

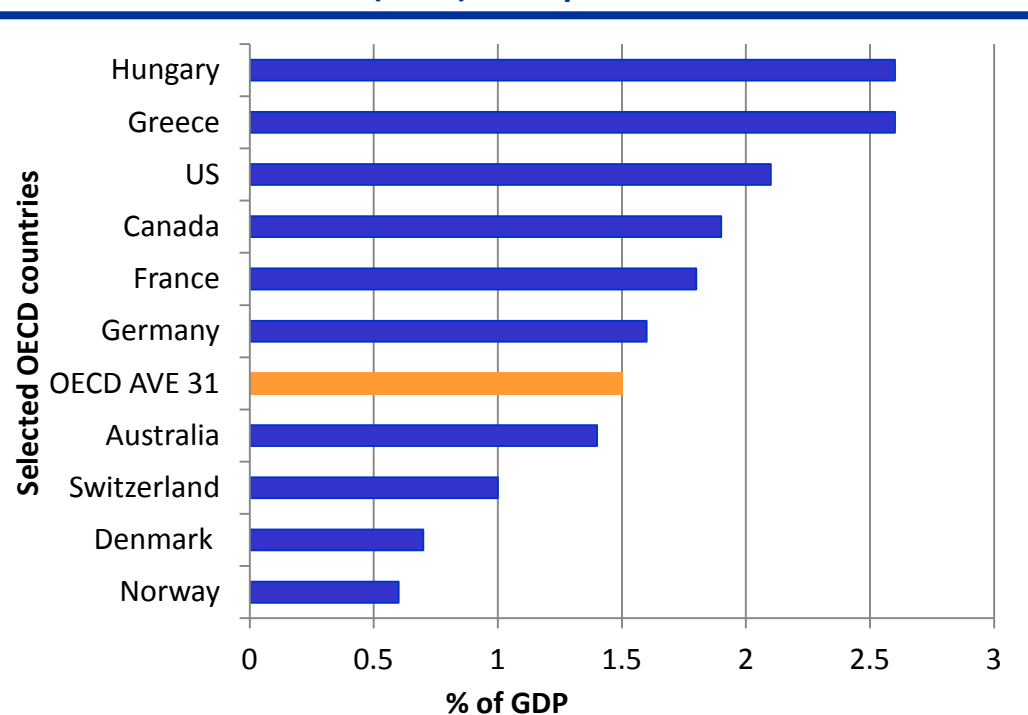
THE GREEK HEALTHCARE REFORM AFTER TROIKA: THE POTENTIAL IMPACT ON GLOBAL PRICING AND ACCESS STRATEGY

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BACKGROUND

- In 2009, Greece was reported to have the highest expenditure on pharmaceuticals of all the OECD (Organization for Economic Co-operation and Development) countries (2.4% of GDP/ €6.6 billion); the average 2009 OECD country spend was 1.6%¹
- In 2010, the Greece drug price list was revised by the authorities and all pharmaceutical prices were cut by 20%². Despite the actions taken, by 2011 expenditure still remained high at 2.6% of GDP (Chart 1)³
- In May 2010, the Greek Government agreed to a financial bailout package of €110 billion with the promise of implementing austerity measures and structural reforms overseen by the international counterparts (Troika). In February 2012 a second package of €130 billion was received⁴
- Several important changes were introduced since the start of the Economic Adjustment Programme with the overarching objective to keep public health expenditure at or below 6% of the GDP⁴ and consequently to decrease the public spending on pharmaceuticals to 1.33% in 2012 and to 1% by 2014²
- These policy reforms have dramatically changed the way healthcare is funded, managed and delivered, and how pharmaceuticals are priced, accessed and reimbursed

Chart 1: Pharmaceutical expenditure as a % of GDP in selected OECD countries (2011) – adapted from OECD 2013³



AVE 31, Average of 31 countries; GDP, Gross Domestic Product; OECD, Organization for Economic Co-operation and Development; US, United States

OBJECTIVES

- This study examines the changes to the Greek system and explores the wider potential impact on global pricing and market access (P&MA) strategies
- The research focuses on the reforms that directly affect the P&MA outlook for pharmaceuticals and not the broader healthcare environment in Greece

METHODS

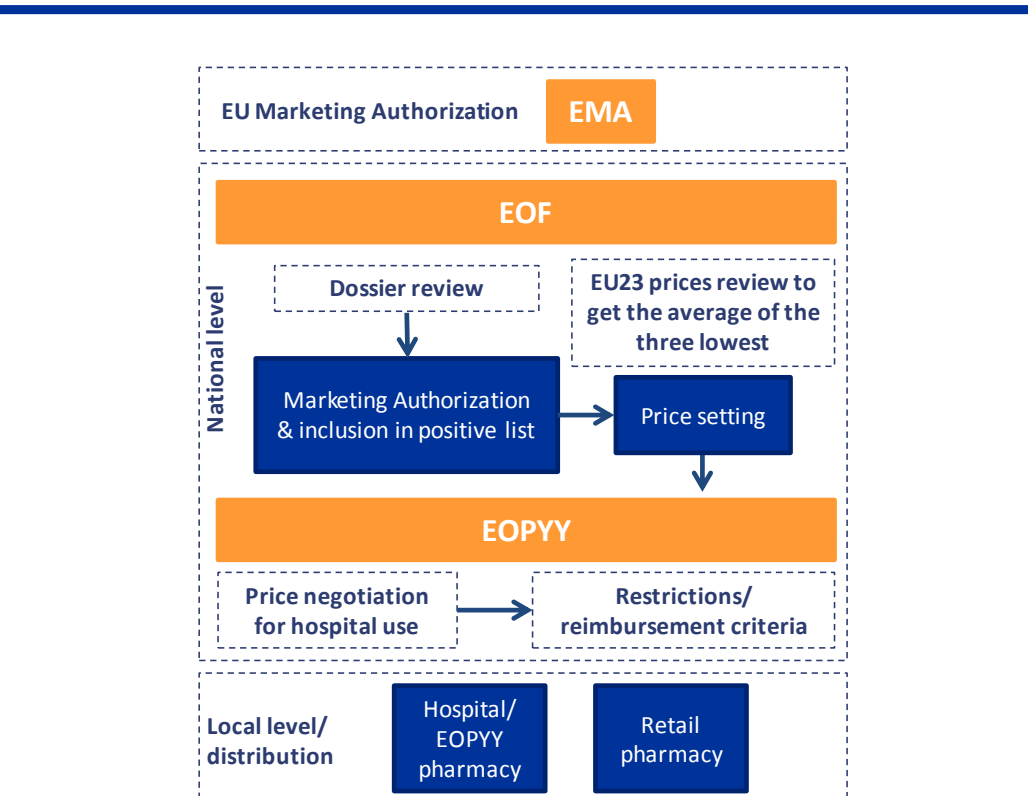
- We utilized a mixed methods approach to collect and analyze the policy reforms affecting the pharmaceutical market in Greece from May 2010, when the first bailout package was agreed, until September 19 2014
- To identify the government measures and understand their implications for pharmaceutical companies, we conducted a structured literature review of public domain sources, including the Greek Government Gazette, and articles listed in PubMed and EMBASE
- Local (Greece) news websites and social media were also researched to cross check information; where available, information was also collected on the implementation outcomes
- Searches were conducted in English and Greek language, and materials were translated into English
- From our findings a road map diagram was developed, outlining the potential impact of the reforms on the pharmaceutical companies operating in Greece as well as the impact on global pricing and access strategies
- To validate our assumptions and findings we conducted five, hour-long in-depth interviews with local health policy and pharmaceutical market experts; during the discussions, future developments were also addressed and taken into account

FINDINGS

Overview of the Greek Pricing and Market Access system

- Upon Marketing Authorization at the EMA level, pharmaceuticals require national authorization from the EOF (National Drug Organization)
- In Greece, there is no HTA body and the price of innovative drugs is set as the average of the three lowest prices of EU member states (Figure 1)

Figure 1: P&MA Roadmap in Greece*



*Based on MKTXS Analysis; EMA, European Medicines Agency; EOPYY, National Organization for the Provision of Health Services (Ethnikos Organismos Parohis Ipiresion Igiast); EU, European Union; EOF, National Drug Organization (Ethnikos Organismos Farmakou)

- EOF monitors pharmaceutical prices biannually and revises the drug price list accordingly
- A special Innovation Committee within EOPYY (the National Organization for the Provision of Health Services) functions to negotiate price of pharmaceuticals and medical services for the public sector
- The Innovation Committee is also authorized to⁸:
 - Impose further restrictions for the reimbursement of the medicines in the positive list
 - Allocate fixed budgets per therapeutic category of medicines or specific drug and set claw-backs for the marketing authorization holders
 - Negotiate price-volume or risk-sharing agreements

Measures to reduce pharmaceutical expenditure

Since 2010, the Greek Government, under the direction of Troika, has introduced measures to contain spending on pharmaceuticals to within the €2 billion limit (Table 1). The reforms aim to:

- Increase the efficiency and transparency of the public health system
- Generate cost savings
- Shift financing to patients
- Ensure the lowest possible prices

Table 1: Reforms in Greece 2010–2015 ^{5–10}	
Policy reforms	What has changed in the last 3–4 years
Price cuts and international price referencing	<ul style="list-style-type: none"> Drug prices are based on an average of the three lowest prices of 23 EU Member States—this is reviewed biannually For off-patent and generic medicines the price is fixed at either the average of the three lowest in EU23, or 50% and 65% (for off-patent and generics, respectively) of the branded price prior to expiration
Incentives for generic usage	<ul style="list-style-type: none"> Minimum percentage of prescription for generics and off-patent drugs is set; an award system for physicians who exceed the set limits is under discussion Generic substitution is encouraged
Reimbursement control	<ul style="list-style-type: none"> A positive list of reimbursed and negative list of non-reimbursed medicines has been introduced Diseases are re-classified to reduce number of diseases with 0% co-payment Therapeutic reference groups have been created and only the cheapest price is reimbursed, with top-ups available Discussions are ongoing for introducing a Committee to assess the clinical and economic value of new drugs before they are included in the positive list
Prescription monitoring	<ul style="list-style-type: none"> e-prescribing and prescribing by active substance has been introduced Prescription protocols are incorporated into the e-prescribing system Prescription data are audited monthly and feedback and warnings are sent to physicians
Rebates and claw-backs	<ul style="list-style-type: none"> Rebates are increased from 9% to 11% for on-patent drugs Quarterly claw back is imposed if the bimonthly targets for expenditure have been surpassed
Spending caps	<ul style="list-style-type: none"> Spending cap and prescription budgets have been introduced for each doctor based on specialty, number of patients and geographic location EOPYY is discussing the introduction of award system for physicians who stay within the set limits
Tendering and further discounts for hospital drugs	<ul style="list-style-type: none"> Hospital products are now purchased through National tenders For innovative drugs EOPYY has imposed an additional fixed discount of 5% for dispensing through the hospital or EOPYY pharmacies

EOPYY, National Organization for the Provision of Health Services (Ethnikos Organismos Parohis Ipiresion Igiast); EU, European Union

Effectiveness of measures

Some measures are now integrated within the system:

- More than 90% of physicians now use e-prescribing and reports on prescribing behaviours are being issued and monitored on a monthly basis
- Therapeutic protocols have been developed and their implementation is monitored
- Rebates and claw-backs have been put in place in order to keep pharmaceutical spending within budget

There are still a number of measures yet to be implemented and/ or finalized:

- Generic use in Greece now stands at 18–20%, while the target was to increase to 60% by the end of 2014¹¹
- Clinical and economic value assessment for new medicines has not yet been implemented
- Implementation of risk-sharing schemes is being discussed but there are none in place yet; thought to be due to a lack of experience with clinical and cost effectiveness assessments
- EOF and EOPYY capacity is low causing delays in pricing and reimbursement decisions as well as barriers to the robust monitoring of pharmaceutical spending

Stakeholder opinion on the evolving P&MA system in Greece

Healthcare policy experts and pharmaceutical manufacturers are sceptical about the future of the Greek pharmaceutical industry

- The Association of Hellenic Pharmaceutical Companies (SFEI, *Sindesmos Farmakeftikon Epihiriseon Ellados*) are particularly concerned with the levels of rebates and claw-backs they are called to pay to the Greek Authorities for reimbursement spending above the budget
- The overall payback amount for 2014 is estimated at 585 million, that accounts for 30% of the National pharmaceutical spending budget¹²
- Payback (rebates and claw back) levels represented 6.9% and 15.3% of the total pharmaceutical expenditure for 2012 and 2013, respectively
- It is reported that there are some discrepancies in the pricing of pharmaceuticals, as well as delays in clearing EOPYY's debts towards the pharmaceutical companies¹²

- Furthermore, healthcare policy experts, want to see more radical reforms to boost competitiveness and ensure that clinical and economic evaluations are performed (as in most Western EU countries)
- The implementation of registries, risk-sharing agreements and innovative access schemes are also positively perceived and attempts are being made to ensure that the technological infrastructure and know-how is being established to support such initiatives

DISCUSSION

- The changes in the Greek pharmaceutical sector has been dramatic during the last 4 years, and has led to a sharp decline in pharmaceutical expenditure from €4.37 billion in 2010 to €2 billion in 2014⁴
- The implemented reforms and uncertainty over future policy changes have brought unique challenges to the manufacturers at both local and international levels

Impact on the local P&MA strategies

- The profit margins have diminished for those global pharmaceutical companies operating in Greece owing to huge price cuts and discounts, delays in access of innovative drugs and obligations for paybacks to keep the budget within the set limits
- As GDP contracts, there are fears of further reductions in public health expenditure and consequently increased calls for paybacks
- Profit potential is also decreasing as patient co-payments increase, resulting in more patients not being able to afford access to healthcare
- With the development of therapeutic reference groups price of new drugs will need to be aligned with their therapeutic alternatives. Also, there is a risk for currently available drugs—market share may fall if manufacturers are not prepared to reduce their prices

Impact on the global P&MA strategies

- Greece drug prices are referenced by 13 EU countries¹³, and other international markets
- Prices can be occasionally miscalculated, which can affect the prices in the reference markets
- Lower prices in Greece can erode global profits, especially on drugs that represent a high percentage of revenue to the pharmaceutical manufacturer
- The low Greece prices can also induce parallel trade, causing the manufacturer to lose the difference between the price in Greece and the higher price in the destination country

Box 1: Defence strategies for pharmaceutical companies operating in Greece

- Build relationships with regulatory bodies and decision-makers and raise awareness of the product value
- Prepare to offer discounts for hospital and out-patient drugs
- Educate the local market access team and ensure that they are ready and able to negotiate innovative access schemes and risk-sharing agreements as needed
- Develop dynamic pricing platforms to effectively monitor and manage international price referencing scenarios
- Strengthening the product portfolio by adding generics and/or divesting less profitable brands in Greece
- Monitor impending policy changes that may impact P&MA to help optimize strategies for new drugs and protect and maintain the position of existing products

CONCLUSIONS

- The recent healthcare reforms in Greece has and will continue to have a high impact on local and global P&MA strategies
- Greek healthcare reforms are continuing to evolve with substantial delays observed in decision making and implementation, further impacting P&MA strategies
- There has been shift in influence from prescribers to Payers and this trend is expected to continue—industry needs to engage with Payers early in development to optimize access
- Monitoring the outcomes of current and future reform policies is essential to developing and implementing successful P&MA strategies

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