Pharmaceutical Health Information System

PHIS indicators Taxonomy

Final Version
August 2009

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In collaboration with Gesundheit Österreich GmbH
PHIS project leader

Commissioned by the European Commission, Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health (BMG)

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INDICATORS INDEX

This report presents the taxonomy for indicators in the framework of the project PHIS (Pharmaceutical Health Information System) Work Package 6 (WP6). Objectives of this work package are twofold:

- Develop a taxonomy for PHIS indicators
- Build a PHIS database filled with data from the EU Member States.

1 Introduction

Several exercises have been undertaken to develop public health indicators. However, there are relatively few indicators specifically relating to the field of pharmaceuticals. The PHIS project aims at reviewing the existing pharmaceutical indicators from a public health perspective and, based on the review, to develop appropriate and reliable indicators. Important previous work on indicators in the pharmaceutical sector have been undertaken by the EU-funded projects EUROMEDSTAT[1], SOGETI indicators[2] and PPRI[3], which is considered in the review.

Based on the review of existing pharmaceutical health indicators, a **taxonomy for PHIS indicators was produced** and is presented in this report. This taxonomy was revised after presentation and discussion at the second PHIS Network Meeting (month 10 – June 2009) and after a separate feed-back round with the PHIS Adviosory Board (cf. section 3.1.5) and was finalised in month 12 (August 2009).

The development of the taxonomy is a milestone in the process of setting up the PHIS database, which will be filled with data from the EU Member States. The information and data for the pharmaceutical health indicators will be provided by the PHIS network members. The PHIS database, due in month 29 (January 2011), is considered as an important element of the European Health Information system.

This report presents in a first stage the scope and sources considered and then details the PHIS indicators according to the taxonomy developed.

Finally, we present the framework for implementation and data collection for the PHIS database to be conducted in the next stage of the Work Package 6 of this project.

2 Determining the scope and sources to consider

2.1 Scope

2.1.1 Scope of the exercise

The scope of the exercise depends on and is influenced by who will use the indicators to be developed and in which purpose. Such users could be policy makers from a national authority, the European Commission, sectors in charge of protecting health or responsible for the management of resources.

[1] http://www.euromedstat.cnr.it/
[2] http://ec.europa.eu/health/ph_overview/Documents/keydoc_G1200306_tech_en.pdf
[3] http://ppri.goeg.at/

To this end and since a wide range of indicators were identified by the work already carried out to develop public health indicators, there should be **two sets** of indicators:

- A **core list** mainly intended to policy makers;
- A **supplementary list** with a broader perspective.

Based on previous experience from developing public health indicators and input by experts and partners of the project, the scope was defined as follows:

- It should cover both out-patient an in-patient sector, specific indicators for a sector and not relevant for the other one may be selected and should be clearly identified if so;
- From the public health and policy perspectives: for safe and effective provision of pharmaceuticals with a focus on price and reimbursement issues.

Both in-patient and out-patient sector should be covered, however **indicators specific to a sector** may be implemented. Most projects tackling indicators on pharmaceuticals covered mainly the out-patient sector. **The PHIS Taxonomy explicitly aims at also integrating the in-patient sector, thus having an integrative and holistic approach.** Indicators for the in-patient sector were driven from research work and in collaboration with the work undertaken through the PHIS work package on Hospital Pharma and the PHIS Hospital Pharma Reports.

The **disease approach** tackled by the SOGETI project is a very interesting approach from the public health perspective but indicators by disease are **not well enough developed so far** to be fully considered in the framework of this project. The development of such indicators need significant work to be carried out and improvements in data collection.

Data collection for indicators will be conducted **through the PHIS Pharma Profiles and the PHIS Hospital Pharma Reports** from the other work packages of this project. All partners are working closely to ensure compatibility of information.

2.1.2 Scope of indicators

This section reviews the criteria for selecting indicators and other issues such as: geographical coverage (national representativeness), overall number of indicators to be considered, changes in the set of indicators over time and composite measures.

The main criteria chosen for the selection of and recommendations for a set of key indicators include as much as possible of the following ones [4,5]:

- **Evidence base** supporting indicator validity. Explicitness of the evidence base evaluates if there is scientific evidence available to support the measure and if the measure is already in use by other institutions. In the scope of this project, evidence

[4] OECD HCQI project conceptual framework: http://www.oecd.org/dataoecd/1/36/36262363.pdf, Box 7
[5] The National Quality Measures Clearinghouse™ (NQMC) Template of Measure Attributes, sponsored by the Agency for Healthcare Research and Quality (AHRQ), U.S. "Complete summary" http://qualitymeasures.ahrq.gov/about/measureviewsdescrip.aspx

was mainly supported by litterature, use in other relevant projects and databases, or by needs expressed by the PHIS Advisory Board and network.

  - **Validity** aims at evaluating if the indicator actually measures what it is intended to? The indicator should [6,7]:
    - Face validity as making sense logically and clinically;
    - Construct validity as correlating well with other measures of the same aspects of care;
    - And capture meaningful aspects of this care (content validity).

- The **feasibility** and **burden or cost** of obtaining internationally comparable data for the measure:

  - **Availability of data** and **geographical coverage** since the ultimate aim is to enable European comparisons (number of countries available could be an exclusion criteria for the indicators). Is the measure being collected for sufficient countries in the time frame required? A few indicators can already be found for most EU Member States while there will be many potential indicators for which few if any countries could provide any data in the foreseeable future. In between, there are likely to be some indicators for which data would be readily available at national level for a significant group of countries, but with variations in the precise definitions of numerators and denominators.

  - **Cost or burden** of data collection needed for the measure. Straightforward indicators are more often preferred to much more sophisticated ones involving a complex estimation process.

- The data sources **regularity** and data collection **timeless** in terms of:

  - Data sources regular updates, reliability of availability in the future;

  - Delivery time frame of updated data from original sources.

- The **communication** in terms of easiness to communicate to and understand from experts and non-experts.

- **Number of indicators:**

  - It is proposed that the target number of indicators should be no more than **30** in the first instance. Fewer, more comparable indicators are more desirable than a broader, less comparable set of indicators. Data restrictions may limit the size of the final initial set.

  - A subset of **no more than 5 core indicators** should be proposed, indicators intended to **policy makers**;

  - It is very likely that the indicator set changes through time. It can be envisaged that the initial indicator set might be defined as much by the availability of data as by the priority which was accorded to the indicators. If so, the indicator set could be expected to change subsequently as more important, valid and accurate data became available. In addition, the content of the preferred set might well change in the medium term as policy priorities change.

[6] "Reliability and viability assessment." Carmines, E.G., & Zeller, R. A. (1991). Thousand Oaks, CA: Sage.
[7] "Psychometric theory" Nunnally, J. C. (1978) (2nd ed.). New York: McGraw-Hill.

- **Updates** to the measure set should be made on a **periodic basis** agreed upon by the participating countries. Ideally, indicators would be subtracted from the core set to allow for additions to take place if there were an overall target.

In order to be close to reality, the **selection of indicators** needs to be associated to existing information:

- A minimum set of 5 countries with data available is an exclusive condition for selecting an indicator. It may need flexibility for in-patient indicators since data are not as much available as for out-patient sector. Indicators where absolutely no data were available, were not taken into account, unless a strong need if the PHIS network members and the PHIS Advisory Board was announced.
- The time range starts in 2000 which will also be asked for in the PHIS Pharma Profiles;
- Availability of data on a regular and sustainable basis is necessary;
- If data is not publicly available or on a restrictive basis, it should be clearly stated. Such information may be excluded for practical reasons;
- Improvements for indicators may be proposed.

Once the breakdowns of the taxonomy are defined it may be stated if non-availability of data at a breakdown level is an exclusion criteria.

The selection or exclusion criteria may be more flexible for in-patient indicators since data are not as much available as for out-patient sector.

Only **medicines** as defined hereafter should be considered in the framework of this monitoring:

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (PHIS Glossary).

All references to medicines will be given according to its **active ingredient** (or substance) as defined as follows: Ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a pharmaceutical (PHIS Glossary).

2.2 Relevant projects and sources

2.2.1 Relevant projects considered

At this stage of the project, a review of relevant projects and sources dealing with pharmaceutical indicators was conducted. An inventory of available indicators along with a complementary analysis of relevant potential sources matching with the scope of the exercise defined in a first stage were conducted. Then, these sources were reviewed according to the:

- identification of the methodology employed in each of these projects;
- evaluation of these sources and inventory of pertinent indicators and availability of data, considering the handling of computing methods (i.e. characteristics, limits, etc.)

At the time of this project the most relevant European projects regarding pharmaceutical indicators were:

- the EURO-MED-STAT project (Box 1) and database (Box 2);
- the SOGETI Pharmaceutical Indicators project (Box 3);
- the PPRI project (Box 4).

The project conducted by the Escuela Andaluza de Salud Pública (EASP) - Andalusian School of Public Health - "Analysis of differences and commonalities in pricing and reimbursement systems in Europe" (Box 5) was also considered. Since developing indicators was not an objective of that project, still the outcomes of that project were used as background information and had a more significant impact on the selection of indicators on pricing and reimbursement.

Additional relevant sources not specific to medicines but with a more broader perspective on health were included:

- The European Community Health Indicators Monitoring (ECHIM) project (Box 6);
- The Health Care Quality Indicators (HCQI) of the Organisation for Economic Co-operation and Development (OECD) (Box 7);
- The work undertaken by the World Health Organisation:
    - The World Medicines Situation;
    - The World Health Report 2000;
    - Priority Medicines for Europe and the World, 2004.

Box 1: Euro-Med-Stat (EMS)

Title: Monitoring expenditure and utilisation of pharmaceutical products in the European Union: a public approach

Aim: To develop indicators for monitoring price, expenditure and utilisation of medicines under a public health point of view and to build a European database of licensed medicines.

Funding: Project funded by the European Commission and co-funded by the National Research Council

Approach: 4 tasks project:

- Task 1: Performing an inventory of data sources and a survey of available data in the EU Member States
- Task 2: Assessing data reliability and comparability between countries
- Task 3: Developing Standard Operating Procedure (SOPs) for data management (collection, validation and comparison)
- Task 4: Pooling and comparing the validated data with special reference to cardiovascular medicines

Outcomes: 4 reports were published
- Recommendations for national registers of medicinal products with validated ATC codes and DDD values
- Price Indicators
- Expenditure / Utilisation indicators
- Executive summary

Geographical coverage: EU-15

Duration: Jan. 2002 to Dec. 2003

Website: http://www.euromedstat.cnr.it/default.asp

Box 2: Euro-Med-Stat database

Title: EUROMEDSTAT-Database

Aims:
- To build a Library of EU Pharmaceutical Care Indicators (with metadata).
- To build a comprehensive list of European medicines with information about their price, expenditure, utilisation and licensed clinical properties and make this information available on the web in many European languages.
- To verify the feasibility of a European database of GPs prescriptions with indications for which the medicines are prescribed and characteristics of the patients receiving the medicines.

Description: Based on the work performed in the EURO-MED-STAT project (described above). The specific objectives of this project were:
1. To refine the EURO-MED-STAT selection of indicators about price, expenditure and utilization of medicines and complete and update the Library of Pharmaceutical Indicators produced by the EURO-MED-STAT project.
2. To establish systems to build a comprehensive list of licensed medicines for European Union Member, according to the standards defined by the EURO-MEDSTAT project for European harmonized lists of medicines, with validated ATC codes and DDD values.
3. To complete the pilot EURO-MED-STAT web based database including data for the licensed medicines from the EU Member States and to establish the feasibility of its regular (twice per year) update.
4. To define a standard for European data collection of licensed properties of medicines (indications, contraindications, adverse reactions, warnings, etc), using a selected sample of medicines as a test case
5. To enlarge the EURO-MED-STAT web based database to include a section with information about licensed clinical properties.
6. To establish a comprehensive list of medicines withdrawn from the market in any EU state, and to define criteria to determine whether such withdrawals were for public health reasons (safety and / or ineffectiveness) or commercial / non-safety related reasons; and to make this information publicly available on the internet.
7. To study the feasibility of establishing a European database of the indications for which medicines are prescribed in general practice prescriptions and characteristics of the patients receiving the medicines.

Funding: Project funded by the European Commission and co-funded by the CNR / IRPPS (Consiglio Nazionale delle Ricerche - Istituto di Ricerche sulla Popolazione e le Politiche Sociali)

Outcomes:
- The Library of EU Pharmaceutical indicators
- The EU database of licensed medicines for one year with information on medicines withdrawn from the market for safety reasons. Data for indicators on pricing, expenditure and utilisation were not collected due to difficulties to obtain national inputs.

Geographical coverage: EU-25 but data availability for Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Italy, Netherlands, Portugal, Slovakia, UK only

Duration: 15 Dec. 2004 to 15 Dec. 2006

Website: http://www.euromedstat.cnr.it/default.asp

Box 3: SOGETI pharmaceutical indicators project

Title: Development of public health performance indicators for the pharmaceutical sector

Aim: Developing a first set of indicators for monitoring the performance of the pharmaceutical industry in meeting public health objectives.

Description: It consisted in scoping the type and range of indicators that could be developed to monitor the extent to which the pharmaceutical sector is aligned with public health and other social objectives. Emphasis was made on indicators feasible now and in the future with improved data collection. The analysis also considered the range of non-statistical indicator forms such as process indicators or indicators related to regulatory conditions.

To meet this objective, the project was structured into two phases conducted in parallel:
- Phase I: Determining the scope of the exercise, through consultation with public health stakeholders;
- Phase II: Review of existing data and proposals for development.

Funding: Project funded by the European Commission.

Outcomes:
- A detailed description of 71 indicators with regards to its description, data sources and availability, limitations, evaluation, and recommendation (Phase II report)
- Two sets of indicators were proposed for monitoring (Final report):
    - A core list of 21 indicators to be regularly collected for all priority diseases from which a stringent selection of 8 key indicators;
    - A supplementary list of 24 indicators to be collected on a less regular basis for focus on specific issues or diseases.
- Two case studies to on Diabetes mellitus and Acute stroke to evaluate the feasibility of the indicators (Case studies report)

Geographical coverage: EU-25

Duration: June 2005 to May 2006

Website: http://ec.europa.eu/health/ph_information/indicators/pharmaceutical_en.htm

Box 4: Pharmaceutical Pricing and Reimbursement Information (PPRI)

Title: Pharmaceutical Pricing and Reimbursement Information (PPRI)

Aims: The objective of the PPRI project was to provide knowledge and information on pharmaceutical systems in the 27 Member States of the European Union.
The general objective of the PPRI project was to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe. This network should facilitate a regular exchange of information and allow a process of learning from each other. A key outcome is a comprehensive report with more than 20 country reports (PPRI Pharma Profiles) on pharmaceutical pricing and reimbursement in the Member States and associated countries whose finding are benchmarking in a comparative analysis.

Description: This project was coordinated by ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen) / Austrian Health Institute and involved the associate partner WHO EURO as well as a network of institutions and organisations from all Member States of the enlarged European Union.

Funding: It was funded by the European Commission, Health and Consumer Directorate-General and co-funded by the Austrian Federal Ministry for Health and Women's Issues.

Outcomes:
- Set up of a network of more than 50 institutions, mainly competent authorities and third party payers. In the on-going PPRI initiative, the networking of the EU Member States continues, via regular networking meetings and continuous sharing of relevant information for decision-making, including an up-date of country-specific information.
- PPRI Pharma Profiles: 22 country specific reports on health and pharmaceutical systems, with a special focus on pricing, reimbursement and rational use of pharmaceuticals.
- Set of pharmaceutical indicators, filled with real data from 27 PPRI countries and a comparative analysis.
- Dissemination of information at the PPRI Conference held in Vienna on 29 June 2007.

Geographical coverage: European Union, Albania, Canada, Norway, Switzerland and Turkey.

Duration: April 2005 until summer 2007. The networking of the EU Member States continues, via regular networking meetings and continuous sharing of relevant information for decision-making, including an up-date of country-specific information.

Website: http://ppri.goeg.at/

Box 5: EASP project ("Tool box")

Title: Analysis of differences and commonalities in pricing and reimbursement systems in Europe

Aims: The objectives of the project were to:

1. Obtain an updated overall picture of how pharmaceutical policies and practices are being applied in European countries.
2. Build an in-depth understanding of selected practices as implemented in different countries, particularly regarding set-up, risks, success factors and impact on expenditure, reward for innovation and patient access.
3. Help EU Member States to learn about experiences from other countries.

Description: 3 phases:

- Phase I: Overview of systems and practices in EU-25
- Phase II: Assessment of impact for government, patients, industry and other stakeholders
- Phase III: Highlight conditions and success factors; opportunities for exchange of practices

Funding: It was funded by the European Commission, DG Enterprise and Industry.

Outcomes:

- Analysis based on answers regarding the situation in 2006 to questionnaires sent to Member States;
- A literature review was conducted and questionnaire sent to Member States;
- A final report structured in four parts:
  1. Part A: introduction that lays down the study's objectives, justification and methods.
  2. Part B: overview which presents an overall picture of the variety of pricing and reimbursement practices, presenting a structured overview of those currently in use. It focuses on supply-side mechanisms, such as price controls, expenditure and industry profits, as well as demand-side mechanisms (physicians, patients and pharmacists).
  3. Part C: assessment or evaluation of impact. It offers an in-depth assessment of 6 practices and policies, and looks for evidence on the establishment and impact of selected practices in different countries.
  4. Part D: highlights risk and success factors and looks for interactions between different practices within the framework of global pricing and reimbursement policies.

Geographical coverage: European Union, Norway.

Duration: 2006-2007

Website: http://ec.europa.eu/enterprise/phabiocom/docs/study_pricing_2007

Box 6: European Community Health Indicators Monitoring (ECHIM)

Title: European Community Health Indicators Monitoring (ECHIM)

Aims: To develop and implement health indicators and health monitoring in the EU and all EU Member States.

Description: This project continues the work of the ECHI and ECHI-2 projects (European Community Health Indicators-ECHI) and was coordinated by the Finnish Public Health Institute:

1. To define the areas of data and indicators to be included, following a set of explicit criteria;
2. To define generic indicators in these areas, again following these criteria; and
3. As a novel element, to imply a high degree of flexibility in the indicator set, by defining subsets of indicators, or 'user-windows', tuned to specific users.

The tasks of the project were grouped into six work packages:

1. Coordination and organisation.
2. Coordination and carries out liaison jointly with other work packages and members of the core group in order to reduce the burden otherwise to be carried by very few persons.
3. Research and development tool.
4. Two main tasks: to develop the ICHI database and to take into account regional indicators, their need and availability.
5. Assessment of the current situation on availability, comparability and the use of health

indicators in the MS and EEA / EFTA countries.

6. Promotion of ECHIM, for disseminating results and recommendations and for drafting and finalising reports.

Funding: European Union through the Programme of Community Action in the Field of Public Health (2003-2008).

Outcomes:

- ECHIM short list: a priority list of indicators selected by EU experts for starting the collection and presentation of actual data and contents, and to improve the comparability of data between Members States. This list contains the documentation sheets produced by the ECHIM project.
- ECHIM comprehensive lists: the ECHI-2 long list of indicators and a list of EC projects involved in indicator development (after ECHI-2 period, i.e. after 2003).
- Indicators on the web: hyperlinks to the websites of EC projects and organizations (WHO, OECD and EUROSTAT) involved in health indicator development, when possible deep linking to indicator definitions.
- International Compendium of Health Indicators part two (ICHI-2) hyperlink to the ICHI-2 website updated until 2005, containing all the ECHI-2 indicators and a large selection of indicators from the WHO, EUROSTAT and the OECD (background info).
- ECHIM project reports hyperlinks to all relevant reports produced by the ECHIM project.

Geographical coverage: European Union, EEA / EFTA countries

Duration: 2005-2008, continuation in discussion through the "Joint Action", new funding mechanism in the recently started Health Programme (2008-2013). It can be expected to provide funding for development and implementation of the ECHI System at least until 2011.

Website: http://www.echim.org/
http://www.healthindicators.org/healthindicators/object_document/o4958n28314.html

Box 7: Health Care Quality Indicators (HCQI) of the OECD

Aim: To collect internationally comparable data reflecting the health outcomes and health improvements attributable to medical care delivered in OECD countries.

Scope: The focus of the HCQI project is to develop national-level indicators for the technical quality with which medical care is provided. Other important dimensions of health system performance, such as responsiveness to patient needs and equity, have so far been addressed under different components of the OECD Health Project.

Approach: The HCQI project will follow a two-stage process. The first stage will be an attempt to build on the existing international collaborations and to extend the indicators proposed to other countries. The second stage will assess the gaps left in those indicator sets and will try to fill them. These two steps will be accomplished with the help of a series of collaborative meetings of experts from the 24 participating OECD countries.

Description: It aims at measuring and reporting the quality of medical care. “Quality indicators”, here, means: indicators for the technical quality with which medical care is provided, i.e. measures of health outcome or health improvement attributable to medical care. Such measures could be said to represent the “value” side of the “value for money” equation in health care - a key issue in measuring the performance of health systems.
HCQI builds on the efforts of several OECD countries and two international collaborations in developing indicators of health care quality at the national level, bringing the total number of participants to 24 countries.

Geographical coverage: 21 OECD countries

Outcomes: In October 2004, 5 technical papers were released containing the recommendations of 5 Expert Panels, respectively, on additional indicators in 5 priority areas. The Panels made recommendations for health care quality indicators in the areas of:

- Cardiac Care
- Diabetes Care
- Primary Care and Prevention
- Mental Health

- Patient Safety

HCQI project indicators identified: current measures (see report DELSA/HEA/WD/HWP(2006)2)

- Breast cancer five-year survival rate
- Mammography screening rate
- Cervical cancer five-year survival rate
- Cervical cancer screening rate
- Colorectal five-year survival rate
- Asthma mortality rate, age 5-39
- Acute myocardial infarction 30-Day / in-hospital mortality rate
- Stroke 30-Day case –facility rate / in-hospital mortality rate
- Annual HbA1c test for patients with diabetes
- Patients with diabetes with poor glucose control
- Retinal exams in diabetics
- Major amputation in diabetics
- Influenza vaccination for adults over 65

The OECD envisions the eventual addition of indicators that are recommended for retention in the HCQI measure set to Health Data on a gradual basis.

Data availability assessment:

- Ready for publication with minimal work: Mammography screening rate, cervical cancer screening rate, Influenza vaccination for adults over 65
- Requiring additional work: Breast cancer five-year survival rate, cervical cancer five-year survival rate, colorectal five-year survival rate, incidence of vaccine preventable diseases, Asthma mortality rate, age 5-39, acute myocardial infarction 30-Day / in-hospital mortality rate , Stroke 30-Day case –facility rate / in-hospital mortality rate, retinal exams in diabetics, Major amputation in diabetics
- Currently inadequate data coverage: Annual HbA1c test for patients with diabetes, patients with diabetes with poor glucose control

Website: http://www.oecd.org/health/hcqi.

2.2.2 Health databases

A review of databases relative to health information and indicators was also conducted. The most relevant databases identified are as follows:

- EUROSTAT (Box 8);
- OECD health database (Box 9);
- WHO Open health platform (in progress; Box 10 and Box 11);

To ensure further better dissemination, the taxonomy and the database development should be compatible with the work in progress at WHO on Open health information platform (Box 10 and Box 11).

Box 8: EUROSTAT

Description: Statistical Office of the European Communities with mission to gather and analyse figures from the different European statistics offices in order to provide comparable and harmonised data to the European Institutions so they can define, implement and analyse Community policies. Data cover the European Union, its Member States and its partners, and are published under a variety of Themes and Collections.

Website: http://epp.eurostat.ec.europa.eu/portal/

Box 9: OECD Health Database

Description: OECD Health Data is an interactive database presenting systematically collected data on a large number of key aspects of the health care systems in the 30 OECD Member countries which are presented in a general demographic, economic and social context.
Time coverage: The data comprise long-time series from 1960 onwards. Most data cover the 1980s and 1990s, many series continue up to 2006 or 2007.
Content: It includes definitions, sources and methods detailed information by countries, covering all indicators in the database. The OECD health files are classified into ten Parts (the detailed variables are listed in chapter three of the User's Guide):
1. Health Status
2. Health Care Resources
3. Health Care Utilization
4. Expenditure on Health
5. Health Care Financing
6. Social Protection
7. Pharmaceutical Market
8. Non-medical Determinants of Health
9. Demographic References
10. Economic References
The complete list of variable is available at: http://www.oecd.org/document/9/0,2340,fr_2649_37407_2085193_1_1_1_37407,00.html
Website: http://www.oecd.org/document

Box 10: Open Health information platform, WHO

Title: Open Health information platform

Aim: Development of an open information platform regarding public health data

Description: Open Health is a public health information platform with tools designed for application in disease surveillance and management activities at all levels of health delivery and management; District, National, Regional and Global. It provides data and technological integration capabilities which enable the definition, collection, reporting, charting, analysis and mapping of all types of health data.

Open Health is an evolution of the very successful WHO Health Mapper and Global Atlas products which have addressed important health data needs at the District, National and Global levels for over 6 years. Open Health extends the capabilities these products introduced, exploiting advances in technologies and the emergence of standards for data and technology integration, which have occurred over the last few years.

Funding: WHO

Outcomes:
- The provision of a common data model to support a diverse range of public health data collection, mapping, reporting and analysis activities;
- A standards based and extensible platform for technology and data integration;
- Improvements in usability, query, reporting and analysis capabilities.

Geographical coverage: WHO member states

Duration: Ongoing project

Website: http://208.76.222.114/confluence/download/attachments

Box 11: Open Health information platform of WHO – Metadata recommendations

- Definition (text or link pointing to an existing definition)
- Unit of measure (text or from a predefined list)
- Data collection methods (text)
- Associated terms (text, terms in the definition or other relevant terms)
- Data quality (text or from a predefined list)
- Rationale for use (text, why is this indicator important to measure)

- Data source (text)
- Methods of estimation (text, short explanation of any statistical methods applied to raw data)
- Disaggregation (text, e.g. age, gender, geographical areas, disease …)
- Frequency and format of dissemination (text, how often is data updated and through what medium is it released)
- Reference (text, for further research)
- Comments (text, any additional information useful to users)
- Footnotes (text)

2.2.3 Methodology for gathering information

From the review of relevant projects and sources identified in the previous stage several list of indicators on pharmaceuticals from a public health perspective were reviewed for out-patient sector (see Table 1 hereafter).

For in-patient indicators, the selection was carried out from research work and on the basis of collaborative work undertaken with the work package Hospital Pharma within the PHIS project, also covered by PHIS Hospital Pharma reports. The list of indicators included in the PHIS Hospital Pharma Report template is provided (Table 2).

Table 1: Pharmaceutical indicators identified by work already undertaken previously, out-patient sector

TAXONOMY	SOGETI	PPRI	EURO-MED-STAT[1]	ECHIM
Background				
Demographics		Population age structure		Population by age (ECHI short list)
Economics		Gross domestic product per capita in € Purchasing Power Parities (PPP)		
Health expenditure		Public / private funding of health expenditure		Expenditure on health as percentage of gross domestic product, public / private
		Total health expenditure per capita in € Purchasing Power Parities (PPP)		
Health status	Disability Adjusted Life Years (DALY)			Health expectancy: healthy life years
	Prevalence of disease			Disease specific mortality
	Exposure to main risk factors			
	Therapies availability overview			
Pharmaceutical system				
System		Regulatory framework for pharmaceutical policy		
		Key data on pharmaceutical industry		
		Inhabitants per "prescription-only medicines dispensary" (POM dispensary)		
Access to market	Share of non-marketed medicines in newly authorised medicines		Licensed medicines	
	Time from license to market			
	Main active ingredients sales and status			
Pricing	Price of medicines in number of days wages	Pricing policies at manufacturer level	Price in € per DDD[1]	
		Pricing policies at distribution level	Market Efficiency Index [1]	
		Taxes on pharmaceuticals	Potential savings [1]	
			Ratio of highest to lowest price[1]	
Reimbursement	Share of reimbursed medicines on out-patient market	Positive / negative list		
	National reimbursement systems	Reference price system		
	National co-payment systems	Mechanisms for vulnerable groups		
Prescription	Average number of medicines prescribed per inhabitant	Number of prescriptions per capita in volume and value		
Expenditure	Share of public expenditure on pharmaceuticals	Total pharmaceutical expenditure as percentage of total health expenditure	Expenditure in Euro per DDD[1]	
		Public / private funding of pharmaceutical expenditure	Pharmaceutical expenditure as % of health expenditure	
			Pharmaceutical expenditure per capita	
Utilisation	Utilisation in DDD / 1000 inhabitants / day		Number of DDDs[1]	Utilisation in DDD or sales in value for main ATC groups [2]
			DDD / 1000inh / day[1]	
			Medicine utilisation 90%[1]	
			Ratio indicators[1]	

TAXONOMY	SOGETI	PPRI	EURO-MED-STAT[1]	ECHIM
Adherence	Adherence to treatment Share of medicines actually dispensed			
Generics		Share of generics in volume and value as percentage of out-patient market	Expenditure on generics	
Prescription guidelines		Prescription guidelines		
		Mandatory guidelines for decision-makers / role of pharmaco-economics		
Information to patients		Information to patients		
Monitoring		Monitoring of consumption		
Quality of life	Ease of use			
Medicines effectiveness	Incremental cost-effectiveness ratio			
	Improvement of medical service			
Innovation	Uptake of new medicines[3]			
	Share of New Chemical Entities within the last 5 years			

[1] Indicators defined in the framework of the project but feasibility for data collection needs to be confirmed. Data on expenditure and utilisation only available for a few ATC codes and countries due to difficulties to obtain national information.
[2] Not collected
[3] Initially developed in the framework of the Competitiveness indicators of the European Commission but not monitored anymore.

Table 2: Pharmaceutical indicators identified, in-patient sector

TAXONOMY	INDICATOR	CALCULATION	EVIDENCE	TYPE AND BREAKDOWNS		DATA SOURCE PREFERRED	COMMENTS
Background							
In-patient health care resources	No. of hospitals	Total number	PHIS	Quantitative	General, mental health, other	Following OECD definition and classification or national statistics	Comparability as only a wide definition of hospital exists, national difference
	Ratio of public / private hospitals	Percentage	PHIS	Quantitative		National statistics	Public / private definition does not only refer to the ownership, but also the benefit of the hospitals
	No. of acute care beds	Total number	PHIS	Quantitative	Public, private		
	Average length of stay in hospitals	in days	PHIS	Quantitative			
	No. of hospital pharmacies	Total number Percentage: No. of hospital pharmacies / No. of hospitals	PHIS	Quantitative	Hospital only for in-patients / Hospital pharmacies serving as community pharmacies		Please be aware that the PPRI Indicator "Inhabitants per POM dispensary" takes in consideration all hospital pharmacies serving as community pharmacies
Pharmaceutical system							
System	Hospital-only-medicines as percentage of authorised pharmaceuticals	(Hospital- only-medicines / authorised medicines) x 100	PHIS	Quantitative			
Expenditure	Total hospital expenditure as percentage of total health expenditure	(Total hospital expenditure / total health expenditure) x 100	PHIS	Quantitative	Public / private		
	Total pharmaceutical expenditure as percentage of total health expenditure	(Total pharmaceutical expenditure / total health expenditure) x 100 and (annual) growth rates	PPRI	Quantitative	Out-patient / in-patient Public / private	OECD PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
	In-patient pharmaceutical expenditure as percentage of the total hospital expenditure	(In-patient pharmaceutical expenditure / total hospital expenditure) x 100 and (annual) growth rates	PHIS	Quantitative	Public / private		
	Public / Private funding of pharmaceutical expenditure in hospitals	(Public (private) pharm. expenditure in hospitals / Total pharm. expenditure in hospital) x 100	PPRI, SOGETI	Quantitative	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	

TAXONOMY	INDICATOR	CALCULATION	EVIDENCE	TYPE AND BREAKDOWNS		DATA SOURCE PREFERRED	COMMENTS
Delivery chain	Common delivery chain	Role of direct distribution and wholesalers, role of hospital pharmacies as logistic centers	PHIS	Qualitative			
Pricing	Pricing policies	Common pricing policies (e.g. procurement, negotiations)	PHIS	Qualitative		PHIS Hospital Pharma Reports, Case studies in PHIS Hospital Pharma	
	Price transparency	Publicly available price information	PHIS	Qualitative		PHIS Hospital Pharma Reports	
	Difference between the pharmaceutical prices achieved in hospitals and in the out-patient market as percentage	On average, per specific products	PHIS	Quantitative		PHIS Hospital Pharma Reports, Case studies in PHIS Hospital Pharma	Difficult to collect these data
Reimbursement	Funding policies for pharmaceuticals in hospitals	Hospital pharmaceutical formularies (HPF) per hospitals or joint HPF, joint budgets for pharmaceuticals in hospitals	PHIS	Qualitative		PHIS Hospital Pharma Reports	
Consumption	Annual pharmaceutical consumption in hospitals	Total number per capita, and growth rates	PHIS	Qualitative	In packs In DDD In other measures unit (e.g. unit doses)		
	Top 10 in-patient active ingredients sales in hospitals	List of Top 10 active ingredients in value and volume in hospitals	PHIS	Qualitative	Volume / value	PHIS Pharma Profiles and PHIS Hospital Pharma reports	
Evaluation	Monitoring activities	Monitoring of prices, consumption and expenditure – activities	PHIS	Qualitative		PHIS Hospital Pharma Reports	
	Asessment	Assessment instruments e.g. HTA, cost-effectiveness analyses	PHIS	Qualitative		PHIS Hospital Pharma Reports	

3 Taxonomy

3.1 Taxonomy framework and development

This section presents the methodology to develop the taxonomy.

3.1.1 Methodology

The development of the taxonomy for Pharmaceutical Health Information System (PHIS) indicators and selection of indicators followed the steps described below.

- Definition of a taxonomy for indicators;
- Review of relevant sources dealing with pharmaceutical indicators from a public health perspective;
- Sets of indicators for monitoring the performance of the pharmaceutical sector in meeting public health objectives according to the work already carried out
- Recommendations and report submitted to the PHIS project partners, Advisory Board and network members.

3.1.2 Definition

Taxonomy is a classification method of elements in groups or categories. Such groups have to be determined and defined according to the characteristics of the elements of the taxonomy and the objectives of the taxonomy.

In the framework of this project, it consisted in developing set(s) of indicator(s) according to categories grouping the indicators according to their aim and scope. Detailed profiles defining the indicators which include a definition, the break-down and an in-depth description including an indication of current use and a discussion of limitation were produced according to the taxonomy.

3.1.3 Data availability assessment

Data availability assessment for selected core and supplementary indicators was conducted at the data source collection whenever possible and according to the data availability reviews and assessments already carried out in the relevant projects tackling indicators in the public health and pharmaceutical fields.

3.1.4 Data collection

Most of the information and data for the pharmaceutical health indicators will be provided by the PHIS network members through the outcomes of the other work packages of the project:

- PHIS Hospital Pharma Reports from the PHIS work package Hospital Pharma for indicators on in-patient pharmaceutical systems;
- PHIS Pharma Profiles otherwise, which consist of information and data for the out-patient sector and the in-patient, where parts of the PHIS Hospital Pharma Reports are included.

The profile template will be developed according to the indicators list defined in this taxonomy so all indicators are covered by the PHIS Pharma Profiles.

For better comparability of the set of indicators developed, standardized data are preferred. To meet this aim, data on health and pharmaceutical expenditure should be collected from wellknown international health data sources thus guaranteeing comparability when available, data collection from national sources should only be considered if no other comparable data source is accessible. The preferred data sources are explicitely defined in the profiles of each indicator.

3.1.5 Validation

A draft taxonomy was presented and discussed in detail (via group work) with the PHIS network incl. the PHIS Advisory Board at the second PHIS Network Meeting (8 and 9 June 2009). Based on the feed-back and considering the needs expressed by the PHIS Advisory Board and network the final list of indicators was developed and agreed upon within the PHIS project. The draft indicators report (methodology, set of PHIS indicators, detailed description) was sent to the PHIS Advisory Board and network for another round of feed-back at the beginning of July 2009. The final version considers the ideas and recommendations of this feed-back.

The development of the taxonomy is a milestone in the process of setting up the PHIS database, which will be filled with data from the EU Member States and further countries associated to the PHIS project. The PHIS database, due in month 29 (January 2011), is considered as an important element of the European Pharmaceutical Health Information system.

3.2 Taxonomy

Based on the work described in the previous sections, the following taxonomy grouping the indicators on pharmaceutical health information was developed. The taxonomy includes four main categories as described in the Table 3 hereafter. All indicators will be arranged in the PHIS database according to this taxonomy.

Table 3: PHIS taxonomy

Background	**Pharmaceutical system**	**Accessibility to medicines**	**Consumption**
Demographics Health status Economics Health expenditure	Pharmaceutical provision Expenditure	Access to market Innovation Pricing Reimbursement	Prescription Consumption Adherence Generics Interface management

3.3 Indicators sets

From all the information gathered and discussion with experts including the PHIS Advisory Board, a synoptic table synthesizes the indicators selected according to the taxonomy developed.

There is a set of PHIS Indicators, set up by a core list of a few indicators, which is complemented by further indicators (supplementary list). A **total of 23 indicators** were defined including:

- **3 core (C) indicators** intended to policy makers;
- **20 supplementary (S) indicators** for a broader perspective.

Table 4: Pharmaceutical Health Information System (PHIS) Indicators developed in the PHIS project

TAXONOMY	C/S[8]	INDICATOR	CALCULATION AND UNITS	EVIDENCE	TYPE[9] AND BREAKDOWNS		DATA SOURCES PREFERRED	LIMITATIONS
Background								
Demographics	S 1	Population age structure	Total population in thousands Frequency by age class in percentage	ECHI short list, PPRI	QT	Total and 3 age classes: 0-14; 15-64, over 64 years old	EUROSTAT, OECD, WHO	
Health status	S 2	Life expectancy	Life expectancy at birth and at age 65	ECHI short list	QT	At birth and at age 65	EUROSTAT, OECD, WHO	
Economics	S 3	Gross domestic product (GDP) per capita	GDP in € Purchasing Power Parities (PPP) per capita = GDP / (total population) Annual growth rates or index	PPRI	QT		EUROSTAT, OECD, WHO	
Health expenditure	C 1	Health expenditure (HE) per capita, per funding and segment: • Total health expenditure (THE) • Public HE • Private HE • In-patient HE • Out-patient HE	Values in € PPP and annual growth rates or index for every subindicator THE per capita = THE / (total population) THE in % of GDP = (THE / GDP) x 100 (Public HE / THE) x 100 (Private HE / THE) x 100 (In-patient HE / THE) x 100 Shares of public and private funding in in-patient HE: $= \frac{\left([\text{Public or private}]\ \text{in-patient HE}\right)}{\left(\text{In-patient HE}\right)} \times 100$ (Out-patient HE / THE) x 100 Shares of public and private funding in out-patient HE: $= \frac{\left([\text{Public or private}]\ \text{out-patient HE}\right)}{\left(\text{Out-patient HE}\right)} \times 100$	PPRI, ECHI short list	QT		EUROSTAT-OECD-WHO Joint SHA collection if available PHIS Pharma Profiles and PHIS Hospital Pharma Reports otherwise	Depending on data quality and availability. Data availability may be partial for the in-patient sector

[8] C = core / S = supplementary
[9] QT = quantitative / QL = qualitative

TAXONOMY	C/S[10]	INDICATOR	CALCULATION AND UNITS	EVIDENCE	TYPE [11] AND BREAKDOWNS	DATA SOURCES PREFERRED	LIMITATIONS
Pharmaceutical system							
Pharmaceutical provision	S 4	Inhabitants per prescription-only medicines dispensary	Total population / number of prescription-only medicines dispensaries (e.g. community pharmacies, dispensing doctors, ..)	PPRI	QT	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
Expenditure	C 2	Pharmaceutical expenditure (PE) per capita, per funding and segment: • Total PE (TPE) • Public PE • Private PE • In-patient PE • Out-patient PE	Values in € PPP and annual growth rates or index for every subindicator TPE per capita = (TPE / Total population) TPE in % of GDP = (TPE / GDP) x 100 TPE in THE = (TPE / THE) x 100 (Public PE / TPE) x 100 (Private PE / TPE) x 100 (In-patient PE / TPE) x 100 (In-patient PE) / (in-patient HE) x 100 Shares of public and private funding in in-patient PE: $= \frac{\left([\text{Public or private}]\ \text{in-patient PE}\right)}{\left(\text{In-patient PE}\right)} \times 100$ (Out-patient PE / TPE) x 100 (Out-patient PE) / (out-patient HE) x 100 Shares of public and private funding in out-patient PE: $= \frac{\left([\text{Public or private}]\ \text{out-patient PE}\right)}{\left(\text{Out-patient PE}\right)} \times 100$	PPRI, SOGETI	QT	EUROSTAT-OECD-WHO Joint SHA collection if available PHIS Pharma Profiles and PHIS Hospital Pharma Reports otherwise	Data availability may be partial at national level for the in-patient sector. TPE often only refers to put-patient PE. For determining the TPE, data from different sources, including national sources, though not defined as preferred source, will be needed to be taken and combined.
	S 5	Top 10 medicines by active ingredients	List of 10 medicines by active ingredients according to expenditure in value and volume	SOGETI core list, PPRI reports	QL	Out-patient / in-patient Volume / value	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	For total market or reimbursement market depending on data availability at national level

[10] C= core / S = supplementary
[11] QT = quantitative / QL = qualitative

TAXONOMY	C/S[12]	INDICATOR	CALCULATION AND UNITS	EVIDENCE	TYPE [13] AND BREAKDOWNS		DATA SOURCES PREFERRED	LIMITATIONS
Accessibility to medicines								
Access to market	S 6	Average time period between marketing authorisation and access to patient	Time period between marketing authorisation and patient accessibility defined as the medicines being available on the market	SOGETI core list	QT	Total market	PHIS Pharma Profiles EFPIA: Patient WAIT indicator published twice a year	
	S 7	Evaluation of medicines	Is evaluation assessment conducted and description: scope, purpose, frequency, status of guidance, type etc.	PPRI, SOGETI	QL	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
Innovation	S 8	Uptake of new medicines	Number of New Molecular Entities (NMEs) launched within the last 5 and 10 years	SOGETI core list, DG ENTR Com-petitiveness ind.	QT	In the last 5 and 10 years	PHIS Pharma Profiles DG ENTR (however not monitored anymore)	Feasibility of data collection to be assessed at country level
Pricing	C 3	Pricing policies	Is price control applied in the out-patient and in-patient sector? If which, how - which pricing policies (e.g. free pricing, statutory pricing, negotiations, procurement) and which pricing procedures (e.g. external price referencing, internal price referencing) are applied; which price type (e.g. ex-factory price) is controlled; which regulations (mark-up) exist for distribution actors)	PPRI	QL	Out-patient / in-patient, reimbursement / non-remb. market, prescription / non-prescription medicines	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
	S 9	Taxes on pharmaceuticals	Value Added Tax (VAT) and further taxes or tax-like fees	PPRI	QT	Standard / Pharm. types (reimb, non-reimb…) / Other relevant taxes	PHIS Pharma Profiles	
Reimbursement	S 10	Reimbursement list	Out-patient: Reimbursement lists (positive / negative lists) in place In-patient: hospital pharmaceutical formularies / hospital national list / positive list for out-patient sector also valid for in-patient sector	PPRI, SOGETI core list	QL	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
	S 11	Reimbursement schemes	Reimbursement schemes which cover the majority of residents, in connection with the eligibility (product-specific, disesase-specific, consumption-based etc. Reimbursement)	PPRI, SOGETI core list	QL	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
	S 12	Out-of pocket payments	Co-payment mechanism in place (prescription fee / % co-payment / reference price system / deductible); Mechanisms for vulnerable groups.	PPRI, SOGETI core list	QL	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	
	S 13	Reference price system (RPS)	Is reference price system in place? If yes: Year of introduction, definition of reference groups, calculation method of the reference price	PPRI	QL	Out-patient only	PHIS Pharma Profiles	

[12] C= core / S = supplementary

[13] QT = quantitative / QL = qualitative

TAXONOMY	C/S[14]	INDICATOR	CALCULATION AND UNITS	EVIDENCE	TYPE [15] AND BREAKDOWNS		DATA SOURCES PREFERRED	LIMITATIONS
Consumption								
Prescription	S 14	Prescriptions per capita	Prescription refers to items prescribed Number of items prescribed / Total population Annual growth rates	PPRI, SOGETI core list	QT	Out-patient only	PHIS Pharma Profiles	
	S 15	Monitoring of prescribing practices	Implementation of prescription guidelines and / or prescription monitoring	PPRI	QL	Out-patient / in-patient	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	Partial geographical coverage
Consumption	S 16	Consumption	Consumption of pharmaceuticals in number of packages or in Defined Daily Doses (DDD) depending on data availability at national level Annual growth rates	EURO-MED-STAT, SOGETI core list	QT	Total / out-patient / in-patient market	PHIS Pharma Profiles and PHIS Hospital Pharma Reports	Unit depends on data availability at national level Partial geographical coverage In-patient data availability uncertain
Adherence	S 17	Share of prescribed medicines dispensed	(Number of medicines actually dispensed / number of medicines prescribed) x 100	SOGETI core list	QT	Out-patient only	National electronic prescribing systems	Partial geographical coverage Feasibility only for countries with electronic prescribing system in place
Generics	S 18	Generic policies	Information on generic promotion tools like generic substitution (indicative / obligatory, since when) or INN prescribing (indicative / obligatory, since when)	PPRI	QL		PHIS Pharma Profiles	
	S 19	Share of generics	Share of generics as percentage of different markets Volume = (Number of generic prescriptions / Total number of prescriptions) x 100 Value = Pharmaceutical expenditure for generics / (Total pharmaceutical expenditure) x 100 Annual growth rates	PPRI	QT	Total (out-patient / in-patient market / total out-patient market / reimbursement market / unprotected market	PHIS Pharma Profiles	Data availability may be partial for some sub-market in particular the unprotected market
Interface management	S 20	Interface management of medicines	Is there an interface management system in place fo rmedicines? Description of programs, initiatives of mechanisms of cooperation between in-patient and out-patient sector.	PHIS Advisory Board and network	QL		PHIS Pharma Profiles and PHIS Hospital Pharma Reports	

[14] C = core / S = supplementary
[15] QT = quantitative / QL = qualitative

3.4 Indicators taxonomy profiles

This section presents each selected indicator, either core or supplementary; this chapter is intended to serve as the core reference section of the report.

3.4.1 Profile template

Each indicator is described with a brief statement that includes:

INDICATOR NAME: SHORT TITLE TO IDENTIFY THE INDICATOR

Description and aim

Objective

What does the indicator intend to measure?

Definition

What is the purpose of the indicator? What will this indicator measure? What are the definitions of key terms?

Taxonomy

Category / sub-category Importance: Core / Supplementary

Type and breakdowns

Quantitative / qualitative

Indicator broken down by sector (e.g. in-patient / out-patient), funding (public / private), relative shares; annual growth rate or index etc.

Calculation of quantitative indicators / Description of qualitative indicators

How should the indicator be calculated (method, numerator, denominator, etc.)?

What is the unit of the indicator?

For most qualitative indicators, a comparative table will be provided as an example.

Data source(s) preferred

Data source preferred for data collection and input to the PHIS database.

Current use or evidence

Is there scientific evidence available in literature? If possible, also the source for the evidence is stated.

Is this indicator already in use, collected in other institutions or reviewed by an expert panel?

Is it a standard indicator?

Limitations and recommendations

What are the main limitations of the indicator? Depending on the indicator, it may concern issues such as:

- Comparability
- Feasibility
- Interpretation
- Any recommendation

Example

Wherever possible, an example illustrating the indicator is provided. Please be aware that the examples provided are not based on real data and do not refer to a specific country.

For a few indicators, an example was not provided since data collection is done in the course of the PHIS project at national level through the PHIS Pharma Profiles and PHIS Hospital Pharma Reports.

3.4.2 Background

1. POPULATION AGE STRUCTURE

Description and aim

Objective

To assess the age structure in order to analyse the impact on using health care / pharmaceutical resources and to get an overview of target groups of pharmaceutical provision in one country.

This background indicator provides basic data that a policy-maker or any person comparing health data across countries should know and have available. It can be used to help identify major problems in health status, in the health system and in the pharmaceutical sector. It should also help setting the pharmaceutical policy within the broader national health context for assessing the country situation.

Definition

Total population is defined by the OECD as the resident population, that is, all nationals present in, or temporarily absent from, the country and foreigners who have a permanent place of residence in the country. For most OECD countries, population estimates are based on regular ten-yearly censuses, adjusted with administrative data for the intercensal years. Data on population come mainly from the OECD Labour Force Statistics Database (as of May 2007), and refer to mid-year estimates (Health at a glance, OECD, 2007).

Note that for some countries such as France and the United Kingdom which have overseas colonies, protectorates and territories, these populations are generally excluded. The total population of the country consists of all persons falling within the scope of the census.

Taxonomy

Category: Background Importance: Supplementary

Type and breakdowns

Quantitative
Total population in thousands
3 age groups in percentage: 0-14; 15-64 and over 64 years old

Calculation

$$\frac{\text{Total population aged from 0 to 14 years}}{\text{Total population}} \times 100 \qquad \frac{\text{Total population aged from 15 to 64 years}}{\text{Total population}} \times 100$$

$$\frac{\text{Total population aged over 64 years}}{\text{Total population}} \times 100$$

Units: Total population in thousands of persons, structure in percentage

Data source(s) preferred

EUROSTAT, OECD, WHO

Current use or evidence

This indicator is standard and used in several projects and studies (e.g., OECD Health Data 2008, WHO European Health for all Database, ECHI short list, PPRI indicators).

Limitations

The age structure alone is not the only factor that explains the demand of medicines in a country. Other factors like the health status of the population, organisation of the health care system, easy access to medicines, financial barriers for patients and supply side factors (e.g., advertising, number of pharmaceutical retailers and prescribing culture) might also influence the demand for medicines.

Example

	TOTAL (Thousands)	**0 to 14 years**	**15 to 64 years**	**Over 64 years**
Country A	10,479	16%	68%	16%
Country B	42,377	18%	63%	19%

2. LIFE EXPECTANCY

Description and aim

Objective

To compare life expectancy at birth and age 65 across Member States. Life expectancy at birth is a summary measure of the age-specific all cause mortality rates in an area in a given period.

This background indicator provides basic data that a policy-maker or any person comparing health data across countries should know and have available. It can be used to help identify major problems in health status, in the health system and in the pharmaceutical sector. It should also help setting the pharmaceutical policy within the broader national health context for assessing the country situation.

Among other things it is also an indicator on the quality of the health care system and indirectly on the pharmaceutical system.

Definition

Life expectancy measures the average number of years an individual of age x is expected to live if current mortality rates continue to apply.
At birth, it is the average number of years a new-born baby would survive, were he or she to experience the particular area's age-specific mortality rates for that time period throughout his or her life.

Taxonomy

Category: Background Importance: Supplementary

Type and breakdowns

Quantitative
At birth, at age 65

Calculation

The mean number of years still to be lived by a person who has reached a certain exact age, if subjected throughout the rest of his or her life to the current mortality conditions (age-specific probabilities of dying).
Calculation of life expectancy at birth is based on age-specific death rates, which may be calculated separately for males and females, or for both sexes combined. Several steps are needed to derive life expectancy from age-specific death rates.

Data source(s) preferred

EUROSTAT, OECD, WHO

Current use or evidence

This is a standard and well-known indicator. It is monitored in several health databases and projects (e.g. EUROSTAT, OECD Health Data, WHO Health for all Database, and ECHI short list).

Limitations

Life expectancy is a standard and basic measure of health status. It does not measure if life expectancy is healthy or with increasing disability and dependence, which is of importance for governments. So other more complex measures have been developed to answer those issues.

Example

	At birth	At the age of 65 years
Country A	79.5 years	18.8 years
Country B	72.4 years	15.9 years

3. GROSS DOMESTIC PRODUCT PER CAPITA

Description and aim

Objective

To assess the economic situation in order to analyse the economic wealth of a country.

This background indicator provides basic data that a policy-maker or any person comparing health data across countries should know and have available.

In general richer countries with a higher GDP per capita are able to spend more money on health care resources. A higher GDP per capita is often linked with more spending per capita for health care.

Definition

The gross domestic product (GDP) is defined as the gross expenditure on the final uses of the domestic supply of goods and services valued at purchasers values less imports of goods and services. Comparisons of gross domestic products are arguably best based on purchasing power parities (PPP) and not on market exchange rates.

Purchasing Power Parity (PPP): Spatial deflators and currency converters, which eliminate the effects of the differences in price levels between countries, thus allowing volume comparisons of Gross Domestic Product (GDP) components and comparisons of price levels.

PPPs at all stages are price relatives. They show how many units of currency A need to be spent in country A to obtain the same volume of a product or a basic heading or an aggregate that X units of currency B purchases in country B.

In the case of a single product, the "same volume" means "identical volume". But in the case of the complex assortment of goods and services that make up an aggregate such as GDP, the "same volume" does not mean an "identical basket of goods and services". The composition of the basket will vary between countries according to their economic, social and cultural differences, but each basket will provide equivalent satisfaction or utility. Also referred to as "parity" or "parities". (Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPP))

Taxonomy

Category: Background Importance: Supplementary

Type

Quantitative

Calculation

$$\frac{\text{Gross domestic product in PPP}}{\text{Total population}}$$

Annual growth rates (%) or index

Unit: € Purchasing power parities (PPP).

PPP are calculated in three stages as follows:

1. The first is at the product level, where price relatives are calculated for individual goods and services.
2. The second is at the product group level, where the price relatives calculated for the products in the group are averaged to obtain unweighted PPP for the group.
3. The third is at the aggregation levels, where the PPP for the product groups covered by the aggregation level are weighted and averaged to obtain weighted PPP for the aggregation level. The weights used to aggregate the PPP in the third stage are the expenditure on the product groups.

(Eurostat-OECD Methodological Manual on Purchasing Power Parities, European Communities / OECD, 2006)

PPP and exchange rates are calculated under the Joint OECD-EUROSTAT PPP Programme. The OECD and EUROSTAT share the responsibility for calculating PPPs. Broadly, EUROSTAT handles the calculations for the EU countries and for the EU "Candidate countries" (i.e. those

countries which have applied for admission to the EU). The OECD deals with the non-European OECD Member countries and the other non-EU related countries such as Russia, Ukraine etc which are included in the PPP Programme.
PPP exchange rates for GDP are available on the OECD website at http://stats.oecd.org/Index.aspx?datasetcode=SNA_TABLE4.

Data source(s) preferred
EUROSTAT, OECD, WHO

Current use or evidence
This indicator is a standard and well-known indicator which is used in several projects and studies (e.g., OECD Health Data, OECD 2001, WHO Health for all Database, PPRI 2008).

Limitations
The GDP alone does not provide information on the distribution of the available resources in a country.

Example

GDP in € PPP per capita: 24,947 € PPP

4. HEALTH EXPENDITURE PER CAPITA, BY FUNDING AND SECTOR

Description and aim

Objective

To assess the expenditure on health in order to analyse the amount spent on health in a country, the main sources of health care funding in order to analyse the relevance of public funding versus private funding of health care and the distribution of health care spending between in-patient and out-patient sector.

Definition

Total expenditure on health (THE) is defined by OECD as the sum of expenditure on activities that – through application of medical, paramedical, and nursing knowledge and technology – have as their goal:

- Promoting health and preventing disease;
- Curing illness and reducing premature mortality;
- Caring for persons affected by chronic illness who require nursing care;
- Caring for persons with health-related impairments, disability, and handicaps who require nursing care,
- Assisting patients to die with dignity,
- Providing and administering public health,
- Providing and administering health programmes, health insurance and other funding arrangements.

Not included are general public safety measures and activities such as food and hygiene control. Health research and development are considered health-related, but are also not included in total health expenditure (OECD Health Data 2006, concept of "System of Health Accounts" (SHA)).

OECD data are collected according to the System of Health Accounts (SHA) manual published in May 2000. This manual contains guidelines for reporting health expenditure according to an international standard. It proposes a common boundary of health care as well as a comprehensive and detailed structure for classifying the components of total expenditure on health. The structure and definitions of the variables in OECD Health Data are consistent with the concepts presented in the SHA manual. Still, comparability issues are a concern since countries are at varying stages in the process of implementing the SHA (please refer to limitations below for more details) (OECD Health Data).

Public expenditure on health care is defined as the health expenditure (HE) incurred by public funds. Public funds are the state, regional and local governmental bodies and social security schemes. Public capital formation on health includes publicly financed investment in health facilities plus capital transfers to the private sector for hospital construction and equipment.

Private expenditure on health care is defined as the privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments, private insurance programmes, charities and occupational health care. Take up of private health insurance is often voluntary, although it may be mandatory by law or compulsory for employees as part of their working conditions.

Purchasing power parities (PPP) reflect the amount of a national currency that will buy the same basket of goods and services in a given country (OECD 2001, Society at a Glance. OECD Social Indicators, p. 22). For details on PPP, see indicator no. 3.

An in-patient is a patient who is formally admitted (or "hospitalised") to an institution for treatment and / or care and stays for a minimum of one night in the hospital or other institution providing in-patient care. In-patient care is mainly delivered in hospitals, but partially also in nursing and residential care facilities or in establishments that are classified according to their focus of care under the ambulatory-care industry but perform in-patient care as a secondary activity.

It should be noted that the term "in-patient" used in the OECD-SHA has a wider meaning compared to some national reporting systems (see limitations below). Included are services delivered to in-patients in prison and army hospitals, tuberculosis hospitals, and sanatoriums.

In-patient care includes accommodation provided in combination with medical treatment when the latter is the predominant activity provided during the stay as an in-patient.

On the other hand, accommodation in institutions providing social services, where healthcare is

an important but not predominant component should not be included in the health function. Examples might include institutions such as homes for disabled persons, nursing homes, and residential care for substance abuse patients.

Out-patient care refers to patients not formally admitted to the facility (physician's private office, hospital out-patient centre or ambulatory-care centre) and who does not stay overnight. An out-patient is thus a person who goes to a health care facility for a consultation / treatment, and who leaves the facility within several hours of the start of the consultation without being "admitted" to the facility as a patient.

Taxonomy

Category: Background Importance: Core

Type and breakdowns

Quantitative
THE: per capita in € PPP, in % of gross domestic product (GDP), annual growth rates or index
Public HE: share in % of in THE, annual growth rates or index
Private HE: share in % of in THE, annual growth rates or index
In-patient HE: share in % of in THE, shares of public and private funding in in-patient expenditure, annual growth rates or index
Out-patient HE: share in % of in THE, shares of public and private funding in in-patient expenditure, annual growth rates or index

Calculation

$$\text{THE per capita} = \frac{\text{THE}}{\text{total population}} \qquad \text{THE in \% of GDP} = \frac{\text{THE}}{\text{GDP}} \times 100$$

$$\text{Shares in \% of HE by source of funding} = \frac{\text{([public or private] HE)}}{\text{THE}} \times 100$$

$$\text{Shares in \% of HE by sector} = \frac{\text{([in-patient or out-patient] HE)}}{\text{THE}} \times 100$$

$$\text{In-patient shares by source of funding} = \frac{\text{([public or private] in-patient HE)}}{\text{in-patient HE}} \times 100$$

$$\text{Out-patient shares by source of funding} = \frac{\text{([public or private] out-patient HE)}}{\text{out-patient HE}} \times 100$$

Units: € Purchasing power parities (PPP), percentages otherwise.

Data source(s) preferred

EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources collected through the PHIS Pharma Profiles otherwise.

Current use or evidence

This indicator and its subindicators are standard and well-known indicators which are used in several projects and studies analysing health care systems, in most cases together with the indicator health care expenditure as a percentage of the gross domestic product (e.g., OECD 2001, OECD Health Data, PPRI 2008, ECHI short list).

The subindicators on in-patient and out-patient health expenditure are standard indicators regarding distribution of expenditure between in-patient and out-patient sector. They are monitored in several health databases (OECD, WHO) and used in several projects and studies (e.g., "Hospitals in the 27 Member States of the European Union", Dexia Editions with the participation of the European Hospitals and Healthcare Federation - HOPE, 2008).

Limitations

Taking the System of Health Accounts (SHA) as the underlying concept, assessment of this indicator is limited by the fact that few countries have not yet implemented this system.

Most European countries report data according to SHA methodology. Several other European countries do not follow SHA so the reporting is based on health spending as reported in the National Accounts. It concerns Greece, Ireland, Italy, Malta and the United Kingdom. Therefore in some cases measurement problems exist; mainly the boundaries between health and social care are drawn in different ways. National accounts are not precise in defining the boundary of health care. Such imprecision may lead to breaks in time series due to changes in interpretation of the boundary of health care. The availability of data sources on the private sector is also limited which prevents some countries from making a complete estimate of private expenditure. However, a number of these countries have either started or intend to start implementation of the SHA.

For instance for Ireland, data is based on "locally produced health accounts" with boundaries that are yet to be mapped to the OECD / SHA boundary of health care. For example, the boundary between health and social care may differ from the OECD / SHA boundary, or health-related items, such as environmental health, research and development, may be treated differently. Moreover the sub-aggregate variables of health expenditure are often defined differently than in the SHA manual.

The fact, that health spending per capita increases more than gross domestic product, includes both a volume and price effect. In addition, as health services are labour intensive and in response to higher standards of living across countries using similar health technology, there is a tendency for the relative price of health care to rise (OECD 2001).

Data should also be interpreted with caution since the boundaries between public and private coverage are sometimes difficult to draw. Total private coverage mixes insurance types that have different functions relative to public systems and it does not show if a person has multiple covers. Some countries with small private insurance markets do not report data (e.g., Luxembourg, Sweden).

The terms “in-patient” used in the Systems of Health Accounts have a wider meaning compared to some national reporting systems where these terms are limited to:

- in-patient care in hospitals: are included services delivered to in-patients in prison and army hospitals, tuberculosis hospitals, and sanatoriums. It includes accommodation provided in combination with medical treatment when the latter is the predominant activity provided during the stay as an in-patient.
- care in out-patient departments of hospitals. In the SHA, all visitors to ambulatory care facilities that are not day cases or over-the-night cases are considered as out-patients.

To consider these limits in best possible form, when collecting data for the PHIS database Member States are encouraged to specify limitations and non-compliance with the definitions of the international database in their data which they provide.

Data availability may be partial for in-patient care.

Example

THE per capita in € PPP: 2,706 € PPP
THE in % of GDP: 9,6 %
Average annual growth rates: + 3 %

	Public HE in % of THE	**Private HE in % of THE**
Country A	53.9	46.1
Country B	77.0	23.0

Note: Limitations or specific definitions for country A or B

	In-patient HE in % of THE	**Out-patient THE in % of THE**
Country A	40	60
Country B	64	36

In %	**In-patient**		**Out-patient**	
	Public HE	**Private HE**	**Public HE**	**Private HE**
Country A	70.3	29.7	37.5	62.5
Country B	83	17	72	28

3.4.3 Pharmaceutical system

5. INHABITANTS PER PRESCRIPTION-ONLY MEDICINES DISPENSARY

Description and aim

Objective

To assess the average number of inhabitants per retailer, that is allowed to dispense prescription-only medicines (POM dispensary), in order to analyse the policies regarding dispensing of medicines (e.g. access for patients).

Definition

POM dispensary is an umbrella term for facilities that are allowed to sell prescription-only medicines (POM) to out-patients. Besides community pharmacies, these may be dispensing doctors or hospital pharmacies serving out-patients. From the perspective of public health (accessibility), it is considered important to include in this indicator all retailers which are allowed to dispense prescription-only medicines. The indicator tells us how many inhabitants on average are served by one POM dispensary. The lower this number, the better the provision with pharmacies and further POM dispensaries, which provides an indication of the accessibility.

Please refer to the PHIS Glossary for more detailed definitions of key POM dispensaries like community pharmacies, dispensing doctors, etc.

Taxonomy

Category: Pharmaceutical system
Importance: Supplementary
Sub-category: Pharmaceutical provision

Type and breakdowns

Quantitative

Calculation

$$\frac{\text{Total population}}{\text{Number of POM dispensaries}}$$

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

Usually, the indicator "pharmacies per inhabitant" is used to assess in the provision of the population with medicines at the retail level. However, studies (e.g., ÖBIG 2000, ÖBIG 2001, ÖBIG 2006, PPRI 2008) have shown that it is important to also consider further retailers of prescription-only medicines.

Limitations

The number of people served per POM dispensary does not provide information on a possible uneven distribution of pharmacies throughout the country. It will not tell us, for example, if more dispensaries are located in attractive city centres than in rural areas.

Example

	2007
Country A	3,663 inhabitants per POM dispensary
Country B	5,421 inhabitants per POM dispensary

6. PHARMACEUTICAL EXPENDITURE PER CAPITA, BY FUNDING AND SECTOR

Description and aim

Objective

To assess how much is spent on the average per person in a country on pharmaceuticals and to set the pharmaceutical expenditure in relation with the GDP, the main sources of pharmaceutical funding in order to analyse the relevance of public funding versus private funding of pharmaceuticals, the distribution of pharmaceutical spending between in-patient and out-patient sector and the expenditure on pharmaceuticals as a proportion of the total health expenditure expenditure. This indicator gives an estimate of the economic relevance of pharmaceutical consumption on healthcare systems.

Definition

Pharmaceutical expenditure (PE)

The PHIS Glossary defines pharmaceutical expenditure as total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. Other medical nondurables comprise a wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.

A key data source is the OECD Health Data base where pharmaceutical expenditure is collected according to the System of Health Accounts (SHA). For information on the SHA methodology see Ind. 4. One of the limitations regarding the collection of total pharmaceutical expenditure is that often total pharmaceutical expenditure only refers to out-patient pharmaceutical expenditure. Also, in the OECD Health Data base in-patient pharmaceutical expenditure is usually not included. There are initiatives by OECD to survey and collect in-patient pharmaceutical expenditure but till now only data from few countries are available.

Public pharmaceutical expenditure includes, according to the OECD, the general government (including central government, state / provincial government and local / municipal government) and social security funds. Private pharmaceutical expenditure is defined as covering private social insurance, private insurance enterprises and private expenditure of national households. Private household expenditure for pharmaceuticals comprises all forms of out-of pocket payments.

The share of public / private funding of pharmaceuticals reflects the financial share of patients and is therefore an indicator for accessibility and affordability.

In-patient pharmaceutical expenditure (PE): Expenditure on pharmaceuticals during in-patient care. For the definition of in-patient care, see Indicator 4. As in-patient pharmaceutical expenditure is, as stated, only available for few countries in international databases like OECD Health Data base, PHIS network members will be encouraged to provide in-patient pharmaceutical expenditure from their national statistics and specify the underlying definition and possible limitations.

Out-patient pharmaceutical expenditure (PE): Expenditure on pharmaceuticals during out-patient care. Out-patient care refers to patients not formally admitted to the facility (physician's private office, hospital out-patient centre or ambulatory-care centre) and who does not stay overnight. An out-patient is thus a person who goes to a health care facility for a consultation / treatment, and who leaves the facility within several hours of the start of the consultation without being "admitted" to the facility as a patient.

Total expenditure on health (THE) is defined by OECD as the sum of expenditure on activities that – through application of medical, paramedical, and nursing knowledge and technology (please refer indicator on HE for further details).

For definition of GDP and purchasing power parities (PPP), please refer to the indicator "Gross domestic product per capita in € Purchasing Power Parities".

Taxonomy

Category: Pharmaceutical system Importance: Core
Sub-category: Expenditure

Type and breakdowns

Quantitative
TPE: per capita in € PPP, TPE in % of gross domestic product, TPE in % of THE, annual growth rates or index
Public pharmaceutical expenditure (PE): share in % of TPE, annual growth rates or index

Private pharmaceutical expenditure (PE): share in % of TPE, annual growth rates or index
In-patient pharmaceutical expenditure (PE): share in % of TPE, shares of public and private funding in % of in-patient PE, annual growth rates or index
Out-patient PE: share in % of TPE, shares of public and private funding in % of out-patient PE, annual growth rates or index
In-patient PE: share in % of in-patient HE, annual growth rates or index
Out-patient PE: share in % of out-patient HE, annual growth rates or index

Calculation

$$\text{TPE per capita} = \frac{\text{TPE}}{\text{total population}} \qquad \text{TPE in \% of GDP} = \frac{\text{TPE}}{\text{GDP}} \times 100$$

$$\text{TPE in \% of THE} = \frac{\text{TPE}}{\text{THE}} \times 100$$

$$\text{Shares in \% of PE by source of funding} = \frac{\text{([public or private] PE)}}{\text{TPE}} \times 100$$

$$\text{Shares in \% of PE by sector} = \frac{\text{([in-patient or out-patient] PE)}}{\text{TPE}} \times 100$$

$$\text{In-patient shares by source of funding} = \frac{\text{([public or private] in-patient PE)}}{\text{in-patient PE}} \times 100$$

$$\text{Out-patient shares by source of funding} = \frac{\text{([public or private] out-patient PE)}}{\text{out-patient PE}} \times 100$$

$$\text{PE in \% of HE by sector} = \frac{\text{([in-patient or out-patient] PE)}}{\text{([in-patient or out-patient] HE)}} \times 100$$

Units: € Purchasing power parities (PPP), percentages otherwise

Data source(s) preferred

In-patient: PHIS Pharma Profiles and PHIS Hospital Pharma Reports (referring to national sources)
Out-patient: EUROSTAT-OECD-WHO Joint SHA collection if available, national sources collected through the PHIS Pharma Reports otherwise.

Current use or evidence

This indicators and its subindicators are standard indicators used in several other projects and studies (e.g., EURO-MED-STAT 2004, ÖBIG 2001, OECD Health Data WHO health system statistics, PPRI 2008).
The need for the in-patient and out-patient pharmaceutical expenditure indicators, in particular to have breakdowns combining sources of funds and sectors, was expressed by the PHIS Advisory Board and network members of the PHIS project.
The share of pharmaceutical expenditure within the health care expenditure are commonly used in international comparisons to have an estimate of the relevance of pharmaceutical expenditure.

Limitations

The extent of pharmaceutical expenditure can vary substantially from country to country. In addition, OECD countries with lower incomes tend to spend a greater share of their health expenditure on pharmaceuticals. This is mainly due to the fact that the prices of pharmaceuticals reflect international market prices whereas labour costs are generally based on national wage structures (OECD 2004, SHA-Based National Health Accounts in Thirteen OECD Countries: A comparative Analysis, OECD Health Working Papers).

Taking the System of Health Accounts (SHA) as the underlying concept, assessment of this indicator is limited by the fact that only a few countries have implemented this system (Please refer to the limitations of the indicator on total health expenditure).

The greatest limitation in this context is that definitions and scope of pharmaceutical expenditure, which has an impact on data availability, differ across countries. For example out-of-pocket payments may be captured or not depending on countries.

The expenditure for pharmaceuticals in the in-patient sector for pharmaceuticals is usually not included in the data base (e.g. OECD data), there is a lack of data in most countries. Usually, so called "informal payments" are excluded and therefore the expenditure for medicines is underestimated.

To cope with the limitations, two approaches are, in parallel, recommended:

1. EUROSTAT-OECD-WHO Joint SHA collection as preferred source, at least for the out-patient sector, but to combine it with national sources, though not normally being a preferred source
2. Member States are encouraged to specify limitations and non-compliance with the definitions of the international database in their data which they provide.

Data availability may be partial depending on national data availability at the breakdowns levels defined.

The terms "in-patient" used in the Systems of Health Accounts have a wider meaning compared to some national reporting systems (Please refer to Ind. 4).

Example

TPE per capita in € PPP: 381 € PPP
TPE in % of GDP: 1.3 %

	Share in TPE in %	
	Public PE	**Private PE**
Country A	66.9	33.1
Country B	64.6	35.4

	Share in TPE in %	
	In-patient	**Out-patient**
Country A	21	79
Country B	10	90

In %	**Share in in-patient PE in %**		**Share in out-patient PE in %**	
	Public PE	**Private PE**	**Public PE**	**Private PE**
Country A	70.3	29.7	63.5	36.5
Country B	76.8	23.2	52.4	47.6

	TPE in % of THE		
	Total	**In-patient**	**Out-patient**
Country A	13.1	9.5	16.7
Country B	21.4	15.6	27.2

7. TOP 10 MEDICINES BY ACTIVE INGREDIENTS

Description and aim

Objective

To compare the medicine with highest expenditure and highest consumption across countries and between in-patient and out-patient sector.

Definition

List of the top 10 medicines by active ingredient according to expenditure in value and volume.

Active ingredient of pharmaceuticals are classified according to the WHO Anatomical Therapeutic Chemical (ATC) classification system level 5. An active ingredient is an ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a pharmaceutical (PHIS Glossary).

Taxonomy

Category: Pharmaceutical system Importance: Supplementary
Sub-category: Expenditure

Type and breakdowns

Qualitative
Value / volume
Out-patient / in-patient

Description

Value: List the top 10 medicines by active ingredient with the highest expenditure in national currency unit for the total market (or for the out-patient sector or the reimbursement market if not available for the total out-patient market, but please mention on which market the list refers to in the table), and split between out-patient and in-patient sector.

Volume: List the top 10 medicines by active ingredient with the highest consumption (i.e. packs or DDD) for the total market (or for the out-patient sector and the reimbursement market if not available for the total market, but please mention on which market the list refers to in the table), and split between out-patient and in-patient sector whenever possible.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

This indicator is used in the PPRI country reports and was selected in the SOGETI 2006 project.

Limitations

For international comparisons it has to be considered that products may have different brand names in different European countries.

This indicator is descriptive and will not allow to compare amounts of sales of the active ingredients listed. A ranking according to this indicator is therefore not possible.

Example

Top 10 medicines in the in-patient sector in value:

Top medicines used in hospitals, indicated by active ingredient ranked with regard to expenditure		
Position	**ATC**	**Brand name**
1	L04AB01	Etanercept
2	L01CD02	Docetaxel
3	L01XX19	Irinotecan
4	V08AB05	Iopromide
5	L01XA03	Oxaliplatin
6	L03AB07	Interferon Beta-1A
7	B01AB06	Nadroparin calcium
8	L01CD01	Paclitaxel
9	L01BC05	Gemcitabine
10	L01XC07	Bevacizumab

Top 10 medicines in the in-patient sector in volume:

Top medicines used in hospitals, indicated by active ingredient ranked with regard to consumption		
Position	**ATC**	**Brand name**
1	N02BE01	Paracetamol
2	L01CD02	Docetaxel
3	L01XX19	Irinotecan
4	V08AB05	Iopromide
5	L01XA03	Oxaliplatin
6	L03AB07	Interferon Beta-1A
7	B01AB06	Nadroparin calcium
8	L01CD01	Paclitaxel
9	L01BC05	Gemcitabine
10	C08CA01	Amlodipine

The same examples could be done for the out-patient sector.

3.4.4 Accessibility to medicines

8. AVERAGE TIME PERIOD BETWEEN MARKETING AUTHORISATION AND ACCESS TO PATIENTS

Description and aim

Objective

To identify the time periods in the Member States till patients have access to the medicines.

Definition

Average time period from marketing authorisation to patient availability, patient availability being defined as the medicines being available on the market.

For each country, all new active substances with an identified first marketing authorisation date are included. For each molecule, only the first marketing authorisation are considered for each new active substance, regardless of the authorisation procedure (centralised, mutual recognition or national, where applicable). After the market authorisation further steps are getting a price, receiving reimbursement approval (if applicable) and the actual bringing on the market by the company.

Average period in number of days.

Taxonomy

Category: Accessibility to medicines
Sub-category: Access to market
Importance: Supplementary

Type and breakdowns

Quantitative
Total market

Description

Time period between marketing authorisation, whatever procedure, and accessibility measured as actual launch of the product by the company.

Delays in access to the medicines for patients might be attributable to the delays in regulatory procedures (pricing, reimbursement) on the one hand, but also to the strategy of the pharmaceutical industry of not bringing a product with a price and a reimbursement approval immediately on the market.

Data source(s) preferred

PHIS Pharma Profiles
European Federation of Pharmaceutical Industries and Associations (EFPIA) "Patients W.A.I.T. Indicator". Phase 8 report (2007) publicly available online: http://www.efpia.org/
EFPIA indicators are published twice a year, data collected in the framework of the PHIS project should refer to the last publication of the calendar year.

Current use or evidence

The need for the indicator was expressed by the PHIS Advisory Board and network members of the PHIS project. This indicator was also identified as a core indicator in the SOGETI 2006 project.

Limitations

A split into out-patient and in-patient market is not meaningful.
A split for innovative medicines and generics might be quite interesting but set up of such data collection is beyond the scope of this project.
Another improvement of the approach could be to distinguish time:

- from marketing authorisation to price approval;
- from price approval to reimbursement approval
- and reimbursement approval to actual launch in a country,

but this is out of scope for this project.

This indicator is sometimes restricted to the delays due to regulatory procedures only; therefore it is important to include further elements of the limited access for the patients (e.g. late launch of a pharmaceutical company).

Example

On average, 380 days between market authorisation and launch of a product on the market.

9. EVALUATION OF MEDICINES

Description and aim

Objective

To identify the use of evaluations and assessments of medicines.

Definition

Systems for measuring the effectiveness of medicines have become an increasing feature of national systems. Assessing the relative effectiveness, the relative therapeutic value or the cost-effectiveness of a medicine is intrinsically linked to the particularities of a Member State's healthcare environment (different morbidity and mortality patterns, different prioritisation of health care resources, different health care funding structures, different direct and indirect cost impacts, etc) and infrastructure. The assessment may vary from one Member State to another depending on public health priorities and the clinical setting environment.

This indicator should describe if an evaluation assessment is conducted. If yes, it could detail:

- Scope of assessment: e.g. medicines, health care technologies – and with regard to medicines: which medicines (e.g. innovative, high-cost ...)
- Status of guidance / obligation: indicative, mandatory, ...
- Purpose of the assessment: for pricing or reimbursement
- Frequency: is it regularly done, in a systematic way
- Type of assessments: HTA, cost-effectiveness analysis
- Actors who undertake the assessement: the authorities themselves, considering reports delivered by the industry ...

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Access to market

Type and breakdowns

Qualitative
Out-patient / in-patient

Description

A comparative table will be developed. Please refer to the example for further details.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

The need for the indicator was expressed by the Advisory Board and network members of the PHIS project. This indicator was also identified as a core indicator in the SOGETI 2006 project. There is scientific evidence available in literature to support an indicator on this issue (e.g., *Health Technologies and Decision Making* OECD 2005, *Survey of Pharmacoeconomic Assessment Activity in Eleven Countries* OECD Health Working Papers 2003, *Health technology assessment agencies: An international overview of organizational aspects*. International Journal of Technology Assessment in Health Care, 23:4 (2007), 414–424, *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience from 4 Countries*. Milbank quarterly Volume 87, Number 2, 2009)

Limitations

This indicator is descriptive, and it is difficult to briefly present it in a comparative way without simplifying too much. A ranking according to this indicator is therefore not possible.

Example

Assessments considered	Pricing decision	Reimbursement decision	Pricing review	Reimbursement review
Country A	No	Yes, in some cases for high-cost medicines	No	Yes, for a few, rather expensive medicines
Country B	Yes, mandatory for innovative medicines; Indicative for others	Yes, mandatory for innovative medicines; Indicative for others	No price reviews	Yes, indicative. In fact, undertaken for expensive medicines

10. UPTAKE OF NEW MEDICINES

Description and aim

Objective

To measure innovation development between countries.

Definition

A new molecular entity (NME) includes new chemical entities (NCE) and biological entities.

New Molecular Entities = New Chemical Entities + New Biological Entities
(NME=NCE+NBE)

A new chemical entity (NCE) is a pharmaceutical that contains no active moiety, i.e. without any molecule or ion, but including those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the pharmaceutical substance. It is a chemical molecule developed by the innovator company in the early discovery stage, which after undergoing clinical trials could translate into a pharmaceutical that could be a cure for some disease (from U.S. Food and Drug Administration and Wikipedia).

The indicator measures the number of New Molecular Entities (NMEs) launched within the last 5 and 10 years in the whole pharmaceutical market.

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Innovation

Type and breakdowns

Quantitative
Within the last 5 years and 10 years

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

This indicator was monitored by the DG ENTR Competitiveness indicators (data derived from IMS Health, not monitored anymore), Centre for Medicine Research International (CMR)[16] "Pharmaceutical R&D Factbook" and was identified as a core indicator by the SOGETI 2006 project.

Limitations

Feasibility of data collection at national level to be assessed.

Example

	Last 5 years	Last 10 years
Country A	7	24
Country B	10	19

[16] http://www.cmr.org/

11. PRICING POLICIES

Description and aim

Objective

To assess the different policies for setting a price of medicines used in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals.

Definition

Pricing policies include regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers (e.g. free pricing, statutory pricing, price negotiation and price control). There is a key distinction between price control, which may be statutory pricing, price negotiations with authorities and procurement, or free pricing where the pharmaceutical company sets the price.

A pricing policy gives an indication of how much relevance a State attaches to specific kinds of pharmaceuticals (e.g. innovative pharmaceuticals, generics, reimbursable pharmaceuticals, OTC products) via the extent of the realised price control or the extent of the allowed free pricing.

The price control can be direct (including setting of fixed margins at various levels - wholesalers, retailers) or indirect (e.g. profit control) and might be linked to reimbursement control.

For out-patient, it should include:

- Control of which price type (e.g. ex-factory price)
- Common pricing policies (e.g. statutory pricing, procurement, negotiations)
- Common pricing procedures (e.g. external price referencing, internal price referencing, procurement) – breakdown to different kind of medicines (e.g. reimbursable medicines)
- Regulation of wholesale and pharmacy mark-ups, in general and for different kinds of medicines (e.g. reimbursement medicines) and their type (linear mark-up, regressive schemes)

For in-patient, it should include:

- Indications of the major pricing policies (e.g. procurement, negotiations, other)
- Organisation, scope, process and frequency as well as common criteria for the major pricing policies applied
- Existence and regulation of possible mark-ups
- Discounts

Taxonomy

Category: Accessibility to medicines Importance: Core
Sub-category: Pricing

Type and breakdowns

Qualitative
Out-patient / in-patient
If applicable and possible: Reimbursement / non-reimbursement market
If applicable and possible: Prescription / non-prescription medicines

Description

A comparative table will be developed. Please refer to the example for further details.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

Similar indicators have been used in several other projects and studies (e.g., Mossialos et al. 2004; ÖBIG 1998, ÖBIG 2001, ÖBIG 2006; EURO-MED-STAT 2004, SOGETI 2006, PPRI 2008).

Limitations

These indicators are descriptive, and they are difficult to briefly present in a comparative way. A ranking according to these indicators is therefore not possible. Even when assuming that price control has a positive impact on access to and affordability of medicines, the respective regulatory framework

alone does not always improve the pharmaceutical provision in a country.

This indicator may need to be accompanied by written statements on what kind of price regulations are used, since they have different policy implications. The indicator does not provide information on the enforcement of these various regulations. This could be described separately.

Example

OUT-PATIENT SECTOR

Pricing policy in general

	Scope of price control	Pricing policy	Controlled price type
Country A	Reimbursable pharmaceuticals	Statutory pricing	Ex-factory price
Country B	All pharmaceuticals	Statutory pricing	Ex-factory price
Country C	No price control	Price notification to Medicines Agency	*No price control at ex-factory price*

Pricing policies for specific products

	Generics	OTC products	Parallel-traded products
Country A	Price control for reimbursable generics	Free pricing for non-reimbursable OTC products	No specific pricing policy
Country B	Price control for all pharmaceuticals, thus also for generics	Price control for all pharmaceuticals, thus also for OTC products	Shorter period for pricing decision
Country C	No price control, obligatory discount of 10% for sickness funds since 2006	Free pricing at manufacturer level	Free pricing

Pricing procedures

	External price referencing		Internal price ref.	Cost-plus
	Scope	Reference countries	Scope	Scope
Country A	Reimburs. ph.	All other EU MS	Reimbursable ph.	–
Country B	All ph.	All other EU MS	Me-too ph., generics, copy products, parallel imported ph.	–
Country C	–	–	–	Locally-produced ph.

Pricing policies at distribution level

	Statutory wholesale mark-up		Statutory pharmacy mark-up	
	Scope	Type	Scope	Type
Country A	All ph.	2 regressive mark-up schemes (depending on the reimbursement category)	All ph.	2 regressive schemes: 1 for "privileged customers" (e.g., sickness funds) and 1 for private customers
Country B	All ph.	Regressive mark-up scheme	All ph.	Regressive mark-up scheme
Country C	POM	Regressive mark-up scheme	POM	Fixed pharmacy fee and linear mark-up

IN-PATIENT SECTOR

Country	Out-patient regulation relevant	Major pricing policies	Procurement done by	Price as decision criterion in proc.	Discounts	Price type of the hospital price
A	No	Negotiations, procurement rather rare but rising	Hospitals individually, hospital procurement bodies of hospital owner	Decisive criterion, not the only one	Yes	Ex-factory price
B	Yes	Public: procurement Private: negotiation	Hospitals individually	Decisive criterion, not the only one	Yes	Ex-factory price
C	Yes	Procurement for public and private	Hospitals individually	Decisive criterion, not the only one	Yes	Ex-factory price

12. TAXES ON PHARMACEUTICALS

Description and aim

Objective

To assess the different tax policies regarding medicines in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals.

Definition

The VAT (Value Added Tax) is a sales-tax on products collected in stages by enterprises. It is a wide-ranging tax usually designed to cover most or all goods and services, including pharmaceutical products. The VAT rate of pharmaceuticals in the EU is often lower than the standard VAT rate (PHIS Glossary).

There may be split VAT rates in place (e.g., lower rates for reimbursable pharmaceuticals or prescription-only medicines).

If VAT rates are also eligible for the in-patient sector it should be specified.

In addition, further taxes or tax-like fees, for example based on the price or on the turnover of a pharmacy, may be levied.

Taxonomy

Category: Accessibility to medicines Importance: Supplementary

Sub-category: Pricing

Type and breakdowns

Qualitative

Standard / pharmaceuticals (if applicable for different types of medicines: e.g. reimbursable / non-reimbursable) / other relevant taxes

Out-patient / in-patient

Description

A comparative table will be developed, indicating the VAT rate(s) for medicines as well as further specific taxes for medicines.

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

Similar indicators have been used in several other projects and studies (e.g., Mossialos et al. 2004; ÖBIG 1998, ÖBIG 2001, ÖBIG 2006, PPRI 2008).

Limitations

Pharmaceutical taxes might have an impact on the remuneration of the distribution actors, and thus need to be analysed in connection with distribution margins. The pharmaceutical taxes should also be analysed in relation to the general taxation climate of the country (e.g. VAT on pharmaceuticals is to be compared with the standard VAT).

Example

	Standard VAT rate	VAT rate on pharmaceuticals	Special VAT rates	Other relevant taxes	VAT relevant for the in-patient sector
Country A	20%	20%		Pharmacy fee	Y
Country B	15%	0%	15% for diagnostic agents	-	Y
Country C	19%	9%			N

13. REIMBURSEMENT LIST

Description and aim

Objective

To assess if a country has implemented measures guaranteeing or limiting the access to medicines which are, at least partially, funded by a Third Party Payer.

Definition

States may use reimbursement lists which may take either the form of a

- positive list: list of medicines that may be prescribed at the expense of the third party payer.
- negative list: list of medicines which cannot be prescribed at the expense of the third party payer (PHIS Glossary).

A country may use a combination of reimbursements lists, a positive and negative one for example.

Reimbursement lists may differ for the out-patient and in-patient sector.

Usually positive and negative lists only refer to the out-patient sector, but in some countries they may also be valid for the in-patient sector.

For the in-patient sector, it should stated if hospital pharmaceutical formularies (HPF), a national hospital list or out-patient positive lists also eligible for hospitals are in place.

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Reimbursement

Type and breakdowns

Qualitative
Out-patient / in-patient

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

This indicator has also been used in several other projects and studies (e.g., WHO 1996, WHO 1999, ÖBIG 2000, ÖBIG 2006, PPRI 2008, SOGETI 2006 core list).

Limitations

The information on the implementation of positive and / or negative lists gives a first indication of cost-containment measures in a country. For further analysis it is recommended to include the scope of the positive / negative lists, which is reflected in the number of reimbursable medicines (in absolute figures and as a percentage of all medicines on the market).

Additionally, since often not all medicines on the positive lists are fully reimbursed, percentage reimbursement rates in place for reimbursable medicines (= on the positive list) also need to be taken into consideration.

Example

OUT-PATIENT SECTOR

	Reimbursement lists	Optional: Reimbursement rates
Country A	Positive list	No fixed reimbursement rates defined
Country B	No positive list, two negative lists	
Country C	Positive list	100%, 85%, 75%, 50%, 0%

IN-PATIENT SECTOR

	Out-patient positive list also relevant	Hospital pharmaceutical formulary
Country A	No	Yes
Country B	Yes, 1 annex on hospitals	Yes
Country C	Yes	Yes

14. REIMBURSEMENT SCHEMES

Description and aim

Objective

To assess the instruments and mechanisms in place for guaranteeing access of pharmaceuticals to patients incl. vulnerable population groups and to display the respective reimbursement schemes by third party payers.

Definition

Reimbursement schemes are the reimbursement system which covers the majority of residents in a country, in some countries also referred to as "general" reimbursement (PHIS Glossary).

Description of reimbursement eligibility according to the 4 general types: product-specific eligibility, disease-specific eligibility, population-group-specific eligibility, consumption-based eligibility.

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Reimbursement

Type and breakdowns

Qualitative

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

This indicator has also been used in several other projects and studies (e.g., Merck Frosst Canada 2004; ÖBIG 2006; WHO 2000, PPRI 2008, SOGETI 2006 core list).

Limitations

The information on reimbursement schemes is just a first indication. Further information as included in other indicators (e.g. on reimbursement lists, including information on reimbursement rates) or out-of pocket payments should be considered in a detailed analysis (see further indicators).

Example

OUT-PATIENT

	Key eligibility scheme	Further schemes
Country A	Product-specific	Disease-specific
Country B	Product-specific	Population-group-specific: higher reimbursement rate in a specific reimbursement category
Country C	Product-specific	Disease-specific (12 diseases listed) Population-group-specific (veteran scheme)

IN-PATIENT

	Hospital pharmaceutical formulary	Remuneration of pharmaceuticals included in hospital remuneration
Country A	Yes	Y, but in two regions exceptions for oncology pharmaceuticals
Country B	Yes	Y, but a few exceptions
Country C	Yes	2 options: either included in lump sum or hospitals charge pharmaceutical expenditure per patients to sickness funds

15. OUT-OF POCKET PAYMENTS

Description and aim

Objective

To assess the instruments and mechanisms in place for guaranteeing access of pharmaceuticals to patients and for special vulnerable population groups.

Definition

The amount a person has to pay for pharmaceuticals within a defined period (often on a yearly basis).

For the out-patient sector, out-of pocket payments include:

- Fixed co-payments: A out-of-pocket payment in the form of a fixed amount (like for example a prescription fee) to be paid for a service, a pharmaceutical or a medical device.
- Percentage co-payments: Cost-sharing in the form of a set proportion of the cost of a service or product. The patient pays a certain fixed proportion of the cost of a service or product, with the social health insurance / national health service paying the remaining proportion.
- Reference price system (RPS) is an example of percentage co-payment (please refer to RPS indicator for a detailed definition).
- Deductibles: Initial expense up to a fixed amount which must be paid out-of pocket for a service or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a social health insurance / national health service.

Specific mechanisms for vulnerable groups in place (e.g. reduced co-payments, exemption from co-payments, ceilings on private pharmaceutical expenses, tax reliefs, etc.) should be included.

Vulnerable groups are groups within a society facing higher risks of poverty and social exclusion compared to the general population. These vulnerable and marginalised groups include but are not limited to: people with disabilities, isolated elderly people and children, migrants, homeless people, ex-prisoners and drug addicts (PHIS Glossary).

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Reimbursement

Type and breakdowns

Qualitative
Out-patient / in-patient

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

This indicator has also been used in several other projects and studies (e.g., PPRI 2008, SOGETI 2006 core list).

Limitations

This indicator is descriptive and does not allow to compare the average levels of out-of-pocket payments between countries. A ranking according to this indicator is therefore not possible.

Example

OUT-PATIENT

	Out-of pocket payments	Mechanisms for vulnerable groups
Country A	Percentage co-payment of 25%, 50%, 60% or 80% for specific pharmaceuticals; Co-payment due to RPS	Reduced co-payment rates of 15% instead of 25% for patients with so-called preferential reimbursement status (widows, orphans, retired persons, disabled people, low income, etc.) Annual threshold for vulnerable groups (criteria: income, age, social status) and maximum co-payment per prescription of € 6.70 to € 26.10 in certain reimbursement categories
Country B	Percentage co-payment of up to 90% for specific pharmaceuticals Co-payment due to RPS	Some exemptions for vulnerable groups
Country C	Percentage co-payment of 50% for specific population groups granted reimbursement eligibility	Access to public health care (free pharmaceuticals or at reduced rate) for specific groups (criteria are profession, income, disease, medical conditions)

IN-PATIENT

	Out-of pocket payments for pharmaceuticals in hospitals
Country A	No
Country B	Yes for patients without health insurance coverage
Country C	No

16. REFERENCE PRICE SYSTEM

Description and aim

Objective

To assess if a country has implemented a reference price system, which is a common measure in the out-patient sector controlling the use of expensive pharmaceuticals while guaranteeing access to equivalent medicines.

Definition

In a reference price system (RPS), the third party payer determines a maximum price (= reference price) to be reimbursed for certain medicines.

On buying a medicine for which a fixed price / amount (~ the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price / amount and the actual pharmacy retail price of the medicine in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all medicines in a given ATC 4 level and / or ATC 5 level group (PHIS Glossary).

The indicator should state if a reference price system is in place or not and describe it. It could include the year of introduction, the definition of reference groups and calculation method of the reference price.

Taxonomy

Category: Accessibility to medicines Importance: Supplementary
Sub-category: Reimbursement

Type and breakdowns

Qualitative
Out-patient only

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

This indicator has also been used in several other projects and studies (e.g., Aaserud M et al. 2006, ÖBIG 2000, ÖBIG 2006, WHO 1996, WHO 1999, WHO 2006, PRRI 2008).

Limitations

The impact of a reference price system strongly depends on the way it is organised (e.g., the definition of reference groups, the calculation of the reference price, etc.). This indicator alone, which says if a reference price system is in place or not, does not enable an analysis of the impact on the rational use of medicines, cost-containment and access to and affordability of medicines. More details on the organisation and functioning of the reference price systems should be considered.

Example

	RPS in place	Year of introduction	Clustering of reference groups
Country A	Yes	N.a.	ATC 5
Country B	No	N.appl.	N.appl.
Country C	Yes	1995	Mix of ATC 4 and 5

3.4.5 Consumption

17. PRESCRIPTIONS PER CAPITA

Description and aim

Objective

To assess the number of prescriptions per capita per year in order to analyse pharmaceutical consumption in the prescription / reimbursement segment and compare prescribing patterns.

Definition

Prescriptions are orders, mostly in written form (receipt), by a qualified health care professional to a pharmacist or other therapist for a pharmaceutical or treatment to be provided to their patient. One prescription may contain several items (PHIS Glossary). The number of prescriptions is a key measure for the consumption of medicines.

A prescription refers to the items prescribed.

The indicator thus refers to the average number of items prescribed per patient within a year.

Taxonomy

Category: Consumption Importance: Supplementary
Sub-category: Prescription

Type

Quantitative
Out-patient only
Annual growth rates

Calculation

$$\frac{\text{Number of items prescribed}}{\text{Total population}} \text{ per year}$$

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

The EURO-MED-STAT project had a focus on the monitoring of pharmaceutical consumption (EURO-MED-STAT 2004). They have shown that a strong relation exists between age and consumption of medicines across countries. These indicators have also been used in other studies (e.g., ÖBIG 2006, PPRI 2008, SOGETI core list).

Limitations

It is important to define prescriptions precisely (as done here) in order to guarantee comparability.

The indicator does not automatically refer to the reimbursement market, as in some countries prescriptions may not be reimbursed.

Prescribing varies significantly across age (more prescribing for children and the elderly). A refinement would be to standardise the indicator by age.

Example

	Number of prescriptions per capita, year A	**Number of prescriptions per capita, year B**
Country A	26	21
Country B	15	16

18. MONITORING OF PRESCRIBING PRACTICES

Description and aim

Objective

To assess the actions undertaken to monitor the prescribing practices in order to analyse and improve methods to guarantee a better rational use of medicines as well as improving cost-containment measures.

Definition

Several countries monitor the prescribing practices and analye the prescription patterns of physicians in the out-patient sector. A major tool for guidance for physicians in prescribing are prescription guidelines. Prescription guidelines ensure that the right medicine in the right dose is given to the right patient at the right time, all the time. These guidelines help improving the rational use of medicines.

Prescription monitoring refers to the act of assessing / observing prescribing practices of physicians. It is sometimes accompanied by feedback to prescribers and in a few cases also sanctions are possible. (PHIS Glossary)

This monitoring is not just a cost-containment measure, but it is particularly a measure that focuses on a more rational use of medicines.

In the hospital sector, monitoring of prescriptions might be a task of the hospital pharmacy.

This indicator should state if prescription practices are monitored and describe the process (e.g. if they are monitored on a regular basis, if feedback id given to prescribers or if sanctions are applied, if monitoring of the compliance with prescription guidelines – if applicable – is in place).

Taxonomy

Category: Consumption
Importance: Supplementary
Sub-category: Prescription

Type and breakdowns

Qualitative
Out-patient / in-patient

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

The need for the indicator was expressed by the PHIS Advisory Board and network members of the PHIS project and it was used in the PPRI project.

Limitations

For an in-depth analysis further information (e.g., which data are monitored and how often) would be necessary.
Geographical coverage may be partial.

Example

	Prescription guidelines		Prescription monitoring	
	Out-patient	**In-patient**	**Out-patient**	**In-patient**
Country A	Compulsory guidelines on economic prescribing	Same guidelines also valid for the in-patient sector	Yes, but regularly only SHI/NHS contract doctors	Partially - on the level of departments and occasionally
Country B	Obligation for physicians to prescribe a minimum of "cheap pharmaceuticals"	Recommendations for in-patient doctors	Yes	Yes, on the level of departments
Country C	No official guidelines, however regulation on terms of prescribing / dispensing	No official guidelines	N.a.	Occasionally

19. CONSUMPTION

Description and aim

Objective

To study the extent of medicines use in order to assess and compare utilisation patterns.

Definition

Consumption is defined as the use of services and supplies.

Consumption of pharmaceuticals might be expressed in units (packs) or in Defined Daily Doses (DDD).

The DDD is a unit of measurement defined as the assumed average maintenance dose per day for a pharmaceutical used for its main indication in the adult. A DDD will normally not be assigned for a substance before a product is approved and marketed in at least one country. The basic principle is to assign only one DDD per route of administration within an ATC code. DDDs for plain substances are normally based on monotherapy. Doses for individual patients and patients groups will often differ from the DDD. DDD does not necessarily reflect the recommended or Prescribed Daily Dose.

DDDs are not established for topical products, sera, vaccines, antineoplastic agents, allergen extracts, general and local anaesthetics and contrast media. (PHIS Glossary)

Taxonomy

Category: Consumption Importance: Supplementary

Sub-category: Consumption

Type and breakdowns

Quantitative

Total / out-patient / in-patient

Annual growth rates

Calculation

Depending on data availability at national level: Consumption expressed in
number of packages
and / or Defined Daily Doses (DDD)

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

It was used in the EURO-MED-STAT, SOGETI core list projects.

Limitations

Some countries can only provide data in packs, others only in DDD. To cope with this limitation, both measurements are asked for.

Geographical coverage may be partial, and in-patient data availability is uncertain.

Example

Total market	No. of annual consumption in packs	No. of annual consumption in DDD
Country A	166,372	n.a.
Country B	n.a.	1,706

The same example can be provided for the out-patient and in-patient sector.

20. SHARE OF PRESCRIBED MEDICINES DISPENSED

Description and aim

Objective

To evaluate and compare patients adherence to treatment prescribed.

Definition

Adherence to long-term therapy is defined as the extent to which a person's behaviour – taking medication, following a diet, and / or executing lifestyle changes, corresponds with agreed recommendations from a health care provider (Adherence to long term therapies – evidence for action" WHO Report, 2003).

Adherence is measured here as the share of medicines dispensed to out-patients in the total of all medicines prescribed for out-patient market.

Taxonomy

Category: Consumption Importance: Supplementary

Sub-category: Adherence

Type

Quantitative

Out-patient only

Calculation

$$\frac{\text{Number of medicines actually dispensed}}{\text{Number of medicines prescribed}} \times 100$$

The counting method regarding the number of medicines (e.g. incl. or excl. different pack sizes) needs to be the same for the nominator and the denominator.

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

It was selected in the SOGETI core list projects, and the PHIS Advisory Board and network expressed a need for such an indicator.

Limitations

There is no standard for measuring patients' adherence to treatment since measurement varies according to multiple factors (measurement approach, type of non-adherence measured, diseases subtypes, age, gender, level of complexity of treatment regimen, nationality and so on). Other drawbacks of such an estimation are counting inaccuracies which result in overestimation of adherence behaviour and important information (e.g. timing of dosage and patterns of missed dosages) that is not captured using this strategy. Moreover, one problem with this approach is that obtaining the medicine does not ensure its use. Also, such information can be incomplete because patients may use more than one pharmacy or data may not be routinely captured (WHO Adherence report, 2003).

Feasibility may be limited to countries with electronic prescribing system in place. Partial geographical coverage.

Example

	Share of prescribed medicines dispensed
Country A	78%
Country B	89%

21. GENERIC POLICIES

Description and aim

Objective

To assess authorities commitment to promoting generics expressed in different instruments for doing so.

Definition

A generic is a pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Generic policies include any policy in place to promote the use of generics. It includes generic substitution, International Non-proprietary Name (INN) prescribing or a range of other measures (PHIS Glossary).

Generic substitution is defined as the practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient(s). In a country, generic substitution by all pharmacists or only by some of them (the ones in the public sector, or the ones in the private sector, etc.), or by other paramedical personnel (e.g. nurses), can be allowed through laws or regulations.

INN prescribing refers to physicians prescribing medicines by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory INN prescribing) (PHIS Glossary).

The indicator should state which are the mechanisms in place for promoting the use of generics. It should detail the type of generic policies used, if they are indicative or obligatory (enforced by sanctions, and / or promoted by incentives) and the year of introduction, including at least:

- Generic substitution
- INN prescribing

Possible further generics promotion policies (e.g. exemption from or lower co-payments for generics, information campaigns) should be mentioned.

Taxonomy

Category: Consumption
Sub-category: Generics

Importance: Supplementary

Type

Qualitative
Out-patient only

Description

A comparative table will be developed as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

It was used in the PPRI project.

Limitations

This indicator does not state whether and to which extent generic policies are actually practised. For example, even when generic substitution is legally permitted, it is not always practised unless accompanied by a pricing policy which provides incentives to the pharmacists and also by a large promotion campaign among the general public. Furthermore it is important to state the ‘‘formality of the generic policy (e.g. mandatory, indicative etc.) and if there are mechanisms for enforcement (e.g. financial sanctions).

Example

	Generic prescribing	Generic substitution	Further generic promotion
Country A	Indicative INN prescribing	Obligatory generic substitution, with sanctions for doctor if opposed not on founded grounds	Information activities to prescribers by some sick funds
Country B	Not allowed	Obligatory generic substitution (also for non-reimbursable pharmaceuticals)	The Medicines Agency regularly promote generic substitution to general practitioners
Country C	Obligatory INN prescribing	Indicative generic substitution, supported by a financial incentive for pharmacists	Promotion through the reference price system

22. SHARE OF GENERICS

Description and aim

Objective

To assess the use of generics in order to analyse the efficiency of the pharmaceutical system and to show the generic uptake.

Definition

A generic is a pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

The indicator "share of generics in volume" is defined with regard to generics prescriptions as share of the total of prescriptions. In case that data for generics prescriptions were not available, the data could be provided as expressed in consumption (generics in packs or DDD consumed per total consumption in packs or DDD respectively) – but this should be indicated.

The indicator "generics in value" is the expenditure for generic pharmaceuticals in percentage of total expenditure for pharmaceuticals. In case that data for generics expenditure were not available, the data could be provided as expressed in sales (generics in packs or DDD sold per total sales in packs or DDD respectively) – but this should be indicated.

The indicators will be surveyed for the following pharmaceutical sub-markets:

- Total market (in- / out-patient) – if available
- Total out-patient market
- Out-patient reimbursement market
- "unprotected market".

The "unprotected market" market indicates the market where generics should be available because the patents have been expired.

Taxonomy

Category: Consumption Importance: Supplementary
Sub-category: Generics

Type and breakdowns

Quantitative
Total market (in- / out-patient)
In the out-patient market: total out-patient / out-patient reimbursement market / unprotected market depending on data availability at national level
Annual growth rates

Calculation

$$\text{Volume} = \frac{\text{Number of generic prescriptions}}{\text{Total number of prescriptions}} \times 100$$

$$\text{Value} = \frac{\text{Pharmaceutical expenditure for generics}}{\text{Total pharmaceutical expenditure (or other sub-market depending on national data)}} \times 100$$

Data source(s) preferred

PHIS Pharma Profiles

Current use or evidence

Similar indicators have been used in other projects and studies (e.g., ÖBIG 2000, ÖBIG 2006; EURO-MED-STAT 2004, PPRI 2008, SOGETI).

Limitations

Data availability may be partial for the indicator in some sub-markets.
Availability of data regarding generics may arise; in some countries only data for the share of generics in the reimbursement market or prescription market is available.
Some countries might only have data on the generics shares in total (out-patient and in-patient). This should be indicated.

Example

	Generic market shares in % of the total out-patient market	
	Volume	**Value**
Country A	57.3	34.6
Country B	35	15
Country C	67.7	44.7

Same table for out-patient reimbursement market and unprotected market.

23. INTERFACE MANAGEMENT OF MEDICINES

Description and aim

Objective

To assess the mechanisms in place to promote cooperation between in-patient and out-patient sector regarding pharmaceutical provision.

Definition

Interface management is defined as the mechanisms of cooperation between in-patient and out-patient sector.

The indicator should detail the interface management projects, initiatives regarding the provision of pharmaceuticals and includes a description of systems, programs or experiments in place.

Taxonomy

Categor: Consumption Importance: Supplementary
Sub-category: Interface management

Type and breakdowns

Qualitative
Out-patient / in-patient

Description

A comparative table will be developed based on the analysis of the PHIS Pharma Profiles and PHIS Hospital Pharma Reports as detailed in the example.

Data source(s) preferred

PHIS Pharma Profiles and PHIS Hospital Pharma Reports

Current use or evidence

The need for the indicator was expressed by the PHIS Advisory Board and network members of the PHIS project.

Limitations

This indicator is descriptive and does not allow to measure interface management impact on consumption or expenditure of pharmaceuticals.

Example

	Interface managment regarding pharmaceutical provision
Country A	Electronic system in place linking the in-patient and out-patient sector
Country B	Hospital pharmacists also take care of the further medication of the patient

4 Summary

This final report presents the taxonomy for Pharmaceutical Health Information System (PHIS) indicators to be the most sufficiently acute and relevant for the purpose of the PHIS database. The development of the taxonomy is a milestone in the process of setting up the PHIS database, which will be filled with data from the EU Member States and is due in month 29 (January 2011).

A **total of 23 indicators** were **defined according to the taxonomy** developed. A larger number of indicators was considered, taking in consideration specific needs for indicators expressed by the PHIS Advisory Board and network members of the PHIS project. Finally, a selection was conducted and validated by the PHIS Advisory Board and network.

There are two different sets of indicators:

- **3 core indicators** intended to policy makers:
  - Health expenditure and sub-indicators
  - Pharmaceutical expenditure and sub-indicators
  - Pricing policies
- **20 supplementary indicators** for a broader perspective.

All indicators should be arranged in the PHIS database according to the taxonomy which includes four main categories (Box 12).

Box 12: PHIS taxonomy

1. **Background**
   - *Demographics*
     Population age structure (S[17]1)
   - *Health status*
     Life expectancy (S2)
   - *Economics*
     Gross domestic product (GDP) per capita (S3)
   - *Health expenditure*
     Health expenditure (HE) per capita, by funding and sector (C[19]1)
2. **Pharmaceutical system**
   - *Pharmaceutical provision*
     Inhabitants per presecription-only medicines dispensary (S4)
   - *Expenditure*
     Pharmaceutical expenditure (PE) per capita, by funding and sector (C2)
     Top 10 medicines by active ingredients (S5)

[17] S = supplementary / C = core

3. Accessibility to medicines

- *Access to market*
  Average time period between marketing authorisation and access to patients (S6)
  Evaluation of medicines (S7)
- *Innovation*
  Uptake of new medicines (S8)
- *Pricing*
  Pricing policies (C3)
- *Reimbursement*
  Reimbursement list (S10)
  Reimbursement schemes (S11)
  Out-of pocket payments (S12)
  Reference price system (S13)

4. Consumption

- *Prescription*
  Prescriptions per capita (S14)
  Monitoring of prescribing practices (S15)
- *Consumption*
  Consumption (S16)
- *Adherence*
  Share of prescribed medicines dispensed (S17)
- *Generics*
  Generic policies (S18)
  Share of generics (S19)
- *Interface management*
  Interface management of medicines (S20)

Such a project of developing indicators for the purpose of monitoring is a multi-cycle process. The proposed indicators may be slightly reviewed through the development of the PHIS database. Many efforts in the area of health reporting have shown that truly comparable data and indicators between EU countries are rare. Work to improve the health information knowledge system and the validity, relevance and comparability of health information from different Member States is a continuous process. The maintenance of PHIS indicators and their full and high quality implementation in all Member States will require added efforts.

Regarding in-patient sector and data availability, this project is a first milestone to data collection of pharmaceutical indicators at European level. As a first attempt, the work carried out should be considered as a first stage for improvement in evaluating comparability and differences in methodology plus identification of data availability and gaps. The need to improve and straighten the data availability for in-patient sector will remain for many years.

Finally, this report is a first start with, in some cases, raw data that need further refinement. The real benefit of these indicators will only be realised as the database is updated and sustainable over a number of years along with indicators data collection improvements, which would allow for a proper evaluation.

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