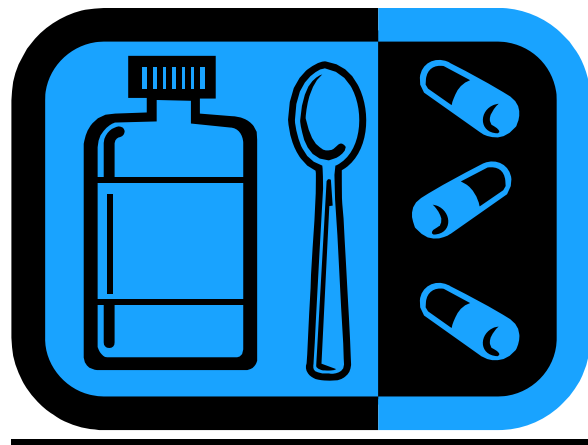


# AUSTRIA



## PHARMACEUTICAL COUNTRY PROFILE



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## Foreword

This 2010 Pharmaceutical Country Profile for Austria has been produced by the Austrian Federal Ministry of Health with support of the World Health Organization.

This document contains information on structures, process and outcomes of the pharmaceutical sector in Austria. Some of the data comes from global sources (e.g. the World Health Statistics) or from surveys conducted in the previous years, while other pieces of information have been collected at country level in 2010. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On behalf of the Federal Ministry of Health of Austria, I wish to express my appreciation towards Dr Sabine Vogler from Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute for her contribution to the data collection and to the development of this profile and Ms Christine Leopold for her support in the data collection. Additional thanks are expressed to the following organizations and institutions for providing data and information: Austrian Federal Ministry of Health, Austrian Federal Ministry of Finance, Austrian Medicines Agency (AGES), Main Association of Austrian Social Security Institutions, Austrian Chamber of Pharmacists, Austrian Association of Pharmaceutical Manufacturers.

It is my hope that partners, researchers and all those that are interested in the pharmaceutical sector of Austria will find this profile a useful tool in their activities.



Name: Dr. Clemens Martin AUER

Function in the Ministry of Health: Director General

Date: 23. September 2010

Signature:

A handwritten signature in blue ink, appearing to be 'CMA', written over a light blue horizontal line.

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## Introduction

This Pharmaceutical Country Profile provides data on structures, processes and outcomes of the pharmaceutical sector of Austria. The aim is to put together existing information and to make all relevant information on the pharmaceutical sector available to the public in a user-friendly format. In 2010, country profiles similar to this one have been developed for 13 pilot countries. During 2011, the World Health Organization plans to support all WHO Member States to develop similar country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Regulation, (5) Medicines Financing, (6) Supply of Pharmaceuticals, (7) Rational Use of Medicines, and (8) Household Surveys. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). The narrative profile is based only on the core indicators; while the tables in the annexes present all indicators. For each piece of information, we have tried to indicate the year and source of the data; these are used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links are provided to the source documents so that the user can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Health Institute (GÖG) and representatives from 13 pilot countries. Data collection in the pilot countries was conducted using a user-friendly electronic questionnaire that included a comprehensive glossary. Countries were requested not to conduct any additional surveys, but

only to enter the results from previous surveys and to provide information available at the central level. To facilitate the work of national counterparts, the questionnaires were pre-filled using all data available at WHO HQ before being sent out to countries. A coordinator was nominated for each of the 13 pilot countries. The coordinator for Austria was Dr Sabine Vogler.

The completed questionnaires were then used to produce the country profiles. In order to do this in a structured and efficient manner, a text template was developed. Member states took part in the development of the profile and, once the final product was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the web site of WHO.

This profile will be regularly updated by country teams. If you have any suggestions on corrections to make please send them to Dr Sabine Vogler, [sabine.vogler@goeg.at](mailto:sabine.vogler@goeg.at), Gesundheit Österreich GmbH (GÖG), Stubenring 6, 1010 Vienna.

## Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Austria.

### 1.1 Demographics and Socioeconomic Indicators

The total population of Austria in 2008 was 8,355,000 with an annual population growth rate of 0.4 %. The annual GDP growth rate is 2%. The GNI per capita is € 27,398 [\[1\]](#).

### 1.2 Mortality and Causes of Death

The life expectancy at birth for men is 77.6 years and for women is 83 years. The infant mortality rate is 5.4/1,000 live births. For children under the age of 5, the mortality rate is 4/1,000 live births. The maternal mortality rate is 4/100,000 live births.

The top 10 diseases causing mortality in Austria are:

1. Diseases of the circulatory system
2. Neoplasm's
3. Endocrine, nutritional and metabolic diseases
4. Injury, poisoning and certain other consequences of external causes
5. Diseases of the respiratory system
6. Diseases of the digestive system
7. Diseases of the nervous system
8. Diseases of the genitourinary system
9. Mental and behavioral disorders
10. Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

The top 10 diseases causing morbidity in Austria are:

1. Injury, poisoning and certain other consequences of external causes
2. Diseases of the musculoskeletal system and connective tissue
3. Diseases of the circulatory system
4. Diseases of the digestive system
5. Neoplasm's
6. Diseases of the genitourinary system
7. Diseases of the respiratory system
8. Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
9. Pregnancy, childbirth and the puerperium
10. Diseases of the nervous system [\[1\]](#) [\[2\]](#)



## Section 2 - Health Services

This section provides information regarding health expenditure and human resources in Austria. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

### 2.1 Health Expenditures

In Austria, the total annual expenditure on health (THE) in 2008 was EURO 28,587 million (US\$ 42,122 million)<sup>1</sup>. The total health expenditure is 10.1 % of the GDP. The total annual expenditure on health per capita was EURO 3,419 (US\$ 5,038).

The government expenditure<sup>2</sup> on health accounts for 76.6% of the total expenditure on health, with a total per capita public expenditure on health of EURO 2,618 (US\$ 3,857). The government annual expenditure on health represents 15.9% of the total government budget.

The private health expenditure covers the remaining 23.4% of the total health expenditure [3].

98.8% of the population is covered by health insurance; and 33.7% of the population are covered by a private health insurance scheme [4] [5].

The total pharmaceutical expenditure (TPE) in Austria in 2007 was EURO 3,648 million (US\$ 4,997 million). The total pharmaceutical expenditure per capita was EURO 439 (US\$ 601). The pharmaceutical expenditure accounts for 1.35 % of the GDP and makes up 13.29 % of the total health expenditure (Figure 1).

Public expenditure on pharmaceuticals represents 65.35 % of the total expenditure on pharmaceuticals (Figure 2). The total public expenditure on pharmaceuticals per capita in 2007 was EURO 287 (US\$ 393).

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<sup>1</sup> According to NHA definition

<sup>2</sup> According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, insurance funds and parastatal companies.

FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure in 2007

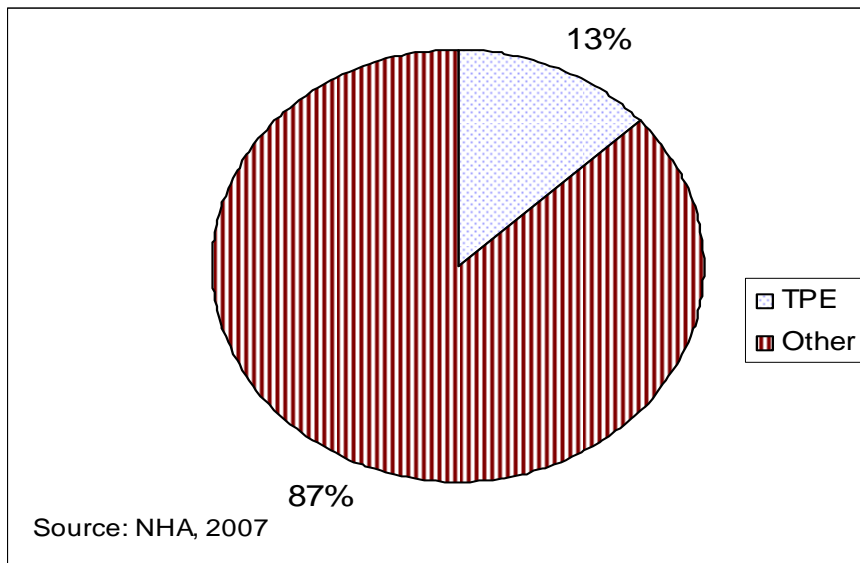
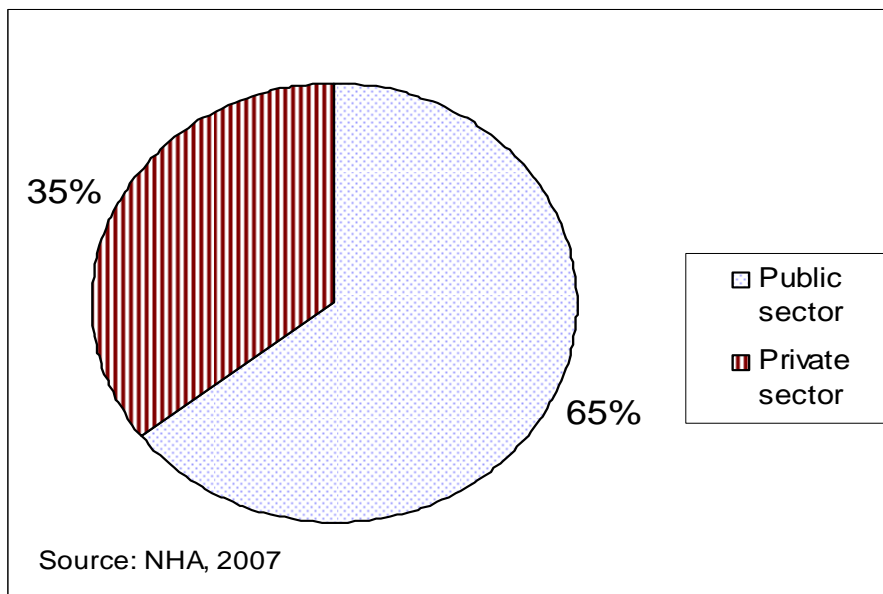


FIGURE 2: Share of public and private sector to Total Pharmaceutical Expenditure in 2007



The total private expenditure on pharmaceuticals in 2007 was EURO 1,264 million (US\$ 1,732) [3]. In 2007-2008, the annual growth rate of the total pharmaceuticals market value was 7.5 % [7]. The market share of generic pharmaceuticals [branded and INN] by value in 2007 was 11 % [6].

## 2.2 Health Personnel

The health workforce is described in the table below and in Figures 3 and 4. In Austria, hospital pharmacies are considered as the public sector and community pharmacies as the private sector.

Licensed pharmacists (working in community and hospital pharmacies) <sup>3</sup>	6.37/10,000 inhabitants
Pharmacists in the public sector (only hospital pharmacies)	0.34/10,000 inhabitants
Pharmaceutical technicians and assistants (all sectors)	5.15/10,000 [8]
Physicians (all sectors)	50/10,000 [9]
Nursing and midwifery personnel (all sectors)	36.4/10,000 [10]

Figure 3: The density of the Health Workforce 2008 in Austria

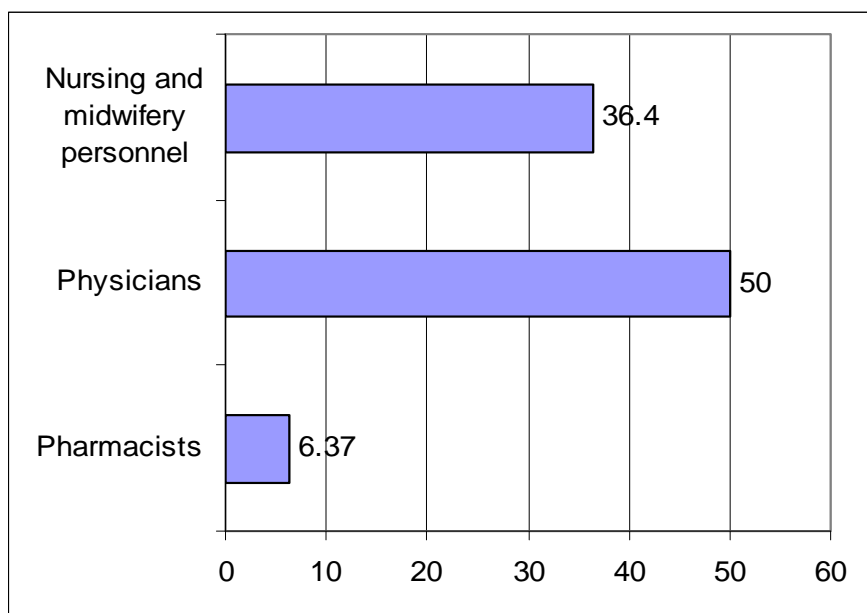
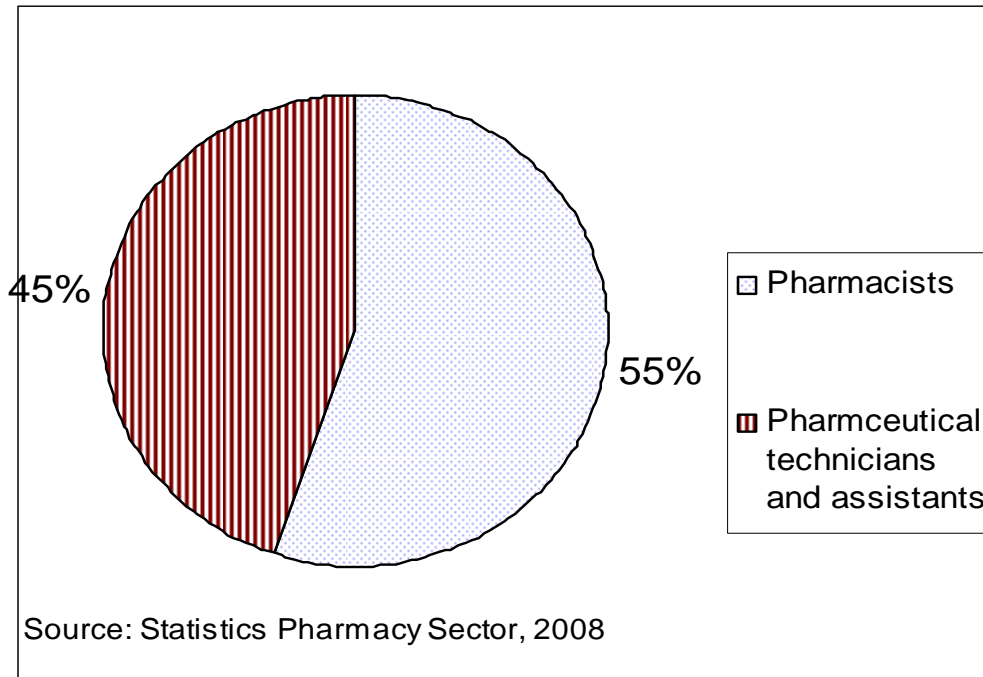


Figure 4: Distribution of Pharmaceutical Personnel, Austria, 2008

<sup>3</sup> In addition, there are 950 self-dispensing doctors in Austria who are allowed to dispense prescription-only medicines and OTC products to patients.



### 2.3 Health Infrastructure

The health centre and hospital statistics are described in the table below.

Hospitals	0.32/10,000 <a href="#">[11]</a>
Hospital beds	76/10,000 <a href="#">[2]</a>
Licensed pharmacies <sup>1</sup>	4.2/10,000 <a href="#">[8]</a>

<sup>1</sup> This statistics does not refer to licensed pharmacies only, but to prescription-only medicines (POM) dispensaries in total. It is based on 2,261 POM dispensaries, consisting of 1,311 pharmacies (1,252 community pharmacies, 23 branch pharmacies and 46 hospital pharmacies - thereof 5 operate parallel a community pharmacy) and 950 self-dispensing doctors.

## Section 3 - Policy Issues

This section addresses the main structure of the pharmaceutical policy in Austria. Information about the capacity for manufacturing medicines and regulations regarding patents is also provided.

### 3.1 Policy Framework

In Austria, a National Health Policy (NHP) exists, in a way that there is a group of health regulations which are regularly updated. Its pieces are regularly updated. The different laws, decrees and further pieces of medicines regulations can be understood the official National Medicines Policy. The pharmaceutical regulatory framework is regularly updated. The pharmaceutical regulatory framework [\[12-29\]](#), which is harmonised to European legislation [\[30\]](#), covers:

Selection of essential medicines	<u>Yes</u>
Medicines financing	<u>Yes</u>
Medicines pricing	<u>Yes</u>
Procurement	<u>Yes</u>
Distribution	<u>Yes</u>
Regulation	<u>Yes</u>
Pharmacovigilance,	<u>Yes</u>
Rational use of medicines	<u>Yes</u>
Human resource development	<u>Yes</u>
Research	<u>Yes</u>
Monitoring and evaluation	<u>Yes</u>
Traditional Medicine	<u>No</u>

Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in national legislation. There are official written guidelines on medicines donations. The implementation of the pharmaceutical policy is being regularly monitored by the Ministry of Health.

There is multisectoral national good governance policy in Austria and a good governance policy for the pharmaceutical sector.

A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is a formal code of conduct for public officials. There is a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of Austria. Patients may address their concerns to the ombudsman, but also to the Chamber of Labour either in written form or via phone [10] [21].

### 3.2 Intellectual Property Laws and Medicines

Austria is a member of the World Trade Organization [31]. The country has patent law and the National Legislation has been modified to implement the TRIPS Agreement [25].

Austria is not eligible for the transitional period to 2016.

The following (TRIPS) flexibilities and safeguards are present in the national law:

Compulsory licensing provisions that can be applied for reasons of public health	<b>No</b>
Bolar exceptions	<b>No</b>
Parallel importing provisions	<b>No</b>

The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health. There are legal provisions for data exclusivity for pharmaceuticals. Legal provisions exist for patent extension. Laws exist for linkage between patent status and marketing authorization [25].

Beside national regulations, the patent situation in Europe is to some extent harmonized in the European Union, with European Medicines Agency and the European Patent Office being responsible, e.g. Directive 2001/83/EC [30:1] regulates data exclusivity within the European Union.

### 3.3 Manufacturing

There are 220 licensed pharmaceutical manufacturers in Austria. Austria has the capacity for:

The Research and Development for discovering new active substances	<u>Yes</u>
The production of pharmaceutical starting materials (APIs)	<u>Yes</u>
The production of formulations from pharmaceutical starting material	<u>Yes</u>
The repackaging of finished dosage form	<u>Yes</u>

[32].

## Section 4 - Regulation

This section covers a broad range of pharmaceutical regulatory policies, institutions and practices in Austria.

### 4.1 Regulatory Framework

In Austria, there are legal provisions establishing the powers and responsibilities of the medicines regulatory authorities (MRA). The MRA is a semi-autonomous agency [12]. The MRA has its own website. The URL address is <http://www.basg.at/bundesamt-fuer-sicherheit-im-gesundheitswesen-basg/> (Austrian Federal Agency for Safety in Health Care). The MRA is involved in harmonization/collaboration initiatives. These include working groups of the [European Medicines Agency](#) where there is collaboration with other MRA within the EU. An assessment of the medicines regulatory system has been conducted in the last five years. In 2006 the institute was outsourced by the Ministry of Health. In the course of this process an assessment has been conducted [33].

### 4.2 Marketing Authorization

In Austria, there are legal provisions requiring a marketing authorization (registration) for all pharmaceutical products on the market. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. In 2010, the number of pharmaceutical products registered in Austria was 13,168. This is counted including different pharmaceutical forms and dosages, excluding different pack sizes, and it includes homeopathic products. Legal provisions require the MRA to make the list of registered pharmaceutical products publicly available regularly. This register is updated continuously and it can be accessed through [http://pharmaweb.ages.at/pharma\\_web/index.jsf](http://pharmaweb.ages.at/pharma_web/index.jsf). Medicines are registered by their Brand name, supplementary information on INN (International Non-proprietary Names) is available [12; § 27] [33]. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications [27].

Please note the in the European Union marketing authorisation is harmonised. National marketing authorization has been playing a minor role since harmonization.



### 4.3 Regulatory Inspection

In Austria, there are legal provisions allowing for appointment of government pharmaceutical inspectors [12; § 28]. The Regulatory Authority has inspectors [33]. There are legal provisions permitting inspectors to inspect premises where pharmaceutical activities are performed [34] and requiring inspections to be performed. Inspection is a pre-requisite for licensing facilities. Inspection requirements are the same for public and private facilities [12; § 28].

### 4.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing.

There are legal provisions requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at the authorized port of entry [12; § 10c] [26].

### 4.5 Licensing

In Austria, there are legal provisions requiring manufacturers to be licensed and requiring manufacturers to comply with Good Manufacturing Practices (GMP) [12; § 62-71]. Good Manufacturing Practices are published by the government [33].

There are legal provisions requiring importers, wholesalers and distributors to be licensed and requiring wholesalers and distributors to comply with Good Distributing Practices. These are published by the government [12; § 62-71].

Legal provisions exist requiring pharmacists to be registered. Legal provisions exist requiring all pharmacies to be licensed [12].

National Good Pharmacy Practice Guidelines are published by the government [28].

### 4.6 Market Control and Quality Control

In Austria, there are legal provisions for controlling the pharmaceutical market [12]. A laboratory exists in Austria for Quality Control testing. The testing of medicines is done at the Austrian Official Medicine Control Laboratory (OMCL).

Samples are collected by government inspectors for undertaking post-marketing surveillance testing. In the past 2 years, 33 samples were taken for quality control

testing and 3 of them failed to meet the quality standards. The results are publicly available [\[33\]](#).

#### 4.7 Medicines Advertising and Promotion

In Austria, there are legal provisions to control the promotion and/or advertising of prescription medicines. The Austrian Federal Ministry of Health is responsible for regulating promotion and/or advertising of medicines. There are legal provisions prohibiting direct advertising of prescription medicines to the public and requiring a pre-approval for medicines advertisements and promotional materials. Legal provisions exist for advertising and promotion of non-prescription medicines [\[12; § 50 ff\]](#). A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders. The code of conduct applies to domestic manufacturers and multinational manufacturers. Adherence to it is voluntary. The code does not contain a formal process for complaints and sanctions. A list of the complaints and sanctions for the last two years is not publicly available [\[35\]](#).

#### 4.8 Clinical Trials

In Austria, there are legal provisions requiring authorization for conducting Clinical Trials by the MRA. Laws require the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed. Registration of the clinical trials into national registry is required by law [\[12; § 40\]](#).

#### 4.9 Controlled Medicines

Austria is signatory to the:

- Single Convention on Narcotic Drugs, 1961
- 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961
- Convention on Psychotropic Substances 1971
- United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 [\[36\]](#)

There are laws for the control of narcotic and psychotropic substances, and precursors [\[29\]](#). The annual consumption of Morphine is 152.36 mg/capita [\[36\]](#).

#### 4.10 Pharmacovigilance

In Austria, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws about monitoring Adverse Drug Reactions (ADR) exist in Austria [12; § 75]. A national Pharmacovigilance centre linked to the MRA exists in Austria. The Pharmacovigilance centre has 16 full-time staff members. It has published at least one analysis report in the previous two years and it publishes an ADR bulletin regularly. An official standardized form for reporting ADRs is used in Austria. A national ADR database exists in Austria. In the past 2 years, no ADR reports are sent to the WHO database in Uppsala [33].

## Section 5 - Medicines Financing

In this section, information is provided on the structure of user fees for medicines and on the existence of public programmes providing free medicines. Policies and regulations in place that affect the prices of medicines (e.g. price control and taxes) are presented.

### 5.1 Medicines Coverage and Exemptions

In Austria 99% of the population is covered by social health insurance, granting access to reimbursable medicines to all patients covered, and in particular to:

Patients who cannot afford them	<u>Yes</u>
Children under 5	<u>Yes</u>
Pregnant women	<u>Yes</u>
Elderly persons	<u>Yes</u>

[13].

As such, free medicines are provided for:

All diseases	<u>Yes</u>
Any non-communicable diseases	<u>Yes</u>
Malaria	<u>Yes</u>
Tuberculosis	<u>Yes</u>
Sexually transmitted diseases	<u>Yes</u>
HIV/AIDS	<u>Yes</u>
EPI Vaccines for children (expanded programme of immunization)	<u>Yes</u>

[13].

People covered by social health insurance have access to reimbursable medicines i.e. medicines included on the positive list (Erstattungskodex). The medicines are 100% publicly funded (apart from a prescription fee). Medicines that are included in the reimbursement system have to be prescribed by a doctor or in some cases need to have a special permission by a 'chief physician' for approval.

In hospitals patients receive medicines cost-free. In the out-patient sector reimbursable medicines are 100% paid by Social Health Insurance, but there is a modest prescription fee to be paid [\[6\]](#) [\[10\]](#) [\[11\]](#).

## 5.2 Patients Fees and Copayments

In the health system of Austria, at the point of delivery, there are copayments-for consultations and medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility. In the out-patient sector, there is a flat prescription fee per product on the prescription form (€5 in 2010, annually adjusted to the inflation rate). There is also an annual fee for an E-card which is used as an electronic health insurance voucher [\[6\]](#) [\[10\]](#) [\[11\]](#).

## 5.3 Pricing Regulation for the Private Sector

In Austria, there are legal regulatory provisions affecting pricing of medicines [\[13\]](#) [\[15\]](#). These provisions are aimed at the level of manufacturers [\[13; § 351\]](#), wholesalers [\[17;\]](#) and retailers [\[14; § 3\]](#). Statutory pricing for reimbursable medicines at ex-factory price level are based on EU average price followed by price negotiations with Social Health Insurance. Wholesale and pharmacy mark-ups are regulated on a statutory basis. The government runs an active national medicines price monitoring system for prices. Regulations (exist mandating that retail medicine price information should be publicly accessible. The prices of reimbursable medicines are published in the reimbursement code in paper format and electronically [\[6\]](#).

## 5.4 Duties and Taxes on Pharmaceuticals (Market)

There is a value-added tax of 10% on all medicines. Until the beginning of 2009, the VAT on medicines amounted to 20%, which is the same as the standard VAT [\[6\]](#). There are no duties on API/ imported pharmaceuticals.

## Section 6 - Pharmaceutical procurement and distribution in the public sector

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Austria.

### 6.1 Public Sector Procurement

The public sector procurement in Austria is centralized and decentralized. It is centralized under the responsibility of a government agency that procures all public goods. Individual hospitals or hospital associations conduct their own procurement. While procurement plays an important role in the hospital scenery (mainly direct purchasing rather than tendering), it has a minor role in the out-patient sector (e.g. vaccines, medicines used in pandemic plans). The public sector tender bids are publicly available and public sector awards are publicly available. Procurements are based on prequalification of suppliers. The Law on Procurement defines the legal framework and criteria [\[37\]](#).

### 6.2 Public Sector Distribution

The government supply system department in Austria does not have a Central Medical Store at a National Level [\[11\]](#). There are national guidelines on Good Distribution Practices (GDP). There is a licensing authority that issues GDP licenses [\[12; § 57 ff\]](#).

### 6.3 Private Sector Distribution

There are legal provisions for licensing wholesalers and distributors in the private sector of Austria. A list of GDP certified distributors exists in the private sector [\[12\]](#). The pharmaceutical concept is implemented in Austrian pharmacies [\[37\]](#).

## Section 7 - Selection and rational use of medicines

This section presents the structures and policies that are in place in Austria for selection of essential medicines and promotion of rational drug use.

### 7.1 National Structures

National Standard Treatment Guidelines (STGs) for the most common illnesses have been produced/endorsed by the MoH in Austria. The national STGs have been updated in 2010. They cover major areas of primary care, secondary care and paediatric conditions. A National Essential Medicines List (EML) represent in Austria, and it is publicly available. The EML is actually the positive list for reimbursement under the Social Health Insurance (EKO). There are 6,000 medicines on the list, counted in different pharmaceutical forms and dosages. There is a well-defined process based on written rules for selecting medicines on the EML. All doctors have access to the positive list, either in a hardcopy or online version [\[39-41\]](#).

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers. Public education campaigns on rational medicine use topics have been conducted in the last two years. A survey on instruments of rational use of medicines has been conducted in the previous two years [\[42\]](#). There is a national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines [\[10\]](#) [\[13\]](#) [\[39-41\]](#).

## 7.2 Prescribing

In Austria, there are legal provisions to govern the licensing and prescribing practices of prescribers [12] [39]. Legal provisions exist to restrict dispensing by prescribers [12; 6]. Though, under specific criteria prescribers are allowed to act as dispensing doctors. Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs) [20].

The core medical training curriculum includes components on

The concept of EML	<b>No</b>
Use of STGS	<b>Yes</b>
Pharmacovigilance	<b>Yes</b>
Problem based pharmacotherapy	<b>Yes</b>

Mandatory continuing education that includes pharmaceutical issues is required for doctors [6] [10] [11].

The average number of medicines prescribed per patient contact in public health facilities is 13.95. De facto all medicines prescribed to outpatients in public health care facilities are on the national positive list. Under specific circumstances non-reimbursable medicines may be prescribed and reimbursed (individual applications). All (100%) medicines dispensed in public health facilities are adequately labelled [4].



### 7.3 Dispensing

In Austria, there are legal provisions to govern dispensing practices of pharmaceutical personnel. The core pharmacist training curriculum includes components on:

The concept of EML	<u>Yes</u>
Use of STGs	<u>Yes</u>
Drug information	<u>Yes</u>
Clinical Pharmacy	<u>Yes</u>
Medicine Supply Management	<u>Yes</u>

Mandatory continuing education that includes pharmaceutical issues is required for pharmacists [8].

Substitution of generic equivalents at the point of dispensing is not allowed. Antibiotics are not sold over-the-counter without a prescription. Injectable medicines are not sold over-the-counter without a prescription [6] [10].

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- 1 Directive 2001/83/EC
- 2 Directive 2004/18/EC

- 3 COMMISSION REGULATION (EC) No 1277/2005
- 4 Directive 2004/726/EC
- 5 Directive 2005/36/EC
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# **Austria Pharmaceutical Country Profile**

## **ANNEX**

### **Survey Data**

Respondents to the questionnaire:

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<b>Section 1 Health and Demographic data</b>			
<b>1.01 Demographic and Socioeconomic Indicators</b>			
<b>Core Questions</b>			
Population, total (,000)	8,355	2008	Statistics Austria
Population growth rate (Annual %)	0.4	2008	Statistics Austria
GDP growth (Annual %)	2	2008	Statistics Austria
GNI per capita (US\$ current exchange rate)	€ 273.98	2009	Statistics Austria
Comments			
<b>Supplementary questions</b>			
Population < 15 years (% of total population)	15	2008	Statistics Austria
Population > 60 years (% of total population)	22.8	2007	Statistics Austria
Urban population (% of total population)	67	2007	World Health Statistics
Fertility rate, total (Births per woman)	1.4	2007	World Health Statistics
Population living below nationally defined poverty line (%)	12.4	2008	Statistics Austria
Income share held by lowest 20% of the population (% of national income)	10	2008	Statistics Austria
Comments	In 2008 12.4% of the population was considered at risk of poverty (=population living below an at-risk-of-poverty threshold of 60% of the median='poverty line'). Projected to the Austrian population as a whole the figure – with a 95% reliability probability - is between 11.2% and 12.9%, i.e. between 917,000, and 1,060,000 Austrians can be considered as being at risk of poverty.		
<b>1.02 Mortality and Causes of Death</b>			
<b>Core questions</b>			
Life expectancy at birth for men (Years)	77.6	2008	Statistics Austria
Life expectancy at birth for women (Years)	83	2008	WHS
Infant mortality rate, between birth and age 1 (/1,000 live births)	5.4	2008	Statistics Austria
Under 5 mortality rate (/1,000 live births)	4	2007	WHS
Maternal mortality ratio (/100,000 live births)	4	2005	WHS

Please provide a list of top 10 diseases causing mortality	I00-I99, C00-D48, E00-E90, S00-T98, J00-J99, K00-K93, G00-G99, N00-N99, F00-F99, R00-R99	2008	Statistics Austria
Please provide a list of top 10 diseases causing morbidity	S00-T98, M00-M99, I00-I99, K00-K93, C00-D48, N00-N99, J00-J99, R00-R99, O00-O99, G00-G99.	2008	Statistics Austria
<b>Supplementary questions</b>			
Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	78	2007	WHS
Neonatal mortality rate (/1,000 live births)	2.7	2008	Statistics Austria
Age-standardized mortality rate by non-communicable diseases ( /100,000 population)	409	2004	WHS
Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	77.15	2008	Statistics Austria
Age-standardized mortality rate by cancer ( /100,000 population)	475.7	2008	Statistics Austria
Mortality rate for HIV/AIDS (/100,000 population)	1.1	2008	Statistics Austria
Mortality rate for tuberculosis (/100,000 population)	1.2	2008	Statistics Austria
Comments	Mortality rate for Malaria is not monitored in the Austrian health statistics.		

## Section 2 Health Services

### 2.01 Health Expenditures

#### Core Questions

Total annual expenditure on health (millions US\$ average exchange rate)	42,122	2008	Calculated for the NHA
Total annual expenditure on health (millions NCU)	28,587	2008	National Health Accounts
Total health expenditure as % of Gross Domestic Product	10.1	2008	NHA
Total annual expenditure on health per capita (US\$ average exchange rate)	5,038	2008	NHA
Total annual expenditure on health per capita (NCU)	3,419	2008	Calculated for the NHA
General government annual expenditure on health (millions US\$ average exchange rate)	32,248	2008	Calculated for the NHA
General government annual expenditure on health (millions NCU)	21,888	2008	NHA
Government annual expenditure on health as percentage of total government budget (% of total government budget)	15.9	2008	NHA
Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	76.6	2008	NHA
Annual per capita government expenditure on health (US\$ average exchange rate)	3,857	2008	NHA
Annual per capita government expenditure on health (NCU)	2,618	2008	Calculated for the NHA
Private health expenditure as % of total health expenditure (% of total expenditure on health)	23.4	2008	NHA
Population covered by a public health service or public health insurance or social insurance, or other sickness funds (% of total population)	98.8	2008	Statistic Book Social Health Insurance 2009
Population covered by private health insurance (% of total population)	33.7	2007	OECD
Total pharmaceutical expenditure (millions US\$ current exchange rate)	4,997	2007	Calculated for the NHA
Total pharmaceutical expenditure (millions NCU)	3,648	2007	NHA
Total pharmaceutical expenditure per capita (US\$ current exchange rate)	601	2007	Calculated for the NHA
Total pharmaceutical expenditure per capita (NCU)	439	2007	Calculated for the NHA

Pharmaceutical expenditure as a % of GDP (% of GDP)	1.35	2007	Calculated for the NHA
Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	13.29	2007	Calculated for the NHA
Total public expenditure on pharmaceuticals (millions US\$ current exchange rate)	3,265	2007	Calculated for the NHA
Total public expenditure on pharmaceuticals (millions NCU)	2,384	2007	NHA
Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	65.35	2007	Calculated for the NHA
Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)	393	2007	Calculated for the NHA
Total public expenditure on pharmaceuticals per capita (NCU)	287	2007	Calculated for the NHA
Total private expenditure on pharmaceuticals (million US\$ current exchange rate)	1,732	2007	Calculated for the NHA
Total private expenditure on pharmaceuticals (millions NCU)	1,264	2007	NHA
Market share of generic pharmaceuticals [branded and INN] by value (%)	11	2007	PPRI Pharma Profile Austria
Annual growth rate of total pharmaceuticals market value (%)	7.5%	2008/2007	AESGP
<b>Supplementary Questions</b>			
Social security expenditure as % of government expenditure on health (% of government expenditure on health)	58.6	2008	NHA
Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	65.2	2008	NHA
Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	19.3	2008	NHA

<b>2.02 Health Personnel and Infrastructure</b>			
<b>Core Questions</b>			
Total number of pharmacists licensed/registered to practice in your country	5,326 (total number of pharmacists working in Austria (=in community pharmacies /private sector + hospital/public). In addition, 950 self-dispensing doctors serve the Austrian patients.	2008	Statistics Pharmacy Sector 2010
Total number of pharmacists working in the public sector	280 (only hospital pharmacists)	2008	Statistics Pharmacy Sector 2010
Total number of pharmaceutical technicians and assistants	4,302	2008	Statistics Pharmacy Sector 2010
A strategic plan for pharmaceutical human resource development is in place in your country?	Unknown		
Total number of physicians	41,830	2008	Written communication by Austrian Doctors' Association
Total number of nursing and midwifery personnel	71,570	2008	Data by GÖG/ÖBIG
Total number of hospitals	266	2008	PHIS Hospital Pharma Report 2009
Total number of hospitals bed	63,544	2006	WHS
Total number of licensed pharmacies	2,261 dispensaries for prescription-only medicines, consisting of 1,311 pharmacies (1,252 community pharmacies, 23 branch pharmacies and 46 hospital pharmacies – thereof 5 operate parallel a community pharmacies) and 950 self-dispensing doctors	2009	Statistics Pharmacy Sector 2010
<b>Supplementary Questions</b>			
Starting annual salary for a newly registered pharmacist in the public	€ 45,780 (monthly €	2010	Written communication by Pharmacy

sector - NCU	3,270)		Association
Total number of pharmacists who graduated (first degree) in the past 2 years in your country	221	2008/09	Written communication by Pharmacy Association
Are there accreditation requirements for pharmacy schools?	Yes (they are specified by EU regulations according to the EU Directive 2005/36/EC)	2010	Written communication by Pharmacy Association
Is the Pharmacy Curriculum regularly reviewed?	Yes	2010	Written communication by Pharmacy Association

## Section 3 Policy issues

### 3.01 Policy Framework

#### Core Questions

National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes, not one document, but a regulatory framework	2010	Assessment by GÖG/ÖBIG
National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Not one document, but a regulatory framework with a range of regulations	2010	Assessment by GÖG/ÖBIG
Group of policies addressing pharmaceuticals exist.	Yes	2010	Assessment by GÖG/ÖBIG - see also uploaded documents
National Medicines Policy covers the following components:			
Selection of Essential Medicines	Yes		
Medicines Financing	Yes		
Medicines Pricing	Yes		
Medicines Procurement	Yes		
Medicines Distribution	Yes		
Medicines Regulation	Yes		
Pharmacovigilance	Yes		
Rational Use of Medicines	Yes		
Human Resource Development	Yes		
Research	Yes		
Monitoring and Evaluation	Yes		
Traditional Medicine	No		
National medicines policy implementation plan exists. If yes, please write year of the most recent document in the "year" field.	Unknown		
Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes	2010	Assessment by GÖG/ÖBIG
There are official written guidelines on medicines donations.	Yes	2010	Medicines Act
Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes	2010	Assessment by GÖG/ÖBIG
Who is responsible for pharmaceutical policy monitoring?	Ministry of Health		
Is there a national good governance policy?	Yes		
Multisectoral	Yes		

For the pharmaceutical sector	Yes		
Which agencies are responsible?	Not Applicable		
A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes		
There is a formal code of conduct for public officials.	Yes	2010	Civil Servant Law
Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsman)?	Yes	2010	GÖG/ÖBIG
Please describe:	Patients may address their concerns to the ombudsman but also to the Chamber of Labour either in written form (e-mail) or via phone.		
Comments	Good governance policy exists, but not in one written document.		
<b>3.02 Intellectual Property Laws and Medicines</b>			
<b>Core Questions</b>			
Country is a member of the World Trade Organization	Yes	Since 1995	<a href="http://www.wto.org">www.wto.org</a>
Legal provisions provide for granting of Patents on pharmaceuticals	Yes	2010	Patent Law
National Legislation has been modified to implement the TRIPS Agreement	Yes	2010	Patent Law
Current laws contain (TRIPS) flexibilities and safeguards	No	2010	<a href="http://www.wto.org">www.wto.org</a>
Country is eligible for the transitional period to 2016	No	2010	<a href="http://www.wto.org">www.wto.org</a>
Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
Compulsory licensing provisions that can be applied for reasons of public health	No	2010	<a href="http://www.wto.org">www.wto.org</a>
Bolar exception	No	2010	<a href="http://www.wto.org">www.wto.org</a>
Are parallel importing provisions present in the national law?	No	2010	<a href="http://www.wto.org">www.wto.org</a>
The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes	2010	
Are there legal provisions for data exclusivity for pharmaceuticals	Yes	2010	National and EU legislation
Legal provisions exist for patent extension	Yes	2010	National and EU legislation
Legal provisions exist for linkage between patent status and marketing	Yes	2010	National and EU legislation



authorization			
Comments	The regulatory framework for marketing authorisation (incl. patent) is harmonised in Europe - Directive 2001/83/EC.		
<b>3.03 Manufacturing</b>			
<b>Core Questions</b>			
Number of licensed pharmaceutical manufacturers in the country	220	2009	Pharmig Facts & Figures 2010
Country has manufacturing capacity for:		2010	Pharmig Facts & Figures 2010
R&D to discover new active substances	Yes		
Production of pharmaceutical starting materials (APIs)	Yes		
Production of formulations from pharmaceutical starting material	Yes		
Repackaging of finished dosage forms	Yes		
Percentage of market share by value produced by domestic manufacturers (%)	Unknown	2010	Association of Austrian Pharmaceutical Industry
<b>Supplementary Questions</b>			
Percentage of market share by volume produced by domestic manufacturers (%)	Unknown	2010	Association of Austrian Pharmaceutical Industry
Number of multinational pharmaceutical companies manufacturing medicines locally	Unknown	2010	Association of Austrian Pharmaceutical Industry
Number of manufacturers that are GMP certified	All	2010	Association of Austrian Pharmaceutical Industry
Comments	Domestic manufacturer play minor role, hence not a lot of information		

<b>Section 4 Regulation</b>			
<b>4.01 Regulatory Framework</b>			
<b>Core Questions</b>			
Are there legal provisions establishing the powers and responsibilities of the medicines regulatory authority?	Yes	2010	Austrian Medicines Act
Part of MOH	No		
Semi autonomous agency	Yes		
The MRA has its own website	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
- If yes, please provide MRA Web site address (URL)	Austrian Federal Agency for Safety in Health Care (BASG) : <a href="http://www.basg.at/bundesamt-fuer-sicherheit-im-gesundheitswesen-basg/">http://www.basg.at/bundesamt-fuer-sicherheit-im-gesundheitswesen-basg/</a>		
The MRA is involved in harmonization/ collaboration initiatives	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
- If yes, please specify	Among others especially in working groups of the European Medicines Agency.		
An assessment of the medicines regulatory system has been conducted in the last five years.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Comments	In 2006 the institute was outsourced of the Ministry of Health. In the course of this process an assessment has been conducted.		
<b>Supplementary Questions</b>			
Formal code of conduct exists for staff involved in medicines regulation	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Medicines Regulatory Authority gets funds from regular budget of the government.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Medicines Regulatory Authority is funded from fees for services provided.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Medicines Regulatory Authority receives funds/support from other sources	No	2010	Austrian Federal Agency for Safety in Health Care (BASG)
- If yes, please specify			
Revenues derived from regulatory activities are kept with the regulatory authority	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
The Regulatory Authority is using a computerized information management system to store and	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)

retrieve information on registration, inspections, etc.			
<b>4.02 Marketing Authorization (Registration)</b>			
<b>Core Questions</b>			
Legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Number of pharmaceutical products registered in your country	13,168 incl. homeopathic products (counted incl. different pharmaceutical forms and dosages, excl. different pack sizes)	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Legal provisions require the MRA to make publicly available the registered pharmaceutical with defined periodicity	Yes	2010	Austrian Medicines Act § 27
- If yes, how frequently updated	Continuously		
- If yes, please provide updated list or URL *	<a href="http://pharmaweb.ages.at/pharma_web/index.jsf">http://pharmaweb.ages.at/pharma_web/index.jsf</a>		
Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN	Yes, by brands	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Legal provisions require paying a fee for Medicines Market Authorization (registration) applications	Yes	2010	AGES fees_2010
<b>Supplementary Questions</b>			
Legal provisions require marketing authorization holders to provide information about variations to the existing marketing authorization	Yes	2010	Austrian Medicines Act § 27
Legal provisions require to publish the Summary Product Characteristics (SPCs) of the medicines registered	Yes	2010	Austrian Medicines Act § 27
Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes	2010	Austrian Medicines Act § 27
Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the marketing authorization application	Unknown		
Legal provision require declaration of potential conflict of interests for the experts involved in the assessment	Yes	2010	Austrian Medicines Act § 27

and decision-making for registration			
Legal provisions allow applicants to appeal against MRAs decisions	Yes	2010	Austrian Medicines Act § 27
Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity, NCE (US\$)	See attached document - AGES fees 2009	2010	AGES fees 2010
Registration fee - the Amount per application for a multisource pharmaceutical product (US\$)	See attached document - AGES fees 2009	2010	AGES fees 2010
Time limit for the assessment of a marketing authorization application (Months)	According to EU law decisions have to be taken within 210 days	2010	EU Directive 2004/726 EC
Comments	Market authorization is regulated at EU level through different procedures - national authorization has only a minor relevance.		
<b>4.03 Regulatory Inspection</b>			
<b>Core Questions</b>			
Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes	2010	Austrian Medicines Act § 28
Does the Regulatory Authority have inspectors?	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
If yes, how many?			
Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes	2007	WHO Level I
Legal provisions exist requiring inspection to be performed	Yes	2010	Austrian Medicines Act § 28
Inspection is a pre-requisite for licensing of facilities	Yes	2010	Austrian Medicines Act § 28
Inspection requirements are the same for public and private facilities	Yes	2010	Austrian Medicines Act § 28
<b>4.04 Import Control</b>			
<b>Core Questions</b>			
Legal provisions exist requiring authorization to import medicines	Yes	2010	Austrian Medicines Act § 10c and Medicines Import Law
Legal provisions exist allowing the sampling of imported products for testing	Yes	2010	Austrian Medicines Act § 10c and Medicines Import Law
Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes	2010	Austrian Medicines Act § 10c and Medicines Import Law
Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized port of entry	Yes	2010	Austrian Medicines Act § 10c and Medicines Import Law
<b>4.05 Licensing</b>			
<b>Core Questions</b>			

Legal provisions exist requiring manufacturers to be licensed If yes please provide documents below.	Yes	2010	Austrian Medicines Act § 62 - 71
Legal provisions exist requiring manufacturers to comply with Good manufacturing Practices (GMP)	Yes	2010	Austrian Medicines Act § 62 - 71
GMP requirements are published by the government. If yes, please provide reference or URL below *	Yes	2010	<a href="http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/">http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/</a>
Legal provisions exist requiring importers to be licensed	Yes	2010	Austrian Medicines Act § 62 - 71
Legal provisions exist requiring wholesalers and distributors to be licensed	Yes	2010	Austrian Medicines Act § 62 - 71
Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices	Yes	2010	Austrian Medicines Act § 62 - 71
National Good Distribution Practice requirements are published by the government	Yes	2010	Austrian Medicines Act § 62 - 71
Legal provisions exist requiring pharmacists to be registered	Yes	2010	Pharmacy Act
Legal provisions exists requiring private pharmacies to be licensed	Yes (all community pharmacies are private with contracts with the Social Health Insurance; hence distinction private/public not not applicable)	2010	Pharmacy Act
Legal provision exist requiring public pharmacies to be licensed	Yes	2010	Pharmacy Act
National Good Pharmacy Practice Guidelines are published by the government	Yes		Regulation on the Operation of Pharmacies
<b>Supplementary Questions</b>			
Legal provisions require the publication of different categories of all pharmaceutical facilities licensed	Yes	2010	Austrian Medicines Act
<b>4.06 Market Control and Quality Control</b>			
<b>Core Questions</b>			
Legal Provisions for controlling the pharmaceutical market exist	Yes	2010	Austrian Medicines Act
Does a laboratory exist in the country for Quality Control testing?	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Please describe where the Regulatory Authority Contracts services	Regarding the testing of medicines, it is done at the Austrian Official Medicine Control Laboratory <a href="http://www.basg.at/en/omcl/">http://www.basg.at/en/omcl/</a>		

Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
How many Quality Control samples were taken for testing in the past two years?	33	2010	Austrian Federal Agency for Safety in Health Care (BASG)
What is the total number of samples tested in the previous two years that failed to meet quality standards?	3	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Results of quality testing in past two years are publicly available	Yes	2010	<a href="http://www.basg.at/en/news-center/statistics/ages-pharmmed-statistic/">http://www.basg.at/en/news-center/statistics/ages-pharmmed-statistic/</a>
<b>4.07 Medicines Advertising and Promotion</b>			
<b>Core Questions</b>			
Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes	2010	Austrian Medicines Act § 50 ff
Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Austrian Federal Ministry of Health		
Legal provisions prohibit direct advertising of prescription medicines to the public	Yes	2010	Austrian Medicines Act § 50 ff
Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes	2010	Austrian Medicines Act § 50 ff
Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes	2010	Austrian Medicines Act § 50 ff
A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes	2010	Code of conduct for pharmaceutical industry
If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both	Both	2010	Code of conduct for pharmaceutical industry
If yes, adherence to the code is voluntary	Yes	2010	Code of conduct for pharmaceutical industry
If yes, the code contains a formal process for complaints and sanctions	No	2010	Code of conduct for pharmaceutical industry
If yes, list of complaints and sanctions for the last two years is publicly available	No	2010	Code of conduct for pharmaceutical industry
<b>4.08 Clinical trials</b>			
<b>Core Questions</b>			
Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes	2010	Austrian Medicines Act § 40

Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes	2010	Austrian Medicines Act § 40
Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes	2010	Austrian Medicines Act § 40
<b>Supplementary Questions</b>			
Legal provisions exist for GMP compliance of investigational products	Yes	2010	Austrian Medicines Act <a href="http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/">http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/</a>
Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes	2010	Austrian Medicines Act <a href="http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/">http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/</a>
National GCP regulations are published by the Government.	Yes	2010	Austrian Medicines Act <a href="http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/">http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/</a>
Legal provisions permit inspection of facilities where clinical trials are performed	Yes	2010	Austrian Medicines Act <a href="http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/">http://www.basg.at/inspektionen/good-manufacturingdistribution-practice/gmp-inspektion/</a>
<b>4.09 Controlled Medicines</b>			
<b>Core Questions</b>			
The country is a signatory to conventions			
Single Convention on Narcotic Drugs, 1961	Yes	2009	International Narcotics Control Board Report
The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes	2009	INCB
Convention on Psychotropic Substances 1971	Yes	2009	INCB
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes	2009	INCB
Laws for the control of narcotic and psychotropic substances, and precursors exist.	Yes	2010	Narcotics Substances Law and further
Annual consumption of Morphine (mg/capita)	152.36	2007	INCB

<b>Supplementary Questions</b>			
The laws and regulations for the control of narcotic and psychotropic substances, and precursors has been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Unknown		
If yes, year of review. Please attach a copy of the review or provide link to it if available on the web *			
Annual consumption of Fentanyl (mg/capita)	2.035	2007	INCB
Annual consumption of Pethidine (mg/capita)	1.030	2007	INCB
Annual consumption of Oxycodone (mg/capita)	4.818	2007	INCB
Annual consumption of Hydrocodone (mg/capita)	Unknown		
Annual consumption of Phenobarbital (mg/capita)	Unknown		
Annual consumption of Methadone (mg/capita)	6.864	2007	INCB
Comments	The Austrian REITOX Focal Point of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is located with GÖG/ÖBIG.		
<b>4.10 Pharmacovigilance</b>			
<b>Core Questions</b>			
There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes	2010	Austrian Medicines Act § 75
Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes	2010	Austrian Medicines Act § 75
Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes	2010	Austrian Medicines Act § 75
A national Pharmacovigilance centre linked to the MRA exists in your country	Yes	2010	<a href="http://www.basg.at/en/pharmacovigilance">http://www.basg.at/en/pharmacovigilance</a>
If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	16	2010	Austrian Federal Agency for Safety in Health Care (BASG)
If a national pharmacovigilance center exists in your country, an analysis report has been published in the previous two years.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG) <a href="http://www.basg.at/pharmakovigilanz/amtliche-nachrichten">http://www.basg.at/pharmakovigilanz/amtliche-nachrichten</a>



If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
An official standardized form for reporting ADRs is used in your country.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
A national Adverse Drug Reactions database exists in your country.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Are ADR reports set to the WHO database in Uppsala?	No	2010	Austrian Federal Agency for Safety in Health Care (BASG)
ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	No	2010	Austrian Federal Agency for Safety in Health Care (BASG)
<b>Supplementary Questions</b>			
How many ADR reports are in the database?	10,000 case reports	2010	Austrian Federal Agency for Safety in Health Care (BASG)
How many reports have been submitted in the past two years?	6,000	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Feedback is provided to reporters	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
The ADR database is computerized	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Medications errors (MEs) are reported.	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
In the past two years, who has reported ADRs?		2010	Austrian Federal Agency for Safety in Health Care (BASG)
Doctors	Yes		
Nurses	Yes		
Pharmacists	Yes		
Consumers	No		
Pharmaceutical Companies	Yes		
Was there any regulatory decision based on local PV data in the last 2 years?	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Are there training courses in Pharmacovigilance?	Yes	2010	Austrian Federal Agency for Safety in Health Care (BASG)

If yes, how many people have been trained in the past two years?	At least 2 people per year	2010	Austrian Federal Agency for Safety in Health Care (BASG)
What is the percentage of preventable ADRs in the database for the past two years (%)?	Unknown	2010	Austrian Federal Agency for Safety in Health Care (BASG)
Comments	In Austria the (pilot) project Pharmaceutical Safety Belt with the aim of preventing ADR and multiple-prescribing and improving compliance was undertaken		

## Section 5 Medicines Financing

### 5.01 Medicines Coverage and Exemptions

#### Core Questions

If a public programme providing free medicines exists, medicines are available free-of-charge for:		2010	ASVG
Patients who cannot afford them	Yes		
Children under 5	Yes		
Pregnant women	Yes		
Elderly persons	Yes		
Please describe/explain your yes answers for questions above	People covered by social health insurance have access to reimbursable medicines i.e. medicines included in the positive list (called "Erstattungskodex"). The medicines are 100% publicly funded.		
If a public programme providing some/all medicines free exists, the following types of medicines are free		2010	ASVG
All medicines for all conditions	Yes		
Any non-communicable diseases	Yes		
Malaria medicines	Yes		
Tuberculosis medicines	Yes		
Sexually transmitted diseases medicines	Yes		
HIV/AIDS medicines	Yes		
EPI vaccines	Yes		
Please describe/explain your yes answers for questions above	Medicines that are included in the reimbursement system have to be prescribed by a doctor or in some cases need to have a special permission by a "chief physician" for approval. AT PPRI Profile		
Does a public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage	Yes	2010	PPRI Pharma Profile Austria 2008
Does it provide coverage for medicines that are on the EML for inpatients	Yes	2010	PHIS Hospital Pharma Report Austria
Does it provide coverage for medicines that are on the EML for outpatients	Yes	2010	PPRI Pharma Profile Austria
Does it provide at least partial medicines coverage for inpatients	Yes	2010	PHIS Hospital Pharma Report Austria
Does it provide at least partial medicines coverage for outpatients	Yes	2010	PPRI Pharma Profile Austria
Please describe/explain your answers for questions above	In hospitals patients receive medicines cost-free. In the out-patient sector reimbursable medicines are 100% paid by Social Health Insurance. For detailed information see PPRI Pharma Profile Austria		
Do private health insurance schemes provide any medicines coverage?	Unknown		

Comments	Coverage for medicines in the out-patient sector is a distinct system from funding in the in-patient sector. Questions might suggest that this could be one system.		
<b>5.02 Patients Fees and Copayments</b>			
<b>Core Questions</b>			
In your health system, at the point of delivery, are there any copayment/fee requirements for consultations	Yes	2010	ASVG, PPRI Pharma Profile Austria 2008
In your health system, at the point of delivery, are there any copayment/fee requirements for medicines	Yes	2010	ASVG, GÖG/ÖBIG
Is revenue from fees or from the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility	No	2010	GÖG/ÖBIG
Please describe the patient fees and copayments system	In the out-patient sector there is a flat prescription fee per product on the prescription form (€ 5 in 2010, annually adjusted to the inflation rate). Annual fee for the E-Card.		
Comments	E-Card refers to all health services (e.g. visits to doctors, etc.)		
<b>5.03 Pricing Regulation for the Private Sector</b>			
<b>Core Questions</b>			
Are there legal or regulatory provisions affecting pricing of medicines	Yes	2010	Price Act, ASVG
If yes, are the provisions aimed at Manufacturers	Yes	2010	ASVG §351c
If yes, are the provisions aimed at Wholesalers	Yes	2010	Enactment maximum wholesale mark-ups 2004
If yes, are the provisions aimed at Retailers	Yes	2010	Arzneitaxe § 3
Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.	Statutory pricing for reimbursable medicines at ex-factory price level based on EU average price followed by price negotiations w. Social Health Insurance. For details Austria PPRI Pharma Profile 2008		
Government runs an active national medicines price monitoring system for retail prices	Yes	2010	PPRI Pharma Profile Austria 2008
Regulations exists mandating that retail medicine price information should be publicly accessible	Yes	2010	PPRI Pharma Profile Austria 2008
-if yes, please explain how the information is made publically available	The reimbursement prices of reimbursable medicines are published in the reimbursement code (Erstattungskodex) in paper format and electronically. For more details please read the Austrian PPRI Pharma Profile 2008 in chapter 3 Pricing.		

<b>5.05 Price Components and Affordability</b>			
<b>Core Questions</b>			
Please state if a survey of medicines price components has been conducted in the past 5 years in your country. If yes, please indicate the year of the survey and use the results to fill in the questions below	No	2010	
Comment	Austria did not participate at the WHO/HAI survey but in other surveys as well as GÖG/ÖBIG does regular price monitoring		
<b>5.06 Duties and Taxes on Pharmaceuticals (Market)</b>			
<b>Core Questions</b>			
There are duties on imported active pharmaceutical ingredients (APIs)	No	2010	GÖG/ÖBIG, information by Federal Ministry of Finance
There are duties on imported finished products	No	2010	GÖG/ÖBIG, information by Federal Ministry of Finance
VAT (value-added tax) or any other tax on pharmaceuticals	Yes	2010	GÖG/ÖBIG
- If yes, please specify categories of pharmaceuticals on which the taxes are applied	VAT on all medicines is 10%. Till beginning of 2009, VAT on medicines amounted to 20% (20% is also the standard VAT rate).		
<b>Supplementary Questions</b>			
Amount of VAT on pharmaceutical products (%)	10	2010	

## Section 6 Pharm.procurement and distribution

### 6.01 Public Sector Procurement

#### Core Questions

Public sector procurement is		2010	ÖBIG Tendering report
Decentralized	No		
Centralized and decentralized	Yes		
Please describe	Procurement is mainly relevant in the in-patient sector, organised by individual hospitals or hospital associations. In the out-patient sector, it is rare, mainly concerns vaccines & MD (pandemic).		
If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:			
Part of MoH	No		
Semi-Autonomous	No		
Autonomous	No		
A government procurement Agency which procures all public goods	Yes		
Public sector tenders bids documents are publicly available	Yes	2010	ÖBIG Tendering report
Public sector awards are publicly available	Yes	2010	ÖBIG Tendering report
Procurements are based on prequalification of suppliers	Yes	2010	ÖBIG Tendering report
If yes, please describe how it works	Public Procurement Act (Bundesvergaberecht), implementing EU legislation, defines legal framework and criteria		

#### Supplementary Questions

Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field.	Yes	2010	Procurement Act
Are there provisions giving priority in public procurement to goods produced by local manufacturers?	No	2010	EU legislation
The key functions of the procurement unit and those of the tender committee are clearly separated	Yes	2010	
A process exists to ensure the quality of products procured	Yes		
If yes, the quality assurance process includes pre-qualification of products and suppliers	Unknown		
If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Unknown		
If yes, a list of pre-qualified suppliers and products is publicly available	Unknown		
List of samples tested during the	Unknown		

procurement process and results of quality testing is available			
Which of the following tender methods are used in public sector procurement:		2010	PHIS Hospital Pharma Report Austria 2009
National competitive tenders	Yes		
International competitive tenders	Yes		
Direct purchasing	Yes		
Comments	These questions are answered for the in-patient sector (out-patient sector: unknown)		
<b>6.02 Public Sector Distribution</b>			
<b>Core Indicators</b>			
The government supply system department has a Central Medical Store at National Level	No	2010	Information provided by GÖG/ÖBIG
Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	Not Applicable	2010	Information provided by GÖG/ÖBIG
There are national guidelines on Good Distribution Practices (GDP)	Yes	2010	Austrian Medicines Act § 57 ff
There is a licensing authority that issues GDP licenses	Yes	2010	Austrian Medicines Act § 57 ff
<b>Supplementary Questions</b>			
<b>6.03 Private Sector Distribution</b>			
<b>Core Questions</b>			
Legal provisions exist for licensing wholesalers in the private sector	Yes		Austrian Medicines Act § 57 ff
Legal provisions exist for licensing distributors in the private sector	Yes		Austrian Medicines Act § 57 ff
List of GDP certified wholesalers in the private sector exists	Unknown		
List of GDP certified distributors in the private sector exists	Yes		Written communication by Association of Pharmacists

## Section 7 Selection and rational use

### 7.01 National Structures

#### Core Questions

National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field.	Yes	2010	GÖG/ÖBIG
If yes, STG's are applied to Primary care. Please use the "year" field to write the year of last update of primary care STGs.	Yes	2010	GÖG/ÖBIG
If yes, STG's are applied to Secondary (hospitals). Please use the "year" field to write the year of last update of secondary care STGs.	Yes	2010	GÖG/ÖBIG
If yes, STG's are applied to Paediatric conditions. Please use the "year" field to write the year of last update of paediatric condition STGs.	Yes	2010	GÖG/ÖBIG
National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field.	Yes	2010	GÖG/ÖBIG
If yes, number of medicines on the EML	Around 6,000 medicines (counted by pack, incl. different pharmaceutical forms and dosages, excl. different pack sizes)		
If yes, there is a written process for selecting medicines on the EML	Yes	2010	Procedural rules for publication of the positive list
If yes, the EML is publicly available	Yes	2010	Main Association of Austrian Social Security Institution's website for official documents: <a href="https://www.avsv.at/avi/allgemein/startseite.xhtml">https://www.avsv.at/avi/allgemein/startseite.xhtml</a>
% of public health facilities with copy of EML (mean)- Survey data	All doctors have access to the positive list - either in print version or online.	2010	Information provided by GÖG/ÖBIG
% of public health facilities with copy of STGs (mean)- Survey data	Not Applicable		



A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	No	2010	Information provided by GÖG/ÖBIG
Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes, e.g. generics	2010	Information provided by GÖG/ÖBIG
A survey on rational use of medicines has been conducted in the previous two years	Yes	2010	GÖG/ÖBIG Report on Rational use of medicines
A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes, a committee for promoting rational use of medicines	2010	Austrian Medicines Law
A written National Strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field.	Unknown	2010	GÖG/ÖBIG
Comments	Positive list (reimbursement list) by Social Health Insurance (called EKO) is considered as EML.		
<b>Supplementary Questions</b>			
The EML includes formulations specific for children	Yes	2010	Positive list (EKO)
There are explicit documented criteria for selection of medicines in the EML	Yes	2010	ASVG
There is a formal committee or other equivalent structure for the selection of products on the national EML	Yes	2010	ASVG
If yes, provide the official documentation establishing the committee *	ASVG, BGBl. 150/2009		
If yes, conflict of interest declarations are required from members of national EML committee	Yes		
National medicines formulary exists	Yes (Answer refers to EKO (national formulary in the out-patient sector), no national medicines formulary in the in-patient sector (hospital formularies at hospital (association) level))	2010	Main Association of Austrian Social Health Insurance Institutions
Is there a funded national inter-sectoral task force to coordinate the	Unknown		

promotion of appropriate use of antimicrobials and prevention of spread of infection?			
A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes	2007	WHO Level I
<b>7.02 Prescribing</b>			
<b>Core Questions</b>			
Legal provisions exist to govern the licensing and prescribing practices of prescribers.	Yes	2010	Austrian Medicines Act, Guidelines on Economic Prescribing
Legal provisions exist to restrict dispensing by prescribers, if yes please attach document or provide URL below *	Yes (Prescribers are under specific criteria allowed to act as dispensing doctor)	2010	Austrian Medicines Act, Pharmacy Act
Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes	2010	Federal Hospital Act, Provincial Hospital Acts
The core medical training curriculum includes components on:		2010	
Concept of EML	No		
Use fo STGs	Yes		
Pharmacovigilance	Yes		
Problem based pharmacotherapy	Yes		
The core nursing training curriculum includes components on:			Unknown
Concept of EML	No		
Use of STGs	No		
Pharmacovigilance	No		
The core training curriculum for paramedical staff includes components on:			Unknown
Concept of EML	No		
Use of STGs	No		
Pharmacovigilance	No		
Mandatory continuing education that includes pharmaceutical issues is required for Doctors	Yes	2010	GÖG/ÖBIG
Mandatory continuing education that includes pharmaceutical issues is required for Nurses	Unknown		
Mandatory continuing education that includes pharmaceutical issues is required for Paramedical staff	Unknown		
Prescribing by INN name is obligatory in:			
Private sector	No		No, INN prescribing is forbidden

Public sector	No		No, INN prescribing is forbidden
Average number of medicines prescribed per patient contact in public health facilities (mean)	13.95 ( Please specify health care facilities - in Austria measured now in doctor contacts)	2008	Main Association of Austrian Social Security Institutions
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	around 100%, under specific circumstances non-reimbursable medicines may be prescribed and reimbursed (individual applications)	2010	Main Association of Austrian Social Security Institutions
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	0%, because it is not allowed	2010	Main Association of Austrian Social Security Institutions
% of patients in outpatient public health care facilities receiving antibiotics (mean)	Unknown	2010	Main Association of Austrian Social Security Institutions
% of patients in outpatient public health care facilities receiving injections (mean)	Unknown	2010	Main Association of Austrian Social Security Institutions
% of prescribed drugs dispensed to patients (mean)	Unknown	2010	Main Association of Austrian Social Security Institutions
% of medicines adequately labelled in public health facilities (mean)	100	2010	Main Association of Austrian Social Security Institutions
<b>Supplementary Questions</b>			
A professional association code of conduct exists governing professional behaviour of doctors	Yes	2010	Code of Conduct for Doctors 2010
A professional association code of conduct exists governing professional behaviour of nurses	Unknown		
Diarrhoea in children treated with ORS (%)	Unknown		
<b>7.03 Dispensing</b>			
<b>Core Questions</b>			
Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes	2010	Austrian Pharmacists Association
The basic pharmacist training curriculum includes components on:		2010	Austrian Pharmacists Association
Concept of EML	Yes		
Use of STGs	Yes		
Drug Information	Yes		
Clinical pharmacology	Yes		

Medicines supply management	Yes		
Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes	2010	Austrian Pharmacists Association
Substitution of generic equivalents at the point of dispensing in public sector facilities is allowed	No (In Austria only private sector pharmacies are allowed, hence the question is not applicable)	2010	PPRI Pharma Profile Austria 2008
Substitution of generic equivalents at the point of dispensing in private sector facilities is allowed	No	2010	PPRI Pharma Profile Austria 2008
Antibiotics are sold over-the-counter without a prescription	No	2010	GÖG/ÖBIG
Injectable medicines are sold over-the-counter without a prescription	No	2010	GÖG/ÖBIG
<b>Supplementary Questions</b>			
A professional association code of conduct exists governing professional behaviour of pharmacists	Yes	2010	PPRI Pharma Profile Austria 2008
Are the following categories of staff prescribing prescription-only medicines at primary care level in the public sector?		2010	PPRI Pharma Profile Austria 2008
Doctors	Yes		
Nurses	No		
Pharmacists	No		