Deputada Maria de Belém Roseira
Presidente do Partido Socialista

Paths towards a responsible introduction of Public Health Genomics

PACITA – 2nd Parliamentary TA Debate
Assembleia da República
08 de Abril de 2014

Political and Legislative Responsabilities

The Assembly of the Republic is responsible for approving the essential instruments of the Portuguese legal system, such as:

- Constitutional amendments;

- the political/administrative statutes and the laws on the election of Members of the Legislative Assemblies of the autonomous regions
- the laws involving the Major Options of the National Plans and the State Budget;

- treaties – particularly those on Portugal's participation in international organisations, friendship, peace, defence, the rectification of borders, and military affairs –and international agreements which concern matters that fall within the Assembly's exclusive areas of responsibility, or which the Government sees fit to submit to the Assembly for consideration.

Political and Legislative Responsabilities

The Assembly of the Republic's **political and legislative responsibilities** also include:

- granting the Legislative Assemblies of the autonomous regions authorisation to legislate on certain matters;

- granting generic amnesties and pardons;

- authorising the President of the Republic to declare war and make peace:

- proposing to the President of the Republic that issues of important national interest should be put to referendum;

- authorising and confirming declarations of a state of siege or a state of emergency;

- granting the Government authorisations to legislate

Responsabilities in Relation to Other Bodies that Exercise Sovereign Power

ASSEMBLEIA DA REPÚBLICA

MONITORING AND SUPERVISORY

- bear witness to the President of the Republic's installation;
- consent to the President of the Republic's absence from Portuguese territory;
- take steps to ensure that proceedings are brought against the President of the Republic for crimes committed in the performance of his/her functions;
- **consider the Government's Political Programme;**
- **monitor and consider Portugal's participation in the process of constructing the European Union;**
- in accordance with the Constitution, appoint:

10 Constitutional Court Justices/the Ombudsman/the President of the Economic and Social Council/7 members of the Supreme Judicial Council/5 members of the Supreme Council of the Public Prosecutor's Office/5 members of the Council of State/4 members of the Media Regulatory Body;

- vote on motions of confidence and no confidence in the Government;
- decide whether members of the Government should be suspended when criminal charges are definitively brought against them (except in cases where the crime is punishable by more than three years in prison, when suspension is automatic);
- authorise the Government to take out and grant loans, and also decide their general terms and conditions.

Responsabilities in Relation to Other Bodies that Exercise Sovereign Power

ASSEMBLEIA DA REPÚBLICA

The Assembly of the Republic is responsible for ensuring that the Constitution and laws are complied with and considering the state's accounts and the reports on the implementation of national plans. It is also charged with considering the actions of the Government and the Public Administration. The Rules of Procedure give it a number of tools for this purpose. Some of the most important are:

- motions for the consideration of executive laws;
- fortnightly Prime Minister's question times;
- **the right to call on the Government to attend the Assembly in relation to general or sectoral policy matters;**
- **written questions and motions on any action taken by the Government or the Public Administration;**
- parliamentary committees of inquiry, which enjoy the same investigative powers as the judicial authorities.

Health Care System

Objectives

Improve efficiency and effectiveness in the health care system, inducing a more rational use of services and control of expenditures; generate additional savings in the area of pharmaceuticals to reduce the public spending on pharmaceutical to 1.25 per cent of GDP by end 2012 and to about 1 per cent of GDP in 2013 (in line with EU average); generate additional savings in hospital operating costs.

The Government will take the following measures to reform the health system:

Pricing and reimbursement of pharmaceuticals

3.54. Set the maximum price of the first generic introduced in the market to 60% of the branded product with similar active substance. **[Q3-2011];**

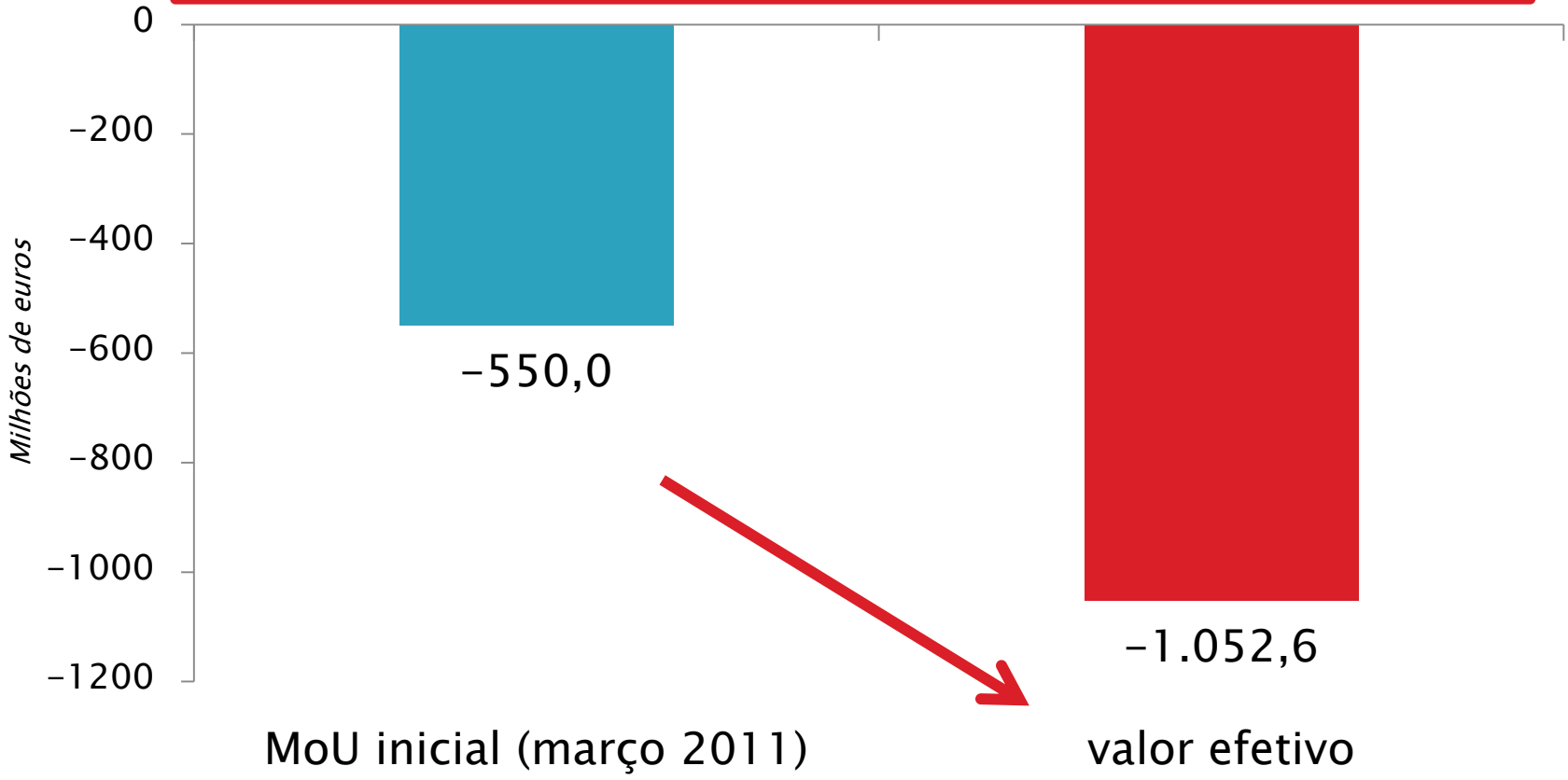
3.55. Revise the existing reference-pricing system based on international prices by changing the countries of reference to the three EU countries with the lowest price levels or countries with comparable GDP per capita levels. **[Q4-2011];**

Prescription and monitoring of prescription

3.56. Make electronic prescription for medicines and diagnostic covered by public reimbursement fully compulsory for physicians in both the public and private sector. **[Q3-2011]**;
3.57. Improve the monitoring system of prescription of medicines and diagnostic and set in place a systematic assessment by individual doctor in terms of volume and value, vis-àvis prescription guidelines and peers. Feedback is to be provided to each physician on a regular basis (e.g. quarterly), in particular on prescription of costliest and most used medicines, starting from **Q4-2011. The assessment will be done through a dedicated unit** under the Ministry of Health such as the Centro de Conferência de Facturas. Sanctions and penalties will be envisaged and enforced as a follow up to the assessment. **[Q3-2011]**;
3.58. Induce physicians at all levels of the system, both public and private, to prescribe generic medicines and the less costly available branded product. **[Q3-2011]**;
3.59. Establish clear rules for the prescription of drugs and the realisation of complementary diagnostic exams (prescription guidelines for physicians) on the basis of international prescription guidelines. **[Q4-2011]**;
3.60. Remove all effective entry barriers for generic medicines, in particular by reducing administrative/legal hurdles in order to speed up the use reimbursement of generics. **[Q4-2011].**

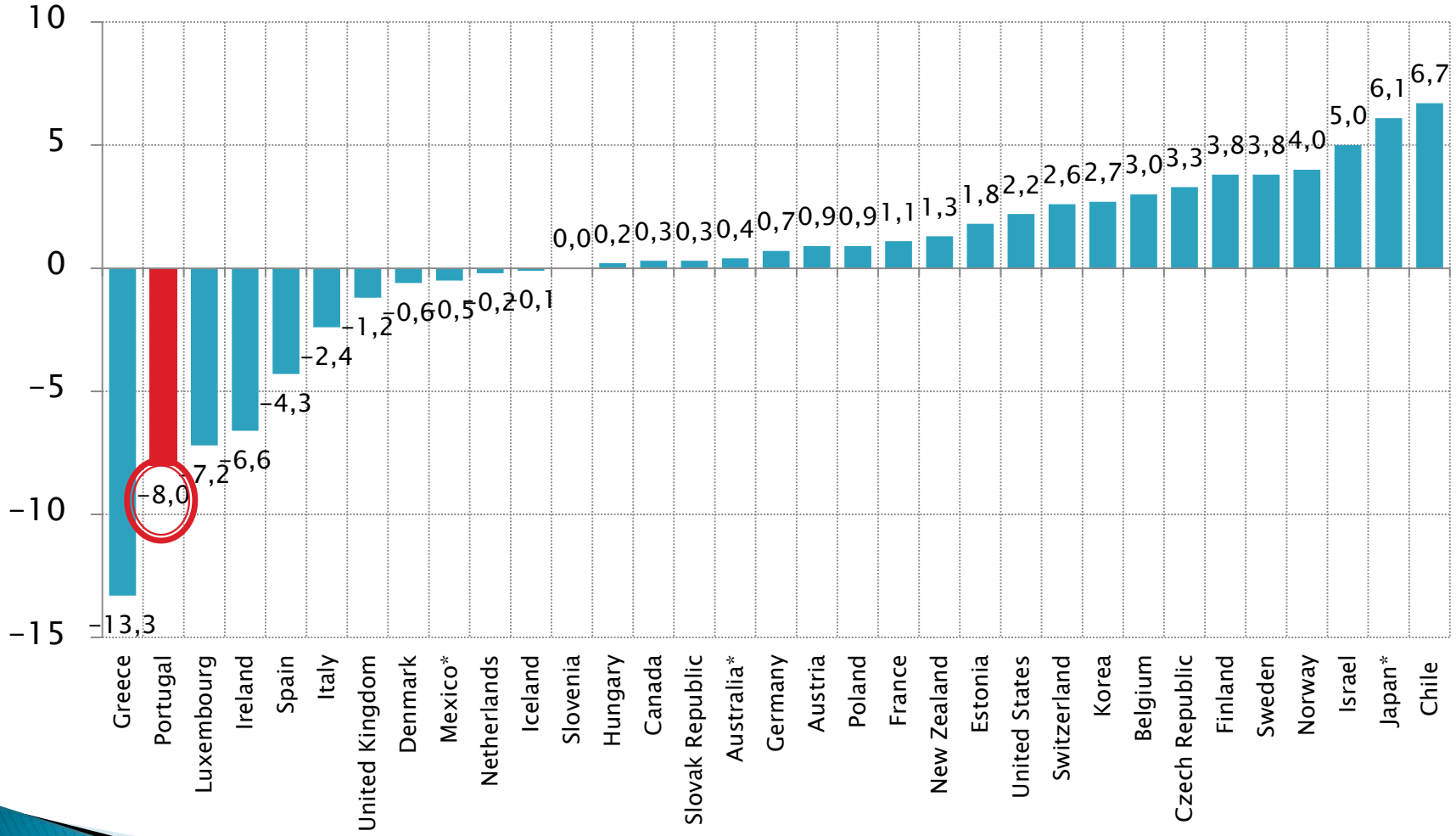
Portugal: corte no setor da Saúde em 2012
acordado no memorando da troika e valor observado

Em 2012, a despesa com saúde pública registou uma quebra de 91% face ao inicialmente acordado com a *troika* : praticamente o dobro!



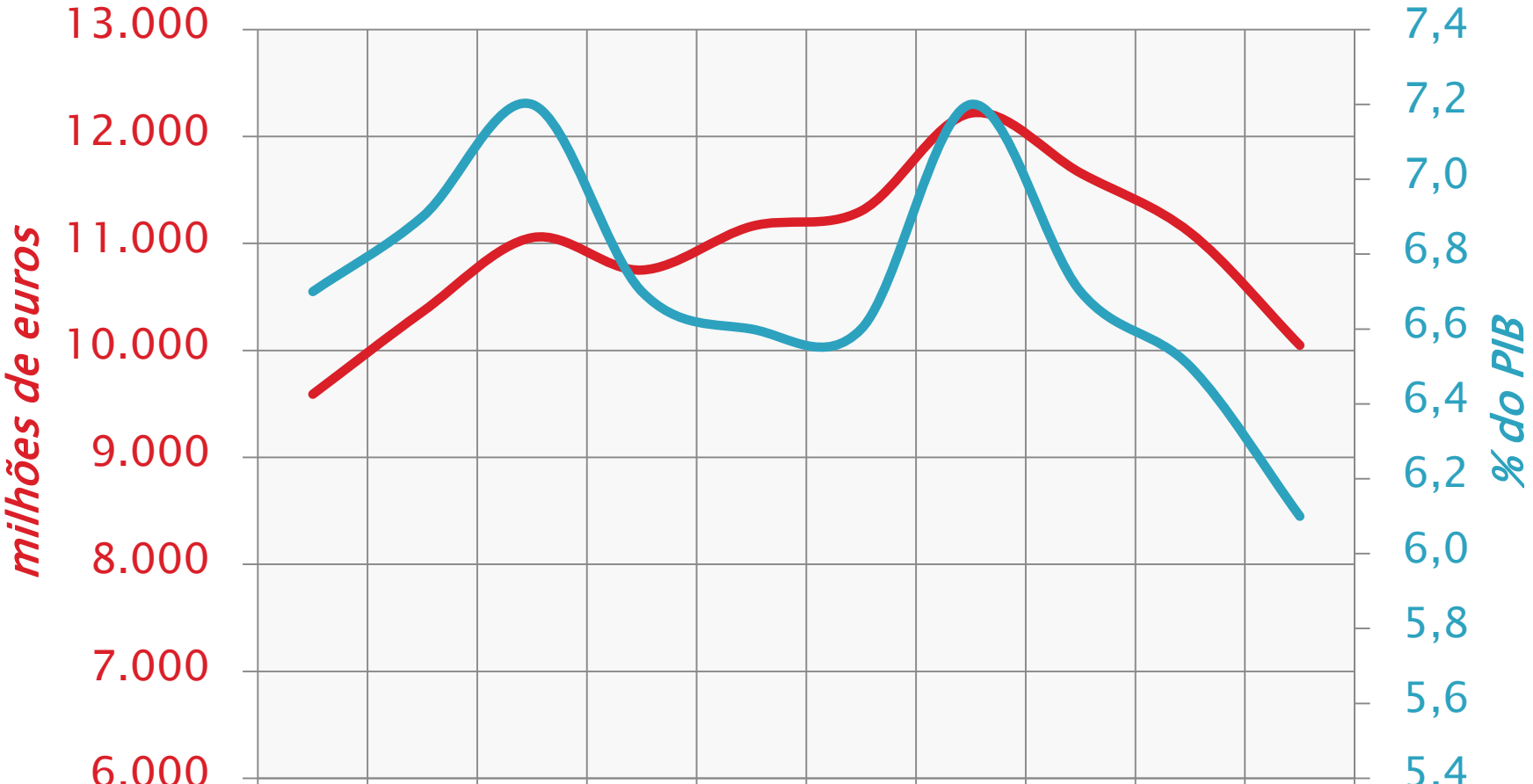
Eurostat
Nota: Ainda não estão disponíveis os dados referentes a 2013

OECD: Annual growth rate of public expenditure on health, in real terms, 2011



OECD

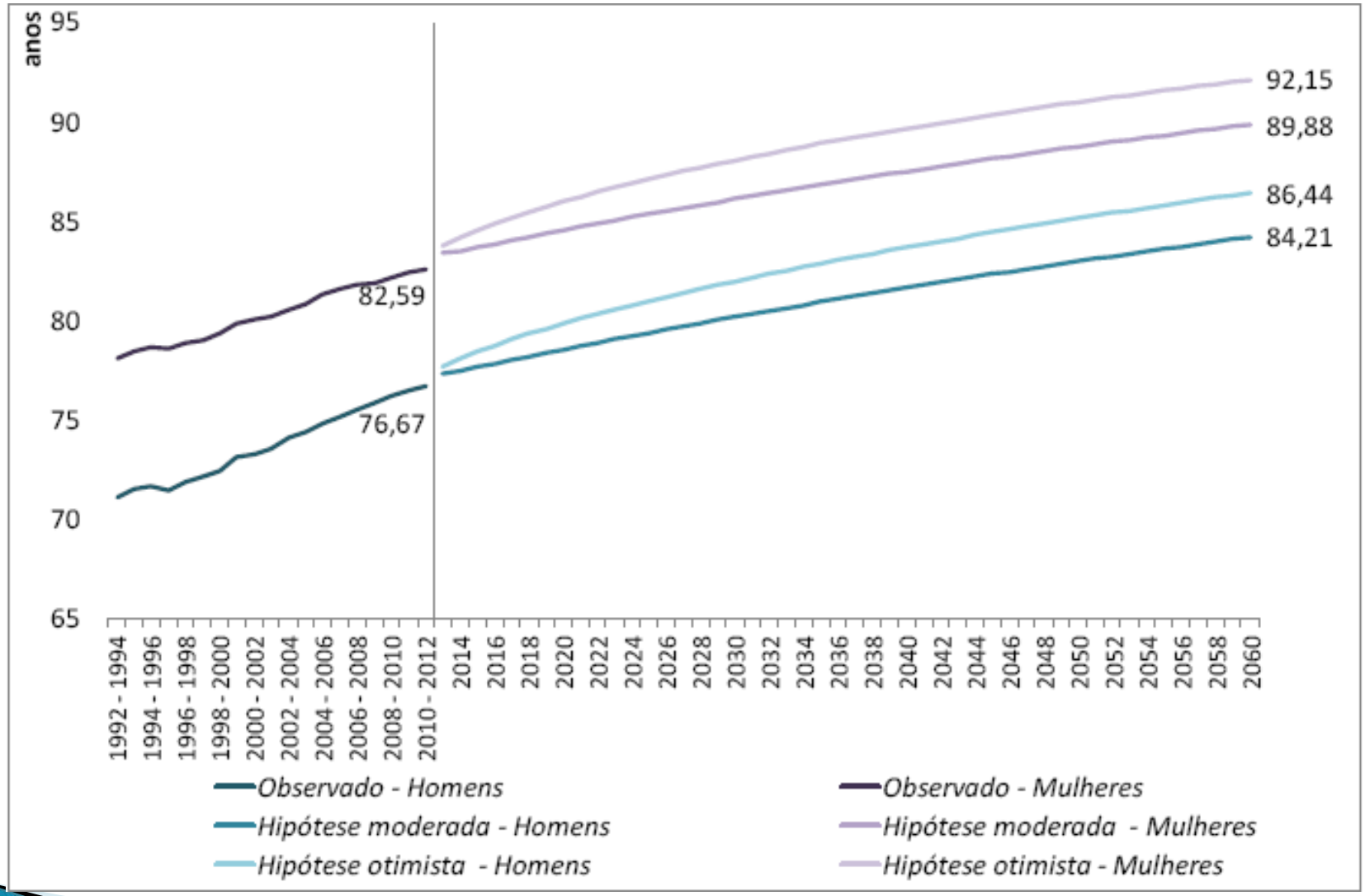
Portugal: Despesa Pública com Saúde 2003-2012
valor e % do PIB



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
milhões de euros	9.590,8	10.361,	11.054,	10.751,	11.159,	11.302,	12.217,	11.658,	11.100,	10.048,
% do PIB	6,7	6,9	7,2	6,7	6,6	6,6	7,2	6,7	6,5	6,1

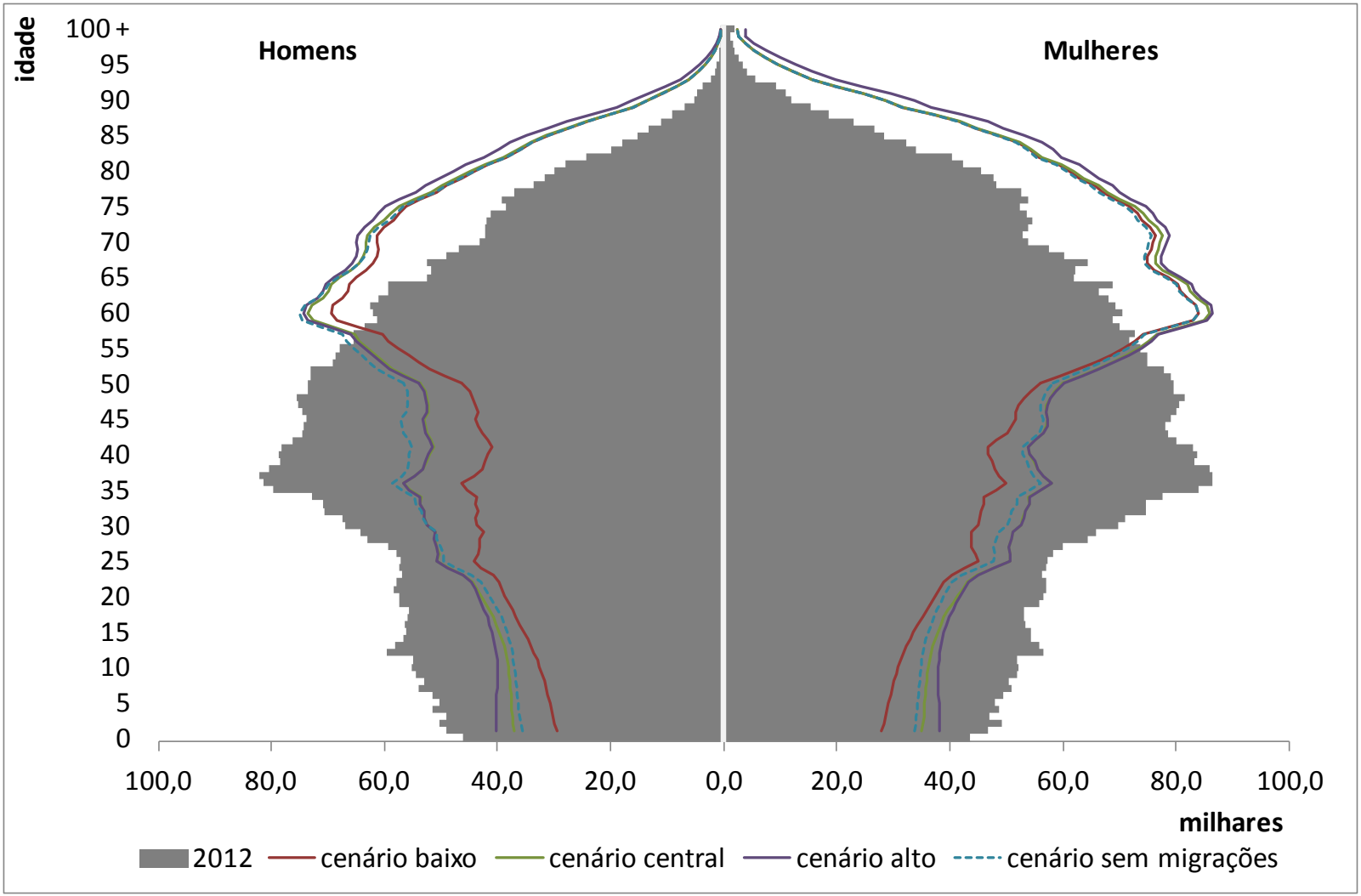
Eurostat

Esperança de vida à nascença, por sexo, 1992-2060 (observada e hipóteses)



INE: Projeções da população residente 2012-2060 (cenário central)

Pirâmide etária, 2012 (estimativas) e 2035 (projeções)



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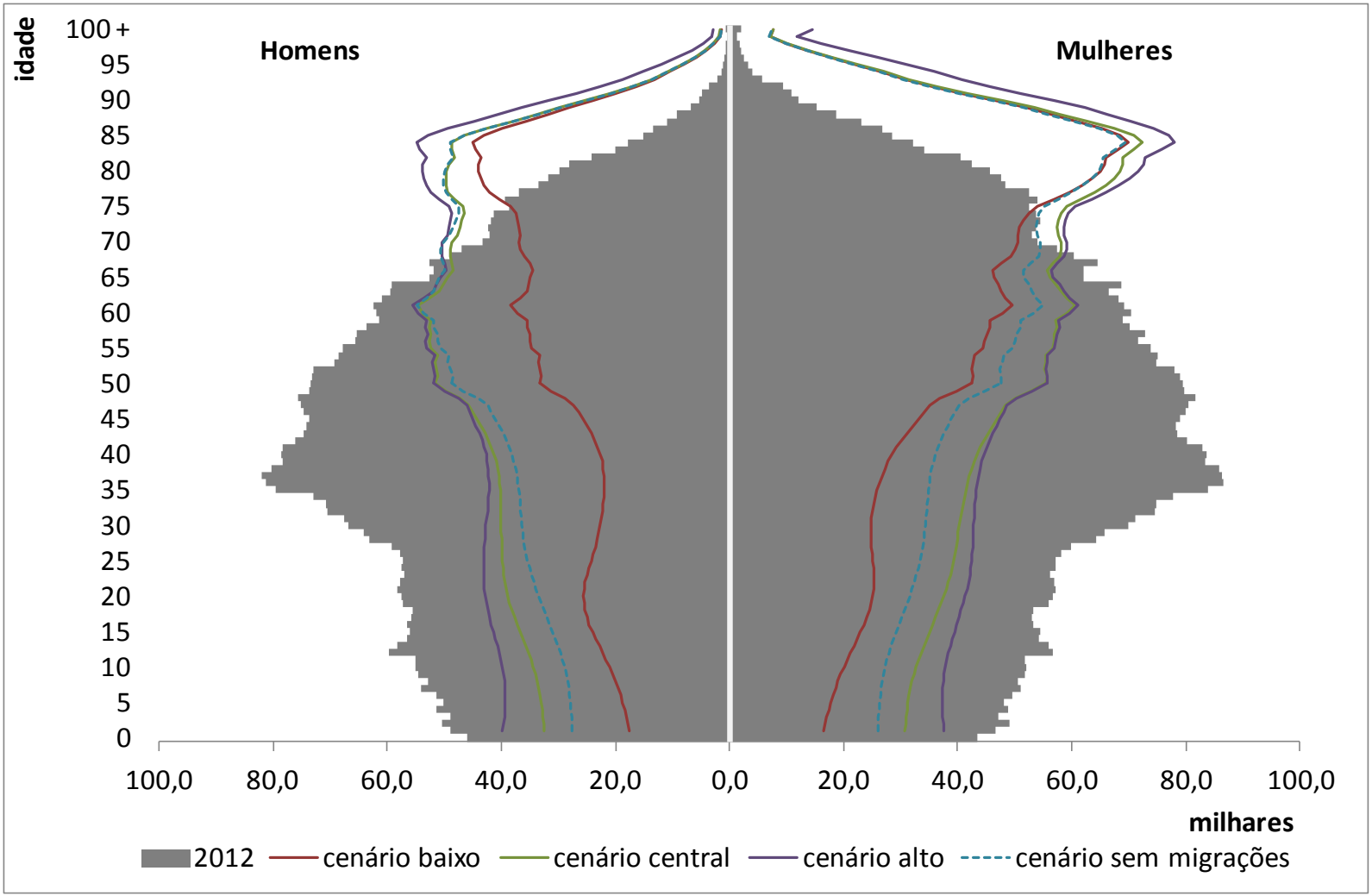


INE: Projeções da população residente 2012-2060 (cenário central)

Health policy responses to the financial crisis in Europe

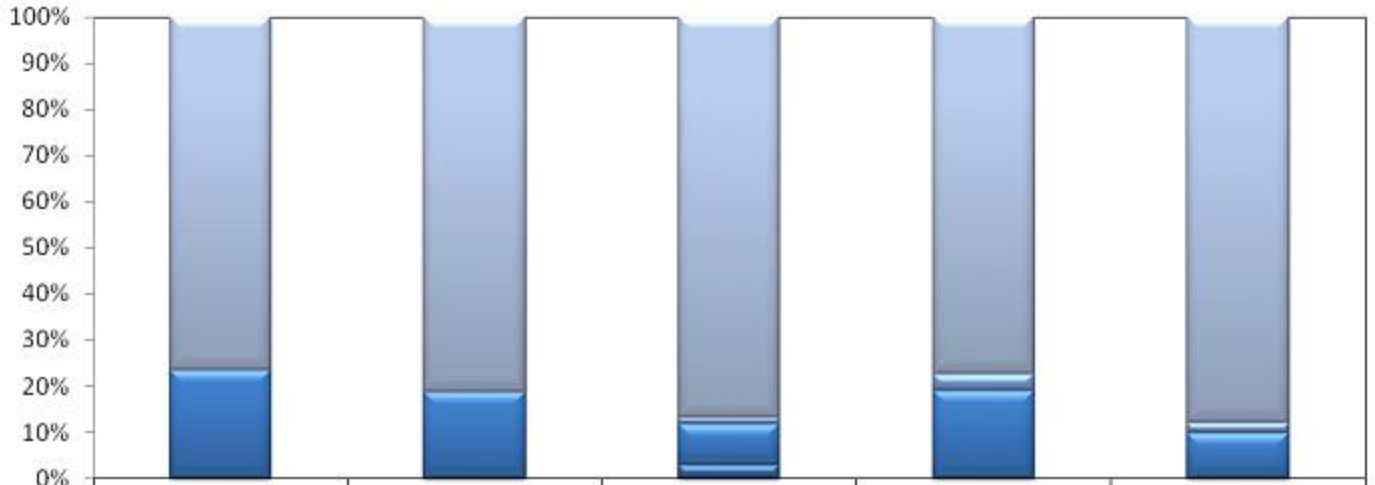
In the context of pressure for cuts in public spending, the health sector is likely to be affected. Research suggests that public spending on health in Europe has tended to fall after previous economic crises, often at a faster rate than other types of government expenditure (Cylus, Mladovsky & McKee, in press). Recent health expenditure data suggest that a similar pattern is emerging in many countries (see section 4). The health sector may be vulnerable to budget cuts for a range of reasons. Public spending on health accounts for a substantial proportion of total government expenditure: nearly 13% on average in the European Region (see Table 1). Health system inefficiencies may make it politically difficult to argue for maintaining current levels of public expenditure on health during a period of fiscal austerity. It may also be easier to cut public spending on health than to make cuts in other areas of social protection, such as pensions, either because there is more scope for efficiency gains in the health system or because health benefits are less clearly defined than other benefits (Fahy, 2012). Conversely, counter-cyclical health policies such as holding financial reserves earmarked for health or linking government contributions for economically inactive groups of people to average earnings in previous years may ease pressure to cut public spending on health (WHO Regional Office for Europe, 2011b).

infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

- **The independent public structure with technical autonomy** with a **mission** to develop **national guidelines on health technologies** (drugs and medical devices) based on the added therapeutic value, comparative effectiveness and achieving gains in health. These guidelines are for use in all units of the National Health System.

National Healthcare Plan 2011-16
"Medicine and medical devices policy and evaluation of health technologies"

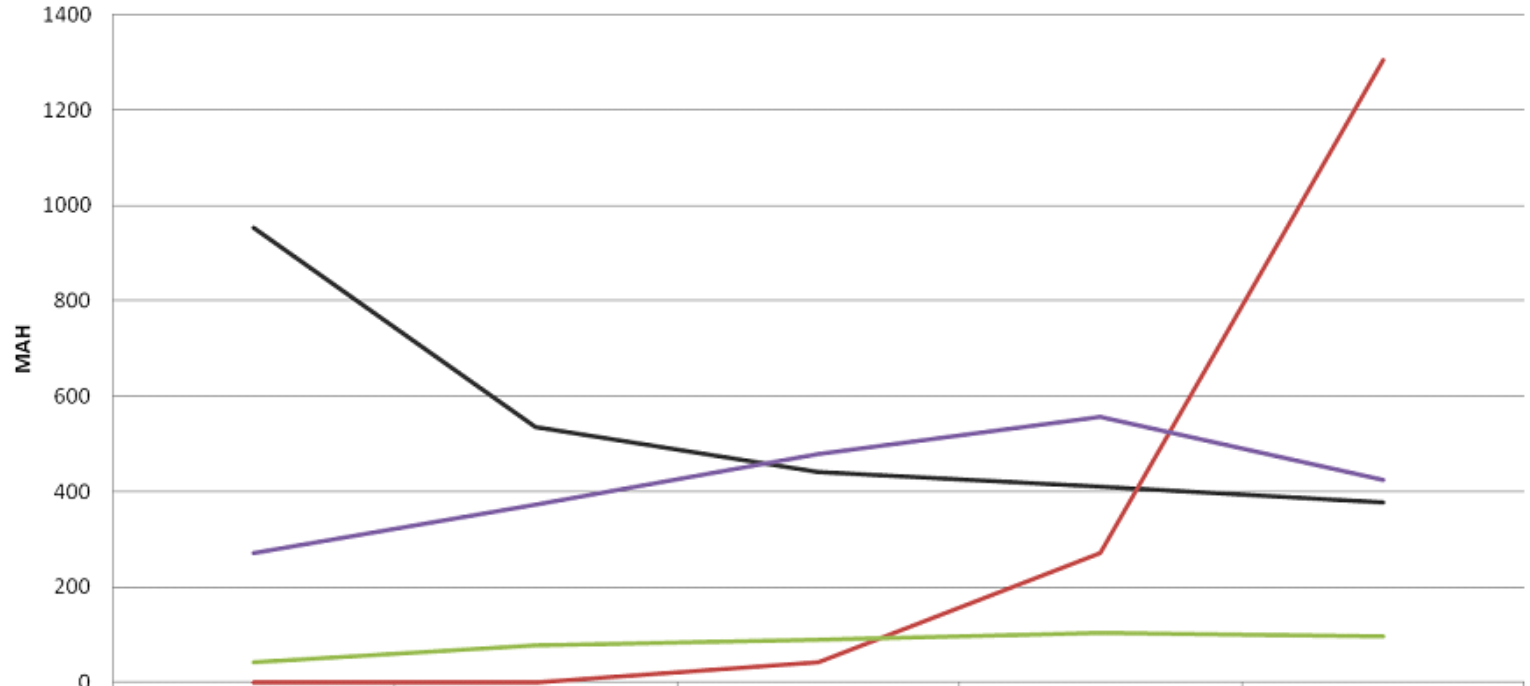
Fig 3 - Absolute and relative frequency of new active substances approved by type of procedure in Portugal and in EU 2005-2009



	2005	2006	2007	2008	2009
Centralized	26	48	59	41	36
DC		0	1	2	1
MR	8	11	6	10	4
National		0	2	0	0

National Healthcare Plan 2011-16
"Medicine and medical devices policy and evaluation of health technologies"

Figure 4 - Evolution in the number of MAH processes finalized by type of procedure between 2005-2009



	2005	2006	2007	2008	2009
RM	954	535	441	411	378
DC	0	0	41	271	1304
EMA	41	78	90	103	96
NAC	271	373	479	556	424

Genomics and Policy

World Health Organization

'Biotechnology, genomics and informatics offer a growing range of approaches to help prevent monitor and detect, diagnose and treat infectious disease. Appropriate policies are however necessary to ensure that the right tools reach the right right people at the right time.'

Biotechnology and Sustainability:The fight against infectious disease, OECD.

Genomics suggests significant benefits for the future of medicine and public health. The implications of genomics for public health should neither be underestimated or ignored. In light of existing health challenges, policy makers can capture the potential of genomics to meet public health goals through health policy.

In many countries health policy has yet to integrate genetics approaches into health care. This requires **policy makers** to be knowledgeable about the science and its possibilities, to keep abreast with the progress in genetic science and technology and also include genomics in the design and renewal of health interventions.

Genomics and Policy

The expanding role of genetics in medicine and health necessitates international collaborative efforts to create sound and just frameworks from which to build and further the research and applications of genomic technologies. Policy makers have a significant role to play in the redirection of local and global resources into genetic research and development to target the specific health needs of their communities. Their advocacy can advance genomics research and technologies, enhance the transfer and exchange of genomic information, encourage global collaborations, and improve health services worldwide.

Health Policy and the Ethical, Legal and Social Issues (ELSI) in Genomics

World Health Organization

The number of innovations in genomics leading to useful health applications is steadily growing. At this juncture, when this burgeoning field is still in its relatively early states, it is important for countries to develop strategies to ensure that these advances are harnessed to benefit the health of their citizens, and to undertake an appraisal of the potential of genomics for their citizens. **This means taking careful account in the creation of policy** of not only the scientific and technical aspects of genomics, but also of the not inconsiderable ethical and social implications its development and application may pose.

Health Policy and the Ethical, Legal and Social Issues (ELSI) in Genomics

World Health Organization

Policy can have an enormous impact at each stages of this process. Careful and informed decision-making, which takes account of local health needs, capacity, and customs, is essential to harnessing the full potential of genomics and its applications for improved health.

- **Public Education and Public Engagement**

  For policies to be sustainable and effective, they need to be socially acceptable.

- **Research and Development**

  A further area of challenge for policy makers in the case of genomics and policy concerns the funding of research and development (R&D). The source of funding, be it the private or the public sector or a mixture of both, has implications for the affordability and accessibility of research findings, as well as their relevance to local needs.

Health Policy and the Ethical, Legal and Social Issues (ELSI) in Genomics

World Health Organization

- **Building Capacity**

  Better training of health professionals in genomics and its ethical implications is essential for assuring that the potential of new technologies is realized for the full benefits of patients.

- **ELSI**

  Existing guidelines can provide helpful direction for national governments and regulatory bodies, who can then adapt them to their local contexts. Creating national standards is therefore the first critical step

Health Policy and the Ethical, Legal and Social Issues (ELSI) in Genomics

World Health Organization

- In its 2002 report on Genomics and World Health, WHO's Advisory Committee on Health Research summarizes these policy concerns in its recommendations:

- "WHO encourages its Member States to develop **clear and concise ethical frameworks** to guide the conduct of genomics research and its medical application in conjunction with the social, economic and religious context unique to their countries. These frameworks should build from universal codes of practice, which can be created by partnerships and collaborations between countries. Such partnerships will enhance ethical review structures and build bioethics capacity globally. Member States should also facilitate a two-way dialogue between public and policy makers to guide the development of ethical and regulatory systems. In order **to build this capacity**, partnerships between academic, public research institutions and the commercial sector are recommended. Member States should develop sufficient numbers of clinicians trained in the field of clinical genetic services and implement educational programmes to raise awareness of genetics among the public."

Your gateway to trustworthy information on public health

PUBLIC HEALTH

- **Project PHGEN II**

- A genome is both the comprehensive blueprint of the individual organism and the entirety of an organism's hereditary information. In other words, it is an inbuilt information system in the human body and plays a key role in the understanding of any disease, including hereditary ones.

- Personalised medicine can offer tremendous opportunities for better care. For example, if it is able to target the right patient for certain medications, side effects can be reduced, thus avoiding much suffering and in addition waste of money. In other words, the right diagnosis and therapy at the right time for the right patient.

Your gateway to trustworthy information on public health

PUBLIC HEALTH

- **Guidelines published**
- The PHGEN II's 'European best practice guidelines for quality assurance, provision and use of genome-based information and technologies' were officially endorsed as the 'Declaration of Rome 2012' by all European countries as well as European key institutions and organisations such as the European Medicines Agency (EMA).

- **A brief summary of what the guidelines cover:**
- **Research** – Promote funding for research to produce neutral and trustworthy information.
- **Health monitoring** – Develop prospective surveillance systems for personal health data.
- **Diagnosis and investigation** – Better diagnostics to identify which information is relevant to an individual.
- **Information, education, empowerment** – Promote health literacy amongst all stakeholders, to enable citizens (including health professionals) to access, understand, appraise and apply information for the benefit of individual citizens and their communities.
- **Policy development –** The guidelines will assist all EU countries with evidence-based guidance on the timely and responsible integration of genome-based information and technologies into healthcare systems for the benefit of the populations' health.

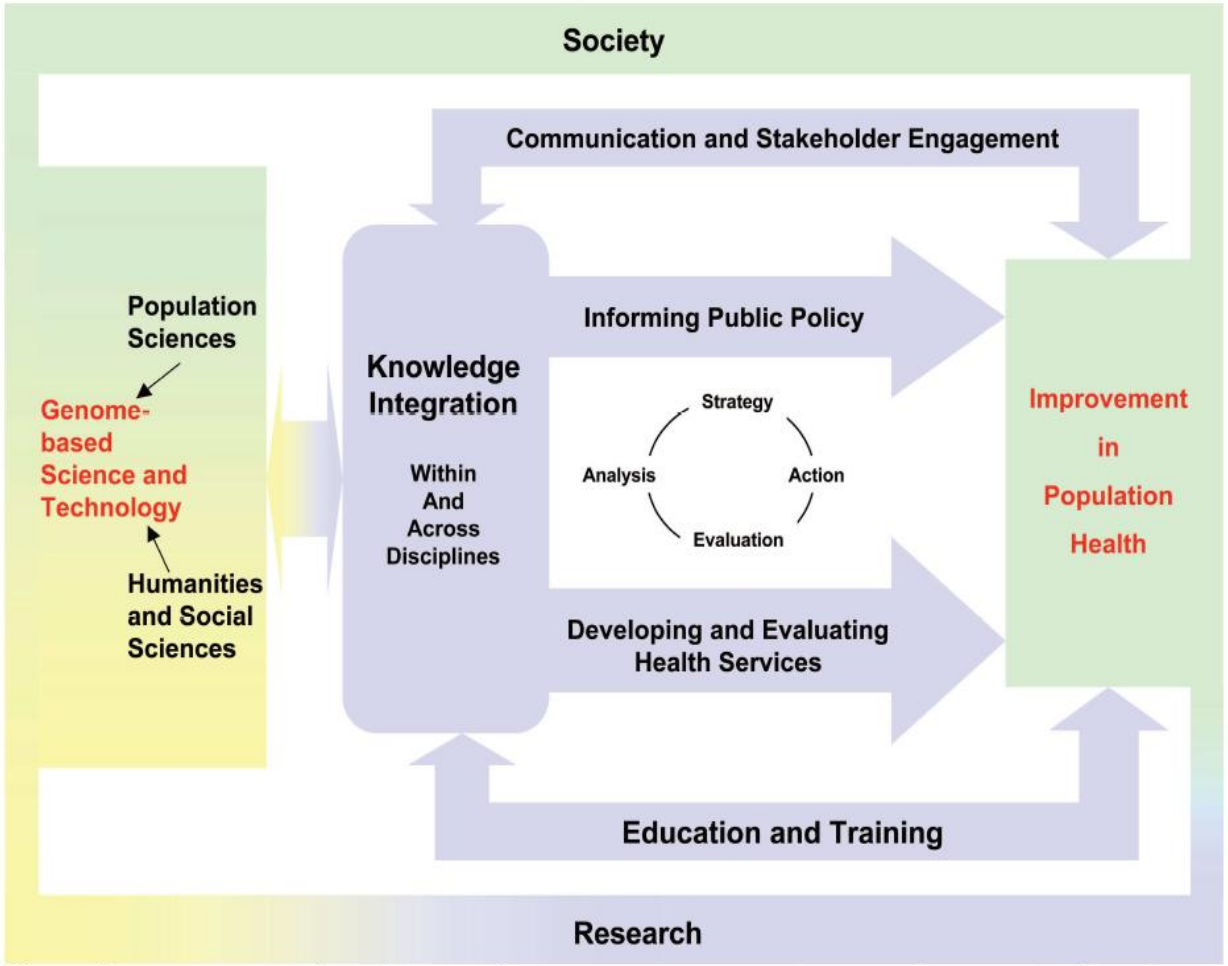


Figure 1 Components of the Public Health Genomics enterprise (Source: Burke W et al. The path from genome-based research to population health: Development of an international public health genomics network. Genomics in Medicine, 2006. 8(7):451-458)

- **The legal discourse** in Public Health Genomics differs from the legal discourse in human genetics as it tries to set up an integrated approach towards both modifiable and non-modifiable health risks. Therefore Public Health Genomics focuses on the legal environment of common disorders with a low genetic risk, yet it must not neglect the needs of underserved patient groups in the field of orphan diseases.
- Health regulations require a solid evidence base; the legal discourse must be provided with this evidence by knowledge generating professions as it can only provide stakeholders with a secondary analysis of scientific findings.
- The "health in all policies" approach offers the opportunity to strive, in the long run, for a consistent and coherent health regulation in fields other than traditional health law.
- Public Health Genomics Law also needs to focus on health systems regulation and medical law. The legally relevant interfaces of traditional health regulation and new concepts like "health in all policies" have not yet been fully explored.
- Law can serve as a tool and a platform for reasoning as it strives to integrate scientific knowledge, ethical and legal principles as well as modes of regulation. If the evidence is rightfully transposed into regulations, law is equipped to reach a concordance amongst the individual and collective rights at stake.
- Health regulation is a multi layer enterprise with a wide range of regulatory bodies, different modes/models of regulation applied. While some stakeholders will follow a certain professional or patient perspective, democratically legitimised regulators must aim to integrate and balance individual as well as collective rights and duties of professions and citizen.

European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome based Information and Technologies: the 2012 Declaration of Rome

- Genomics is a highly dynamic field and, as such, represents a moving target for public health. Public health is shifting from a focus on the population towards an emphasis of the individual as a means of supporting the well being of the population. In particular, we are entering the era of predictive, personalised, preemptive and participatory (P4) medicine supported by advanced technological infrastructure. These changes represent a paradigm shift in our approach to healthcare and will go hand-in-hand with a major reclassification of diseases.

- The challenge now is to understand how all of these changes will impact public health and how to ensure that they are translated effectively into benefits for individual citizens and society as a whole. Thus, there is a need to develop guidelines aiming not to close doors. Instead, the goal is to create a vision that allows for flexibility and adaptability in their implementation in order to have a maximum impact on health, the healthcare infrastructure, health technologies and economic growth in the health sector.

Angela Brand * and Jonathan A. Lal for the Public Health Genomics European Network (PHGEN II)

European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome based Information and Technologies: the 2012 Declaration of Rome

Declaration of Rome – 19 April 2012

Figure 1 Public health trias/public health wheel (Institute of Medicine, 1988).

Angela Brand * and Jonathan A. Lal for the Public Health Genomics European Network (PHGEN II)

European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome based Information and Technologies: the 2012 Declaration of Rome

- **Enforce laws**

- Use the dynamics of GBIT as a unique opportunity to frame and enforce laws and regulations proactively;

- Ensure that GBIT and their use in public health meet applicable legal standards. In this regard, the privacy and security of personal health information should be safeguarded in accordance with applicable law;

- Work to correct perceptions of genetic exceptionalism and promote laws and regulations that address personal health information as a whole;

- Use modern ICT to protect personal health data;

Angela Brand * and Jonathan A. Lal for the Public Health Genomics European Network (PHGEN II)

European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome based Information and Technologies: the 2012 Declaration of Rome

- **Enforce laws**

- Assess existing legal frameworks applicable to public health genomics on a regular basis and adapt them when necessary to ensure the consistency and visibility of enforceable rules on the use of GBIT in different contexts;

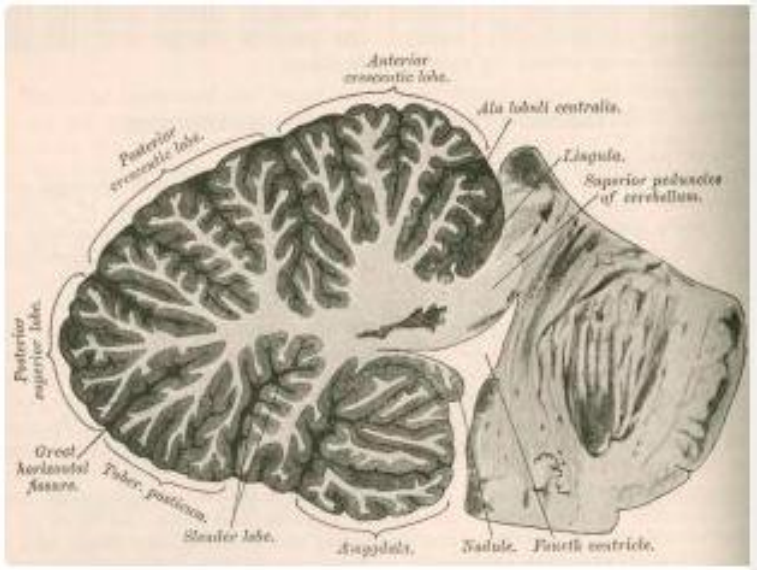
- Support implementation of the EU Data Protection Directive amongst European Member States to allow the use of personal health data for personal and public health purposes and to improve the outcome of health interventions.

- **Link to/provide care**

- Reduce inequalities in health through sustainable access to and use of GBIT.

Brain Waves 4: Neuroscience and the law

- Neuroscientists seek to determine how brain function affects behaviour, and the law is concerned with regulating behaviour. It is therefore likely that developments in neuroscience will increasingly be brought to bear on the law. This report sets out some of the areas where neuroscience might be of relevance, along with some of the limits to its application. Specific issues discussed include risk assessment in probation and parole decisions; detecting deception; assessing memory; understanding pain; and Non-Accidental Head Injury NAHI).



THE ROYAL SOCIETY

Brain Waves 4: Neuroscience and the law

Key messages of the report include:

There is a big gap between research conducted by neuroscientists and the realities of the day to day work of the justice system. There is currently no forum in the UK for bringing together neuroscientists and legal professionals to explore areas of mutual interest.

It is important that professionals at all stages of the legal system who might encounter neuroscience understand some of the key principles on which it is based; the limitations to what studies can tell us; and some of the generic challenges of its application. Lawyers and judges in England and Wales often have no training in scientific principles. Undergraduates in neuroscience are not necessarily taught about the societal implications of the discipline.

Almost all neuroscientific research in the UK is related to health. However, findings from research **have wider policy implications**. Important insights for the law would be provided by further research into areas including neuropathology studies to characterise Non-Accidental Head Injury (NAHI); and studies into the relative efficacy of different models of risk assessment in the context of probation, and a possible role for neuroscience to be used in combination with existing approaches.

Brain Waves Module 3: Neuroscience, conflict and security

DARPA is currently funding the following programmes:

- Training and Human Effectiveness: Research efforts are under way to discover and apply advances in neuroscience to improve information processing under stress and to increase the rate and quality of learning.

- Enabling Stress Resistance: The program strives to develop and implement cognitive, behavioral, and pharmacological interventions that will prevent the deleterious effects of stress on warfighters.

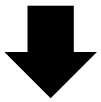
- Neurotechnology for Intelligence Analysts (NIA): NIA seeks to identify robust brain signals that can be recorded in an operational environment and process these in real-time to select images that merit further review. The program aims to apply these triage methods to static, broad area, and video imagery.

Brain Waves Module 3: Neuroscience, conflict and security

Neuroscience was recently identified by the UK Ministry of Defence (MOD) as an important rapidly developing field with potential relevance to defence and security:

Knowledge about the human brain is rapidly increasing including: understanding pharmacological effects to enhance performance and using brain activity to control systems. As such it offers significant opportunities for defence and security in understanding adversaries' behaviours, training and improving human performance on the battlefield or in human-based security situations such as guarding or search

Blindness Fight



Strategic Thinking

coimbra genomics

genetically informed medicine

A *Coimbra Genomics* desenvolve novas ferramentas que permitirão a qualquer médico consultar a sequência genómica completa dos seus doentes e retirar informação específica, relevante para prescrição, rastreio, prognóstico e diagnóstico.

Projeto 1: **software para apoio à decisão clínica baseado na sequenciação genómica**

Projeto 2 (I&D): **caracterização genómica do cancro do estômago**

Consórcio-Parceiros institucionais:

CHUC CENTRO HOSPITALAR E UNIVERSITÁRIO DE COIMBRA

CRITICAL SOFTWARE

biocant PARK PORTUGUESE BIOTECHNOLOGY PARK

Centro de Direito Biomédico

华大科技 BGI tech

25 ANOS A DESCOBRIR O CANCRO ipatimup

Investidores:

PORTUGAL VENTURES Growing.Global

CRITICAL ventures

Beijing Genomics Institute
A maior empresa de genómica do mundo

Thank you for your attention