Management Summary

Rationale and objectives

In a reference price system (RPS) Third Party Payer (social health insurance or national health service) determines a maximum amount (=known as the reference price) which is the basis for reimbursement for certain pharmaceuticals. On buying a pharmaceutical under the RPS, an insured person must pay the difference between the reference price and the actual pharmacy retail price in addition to any fixed co-payments or percentage co-payment rates.

Many European Union (EU) Member States, among them all Austrian neighbouring countries, have a RPS. So far Austria has not introduced such a system.

The Austrian research institute ÖBIG Forschungs- und Planungsgesellschaft mbH (ÖBIG FP) was commissioned by the Main Association of Austrian Social Security Institutions (HVB) to analyse European reference price systems with a view to possibly incorporating it into the Austrian reimbursement system. Therefore the study was conducted from the payers' (HVB) perspective.

The project was designed as follows:

Phase 1: systematic review of European RPS

Phase 2: detailed investigation of six specially selected EU Member States to identify what lessons could be learned in terms of good practice / bad practice

Phase 3: development of an implementation strategy in case a RPS would be introduced in Austria including an estimation of possible potential savings for the sickness funds.

A project steering group was set up. It consisted of three representatives of the HVB, one of whom Ms. Deputy General-Director Mag. Beate Hartinger acted as chair, and three of sickness funds. The main contact and interface between the project steering group and the ÖBIG FP was Ms. Mag. Susanne Führlinger of the Department „Vertragspartner Medikamente" of the HVB.

International Overview

In 14 of the 25 surveyed countries (EU Member States as of the year 2006) healthcare is organised as a social insurance system. This is, for instance, the case in Austria, France and Germany and several new Member States in Central and Eastern Europe which introduced social insurance systems in the 1990s. 11 EU Member States have a National Health Service (NHS). The British NHS was the pioneer but this system also exists in Scandinavia and in the Mediterranean countries.

In total the EU Member States spend 1,000 billion euro on health. In Purchasing Power Parities (PPP) this amounts to 1,900 € PPP per inhabitant per year spent on health care.

On average one fifth of total health expenditure is used for pharmaceutical expenditure. In the year 2005 154 billion € PPP were spent on pharmaceuticals. This amounts to 320 € PPP per EU inhabitant per year (EU-25 excl. Malta). Pharmaceutical expenditure varies considerably among the Member States, in particular pharmaceutical expenditure – like health expenditure – is usually lower in the new Member States (EU-10: 105 € PPP compared to EU-15: 360 € PPP).

The shares of publicly funding of pharmaceutical expenditure vary among the Member States: Whilst 98 percent are publicly funded in the Netherlands (prescription-only medicines only) and nearly 90 percent in the UK and Ireland, it is only less than 50 percent in Latvia, Lithuania and Poland.

Pharmaceutical consumption also varies among the EU Member States – no matter if it is expressed in packages sold or in prescriptions (Estonia: 4.0 packages per inhabitant, Lithuania: 26.3 packages per inhabitant). Austria has 13 prescriptions per year and insured person which corresponds to the European average.

Pharmaceuticals are dispensed to outpatients mainly by community pharmacies. Pharmacies are more densely located in the new EU Member States (EU-10-average: 3,360 inhabitant per pharmacy) than in the old Member States (EU-25-average: 5,483 inhabitant per pharmacy). A particular low pharmacy density is observed in the Nordic countries.

In 2007/2008 17 of the 25 surveyed EU Member States have a RPS in place. In addition, Sweden runs a system of obligatory generic substitution which functions similar to a RPS. In 1989, Germany was the first to introduce a reference price system (what is called “Festbetragssystem” in German) – followed by the Netherlands (1991), Denmark and Sweden (both 1993). In Hungary a legal basis for a RPS was already prepared in 1991 but it was only implemented in 1997. As the last of the group, Greece introduced a reference price system in May 2006.

In all analyzed countries the RPS was introduced on a legal basis. The authorities in charge of implementing the RPS are usually the same ones as those responsible for reimbursement.

The way how a RPS is organized differs among the countries. There are different approaches in the design of the clusters (reference groups), the kind of pharmaceuticals included in the RPS and the methodology applied for determining the reference price. Some countries (Denmark, Italy or Portugal) build the reference groups on ATC 5[1] level whereas others (Czech Republic, Germany, the Netherlands) use a broader definition. Some countries (e.g. Germany, Slovenia) include not only generics but also copy and me-too products. If a sufficient number of parallel imported pharmaceuticals are on the market, they are also included in the RPS. Parallel imported pharmaceuticals play a role in Denmark and the Netherlands.

[1] ATC 5 defines a single active ingredient or a fixed combination of active ingredients within the anatomic therapeutic chemical classification system of the WHO (Example: A10BA02 – Metformin).

A RPS stands in connection to a country's generics policy. Prior to the introduction of a RPS an appropriate number of equivalent or similar products (in general generics) need to be on the market. A way to promote generics is generic substitution (i.e. substituting an original product with a generic by the pharmacist). Generic substitution is allowed in 18 EU Member States (Cyprus not included). In six Member States, the pharmacist is obliged to dispense the cheapest available equivalent pharmaceutical (cf. Table I).

Table I: *Management Summary – RPS and generic substitution in the EU Member States 2007*

Generic substitution	RPS	No RPS
Not allowed	BE, EL	AT, CY[1], IE, LU, UK
Allowed	CZ, EE, ES[2], FR, HU, IT, LT, NL, PL, PT, SI	MT
Obligatory	DE, DK, LV, SK	FI, SE[3]

[1] not allowed in the private sector, obligatory in the public sector

[2] indicative generic substitution, however it is mandatory under two prerequisites (1. under the RPS 2. the generics has the lowest price)

[3] RPS was abolished in the year 2002

Source: ÖBIG survey

The generics share is quite high in countries having a RPS. For instance, it amounts to 65 percent in volume in e.g. Estonia, Slovakia. In the Central and Eastern European countries the relatively high generics share is the result of a strong local generics industry.

Among the group of the EU-15 Denmark, Germany and the Netherlands have the highest generics shares (e.g. Germany 57% volume and 32% value share). These countries also were the first ones to introduce a RPS.

Detailed analysis of six case study countries

As discussed and agreed with the project steering group six countries were selected under the following criteria:

- geographic, demographic and economic characteristics
- aspects of the organisation and funding of the pharmaceutical system that are relevant for the framework of a RPS (size of reference group, regulation of generic substitution)
- experience with the RPS (e.g. frequency of adjustments, period of being in force, acceptance by the population and actors in the pharmaceutical system)

Accordingly, Denmark, Germany, Hungary, the Netherlands, Portugal and Slovakia were chosen. These countries were then closely examined with a view to possible relevance as a good practice model for Austria.

Products

The RPS of the six countries mainly includes reimbursable pharmaceuticals and a few OTC products. An important requirement for a good functioning RPS is the availability of a sufficient number of off-patent products – these are primarily generics. In Slovakia copy-products are also included in the RPS. Those products are excluded in Portugal as the bioequivalence is not verified. Parallel imported pharmaceuticals are included in those countries where they play an important role (Denmark, Germany and the Netherlands). In Germany also on-patent pharmaceuticals can be included into the RPS provided they are not assessed as a "novelty" pharmaceutical.

In all six countries generic substitution is permitted. In Denmark, Germany and Slovakia the pharmacist is even obliged to substitute the prescribed pharmaceutical with a cheaper one ("aut-idem") provided that the doctor or the patient does not reject the decision.

Reference groups

The size of a reference group varies. With 57,100 included pharmaceuticals as at 1 November 2007 Germany has by far the highest number of pharmaceuticals in a RPS. There are two reasons for that: Germany was the first country to introduce a RPS in Europe and builds comprehensive reference groups including also on-patent products. Slovakia on the other hand with 1,000 products has the lowest number of pharmaceuticals in a RPS among the surveyed countries, reflecting for the comparably low number of products on the market.

In Denmark and Portugal the ATC 5 level is exclusively used for building the reference groups. However, Hungary and Slovakia cluster on ATC 5 and ATC 4 level. In Germany and the Netherlands forming reference groups is more complex. In Germany a group may include on-patent pharmaceuticals if they are no novelties. In the Netherlands therapeutically interchangeable products are formed into mixed groups of ATC 5, ATC 4 and ATC 3 level.

Reference prices

Reference prices (reimbursement limits) are set based on a price per unit in Denmark and Portugal, on daily and individual case doses in Germany and on defined daily doses (DDD) in Hungary, the Netherlands and Slovakia. DDD is a technical unit developed by the World Health Organisation (WHO) to measure the consumption of pharmaceuticals in a comparable way. According to the WHO DDD should not be used for price comparisons and reimbursement decisions.

In Denmark, Hungary (for those pharmaceuticals clustered at ATC 5 level) and Slovakia the reference price is set at the price of the cheapest pharmaceutical of a reference group. In Germany the reimbursement limit is calculated in line with a complex model but basically it lies in the lower third of the prices of the reference group. In Hungary and the Netherlands the reference price approximately corresponds to the average price of that group (at ATC 4 level). In Portugal, however, the most expensive pharmaceutical of a reference group becomes the reference product and thus defines the reimbursement limit. As a result reference prices are high and hence the full savings potential cannot be used.

The procedures of determining reference prices are different among the surveyed countries. In Denmark, Hungary and Slovakia a kind of auction is applied in the pricing and reimbursement process. Regarding the frequency for updating the reference prices different approaches are used. Whereas reference prices have not been adjusted in the Netherlands since 1999, reference groups and prices are usually regularly updated in the other countries: They are quarterly updated in Hungary, Portugal and Slovakia. German law provides for an annual update but in practice it is done more often. In Denmark prices are even adjusted every two weeks, asking for an appropriate logistics to prevent any delivery problems.

Market players

In Hungary and Portugal the administration of the RPS is done by the competent authorities, further market players are not involved. In Denmark, Germany and Slovakia the doctors' association is represented in the reimbursement committee and involved in decisions regarding the RPS (building of reference groups). Among the surveyed states, Germany is the only country where also patients' representatives are involved in the implementation of the RPS. In the Netherlands the market players are consulted in case of planned reforms. In Denmark market players are not engaged with practical aspects of the implementation but thanks to their involvement from the beginning on they are committed to a good functioning of the reference price system and they know and accept their role and tasks.

In addition to any other out-of pocket payments (e.g. prescription fee) patients need to pay the difference between the reference price and the actual pharmacy retail price of a pharmaceutical if they ask for a pharmaceutical included in the reference price system which has a higher price than the reference price. In Denmark, Hungary and Portugal percentage co-payments are in place, which are also applicable for products under the reference price system. As a result, patients need to co-pay for pharmaceuticals priced at or even below the reference price. In Portugal the reference prices (reimbursement limits) are set at higher levels for old age pensioners with a low income in order to minimize their co-payments.

Usually (except for Denmark) the introduction of the RPS was not fully accepted and it was negatively perceived by some market players, in particular by the research-oriented industry and patients' representatives. For instance, in Hungary and Portugal a major point of criticism concerned the lack of information before and at the time of the introduction of the RPS. However, pharmacists usually reacted positively to the RPS, while doctors disapproved of generic substitution which was often introduced together with the RPS. However, in Denmark doctors along with all other market players reacted positively to generics substitution and the RPS.

Savings

Considerable savings could be made due to a RPS, whereas there has been no evidence for showing negative effects on public health. However, a reduction in pharmaceutical consumption was not observed. In general new reference groups were best to offer savings. However, the cost-containment effect might after a few years, e.g. should no off-patent products enter the market. For optimizing the savings potential reference groups and reference prices need to be adjusted regularly, e.g. when a product goes off-patent.

Requirements for the introduction of a RPS

The analysis identified the following factors as being supporting and essential for a RPS to function well:

- Generic substitution should be in place, if possible mandatory in order to guarantee its use in practice. Alternatively, prescription by international non-proprietary name (INN) might also be a good prerequisite – in such a case mandatory INN prescribing is considered as more useful than indicative one.
- The market players (doctors, pharmacists, industry, patients) should be involved – from the beginning on. A comprehensive and continuous information policy targeted to patients is required so that patients accept the new system.
- A sufficient number of pharmaceuticals should be available on the market, and their actual deliveries in short time should be guaranteed. This might be achieved with delivery clauses and/or contractual penalties. Additionally, price competition in a pharmaceutical system works supportive.
- Patients should be offered incentives to ask explicitly for pharmaceuticals included in the RPS.

The Austrian reference price model

ÖBIG FP was asked to propose a model for a RPS to be incorporated in the Austrian reimbursement system. Based on the experience from other countries, the following RPS model for Austria was suggested: It should primarily include comparable off-patent products, and the reference groups should be built applying strict aut-idem criteria. A reference group should consist of pharmaceuticals

- with identical active ingredients or combination of active ingredients at ATC 5 level,
- with the same strength and dosage of active ingredients,
- with practically the same pharmaceutical form as in § 23, Abs. 2, Zi. 1 VO-EKO,
- with the same therapeutic effect and field of application as well as
- with similar package size, whereas a variation of 20 percent within a reference group should be allowed.

Whether a product is assigned to the red, yellow or green box of the reimbursement code (EKO) or if it is a no-box-product, this is not relevant for building a reference group. In the long run all prescription only-medicines and off-patent pharmaceuticals that are on the market could be included in the RPS if they qualify for the criteria listed.

In the RPS model developed, the reimbursement price of the lowest priced product within a reference group is proposed as reference price which defines the maximum reimbursement amount paid the Austrian sickness funds. The product with the lowest reimbursement price per unit (package) at the beginning of a quarter is the one considered as this lowest priced product.

In order to effectively use the savings potential of a RPS a continuous adjustment of the reference substances as well as the reference groups and reference products is needed. In consultation with the project steering group, ÖBIG FP suggests to introduce in a first step 58 reference substances (common substances that are included in the RPS of the case study countries) with four to 15 reference groups each and to adapt them once a year (depending on the patent expiry and market entry of the followers products). The reference price should be evaluated together with the on-going regular adjustment of the EKO and, if applicable, be newly defined at the beginning of each quarter.

The RPS model proposes the following dispensing rules: In general the pharmacist has to dispense the lowest priced product of a reference group when the patient hands in a prescription. Three exceptions of this rules should be introduced:

1. The patient refuses the substitution.
2. The prescribing doctor prohibits the substitution.
3. a) The reimbursement price of the prescribed product only differs a little from the reference price.

   b) The reference product is not available at the pharmacy.

Consequences of 1:

The patient needs to pay out-of pocket the difference between the reference price and the pharmacy retail price of the prescribed pharmaceutical, in addition to the prescription fee. This out-of pocket payment would – as it is the case in Denmark or Slovakia – also address people who are exempted from the prescription fee, because otherwise the effects of the system would get lost.

In January 2008 a prescription fee ceiling of two percent of the net income was introduced in Austria. The effects on this ceiling could not be assessed at the time of writing this report. In countries where a co-payment ceiling exists (e.g. in Denmark or Finland), co-payments that result from the refusal of the substitution by the patient are excluded from this cap.

Consequences of 2:

Should the prescribing doctor exclude the substitution by marking that on the prescription, the patient usually needs to pay out-of pocket the difference between the reference price and the pharmacy retail price.

There should be provided an exception of this rule if the doctor can well argue the reasons behind the refusal of the substitution. A possible reason could be the indication regulation of the product. A product of the yellow box, accredited as a second-line-therapy, could thus be dispensed without co-payment as long as the dispensing rules were followed or if the patient is allergic to a component such as the colorant of the product which would be given as substitute.

For an easy administrative and monitoring of these exemptions the already existing ABS system could be used. The ABS system is in place for pharmaceuticals in the red box of the EKO and the "no-box" needing an approval by the head physician of the sickness funds.

Consequences of 3:

In order to reduce the financial burden for the patients pharmacists should be allowed two exemptions from obligatory substitution.

Case 3a): The reimbursement price per unit of the prescribed product is less than five percent above the reference price.

In such a case the pharmacist can dispense the prescribed product and the patient does not need to pay the difference out-of pocket.

Case 3b): The reference product is not available at the pharmacy (or self-dispensing doctor).

In that case the pharmacist or the self-dispensing doctor can dispense the second lowest priced product and again the patient is exempted from paying the difference out-of pocket.

However, to limit the exemptions to a few cases in practice, the framework agreement between the HVB and the Chamber of Pharmacists (ÖAK) could include a clause that the ÖAK should do everything possible to keep these cases at a minimum level.

Possible savings

Possible savings which would be gained from a RPS in Austria were calculated, based on the assumption of applying strict aut-idem criteria for the substitution of the prescribed pharmaceutical by the lowest priced product with the same active substance. Data were provided by FOKO and Pegasus respectively. The calculation was carried out from the sickness funds' perspective.

Pharmaceuticals which are eligible for a RPS in Austria were identified after having examined the reference price lists ("lists with substitutable and interchangeable pharmaceuticals") of the six case study countries. Analysing these lists, all active ingredients and combinations of active ingredients at ATC 5 level which are in the RPS of the surveyed countries were selected: This corresponded to between 100 and 487 substances per country: in total around 560 different active substances and combinations of active substances were analysed. As a result, a total of 56 substances that are in the RPS in at least five out of the six countries were identified. In addition to these 56 reference substances, three further groups (non-oral insulins) were included in the calculation.

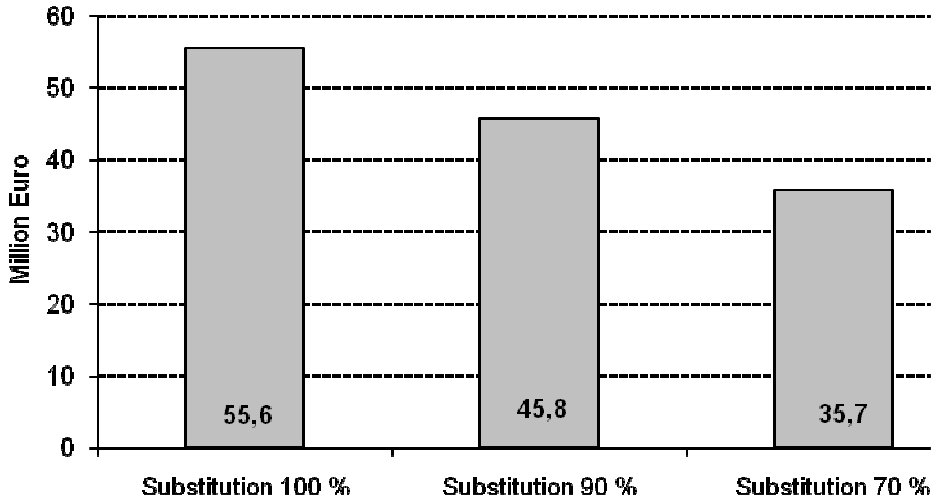
The calculations are based on reimbursable pharmaceutical expenditure in the outpatient sector in the year 2006. Pharmaceuticals with a reimbursement price below € 3.80 were only considered for the calculation if they were dispensed to a person exempted from the prescription fee. Only pharmaceuticals that had already been assigned to an ATC code were considered for the analysis.

On the assumption that a RPS according to the framework which ÖBIG FP had proposed had been in place in 2006, three scenarios were analysed

- Complete substitution: all off-patent pharmaceuticals were substituted by the lowest priced product of the reference group (100% substitution rate)
- Nearly complete substitution: 90% substitution rate
- Partial substitution: 70% percent substitution rate

Figure I shows the savings potential for 57 of the 59 evaluated substances.[2]

Figure I: Management Summary – Possible savings in € million in case of a RPS in the year 2006 (three scenarios)



Source: ÖBIG-FP

On average around ten percent of the pharmaceutical expenditure could have been saved in case of a 100 percent substitution. In 2006, total pharmaceutical expenditure for the Austrian sickness funds accounted for € 2.6 billion for a total of 108 million prescriptions.

Given an optimal framework, savings of around € 55 million are possible in a relatively short period of time. (One should consider about one year of preparation till the implementation of a RPS.)

Up to € 70 million savings per year could be achieved if a moderate expansion in the model (e.g. broader range regarding the package size or the inclusion of further pharmaceuticals and/or substances in the RPS model, e.g. Atorvastatin) took place.

[2] For Atorvastatin (C10AA05, Tradename Sortis®) no follower products were available in the reimbursement list (EKO) in the year 2006, and Trandolapril (ATC C09AA10) is not on the market in Austria.

Evaluation of the Austrian Framework

Table II shows that in Austria for implementing a RPS in the form of the proposed model some changes would be needed. A key requirement would be amendments of the legal framework of the generics policies.

Table II: Management Summary – Evaluation of the framework for the implementation of a RPS in Austria

Framework	Status	Activity
Generic substitution	Not allowed	Several legal changes are needed (e.g. Regulation of the Operation of Pharmacies) in order to aut-idem substitution by pharmacists. In addition appropriate technical and administrative procedures (e.g. adapting the accounting systems in pharmacies) are needed to be in place.
INN prescribing	Not allowed	Legal changes would be required in case of the introduction of INN prescribing, e.g. in the Prescription Act. In the case of the introduction of obligatory generics substitution there is no need for INN prescribing.
Market availability of generics	Sufficient	Generic competition should be promoted. This would include incentives for further generic manufacturers to enter the market.
Generic promotion	Sufficient	The existing promotion activities, as the RöV asking contract doctors to prescribe in an economic way, should be kept and extended respectively.
Compatibility with the box model of the current EKO	Given	No explicit measures needed. The framework of a RPS should be taken into consideration when it comes to (re-)wording of indication rules.
Confidence of insured people in safety, quality, and cost-effectiveness of "followers"(generics, parallel imports)	Currently low	In order to promote the credibility of generics at the population, information and dissemination activities are needed. Such an information campaign should be carried out in consultation and cooperation with all relevant stakeholders of the Austrian health and pharmaceutical system.

RöV = Guidelines on Economic Prescribing of pharmaceuticals and medicinal products, INN = International Non-Proprietary Name

Source: ÖBIG-FP

Conclusion

The introduction of a RPS would be a significant change in the current social insurance system. A RPS could contribute to the decrease of the pharmaceutical expenditure of around € 55 million. The implementation of such a system would require some legal, technical and administrative changes which would have to follow political decisions.

In the 17 EU Member States in which a RPS or a similar system is in place the introduction was implemented based on a law. These laws introducing a RPS usually nominated a key

institution in health care to define and implement the details of the system (e.g. the range of the pharmaceuticals included or further methodology issues). In Austria such an institution could be the Main Association of Austrian Social Security Institutions (HVB).

A major requirement for the implementation of a RPS is a sufficient number of "follower" products (i.e. generics or parallel imported pharmaceuticals) in the reimbursement list. It is a general aim to promote the generics share, also in cooperation with pharmaceutical companies, in order to increase possible savings.

Technical requirements and sufficient resources for the implementation of a RPS should be taken in sincere consideration. These prerequisites include, for instance, the availability of a sufficient number of lower priced pharmaceuticals in pharmacies as well as comprehensive integrated computer systems for the administration of the generic substitution's regulation or patients' co-payments.

Therefore, the implementation of technical and administrative requirements and changes in the legal framework are of major importance. However, in addition, a change management is, in any case, highly needed.

If a RPS were introduced, exemptions for vulnerable groups would need to be introduced since by setting the reference price at the level of the reimbursement price, the patient is required to pay the difference between the reference price and the pharmacy retail price of the prescribed pharmaceutical. In order to protect vulnerable persons exemptions could be defined for cases when substitution may be refused without any (financial) consequence for the patient.

In the surveyed countries obligatory generic substitution was identified as a major prerequisite for the functioning of a RPS. The implementation of obligatory generic substitution in Austria would mean that all pharmacists and self-dispensing doctors would be obliged to dispense the lowest priced pharmaceutical with the same active substance (aut-idem) instead of the prescribed product. Such an aut-idem regulation would still guarantee the protection of vulnerable groups, as at least one product of a reference group would be accessible for the patient without any further co-payment. The only co-payment the patient would be required to pay is – as it is already the case – the prescription fee.

As the analysis in the six case study countries gave evidence, the involvement of doctors and pharmacists at an early stage resulted in a considerably higher acceptance of the RPS by the stakeholders. Plans for a possible introduction of a RPS should therefore be discussed with all relevant stakeholders of the pharmaceutical system (sickness funds, doctors, administration, pharmacists, patient representatives, pharmaceutical industry including generic manufacturers).

In addition, large-scale information and dissemination activities are indispensible to make generics better known to the public and to show their role as cost-effective alternatives to brands.

Recommendation

If, after having considered all possible consequences, policy-makers decide to introduce a RPS in Austria, this should be implemented by a step-by-step wise approach which involves all relevant stakeholders.

In this project, it was proposed that a possible introduction of a RPS should be based on substance level (= ATC 5). However, this should be considered as a starting point which might be changed to a broader approach later. In the model which ÖBIG FP developed with the view of possibly introducing a RPS the reimbursement price of the lowest priced product of a reference group was proposed as the reference price, and the reference groups were suggested to be built by applying strict aut-idem criteria. In the model proposed, the patient still has the choice between a product which s/he receives without any co-payment (apart from the prescription fee) after substitution by the pharmacist and a higher priced pharmaceutical prescribed by the doctor.