

Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 16 Number 4, 2010

European Union law and health

NHS engagement with
European affairs

Institutional overview
on EU law and the
health care sector



HTA and implantable medical devices in Greece, Poland and Serbia • Croatia: pharmaceutical reform
Netherlands: managed competition • Spain: pharmaceutical consumption

COMMENT

EU law and health

Recently, the European Court of Justice has provided Opinions on a range of disputes related to health, from orphan drug designation to reimbursement of health care abroad. Despite European Union Member States having the authority to make their own health service decisions, they must still implement European Directives into national law or risk being held to task.

In the first section of this issue, Rachel Irwin reports from a 2010 meeting organised by LSE Health and the National Health Service (NHS) Confederation on European Union Law and Health. She notes interestingly that non health-specific aspects of EU law are inclined to have the largest impact on health and health care. Later, she poses two challenges for health care providers and policy-makers: to understand how EU law affects the health system and to understand how to fully engage with it.

Following on, the institutional context of EU law and health is examined by Tamara Hervey. Among other things, she discusses the supremacy of EU law (how it trumps national law) and the direct effect (how individuals can uphold the rights conferred from it in national courts). Also, Elisabetta Zanon points to the NHS European Office, established in 2007, to represent the various NHS stakeholders in European debates and also to monitor relevant developments. She explores the many challenges that the NHS will face in implementing the provisions of the new European Directive on patients' rights in cross-border health care.

Moving on to the assessment and uptake of interventions within the health sector, Miro Palat, President of the Czech medical device industry association (CzechMed), argues for broadening the scope of health technology assessment (HTA) to include all interventions used in prevention and treatment. Next, snapshots are provided for three countries – Greece, Poland and Serbia – which specifically address HTA for implantable medical devices. For all countries, the authors present an overview of the health care system, pathways for the reimbursement of medical devices and offer prospects for the future.

In our Health Policy Developments section, we provide a couple of articles on pharmaceuticals including recent policy reforms in Croatia and an analysis of pharmaceutical consumption in Spain. On health systems, the challenges presented by the introduction of managed competition in the Netherlands are discussed by van Ginneken and colleagues, while van den Berg and colleagues identify the tradeoffs that come to light when assessing the performance of the system.

Sherry Merkur *Editor*
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Lucia Kossarova *Assistant Editor*
Azusa Sato *Assistant Editor*

Eurohealth

LSE Health, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK
fax: +44 (0)20 7955 6090
<http://www.lse.ac.uk/collections/LSEHealth>

Editorial Team

EDITORS:

David McDaïd: +44 (0)20 7955 6381
email: d.mcdaïd@lse.ac.uk
Sherry Merkur: +44 (0)20 7955 6194
email: s.m.merkur@lse.ac.uk

FOUNDING EDITOR:

Elias Mossialos: +44 (0)20 7955 7564
email: e.a.mossialos@lse.ac.uk

DEPUTY EDITOR:

Philipa Mladovsky: +44 (0)20 7955 7298

ASSISTANT EDITORS:

Azusa Sato +44 (0)20 7955 6476
email: a.Sato@lse.ac.uk
Lucia Kossarova +44 (0)20 7107 5306
email: l.kossarova@lse.ac.uk

EDITORIAL BOARD:

Reinhard Busse, Josep Figueras, Walter Holland, Julian Le Grand, Martin McKee, Elias Mossialos

SENIOR EDITORIAL ADVISER:

Paul Belcher: +44 (0)7970 098 940
email: pbelcher@euhealth.org

DESIGN EDITOR:

Sarah Moncrieff: +44 (0)20 7834 3444
email: sarah@westminstereuropean.co.uk

SUBSCRIPTIONS MANAGER

Champa Heidbrink: +44 (0)20 7955 6840
email: eurohealth@lse.ac.uk

Advisory Board

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Published by LSE Health and the European Observatory on Health Systems and Policies, with the financial support of Merck & Co and the European Observatory on Health Systems and Policies.

Eurohealth is a quarterly publication that provides a forum for researchers, experts and policymakers to express their views on health policy issues and so contribute to a constructive debate on health policy in Europe.

The views expressed in *Eurohealth* are those of the authors alone and not necessarily those of LSE Health, Merck & Co. or the European Observatory on Health Systems and Policies.

The European Observatory on Health Systems and Policies is a partnership between the World Health Organization Regional Office for Europe, the Governments of Belgium, Finland, Ireland, the Netherlands, Norway, Slovenia, Spain, Sweden and the Veneto Region of Italy, the European Commission, the European Investment Bank, the World Bank, UNCAM (French National Union of Health Insurance Funds), the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

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Design and Production: Westminster European
Printing: Optichrome Ltd

ISSN 1356-1030

LSE Health

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Predrag Djukić is Consultant, Project Coordination Unit, Ministry of Health, Belgrade, Serbia.

Richard Heijink is Researcher, University of Tilburg and the National Institute for Public Health and the Environment (RIVM), the Netherlands.

Cristina Hernández-Quevedo is Research Officer, European Observatory on Health Systems and Policies, LSE Health, London School of Economics and Political Science, UK.

Tamara Hervey is Jean Monnet Professor of European Union Law, School of Law, University of Sheffield, UK.

Rachel Irwin is Research Assistant, LSE Health, London School of Economics and Political Science, UK.

Dolores Jiménez Rubio is Associate Professor, Department of Applied Economics, University of Granada, Spain.

Madelon Kroneman is Senior Researcher, Netherlands Institute for Health Services Research, the Netherlands.

Nikos Maniadakis is Professor and Department Director, Health Services Organisation and Management, National School of Public Health, Greece.

Maciej Nowicki is President, HTA Audit Nowicki Landa Partners, Poland.

Miro Palat is President of CzechMed, Prague, Czech Republic.

John Relakis is Doctoral Researcher – Research Fellow, Health Services Organisation and Management, National School of Public Health, Greece.

Willemijn Schäfer is Researcher, Netherlands Institute for Health Services Research, the Netherlands.

Tihomir Strizrep is Managing Director, Croatian Institute for Health Insurance, Zagreb, Croatia.

Michael van den Berg is Researcher, RIVM, the Netherlands.

Ewout van Ginneken is Senior Researcher, Department of Health Care Management, Berlin University of Technology, Germany.

Harry Verkleij is Researcher, RIVM, the Netherlands.

Luka Voncina is Head of Department for Drugs and Medical Products, Croatian Institute for Health Insurance, Zagreb, Croatia.

Gert Westert is Head of IQ-healthcare and Professor at Radboud University, Nijmegen, the Netherlands.

Elisabetta Zanon is Director of the NHS European Office, Brussels, Belgium.

Laurens Zwakhals is Researcher, RIVM, the Netherlands.

EU law and health: an introduction

Rachel Irwin

Health is never just about health

Health is never about just about health. Addressing nutrition-related chronic disease involves transport policy, food labelling and advertising, agriculture and education policies and always the finance ministry to look at the financial implications of these other policies. Similarly, in on-going debates on access to medications, policy-makers are constantly balancing trade and health policies.

The role of the European Union in health provides another clear example of the intersectorality of health policy. Recognising the need for intersectoral action and the impact of non-health policies on health, the Finnish government started the Health in All Policies initiative during their presidency in 2006. After all Article 152 of the Treaty of Amsterdam states that “a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.” Good health and well-being in the population contributes to prosperity, solidarity, safety and social cohesion. Good health also helps in the continuation of what many deem to be core European social values.

Direct and indirect impacts

However, despite these provisions, the aspects of EU law which have had the greatest impact on health and health care are not health-specific. Under the principle of subsidiarity individual Member States are responsible for the delivery of health care and the design of health care systems. The EU only becomes involved where cooperative action can be more effective, or in the case of specific cross-border issues, including international health threats, such as pandemics or bioterrorism. Specific areas in which there are relevant EU directives include food safety and quality standards for blood, organs and

tissue. However, in many ways both the World Health Organization’s International Health Regulations and the Framework Convention on Tobacco Control that supersede European law, have removed some, albeit not all, of the need for European law in some areas.

The internal market ensures the free movement of goods, services and people, with consumer protection. The EU’s impact on health comes primarily under legislation to ensure these freedoms: mobility of workers (including health care workers) and mobility of people (and disagreements over cross-border health care). Labour directives on the length of working time and worker safety and procurement legislation apply to many health care providers in the same way they apply to other sectors.

That European law about health is not really about health is partly by design. The ‘European Experiment’ began as an economic and trade union – not a union for social protection. This history has consequences to this very day. For instance, the role of the Directorate-General for Health and Consumers is relatively weak in comparison to the other Directorate-Generals. Although it oversees the work of the European Food Safety Agency, most of the day-to-day work on food safety lies within the Agency. Similarly, the European Centre for Disease Control is in no way comparable to its US counterpart. One of the more influential European health bodies is the European Medicines Agency, but impetus here lies in upholding the free movement of goods.

Arguably the biggest impact the EU has on health directly is in its funding. From 2008–2013, the 7th Framework Programme for Research is giving out €53 billion to projects on basic research, as well as for health and some public health research. The current Community Health Programme (2008–2013) is funding €321 million of health activities and programmes, while other health-related work is funded by the Consumer Programme and the Fundamental Rights

and Justice Programmes.

Although not hard law, the EU also runs strategies that can have influence, both within member states, as well as internationally. For example, the European Community Health Indicators (ECHI) project aimed to standardise health data collected across member states. The European Platform on Diet, Physical Activity and Health brought together policy-makers, consumer groups and private industry to address obesity and other nutrition-related non-communicable disease. Regardless of one’s views on the usefulness or legitimacy of public-private-government partnerships, this approach is viewed globally by many as a model for action. Similarly, out of the Strategy on Nutrition, Overweight and Obesity emerged directives on food labelling, nutrition claims and limits on the advertising of sugary food to children. What we think of as health issues tend to be handled through ‘soft’ law and initiatives, while ‘hard’ law impacts upon health and health care in more unexpected ways. Both have their place.

Two articles in this issue of *Eurohealth* examine some aspects of the impact of EU law upon health and health care. Both are based on presentations at a seminar jointly organised by LSE Health and the National Health Service (NHS) Confederation and funded by the Higher Education Innovation Fund of the UK’s Department for Business, Skills and Innovation. The seminar took place at the Confederation’s Annual Conference in Liverpool in June 2010. Its overall theme was to examine how EU directives, regulations and other activities impact on the range of NHS activities and also to understand how NHS organisations – and by extension health care organisations in other member states – can engage more fully with European policy-makers.

Tamara Hervey from the University of Sheffield provides a general overview of EU law and competencies and how these are integrated and enforced within national policies. She focuses on laws upholding the

Rachel Irwin is Research Assistant, LSE Health, London School of Economics and Political Science, UK.

Email: r.irwin@lse.ac.uk

free movement of people, goods and services and competition law, looking at how these can affect health care practice in member states. Meantime, the NHS European Office's Elisabetta Zanon discusses what national health organisations need to know about EU law and also how they can engage with policy-makers and other actors on the European level. The latter is needed not only to ensure one's organisation is following the rules, but also to facilitate the exchange of knowledge and best practice and to influence the policy process through formal and informal channels.

Free movement, competition and procurement

In addition to these articles, another important perspective at the seminar was provided by Leigh Hancher from the international law firm Allen and Overy's Amsterdam office. She examined rules governing free movement, competition and procurement and how these affect individual health systems. Free movement rules apply to national governments and to associations that are given policy tasks, such as professional associations for pharmacists or physicians. These include patient mobility and patient rights. The European Court of Justice interprets these rules very widely; in general, states are free to regulate themselves, but must take free movement as the starting point and then justify any limitations on this. For example, states may argue that too many providers will create excess demand. In her presentation Hancher cited the Perez case in which the licensing law in Andalucia on establishing a pharmacy limited the number of pharmacies per person. However it was ruled by the European Court that if a national from another state was able to set up a pharmacy, so could someone from within Spain. That is, the EU law necessitates freedom of mobility both across and within member states.

Competition and state aid rules apply to firms/undertakings. In general, an undertaking is an entity which provides economic services; typically it does not cover health bodies but this is not always the case. Similarly, competition rules can apply to member states in certain circumstances, even though they are not undertakings. These are 'fuzzy' categories and an entity – such as a health provider – can be an undertaking in some of its activities and not in others. Competition rules exist to combat cartels and abuses of dominant positions, for example pharma-

ceutical companies which register their products strategically in different markets to extend the lifetime of their patents. State aid rules only apply to undertakings and in situations when public and private providers are competing, the private sector may complain on how the public sector is operating, as the public sector is generally immune from fines and other types of regulation.

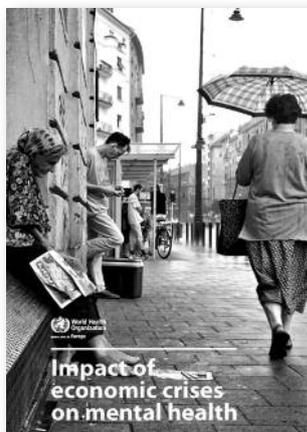
With regard to procurement Hancher also noted that the distinction between undertakings and non-undertakings is particularly important because these directives only apply to not-for-profit organisations because competition law in addressing the same issues covers undertakings. However, the logic behind procurement law is to promote free movement. Thus, not-for-profit entities must also advertise properly and allow undertakings from abroad to tender. Other specific policies that will affect national health care providers include new climate change legislation on energy savings, which also affect procurement strategies.

Conclusions

As all presentations at the seminar, and both detailed articles here explain, overall EU law is a piecemeal amalgamation of directives, regulations and European Court of Justice rulings. It involves input from the European Parliament, European Commission and Council of the European Union, as well as external pressure from the Council of Europe and interest groups. The challenge for national health care providers and policy-makers is two-fold: firstly, to understand how this system of law and policy-making affects the work they do and secondly, to understand how to fully engage with it, as increased EU engagement also provides ample opportunities for funding and cross-border knowledge exchange.

A podcast and presentations from the session at the NHS Confederation conference in Liverpool are available at <http://www2.lse.ac.uk/LSEHealthAndSocialCare/LSEHealth/eventsAndSeminars/EU%20Law.aspx>

Impact of economic crises on mental health



Kristian Wahlbeck, Peter Anderson, Sanjay Basu, David McDaid, David Stuckler

Copenhagen: World Health Organization Regional Office for Europe, 2011

This new report from the World Health Organization aims to present current knowledge on how economic downturns affect population mental health and outlines some of the benefits of action that could be implemented to reduce the harmful effects on mental health of the current economic crisis.

The economic crisis is expected to produce secondary mental health effects that may increase suicide and alcohol-related death rates. However, the mental health effects of the economic crisis can be offset by social welfare and other policy measures, for example:

- Active labour market programmes aimed at helping people retain or regain jobs counteract the mental health effects of the economic crisis.
- Family support programmes contribute to counteracting the mental health effects of the crisis.
- Increasing alcohol prices and restricting alcohol availability reduce the harmful effects on mental health and save lives.
- Debt relief programmes will help to reduce the mental health effects of the economic crisis.
- Accessible and responsive primary care services support people at risk and prevent adverse mental health effects.

<http://www.euro.who.int/en/what-we-do/health-topics/diseases-and-conditions/mental-health/publications/2012/impact-of-economic-crises-on-mental-health>

The NHS' engagement with European affairs

Elisabetta Zanon

Summary: EU policy and legislation are having an increasing impact on NHS organisations, not only as providers and commissioners of health care, but also as employers and as businesses. The NHS European Office was established in 2007 to engage with EU developments that impact on the NHS by contributing NHS views and frontline expertise to EU decision-makers. The article highlights some of the impacts of EU policy and legislation on the NHS, and sets out the role now being played by the NHS European Office.

Key words: NHS, European legislation, health policy

EU policy and legislation are having an increasing impact on NHS organisations, not only as providers and commissioners of health care, but also as employers and as businesses. EU laws carry legal force in the UK and in recent years the NHS has had to implement and comply with legislation coming from Brussels in areas as diverse as the mobility of health professionals and patients, working time, public procurement, waste management, energy efficiency and many more. By and large these have been new challenges for the NHS; for managers, clinicians and policy-makers alike.

This is why the NHS European Office was established in 2007 as a nationwide resource to monitor EU developments that impact on the NHS and to contribute NHS views and frontline expertise to EU decision-makers. Its aim was to act as one focal point through which EU institutions could easily access views, advice and expertise from the NHS.

A European Health Service?

When the Office was established was important. Recent European Court rulings had shown that the debate had moved on from *whether* EU Internal Market rules applied to the NHS as to *how* they apply. For the first time the European Commission was planning legislation

specifically in the area of health care services. This led to a proposal for an EU Directive on patients' rights in cross-border health care in summer 2008, with potentially far reaching implications for NHS organisations.

Some provisions in the original proposal gave rise to the potential for both confusion and conflict between the scope of the legislation and the national government's responsibilities for the organisation, management and funding of health care. On entitlements, for example, whilst the principle of patients having the right to access in other EU Member States the same health care that they are entitled to receive under the NHS sounded simple, the NHS does not have a defined list of care to which patients are automatically entitled. Likewise, a key difference between patient choice in England and cross-border health care is that domestically patient choice is limited to providers contracted to the NHS, rather than any health care provider.¹ The Directive on cross-border health care was finally agreed by both the European Parliament and the Council of Ministers in early 2011 after more than two years of difficult negotiations. Member States will now have until mid 2013 to transpose it into national law.²

Whilst the Directive on the mobility of patients has only just been agreed, legislation on the mobility of professionals was passed in 2005. The Directive on the Mutual Recognition of Professional Qualifications was seen as a key tool in helping

to abolish obstacles to the free movement of workers across and within the EU, of which health care professionals formed a key group.

Five years on, this issue has become highly controversial for our health service; with regulators and the UK Parliament's Health Select Committee calling for enhanced language and competence checks for professionals coming from other EU Member States, as well as for a more systematic exchange of information between regulators in EU countries on disciplinary actions against professionals.

Beside internal market rules, the EU's labour law has also had important implications for the NHS. This includes, in particular, the European Working Time Directive, which has applied to the vast majority of NHS employees since 1998, but whose provisions were phased-in gradually for doctors in training, with their maximum weekly average working hours reduced eventually to 48 hours from August 2009. Whilst the NHS had to adapt and adjust to these rules, this has not been the end of the matter. Subsequent cases brought before the European Court of Justice by a Spanish medical union and a German doctor led to rulings that on-call time, when a doctor is obliged to be resident in a hospital or health centre, counts as working time and that compensatory rest for missed rest must be taken immediately after the end of the working period, rather than aggregated and taken at a later time.

Elisabetta Zanon is Director of the NHS European Office, Brussels.
 Email: Elisabetta.Zanon@nhsconfed.org

EU developments in many other policy areas such as environment and energy performance, innovation and research, commercial transactions or state subsidies also permeate to the heart of the NHS.

The role of the NHS European Office

The policy areas may differ but the role of the NHS European Office in responding to EU developments is the same: to represent the interest of the NHS. Whether a proposal is in the early planning stages, being voted on in the European Parliament or about to be implemented into national law, the Office has a role. By contributing views and expertise at the earliest possible opportunity, we can shape the direction of a new or revised piece of legislation and ensure that EU decision-makers are aware of the potential impact of EU proposals on frontline services. Once legislation is agreed at European level, our role then is to assist NHS organisations to prepare for implementation.

Of course, the applicability of EU law to the NHS is not solely dependent on the passing of new legislation in Brussels. The NHS should be aware of the boundaries and reach of European law when it itself is organising how it provides services to its patients. This is particularly relevant in relation to the EU's powerful and complex set of competition rules, which govern trading market structures and behaviour in order to uphold 'fair play' within the EU's internal market.

NHS activity has traditionally been considered as fulfilling a social function, and therefore not subject to the EU competition rules. However, as the NHS further develops the way it delivers health care to incorporate patient choice and a wider role for independent health care providers, the extent to which it could be challenged under these rules becomes less clear.

The NHS European Office reviewed past European Court rulings to understand the legal framework and the range of potential implications for the NHS and provided briefings and advice to NHS organisations in this area.³ In light of the proposed programme of NHS reforms in England put forward by the UK Government recently, there is uncertainty about how EU competition law will affect relationships within and across the NHS in future years. What is certain, however, is that it is important that there is an informed NHS, aware of what EU competition rules may mean for its many parts as they develop the way they provide and structure their services.

Challenges, but also opportunities

In parallel to this work, we also provide information and advice to NHS managers and clinicians on opportunities emerging from different EU programmes and initiatives. Particularly in the current economic climate, NHS organisations should be aware of funding opportunities available at EU level but also be looking at opportunities to cooperate with our counterparts across Europe and learn from their experiences and good practice.

The benefits of participating in European-funded projects are wide ranging.⁴ They can complement local NHS initiatives with European Commission matched funding; improve service delivery through information-sharing and the exchange of good practice with European partners; benchmark and compare NHS organisational data with partners from other EU Member States; and showcase an organisation's achievements in a specific field or topic to international colleagues.

The NHS European Office is actively involved in a number of European partner organisations, which facilitate collaboration between NHS representatives and their counterparts across the EU in different areas. For example, the annual Exchange Programme run by the European Hospital and Healthcare Federation, has allowed dozens of NHS managers to 'experience' and learn from other health care systems in Europe.

Looking ahead, the NHS European Office will continue to feed NHS expertise to EU decision-makers, notably in view of the forthcoming revisions of EU Directives on working time, professional qualifications,⁵ public procurement,⁶ clinical trials and medical devices. We will also build on our successful European partnerships and continue to facilitate NHS participation in EU projects and joint initiatives for the devel-

opment of responses to the common challenges lying ahead of Europe's health care systems and organisations.

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The NHS European Office is part of the NHS Confederation and is funded by the Strategic Health Authorities in England. For more detailed information on the work of the Office, visit www.nhsconfed.org/europe

New HiT on United Kingdom/England



The Health System in Transition report on England is the most comprehensive overview of the health and social care system in England produced this century. It provides a wealth of detail about all aspects of the health care system, as well as developments in the health of the population.

Drawing on a detailed analysis of the changes to health care introduced by a series of Labour governments between 1997 and 2010, the report's author Seán Boyle gives his assessment of the impact that these changes have had in terms of access, equity, efficiency, quality and health outcomes. This definitive report on one of Europe's largest and complex health care systems will be a valuable resource for policy analysts and health system researchers for years to come.

Available online in March 2011 at www.healthobservatory.eu

The impacts of European Union law on the health care sector: Institutional overview

Tamara Hervey

Summary: The logic and structures of European Union (EU) law are not the logic and structures of health care. The institutional structures that support law and policy-making at EU level are often unsupportive of (or even unaware of) health care concerns. The special nature of EU law means it has much more significance in practice for national actors than 'ordinary' international law. Sometimes, that significance can have – or threaten to have – challenging effects for national health care systems. Nevertheless, the EU also offers potential benefits to health care actors across the Member States.

Keywords: health care, law, European Union

There is an increasing interest in the impacts of European Union (EU) law on the health care sector. Focusing on institutional matters in this respect, this article will consider three questions: What is special about EU law? What challenges and opportunities for those in the health care sector therefore arise? What kinds of questions should those involved in managing the health care sector therefore be asking themselves?

To understand the answers to these questions, we need to understand the limited competence of the EU in the field of health care; EU law making processes (both legislative and judicial); the structure of EU law, and in particular the centrality of 'internal market' law; and the concepts of supremacy and 'direct effect' or individual enforceability of EU law. We also need to consider the policy responses that the EU has adopted, and may adopt, to 'add value' to health care systems using EU institutions and processes.

EU law making and the competence of the EU

The EU is not a state. Its institutions may not make any law or adopt any policy they

wish. They may only act within the powers given to the EU by its Member States.¹ This is the idea of limited competences. It is an important feature of EU law and policy-making, for it both constrains the EU and also means that the EU sometimes uses its powers for unexpected purposes. For instance, who would have thought that the power to create a single market within the EU (an area where goods and services move freely) would give the power to adopt a Directive (an EU law) that forbids the advertising of tobacco on television;² or EU law that covers the social security entitlements of people who work in another EU country;³ or a Directive that forbids direct to consumer advertising of prescription-only pharmaceuticals?⁴

If the EU has a law-making power, the way that it can exercise that power is through a law-making process that involves three key institutions. The European Commission makes the original proposal. The European Parliament and the Council must then agree to it. But the European Commission does not have a specific 'health care ministry', and often the national ministers in Council that are present or involved in adopting a piece of EU law with effects for the health care sector are not ministers of health. The EU law-making process can therefore inadvertently fail to consider important ramifications for health care systems.

The structure of EU law

The way that EU law has developed is a product of the history of the EU. Historically, the *raison d'être* of the EU was to bring together the economies of the Member States (the countries that are part of the EU) – especially their coal and steel industries, which were the engines of warfare – in such a way as to prevent future wars in Europe. Integrated economies would mean that war was a practical impossibility. Also, the idea was to capitalise on the economies of scale that are associated with having large markets for goods and services.

Because of its history, EU law is structured around the key ideas of free movement and fair competition within a single European market. The law plays a crucial role in the process of integrating Europe's economies. EU free movement law and EU competition law form the bedrock of EU law.

EU free movement law applies essentially to the acts of 'states' or public authorities. It prohibits 'restrictions' on the free movement of goods and services within the EU's internal market. It also includes public procurement law, to make sure that public contracts can be won by providers from anywhere in the EU, not simply given to local firms. Most EU public procurement law does not apply to the health care sector, but some of it does. EU free movement law does not simply contain

Tamara Hervey is Jean Monnet Professor of European Union Law, School of Law, University of Sheffield, UK.

Email: t.hervey@sheffield.ac.uk

unfettered rights to free movement – some restrictions are justified, for ‘objective public interests’, such as protecting consumers; or ensuring sufficient and permanent access to a balanced range of high quality hospital services in the Member State; or maintaining the financial viability of a health care system.^{5,6}

So those within the health care sector need to ask questions about whether their policies or practices restrict free movement in the internal market, and if so, whether they comply with EU law.

EU competition law applies essentially to private actors – to ‘undertakings’ or firms operating within the EU. Most EU competition law therefore does not apply to the public health care sector. But there are exceptional cases where it does – if a part of the health care sector is acting as an ‘undertaking’, i.e., if it is engaged in an economic activity.⁷ Again, exceptions to EU competition law apply to public bodies, if they need to have a special monopolist position in the market, in order to provide a public service of special interest, such as health care.

So those within the health care sector need to ask questions about whether they are acting as an undertaking, and if so, if they are complying with EU law.

In addition to free movement and fair competition, even from the beginning, the EU had the power to adopt law and policy to soften or make fairer the impacts of creating a single market. For instance, to make sure that workers did not lose out in the process, EU law covers health and safety in the workplace. To make sure that consumers are not harmed by products or services circulating in the internal market, EU law sets safety and consumer protection standards. To make the internal market run smoothly, EU law governs commercial contracts. For instance, the system of medicines authorisation in Europe is a product of EU law. To make sure that the single market does not adversely affect the environment, a large body of EU environmental law covers matters such as air and water quality and the disposal of waste. To protect patients, EU law covers blood safety and regulates the use of human tissue and organs.⁸

Those within the health care sector therefore need to be aware of a wide range of substantive rules of EU law that apply to them as employers, as contractors, as producers of waste, as providers of services and so on. Specific details vary, so of course

specific advice should always be sought.

The supremacy of EU law

Unlike ordinary international law, EU law has a special legal status in the legal systems of its Member States. This legal status was not explicitly agreed by the Member States, but has been ‘created’ by the European Court of Justice (ECJ). However, it has been accepted by national courts. This is the idea of supremacy of EU law – it means that EU law applies over any contradictory national law, and national law that contradicts EU law must be ‘disapplied’.⁹ The consequence of supremacy of EU law is that national parliaments cannot legislate their way out of EU law that they do not support. Nor can, for instance, self-regulating professional associations do so. They must comply with EU law.

The consequence of non-compliance for a state is first political censure and (eventually) being brought before the ECJ. But for public bodies within states, a much more important dynamic is at work. This is known as the ‘direct effect’, or enforceability of EU law.

The enforceability of EU law

Not only is EU law supreme, but it also has another very important feature – it is enforceable by individuals before their national courts. Not all of EU law is enforceable in this way, and not all of it is enforceable in this way against private individuals. But it is enforceable against state bodies, which would include a wide range of public health care institutions within the Member States.¹⁰

The consequence of the ‘direct effect’ of EU law is that a private individual may enforce a right in EU law against their own state, or any part of it, or public body within it, such as national health care bodies. This enforcement happens within national courts.

This is the basis on which the by now infamous patient mobility cases were brought to court.^{5,6,11} Various patients, unhappy with the level of provision in their national health care systems for various reasons – too long a wait; not the treatment that they hoped to get; cheaper treatment available abroad – brought cases in their own national courts, challenging their health authorities’ refusal to authorise them to receive treatment abroad. In some of these cases, the ECJ (which is asked by national courts for its interpretation of EU law in such cases) found that there was an unjustified restriction on free movement,

and so a breach of EU law. The best-known of these cases in the UK is the *Watts* case.¹² The UK has now changed its practice, to comply with EU law on this point, and guidelines for local health commissioners are available. Other cases include a recent decision involving restricted access to university medical training, which was challenged on the basis that it breached EU law allowing citizens of EU states to move freely, including for the purposes of education.¹³

What may turn out to be more significant than individual human beings (patients) relying on EU law in the health care sector is the use of EU law by firms, particularly larger firms, operating in the health care sector, that seek to challenge national policies that impede their marketing or operational strategies. So, for instance, Spanish law on the licensing of pharmacies, which limited the number of pharmacies by population density, has recently been challenged (with partial success) as breaching EU law on freedom of establishment.¹⁴

All of this means that people working in a sector such as the health care sector, which is not structured according to market logic, have to be vigilant in terms of where EU law – which nevertheless has binding force within the Member States of the EU – might interface with their activities.

Policy responses

The EU not only adopts laws to achieve its aims. It also makes use of a wide range of policy instruments. These include EU funding for research. EU research funding is organised into ‘Framework Programmes’ and gives opportunities to conduct collaborative research across borders. Many research projects – for instance, on rare diseases – have been supported by the EU. ‘European Reference Networks’ – groups of health care experts in a particular field – work together, supported by the EU, to share knowledge and expertise in state of the art medical practice. The idea is that the EU can ‘add value’ to activities that would not be so effective if carried out at national level alone. The EU’s public health programmes also provide opportunities for funding for collaborative work in the health field.

There is also the opportunity to feed into the development of ‘best practice’ at EU level. The EU gathers and compares a wide range of health data that can be used to inform decision-making processes at all levels. From this, we can begin to discern

best practice. So, for example, the Council has adopted a recommendation on patient safety, including health care associated infections. For example, the EU has been instrumental in developing the 'European Code Against Cancer', a collection of recommended protocols on cancer screening, as well as best practices for the prevention and treatment of all cancers.^{15,16}

Conclusions

In one sense, there is no EU health care law or policy – there is a patchwork of different laws and policies that apply in the health care sector. It is very difficult to make sense of the patchwork through the lens of health care.¹⁷

European public health care systems are based on the sharing of resources with those in need through taxation and redistribution organised by the state for those within that state – a model of solidarity. Health systems are organised on a national basis, and the benefits for those within each system are achieved, in part, by exclusion of those outside the nation state concerned. By contrast, the EU's internal market law is concerned with abolishing national barriers to the movement of the factors of production. The benefits of internal market law include access to a wider market, with consequent efficiencies and economies of scale, that are implied in removing national laws, administrative practices and other barriers to cross-border trade. In other words, the logic of public health systems is based on protection through exclusion and closure; the logic of internal market law is based on the benefits of inclusion and openness.

This 'clash of logic' explains why the application of EU law within the health care sector is so problematic and challenging. However, harnessing the benefits of collaborating and cooperating at EU level also presents an opportunity for those involved in the health care sector.

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Health systems governance in Europe: the role of European law and policy



Edited by Elias Mossialos, Govin Permanand, Rita Baeten, Tamara Hervey

There is a fundamental contradiction at the core of health policy in the EU that makes it difficult to draw a line between EU and Member State responsibilities. This raises a number of difficult questions for policy makers and practitioners as they struggle to interpret both 'hard' and 'soft' laws at EU and Member State level and to reconcile tensions between economic and social imperatives in health care.

The book addresses these complex questions by combining analysis of the underlying issues with carefully chosen case studies that illustrate how broader principles are played out in practice. Each chapter addresses a topical area in which there is considerable debate and potential uncertainty. The book thus offers a comprehensive discussion of a number of current and emerging governance issues in EU health policy, including regulatory, legal, 'new governance' and policy-making dynamics, and the application of the legal framework in these areas.

Cambridge: Cambridge University Press, 2010

Paperback 784 pages

ISBN: 9780521747561

£29.99

http://www.cambridge.org/gb/knowledge/isbn/item2713652/?site_locale=en_GB

Debate:

Is HTA going to save health care budgets or are its premises inherently flawed?

Miro Palat

Summary: Does the very nature of health technology assessment point the finger of blame for soaring medical costs at the health care industry? Is it time to challenge the scope of HTA and call for comparative studies of all health care interventions so that the real value of medical technology is more accurately understood in the overall health care framework? These questions are the basis of this open debate article.

Key words: health technology assessment, medical devices, value, Czech Republic

Medical devices and health technology per se are often quoted – along with pharmaceuticals – as the key drivers of growing health care budgets. Health technology assessment (HTA) seems a natural tool for harnessing medical technology in this role. The medtech industry, almost by default, accepts its role for keeping rising health care costs at bay by playing along with national and international schemes, projects and institutions, which are promoting the concept of HTA. But does all of this really make sense in pinpointing where money is being spent effectively to treat patients efficiently? Or are there basic flaws in our ability to measure real value?

In reality, once health care is viewed as the broad, complex and adaptive system that it is, a great many reasons can be identified – some completely unrelated to health technology – to explain why health care budgets are rising. So why should industry have to continue accepting its role in the HTA schemes, ultimately playing scapegoat for an ever growing global health expenditure? Surely, it is time to challenge the effectiveness and logic behind the whole HTA concept as it generally operates in countries across Europe, and indeed the world?

*Miro Palat is President of CzechMed, the Czech medical device industry association, Prague, Czech Republic.
Email: miroslav.palat@czechmed.cz*

A glimpse of history and the questions of purpose

The phenomenon of HTA, in its essential sense of evaluating one intervention against another, can be traced as far back in history as the mid-18th century. Literature dating from that time reported that a James Lind, from an Edinburgh medical school, conducted a controlled trial of six different treatments of scurvy. One example of HTA from the following century comes from Pierre Louis in Paris, who, in 1830, proved that patients suffering from pneumonia received no benefit from phlebotomy.

For a more contemporary view, namely the 1980s and 1990s, the ‘call for HTA’ can be attributed to the following:

- concerns about the adoption – and sustained use – of unproven technologies;
- rising costs; and
- the rise in consumer expectations.

After a few decades of HTA, there seems but little evidence of the practice helping to stagnate – let alone decrease – overall costs of health care. On the contrary, health care expenditure continues to rise at a pace roughly two percentage points over the respective GDP growth of a country.

So what is going wrong?

Are we using HTA like a panacea, rather than digging deeper into the issue that really needs addressing – namely making

health care truly efficient? And why are we failing in this respect? It is because in each and every country, there is a political agenda attached to health care and a fear of making unpopular cuts. So the fundamental question remains: can HTA really bring about what it promises – more effective allocation of money in health care?

To answer this, it is worth broadening the argument to look at health technology in the context of health care interventions overall.

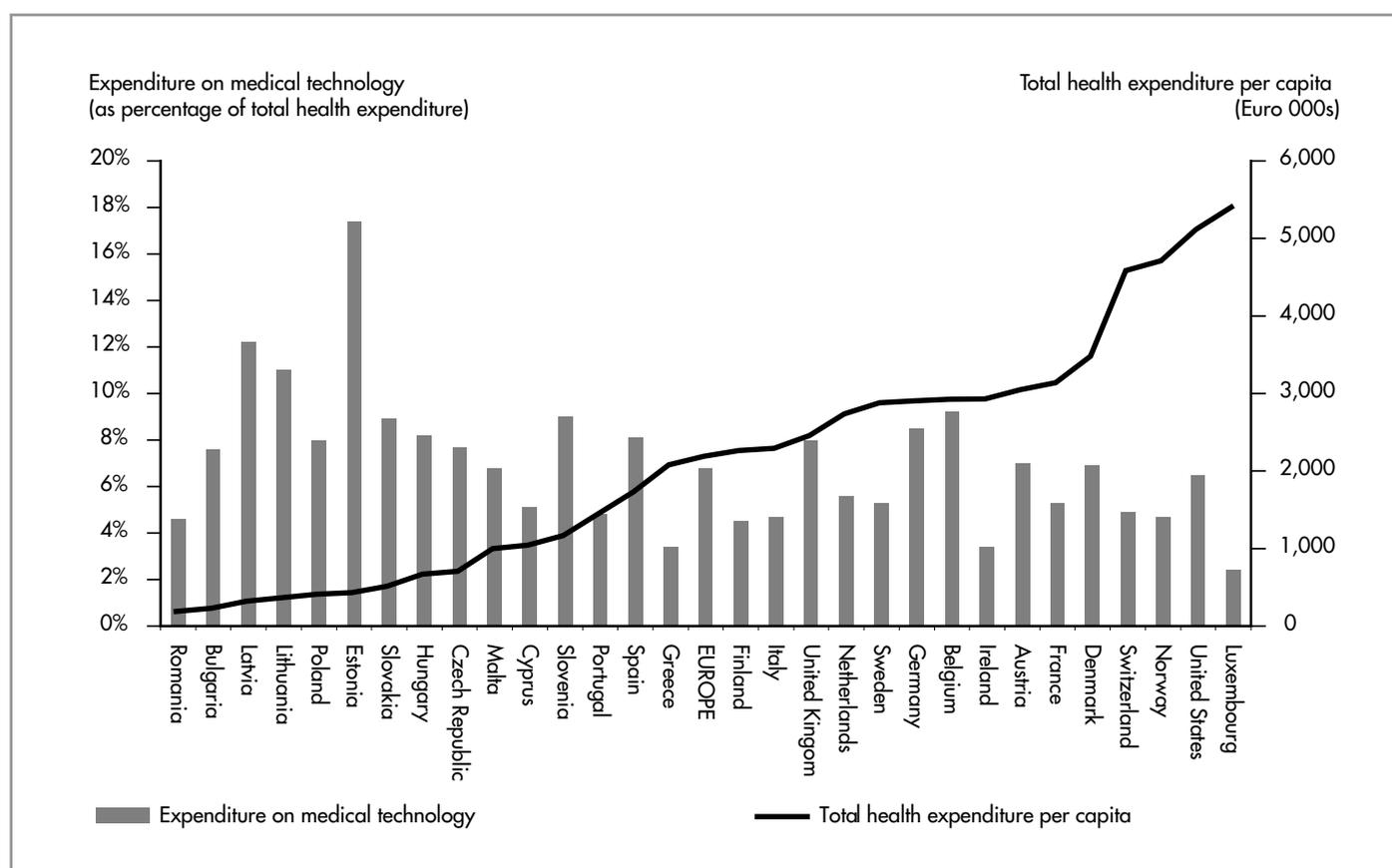
A question of scope

HTA in the general sense of the word covers much more than just technology. When we talk of HTA the first reason for misunderstanding lies in the discrepancy between the term and its scope. Contrary to common practice, to ascertain a real picture of where the most effective or least effective procedures lie, the word ‘intervention’ should be used instead of ‘technology’.

The scope of what is called HTA should include all pharmaceuticals, vaccines, medical devices and diagnostics, medical and surgical procedures, decisions and interventions used to prevent disease and maintain and restore health. If the technology has to prove its case, why not every other intervention?

If we are to consider evidence-based decision making in health care, we should

Figure 1: Regaining perspective – technology and the other health care expenses, 2008



* Source: Eucomed

be looking at evaluating all practices, any intervention, not only those related to technology. More often than not, the term Health 'Technology' Assessment implies, that it is health technology in particular that causes health care costs to rise and therefore requires particular attention and evaluation. In other words, is the message being delivered saying that HTA ultimately aims to curb health care costs by putting a finger on the perceived driver of all the financial misery – health technology?

Based on data from the EUCOMED, a body representing 4,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability, the average proportion of health technology over total health care spending in the 'EU15 + Switzerland' countries has risen between 2004 and 2008 from 4.98% to 5.84%. That represents a growth of less than one percentage point. At the same time the average per capita health care spending in the same group of countries has risen by 39.25%.

With all respect to market spread and pen-

etration of health technology, it is more than doubtful that health technology does play a significant role in this overall increase in health care spending. So what are the more likely drivers of the high increases in health care costs? Is there possibly a role for health technology to contain costs that may not be seen clearly from the outset? Here are some suggestions.

The first is that there is the ever broadening scope of conditions that are treated or followed-up nowadays. Long ago these conditions had passed the boundaries of actual, perceptible disease and expanded in the realm of abnormality. Let's not get into a misunderstanding here. There is a natural and commendable tendency to research and to understand the cause of diseases, their natural course and factors leading to them and to adopt a preventative approach. Yet, such an approach leaves scores of people, who appear otherwise healthy, to undergo numerous check-ups, interventions etc, often for the rest of their lives and at times doing more harm than good. Even for certain cancer screening programmes, when looking for hard evidence of out-

comes, like reducing mortality rates, they do not hold as much as they promise.

In such cases, the absence of market mechanisms leads to a situation where there is a risk of spending with unproven benefit over a long term. In other words, once a health care facility is "under contract", that means its services are covered by health insurance or sickness fund schemes and it is rarely seen that such facility is closed down due to low quality or reduced need. Indeed, more services are being opened than closed.

Another approach which carries of risks of ineffective spending is the concept of entitlement to service. The original idea of a universal health insurance system was to secure access to care for all; but more recently, during the 20th century – at least in Europe – the population's perception has moved to a notion of entitlement to health service – almost like a state pension or other types of benefits. We all perceive we have a right to care and treatment when we want and need it. And to challenge such an attitude in the political arena is not a means for gaining popularity, and therefore given a wide berth.

Budgets creating demand, not technology driving budgets?

Another cause of soaring health care costs is the fragmentation of health services, the absence of coordination of care, and the duplication of procedures. In some aspects, waste is also generated when services fail to provide minimum quality requirements. If medical technology plays a role in any of the above factors that push up health care costs, it may do so in the ever increasing spread of supply of diagnostic and therapeutic procedures. However, how much influence the medtech industry and the medical profession (or health care providers in the broader sense) have on inflating the volume of procedures carried out remains largely a chicken-or-egg question.

Is it the industry luring health care professionals into an ever larger supply of procedures, for all of which eventually there will be patients recruited and the costs paid? Or is it the medical profession trying to dig ever deeper into the roots of disease, inventing newer and finer methods that the industry can deliver in a profitable way?

In any case both – industry and medical professionals – are driven by the fundamental incentive of doing business and making acceptable profit from monies that are just sitting there waiting to be spent on health care. But contrary to the widespread belief that health technology is one of the few key drivers of health care expenditure, there are deeper reasons behind soaring health care budgets.

The underlying question of health care financing is not whether this or that technology is marginally/significantly more (cost-) effective. The underlying question is: do we need this much care as provided today?

If we delve further into this question, we would go beyond the scope of this article. But briefly considering this fundamental question, surely, there is no linear correlation between ‘more medicine’ and ‘better outcomes’ - neither from the point of the patient, who is largely kept in ignorance over this, nor from the point of the health care payers – who in contrast to patients are already very vocal.

Medtech wish-list for HTA

The industry wants to avoid being drawn into the HTA game of apologetics, where medtech needs to prove its ‘right for life’ over and over again. However, HTA

cannot be stopped and the medtech industry can hardly bypass the hurdles set out in the various forms of HTA. But given the perceived shortfalls in HTA, as established in this article, how would industry propose that HTA policies be modified in order to truly evaluate the comparative costs of health care technology against other health care practices and decisions?

What should be evaluated?

For the sake of fairness, the terminology should be changed. Instead of Health ‘Technology’ Assessment, we should be talking of Health ‘Intervention’ Assessment (HIA). The point being that plentiful interventions remain in place without having ever been proven to work. Indeed, a quick search on the internet of the phrase "no proven benefits", shows scores of threads to follow. If medical technology is put under the scrutiny, is it not pertinent for other interventions to follow suit?

What should be measured?

There are basically two dimensions that should be evaluated: whether "it" works; and how much "it" should cost? Let us stick to efficacy for now. For the individual person, the case seems to be very straightforward in favour of a novel technology. For example, a circular CT is more sensitive and therefore superior in detecting early stage lung cancer than the common chest X-ray. However, opening this argument out to the population can result in a different efficacy ration. For instance, from the point of a population, routinely screening smokers and former smokers with circular CT for early stage lung cancer to prevent death is equivocal. Research suggests that by routinely applying this technique with consequent surgical removal of the tumours, long term survival rates have not improved. One explanation is that there are certain tumours that would not have killed the carriers if left alone, whilst the truly dangerous cancers might still get missed. So the setting – the individual versus the population – can be of decisive difference in respect to the question: does ‘it’ work or not?

The same consideration then flows into the

financial aspect. If ‘it’ works, how much does it cost to achieve the effect? Here the industry calls for a level playing field. If an innovative technology is evaluated, so should the long established alternatives. If a technological procedure ‘candidate’ is checked for cost per QALY (quality-adjusted life year) or cost per life saved etc, so should be the other treatment options as well. Many of these are widely accepted, and perhaps were never evaluated in such a manner, having mostly have entered the arena long before health care costs was such a pressing issue.

Once the evaluation is done, what should the outcome be?

There should be clear a consequence of HTA (or to use a better term, HIA) evaluation. A decision: to use or not to use; to fund or not to fund; under what conditions? The last thing the industry is looking for is yet another hurdle in the form of a HTA evaluation without the prospect of obtaining reimbursement for an innovative technology. Better still, HTA should be used to weed out well established procedures of doubtful efficacy and value.

Even though the will for the latter has been expressed in personal communication by stakeholders and academics working on HTA, putting this into reality is still a bit further down the road.

In conclusion, the medtech industry is right to watch the whole notion of HTA with a degree of suspicion. There may be good reasons for industry to fear it is being drawn into the position of the sole (along with pharma) agent responsible for ever-rising health care costs. By accepting the HTA game without challenge, the industry – by default – accepts this role and can do nothing but remain apologetic: "yes, we are expensive, but at least we can prove our products work and are worth the money".

Now, however, with all the medical progress that has come with innovative medtech products, the industry can be bolder about the value its products and demand a level playing field with other interventions in health care. It is time for industry to be vocal too.

This article was originally published on 2 November 2010 in *Clinica Medtech Intelligence* and is available online at www.clinica.co.uk

Do you have a view on this article? If you are interested in writing a response for a future article in *Eurohealth* please contact Sherry Merkur s.m.merkur@lse.ac.uk to discuss further

Developing HTA frameworks in emerging markets: the road ahead

The case of Greece

John Relakis and Nikos Maniadakis

Health care system organisation

Historically, social insurance has played the predominant role in the organisation and financing of health care services in Greece. However, the system has been characterised by a lack of infrastructure, inadequate funding and great inequalities in access to and provision of services.^{1,2} In the early 1980s a National Health Service (NHS) was introduced to provide free, universal, equitable and comprehensive health coverage. Ever since, much effort has been devoted towards making improvements in the human, technological and capital infrastructure of the system.

Recently there have been significant efforts to improve management and organisation, in order to increase efficiency, effectiveness and service quality. The reforms have not been that successful. Complexity, disorganisation, deficiencies and public dissatisfaction have led to significant growth in private health care, particularly in secondary and primary care settings.

Today, the Greek health care system is in essence characterised by the coexistence of three sub-systems, all of which are in transition, especially after the recent financial crisis and rapid reforms initiated as part of the obligations agreed in a memorandum signed with the Troika (European Union, European Central Bank and International Monetary Fund) within the context of the rescue package agreed in May 2010.

Health care provision structures

Secondary care encompasses 132 hospitals in the NHS with 36,621 beds. There are

also fourteen military hospitals, two university hospitals, two prison, five Social Security and six special status hospitals with a total of 4,000 beds. The public sector accounts for three quarters of capacity. The private sector includes 218 hospitals with a capacity of 15,082 beds.

The NHS provides primary care through 202 primary care health centres, 1,458 rural medical surgeries and 114 outpatient hospital departments. There are also around thirty Social Security Funds covering different occupational groups, supervised by the Ministry of Labour and Social Affairs. The most significant funds, which cover the majority of the population, include the Social Insurance Fund (IKA), the Social Insurance Fund for Farmers (OGA), the Fund for Merchants, Manufacturers and Related Occupations (OAEE) and the Fund for Civil Servants (OPAD). These entities provide primary care services through their own facilities and contracted physicians. IKA, in particular, is a decentralised network of more than 300 health centres, polyclinics and large laboratories. It employs 8,320 general and specialist physicians, as well as 3,934 nurses and other employees.

Apart from access to the NHS, the OGA, OAEE, OPAD and the remaining Sickness Funds offer primary care access to their members through contracts with private physicians, laboratories and diagnostic centres. There are also some primary care services within local authority structures. Primary care services are also provided by 25,000 private physicians, practices and lab-

oratories and in 400 private diagnostic centres and the outpatient departments of private hospitals. This sector has seen significant growth in recent decades, mainly due to public dissatisfaction with access and quality of care in the public system, as well as an oversupply of medical doctors.^{3,4}

Emergency care is provided both within NHS and the private hospital sector. It is supported by a public national ambulance service network. Finally it should be noted, that despite continued efforts and investment, shortages remain in the areas of rehabilitation, long term, palliative and mental health care.

Health care expenditure and financing

Total health care expenditure reached 9.6% of GDP in 2007, slightly above the average for Organisation for Economic Co-operation and Development (OECD) countries. Private expenditure accounts for 39.7% of total expenditure. Public expenditure from taxation and social security payments account for 29.1% and 31.2% of total expenditure respectively. This reliance on private care is a characteristic which differentiates the Greek from many other European health care systems.² Public expenditure for primary care is 22.9%, for hospital care 55.9%, for dental care 1.2% and for pharmaceutical care 15.8%, whilst the corresponding figures for private expenditure are 31.4%, 12.4%, 34% and 15.4% respectively.

NHS staff salaries are financed directly through the state budget. Other operating expenses are financed through service charges to Social Security Funds and patient charges. Charges are defined either on a per diem, per case or per service basis and are made retrospectively. It is notable that they have not been updated for a long time. This contributes to the generation of

John Relakis is Doctoral Researcher – Research Fellow and Nikos Maniadakis is Professor and Department Director, Health Services Organisation and Management, National School of Public Health, Greece.

Email: nmaniadakis@esdy.edu.gr

significant hospital deficits which have to be covered by the state budget. In addition, public sickness funds finance the health care services they provide directly to their covered population. Doctors employed directly or via contract are paid either on a capitation or fee-for-service basis and the funds also cover drug and examination prescriptions. The private sector is financed through charges to sickness funds, private insurers and patients.

Comparisons with other OECD countries

Overall, the number of acute care hospital beds is 3.9 per 1,000 inhabitants, similar to the OECD average. However, there are more physicians per capita than in any other OECD country. In recent decades, the number of practising doctors has increased rapidly to 5.4 per 1,000 population, with the corresponding figures for specialists being 3.4, dentists 1.3 and pharmacists 0.9. Thus the country is at the top of the OECD list for the employment of these professionals.² Yet, there are only 3.2 practising nurses per 1,000 population and 0.31 practising general practitioners (GPs), much lower than the OECD average. These peculiarities create distortions in the efficient organisation and delivery of health care.

During the past decade, there has also been rapid growth in the availability and use of diagnostic and interventional technologies, especially in the private sector. The number of CT scanners reached 25.8 per million inhabitants in 2007, above the OECD average of 22.8. The number of magnetic resonance imagers (MRI) is also relatively high: 13.2 MRIs per million inhabitants compared to an OECD average of 11.8. There were 36.5 and 19.9 mammography machines per million inhabitants in Greece and across the OECD respectively. It is notable that due to strong supplier-induced demand, in combination with an absence of control and guidelines, Greece has the highest per capita number of examinations with these technologies in the OECD. Pharmaceuticals account for more than 2% of GDP, ranking Greece at the top of OECD countries, as a result of high volume and expensive drug mix consumption.^{1,2}

Current health care reforms

There is an enormous effort at present to reform the health care system under the surveillance and guidance of the Troika. Hundreds of measures aim to contain cost and increase service efficiency and quality.

An emphasis is given to the introduction of information technology and modern financial management mechanisms, e-prescription, the introduction of guideline implementation, the rationalisation of drug and medical device procurement and use, reduction in the costs of personnel, reorganisation of social security and health care services, and to the re-definition of the relationship with the private sector. In this context major social security and health service reform is unfolding. Most notably the provision of health services is being taken away from the Sickness Funds and incorporated in the NHS. Additionally, the Sickness Funds are being merged to a single monopsonistic body vis a vis the public and private producers.

Impact on Implantable Medical Devices

The past year has been a turning point for the medical devices sector. Specifically, this sector had been growing fast in recent years, with sales of €1.9 billion in 2009, a 15% increase on 2008.⁵ It has been characterised by the presence of many local distributors working on behalf of international manufacturers, who wish to avoid the bureaucracy and late payments in the health care system. There was a high dependency on the public hospital sector, which generated 65% of the business.

In 2010 the sector experienced significant changes. After many years of delays and unfulfilled promises, the public sector debt was addressed partly through cash injections but mainly through zero coupon bonds, which imposed a further burden on companies. Moreover, because of the financial status of the country and its banking system, access to financing became expensive and difficult. Hence firms had to cope with a challenging financial situation. Furthermore, hospital administrators negotiated prices down and this, together with Sickness Fund mandates and the introduction of a Price Observatory, led to significant price reductions, which in some cases amounted to 50% within the year.

The procurement of medical devices in public hospitals had mainly been through competitive tenders. Successful bidders had to sign annual contracts obliging them to maintain normal delivery of services to hospitals. Devices and all other medical materials used for interventions were invoiced in most cases on an individual patient basis, at the time of actual use, raising administration costs for all parties. In respect of implantable pacemakers and

implantable cardiac defibrillators, for much of the past decade special legislation setting maximum procurement prices was in place. This system was criticised at a European level because it distorted competition and has now been abandoned.

In this context national tenders for services and technologies were issued by the newly established National Procurement Committee, for two-year framework agreements for public hospitals across the entire country. Initial tenders focussed on coronary stents and cardiac rhythm devices. Tender competition and consequently price erosion has been significant. These developments inevitably will lead to greater concentration of market share and to significant changes in its organisation and structure. Some traditional medical device distributors have been replaced by the device manufacturers. It is notable that some multinational manufacturing companies were successful in winning tenders, implying distributors will be out of the market for some time.

Constant reforms to the public procurement processes mean that the system remains very uncertain and complicated. These constant changes mean hospitals are still procuring devices through direct negotiations with providers; these are not strictly legal when the amount concerned exceeds €20,000. At the same time hospitals are trying to complete more than 10,000 hospital level tenders initiated in 2010. Simultaneously, the National Procurement Committee has published a dozen significant tenders for the entire country. All these imply that there are many systems running in parallel raising complexity and costs.

Moreover, the Government passed legislation in March 2011 that will transform the National Procurement Committee into a Technical Specifications Committee. Tenders will be shifted to Regional Health Authorities to be implemented on a regional or national basis. A Supreme National Council has been created at the Ministry of Health, comprising the Secretaries of Health and the Heads of the Regional Health Authorities, to oversee and coordinate the operation of the NHS procurement system and to delegate tenders to various authorities, including hospitals. There is also a provision that the Ministry of Health has the right to outsource the entire tendering process, logistics and the provision of medical devices to a single entity that can be a private enterprise or a joint venture

between the public and the private sector.

In any case, regardless of which party will complete the tender (hospital, national committee, regional health authority, private entity), when the process is concluded public hospitals will still sign agreements to buy devices on the basis of need. In some cases the costs of devices will be covered by the treatment tariff charged to the Sickness Funds. In other cases hospitals will still be charging the Funds a tariff covering daily hospitalisation cost in addition to the costs of devices used. This is, for instance, the case for pacemakers and defibrillators. There can also be combinations of approaches. For instance, there is a prefixed tariff for coronary angioplasty which covers all consumables, hospital stay, the first stent and the first balloon. Additional stents or balloons will incur additional charges.

The Ministry of Health is now considering the introduction of a Diagnosis Related Group (DRG) type prospective reimbursement system. In the meantime Sickness Funds and hospitals have recently started to reimburse only those devices whose prices are in parity with those published by the National Medical Device Price Observatory of the Procurement Committee. The classification systems of the European Diagnostic Manufacturers Association (EDMA) and the Global Medical Device Nomenclature (GMDN) will be used to classify products in the database of the Observatory.

It is notable that, depending on the type of procedure undertaken (implantation of stent, pacemaker, percutaneous valve), it is often not possible for hospitals to charge sickness funds for many of the services provided, or they may be charged at levels well below cost. This explains why public hospitals can still generate significant deficits and why providers often get paid two or three years after invoice. Payment can only be made once a special subsidy from the Government and legal clearance are received which delays matters further. As a result there is fragmentation, bureaucracy, legal costs and discounts imposed upon debt settlement. To counter this providers charge public hospitals, who in turn charge social security funds, much higher prices than to other European countries. Given recent price decreases, company margins will be squeezed if organisational weaknesses in the NHS persist in the short to medium term.

Looking at medical device use in the

private sector, the procurement subsidiaries of private hospitals often enter into direct negotiations with manufacturers or their local distributors. They demand, and usually obtain, prospective or retrospective price discounts and thus make a profit on the device procured. They charge sickness funds the (undiscounted) cost of the device and they also get a fee for the service either from the sickness fund, private insurer or the patient, depending on the type of procedure. In some cases, the cost of the device is charged directly to patients, even if this is being covered retrospectively by their sickness funds. This raises administration costs and risks to medical device providers. Moreover, as private hospitals are concentrated in a few large firms, they also often exercise their negotiating power by delaying paying medical device providers. Hence, there are also significant hidden transaction costs in the private hospital sector.

Finally, it is notable that due to the high prices of the past, some private and public hospitals have started to import products (e.g. stents) outside of the official distribution channel; this raises issues around effective vigilance, quality and patient safety. However, recent price reductions will probably end this practice.

Health Technology Assessment and devices

Health Technology Assessment (HTA) has been termed 'the bridge between evidence and policy making'. HTA has for a long time been extensively applied in many countries for assessing pharmaceuticals, but devices are somewhat different and pose many challenges that stem from their specific nature and short life cycle. Nonetheless, despite these difficulties, HTA is increasingly used to improve decision making regarding the utilisation and funding of medical devices across many European countries. However, currently Greece does not have any structure or formal process in place for assessing devices, while there has been much discussion about the need for assessing pharmaceuticals. Recent legislation ensures that pharmaceuticals will be assessed in the new reimbursement system on the basis of effectiveness and cost effectiveness. Specifically, there will be a reference reimbursement price for drugs, based on the average price of the drugs in a specific cluster. Anyone seeking a premium on this price will have to provide solid evidence of economic and clinical benefits.

Devices, in contrast, are used as long they have a CE Mark; procurement and reimbursement is currently based solely on their price. Only in extremely rare cases may other HTA criteria such as quality, innovation, safety, effectiveness and budget impact have been considered. In each hospital, or in other regional and national settings, various committees comprised of members from different backgrounds, set arbitrary procurement criteria and device technical specifications. Various committees also evaluate offers based solely on technical specifications and price. This process has generated a lot of inefficiency, bureaucracy, corruption and legal battles and it distorts hospital operation.

The landscape for IMDs over the next five years

Greece has now entered a new era where for many years there will be efforts to address inefficiencies and to reduce the size and the costs of the entire public sector. 2010 was a tough year following the revelation that the country had a budget deficit in 2009 equivalent to about 15% of GDP. In May 2010 the country agreed a long term rescue programme which includes many austerity measures. The government has looked to trim a few billion euros off the budget deficit through tax increases and cuts in many areas, including health care. This effort inevitably had a negative impact on expenditure for medical devices in 2010; and it will certainly continue to do so for years to come.

There was a need not only for reform and modernisation in the procurement, assessment and use of medical devices, but also in the health care system as a whole. This need has been exacerbated by the recent financial crisis, which offers an environment and opportunities for tough, but necessary changes and health care reform. Reimbursement prices for medical devices are being forced down dramatically in an effort to reduce expenditure. In the next few years, the prices of most devices will reduce further coming closer to the European average. It remains to be seen whether the prevailing conditions in the health care system will also converge to European norms. At the same time the government will make efforts to evaluate and monitor the volume of devices used, through the use of modern information technology and guidelines. These trends will in the short term shrink but also rationalise the device market. They will lead to consolidation and company closures. In the future most manufacturers may operate

directly in the market rather than use distributors, as margins will be much lower.

Nonetheless, in the medium and long term the landscape may improve. There are many initiatives underway to improve organisation and financing of the health care system so as to make its dealings with providers more efficient and less cumbersome, risky and costly. Despite rapid growth over the past few years, implantation rates for most devices are still much lower than in other European countries, leaving great opportunities to address unmet need. Implantations of pacemakers, have reached 700 per million inhabitants (versus 1,200 in Germany), while implantable cardiac defibrillators reached 90 per million (versus 260 in Germany). There were 1,800 percutaneous coronary interventions per million inhabitants compared to 3,660 per million in Germany.⁶

Despite a determination to introduce HTA in the assessment of drugs, it is very unlikely that this will be the case for medical devices anytime soon, due to technical limitations. However, as changes in demographics and technology put more pressure on health care and medical device expenditure, there will be an ever increasing need to improve the system for evaluating, purchasing, using and reimbursing devices. This will increase pressure for the introduction of HTA in this area. The experience of other European countries will be valuable in this respect, even if this takes some time to come.

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Developing HTA frameworks in emerging markets: the road ahead

The case of Serbia

Predrag Djukić

An overview of the health care system

Serbia has a tradition of a publicly provided health care system financed through social health insurance. Public expenditure on health was approximately 6.3% of Gross Domestic Product (GDP) in 2008.¹ Life expectancy at birth in the country in 2008 was 73.65; 71.06 for men and 76.23 years for women.² There has been a long term decline in rates of infant mortality, with the rate decreasing from 8.1 per 1,000 live births in 2004 to 6.7 in 2008.

The Ministry of Health (MoH) and local municipalities provide finance for capital investment in health service provision, while the Health Insurance Fund (HIF) covers recurrent expenditure through input-based provider payments. The HIF is financed through social insurance contributions, equivalent to 12.3% of gross salary, equally shared by employers and employees. About half of all HIF funds are used to support care in secondary and tertiary Health Care Institutions (HCIs).

The current national policy is to transfer accountability for the management of the primary health care sector to local government. Primary care is delivered through a network of primary health centres (*Dom zdravlja*, DZ), whose structures vary slightly depending on the size of the municipality covered. A DZ may incorporate a network of health stations (*ambulanta*) in the municipality. They provide primary health care, limited specialist consultation services, public health services, tuberculosis control and some

other services. Public pharmacies associated with each DZ dispense prescriptions.

Hospital infrastructure is extensive and complex comprising a wide range of hospital types. In 2008 there were 107 inpatient health institutions in the country, (not including the 21 DZs that have inpatient beds).² Basic acute hospital care is provided through 40 general hospitals. There are also 37 specialised hospitals, sixteen institutes, six clinics, four clinical-hospital centres and four clinical centres. These institutions comprise specialist inpatient facilities providing tertiary care, institutions targeting special population groups (children, women), or institutions targeting patients suffering from a particular type of disease, including tuberculosis, cerebral palsy and addiction disorders.

In terms of bed numbers, the 107 facilities included 40,908 hospital beds, of which 24,659 were in surgical, general medicine or paediatric wards and 8,775 in gynaecological and psychiatric wards. Another 6,222 beds were used for rehabilitation. In addition there were a further 346 beds in DZs providing primary health care. Overall this is equivalent to 5.6 beds per 1,000 population.

In terms of the utilisation of hospital services, in 2007 the rate of hospitalisation was 139.76 patients per 1,000 people, with an overall average length of stay (ALOS) of 9.2 days (including psychiatric care) and an overall average bed occupancy rate of 74.7%, based on approximately 1,027,000

Predrag Djukić is Consultant, Project Coordination Unit, Ministry of Health, Belgrade, Serbia. Email: pedja.djukic@gmail.com

This article reflects the views of the author and not the official opinion of the Ministry of Health in Serbia

total admissions. This level of hospital provision is broadly comparable with that in other countries in central Europe. However, comparisons in ALOS performance with countries in western Europe, for instance the UK (5–6 days), are unfavourable. Bed levels in most countries are now reducing significantly due to demographic change and the impact of modern forms of treatment that reduce dependency on inpatient care. These factors have not yet significantly influenced the hospital sector in Serbia.

Payment and performance

The HIF is the single financing agent responsible for paying health care providers for the expenses incurred in delivering health care to the insured. Historically HIF payments to providers had been based on a fee-for-service approach, where a long list of services increased the complexity of reporting. During the last two decades, while fee-for-service served as a reporting and validation mechanism, line budget payments to institutions became the de facto payment system. The HIF pays providers according to line items (i.e., salaries for a set number of employees, costs of fuel, heat and lighting, medicines and other medical supplies). It is therefore an input-based provider payment mechanism, which controls overall public health expenditure, but does not provide any incentives to contain costs at the level of individual HCI, improve efficiency and quality of care. Performance results in HCIs point to low productivity levels and idle resources. In addition, diagnostic information suggests that a significant proportion of hospital contacts could be dealt with at the primary health care level. While contracts between the HIF and HCIs do require HCIs to report performance, there are no actions or penalties associated with poor performance.

Serbia, like other countries, is moving from retrospective to prospective payment methods to manage health care expenditure. This will also help provide incentives for providers to contribute towards the overall health policy objectives of improving efficiency and quality of care, financial sustainability for the health care sector, as well as equity in access to care and in population health status. It has been determined that the provider payment system for primary care will be based on capitation payments, while payments for acute secondary and tertiary care will be based on a system of Diagnosis Related Groups.

It is also important to bear in mind that in Serbia there is a burgeoning but largely unregulated private sector, focused mainly on outpatient and ambulatory care and including private pharmacies. Private health care still does not offer an effective alternative to the public sector. In the future, the MoH envisages increasing the involvement of the private sector in the delivery of publicly financed health care services, underpinned by contracting, quality assurance and performance management mechanisms.

Medical devices

The Medicines and Medical Devices Agency of Serbia is a governmental body responsible for market authorisation of medical devices, while decisions on reimbursement are made by the HIF in its role as public payer. The process of obtaining market authorisation is clear with every step described by the Agency.³

The HIF makes its reimbursement decisions taking into account a number of factors including its annual financial plan, the number of expected patients, efficiency and effectiveness of the intervention/device and unit price, where this has a substantial budgetary impact. Until recently, in an attempt to get lower unit prices and thus control costs, the HIF organised nationwide tenders for high-priced medical devices (specifically in cardiology, cardiovascular surgery and orthopaedics). This managed to reduce prices considerably. Nowadays tendering responsibility is being returned to individual hospitals. This shift in responsibility should remain in future given changes in the provider payment system, coupled with an increase in the autonomy and responsibility of hospitals.

Health Technology Assessment (HTA) is slowly gaining momentum in Serbia. There is a growing HTA department in the HIF whose work supports reimbursement decisions. There is also an HTA Committee at the MoH with very wide responsibilities, although probably not with enough technical support. The reality is that although the significance of HTA is increasing in Serbia, there remains a lot of room for further development and use in decision-making.

In recent years, the medical devices market in Serbia has grown considerably. One illustration of this can be seen in the number of heart valve implantations financed by the HIF. This grew from 973 in 2005 to 1,350 in 2009.⁴ An even more striking example can be seen with the use

of devices for invasive cardiology. The number of implanted pacemakers grew from 350 in 2004 to 4,200 in 2009, while the number of implanted stents grew from 1,900 in 2004 to 13,500 in 2009. The situation is similar to that for other medical devices; growth can also be seen in the pharmaceutical sector.

What is the future for implantable medical devices?

This rosy picture could be darkened by the impact of the current economic crisis. Over the past decade, Serbia has begun recuperating from the very difficult time experienced in the 1990s; however the global financial crisis may lead to a slowdown in economic growth that may well be much greater than anticipated. The provision of health care services in Serbia is dependent on the size of the HIF budget, which is itself dependent on the rate of employment and level of salaries in the population. This in turn will have an impact on funds available for medical devices. With growing unemployment, fewer people will be able to make contributions to the HIF, reducing the overall available budget. Another threat is inflation: a decline in the value of the Serbian Dinar would also impact adversely of the HIF budget. A key question therefore, will be the way in which the economic crisis is handled. If Serbia manages to absorb the impact of the recent global financial crisis and return to a path of strong economic growth, then the medical devices market will continue to follow the growth path seen in recent years.

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Developing HTA frameworks in emerging markets: the road ahead

The case of Poland

Maciej Nowicki

Poland has a mixed system of public and private financing of health care. The 1997 Law on Universal Health Insurance established the framework for mandatory health insurance, including the universal health insurance contribution and budgetary contributions to expenditure by the state voivodship*, county and commune authorities. Mandatory health insurance contributions are the major public source of health care financing; it is not possible to opt out of the system. The National Health Fund (NHF) has the responsibility for overall planning and the allocation of resources in the Polish health care system.

The state budget plays a limited role in the publicly funded health care system. It covers the costs of some public health activities, the health insurance contribution for specific population groups, investments in public health care institutions, and reimbursement of health services provided for a number of listed life-threatening situations (called highly-qualified provisions). Private financing includes both formal and informal sources of payments, as well as prepaid plans. There are public discussions underway on the development of a system of alternative (private) or complementary health insurance which could be offered to the public.

This insurance-budgetary model of health care funding is regulated by the Law on the Basic Benefit Package (BBP). BBP regulations were set out by an Act of Parliament in 2004 and respective Government Orders. Important changes to these regulations were introduced in the second half

of 2009; because these changes are so recent, the law contains a lot of imperfections, divergence and ambiguity that requires constant improvement.

The BBP covers a number of areas including: basic health care, ambulatory specialist care, hospital treatment, psychiatric care, long-term nursing care, dental care, medical devices (orthopaedic and medical equipment) and prescription drugs. Each of the BBP provisions is well described in the relevant Government Orders, and these descriptions include the names of procedures, as well as International Classification of Disease codes Version 9 (ICD-9) for procedures and ICD-10 for disease indications. In some cases, there are detailed requirements for health care providers (for example, hospital/department conditions/equipment to be used, number of doctors and their experience, diagnostic tool availability etc). Government Orders are announced by the Ministry of Health on an annual basis, with the first of these issued in September 2009.

These Government Orders are also the basis for the NHF to set tariffs and enter into contracts with health care providers. Only procedures listed in Government Orders may be performed by health care providers and reimbursed by the public budget. Indications (according to ICD-10) are also guidelines for NHF reimbursement. The most recent Government Orders were issued in October 2010/January 2011.

Pathway for reimbursement

The BBP Act also describes the reimbursement pathway for procedures and technologies to be included in the BBP catalogue and also how the conditions or level

of reimbursement can be changed. In this article, the focus is on procedures related to medical devices. In order to be included in the BBP catalogue, a technology is assessed in terms of impact on: health improvement of the population; consequences of illness; clinical efficacy and safety; risk of use; cost-effectiveness; and impact on the health care system.

New medical technologies

The process for the introduction of a new medical technology into the BBP catalogue is initiated by the Ministry of Health, which orders the President of the Polish Health Technology Assessment Agency (AHTAPol), a body comparable to NICE in England, to make recommendations. AHTAPol has published guidelines on conducting a health technology assessment (HTA), which are strictly respected by the authorities¹.

Following a request from the Ministry of Health, the President of AHTAPol invites opinions about the new technology from (i) National Consultant bodies in the appropriate medical specialisation and (ii) the NHF for financial concerns. These two groups have thirty days to issue their opinions, which are then passed on to a Consulting Committee (CC) working under AHTAPol umbrella. This CC analyses the opinions and presents a position to the President of AHTAPol as soon as possible. Finally the President of AHTAPol will make recommendations to the Ministry of Health based on the CC's position and the results of the assessment.

There are, however, several limitations in this process including the lack of clear indications on how the Ministry of Health decides when to initiate this process. There

Maciej Nowicki is President of HTA Audit Nowicki Landa Partners, Poland. Until October 2010, he was Reimbursement Manager, Medtronic Poland, Warsaw. Email: nowicki@htaaudit.eu

* There are currently sixteen voivodship or provinces in Poland.

is also a lack of a clearly defined timeframe for the entire process and no clear definition on how and by whom the assessment is performed. Moreover delays are also due to the need for an announcement of new technologies through Government Orders. These announcements are needed before the NHF starts negotiations with health care providers.

Changes in the conditions for reimbursement

Changes in the conditions for procedures or technologies in the BBP catalogue (such as changes in ICD-9 or ICD-10 related codes or hospital/department requirements) must be initiated and approved by the Ministry of Health. Applicants may be one of the following: the National Consultant body for the relevant medical specialisation; professional medical societies via the National Consultants; the President of the NHF; societies and/or foundations protecting patient rights (according to their statutory objectives) via the National Consultants. The assessment criteria are the same as those for inclusion in the BBP catalogue. The limitations described previously in reimbursing new medical technologies, also present barriers to any change in the catalogue. There are also additional requirements to present basic information about epidemiology, determination of any societal health improvement and the financial implications for the publicly funded health care sector.

Changes in the level of reimbursement

The Ministry of Health is also responsible for any change in the level of reimbursement for a medical technology. An application for change may be made by any of the bodies already identified. The President of AHTAPol then produces a HTA report in respect of changes in the level of reimbursement; this is then considered by the CC. The position of the CC is then submitted to the President of AHTAPol who in turn makes a final recommendation to the Ministry of Health on the need for any change in the level of reimbursement.

In addition to the barriers discussed previously, one further key challenge is the limited level of resources available within AHTAPol to produce these HTA reports. Moreover new reimbursement rates have to be announced in advance by the NHF to establish for contracts with health care providers. There is also no direct and clear

relation between the AHTAPol's recommendations, the Ministry of Health decision and NHF responsibility for the implementation of any changes in rates of reimbursement.

Reimbursement of Implantable Medical Devices

The idea of a BBP is still very fresh in Poland. In fact the Diagnosis Related Group (DRG) system that was put in place in hospitals in 2009 drew on historical data. This means that today many of the procedures with implantable medical devices (IMDs) are reimbursed.

The DRG tariff includes the costs of hospital stay, medical service (surgery, nurse and medical care etc.), medical devices and drugs, as well as other direct and indirect costs. DRG tariffs are updated by the NHF on an annual basis with some corrections on a quarterly basis. However, the initial use of historical data has meant that the level of the tariff used for reimbursement is, in the majority of the cases, too low for health care providers. This had led to long patient waiting lists for innovative procedures, as well as growing debts within hospitals.

Some examples of major procedures in the Polish DRG system with usage of IMDs include:

- Deep brain stimulation
- Spinal cord stimulation
- Implantation of ophthalmic lenses
- IMDs for hearing-impaired patients
- Angioplasty with bar stents/drug eluting stents
- ICD, pacemakers, CRT
- Orthopaedic surgery with implants (total knee replacement, total hip replacement, spinal surgeries with dynamic stabilisation of vertebrae)

- Meshes in abdominal/uro-gynaecology surgeries

For new innovative procedures that are not already listed in the BBP catalogue, there is an application pathway (see above), where HTA guidelines must be respected by the applicant.

Future for Implantable Medical Devices

In the future, one can expect growing demand for IMDs in Poland. Firstly, this is due to the constant increase in medical knowledge and skills of the professionals. Secondly, there is a tendency for total and public health care expenditures to grow as new innovative technologies replace old and less effective surgeries. Thirdly, there is growing awareness among patients about new technologies. Finally, the expected development of private/alternative health insurance will additionally have a positive impact on the development of implantable procedures in Poland.

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ACKNOWLEDGMENT

The papers on health technology assessment follow on from an expert meeting on "The development of HTA for implantable medical devices in emerging markets", held in Prague in March 2010 and funded by Medtronic Trading NL BV. The views expressed in these articles are those of the authors alone and not necessarily those of Medtronic Trading NL BV.

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Spain: the effect of country of birth on patterns of pharmaceutical use

Dolores Jiménez Rubio and Cristina Hernández Quevedo

Summary: Despite the universality of health care in Spain for virtually all of the population, irrespective of nationality or country of origin, there is substantial evidence that the level of health and especially the use of health services differs in important ways between immigrants and the Spanish-born population. Differences in pharmaceutical use on the basis of immigrant status have, however, received much less attention. This study reviews the limited evidence in Spain on this issue, finding a lower consumption of medicines by some immigrant groups relative to Spaniards.

Key words: immigrants, Spain, access, drug consumption, self-medication

Ensuring equal access to effective treatments for individuals in equal need of health care, regardless of their country of origin, is a fundamental goal for any health care system. The Spanish case is relevant from a policy perspective, given that the rapid increase in immigration has placed important pressures on health expenditure in a health system where virtually all the population are legally entitled to free access to health care. While a growing body of literature in Spain has explored whether, despite the universality of health benefits, differences in health status and in the utilisation of health services exist between immigrants and the Spanish population, differences in the consumption of medications or self-medicated drug use have received less attention. The common practice in many countries of consuming drugs without a medical prescription could not only have important direct consequences for the health of the individual but also considerable unintended consequences for the health of the population at the community level, namely that an inad-

equated consumption of medications might reduce drug resistance. In Spain both the demand for and sale of drugs without the need for a medical prescription is a relatively frequent phenomenon. As a consequence, the Spanish Ministry of Health has now launched specific campaigns aimed at improving the rational use of medicines.

The international context

The international literature, mainly from the United States, provides evidence of significant differences in the consumption of pharmaceuticals by immigrant populations. For example, one study found that Black or Hispanic users of Medicare consume fewer pharmaceuticals than White users with the same chronic illness and pharmaceutical coverage. Another important conclusion of this study is that the type of pharmaceutical consumed by ethnic minorities is also cheaper.¹ More recently, another US study confirmed these results, showing that a large proportion of the disparities in out-of-pocket expenditure and in the consumption and expenditure in pharmaceuticals of White, Black and Hispanic ethnic minorities are not completely due to differences in population characteristics, such as the lower socioeconomic status of minority groups, but to factors related to the race or ethnicity of the individual.² The authors attribute ethnic inequalities in the consumption of pharmaceuticals to the

scepticism of these patients with respect to medicine and health care in general, lower compliance with medical advice, communication problems with doctors and possibly differences in physician prescribing habits.

The Spanish case

While there is a growing number of studies in Spain that explore differences in health and health care use between immigrants and Spaniards, the literature on differences in pharmaceutical consumption is limited. One recent report shows that the (age-sex adjusted) pharmaceutical spending of immigrants is much lower than that of their Spanish counterparts.³ The findings of another study in the city of Lleida in Catalonia suggest that both pharmaceutical drug spending and drug consumption are lower for non-Spanish-born individuals relative to Spanish-born individuals of the same age and sex⁴. Finally, one study using data from the 2003 Spanish National Health Survey also reaches similar conclusions.⁵ However this study found no significant difference between the Spanish national and non-national populations in self-medication patterns.

Another study has made use of the 2006 Spanish National Health Survey. This survey includes a sufficiently large sample of the foreign-born population.⁶ The use of this survey allowed the authors to make a detailed comparison of drug consumption between Spaniards and several

Dolores Jiménez Rubio is Associate Professor, Department of Applied Economics, University of Granada, Spain.

Cristina Hernández-Quevedo is Research Officer, European Observatory on Health Systems and Policies, LSE Health, London School of Economics and Political Science, UK. Email: dolores@ugr.es

categories of immigrants, thus taking into account the heterogeneity inherent to the immigrant population living in Spain. The analysis is based on a multilevel multinomial probit model that compares three consumption options (no consumption of drugs, consumption of prescribed drugs and self-medicated consumption) for the five most consumed drugs in Spain. Evidence from this study suggests that there are some important differences in pharmaceutical consumption linked to country of birth. In particular, Africans, Europeans (from non European Union countries) and European Union individuals show a lower probability of consuming prescription medicines than Spaniards, while citizens from the European Union and Africa also show a higher probability of using no drug treatment at all for the same level of need. Interestingly, the results obtained by this study reveal that for Romanian born citizens the probability of consuming medicines without a medical prescription is higher than for Spanish born citizens, while individuals born in the European Union have a lower probability of self-medication.

While there are many factors that could explain differences in prescribed consumption and no consumption of medicines,² the observed disparities in patterns of self-medication could be attributed to cultural differences. This is because according to one recent survey of nineteen European countries, Romania has one of the highest self-medication rates for antimicrobial drugs, while other European countries show lower self-medication rates than Spain.⁷

Another important result from this study is that there are factors, in addition to those accounting for the effect of cost sharing, such as health limitations and retirement status, that are relevant in explaining drug consumption in Spain. In particular, being in receipt of private insurance is found to be associated with a higher probability of drug consumption, implying that the actual cost sharing structure in Spain, which is not means tested, may generate inequalities in access to drugs, particularly for poorer individuals who do not meet age and disability criteria to be exempt from co-payments.

Key conclusions

The rapid increase in the immigration phenomenon in Spain has placed important pressures on health care expenditure in a health system where virtually all the pop-

ulation is legally entitled to free access to health care. While there is a growing body of research in Spain that analyses whether, despite the universality of health benefits, differences in health status and health care access exist on the basis of the country of origin of an individual, to date there is limited evidence on the existence of differences in the consumption of prescription medicines or self-medication.

According to the most recent empirical literature reviewed in this article, in Spain, as in other countries with a longer tradition as immigrant recipient countries such as the United States, consumption of medicines varies by country of birth. Overall, immigrants tend to consume fewer pharmaceuticals and are more likely not to have any treatment at all compared to Spaniards with the same illness and socioeconomic characteristics. A small group of immigrants, however, tend to have higher self medication rates than the Spanish population, which all else being equal is probably due to cultural factors.

The differences in the use of health services and in the consumption of medicines in Spain suggest that the Spanish National Health System has an important role to play in the design of more effective health services for immigrants. Policy proposals have been put forward and discussed elsewhere.⁸ Given the decentralisation of the health system, it is expected that only those regions with a higher proportion of immigrants in their total population will bring forward measures to better integrate immigrant groups.

However, the reduction in the foreign-born population now being observed as a consequence of the current economic recession in Spain might reduce incentives to adopt new measures to improve the access of ethnic minorities to health services. At the same time, if the arrival of new immigrants decreases, it is likely that the differences in pharmaceutical use between established immigrants and the native population will narrow significantly, since most of the international evidence suggests that disparities in the use of health services tend to decrease with the number of years in the recipient country.

There is a wide scope for future research in this area. Most of the limitations of studies in this area are related to data availability. If data become available, it would be very interesting to explore whether divergences in drug consumption really tend to reduce with the number of years living in Spain.

Also, future studies may consider exploring the links between disparities in drug consumption related to country of birth and inequalities in health, or in access to medications, respectively.

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Croatia: 2009/2010 pharmaceutical pricing and reimbursement reform

Luka Voncina and Tihomir Strizrep

Summary: In 2009/2010, Croatia substantially reformed its pricing and reimbursement regulation of medicines with the aims of maximising value for invested funds, increasing efficiency and transparency in high level decision making, as well as ensuring ethical pharmaceutical marketing practices. Most notably, the reform measures included: clearly defined judgment criteria and full public disclosure of the reimbursement decision-making process; pricing reforms; strengthening of evidence-based medicine and health economic requirements for submissions; pay back, rebate and cross-product agreements; and mandatory reporting of promotional expenses and all financial transactions between pharmaceutical companies and doctors employed by the public health care system.

Key words: Pricing, reimbursement, medicines, transparency, value for money

As part of Minister of Health and Social Welfare Darko Milinović's overall health care reform, in 2009 and 2010 Croatia substantially reformed its pricing and reimbursement regulation for medicines. The main goals of the reform were to (a) maximise value for tax payers' money, (b) improve efficiency and transparency in high level decision making, and (c) ensure ethical medicines promotion practices. The results of the reform enabled the Croatian national health insurance fund (Croatian Institute for Health Insurance – HZZO) to generate extensive savings, while at the same time improving access to innovative medicines.

In 2009, HZZO expenditure on prescription medicines amounted to 2.9 billion Kuna (kn) (€393 million)*, with an additional 2 billion kn (€271 million) spent on hospital medicines, of which HRK480 million (€65 million) went on expensive products funded from a budget separate to that for regular hospital expenditure. Due to the introduction of modest co-payments

(15kn or €2 per prescription) and reference pricing, HZZO expenditure on prescription medicines decreased by 2.9% in comparison with 2008.¹

In the twelve month period from July 2009 to July 2010 as many as 47 innovative molecules were added to the different HZZO lists of reimbursed medicines and thirteen innovative molecules to its list of expensive hospital medicines. For comparison, a total of 45 products were listed in the period from 2002 to 2009. Comparing expenditure in the first six months of 2009 and 2010, HZZO expenditure on prescription medicines decreased by an additional 13% from 1.7 to 1.5 billion kn (€230.5 to €203.4 million), while its expenditure on expensive hospital medicines decreased by 28.5% from 219 to 157 million kn (€30 to €21 million). Total savings generated by the reform across the two periods amounts to 295 million kn (€40 million). HZZO due arrears have also substantially decreased, from 1.3 to 1 billion kn (€176 to €135.6 million), a 22% reduction.²

So what did the reforms involve? We now summarise the pricing and reimbursement system in Croatia along with the major changes introduced by the reform.

The pharmaceutical pricing and reimbursement system

The HZZO holds a virtual monopsony on pricing and reimbursement in the markets for prescription and hospital medicines. Only HZZO contracted hospitals and primary care physicians can prescribe medicines that are paid by mandatory health insurance. The HZZO implements two lists: the 'basic' list with all essential medicines covered by mandatory insurance, and the 'complementary' list with medicines covered partially through mandatory insurance and partially by out-of-pocket payments. Applications for reimbursement are submitted to the HZZO Committee for Medicines for consideration. The committee delivers a non-binding opinion on all applications to the HZZO management board, which makes the final decision.

In Croatia, international price comparisons are used for setting maximum wholesale prices (Table 1). The system takes into account drug prices in Italy, France and Slovenia. Prices in Spain and the Czech Republic are consulted if data from Italy, France and Slovenia are not available.

The HZZO also sets reimbursement limits for most prescription medicines through annual internal reference pricing. Forty-one clusters are formed at Anatomical Therapeutic Chemical Classification

Luka Voncina is Head of Department for Drugs and Medical Products and Tihomir Strizrep is Managing Director, Croatian Institute for Health Insurance, Zagreb, Croatia. Email: lvoncina@gmail.com

* One Croatian kuna equals €0.135

Table 1: HZZO international price comparison mechanism for setting maximum wholesale prices

Listed drugs determined through annual price recalculations	New drugs introduced to lists
Drugs protected under patent in Croatia or any EU member state: up to 90% of the average price in Italy, France and Slovenia.	Original breakthrough products: up to 100% of the average price in Italy, France and Slovenia.
Drugs not under patent in Croatia or any EU member state: up to 65% of the average price in Italy, France and Slovenia.	Original 'me-too' products: up to 90% of the average price of equivalent drugs in Croatia
	Generic products: up to 70% of the average price in Italy, France and Slovenia and up to 90% of the price of the last bioequivalent generic introduced to the list.

(ATC) levels 3, 4 and 5* using the Defined Daily Dose (DDD) approach. Payment is only granted up to the level of the reference price, while the difference with the actual market price has to be paid by the patient if the company does not accept the reference price (the B list). Companies may opt to negotiate a higher price than the one determined through the reference pricing mechanism, but are obliged to generate equivalent savings to the HZZO through price decreases on other products or through rebate agreements.

The reform: improved decision making and transparency

Two ordinances that regulate the market introduced most of the reform measures: one ordinance established the criteria for wholesale pricing and reporting of the wholesale prices of medicines and a second ordinance established the criteria for inclusion of medicines in the basic and supplementary reimbursement lists of the HZZO.³

As a result of the reform, applications for the inclusion of productions on any of the HZZO lists are now published on the HZZO web page (<http://www.hzzo-net.hr>) within five working days of receipt. The information includes the identity of the applicant, the date of application receipt and the subject of the application. The list of HZZO Committee for Medicinal Products members with short CVs, as well as the dates and agendas of committee sessions, are also published online.

Improvements have been made in the committee's methodology for making recommendations and transparency has been increased. The committee now

operates in two semi-annual cycles. The cycles consist of four regular sessions where the committee discusses submitted applications and a fifth regular session where it ranks the applications in terms of those that may increase HZZO drug expenditure. Ranking is undertaken using a Delphi process – a consensus building method ensuring that all members of the committee carry equal weight in the decision-making process.

In addition, the new ordinances introduced detailed criteria on which the committee must base their recommendations. These include: (a) the product's importance from the public health perspective; (b) its therapeutic importance; (c) its relative therapeutic value; (d) an assessment of ethical aspects; and (e) the quality and reliability of data and assessments from reference sources. For example, with regard to relative therapeutic value, a product may be classified in one of three groups:

1. A product with new therapeutic value, when it concerns a medicinal product for treatment or prevention of diseases, conditions or disorders with no currently available effective treatment.
2. A product with added therapeutic value when, compared to a standard or typical medicinal product or treatment, it refers to:
 - more favourable effect on final treatment results,
 - more favourable effect on substitute treatment results,
 - more favourable effect on quality of life,
 - efficient treatment of disease symptoms,
 - improved safety profile of a medicinal product,

– a more patient-friendly use of a medicinal product,

3. A product without proof of new or added therapeutic value.

Furthermore, there are increased requirements in the application which the committee assesses. Most importantly, these include having a tabular presentation of the status of the product in respect of health insurance or health care systems of all Member States of the European Union and, if available, a decision or opinion about financing of the product issued by the competent authority engaged in health technology assessment. Information should also be presented on indications and instructions for use, the amount covered by compulsory health insurance, any surcharges and other information relevant to the financing of the medicinal product in individual Member States. Scientific evidence must also be presented demonstrating the advantages of the medicinal product for suggested indication(s) over comparator treatments, primarily over medicinal products already included in the basic or supplementary reimbursement lists of the Institute. Meta analyses and systematic appraisals should be presented where available.

The therapeutic guidelines of both Croatian and European expert associations for indications for which an application has been submitted will be taken into account. A description of current clinical practice in Croatia by indication for which the application has been submitted and for which the medicinal products already included in the Institute's lists are used, must be provided along with comments on efficacy and safety, and a table comparing the relative price of treatment. There is also a requirement for a description and analysis of the effect of the use of the new pharmacological therapy on patient health care resulting from the inclusion of the medicinal product on the list (including the use of complementary products and services). An estimate of the number of patients likely to receive the product over a three-year period is also required, as well as an estimate of the proportion of patients who could only be satisfactorily treated with the new medicinal product, compared to those satisfactorily treated with products already on the Institute's approved lists.

Criteria for the inclusion of products in the HZZO list of expensive products have also been defined. These include a need to show

* Level 3 corresponds to the therapeutic/pharmacological subgroup; level 4 to the chemical/therapeutic/pharmacological subgroup; and level 5 to the chemical substance.

that use of the product represents a breakthrough in the risk-benefit ratio of treatment for a given indication, in comparison with medicinal products already included in the basic reimbursement list of the Institute. The product must be intended for hospital use and not subject to medical prescription. Both guidelines for prescription, as well as the clinical pathway for the condition for which the medicinal product is to be used, must be strictly defined by the Croatian Medical Association. There must be no generic equivalent or the product must be on the European Commission Register of Designated Orphan Medicinal Products. In terms of cost, a budget impact analysis must demonstrate that use of the product could not be financed through routine hospital budgets because of the very high treatment costs. It should also be noted if products with similar therapeutic and pharmacological properties, but higher therapy costs, are already included in the list of expensive medicinal products.

One additional change introduced as part of the reforms means that when a company now wishes to appeal against a decision made by the HZZO management board on the listing of a medicinal product, the case must proceed to court, unlike the situation previously where arbitration procedures were used.

Ensuring value for tax payers' money

All applications for reimbursement have to be accompanied by budget impact analyses. These are undertaken according to strict criteria that largely adhere to ISPOR (International Society for Pharmacoeconomics and Outcomes Research) principles of good practice for budget impact analysis.

The financing of 'expensive products' is now regulated by payback agreements concluded between the marketing authorisation holder and the HZZO. The HZZO finances the treatment of a precisely defined number of insurants (based on the results of the budget impact analysis), while the marketing authorisation holder ensures the supply of its medicinal product to additional insurants (if needed) at its own cost through donations or pays back the overspend to the HZZO. Prices can also be determined using a cascading approach with regard to the number of insurants receiving the medicinal product.

When concluding the agreement, the HZZO takes into account the total consumption of all medicinal products for the

given therapeutic indication. This can translate to disease-wide agreements for all market authorisation holders with medicinal products for a particular condition. The new byelaws also introduce cross product agreements. Applicants are allowed to submit binding offers where the application, which refers to the product considered by the Committee for Medicinal Products, is connected with a parallel proposal for the reduction in the price of the medicinal product already included in the Institute's basic reimbursement list. In this way new drugs are added to HZZO lists without additional costs, as the costs borne by the introduction of new products are offset through savings achieved by price reductions in products that are already reimbursed.

Furthermore, internal reference pricing is now better regulated. Groups are formed at the third or higher ATC levels. Reference prices are determined (to a large extent by taking account of the price by DDD) by unit dosage form for the same or similar pharmaceutical forms for each strength level of the active substance and each pack size separately. Reference prices are determined on the basis of the lowest price of a product which recorded at least 5% of sales within a therapeutic group over a twelve month period preceding the reference pricing process. This principle was adopted to avoid the possibility of market shortages.

Ethics

All applicants to the lists are obliged to enter into a uniform agreement on the ethical promotion of medicines. This entails substantial financial penalties for unethical promotion. The main features of the agreement are shown in the panel above.

All features of the agreement apply to third persons working on behalf of the marketing authorisation holder. A financial revolving deposit mechanism has now been put in place to guarantee implementation. Companies are obliged to deposit their promotional budgets (estimated in the first year of agreement implementation at a minimum of 3% of annual revenue from the HZZO) to the HZZO in quarterly instalments and present all promotion based expenses, including all payments to individuals employed in the public system, quarterly. Payback of the funds in question is also delivered quarterly.

Penalties for unethical promotion include delisting, informing the general population

Key features of uniform agreement on the ethical promotion of medicines

Mandatory reporting of all promotional expenses and financial transactions between companies and doctors employed by the public health care system.

Ban on advertising and distribution of prescription drugs to the general population.

Ban on informing the general population of ongoing applications to avoid unethical pressure on the HZZO Committee for Medicinal Products.

Ban on promotion targeted at doctors based on information that has not been scientifically proven.

Ban on financial remuneration or remuneration of any kind to doctors for prescribing.

All promotional events have to be educational and professional. They may not include more than 25% of time for unprofessional activities.

Companies must provide detailed information to the HZZO of any organised promotional events 15 days in advance.

The HZZO has to be notified of all clinical studies, including post marketing surveys.

Representation costs are limited to 1,000 kn (€135) per doctor (does not include education).

Individual sales representatives are allowed 15 minutes contact time per doctor per month.

of unethical behaviour and withdrawal (in part or total) of the quarterly deposit. The HZZO Committee for Medicinal Products then functions as the arbiter ensuring the implementation of the agreement, while the management board takes any final decision on any punishments and penalties to be incurred.

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Managed competition in the Netherlands: an example for others?

Ewout van Ginneken, Willemijn Schäfer and Madelon Kroneman

Summary: The introduction of managed competition in the Netherlands in 2006 fundamentally changed the roles of patients, insurers, providers and the government. Health insurers are expected to negotiate with providers and purchase efficient care of good quality. Patients are expected to critically assess and select the health insurer and provider of their choice. In this ongoing transition process all players should receive the appropriate tools to fulfil these roles. Important challenges remain: patient information on price and quality should be continuously improved; the risk adjustment system needs continuous refining; quality has to be made visible and measurable; the DBC (Diagnose Behandelings Combinatie) system, comparable to a DRG system, must be reformed; and the negotiation and purchasing process should be optimised and shortened. Other countries planning to introduce a similar system can learn from the Dutch experience. The introduction of managed competition is not merely a simple exercise but a process that requires continuous efforts from all market players.

Key words: Health reform, managed competition, health financing, the Netherlands

Recently, we published the 2010 Health Systems in Transition review for the Netherlands.¹ It is the first attempt to give a full blown description of the Dutch health system after major health reform in 2006. This reform, introduced after almost two decades of preparation, has brought important new regulatory mechanisms and structures to the Dutch health system. The reform can be seen as the realisation of a long-standing political wish to unite the old sickness fund scheme, which covered about two-thirds of the population, and the voluntary private health insurance scheme, for individuals with an income above a certain threshold. As a regulatory mechanism the reform introduced managed competition among actors in health care. Early attempts to unite all health insurance schemes into a single mandatory scheme failed at the beginning of the 1990s, mainly because of strong opposition from health insurers,

employers and physicians. During the 1990s, however, smaller reforms originating from early plans were gradually implemented. This helped pave the way for the final and successful attempt at reform in 2006.

The reform's rationale is threefold:

1. The new system aims to contain rising health expenditures by increasing health system efficiency, i.e. higher quality at lower costs, through the introduction of managed competition.
2. The reform aimed to reduce inequity in the system. Age, income and health status all had a potential influence on insurance form, contribution level and access to health services. Most notably, high-risk individuals with incomes above the threshold and whose only option was to purchase private health insurance were negatively affected by risk selection and

high premiums. Under the new system everybody is insured under the same conditions and all health insurers are obliged to accept all individuals.

3. It was hoped the new system would increase transparency. The old system was characterised by a high level of government intervention, resulting in a fragmented insurance market with complex rules and regulations, especially from the perspective of the individual.

Although the major political parties agreed on the goal of uniting the health insurance scheme, some key aspects of the system were heavily debated political decisions. Basically two models were discussed: (i) a model with community-rated premiums and (ii) a model with income-related contributions, as preferred by the opposition. Furthermore, discussions involved the decision to choose either a system under private law with strong government guarantees or a system under public law with some market mechanisms. In the end the then ruling coalition of Christian Democrats and Liberals adopted the model of community-rated premiums under private law.

Ewout van Ginneken is Senior Researcher in the Department of Health Care Management at the Berlin University of Technology. Willemijn Schäfer is Researcher and Madelon Kroneman Senior Researcher at the Netherlands Institute for Health Services Research (NIVEL), the Netherlands. Email: W.Schafer@nivel.nl

In this review, we examine managed competition in the Netherlands almost five years after its introduction. After a description of the system, some important challenges will be discussed. We conclude with a discussion of the system and its lessons for countries contemplating the introduction of a similar system.

Main elements of managed competition in the Netherlands

The 2006 Health Insurance Act (*Zorgverzekeringswet, Zvw*) and the Health Care Market Regulation Act (*Wet marktordening gezondheidszorg, Wmg*) were introduced as a legislative framework for managed competition. This fundamentally changed the role of the players in the Dutch health system. The role of the government was envisaged to change from direct control of volumes, prices and productive capacity to safeguarding the process from a distance. Responsibilities have been transferred to insurers, providers and the insured individuals. The government supervises the quality, accessibility and affordability of health care. The health insurers, health care providers and the insured or patients are the market

players. Interactions between these players take place in three markets: the markets for health insurance, health care provision and health care purchasing (see Figure 1). The establishment of new 'watchdog' agencies in the health sector aims to avoid undesired market effects in the new system.

Health insurance market

In the health insurance market, individuals are obliged to purchase their basic health insurance from health insurers. Health insurers must compete on price and quality and have to accept all individuals. Health insurers are not allowed to differentiate their premiums according to the risk profile of the applicants (community rating). Tax subsidies, called health care allowances, partly compensate those on lower incomes for their health insurance costs. Basic health insurance covers essential curative care tested against the criteria of demonstrable efficacy, cost-effectiveness and the need for collective financing. The basic health insurance benefit package is determined by the Ministry of Health Welfare and Sport based on the advice of the Health Insurance Board (CVZ). Individuals are

free to choose their health insurer, level of their voluntary deductible (€0–€500), reimbursement or an in-kind policy and switch insurers every year.

If an individual opts for an in-kind policy, choices between providers can be restricted to contracted providers, but financial risk will be absent. If the insured individual nevertheless wants to visit a non-contracted provider, additional out-of-pocket (OOP) payments may apply. When an individual opts for a reimbursement policy, a free choice of provider exists, but also here there is a reimbursement limit that in some cases could lead to additional OOP payments. In addition, a compulsory deductible (currently €170) is applied. However, both the voluntary and the compulsory deductible do not apply to general practitioner care (GP), maternity care and dental care for those under the age of 18. The government committed itself to provide information on health plans in terms of price, quality, and benefits. This should help individuals in making informed choices, which is essential for the proper functioning of the competitive insurance market.

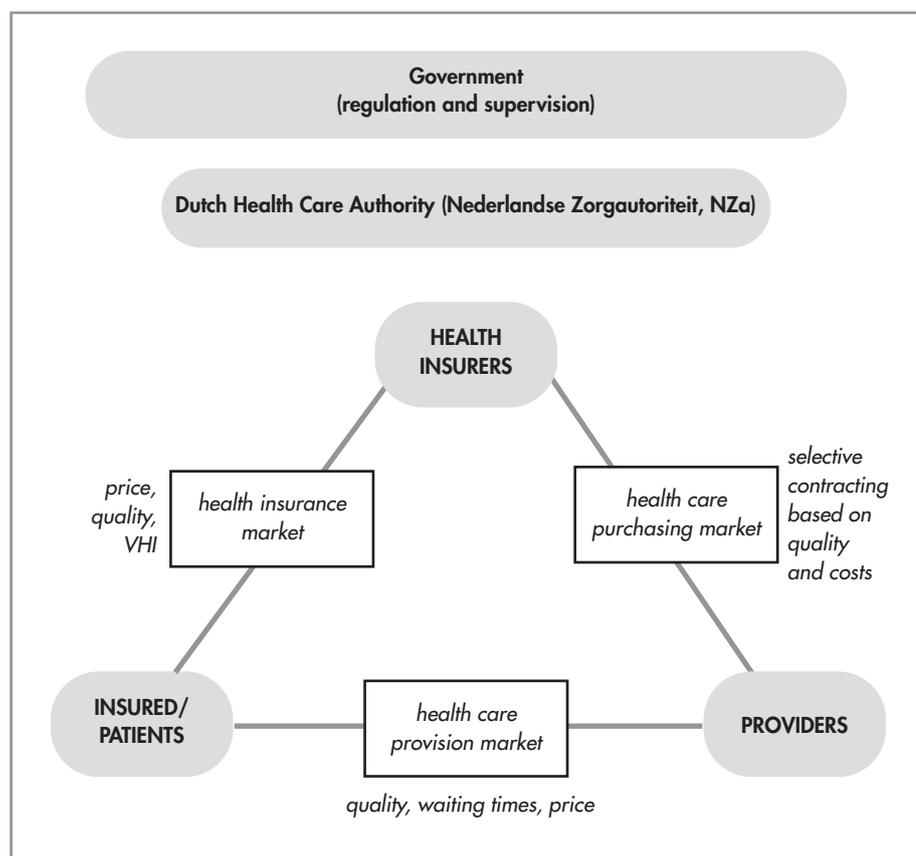
An interesting feature of the Dutch system is the collective contract. Collective contracts are established between groups of insured and the health insurer. Health insurers may offer a maximum 10% reduction on the individual premium. Collective arrangements can be made by several legal bodies such as employers and patient organisations. This system should give the insured more influence ('voice') with the health insurers.²

Besides basic health insurance, patients may purchase complementary voluntary health insurance (VHI) from any health insurer. Complementary VHI may only cover health services that are not covered under basic health insurance or the long-term care insurance scheme, regulated by the Exceptional Medical Expenses Act (*Algemene Wet Bijzondere Ziektekosten, AWBZ*). Health insurers may use risk-rating and are not obliged to accept individuals for VHI. Consequently, choice on complementary VHI can be limited for patients.

Health care purchasing market

In the health care purchasing market health insurers can negotiate with providers on price, volume and quality of care. In this process, insurers are free to use selective contracting. The use of these tools should result in the purchasing of efficient care.

Figure 1. Netherlands health care market interactions



Source: authors' own compilation

The payment mechanisms of the health care providers have also changed to accommodate negotiations and competition. A case-mix related financing system became necessary in which money would follow the patient.

GPs are now paid via a combination of capitation fees and fee-for-service. So far, these fees are negotiated centrally between the National Association of General Practitioners (LHV), Health Insurers Netherlands (*Zorgverzekeraars Nederland*) and the Ministry of Health, Welfare and Sport. However, direct negotiation between insurers and GPs for lower fees is allowed.

For hospital care an elaborate diagnosis-related groups (DRG)-type system called Diagnosis and Treatment Combinations (*Diagnose Behandeling Combinaties, DBCs*) has been in place since 2005. Freely negotiable DBCs can be negotiated between insurers and providers, on price, volume and quality. They are introduced gradually, amongst other reasons to give the health insurers time to build up the necessary expertise and experience to assume their purchasing role. For example, in 2005, freely negotiable DBCs accounted for 7% of annual hospital turnover. In 2010, this percentage stood at 34%. For the remaining DBCs the Dutch Health Care Authority (NZa) establishes the prices; insurers and providers can only negotiate volume and quality.

Health care provision market

In the health care provision market, providers should compete for patients on the basis of quality of care. The government provides information on quality and waiting times of providers so that individuals can make informed choices. This assumes, however, that individuals are willing or able to make these choices and have a free choice of provider. Yet the latter may be restricted if the individual chose an in-kind basic health insurance plan with selectively contracted providers and if the individual faces access barriers, such as waiting lists or travel distance for certain providers.

Financing of the scheme

All Dutch residents contribute to this scheme in two ways. First, they pay premiums, directly to the health insurer of their choice. Second, an income-dependent employer contribution is deducted through their payroll and transferred to the Health Insurance Fund (HIF). Children up

to the age of eighteen are covered through one of their parent's health plans. The government makes a payment on their behalf directly into the HIF. The resources from this fund are then allocated among the health insurers according to a sophisticated risk-adjustment scheme, which was inherited from the former sickness fund scheme. A well functioning risk adjustment scheme should make both good and bad risks equally attractive to insurers through adjusted financial compensation. This should guarantee access to affordable care for all citizens and take away the incentive for risk-selection. Risk adjustment is an essential precondition for reaping the benefits of a competitive health insurance market.³

Supervision of the scheme

Competition in health care may lead to undesired market effects. The Health Care NZa, an independent administrative body established in 2006 and funded by the Ministry of Health, Welfare and Sport, is responsible for the supervision of the three health care markets in the Netherlands and the lawful implementation of the Health Insurance Act. The NZa may impose tariff and performance regulation and impose specific sanctions on players that have obtained significant market power.

Four bottlenecks in the Dutch version of managed competition

Almost five years after its implementation, it has been a steep learning curve for all market players. Many short-term problems needed immediate attention. To name but a few, competition on premiums led to financial problems for many insurers; a wave of mergers resulted in just four insurers having 88% of the market; excessive DBC tariffs led to overfunding of hospitals, which then had to be paid back; GP payments were delayed; GPs received more funding than anticipated; and there remained a pervasive problem with uninsured individuals and defaulters. All of these problems had (and still have) to be dealt with on an ad hoc basis. On a positive note, although the demands on all actors have been high the situation has never become chaotic.

Below, we will not focus on these issues, but rather on some structural problems that still need to be solved for managed competition to work. Particular attention will be paid to those aspects which are crucial for the different market players to fulfil their roles.

Patient information

Patients are assumed to make informed choices while selecting their health care providers. This requires sufficient and reliable information being readily available for patients. Improvements in this area are needed. Many initiatives have been made to make quality of care more transparent. For example, the government provides information on waiting lists, quality and prices of care through the Internet (www.kiesbeter.nl). However, this information is far from complete and the information needs differ strongly between patients. Information on performance of the various health care institutions only meets the demands of a limited group of patients with a limited set of health problems.⁴ In addition, the NZa concluded that more time would be needed to achieve an efficient provision of information that matches the needs of patients.⁵ In addition, patients may have to visit a preferred provider of their insurer or risk making an additional payment OOP. Insured individuals will have to rely on their insurer to contract care of good quality on their behalf. A future issue for debate for the Dutch government will be whether free choice of provider will remain an integral part of the system or that insurers will become agents for the insured.

The health insurance market on the whole seems to function better than the health provision market. Individuals mostly choose their health plan based on easy-to-compare price information. However, the service level of the insurer, largely similar with only four major insurers left, or the quality of purchased care, which is difficult to assess for individuals, play a smaller role.⁶ Furthermore 64% of individuals are covered by collective contracts.⁷ Since most group contracts are negotiated on premium level, not on the basis of the quality of the contracted care, quality choices in this market do not yet influence the quality of purchased care.⁶ As of 2010, the insurance market seems to have stabilised. It was only in 2006, the first year of the new system, that a considerable number of people switched insurer (21%),⁸ many of them members of a renegotiated collective contract. In the period 2007–2009, the percentage of people switching health insurers stabilised below 5%,⁹ which is the same percentage as under the old (pre-2006) sickness fund scheme.¹

The negotiation process

At present, there are several problems that

complicate the active purchasing role of insurers. First, contracting mainly focuses on price and volume, not on quality. Sound performance indicators that health insurers can use to evaluate the quality of providers are lacking. Second, an insufficient supply of health care providers (in numbers and variety) limits the possibilities for health insurers to selectively contract providers. In addition, health insurers fear damage to their public image if a given hospital is not contracted.¹⁰ Not surprisingly, selective contracting of providers is not yet very common.^{1,11} Third, the negotiation process between insurers and providers often takes until the summer of a given year, whereas nominal premiums must be set on the 1st January.¹ The former is mostly due to the late public announcement of any legal changes in the insurer's operating environment and the large number of DBCs that have to be negotiated. This complicates the contracting process and the setting of realistic premiums. Moreover, new applicants do not know which care will be contracted and have to make choices on the basis of incomplete information. This may seriously hamper patient mobility.¹⁰

The payment method for hospitals

The DBC system for hospital financing is not yet stable and has led to the overfunding of hospitals and increased bureaucracy. For each DBC a price is either negotiated between a hospital and insurer or settled by the NZa. There are problems with the large number of DBCs (about 30,000). This complicates negotiations and the finalisation of contracts. Currently all actors in the field are working on a major revision which should reduce the number of DBCs to 3,000. This should simplify the contracting process. The new system should be implemented in 2012. Furthermore, the DBC system hinders an effective purchasing process. Because DBCs are reimbursed after completion of treatment, the true financial results in a given accounting year will only become clear after a three-year delay.¹⁰ Finally, another important problem with the DBC system is the remuneration of the physician in each DBC. Since this share does not always reflect reality, the incomes of some physicians have increased significantly.

Risk adjustment

The risk adjustment scheme needs constant refining to eliminate perverse incentives for insurers and to ensure fair competition.¹ At

present, the scheme is not working optimally, in particular, for certain high risk groups there are still failures within the scheme. This may lead to predictable losses among insurers which may in turn increase the incentives for risk selection. Risk selection by health insurers for basic health insurance is difficult, since insurers are obliged to accept all applicants and they cannot raise the premium for individuals. However, there are several other opportunities for cream skimming. For example, complementary VHI can in theory be used as a tool for risk selection. VHI can be sold at a low premium in combination with basic health insurance to attract those insured individuals with expected higher profitability levels. So far, however, this has not led to cream skimming.¹⁰

Conclusion

The introduction of managed competition in the Netherlands has attracted a great deal of international attention. Countries contemplating the introduction of a similar system are well advised to follow these developments closely. Introducing managed competition, or more market mechanisms, should not be underestimated. Shifting responsibilities to market players does not mean that there is nothing left for the government to do. The Dutch experience demonstrates that even though complete chaos has not arisen, not everything has turned out in the way that was anticipated. Many problems have had to be solved by ad hoc measures. Furthermore, managed competition is demanding on all players in the system, including the government and its agencies. It clearly shows the need to have a strong institutional structure in place, with enough technological capacity and sufficient regulatory power to manage such an innovative system.

The reform has changed the roles of patients, insurers, providers and the government. Health insurers are expected to negotiate with providers and purchase efficient care of good quality. Patients are expected to critically assess and select the health insurer and provider of their choice. The government presumes that this will increase efficiency and quality in the health care system, as well as make care more demand-driven. However, this reform is still in progress. In this transition process it seems critical that all players receive the appropriate tools to assume these roles. Important challenges remain: patient information on price and quality should be continuously improved; the risk

adjustment system needs continuous refining; quality has to be made visible and measurable; the DBC system must be reformed; and the negotiation and purchasing process should be optimised and shortened. Not until the system is fully implemented, will we be able to evaluate if managed competition has had the intended effects in terms of efficiency and quality.

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Health care performance in the Netherlands:

Easy access, varying quality, rising costs

Michael van den Berg, Richard Heijink, Laurens Zwakhals, Harry Verkleij and Gert Westert

Summary: To monitor trends in health care performance, the Dutch Ministry of Health has commissioned the Dutch National Institute for Public Health and the Environment (RIVM) to produce the Dutch Health Care Performance Report (DHCPR) every two years. Using a set of 125 indicators, the DHCPR 2010 assessed the quality, accessibility and costs of the Dutch health care system by comparing performance with standards, with previous years and with other countries. The report confirms many of the Dutch achievements reported in international comparisons, but also reveals some urgent challenges for Dutch health care.

Keywords: performance assessment, the Netherlands

The Dutch health care system tends to do very well in international comparisons; patient organisations have a strong position, and health services are just around the corner and easily accessible for all. The Netherlands is, without doubt, a relatively wealthy and healthy nation, but is it really a patients' paradise? The *Dutch Health Care Performance Report 2010*¹ confirms many of the Dutch achievements, but it also reveals some urgent challenges for Dutch health care.

To monitor trends in health care performance, the Dutch Ministry of Health has commissioned RIVM to produce the *Dutch Health Care Performance Report (DHCPR)* every two years. Using a set of 125 indicators, the DHCPR 2010, published in English in November 2010, assessed the quality, accessibility and costs of the Dutch health care system by comparing performance with standards, with

previous years and with other countries.

The conceptual framework used for the DHCPR is based on an extensive international literature review.^{2,3} In the applied framework, health care is divided into four specific health care needs: staying healthy (prevention), getting better (cure), living independently with a chronic illness or disability (long-term care), and end-of-life care. The indicator framework used is well accepted internationally. The Organisation for Economic Co-operation and Development (OECD) has adopted this framework for the further development of international comparisons of health care system performance.⁴ Results of the previous DHCPRs were also used in the recently published Health System Review of the Netherlands.⁵ To fill the indicators, RIVM used 68 different national and international data sources from 30 different organisations.

How is the Dutch health care system performing?

What does the DHCPR 2010 teach us about the Dutch health care system? We will discuss some of the major challenges and the successes of Dutch health care that stand out in the report.

Easy access; health care for all

Overall, we concluded that the Netherlands provides excellent access to health services. Following the definition of Smits and colleagues,⁶ accessible care implies that 'people, who need care, can access care in a timely manner and without great barriers'. The Netherlands has a very intricate network of health services. Geographical analyses show that the average driving time from home to the nearest general practitioner (GP), physiotherapist or pharmacy is 1.3 minutes. For hospitals this is 7.7 minutes. Hardly anyone has to drive more than fifteen minutes to reach any of these services.

Costs of care seldom pose a problem. Under a mandatory health insurance scheme practically all residents are insured for curative health care costs. Most long-term care services are paid for by a social insurance scheme that covers all Dutch residents. Co-payments are amongst the

Michael van den Berg, Laurens Zwakhals and Harry Verkleij are researchers at the National Institute for Public Health and the Environment (RIVM), Bilthoven.

Richard Heijink is a researcher at the University of Tilburg and RIVM.

Gert Westert was project leader of the Dutch Health Care Performance Report 2010, researcher at RIVM and professor at the University of Tilburg, since January 2011 he has been Head of IQ-healthcare and professor at Radboud University, Nijmegen.

Email: michael.van.den.berg@rivm.nl

lowest in the OECD countries. In comparison with six other affluent countries, the Netherlands reported the smallest percentage of residents (1%) and people with chronic illnesses (3%) who forego visits to the doctor for financial reasons.

Still, it appears that this easy access might be under threat in some areas. Waiting times for certain health services have been a persistent problem in the Netherlands. For 25% to 33% of clients receiving mental health care, waiting times for treatment were longer than the agreed standard. Likewise, waiting times in outpatient clinics and long-term care often exceeded the standard. Poor telephone access to GP practices during office hours was reported as a problem by many people and one third of emergency calls to GP practices were not answered within the thirty-second standard.

Quality of care stands out in many ways, but varies between providers

Nine out of ten citizens evaluated health care positively. More than 90% were satisfied with the interaction between themselves and their health care providers. Moreover, outcome indicators show positive figures and trends: hospital mortality rates have been decreasing for five years in a row, while infant mortality has decreased by some 20% since 2005. Survival rates for cancer are high by international comparison and there are only a few avoidable hospital admissions compared with other countries. The latter is due to a strong developed primary care system and outpatient clinical care.

A typical characteristic of Dutch health care is a somewhat reserved approach towards medical interventions. This results, for example, in low referral and admission rates, low prescription of antibiotics, and low numbers of revascularisations and caesarean sections compared to most other countries.

Although the overall level of curative care is acceptable for many treatments, it makes quite a difference where the treatment takes place. A number of indicators show wide variations between health care providers:

- the percentage of prescriptions by GPs in accordance with guidelines varied from 49% to 77%;
- the percentage of hip fracture patients operated on within 24 hours ranged from 67.5% to 100% across hospitals;

- the percentage of caesarean sections in low risk pregnant women varied widely between hospitals, ranging from 7% to 30%;
- for a number of conditions treated in mental health care, drop-out rates ranged from less than 5% to 28%.

These findings appear to confirm the importance of a best practice approach and of the use of benchmark or reflective information for health care providers. Moreover, patients and health insurers need such information to make informed choices on the health care market. However, suitable information about quality of care, and patient outcomes in particular, is still lacking.

Long-term care is under pressure. The demand for care is growing and intensifying and becoming increasingly complex. Meanwhile, qualified staff are hard to find. There is also criticism about the quality of care, from both the consumers and providers of long-term care. Just one third of the representatives of psychogeriatric patients state that physical care is always of good quality. Nurses and carers in nursing homes are not always positive about the quality of care; a significant number consider that it is below standard.

The problems in long-term care are taken seriously in the field, as well as in politics. In recent years health care professionals, patient organisations and the government have worked hard to improve the measurability of the quality of long-term care. An Evaluation Framework for Responsible Care has been developed. Institutions use this framework as a tool to account for the quality of care they provide. This framework was described previously in Eurohealth by Frijters.⁷ The new Dutch government has now announced that they will invest an extra billion euro in long-term care, particularly in care for older people. Such an investment at a time of huge cutbacks in public spending indicates that there really is a sense of urgency to improve this sector.

Costs: do we get value for money?

In the period 2007–2009, health care expenditures grew at an annual rate of 6% to 7%, which is slightly more than in preceding years. The most recent OECD time-series data (2000–2007) show that the growth in Dutch real health expenditure was about average compared to other OECD countries. Health spending growth resulted largely from an increase in the

volume of care – that is, more services were delivered. Since 2002, the volume of care provided by Dutch hospitals has grown by 4.2% per annum compared to an average price rise of 1.6%. Inpatient admissions grew by 3% yearly and day-patient admissions by 10%. At the same time, the volume of Dutch hospital care has remained relatively low by international standards. Interestingly, the price of medicines has fallen dramatically in recent years, but the volume of medication prescribed (the number of prescriptions filled) increased in 2008 by almost 15%. The volume of outpatient care grew substantially in different areas: by yearly averages of 5.5% in care for older people, by 8% per year in mental health care and by an average of 9% per year since 2004 in care for the disabled.

These growth figures may turn out to be critical from the perspective of public finances. Since 1990 the share of health care in total public expenditure has doubled (now being 20%) and health care has consumed a considerable part of national income growth. The question is whether this seemingly autonomous growth in the health care sector can be maintained in comparison with growth in other sectors, and whether it will affect the purchasing power of Dutch residents. The recent economic crisis and deterioration of public finances have rekindled the debate on health care spending.

High and rising health care costs may be less of a problem as long as investments pay off. Moreover, the removal of any waste or inefficiency in the health care system would alter health spending levels without adverse effects on quality and accessibility of care. Efficiency analyses of the relationship between costs and quality show that despite rising costs, overall mortality and avoidable mortality have dropped significantly since 2003. The same is true for most other western European countries. In international macro level cost-benefit comparisons, the Netherlands performs about average. Meso level indicators demonstrate signs of inefficiency, for example, the substantial variation in freely negotiable hospital prices, in the average length of hospital stays, in GP tariffs and in GPs prescribing cheaper generic drugs.

Final remarks

The Netherlands is facing the same health care challenges as many other European countries. How to control rising costs?

How can the system cope with an ageing of the population? How can it rise to the challenges of scarcity in human and financial resources, as well as to the rising numbers of the chronically ill? The Netherlands has chosen to adopt a system of managed competition with a range of measures that aim to protect citizens against undesired side effects of market forces (see the article of Van Ginneken et al in this issue) [8]. Health insurers and health care suppliers are primarily accountable for good quality care. Ministerial accountability concerns the functioning of the health care system at a macro level and 'the rules of the game'. The DHCPDR helps the minister to carry out this role, by providing a monitoring instrument on all aspects of care.

It is still too early to draw firm conclusions regarding the successes or failures of reforms in the system. Nevertheless, it goes without saying that in a system of managed competition in which market forces play an increasingly important role, policy makers are facing new challenges regarding quality, costs and access.

We end by highlighting three issues.

It is assumed that health insurers do not simply purchase any health care service, but instead act as critical purchasers. In the DHCPDR we concluded, however, that insurance companies mainly competed on the price of health insurance policies and the cost of health care services. In contrast, the quality of care is still of limited influence in the purchasing process. One of the underlying problems is that quality of care lacks transparency. Choice requires clear and valid information about providers. Several projects have started to collect and publish such information, but there is still a long way to go.

Easy access to health services is an important achievement. However, there might be a trade-off between access and quality. There is evidence that concentration of especially highly complex surgery improves quality and reduces mortality rates. Critical purchasers of care are looking for high quality providers and may selectively contract with those providers. This means that many patients may not be able to visit their nearest hospital. The system may have to make trade offs between access and quality. An interesting question is what differences in quality outcomes justify additional travelling time or waiting lists.

The same is true for the trade off between

prices and access. Health insurers can offer cheap policies that restrict freedom of choice. By contracting only a limited number of health care providers, health insurers are able to negotiate for cheaper care for many services. In this case patients sacrifice some access for cheaper insurance. Interesting questions will concern whether insureds will accept such restrictions and what impact this will have on equity and quality in the long term, given that premiums are rising. Another question will be whether contracting changes the structure in health care markets (market power).

The DHCPDR will continue to monitor trends in quality, accessibility and costs of Dutch health care. This information will be regularly updated at www.healthcareperformance.nl

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New HiTs on Greece and Spain



GREECE

Charalambos Economou
180 pages

Despite success in improving the health of the population, the Greek health care system faces serious structural problems concerning the organisation, financing and delivery of services. It suffers from the absence of cost-containment measures and the high percentage of private expenditure goes against the principles of fair financing and equity. Efficiency is also in question due to the lack of incentives to improve performance in the public sector. In addition, the oversupply of physicians, the absence of a referral system and irrational pricing and reimbursement policies are the factors encouraging under-the-table payments and the black economy. These shortcomings result in low satisfaction with the health care system expressed by citizens.



SPAIN

Sandra García-Armesto, María Begoña Abadía-Taira, Antonio Durán, Cristina Hernández-Quevedo and Enrique Bernal-Delgado
295 pages

The new Spain HiT focuses on the consequences of the totally devolved status of the health system, consolidated in 2002, and the implementation of the road map established by the 2003 Spanish National Health System (SNS) Cohesion and Quality Act. The reforms have paved the way for a brand new consensus-based policy-making process grounded in knowledge management, the effects of which are progressively starting to be evident.

Available online at www.healthobservatory.eu

Hungarian Presidency of the Council of the European Union

News and information on the Hungarian Presidency of the EU.

<http://www.eu2011.hu/>

The European Public Health Law Network (EPHLN)

The EPHLN is a European Commission funded website which aims to disseminate resources related to public health law. In particular, EPHLN was set up as part of a Pandemic Influenza project, PHLawFlu, which looks at the use of law as a tool in promoting and protecting public health. Visitors to the site are able to download publications, listings of past events and legislation. On the homepage news and twitter feeds highlight relevant postings. In addition useful links, a search tool and a glossary are accessible. Users may sign up to the EPHLN newsletter. The website is available in English and partly in French.

<http://www.ephln.org/>

The European Association of Health Law (EAHL)

The European Association of Health Law was established in 2007 by a group of health lawyers in academic institutions from around Europe to provide a forum for health lawyers from countries in the Council of Europe and beyond to discuss and collaborate on issues of importance in the development of health law and related policies. The website contains newsletters (published bi-annually), information on upcoming events, conferences, seminar series and other related events. The progress of three working groups – ‘Research and Networks’, ‘Institutions’, and ‘Teaching and training’ – can be tracked online. Users may sign up for membership, whereupon a forum provides opportunities to interact in discussions and the *European Journal of Health Law* becomes fully accessible. Contact information is provided online. The site is available in English only.

<http://www.eahl.eu>

Patient rights in the EU

Founded in 2008 as a collaboration between the Centre for Biomedical Ethics and Law (Catholic University of Leuven, Belgium) and EuroGentest (an EU funded initiative that deals with all aspects of genetic testing), this website provides a general overview of national patients rights legislation in all European member states. Users are able to browse topics by country, whereupon more detailed information and further links are given. There is a section dedicated to the European Convention on Human Rights and Biomedicine. European ethical-legal papers linked to the university faculty are available for perusal, with direct web access to the University and EuroGentest provided. The site is available in English only.

<http://europatientrights.eu/>

Eucomed

The Brussels based Eucomed represents 4500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Its mission is to improve patient and clinician access to modern, innovative and reliable medical technology. The website contains industry information, press releases, Eucomed’s code of ethics, patient stories and downloadable newsletters. Users can follow twitter feeds and subscribe to the newsletter, press releases and participate in Eucomed’s blog. Vacancies and contact details are also found online. A search box allows for easy navigation. The site is available in English only.

<http://eucomed.org/>

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA is an executive agency of the UK Department of Health. It is responsible for ensuring that medicines and medical devices work and are acceptably safe. The website details the background of MHRA and the site is divided between the ‘Pharmaceutical Industry’ and ‘Patients and public’, each with further links and perspectives. Individual sections are dedicated to regulation, safety, committees, conferences and learning centre, online services and extra sources of information, including publications, a news centre and a portal for feedback. Many reports and publications are freely available to download and users can sign up to an email alert. A search box, contact information, glossary and other user friendly tools allow for ease of access.

<http://www.mhra.gov.uk/>

Eurohealth aims to provide information on new publications that may be of interest to readers. Contact Azusa Sato at a.sato@lse.ac.uk if you wish to submit a publication for potential inclusion in a future issue.

Physical Activity in the Prevention and Treatment of Disease

Sweden: Professional Associations for Physical Activity, 2010



ISBN 978-91-7257-715-2

623 pages

Freely available online at:
<http://www.fhi.se/PageFiles/10682/Physical-Activity-Prevention-Treatment-Disease-webb.pdf>

This extensive report outlines the role of physical activity in the prevention and treatment of disease. The authors of this compilation advocate regular exercise as a proven way to combat different diseases including diabetes, cardiovascular disease, colon cancer and depression. Furthermore, the European Union Public Health Information System (EUPhix) estimates that physical inactivity costs between €150 and €300 per citizen per year, while the medical costs of physical inactivity in the United States alone were estimated at \$75 billion in 2000. The report also supports exercise to encourage the active involvement of patients in their own treatment and taking personal responsibility for their own health.

The document is split into two parts, with a total of 47 chapters written by 95 experts. The first part provides a background and scientific rationale for the argument, whilst the second lists the benefits by specific disease. Each chapter

outlines a summary, definition of the disease, effects of physical activity, indications, existing prescriptions, functioning mechanisms and tests, interaction effects and contraindications, as well as risks associated with physical exercise.

The authors argue that the report can be used as a handbook by health care professionals when prescribing physical activity, in addition to serving as a textbook for health care workers.

Contents:

Preface

Background

Part 1: benefits and scientific rationale of physical activity

Part 2: benefits by disease (33 types)

World Health Report – Health systems financing: the path to universal coverage

Geneva: World Health Organization, 2010



ISBN 978 92 4 156402

ISBN 978 92 4 068480 5 (electronic version)

106 pages

Freely available online at:
<http://www.who.int/whr/2010/en/index.html>

As demand for universal coverage has moved higher up the political agenda, the member states of the World Health Organization have committed themselves to achieving this goal by developing their health financing systems. In this edition of the World Health Report, countries are advised on how to best move forward and sustain gains.

The report begins by outlining the current situation (that of generally low universal coverage and high direct payments by individuals) and continues to summarise the role of government and donor assistance in covering the costs. It is argued that prepayment and/or pooling are the best mechanisms, but governments must also support additional barriers to obtaining access to health care, such as transport and accommodation costs. Furthermore, the incentives of all actors must be aligned to achieve optimal efficiency and equity.

In the final chapter, the report recommends seven key actions and emphasises the importance of the international community in aiding lower income countries to achieve universal coverage and improve health outcomes.

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NEWS FROM THE INSTITUTIONS

Health priorities under the Hungarian Presidency

Hungary took over the six-month rotating presidency of the EU Council of Ministers on 1 January. An Informal Health Minister Meeting will take place in Budapest on the theme of sustainability and efficiency of health systems on 4–5 April. Council conclusions on the subject will be prepared on the basis of discussions in the ministerial meeting.

Other topics during the Hungarian Presidency will include the third action programme in the field of health, as well as on health professionals. A ministerial conference will be held as part of the e-Health Week on 10–13 May in Budapest in order to show the key role of e-Health in modernising health services.

The future of the EU Public Health programme will be discussed and attention will also be focused on mental health and healthier lifestyles for children and young people, as well as on injury prevention and safety promotion. Mental health is a priority for Hungary. The last of five conferences under the EU Mental Health Pact has been held during the Hungarian Presidency and emphasises the role reconciliation of work and family life plays in demographic change. It will also be a topic for the Informal Ministerial Meeting taking place between 31 March and 1 April 2011. The debates during the informal ministerial meeting will be included in the conclusions on the issue.

Further information at
<http://www.eu2011.hu/>

Directive on cross-border health care adopted

On 28 February 2011, the Council of the European Union approved the European Parliament's amendments on a draft directive facilitating access to safe and high-quality cross-border health care and promoting cooperation on health care between member states.

The European Parliament's amendments reflect a second-reading-compromise reached between the Belgian Presidency and representatives of the European Parliament in an informal triologue on 15 December 2010. In line with Article 294 of the Lisbon Treaty the cross border health care directive has now been adopted. Member states will have thirty months to transpose the directive's provision into national legislation. According to the European Commission, the current scale of cross-border mobility amounts to 1% (€10 billion) of overall EU-27 public health spending (€1,000 billion). The Commission estimates the cost increase under the new rules will be just €30 million a year.

The new directive provides clarity about the rights of patients who seek health care in another member state and supplements the rights that patients already have at EU level through the legislation on the coordination of social security schemes (Regulation 883/04). It meets the Council's wish to fully respect the case law of the European Court of Justice on patients' rights in cross-border health care while preserving member states' rights to organise their own health care systems.

More specifically, the new directive as a general rule will allow patients to receive health care in another member state and be reimbursed up to the level of costs that would have been assumed by the member state of affiliation, if this health care had been provided on its territory. Instead of reimbursing the patient, member states of affiliation may also decide to pay the health care provider directly. However if there are overriding reasons of general interest (such as planning requirements for ensuring permanent access to a balanced range of high-quality treatment or the wish to control costs and to avoid any waste of resources) a member state of affiliation may limit the application of the rules on reimbursement for cross-border health

care. Member states may also introduce a system of prior authorisation to manage the possible outflow of patients, but this is limited to health care that is subject to planning requirements, such as hospital care (defined as care involving overnight hospital accommodation) and health care that involves highly specialised and cost-intensive medical infrastructure or equipment, health care that involves treatments presenting a particular risk for the patient or the population, or health care which would be provided by a health care provider which could raise serious concerns with regard to the quality or safety of the care.

Equally member states may also adopt measures concerning access to treatment where this is justified by overriding reasons of general interest. Member states will also have to establish national contact points that must provide patients with information about their rights and entitlements and practical aspects of receiving cross border health care, for example information about health care providers, quality and safety, accessibility of hospitals for persons with disabilities, to enable patients to make an informed choice.

Cooperation between member states in the field of health care has been strengthened, for example, in the field of e-health and through the development of a European network which will bring together, on a voluntary basis, the national authorities responsible for e-health; another example is rare diseases, where the Commission will have to support member states in cooperating in the field of diagnosis and treatment capacity.

The recognition of prescriptions issued in another member state has been improved; as a general rule, if a product is authorised to be marketed on its territory, a member state must ensure that prescriptions issued for such a product in another member state can be dispensed in its territory in compliance with its national legislation.

News

The directive does not cover sales of medicinal products and medical devices via internet, long-term care services provided in residential homes and the access and allocation of organs for the purpose of transplantation.

More information at http://ec.europa.eu/health/cross_border_care/policy/index_en.htm

WHO European Member States plan for health in 2020

Governments are facing new and difficult challenges that affect the health of their populations. It is time not only to coordinate a coherent response to the current situation but also to plan for the next ten years, using the evidence on which approaches and solutions work best. This is the background to the development by WHO Europe of a new health policy framework for Europe called Health 2020. The first consultation on the process began in Andorra from 9–11 March 2011.

Senior government officials representing the 53 Member States came together to discuss the vision, strategic goals, scope and content of Health 2020, and to share experiences and strategies in implementing the Tallinn Charter, Health Systems for Health and Wealth. This first meeting of the European Health Policy Forum for High-Level Government Officials was hosted by the Ministry of Health, Well-being and Labour of Andorra and opened by Andorran Prime Minister Jaume Bartumeu.

The Health 2020 framework will be built on the Health for All strategy and other key European health policy frameworks including the Tallinn Charter. An interim report on the follow-up of the Tallinn Charter commitments was discussed at the meeting. It highlights innovative examples of actions by countries and WHO that are consistent with the commitments of the Tallinn Charter, especially in light of the financial crisis. It also emphasises the need for a rejuvenated effort in public health, and explains how Health 2020 will further many of the key concepts put forward in the Charter.

Health 2020 puts special emphasis on the key role of ministers of health as advocates and catalysts of action for health, both within and beyond the boundaries of the health sector. Another positive development is the increasing involvement in decision-making of patients and citizens, who are no longer passive but, thanks to information technology, are more

empowered than ever before to take more responsibility for their health in a different relationship with the health system.

Member States have agreed that new and innovative policies are needed to deal with the pressing health issues in the European Region in a comprehensive, cost-effective and coordinated way. These issues include the epidemics of obesity, cancer and heart disease; large differences in health status and life expectancy; increasing mental disorders; re-emerging communicable diseases; and the need to plan for emergencies and pandemics. Action to address these issues has to take account of the impact of factors such as globalisation, urbanisation, climate change, a larger ageing population and the economic crisis.

“We want Health 2020 to mobilise decision-makers everywhere,” said Ms Zsuzsanna Jakab, WHO Regional Director for Europe. “Governments’ engagement and early feedback are absolutely crucial, as we want this to be a fully participatory policy development process. It is the start of a determined effort to work together for the health and well-being of the people of Europe, both now and in the future, based on the evidence on the causes of ill health and good solutions that make economic sense. At the same time, we also continue our efforts to strengthen health systems and invest more in health protection, disease prevention and health promotion. Europe is truly committed to strengthening health systems and thus the follow-up to the Tallinn Charter is a flagship project for WHO/Europe and the Division of Health Systems and Public Health.”

WHO/Europe has also recently commissioned a number of studies that will inform Health 2020, including a European review of the social determinants of health and the health divide, led by Sir Michael Marmot, of University College London, United Kingdom; and a study on governance for health in the 21st century, led by Professor Ilona Kickbusch, of the Graduate Institute of International and Development Studies, Geneva, Switzerland. Other studies will address other key aspects of the Health 2020 policy framework such as the economics of prevention and an anticipatory analysis of drivers of and trends affecting health.

More information on the first meeting of the European Health Policy Forum at <http://www.euro.who.int/en/home/conferences/first-meeting-of-the-european-health-policy-forum>

EU Mental Health Pact Conference: Promotion of mental health and well-being in workplaces

Improving mental health and well-being in the workplace can have many benefits to employers and employees, as well as to public health. This includes economic advantages for businesses and social security systems. Healthy, productive employees make a vital contribution to a company’s success and competitiveness, but psychological strain is increasing at workplaces. For those who have experienced poor mental health, getting and keeping a job can be vital to the recovery process, boosting self esteem, confidence and social inclusion. A high level of mental health at work is essential for the implementation of the Europe 2020 strategy, including the objective of higher rates of employment.

The conference Promotion of Mental Health and Well-being in Workplaces, which opened in Berlin on 3 March, aimed to raise awareness of the relevance of mental health and well-being for workplaces. Organised by the European Commission and the German Federal Ministry of Health, in cooperation with the German Federal Ministry of Labour and Social Affairs and with the support of the Hungarian EU Presidency, it brought together around 350 experts to discuss the role of workplaces in improving the mental health and well-being of the population.

The case for action from a public health perspective was the focus of the conference. The workplace constitutes a key area for health promotion and the prevention of mental disorders. Conference sessions included the case for investing in mental well-being and practical steps for social security actors to build mentally healthy workplaces – in both corporate and public sector spheres.

Opening the conference, Stefan Kapferer, Secretary of State, German Federal Ministry of Health stated that addressing mental health in the workplace is one of the key priorities of the German federal government for preventative action. Having a healthy environment in the workplace offers the opportunity to eliminate risk factors for poor mental health and promote the health of employees. The changing nature of work increases the demands on many employees. He highlighted the economic impact of poor mental health, pointing out that it was one of the major causes of absenteeism from work in Germany and other countries.

In addition to an economic argument for taking action, he also stated that there is also a strong public health case for taking action in the workplace. The costs of poor mental health impact not just on individuals themselves but also insurers and employers. The workplace is a setting where a large proportion of the adult population can be reached, given that many go to work on a regular basis. Politicians, he argued, must respond to these issues and develop strategies to prevent the emergence of mental disorders.

Among the many conclusions of the conference it was acknowledged that mental health is an important indicator of the quality of social cohesion and the quality of work. It is also a core element of Europe's social model. Only a high degree of mental health will allow Europe to meet its economic and social challenges, while further advancing its aims of competitiveness and social cohesion. Moreover, the protection and promotion of mental health can make a vital contribution to the implementation of the European Union's 'Europe 2020' agenda with its objective of smart, sustainable and inclusive growth. This is especially necessary to achieve one of the specific objectives of the agenda: raising the employment rate of the population, between the ages of 20 and 64 years, from the current level of 69% to at least 75%.

The need for action is particularly pronounced in the case of small and medium sized enterprises that are least likely to invest in the promotion of mental health and wellbeing at work. Actions by health and social security agencies discussed at the conference included measures to provide financial and non-financial incentives and support to companies to promote workplace mental health. Cooperation between companies and social security organisations is already being supported in Germany. €40 million per annum are invested by health insurers in relevant occupational health promotion tasks.

This was the fifth and final conference under the European Pact for Health and Well-being, launched in 2008. This Pact provides an EU framework enabling exchange and cooperation between stakeholders in different sectors, including health, employment and education, on the challenges and opportunities in promoting better mental health. Conferences on the other themes under the Pact – Mental Health in Youth and Education, Prevention of Depression and Suicide,

Mental Health and Well-being in Older People and Promoting Social Inclusion and Combating Stigma – were held in 2009 and 2010.

Conference conclusions, a detailed background document, presentations and other information are available at http://ec.europa.eu/health/mental_health/events/ev_20110303_en.htm

Workers' and employers' agreement helping to deal with stress at work

The European Commission has published an evaluation of the 2004 social partners agreement on work-related stress, concluding that it has had positive effects where implemented. Although the agreement has not been implemented evenly, nineteen countries now have legislation or binding collective agreements that address stress or other psychological risks at work.

Over the last ten years, work-related stress has increased in nine EU countries and has only fallen in Sweden. Studies suggest that between 50% and 60% of all lost working days are related to stress. In France for example, the cost of stress has been reported to reach at least €2 to €3 billion each year. In the UK it is estimated that ten million working days are lost due to anxiety, stress and depression linked to work. The direct costs related to stress at work are now estimated to be as high as 4% of EU GDP.

In response to these developments, the 2004 social partner agreement – concluded by all cross-industry European social partners (Business Europe, the European Association of Craft, Small and Medium Sized Enterprises, the European Centre of Employers and Enterprises and the European Trade Union Confederation) – aims to raise awareness of work-related stress and provide a framework for action. The role of employers is to identify risk factors for stress and to try to match responsibility better with skills; consult workers on restructuring and new technologies; and to provide support to individuals and teams.

The Commission's evaluation of the agreement concludes that it has successfully triggered social dialogue and policy developments in the field of occupational stress in most EU countries. At the same time, the agreement has not been implemented evenly throughout Europe. Social partners in Malta, Cyprus, Poland and Slovenia have not reported on the follow-up to their

commitments, while results in Bulgaria, the Czech Republic, Germany and Estonia have fallen short of expectations.

The report can be viewed at <http://ec.europa.eu/social/BlobServlet?docId=6560&langId=en>

MEPs approve laws to curb counterfeit drugs

A new law to prevent fake medicines from entering the legal supply chain was approved by Parliament on 16 February. Internet sales will be covered by the law, which also introduces new safety and traceability measures, as well as sanctions against counterfeiters. This law still needs to be formally approved by the Council of Ministers.

"Falsified medicines are silent killers, either because they are devoid of effect or because they contain toxic substances that may harm, or even kill, those who take them. The absence of a legal framework encourages counterfeiting, an organised crime. We have been witnessing a huge growth of this criminal activity, with an increase of 400% in seizures of fake drugs since 2005. Protecting patient safety is the core aim of this directive", said Portuguese MEP Marisa Matias, who led discussions in Parliament. The resolution was adopted with 569 votes in favour, 12 against and 7 abstentions.

It is estimated that 1% of medicinal products currently sold to the European public through the legal supply chain are counterfeit and the share is growing. There were more than eleven million counterfeit medicines seized at EU borders in 2009, a fourfold increase in just three years, according to a report on EU customs enforcement. In other parts of the world, up to 30% of the medicines on sale may be fake. In particular, more and more innovative and life-saving drugs are counterfeit.

MEPs also deemed it necessary to regulate internet sales of medicines because this is a key route by which fake products enter the EU market. The Commission's original proposal did not cover internet sales. Under the new law, in those EU Member States where internet pharmacies are allowed to operate, they will need to be authorised to supply pharmaceuticals to the public.

Currently, six EU members allow patients to buy prescriptions online: Denmark, Germany, the Netherlands, Portugal, Sweden and the United Kingdom. Under the new laws, pharmacies that comply with

the rules will have an EU logo on their websites. Under the rules, the chief pharmacist must be identified on the websites for all mail-order pharmacies, and the doctor's original prescription must be obtained before mailing out the medicine.

Internet pharmacy sites will be required to display a common logo, which should be recognisable throughout the EU, so as to help the public to ascertain that they are linked to an authorised pharmacy. All authorised internet pharmacies will be linked to a central web site in each member state and will be listed on that web site. The various national web sites will in turn be linked to an EU web site. Citizens will also have to be informed about the risks involved in buying medicines via the internet.

The legislation updates current rules and provides for new safety features to be placed on individual packs in order to identify them, guarantee their authenticity, and enable pharmacists to check whether the outer packaging has been tampered with. These safety features – which still need to be developed by the European Commission – could, for example, include a serialisation number which can be 'read' by the pharmacy to ascertain that the pack is authentic.

As a general rule these features would apply to all prescription medicines, unless there is clearly no risk. They would apply to non-prescription medicines only in exceptional cases, where there is a risk of falsification. Where medicines are repackaged, these safety features must be replaced by equivalent ones.

The text approved by MEPs results from an agreement reached with Council, which must also give its formal approval. The Commission have estimated the cost of this legislation would be between €6 billion and €11 billion, the bulk of which would fall on the industry. Consumer advocates are also concerned about data privacy. With serial tracking numbers, a lot of sensitive health information will be stored in pharmacy databases and shared across national borders. Once it is signed into law, Member States have eighteen months to make any necessary changes to their national legislation.

More information under texts published on 16 February at <http://www.europarl.europa.eu/activities/plenary/ta/calendar.do?language=EN#>

World Cancer Day – WHO stresses importance of physical activity for cancer prevention

On World Cancer Day (4 February 2011), the world's cancer control community promoted preventive measures that can reduce the burden of cancer and potentially save millions of lives. This year's event was also an important milestone in the preparations for the United Nations high-level meeting on the prevention and control of Noncommunicable Diseases (NCDs), to be held in New York on 19–20 September 2011. The high-level meeting will be a historic opportunity to secure renewed global commitment to tackling cancer, cardiovascular diseases, chronic respiratory diseases and diabetes, and to push for the implementation of the WHO Global Strategy for the Prevention and Control of NCDs and its Action Plan for 2008–2013. In addition, health ministers and other stakeholders will gather in Moscow, Russian Federation, on 28–29 April 2011 for the first global ministerial conference on healthy lifestyles and NCD control.

Meantime, on 2 February 2011, in a new set of global recommendations on physical activity for health, the WHO has set out guidance to governments on the dose–response relationship between the frequency, duration, intensity, type and total amount of physical activity needed to prevent NCDs in various age groups.

Levels of physical inactivity are rising in many countries in the world, with major implications for people's general health and the prevalence of NCDs (such as cardiovascular disease, diabetes and cancer) and their risk factors (such as high blood pressure and blood sugar, and overweight). Physical inactivity is estimated to be the primary cause of about 21–25% of breast and colon cancer cases, 27% of diabetes and 30% of ischaemic heart disease in the world. In the 53 countries in the WHO European Region, NCDs cause 86% of deaths.

“These diseases are largely preventable through effective interventions that tackle four common risk factors: tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol,” commented Dr Gauden Galea, Director of the Division of Noncommunicable Diseases and Health Promotion at the WHO Regional Office for Europe.

The global recommendations are available at http://www.who.int/dietphysicalactivity/factsheet_recommendations/en/index.html

COUNTRY NEWS

England: major reforms proposed for National Health Service

On 19 January 2011, extensive legislation to reform the National Health Service (NHS) in England was laid before the UK parliament. The 367 page draft Bill proposes to introduce some of the most sweeping reforms of the NHS in its 63 year history. Key proposals include the abolition of Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs), to be replaced by regional general practitioner (GP) commissioning consortia to control approximately 80% of the NHS budget for England (around £80 billion) by 2013. The bill indicated that these commissioning consortia could enter into commercial contracts with 'any willing provider' for all health services and will set terms and conditions of staff.

English Minister of Health, Andrew Lansley, introducing the bill to Parliament, said it would create “dramatic opportunities” to improve the delivery of care, whilst reducing the “£5.3 billion of administration costs”, and that the government's intention “is to produce health outcomes that are at least as good as anything found elsewhere in the world”.

A new patients' organisation called HealthWatch and Health and Wellbeing Boards will be established, to scrutinise local plans and implementation of the reforms. The previously independent NHS body Monitor will be turned into an economic regulator with responsibilities for tariff price setting and for licensing trusts with the Care Quality Commission. It will be able to challenge NHS staff pension arrangements on the basis of an 'unlevel' playing field between the NHS and private provider. In turn, Monitor may be 'directed' by the Health Secretary where it is deemed to have committed a 'serious failure' to carry out its functions. Where Monitor fails to follow the 'direction', the Secretary could override it. The Secretary already has similar powers over the Care Quality Commission but has said that these reforms will limit his power more generally and, according to Department of Health notes accompanying the Bill, the reforms will actually end health secretaries' “general power of direction” over the NHS.

An NHS Commissioning Board, to be headed up by current NHS chief executive Sir David Nicholson, will take over the

day-to-day running of the NHS by April 2011, with wide-ranging powers to determine the structure and shape of GP consortia, including the power to remove or reduce GP consortia's functions, bail them out, or abolish a consortium altogether if it is perceived to be under-performing.

In such an event and, more commonly, where consortia are unable or unwilling to provide commissioning services, the Bill allows private health care firms to step in to fulfil those services. This aspect of the draft legislation, which represents a huge opportunity for both UK and overseas private health care providers, is one of the most controversial aspects of the entire Bill, and has led to claims that the coalition government is seeking to privatise the NHS without being fully open about its aims. In particular, the proposed legislation would have allowed competition to be forced on commissioners, even when they believe the best and most appropriate services can be provided by local hospitals."

The bill has faced opposition from some Liberal Democrat and Conservative backbenchers within the Coalition, as well as criticism from health professional bodies and independent think tanks. The British Medical Association has called the reforms a "massive gamble" likely to "damage local services" and warned that although it supports the greater involvement of clinicians in planning NHS services, it believes these "benefits... are threatened by other parts of the Bill. Meantime, writing in the British Medical Journal on 22 March, academics Allyson Pollock and David Price called for a large number of amendments to be tabled to legislation to "ensure continuation of NHS comprehensive care". They argue that the original legislation removes the Health Minister's duty of care to provide or secure comprehensive health care services, with no transfer of this duty to the local commissioning boards. They also call for a removal of a clause in legislation which would allow local commissioning boards more scope for charging for health care services.

The government has made some concessions, ruling out price competition and the 'cherry-picking' of services by private providers, and is open to the possibility of further concessions to get the Bill passed into law. The draft Bill also introduces new requirements for the National Institute for Health and Clinical Excellence (NICE) to consider social care costs and the "desir-

ability of promoting innovation" when assessing a drug's cost effectiveness. These considerations have not previously been part of NICE's criteria for analysing new products, but were recently used in its October 2010 recommendations on increasing the use of drugs in the NHS for the treatment of Alzheimer's disease, and are in accordance with the government's current consideration of introducing a new value-based approach to the pricing of branded medicines.

An impact assessment for the Bill has also been published. This predicts the reforms will cost up to £1.5 billion, mainly due to redundancy costs at PCTs and SHAs (the average redundancy cost per manager is expected to be £48,000), but that by reducing the cost of commissioning across the health service, the reforms could bring savings of up to £8.8 billion. However, the anticipated cost savings for management may fail to materialise if the GP consortia are too small to achieve the required economies of scale.

Progress on the Health and Social Care Bill 2011 can be viewed at

<http://services.parliament.uk/bills/2010-11/healthandsocialcare.html>

The commentary by Allyson Pollock and David Price is available at

<http://www.bmj.com/content/342/bmj.d1695>

Commission asks Italy to end discrimination against doctors with experience and qualifications from other Member States

The European Commission has requested Italy to take professional experience and seniority acquired by doctors in another Member State into account when determining their rank or working conditions (like salary, grade career development) in the Italian public sector. The Commission considers that the current rules are discriminatory since they affect primarily workers of other Member States. The Commission's request (along with a similar request in respect of teachers) takes the form of a 'reasoned opinion' under EU infringement procedures. Italy has two months to bring its legislation in both areas into line with EU law. Otherwise, the Commission may decide to refer Italy to the EU's Court of Justice.

According to EU law, free movement of workers does not apply to employment in the public sector so access to the public service can be restricted to nationals of the host Member State. However, this deroga-

tion has been interpreted in a very restrictive way by the Court of Justice of the EU and only posts that involve public authority and the responsibility for safeguarding the general interest of the State can be restricted to their own nationals. The restriction therefore neither applies to doctors working in the public health institutions, nor teachers working in the public education institutions.

In line with the case law of the Court, previous periods of comparable employment acquired in the health sector of other Member States must be taken into account by the Italian health services when determining professional benefits (for example, salary, career development), just as experience acquired in the Italian system is considered. This specific Italian condition that requires continuity in work experience in establishing a doctor's rank constitutes an indirect discrimination of migrant workers in determining their working conditions for posts in the Italian public sector. Migrant workers usually put an end to employment in the Member States of origin to move to another Member State with their move typically resulting in a career break.

For more information on the infringement procedures: http://ec.europa.eu/eu_law/infringements/infringements_en.htm

For more information on EU infringement procedures, see MEMO/11/86

Early assessment of the deregulation in the Swedish pharmacy market

On 1 July 2009, the Swedish pharmacy market was opened up for parties other than the Swedish state-owned Apoteket AB to conduct retail operations for both prescription and non-prescription pharmaceuticals. The purpose of this deregulation was to provide consumers with increased accessibility, improved services and reduced costs for pharmaceuticals. In a second phase of the deregulation of the Swedish pharmacy market, the marketing and sale of non-prescription pharmaceuticals in sale outlets other than pharmacies, such as supermarkets and petrol stations was permitted from November 2009. The prices for prescription pharmaceuticals are still regulated but non-prescription pharmaceuticals are subject to market prices.

The Swedish National Audit Office (Riksrevisionen, SNAO), which is responsible for auditing the activities of the entire Swedish state, has now reviewed the preparatory work for the deregulation. It

has identified several problems in the deregulation process, which have made it difficult for operators (particularly small independent operators) to enter the pharmacy market and thus may restrict competition.

One such example is the requirement for pharmacy operators to obtain prior approval of their IT system from Apoteket Service AB in order to be permitted to establish a pharmacy in Sweden. The SNAO is critical of the fact that it is not possible to appeal against Apoteket Service's decisions in this regard and that Apoteket Service has no obligation to comply with general Swedish administrative law principles, although it exercises official authority in this way. It has recommended that the government restricts and clarifies the extent of Apoteket Service's supervisory role. It has also been critical of the pricing model for the process of IT system approval, stating that it may discriminate against small independent pharmacy operators due to the high costs of such IT systems.

Despite these limitations many new entrants to the pharmacy market can however be seen, with more than 200 new pharmacies having opened. There are now four dominant market operators (Apoteket Hjärtat, the state-owned Apoteket, Medstop and Kronans Droghandel). The British company Alliance Boots also plans to open at least 100 Boots-branded pharmacies in a joint venture with Farmaceutföretagarna AB, a company owned by the Swedish Pharmaceutical Association. Many pharmacies have been established in locations where previously none existed and opening hours have increased (before the deregulation, there was only one 24-hour pharmacy in Sweden).

A large number of retail stores have also begun to sell non-prescription pharmaceuticals.

England: changes to the regulation of unlicensed herbal medicines

Under the European Directive on the Community Code Relating to Medicinal Products for Human Use (2001/83/EC), from 30 April 2011 it will be illegal for practitioners to supply unlicensed herbal medicines. On 16 February 2011, the UK health minister Andrew Lansley stated that practitioners may continue to supply unlicensed herbal medicines if they register with the Health Professions Council (HPC).

In announcing the creation of the HPC register process, the government is intending to make use of the derogation in Article 5(1) of the Directive, which allows national arrangements to permit 'authorised health care professionals' to commission unlicensed medicines to meet the special needs of their patients. The idea is to create a scheme enabling practitioners who are listed on the Register ('Registered Practitioners') to order unlicensed herbal medicines to meet the special needs of their patients.

The creation of the Register will also affect Section 12(1) of the Medicines Act 1968. Under this provision, practitioners may prepare unlicensed herbal medicines on their own premises for use following consultation with individual patients. Once the Register is created, only Registered Practitioners will be able to rely on Section 12(1) of the Medicines Act 1968.

A formal consultation exercise run by the Medicines and Health Care products Regulatory Agency (MHRA) is to take place on specific legislative proposals for establishing the Register and proposed reforms of medicines legislation by 2012.

The Health Secretary's announcement has received a mixed reception. As reported in *The Telegraph*, Desiree Shelley, president of the National Institute of Medical Herbalists, has congratulated the government on "making the right decision". In contrast, Professor David Colquhoun, a pharmacologist at University College London, said the plans ran contrary to mainstream scientific thinking, by allowing herbalists to sell treatments that had not been rigorously tested, in contrast to the clinical trials procedure faced by pharmaceutical companies. He also felt that herbal practitioners "should not have been given the badge of governmental approval that state regulation confers on them." Similarly, Sir Richard Thompson, president of the Royal College of Physicians has expressed his disappointment to hear of the plans, stating that "the proposed register will imply herbal therapies have the same legitimacy as medicine, nursing and dentistry, despite offering patients no proven benefit."

Ireland: new government committed to universal health insurance by 2016

Incoming Minister for Health in the new Fine Gael and Labour Party Coalition government in Ireland, Dr James Reilly, has reaffirmed the government's commitment to introducing a universal health

insurance system within the lifetime of the first term of the government (by 2016). The government has also promised to strengthen the primary care system and introduce free primary care for all, in contrast to the current situation where more than two-thirds of the population have to pay a fee to consult with a general practitioner (GP). Speaking to *irishhealth.com* the Minister, who is a former President of the Irish Medical Organisation, stated that free GP care would be funded from savings from the Health Service Executive (HSE), which the new Programme for Government states will "cease to exist over time, with its functions returning to the Minister for Health and the Department of Health and Children; or be taken over by the Universal Health Insurance system". The system will be introduced in phases so that additional doctors, nurses and other staff can be recruited. GPs will be paid primarily by capitation for the care of their patients and will work in primary care teams with other primary care professionals.

The Programme for Government states that the Universal Health Insurance system "will be designed according to the European principle of social solidarity: access will be according to need and payment will be according to ability to pay. The principle of social solidarity will underpin all relevant legislation." Furthermore "as a statutory system of health insurance, guaranteed by the State, the Universal Health Insurance system will not be subject to European or national competition law." The coalition agreement also states that, "insurance with a public or private insurer will be compulsory with insurance payments related to ability to pay. The State will pay insurance premia for people on low incomes and subsidise premia for people on middle incomes. Everyone will have a choice between competing insurers." The largest insurer the VHI will be kept "within public ownership to retain a public option in the Universal Health Insurance system."

The Minister refused however to be drawn on how the proposed universal health insurance system would be funded, saying that it was far too early to comment with the new system still at the planning stage.

The new government are also committed to introducing a system of risk equalisation for the current health insurance market. Among other objectives, the embedding of mental health services within primary care was highlighted as one priority. Ring-

fenced funding will be provided to recruit additional psychologists and counsellors to community mental health teams, working closely with primary care teams to ensure early intervention, reduce the stigma associated with mental illness and detect and treat people who are at risk of suicide. Another pledge is to change the organ donation to an opt-out system for organ transplantation, rather than an opt in system so as to improve the availability of organs for patients in desperate need.

The programme for government, including full plans on health, can be accessed at http://www.taoiseach.gov.ie/eng/Publications/Publications_2011/Programme_for_Government_2011.pdf

Similar shortcomings in Nordic countries following mental health care reforms

In Denmark, Norway, Finland and Sweden reforms within psychiatry have transformed inpatient care to the point where it has increasingly been replaced by outpatient care. The different countries have applied different solutions when reforming their mental health care systems, yet certain shortcomings such as complex service systems in which patients end up in a state of limbo and where cooperation among staff becomes difficult, can be found in all four countries. It is thus not possible to speak of a common Nordic welfare model within this area.

The first evaluation of the mental health care reforms in the Nordic countries generally shows that inpatient admission rates have greatly decreased and that the use of antipsychotic drugs has increased. It is a complex and slightly ambivalent picture that is being painted; as the Nordic mental health care reforms proceed they face the dilemma of optimising the selection of treatments and social services, as well as providing users with greater influence when it comes to the contents of care.

Professor Rafael Lindqvist and his research colleagues are responsible for a comparative analysis where results of the mental health care reforms in Denmark, Finland, Norway and Sweden are presented. The results show that the transition from a mental health care system where most service users are given treatment at one institution to outpatient care practices results in a number of deficiencies.

In spite of similar intentions, variations in service structure and work modes are significant in the four countries. This is true also when it comes to the service users. The

number of inpatient beds has been greatly reduced in all countries but in other aspects, the results differ. For instance, when it comes to antipsychotic drug consumption, Finland is at the top while Norway is at the bottom. In Sweden accessibility to both inpatient and outpatient care is lacking. Furthermore, the most vulnerable sections of the population vary between the different countries.

The report highlights the common problem of how to make the role of primary care clear and effective in the care and support system; both in relation to inpatient psychiatric care services and social services. There has been no real development in user influence following the mental health care reforms. It is also obvious that equality in care is difficult to realise, especially in sparsely populated areas. The current challenge is to promote a change in attitudes and counteract stigmatisation and discrimination.

The report will be presented during a symposium at the Nordic School of Public Health (NHV) on 12 April 2011. The symposium will conclude with a panel discussion among decision-makers from the Nordic countries.

The report can be ordered (in Swedish) by contacting the Nordic School of Public Health from lars.freden@nhv.se

Belgium: new code of ethics regarding the medical device industry's interactions with health care professionals

The Belgian Association for producers and distributors of medical devices (Unamec) has established a new Code of Ethics, which came into force on 1 January 2011. Unamec members recognise that adherence to ethical standards and compliance with applicable laws is critical to the medical devices industry's ability to continue its collaboration with health care professionals. The Code of Ethics sets the standards appropriate to various types of relationships between the medical device industry and health care professionals, based upon the principles of separation, transparency, equivalence and documentation.

The Code has two main parts. First, the basic rules are set, including rules governing verbal and written communications, the provision of sample products, the provision of equipment, arrangements around scientific events, sponsorship arrangements, consultancy agreements, gifts, charitable donations and educational

grants. The second part relates to scientific studies.

The new Code is based upon the Eucomed Code of Ethical Business Practice – Guidelines on Interactions with Healthcare Professionals, and now complies with the requirements of article 10 of the Belgian Medicines Act of 25 March 1964 regarding, notably, the Mdeon visa requirement.

Unamec's Code of Ethics is available (in Dutch and French) at: <http://www.unamec.be>

France: reform promised after diabetes drug scandal

French Health Minister Xavier Bertrand has promised a complete overhaul of the country's medical regulatory system. He was speaking after an official independent 260-page report by the Inspection Générale des Affaires Sociales (IGAS) said a diabetes drug which caused up to 2,000 deaths should have been banned ten years earlier. The drug, benfluorex, but more commonly known as Mediator, should have been banned as early as 1999, when it began to emerge that it could cause heart disease, the report said. Several other European countries and the US then withdrew it. Mediator remained on sale in France for another ten years. The French Health Products Safety Agency has estimated that between 500 and 2,000 people in France died because of its side effects. The drug was developed to treat diabetics but millions of people took it simply to lose weight.

The IGAS said it was incomprehensible that the authorities had failed to act sooner. Speaking to *The Lancet*, Irène Frachon, a chest physician at CHU de Brest, said that she was surprised by the report's findings "because it showed the scandal was worse than I had expected", adding that "perhaps I am naive, but I thought at first that there had just been a mistake. I hadn't realised that there were so many alarm bells and warnings during all those years."

Mr Bertrand said it was now his duty to rebuild the regulatory system to protect the public, saying that France needed to move to a more transparent system where drug safety approval deliberations were recorded, debates published and public hearings held when needed. On Europe 1 radio on 16 January he also said that he and all French health ministers since 1976, when benfluorex first hit the market, should speak at the parliamentary hearings on the issue that are now getting underway.

He also stated that the regulatory agency should have sufficient state funds so as not to have to rely on the industry it is supposed to oversee and that all medical experts would be obliged as a matter of course to declare any links to drug firms. In June, the IGAS will present the government with a second report proposing ways to reform the pharmacovigilance system and the French Health Products Safety Agency (AFSSAPS).

The *Lancet* article on the report is available at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2960334-6/fulltext>

The IGAS report in French can be downloaded at <http://www.igas.gov.fr/spip.php?article162>

Spain: report on implantation cards and security

The Spanish Data Protection Authority (SDPA) has issued a report on the level of security that the data controller or, where appropriate, the data processor, must provide for a file containing copies of device implantation cards completed in accordance with Article 33 of Royal Decree 1591/2009 of 16 October, which regulates medical devices. This was prepared in response to a request filed by a manufacturer of implantable medical devices.

The report states that “in this case where the file will contain a set of data relating to the medical act of the implant in relation to a particular person, identified by her/his ID or passport, health related data are processed and therefore are subject to measures of high-level security, in accordance with Article 81.3 of the Spanish Regulations implementing Law 15/1999.”

According to Royal Decree 1591/2009, the implantation card is completed in triplicate: a copy is stored with the patient's medical notes, another is provided to the patient and the third is sent to the supplier (manufacturer or distributor of the product), which, where appropriate, sends a copy to the relevant national registry of implants.

The following implants being distributed in Spain are required to be accompanied by an implantation card: cardiac implants and vascular implants of the central circulatory system; central nervous system implants; spinal implants; hip implants; knee implants; breast implants; and lens intraocular implants. The implantation cards, which must be completed by the

health centre immediately after the device implantation has been undertaken must contain the following information: name and model of the product; batch code or serial number; name and address of the manufacturer; name of the health centre that carried out the implantation and the date; and patient identification (identity card or passport number).

More information is available (in Spanish) at: <http://www.agpd.es/porta/webAGPD/index-ides-idpbb.php>

Sweden: new legislation on the collection and storage of human biological material

A new Biobanks Act regarding the collection and storage of tissue samples and other human biological material has been proposed in Sweden. It aims to clarify the requirements for the release of tissue samples from biobanks. The previous Act of 2003 was viewed as overly complicated and unclear, thus a report was produced to find an appropriate balance between the importance of making tissue samples available for care, treatment and research on the one hand, and ensuring the privacy and right to self-determination of the donor on the other.

The scope will be extended as the current Act applies to tissue samples from the medical care system only, whilst the proposed new Act also covers samples from other activities such as from within the pharmaceuticals industry. Also, under the current Act, it is always necessary to obtain the consent of the donor to collect and store tissue samples. Under the proposed new Act, it will be possible to collect and store tissue samples for certain limited purposes, provided the donor does not object to this. The donor must, however, be informed. In other cases, express consent is required.

Regulations on traceability are proposed in the new Act; tissue samples from the medical care system would have to be registered in the Swedish Biobank Registry and other samples must be registered at the biobank itself. It is proposed that processing of personal data by biobanks shall be subject to regulation, which is not the case in the current Act. Such regulatory provisions would clarify where responsibility for personal data lies, the purposes for which personal data may be processed and what personal data may be processed.

In order for the proposed legislation to be implemented, the abovementioned report

will be reviewed and subjected to comment by various government authorities and companies affected. Next, the Ministry of Social Affairs will draw up a finalised bill that will be referred to the Council on Legislation before it is finally submitted for approval to the Swedish Parliament. If all goes to plan, the new Act will likely enter into force on 1 January 2012.

The report is available (in Swedish) and a summary (in English) at: <http://www.regeringen.se>

Germany: uniform standards for a European-wide harmonised risk assessment

The Federal Institute for Risk Assessment (BfR) has published a guidance document for health assessments in the field of consumer protection. This Guidance Document shall serve as a basis for the assessment of possible health risks of foods, chemicals, and consumer products and will pave the way for a harmonisation of risk assessment.

BfR is a scientific institution responsible for preparing expert reports and opinions on food and feed safety, as well as on the safety of substances and products. It comes under the portfolio of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV). The main areas of BfR's work encompass the health assessment of biological and material-chemical safety of food, health assessment of the safety of substances (chemicals, pesticides and biocides) and selected products (consumer products, cosmetics, tobacco products, textiles and food packaging). Additionally, BfR assesses risks of genetically modified organisms in food, feed, plants and animals and is responsible for risk communication.

The Guidance Document implements international principles of risk assessment. Specifications for the scientific content and the appropriate structuring of health assessments as they result from science and legislation as well as practical experience are compiled. The Guidance explains the fundamentals of BfR health assessments; particularises the content and structure of BfR Opinions; explains typical risk terminology; and lists important documents for the risk assessment.

The Guidance Document is available at: http://www.bfr.bund.de/cm/364/guidance_document_for_health_assessments.pdf

News in Brief

New report: How health systems make available information on service providers: experience in seven countries

This new report produced by RAND Europe and the London School of Hygiene and Tropical reviews information systems that report on the quality or performance of providers of health care in seven countries (Denmark, England, Germany, Italy, the Netherlands, Sweden and the United States). This is to help inform the use and further development of quality information systems in the English NHS. The review highlights that as the policy context for quality reporting in countries varies, so also does the nature and scope of quality information systems within and between countries.

The report is available at http://www.rand.org/content/dam/rand/pubs/technical_reports/2011/RAND_TR887.pdf

Scotland: Free prescriptions for all from April 2011

On 2 March, the Scottish Parliament's Health Committee passed legislation that will result in prescriptions for all patients in Scotland being free from 1 April. Prescription charges have been falling steadily since 2007. In 2007 a single item prescription cost £6.85, this was reduced to £5.00 in 2008–09, £4.00 in 2009–10 and £3.00 in 2010–11.

eHealth moves ahead in Europe

A report produced for the European Commission by a consortium led by the German consultancy Empirica, reports on eHealth strategies and implementation in thirty countries.

The report notes that EU countries are making substantial progress towards modern eHealth infrastructures and implementation. Virtually all have already started with, or will undertake, the implementation of national systems to make basic patient data available to all health-care professionals whenever and wherever needed.

While electronic health record (EHR) systems are a consistent element in almost all strategies and roadmaps, they are not well and/or consistently defined, often referring only to a patient summary or similar basic electronic patient record. Clinicians enthusiasm for comprehensive

EHR relates to perceived benefits in their immediate surroundings (their day-to-day work processes) rather than to a geographically widespread sharing of detailed patient data.

The report can be accessed at http://www.ehealth-strategies.eu/report/eHStrategies_Final_Report.pdf

Nuffield Trust report on US experience of GP commissioning

Substantial investment in leadership, management and informational technology, combined with a focus on helping general practitioners (GP), work in new ways and collaborate more closely with their specialist colleagues is vital if the English Government's plan to hand control of NHS budgets over to groups of GPs is to succeed.

This is the verdict of a new Nuffield Trust report, *GP commissioning: insights from medical groups in the United States*, by Ruth Thorlby, Rebecca Rosen and Judith Smith. It examines the American experience of handing the equivalent of commissioning budgets to doctors over the past twenty years. The researchers visited a number of medical groups led by doctors in California and argue that the experiences of these organisations reveal important lessons for the NHS in England as the Government prepares to transfer control of £80 billion of the NHS budget to GP consortia.

The report is available at <http://www.nuffieldtrust.org.uk/publications/detail.aspx?id=145&PRid=756>

Workplace violence and harassment on the increase in Europe

Violence, bullying and harassment are becoming increasingly common features of European workplaces, according to a new report by the European Agency for Safety and Health at Work (EU-OSHA). Yet the response from organisations and national governments is widely felt to be inadequate. Third-party violence and harassment affect from 5% to 20% of European workers, depending on the country, sector, and methodology employed.

The report *Workplace Violence and Harassment: a European Picture* includes international statistics collected by the European Risk Observatory, part of

EU-OSHA. Its recent pan-European workplace survey of enterprises on new and emerging risks (ESENER) also shows that 40% of European managers are concerned by workplace violence and harassment, but only around 25% have implemented procedures to deal with it – in many EU countries not more than 10%. The problem is even more acute in health and social work and in education with more than 50% of managers identifying it as a health and safety problem.

The full report is available at <http://osha.europa.eu/en/publications/reports/violence-harassment-TERO09010ENC/view>

Launch of consultation on health security in the EU

On 3 March, the European Commission launched a consultation to gather views on possible actions that can protect EU citizens more effectively against serious cross-border health threats.

Current EU legislation does not cover cross-border health threats other than infectious diseases. The aim of this initiative is to consider the possibility and need to ensure that all types of public health threats are addressed in a similar way to infectious diseases. The overarching question is: How can the response to infectious diseases and other serious cross-border health threats, such as chemical, biological, radiological, nuclear and environmental events, be strengthened at EU level?

The consultation includes questions on preparedness planning, risk assessment, management of health threats and on how to better communicate with citizens and professional groups.

The consultation paper and online questionnaire can be viewed at: http://ec.europa.eu/health/preparedness_response/consultations/preparedness_cons_02_en.htm. Comments should be submitted by 29 April 2011.

Additional materials supplied by
EuroHealthNet

Rue de la loi, 67, B-1040 Brussels.
Tel: + 32 2 235 03 20
Fax: + 32 2 235 03 39
Email: info@eurohealthnet.eu

Eurohealth is a quarterly publication that provides a forum for researchers, experts and policy makers to express their views on health policy issues and so contribute to a constructive debate on health policy in Europe

European
Observatory 
on Health Systems and Policies

LSE Health

ISSN 1356-1030