

# Rational Use of Medicines in Europe

Commissioned by the Austrian Federal Ministry of Health

A business unit of Gesundheit Österreich GmbH



**ÖBIG**

Österreichisches Bundesinstitut  
für Gesundheitswesen



# Rational Use of Medicines in Europe Executive Summary

Sabine Vogler  
Bettina Schmickl

Project secretariat:  
Monika Schintlmeister

Translation:  
Christel Zuidberg  
Nina Zimmermann

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1010 Wien, Tel. +43 1 515 61, Fax 513 84 72, e-mail: name.surname@goeg.at,  
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# Rationale

The Austrian Federal Ministry of Health (BMG) commissioned Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen (GÖG/ÖBIG – Austrian Health Institute) to work on promoting a more rational use of medicines in Europe. One element of this multi-annual project was a survey of instruments for a rational use of medicines in Europe in 2009.

The survey was divided into two phases:

- » Phase 1: Overview of mechanisms aimed at promoting a rational use of medicines in the 27 EU Member States covering different actors (e.g. monitoring the prescription behaviour of doctors, generic substitution, information to patients)
- » Phase 2: Detailed research of various tools for a rational use of medicines in selected case study countries, which were chosen on the basis of the identified instruments in phase 1 and in coordination with the commissioning party Austrian Federal Ministry of Health (in total five case studies: Denmark, France, Germany, Italy and the Netherlands)

This is an English summary of the report “Rationale Arzneimitteltherapie in Europa” (“Rational use of medicines in Europe”) published in German. It contains an overview of the instruments of a more rational use of medicines in all 27 Member States, and a summary of the approaches and tools applied in the five case study countries. The complete information on the five case studies is only available in the German full report.

The authors thank the members of the PPRI network (Pharmaceutical Pricing and Reimbursement Information) and the CAPR network (Network of Competent Authorities for Pricing and Reimbursement of Pharmaceuticals) for having provided information for the survey.

# Overview of instruments to promote a more rational use of medicines in the 27 EU Member States

Key instruments for a rational use of medicines, whose implementation in the 27 European Member States will be presented on the next pages, include:

- » INN prescribing: It refers to physicians prescribing medicines by its INN, i.e. the active ingredient name instead of the brand name.
  - » Prescription guidelines: Prescription guidelines ensure that the right medicine in the right dose is given to the right patient at the right time. These guidelines help improving the rational use of medicines.
  - » Pharmaceutical budgets for doctors: When third party payers (sickness funds or national health services) apply this cost-containment measure, the maximum amount of money to be spent on medicines in a specific region or in a period of time is fixed ex-ante.
  - » Generic substitution: Practice of pharmacists of substituting a generic or another cheaper medicine containing the same active ingredient(s) for another medicine, usually a brand.
  - » Prescription monitoring: The act of assessing/observing prescribing practices of physicians applied by payers (sickness funds or national health services). It is sometimes accompanied by feedback to prescribers.
  - » Information activities targeted at the general public: Information work of the payers to convey the reasons for a rational pharmaceutical therapy and for their instruments (e.g. campaigns to promote generics).
- (For definitions see the PHIS Glossary, PHIS/AIFA/GÖG 2009).

These instruments can be established on an indicative or obligatory basis. A mandatory implementation might include sanctions for the actors concerned.

Abbreviations of the EU Member States:

AT	Austria	ES	Spain	MT	Malta
BE	Belgium	FI	Finland	NL	Netherlands
BG	Bulgaria	FR	France	RO	Romania
CY	Cyprus	HU	Hungary	PL	Poland
CZ	Czech Republic	IE	Ireland	PT	Portugal
DE	Germany	IT	Italy	SE	Sweden
DK	Denmark	LT	Lithuania	SI	Slovenia
EE	Estonia	LU	Luxembourg	SK	Slovakia
EL	Greece	LV	Latvia	UK	United Kingdom

Source: European Commission

Instruments to promote a more rational use of medicines in the 27 EU Member States, 2009

Country	INN prescribing		Prescription guidelines		Pharmaceutical budgets for doctors		Generic substitution		Prescription monitoring	Information activities targeted at general public
	Y/N	Enforcement	Y/N	Enforcement	Y/N	Enforcement	Y/N	Enforcement	Y/N	
AT	No	-	Yes	Obligatory	No	-	No	-	Yes	Yes
BE	Yes	Indicative	Yes	Obligatory: Doctors are obliged to prescribe a certain amount of low-priced medicines	No	-	No	-	Yes	Yes
BG	Yes	Indicative	No	(No official guidelines) but regulation on prescriptions	No	-	No	-	N. a.	N. a.
CY	No	Not allowed in private sector (= pharmacies); obligatory in public sector (=NHS)	Yes	Only in public sector	No	-	No	Not allowed in private sector (= pharmacies); obligatory in public sector (=NHS)	Not relevant in private sector	N. a.
CZ	Yes	Indicative	Yes	Indicative guidelines of the Doctor's Association	Yes	Sanctions are possible	Yes	Indicative	Yes	N. a.
DE	Yes	Indicative	Yes	Obligatory	No	Prescription volume target agreements (sanctions are possible)	Yes	Obligatory	Yes	Yes
DK	No	-	Yes	Indicative	No	-	Yes	Obligatory	Yes, Ordiprax prescribing System	Yes
EE	Yes	Obligatory	Yes	Indicative	No	-	Yes	Indicative	Yes	Yes
EL	No	-	No	-	No	-	No	-	Yes	N. a.
ES	Yes	Indicative	Yes	Depending on region	Yes	In some regions, with financial incentives (e.g. Andalusia)	Yes	Indicative	Yes, in some regions test with different electronic systems	Yes
FI	Yes	Indicative, not applied in practice	Yes	Indicative	No	-	Yes	Obligatory	Yes	Yes
FR	Yes	Indicative	Yes	Indicative	No	Prescription targets with financial incentives	Yes	Indicative	Yes	Yes
HU	Yes	Indicative	Yes	Obligatory	No	-	Yes	Indicative	Yes	Yes

Continuation Table

Country	INN prescribing		Prescription guidelines		Pharmaceutical budgets for doctors		Generic substitution		Prescription monitoring	Information activities targeted at general public
	Y/N	Enforcement	Y/N	Enforcement	Y/N	Enforcement	Y/N	Enforcement	Y/N	
IE	Yes	Indicative	No	-	~ Yes	„Indicative Drug Target Scheme“, with financial incentive – however abolished	No	-	Yes, in the frame of the „Indicative Drug Target Scheme“	Yes
IT	Yes	Indicative	Yes	Product specific guidelines	No	-	Yes	Indicative	Yes	Yes
LT	Yes	Obligatory	Yes	Indicative	No	-	Yes	Indicative	Yes	Yes
LU	Yes	Indicative	Yes	Indicative	No	-	No	-	Yes	N.a.
LV	Yes	Indicative	Yes	Indicative	Yes	Obligatory, sanctions possible	Yes	Indicative	Yes	No
MT	Yes	Indicative	No	-	No	-	Yes	Obligatory (reimbursement market)	N. a.	N. a.
NL	Yes	Indicative, supported by prescribing software	Yes	Indicative	No	-	Yes	Indicative, financial incentive for year (abolished)	Yes	Yes
PL	Yes	Indicative	Yes	Indicative	No	-	Yes	Indicative	No	No
PT	Yes	Obligatory	Yes	Indicative	No	-	Yes	Indicative	No	Yes
RO	Yes	Obligatory	Yes	Obligatory	No	Budgets for pharmacies	Yes	Indicative	Yes	N. a.
SE	No	-	Yes	Indicative	Yes	Different regulations depending on the region	Yes	Obligatory	Yes	Yes
SI	Yes	Indicative, not applied in practice	Yes	Indicative	No	-	Yes	Indicative	Yes	No
SK	Yes	Indicative	Yes	Obligatory	Yes	No sanctions	Yes	Obligatory	Yes	No
UK	Yes	Indicative, strongly encouraged and widely practiced	Yes	Indicative	Yes	For NHS doctors	(No)	(Introduced in 2010)	Yes	Yes

INN = international non-proprietary name, N. a. = not available, NHS = National Health Service, Y/N = Yes/No

Sources: ÖBIG 2007, ÖBIG Forschungs- und Planungsgesellschaft mbH 2008, PPRI 2008c, research and personal queries to the members of the PPRI network and the CAPR network

# Rational use of medicines in the case study countries

Based on the findings of the European survey, five countries were selected to be analysed in detail. These are Denmark, France, Germany, Italy and the Netherlands. Their key characteristics are as follows (for an in-depth description see the report in German).

## Denmark

Transparency and the inclusion of all stakeholders (e.g. doctors, pharmacists, patients) characterise the Danish pharmaceutical system. A rational use of medicines is monitored by the Danish Medicines Agency (DKMA) in the out-patient sector and by the regions, which are the owners of the hospitals, in the in-patient sector. When observing pharmaceutical consumption, the Danish Medicines Agency is supported by its Institute for Rational Pharmacotherapy (IRT), which was founded in 1999.

A major tool is the electronic monitoring system (Odriprax) which allows the authorities to assess pharmaceutical consumption at central and local levels as well as at the level of the prescribing doctors. Doctors also have access to the Odriprax system and can compare their prescription pattern to those of other doctors in the region. The Odriprax data are also accessible for the patients who can monitor their pharmaceutical expenditure in their personal "medicines profile". This is important information to them since their co-payments for medicines within one year will decrease the more they have already spent on medicines. Denmark runs a system of mandatory generic substitution which seems very well accepted. Nevertheless the patients have the option of refusing a generic without giving any reason.

## Germany

Germany was the first country in Europe to introduce a reference price system: In 1989, it implemented the so-called "Festbetragssystem". Over the course of time, the reference price system has been adapted. Today, it is accompanied by obligatory generic substitution („Aut-idem-Regelung") and practice-specific prescription volume target agreements for doctors. From 1993 to 2001, pharmaceutical budgets, which were organised differently (regional budgets, possibility for sanctions, etc.), were applied. The pharmaceutical budgets were replaced by today's target agreements with the prescribing doctors which take the characteristics of the doctor's practice into account. The target agreements are connected to financial sanctions: If the prescription volume target is exceeded by 25%, doctors have to re-pay overspending.

A scientific institute of a sickness fund (Wissenschaftliches Institut der deutschen Ortskrankenkassen, WIdO) monitors pharmaceutical expenditure and consumption. A key information tool is a report analysing the development of pharmaceutical prescriptions (“Arzneiverordnungs-Report”) which has been published on a yearly basis for 25 years.

## **France**

Monitoring of pharmaceutical expenditure and consumption is done by the Social Health Insurance and the French Medicines Agency (AFSSAPS), which hosted for some years a department called “National Observatory for Prescriptions and Consumption of Medicines” producing analysis reports on the development of consumption in specific pharmaceutical groups. A typical feature of the French system is agreements between the Social Health Insurance and actors (e.g. with pharmacists to reach a certain generic substitution target, and with doctors to prescribe cost-effectively). In 2009, the Social Health Insurance started concluding individual contracts with doctors, in addition to the existing framework agreement with the doctor’s associations. Representatives of the Social Health Insurance (Délégués d’Assurance Maladie, DAM) visit prescribing doctors, inform them about measures for a more rational use of medicines and advice them.

For generic substitution, which is allowed but not obligatory, pharmacists are granted a financial incentive. When dispensing a generic, they receive the same amount of money as remuneration as they would get for the original product.

Information campaigns targeted at the general public are regularly organised by the French Social Health Insurance.

## **Italy**

Since 2000 the Italian Medicines Agency AIFA has been operating a “National Observatory on the Use of Medicines” (Osservatorio nazionale sull’impiego dei medicinali, OSMED) which monitors and analyses pharmaceutical consumption (e.g. impact of policy measures, comparison to other countries) on a monthly basis. Additionally, yearly reports on pharmaceutical consumption and expenditure are published. At regular intervals, AIFA runs information campaigns targeted at the general public (e.g. a campaign on the rational use of antibiotics and another for promoting generics).

INN prescribing is indicative for the doctors and generic substitution is allowed but not obligatory for the pharmacists.

Italy has launched a project to trace all medicines brought on the Italian market (Progetto Tracciabilità del Farmaco), which implied extensive preparatory work (legal framework, IT tools).

### **The Netherlands**

Elements to promote competition characterise the Dutch pharmaceutical system. An example of such a competitive approach is the “generic preferential policy” allowing social health insurance institutions to limit reimbursement to lower priced labels of off-patent active ingredients. Under the “generic preferential policy”, the insurance institutions tender for specific active ingredients where generic alternatives exist and they reimburse the medicine offering the lowest price.

Instruments to promote generics have been in place for a long time and are generally accepted. Generic substitution had been connected with a financial incentive for the pharmacists for many years (i.e. they could keep one third of the savings due to generic substitution), which was abolished in 2004. Nonetheless, the substitution rates have not decreased. INN prescribing is indicative, but supported by a prescribing software which automatically changes the brand name into the INN.

## Summary of the key results

A number of instruments to promote the rational use of medicines is targeted at doctors:

- » In 23 of the 27 EU Member States the payers (social health insurance or national health service) have introduced prescription guidelines. In nine Member States these guidelines are obligatory.
- » In nearly all EU Member States the prescribing behaviour of doctors is observed by the payers. Still there is some differences among the countries how often and how institutionalised doctors get feedback and are asked to explain their prescribing behaviour.
- » Pharmaceutical budgets for doctors are rather uncommon. This approach is only applied in six of the 27 EU Member States. Only in Latvia and the Czech Republic budgets are linked to sanctions.

Generics are seen as important products in this context. Two key measures for promoting generic use are INN prescribing and generic substitution.

- » In case of INN prescribing doctors are encouraged to prescribe the international non-proprietary name instead of the brand name. This measure exists in 22 EU Member States, in four countries (Estonia, Lithuania, Portugal and Romania) INN prescribing is mandatory.
- » In 21 EU Member States pharmacists may substitute an equivalent cheaper product (e.g. a generic or a parallel imported product) for a prescribed medicine (in general an original product). In six countries (Denmark, Germany, Finland, Malta, Sweden and Slovakia) the pharmacists are obliged to apply generic substitution – unless the patient or the doctor opposes substitution, the latter only being possible under clearly defined conditions.

Five countries, which were analysed in detail, show the following interesting models and developments for promoting a rational use of medicines:

- » Denmark: Denmark is characterised by a very transparent system, where the Danish Medicines Agency provides a lot of information to various actors (doctors, pharmacists, patients). The electronic monitoring system (Odriprax) operated by the Danish Medicines Agency allows the authorities to monitor pharmaceutical expenditure as well as doctors to compare their prescribing behaviour to other doctors in the same region. Patients whose co-payments are linked to their pharmaceutical spending (the higher expenditure within a year, the lower the co-payments) have the opportunity to access information on their spending on medicines.

- » France: The Social Health Insurance concludes agreements with doctors (e.g. to prescribe rationally) and with pharmacists (e.g. to reach a certain generic substitution target). Doctors are visited by representatives of the Social Health Insurance who discuss with them about rational therapy. Furthermore, the Social Health Insurance organises information activities targeted at patients.
- » Germany: Germany was the first country in Europe to establish a reference price system (1989). Additionally, obligatory generic substitution („Aut-idem-Regelung“) and practice-specific prescription volume target agreements are applied. Pharmaceutical expenditure and consumption are monitored by a scientific institute of a sickness fund, and an analysis of the development of publicly funded pharmaceutical expenditure and consumption is published in a well-known monitoring report („Arzneiverordnungs-Report“) each year.
- » Italy: The Medicines Agency AIFA has established an observatory which monitors and analyses pharmaceutical consumption and makes the information publicly accessible (e.g. annual reports). This task is accompanied by further information activities of the Medicines Agency (e.g. campaigns targeted at the general public to promote generics). Furthermore, Italy runs a project to trace all medicines brought on the Italian market.
- » The Netherlands: Elements to promote competition characterise the Dutch pharmaceutical reimbursement system. For instance, social insurance institutions apply a “generic preferential policy“, which is based on a tendering model where only the best offers are reimbursed. Instruments to promote the prescription of generics (e.g. INN prescribing – supported by a prescription software) have been implemented for a long time and are generally accepted. Even after a financial incentive for generic substitution had been abolished, substitution rates continued to stay at a high level.

# Web links

## Denmark

Danish Medicines Agency: [www.dkma.dk](http://www.dkma.dk)

Institute for Rational Pharmacotherapy: [www.irf.dk](http://www.irf.dk)

## Germany

Scientific institute of the German sickness fund AOK (WIdO):  
[www.wido.de/arzneimittel.html](http://www.wido.de/arzneimittel.html)

## France

French Medicines Agency: [www.afssaps.fr](http://www.afssaps.fr)

National Social Health Insurance institutions: [www.ameli.fr](http://www.ameli.fr)

Reports of the French Medicines Agency of analyses of specific pharmaceutical groups:  
[www.afssaps.fr/Afssaps-media/Publications/Rapports-et-syntheses](http://www.afssaps.fr/Afssaps-media/Publications/Rapports-et-syntheses)

## Italy

Italian Medicines Agency: [www.agenziafarmaco.it/](http://www.agenziafarmaco.it/)

National Observatory for the Use of Medicines:  
[www.agenziafarmaco.it/ATTIVITA\\_EDITORIALE/gotopage\\_section318e.html?target=%A7ion\\_code=AIFA\\_PUB\\_RAP\\_OSMED](http://www.agenziafarmaco.it/ATTIVITA_EDITORIALE/gotopage_section318e.html?target=%A7ion_code=AIFA_PUB_RAP_OSMED)

Annual report about the use of medicines in Italy:  
[www.agenziafarmaco.it/ATTIVITA\\_EDITORIALE/gotopage\\_section318e.html?target=%A7ion\\_code=AIFA\\_PUB\\_RAP\\_OSMED](http://www.agenziafarmaco.it/ATTIVITA_EDITORIALE/gotopage_section318e.html?target=%A7ion_code=AIFA_PUB_RAP_OSMED)

National guideline programme: [www.pnlq.it](http://www.pnlq.it)

Project for the traceability of medicines:  
[www.ministerosalute.it/tracciabilita/tracciabilita.jsp](http://www.ministerosalute.it/tracciabilita/tracciabilita.jsp)

## Netherlands

Foundation for Pharmaceutical Statistics: [www.sfk.nl](http://www.sfk.nl)

Information website for patients about pharmaceutical prices:  
[www.medicijnkosten.nl](http://www.medicijnkosten.nl)

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ÖBIG (2006a): Nahtstellenmanagement bei Arzneimitteln. Österreich und Niederlande im Vergleich. Commissioned by the Federal Ministry of Health and Women. Vienna

ÖBIG (2006b): Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States. Commissioned by DG Competition. Luxembourg

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Downloads: [www.goeg.at](http://www.goeg.at)

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## **PHIS Hospital Pharma Reports (Eng.)**

Country reports on 7 EU Member States  
(as of February 2010)  
Commissioned by the Federal Ministry of  
Health  
GÖG/ÖBIG, Vienna 2009/2010  
Download: <http://phis.goeg.at>

## **Arzneimittelsystem Kroatien – Factsheet (Ger.)**

Commissioned by the Federal Ministry of  
Health  
8 p.  
GÖG/ÖBIG, Vienna 2009  
Download:  
<http://www.goeg.at/de/BerichtDetail/Arzneimittelsystem-Kroatien-2009.html>

## **Access to essential medicines in Poland (Eng. & Pol.)**

Commissioned by Health Action Interna-  
tional Europe  
~ 30 p., 1 fig., 5 tab.  
ÖBIG FP, Vienna 2009

## **Access to essential medicines in Portugal (Eng. & Port.)**

Commissioned by Health Action Interna-  
tional Europe  
~ 30 p., 5 tab.  
ÖBIG FP, Vienna 2009

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Commissioned by the Federal Ministry of  
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~ 35 p., 21 fig., 2 tab.  
GÖG/ÖBIG, Vienna 2008

## **PPRI Report (English)**

Commissioned by the European Commis-  
sion, Directorate-General Health and  
Consumer Protection and Austrian Federal  
Ministry of Health, Family and Youth  
180 p., 23 fig., 28 tab.  
GÖG/ÖBIG, Vienna 2008  
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Printable version: € 50.–  
Executive Summary (in German ~15 p.)  
available from <http://ppri.goeg.at>

## **PPRI Pharma Profile Austria 2008 (Eng. & Ger.)**

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95 p., 6 fig., 24 tab.  
GÖG/ÖBIG, Vienna 2008  
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**Arzneimittelsysteme in Bulgarien und Rumänien (Ger.)**  
Commissioned by the Federal Ministry of Health, Family and Youth  
80 p., 2 fig., 24 tab.  
GÖG/ÖBIG, Vienna 2008

**Pharmaceutical systems in the European Union 2006. Fact sheets (Eng.)**  
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Commissioned by PGEU (Pharmaceutical Group of the European Union)  
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ÖBIG, Vienna 2006  
Download:  
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ÖBIG, Brussels 2006

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Commissioned by the Main Association of Austrian Social Security Institutions  
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GÖG/ÖBIG, Vienna 2008  
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GÖG/ÖBIG, Vienna 2006  
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**Nahtstellenmanagement bei Arzneimitteln (Ger.)**  
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~ 80 p., 5 fig., 8 tab.  
ÖBIG, Vienna 2006  
Printable version: € 25.–

**Arzneimittel in den neuen EU-Mitgliedstaaten (Ger. & Eng.)**  
Commissioned by the BMGF and the Main Association of Austrian Social Security Institutions  
~ 175 p. (Ger.); ~ 100 p. (Eng.)  
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ÖBIG, Vienna 2005  
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**Öffentliche Ausgaben für Prävention und Gesundheitsförderung in Österreich 2001 (Ger.)**

Expert version. Commissioned by the Federal Ministry of Health and Women  
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ÖBIG, Vienna 2005  
Printable version: € 45.–

**Internationale Arzneimittelpreisvergleiche – Meta-Analyse (Ger.)**

Commissioned by Pharmig  
35 p., 5 tab., 27 fig.  
ÖBIG, Vienna 2004  
Printable version: € 25.–

**Screening aus ökonomischer Perspektive – Dickdarmkarzinom (Ger.)**

Commissioned by Siemens Austria  
~ 25 p., 5 tab., 1 fig.  
ÖBIG, Vienna 2004  
Printable version: € 20.–

**Impfungen. Ökonomische Evaluation (Ger.)**

Commissioned by the Federal Ministry of Health and Women  
~ 100 p. 9 tab., 9 fig.  
ÖBIG, Vienna 2003  
Printable version: € 29.–

**Arzneimittel. Distribution in Skandinavien (Ger.)**

Commissioned by the Federal Ministry of Social Security and Generations  
132 p., 34 tab., 13 fig.  
ÖBIG, Vienna 2003  
Printable version: € 45.–

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Commissioned by the Federal Ministry of Social Security and Generations  
50 p., 11 tab.  
ÖBIG, Vienna 2003  
Printable version: € 28.–

**Selbstbeteiligung – Internationaler Vergleich und Implikation für Österreich (Ger.)**

Commissioned by the Federal Ministry of Social Security and Generations  
~ 200 p., 52 tab., 73 fig.  
ÖBIG, Vienna 2003  
Printable version: € 30.–

**Arzneimittelausgaben – Strategien zur Kostendämpfung – Länderportraits (Ger.)**

Commissioned by the Federal Ministry of Social Security and Generations  
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