

# THE GREEK PHARMACEUTICAL MARKET: A COMPETITION POLICY ANALYSIS

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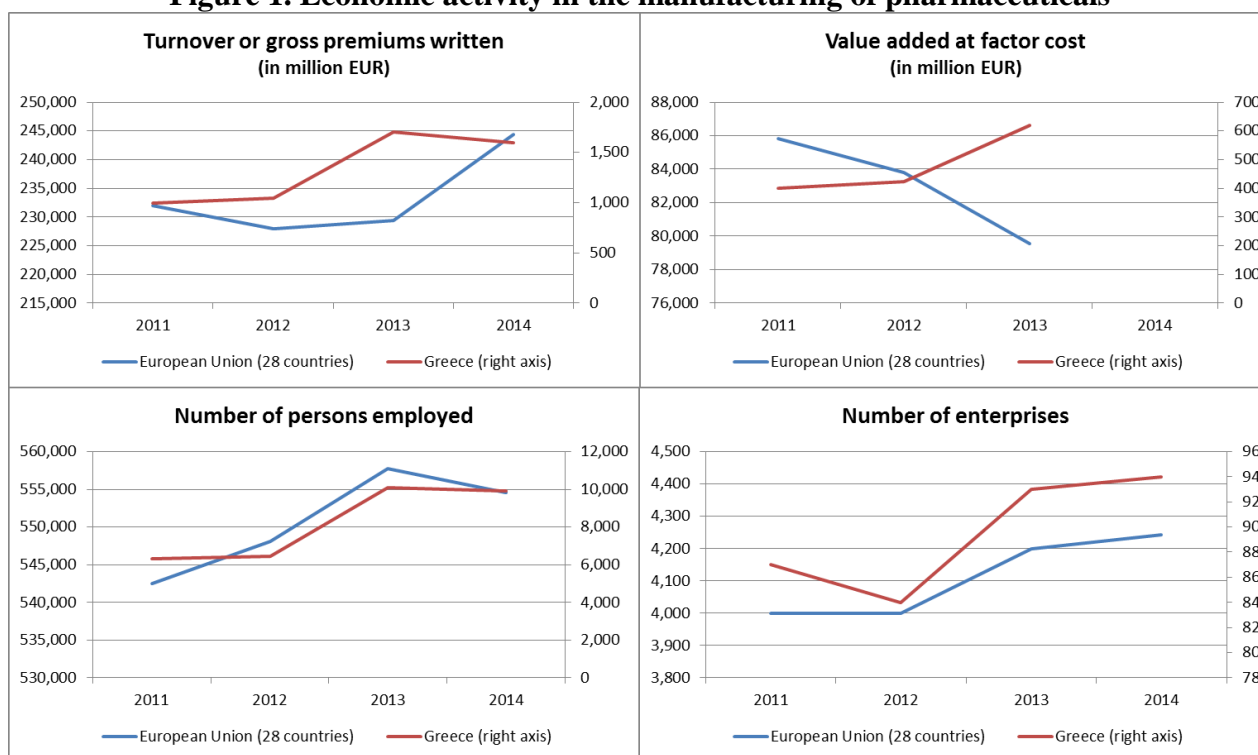
## *Abstract*

This paper analyses competition distortions arising from policy interventions in the sector of pharmaceuticals. It aims at identifying health policy regulations in the pricing policy that impede healthy competition among pharmaceuticals. We focus on the pricing of generic medicines and analyse in detail the impact of a specific pricing rule applied in Greece in 2016. The comparative analysis with other countries and the quantification of particular interventions in the relevant legislation allows to outline detailed policy solutions that aim at increasing consumer welfare and promote competition-friendly growth. The recommended reform would lift unnecessary burden and allow for more effective and fairer market competition without incurring a public expenditure burden for the reimbursement policy.

## Introduction

Despite the economic recession, economic activity in the manufacturing of pharmaceuticals sector has accelerated both in the EU and Greece. Between 2011 and 2014 the turnover or gross premium written increased in the EU28 by 5%. In Greece, Eurostat data show a turnover increase of the sector of more than 60%. Research and official data estimate the overall contribution of the sector in the GDP to be around 4% or about EUR 7.55 billion (SFEE 2016). Unlike the EU trend (-7%), value added of pharmaceuticals increased by more than 50% with a parallel 58% increase in the number of persons employed to almost 10,000 people. The number of pharmaceutical companies also increased from 87 to 94, outpacing the respective 6% increase across the EU28 as well as their effect in employment. Figure 1 shows that the sharpest increase in all four aspects of the economic activity depicted thereby took place between 2012 and 2013.

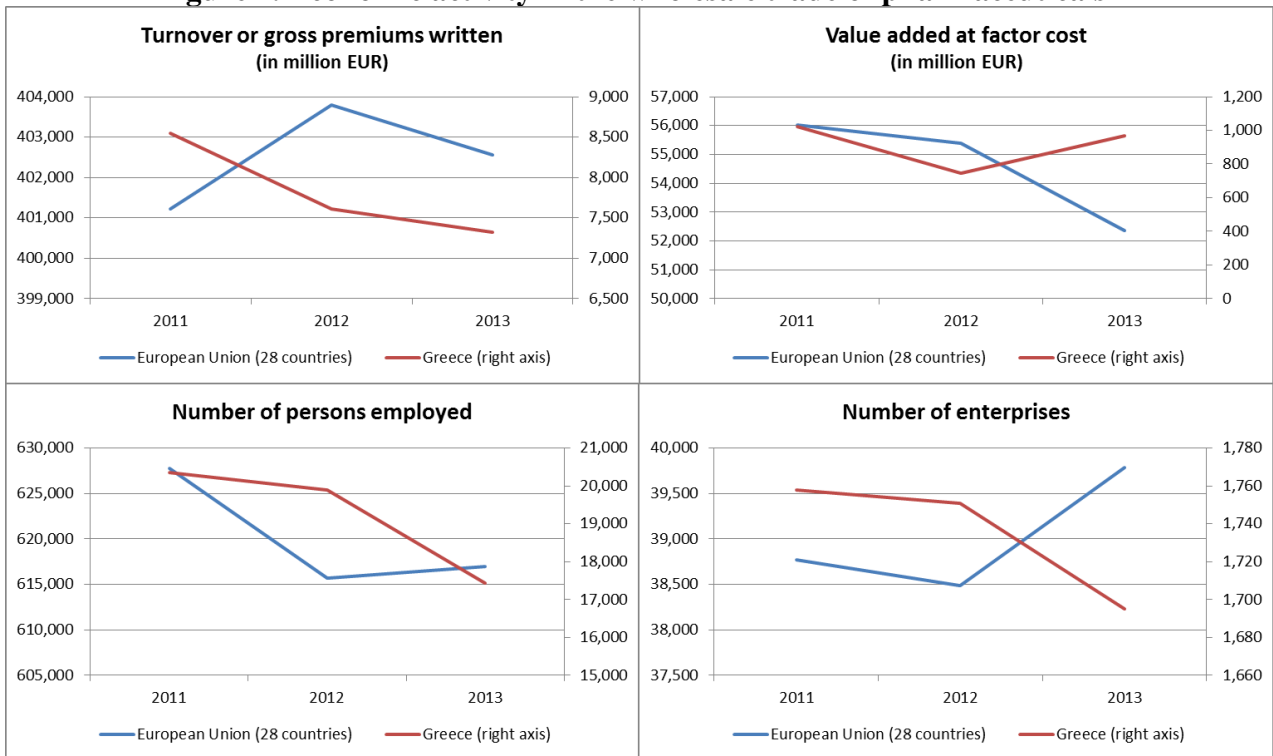
**Figure 1. Economic activity in the manufacturing of pharmaceuticals**



Source: Eurostat

Mixed effects have been observed between 2011 and 2013 in Greece in the wholesale trade of pharmaceuticals. In 2013, Greece accounted for 2% of the EU28 turnover and value added, 3% of the number of persons employed and 4% of the number of enterprises of this sector. According to Eurostat, the turnover or gross premium written saw a marginal increase of 0.3% in the EU28 between 2011 and 2013, whereas in Greece it declined by 14%. The number of pharmaceutical wholesale trade companies in Greece dropped by 4% with a larger decrease in the number of persons employed (14%). The corresponding figures in the EU28 show a 3% increase in the number of enterprises and a 2% decline in employment. These resulted in a 5% decline in the value added of the wholesale trade of pharmaceuticals, while the total value added in the EU28 declined more significantly (-7%).

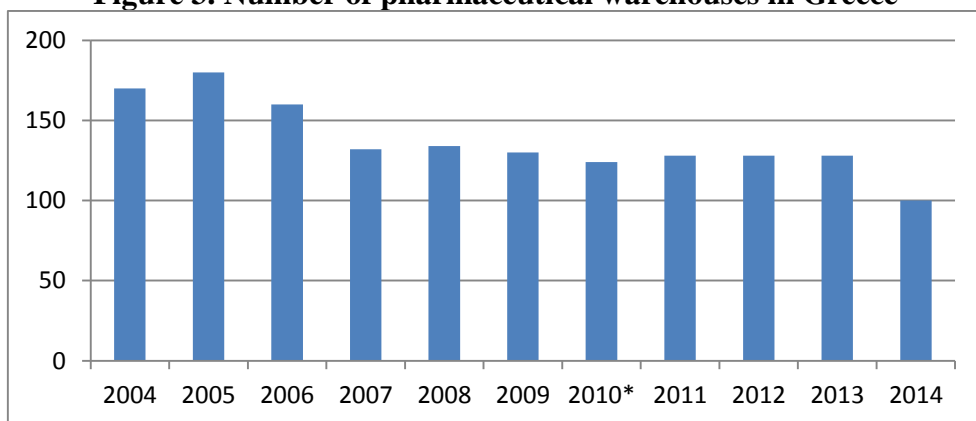
**Figure 2. Economic activity in the wholesale trade of pharmaceuticals.**



Source: Eurostat

Wholesale trade of pharmaceuticals may be performed by Market Authorisation Holders (MAHs) and pharmaceutical warehouses. Out of a total of about 1,700 enterprises conducting wholesale trade, about 100 of them were pharmaceutical warehouses. As seen in Figure 3, the number of pharmaceutical warehouses operating in Greece has declined during the last decade by more than 40%.

**Figure 3. Number of pharmaceutical warehouses in Greece**



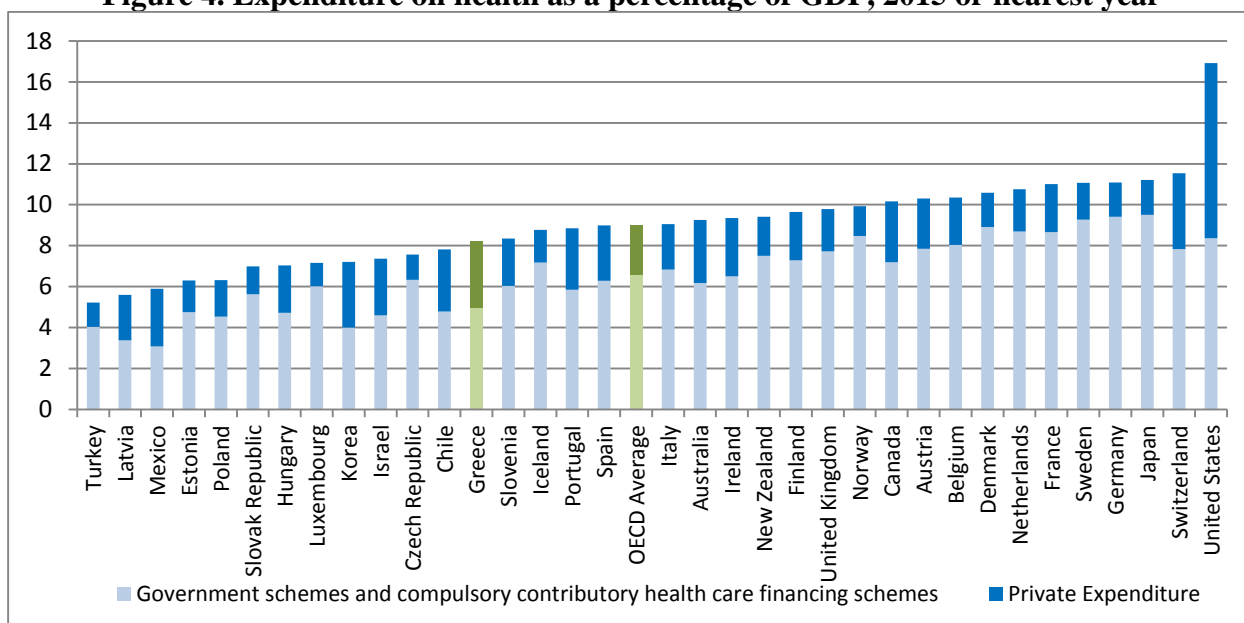
Note: \* Provisional data for 2010.

Source: Panhellenic Pharmaceutical Association - ELSTAT business registry

People and governments devote significant fractions of their budgets in health and pharmaceutical expenditure. Total health spending in Greece remains below the OECD average (Figure 4). In 2015, the total of privately and publicly funded health expenditure stood at about

EUR 14.4 million, or about 8.2% of GDP. Compared to 2009, this represented a decline in total health expenditure of more than 35%, which constitutes a larger decline than the OECD trend. Due to the parallel economic deceleration of the Greek economy, the share of health expenditure to GDP also declined, but at much slower pace. About 60% of total spending came from government and compulsory contributory health care financing schemes and this comprised of about 5% of the Greek GDP. This, in turn, implies the third highest level of private health spending to GDP (3.2%) among OECD member countries, after the United States and Switzerland (8.6% and 3.7% respectively).

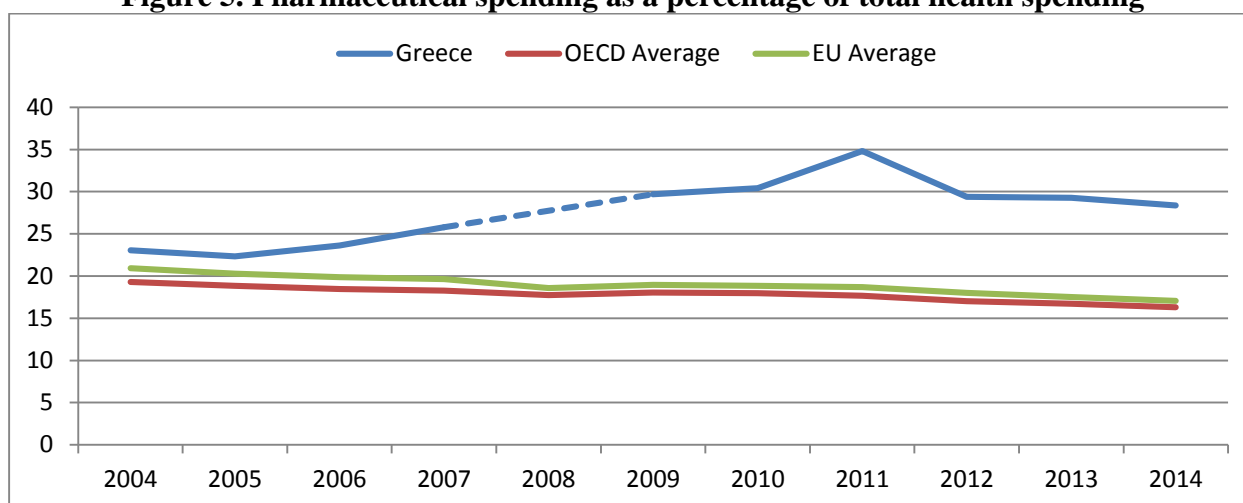
**Figure 4. Expenditure on health as a percentage of GDP, 2015 or nearest year**



Source: OECD database (<https://data.oecd.org/healthres/pharmaceutical-spending.htm>)

OECD data show that, despite the decline in total and public health expenditure, the share of pharmaceutical expenditure in the total health spending in Greece was relatively high in 2014. In this respect, Greece ranked second among OECD member countries, with only Hungary surpassing it. Having reached its peak in 2011 (34.8% of total health expenditure) and started a downward trend since then, pharmaceutical expenditure accounted in 2014 for 28.4% of the total health expenditure, which is almost double of the OECD average (16.3%) and the EU average (17.1%), implying a relatively high fraction of health expenditure devoted to pharmaceuticals (Figure 5).

**Figure 5. Pharmaceutical spending as a percentage of total health spending**



Note: 2008 data for Greece are missing.

Source: OECD database and author's calculations (<https://data.oecd.org/healthres/pharmaceutical-spending.htm>)

Pharmaceutical spending as a share to GDP stood at 2.35% in 2014. This was the highest among OECD country members. In other OECD countries it ranged from 0.53% in Luxemburg to 2.17% in Hungary, averaging at about 1.41%. Pharmaceutical expenditure and the issue of generics penetration have featured prominently on the policy agenda in Greece, with adopted measures including external reference pricing, generic substitution and international non-proprietary name (INN) prescribing.

The significant and frequent changes in legislation have resulted both in reduction of health expenditure and the shift of a big share of the burden from the public to the private sector. The main restrictions identified in the manufacturing and wholesale trade of pharmaceuticals, as traced in the Greek legislation, are presented in detail in the following sections. Their harm to competition is also presented, while useful international comparisons and further analysis is conducted and presented in the following sections in order to provide recommendations lifting unnecessary burden and allowing for more effective market competition.

## Pricing and reimbursement framework

Since pricing and reimbursement rules for medicines are not harmonised at EU level, the EU regulatory framework allows for substantial cross-country variations. Member States are free to develop their national pricing policies according to various price setting criteria and mechanisms (Vogler 2012).

According to the European Commission Working Group on Pricing and Reimbursement of Pharmaceuticals (European Commission 2008), Member States through implementation of national pricing and reimbursement practices, should aim at achieving 3 overall objectives:

1. Optimal use of resources to maintain a sustainable financing of healthcare.
2. Access to medicines for patients.
3. Reward for valuable innovation.

Under Greek legislation, the prices of all medicinal products are explicitly regulated.<sup>1</sup> The National Organisation of Medicines (EOF) prepares and issues bi-annually the drugs Price Bulletin which sets the prices of all medicines. The maximum manufacturer's price (ex-factory price) level is fixed. However, market authorisation holders are free to ask for a price lower or equal to the maximum price set.<sup>2</sup>

There are different techniques deployed separately or combined to regulate maximum prices: external reference pricing, internal reference pricing, economic evaluation, cost plus pricing and profit ceilings (OECD 2008).

Greece applies a combination of techniques in setting price limits. In the context of the national legal framework currently in force (Legislative Decree 96/1973, Law 4336/2015, 4337/2015 and Ministerial Decision 28408/2016), external price referencing<sup>3</sup> is applied to define the prices of the originator<sup>4</sup> pharmaceutical products. Generics<sup>5</sup> entering the market receive a price by reference to the originator product (generic price linkage<sup>6</sup>).<sup>7</sup>

Pursuant to the national pricing framework, the expiration of the ten-year or possible eleven-year data protection period<sup>8</sup> constitutes the triggering point for a price change of the originator pharmaceutical products, the so-called for pricing purposes, reference products. During the data protection period, the maximum manufacturer's price (ex-factory) of the reference products is defined as the average of the three EU lowest prices for the same pharmaceutical product as to the active substance, pharmaco-technical form, strength and packaging.

With regard to generic medicinal products, their price is defined at 65% of the price of the respective reference medicinal products after the expiration of their data protection period.<sup>9</sup> According to the bi-annual price revision procedure laid down in Article 8, paragraphs 2 and 3 of the Ministerial Decision 28408/2016, any price revision of generic medicinal products cannot result in a price drop exceeding 15% of the wholesale price previously set. In case the revision of a generic price results in a price higher than the price of the respective reference product whose protection period has expired, then the price of the reference product shall be defined as equal to the revised generic price.

As regulators seek to balance an array of objectives not limited to cost-containment, it seems that this safety net of 15% maximum reduction aims at preventing severe reductions of generics' prices in view of implementing the national policy to provide incentives to the generics pharmaceutical industry and increase generics' penetration in the market.

The figures below compare the share of generics among OECD countries and showcase that there is a relatively high price of them compared to the reference products in the case of Greece. For the calculation of the ratio of average prices, we have used the OECD data on the share of generics in terms of value (V) and in terms of volume (Q) in each country. We decompose the value share of generics ( $V_G/V_T$ ), where

$$V_G = Q_G * P_G^-, V_T = Q_T * P_T^-$$

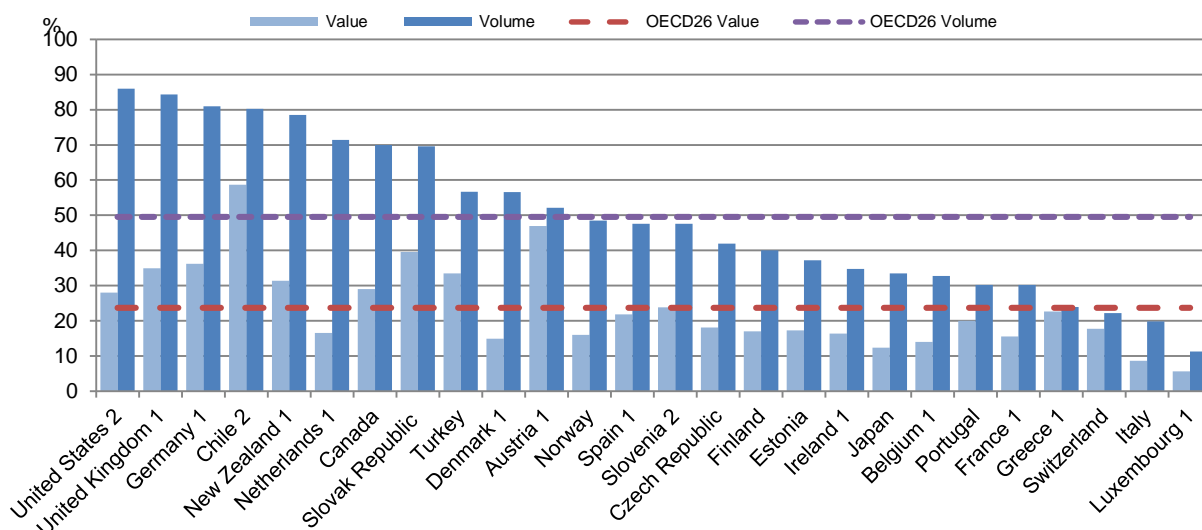
Then by dividing this ratio by the volume share of generics ( $Q_G/Q_T$ ), we get:

$$(V_G/V_T) / (Q_G/Q_T) = (Q_G * P_G^- / Q_T * P_T^-) / (Q_G/Q_T) = P_G^- / P_T^-$$

where  $V_T$  and  $Q_T$  are the value and volume of all pharmaceuticals in the pharmaceutical market in 2015.

Values (V) are decomposed as quantities sold (Q) multiplied by the average price (P̄). The results show Greece ranking first concerning the price ratio of generics versus all pharmaceuticals, followed by Austria and Switzerland.

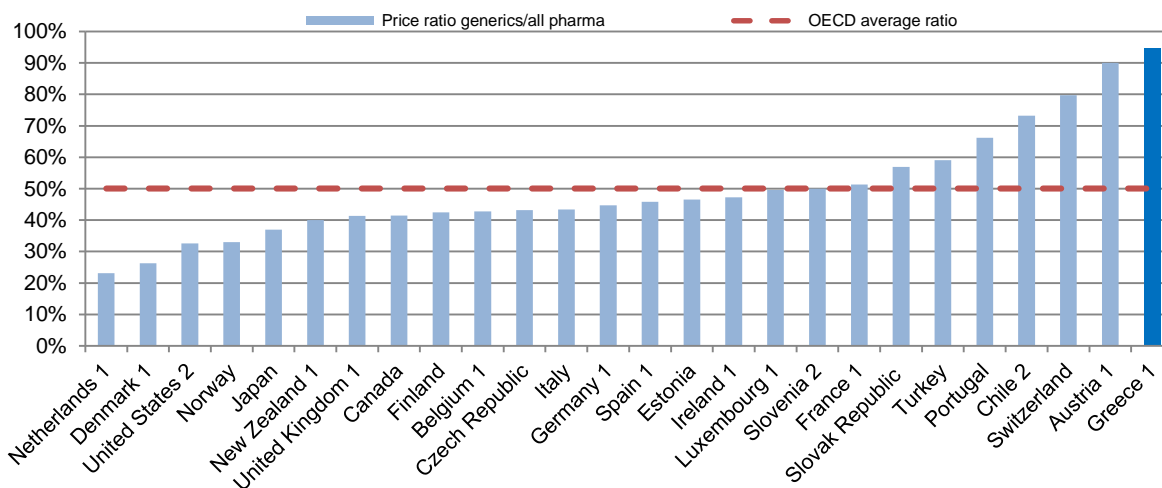
**Figure 6. Share of generics in the total pharmaceutical market, 2015 (or nearest year)**



Note: 1. Reimbursed pharmaceutical market; 2. Community pharmacy market

Source: OECD Health Statistics 2015, (OECD 2015)

**Figure 7. Price ratio of generics vs. all pharmaceutical, 2015 (or nearest year)**



Note: 1. Reimbursed pharmaceutical market; 2. Community pharmacy market

Source: Author's calculations based on OECD Health Statistics 2015, (OECD 2015)

## Discussion

The 15% threshold was introduced with the aim to promote the use of generic products and to secure the supply of medicines in the Greek market. However, the provision artificially distorts competition between off-patent and generic medicines with a cost to the Greek state. First, the provision creates a welfare loss for consumers. Second, it reduces the scope for competition

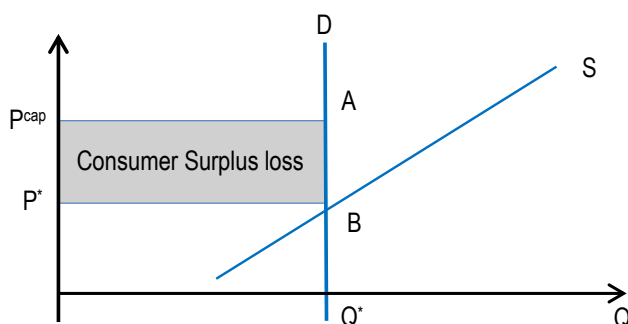
between generics and off-patent drugs. Instead of serving the objective of achieving a higher volume use of generics, the provision limits the incentives of patients to choose generics over off-patent products already circulating in the market. Since the law provides for obligatory setting of equal prices to the off-patent products and generics, it deprives the latter of their price advantage compared to the original product, leaving no room for competition and further market penetration.

By placing a cap (15%) on the price reduction of generics and, in some cases, by increasing the prices of the reference off-patent products, their prices are higher than what would otherwise be based on the reference pricing scheme. Based on the August 2016 price revision there are 2,489 (out of the 9,523 total number of prescription drugs) affected by this provision, or roughly 26% of the total number of prescription drugs. If one compares the final wholesale price assigned to these products to the wholesale price that would have prevailed given the 65% reference pricing rule, then the mean difference across all products would be EUR 5.58 (with a range from EUR 0.15 in the 5<sup>th</sup> percentile to EUR 12.53 in the 95<sup>th</sup> percentile, as shown in row 1 in Table 1 below).

**Table 1. The distribution of price difference in wholesale price of affected medicinal products**

	Mean	Standard deviation	Percentile 5%	Percentile 10%	Median	Percentile 90%	Percentile 95%	N
Price Difference	5.58	29.96	0.15	0.26	1.14	7.83	12.53	2 489
Price difference weighted by quantity sold	1.63	1.85	0.05	0.06	0.72	4.06	5.89	1 330
Quantity (2015)	19 963	56 854	23	85	4 547	49 928	83 088	1 330

**Figure 8. Calculating the consumer welfare effect of the 15% maximum price reduction cap**



To calculate the effect on consumer welfare of the 15% maximum price reduction cap, we approximate the market as in Figure 8. The current equilibrium is given in point A. The demand is vertical as these are prescription drugs and we make the simplifying assumption that demand is driven by doctors' prescriptions and is not responsive to price in the short run. At the current market equilibrium the wholesale price is  $P^{cap}$  and, based on this price, the quantity is  $Q^*$ . If the 15% maximum price reduction cap were to be abolished the new equilibrium would have been at point B, where the average regulated price would have fallen to  $P^*$ , whereas the quantity would have remained constant at  $Q^*$ . The grey shaded area indicates the loss in consumer surplus due to the maximum price reduction cap.

To calculate the impact on consumer welfare we use detailed (drug barcode level) information on the sales of the affected products in 2015. As shown in row 2 of Table 1, which contains the price difference weighted by quantity sold, many of the affected drugs had no sales in 2015 and hence their sales weighted mean difference across all products is lower than shown in row 1. The weighted price difference is EUR 1.63, with a range from 0.05 in the 5<sup>th</sup> percentile to

EUR 5.89 in the 95<sup>th</sup> percentile. At the same time, average sales for these drugs were 19,963 units ranging from 23 in the 5<sup>th</sup> percentile to 83,088 in the 95<sup>th</sup> percentile as shown in row 3 of Table 1. Using these two numbers we can precisely calculate the consumer welfare loss (as shown in Figure 8) for each affected drug assuming that the demand and the supply will be unaffected, at least in the short run. The total consumer loss due to maximum price reduction cap is estimated to be EUR 43 million. This calculation is an upper bound on the harm, since it is based on the comparison between the current provision and the removal of the 15% maximum price reduction.

In addition, by placing a restriction on the price reduction of the generic drug and by equating them to the off-patent products, the provision deprives the former of their price advantage compared to the original product, leaving little room for competition.

## Conclusion

Given the considerations above, this paper aims to show that complex pricing systems could eliminate the objective of policies or provide for the opposite result than the intended one. An alternative way of achieving the policy maker's objective would be the introduction of a maximum threshold for off-patent medicines price reductions during the re-pricing procedure or the application of the current rule only when generics prices remain below those of reference products. The suggested threshold follows the rationale of the 'generic price linkage' applied for the pricing of the generics. As a result, price reductions of generics would follow price reductions of the off-patent medicines which would be still not severe ensuring the continued presence of off-patent and generic medicines in the market.

## Notes

- 1 According to Law 4254/2014 (Official Gazette A' 85/7.4.2014) Paragraph ΣΤ', price controls on OTC medicines will be lifted in January 2017.
- 2 See Art. 2, par. 5 of Ministerial Decision 28408/2016 (Official Gazette B' 1102/19.4.2016).
- 3 External price referencing or external price benchmarking is defined as the practice of comparing pharmaceutical prices across countries (OECD 2008).
- 4 Original medicines are defined as the first version of a medicine developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 20 years. An original product has a unique trade name for marketing purposes, the so called brand name. (WHO Glossary of Pharmaceutical Terms 2013).
- 5 Generics are defined as medical products, which display the same qualitative and quantitative composition in active substances as well as the same pharmaceutical form as a reference medicine (originator pharmaceutical product). The bioequivalence with the reference product has to be demonstrated in accordance with current guidelines of the authorized authorities. The generic pharmaceutical product market distinguishes two sub-markets: Unbranded and branded generics. The unbranded generic is a product marketed under the generic name of its molecule ingredient(s). The branded generic sub-market can be divided in original (marketed by the originator), licensed (marketed by a company with a license) or other brands (residual suppliers).

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- 6 This is an internal reference pricing technique to regulate the price of generics entrance. Through this practice, the generic is priced at market entry at a discount by reference to the price of the original product (OECD 2008).
- 7 We further note that Greece applies cost-plus pricing for domestically produced medicinal products pursuant to Article 10 of the Ministerial Decision 28408/2016 in accordance with the conditions provided therein.
- 8 The data protection period is provided for by article 11, par. 1 of the Joint Ministerial Decision ΔΥΓ3α/Γ.Π.32221/2013 transposing Directive 2001/83. According to Article 10 of the Directive, generic products must not be placed on the market until ten years have elapsed from the initial authorisation of the reference product. This ten year period may be extended to eleven if the conditions of the fourth subparagraph of Article 10(1) are fulfilled. The period of eight years from initial authorisation of the reference product provides a period of so-called “data exclusivity”, after which valid applications for generic products can be submitted and lead to the granting of a marketing authorisation. The period of ten years from initial authorisation of the reference product provides a period of so-called “market protection” after which generic products can be placed on the market.
- 9 For generics with a retail price exceeding EUR 12, dynamic pricing shall be implemented. More specifically, for each increase in sales corresponding to EUR 250,000 in wholesale prices occurred in the year preceding the publication of the Price Bulletin, the prices determined shall be reduced, so that dynamic pricing is effected in the range between 1% and 15%.

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