses in therapeutic classes.

TASK 4: developing a set of indicators for price, expenditure and utilisation of medicines and pooling and comparing a sample of validated data with special reference to cardiovascular medicines
After harmonisation of their electronic format the validated data will be pooled together and reported according to the established indicators. Cardiovascular products will serve as a test case for the process of pooling, comparing and reporting the validated data.

14. OUTCOMES OF THE PROJECT / KEY HEALTH MESSAGES

The EURO-MED-STAT project has produced a set of indicators known as The Library of European Union pharmaceutical indicators. (http://www.euromedstat.cnr.it/indicators/indicators.asp).

The project has also inventoried more than seventy data sources and identified the most suitable for a European database of medicines.

The Library of EU pharmaceutical indicators includes:

1- Recommendations for national registers of medicinal products with validated ATC codes and DDD values http://www.euromedstat.cnr.it/pdf/sop%2004-07-08.pdf
2- Price Indicators http://www.euromedstat.cnr.it/pdf/price%2004-07-13.pdf
3- Expenditure and Utilisation Indicators http://www.euromedstat.cnr.it/pdf/utilisation%2004-07-30.pdf

15. CONCLUSIONS

The EURO-MED-STAT project has identified and selected the best data sources for collecting data on price, expenditure and utilisation of medicines across European countries. The project has proved the feasibility of using these administrative sources for collecting comparable data on price, utilisation and expenditure.

16. PUBLICATIONS RELATED TO THE PROJECT

http://www.euromedstat.cnr.it/publications/publications.asp

Chapters in Books

P. Folino-Gallo, T Walley, A. Melander, K deJoncheere, E. vanGanse, U. Schwabe on behalf of the EURO-MED-STAT Group : Public Health Challenges. Statin Utilisation and Coronary Heart Disease Mortality: Assessing the Impact of Medicine Utilisation on Population Health. *In G. Tellnes (editor). Urbanization and health. New challenges to health promotion and prevention. 2005 (in press)*

P. Folino-Gallo, T Walley, K deJoncheere, R vanderStichele on behalf of the EURO-MED-STAT Group: EURO-MED-STAT: Monitoring expenditure and utilisation of medicinal products in the European Union countries. A public health approach. *In W.Kirch (editor): Public Health in Europe. 10 years EUPHA. Selected manuscripts from the 10th Annual Congress of the European Public Health Association. 28-30 November 2002. Dresden Germany. Springer Verlag Berlin 2003 (ISBN 3-540-40240-3)*

Papers
Walley T, Folino-Gallo P, Schwabe U, Van Ganse E, Stephens P. Comparison of national administrative and

commercial databases to monitor expenditure and costs of statins across Europe. Eur J Clin Pharmacol (2004) 60: 503–511

I Rosian, S Vogler. Arzneimittel-Monitoring in der EU. Preise, Ausgaben und Verbrauch im Visier der Gesundheitsberichterstattung (in German). Welldone, June 2004

K Nink , H Schröder. Europas Märkte unter der Lupe. Brüssel will's wissen: Experten aus 15 europäischen Ländern sind dabei, die nationalen Arzneimittelmärkte zu vergleichen. Erste Ergebnisse zeigen: Die Kosten für medikamentöse Therapien variieren erheblich (in German). In: Gesundheit und Gesellschaft 02/2004 S. 16-17

Martikainen J, Klaukka T. Statiinien. Käyttö vaihtelee Euroopan maissa - Suomessa keskitasoa (in Finnish) Suomen Lääkärilehti 2004; 59: 1402-1403.

T Walley, P Folino-Gallo, U Schwabe, E van Ganse. Variations and increase in use of statins across Europe: data from administrative database. Br Med J 2004; 328: 385-386

I Rosian, S Vogler. EURO-MED-STAT. Monitoring von Arzneimittelausgaben und –verbrauch in der EU (in German). Mitteilungen der Sanitätsverwaltung 12/2003

EURO-MED-STAT Group. EURO-MED-STAT: Monitoring Expenditure and Utilisation of Medicinal Products in the European Union Countries. A Public Health Approach. Eur J Public Health 2003; 13(3): 95-100

Sainz M, Carvajal A, Folino Gallo P, Garcia del Pozo J Grupo de Investigacion Euro-Med-Stat. Availability of drugs in the European Union. The case of antiplatelet agents. Med Clin 2003; 120(20):793-4

Rosian, S Vogler. Arzneimittel-Monitoring (in German). Österreichische Gesellschaft für Gesundheitswissenschaften und Public Health. Public Health, Newsletter 4/ 2002

Abstracts in peer review journals

P. Folino-Gallo on behalf of the EURO-MED-STAT group. A web-based European database of medicines. Eur J Public Health 2003; 13(4):26-27

M. Rønning on behalf of the EURO-MED-STAT Group. The EURO-MED-STAT project: Minimal Data Set for European harmonised lists of medicines with validated ATC codes and DDD information. Eur J Public Health 2003; 13(4):27

T. Walley on behalf of the EURO-MED-STAT Group. The EURO-MED-STAT project: Price Indicators. Eur J Public Health 2003; 13(4):27

U. Schwabe on behalf of the EURO-MED-STAT Group. The EURO-MED-STAT project: Expenditure/utilization indicators. Eur J Public Health 2003; 13(4):27

A. Carvajal, P. Folino-Gallo, M. Sainz, J. García del Pozo on behalf of the EURO-MED-STAT Group Availability of medicines in the European Union: the case of the antiplatelet medicines. Eur J Public Health 2003; 13(4):69

P. Folino-Gallo on behalf of the EURO-MED-STAT group. EURO-MED-STAT: Monitoring expenditure and utilisation of medicinal products in the European Union. A public health approach. Eur J Public Health 2002;

I. Rosian, S. Vogler. EURO-MED-STAT: Monitoring expenditure and utilisation of medicinal products in the European Union. A public health approach. Pharmacology 2002; 66:212

Workshops

Results from the EURO-MED-STAT project. Eleventh Annual European Public Health Association (EUPHA) Conference, Rome November 2003

website

www.euromedstat.cnr.it

17. FUTURE POLICY DEVELOPMENT

It is hoped that the EURO-MED-STAT project can have a follow-on to implement the European database of medicines according to the standard suggested by the project.

A refinement of the Library of EU pharmaceutical indicators is needed for linking utilisation of medicines to their impact on population health. This objective will be performed in cooperation with the European Public Health Association (EUPHA) section on utilisation of medicines.