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Pharmaceutical Price Policy - Follow Up Report

Country: Austria

Partner Institute: Institute for Advanced Studies (IHS), Vienna

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Health Policy Issues: System Organisation/ Integration, Pharmaceutical Policy

Current Process Stages

Idea	Pilot	Policy Paper	Legislation	Implementation	Evaluation	Change	

1. Abstract

There are ongoing efforts to contain cost growth in the pharmaceutical sector. This article aims to report about the latest developments in this area especially in view of the introduction of a new system of pharmaceutical price policy in 2005. Additionally this report aims to evaluate the outcome of these measures by looking at expenditure growth trends. It further summarizes recent developments in this area.

2. Recent developments

There are ongoing efforts to contain cost growth of pharmaceuticals. While measures introduced in 2000 have been short-lived, e.g. the distributors (reduction of wholesale margins), pharmacies (recovery of excess turnovers) and patients (exceptional increase of the prescription fee) contributed to cost containment goals, a new price regulation policy was adopted in 2003 and 2004. Furthermore, pilots are currently under way to ensure better compliance of patients, e.g. the pharmaceutical safety belt - see <u>survey 10(2007)</u> - which is likely to be phased in on a national scale. In current reform debates the focus is on generic substitution (see <u>survey 11(2008): Ensuring financial sustainability</u> for health care).

The goal in 2003 and 2004 was to bring down price increases from nearly 9 % annually in the 90ies to around 4%. This report aims to evaluate the success of the different measures taken in 2003 and 2004 and briefly describes current approaches.

A core project in 2003 was the replacement of the former Index of Medicinal Products, the so called Heilmittelverzeichnis by the **Code of Reimbursement** (Erstattungskodex, **EKO**) that was established as the new positive list in 2005. (see also <u>survey 2(2003)</u>) All pharmaceuticals included in the EKO qualify for general reimbursement; however there are different conditions regarding the prescription applied. The EKO has the following main segments:

Green box:

Pharmaceutical products contained in the green box are automatically reimbursed. Restrictions based on specific diseases, age group or prescriptions by specialists may apply.

Yellow box:

The yellow box contains pharmaceuticals with an additional therapeutic benefit that are not part of the green box due to medical and/or economic reasons. Pharmaceuticals in this box can be divided into two groups: The "light" yellow box (RE2) and the "dark" yellow box (RE1). Reimbursement for all pharmaceutical products listed in the yellow box is

restricted according to defined reimbursement rules. Additionally regulations for all "yellow" products are:

- Reimbursement for the products listed in the "dark yellow box" is only possible after an ex-ante approval by the head physicians of the respective health insurance fund.

- Reimbursement for the products listed in the "light yellow box" is subjected to an ex-post supervision of the prescription by the head physicians of the respective health insurance fund.

Red box:

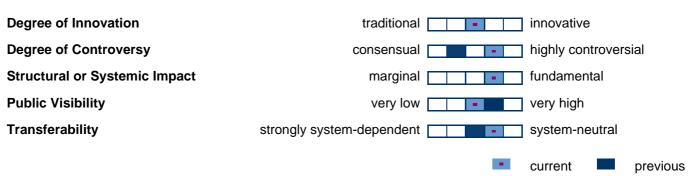
The red box pharmaceuticals are treated in the same way like the "no box" pharmaceuticals - with the difference that the products have currently applied for reimbursement and are awaiting the decision of their inclusion in the yellow or green box or their eventual exclusion from general reimbursement. A prescription needs the prior approval of a monitoring doctor.

No Box:

The no box contains pharmaceuticals that are licensed in Austria but are not eligible for general reimbursement by the social health insurance. However, there is the possibility that reimbursement may be granted on an individual patient basis provided an application of the prescribing doctor exists and with prior approval of the monitoring doctor. Generally pharmaceuticals of the green box are preferred over those of the yellow box, and the yellow box drugs are preferred over the ones in the red box. Furthermore the Austrian price commission has to determine an average EU price for drugs that is relevant for the acceptance into the Code of Reimbursement. (see section "Purpose and process analysis").

For the acceptance of a generic pharmaceutical in the Code of Reimbursement the following procedure was developed: Economic efficiency of the first generic product is established if the price is at least 48% below the price of the now off-patent original brand. Economic efficiency is further assumed if the second and each subsequent generic "follower" offer a sufficiently high price difference to the previously included generic (e.g. second follower needs to reduce it's price by 15% compared to the first follower and third follower needs to reduce minus 10% compared to the second follower). The price of the original has to be reduced by at least 30% within three months of the inclusion of the first generic into the green box to ensure the economic efficiency of the original and for the same reason, three month after the third generic has entered the Code of Reimbursement the original as well as the first and second generic have to reduce their price to the price of the third generic. The cost effectiveness of all further pharmaceuticals is given if the price is at least 0,10€ under the price of the cheapest listed drug in the green box. The decision to which box a new pharmaceutical is allocated depends mainly on economic facts. New innovative products are mostly to be listed in the "dark yellow box". For the acceptance the cost effectiveness requires that the expected cost/benefit ratio is traceable and justifiable.

If comparable pharmaceuticals are already listed in the yellow box, the average EU price must not be exceeded. If the new pharmaceutical is allocated to the green box, the price must be below the EU average price.



3. Characteristics of this policy

4. Purpose and process analysis

	Idea	Pilot	Policy Paper	Legislation	Implementation	Evaluation	Change	
Initiators of idea/main actors								
- Government								
-	- Patients, Consumers							
-	- Private Sector or Industry							
-	Others							

Stakeholder positions

The **Ministry of Health**, who initiated the box system, and the social health insurance are, as the major players in the health system, still very supportive towards the new system in order to contain cost increases in the pharmaceutical sector.

The **Austrian Pharmaceutical Chamber** holds a more ambivalent position. On the one side cost containment in the pharmaceutical sector as a whole and especially at the level of pharmacies (above all at the pharmacists' profit margin) are seen as not effective for sustainable savings in the health sector. Furthermore the current regulations that oblige pharmacies to deliver all drugs in short time is not seen as practicable due to the increasing amount of generics. On the other side there is no general opposition against an intensified prescription of generics, also because the percental profit margin for cheaper drugs is higher.

The **Austrian Medical Chamber** is more opposed to the new system as they see a constraint in the possibilities for the doctors to prescribe what they consider best and furthermore claim an additional administrative effort e.g. in documenting prescriptions from the yellow box.

In the private sector, the **pharmaceutical industry** is the main actor involved in that topic. While the researching pharmaceutical industry is opposed to a severe price regulation, the producers of generic drugs are supportive because of the possibility of an increasing turnover.

Patients and consumers of pharmaceuticals also see the new price regulation ambivalent. On the one hand the aim to contain the prices for pharmaceuticals is positive for the patients. On the other hand additional bureaucratic barriers to get certain pharmaceuticals can cause difficulties especially for chronically ill persons, e.g. formerly reimbursed drugs that are no longer available in the EKO.

The Austrian Federal Economic Chamber and the Austrian Chamber of Labour are supportive concerning the reform measures in the pharmaceutical sector. They see their legitimacy to act in this field as the agents of insurees. In April 2008 they made suggestions for a health reform including also some changes in the pharmaceutical sector. They see possibilities for economizing in the pharmaceutical sector through

- a further extension of the share of generic drugs
- the extension of the EKO to the inpatient sector and the implementation of monitoring doctors in hospitals to align drug therapy with the outpatient sector
- agreements with the Austrian medical chamber concerning incentives for enhanced economic prescribing or an intensified controlling through health insurance

- introduction of generic substitution (aut idem prescriptions) i.e. the prescription of the active ingredient through the doctor and a decision about the product by the pharmacist.

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- nation-wide implementation of the pharmaceutical safety belt (see survey (10) 2007)
- decrease of the wholesale margins and the pharmacy margins.

Actors and positions

Description of actors and their positions

Government Ministry of Health	very supportive
Patients, Consumers Patients, Consumers	very supportive
Private Sector or Industry Researching Pharmaceutical Industry	very supportive strongly opposed
Producers of Generic Drugs	very supportive
Others	
Social Health Insurance	very supportive - strongly opposed
Austrian Pharmaceutical Chamber	very supportive strongly opposed
Austrian Medical Chamber	very supportive strongly opposed
Austrian Federal Economic Chamber	very supportive strongly opposed
Austrian Chamber of Labour	very supportive
	current previous

Influences in policy making and legislation

Since 2003 a process has been established to determine the **average EU price**. It is now regulated through the social insurance law, §351c Abs. 6 ASVG.

The average EU price is determined by the arithmetic mean of the ex factory price of pharmaceuticals in those Member States where identical products (i.e. the same agent and intensity, same pharmaceutical form and packing size, without VAT) are authorized. In case of reimbursed products, listed in the red box, the manufacturer has to pay back the price difference if the Austrian price is above the EU average.

In the context of current debates about pharmaceutical prices some stakeholders claim the VAT tax of 20% as being too high. Social health insurances as well as the Austrian Pharmaceutical Chamber envisage a VAT rate of 10%. Compared to other European countries the VAT rates for prescribed pharmaceuticals are only higher in Denmark and Norway (efpia 2007).

Legislative outcome

Actors and influence

Description of actors and their influence

Government

Ministry of Health

Patients, Consumers Patients, Consumers

Private Sector or Industry

Researching Pharmaceutical Industry

Producers of Generic Drugs

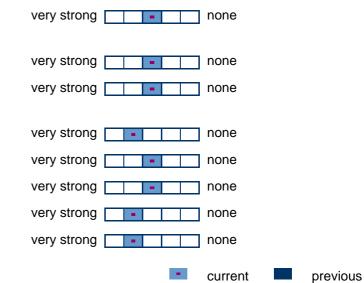
Others

Social Health Insurance Austrian Pharmaceutical Chamber

Austrian Medical Chamber

Austrian Federal Economic Chamber

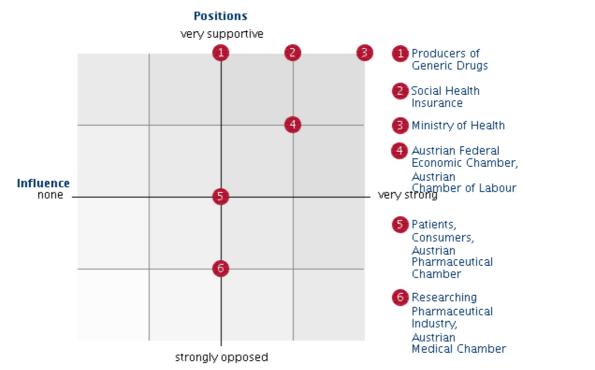
Austrian Chamber of Labour



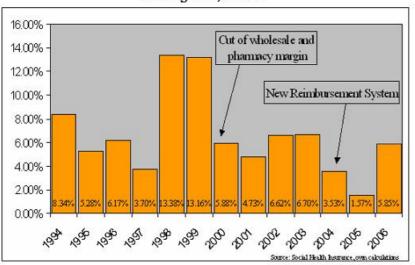
none

very strong

Positions and Influences at a glance



Adoption and implementation



Social Insurance Pharmaceutical Expenditure Annual growth, nominal

Monitoring and evaluation

In current debates about pharmaceutical expenditure growth different figures and opinions are presented to the public. While social health insurance tends to present a high level of growth, industry mostly claims this as being incorrect and presents lower figures. A closer look at the figures shows the following:

High annual growth rates in the 1990s

Between 1990 and 1999 pharmaceutical costs increased from 715.4 Mio € to 1552,5 Mio €. This corresponds to an average annual increase of 9%.

Various measures taken since 2000 seem to have helped to contain cost growth. Between 2000 and 2006 annual average cost growth ranged at 4,8%. In absolute terms cost increased from 1643.9 Mio € to 2180.1 Mio. €. In real terms, deflated by the HICP, growth has been annually at 2,08% on average. (Admittedly the harmonized index of consumer prices (HICP) reflects not only prescribed pharmaceuticals but also OTC products, "no" box pharmaceuticals and homeopathic products.)

EKO shows positive impact on public expenditure - growth rates decreasing

The introduction of EKO seems to have helped achieving cost containment as between 2005 and 2006 cost increased 2,9% annually in nominal terms. This would seem to be consistent with the spread of 3-4% annual price increase as envisaged by policy makers (own calculations, based on statistics from the social health insurance) Furthermore by 2005 the goal to increase the share of generic drug consumption to 20% could be reached. In value

terms the share was still below this target (13,4%) (Pharmig 2007).

Increase in private expenditure on drugs

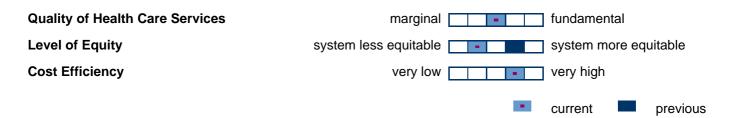
The 2005 health reform envisaged lower co-payments for generic drugs but this measure was not implemented. Thus, the full fee is charged also for generics.

20% of the pharmaceutical budget comes from co-payments. Between 2000 and 2006 these co-payments increased on average 5,4% annually. Thus, growth in private expenses for drugs was about twofold when compared to annual public expenditure growth (2.9%). Thus, the private share in total pharmaceutical spending increased from 19,7% in 2000 to 20,5% in 2006. The rate of growth of co-payments was also higher between 2005 and 2006 after EKO was introduced (co-payments increased on average 3,9% annually). In absolute terms co-payments increased more than 100 Mio. \in from 271 Mio. \in in 2000 to 371,1 Mio \in in 2006. This trend has been a constant concern and led to the introduction of a cap on prescription fees. Since January 2008 co-payments for drugs may not exceed 2% of the

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annual income. Currently the prescribtion fee is 4,80€ for each item on the prescription. In volume terms the number of prescriptions increased only 1% between 2000 to 2006.

5. Expected outcome



The policy measures described do not have substantial influence on the **quality of health care services**. As co-payments for drugs increased above growth of public spending in recent years, equity issues became a concern. Thus, since January 2008 not more than 2% of annual income should be spent on co-payments. With this measure in place it is hoped that the **level of equity** can be maintained.

Various measures implemented in recent years seem to have promoted **cost efficiency** because growth of expenses could be held down. However, this emerged at the expense of growing co-payments in this area.

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Reform formerly reported in

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