Research Article

Pharmaceutical policies in European countries in response to the global financial crisis

Sabine Vogler[1], Nina Zimmermann[1], Christine Leopold[1], Kees de Joncheere[2]

[1] *Health Economics Department, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG – Austrian Health Institute, Vienna, Austria*

[2] *WHO Country Office Ukraine*

Address for Correspondence: Sabine Vogler, Health Economics Department, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG – Austrian Health Institute, Stubenring 6, 1010 Vienna, Austria. E-mail: sabine.vogler@goeg.at

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Abstract

Objective: The objective of this paper is to analyze which pharmaceutical policies European countries applied during the global financial crisis.

Methods: We undertook a survey with officials from public authorities for pharmaceutical pricing and reimbursement of 33 European countries represented in the PPRI (Pharmaceutical Pricing and Reimbursement Information) network based on a questionnaire. The survey was launched in September 2010 and repeated in February 2011 to obtain updated information.

Results: During the survey period from January 2010 to February 2011, 89 measures were identified in 23 of the 33 countries surveyed which were implemented to contain public medicines expenditure. Price reductions, changes in the co-payments, in the VAT rates on medicines and in the distribution margins were among the most common measures. More than a dozen countries reported measures under discussion or planned, for the remaining year 2011 and beyond. The largest number of measures were implemented in Iceland, the Baltic states (Estonia, Latvia, Lithuania), Greece, Spain and Portugal, which were hit by the crisis at different times.

Conclusions: Cost-containment has been an issue for high-income countries in Europe – no matter if hit by the crisis or not. In recent months, changes in pharmaceutical policies were reported from 23 European countries. Measures which can be implemented rather swiftly (e.g. price cuts, changes in co-payments and VAT rates on medicines) were among the most frequent measures. While the "crisis countries" (e.g. Baltic states, Greece, Spain) reacted with a bundle of measures, reforms in other countries (e.g. Poland, Germany) were not directly linked to the crisis, but also aimed at containing public spending. Since further reforms are under way, we recommend that the monitoring exercise is continued.

Keywords: medicines, Europe, global financial crisis, cost-containment, policy measures, pricing, reimbursement

Introduction

Pharmaceutical pricing and reimbursement systems in European countries differ from the ones in many countries the world over. This is due to the overall organisation and funding of health care in which the pharmaceutical systems are embedded. All countries have as part of their obligation to the fulfillment of the right to health, the obligation to grant access to essential medicines, i.e., medicines that fulfill the priority needs of their population[1-3]. This is ensured in many countries outside of Europe by the provision of a range of selected medicines (i.e. essential medicines) in public sector facilities that are procured by the state. While eligible patients can access essential medicines in the public sector either free of charge or with a modest co-payment, they have to purchase medicines "out-of-pocket" in the private sector[4-7]. In European countries, the distinction between the public and private sectors is not always clear (medicines are often supplied through private channels, but largely publicly funded). Further, the health service coverage, i.e., reimbursement of health expenditure by a social health insurance or a national health service, is in general more comprehensive compared to the rest of the world.

Pharmaceutical coverage usually includes for the majority of the medicines dispensed in hospitals and medicines prescribed by physicians but the scope of coverage varies[8]. Around 75% of

health expenditure and two thirds of pharmaceutical expenditure is on average covered by the public payers[9]. While marketing authorization has been harmonized in the EU[10], pharmaceutical pricing and reimbursement remains the competence of the Member States. A key provision which all EU Member States have to comply with is the Transparency Directive[11], which aims at guaranteeing pricing and reimbursement decisions to be taken in a transparent way within specific time-frames. It is however up to individual countries as to how they organize their pharmaceutical pricing and reimbursement system. While there are a few policies commonly used in several European countries (e.g. external price referencing), the specific design of the policy measures differs in the details[8,12-14]. As a result, there are 27 different pharmaceutical pricing and reimbursement systems in the EU[9,15].

Even though the countries in Europe, in particular in the EU, are mostly high-income countries, cost-containment of pharmaceutical expenditure and equitable access to medicines have been long-standing issues because of public sector spending limits. Since the 1990s, countries have been undertaking reforms with the aim of containing cost, in particular those costs borne by public payers[16-17]. On average, public pharmaceutical expenditure in the out-patient sector has increased in EU countries by 76 percent between 2000 and 2009 (median: 53 percent; lowest value: 21 percent; highest value: 243 percent), with a growth of 79% in the EU-15 (i.e. EU Member States before 2004 – in general, high income countries in Western, Northern and Southern Europe) and 71% in the EU-12 (i.e. "new" EU Member States which acceded on or after May 2004 to the EU; mainly Central and Eastern European countries)[i].

The financial global crisis hit European countries from 2008 on. The first country affected in Europe was Iceland with the collapse of all three major banks in September 2008. Shortly afterwards the crisis hit the three Baltic states Estonia, Latvia and Lithuania. From early 2010 onwards the Eurozone countries (i.e. countries with the Euro as currency) of Greece, Spain, and Ireland were hit by a debt crisis. In 2011, the Greek crisis escalated, concerning mostly the refinancing of Greek public debts; and Greece, together with Portugal and recently Italy, appeared on the political agenda of the EU meeting in spring/summer 2011. These countries were urged to implement measures for budget savings.

The aim of this study was to explore that how the global financial crisis impacted the regulatory framework in the pharmaceutical sector in European countries. Another objective was to determine the type of pharmaceutical policies implemented over this time and in particular, those relating to pricing and reimbursement. However, an assessment of the impact of this policy implementation is beyond the scope of this paper.

Methodology

We collected information about pharmaceutical policies implemented by European countries via a survey conducted with the public authorities for pricing and reimbursement represented in the PPRI (Pharmaceutical Pricing and Reimbursement Information) network.

PPRI is a networking and information-sharing initiative on pharmaceutical policies from a public health perspective which emerged from a European Commission co-funded project under the same name[18]. At the time of writing, PPRI consisted of more than 60 institutions; mainly Medicines Agencies, Ministries of Health, and Social Insurance institutions, from 38 countries, thereof all 27 EU Member States, eight further European countries and three non-European countries, plus European and international institutions (European Commission services and agencies, OECD, WHO and World Bank)[ii].

The reasons why we decided to survey the information via PPRI were three-fold: Firstly, we consider the PPRI representatives as the ideal agency to have access to this kind of information, since they are dealing with pricing and/or reimbursement decisions on a daily basis in the representative countries. Secondly, a common understanding of concepts and a shared language built on a joint terminology has developed among members[19], and this provides a level of quality assurance. Thirdly, this study was initiated by PPRI network members who, in the light of changes due to the financial crisis, proposed in spring 2010 to regularly monitor the reforms in the national pharmaceutical systems.

To collect the information, we developed a questionnaire asking for specific measures in the field of pricing (price cuts, price reviews, margin changes, discounts/rebates, changes in value-added tax) and reimbursement (changes with regard to reimbursement lists, reimbursement rates, co-payments, reference price systems, reimbursement reviews) and changes in generic policies. The questionnaire explicitly asked to list further measures. The first round of this policy monitoring exercise was launched on 1st September 2010, and the questionnaire surveyed the period from January 2010 to September 2010 including a discussion on planned measures. The investigation was repeated on 2nd February 2011 in order to obtain updated data for the second half of 2010 and the beginning of 2011, with an outlook on the first half of the year 2011.

In both rounds, the questionnaires were sent to all 33 PPRI member countries. Although the same cohort of countries were included in both rounds of surveys, some countries participated in only one round: 20 countries, thereof 15 EU Member States, out of the total of 33 European countries which were at that time represented in PPRI responded to at least one of the surveys. Sixteen countries, of 11 EU Member States, participated in the first survey and 13 countries, thereof

[i] Data from the PHIS (Pharmaceutical Health Information System) database, accessed on 11 August 2011; further information regarding the methodology (data sources, limitations, etc.) see the PHIS database, publicly accessible at http://phis.goeg.at and http://whocc.goeg.at from October 2011 on.

[ii] It is PPRI's policy not to list the names of staff and officials of institutions represented. The institutions which are members of PPRI are listed on the PPRI website (http://ppri.goeg.at).

Table 1. Countries participating in the survey

European countries participating in PPRI *	Answered 1st round	Answered 2nd round	Provided further info. in review **	Supplementary research ***	Survey country of this study
European Union (EU) Member States					
Austria	Yes	Yes	No	No	Yes
Belgium	No	Yes	No	No	Yes
Bulgaria	No	No	No	No	Yes
Czech Republic	Yes	Yes	No	No	Yes
Cyprus	No	No	No	No	Yes
Denmark	Yes	Yes	Yes	No	Yes
Estonia	No	No	No	Yes	Yes
Finland	Yes	Yes	No	No	Yes
France	No	Yes	No	No	Yes
Germany	No	No	No	Yes	Yes
Greece	No	No	No	Yes	Yes
Hungary	No	No	No	No	Yes
Ireland	No	No	No	Yes	Yes
Italy	No	No	No	Yes	Yes
Latvia	No	Yes	No	Yes	Yes
Lithuania	Yes	No	No	Yes	Yes
Luxemburg	No	No	No	No	Yes
Malta	Yes	Yes	No	No	Yes
Netherlands	Yes	No	No	No	Yes
Poland	No	Yes	No	No	Yes
Portugal	Yes	Yes	Yes	No	Yes
Romania	Yes	No	No	No	Yes
Slovakia	No	No	No	Yes	Yes
Slovenia	No	No	No	No	Yes
Spain	Yes	No	Yes	Yes	Yes
Sweden	No	No	No	No	Yes
United Kingdom (UK)	Yes	Yes	Yes	No	Yes
Subtotal Yes / No	**11 / 16**	**11 / 16**	**4 / 23**	**9 / 18**	**27 / 0**

European countries participating in PPRI *	Answered 1st round	Answered 2nd round	Provided further info. in review **	Supplementary research ***	Survey country of this study
Further European, non- European Union (EU) member countries					
Albania	No	No	No	No	Yes
Croatia	Yes	No	No	No	Yes
Iceland	Yes	Yes	No	No	Yes
Norway	Yes	Yes	No	No	Yes
Switzerland	Yes	No	No	No	Yes
Turkey	Yes	No	No	No	Yes
Subtotal Yes / No	**5 / 1**	**2 / 4**	**0 / 6**	**0 / 6**	**6 / 0**
Total Yes / No	**16 / 17**	**13 / 20**	**4 / 29**	**9 / 24**	**33 / 0**

* As of September 2010 (i.e. start of the survey). Afterwards, two further countries (Republic of Serbia, and Macedonia) joined the PPRI network. The three non-European PPRI member countries (Canada, South Africa, South Korea) were disregarded for this study.

** Provided further information, clarifications and/or updates on their countries in the review of the draft article

*** Supplementary desk-top research (incl. grey literature and presentation provided by country representatives during meetings) and individual requests for information for those countries which were known to be strongly hit by the crisis but did not participate in (both rounds of) the survey

11 EU Member States, in the second round in February 2011. To ensure the highest possible level of information coverage, we undertook supplementary research, checking peer-reviewed and grey literature and considering information provided to us by country representatives in writing and through personal communications. In particular, we included information from presentations which country officials from Greece, Ireland, Spain and the three Baltic states (Estonia, Latvia, Lithuania) represented regarding their countries responses to the financial crisis. In a few cases, we contacted country representatives for updates and/or validation. Table 1 provides information about the involvement of the European PPRI countries in this study.

The survey was conducted from January 2010 to February 2011 with a discussion on planned measures. The rationale of having two rounds was to obtain updated information, as well as to receive information from those countries which had not participated in the first round. At the time of writing, a new round of the survey was being prepared which will be launched at the beginning of September 2011.

The terminology used in this paper is consistent with the PHIS (Pharmaceutical Health Information System) Glossary[20], which is the accepted terminology resource for pharmaceutical policy.

Data validation by the information providers was ensured in two ways: At the end of February 2011, a working paper summarizing all received information about policies was shared with the PPRI network members. Additionally, one of the authors (SV) presented the results during a network meeting in February 2011[21].The authors informed the data providers about their intention to publish the information in this paper and shared a draft version with them.

Results

This paper provides an overview of the changes in response to the global financial crisis of pharmaceutical policies in the 27 EU Member States plus Croatia, Iceland, Norway, Switzerland and Turkey. From the beginning of 2010 to February 2011, 89 pharmaceutical policy measures were identified in 23 of the 33 countries surveyed. Fourteen countries reported measures under discussion or planned for the remainder of 2011 and beyond. Tables 2 and 3 provide an overview of the policy measures.

Policy interventions by type

Price reductions of pharmaceuticals were the most frequent cost-containment measure, which countries applied during the review period (a total of 15 price reductions in 11 countries).

The second most common measure was a change in co-payments, which constituted usually but not always an increase in cost for the patients (a total of 13 measures in nine countries, thereof increases in the prescription fee and higher co-payment due to the lower reimbursement rates). On eight occasions a policy change affected reimbursement lists and procedures (i.e. de-listings, introduction of a positive and/or negative list), and in 10 instances the reference price system (changes in the methodology allowing lower reference prices, broader clusters of similar medicines) and/or the pricing of generics in a cluster ("generic price link") were observed. Generic promotion measures (e.g. making indicative INN prescribing mandatory, public awareness-raising campaigns) were among the most frequently mentioned measures in the category of "other measures".

Table 2. Pharmaceutical pricing policy measures in 33 European countries in 2010 and 2011

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
Price reductions	**Czech Republic:** price cut of 7% on reimbursable medicines **UK:** price cut of 1.9% on branded NHS medicines as part of 2009 PPRS **Spain:** price cut of 30% on generics **Greece:** quarterly price reviews followed by price cuts **Ireland:** price reductions on generics **Lithuania:** price cuts of 11% on non-reimbursable medicines **Turkey:** price cut under reference price on 20 years old medicines	**Lithuania:** price cut of 10% on reimbursable medicines **Switzerland:** implementation of price review into practice **Portugal:** price reduction for original medicines and for generics following annual price review **Ireland**: another price reduction on generics **Germany:** price freeze of reimbursable medicines	**Czech Republic:** price cut of 7% on non-revised medicines **Ireland:** price reductions on on-patent medicines **Malta:** price cuts in the private market	**Iceland:** price review of all medicines with predicted price cuts of 3%-5% **Turkey:** price cut on off-patent medicines under discussion
Discounts, rebates, claw-backs/pack-back & other agreements	**Spain:** 7.5% discounts on original medicines and 4% on orphans **Romania:** introduction of claw-back **Lithuania:** introduction of price notification for non-reimbursable medicines (before not regulated)	**Estonia:** introduction of price agreement also for 50% reimbursable medicines (before not regulated) **Germany:** increase in mandatory manufacturer's rebate to social health insurance (6% → 16%) **Portugal:** discount of 6% for reimbursable medicines **Italy:** choice between pay-back and price cuts **Lithuania:** extension of price-volume agreement to high-cost medicines	**Portugal:** 7.5% lower price than 2010 needs to be granted to NHS institutions for specific biologicals	**Poland:** new reimbursement law valid from 2012 on – several changes, e.g. obligatory pay-back in case of budget excess, voluntary in risk-sharing schemes; tax on manufacturers' income to publicly fund clinical trials
External price referencing (EPR)	**Malta:** introduction of EPR **Switzerland:** extension of basket (4 → 6 countries) **Spain:** specification in law to have EU Member States as reference countries	**Lithuania:** extension of basket (6 → 8) **Iceland:** change in calculation methodology for hospital medicines (lowest price)	**Germany:** EPR-like procedures provided for in law (implementation from 2012 on)	**Slovakia:** change in calculation methodology (6 lowest prices → 2 lowest prices of EU-26; in Parliament)
Distribution remuneration (margin*)	**Iceland:** pharmacy margin increase **Switzerland:** pharmacy margin cut **Spain:** increase of a part of pharmacy margin for expensive medicines **Greece:** wholesale margin cut for expensive medicines **Lithuania:** introduction of wholesale and pharmacy margin regulation for non-reimbursable medicines **Portugal:** pharmacy margin increase for non-reimbursable medicines **Belgium:** new pharmacy margin	**Italy:** wholesale margin cut & pharmacy margin increase	**Latvia:** wholesale margin cut	**Portugal:** discussion about pharmacy margin cut **Germany:** change in structure of wholesale margin from 2012 on **Poland:** new reimbursement law valid from 2012: pharmacy margin change

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
Value added tax (VAT) on medicines	**Czech Republic:** increase (9 → 10%) **UK:** increase on OTC/standard rate (had been temporarily reduced in 2008: 15 → 17.5%) **Greece:** increase (9 → 10%)	**Finland:** increase (8 → 9%) **Portugal:** increase (5 → 6%) **Greece:** increase (10 → 11%)	**Greece:** decrease (10 → 6.5%) **Latvia:** increase (10 → 12%) **UK:** increase on OTC (17.5 → 20%) **Poland:** increase (7 → 8%)	

Abbreviations: EPR = external price referencing (= international price comparison), EU = European Union, NHS = national health service, OTC = over-the-counter medicines, PPRS = Pharmaceutical Price Regulation Scheme (UK)

* Please note that the term "margin" is used in this table as a broad term covering different kinds of distribution remuneration (e.g. margins, mark-ups, fees).

Table 3. Pharmaceutical reimbursement and other policy measures in 33 European countries in 2010 and 2011

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
Reimbursement lists / (de)listing/ reimbursement procedure	**Malta:** listing of new medicines (on-going 2010/2011) **Iceland:** changes in reimbursement status (from general to individual) for some medicines (e.g. respiratory) **Portugal:** procedural changes (shorter reimbursement decision time for generics)	**Greece:** re-introduction of positive list and negative list **Iceland:** changes in reimbursement status (from general to individual) for some medicines (e.g. antidepressants)	**Czech Republic:** ongoing review of all medicines (started already in 2008) **Germany:** new reimbursement law – value assessments **Portugal:** Delisting of OTC medicines	**Poland:** new reimbursement law valid from 2012 – several changes, e.g. quicker reimbursement decision, but granted for limited time (2-5 years) **Czech Republic:** discussion about introduction of negative list **France:** change of reimbursement system under discussion **Netherlands:** change in funding of TNF-inhibitors (2012)
Co-payments	**Austria:** annual increase of prescription fee **Belgium:** annual indexation of co-pay. **Iceland:** increase in co-pay. **Portugal:** temporary exemption (6/2009 – 5/2010) from co-pay. for low-income pensioners for generics was changed (from generics to 5 lowest priced medicines in a cluster)	**Belgium:** increase of percentage co-pay. for some medicines (at different times during 2010) **Lithuania:** change in minimum co-pay. **Latvia:** increase of reimbursement rate for cardiovascular medicines (50% → 75%) **Portugal:** introduction of co-pay. on medicines which low-income pensioners had been exempted from before	**Denmark:** increase in co-pay. for fertility products **France:** decrease of reimbursement rate (35 → 30%) **Austria:** annual increase of prescription fee **Belgium:** annual indexation of co-pay. **Iceland:** increase in co-pay. **Latvia:** change in new co-pay.	**Poland:** changes in co-pay. following new reimbursement law Under discussion in Czech Republic, France, Iceland, Latvia, Portugal
Reference price system (RPS)	**Portugal**: higher RP for more patients **Spain:** change in methodology allowing lower RP (average of 3 lowest prices → lowest priced product in a cluster) **Lithuania:** new rules of price of generics compared to equivalents	**Estonia:** inclusion of 50% reimbursable medicines in RPS (before not) (7/2010) **Romania:** change to therapeutic reference pricing (broader clusters) **Estonia:** new rules for price of generics and biologicals in the RPS (10/2010)	**Latvia:** new rules for price of generics in a cluster (lower prices) **Portugal:** change in methodology of RP (lower RP) **Belgium:** new rules for price of generics in a cluster (lower RP) **Lithuania:** change in methodology of price of most expensive medicines in a cluster (lower prices)	**Czech Republic:** discussion about tendering for generics **Lithuania:** discussion about change to therapeutic reference pricing (broader clusters) **Ireland:** introduction of RPS planned **Poland:** changes in generic price links due to new reimbursement law (2012) **Romania:** discussion about extending RPS

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
Other measures (not directly linked to pricing & reimburse-ment)	**Lithuania:** obligation for pharmacies to offer least expensive medicine to patients and to have it on stock (1/2010) **Estonia:** introduction of e-prescribing (1/2010) **Estonia:** obligation for pharmacies to offer least expensive medicines to patients and to have it on stock (4/2010) **Lithuania:** obligation for pharmacies to install price monitoring systems (5/2010) **Lithuania:** INN prescribing becomes mandatory (6/2010)	**Estonia:** generics promotion campaign addressed to the public **Spain:** generics promotion campaign addressed to the public	**France:** definition for "quasi-generic" **UK:** Quality, Productivity and Prevention programme on-going (introduced 2009)	**Czech Republic:** enforcement of INN prescribing **Portugal:** e-prescribing as prerequisite for reimbursement (originally planned from 3/2011 on, postponed for 8/2011) **Portugal:** continued generics promotion **Slovakia:** draft law about INN prescribing becoming mandatory **Poland:** new reimbursement law valid from 2012 on: information duties of pharmacies about least expensive equivalent medicines and having them on stock **UK:** discussion about introduction of value-based pricing in 2013 (after PPRS ending)

Abbreviations: co-pay. = co-payment, INN = international non-proprietary name, OTC = over-the-counter medicines, PPRS = Pharmaceutical Price Regulation Scheme (UK), RP = reference price, RPS = reference price system (= reimbursement system in which identical or similar medicines in a cluster are granted a specific reimbursement limit), TNF = tumor necrosis factors

Further, frequently reported measures included increases in the value-added tax (VAT) rates on medicines (in seven countries, with Greece raising its VAT twice during 2010 and then reducing again in 2011) and changes in the payment schemes for the distributors (nine countries). It is worth noting that some countries (e.g. Spain) increased the standard VAT rate, but normally this had no impact on medicines (except UK: standard rate is applied for OTC medicines), since usually lower VAT rates apply specifically to medicines. There were decreases in pharmacy margins in Switzerland and in the wholesale margins in Greece and Italy. However, Spain, Portugal, and Italy increased the pharmacy margin, or parts of it for the expensive price segment.

With regard to external price referencing (i.e. comparing to medicines prices in other countries as basis for a pricing and/or reimbursement decision), two countries (Malta, Germany – under specific circumstances, only applicable from 2012 on) introduced this pricing procedure, while four European countries changed their already existing external price referencing system, mainly extending their basket of reference countries, but also changing the methodology for calculation aimed at obtaining a lower price.

Policy interventions by countries

The highest number of measures were implemented in the Baltic states, Greece, Spain, Portugal and Iceland.

Greece started to react to the crisis in spring 2010, with a bundle of emergency measures – some of which implemented temporarily. From May 2010 onwards, several price reductions were implemented, together with a reduction in the wholesale margin and twice an increase in the VAT on medicines followed by a decrease at the beginning of 2011. The frequency of price reviews for medicines having entered the market during the last four years increased from one, to three times a year. Generic prices were set at 90% of the original medicines' prices (before: equal level). A positive list and a negative list were planned to be re-introduced. The competence for pricing, previously split among three ministries, was shifted to the Ministry of Health in spring 2011[22].

Spain introduced two emergency laws in March and May 2010. The price of expensive generics were cut by 30%, while original medicines and orphan medicines were discounted by 7.5% and 4% respectively on the pharmacy retail price, which were borne by industry, wholesale and pharmacies together, were implemented instead of price cuts. Spain also instituted procedural changes, e.g. in the reference price system and external price referencing, allowing lower prices and aligning the laws with existing practice[23].

The reaction of Ireland, the third country hit by the crisis during 2010, was slightly different. Ireland did not take so many measures as Spain and Greece, and also considered the pharmaceutical industry as a considerable investor and employer within the Irish economy. Some policies had already been implemented earlier, such as the wholesale and pharmacy margin in 2009, and a refinement in external price referencing (e.g. HTA assessment for new medicines from 2009 on). In 2010, Ireland imposed different waves of price reductions, negotiated with and offered by the pharmaceutical industry, on generics. This occurred in February and October 2010 and on on-patent medicines at the end of 2010. A political decision to implement a reference price system was taken in 2010. However, legislation

is still awaited as it was postponed until after the elections to be held in spring 2011[24].

During the survey period, major reforms of the pharmaceutical system were also planned or underway in Germany and Poland.

In Germany, the reform was prepared after a change in government in 2009 and came into effect on 1 January 2011. Pharmaceutical companies in Germany are now obliged to produce a scientific dossier with a value assessment demonstrating the added therapeutic benefit of a new medicine compared to treatment alternatives – which can be used later for negotiations about the price and rebates with the sickness funds. Furthermore, the reform law expects that medicine prices in other countries should be taken into consideration in the decision about the reimbursement prices in Germany. Cost-containment measures applied in August 2010 until the end of 2013, comprised of a freeze on pharmaceutical prices and an increase from 6% to 16% in the mandatory rebate the Social Health Insurance imposes on pharmaceutical manufacturers[25].

Poland drafted a law to significantly reform the pharmaceutical reimbursement system in order to contain costs and, to comply with the EU law after an infringement procedure. This related to time-lines for decision on pricing and reimbursement regulated in the EU Transparency Directive. The new reimbursement law, which was passed in Parliament in spring 2011 after much discussion and with alterations and will come in effect in 2012, contains a number of policy changes in several fields (see Tables 2 and 3).

The Baltic countries (Estonia, Latvia, Lithuania) started to implement several new cost-containment measures in reaction to the crisis from 2008/2009 onwards. Lithuania reported approximately 28 measures undertaken in recent years[26]. In 2010, the policy interventions within the Baltic states were focused on improving rational use of medicines, including generics promotion and, in some cases, cancelling strict cost-containment measures from the year before[27-29].

Discussion

In 2010 through to the beginning of 2011 a large number of cost-containment measures (around 90) were undertaken in 23 of the 33 European countries surveyed. On average 2.7 policy interventions per country were set in the 14 month investigation period. The reforms were concentrated in Iceland, the Baltic states, Greece, Spain and Portugal, which were, starting at different times, hit by a budget crisis. Price reductions, changes in the co-payments, in the VAT rates on medicines and in the distribution margins were among the most common measures.

The contribution of this research is that it focuses on changes in pharmaceutical policies. While the pharmaceutical systems of European countries, or some elements of them are well described (in particular of the larger countries such UK, France, Germany, but increasingly also other countries[30-33]), cross-country surveys of policy changes are few in number[12,16].

The average number of 2.7 policy interventions per country demonstrates that European countries were active in developing and implementing pharmaceutical policies over the time period of the survey. Our study supports a previous observation from the 1990s that EU Member States perform, on average, at least one policy measure per year[34]. However, it is important to realize that the average number of measures implemented per country might be misleading. This is because, at least for the years 2010/2011, policy changes were concentrated in a few countries – labeled "crisis countries", as well as a few other countries which had reforms that were not directly attributable to the financial crisis (e.g. Germany, Poland, a current discussion about organizational changes in France following the Mediator scandal[35]). Whether affected by the crisis or not, containing pharmaceutical expenditure appears to be the key reason for countries aiming to reform their pharmaceutical sector. Our study adds to previous findings that cost-containment has been an issue for high-income countries, who aim to maintain equitable access to medicines within public sector spending constraints[9,16-17].

This paper does not assess the impact of the measures since, though considered important and adding on the impact analysis of the global economic recession on countries world-wide done by the World Health Organization[36], this would be premature and incomplete for the most recent crisis countries. Commonly set measures like increases in co-payments (including decrease in reimbursement rates) and in the VAT rates might be an indication for limited accessibility of medicines, even if exemptions from co-payments for vulnerable groups were observed (e.g. Portugal) and in some countries VAT for reimbursable medicines is not (fully) borne by the patients. Concerns arose about accessibility after the first wave of policy measures in response to the crisis in the Baltic countries in 2008/2009, and some of the measures instituted in 2010 aimed to reduce the burden for patients and improve equity of access to medicines by withdrawing, or easing some of the cost-containment measures[27-29].

In the 1990s policy interventions in high-income European countries were successful in containing growth rates in pharmaceutical expenditure and, in particular, in public pharmaceutical expenditure, but this was done at the expense of the patients with increases in private pharmaceutical expenditure[16,34]. In the new millennium some policy intervention proved successful in terms of cost-containment for public payers, and this was achieved without an increase of the out-of pocket payments[9]. This was mainly due to more rational use of medicines, including greater application of instruments of health economics including HTA[37-38] and a rational selection process for reimbursement in which reference price systems increasingly play a role[39]. Demand-side measures collated under the "4 Es" methodology (i.e. education, engineering, economics, and enforcement)[40-42] are recommended. In the Baltic states strict cost-containment measures targeting all stakeholders, including patients, were observed as first reaction to the crisis; follow-up measures were implemented in the field of the "4 Es" and had a focus on the enforcement aspect (e.g. making INN prescribing

obligatory). We need to see if such developments will also take place in the more recent crisis countries. For this phase of the financial crisis we have data that the crisis response was successful in terms of savings in public expenditure which Spain, Greece and, to some extent, also Ireland could achieve[22-24], but equity and accessibility aspects should also be explored. Another issue for future analyses could be an assessment if the outcomes achieved are worth the efforts made since these measures – no matter if in response to the crisis or generally aiming at cost-containment – are time-intensive for the officials, and if and how they might be implemented more efficiently. Nonetheless, the need to regularly refine and adjust pharmaceutical policies cannot be questioned: The impact of policies usually appears to be rather short-term, and its effect will probably fade out after two and three years unless no further and/or accompanying measures are set, since actors will adjust the situation according to their interests[34].

Measures affecting the pharmaceutical industry raised concerns about medicines availability, which has been an issue, especially for small national markets in European countries. At the beginning of the crisis in Greece, some pharmaceutical companies announced their withdrawal from the Greek market[43], as they claimed that they could not accept the price reductions, but to date this has not been the case (personal communication).

In the distribution chain, wholesale and pharmacies were equally affected by changes in their payment schemes, following on changes performed in the years before (e.g. in the Czech Republic, Ireland, Romania)[44]. In spite of the crisis in a few countries (e.g. Spain, Portugal) pharmacy margins, or at least a part of it, were increased, partly following an agreement that pharmacies were compensated in return for other crisis-related reforms. In some cases, the margin changes were not linked to the crisis.

We acknowledge that countries might have undertaken further policy measures which were not included in our summary of results. Nonetheless, we attempted to gather information about the major reforms since we asked the technical people responsible for pharmaceutical pricing and reimbursement in the countries. We also repeated the survey after seven months (thus also guaranteeing full coverage for the survey period for those countries only answering the second round), and ensured data validation by the information providers and checked literature and materials, in particular for some missing countries. Due to their repeating character, annual measures (e.g. price and/or reimbursement reviews) are likely not to have been listed by all countries undertaking them. We could only assess policy measures to the extent as they were publicly known. As a result, confidential arrangements including discounts or other savings offered in return for avoiding other measures, which might have taken place, are not included in the results.

The counting of the measures posed some problems, as some (planned) reforms included a bundle of, sometimes, interlinked measures. Measures like price cuts and de-listings which affected individual products were only considered when undertaken systematically for a group of medicines and in such cases counted once.

One limitation of the study is the short survey period. The survey started at the beginning of 2010, i.e. in the middle of the global financial crisis. In order to allow analyses over a longer time period and as the global financial crisis continues the authors plan to continue this policy monitoring exercise on a bi-annual basis. The survey methodology proved to be adequate for the purpose and will be, with some minor modification of the questionnaire, continued to be used. This regular exercise will also allow us to check which of the discussed and planned policy measures were actually implemented and in which form, and what the results have been, and share the findings with interested parties, among those competent authorities, thus offering the possibility to learn from the experiences of other countries.

Conclusions

This study demonstrates that numerous cost-containment measures were undertaken in mainly high and middle income European countries during the 2010-2011 financial crisis. While a bundle of policy measures were implemented in countries which were hit significantly by the crisis, all countries appear to be constantly working on optimizing their pharmaceutical systems. In several countries reforms were undertaken, which also aimed at containing public pharmaceutical expenditure, but they were not directly linked to the crisis. Price cuts, changes in co-payments, distribution margins and VAT rates on medicines, which could be implemented rather swiftly, were used as first tools. Many initiatives included the promotion of generic medicine use and the enforcement of policies for more rational use of medicines. Since further reforms are under way, changes in pharmaceutical policies will continue to be monitored. It is recommended to follow up with the applied methodology of this policy monitoring exercise which was piloted successfully in this study. Further research, in particular an impact assessment of the effects of the reforms on the availability and accessibility of medicines, is suggested and should also consider information collected in future policy monitoring exercises.

Authors contributions

All authors contributed to the paper's conception, design and production. SV drafted and revised the article with contributions from NZ, CL and KDJ and considering feed-back by PPRI network members. NZ developed the policy monitoring exercise tool in close cooperation with the other authors, performed the survey and compiled the preliminary results. All authors participated in a critical revision and have approved the final version for submission.

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Conflict of interest

None

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