

# Cost-containment policies in public pharmaceutical spending in the EU

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Abstract

This paper presents and evaluates pharmaceutical policies in the EU aimed at the rational use of medicines and at keeping pharmaceutical spending under control. Policy makers are growing more aware that by regulating pharmaceutical markets correctly, considerable savings can be achieved without compromising the quality of care. Specifically, the paper makes the case that, by following numerous best-practices in pharmaceutical sector regulations, the value for money of pharmaceutical consumption could be substantially increased. Appropriate regulations can be relevant for pricing, reimbursement, market entry and expenditure control, as well as specific policies targeted at the distribution chain, physicians and patients.

JEL classification: I11, I18.
Key words: rational use of medicines, generic substitution, public pharmaceutical expenditure, pharmaceutical policies, cost-containment, value for money, pharmaceutical sector regulations.

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*The views expressed in this paper are those of the authors and should not be attributed to the European Commission.

**Contents**

## Tables



## Graphs

**Abbreviations**

| | |
|---|---|
| ATC | Anatomical Therapeutic Chemical (Classification System) |
| DDD | Defined daily dose |
| DG | Directorate-General |
| EMA | European Medicines Agency |
| ERP | External reference pricing |
| EUNetHTA | European network for Health Technology Assessment |
| ExFP | Ex-factory price |
| HTA | Health-technology assessment |
| INFARMED | National Agency for Pharmaceuticals in Portugal |
| INN | International non-proprietary name |
| IRP | Internal reference pricing |
| NICE | (UK) National Institute for Health and Clinical Excellence |
| OTC | Over-the-counter (products) |
| POM | Prescription-only medicine(s) |
| PPRI | Pharmaceutical Pricing and Reimbursement Information |
| PPP | Pharmacy purchasing price |
| PPS | Purchasing power standards |
| PPRS | Pharmaceutical Price Regulation Scheme |
| PRP | Pharmacy retail price |
| QALY | Quality-adjusted life-year |
| Reimb | Reimbursed medicines |
| VAT | Value-added tax |

## 1. Introduction

This paper describes and attempts to evaluate pharmaceutical policies in the EU with a focus on cost-containment. The paper pins down those policies which favour the rational use of medicinal products[1] and contribute to control public expenditure. Its purpose is to provide evidence-based guidance for elaborating country-specific pharmaceutical policies. While country specificities can be observed, there is a basket of core pricing and reimbursement policies, directed at providers and users, are being put in place to encourage a more rational use of medicines. Given the fiscal impact of the economic and financial crisis and the projected costs of an ageing population[2], these policies are of increasing interest to the public healthcare payers and are assessed in this paper.

Medicinal products for human use are defined as substances or combination of substances presented for treating or preventing diseases in human beings. Demand for pharmaceuticals is sizeable and the potential benefits of pharmaceutical consumption have been reportedly significant (Cutler 2006, Lichtenberg 2010). However, these benefits come at a substantial direct cost. In the EU, public and private outpatient pharmaceutical spending accounts for roughly 16% of total expenditure on health care and 1.6% of GDP (Table 1). Public expenditure alone represents about 1.1% of GDP in 2010. After the USA, the EU is the second biggest pharmaceutical market with a share of 27% of worldwide turnover in sales, totalling € 192 billion in 2010 (IMS 2011a, BPI 2011).

Because pharmaceutical expenditure is increasing, pharmaceutical policies aiming at cost-containment are more and more in the focus of national health authorities and European policy makers. Policy makers are growing more aware that, by regulating pharmaceutical markets correctly, savings can be achieved without compromising the quality of care.[3] This is why policies promoting the use of generic medicines are often at the forefront in the attempt of increasing the cost-effectiveness of medicinal products.

At the European level, many initiatives related to the pharmaceutical sector have been undertaken. These include recommendations and directives, among others on the transparency of pricing and reimbursement procedures[4] and the safety and efficacy of medicines[5]. Other

[1] In this publication, the terms medicinal or pharmaceutical products, pharmaceuticals and medicines are used interchangeably.

[2] See EC(DG ECFIN)-EPC (AWG), "The 2012 Ageing Report – Economic and budgetary projections for the 27 EU Member States (2010-2060)", European Economy, No 2/2012.

[3] A key opportunity in this respect is generic medicines. Generics are therapeutic alternatives to originator medicines. They are as effective (Aaserud et al. 2009), but on average three to four times cheaper than the respective off-patent originals. In the next four years, up to 40% of currently patent protected pharmaceuticals will be available to generic medicines, creating a huge savings potential (IMS 2010).

[4] Directive 89/105/EEC relating to the transparency of measures regulating the pricing and reimbursement of medicinal products for human use.

initiatives relate to the assessment of cost-effectiveness of pharmaceutical spending by fostering common best practices in health-technology analyses[6]. The "Joint EC(ECFIN)-EPC Report on Health Systems"[7] by the Directorate-General for Economic and Financial Affairs (DG ECFIN) and the Economic Policy Committee (European Commission 2010) has stressed the need to keep public budgets under control through targeted policies promoting the rational use of pharmaceuticals. This has also been pointed to extensively by the High Level Pharmaceutical Forum[8], the Pharmaceutical Sector Inquiry[9] by DG Competition (European Commission 2009), the report on pricing and reimbursement systems in Europe"[10] funded by DG Enterprise and Industry (Espin 2007) and the PPRI initiative[11] partly funded by DG Health and Consumers.

The paper is structured as follows. Firstly, a snap-shot of the evolution and the current situation of outpatient pharmaceutical spending in the EU is presented (section 2). Secondly, an overview of the main pharmaceutical policies in the EU Member States is given (section 3). A more detailed examination of the application and impact of individual policies is presented in sections 4 - 16. The most frequent past and recent reforms and their reported impact are documented in section 17, while policy options for the EU are evaluated in section 18. Section 19 draws conclusions.

## 2. Pharmaceutical spending in the EU – Evolution and current status

Medicines are consumed in the inpatient (mostly hospitals) and outpatient (mostly pharmacies) sector. However, comparable cross-country data on pharmaceutical spending is not available for the inpatient sector for most of the EU Member States.[12] Consequently, the paper describes and analyses expenditure on outpatient pharmaceuticals.[13] Total, i.e. public and private, spending on outpatient pharmaceuticals varied from 0.6 to 2.6% of GDP in 2010

[5] E.g. the European Medicines Agency (EMA) being responsible for the evaluation and supervision of medicines for human and veterinary use: http://www.ema.europa.eu/ema/

[6] E.g. EUnetHTA, increasing the collaboration of national health-technology assessment agencies at European level: http://www.eunethta.eu. At the current moment, EUNetHTA is limited to studying effectiveness i.e. it excludes cost-effectiveness.

[7] http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/pdf/ocp74_en.pdf

[8] http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf

[9] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[10] http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/study_pricing_2007/andalusian_school_public_health_report_pricing_2007_en.pdf

[11] http://ppri.goeg.at/

[12] The inpatient sector relates to hospitals, nursing and residential care facilities. The outpatient sector covers also the services of ambulatory health care.

[13] The OECD has started providing specific data for inpatient pharmaceutical spending only recently and for a limited number of countries. Inpatient pharmaceutical spending adds another 15% of spending on average in OECD countries.

(EU: 1.6%) (Table 1).[14] Since the 1990s, it has increased as a share of GDP in all EU Member States except for Luxembourg. Countries with high total pharmaceutical expenditure as a percentage of GDP (e.g. those above 2% of GDP) include Bulgaria, Greece, Lithuania, Hungary, Portugal and Slovakia. Those with low pharmaceutical expenditure in terms of GDP, as well as a percentage of total health expenditures, include Denmark, the Netherlands, Luxembourg, Sweden and the UK. In the EU, between 7.7 and 35.3% of total spending on health is accounted for by outpatient pharmaceutical spending. There is no overall trend, as to what percentage of total health care spending is devoted to pharmaceuticals.

Public spending on outpatient pharmaceuticals varied from 0.3 to 1.7% of GDP in 2010 (EU: 1.1%). Since the 1990s, it has increased as a share of GDP for all countries in the EU except the Czech Republic, Denmark, Luxembourg, Italy, Poland and Sweden. Some countries, such as Germany, Greece, Spain, France and Slovakia, have relatively high public spending on pharmaceuticals and a relatively low share of private co-payment. Bulgaria, Denmark, Cyprus, Latvia, Luxembourg, Romania spend relatively little public money on pharmaceuticals in terms of GDP. Except for Luxembourg, this is because the private share in total pharmaceutical spending is relatively high.

Whilst health care in EU Member States is to a large extent publicly funded, this is less the case for pharmaceutical spending, where private co-payment can be extensive. Still, public spending is considerable. In the EU, around 60% of total pharmaceutical spending is public spending. It is predominantly private in Bulgaria, Estonia, Italy, Cyprus, Latvia, Lithuania, Poland and Romania (Table 2). For Member States with available long-term data, it appears that the public share in total spending went up for some (e.g. Germany, Netherlands, Finland, UK) and down for others (Czech Republic, Slovakia), with no apparent overall trend for the EU.

The variation in spending as a share of GDP conceals a much more considerable variation in total and per capita spending. As expected, given the size of the population, in 2010, Germany was the biggest pharmaceutical market in the EU (Euro 42,383 million), followed by France (€ 36,006 million), Italy (€ 24,872 million), Spain (€ 18, 500 million), and UK (€ 18,154 million) (Table 1). These five countries account for over 70% of pharmaceutical turnover in the EU. In per capita terms, between 152 Euro PPS (Romania) and 492 Euro PPS (Germany) are spent annually (EU: 409 Euro PPS). Public per capita expenditure varies between 46 in Bulgaria and 403 Euro PPS in Ireland (EU: 283). Both total and public per capita expenditure have increased considerably over the last decades.

[14] Differences in spending on outpatient pharmaceuticals may results partly from differences in accounting standards, such that some expensive pharmaceuticals may be accounted for in some countries in hospitals and in other countries in pharmacies.

## Table 1 – Evolution of total (public and private) outpatient pharmaceutical expenditure (1970 – 2010)

| | Total current expenditure on health (% GDP) | | | | | Total expenditure on pharmaceuticals (% GDP) | | | | | Total expenditure on pharmaceuticals (as % total current health expenditure) | | | | | Total per capita expenditure on pharmaceutials (in purchasing power standards) | | | | | Total expenditure on pharmaceuticals (in million Euro) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 2010* |
| **Belgium** | 3.9 | 6.3 | 7.2 | 8.1 | 10.5 | 1.1 | 1.1 | 1.1 | 1.6 | 1.7 | : | : | : | : | 15.8 | 27 | 90 | 189 | : | 482 | 5,926 |
| **Bulgaria** | : | : | 4.9 | 6.1 | 6.9 | : | : | : | : | 2.4 | : | : | : | : | 35.3 | : | : | : | : | 250 | 857 |
| **Czech Republic** | : | : | 4.1 | 6.2 | 7.3 | : | : | 1.0 | 1.5 | 1.5 | : | : | 24.2 | 24.7 | 20.4 | : | : | 106 | 200 | 288 | 2,217 |
| **Denmark** | : | 8.6 | 8.2 | 8.1 | 10.7 | : | 0.5 | 0.6 | 0.7 | 0.8 | : | 6.3 | 7.6 | 9.0 | 7.7 | : | 44 | 104 | 182 | 255 | 1,942 |
| **Germany** | 5.7 | 8.1 | 8.0 | 9.9 | 11.2 | 1.0 | 1.1 | 1.2 | 1.4 | 1.7 | 17.0 | 13.9 | 14.7 | 14.1 | 15.3 | 28 | 104 | 226 | 316 | 492 | 42,383 |
| **Estonia** | : | : | : | 5.2 | 6.3 | : | : | : | 1.2 | 1.4 | : | : | : | 22.8 | 22.0 | : | : | : | : | 217 | 198 |
| **Ireland** | 5.1 | 7.7 | 5.8 | 5.7 | 8.9 | : | 0.9 | 0.7 | 0.9 | 1.7 | : | 11.7 | 12.8 | 15.1 | 19.1 | : | : | : | : | 528 | 2,646 |
| **Greece**** | 5.4 | 5.9 | 6.6 | 7.5 | 10.5 | 1.4 | 1.1 | 0.9 | 1.5 | 2.1 | : | : | 14.9 | 19.9 | 19.6 | 31 | 76 | 109 | 239 | 432 | 4,515 |
| **Spain** | 3.2 | 5.1 | 6.3 | 7.0 | 9.3 | : | 1.1 | 1.2 | 1.5 | 1.8 | : | 21.8 | 18.6 | 22.0 | 18.8 | : | 62 | 140 | 284 | 431 | 18,500 |
| **France** | 5.3 | 6.9 | 8.2 | 9.8 | 11.2 | 1.3 | 1.1 | 1.4 | 1.7 | 1.9 | 24.4 | 16.4 | 17.3 | 16.9 | 16.5 | 30 | 87 | 219 | 365 | 488 | 36,006 |
| **Italy** | : | : | 7.3 | 7.7 | 8.8 | : | : | 1.6 | 1.8 | 1.6 | : | : | 21.4 | 23.1 | 17.9 | : | : | 247 | 394 | 393 | 24,872 |
| **Cyprus** | 2.7 | 2.8 | 4.5 | 5.3 | 5.8 | : | : | : | : | 1.3 | : | : | : | : | 21.6 | : | : | : | : | 304 | 218 |
| **Latvia** | : | 2.1 | 2.5 | 6.0 | 6.0 | : | : | : | : | 1.3 | : | : | : | : | 21.5 | : | : | : | : | 180 | 293 |
| **Lithuania** | : | : | 3.3 | 6.5 | 7.5 | : | : | : | : | 2.0 | : | : | : | : | 26.6 | : | : | : | : | 254 | 528 |
| **Luxembourg** | 3.1 | 5.2 | 5.4 | 5.8 | 6.2 | 0.6 | 0.8 | 0.8 | 0.6 | 0.6 | : | : | : | 11.1 | 10.0 | : | : | : | 243 | 432 | 246 |
| **Hungary** | : | : | : | 6.8 | 7.6 | : | : | : | : | 2.6 | : | : | : | : | 34.6 | : | : | : | : | 414 | 2,544 |
| **Malta** | : | : | : | 6.0 | 6.9 | : | : | : | : | 1.6 | : | : | : | : | 22.8 | : | : | : | : | 306 | 92 |
| **Netherlands** | : | 7.0 | 7.5 | 7.6 | 11.2 | : | 0.6 | 0.8 | 0.9 | 1.1 | : | 8.4 | 10.2 | 12.3 | 10.2 | : | 47 | 122 | 238 | 370 | 6,715 |
| **Austria** | 4.9 | 7.1 | 7.8 | 9.4 | 10.4 | : | : | 0.8 | 1.2 | 1.3 | : | : | 10.6 | 13.0 | 12.6 | : | : | 144 | 302 | 404 | 3,761 |
| **Poland** | : | : | 4.4 | 5.3 | 6.5 | : | : | : | : | 1.6 | : | : | : | : | 24.3 | : | : | : | : | 242 | 5,613 |
| **Portugal** | 2.4 | 5.0 | 5.8 | 8.5 | 9.8 | 0.3 | 1.1 | 1.5 | 2.0 | 2.0 | 14.2 | 21.0 | 25.3 | 23.4 | 19.7 | : | 40 | 139 | 293 | 404 | 3,450 |
| **Romania** | : | : | 2.9 | 5.2 | 5.6 | : | : | : | : | 1.5 | : | : | : | : | 26.9 | : | : | : | : | 152 | 1,816 |
| **Slovenia** | : | : | : | 8.2 | 8.6 | : | : | : | : | 1.8 | : | : | : | : | 20.3 | : | : | : | : | 363 | 621 |
| **Slovakia** | : | : | : | 5.4 | 8.5 | : | : | : | 1.9 | 2.4 | : | : | : | 34.7 | 28.0 | : | : | : | 126 | 427 | 1,567 |
| **Finland** | 5.1 | 6.0 | 7.4 | 6.9 | 8.5 | 0.7 | 0.7 | 0.7 | 1.1 | 1.2 | 13.8 | 11.2 | 9.9 | 15.5 | 14.6 | 15 | 49 | 116 | 238 | 348 | 2,216 |
| **Sweden** | 6.8 | 8.9 | 7.7 | 7.8 | 9.1 | 0.4 | 0.6 | 0.7 | 1.1 | 1.2 | : | : | 8.6 | 14.5 | 13.3 | 13 | 50 | 115 | 275 | 365 | 4,212 |
| **United Kingdom** | 4.2 | 5.3 | 5.5 | 6.7 | 9.1 | 0.7 | 0.7 | 0.8 | 1.0 | 1.0 | 15.8 | 13.5 | 14.5 | 14.8 | 11.0 | 15 | 49 | 117 | : | 305 | 18,154 |
| **EU** | **5.0** | **6.9** | **7.2** | **8.2** | **9.9** | **1.0** | **1.0** | **1.2** | **1.4** | **1.6** | **19.0** | **14.3** | **15.9** | **16.5** | **15.7** | **25** | **77** | **187** | **321** | **409** | **192,108** |
| **EU - unweighted average** | **4.4** | **6.1** | **6.0** | **7.0** | **8.5** | **0.8** | **0.9** | **1.0** | **1.3** | **1.6** | **17.0** | **13.8** | **15.0** | **18.1** | **19.5** | **23** | **63** | **150** | **264** | **353** | **192,108** |

***Source:*** Eurostat, OECD Health Data 2012, Commission services (DG ECFIN).
***Notes***: * 2010 or latest data. ** For Greece, preliminary 2010 data. Public as % of total expenditure on pharmaceuticals is calculated as the ratio between public and total spending expressed in Euro (and not e.g. as % of GDP). Country-specific GDP's are used to compute EU weighted averages.

## Table 2 – Evolution of public outpatient pharmaceutical expenditure (1970 – 2010)

| | Public current expenditure on health (% GDP) | | | | | Public expenditure on pharmaceuticals (% GDP) | | | | | Public per capita expenditure on pharmaceutials (in purchasing power standards) | | | | | Public as % of total expenditure on pharmaceuticals | | | | | Public expenditure on pharmaceuticals (in million Euro) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 1970 | 1980 | 1990 | 2000 | 2010* | 2010* |
| **Belgium** | : | : | : | 6.6 | 8.0 | 0.6 | 0.6 | 0.5 | : | 1.1 | 16 | 51 | 89 | : | 305 | 55 | 55 | 45 | : | 63 | 3,754 |
| **Bulgaria** | : | : | 5.2 | 3.7 | 4.4 | : | : | : | : | 0.4 | : | : | : | : | 48 | : | : | : | : | 18 | 156 |
| **Czech Republic** | : | : | 4.6 | 5.9 | 6.3 | : | : | 0.9 | 1.2 | 0.9 | : | : | 94 | 153 | 184 | : | : | 90 | 80 | 64 | 1,412 |
| **Denmark** | : | 7.9 | 6.9 | 6.8 | 9.5 | : | 0.3 | 0.2 | 0.4 | 0.4 | : | 22 | 35 | 89 | 134 | : | 60 | 33 | 57 | 53 | 1,023 |
| **Germany** | 4.4 | 6.6 | 6.3 | 8.2 | 8.9 | 0.6 | 0.8 | 0.9 | 1.0 | 1.3 | 18 | 77 | 165 | 228 | 376 | 60 | 73 | : | 71 | 76 | 32,397 |
| **Estonia** | : | : | : | 4.1 | 5.0 | : | : | : | 0.5 | 0.7 | : | : | : | : | 106 | : | : | : | 42 | 49 | 97 |
| **Ireland** | 4.1 | 6.8 | 4.4 | 4.6 | 6.4 | : | 0.5 | 0.5 | 0.6 | 1.3 | : | : | : | : | 403 | : | 56 | 71 | 67 | 76 | 2,020 |
| **Greece**** | 2.3 | 3.3 | 3.5 | 4.7 | 5.6 | 0.8 | 0.7 | 0.5 | 0.9 | 1.8 | 15 | 47 | 61 | 150 | 495 | 57 | 64 | 56 | 60 | 89 | 4,000 |
| **Spain** | 2.3 | 4.2 | 5.1 | 5.2 | 7.1 | 0.7 | 0.7 | 0.8 | 1.1 | 1.3 | 14 | 38 | 101 | 210 | 312 | : | 64 | 67 | 73 | 72 | 13,380 |
| **France** | 4.1 | 5.6 | 6.4 | 8.0 | 9.0 | 0.9 | 0.7 | 0.9 | 1.1 | 1.3 | 20 | 57 | 136 | 245 | 334 | 69 | 64 | 64 | 65 | 68 | 24,545 |
| **Italy** | : | : | 6.1 | 5.8 | 7.2 | : | : | 0.9 | 0.8 | 0.8 | : | : | 150 | 176 | 190 | : | : | 56 | 44 | 48 | 12,029 |
| **Cyprus** | 0.9 | 1.5 | 1.8 | 2.4 | 3.1 | : | : | : | : | 0.3 | : | : | : | : | 75 | : | : | : | : | 24 | 52 |
| **Latvia** | : | : | 2.5 | 3.2 | 4.1 | : | : | : | : | 0.5 | : | : | : | : | 67 | : | : | : | : | 38 | 110 |
| **Lithuania** | : | : | 3.0 | 4.5 | 5.6 | : | : | : | : | 0.8 | : | : | : | : | 98 | : | : | : | : | 39 | 204 |
| **Luxembourg** | 2.8 | 4.8 | 5.0 | 5.2 | 6.6 | 0.5 | 0.7 | 0.7 | 0.5 | 0.5 | : | : | : | 199 | 364 | 83 | 88 | 88 | 83 | 84 | 206 |
| **Hungary** | : | : | : | 5.0 | 5.0 | : | : | : | 1.2 | 1.3 | : | : | : | 130 | 200 | : | : | : | : | 48 | 1,227 |
| **Malta** | : | : | : | 4.9 | 5.8 | : | : | : | : | 1.0 | : | : | : | : | 192 | : | : | : | : | 61 | 57 |
| **Netherlands** | : | 5.1 | 5.4 | 5.0 | 9.5 | : | 0.4 | 0.5 | 0.5 | 0.9 | : | 31 | 81 | 138 | 292 | : | 67 | 63 | 56 | 79 | 5,297 |
| **Austria** | 3.3 | 5.1 | 6.1 | 7.6 | 8.4 | : | : | 0.4 | 0.8 | 0.9 | : | : | 75 | 202 | 271 | : | : | 50 | 67 | 67 | 2,515 |
| **Poland** | : | : | 4.4 | 3.9 | 5.0 | : | : | : | 0.6 | 0.6 | : | : | : | 56 | 97 | : | : | : | : | 40 | 2,247 |
| **Portugal** | 1.5 | 3.4 | 3.8 | 6.4 | 7.1 | 0.2 | 0.7 | 0.9 | 1.1 | 1.2 | : | 30 | 86 | 165 | 243 | 67 | 64 | 60 | 55 | 62 | 2,146 |
| **Romania** | : | : | 2.9 | 3.6 | 4.7 | : | : | : | : | 0.8 | : | : | : | : | 94 | : | : | : | : | 56 | 1,021 |
| **Slovenia** | 4.2 | 4.4 | 5.6 | 6.1 | 6.6 | : | : | : | : | 1.0 | : | : | : | : | 203 | : | : | : | : | 56 | 347 |
| **Slovakia** | : | : | : | 4.9 | 6.0 | : | : | : | 1.5 | 1.7 | : | : | : | 104 | 296 | : | : | : | 79 | 69 | 1,086 |
| **Finland** | 4.1 | 5.0 | 6.2 | 5.1 | 6.6 | 0.2 | 0.3 | 0.3 | 0.5 | 0.7 | 5 | 23 | 55 | 115 | 191 | 29 | 43 | 43 | 45 | 55 | 1,219 |
| **Sweden** | 5.8 | 8.2 | 7.4 | 7.0 | 7.7 | 0.3 | 0.4 | 0.5 | 0.8 | 0.7 | 8 | 36 | 82 | 192 | 210 | 75 | 67 | 71 | 73 | 57 | 2,416 |
| **United Kingdom** | 3.9 | 5.0 | 4.9 | 5.6 | 8.2 | 0.4 | 0.5 | 0.5 | 0.8 | 0.9 | 10 | 33 | 78 | : | 255 | 57 | 71 | 63 | 80 | 90 | 16,339 |
| **EU** | **4.0** | **5.7** | **5.8** | **6.7** | **8.1** | **0.6** | **0.6** | **0.7** | **0.9** | **1.1** | **16** | **52** | **121** | **199** | **285** | **58** | **58** | **58** | **54** | **60** | **114,963** |
| **EU - unweighted average** | **3.4** | **5.1** | **4.9** | **5.3** | **6.6** | **0.5** | **0.6** | **0.6** | **0.8** | **1.1** | **13** | **40** | **92** | **159** | **223** | **61** | **64** | **61** | **65** | **60** | **114,963** |

***Source:*** Eurostat, OECD Health Data 2012, Commission services (DG ECFIN).
***Notes***: See Table 1.

## 3. Overview of pharmaceutical policies

This section briefly describes the most common pharmaceutical policies in the EU. A more detailed account of the characteristics, rationale, application and impact of these policies is given in the following sections.

Next to income and health care needs, it is the regulatory framework of pharmaceutical markets which determines the level and quality of pharmaceutical spending. Regulating pharmaceutical markets comes as an answer to classical market failures of health care markets. Adverse selection, moral hazard and asymmetric information are the main well-known economic rationales for public sector regulations of health care markets, based on efficiency and equity considerations.[15] Regulations are many, but despite national idiosyncrasies, there is a basket of core pricing and reimbursement policies common to many EU Member States promoting the rational use of pharmaceuticals. These policies are of rising interest to the public payers and are explored in this paper.

Pharmaceutical policies are related to pricing, reimbursement, market entry and expenditure control (Table 3), as well as targeted at specific agents such as distributors, physicians and patients (Table 4).[16]

In most EU Member States, prices of pharmaceuticals are set through external reference pricing (ERP).[17] ERP establishes a price on the basis of prices of the same product in other countries. Mostly, price controls apply to reimbursable medicines, whereas non-reimbursable medicines are usually priced freely. Also, prices are set by the pricing authorities alone or are negotiated between the manufacturers and the pricing authority. Governments may make pricing conditional on the evidence of the value added of innovations relative to existing treatment options via health-technology assessment (HTA) (see section 5). Also, external reference pricing and HTA may be combined to guide pricing decisions.

Policies of product reimbursement define the maximum price reimbursable by third party payers (internal reference pricing). In addition, positive and negative lists may be defined to specify which pharmaceuticals are reimbursed or explicitly excluded from public reimbursement. Positive and negative lists are revised over time according to new information. The timing for market entry for reimbursable medicines depends (partially) on

[15] Among the market failures are adverse selection (insurance companies attract patients with lower health risks), moral hazard (insured people may over-consume health care services), and asymmetric information (physicians may know health needs of the patients better than the patient himself, leading to supply-induced demand).

[16] The distinction is not clear-cut, as some policies affect multiple agents at the same time.

[17] Denmark, Sweden, Germany and UK apply to a varying degree free pricing, which allows the producers to set the price at launch without restrictions. However, these countries regulate either profits of companies (UK) or/and apply reimbursement regulations. Since 2012, Germany selectively applies external reference pricing as one pricing criterion.

the pricing and reimbursement procedures, which may delay the market entry of new medicines.[18]

Policies may also aim directly at controlling expenditure. This may be done through price freezes and cuts, mandatory discounts and rebates granted by producers and distributors of pharmaceuticals to purchasers. Payback/clawback policies aim at preventing budget overshooting, by claiming refunds from the industry once a target budget is exceeded. Increasingly, public tendering is used to increase price competition and to reduce purchase prices.

Further policies are targeted towards wholesalers, pharmacists, physicians and patients (Table 4). For pharmacists, generic substitution offers the right or obligation to dispense the cheapest equivalent - often generic - medicine. The design of mark-ups for distributors of pharmaceuticals may also affect dispensing behaviour. Physicians may face a number of regulations: monitoring of their prescription patterns, (binding) prescription guidelines, budget ceilings, prescription quotas, financial (dis-)incentives and educational and informational policies. At the patient level, co-payment rules define the share of costs borne privately by the patients. Patients may also be targeted by informational campaigns.

[18] As described in section 7, the timing for market entry also depends on companies' decisions not to market a product, to deliberately postpone its introduction or to market it directly in the hospital setting only, where sometimes free pricing applies.

| Table 3 – Policies related to pricing, reimbursement, market entry and expenditure controls |
|---|
| **Price regulations** |
| **External reference pricing:** ERP - also called cross-country referencing and international price comparison – is applied in 24 EU Member States (except Denmark, Sweden and the UK). It benchmarks product prices in one country against prices of the same product in a selected basket of other countries. |
| **Internal reference pricing:** 20 EU Member States set the price to be paid by the public payers by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group. This is the system of internal reference pricing determining the maximum price to be reimbursed by a third payer ("reference price"). The patient pays the difference between the retail price and the "reference price", in addition to any co-payment arrangement. The "reference price" applies to all pharmaceuticals within the corresponding group of products. |
| **Price updates:** Prices may be updated regularly according to pricing regulations. |
| **VAT:** Mostly, medicines have a value-added tax below the standard VAT rate. Sometimes, the VAT depends on the group of pharmaceuticals. |
| **Product reimbursement** |
| **Health-technology assessment:** Reimbursement may be conditional on meeting specific clinical and/or economic (cost-) effectiveness criteria. Health-technology assessment (HTA) is an assessment of the additional cost-effectiveness of an innovative medicine relative to existing treatment alternatives. This gives evidence-based guidance to pricing (and reimbursement). |
| **Positive/negative lists**: All EU Member States have positive lists specifying which specific pharmaceuticals are reimbursed. A few countries also have negative lists, excluding specific pharmaceuticals from reimbursement. |
| **Market entry** |
| **Time to market entry:** Pricing and reimbursement procedures may delay the market entry of medicines. In the EU, the time span for taking pricing and reimbursement decisions is regulated by the Transparency Directive. In addition, companies may deliberately choose to delay market entry. |
| **Expenditure controls** |
| **Discounts/rebates:** Discounts and rebates are imposed upon manufacturers and pharmacists, such that they have to return a part of their revenue. |
| **Clawback:** Clawback policies are applied to pharmacies, requiring them to pass a part of their turnover to third party payers. |
| **Payback**: Payback requires manufacturers to pay back a share of their revenue, if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded. |
| **Risk-sharing arrangements:** These are financial or performance-based schemes which trigger lower prices or refunds from the manufactures if pre-agreed targets are not reached. |
| **Price freezes and cuts:** Prices are frozen or cut by law or as an outcome of a negotiated agreement. |
| **Public tendering:** Increasingly more countries are using public procurement in the outpatient sector to decrease the prices of pharmaceuticals. Currently, the Netherlands and Germany are well known examples for ample use of public tendering. |
| ***Sources***: Espin, J. and J. Rovira (2007), PPRI (2008), Zuidberg (2010), Commission services (DG ECFIN). |

| Table 4 – Policies targeted at distributors, physicians and patients |
|---|
| **Wholesalers and Pharmacists** |
| **Generic substitution:** Pharmacists may be induced or mandated to dispense the cheapest bioequivalent medicine, which is often called "generic substitution". It is mandatory in 8, indicative in 14 and disallowed in 7 EU Member States. |
| **Mark-ups:** 23 EU Member States* apply wholesalers' and all EU Member States apply pharmacists mark-ups on the price of the pharmaceuticals as set by law. These can be linear, regressive, a fixed-fee (NL) or fee-for-service (SI, the UK). |
| **Physicians** |
| **Monitoring of prescribing behaviour:** At least 22 EU Member States monitor prescription behaviour to some extent, e.g. by using electronic prescriptions. |
| **Clinical practices/prescription guidelines**: Most EU Member States have indicative, non-binding prescription guidelines for physicians. In few countries, physicians must prescribe by the international-non-proprietary-name (INN) instead of the medicine name. INN is mandatory in five, indicative in 18 and disallowed in four EU Member States. |
| **Pharmaceutical budgets:** A maximum pharmaceutical budget may be defined per period, region, field of specialty and physician (at least 9 EU Member States). |
| **Prescription quotas:** These may define a target of the percentage of generics to be prescribed by each physician or may target the average cost of prescriptions (at least 6 EU Member States). |
| **Financial incentives:** Physicians may be incentivised or punished financially by following or ignoring prescription guidelines, quotas and budgets (at least 11 EU Member States). |
| **Education and information:** Physicians may receive prescribing advice, IT decision support etc. This is the case in most EU Member States. |
| **Patients** |
| **Information/education campaigns:** Patients may be targeted by information campaigns raising awareness of rational use of medicines, e.g. for antibiotics and generics. |
| **Co-payment:** Most EU Member States have co-payment, applying differentiated reimbursement rates, such as 100% reimbursement for essential, 80% for chronic and 60% for other pharmaceuticals (AT, IT, DE, NL and UK have 100% reimbursement; prescription fees may apply though). Often, vulnerable groups are protected from excessive out-of-pocket payments through specific rules. |
| ***Sources***: Espin, J. and J. Rovira (2007), PPRI (2008), Zuidberg (2010), Commission services (DG ECFIN).<br>***Notes***: *MS=Member States. |

## 4. External reference pricing: popular, but impact on cost reduction is uncertain

External reference pricing (ERP) is a direct price control. It usually takes the form of setting a maximum price per standardised unit, e.g. per defined daily dose (DDD),[19] based on prices of the same product in other countries. The rationale is to control prices of products which are protected by intellectual property rights and benefit from a legal monopoly.

In 2010, 23 EU Member States used ERP (Table 5). Denmark, Sweden and the United Kingdom did not use ERP, whilst Germany introduced it in 2012 for specific medicines as a

[19] DDD is used as a unit for measuring a prescribed amount of a pharmaceutical.

supporting decision criterion. Typically, prices are controlled for reimbursable products only, but sometimes also for non-reimbursable products. Prices are usually set at the producer's level (ex-factory price), and sometimes at the wholesaler's level (pharmacy purchase price, i.e. ex-factory price plus wholesaler's profit mark-up) or the pharmacy's level (pharmacy retail price, i.e. ex-factory price plus wholesaler's and pharmacist's profit mark-up plus VAT). Countries choose mostly the lowest or an average price within the specified basket of prices of other countries. The most-often referenced countries are France and Spain (referenced by 14 EU Member States), followed by Ireland and Spain (11). The least referenced countries are Bulgaria, Romania and Malta (3) (Table 6). In general, each country chooses a basket of countries which are economically comparable and geographically close. Choosing countries with similar levels of economic wealth may be perceived as a good anchor for choosing a "correct" and affordable price level, whereas geographic closeness may ease updating pricing through ERP.

The choice of referenced countries is important in determining the price level of a specific medicine, as listed prices of medicines vary substantially across EU Member States.[20] According to EUROSTAT (2007), price levels in the EU varied by 60 percentage points in 2005 (Graph 1). East European countries had the lowest average prices (around 70% of EU average), whilst Germany had by far the highest price level of all EU Member States. Based on more recent data, Kanavos et al. (2011a) confirm that there continues to be significant price variation across countries. For a sample of expensive medicines, they found ex-factory price gaps of 93% between highest and lowest priced countries; for low priced medicines the gap could be much higher. By using external reference pricing, countries can import low price levels and generate rapid savings – however, at the risk of non-availability or delayed market entry of the respective product.

Interestingly, differences in price levels are only partly related to country-specific income levels (Graph 1). Relative price levels, defined as pharmaceutical prices divided by GDP per capita, show that countries with high absolute price levels of pharmaceuticals, such as DE, DK, IE and IT, seem to have low relative price levels. Contrary to that, low price countries, such as PL, RO, BG, seem to pay relatively much compared to GDP per capita. This is partly because medicinal products are traded on international markets, with parallel exportation as an allowed market practice.[21] This allows for price arbitrage and is a deterrent to producers to set prices fully in function of local purchasing power. The effect is that differences in pharmaceutical price levels are substantially smaller than differences in local purchasing power, i.e. one would expect countries with a lower GDP per capita to pay relatively lower pharmaceutical prices, but this is not necessarily the case.

[20] Based on comparative price levels for pharmaceutical products in 2005 for EU25 (Eurostat 2007).

[21] Parallel exports have potentially detrimental effects on the availability of medicines in the exporting countries. It is questionable whether cross-border trade according to free market rules should fully apply to products with regulated prices.

The cost-saving potential of "importing" lower price levels from other countries through ERP is high. Based on the 2005 price levels and assuming that all countries above the EU average price level converge to it, leads to expenditure savings of 8% or an equivalent of € 15 billion (Graph 2). Savings in the group of countries exceeding the EU average price level are estimated at: above 20% or € 9 billion for Germany, 17% or Euro 332 million for Denmark and 15% or € 4 billion for Italy. Whilst these estimations are based on rough assumptions, other studies come to similar conclusions. For Germany, WIdO (2011) estimates that if Germany had UK price levels for high volume on-patent and generic pharmaceuticals, € 7 billion could be saved.[22] Thus, depending on the referenced countries, the introduction of ERP can lead to lower prices.

However, achieving cost-containment through ERP is limited due to several facts. Firstly, comparing pharmaceutical prices is difficult because published list prices may differ substantially from effective prices. This is due to different pricing regimes and little price transparency. Profit margins for pharmacists and wholesalers and the value-added tax on pharmaceuticals differ across countries (see section 15). Also, the industry negotiates discounts with distributors of pharmaceuticals, which are not communicated to the public and leave listed prices unaffected. Pay-back mechanisms (see section 9) may ex-post lower the effective prices of pharmaceuticals, but their impact on price levels is not published. Also, parallel trade may lower effective prices in high price countries.[23] Packaging also differs across countries, making price comparisons partially invalid.

Secondly, the industry may adapt strategically and continuously to ERP, partially eroding the potential for cost-containment. The industry can launch products in countries with high pharmaceutical prices first (e.g. Germany). Thereby, prices may increase in all other countries which directly or indirectly refer to high-price countries. Moreover, the industry may avoid competition on prices and rather competes on discounts, which benefit wholesalers and pharmacies rather than consumers. These adaptation strategies result in list-price inflation and cross-country convergence of prices. Consequently, ERP may lead to prices being too high and not reflecting national market conditions.

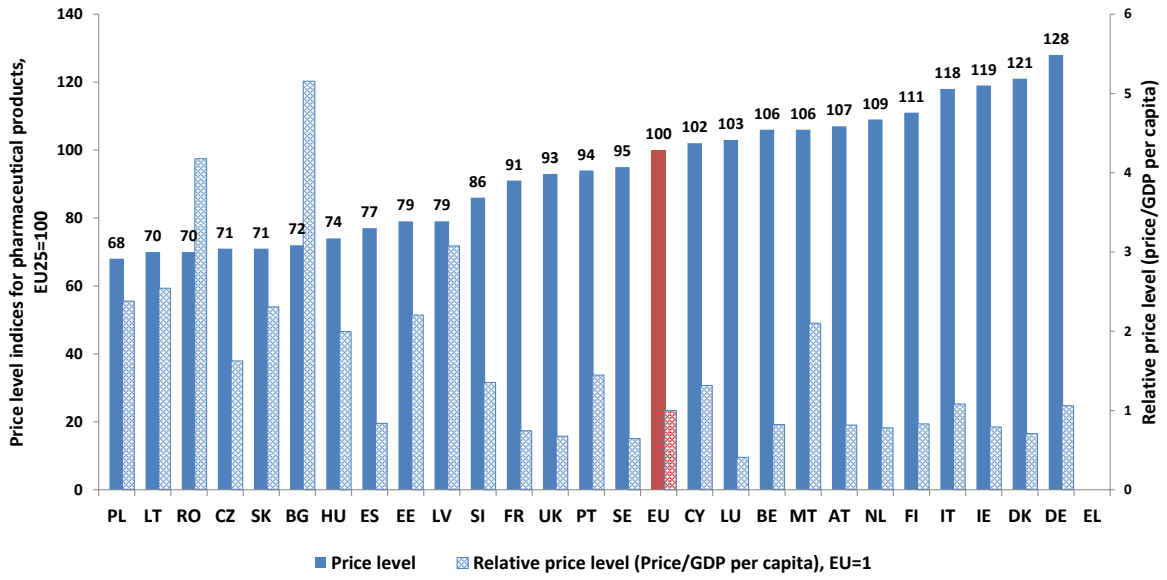
Thirdly, price reductions are not automatically translated into price decreases in referencing countries (Vogler, S. et al 2011a). This is because prices of pharmaceuticals are not reviewed regularly. A regular monitoring should therefore be ensured, possibly including "hidden" price changes, such as through discounts, which are not translated into changes of listed prices.

[22] In total, WIdO (2011) estimates € 12 billion saving potential in pharmaceutical expenditure in Germany. In addition to lower prices, as discussed above, € 5 billion could be saved by switching from on-patent analogue pharmaceuticals to lower price generics. A further € 2 billion could be saved by prescribing the lowest-price generic only.

[23] Parallel trade refers to legal trade of patented pharmaceuticals from countries with low to countries with high pharmaceutical ex-factory prices. Kanavos and Costa-Font (2005) state that parallel trade increases the profits of the distribution chain rather than generating saving for health insurers or consumers. This is because imported pharmaceuticals are priced just below the prices of pharmaceuticals in the destination country.

Finally, the increasing popularity of ERP can make pricing circular. The more countries are used as reference countries, the less clear it becomes which country's prices are the reference (e.g. BE uses SK as a reference country and vice versa). Also, price revisions in one country may, at least in theory, trigger a sequence of (circular) price revisions, which are heavily criticised by the industry and which induce strategic launching of new pharmaceuticals, as described above. Still, ERP is a technically interesting instrument to be used, especially in times of economic crisis, as it may lead to rapid savings by referencing to low-price countries.

**Graph 1 - Price level index for pharmaceutical products in 2005, EU25=100**



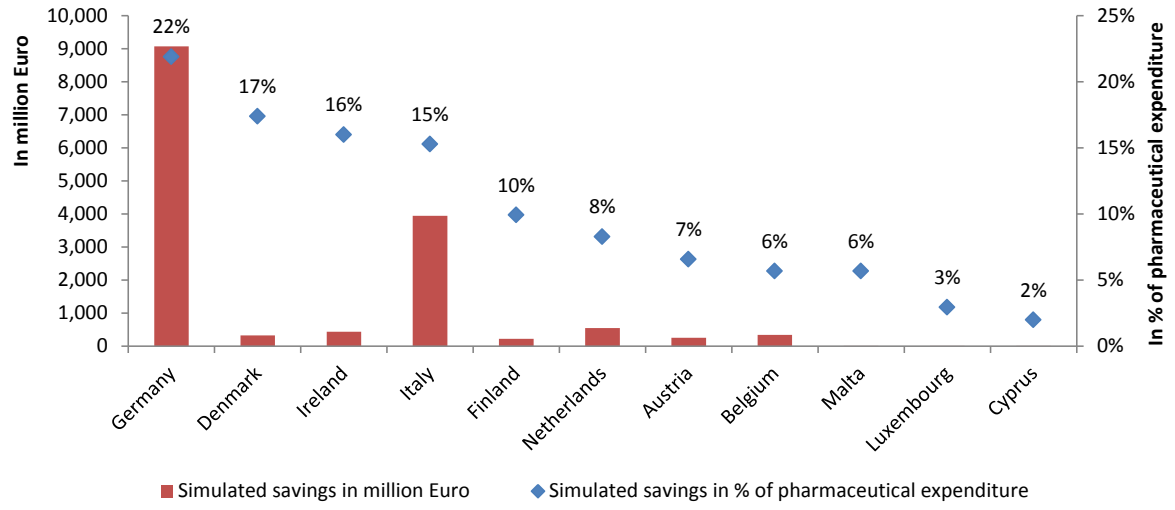

***Source*:** Eurostat (2007); Commission services (DG ECFIN)
***Notes***: Price level for EL not available.

Overall, the impact of ERP on cost-containment may not always be as expected due to counteracting factors. On the one hand, ERP gives the authorities a tool to control prices and thus to set one key parameter of expenditures (besides volume). It is also a relatively transparent pricing method in terms of procedure. On the other hand, the objective of controlling expenditure may fail, if price reductions are out-balanced by volume growth. Moreover, one should also consider the risk that too low prices may lead to access problems, as companies may postpone or not introduce pharmaceuticals in low-price countries. Also, importing prices of other countries implies importing their health care priorities, which may not correspond to the health needs of the population at stake. Therefore, price control should be supplemented by other policies promoting the rational use of medicines. For example, it is crucial to choose a correct basket of countries to achieve savings and to avoid paying too high prices by referencing to high-price countries only.

To sum up, ERP is an accepted and widely used policy for cost-containment. For "big" countries, ERP offers an opportunity for low prices, as companies may nonetheless compensate these by high volume sold in large markets. For "small" countries, ERP is an

affordable administrative tool for setting prices, without recurrence to more resource intensive strategies, such as those based on health-technology assessment.

**Graph 2 - Simulated savings due to a price convergence of countries with above EU level prices to EU level prices**




***Source*:** Eurostat (2007, 2011), OECD (2011), Commission services (DG ECFIN).
***Notes***: Total expenditure divided by 10; based on price levels from 2005 and pharmaceutical expenditure in 2010 or most recent; price level for EL not available; own calculations.

## Table 5 – Characteristics of external reference pricing

| | Scope | Price level | # of countries in basket | Calculation of reference price |
|---|---|---|---|---|
| **Austria** | Reimb. | ExFP | 24 | Avg. of all countries |
| **Belgium** | All | ExFP | 24 | Avg. of all countries |
| **Bulgaria** | POM | EXFP | 9 | 3 lowest prices |
| **Cyprus** | Imported POM and OTC (in private sector) | PPP | 4 | Avg. of the 4 lowest plus 3% to cover |
| **Czech Republic** | All | ExFP | 8 | Avg. of all countries |
| **Germany** | Specific reimb. medicines | n.a. | 15 | n.a. |
| **Denmark** | ERP not applied | - | - | - |
| **Estonia** | Innovative reimb. | ExFP | 4 | Not defined |
| **Greece** | All excl. generics | ExFP | 22 | Avg. of the 3 lowest prices |
| **Spain** | Innovative reimb. | ExFP | Not defined | Not defined |
| **Finland** | Reimb. | PPP | 16 | Checking of the price level and the range of the prices in EEA countries according to this ranking: NL, BE, BG, ES, IE, IS, UK, IT AT, EL, CY, LV, LI, LU, MT, NO, PT, PL, FR, RO, SE, DE, DK, SI, |
| **France** | Innovative reimb. | ExFP | 4 | Prices “similar” to those in the reference countries (DE, ES, IT, UK) |
| **Hungary** | Reimb. | PPP | 14 | Lowest price per basket |
| **Ireland** | POM incl. generics | PPP | 9 | Avg. of all countries |
| **Italy** | Reimb. | ExFP | Not defined | Avg. of all countries |
| **Lithuania** | POM incl. generics | ExFP | 6 | Declared manufacturer price is compared with 95% of the average manufacturer prices in reference countries |
| **Latvia** | Reimb. | ExFP | 2 | Third lowest price and not higher than the price in LT + EE |
| **Luxembourg** | All | PRP | 1 | Lowest price per basket |
| **Malta** | n.a. | n.a. | 12 | n.a. |
| **Netherlands** | POM | PRP | 4 | Avg. of all countries |
| **Poland** | Reimb. | ExFP | 17 | Lowest price per basket |
| **Portugal** | POM and reimb. OTC (excl. generics) | ExFP, PRP | 3 | Avg. of all countries |
| **Romania** | POM | ExFP | 12 | Lowest price per basket |
| **Sweden** | ERP not applied | - | - | - |
| **Slovenia** | Reimb. | ExFP | 3 | 95% of the average of the 3 countries |
| **Slovakia** | Reimb. | ExFP | 26 | Avg. of the 6 lowest countries in the basket |
| **United Kingdom** | ERP not applied | - | - | - |

***Sources:*** Leopold et al. (2012), Commission services (DG ECFIN).

***Notes***: In Germany the system has been introduced in 2012. In Belgium, ERP was used as supportive to the pricing decision only. From 2012 on, it is used as the main pricing criterion for all patented medicines, which have been at least 5 years on the market.

Reimb = Reimbursed medicines; POM = Prescription-only medicine(s); OTC = Over-the-counter (products); ExFP = Ex-factory price; PPP = Pharmacy purchasing price; PRP = Pharmacy retail price; n.a. = not available.

## Table 6 – Country baskets in external reference pricing

| | AT | BE | BG | CY | CZ | DE | DK | EE | EL | ES | FI | FR | HU | IE | IT | LT | LU | LV | MT | NL | PL | PT | RO | SE | SI | SK | UK | Additional countries | Countries in basket |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AT | | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | | 24 |
| BE | ■ | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | | 24 |
| BG | ■ | | | | ■ | | | | | ■ | | | ■ | | | | | | | | ■ | ■ | ■ | | | ■ | | Russia | 9 |
| CY | ■ | | | | | | | | ■ | | | ■ | | | | | | | | | | | | ■ | | | | | 4 |
| CZ | | | | | | | | ■ | ■ | ■ | | ■ | ■ | | ■ | ■ | | | | | | ■ | | | | | | | 8 |
| DE | ■ | ■ | | | ■ | | ■ | | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | ■ | | ■ | | ■ | ■ | | ■ | | 15 |
| DK | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| EE | | | | | | | | | | | | | ■ | | | ■ | | ■ | | | | | | | | | | Country of origin | 4 |
| EL | ■ | ■ | ■ | ■ | ■ | ■ | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | | 22 |
| ES | | | | | | | | | | | | | | | | | | | | | | | | | | | | Euro zone countries | |
| FI | ■ | ■ | | | | ■ | ■ | | ■ | ■ | | ■ | | ■ | ■ | | ■ | | | ■ | | ■ | | ■ | | | ■ | Iceland and Norway | 16 |
| FR | | | | | | ■ | | | | ■ | | | | | ■ | | | | | | | | | | | | ■ | | 4 |
| HU | ■ | ■ | | | ■ | ■ | | | ■ | ■ | | ■ | | ■ | ■ | | | | | | ■ | ■ | | | ■ | ■ | | 1 more | 14 |
| IE | ■ | ■ | | | | ■ | ■ | | | ■ | ■ | ■ | | | | | | | | ■ | | | | | | | ■ | | 9 |
| IT | | | | | | | | | | | | | | | | | | | | | | | | | | | | Not specified | |
| LT | | | | | ■ | | | ■ | | | | | ■ | | | | | ■ | | | ■ | | | | | ■ | | | 6 |
| LU | | | | | | | | | | | | | | | | | | | | | | | | | | | | Country of origin | 1 |
| LV | | | | | | | | ■ | | | | | | | | ■ | | | | | | | | | | | | | 2 |
| MT | | | | ■ | ■ | | | ■ | ■ | | | | ■ | | | ■ | | ■ | | | ■ | ■ | | | ■ | ■ | ■ | | 12 |
| NL | | ■ | | | | ■ | | | | | | ■ | | | | | | | | | | | | | | | ■ | | 4 |
| PL | | ■ | | | ■ | ■ | ■ | | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | | | ■ | | ■ | | ■ | | | ■ | Switzerland | 17 |
| PT | | | | | | | | | | ■ | | | | | ■ | | | | | | | | | | ■ | | | | 3 |
| RO | ■ | ■ | ■ | | ■ | ■ | | | ■ | ■ | | | ■ | | ■ | ■ | | | | | ■ | | | | | ■ | | | 12 |
| SE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SI | ■ | | | | | | ■ | | | | | ■ | | | | | | | | | | | | | | | | | 3 |
| SK | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | | 23 |
| UK | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Reference frequency | 11 | 10 | 3 | 5 | 11 | 11 | 8 | 7 | 11 | 14 | 6 | 13 | 11 | 8 | 12 | 10 | 6 | 7 | 3 | 8 | 9 | 11 | 3 | 7 | 8 | 8 | 11 | | |

***Sources:*** Leopold et al. (2012), Commission services (DG ECFIN).

## 5. Health-technology assessment: focusing on the value added of pharmaceuticals

Health-technology assessment (HTA) assesses the additional value of a medicine relative to treatment alternatives. Thus, it gives evidence-based guidance to pricing and reimbursement. Up to now, HTA has been primarily used in the EU for coverage and reimbursement decisions, though sometimes also for pricing. HTA contributes to evidence-based decisions and identifies those pharmaceuticals which offer the highest value for money. HTA is mostly used to evaluate pharmaceuticals, although medical devices, clinical procedures and public health interventions are increasingly subject to HTA.

As many pharmaceuticals currently being reimbursed have not undergone any or a proper HTA, the overall value added of pharmaceuticals is unknown. Evidence for Germany suggests that, in the 1990s, 40% of all prescriptions were on pharmaceuticals with contested effectiveness (WIdO 2011). Increasingly, countries limit arbitrary decisions and free pricing of pharmaceuticals and use HTA instead. In Germany and the UK, manufacturers will have to argue how they choose their prices partly based on the value to patients. Germany had free pricing of new medicines and, as shown in section 4, registers some of the highest medicine prices in the EU. According to the new rules, if a new treatment has no additional therapeutic benefit, reimbursement will be set at a level no greater than the comparable medicine already in the market.

Because of its widely-acknowledged benefits, HTA is used in numerous countries: Belgium, Denmark, Sweden, Finland, the Netherlands, England, Ireland, Portugal, Norway, Estonia, Latvia, Lithuania, Poland, Hungary, and Germany. Moreover, its introduction as a systematic tool is being prepared in France, Spain, Slovenia, Czech Republic and Slovakia. At the European level, EUnetTHA[24] - a cooperation of European HTA agencies for the promotion of HTA - provides a platform for exchange of information and best practices in HTA, elaborating internationally accepted standards for HTA.

HTA consists of an assessment and an appraisal process, during which the assessment results are interpreted. Ideally, HTA should address the following main questions (Le Polain et al. 2011): *Is there any medical or societal need for the product? Should the medicine be publicly reimbursed and can the public payer afford it? How much more would society be willing to pay for it compared to an existing alternative medicine? Should the former alternative healthcare interventions (be it pharmaceuticals or devices across all possible clinical indications) be excluded from reimbursement, if they are less cost-effective*? As such, HTA assesses the valued added of the medicine and the budget impact given the public willingness to pay and existing alternative pharmaceuticals.

[24] http://www.eunethta.eu/

The decision to pay for a medicine with public money should be transparent, based on relevant criteria and the decisions should be revisable (Le Polain et al. 2011). Transparency means that all decision criteria and steps in the assessment of a product and the appraisal of its value added are at best objective and verifiable and accessible by the public. This is important, because decisions often have to strike a balance between conflicting objectives of health systems, such as sustainability of public finances, equity and patients' expectations towards quality of care. Payers, providers of health care and patients represent different interests and should be part of the decision process and be informed on the criteria on which decisions are taken.

The assessment process is detailed out in Table 7 for some countries. HTA is done by review agencies, which may be or not closely related to the government.[25] They may give recommendations for coverage and/or pricing decisions for a selected group of or all new pharmaceuticals. Assessment is based on evidence provided either exclusively by the manufacturer and can be complemented by literature reviews and own analyses. Key decision criteria are the therapeutic benefit, cost-effectiveness, the availability of alternatives and budget impact of the assessed medicine.

However, whilst many countries define explicit objective assessment criteria, in practice, the decision-making process is often not transparent and could be substantially improved (Le Polain et al. 2011). The roles of different stakeholders are often not explicitly defined. There is often no explicit framework specifying the criteria, the valuation of choices and decisions of the assessment and appraisal process. This is a serious draw-back for the value of HTA. Moreover, the lack of a reimbursement threshold weakens the relevance of HTA for decision making. The decision makers cannot objectively know against which scale the cost-effectiveness of a medicine can be measured. As a consequence, any medicine may be reimbursed, which inhibits the transparency of decision-making. As an exception, in the UK the National Institute for Health and Clinical Excellence (NICE) defines a quantitative threshold (£20,000-30,000). The threshold reflects the willingness to pay for an additional quality adjusted life-year (QALY). Above the threshold, pharmaceuticals are in general not reimbursed.[26]

Reimbursement decisions for pharmaceuticals should be revised regularly. This is because the assessed cost-effectiveness involves a substantial amount of uncertainty. Similarly, the budget impact may be different than thought. Also, a new, more cost-effective medicine may become available. In these cases, systematic revisions ensure that the prior decision to spend public money for a medicine may be re-evaluated based on new evidence. Austria, Belgium, France, Germany, the Netherlands and Sweden do have – among others – revisions of reimbursement decisions. However, these are not done systematically. Also, they most often lead to changes

[25] For more cross-country information on this issue see also: http://www.ispor.org/PEguidelines/COMP1.asp

[26] For end of life pharmaceuticals, this threshold is not used. Also, there are exceptions due to specific societal considerations and other countries may use implicit thresholds.

in reimbursement decisions rather than a delisting of the medicine from public reimbursement.

Starting in 2014, the UK will launch an obligatory value-based pricing for new medicines, possibly extending to all medicines in the long-term. That system will replace the Pharmaceutical Price Regulation Scheme (PPRS) possibly after 2014. NICE will continue to evaluate treatments as at present. In negotiations with companies, the UK will make price decisions on new pharmaceuticals based on treatment value, innovation, societal impact, and unmet needs. The regulators can also change prices at a later stage based on real-world evidence including patient-reported outcomes. Overall, however, there is a risk that cost-ineffective pharmaceuticals remain reimbursable, generating expenditures with no or little value added for the treated patients.

A largely ignored problem is that there exists almost no evidence on how more than two pharmaceuticals interact when consumed at the same time. Particularly, older patients have multiple co-morbidities and receive co-medication on several pharmaceuticals. There is a risk that the benefits of taking only one medicine are reversed and turned into a health risk when taken together with other pharmaceuticals. This calls for more research in this area, but also for a necessary monitoring and possible blocking of prescription and reimbursement of systemic co-medication.

As a conclusion, HTA is a well-tested tool that can be of great help in closing the current gap in publicly available, credible, up-to-date, and scientifically based comparative information on the effectiveness of pharmaceuticals and other health interventions. This information can be used to base coverage and pricing decisions on evidence of value, thereby facilitating access to and public and private investment in the most valued new pharmaceuticals and technologies (Sorenson 2010). It can be used for cost-containment by excluding those pharmaceuticals from reimbursement which offer no or insufficient value for money.

HTA may also create a better link between coverage and pricing decisions, as the value added of a medicine is assessed for specific groups of patients targeted by the product. The move to HTA should also reduce the impact of medicine marketing strategies, strengthening the rational prescription behavior by physicians. Countries should consider extending HTA from new pharmaceuticals to already introduced on-patent pharmaceuticals and should revise reimbursement decisions systematically in the light of new evidence. HTA will help shifting from supply to demand driven reimbursement systems, by specifying the willingness to pay and taking into account the national ability to pay. As an alternative to internal HTA, which can be costly, small countries could make systematic use of HTA carried out by other countries with developed capacity.

## Table 7 – Characteristics of health-technology assessment in some EU Member States

| | Review body | Function | Scope | Evidence sources | Key decision criteria | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Therapeutic benefit | Cost-effectiveness | Alternatives | Budget impact |
| **Belgium** | National Institute for Health and Disability Insurance (INAMI-RIZIV) | Coverage | Selected drugs based on health impact, disease burden, policy relevance | Reviews, analyses and manufacturer | Y | Y | Y | Y |
| **Denmark** | Reimbursement Committee of the Danish Medicines Agency (DKMA) | Coverage | Every new drug | Manufacturer | Y | * | N | N |
| **England** | National Institute of Health and Clinical Excellence (NICE) | Coverage and pricing** | Selected drugs based on health impact, disease burden, policy relevance | Reviews, analyses and manufacturer | Y | Y | Y | Y |
| **France** | Evaluation Committee for Medical Products of the National Health Authority (HAS) and Economic Committee for Health Products (CEPS) | Coverage and pricing | Every new drug | Manufacturer | Y | * | N | Y |
| **Germany** | Institute for Quality and Efficiency in Health Care (IQWiG) | Coverage | Selected drugs based on health/cost impact, drugs with inconclusive evidence | Reviews, analyses and manufacturer | Y | Y | Y | N |
| **Netherlands** | Health Care Insurance Board, Committee for Pharmaceutical Aid (CHF) | Coverage and pricing | Drugs not classifiable under reference pricing system | Manufacturer | Y | Y | Y | Y |
| **Sweden** | Dental and Pharmaceutical Benefits Board (TLV) | Coverage and pricing | Every new drug | Reviews, analyses and manufacturer | Y | Y | Y | N |

***Sources:*** Sorenson (2010), Commission services (DG ECFIN).
***Note***: *Not clear when cost-effectiveness is applied.
** Starting in 2014, the UK will launch an obligatory value-based pricing on all medicines.

## 6. Internal reference pricing: defining reimbursement rates

Internal reference pricing (IRP) typically means determining the maximum price for generics and the maximum reimbursement rate for each medicine. At least 20 EU Member States apply IRP (Table 8). The rationale of setting maximum prices is to generate or reinforce competition in pharmaceutical markets. In general, the maximum price for generics is defined as a percentage of the originator's price. A condition for IRP is to have therapeutically interchangeable medicines, often generics, available on the market. Interchangeable medicines are grouped often by the same active ingredient (ATC-5) or chemical subgroup (ATC-4). Within each group a reference price is defined, which can be the lowest price or the average of a set of medicines in each group.

Most countries cluster medicines by ATC-5 level, while others use ATC-4 or ATC-3 or a mix of different levels. When no generics are available, groupings may be broader, including comparisons of treatments, such as in the Netherlands and Germany. In terms of reimbursement, many EU Member States set the maximum reimbursement rate at the price of the cheapest medicine per group. Others choose an average group price.

**Table 8 – Overview of internal reference pricing**

| | Internal reference pricing | | |
|---|---|---|---|
| | **Clustering** | **Pricing** | **Updates** |
| **Austria** | - | - | - |
| **Belgium** | ATC-5 | 31% below original | Every 6 months |
| **Bulgaria** | ATC-5 and 4 | Lowest price | n.a. |
| **Cyprus** | - | - | - |
| **Czech Republic** | ATC-5 and 4 | Lowest price | Every 6 months |
| **Germany** | ATC-5 and other levels | Combination of prices | Minimum once a year |
| **Denmark** | ATC-5 | Lowest price | Every two weeks |
| **Estonia** | ATC-5 | Lowest price | Quarterly |
| **Greece** | - | - | - |
| **Spain** | ATC-5 | Avg. of the lowest 3 prices | n.a. |
| **Finland** | ATC-5 | Lowest price plus a flat amount | n.a. |
| **France** | ATC-5 | Lowest price | n.a. |
| **Hungary** | ATC-5 and 4 | Lowest price | Annually |
| **Ireland** | - | - | - |
| **Italy** | ATC5, 4 and 3 | Lowest price | Monthly |
| **Lithuania** | ATC-5 | Lowest price | n.a. |
| **Latvia** | ATC5, 4 and 3 | Lowest price | n.a. |
| **Luxembourg** | - | - | - |
| **Malta** | - | - | - |
| **Netherlands** | ATC-4 | Avg. price or below | n.a. |
| **Poland** | ATC5, 4 and 3 | Lowest price | n.a. |
| **Portugal** | ATC-5 | Avg. of the lowest 5 prices | Quarterly |
| **Romania** | ATC-5 | Lowest price | n.a. |
| **Sweden** | - | - | - |
| **Slovenia** | ATC-5 | Lowest price | Every 6 months |
| **Slovakia** | ATC5 and 4 | Lowest price | Quarterly |
| **United Kingdom** | - | - | - |

***Sources:*** GÖG 2010, EGA 2011, Esprin and Rovira (2007), Vrijens et al. (2010), Commission services (DG ECFIN).
***Notes***: Greece is considering introducing internal reference pricing; n.a. = not available.

IRP has several advantages. Firstly, IRP makes patients and physicians more price sensitive, especially if patients are well informed about product alternatives. If a patient chooses a higher priced medicine within the same reference group, he/she has to pay the difference between the actual and the reference price. Secondly, pharmaceutical companies often compete by marketing rather than pricing. IRP, instead, forces companies to enter into price competition, as they may choose to reduce prices in line with the reference price in order to keep or increase their sales.

As to the impact of internal reference pricing, it has been reported to generate savings for third party payers due to an increase in co-payment, price reductions and reduced use of pharmaceuticals within the IRP scheme (Aaserud et al. (2006), Espin and Rovira (2007)). IRP was found to have a limited impact on access, having increased out-of-pocket expenses and generating some supply problems. There is no evidence of adverse health effects or disincentives in pharmaceutical innovation.

Internal reference pricing has nevertheless some limitations in achieving full price competition. This is because IRP reduces the prices of pharmaceuticals subject to this policy to the level (price cap) imposed by the regulation (Dylst and Simoens 2010, Puig-Junoy 2010) but, without other complementary measures, there is no incentive for lowering prices below the regulated price-caps. Interestingly, in countries with already a high generic market share, generic firms compete on prices (Dylst and Simoens 2011b). In these markets, free pricing appears to work better than setting price-caps, as these would possibly lead to less price competition. Therefore, any measures increasing the share of generics in pharmaceutical consumption improve the conditions for price competition based on IRP but also based on free pricing.

Secondly, IRP may lead to higher ex-factory prices. The reason is that producers anticipate that if they reduce prices, the health authorities will drive the reference prices further down. Also, within a reference price system, producers prefer to compete via discounts to pharmacies (e.g. discounts of 50% and more in the UK, 20-70% in France) rather than through lowering list prices. Discounts are, however, to the detriment of the consumer, as pharmacies do not transfer these by lowering consumer prices (Puig-Junoy 2010).

Thirdly, the effectiveness of IRP depends also on the availability of complementary insurance schemes. Complementary insurances partly or fully cover the non-reimbursed share of the medicines' price and therefore neutralize any incentives for patients to buy the cheaper alternative. This may indirectly have adverse effects on cost-saving efforts of third party payers, as complementary insurance will lower price competition and also the market penetration of cheaper pharmaceuticals.

Overall, IRP can be considered a useful policy for cost-containment. By reinforcing price competition and favouring generic penetration, it generates savings without any reported adverse health effects or negative impact on innovation. As such, it may be preferred to free pricing schemes, even if it foregoes all potential savings that may be reaped in free pricing

markets. IRP should be backed up by other policies increasing generic penetration, as these will increase the market share of generics and thus allow for reducing the reference prices further. The main disadvantage of reference pricing leading to discounts to pharmacies may be straightened by implementing claw-back policies to recover these discounts. As such, third party payers and consumers may benefit from those hidden price reductions. Finally, reference pricing should be viewed in line of the availability of complementary insurance schemes, as these may negatively impact saving efforts of third party payers.

### 7. Time to market entry for generics should be shortened

In all European countries, marketing authorisation is required for all pharmaceutical products. Even after having obtained marketing authorisation, all medicines including generic medicines need to await the pricing and reimbursement status to enter the market. The current Transparency Directive (89/105/EEC) lays down maximum time-limits for pricing and reimbursement decisions, which also allows Member States to establish faster decision-making procedures. Currently, the directive is under revision, aiming at accelerating pricing and reimbursement within 120 days for innovative medicines and within only 30 days for generic medicinal products, instead of the 180 days today. The possible drawback of speeding up the pricing and reimbursement process for innovative medicines is that health-technology assessments have to be done faster, which may possibly reduce their scientific rigour and weaken subsequent political decision making based on the scientific evidence.

The time spanning from companies' request for pricing and reimbursement, after having been granted marketing authorisation, and the pricing and reimbursement decision varies substantially across the EU (Table 9). In Germany and the UK both steps are immediate. Denmark, Finland, Hungary, the Netherlands, Sweden have waits up to one month. However, Belgium, the Czech Republic, Latvia, Romania and Slovakia have average waiting times of over half a year, considerably delaying the entry of generics and thus foregoing potential savings.

Granting pricing status can be sped up. Firstly, pricing and reimbursement could be combined in the same process. Countries doing this have on average lower waiting times. Secondly, in several EU Member States registration and marketing authorisation decisions for generics could be delinked from patents. This would allow Member States to take such decisions before a patent expires as is the case in several Member States and in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001.[27] Then, ideally, generics could enter the market immediately after the patent of the originator

[27] Directive 2001/83/EC establishes a complete and harmonised regulatory framework for registration and marketing authorisation procedures in respect of medicinal products for human use. The patent status or the Summary of Product Characteristics (SPC) status of the reference medicinal product or of an active substance contained in the reference medicinal product are not legal requirements to be considered for the submission of an application for marketing authorisation of generic medicinal products.

medicine has expired. Thirdly, in countries with internal reference pricing, where generics prices are linked to an originator reference product, pricing can also be automatic and immediate (European Commission, 2009).

**Table 9 – Time span for price and reimbursement approval for generic medicines after marketing authorisation**

| | Austria | Belgium | Bulgaria | Czech Republic | Germany | Denmark | Estonia | Spain | Finland | France | Ireland | Hungary | Italy | Latvia | Luxembourg | Netherlands | Poland | Portugal | Romania | Slovenia | Slovakia | Sweden | United Kingdom | European Union |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Average number of days until price approval | 150 | 30 | 90 | 150-240 | 0 | 14 | 90 | 30 | 30 | 60 | 45 | 30 | 90 | 30 | 30 | 30 | 180 | 21 | 90 | 15 | 120 | 5-30 | 0 | 62 |
| Average number of days until reimbursement approval | 150 | 180 | 30 | 150-500 | 0 | 14 | 90 | 30 | 30 | 60 | 45 | 30 | 90 | 180 | 180 | 30 | 180 | 120 | 180 | 180 | 150 | 5-30 | 0 | 103 |
| Applications for pricing and reimbursement are separate | No | Yes | Yes | No | No | No | No | Yes | No | No | No | No | No | Yes | No | No | No | Yes | Yes | No | Yes | No | No | Yes: 7; No:16 |
| Average days until price and reimbursement approval | 150 | 210 | 120 | 150-500 | 0 | 14 | 90 | 60 | 30 | 60 | 45 | 30 | 90 | 210 | 180 | 30 | 180 | 141 | 270 | 180 | 270 | 5-30 | 0 | 122 |
| Is granting of price allowed during patent period? | No | Yes | No | No | No | na | na | No | Yes | Yes | na | No | Yes | No | na | na | Yes | Yes | na | na | na | Yes | na | Yes: 7; No:7; na: 9 |
| Is granting of reimbursement allowed during patent period? | Yes | Yes | No | No | No | na | na | No | Yes | Yes | na | No | Yes | No | na | No | Yes | Yes | na | na | na | Yes | na | Yes: 8; No:7; na: 8 |

***Sources:*** EGA (2009), EGA (2011), Commission services (DG ECFIN).
***Notes***: No information was available for Cyprus, Greece, Lithuania and Malta.

The European Commission (2009) has documented that for a sample of medicines analysed in its report, 20% additional savings due to generic entry could have been realised, if entry of these generics had taken place immediately after the expiry of the patent periods. These could have added up to € 3 billion savings on top of the € 15 billion savings through the observed generic entry. In order to speed up market entry, the European Commission (2009) has recommended giving immediate pricing and reimbursement status to generic medicines in a reference pricing system.

Another significant concern behind delayed market entry of generics is patent linkage, which has extensively been analysed by the European Commission (2009). The originator industry effectively creates barriers to entry to generic medicines, by multiple patent applications for the same molecule and increased patent litigation. These practices lead to extensive delays to market entry of generics and to foregone savings of the public payers. As a remedy, the establishment of a Community patent and a unified specialised patent litigation system in Europe should be undertaken.

## 8. Positive/negative lists: cost-saving mechanism if properly designed

All EU Member States use reimbursement lists (Table 12). Most Member States have positive lists specifying which pharmaceuticals are reimbursed. A few countries also have negative

lists excluding specific medicines from reimbursement. In most EU Member States reimbursement lists are linked to co-payment regulations (Table 16).

The impact of reimbursement lists on cost-saving appears straightforward: reducing the number of medicines on the positive list (i.e. the number of medicines that are reimbursed) reduces public expenditure. Nevertheless, including medicines in a negative list, i.e. excluding them from public reimbursement, may have uncertain effects on cost-saving if not properly designed. If a medicine on a negative list has substitutes in the positive list, expenditures may increase if substitutes are more expensive. This happened in Spain, when the average price of prescribed pharmaceuticals increased after the exclusion of some previously publicly reimbursed medicines (Puig-Junoy 2007). In general, negative lists reduce the number of prescribed medicines, but there is a risk of a shift towards more expensive prescriptions, which may nullify cost-saving effects.

The cost-saving effect of positive lists largely depends on the choice of reimbursement criteria. Inclusion of pharmaceuticals on a positive list should be based on cost-effectiveness criteria as one key criterion, i.e. after having assessed their value added via health-technology assessment (see section 5). Also, positive lists should undergo systematic and regular up-dates, as new pharmaceuticals may make delisting and re-pricing of existing alternatives necessary.

## 9. Discounts/rebates, payback and clawback policies: controlling excess spending

There are different mechanisms requiring manufacturers and pharmacists to return a part of their revenue to third party payers:

- *Payback* policies require manufacturers to pay back a share of their revenue, if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded.

- *Discounts and rebates* are imposed on manufacturers, wholesalers and pharmacists, such that they have to return a part of their revenue. The rebate does not have to be linked to a specified target budget as in the case of payback policies. It is often seen as an alternative to decreasing list-prices, which has implications in ERP applying countries.

- *Clawback* policies are usually applied to pharmacies. Clawbacks capture discounts on either the dispensing fees of pharmacies or discounts on medicine purchases by pharmacies. The rationale of clawback mechanisms is to seize these discounts, which increase pharmacies' profit, and to pass them on as income/revenues to the public payer.[28]

[28] Note that sometimes the term clawback is used instead of payback.

The common element of all these mechanisms is to share the financial risk of a budget overshooting between all stakeholders (manufacturers/wholesalers or pharmacists and payers). These mechanisms rest on the assumption that the industry, wholesalers and pharmacists steer the volume and can be held responsible for volume increases.

These measures are widespread. Table 12 shows which countries have used discounts and payback policies in the past. In France, the industry pays annual rebates to the French health insurance funds. In Germany, the government increased in 2010 the rebate on total turnover from manufacturers from 6 to 16%. The savings from the rebate have increased from € 600 million in 2005 to 1,5 billion in 2010 and are projected to increase to € 2 billion in 2011 (BPI 2011). In the Netherlands, pharmacists are clawed-back around 6.8% of their turnover. Recently, Spain has introduced a 7.5% discount on patented and 4% on orphan medicines. Similarly, a discount of 6% on reimbursed medicines has been imposed in Portugal in 2010. There is no systematic review of discount/rebate and clawback policies for EU Member States. In the following, a more detailed account of payback mechanisms is given, as these have become more widely used recently.

In Europe, at least eight countries have introduced payback policies (Table 10). These are most often based on an annually approved global target-budget. Manufacturers pay a part of the overall excess consumption based on their individual market shares and/or growth rates without a ceiling defining the maximum payback. There are sometimes exemptions for generic and innovative medicines.

Payback policies are a powerful tool for public authorities to prevent budget overshooting. Payback also increases the predictability of the level of public pharmaceutical expenditures. Moreover, it is an alternative to price reductions of pharmaceutical products and is therefore often preferred by the industry (given negative spill over effects on other markets through the ERP mechanisms). In contrast to price reductions, payback does not aggravate the problem of parallel trade, as listed prices are unchanged. Furthermore, it is technically relatively easy to implement, provided that there is a well-functioning IT-system registering all sales of reimbursed medicines.

Payback policies have some downsides. Firstly, if the budget is set too high with respect to actual health care needs, then the over-consumption of pharmaceuticals is incentivised. If the target budget is set too low, then the industry is penalised by payback for serving actual health care needs of the population, which might necessitate spending over the target budget. Secondly, payback may lower incentives for structural reforms of the health care sector, as it in theory guarantees that all excess consumption as defined by the target budget is paid back. Thirdly, payback reduces the transparency in effective prices of pharmaceuticals, as payback is changing the effective prices but not the listed prices, thereby reducing the effectiveness of external reference pricing (see section 4). Fourth, payback may discourage introducing new pharmaceuticals, if budget overshooting is an issue and the expected turnover on the new

pharmaceuticals has to be paid back. However, a payback agreement and the setting of an expenditure target may be conducive to government and industry working towards ensuring reduction of unnecessary consumption. It may encourage the implementation of a set of measures such as those describe in this paper that ensure a more rational use of medicines.

Several countries, such as Germany, France, Italy and Portugal, have reported savings due to payback policies (Espin and Rovira 2007). However, so far there is no formal assessment of the overall impact of payback policies on expenditure, i.e. including a shift in expenditure to pharmaceuticals exempted from payback. Similarly, there is little evidence available on the long-term effect of claw-back and discount policies, which do not define an expenditure ceiling. Whilst in short-term considerable savings are achievable, as in Germany, these policies have been found in some cases to be counter-balanced by volume increases (see section 17), annihilating any savings potential.

Overall, rebates, clawback and payback policies are widely used and powerful policy tools for cost-containment. Especially in countries where growth rates in pharmaceutical expenditures are high and more difficult to predict, or where price reductions are difficult to obtain, they are practical tools for generating savings. In case of payback, they also significantly increase the predictability in public pharmaceutical spending. However, these policies should be aligned with existing or additional incentives for rational use of medicines aimed at the distributors of medicines and physicians, as these are also decisive for steering the volume of pharmaceuticals sold.

**Table 10 –Characteristics of payback/clawback policies**

| Modalities | Belgium | Latvia | Hungary | France | Portugal | Romania | Greece | Poland | Italy |
|---|---|---|---|---|---|---|---|---|---|
| **Scope** | Global target-budget | Global target-budget | Global target-budget | Global target-budget and growth rate | Global target-budget | Global target-budget | Global target-budget | No specifics, as only recently legislated | Global target-budget |
| **Tax base** | Annual approved budget | Annual approved budget | Annual approved budget | A predetermined turnover rate is set for each producer. | Annual approved budget | Annual approved budget | Annual approved budget | n.a. | n.a. |
| **Tax rate** | Industry pays only part of the consumption excess. | Industry pays only part of the consumption excess. | Industry pays 100% excess consumption when budget exceeded by 10%. | 3 thresholds ranging from 50 to 70% payback growing with excess consumption | Around 70% payback above budget allocation | 100% payback above budget allocation | 100% payback above budget allocation | n.a. | Industry pays 40% excess consumption |
| **Differentiated tax rate** | n.a. | Market share | Market share | A predetermined turnover rate is set for each producer (market share and growth) | Market share and growth | Market share | Market share | n.a. | Market share and growth |
| **Payback period** | n.a. | Quarterly | n.a. | n.a. | Annually | Quarterly | Bi-monthly | n.a. | n.a. |
| **Ceiling value** | No | Company payback limit of LVL 1.000.000 | n.a. | No | No | No | No | n.a. | n.a. |
| **Exemptions** | Generics exempted. | n.a. | No | Innovations, generics, orphan pharmaceuticals | No | No | No | n.a. | n.a. |

***Sources:*** Espin and Rovira 2007, Commission services (DG ECFIN).
***Notes***: n.a. = not available

## 10. Risk-sharing arrangements: speeding up access to pharmaceuticals and sharing financial risks

Risk-sharing agreements[29] are agreements between payers (health insurance and social security funds) and pharmaceutical companies to diminish the impact on the public budget for mainly new, but also existing, pharmaceuticals brought about by uncertainty on the budgetary impact or limited budgets.[30] The rationale of these agreements is to speed up access of patients to pharmaceuticals, whilst ensuring that financial risks are shared based on an estimated or actual cost-effectiveness and the budget impact of the medicine. Their need is accentuated by the fast growing share in pharmaceutical costs of some treatments (e.g. cancer products) and the increasing concern over a relatively low level of health gain of new pharmaceuticals as compared to standard pharmaceuticals.

There are various risk-sharing schemes:

- *Price-volume agreements* are financial-based schemes which trigger refunds from the manufactures if pre-agreed sales / volumes are exceeded. Refunds may be in form of lowering reimbursed prices. Payback policies are also a form of price-volume agreements, mostly on the level of total pharmaceutical spending (see section 9).

- Under *patient access schemes* pharmaceuticals are granted for free or at a lower price for a limited time period, so as to improve funding. They may also set an expenditure cap for a specific medicine at patient level, granting free treatment once the cap is reached.

- *Performance based models* trigger refunds if a pre-agreed performance level, e.g. a desired health gain, is not reached.

Risk-sharing agreements diminish the risk of budget overshooting for the public payer. They are particularly useful to limit the use of pharmaceuticals to those segments of populations where they generate the highest benefits. Similarly, they may be used to control off-label prescriptions, i.e. prescriptions of pharmaceuticals for unapproved indications or unapproved segments of population. Price-volume agreements are well established and their implications are well understood. In what concerns *patient access schemes* and *performance based models*, their use should probably be restricted to pharmaceuticals linked to health priority diseases, where there is a likely health gain within a limited time frame, where no effective and low cost standard already exists, and where the administrative burden is manageable. In particular, by granting access to innovative pharmaceuticals without having assured their benefits may run the high risk that the medicine is prescribed to broader patient populations where the

[29] These are also known as "access with evidence development schemes", "innovative pricing schemes", "patient access schemes", "coverage with evidence", "managed entry agreements" (Espin, Rovira et al. 2011).
[30] This section widely borrows from Adamski et al. (2010).

medicine is not effective. It may be then politically difficult at later stage to delist the medicine from public reimbursement.

No systematic assessment of risk-sharing arrangements is available up-to-date (Espin, Rovira et al. 2011). This is because, except for payback policies as a form of price-volume agreements, many risk-sharing arrangements are rather recent and their design is "medicine dependent". As innovative policy tools, which limit the impact on public spending especially for innovative pharmaceuticals with uncertain benefit, they are an interesting way forward in terms of cost-containment of pharmaceutical expenditures.

### 11. Price freezes and cuts: widely used for immediate savings

Price freezes and cuts of listed prices are negotiated or set unilaterally by public authorities. They may be used as a complement or alternative to rebates, payback, clawback and other risk-sharing arrangements, as described above. In contrast to the former, price cuts are applied on listed prices. This has further implications on price evolution in other countries through external reference pricing.

Price freezes and cuts are widely used. In 2010 and beginning of 2011 only, they have been applied in at least 10 EU Member States (see section 17). The medium- and long-term impact of these policies on cost-containment is not clear-cut, as over time they are often counterbalanced by volume increases (see section 17). However, they are practical policy tools, leading to short-term savings, especially in times of tight public budgets.

### 12. Public tendering: increasingly applied in the outpatient sector

Eighteen EU Member States used public tendering for purchasing pharmaceuticals in 2009 (Table 11**)**. It is mostly used in hospital settings, although an increasing tendency to use it in ambulatory care can be observed. In hospital care, public tendering can cover up to 25% of all purchased medicines in some countries, whilst it is much less relevant in ambulatory care (Leopold et al. 2008, Kanavos et al. 2009). Medicines purchased through tendering procedures are vaccines, pharmaceuticals in pandemic plans, but also branded pharmaceuticals and generics prescribed against non-communicable diseases. Price is the most important criterion for winning a tender. Other criteria include the availability of the medicine.

In the Netherlands, the bidding company with the lowest price gets exclusive contracts for a period of three or six months with the insurance who issued the tender (Preference Policy). The average price concessions of the winning companies in 2008 were 85% of the retail price before tendering, generating savings of € 355 million or 1/3 of their market value (Kanavos et al. 2009). In Germany, tendering works as an invitation for manufacturers to reduce the list prices by providing a discount on the price (Rebate Policy). 98% of all tenders in 2008 were for generic products and only 2% for patented pharmaceuticals. In 2010, it has been estimated

that up to € 1.3 billion could have been recuperated through tendering, an equivalent of 4.3% of expenditure (WIdO 2011).

Tendering systems for outpatient pharmaceuticals have achieved considerable reductions of prices. Cost-containment increases with purchasing power of third party payers and competition among interchangeable products. If generics are available, bidding may reduce payments to the level of marginal production costs (OECD 2008, Dylst et al. 2011a).

So far, the long-term impact of tendering is unclear. Firstly, it remains to be seen, if the low prices achieved through tendering can be sustained over time. Tendering, especially in the form of "preference policy" may force some producers out of the market, creating dominant positions for a few companies. This may erode competition and future price increases may even be the unintended consequence. Until now, however, tendering in the Netherlands and Germany did not have these unintended consequences.

A substantial benefit of tendering is that it increases the transparency of prices. Tendering shifts the balance of power to insurers, who can recuperate price discounts normally granted to the distributors. Those discounts become directly observable through tendering. This is important, as most EU Member States use external price referencing, which induces discounts between manufacturers and distributors instead of discounts between manufacturers and insurers (see section 4).

Overall, tendering is a well-established and successful tool for purchasing pharmaceuticals in hospital settings and more and more in ambulatory care, having a substantial cost-containment potential. A possibility to be explored in future, notwithstanding possible legal considerations, is whether tendering could be made international. In this case insurers from a group of countries could set up a tender and possibly reap even greater benefits in terms of reduced prices.

## Table 11 – Characteristics of public tendering

| | Tendering in place | Applied to | Pharmaceuticals procured | Criteria |
|---|---|---|---|---|
| **Austria** | Y | Hospital care | Vaccines, pharmaceuticals as defined in pandemic plans; | Best price/offer |
| **Belgium** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans and specific therapeutic groups of pharmaceuticals; | na |
| **Bulgaria** | na | na | na | na |
| **Cyprus** | Y | Hospital and ambulatory care | na | na |
| **Czech Republic** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans; pharmaceuticals relevant for public hygiene in competence of MoH | na |
| **Germany** | Y | Ambulatory care | Mostly generics (also biosimilars), some branded | Lowest price, product portfolio, supply |
| **Denmark** | Y | Hospital care | Vaccines, pharmaceuticals against communicable diseases, pandemics | na |
| **Estonia** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals against communicable diseases and drug addiction disorders | na |
| **Greece** | Y | Hospital care | na | na |
| **Spain** | | na | na | na |
| **Finland** | Y | Hospital care | na | Price, quality, supply |
| **France** | Y | Hospital care | na | na |
| **Hungary** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals against communicable disea ses, pandemics | Lowest price, supply |
| **Ireland** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics | Most Economically Advantageous Tender |
| **Italy** | na | na | na | na |
| **Lithuania** | na | na | na | na |
| **Latvia** | Y | Hospital and ambulatory care | Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics and oncology drugs | Lowest price |
| **Luxembourg** | na | na | na | na |
| **Malta** | Y | Hospital and ambulatory care | na | na |
| **Netherlands** | Y | Ambulatory care | Many molecules | Lowest price |
| **Poland** | na | na | na | na |
| **Portugal** | Y | Hospital and ambulatory care | na | na |
| **Romania** | Y | Hospital and ambulatory care | Hospital care: Vaccines and pharmaceuticals as defined in pandemic plans | Lowest price |
| **Sweden** | Y | Hospital care | na | na |
| **Slovenia** | Y | Hospital and ambulatory care | na | na |
| **Slovakia** | na | na | na | na |
| **United Kingdom** | Y | Hospital care | Vaccines, pharmaceuticals against communicable diseases, pandemics | Most Economically Advantageous Tender |

***Sources:*** Leopold et al. 2008, Kanavos et al. (2009), Commission services (DG ECFIN).

## Table 12 – HTA, positive/negative lists, expenditure controls

| | Health-technology assessment | Positive/negative lists | Expenditure controls | | | |
|---|---|---|---|---|---|---|
| | | | Discounts/ rebates | Payback | Price-volume agreements | Price freezes and cuts |
| **Austria** | | Positive | Y | | | |
| **Belgium** | Y | Positive | | Y | Y | Y |
| **Bulgaria** | | Positive | | | | |
| **Cyprus** | | Positive | | | | |
| **Czech Republic** | Y | Positive | | | | |
| **Germany** | Y | Negative | Y | | Y | Y |
| **Denmark** | Y | Positive | | | | Y |
| **Estonia** | Y | Positive | | | Y | |
| **Greece** | | Positive, negative | Y | Y | | Y |
| **Spain** | Y | Negative | Y | | | Y |
| **Finland** | Y | Positive | | | | Y |
| **France** | Y | Positive | Y | Y | Y | Y |
| **Hungary** | Y | Positive, negative | Y | Y | Y | Y |
| **Ireland** | Y | Positive | Y | | | Y |
| **Italy** | | Positive | Y | Y | Y | Y |
| **Lithuania** | Y | Positive | | | Y | |
| **Latvia** | Y | Positive | | | Y | |
| **Luxembourg** | | Positive | | | | |
| **Malta** | | Positive | | | | |
| **Netherlands** | Y | Positive | | | | Y |
| **Poland** | Y | Positive | | | | |
| **Portugal** | Y | Y | | Y | Y | Y |
| **Romania** | | Positive | Y | Y | | Y |
| **Sweden** | Y | Positive | | | Y | |
| **Slovenia** | | Positive | | | | Y |
| **Slovakia** | Y | Positive | | | Y | |
| **United Kingdom** | Y | Negative | | Y | Y | Y |

***Sources:*** GÖG 2010, EGA 2011, Esprin and Rovira (2007), Commission services (DG ECFIN).

## 13. Physicians: improving prescription performance

In most EU Member States, physicians have the exclusive right to prescribe medicines.[31] Therefore, they play a crucial role in determining whether medicines are consumed rationally or not. As medical experts, physicians evaluate the health needs of their patients and assess the pros and cons of specific treatments. Acting in the interest of patients' health is clearly a key ethical imperative for physicians. However, in reality, physicians face different pressures and contrasting "incentives", such as earning an income, being up-to-date with innovations in medical treatment, keeping allocated budgets (if this applies), staying objective in the choice of treatment despite pressure from third party payers, the industry or the patients. As a result, prescriptions may sometimes be sub-optimal, in the sense of being unnecessary or costly, despite the availability of lower-cost alternatives.

There are a number of measures to improve physicians' prescription behaviour (Table 13): prescription monitoring, prescription guidelines including requirements for prescribing by the international non-proprietary name (INN), targets for prescription costs, prescription quotas, financial incentives, educational and information tools.

In at least 22 EU Member States physicians' prescription patterns are monitored. Third party payers may monitor individual physicians' prescriptions and benchmark these with prescriptions of their colleagues with same specialty in a given region or country. Ideally, each prescription is sent electronically to third party payers. Physicians may get feedback on their performance relative to the benchmark, and may be visited by representatives of third party payers. In case of large divergences from the benchmark, physicians may be asked to explain these. In case of unexplained deviations, physician may be required to pay fines, undergo legal action or see their prescription rights waived.

At least 24 EU Member States have prescription guidelines. Guidelines may consist of clinical prescription protocols based on evidence and may include financial considerations. In Austria, Belgium, Germany, Hungary and Slovakia these are compulsory (in Greece they have just been legislated), whilst they are indicative in the remaining countries.

Prescription by international-non-proprietary-name (INN), i.e. by the active ingredient instead of the brand name, is a key tool for improving prescription behaviour. The rationale of prescribing by INN is to promote the use of the cheapest medicine with same active ingredient, so as to generate savings for both third party payers and patients without impacting adversely on patients' health status. INN is mandatory in five, indicative in eighteen and disallowed in four EU Member States. One promising way of promoting INN is to install an electronic prescribing system in which the brand name on a prescription is automatically changed into the generic name, such as in the Netherlands (Zuidberg 2010).

[31] Increasingly, nurses and midwives have the limited right of prescribing medicinal products, see e.g. http://www.biomedcentral.com/1472-6963/11/127.

Setting budget targets for each physician is another tool for rationalizing prescription behaviour. At least 10 EU Member States use this policy tool to a varying degree. Targets may be informative or may trigger financial benefits in case of overperformance (e.g. France) and/or sanctions in case of underperformance (e.g. Czech Republic, Germany).

Doctors may also be required to fulfil prescription quotas within their total budget, i.e. to prescribe a certain share of cheap, usually generic, pharmaceuticals. This is the case in six EU Member States. Finally, physicians may be targeted by education and information tools, which is the case in most EU Member States. For instance, they may be informed about prescription guidelines and may be required to participate in continuous on-the-job education. Prescription patterns may be published, so as to educate physicians on regular prescription behaviour.

Prescription behaviour may also be improved, when the (family) doctor is aware of all the pharmaceuticals a patient is taking, by using medicine interaction tools. These provide information on whether the effect of a particular medicine is altered when taken with another medicine or with specific food. This may reduce the risk of wrong co-medication. It may also be used to block the prescription and reimbursement of "excessive" systemic co-medication, as virtually nothing is known about its impact on the health status of the patient.

It is difficult to evaluate the impact of all tools for improving prescription behaviour on cost-containment due to their quantity and variety in actual implementation. Up-to-date, no global formal assessment of these policies exists (Espin and Rovira 2007). Literature suggests that, in general, a mix of interventions, such as monitoring including feedback systems combined with group or one-to-one educational interventions, have a positive impact, whereas focusing on information dissemination alone is not effective (Gill et al 1999, Soumerai et al. 1989, Gray 2006). IT rule-based prescription systems can contribute to improve the quality of prescriptions and to lower prescription costs (Anton et al 2004, McMullin et al 2004). Chaix-Couturier et al. (2000) and Ashworth et al. (2004) report that financial (dis-)incentives have a cost-containing effect on the use of pharmaceuticals, and that they improve the compliance with clinical guidelines.

To sum up, tools for improving prescribing behaviour are widely used in the EU and may be regarded as standard policies aiming at the rational use of medicines. Combining different measures, such as electronic prescription monitoring and guidelines linked with electronic systems, which support decision making and give feedback to the physician, appears an effective way of improving prescription behaviour. In addition, education and information tools should be enhanced where possible. INN prescription and prescription quotas, possibly coupled with target budgets and financial incentives appear to be effective tools for cost-containment purposes.

**Table 13 – Policies targeted at physicians**

| | Prescription monitoring | Prescription guidelines | INN prescribing | Target budgets | Financial incentives | Prescription quotas | Education and information |
|---|---|---|---|---|---|---|---|
| **Austria** | Y | Obligatory | - | | Y | | Y |
| **Belgium** | Y | Obligatory | Indicative | | Y | Y | Y |
| **Bulgaria** | N. a. | Indicative | Indicative | | | | Y |
| **Cyprus** | - | Indicative | | | | | |
| **Czech Republic** | Y | Indicative | Indicative | Y | Sanctions | | Y |
| **Germany** | Y | Obligatory | Indicative | Y | Incentives and sanctions | Y | Y |
| **Denmark** | Y | Indicative | - | | | | Y |
| **Estonia** | Y | Indicative | Obligatory | | | | Y |
| **Greece** | Y | Obligatory | Obligatory | Y | | | |
| **Spain** | Y | Indicative | Indicative | Y | Incentives | Y | Y |
| **Finland** | Y | Indicative | Indicative | | | | Y |
| **France** | Y | Indicative | Indicative | Y | Incentives | | Y |
| **Hungary** | Y | Obligatory | Indicative | Y | Sanctions | | |
| **Ireland** | Y | - | Indicative | Y | | | Y |
| **Italy** | Y | Indicative | Obligatory | | | | Y |
| **Lithuania** | Y | Indicative | Obligatory | | | Y | |
| **Latvia** | Y | Indicative | Indicative | Y | Sanctions | Y | |
| **Luxembourg** | Y | Indicative | Indicative | | | | Y |
| **Malta** | N. a. | - | Indicative | | | | |
| **Netherlands** | Y | Indicative | Indicative | | Y | | Y |
| **Poland** | | Indicative | Indicative | | | | Y |
| **Portugal** | Y | Indicative | Obligatory | Y | | | Y |
| **Romania** | Y | - | Obligatory | | | | Y |
| **Sweden** | Y | Indicative | - | Y | Y | | Y |
| **Slovenia** | Y | Indicative | Indicative | | | | Y |
| **Slovakia** | Y | Obligatory | Indicative | Y | | Y | Y |
| **United Kingdom** | Y | Indicative | Indicative | For NHS | Y | | Y |

***Sources:*** GÖG 2010, EGA 2011, Esprin and Rovira (2007), Commission services (DG ECFIN).

### 14. Pharmacists: right or obligation to generic substitution

Generic substitution is a right or an obligation of pharmacists to substitute a cheaper (generic) medicine with the same active ingredient(s) for another, usually a brand medicine. It is obligatory in seven, indicative in 15 and disallowed in five EU Member States (Table 14). The main rationale of generic substitution is to contain pharmaceutical expenditure without compromising health objectives.

Currently, roughly 43% of the volume of pharmaceuticals in the EU is supplied as generics medicines, but this is just 18% in value terms. Shares in volume and value vary largely across countries: 79% of all pharmaceuticals sold in Latvia are generics, but only 27% in Austria; similarly, in terms of value, the shares of generics vary between 12% in Sweden and 40% in Poland and Romania (Graph 3).

In the next four years, up to 40% of currently patent protected pharmaceuticals will be available as generic medicines (IMS 2010). This "*patent cliff*" will open a large segment of the market to generics, creating a huge savings potential. In European countries, generics are on average three-to-four times cheaper than the respective off-patent originals. In addition, generics have been shown to be as good for health as the original pharmaceuticals (Aaserud et

al. 2009). Literature suggests that generic substitution leads to lower expenditures, including a decrease in the growth rate of pharmaceutical expenditures. It also leads to reduced product prices and an increase in the use of cheapest interchangeable medicines (Espin and Rovira 2007). As such, generic substitution bears a high potential to generate savings.

The cost-saving potential of generic substitution is high. A detailed recent study estimates the net budget impact of savings for the public payer created through products going off-patent versus costs created by new entries of medicines in seven EU Member States (UK, DE, FR, PL, EL, PT, HU) for the period 2012 to 2016 (European Commission 2012). The cumulative net budget impact is € 19 billion: € 30 billion of savings generated through brand medicines going off-patent against € 11 billion of costs due to new entries of medicines. This corresponds to a roughly 20% reduction in public pharmaceutical spending for these seven countries.

**Table 14 – Generic substitution**

| | Generic substitution | | Generic substitution |
|---|---|---|---|
| **Austria** | Disallowed | **Italy** | Indicative |
| **Belgium** | Partly obligatory* | **Lithuania** | Indicative |
| **Bulgaria** | Disallowed | **Latvia** | Indicative |
| **Cyprus** | Obligatory in public sector | **Luxembourg** | Disallowed |
| **Czech Republic** | Indicative | **Malta** | Obligatory in public sector |
| **Germany** | Obligatory | **Netherlands** | Indicative |
| **Denmark** | Obligatory | **Poland** | Indicative |
| **Estonia** | Indicative | **Portugal** | Obligatory |
| **Greece** | Obligatory | **Romania** | Obligatory |
| **Spain** | Obligatory | **Sweden** | Obligatory |
| **Finland** | Obligatory | **Slovenia** | Indicative |
| **France** | Indicative | **Slovakia** | Obligatory |
| **Hungary** | Indicative | **United Kingdom** | Disallowed |
| **Ireland** | Disallowed | | |

***Sources:*** Vogler, S. (2012), GÖG 2010, Commission services (DG ECFIN).
***Notes***: *Obligatory substitution for antibiotics and antimycotics only.

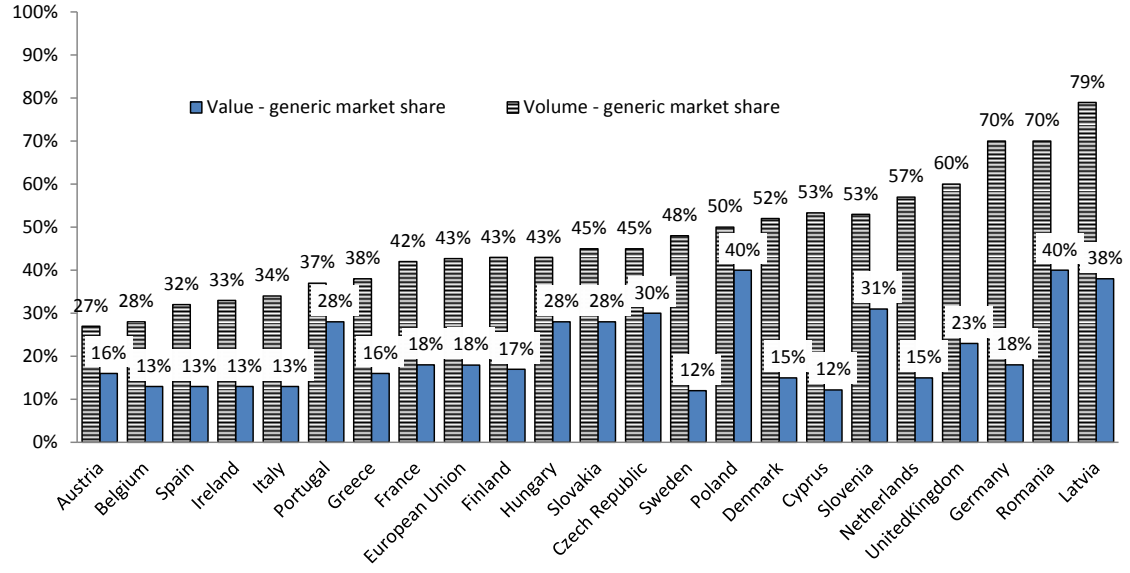
Based on a simple simulation, using data on the generic market shares in volume and value (Graph 3), and assuming that the market share in volume increases in all countries to 80% - as in Latvia -, we calculate that savings in public pharmaceutical expenditure of 33% or an equivalent of € 43 billion in the EU are possible (Graph 4).[32] Potential savings are of course highest for countries with currently lower market shares in volume for generics and with higher relative price ratios between originator and generic pharmaceuticals. This back-to-the envelope estimate points to as much as 40% or more of current public pharmaceutical

[32] Savings are estimated by exploiting the inherent information on relative prices between originator pharmaceuticals and generics, given the data on the market shares of generics in both volume and value. It is assumed, that the increase in the market share of generics in volume to 80% does not change the initial relative price ratios.

expenditure that could be saved in Italy and Spain. Whilst these estimations are based on rough assumptions, other studies come to similar conclusions. The EGA have estimated savings in the EU of around € 30 billion (EGA 2009). Simoens (2006, 2011a, 2011b) estimates savings of up to 48%, if the full potential in generic medicines was realised; up to € 16 billion savings based on the major disease categories are possible. EGA (2011) estimates that nine EU Member States achieved savings in the order of € 26 billion in 2010.

Potentially, savings may be higher. Firstly, prices of generics differ substantially, both across countries and among interchangeable generic pharmaceuticals. This is foremost the case for branded versus not-branded generics. If governments chose reimbursing only the cheapest medicine for a specific treatment, considerable savings are possible. Secondly, increased generic volume may imply an increased price competition among generic alternatives leading to lower prices. Thirdly, public tendering has been shown to generate substantial savings, which might be exploited to a higher degree, once generic volumes increase (see section 12).

**Graph 3 – Generic market shares in volume and value, 2010 or most recent data.**

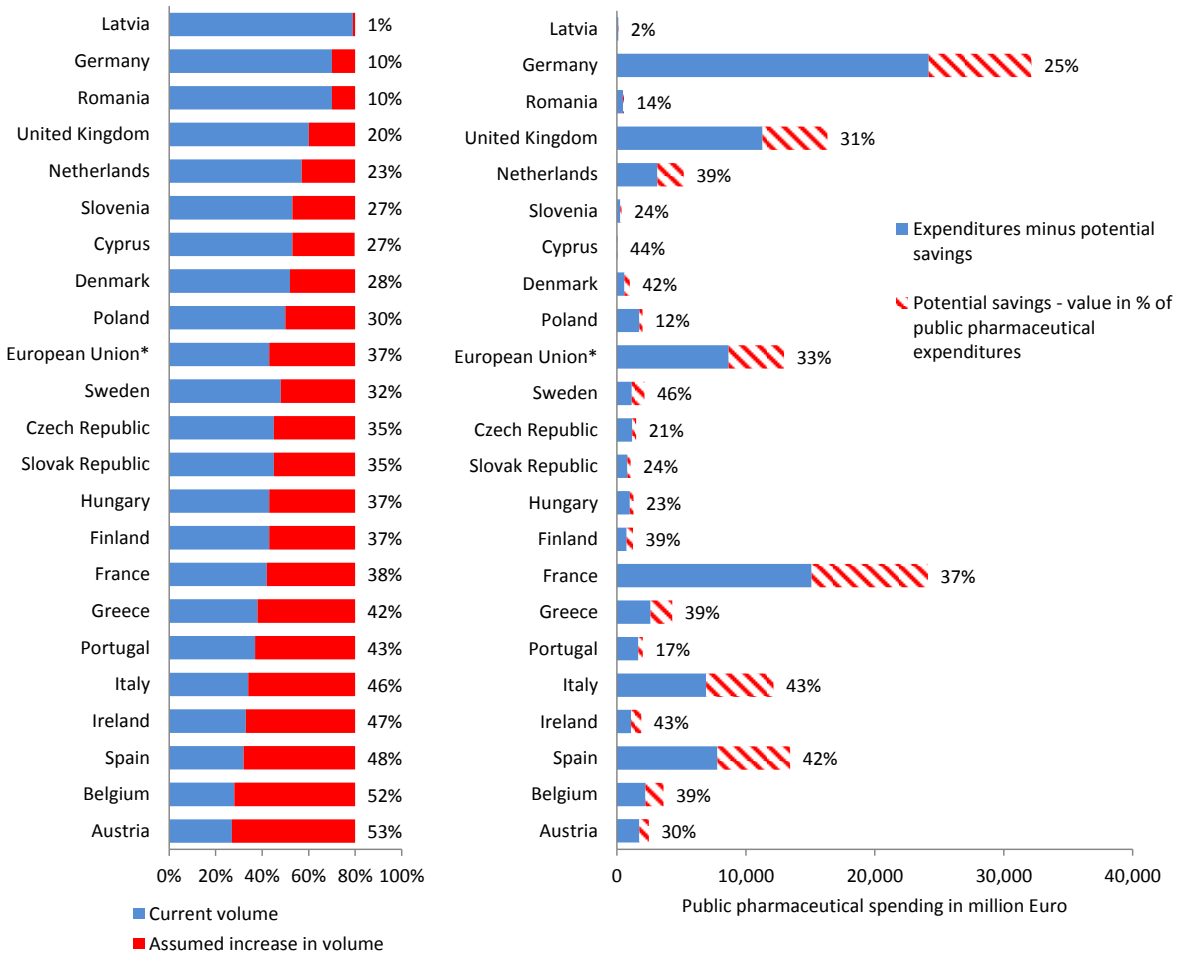



***Source:*** IMS 2010, EGA 2011, 2010 or most recent data, Commission services (DG ECFIN).
***Notes***: No information was available for Bulgaria, Estonia, Lithuania, Luxembourg and Malta. The EU average is thus estimated excluding these countries. Cyprus: public sector only.

Whilst generic substitution has a huge saving potential, sales of on-patent medicines are driving increases in expenditures to a considerable extent. Indeed, whilst the volume of generics has increased in many European countries, the market share of generics in value has remained rather low. Regulated and competitive price decreases of generic medicines have partly contributed to the stable share in market value. But also, increases of prices of patented medicines contribute to this. Evidence from Germany suggests that the share of generics in prescriptions increased from 38 to 71% since 1993 (WIdO 2011). In contrast, the share in value has stayed constant. This is driven by both an average 30% increase of prices of on-

patent medicines and a 30% decrease of prices of off-patent medicines. Consequently, key drivers of increases in expenditures seem to be on-patent medicines. Generic substitution will accordingly only partially contribute to cost-containment, whilst improving the value for money of patented pharmaceuticals will remain an important policy.

**Graph 4 – Potential savings by increasing the volume of generics to 80% of market share, in million Euro and % of public pharmaceutical expenditure in 2009**




***Source:*** IMS (2010), EGA (2011), Commission services (DG ECFIN).
***Notes***: In the right graph, expenditure for the EU is divided by 10. Cyprus: public sector only.

### 15. Remunerating wholesalers and pharmacists: setting the right incentives

Most EU Member States have regulated the reimbursement of wholesalers' and pharmacists' services for, at least, reimbursable medicines, mostly by means of regressive, but sometimes also linear mark-ups and profit margins (Kanavos et al. 2011a). Only in Denmark, Finland, Sweden, the Netherlands and the UK, wholesale mark-ups are unregulated.[33] Sometimes, countries use dispensing fees or a mix of regressive/linear margins and dispensing fees for

[33] Instead the pharmacy purchasing price is controlled and the ex-factory price is negotiated between producers and wholesalers.

pharmacies. In Slovenia and the UK, pharmacists are paid on a fee-for-service basis. Based on a sample of 22 EU Member States, the average margins for wholesalers range between 2.5 (Sweden) and 18% (The Netherlands) of the pharmacy purchasing price, with most countries range between 3 and 13% (Table 15). According to the information available on pharmacy margins of 15 EU Member States, the range is between 17 and 48% of the pharmacy retail price (Romania and Luxembourg, respectively), mostly ranging between 18 and 25%.

The effective margins may differ from the regulated margins due to two factors. On the one hand, wholesalers and pharmacists are sometimes granted considerable discounts by manufacturers, which increase their effective margins (see section 4). On the other hand, public authorities require the distributors to offer discounts to the public payer, effectively reducing the distributors' margins (see section 9).

The impact of the distributors' margins on the final retail price of prescription medicines varies strongly between EU Member States (Kanavos et al. 2011a). Margins impact more on generic than patented pharmaceuticals and more on less expensive than more expensive medicines. Kanavos et al. (2011a) report that in some outlier cases distribution costs and VAT make up to 90% of total costs to the payer.

The remuneration of pharmacies may discriminate against the use of cheaper medicines, e.g. if profit margins are regulated as a percentage of the product price. This sets incentives to dispense more expensive medicines and is only partly offset by regressive percentage margins. Fixed-fees, such as in Belgium, may be a neutral incentive to dispense originator and generic pharmaceuticals. In the Netherlands, pharmacies are rewarded to dispense pharmaceuticals below the reference price by being able to retain a percentage of the difference between the cheaper and the originator pharmaceutical.

The number of wholesalers and the density of pharmacies across EU Member States vary considerably. The number of wholesalers ranges widely between 5 and 160 wholesalers per country (low in e.g. Germany and high in Greece) (Table 15). Also, the density of pharmacies varies across EU Member States between 0.6 and 8.3 per 10,000 of population (Denmark and Greece, respectively), with an unweighted average in the EU of 3.1 pharmacies per 10,000 of population. Distribution costs may be lowered by greater consolidation in the number of wholesalers and/or pharmacies in some countries. This is especially the case for wholesalers, which can benefit from economies of scale. This is partly also true for pharmacies, where the trend goes towards the build-up of pharmacy chains. Consolidation in the pharmacy sector may imply that physicians get the right of dispensing medicines in remote areas.

In view of cost-containment, empirical evidence indicates that reducing wholesalers' and pharmacists' profit margin, and in particular, doing so in a way that counteracts the incentive to sell more expensive medicines, may be a valid tool for reducing pharmaceutical expenditures. In fact, this policy is often applied in European countries (see section 17). Similarly, reducing the density of pharmacies and the number of wholesalers may generate

considerable savings. A further possibility to reduce costs to the payers could be to expand the use of direct distribution, in which the wholesalers are bypassed. In addition, a broader (controlled) use of "internet pharmacies", which compete on price and may pass on considerable discounts to the payers, can be cost-saving.

**Table 15 – Number of wholesalers and pharmacies and their average margins**

| | #pharmacies per 10,000 population | #whole-salers* | Avg. wholesaler margin (%PPP)** | Avg. pharmacy margin (%PRP) | Type of wholesaler markup | Type of pharmacy markup | VAT* | |
|---|---|---|---|---|---|---|---|---|
| **Austria** | 1.5 | 10 | 10.0% | 19.2% | Regressive | Regressive + dispensing fee | 10.0% | 20.0% |
| **Belgium** | 4.8 | 15 | 8.5% | na | Regressive | Regressive + dispensing fee | 6.0% | 21.0% |
| **Bulgaria** | 5.9 | 20 | 8.5% | 20% | Regressive | Regressive | 20.0% | 20.0% |
| **Cyprus** | 5.6 | na | na | na | Differs for locally manufactured versus imported drugs | Linear | 5.0% | 15.0% |
| **Czech Republic** | 2.3 | 30 | 4.3% | na | Regressive | Regressive | 10.0% | 20.0% |
| **Germany** | 2.6 | 5 | 5.0% | 24% | Regressive | Linear | 19.0% | 19.0% |
| **Denmark** | 0.6 | 5 | 6.5% | 19.30% | Negotiations with manufacturers | Linear + dispensing fee | 25.0% | 25.0% |
| **Estonia** | 2.3 | 50 | na | 19% | Regressive | Regressive | 9.0% | 20.0% |
| **Greece** | 8.3 | 160 | 4.0% | na | Regressive | Regressive | 6.5% | 23.0% |
| **Spain** | 4.5 | 60 | 3.5% | na | Regressive | Regressive | 4.0% | 18.0% |
| **Finland** | 1.5 | 5 | 3.0% | 24% | Negotiations with manufacturers | Regressive + dispensing fee | 9.0% | 23.0% |
| **France** | 3.6 | 10 | 6.2% | na | Regressive | Regressive + dispensing fee | 2.1%/5.5% | 19.6% |
| **Hungary** | 2.4 | 10 | 6.2% | 19% | Regressive | Regressive | 5.0% | 25.0% |
| **Ireland** | 3.4 | 5 | na | na | na | Dispensing fee | 0%/21% | 21.0% |
| **Italy** | 2.9 | 70 | 3.0% | na | na | Linear | 10.0% | 20.0% |
| **Lithuania** | 4.5 | na | 8.5% | na | Regressive | Regressive | 5%/21% | 21.0% |
| **Latvia** | 3.8 | na | 3.3% | 19% | Regressive | Regressive | 12.0% | 22.0% |
| **Luxembourg** | 1.9 | 5 | na | 48% | Differs by country of origin of the drug | Linear | 3.0% | 15.0% |
| **Malta** | 5.3 | na | 15.0% | 20% | Differs for public versus private market | Linear | 0.0% | 18.0% |
| **Netherlands** | 1.2 | 10 | 18.0% | na | Negotiations with manufacturers | dispensing fee | 6.0% | 19.0% |
| **Poland** | 2.8 | na | 9.8% | na | Regressive | Regressive | 8.0% | 23.0% |
| **Portugal** | 2.6 | 10 | 6.9% | 18% | Regressive | Regressive | 6.0% | 23.0% |
| **Romania** | 2.3 | 40 | 12.0% | 17% | Regressive | Regressive | 9%/24% | 24.0% |
| **Sweden** | 1.0 | 10 | 2.5% | 21% | Negotiations with manufacturers | Regressive | 0%/25% | 25.0% |
| **Slovenia** | 1.5 | 10 | 8.5% | 2.10 € | Regressive | Regressive + dispensing fee | 8.5% | 20.0% |
| **Slovakia** | 3.6 | 10 | na | 21% | Regressive | Regressive + dispensing fee | 10.0% | 20.0% |
| **United Kingdom** | 2.1 | 10 | 12.5% | na | Negotiations with manufacturers | Linear + dispensing fee | 0%/20% | 20.0% |

***Sources:*** Abda (2011), Kanavos et al. (2011a), Commission services (DG ECFIN).
***Notes***: na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax.
* Numbers are approximated from graph 3.1 in Kanavos et al. (2011a).
** Average, when range of margins was provided by Kanavos et al. (2011a).
*** Romania and Sweden: lower rate for prescription pharmaceuticals; Lithuania and France: lower rates for refundable pharmaceuticals; Ireland: 0% for oral medication; UK: 0% for National Health Services pharmaceuticals.

### 16. Cost-sharing for patients: increased patient responsibility against possible risk of reduced treatment compliance

Cost-sharing requires patients covered by a health insurer to share the cost of the pharmaceutical product acquired. Cost-sharing may be applied as deductibles, co-insurance or co-payment. Co-insurance, whereby patients pay a percentage of the price of the medicine, is the most commonly used in the case of pharmaceuticals. The rationale for using cost-sharing

is to increase the price sensitivity of patients, reduce the unnecessary use of medicines and generate income for and reduce expenditure of public payers. It is generally found that the demand for health care is price inelastic, i.e. a 1 per cent increase in the price of health care will lead to a less than 1 per cent reduction in demand for health care. However, demand elasticity increases with increasing levels of cost-sharing, i.e. cost-sharing makes patients more price sensitive (Ringel et. al 2005).

Most EU Member States have cost-sharing rules (Table 16). These may vary by applying differentiated reimbursement rates, such as 100% reimbursement for vital, 80% for chronic and 60% or lower for other medicines. Also, most often (vulnerable groups of) patients are protected from excessive out-of-pocket payments through specific (often means-tested) rules, such as reduced cost-sharing rates, exemptions, tax deductibles of cost-sharing or annual co-payment ceilings.

Cost-sharing may improve the rational use of medicines, but its effects are uncertain:

- The overall impact of cost-sharing policies on cost-containment in EU Member States has not been assessed. No country has compared the impact of cost-sharing on pharmaceutical expenditures against a no cost-sharing alternative (Espin and Rovira 2007). However, cost-sharing appears to increase the use of cheaper generic pharmaceuticals, thus generating savings.

- Different studies show that patients use less of both essential and non-essential pharmaceuticals because of changes in cost-sharing (OECD 2008, Puig-Junoy et al. 2011, Manning et al. 1988). Decreased use of essential pharmaceuticals may negatively impact on health. Cost-sharing may also reduce medication adherence, leading to worse health outcomes (Cutler and Everett 2010).

- Where product alternatives for treating a specific condition exist, cost-sharing are often used as a disincentive for consuming cost-ineffective pharmaceuticals. However, patients often cannot judge on the benefits of medicines. Delisting is a clearer signal for patients as for the benefits of a medicine instead of cost-sharing.

- Cost-sharing may be perceived as unfair and may excessively tax vulnerable groups. Whilst exemptions from cost-sharing are a way of avoiding regressive taxation, these have to be well designed. Also because too many exemptions may render the system ineffective, whilst imposing an administrative cost on the collection of cost-sharing. In 2008/2009, 24 out of 29 countries exempted vulnerable groups from cost-sharing (according to a range of income or health related, criteria), who are responsible for a bulk of pharmaceutical expenditure. This obviously makes cost-sharing less effective (Puig-Junoy et al. 2011).

- Cost-sharing may increase the prices of pharmaceuticals, as it increases the funding sources for consumption through additional private resources.

Overall, cost-sharing may have an uncertain impact on cost-containment. It must be designed to insure against over-consumption, whilst avoiding the underuse of essential medicines especially for vulnerable groups. Delisting of particularly (cost-) ineffective medicines may be an alternative. For a cost-saving purpose, one could allow for lower cost-sharing for lower priced products. This would serve as an additional incentive for patients to buy cheaper products and for the industry to reduce product prices.

**Table 16 – Cost-sharing policies**

| | Cost-sharing | | Cost-sharing |
|---|---|---|---|
| **Austria** | Fixed | **Italy** | Fixed |
| **Belgium** | % | **Lithuania** | % |
| **Bulgaria** | % | **Latvia** | % |
| **Cyprus** | % (public sector) | **Luxembourg** | % |
| **Czech Republic** | % | **Malta** | No |
| **Germany** | % | **Netherlands** | Yes |
| **Denmark** | Fixed, %, deductible | **Poland** | % |
| **Estonia** | Fixed, % | **Portugal** | % |
| **Greece** | % | **Romania** | % |
| **Spain** | % | **Sweden** | %, deductible |
| **Finland** | Fixed, % | **Slovenia** | % |
| **France** | Fixed, % | **Slovakia** | Fixed, % |
| **Hungary** | Fixed, % | **United Kingdom** | Fixed |
| **Ireland** | No | | |

***Sources:*** GÖG 2010, EGA 2011, Commission services (DG ECFIN).

### 17. Pharmaceutical reforms and their impact

In 2010, 2011 and 2012, 23 European countries underwent or were planning a substantial number (estimated to be about 89 by Vogler et al. 2011b) of reforms of pharmaceutical policies.

Most often policies included:

- Discounts/rebates and clawback policies: EE, LT, ES, DE, PT, IT;
- Introduction of payback systems for the industry: PL, RO, PT, EL;
- Price freezes and cuts: CZ, UK, ES, EL, DE, LT, PT, IE, MT;
- Changes in the VAT on medicines: LT, CZ, UK, EL, FI, PT, LV, PL;
- Changes in the external referencing to countries with lower price levels: LT, SW, EE, SK, DE;
- Introducing external referencing as a pricing criterion: BE, DE;
- Changes in internal reference pricing rules: PT, ES, LT, ES, LV, BE, PL, EL;
- Planned introduction of internal reference pricing in IE;
- Broader clustering at ATC-3 level in RO;

- Introducing positive and negative lists (EL, RO);
- Requiring mandatory value assessment for new medicines in DE, EL, RO;
- Introduction of value-based pricing in 2012 in UK.

Less often measures were aimed at:

- Decreases in distribution margins: ES, EL, LT, PT, BE, IT, DE, PL, LV;
- Revising the reimbursement eligibility for all medicines in CZ;
- Increasing cost-sharing for patients: AT, BE, DK, LV, LT, EL, PT;
- Introducing or enforcing mandatory INN prescribing: LT, CZ, SK, EL, PT, IT;
- Obligation to offer least expensive medicines to patients and have them on stock: LT, EE, PL, EL, PT;
- Introduction or reinforcing e-prescribing: EE, LT, PT, EL, RO;
- Generics promotion campaigns for the public: EE, ES, PT.

Most of the measures were concentrated in countries which were more strongly affected by the economic crisis, such as the Baltic States, Greece, Portugal, and Spain. The measures are supposed to lead to short-term savings by directly reducing price levels of pharmaceuticals (e.g. through discounts, clawback, payback, price cuts and freezes, changes in external reference pricing). Some countries have also undertaken important measures promoting the rational use of medicines, such as the introduction and reviews of reimbursement lists, mandatory INN prescribing, e-prescription and generics promotion campaigns.

It is too early to evaluate the impact of these recent policy reforms on cost-containment. Empirical research on past experiences is still scarce and sometimes points to mixed results. Some measures, such as mandatory generic substitution, regressive pharmacy mark-ups and claw-backs do effectively reduce pharmaceutical prices (Schulenburg et al. 2011). There is less consistent evidence on other measures. Whereas the use of cost-effectiveness evidence reduces prices, evidence on reference pricing is unclear, although originator prices are reduced by drops in generic prices after patents expiry.

Whether a certain policy is successful or not, depends also on whether it is introduced in a largely unregulated market or is just partially changing existing regulations. Most of the reforms described above took place in countries which already had regulated markets to a certain degree, such that the subsequent reforms were only incremental. Sood et al. (2008) find – by analysing pharmaceutical regulations in 19 developed countries - that incremental or partial reforms have indeed only a minor impact on cost-containment. However, they also find that regulating completely or partially unregulated segments of pharmaceutical markets can lead to considerable long-term savings.

Indeed, in the past, incremental or partial reforms have often failed to achieve their targets. A recent article shows that in Spain, all of the measures introduced between 1997 and 2006 to contain the growth in pharmaceutical expenditure were ineffective in the long term (Moreno-Torres et al. 2010). These cost-containment measures included revisions of a reference pricing

system, reductions of ex-factory prices, mark-up adjustments, prescribing incentives and exclusion of pharmaceuticals from reimbursement. Possible reasons for the failure of these measures were that price reductions were counterbalanced by more prescriptions; the dosage per prescription was increased; more expensive instead of cheaper pharmaceuticals were prescribed; and new medicines for new treatments got on the reimbursement list.

Similarly, in Germany in 2010, the 16% obligatory price cut on ex-factory prices of on-patent pharmaceuticals has in the short term reduced the growth rate in pharmaceutical expenditure. Manufacturers and distributors have however already partly counterbalanced the drop in income by selling higher-priced pharmaceuticals.

A study based on Belgian data shows that policy regulations for generic promotion throughout 1995-2009 (changes in reimbursement conditions, public tendering, and entry of generic competitors in reference pricing) did not have any long-term effects (Fraeyman 2011).

Thus, whilst targeting prices may generate savings in the short term, it appears that in the past stakeholders have often been able to counterbalance the drop in price by selling, prescribing and dispensing higher volumes and more expensive pharmaceuticals. Also, there may be a risk of price cuts jeopardizing the rational use of medicines, if price cuts lead to increased volumes of pharmaceuticals reimbursed and consumed. However, the low cost-saving effects of some of the past reforms would wrongly lead to the conclusion that reforms are not needed. They may, however, point to the already large cost-containing effects in place of given regulations, which if discarded, could spur an unprecedented growth in pharmaceutical spending.

All these considerations point to the need for a more comprehensive approach, with a set of measures addressing "strategic" behaviour and appropriate incentives of all stakeholders.

**Box: Pharmaceutical reforms in Ireland, Greece, Portugal and Romania**

This box describes the pharmaceutical policies put in place under the financial assistance programmes of the European Commission, the European Central Bank and the International Monetary Fund (EC-ECB-IMF) for Ireland, Greece, Portugal and Romania. It briefly describes the challenges faced by these countries and the main measures undertaken to ensure a more cost-effective and financially sustainable use of pharmaceuticals.[34]

**1) Ireland: Cutting costs in public pharmaceutical spending**

In Ireland, authorities reduced the prices of off-patent medicines with a generic equivalent by 20% in 2007, 15% in 2009 and a further 40% in 2010. As a consequence, prices of generics have been realigned. Further, wholesaler margins and pharmacy mark-ups have been cut substantially. Some of these measures effectively reduced expenditure on patented, off-patent and generic pharmaceuticals. However, the effect on spending may have been rather limited (Usher, C. et al 2011). Complementing such price measures with policies that control volume/ consumption may be necessary to promote the rational use of pharmaceuticals. These would render the price measures more effective.

**2) Greece: overhauling the pharmaceutical sector and the introduction of much needed reforms**

Prior to the First Economic Adjustment Programme for Greece, public expenditure on outpatient pharmaceuticals (i.e. not considering hospital expenditure on pharmaceuticals) was the highest in the EU and considerably above the EU average (about 1% for 2008 and 1.1% in 2009). According to the WHO, public expenditure on outpatient pharmaceuticals was about 1.9% of GDP in 2008 and data from social security funds put public expenditure on outpatient pharmaceuticals at about 2.2% of GDP in 2009 (about €5 100 million). Expenditure had increased substantially since 1998 (0.8% of GDP) and especially in recent years. Greece also appeared to have the highest rate of antibiotic prescriptions in an analysis conducted in 13 OECD countries in the late 1990s.

In 2010, and just prior to the Economic Adjustment Programme, authorities revised the price list and introduced a 20% cut in prices of pharmaceuticals with only some exceptions. This led to a reduction in public expenditure on outpatient pharmaceuticals of 0.4 p.p. of GDP (about € 1 200 million savings). Nevertheless, expenditure remained high, at 1.8% of GDP in 2010.

[34] European Commission publications related to the Economic Adjustment Programmes for Ireland, Greece and Portugal and the Balance of Payments Programme for Romania can be accessed here: http://ec.europa.eu/economy_finance/publications/occasional_paper/index_en.htm.

Moreover, contrary to most EU Member States, Greece lacked a coherent set of policies that help control and monitor public expenditure on pharmaceuticals and contribute to an effective and cost-effective use of pharmaceuticals. Even when some tools were set by law, they lacked effective implementation. In this context, reducing expenditure on pharmaceuticals and ensuring a cost-effective use of pharmaceuticals was deemed crucial and urgent for both a public finances and public health point of view.

Therefore, a wide range of policy reforms was agreed in the context of the Economic Adjustment Programme, aligning Greece with the common tools used by other EU Member States to control expenditure in this sector. An initial target of 1% of GDP by end 2012 was set for outpatient public spending on pharmaceutical. This corresponded to savings of at least € 3 000 million. This was complemented by setting a target for the use of generics in hospitals to 50% of the volume of pharmaceuticals used in hospitals.

However, policy implementation regarding pharmaceuticals was faced with a number of hurdles. Data limitations, out-dated and complex administrative procedures, weak/limited information flows across relevant agencies and important vested interests led to implementation delays of crucial reforms. As a consequence, public expenditure on outpatient pharmaceuticals was still 1.7% of GDP in 2011 (about € 3 700 million, following a rebate from pharmaceutical industry).

Nevertheless, several important changes have been introduced since the start of the Economic Adjustment Programme and an important reform impetus in the area of pharmaceuticals took place in March 2012 with the start of the Second Economic Adjustment Programme. Legislation has been passed in Parliament and Ministerial Decrees have been published. The target was revised to $1^{1/3}$% of GDP by 2012 (about € 2 880 million) and 1% of GDP by 2014. Authorities are now focusing on the implementation of the policies agreed in March 2012 and policy impact is starting to be visible.

Reforms meant deep policy changes and were directed at pricing, prescription, monitoring assessment, mark-ups for wholesalers and pharmacies, more use of generic pharmaceuticals and a tighter monitoring and assessment of prescription, consumption and expenditure. It was felt that there was room to reduce expenditure via significant cuts in waste, fraud and corruption, which had led to over-prescription or prescription of the most expensive pharmaceuticals in detriment of cheaper ones. These measures intended to improve public finances but also benefit patients.

Regarding pricing and reimbursement of pharmaceuticals, authorities have:

| Measures on pricing | Measures on reimbursement |
|---|---|
| Introduced an external price reference system for pricing medicines, so that price is set on the basis of the three lowest prices of 23 EU Member States<br><br>Introduced legislation reducing the price of generic medicines to 40% of the branded product with the same active substance;<br><br>Introduced legislation reducing the price of off-patent medicines to 50% of their price when patent expires;<br><br>Reduced fixed mark-ups for wholesalers and pharmacies;<br><br>Introduced a fixed flat fee for expensive medicines to reduce the possible incentive for pharmacies to sell the most expensive medicine;<br><br>Introduced a progressive rebate system on the turnover of pharmacies for those with turnovers above a certain threshold;<br><br>Concentrated market authorisation, pricing and reimbursement decisions under the Ministry of Health to induce faster pricing and reimbursement decisions. | Introduced a negative list of non-reimbursed medicines;<br><br>Revised the list of over-the-counter medicines;<br><br>Introduced a positive list of reimbursed medicines;<br><br>Reclassified some diseases and therefore respective medicines in order to reduce the number of medicines in the lowest co-payment (0%) group;<br><br>Created therapeutic reference groups, although so far they have not been used for the purpose of setting a reference price for reimbursement for patients. Therapeutic groups have been used to help defining prescription guidelines and to obtain the rebate from pharmaceutical companies. |

Regarding prescription, monitoring and assessment of prescription behaviour, authorities have:

| Measures changing prescription rules | Measures strengthening the monitoring and assessment of prescription behaviour |
|---|---|
| Introduced compulsory e-prescription for all physicians with a contract with EOPYY or the NHS;<br><br>Introduced sanctions and penalties in the case of fraudulent prescription behaviour;<br><br>Defining prescription guidelines based on international good practice and together with the different medical specialties. These are to become gradually compulsory;<br><br>Introduced compulsory prescription by INN (active substance) in a gradual manner, starting with the 10 most common active substances. | Started to conduct basic analysis of prescription data generated by e-prescription;<br><br>Started to provide feedback to physicians on their prescription behaviour. |

In the field of generics, it was felt that generic consumption was very low by EU standards, despite the importance of the Greek generic industry. The low consumption was partly due to 1) generic prices being very high, fixed at 90% of the price of the branded product and 2) the lack of price competition between them, i.e. 90% was fixed for all the generics. In addition, there was no use of centralised procurement procedures and NHS hospitals did not necessarily use generics even when these were available. Time to market entry was also long. Therefore, there was and still is much potential to increase consumption of cheaper generics.

To encourage the use of generics, authorities have:

| Measures reducing barriers to entry | Measures encouraging prescription and consumption |
|---|---|
| Introduced legal changes to eliminate patent linkage and allow a faster process of litigation. | Reduced price of generics (see above);<br>Introduced INN prescription (see above);<br>Introduced compulsory generic substitution by pharmacies of the cheapest available medicine (although price competition among generics is due to be introduced in October 2012);<br>Created a centralised procurement agency for the health sector and recently launched several tenders for hospital pharmaceuticals. |

In addition to the above policies, authorities are currently exploring the ways to introduce price competition in the generic and off-patent market by setting a lower price to the followers. To control the overall level of expenditure and keep outpatient pharmaceutical expenditure within the target of $1^{1/3}$% of GDP by 2012, authorities have established a payback/clawback system which gets a payback from the pharmaceutical industry every quarter if the bi-monthly targets for expenditure have been surpassed.

Regarding pharmacies, some legal changes have taken place prior to the programme, aiming at reducing ownership and location restrictions.

The focus is now on fully implementing the set of measures that was legislated in 2011 and in March 2012. If effectively implemented, the impact of such measures on expenditure should be visible already at the end of 2012.

**3) Portugal: the case for deepening reforms and improving cost-effectiveness**

At the start of the Economic Adjustment Programme for Portugal, Portuguese authorities identified a number of areas in the healthcare sector where there was room to improve efficiency and achieve cost savings. Reducing overall expenditure on pharmaceuticals and ensuring a cost-effective use of pharmaceuticals was set as a policy priority. A target was set to reduce overall (outpatient and inpatient) public spending on pharmaceutical to 1.25% of GDP by end 2012 and to about 1% of GDP by end 2013.

Reforms under the programme would intensify the strategy deployed over recent years to ensure cost control and increase efficiency in the sector. Portugal already had in place a number of policies to control public expenditure on pharmaceuticals. However, these measures were not sufficient to achieve the desired savings. Thus, it was felt that reforms could be deepened in line with the experience of other EU Member States. In 2010, public expenditure on outpatient pharmaceuticals was approximately 1.2% of GDP according to the national satellite accounts of National Statistical Office (INE) and, therefore, above the 1.1% average for the EU.

In particular, the following policies were considered to realize important savings: changes in pricing in general and a reduction in the price of generics more specifically; a reduction of the mark-ups for wholesalers and pharmacies; changes in prescription behaviour; more use of generic medicines and a tighter monitoring and assessment of prescription, consumption and expenditure. These measures intended to improve public finances but also benefit patients in Portugal, who pay a substantial part of the price through cost-sharing.

In reality, important policies were implemented since the start of the Economic Adjustment Programme. Regarding pricing and reimbursement of pharmaceuticals, authorities have:

| **Measures on pricing** | **Measures on reimbursement** |
|---|---|
| Re-examined and changed the reference countries for pricing medicines. The reference countries are now ES, IT and SI;<br><br>Reduced the price of generic medicines to 50% of the reference branded product with the same active substance;<br><br>Reduced mark-ups for wholesalers and pharmacies in general;<br><br>Changed the mark-up system by introducing a regressive mark-up profit margin to reduce the possible incentive for pharmacies to sell the most expensive medicine;<br><br>Concentrated market authorisation, pricing and reimbursement decisions under the Ministry of Health to induce faster pricing and reimbursement decisions. | Reclassified medicines into the different existing severity categories and, therefore, co-payment categories, to reduce the number of medicines in the lowest co-payment (5%) category. |

Regarding prescription, monitoring and assessment of prescription behaviour, authorities have:

| Measures changing prescription rules | Measures strengthening the monitoring and assessment of prescription behaviour |
|---|---|
| Introduced compulsory e-prescription for all physicians with only some limited and specific exemptions;<br><br>Implemented prescription guidelines based on international good practice and together with the different medical specialties;<br><br>Introduced compulsory prescription by INN. | Started to conduct regular analysis of prescription data generated by e-prescription;<br><br>Started to provide regular feedback to prescribers, comparing their prescribing behaviour with that of their peers and prescription guidelines (started with primary care, followed by outpatient care in hospitals and to move to inpatient settings and finally private physicians' offices). |

In the field of generics, it was felt that generic uptake was low by EU standards, despite the policies of recent years, and there was much potential to increase it. The low consumption was partly due to important legal and administrative hurdles that considerably delayed the effective entry of generics into the market. Centralised procurement procedures were also underused in comparison with other EU Member States. Therefore, to encourage the use of generics, authorities have:

| Measures reducing barriers to entry | Measures encouraging prescription and consumption |
|---|---|
| Introduced legal changes to eliminate patent linkage and allow a faster process of litigation. | Reduced price of generics (see above);<br><br>Introduced compulsory INN prescription;<br><br>Introduced compulsory generic substitution by pharmacies;<br><br>Conducted information campaigns directed at consumers and physicians;<br><br>Created a centralised procurement agency for the health sector and launched a number of tenders. |

In addition to the above policies, authorities are currently exploring the ways to include prescription guidelines into the e-prescription system and making them compulsory. They have introduced incentives for good prescription (targets) and are considering complementing this with sanctions and penalties in the case of fraudulent prescription behaviour. To control the overall level of expenditure and keep total (hospital and outpatient) public pharmaceutical expenditure within the target of 1.25% of GDP for 2012, authorities have established a payback agreement with the pharmaceutical industry for 2011, 2012 and 2013.

Regarding pharmacies, important legal changes had taken place prior to the programme. Those changes had reduced ownership and location restrictions, allowing the sale of over-the-

counter medicines outside pharmacies, allowing the sale of medicines by pharmacies over the internet and allowing discounts on the co-payment part of the price. Authorities have recently introduced changes in the existing legislation to ensure access to pharmacies in more remote, less populated or poorer areas, while maintaining the liberalisation that started with the 2007 legal changes.

It is perhaps still early to evaluate the impact of such measures on expenditure, although total (hospital and outpatient) public expenditure on pharmaceuticals has seen a substantial reduction since 2010 and it stood at about 1.35% of GDP at the end of 2011. At the end of 2012, the Portuguese authorities shall start an assessment of the impact of the above policies and will consider the need for introducing further measures.

**4) Romania: Controlling expenditure and improving value for money**

Romania has been and still is facing several challenges, including an exceptionally fast growth in pharmaceutical spending over the past years, a large amount of unpaid pharmaceutical bills by the public health insurer, the lack of an evidence-based list of reimbursable pharmaceuticals and no effective monitoring to help control fraud in the system.

There was a substantial amount of unregistered and unpaid bills with payment delays of 300 days and more. Considerable efforts have been made to collect the information on unpaid bills and to reduce payment delays and the efforts continue up-to-date. To control spending growth and to pay back unpaid bills, a payback system has been installed, setting an effective budget ceiling of around 1% of GDP for public spending on pharmaceuticals.

At the same time, to ensure efficiency gains in the short term, a negative list of health services and pharmaceuticals, based on the recommendations of the technical assistance carried out by the UK National Institute for Health and Clinical Excellence (NICE), has been put into effect. In the same line, a new legal framework for carrying out health technology assessment shall be the basis for introducing new pharmaceuticals or indications in the list of reimbursed pharmaceuticals. For monitoring purposes, a new electronic prescription module and electronic health cards are expected to be operational soon.

## 18. Policy options for the European Union

Drawing on the findings of this report, as well as on the numerous initiatives at the EU level related to the pharmaceutical sector (see section 1), the following policy options emerge at the EU level:

- EU institutions could contribute to addressing the lack in transparency of pharmaceutical prices across European countries, which is contributing to the fragmentation of the internal market.[35] Competent authorities heavily rely on price information as a basis of pricing and reimbursement decisions. Most European countries base pricing decisions by comparing prices in other countries (see section 4). However, the comparisons are very difficult, as not all countries publish prices and often published prices are not reflecting real prices. The EU could therefore help enhancing the comparability of prices of pharmaceutical products across European countries.

- The EU could encourage Member States to reduce delays to market entry for generic products. Directive 2001/83/EC provides a framework for accelerating the registration and marketing authorisation of generic products (see section 7). As pointed out in the Pharmaceutical Sector Inquiry (European Commission 2009), Member States should make better use of the possibility of mutual recognition of marketing authorisations and establish a unified patent litigation system in Europe. These could substantially reduce delays to market entry especially for generic medicines, creating a large savings potential in several Member States.

- The EU could help with the exchange of best practices relative to the relevant decision criteria for product pricing and reimbursement, as well as to the decision-making process itself, which is often not transparent and could be substantially improved (see section 5). An example of this was the "High Level Pharmaceutical Forum on Pricing and Reimbursement" issuing recommendations on these matters[36] and the subsequent process on “platform on access to medicines in Europe under the Process on Corporate Responsibility in the field of Pharmaceuticals". Further, there are voluntary networking initiatives of competent authorities in Europe, such as the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, resulting from an EU co-

[35] The EU (through DG Enterprise and Industry) funds the EURopean Integrated Price Information (EURIPID), which provides on a voluntary participation basis of Member States, a platform for immediate price comparisons of all reimbursed pharmaceuticals: www.euripid.eu

[36] http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/european-initiatives/index_en.htm

funded project. Today, this project is a sustainable, growing and Member State borne initiative.

- Enhanced cooperation across EU Member States could be supported to find economies of scale and pooling of resources in the implementation of systematic HTA, such as through EUNetHTA.

- Exchange of best practices, including impact assessments, could also be encouraged at the EU level with respect to policies favourable to generating savings to the public payers, whilst avoiding a negative impact on health or pharmaceutical innovation. These are particularly relevant in the field of promoting the use of generic medicines through internal reference pricing or price competition of generics (see section 6), price freezes and cuts (see section 11), public tendering (see section 12) and incentives for providers and patients to increase the rational use of pharmaceuticals (see sections 13 to 16).

- An exchange of best practices with regard to policies of direct expenditure control, such as discounts/rebates, clawback and payback policies should be undertaken, as these policies are becoming more popular.

- The sustainability of public finances should be duly taken into account in all pharmaceutical policies at European level.

## 19. Summary and conclusions

This paper presents a description and an evaluation of policies aimed at containing public spending on pharmaceuticals in the EU.

Pinning down policies which favour the rational use of medicines and strengthen the sustainability of public finances is not an easy task, as in-depth assessment of the cost-effectiveness of different measures is still scarce, though growing. However, on the basis of past experience and cases studies, the following broad guidance can be drawn:

- **The decision to pay for a medicine with public money should be transparent, based on relevant criteria and the decisions should be revisable** (Le Polain et al. 2011). This is important, because decisions often have to strike a balance between conflicting objectives of health systems, such as sustainability of public finances, equity and quality of care. Health-technology assessment (HTA) contributes to evidence-based decisions and identifies those medicines which offer the highest value for money. Whilst HTA is mostly used to evaluate medicines, medical devices, clinical procedures and public health interventions are increasingly subject to HTA. Whilst many countries already define explicit objective assessment criteria in line with

HTA criteria and procedures, in practice, the decision-making process is often not transparent and could be substantially improved.

- **Reimbursement decisions for pharmaceuticals should be revisable**, as there is risk that, over time, with development of new pharmaceuticals and based on additional empirical evidence, cost-ineffective medicines remain reimbursable, generating expenditures with no or little value added for the treated patients.

- **External reference pricing (ERP) gives the authorities a tool to control prices and thus to set one key parameter of expenditures (besides volume).** It is also a relatively transparent pricing method and may lead to rapid savings by referencing to low-price countries. Price control should, nevertheless, be supplemented by other policies, including demand-side policies promoting the rational use of medicines.

- **Rebates, clawback and payback policies are widely used and powerful policy tool for cost-containment.** In case of payback, they also significantly increase the predictability in public pharmaceutical spending. These policies should nevertheless be aligned with existing or additional incentives for rational use of medicines aimed at the distributors of medicines and physicians, as these are also decisive for controlling the volume of pharmaceuticals sold.

- **Internal reference pricing (IRP) is a useful cost-containment policy.** When implemented so that it reinforces price competition and favours generic penetration, it generates savings without any reported adverse health effects or negative impact on innovation. As such, it may be preferred to free pricing schemes, even if it foregoes all potential savings that may be reaped in free pricing markets. IRP should be backed up by other policies increasing generic penetration, as these will increase the market share of generics and thus allow for reducing the reference prices further.

- **Allowing pharmacies to operate generic substitution leads to lower expenditures.** It also leads to reduced product prices and an increase in the use of cheapest interchangeable medicines. As such, further extension of generic substitution to cover more European countries bears a high potential to generate budgetary savings.

- **In order to enhance the use of generics, granting marketing authorisation and pricing and reimbursement decisions should be accelerated.** Firstly, pricing and reimbursement could be combined in the same process and delinked from patents, thus allowing taking these decisions already before a patent expires. Directive 2001/83/EC already provides a framework for speeding up the registration and marketing authorisation of generic products. The establishment of a Community patent and a unified specialised patent litigation system in Europe could avoid extensive delays to market entry of generics and generate savings for the public payers.

However, as on-patent pharmaceuticals appear to be the key drivers of increases in expenditures, generic substitution and other policies aimed at enhancing the share of generics can only partially contribute to cost-containment. Improving the value for money of patented pharmaceuticals, including through HTA remain an important policy priority.

- **Tendering is a well-established and successful tool for purchasing pharmaceuticals in the hospital setting but also more and more so in outpatient setting.** It has a substantial cost-containment potential, through considerable reductions of prices. Several EU Member States could make a more systematic and extensive use of tendering procedures. A possibility to be explored in future is international tendering by a group of countries.

- **Cost-sharing may improve the rational use of medicines as patients are made more cost-aware and therefore demand cheaper generic pharmaceuticals.** However, it is important that it does not lead to a decreased use of essential pharmaceuticals, thus negatively impacting on health. Cost-sharing has to be well designed to ensure the use of cost-effective medicines, while exempting the most vulnerable and avoid regressive financing of the system.

- **Tools for improving prescribing behaviour of doctors are widely used in the EU and may be regarded as standard policies aiming at the rational use of medicines.** Combining different policies, such as electronic prescription, monitoring and guidelines linked with electronic systems and providing feedback to physicians appears an effective way of improving prescription behaviour. In addition, education and information tools should be enhanced where possible. INN (active substance) prescription and prescription quotas, possibly coupled with target budgets and financial incentives have been shown to be effective tools for cost-containment purposes. This may reduce the risk of over-prescription and wrong co-medication.

- **EU institutions could help addressing the lack in transparency of pharmaceutical prices across European countries,** which contribute to the fragmentation of the internal market.

To conclude, it is worth stressing that a successful cost-containment policy in public pharmaceutical spending requires a comprehensive regulatory framework of pharmaceutical markets, with a broad set of measures, in order to be able to address "strategic" behaviour and create appropriate incentives for all stakeholders.

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