Executive Summary

This paper focuses on the European pharmaceutical market and reviews the existing situation regarding the pricing differences of pharmaceuticals in a unified market and its consequences.

Tools used by the market to circumvent the pricing difference, including the use of generic drugs, parallel trade and positive and negative lists, are assessed from both the pharmaceutical industry and national governments point of view.

It was found that through changes in legislation, the pricing difference of pharmaceutical is creating side markets that customers are able to exploit with the increased in technologies. That these side markets are often viewed positively by national governments as a method to control expenses but are negatively impacting pharmaceutical companies who had been exploiting pricing differences as a method to recoup investment in development of new drugs.

Although the Community is still struggling to find solutions that will be suitable for all parties involved, options available to mitigate the situation were proposed.

Finally, it was concluded that the consequences of pricing differences, although difficult to manage for the pharmaceutical companies and governments, will tend to disappear has the income of EU countries converge towards an average. Until such time, it is recommended to both parties that they should partner to find solutions that will preserve the quality of the health care systems in Europe and will protect this vital sector of the economy.
Introduction

Today, the branded pharmaceutical industry is entering one of the most challenging periods in its history. In recent years, the worldwide industry has been affected by a number of external forces such as generic competition, parallel imports and patent challenges which all affect the traditional business model of these companies.

The European pharmaceutical market in particular has been impacted further due to the unified market and the pricing difference it had been maintaining between European countries. The pricing strategies of the pharmaceutical companies are being circumvented more and more through different measures by national government and end-users. Understanding these measures and the position of pharmaceutical companies is essential to appreciate the challenges pharmaceutical companies are facing in the EU market.

It is important to mention that the European Commission has attempted to tackle the issue of price divergence but has faced resistance on two fronts: in seeking to harmonize national rules of regulations on pricing and profit controls, the Commission has faced resistance from the Member States who regard this as a matter of health policy and therefore of national competence and from the research-based industry who distrust attempts to set average “European” prices for their product.

In fact, tension between two major public-policy objectives: innovation and development of new drugs, on the one hand, and short-run cost-containment strategies for the health care system and broad access to existing medicines, on the other is an on-going debate that is maintaining a difficult situation for both the pharmaceutical companies and national governments.
1- Lack of coherence between Member States

As mentioned earlier, pricing of pharmaceuticals within the European Union varies widely and, unlike other products, cannot be simplified due to varying legislations.

**European competence:** The European Community has no specific competence with regards to the pricing and reimbursement of medicines under national health care systems. The only principles that the EU provides is the principle of transparency (Price Transparency Directive, CEC 1989a) which implies a transparent process about the national negotiations on drug prices.

However, the European Union does impose the principle of free circulation of goods which is at the source of the new difficulties for the pharmaceutical industry.

**National competence:** As already mentioned, pharmaceutical pricing and reimbursement is a national responsibility. Under current EU law a member state has an exclusive right to define its health care policy including price regulations and benefits.

The mechanism employed to fix prices for locally produced and imported drugs may reflect a variety of factors and usually requires a balance between affordability and a reasonable reward for innovation.

Strategies used to price prescriptions drugs varies, but most countries use a combination of the following criteria:

1. **Product Price Control** - still the most common method for establishing the price of drugs. For example in Portugal, the prices of all prescription drugs are regulated and the price must be equal to or lower than the lowest price in 3 reference countries (Spain, Italy and France).

2. **Reference Pricing** – reference to existing products or prices charged for the same product in other countries. This is used for most imported pharmaceuticals. The price is suggested by the pharmaceutical company, then revised by National experts and compared to other European markets. Finally negotiations, taking into account various parameters that could range from the expected sales, the expected growth in sales to the local operation costs of the subsidiary, are held.

3. **Profit Control** - mainly used in the UK, it evaluates the contribution of the pharmaceuticals to the economy. In fact, under the UK system (Pharmaceutical Price regulation scheme, PPRS), pharmaceutical companies can freely set the prices of patented medicines and branded generics provided that they do not exceed a limit on the rate of return that a company can earn on its sales of prescription medicines to the NHS. In Spain, prices are set based on cost, profit allowance and anticipated volume of sales.

Examples of the various pricing methods used by new EU member countries are indicated in Table 1 and show how varied the methods are.
Table 1: Pricing methodologies in new EU Member Countries

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<tr>
<th>Pricing methodology for imported pharmaceutical products</th>
<th>Bulgaria</th>
<th>Czech Republic</th>
<th>Estonia</th>
<th>Hungary</th>
<th>Latvia</th>
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<td>Pharmaceutical budget is fixed</td>
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<td>Separate budgets for “expensive” products</td>
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</table>

**Problems:**

Various pricing methods are the source of the different prices for the same drugs. Other than problems associated with pricing variation which we will investigate further in the following sections, this causes two immediate problems:

Firstly, the diverse ways to set-up prices are in conflict with the principle of transparency set-up by the EU.

Secondly, in some countries the pricing competence has been transferred from the national level to the regional governments complicating furthermore the system. For example in Spain, since 2002, healthcare is a regional competence and implicitly 17 different new rules were introduced.⁸
2- Current difficulties faced by pharmaceutical companies with the pricing situation

National and regional pricing decisions add significant complications for the pharmaceutical companies having to do businesses differently in each region. However, in addition to the pricing negotiation difficulties, pharmaceutical companies are also faced with continued changes within each region due to the use of various measures and tools used by different players to control health care costs at the expense of the pharmaceutical companies.

The following section reviews these tools and their impact on the pricing strategies of the pharmaceutical companies.

1- Reimbursement scheme: use of Positive and Negative lists

Definition: Positive and negative lists are used to determine at a national level which products will be reimbursed by the National Security System and this system exists in the majority of the European countries.

- The example of Latvia where there is no positive and no negative list is unique: 75% of the drugs consumed on its territory are not reimbursed and are obtained by patients on an out-of-pocket basis.

Appendix 1 demonstrates how the complicated reimbursement processes for the entrant countries similar to what can be found throughout the EU.

Situation: National controls on doctors’ prescribing behavior, in term of only certain products being reimbursable under social security systems, was deemed consistent with the Treaty of Rome where the legal basis for the national implementation of so-called “negative” and “positive” lists was formulated.

In accordance with the European principle of Transparency, any decisions not to include a medicinal product on the positive list have to contain a statement of reasons based upon objective and verifiable criteria. The criteria used to add a drug on a positive list have historically been: safety, efficacy, quality and other clinical criteria. More recently, cost effectiveness study and budget impact analysis have become important factors. In fact, it is becoming common practice for pharmaceutical companies to be requested to submit pharmaco-economic studies following national guidelines.

Problems:
For pharmaceutical companies, being listed on the positive list is critical as it will directly affect the sales of the drugs in the country. Consequently, although negotiations to be included on the positive list are separated from the pricing negotiations, they are seen by the pharmaceutical companies as an extra hurdle that, eventually, directly impacts the validity of the pricing negotiations.

The transfer of the competences to regional levels in some countries further complicates the situation.
As an example, in Spain the regions have different policies concerning nationally approved drugs that they will finance (add to their positive list). Thus the supply of drugs that have to be approved by the region hinder the free circulation of the drugs in the country even if it had been approved at the national level. Also, the list of active materials for prescription (positive list) is not the same in the different regions.

As a third problem, these lists are revised on a regular basis (mostly yearly) by National Reimbursement Committees which decreases the time frame when the sales of a “on-the-positive-list-drug” sales can be boosted.

For example, the Dutch system have excluded certain drugs from the compulsory health care scheme on the basis that there were other medicines, with the same therapeutic effect, available but which were less expensive.

Finally, because of all these problems pharmaceutical companies have difficulties to predict their sales in each country which is an important criteria at the time of price negotiation.

2- Growing Importance of Generics

**Definition:** Generic drug is a prescription drug, which is chemically equivalent to a brand-name product of the same therapeutic value, but it is typically a less expensive drugs. Generic medicines appear on the market when the protection of original leading medicines, assured by a patent, is expired.

**Situation:** At the European level, the Bolar provisions allow generic companies to undertake pre-patent expiry development and registration of generic medicines in order to come to market right after the expiration of the patent. Since June 2\textsuperscript{nd} 2003 and the CEC 2003, the application of the Bolar provisions can be launched 2 years before the expiry of the ten year period.

Besides in many countries, consumption of generics is recommended to curve the overspending in the healthcare sector.

For example in Spain, a law published on January, 1\textsuperscript{st} 2004 explicitly recommends to use the cheapest drug of two equivalent in order to reduce public costs.

Additionally, prescription by chemical active substance is encouraged and favours the use of generic drugs. And finally, other alternatives, competing directly with the ethical pharmaceutical companies, are used. Such as the questionable practice in Spain where some pharmacy services in hospitals are preparing in-situ some drugs to save on the costs on raw materials.

**Problems:** The European legal and political environment favours more and more the consumption of generics and consequently challenge the ethical pharmaceutical companies business models and their pricing structures.
3- Impact of Parallel Trade

For the last several years, parallel trade of prescription drugs has been an important issue for the pharmaceutical industry and numerous policy institutions in Europe, including the European Commission, the European Court of Justice and member states of the EU.

**Definition:** Parallel trade involves the purchase of legitimately produced and branded medicines in one Member State and their sale at below the market price pertaining in another, more expensive Member State. Specifically, this entails a distributor buying drugs from wholesalers in cheaper countries and then exporting them legally to more expensive countries where they are then sold on to local wholesalers (often directly to pharmacies as well) at prices lower than the manufacturer is itself offering them in that market.\(^\text{11}\) This is done without the authorization of a trademark, copyright, or patent holder.

The main reason for the development of parallel trade in prescription medicines is that considerable price differentials exist amongst the Member States. In the UK, for example the retail price for an identical product often exceeds that in France or Spain by up to 100%.\(^\text{10}\)

**Situation:** For national health care systems, parallel trade has considerable cost-saving implications, and it is not surprising that several Member States have effectively endorsed it as a means of reducing health care spending.

Manufacturers prefer restraints on such trade in order to support higher prices in market with weaker price controls.

**Problems:** The research-intensive pharmaceutical industry relies heavily on patents, the value which depends in part on the scope for price differentiation. This scope depends critically on the existence of barriers to arbitrage. Ganslandt and Maskus estimates that parallel imports forced original producers to cut prices by up to 19% and that parallel imports represent a significant form of competition in some markets.\(^\text{3}\)

As shown in Table 2, this parallel import trend represents a substantial percentage of the total pharmaceutical market sales. Recent industry estimates suggest that the lost sales in the EU currently amount to some $3 billion per year.\(^\text{14}\)
4- Entry of new Member States to the EU

**Situation:** The entry of new member states adds additional challenge to the existing pharmaceutical markets at different levels.

The pharmaceutical industry has been concerned that accession of poorer countries where cheap copies of branded drugs are readily available. Although such drugs cannot be legally exported, pharmaceutical firms fear that their presence within the EU market will eventually force them to lower prices on branded medicines in those markets in order to stay competitive, which would in turn trigger reimports into Western Europe.

**Problems:** The main concern about the parallel trading linked to the entry of the new Member State seems to have been addressed as part of the Athens deal in 2003:

- the EU and entrant countries agreed to suspend some of the EU's rules governing free movement of goods, and in some cases will allow drug makers to sue parallel importers in their home market.
- Some entrant countries agreed that “a pharmaceutical product or substance which was not fully protected by a patent in Slovenia could only be exported from Slovenia with the consent of the holder of that patent”. Estonia, Malta and Cyprus have similar agreements and should legally prevent parallel trading from happening.

Although this agreement may come as a relief for Western pharmaceutical firms, the accession of new Member States is bringing other potential difficulties as well.

First, the entry of new members bring new pricing processes and add to the complexity of the overall pricing structure.

- Me-too pricing is used in Hungary (which means that the second or third product in a same category will receive a discount price) whereas Lithuania uses periodic price reduction.

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Table 2: Share of parallel imports in total pharmaceutical market sales in 2001.

<table>
<thead>
<tr>
<th>Country</th>
<th>Share (%)</th>
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<tbody>
<tr>
<td>DK</td>
<td>11%</td>
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<td>DE</td>
<td>5%</td>
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<tr>
<td>NL</td>
<td>9%</td>
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<tr>
<td>NL</td>
<td>5%</td>
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<td>S</td>
<td>9%</td>
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<tr>
<td>UK</td>
<td>15%</td>
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<tr>
<td>GR</td>
<td>16%</td>
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</table>

*Source: European Federation of Pharmaceutical Industries and Associations*
Second, national policy are very volatile, for example in April 2003, Lithuania changed its pricing policy from periodic price reduction to apply the lowest European price + 5% as the domestic Lithuanian price.

Third, entrant Member States are large producers of generics which could impact sales in Western Europe.

Thus it is not surprising that pharmaceutical companies where less than thrill by the expansion of the European Union.

5- Profit Maximization within Europe

**Situation:** Profit optimisation for a pharmaceutical company is linked to the extent they can protect their patented products from competition. It was observed that there was a delay in most European markets between the time the drug was approved for marketing by the European Drug Administration and the actual marketing within the European countries.

In order to address this fact, at the European level, pharmaceutical companies can claim for the Supplementary Protection Certificate which extends the patent life with 5 extra years to compensate the often lengthy period between the patient application and obtaining marketing authorization. As well, although data protection for medicines is of 10 years in Europe, there is a possibility to extend it by one year if it is possible to show that drug can be used for a new treatment.

**Problems:** This market protection could be seen as a barrier to competitiveness, it is however motivated by the fact that only two of the world’s current top ten drugs were developed in Europe, the region’s share of the global market fell from 37.8% in 1990 to 26.8% in 2003, and European R&D spending, which was 50% higher than in the US in 1990 was 32% lower in 2001.

Faced with these declines and with no other way to prop up the industry (except to relax their own price controls), the EU has implemented significantly stronger protection for pharmaceutical companies in the upcoming round of expansion of the EU as discussed in the preceding section.

6- Regional Competencies

**Situation:** Transfer of healthcare competencies to regional levels altered and complicated the relationships of the pharmaceutical companies with the national healthcare system.

**Problem:** This is clearly illustrated in the case of Spain where medical visits are regulated at the regional level in Spain. Therefore marketing and sales operation of the pharmaceutical companies need to be planed differently between the regions thus the information provided to professionals vary greatly.

As well, national governments use taxes on pharmaceutical main development phases to fund their political initiatives. Therefore it complicates drastically the budget planning for the pharmaceutical companies.
For example in Spain: before the new Law (13/2002) was published in January 2003, taxes used to be: the homologation of a drug in the development stage (2080 euros), the human trials (95 euros) but after the New Law new taxes are coming into the picture: inspection of the human trials (600 euros/day), application for post-authorization studies (450 euros/application), elaboration and planning of medical visits (120/4 terms). This national example inspired regions to install new taxes like in Andalusia.

Finally, budget planning is also made difficult by the fact that payment terms in the public sector differs in the different regions.

In Spain the range could be as wide as 93 to 609 days for hospitals.

In order to address this specific problem, there is a project of law at the European level to charge Euribor + 7 points for late payment however this will be perceived by the National Healthcare systems as an extra expense.
3- Impact for Governments of Pricing of Prescriptions

The vast majority of European healthcare costs are state-funded, whether directly as in the UK or indirectly as in countries like France and Germany. As we can see in appendix 2, national healthcare expenses represent a large proportion of the overall national expenses in all the European countries.

In the last 20 years, expenditures on pharmaceuticals – as well as total health expenditures – have grown faster than the gross national product in all European countries and in most OECD countries, expenditure on pharmaceuticals is growing at a faster rate than health care expenditure overall. 

The prescription drug market is an attractive target for governments that want to reduce healthcare expenditure since

- it represents a clearly defined market segment
- it is relatively transparent and, therefore, able to be evaluated
- reductions in revenues usually do not directly affect the income of healthcare providers.

However, most European governments are struggling with balancing two opposing major public-policy objectives:

1. the importance of ensuring the vitality of the pharmaceutical sector
2. the need for cost-containment of the health care system and ensuring broad access to existing medicines.

While the interest of each member states varies, one can regroup these interests in two large categories:

On one hand, the countries with strong pharmaceutical industries located in their country and who are interested in ensuring a strong protection to patents. These countries appear to be willing to pay higher prices for drugs and ensure patent protection in order to ensure the vitality of that sector in their economy. The pharmaceutical industry is viewed as an innovative sector and is a growth platform for the economy.

- For example, in Spain, the spending on drugs is going at 60% to the pharmaceutical industries and 40% to the distributors.

On the other hand, countries with no pharmaceutical industry and who are not as strongly attached to patents but rather are interested in giving a larger priority to ensure that the lowest possible price is given for their health care system.

Additionally, member states of the European Union, must stay within the legislative framework.

As in the previous sections, tools and measures used to set prices of prescriptions will be reviewed from the point of view of national government.
Tools used to control at the national level the price of prescription

Once the price of a prescription drug has been established, governments still have a number of tools that they can use to control costs.

1- Positive/Negative List and Co-Payment

These are used to reduce the patients’ demand for drugs by either denying or limiting reimbursement of products and providing an incentive for patients to reduce their consumption of drugs. These interventions include defining a list either of drugs reimbursed (positive list) or one of drugs not reimbursed (negative list), and patient co-payments, which require patients to pay a proportion of the cost of a prescribed product or a fixed charge.

2- Generics

The use of generic drugs is encouraged in most countries, but only Germany, Denmark, The Netherlands, and recently Switzerland allow pharmacists to substitute generic drugs for proprietary brands.\(^2\)

- Research by a German generic producer found that in Germany today most prescriptions define the compound rather than a specific brand.
- In the UK, although generic substitution is still not permitted, more than 55 per cent of prescriptions are written generically.\(^{12}\)

3- Parallel Trade

Parallel trade could have considerable cost-saving implications for national health care systems. It is not surprising that several Member States have unofficially endorsed it as a means of reducing health care spending.

- The Netherlands, for example, encourages parallel imports actively through financial incentives to pharmacists. When cheaper medicines (generics and imported drugs) are dispensed, pharmacists are allowed to keep a percentage of the difference in price.\(^{12}\)

However, the benefits of parallel trade accrues mainly to the wholesalers undertaking parallel trade. According to a study published in 2002, parallel importers in 6 countries profited to the tune of 622 million euros from parallel imports while government healthcare agencies saved 43.1 million euros. The UK’s national health service saved just 2 percent of its medicines budget by using parallel imports that year, compared with a markup of 49% by the importers.\(^7\)
4- Factors that will influence the future of health care systems in Europe and their impact on pricing policies

Over the following years, it is expected that a number of factors will put national health systems under further pressure. Any policy regarding the pricing system of prescription will have to take into consideration the following:

1- Demographic Changes

**Situation:** The causes of growing drug expenditures in different European countries include an increase in the proportion of elderly residents, an increase in the incidence and duration of chronic diseases, the continuing development of health technologies, and an increase in health expectation by patients and society.

**Problems:** The demand for pharmaceuticals is likely to increase as the population structure changes. Projections show that by the year 2050, 60 per cent of all European adults are expected to be over age 65. Germany, Spain and Italy could have more citizens over 80 than under 20 years of age.  

2- Internet

**Situation:** The implications of the world wide web as both a source of information and a vehicle for purchases has been recognized by the European Commission as having specific implications for pharmaceuticals and highlighted the need for countries to take a stance with regard to e-commerce and direct marketing to end-users through this medium.

**Problems:** New communication channels allow pharmaceutical companies to reach patients and other stakeholders, to interact and to develop relations at an individual level.

And although direct-to-consumer advertising in Europe is banned, a number of internet sites are sponsored by large pharmaceutical firms. This immediately suggests a potential conflict of interest with regard to presentation of the material as it opens the door for manufacturers to promote their own medicines on these sites.

It is clear that patients are increasingly well-informed thanks to faster and wider access to health-related information and that as consumers, they are using that information to influence doctor prescriptions and request access to high-priced medication.

As well, the internet is proving a major contributor to the growing practice of mail – order trade in medicines. Countries will have to develop systems to control access of prescription drugs selling though the internet without the intervention of the doctor or of the pharmacist.

Just as importantly, parallel imports without any controls in placed are gaining market shares by the growing number of Internet-based mail pharmacies.  

5- Options available to mitigate this situation

Problems associated with pricing differences and measures taken by government to control their costs must be addressed through various means in order to ensure the sustainability of the pharmaceutical sector and the quality of medicines available.

1- Technical
   The development of the IT systems could be a way to address the difficulties associated with pricing pharmaceuticals encountered by both national governments and pharmaceutical companies.

   On the National system side, the possibility to relate a prescription with a person (electronic prescription and healthcare ID), which is nowadays pushed in Spain by the article 33 of the Cohesion Law, could help to cure the abuses within the European market, decrease the incident rate due to side effects, dosage, side reactions, curve the over prescription and stimulate teamwork between pharmaceutical companies and pharmacists.

   On the pharmaceutical side, development of IT technologies will help them to get more information about their customers and propose more focused products and services. To illustrate this, we can mention the example of the American pharmacies which are sharing their electronic sales book with the pharmaceutical companies enabling the pharmaceutical companies to focus their offers.

2- Legal
   Another way to decrease the tensions between the National systems and the pharmaceutical companies would be to free up some of the regulations which deals with the prescription drug business. For example, more prescription products could be moved into the over-the-counter market or current restrictions on advertising of prescription products to the public could be relaxed.

   Both examples would be levers on which National systems could negotiate further with pharmaceutical companies to adjust pricing in order to facilitate convergence between countries.

3- Economical
   The overall economical harmonization within the European Union would be the best way to ease the tensions. Indeed, we saw in the previous part that the difference in pricing of the prescription drugs within Europe was closely correlated to the different economical levels of the countries. Thus as countries GDP converge, so should pricing of pharmaceuticals.
Conclusion and Topics Deserving Further Research

European countries have been using interventionist policies to regulate drug prices to curve the healthcare expenses in all countries since 1989.

As described previously and by the Peppers & Rogers Group in Figure 1, the relationships within Europe between the National Health Systems and the pharmaceutical companies are getting more and more complicated and the conflict of interest more and more obvious.

It is essential that a consensus between the public power, the pharmaceutical companies, doctors and health professionals, public researchers and patient association be reached regarding pricing of pharmaceuticals. The European Union is already working in that direction through the DG Research and their Framework Programme. One of the initiative we can mention is the co-funding by the European Commission of special projects proposed by pharmaceutical industries.

In order to achieve this consensus, we think that getting more transparency in the system will be the key. We proposed different ways to get more transparency through the report however the most important in the near future is to develop and manage an Information Technology system. This should help in the future to ensure convergence of prices and, with time, elimination of pricing differences and tools used to control these differences.

Therefore interesting topics to analyse further would be:

a. e-health development and management
b. electronic prescription management
c. impact of direct-to-customer advertising
Appendix 1

Reimbursement Processes of Pharmaceuticals in New EU Member States


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<td>Hungary</td>
<td>Latvia</td>
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<td>Poland</td>
<td>Romania</td>
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<td>X</td>
<td>X</td>
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<td>X</td>
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<td>Neither</td>
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Isabelle de Champlain - 16 - Thomas Philipon
Appendix 2
Health expenses in Europe (% GDP)

Source OECD database
References