

**Study of the Portuguese System of Co-
Participation and Pricing of Medicines, in
the Context of the Health System Reform**

Summary (English)

**Europe Economics
Chancery House
53-64 Chancery Lane
London WC2A 1QU
Tel: (+44) (0) 20 7831 4717
Fax: (+44) (0) 20 7831 4515
www.europe-economics.com**

26 May 2005

TABLE OF CONTENTS

1	EXECUTIVE SUMMARY	1
2	SUMMARY	3
	Recent Trends in the Portuguese Expenditure on Pharmaceuticals	3
	Analysis of Potential Reforms	4
	Conclusions and Recommendations	9
	Model	11

1 EXECUTIVE SUMMARY

1.1 This is a summary of the study on the Portuguese co-participation and pricing system commissioned by INFARMED from Europe Economics.

1.2 The study recommends that the following measures be implemented:

(a) High priority reforms —

- The reference price system should be widened and based on protocols, allowing it to include in-patent drugs. Under this scheme the co-participation rate would be based on therapeutic protocols devised and put forward by a central committee and designed to achieve better therapeutic value. The co-participation regime for chronic diseases would be included under this system.
- Prices of generics should be liberalised. In particular, the existing regulation which hinders the movement of generic prices, and that which limits the price of the first generic in the market at 65 per cent of the reference branded products should be removed.
- The reference pricing system for generics should be changed so that the reference price is defined on the basis of the price of lowest or second lowest price generic.

(b) Lower priority reforms —

- Once the generic market has achieved a sufficient level of maturity (one may use a penetration level of 20 per cent as a measure) the additional 10 percentage points currently given in the co-participation of generics should be removed.
- The additional 25 percentage points that are added into the calculation of the reference price for users under the Special Regime should not be extended beyond December 2005, when the existing law expires.
- New medicines used for the treatment of diseases caught under the protocol based reference price system should not have to negotiate with Infarmed about the co-participation price; these medicines should be allowed to have any price provided it is below that calculated by DGE.
- The parallel import of generic medicines should be encouraged.
- Survey based systems of gathering information about prescription habits should be adopted.
- Once the breadth of the use of the protocols is made clear and once it is possible to obtain a clear view on the levels of the expenditure of medicines borne by patients, it is recommended that consideration should be given to setting a

Executive Summary

threshold for that expenditure, above which the co-participation of the State would be greater.

2 SUMMARY

Recent Trends in the Portuguese Expenditure on Pharmaceuticals

- 2.1 The analysis carried out finds that Portugal marks itself out in contrast to other European countries on the following fronts:
- (a) The volume of prescriptions is high.
 - (b) Pharmaceutical expenditure accounts for a high proportion of GNP (although it is not particularly high in terms of expenditure per capita).
 - (c) The ratio between expenditure borne by patients and GNP is high.
- 2.2 Public expenditure on pharmaceuticals, due to the co-participation regime, has been an important factor in the growth of public expenditure in health. The growth rate of expenditure on pharmaceuticals has fallen in recent years though it is still above the growth rate of GNP.¹

Table 1: NHS expenditure

	1998	1999	2000	2001	2002	2003
NHS budget (10⁶ EUR)	3612	4214	4569	5007	5145	5 460,3
NHS pharmaceutical expenditure (10⁶ EUR)	848	944	1039	1147	1227	1 272,9
NHS pharmaceutical expenditure (% of NHS budget)	23.5%	22.4%	22.7%	22.9%	23.9%	23.3%
NHS pharmaceutical expenditure (% of GNP)	0.84%	0.88%	0.90%	0.93%	0.95%	0.97%

Source: INFARMED, IGIF e INE

- 2.3 It is possible to analyse the relative contribution of changes in price levels or of other factors to the trend in pharmaceutical expenditure. For example, of the increase in pharmaceutical expenditure between 2001 and 2002 (80 million euros), just 15.5 million euros (19 per cent) can be attributed to price increases over the same period (1.4 per cent). In other words, 81 per cent of the increase in pharmaceutical expenditure must be attributable to other factors such as changes in prescription habits, with the prescription of more expensive medicines, an increase of consumption and an increase in the number of prescriptions per capita.

¹ Other than NHS, there are "health sub-systems", which cover around 25 percent of the population. Access to sub-systems is limited to certain professional classes. In particular, public servants have access to the services of ADSE. The users covered by sub-systems also have access to NHS services. Due to sub-systems, around one quarter of the population benefit from double-, or even triple-, -coverage leading to an inefficient use of resources (Oliveira and Bevan, 2003).

- 2.4 Table 2 suggests that in recent years, and in particular during the first quarter of 2003, there was a considerable increase in the number of prescriptions and in the consumption of generic medicines.

Table 2: Penetration of generics

Year	Penetration (value)	Penetration (volume)
2000	0,13%	0,10%
2001	0,34%	0,26%
2002	1,76%	1,08%
2003	5,65%	3,42%
2004	7,90%	4,81%
Jan-Mar 2005	11,37%	7,06%

Source: INFARMED

Analysis of Potential Reforms

- 2.5 Based on an analysis of the constraints, inefficiencies and inequities of the co-participation system for pharmaceuticals in Portugal, as well as of views gathered during the consultation period, the study develops potential reforms which could help meet some of the problems identified.
- 2.6 The analysis of the potential reforms is done taking into account the following criteria:
- (a) Health needs;
 - (b) Efficiency of the pharmaceutical industry;
 - (c) Access and equity;
 - (d) Financial sustainability of the system;
 - (e) Relations between payer and provider;
 - (f) Feasibility.
- 2.7 The analysis makes use of models, developed within the context of the study, which estimate the impact of each reform in relation to:
- (a) NHS expenditure;
 - (b) Expenditure borne by users, distinguishing between those in the Special Regime and those in the Normal Regime;
 - (c) Expenditure borne by users, broken down by income quintile;

- (d) Changes in behaviour, for example, prescription habits and pricing strategy of companies that might offset the intended effect of reform.

2.8 The following themes, related to the regulation of the pharmaceutical sector, are, in our view, the most relevant.

(a) The pharmaceutical sector in Portugal (as in various other European countries) exhibits a low level of competition in terms of prices and the agents are, in general, relatively insensitive to prices. This being so, unless policies are developed with a view to containing the volume of prescription or of containing prices, it is to be expected that expenditure will continue to grow. Wherever possible, it would be desirable for the reforms to encourage greater competition so that expenditure is contained in a “natural” way.

(b) There has been a clear effort in the encouragement of the generic market in recent years, but some features of it suggest that it has not yet reached a level of maturity. In particular, it is noted that:

- There is a smaller tendency for a fall in prices over time than is the case in mature markets and one observes a concentration of prices around the maximum level that is allowed.
- There is some reluctance in the prescription and prescribing of generics.
- Generic penetration is greater in terms of value than in terms of volume. This suggests that generics tend to be present in segments of the market with higher price levels. In European markets with a long history of generic presence, the relation is the reverse.
- Generics receive preferential treatment under the co-participation system, presumably because it is thought that this is necessary to encourage their use.

(c) There are still some ad hoc characteristics in the systems, regulated to meet the needs of particular social or interest groups but which are not properly integrated in the global system (one example is the regime covering specific illnesses, another is the additional 25 percentage points used when calculating reference price for pensioners with low income, a measure that is in place until the end of this year). These measures give rise to two problems:

- They lead to an increase in the administration costs, as the management of the special rules cannot be done automatically by the system;
- They make the system vulnerable to the extension of special regimes to other groups that might think (legitimately or not) that their characteristics should allow them to receive special treatment.

Summary

- The system would be more efficient and more robust if it included clear justifications for the differential treatment of different categories of illnesses and patients.
- (d) The pattern of consumption of pharmaceuticals in Portugal distinguishes itself from those in other EU-15 Member States along various dimensions:
- Portugal has high levels of prescription;
 - Portugal has a high ratio of pharmaceutical expenditure and income;
 - The expenditure borne by users is high and, as a proportion of national income, it is the second highest within EU-15;
 - Prices calculated on the basis of exchange rate are low compared to those in other countries, but high once this is adjusted for purchasing power parity.

2.9 The analysis considered various suggestions, the following being those of greatest interest.

- (a) We studied the effect of changing the co-participation rate by 5 percentage points for each of the four existing categories: 20, 40, 70 and 100 per cent.

The impact of a reduction of 5 percentage points in these co-participation rates is set out in Tables 3 and 4.

Table 3: A reduction of 5 percentage points in co-participation rates

	Impact of reform			
	Sales	Costs borne by users in Special Regime	Costs borne by users in Normal Regime	Co-participation costs of NHS
A fall of 5 percentage points	0,0%	+16,1%	+9,4%	-6,8%

Source: Europe Economics analysis

Table 4: A reduction of 5 percentage points in co-participation rates: impact on private expenditure on pharmaceuticals

Quintile (per capita annual expenditures on medicines)	Per capita annual income(€)	Reduction of co-participation rate by 5 percentage points
1 (€174,0)	1 750,6	+20.52
2 (€160,6)	2 691,0	+18.94
3 (€139,0)	3 651,0	+16.39
4 (€154,4)	5 134,0	+18.21
5 (€168,3)	10 750,5	+19.85
Todos (€159,6)	4 781,6	+18.82

Source: Europe Economics analysis

The impact of a 5 percentage point increase in the co-participation rate, on the other hand, would be the same in absolute terms as that set out in Tables 3 and 4, though the direction of change would be reversed.

- (b) The possibility of defining the reference price on the basis of the second cheapest generic was considered

**Appraisal
Reference price based on cheapest or second cheapest generic**

Response to health needs	Limited effect
Efficiency of pharma industry	Increased (greater competition)
Access and equity	Increases in the medium run given that an increase in price competition could lead to a fall in generic prices and, therefore, to a fall in costs borne by patients. Possible reduction in equity in short run.
Financial sustainability of system	Greater
Payer-provider relation	Greater complexity
Feasibility	Can be implemented; already in place in many countries

- (c) We considered extending the reference price system to include in-patent pharmaceuticals on the basis of treatment protocols for specific diseases. (The protocol system is discussed further below).

**Appraisal
Protocol based reference prices**

Response to health needs	Increases due to a greater use of best-practice and greater incentives for innovation in areas of therapeutic best value.
Efficiency of pharma industry	Increases due to greater incentives to compete amongst branded products and greater incentives for innovation in areas of therapeutic best value.
Access and equity	Increases in the long run, given that prices (and therefore cost borne by consumers) would mirror more closely their therapeutic value. Costs borne by patients could increase in the short term.
Financial sustainability of system	Increase
Payer-provider relation	Greater complexity
Feasibility	Although the process of establishing protocols is lengthy, the measure can be implemented provided a top-down methodology is adopted when developing it and provided protocols are not created for diseases for which they would be clearly inadequate.

- (d) In countries with few restrictions on the price of generics, prices take some time to fall to competitive levels. However, when this is reached, prices are considerably lower than those seen in Portugal. Table 5 compares the prices in Portugal and in the UK of the 10 more significant generic pharmaceuticals whose patent expired during the nineties.

Table 5: Comparison of generic prices between Portugal and the UK

Active ingredient	Patent expiry*	Price (EUR)		Correspondence of price level to that in the UK: potential reduction in cost (10 ⁶ EUR)	
		Portugal	UK	NHS	User co-payment
Ranitidine: 150mg, 60 units	97-3	29.30	10.32	7.3	1.7
Enalapril: 20 mg, 56 units	99-4	35.28	15.70	7.4	1.0
Fluoxetine: 20mg, 60 units	00-1	30.58	5.30	13.6	5.5
Atenol: 50mg, 56 units	90-1	8.49	2.08	2.1	1.0
Cimetidina, 400mg, 60 units	92-1	44.97**	7.97	n/a	n/a
Ciclosporin: 50mg, 30 units	94-4	44.68**	57.50	-3.2	n/a
Captopril: 25mg, 90 units	97-1	19.65	6.70	11.0	3.1
Aciclovir: 800mg, 35 units	95-3	72.54	20.79	2.3	1.7
Piroxicam: 20mg, 30 units	90-2	10.33	4.71	4.4	1.7
Gabapentin: 300mg, 50 units	00-4	21.00	37.86	-0.3	n/a

* Expiry date is that in the UK

** Means there are no generics and consequently we use (as current price) the price of the branded product with greatest sales. For other products we use the generic with greatest sales.

Conclusions and Recommendations

2.10 The following recommendations are made:

Reforms of high priority

- (a) Reference pricing system based on protocols: this reform, which we think important, is the introduction of a system in which the co-participation rates are linked in a more explicit manner to the treatment recommended for each disease.

It would not be necessary (or possible) to implement these protocols across all diseases, but wherever it is possible to devise an acceptable protocol, co-participation should be calculated on the basis of the recommended medicines. If the recommended medicine were one that falls within a homogenous group in which generics already exist, the co-participation should be calculated on the basis of the reference price applicable to that homogenous group.

This change to the reference price system would have the following benefits:

Summary

- It would stimulate price competition amongst manufacturers of products that target the same illness, creating thereby a natural means to control costs as well as giving incentives to introduce innovative products in segments where their therapeutic benefit would be greater, rather than innovation for marginal improvements.
 - It would allow, partly following on from the above, for a fall in the natural tendency of manufacturers to reply to measures that control the prices of generics by promoting me-too products, thereby creating opportunities for the growth of generics.
 - It would allow for chronic diseases to be caught under the same system as all other diseases (and no longer be considered ad hoc cases) given that the co-participation rate would be linked to the condition and not to the medicine.
 - The creation of nationwide protocols would be part of a wider possible health reforms — reforms that go beyond the direct remit of Informed — with the objective of increasing the sensitivity of doctors to the cost of pharmaceuticals and of increasing the ability to audit prescription habits of doctors.
- (b) Eliminate all regulation of generic prices, This reform would liberalize the generic market, encouraging greater competition in this sector by:
- Giving manufacturers greater freedom to lower prices, by making it known that they can always raise them later (until now a decrease in prices is practically irreversible)
 - Making it easier for generics to enter in segments where branded medicines are cheaper;
 - Removing peculiar features such as that which requires for a generic to always be 5 per cent cheaper than the cheapest branded product, a regulation that does not take into account the latter's market share and which leads, at times, to the creation of "ghost" pharmaceuticals, rarely manufactured or consumed but which impede the entry of generics.
 - Removing the regulation which limits the price of the first generic to 65 per cent of the price of the reference product.
- (c) Change the reference price system so that it is based on the price of the cheapest, or second cheapest, generic (in the latter case, the co-participation of the cheapest generic would be done on the basis of the reference price and not that of its own). This measure would lead to greater competition between generic manufacturers and lead to a decrease in NHS expenditure. There would be greater competition because the purchase of the cheapest generic would not only reduce co-payments but would lead to a higher effective co-participation rate.

Low priority reforms

- (a) Remove the additional 10 percentage points attributed to the co-participation of generics. This measure was a useful one to promote the generics market. However, this measure will cease to be useful at some point. We suggest that this additional co-participation be removed once the penetration (in terms of volume) of generics has reached 20 per cent.
- (b) Remove the additional 25 percentage points that are given when calculating the reference price for pensioners with low income. This measure is due to cease being in effect from December 2005, given that by then the effect of the reference pricing system will already have had an impact on prices and therefore one would not expect an increase in the costs to that group of patients when the measure is abandoned.
- (c) Remove the need to set co-participation prices a priori for medicines that fall under the protocol based reference pricing system (provided the price is below that set by DGE). This measure will:
 - Reduce administrative costs;
 - Allow for quick entry into the market of innovative products;
 - Allow greater freedom in the formulation of pricing proposals to the evaluation commission that reflect the therapeutic advantage of new medicines.
- (d) Measures to promote parallel trade and import of generics, linking Portugal to international markets.
- (e) With the aim of improving the information available on which to base future decisions (in particular to improve the understanding of the impact on equity and to develop recommendations of a transitory nature), it would be useful to develop several information systems and to gather, in a systematic fashion and through surveys, information about prescription habits.
- (f) Once it has become clear how wide the use of protocols is and once it is possible to form a clear view on the level of expenditure supported by patients, it is recommended that consideration be given to setting a threshold for that expenditure, above which the co-participation by the State would be greater.

Model

- 2.11 As a complement to the main report, Europe Economics developed a model which allows one to study the impact of reforms to the co-participation system — including, but not limited to those described in the report — on the expenditure borne directly by the NHS and by patients.