Pharmaceutical pricing policies in European countries

Final report

Commissioned by Change to Win

Gesundheit Österreich
Forschungs- und Planungs GmbH

WHO Collaborating Centre
for Pharmaceutical Pricing
and Reimbursement Policies

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1 Introduction

European policy makers have been struggling to fulfil the partially conflicting policy goals of (1) granting equitable and timely access to medicines to their citizens, (2) rewarding innovation to pharmaceutical industry and (3) containing costs in order to ensure long-term financial sustainability of the health care system (Leopold et al. 2014a; Leopold et al. 2013; Vogler et al. 2014b). From 2007/2008 on, Europe was affected by the global financial crisis that hit the countries in the region to different extents. Several countries had to take strict austerity measures, also in the pharmaceutical. (Vogler et al. 2011). Such measures are intended to address market participants such as pharmaceutical industry, wholesalers and pharmacies. Cost-containment is likely to also target patients and consumers by impacting accessibility and affordability of medicines.

Change to Win, a US-based non-profit labor organization, addressed Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH, a legal subsidiary of Gesundheit Österreich GmbH (GÖG/Austrian Health Institute) for non-profit clients, to submit a report about pharmaceutical pricing in European countries in order to investigate measures taken during the global financial crisis and to provide an outlook on planned and future policy measures. The report is intended to be used by CtW Investment Group, which works with pension funds sponsored by unions affiliated with the Change to Win labor federation.

In the results section, we start by providing an outlook on the current pattern and expected trends related to pharmaceutical policies as well as a forecast on pharmaceutical expenditure in the European countries over the next years (section 3.1). This is followed by information about most frequently applied policies related to pharmaceutical wholesale (section 3.2.), pharmaceutical pricing in general (section 3.3), and the commonly applied pricing policy of external price referencing (section 3.4).

2 Methods

The report is based on secondary research. We performed a literature review that also included grey literature such as the PPRI Pharma Profiles (PPRI Network Members (several authors) 2007–2013) and PPRI posters (PPRI Network Members (several authors) 2007–2014), as well as unpublished literature. PPRI (Pharmaceutical Pricing and Reimbursement Information) is a network of around 80 authorities responsible for pricing and reimbursement of medicines in 44, mainly European, countries, and representatives from the European Commission, the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO) and World Bank (Vogler et al. 2014a). In addition, findings from surveys e.g. on implemented policy measures (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014), undertaken with competent authorities for pharmaceutical pricing and reimbursement involved in PPRI, were included in this report. Information related to the wholesale sector, including wholesale remuneration, was gained from GÖG internal databases connected with the Pharmaceutical Price Information (PPI) service, a medicine price information service for 30 European countries (GÖG 2014).

Pharmaceutical expenditure data was retrieved from the Eurostat database (Eurostat 2014), and missing data were imputed OECD Health Data 2014 (OECD 2014).

This report covers 31 European countries, thereof all 28 European Union (EU) Member States plus Iceland (IS), Norway (NO) and Switzerland (CH). The EU Member States (EU-15) are Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE), Italy (IT), Latvia (LV), Lithuania (LT), Luxemburg (LU), Malta (MT), the Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovakia (SK), Slovenia (SI), Spain (ES), Sweden (SE) and the United Kingdom (UK). EU-15 refers to the countries that acceded to the EU before 2004 (AT, BE, DK, FI, FR, DE, EL, IE, IT, LU, NL, PT, ES, SE, UK).

The terminology used in this report is based on the Glossary of Pharmaceutical Terms provided by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2013).

3 Results

3.1 Outlook

Current pattern and trends in pharmaceutical pricing policies

Overall, pricing of reimbursable medicines is regulated in most European countries, whereas there is free pricing (i.e. the manufacturer freely sets the price) for non-reimbursable medicines. The most common pricing policy in European countries is external price referencing (EPR), i.e. international price comparison as basis for price setting (cf. section 3.3.). In recent years, there were regular changes in the methodology of external price referencing, particularly with regard to country baskets. Despite the increasing awareness of limitations of EPR, the authors expect that external price referencing continues to play a role in European countries. Investments of European countries in price information services, e.g. in the European price database Euripid, are another indication for the planned continued use of EPR.

Health Technology Assessments (HTA) and the use of pharmaco-economic evaluations are on the rise in European countries, particularly for new high-cost medicines. At the same time, Sweden is the only European country with a fully integrated value based pricing system (for an explanation see section 3.4). The introduction of value based pricing, in the same way as it is implemented in Sweden, is not planned in other European countries. The UK appeared to refrain from introducing value-based pricing which had originally been planned for 2014.

Differential pricing which would consider the economic wealth of a country has become an issue for discussion. However, the legal and organisational frameworks in Europe constitute major barriers for the implementation of differential pricing in Europe (for further information see section 3.4).

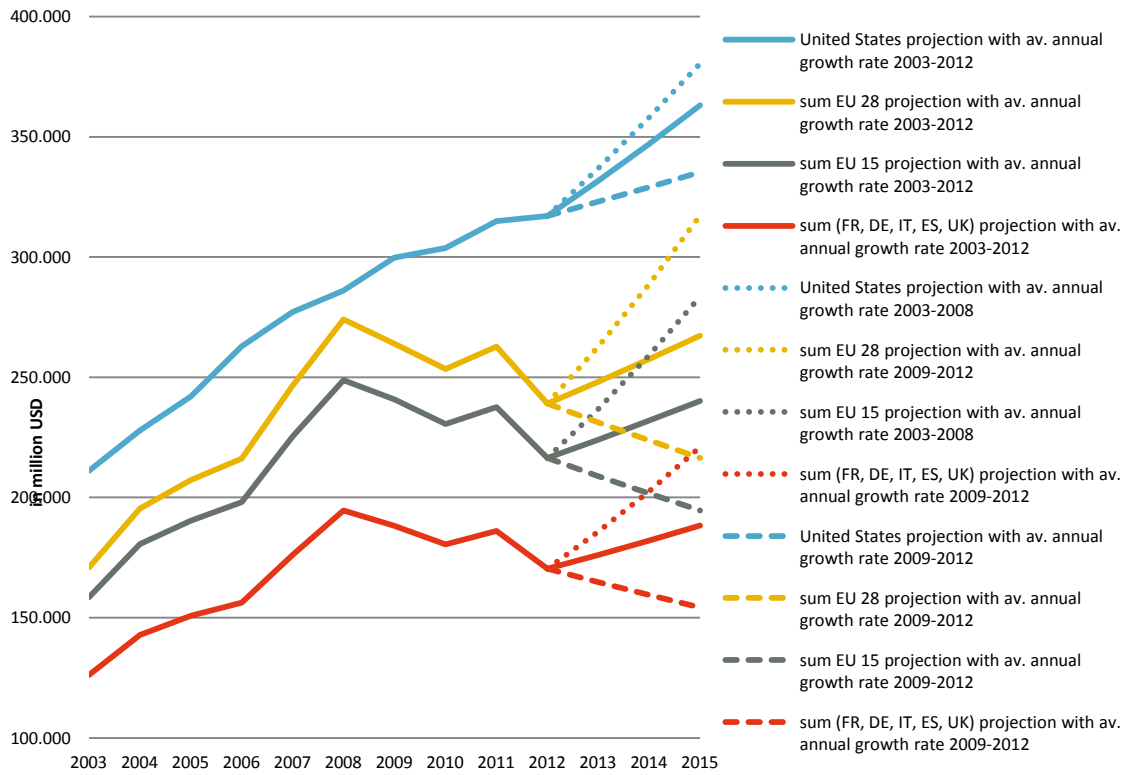
In order to deal with new, high-cost medicines, European countries are increasingly using new pricing and reimbursement strategies and funding models, such as managed-entry agreements and similar discount and rebate arrangements (cf. section 3.3). Such new models are likely to continue to be implemented.

Forecast on pharmaceutical expenditure

We performed a forecast based on total pharmaceutical expenditure (TPE) in USD from 2003 to 2012 for three different scenarios. First, the average growth rate from 2003 to 2012 was used to predict the years 2013 to 2015. Second, the average growth rate from 2003 to 2008 – the years before the crisis, where growth rates tended to be higher than after 2009 – was used to predict the years 2013 to 2015. And third, the average growth rate in the years of the crisis (2009 to 2012) were the basis for a forecast of the three years (2013 to 2015) (cf. Figure 3.1). Each projection was performed for the group of the EU-28 countries (excl. Malta), the EU-15 countries, as well as the subgroup of France, Germany, Italy, Spain, the UK, and the US.

Figure 1 illustrates the influence of the global financial crisis on pharmaceutical expenditure in Europe. Average annual growth rates from 2003 to 2008 were at around 9 to 10% (US 6%), whereas from 2009 to 2012 growth rates decreased, resulting in a negative growth of 3% on average (US 2%). Overall growth rates from 2003 to 2012 amounted to around 3 to 4% (US 5%).

Figure 1:
Total pharmaceutical expenditure in USD, Europe and United States, 2003–2015 – forecast



The primary data source used was Eurostat database, data imputed from OECD database for complete time series: Ireland, Italy; for single years: Denmark (2011, 2012), Greece (2003–2008), Luxembourg (2009–2012), Slovenia (2012), United States (2011, 2012). Imputations based on latest available years: Bulgaria (2008 for 2009–2012), Greece (2007 for 2008), Spain (2011 for 2012), Croatia (2011 for all other years), Cyprus (2008 for 2009–2012), Latvia (2009 for 2010–2012), Lithuania (2011 for 2012), Portugal (2011 for 2012), Romania (2011 to 2012), Finland (2011 for 2012), United Kingdom (2008 for 2009–2012). No data available for Malta.
Calculations based on Euro converted to USD with average annual exchange rates.

Source: Eurostat and OECD database, extraction as of October 2014; Austrian Federal Bank regarding average annual exchange rates EUR/USD, calculations performed by GÖG FP

3.2 Policies in pharmaceutical wholesale

Wholesale remuneration

Wholesale remuneration is statutorily regulated in most of the European countries surveyed. Only in Cyprus, Denmark, Finland, Iceland, the Netherlands, Norway, Sweden, and the UK,

wholesale remuneration is not regulated by law but is the result of negotiations between the pharmaceutical manufacturer and the wholesale company. In these countries with free wholesale remuneration prices, regulation for medicines (or part of medicines) is typically done at the pharmacy purchasing price (wholesale price) level, whereas in the European countries prices are usually regulated at the ex-factory price (manufacturer price) level (updated information as of 2014 surveyed by GÖ FP).

23 European countries have statutory wholesale remuneration. In the Czech Republic, there is a joint statutory wholesale and pharmacy remuneration regulation; i.e. wholesalers and pharmacies have to share the respective margin. In all other countries, there is a distinct remuneration regulation for wholesalers and another one for pharmacies.

In 10 countries, the wholesale remuneration regulation refers to all medicines. In a few of those countries there are different schemes for different types of medicines (e.g. different schemes for medicines of different reimbursement categories in Austria; one scheme for originator products and biosimilars, and another one for generics in Italy). In 10 countries, wholesale remuneration regulation refers to reimbursable medicines only, i.e. those medicines whose costs are, at least partially, covered by public payers. For non-reimbursable medicines there is no statutory wholesale remuneration, and wholesalers and manufacturers freely negotiate the margin. In three countries, statutory wholesale remuneration refers to prescription-only medicines, whereas for Over-the-Counter (OTC) medicines the margin is again the result of negotiations. In European countries, a major part of prescription-only medicines is (co-)funded by public payers.

Statutory wholesale remuneration is either designed as a linear mark-up on the ex-factory price (i.e. defined amount - expressed in a fixed amount or a percentage - of costs that is added to the product to create profit), as is the case in 9 countries, or as a regressive margin scheme, as observed in 13 countries. In a regressive margin scheme the relative remuneration for the wholesaler decreases as the price increases. In one European country, both a linear mark-up and a regressive margin scheme are in place for different products. Other types of remuneration, such as a fixed service fee (as known from pharmacy remuneration), are not applied in European wholesale.

Changes in wholesale remuneration

Changes related to the statutory wholesale remuneration took place in some European countries, particularly in countries that were hit hard by the crisis. Some of these countries (e.g. Greece, Portugal) changed the wholesale remuneration regulation more than once within the last four years. In the year 2012 – a year when the global financial crisis had reached its peak in Europe – seven European countries changed the wholesale remuneration regulation, whereas in other years this was done by 2-3 countries. Usually, the wholesale remuneration regulation was lowered, however, sometimes the scheme was changed more fundamentally, for instance from a regressive scheme to a linear mark-up (e.g. France).

Compared to other pricing measures that hit other market participants (e.g. pharmacists, pharmaceutical industry), the wholesale sector was less frequently affected. Lower ex-factory

prices, however, had not only an impact on pharmaceutical industry, but also on wholesalers and pharmacists in case of margins dependent on the price.

Further changes relevant for pharmaceutical wholesale

Recent years have seen further changes relevant for pharmaceutical wholesale which indirectly had an impact on the profits of the industry.

In general, the pharmaceutical wholesale sector in European countries is characterized by the existence of full-line and short-line wholesalers, the latter often being smaller companies only serving regional and local markets. There were 935 pharmaceutical full-line wholesalers in the EU plus Norway and Switzerland in 2012 (Said et al. 2013).

All surveyed countries but two have a multi-channel system, i.e. a wholesale distribution channel in which medicines of a manufacturer are distributed and supplied in parallel via different wholesalers. Finland and Sweden have single channel wholesale systems where a wholesale has the exclusive right to distribute medicines for a manufacturer (Vogler et al. 2012a). In single-channel countries, the number of wholesale companies are usually low. Mergers in the wholesale sector have been on-going in several European countries, already starting in the 1990s (PPRI Network Members (several authors) 2007-2013).

Vertical integration in pharmaceutical distribution (e.g. between wholesalers and pharmacies, or manufacturers, wholesalers and pharmacies) has been observed in some European countries. A prerequisite is whether pharmacies can be owned by non-pharmacists. In Norway, for instance, after the in the pharmacy sector in 2001, major vertical integration took place, resulting in three large wholesalers owning 97% of the pharmacy market (Anell 2005). In Lithuania, large wholesalers (e.g. Tamro) own pharmacy chains, and in Ireland, the German wholesale company Celesio owns both a local wholesaler (Cahill May Roberts Ltd) as well as a pharmacy chain (Kanavos et al. 2011).

Alternative distribution models, that impact wholesale turnover, have gained momentum in recent years, in particular in the UK. These may be direct sales from manufacturers to pharmacies (i.e. manufacturers use their direct sales system to sell their own medicines directly to pharmacies but also supply in parallel full-line wholesalers), or Direct-to-Pharmacy (DTP) distribution. DTP can take place via a variety of schemes. Typically, under DTP, manufacturers deliver their medicines directly to pharmacies using the services of one or more logistics service providers. The logistics service providers (which may even be full-line wholesalers) do not take ownership of the stock and are thus not in the position to offer any discounts on it. They are remunerated on a fee for service basis. In the UK, there has been a significant uptake of DTP arrangements since 2007. Subsequent to the introduction of the DTP model, pharmaceutical manufacturers in the UK introduced Reduced Wholesaler Arrangements (RWA), in which manufacturers use a very low number of wholesalers (2-3) to distribute medicines. Under this model, wholesalers purchase the stock. While DTP and RWA models are specific for the UK, distribution has also been changing in other European countries, with the introduction of

increasing direct sales and agency models (Kanavos et al. 2011; OFT 2007; Walter et al. 2012a; Walter et al. 2012b).

3.3 Pharmaceutical pricing policies

Overview on European countries

In most European countries, pricing policies are in place that usually address reimbursable medicines (in a few countries, all medicines). Reimbursable medicines are medicines whose cost are covered by public payers, either fully or at least partially (co-payments by the patients in the form of a prescription fee, or via the very common percentage co-payments of the medicine price). As a result, pricing policies in European countries are always somewhat linked with reimbursement policies.

At ex-factory price level (or at the wholesale price level, for those countries with no statutory wholesale remuneration, cf. section 3.2), medicine prices (at least for reimbursable medicines) are regulated by the authorities. Many European countries apply statutory pricing; this means that medicine prices are regulated by a legal provision (e.g. a law, a decree). A few countries (France, Italy and Spain) do not determine the prices statutorily, but the authorities and the manufacturers negotiate on the price. It should be noted that even in countries with statutory pricing, in a second step, negotiations between the manufacturer and the public payer about reimbursement, including the reimbursement price, also can take place. UK is the only European country with no direct price control related to medicines, however their PPRS (Pharmaceutical Price Regulation Scheme) serves as indirect control.

Different methodologies are applied for different kinds of medicines. For new medicines brought on the market, nearly all European countries apply external price referencing (international price benchmarking; i.e. comparing to the prices of medicines in other countries). Value based pricing, on the other hand, is currently only in place in Sweden. Section 3.4 will provide further information on external price referencing and further policies.

Usually, different pricing policies are applied for generic medicines. Many European countries use the so-called 'generic price link' policy, meaning that generics are priced a certain percentage below the prices of the originators ((Vogler 2012b), updated PPRI information). Nordic countries (e.g. Denmark, Sweden) do not apply this generic price link but rather allow for competition (Vogler 2012a).

A major issue for European countries is high-cost medicines that challenge the budgets of public payers. According to a query with competent authorities performed by the authors in 2014 (PPRI Secretariat 2014), there are no specific pricing policies for high-cost medicines, but specific funding schemes and models are applied. One of them are managed-entry agreements (MEAs). A MEA is an arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions

(Klemp et al. 2011). MEAs are designed in different ways and are either financial schemes (e.g. discounts, price-volume agreements or capping) or health outcome related schemes (e.g. risk-sharing schemes, coverage with evidence (CED) or conditional reimbursement) (Ferrario/Kanavos 2013). A particularly high number of MEAs was reported from Italy. Further countries with an increasing use of MEAs are the Netherlands, Poland, the UK (in the UK, MEAs are called 'Patient Access Schemes'), Portugal, Lithuania and Sweden (Ferrario/Kanavos 2013).

Discounts and rebates granted by pharmaceutical industry to public payers are a commonly applied policy, which were reported from nearly all European countries (Vogler et al. 2012b).

However, according to surveys from 2010 to 2014 (Vogler et al. 2011; WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014) the most frequently applied policy measures in the field of the pharmaceutical pricing and reimbursement were price cuts. The number of price cuts was much higher than changes related to the wholesale and pharmacy remuneration and the value-added tax on medicines.

Major markets

The overall pattern and trends outlined are relevant for several European countries, including some of the major markets. The country specific features related to pharmaceutical pricing of the key markets France, Germany, Italy, Spain and UK (England) are described in Table 1.

Table 1:
Pharmaceutical pricing policies in five major European markets: France, Germany, Italy, Spain and UK

Country	France	Germany	Italy	Spain	UK (England)
Scope of price control	Reimbursable medicines	Reimbursable medicines	Reimbursable medicines	Reimbursable medicines	Reimbursable medicines
Controlled price	Ex-factory price (manufacturer price)	Ex-factory price (manufacturer price)	Ex-factory price (manufacturer price)	Ex-factory price (manufacturer price)	Wholesale price (pharmacy purchasing price)
Pricing policies	Price negotiations between manufacturer and Pricing Committee, EPR for innovative medicines	Early benefit assessment and EPR for innovative medicines	Price negotiations between manufacturer and Medicines Agency, prices in other countries (EPR) are taken as supplementary decision criterion	Price negotiations between manufacturer and Pricing Committee, based on EPR	No direct price control. Kind of indirect price control via the PPRS scheme that limits the profits of manufacturers. Plan to introduce VBP in 2014 apparently abolished
EPR: basket, methodology	EPR in place 4 countries (DE, ES, IT, UK) in the basket; prices should be 'similar' to those in reference countries	EPR for few selected medicines in place 15 European countries in the basket; methodology not defined	EPR as supplementary decision criterion in place EU MS with manufacturer price data available; methodology not defined	EPR in place Eurozone countries, lowest price in the reference countries	No EPR in place
Discounts, rebates,...	Existence reported from out-patient & in-patient sectors	Existence reported from out-patient & in-patient sectors	Existence reported from out-patient & in-patient sectors	Existence reported from out-patient & in-patient sectors	Existence reported from out-patient & in-patient sectors
MEA	Existence reported	Existence reported	Existence reported	Existence reported	Existence reported
Specific funding models for high-cost medicines	High-cost medicines in the in-patient sector are not funded via the DRG system, but separately by the SHI (special 'supplementary list'), several price-volume agreements	'Discount agreements' with sickness funds	Major relevance of MEAs and patient registries, special fund to fund orphan medicinal products (fund is financed by manufacturers, based on their expenditure for promotion)	-	Several MEAs, called 'Patient Access Schemes' National Cancer Drug Fund (to fund oncology medicines not recommended by NICE)
Generic price policies	Generic price link in place (generics priced at least 60% below the originator) Kind of RPS in place	No generic price link RPS with broad clusters	Generic price link in place RPS in place	Generic price link in place RPS in place	No generic price link No RPS
Wholesale remuneration	Statutory wholesale remuneration for reimbursable medicines Linear mark-up	Statutory wholesale remuneration for POM and reimbursable OTC medicines Linear mark-up (POM), regressive scheme (reimbursable OTC medicines)	Statutory wholesale remuneration for reimbursable medicines Linear mark-up (different rates for orginators and biosimilars, and for generics)	Statutory wholesale remuneration for all medicines Regressive margin scheme	No statutory wholesale remuneration

Country	France	Germany	Italy	Spain	UK (England)
Pharmacy remuneration	Statutory pharmacy remuneration for reimbursable medicines Regressive margin scheme plus flat fee per package	Statutory pharmacy remuneration for POM and reimbursable OTC medicines Flat fee and linear mark-up (POM), regressive margin scheme (reimbursable OTC medicines)	Statutory pharmacy remuneration for reimbursable medicines Linear mark-up (different rates for orginators and biosimilars, and for generics)	Statutory pharmacy remuneration for all medicines Regressive margin scheme	Statutory pharmacy remuneration for reimbursable medicines A mix of fees and allowances to remunerate pharmacies
VAT on medicines	2.1% on reimbursable med., 10% on non-reimburs. med.	19%	10%	4%	0% for NHS medicines 20% for non-NHS medicines (non-reimb. + hospital med.)
TPE/capita	EUR 548.70 (2012)	EUR 509.64 (2012)	EUR 387.50 (2012)	EUR 368.88 (2012)	-
Public PE/capita	EUR 373.23 (2012)	EUR 385.15 (2012)	EUR 168.60 (2012)	EUR 261.77 (2012)	EUR 202.20 (2012)
Growth in TPE	+17.57% (2003-2012)	+24.48% (2003-2012)	-5.93% (2003-2012)	+15.46% (2003-2012)	-
Growth in public PE	+ 15.54% (2003-2012)	+26.09% (2003-2012)	-18.90% (2003-2012)	+14.92% (2003-2012)	+ 22.47 (2003-2012)

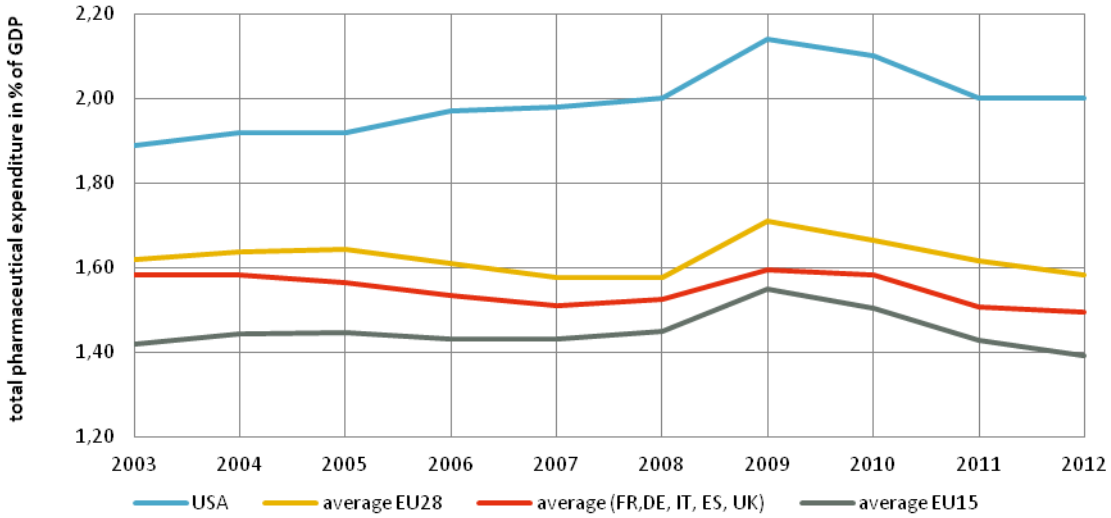
Notes:
Scope of price control: Describes which medicines are price regulated. Price control can cover all medicines in the market, prescription-only medicines, and reimbursable medicines (i.e. those medicines whose cost are, at least partially, covered by a public payer.
Controlled price: The price type that is subject to price regulation. This is usually the ex-factory price, but in countries without statutory wholesale remuneration (cf. section 3.2) the pharmacy purchasing price (wholesale price) is the controlled price.
EPR: External price referencing refers to the policy of international price comparisons. Key methodological elements are the country basket (to which countries it will be referred to) and the calculation of the reference price (e.g. average of the prices in the other countries).
Generic price policies: Generics can be priced at a specific percentage below the price of the originator (so-called 'generic price link'). A reference price system is a policy in which identical or similar medicines are clustered, and a defined amount (so-called 'reference price' is reimbursed, whereas the remainder up to the pharmacy retail price has to be paid by the patient.
Wholesale / pharmacy remuneration: Information is provided as to whether a statutory remuneration scheme is in place, and for which medicines (all medicines in the market, prescription-only medicines, and reimbursable medicines). Typical remuneration models are a linear mark-up (i.e. a defined amount (expressed in a fixed amount or a percentage) of costs that is added to the product to create profit), a regressive scheme (i.e. the respective remuneration decreases with an increase of the product's price), a flat fee (e.g. per pack dispensed) or some other service-oriented remuneration.
DRG = diagnosis-related schemes, EPR = external price referencing, MEA = Managed-entry agreements, med. = medicines, MS = Member State, NICE = National Institute for Health and Care Excellence, OTC = Over-the-Counter, PE = pharmaceutical expenditure, POM = prescription-only medicines, PPRS = pharmaceutical price regulation scheme, reimb. = reimbursable, RPS = reference price system, SHI = Social Health Insurance, TPE = total pharmaceutical expenditure, VAT = value-added tax, VBP = value-based pricing

Source: Ferrario/Kanavos 2013; PPRI Network Members (several authors) 2007-2013; PPRI Network Members (several authors) 2007-2014; PPRI Secretariat 2014; Vogler 2012a; Vogler 2012b; Vogler et al. 2012b; WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014; GÖ FP research with competent authorities involved in the PPRI network

Assessment of policies

In 2012, total pharmaceutical expenditure (TPE) amounted to 1.58% of gross domestic product (GDP) in the European Union (EU 28) and to 1.39% of GDP at EU-15 average. In the European Union, TPE ranged from less than 1% of GDP in Denmark and Luxemburg to more than 2% in Bulgaria, Greece, Croatia, Hungary and Slovak Republic. At the beginning of the crisis in 2008 an upwards shift of pharmaceutical expenditure in % of GDP was observed in Europe as well as the United States (see Figure 3).

Figure 2: Total pharmaceutical expenditure in % of GDP, EU and USA, 2003-2012



Primary data source used was Eurostat database, data imputed from OECD database for complete time series: Ireland, Italy and United Kingdom; for single years: Denmark (2011, 2012), Greece (2003-2008), Luxembourg (2009-2012), Slovenia (2012), Slovakia (2012), United States (2011, 2012). Imputations based on latest available years: Bulgaria (2008 for 2009 to 2012), Greece (2007 for 2008), Spain (2011 for 2012), Croatia (2011 for all other years), Latvia (2009 for 2010-2012 and 2004 for 2003), Lithuania (2011 for 2012 and 2004 for 2003), Netherlands (2005 for 2003-2004), Portugal (2011 for 2012), Romania (2011 for 2012), United Kingdom (2008 for 2009-2012). No available data for Malta.

Source: Eurostat and OECD Health database, extraction as of October 2014

As a percentage of current health expenditure, TPE accounted to 19.7% in EU-28, 14.6% in EU-15 and 14.6% on average for France, Germany, Italy, Spain and the United Kingdom in 2012. The United States had a TPE of around 12% of current health expenditure in 2012 (see Figure 3 in the Annex).

Per capita expenditure on pharmaceuticals and other medical non-durables in the European Union was highest in Belgium, amounting to 615 Euro and lowest in Bulgaria with about 110 Euro in 2012. Shares of public and private expenditure varied significantly between countries (see Figure 4 in the Annex). In some European countries, the share of private pharmaceutical expenditure increased in recent years.

These developments in pharmaceutical expenditure reflect the impact on public payers and patients. During the financial crisis, several European countries performed policy measures in which they managed to contain costs, in particular public pharmaceutical expenditure. This shifted the financial burden to private households (patients). For other health policy areas, concerns were raised that due to increased out-of pocket payments patients might refrain from using health services which is likely to negatively impact health outcomes (Fountoulakis et al.

2012; Karanikolos et al. 2013; Mladovsky et al. 2012). The impact of the global financial crisis on medicine use in European countries has not been studied in detail yet. We know that countries hit by the crisis undertook more policy measures (Leopold et al. 2014a; WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014), and there are indications of decreased medicine consumption (Buysse et al. 2010; Leopold et al. 2014b). Another impact for patients are medicine shortages: In recent years, limited availability of medicines has increasingly become a challenge in many European countries: This is the case in small markets that are not sufficiently attractive to be supplied by the pharmaceutical industry (Heads of Medicines Agencies 2007), but also major markets. Countries strongly hit by the crisis (e.g. Greece, Portugal) have been confronted with medicine shortages since their markets became unattractive due to its low price levels. This is relevant in the light of the frequent use of external price referencing, since low prices in one country may result in reducing the average European price. Therefore, some medicines were not marketed or were brought to the market with delays in these low price countries.

With regard to the market participants, pharmaceutical industry was apparently hit hardest by pricing measures. Several European countries undertook price cuts. For not ruining the average EU price in the EPR models, pharmaceutical manufacturers agreed to, or even proposed, confidential discounts, rebates or similar arrangements to public payers in several European countries. These were a kind of hidden price cuts, but without the impact on prices in other countries. Manufacturers were also targeted by methodological changes in pricing policies, particularly in the commonly used external price referencing (cf. section 3.4), for instance when the methodology of calculating the European average price changed from the average to a weighted average, or to the lowest price in the reference countries, or that the country basket was changed and included more low-priced countries. The latter was observed in some European countries (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014).

Regarding cuts in remuneration, distribution actors were less strongly targeted; pharmacies more so than pharmaceutical wholesale. However, as explained in section 3.2, pharmaceutical wholesalers were hit by other developments in the market.

3.4 External price referencing

External price referencing (EPR) is a major pricing policy applied in European countries. It is defined as 'the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country' (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2013).

28 of the 31 countries surveyed have external price referencing in place, at least for some medicines. No external price referencing is applied in Denmark, Sweden and the UK. Denmark, however, started to apply external price referencing for medicines used in hospitals in 2009 (Leopold et al. 2012). Sweden applies value based pricing instead (see below). England currently has no price control but indirectly regulates medicine prices via the profit control in the PPRS (Pharmaceutical Price Regulation Scheme, cf. section 3.3). England planned to introduce value

based pricing from 2014 onwards. Despite large-scale preparation, this plan has apparently been withdrawn.

As stated in section 3.., external price referencing is typically the pricing policy for new medicines; other policies are applied for generics. Some countries (e.g. Germany) use EPR only for few medicines, and others (e.g. Italy) consider the medicine prices in other countries only as a supplementary criterion ((Leopold et al. 2012), updated PPRI information).

There are different methodological approaches with regard to external price referencing. A key element is the country basket. Considerations about the economic situation and the medicine price level of possible reference countries, historic relationships as well as access to price data are key criteria for selecting countries as reference countries. In recent years, changes in the basket were observed in several countries (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014). Countries aligned baskets to their legislation (e.g. countries that refer to all other EU countries included new EU Member States such as Bulgaria, Romania and Croatia), and they used the country selection as a strategic element. Particularly, countries hit by the crisis frequently changed their basket to include rather low-priced countries. As a trend, the size of the country baskets increased over the years. This might also be attributable to easier access to price data following the establishment of a European price data base for competent authorities (Euripid). There were further methodological changes, e.g. related to the calculation of the 'benchmark price' but less frequent. Most European countries (e.g. Austria, Belgium, Ireland, Portugal) take the average of all countries in the basket, but the lowest price as reference price is also a common approach (e.g. Hungary, Poland, Romania, Spain). A few countries use the weighed average (e.g. Norway – the average of the three lowest prices out of a basket of 9 countries, (Leopold et al. 2012), updated PPRI information).

EPR has its limitations. Public payers risk overpaying since official list prices are taken into consideration for the comparison. Actual prices are lower due to the wide-spread practice of granting discounts and rebates to public payers (Vogler et al. 2012b) but cannot be considered due to their confidential character. EPR provides an incentive for manufacturers to strategically launch medicines first in high-price countries (Cueni 2008; Danzon et al. 2005; Europe Economics 2013), which may result in delays and limited availability in low-price countries, as observed in European countries hit by the crisis (cf. section 3.4).

Alternative pricing policies to EPR are value based pricing (VBP) and differential pricing. A VBP in the narrower sense is an integrated pricing and reimbursement system that links payments for medicines or health care services to evidence-based assessments of value for patients, their relatives and the society as a whole (Paris/Belloni 2013). Thus, the use of health technology assessments (HTA) and pharmaco-economic evaluations are elements in the use of VBP.

Table 2: Use of external price referencing, and country baskets in 31 European countries

Countries	AT	BE	BG	CH	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Additional countries	Nr. of c.
AT		■	■		■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■		27
BE	■		■		■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■		27
BG		■				■			■	■	■	■	■		■			■	■		■				■	■	■		■	■		RU	17
CH	■						■	■					■										■								■		6
CY	■									■			■															■					Back-up countries: DE, DK, IT, BE, ES, PT	4
CZ		■						■		■	■	■	■	■	■	■		■	■		■		■		■	■		■			■		19
DE	■	■				■		■		■	■	■	■			■		■					■			■		■		■	■		15
DK																																	
EE																			■		■									■			3
EL	■	■	■		■	■	■				■	■	■		■	■		■	■	■	■		■		■	■	■		■	■	■		22
ES	■	■			■		■		■	■		■	■			■		■		■	■	■	■			■			■	■			17
FI	■	■	■		■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		29
FR							■				■							■													■		4
HR						■												■												■			Back-up countries: ES, FR	3
HU	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		30
IE	■	■					■	■			■	■	■										■								■		9
IS								■				■												■				■					4
IT	■	■			■	■		■	■	■	■	■	■		■	■	■	■	■		■		■	■	■	■	■	■	■	■	■		25
LT			■			■			■						■						■				■		■			■			8
LU																																Country of origin	1
LV						■		■	■						■				■								■			■			7
MT					■	■			■		■				■			■	■							■	■		■	■	■		12
NL		■					■						■																				4
NO	■	■					■	■				■				■							■					■			■		9
PL									■					■	■				■	■	■									■			6
PT											■		■																■				3
RO	■	■	■			■	■			■	■				■			■	■						■					■			12
SE																																	
SI	■						■						■																				3
SK	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■		■		
UK																																	
Frequency	14	14	8	1	9	14	14	13	12	12	15	12	17	7	13	11	2	15	14	7	13	6	11	4	12	12	10	11	12	15	15		

Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2014), GÖ FP research with competent authorities involved in the PPRI network

While there is an increasing use of HTA and pharmaco-economics in many European countries (supplementary to EPR), a full VBP system is only in place in Sweden. The added value is assessed for all new medicines, and higher prices are granted to those medicines that demonstrate such higher added value. The cost-effectiveness of a medicine is analysed from a broad societal perspective; so the added value can result from of both increased health effects or costs savings either within the healthcare sector as well to society (Bouvy/Vogler 2013; Redman/Köping Höggärd 2007).

Differential pricing has been proposed as an alternative to EPR (Danzon/Towse 2003). Differential pricing (also called 'tiered pricing' or 'Ramsey pricing') results in different prices for different types of customers. In the case of medicines, it would mean that different prices charged by pharmaceutical manufacturers for different countries, taking the economic situation of a country into consideration. At the global level, there has been some experience with differential pricing but a systematic use of differential pricing has been limited to vaccines, contraceptives and antiretro-virals in low- and middle income countries, with global procurers (such as Global Fund, UNICEF) being the sole purchasers for the countries (Babar/Atif 2014; Moon et al. 2011; Yadav 2010). For the EU Member States, the situation is different: Pharmaceutical pricing and reimbursement is the national competence of Member States, and differential pricing would require a coordinated mechanism that all 28 EU Member States agree on an algorithm for discounting from a European price, taking into consideration their respective economic situation. Furthermore, parallel trade is allowed in the European Union, and is considered as a major principle of free trade. Thus, parallel trade as well as the wide-spread use of external price referencing in EU countries are considered as major barriers to implementating of differential pricing in Europe (Bouvy/Vogler 2013).

4 Conclusions

European countries were affected by the global financial crisis to different extents. Some countries (Greece, Ireland, Spain, Portugal) were hit particularly hard. In response to the crisis, European countries undertook several pharmaceutical policy measures; with the 'crisis countries' introducing a higher number of measures. Price cuts addressing ex-factory prices were a frequently applied cost-containment tool, but pharmaceutical manufacturers were also targeted through changes in the methodology of common pricing policies (e.g. a change in the basket of reference countries in the application of external price referencing). Patients were particularly vulnerable to increases in co-payments and out-of pocket payments since cost-containment measures tended to shift the financial burden from public to private payers. Besides pharmaceutical industry, further market participants such as wholesalers and pharmacies were also targeted by policy measures (e.g. decreases in their statutory margin remuneration) but to a lesser extent. Wholesalers are also hit by overall changes in the market (e.g. direct-to-pharmacy models, mergers).

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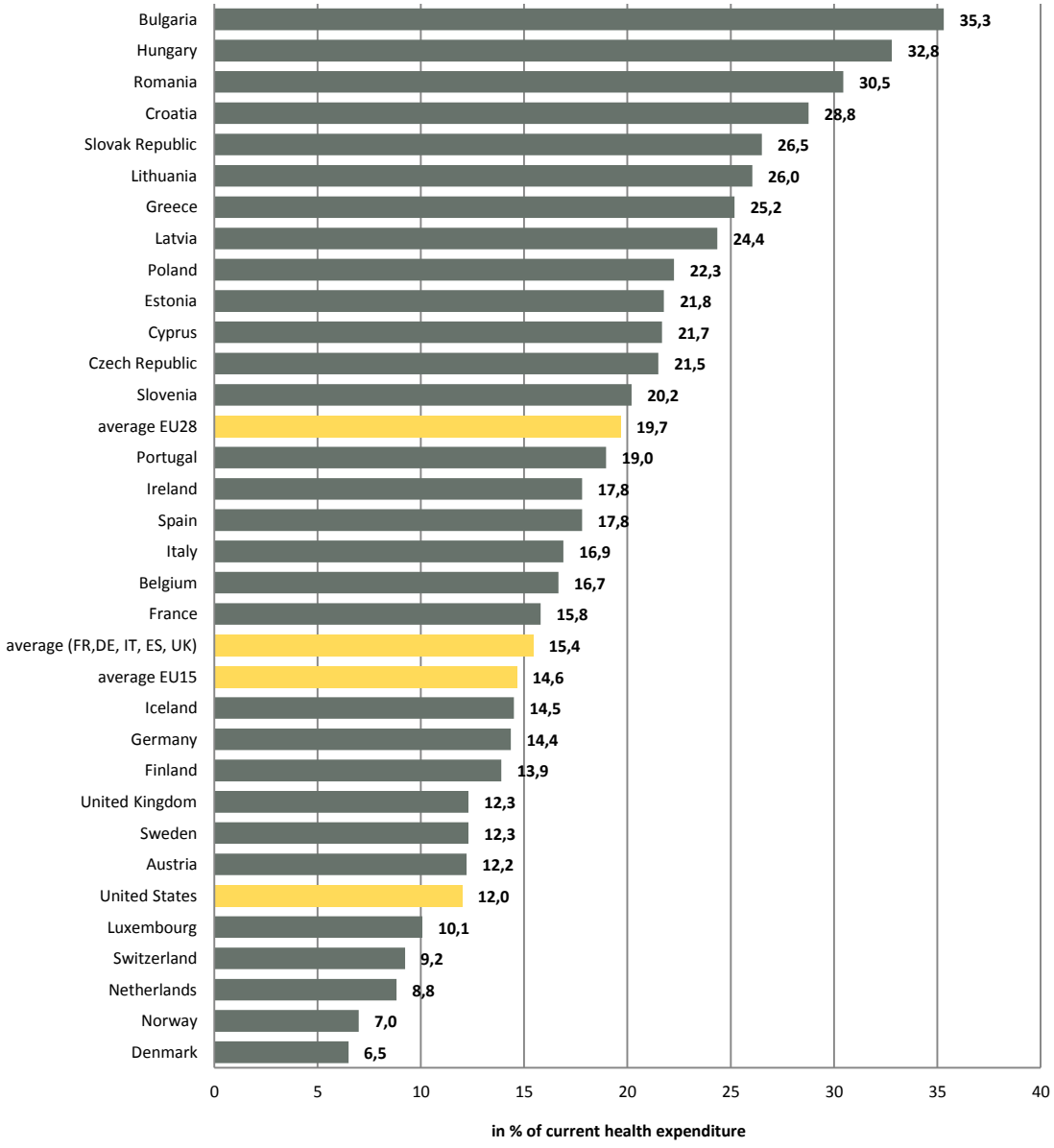
Annex

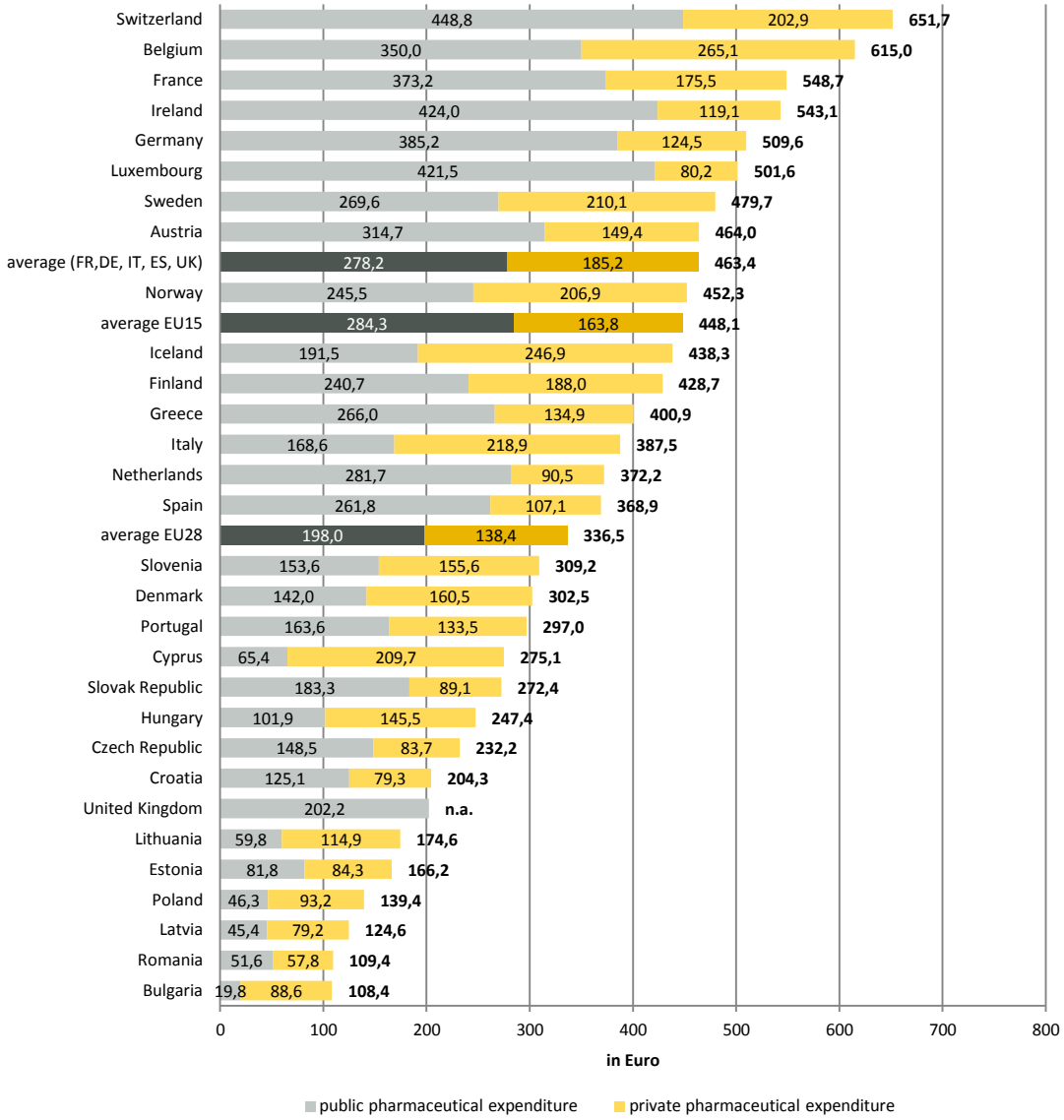
Figure 3:
Total pharmaceutical expenditure in % of current health expenditure, Europe and United States, 2012 or latest available year



The primary data source used was Eurostat database, data imputed from OECD: Denmark, Norway, United States, United Kingdom, Finland, Iceland, Italy, Ireland, Slovenia, Slovakia.Imputations based on latest available years: Luxembourg (2008), United Kingdom (2008), Spain (2011), Portugal (2011), Cyprus (2008), Latvia (2009), Lithuania (2011), Croatia (2011), Romania (2011), Bulgaria (2008). No data available for Malta.

Source: Eurostat and OECD database, extraction as of October 2014

Figure 4:
Public and private pharmaceutical expenditure per capita in Euro, Europe, 2012 or latest available year



The primary data source used was Eurostat database, data imputed from OECD: United Kingdom (public), Slovakia (private and public), Denmark (private and public), Slovenia (private and public), Italy (public), Finland (private and public), Ireland (public). Imputations based on latest available years: Bulgaria (2008), Spain (2011), Croatia (2012), Cyprus (2008), Latvia (2011), Lithuania (2011), Luxembourg (2008), Portugal (2011), Romania (2011), United Kingdom (2008). No available data for private pharmaceutical expenditure in United Kingdom. No available data for Malta.

Source: Eurostat and OECD database, extraction as of October 2014