









PHARMACEUTICAL PRICING AND REIMBURSEMENT INFORMATION (PPRI)

# SET OF CORE PPRI INDICATORS

Gesundheit Österrreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) Stubenring 6, 1010 Vienna, Austria Tel: +43 1 515 61-0 Serie, Fax: +43 1 513 84 72; E-mail: ppri@oebig.at http://ppri.oebig.at



## SET OF CORE PPRI INDICATORS

## Short List

No.	Indicator	Category
1	Population age structure	
2	Gross domestic product per capita in € Purchasing Power Parities (PPPa)	Background
3	Public/Private funding of health expenditure	
4	Total Health Expenditure per capita in € Purchasing Power Parities (PPPa)	
5	Regulatory framework for pharmaceutical policy	
6	Key data on pharmaceutical industry	Pharmaceutical
7	Inhabitants per "Prescription-only dispensary" (POM dispensary)	System
8	Total pharmaceutical expenditure as percentage of total health expenditure	
9	Public/Private funding of pharmaceutical expenditure	
10	Pricing policies at manufacturer level	
11	Pricing policies at distribution level	Pricing
12	Taxes on pharmaceuticals	
13	Positive/negative list	
14	Reference price system	Reimbursement
15	Mechanisms for vulnerable groups	
16	Share of generics in volume and value as percentage of outpatient market	
17	Prescription guidelines	
18	Mandatory guidelines for decision-makers / role of pharmaco-economics	Rational
19	Information to patients	Use
20	Monitoring of consumption	
21	Number of prescriptions per capita in volume and value	



## SET OF CORE PPRI INDICATORS

Background

#### Indicator

1: Population age structure

## Objective

To assess the age structure in order to analyse the effect on using health care/pharmaceutical resources

#### Description

The frequency of three age groups 0-14; 15-64 and over 64 years as a percentage of the total population.

#### Indicator calculation and presentation

Total population aged from 0 to 14 years Total population x 100

Total population aged from 15 to 64 yearsx 100Total population

Total population aged over 64 years Total population x 100

## **Evidence/Expert Opinion**

Elderly people are more in need of health and pharmaceutical resources than younger. Therefore a country with a higher percentage of elderly people will probably have a higher consumption rate of pharmaceuticals. This indicator is used in several projects and studies (e.g., OECD Health Data 2006, WHO Health for all Database, and ECHI Shortlist (Final Version of April 30, 2005)).

## Limitations

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

Background

## Indicator

2: Gross domestic product per capita in € Purchasing Power Parities (PPPa)

## Objective

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

## Description

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 (PPPa) and not on market exchange rates. Purchasing power parities reflect the amount of a national currency that will buy the same basket of goods and services in a given country. When PPPa are taken into account, the differences between poorer countries vis a vis richer countries diminishes (OECD 2001, Society at a Glance. OECD Social Indicators, p. 22).

## Indicator calculation and presentation

Gross domestic product in PPPa Total population

## **Evidence/Expert Opinion**

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. This indicator is a standard indicator which is used in several projects and studies (e.g., OECD Health Data 2006, OECD 2001, WHO Health for all Database).

## Limitations

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

Background

## Indicator

3: Public/Private funding of health expenditure

## Objective

To assess the main sources of health care funding in order to analyse the size of public funding vs. private funding of health care

## Description

Public expenditure on health care can be defined as the health expenditure 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 can be defined as the privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care (OECD Health Data 2006).

## Indicator calculation and presentation

Public expenditure on health Total health expenditure x 100

Private expenditure on health Total health expenditure x 100

In addition, the development of this indicator, expressed for example in growth rates (geometrical mean) and/or as an index, over a period of time shall be taken into consideration.

## **Evidence/Expert Opinion**

Indicators for who pays for health care are important for equity and accessibility issues in health care, such as "Is the population sufficiently covered for health risks?" or "Do the poor have adequate access to medical services?". For the PPRI comparative analysis this indicator can be compared with the private vs. public share of pharmaceutical funding. The indicator is a standard indicator which is used in several other projects and studies (e.g., OECD 2001,OECD Health Data 2006).

## Limitations

Detailed data on financing and especially on private financing of health care is not available for all countries.

Background

## Indicator

4: Total Health Expenditure per capita in € Purchasing Power Parities (PPPa)

## Objective

To assess the expenditure per capita and year on health in order to analyse the amount spent on health in a country

## Description

Total expenditure on health 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")

## Indicator calculation and presentation

Total health expenditure In € PPPa Total population

In addition, the development of this indicator, expressed in growth rates (geometrical means) and/or as an index, over a period of time shall be taken into consideration.

## **Evidence/Expert Opinion**

Relatively wealthy people and countries tend to spend a higher proportion of total income/gross domestic product on health care than relatively poor people and countries. An analysis of the development of health care spending per capita and of the of total income per capita suggests that health care spending per capita has increased more than the income per capita, implying that richer countries and people are spending relatively more on health care (OECD 2001).

#### Limitations

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 (13 OECD countries so far) have implemented this system. The reporting of the other countries is based on health spending as reported in the National Accounts. Therefore in some cases measurement problems exist; mainly the boundaries between health and social care are drawn in different ways.

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). The indicator is a standard indicator which is used in several other studies analysing health care systems, in most cases together with the indicator health care expenditure as a percentage of the gross domestic product.

Pharmaceutical system

## Indicator

5: Regulatory framework for pharmaceutical policy

## Objective

To assess the legal context in order to analyse the national political framework for the provision of the population with effective pharmaceuticals.

#### Description

Each country has a different culture of regulations. Regulations in the field of pharmaceuticals may be directly via Acts, Enactments or Decrees, or indirectly through Agreements with actors or their interest associations. The regulatory scope of EU Member States is, to a large extent, influenced by the EU provisions.

#### Indicator calculation and presentation

Analysis of the key legal provisions in the field of pharmaceuticals with regard to the legal relevance. Possible categories could be as follows (not comprehensive):

- Acts, Decrees, Enactments at federal level
- Acts, Decrees, Enactments at state/regional or local level
- Agreements (e.g. Framework Agreements)
- Policy papers

#### Evidence

This indicator has been used in some other projects (e.g., WHO 2006) and was recommended by indicators experts.

## Limitations

This indicator of regulatory framework does not provide information on the implementation of the legal provision or the quality of pharmaceutical care.

Pharmaceutical system

## Indicator

6: Key data on pharmaceutical industry

## Objective

To assess the relevance of pharmaceutical manufacturers, distributors and retailers in order to analyse their impact on pharmaceutical policies and their role in research and development, production and distribution.

#### Description

The pharmaceutical industry consists of different "branches", such as research-oriented industry, generic manufacturers and biotech industry. Another important distinction concerns the classification into international companies (often research-oriented) and local producers (often generics). By assessing the number of companies, these indicators describe the importance of different branches of the pharmaceutical industry, and of key distribution actors like importers and wholesaler.

#### Indicator calculation and presentation

Approximate number of pharmaceutical companies.

Possible sub-groups:

- Number of research-oriented pharmaceutical companies or relevance expressed as a percentage of all pharmaceutical companies
- Number of generic manufacturers or relevance expressed as a percentage of all pharmaceutical companies
- Number of wholesale companies

For analysis, it might be reasonable to form groups:

- For pharmaceutical industry: e.g. < 10 / 10 100 / > 100
- For pharmaceutical wholesale: e.g. < 10 / 10 50 / > 50

#### Evidence

These indicators have been used in several other projects and studies (e.g., ÖBIG 2001, ÖBIG 2006 (evidence of grouping), WHO 1996, WHO 1999, WHO 2004).

#### Limitations

There are methodological problems concerning the definition of the actors in statistics (e.g., statistics on wholesalers may include importers, number on generic manufacturers may include producers of copy-products). The analysis of the number of companies should be done in consideration of the size of the country and its economic wealth.

Pharmaceutical system

## Indicator

7: Inhabitants per "Prescription-only dispensary" (POM dispensary)

## Objective

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

#### Description

POM dispensary is an umbrella term for facilities that are allowed to sell prescription-only medicines (POM) to outpatients. Besides pharmacies, these may be self-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 pharmaceuticals. 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.

#### Indicator calculation and presentation

Total population Number of POM dispensaries

## **Evidence/Expert Opinion**

Usually, the indicator "pharmacies per inhabitant" is used to assess in the provision of the population with pharmaceuticals at the retail level. However, studies (e.g., ÖBIG 2000, ÖBIG 2001, ÖBIG 2006) 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.

Pharmaceutical system

## Indicator

8: Total pharmaceutical expenditure as a percentage of total health expenditure

## Objective

To assess and analyse the total expenditure on pharmaceuticals as a proportion of the total health expenditure.

## Description

This indicator measures the share of pharmaceutical expenditure as a percentage of health expenditure. For the definition of health expenditure, see indicator 4 "Total Health Expenditure per capita in € Purchasing Power Parities (PPPa)". Whereas according to the definition of the OECD Health Data 2006, total pharmaceutical expenditure includes pharmaceuticals and therapeutic appliances usually provided to out-patients; in the PPRI project pharmaceutical expenditure aims at referring both to the out-patient and in-patient sector (PPRI Glossary).

## Indicator calculation and presentation

Total pharmaceutical expenditure x 100 Total health expenditure

In addition, the development of this indicator, for example expressed in growth rates (geometrical means) and/or as an index, over a period of time shall also be taken into consideration.

## **Evidence/Expert Opinion**

The share of pharmaceutical expenditure within the total health expenditure shows the relevance of pharmaceuticals within the health care sector. The growth in pharmaceutical expenditure raises concerns in terms of affordability and the financing of health care systems. Because of the increasing utilisation of some expensive pharmaceuticals overall expenditure for pharmaceuticals is expected to increase even more in the next years (EURO-MED-STAT 2004). The share of pharmaceutical expenditure within the health care expenditure and growth rates of pharmaceutical expenditure are standard indicators and used in several other projects and studies (e.g., EURO-MED-STAT 2004, ÖBIG 2001, OECD Health Data 2006).

#### Limitations

The extent of health 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).

Pharmaceutical system

## Indicator

9: Public/Private funding of pharmaceutical expenditure

## Objective

To assess the main sources of pharmaceutical funding in order to analyse the amount of public funding versus private funding of pharmaceuticals.

#### Description

Total pharmaceutical expenditure includes, according to the definition of the OECD Health Data base, pharmaceuticals and therapeutic appliances provided to outpatients. Pharmaceuticals and therapeutic appliances used in in-patient treatment are included in inpatient expenditure. Public expenditure for pharmaceuticals includes the general government (including central government, state/provincial government and local/municipal government) and social security funds. The private sector is defined as private social insurance, private insurance enterprises and private households expenditure. Private household expenditure for pharmaceuticals reflects the financial burden of patients and is therefore an indicator for accessibility and affordability.

#### Indicator calculation and presentation

Public pharmaceutical expenditure Total pharmaceutical expenditure x 100

Private pharmaceutical expenditure x 100 Total pharmaceutical expenditure

In addition, the development of these indicators, for example expressed in growth rates (geometrical means) and/or as an index, over a period of time shall be taken into consideration.

## **Evidence/Expert Opinion**

Indicators for who pays for pharmaceuticals are important for equity, affordability and accessibility issues, such as "Does the population have access to pharmaceuticals?" and "Are the people able to afford these pharmaceuticals?". Increased public funding is important to enable the achievement of high public health impact and equitable access (WHO 2006). This

indicator is used in several studies (e.g., OECD Health Data 2006, ÖBIG 2001, ÖBIG 2006, SOGETI 2006, WHO 2006).

#### Limitations

The inpatient sector for pharmaceuticals is usually not included in the analysis, there is a lack of data in most countries. Usually, so called "under the table payments" are excluded and therefore the expenditure for pharmaceuticals are underestimated.

Pricing

#### Indicator

10: Pricing policies at manufacturer level

## Objective

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

## Description

Pricing policies are defined as regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers (PPRI Glossary). There is a key distinction between price control, which may be statutory pricing, price negotiations with state bodies, public 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 price control that is undertaken or of free pricing that is allowed.

#### Indicator calculation and presentation

A comparative table, indicating to which pharmaceuticals price control is applied and which pharmaceuticals are granted free pricing, will be developed. Kinds of pharmaceuticals to be considered may be:

- reimbursable / non-reimbursable pharmaceuticals
- prescription-only medicines (POM) / OTC products
- original products / generics
- if applicable: innovative pharmaceuticals
- if applicable: hospital-only pharmaceuticals
- if applicable: other exceptions (e.g. parallel traded pharmaceuticals)

## 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).

#### 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 pharmaceuticals, the respective regulatory framework alone does not always improve the pharmaceutical provision in a country.

Pricing

#### Indicator

11: Pricing policies at distribution level

## Objective

To assess the different policies for pricing pharmaceuticals at the distribution level (wholesaler, pharmacy) in order to analyse their impact on the provision of the population with affordable and effective pharmaceuticals.

#### Description

Distribution margins are defined as the gross profit of wholesalers and pharmacies respectively (PPRI Glossary), expressed as a percentage of the pharmacy purchasing price (wholesale margin) or as a percentage of the pharmacy retail price (pharmacy margin).

#### Indicator calculation and presentation

A comparative table will be developed, indicating

- if wholesale margins are regulated, and if yes, for which pharmaceuticals
- if pharmacy margins are regulated, and if yes, for which pharmaceuticals

## Evidence

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

#### Limitations

Margins are usually maximum margins. In some countries, distribution actors set their margins equal to the maximum margins, while in other countries the maximum mark-ups might not be adopted, resulting in different pharmacy retail prices between pharmacies. For an indepth analysis, the application of the regulations in practice as well as the impact of possible discounts should be taken into consideration.

Pricing

#### Indicator

12: Taxes on pharmaceuticals

## Objective

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

#### Description

The VAT (Value Added Tax) is a sales tax levied on the sale of goods and services and is compulsory for EU Member States. The VAT rate of pharmaceuticals in the EU is often lower than the standard VAT rate (PPRI Glossary). There may be split VAT rates in place (e.g., lower rates for reimbursable pharmaceuticals or prescription-only medicines).

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

#### Indicator calculation and presentation

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

## Evidence

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

#### 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).

Reimbursement

## Indicator

13: Positive / negative list

## Objective

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

#### Description

States may use reimbursement lists, which may take either the form of a positive list or a negative list: A positive list includes pharmaceuticals that may be prescribed, more or less without further conditions, at the expense of a social health insurance / national health service, whereas pharmaceuticals on a negative list cannot be prescribed at the expense of the social health insurance / national health service (PPRI Glossary).

#### Indicator calculation and presentation

A comparative table will be developed, indicating

- if a positive list is / if positive lists are in place, and
- if a negative list is / if negative lists are in place.

#### Evidence

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

## 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 pharmaceuticals (in absolute figures and as a percentage of all pharmaceuticals on the market).

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

Reimbursement

## Indicator

14: Reference price system

## Objective

To assess if a country has implemented a reference price system, which is a common measure restricting the use of expensive pharmaceuticals while guaranteeing access to equivalent pharmaceuticals

#### Description

In a reference price system, interchangeable pharmaceuticals are grouped (reference groups), usually at the ATC 5 or ATC 4 level. For these groups of pharmaceuticals, the social health insurance / national health service determines a maximum amount (= the so-called reference price) which is the basis for reimbursement. On buying a pharmaceutical under the reference price system, an insured must pay the difference between the reference price and the actual pharmacy retail price of the pharmaceutical in question, in addition to any fixed co-payments or percentage co-payment rates (PPRI Glossary).

## Indicator calculation and presentation

A comparative table, indicating if a reference price system is in place or not, will be developed.

## 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).

## 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 pharmaceuticals, cost-containment and access to and affordability of pharmaceuticals. More details on the organisation and functioning of the reference price systems should be considered.

Reimbursement

## Indicator

15: Mechanisms for vulnerable groups

## Objective

To assess the instruments and mechanisms in place for special vulnerable population groups in order to analyse the access to affordable pharmaceuticals.

#### Description

Significant private expenses on pharmaceuticals (including direct payments and out-ofpocket payments like prescription fees, percentage co-payments, deductibles; for definitions see PPRI Glossary) may act as a barrier which hinders socially disadvantaged population groups to purchase pharmaceuticals. Thus, several countries have introduced various instruments and mechanisms to protect these groups and to offer them equitable access to pharmaceuticals. These measures may include reduced co-payments, exemption from copayments, ceilings on private pharmaceutical expenses, tax reliefs, etc..

#### Indicator calculation and presentation

A comparative table, indicating which mechanism for vulnerable groups are in place, will be developed.

## Evidence

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

## Limitations

This indicator should be considered in combination with an analysis of the burden for the patients resulting from private expenses, because direct payments and out-of-pocket payments for reimbursable pharmaceuticals as well as co-payments for further health care services (e.g., a fees for visiting doctors) may result in poorer people resigning to demand health care services.

Rational Use

#### Indicator

16: Share of generics in volume and value as percentage of outpatient market

## Objective

To assess the use of generics in order to analyse the efficiency of the pharmaceutical system.

## Description

A generic is a bioequivalent of a branded original pharmaceutical, whose patent on the active ingredient has expired (also called "off-patent" or "multi-source" pharmaceutical). By law, a generic product must contain an identical amount of the same active ingredient(s) as the branded product.

The indicator "share of generics in volume" is defined with regard to generic prescriptions as share of the total of prescriptions. The indicator "generics in value" is the expenditure for generic pharmaceuticals in percentage of the total expenditure for pharmaceuticals.

## Indicator calculation and presentation

Number of generic prescriptions x 100 Total number of prescriptions

Pharmaceutical expenditure for generic x 100

Total pharmaceutical expenditure

In addition, the development of these indicators, for example expressed in growth rates (geometrical means) and/or as an index, over a period of time shall be taken into consideration.

## Evidence

Usually the prices of generics are lower than those of original products, therefore a high generic share may contribute to containing pharmaceutical expenditure. Similar indicators have been used in other projects / studies (e.g., ÖBIG 2000, ÖBIG 2006; EURO-MED-STAT 2004).

## Limitations

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.

For more detailed information, the utilisation of generics measured in DDD and also the share of generics in the "potential generic market" would be helpful. The "potential generic" market is the market where theoretically generics could be available because the patents have been expired. There are variations within the European Union Member States regarding the patent expiry of pharmaceuticals.

Rational Use

#### Indicator

17: Prescription guidelines

#### Objective

To assess the implementation of prescription guidelines in order to analyse their impact on rational use of pharmaceuticals as well as on cost-containment

#### Description

Several countries have implemented guidelines for prescribing doctors, thus controlling their prescription pattern. Such prescription guidelines may include sanctions in case of excess.

#### Indicator calculation and presentation

A comparative table, indicating if prescription guidelines are in use, will be developed.

Further information on the content of the guidelines, the monitoring of the adherence to the guidelines and sanctions may be added.

#### Evidence

Similar indicators have been used in other projects / studies (e.g., Mossialos et al. 2004; PICTF 2002; Roughead et al. 2000; WHO 1996, WHO 1999, WHO 2006).

#### Limitations

The sole introduction of prescription guidelines does not automatically guarantee rational prescription behaviour. Further factors for rational prescribing, such as the information policy towards prescribing doctors and patients on rational use of pharmaceuticals, the monitoring of adherence of the doctors to guidelines, supporting IT systems, the options for sanctioning and the actual implementation of sanctions, are of relevance and should also be considered.

Rational Use

#### Indicator

18: Mandatory guidelines for decision makers / Role of pharmaco-economics

## Objective

To assess a country's policies regarding the decision making process in order to analyse the priorities in decision making on pricing, reimbursement and related issues regarding pharmaceuticals

#### Description

Health-economic or pharmaco-economic studies may be considered in decisions on market authorisation, pricing and/or reimbursement of pharmaceuticals. They may be used as a guidance for decision-making; or they may be obligatory (e.g., pharmaceutical companies may be obliged to present pharmaco-economic studies / data). Guidelines for pharmaco-economic analyses may be in place.

#### Indicator calculation and presentation

A comparative table will be developed, indicating

- if pharmaco-economic analyses are considered in decisions on the price of a pharmaceutical,
- if pharmaco-economic analyses are considered in decisions on reimbursement,
- if pharmaco-economic guidelines are in place.

## Evidence

Similar indicators have been used in other projects / studies (e.g., Merck Frosst Canada 2004, Mossialos et al. 2004, PICTF 2002, SOGETI 2006).

## Limitations

The obligatory provision of pharmaco-economic studies by pharmaceutical companies does not automatically mean that pharmaco-economics really plays an important role in the decision-making.

Rational Use

#### Indicator

19: Information to patients

## Objective

To assess the actions undertaken to inform patients in order to analyse their impact on improving the rational use of pharmaceuticals

#### Description

Besides regulatory bodies, doctors, pharmaceutical companies and distribution actors, the patient plays an important role regarding the rational use of pharmaceuticals (e.g., by taking generics and through compliance). In this respect, independent information for patients from Third Party Payers, doctors and pharmacists is important.

#### Indicator calculation and presentation

A comparative table, indicating if actions are undertaken to inform patients on the rational use of pharmaceuticals, will be developed.

#### Evidence

Similar indicators have been used in other projects / studies (e.g., ÖBIG 2000, Roughead et al. 2000, SOGETI 2006, WHO 1996, WHO 1999, WHO 2006).

#### Limitations

This indicator is only a guidance for the analysis.

Rational Use

#### Indicator

20: Monitoring of consumption

#### Objective

To assess the actions undertaken to monitor the use of pharmaceuticals in order to analyse and improve methods for guaranteeing a better rational use of pharmaceuticals

#### Description

Several countries have started to analyse and monitor the use of pharmaceuticals (in general or with a focus on special, e.g., expensive pharmaceutical groups). The monitoring of pharmaceutical consumption is not just a cost-containment measure, but it is particularly a measure that focuses on the rational use of pharmaceuticals.

#### Indicator calculation and presentation

A comparative table, indicating if individual pharmaceutical consumption data are monitored, will be developed.

## Evidence

The EURO-MED-STAT project was focussed on the monitoring of pharmaceutical consumption (EURO-MED-STAT 2004).

#### Limitations

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

Rational Use

## Indicator

21: Number of prescriptions per capita in volume and value

## Objective

To assess the number of prescriptions per capita in order to analyse the utilisation in the prescription/reimbursement segment

#### Description

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. (PPRI Glossary). The number of prescriptions is a key measure for the utilisation of pharmaceuticals.

#### Indicator calculation and presentation

Number of prescriptions x 100 Total population

Expenditure for prescriptions x 100 Total population

## 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 utilisation of pharmaceuticals across countries. These indicators have also been used in other studies (e.g., ÖBIG 2006).

## Limitations

Ideally, in order to remove the effects of differences in age structure, aggregated data of utilisation of and expenditure for pharmaceuticals should be standardised for the population structure. However, this is not always possible, because in national registers there is no information about the patients (EURO-MED-STAT 2004).

#### Annex : References

Brudon-Jakobowicz P, Rainhorn JD, Reich MR 1999 Indicators for monitoring national drug policies: A practical manual. 2<sup>nd</sup> edition. World Health Organization.

Danish National Indicators Project. In online: http://www.nip.dk/nipUK.htm

Department of Essential Drugs and Medicines Policy 1999 How to investigate drug use in health: Selected drug use indicators. World Health Organization

Dickson et al. 2005 Survey of Pharmaceutical Assessment Activity in Eleven Countries. Paris: OECD.

ECHI Shortlist Final Version of April 30, 2005

Grimshaw and Russell 1993 Effects on clinical guidelines on medical practice: A systematic review of rigorous evaluations. *The lancet*, 342: 1317-22.

Haaijer-Ruskamp FM, Hoven JL, Mol PGM 2004 A conceptual Framework for constructing prescribing quality indicators: a proposal. World Health Organization

ICHI

International Compendium of Health Indicators. In online: http://www.healthindicators.org

Instituto de medicina preventiva, faculdade de medicina, universidade de Lisboa 2001 Reproductive Health Indicators in the European Union. Reprostat. In online: http://ec.europa.eu/health/ph\_projects/2001/monitoring/monitoring\_project\_2001\_full\_en.htm#1

EURO-MED-STAT 2004 Euro-Med-Stat: The Library of European Union Pharmaceutical Indicators. In online: http://www.euromedstat.cnr.it/indicators/indicators.asp

Kelley E, Hurst J. 2006 Health Care Quality Indicators Project: Conceptual Framework. OECD. In online: <u>http://www.oecd.org/dataoecd/1/36/36262363.pdf</u>

Merck Frosst Canada 2004

Health System Performance Indicators as a Tool for Maximizing Health Gain in Canada: Where Do Pharmaceuticals Fit? In online:

http://www.merckfrosst.ca/assets/fr/pdf/health\_policy/PerformanceIndicators2004.pdf

Meyer W. 2004

Indikatorenentwicklung: Eine praxisorientierte Einführung. 2. Auflage. In online: <u>http://www.ceval.de/de/downloads/workpaper/workpaper10.pdf</u>

Mossialos E., Mrazek M., Walley T. 2004

Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality

ÖBIG 2000

Öffentliche Apotheken in Europa: Performance Benchmarking. In online: <u>http://www.oebig.at/index.php?set\_language=de&cccpage=publikationen\_detail&set\_z\_publikationen=</u> <u>19&set\_kategorie\_detail\_gespeichert=5</u> ÖBIG 2001

Arzneimittelausgaben: Strategie zur Kostendämpfung in der Europäischen Union. In online: <u>http://www.oebig.at/index.php?set\_language=de&cccpage=publikationen\_detail&set\_z\_publikationen=</u> <u>21&set\_kategorie\_detail\_gespeichert=5</u>

#### ÖBIG 2006

Community Pharmacy in Europe: Lessons for deregulation – case studies. PGEU. In online: <u>http://www.pgeu.org</u>

OECD 2006 OECD Health Data 2006

#### OECD 2004

SHA-Based National Health Accounts in Thirteen OECD Countries: A comparative Analysis, OECD Health Working Papers 16, Paris 2004

OECD 2001

Society at a Glance. OECD Social Indicators. Paris

PICTF 2002

Department of Health, Association of the British Pharmaceutical Industry. Pharmaceutical Industry Competitiveness Task Force: Competitiveness and Performance Indicators.

Publications Health Canada 2006

NPS: National Pharmaceuticals Strategy. In online: <u>http://www.hc-sc.gc.ca/hcs-sss/alt\_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp\_e.pdf</u>

**RIVM 1998** 

National Institute of the Public Health and the Environment. ECHI 1. In online: <u>http://ec.europa.eu/health/ph\_projects/1998/monitoring/monitoring\_project\_1998\_full\_en.htm#8</u>

**RIVM 2001** 

National Institute of the Public Health and the Environment. ECHI. In online: <u>http://ec.europa.eu/health/ph\_projects/2001/monitoring/monitoring\_project\_2001\_full\_en.htm#1</u>

Roughead EE et al. 2000

Report of the national indicators: Evaluating the Quality Use of Medicines component of Australia's National Medicines Policy. Commonwealth Department of Health and Aged Care.

SOGETI 2006

European Commission DG SANCO. Development of public health performance indicators for the pharmaceutical sector: Final report.

The Nuffield Trust 2004 Benchmarking: A Policy Analysis. In online: <u>http://www.nuffieldtrust.org.uk/ecomm/files/210404benchmarking.pdf</u>

World Health Organization 1996 Comparative Analysis of national drug policies: Second workshop.

World Health Organization 2004 The World Medicines Situation

World Health Organization 2006 Using indicators to measure country pharmaceutical situations