Η αποκατάσταση της ασυμμετρίας: μείγμα εξορθολογισμού και συνυπευθυνότητας

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ESDY_Larissa Forum, Saturday 06 April 2019



PHARMACEUTICAL COMPANIE: of **(ohmon∢(ohmon**

Occasional Papers 61 | May 2010



The Economic Adjustment Programme for Greece

Annex 7: Statement by the European Commission, the ECB and IMF on the Second Review Mission to Greece

November 23, 2010

Our overall assessment is that the program remains broadly on track. The end-September quantitative criteria have all been met. While challenges remain, significant progress has been made, particularly in reducing the fiscal deficit.

Regarding the outlook, the economy is expected to begin turning around in 2011. Wage and price inflation is beginning to moderate, setting the stage for improvements in competitiveness.

In the fiscal area, the deficit reduction by 6 percent of GDP in 2010 is larger than the initially targeted change. At the same time, weaker-than-projected revenue collection and data revisions for 2009 mean that an extra effort will be needed to meet the deficit target of 7.5 percent of GDP in 2011, which the government has reaffirmed. New measures have been agreed to broaden tax bases and eliminate wasteful spending, particularly in the areas of:

- Health spending—which is inefficient relative to other euro zone countries;
- State enterprises—which are a heavy burden on the economy with perennial losses for Greek taxpayers; and
- Tax administration—which has instruments now coming into place to strengthen compliance.



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4 Source: http://ec.europa.eu/health/programme/policy/index_en.htm

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Life expectancy at birth has increased steadily but the time spent in good health is declining



In 2015, life expectancy at birth reached 81.1 years in Greece, just above the EU average



In line with the EU average, at age 65 Greek women can expect to live a further 21.3 years but only about one-third of these will be free of disability.



Similarly, men can expect to live around 40% of their remaining 18.5 years in good health





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Greece

Higher Life Expectancy in GR than EU, but <50% of remaining life years are free from health problems

- - While GR citizens will live longer, they will not necessarily enjoy good health into old age.
 - 2/3 of the additional life years for people > 65 are spent with disability.



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OF COMMON

Greece's population is ageing and is shrinking at alarming rates

Total population change in the EU Member States, 2015 (per 1 000 residents) Nations with the highest % of people > 65 years old

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Dependency of old citizens from young in GR is among the highest in EU

The Dwindling Greeks



In the period 2011-2016, Greece **lost** almost 3% of its population



Greece's **population will drop to 9.9 million** by 2030 and to 8.9 million by 2050.



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OF Johnon-Johno

Greece has **one of the lowest fertility rates** in the EU

The old-age dependency ratio as an indication of the level of support available to older persons by the working age population is one of highest in EU.

Sources: State of Health in the EU Where does Greece stand compared with other EU countries? 2018 OECD

The people of Greece are facing further years of economic hardship



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1. "How bad are things for the people of Greece?" by Lucy Rodgers & Nassos Stylianou, BBC News, 2015
(<u>https://www.bbc.com/news/world-europe-33507802</u>)
2.EUROSTAT

Greece has seen the largest contraction of an advanced economy since the 1950s





A financial crisis with a severe impact in the economy as a whole...and especially in health



Sources: IMF, the Maddison Project



With Greek citizens 40% poorer on average in 5 years period



Sources: Eurostat

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Prevention remains a priority

Tobacco is a major risk factor for at least two of the leading causes of premature mortality –cardiovascular diseases and cancer.





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1."Health Policy in Greece", OECD Health Policy Overview, 2016

2."Pooling expertise, strengthening knowledge", State of Health in the EU 2016

While investment in prevention is among the lowest in EU



Sources: "How much do OECD countries spend on prevention?", OECD Health Working Papers 2017

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With cardiovascular diseases and cancer the main causes of mortality



Cardiovascular diseases remain the number one cause of death

Cancer is the second leading cause of death, whereas lung cancer is the leading cause of cancer mortality

Rates for several other types of cancer have remained steady, but with increases in the absolute number of deaths reflecting population ageing:

- colorectal cancer (up 51%)
- breast cancer (up 25%)
- pancreatic cancer (up 55%)
- prostate cancer (up 35%)



Antibiotics consumption indicator of quality in primary care



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HAIs* responsible for 3,000 deaths

Hospital Acquired Infections

 Every year in Greece, HAIs are responsible for the death of 3,000
of Greek citizens and correspond to a total cost of approximately €1.2
billion for the health care system.

'Patients who should live are dying': Greece's public health meltdown

Seven years of austerity have seen hospitals become 'danger zones', doctors say, with many fearing worse is to come





Source: Summary of the latest data on antibiotic consumption in the European Union, ESAC-Net surveillance data, 2017

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When Healthcare is a "Lemon": Asymmetric Information and Market Failure



Preventable bad outcomes and opaque pricing are healthcare's "lemons"

Asymmetric information exchange between providers and patients contributes to medical errors, customer frustration, overtreatment and undertreatment in U.S. healthcare.

Equalizing information exchange engages patients, improves outcomes and reduces unnecessary healthcare expenditure 10% of patients account for 70% of the costs in health care, while for the remaining 90% only 30% of health care services are available.

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Source: 1. When Healthcare is a "Lemon", Asymmetric Information and Market Failure, 2015 2. http://www.4sighthealth.com/when-healthcare-is-a-lemon-asymmetric-information-and-market-failure/

Governments facing severe difficulties to manage budget deficits and public debt



Sources: Bank for international settlements; Economy Watch 2010

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Leaving Greece with 40% reduction of public funding for healthcare vs 2010



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Accessibility: Affordability, Availability and use of services



Sources: "Health at a glance", OECD/European Union 2018

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Breakdown of OOP can only reflect the actual burden for patients



Sources: Health Systems in Transition (HiT) profile of Greece; European Observatory on Health Systems and Policies

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However it is important to consider what is covered and at what rate?



Sources: Economic crisis, health systems and health in Europe: impact and implications for policy Thomson et al 2014, WHO

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Universal coverage to health care granted for all GR citizens in 2016

- A new law in 2016 provided universal health coverage, closing the coverage gap for the 10% of the population that were previously uninsured.
- However, the law was implemented in an "urgent approach" and not after thorough investigation of social protection findings for GR citizens.



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Even with universal coverage patients report other barriers in medical care





Despite efforts to reduce hospital and medical goods costs, still >70% of health spending is allocated



Sources: "Health at a glance", OECD/European Union 2018

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Primary care launched in 2017: a step to reduce overcrowding and hospital costs



Sources: Law 4486 A 115/07.08.2017

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However, Greece has a high number of doctors with a very low number of GPs



Sources: World Health Organization (WHO) 2014

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A pragmatic approach to identify wasteful spending on health



Sources: Tackling Wasteful Spending on Health $\ensuremath{\mathbb{C}}$ OECD 2017

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With uneven geographic distribution of doctors across the country



Sources: ELSTAT

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Possible approaches to reduce spending on pharmaceuticals



Sources: Tackling Wasteful Spending on Health © OECD 2017



Many prescription protocols integrated in the prescription system

1st step

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HCPs not obliged to follow while hospitals lack of treatment protocols





Ηλεκτρονική Συνταγογράφηση > Νέα και ανακοινώσεις > Conten

Οι διαγνώσεις των θεραπευτικών πρωτοκόλλων της ΧΑΠ θα συνταγογραφούνται μέσω πρωτοκόλλων

Posted: 1/22/19, 4:10 PM

Σας ενημερώνουμε ότι από τη Δευτέρα 28-1-2019 οι διαγνώσεις των θεραπευτικών πρωτοκόλλων "Χρόνια Αποφρακτική Πνευμονοπάθεια (ΧΑΠ)" και "Παρόξυνση Χρόνιας Αποφρακτικής Πνευμονοπάθειας" για ασθενείς άνω των 16 ετών θα συνταγογραφούνται αποκλειστικά μέσω των θεραπευτικών πρωτοκόλλων.



Health Technology: Regulation vs Assessment vs Management



Sources: presentation at Healthcare Conference by DrPH Panteli Department of Healthcare Management , Berlin University of Technology WHO Collaborating Center for Health Systems Research and Management European Observatory on Health Systems and Policy

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HTA is a tool supporting informed decision making and award true innovation



Sources: presentation at Healthcare Conference by DrPH Panteli Department of Healthcare Management , Berlin University of Technology WHO Collaborating Center for Health Systems Research and Management European Observatory on Health Systems and Policy

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Different evaluation criteria applied in EU while HTA in GR evaluates the credibility of evidence

		HAS		NICE	AI/-A			Instituto de Salud Carlos III
	Clinically relevant outcomes	Preferred	Yes	Preferred	Yes	Yes	Yes	Yes
	Surrogate outcomes	Accept	Accept	Accept	Accept	Accept	Accept	Accept
	HRQoL outcomes	Yes	Yes (prefer general)	Yes	Yes	Yes	Yes	Yes
(Safety/ Adverse events	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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Sources: Abstracted from Angelis, Lange and Kanavos 2018
HTA has been introduced in 2018, with results still pending...

ΕΦΗΜΕΡΙΔΑ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ THE EAAHNIKHE AHMORPATIAE ΝΟΜΟΣ ΥΠ' ΑΡΙΘΜ. 4512 Ρυθμίσεις για την εφαρμογή των Διαρθρωτικών Μεταρρυθμίσεων του Προγράμματος Οικονομικής Προσαρμογής και άλλες διατάξεις. 15535 ΕΦΗΜΕΡΙΔΑ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ ΤΗΣ ΕΛΛΗΝΙΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ 111coλio v 2018 ΤΕΥΧΟΣ ΔΕΥΤΕΡΟ Αρ. Φολλου 2768 ΑΠΟΦΑΣΕΙΣ Αριθμ. οικ. 52029 Έγκριση του εσωτερικού κανονισμού λειτουργίας της επιτροπής αξιολόγησης και αποζημίω σης φαρμάκων ανθρώπινης χρήσης του ν. 4512/ 2018 (A'5). D. ΕΦΗΜΕΡΙΔΑ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ ΤΗΣ ΕΛΛΗΝΙΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ ΑΠΟΦΑΣΕΙΣ Аріθμ. ок. 63025 Έγκριση του Εσωτερικού Κανονισμού Λειτουργί ας της Επιτροπής Διαπραγμάτευσης Τιμών Φαρ

ΦΕΚ 4512 ΤΗΣ 17¹ ΙΑΝΟΥΑΡΙΟΥ 2018 - ΤΜΗΜΑ Θ΄: ΔΙΑΤΑΞΕΙΣ ΥΠΟΥΡΓΕΙΟΥ ΥΓΕΙΑΣ ΜΕΡΟΣ Α΄: ΑΞΙΟΛΟΓΗΣΗ ΚΑΙ ΑΠΟΖΗΜΙΩΣΗ ΦΑΡΜΑΚΩΝ ΑΝΘΡΩΠΙΝΗΣ ΧΡΗΣΗΣ

Άρθρα 247- 256

ΦΕΚ 2768 ΤΗΣ 11^{ης} ΙΟΥΛΙΟΥ 2018 - ΕΓΚΡΙΣΗ ΤΟΥ ΕΣΩΤΕΡΙΚΟΥ ΚΑΝΟΝΙΣΜΟΥ ΛΕΙΤΟΥΡΓΙΑΣ ΤΗΣ ΕΠΙΤΡΟΠΗΣ ΑΞΙΟΛΟΓΗΣΗΣ ΚΑΙ ΑΠΟΖΗΜΙΩΣΗΣ ΦΑΡΜΑΚΩΝ ΑΝΘΡΩΠΙΝΗΣ ΧΡΗΣΗΣ Άρθρα 1 – 17 ΠΑΡΑΡΤΗΜΑ Ι: ΜΕΘΟΔΟΛΟΓΙΑ ΑΞΙΟΛΟΓΗΣΗΣ ΦΑΡΜΑΚΩΝ ΑΝΘΡΩΠΙΝΗΣ ΧΡΗΣΗΣ ΠΑΡΑΡΤΗΜΑ ΙΙ: ΟΔΗΓΙΕΣ ΓΙΑ ΤΗΝ ΥΠΟΒΟΛΗ ΑΙΤΗΣΗΣ ΑΞΙΟΛΟΓΗΣΗΣ ΦΑΡΜΑΚΟΥ ΚΑΙ ΠΡΟΤΥΠΑ ΥΠΟΒΟΛΗΣ

ΦΕΚ 63025 ΤΗΣ 23^{ης} ΑΥΓΟΥΣΤΟΥ 2018 ΕΓΚΡΙΣΗ ΤΟΥ ΕΣΩΤΕΡΙΚΟΥ ΚΑΝΟΝΙΣΜΟΥ ΛΕΙΤΟΥΡΓΙΑΣ ΤΗΣ ΕΠΙΤΡΟΠΗΣ ΔΙΑΠΡΑΓΜΑΤΕΥΣΗΣ ΦΑΡΜΑΚΩΝ



...and barriers still there



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Governments in other EU countries substantially believe and support HTA....

	Workforce	Budget
Austria	27 FTEs	€ 1,4 mil
Belgium	65 FTEs	€ 1,1 mil
Italy	50 FTEs	€ 8 mil
Portugal	25 FTEs	€ 750
Spain	100 FTEs	€ 1,3 mil
France	107 FTEs	€ 8 mil

DRGs in Greece outdated and not properly measured....how to conduct economic evaluation in GR

Registries and local epi data missing...how to properly assess the eligible population and budget impact

5

Lack of transparent framework to assess true innovation and recommend full reimbursement and award innovation

Horizon scanning

Guidelines economic evaluation

Registries

Treatment guidelines

Consult other universities

In France each year is mentioned in the law the financing from the SSF the allocated budget for HTA activities

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EC agreed on payback mechanisms on excess of pharma spending only if structural reforms



According to Article 168, §7 of the Treaty on the Functioning of the EU, Union action shall respect the **responsibilities of the Member States for the definition of their health policy** and for the organization and delivery of health services and medical care. Hence, it is foremost for Member States to decide on how to ensure access to healthcare for their populations.

Parliamentary questions

9 February 2017

Answer given by Mr Moscovici on behalf of the Commission

In addition, through the MoU the GR authorities **committed** to implement s**tructural measures** focusing on improving efficiency of the health system as a means to contain expenditure to **ensure the spending on pharmaceuticals, but also diagnostics and private clinics, for 2017, is reduced by at least 30%** compared to the previous year.

While pharmaceutical spending in GR is only a small part of total health spending





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Public funding for pharmaceuticals and other medical goods has dropped significantly



A "closed" budget has a ceiling, above which someone else is paying



Payback mechanism entails a risk of preventing rationalization of total spending



Rebates and clawbacks

Italy France Portugal Greece **Italy:** Since 2010, rebates must be paid retrospectively when the cap for reimbursed medicine spending has been exceeded, for example drug spending higher than 11.5 per cent of total healthcare spending. The scheme is administered at a regional level and requires repayment of 6.5 per cent of the drugs sold to Italy's national health service. The industry is responsible for paying 100 per cent of retail overspending and 50 per cent of hospital overspending, with over-budget regional payers also accountable for hospital overspending and mandated to pay the other 50 per cent.⁴¹

Payments for the rebate scheme are calculated twice a year based on two, six-month periods.⁴² The payment required for rebates is based on data collected by the Observatory on the use of Medicines. Companies are provided with an annual budget based on health service purchases of a company's medicines.⁴³

France: Pricing and reimbursement are determined by price/volume agreements where the manufacturer provides an estimate of the patient population and, therefore, the cost of the new drug to the healthcare system. If this cost is exceeded, the manufacturer has to pay a clawback.⁴⁴

Portugal: Introduction of a payback system, whereby the pharmaceutical industry will pay the amount of overspending, if drug spend exceeds the 1.25 per cent of GDP target in 2012 or 2013 respectively.⁴⁵

Sources: Impact of austerity on European pharmaceutical policy and pricing Staying competitive in a challenging environment Deloiite Centre for Health Solutions 2013



ianssei

Public budget for prescribed medicines either increased or decreased...



Sources: 1. MD 201 B/22.12.2018; MD 153 B/30.01.2019; MD 1803 B/20.08.2015. 2. Law 4549 A 105/14.06.20198

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Still not aware of actual patients needs in medicines thus not aware of what we pay for



Sources: Regulatory Opportunities and Challenges in Europe: A proposal from the Italian Experience on Registries presentation in 2016 by Luca Pani, M.D. Director General, Italian Medicines Agency CHMP, SAWP Member, European Medicine Agency

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Italy knows what they pay for in health care

Drug contracts with money-back guarantees

Italy is signing more contracts stipulating refunds when treatments fail, allowing it to take a chance on medicines getting approved with smaller trials



When New Cancer

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Treatments Fail, Italy Wants

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Sources: Regulatory Opportunities and Challenges in Europe: A proposal from the Italian Experience on Registries presentation in 2016 by Luca Pani, M.D. Director General, Italian Medicines Agency CHMP, SAWP Member, European Medicine Agency

Why do we need to increase volume of Gx and biosimilars?

Figure 2.10. Generic market share by volume and value, 2016 (or latest year)



Sources: "Health at a glance", OECD/European Union 2018

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Savings vs Efficiency



Sources: Economic crisis, health systems and health in Europe: impact and implications for policy Thomson et al 2014, WHO

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Proposals

Investment in prevention and public health

Taxation on special products for better health

Cigarettes, alcohol, beverages with high concertation in sugar

VAT adjustment based on "healthness" criteria

Reduction of VAT for fruits, vegetables etc

Universal implementation of antismoking law

e.i. Trikala city



Support and expand primary health care

Incentives to GPs for quality health care services Mapping of geographical distribution of GPs Innovative ways to inform and educate patients

Generate a national hospital map

Introduce electronic systems Re-allocation to rationalize personnel costs Incentivize for quality services

Governance of electronic systems and clear patient pathway

Patient records immediately introduced Link all prescription related systems in one



Sustainability on pharmaceutical market and other cost centers

Control and monitor demand more effectively

Clear timeframe on full switch to treatment protocols

Immediate introduction of treatment protocols in hospitals

Support and better finance/organize HTA

Foster early but controlled access to innovative medicines

Identify approaches to award true innovation (ie RSAs)

Ministry of Health, Finance and Development to sign a contractual agreement with the Industry to reduce Clawback by at least an x% per year

Identify and regulate other cost centers of medical goods

EOPYY to reimburse only based on quality of services provided – pay for performance



The (mistaken) general perception for the industry/ innovation

Pharmaceutical companies set the drug prices without taking into account of the poor third world. Given that these companies have exclusive use of these medicines, international criticism has begun in recent years. Collect data on this subject and make your point of view, documenting it with both humanitarian and economic evidence.





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Thank you for your attention



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