



Project Euro-Med-Stat



Project Euro-Med-Stat

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Presentation

Project Group „Pharmaceuticals“
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WIdO

AOK Research Institute

- Independent entity of the Federal Association of the AOK (largest health insurance organisation in Germany)
- Independent executive committee
- Independent advisory board of experts
- Guiding principle: link between science and practice
- Staff of 40:
 - sociologists
 - economists
 - psychologists
 - mathematicians
 - computer scientists
 - pharmacists ...



AOK Research Institute (WIdO)

- Research for more quality and efficiency in the national health system -

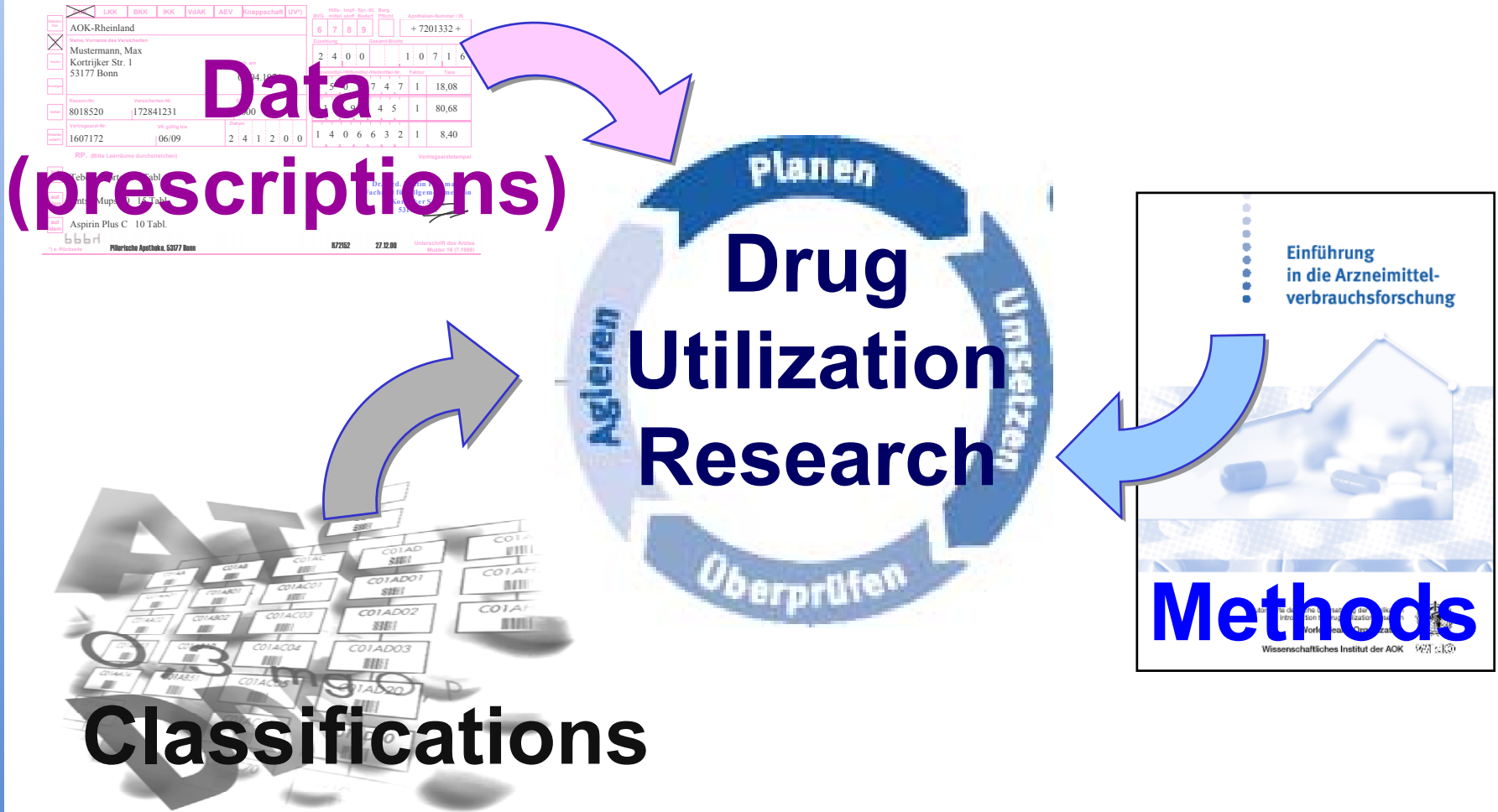
WIdO Projects

Drugs	Hospitals	Ambulatory Care	Research into various issues of health care	Prevention of work related illnesses	Market research	Long term care
<ul style="list-style-type: none"> - German drug index (GKV-AI) - pharmPRO (software for consulting physicians) - <i>Actrapid!</i> 	<ul style="list-style-type: none"> - German hospital report (KH-Report) - Quality management - Diagnosis Related Groups (DRGs) 	<ul style="list-style-type: none"> - Case statistics - Efficiency - Physicians statistics 	<ul style="list-style-type: none"> - Prevention - Dialysis - Quality of dental treatment - ICD 10 	<ul style="list-style-type: none"> - Interviews with employees - Statistics on health related absenteeism 	<ul style="list-style-type: none"> - Analysis - insuree/ patient interviews 	<ul style="list-style-type: none"> - German long term care report - WIdOPuLS

Internal Services: EDP, Graphics, Layout, References, Organisation



Drug Utilization Research: Classifications, Data and Methods



source: Schröder, Nink und Zawinell (2004): Transparenz jetzt nutzen, in: Deutsche Apotheker Zeitung Mai 2004.



Euro-Med-Stat Project

- **Reasons**
- **Aims**
- **Participants**
- **Tasks**
- **Timelines**
- **Results**
- **Future**



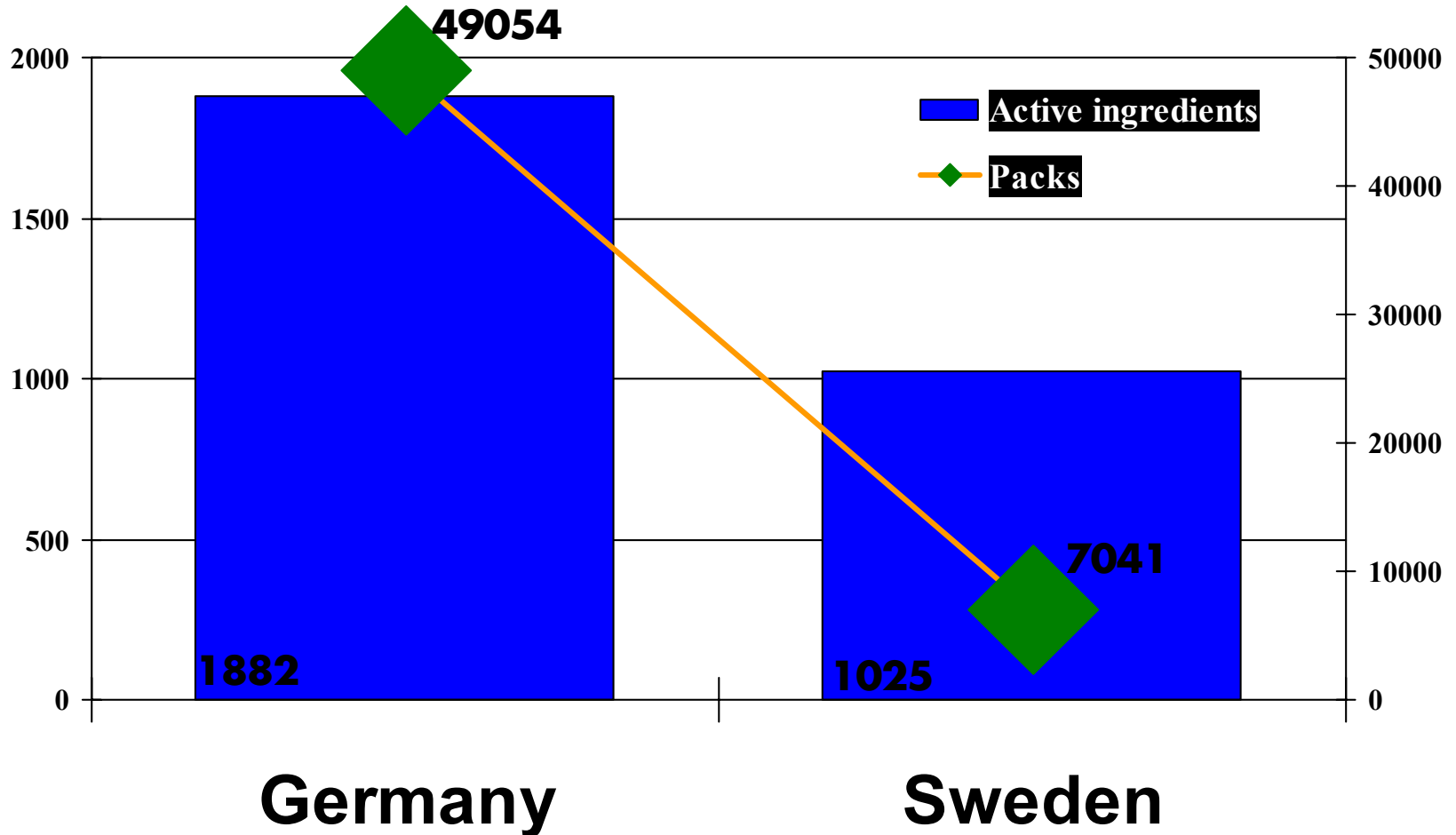
Reasons for an EURO-MED-STAT project

- 1. >100,000 pharmaceutical packs are licensed in the EU-15**
- 2. great differences between (within) countries**
- 3. licensed medicines (active ingredients & packs)**
 - price**
 - expenditure**
 - utilisation**
- 4. Lack of comparable data**
- 5. Need for an increased system transparency**



Number of licensed packs and active ingredients in the year 2000

Source: EURO-Medicines database





Experiences with European database of medicines

- EPI (early 1990s)
European Product Index
(never developed)
- MINE (late 1990s)
Medicines Information Network for Europe
(prototype stopped)
- EURO-Medicines
ATC codes and acceding countries data
available on the internet
(prototype stopped)



European database: Major difficulties

- **National sources are not always easily accessible**
- **Lack of standardisation**
 - Only few sources contain all the relevant information
 - National sources are not harmonised
 - Lack or poor quality of ATC codes (WHO standard) in some countries



European database: Main discrepancies

- Number of licensed medicines (trade names, packs and ingredients)
- Reimbursement classes
- Legal categories
- Price differentials
- Licensed indications
- Utilisation
- Medicines withdrawn from one country still used in others



Aim of the EURO-MED-STAT project

The aim of the project is to develop indicators for monitoring prices, expenditure and utilisation of medicines under a public health point of view and to implement a European database of licensed medicines.

The large amount of available medicines influences public health:

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



Objectives of the EURO-MED-STAT project

- 1. To establish an inventory of data sources and a survey of available data**
- 2. To assess data reliability and comparability between countries**
- 3. To develop recommendations for data management (collection, validation and comparison)**
- 4. To develop a set of indicators for monitoring price, expenditure and utilisation of medicines**



Participants: The EURO-MED-STAT Group



ÖBIG



Heymans Instituut



Medicines Agency



National Social Ins.



Un. of Lyon



Un. of Heidelberg
German Drug Index



Un. of Athens



Irish Nat. Centre
Pharmacoeconomics



It. Ministry of Health
It. Ministry of Economics



CNR (co-ordinator body)
National Inst. for Statistics



Dutch Ministry of Health



Inst. of Public Health Oslo



INFARMED



Pharmacovigilance Center
Castilla y Leon-Un. of Valladolid



Swedish Apoteket



University of Liverpool



WHO-EURO Copenhagen
WHO-CC Oslo



Tasks of the EURO-MED-STAT project

1. Task 1

Performing an inventory of data sources and a survey of available data in the EU member states

Utilisation, price and expenditure data

2. Task 2

Assessing data reliability and comparability between countries

Utilisation, price and expenditure data

3. Task 3

Developing Standard Operating Procedures (SOPs) for data management (collection, validation and comparison)

4. Task 4

Pooling and comparing the validated data with special reference to cardiovascular medicines



Timeline of the EURO-MED-STAT project

	Jan-Apr. 2002	May-Aug. 2002	Sep-Dec. 2002	Jan-Apr. 2003	May-Aug. 2003	Sep-Dec. 2003
TASK 1 Survey of available data	X	X				
TASK 2 Data comparability		X	X	X		
TASK 3 Standard Operating Procedures			X	X	X	
TASK 4 Pooling the validated data				X	X	X



Task 1: Survey of the available data

- EURO-MED-STAT project

Performing an inventory of data sources and a survey of available data in the EU member states (utilisation, price and expenditure data)

Listing bodies/institutions collecting utilisation, price and expenditure data;

Listing the data collected and the methods used for their collection



Result 1: Survey of the available data - EURO-MED-STAT project

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 Amstelveen/Stichting Farmaceutische Kengetallen Den Haag (Health Care Insurance Board, Pharmaceutical Products Information Project Amstelveen/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)



Task 2: Data comparability

- EURO-MED-STAT project

Assessing data reliability and comparability between countries

Covering of the country (nationwide or regional)

Community or hospital utilisation data

Reimbursed medicines or all 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

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



Result 2: Data comparability

- EURO-MED-STAT project

	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	—	2	—	—
Portugal	—	1	2	—
Spain	—	1	2	—
Sweden	1	1	4	1
UK	1	1	3	3
TOTAL	5	15	27	6



Result 2: Data comparability - EURO-MED-STAT project

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	57.8	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



Task 3: Standard Operating Procedure - EURO-MED-STAT project

Developing Standard Operating Procedures (SOPs) for data management (collection, validation and comparison)

Standard Operating Procedures are needed to overcome the difficulties arising from the national discrepancies in health systems and in the classification of medicinal products.

The ATC/DDD methodology, suggested as a standard by the World Health Organisation, will be used for organising raw data and for structuring the analyses into therapeutic classes.

A set of utilisation, cost and expenditure indicators fitting with the available validated data will then be selected for data comparison.

A clear definition of each indicator (objective, definition, description, rationale and data collection) will be provided together with a clear statement of what indicators are intended to measure and what conclusions can be claimed from their use.

The SOPs will also state the level of access and confidentiality of the data.



Result 3: Standard Operating Procedure - EURO-MED-STAT project

Minimal Data Set for National Register of Medicinal Products with Validated ATC Codes and DDD Values:

Registration number or other unique identifier

ATC code

Active ingredient(s)

Medicinal product name with its specifiers

Trade name

Pharmaceutical form

Strength

Pack size

Legal category

Reimbursement

Pharmacy retail price

Date of approval

Date of first marketing

Date of removal from the market

Holder of marketing authorisation

Generic

Parallel import

Value of the DDD

Route of administration

Number of DDD in the pack



Task 4: Pooling the validated data - EURO-MED-STAT project

Pooling and comparing the validated data with special reference to cardiovascular medicines.

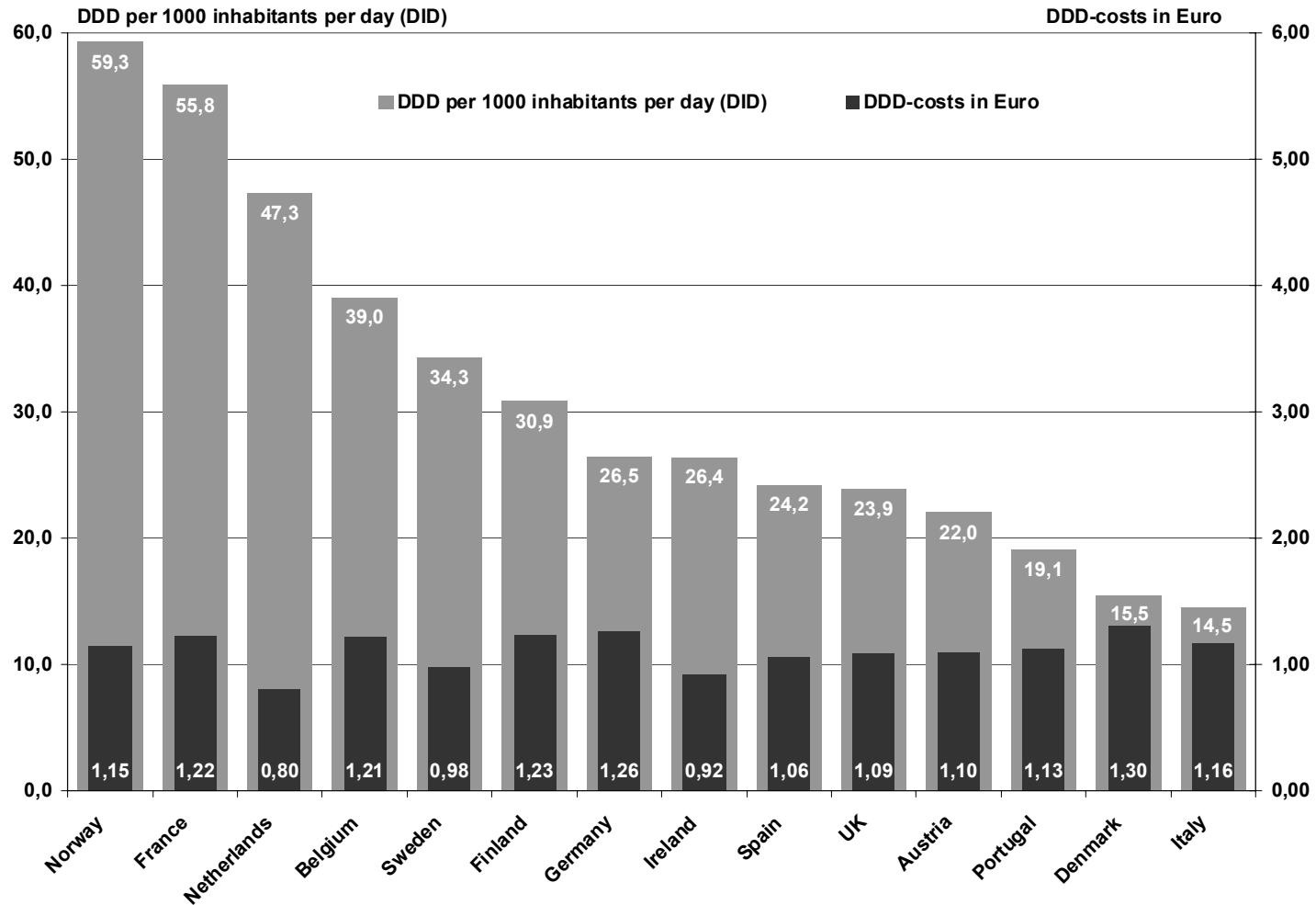
After harmonisation of their electronic format, the validated data will be pooled together and reported according to the established indicators.

Cardiovascular products will serve as a test case for the process of pooling, comparing and reporting the validated data.



Statins in Europe: Enormous variation

- Results of the Euro-Med-Stat project (2000)



Source: Nink K. und Schröder H. 2004: Europas Märkte unter der Lupe. Gesundheit und Gesellschaft 02/2003



Statins in Europe in 2000: Reasons for ...

- Results of the Euro-Med-Stat project

Comment

Our analysis shows enormous variation in statin use across Europe and a rapid increase in use. Variations in morbidity may explain some of the differences in use (such as between Italy and Britain) but not all (as between Norway and Denmark). We must consider other explanations, and these may lie in factors unique to each country: for example, differences between Norway and Denmark may reflect the involvement of Norwegian doctors in seminal trials, while in Denmark these drugs were only reimbursed from 1998 onwards and their use has lagged behind other countries. Low use in Italy may reflect low coronary morbidity or poor adherence of Italian patients to statins, worse than elsewhere in Europe.⁴ Other differences may lie in national guidance and policies. These national figures also hide wide variations within countries.⁵

source: Variations and increase in use of statins across Europe. BMJ Volume 328, 14 February 2004



Timeline of the EURO-MED-STAT project 2002 – 2005 ...

	Jan-Apr. 2002	May-Aug. 2002	Sep-Dec. 2002	Jan-Apr. 2003	May-Aug. 2003	Sep-Dec. 2003
TASK 1 Survey of available data	✓	✓				
TASK 2 Data comparability		✓	✓	✓		
TASK 3 Standard Operating Procedures			✓	✓	✓	
TASK 4 Pooling the validated data				✓	✓	✓



Starting 2005: EURO-MED-STAT database (EMS-db)



Arzneimittel

Thank you for your attention!

- ▶ [Antibiotikastudie](#)
- ▶ [Arzneimittelverbrauchsforschung](#)
- ▶ [ATC/DDD-Klassifikation](#)
- ▶ [Europa](#)
- ▶ [GKV-Arzneimittelindex](#)
- ▶ [Hormone](#)
- ▶ [pharmPRO](#)
- ▶ [Preisinfo](#)
- ▶ [Projekt KV Nordrhein](#)
- ▶ [Publikationen](#)

- ▶ [Arzneimittel-Gutachten BMGS](#)

Qualität und Wirtschaftlichkeit der Arzneimittelversorgung in der Gesetzlichen Krankenversicherung sind bereits seit mehr als 20 Jahren ein wichtiges Forschungsfeld des Wissenschaftlichen Instituts der AOK (WIdO). Mit dem Forschungsprojekt [GKV-Arzneimittelindex](#), das bereits Anfang der 80er Jahre aus der Wiege gehoben wurde, stehen umfangreiche und kontinuierliche Untersuchungen zur Entwicklung der Arzneiverordnungen in der Gesetzlichen Krankenversicherung zur Verfügung, die zur Verbesserung der Transparenz auf dem Arzneimittelmarkt und damit zur Sicherstellung einer bedarfsgerechten und wirtschaftlichen Arzneiverordnung beitragen. Mit dem Projekt [PharmPro](#), können diese Ziele im Rahmen einer individuellen Arzneimittelberatung durch die Beratungsapothekerinnen und -apotheker der AOK direkt in die Arztpraxen getragen werden. Neuere Projekte im Arzneimittelbereich, wie das Gemeinsame Projekt der Spitzenverbände der Gesetzlichen Krankenversicherung GKV-Arzneimittel-Schnellinformation (GAmSi), das im WIdO durchgeführt wird, können die Entwicklung der Arzneiverordnungen zeitnah aufzeigen und damit den Akteuren wichtige Informationen zur Steuerung der Ausgabenentwicklung an die Hand geben.