

Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 12 Number 4, 2006

Every second counts: Doctors who work at night



Improving access
to medicines
in the Russian
Federation

Is Denmark
prepared to meet
future health care
demands?

A corporate
approach to
promoting
global health

Pharmaceutical policy in Spain • Armenia: health care access • Ireland's grey vote grows bolder
Germany: institutional change or political stalemate? • Norway: economic impact of smoke free hospitality venues

Editorial Team

EDITOR:

David McDaid: +44 (0)20 7955 6381
email: d.mcdaid@lse.ac.uk

FOUNDING EDITOR:

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

DEPUTY EDITOR:

Sherry Merkur: +44 (0)20 7955 6194
email: s.m.merkur@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: westminster.european@btinternet.com

SUBSCRIPTIONS MANAGER:

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

Advisory Board

Anders Anell; Rita Baeten; Nick Boyd; Johan Calltorp; Antonio Correia de Campos; Mia Defever; Nick Fahy; Giovanni Fattore; Armin Fidler; Unto Häkkinen; Maria Höfmarcher; David Hunter; Egon Jonsson; Meri Koivusalo; Allan Krasnik; John Lavis; Kevin McCarthy; Nata Menabde; Bernard Merkel; Stipe Oreskovic; Josef Probst; Tessa Richards; Richard Saltman; Igor Sheiman; Aris Sissouras; Hans Stein; Jeffrey L. Sturchio; Ken Thorpe; Miriam Wiley

Article Submission Guidelines

see: www.lse.ac.uk/collections/LSEHealth/documents/eurohealth.htm

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, Greece, Norway, Slovenia, Spain and Sweden, the Veneto Region of Italy, the European Investment Bank, the Open Society Institute, the World Bank, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

© LSE Health 2006. No part of this publication may be copied, reproduced, stored in a retrieval system or transmitted in any form without prior permission from LSE Health.

Design and Production: Westminster European
email: westminster.european@btinternet.com

Printing: Optichrome Ltd

ISSN 1356-1030

LSE Health

C

Every second counts

O

As Roy Pounder writes in this issue of *Eurohealth*, health care is a 24 hour business. Historically, to ensure that the demand for services could be met both day and night, hospitals have relied on resident 'on call' junior doctors, resting and sleeping when not treating patients. While this undoubtedly led on occasion to dangerous levels of exhaustion, the limits imposed on working hours under the European Working Time Directive (EWTD) have posed their own set of problems. Not only has there been a need for significant organisational change, but resources have had to be found to pay for the increased number of staff now needed to deliver services.

M

Working patterns continue to change, so that much more use is made of a shift-based model. Most typically this consists of a simple division between one day and one night shift. Evidence from other sectors indicates however, that the risk of adverse events and accidents is much greater for night shift workers. Moreover, these risks are set to become even more pronounced as further ETWD constraints are introduced.

E

Pounder calls here for a delay in further implementation of the EWTD, suggesting only as few as four Member States are fully compliant with existing regulations. Innovative thinking, he contends, on how to implement change is required, and he puts forward the notion of three overlapping nine hour shifts as one way of countering adverse risks.

N

Time inexorably marches on, no more so than in the Russian Federation. We also feature an article by Khabriev and colleagues illustrating the initial, and largely positive, impact of a scheme to increase access to essential medicines across Russia. Additionally, we reflect on global health, by considering to what extent approaches adopted by the business community in Europe and elsewhere might be used to help foster sustainable health improvements in some of the world's most impoverished regions. Whether thinking about hospital staffing issues, pharmaceutical reform or saving lives in the developing world, it is abundantly clear that every second counts.

David McDaid *Editor*

Sherry Merkur *Deputy Editor*

T

Contents

Eurohealth
Volume 12 Number 4

Health Policy Developments

- 1 Improving access to medicines in the Russian Federation:
The Programme for Supplementary Pharmaceutical Provision
*Ramil U Khabriev, Panos G Kanavos, Elena A Telnova and
Gilea N Gildeeva*
- 5 European junior doctors who work at night
Roy Pounder
- 7 Is Denmark prepared to meet future health care demands?
*Martin Strandberg-Larsen, Mikkel Bernt Nielsen,
Allan Krasnik and Karsten Vrangbæk*
- 11 Institutional change or political stalemate?
Health care financing reform in Germany
Kai Mosebach
- 14 Pharmaceutical policy reform in Spain
Joan Costa-Font and David McDaid

Global Health

- 18 Corporate lifelines: a new approach to making poverty history
David McDaid

Public Health Perspectives

- 22 The impact of smoke-free hospitality venues in Norway
Karl Erik Lund and Marianne Lund

European Snapshots

- 24 Improving access to health care in Armenia
Erica Richardson
- 25 Ireland's grey vote grows bolder
Anne Dempsey

Evidence-informed Decision Making

- 27 "Mythbusters" Managed care = mangled care
- 29 "Bandolier" What is evidence-based medicine?

Monitor

- 32 Publications
- 33 Web Watch
- 34 European Union News

Joan Costa-Font is Research Fellow, London School of Economics and Political Science, UK and Associate Professor of Economics, University of Barcelona, Spain.

Anne Dempsey is a freelance journalist, Greystones, Ireland.

Gilea Gildeeva is Deputy Head, Dept of Medicines and Medical Devices Registration, Federal Service of Health Care and Social Development, Moscow, Russian Federation.

Ramil Usmanovich Khabriev is Head, Federal Service of Health Care and Social Development, Moscow, Russian Federation.

Panos Kanavos is Lecturer, London School of Economics and Political Science, UK.

Allan Krasnik is Professor, Institute of Public Health, University of Copenhagen, Denmark.

Karl Erik Lund is a Researcher, Norwegian Institute for Alcohol and Drug Research, Oslo.

Marianne Lund is an Adviser, Norwegian Institute for Alcohol and Drug Research, Oslo.

David McDaid is Research Fellow, London School of Economics and Political Science, UK.

Kai Mosebach is Health Policy Analyst, Institute of Medical Sociology, Johann Wolfgang Goethe University, Frankfurt, Germany.

Mikkel Bernt Nielsen is Research Fellow, Institute of Public Health, University of Copenhagen, Denmark.

Roy Pounder is Lead, EWTD Working Party, Royal College of Physicians, London, UK.

Erica Richardson is Research Officer, European Observatory on Health Systems and Policies, London School of Hygiene and Tropical Medicine, UK.

Martin Strandberg-Larsen is Researcher, Institute of Public Health, University of Copenhagen, Denmark.

Elena Telnova is Deputy Head of the Federal Service of Health Care and Social Development, Moscow, Russian Federation.

Karsten Vrangbæk is Associate Professor, Department of Political Science, University of Copenhagen, Denmark.

Improving access to medicines in the Russian Federation:

The Programme for Supplementary Pharmaceutical Provision

Ramil U Khabriev, Panos G Kanavos, Elena A Telnova and Gilea N Gildeeva

Summary: In January 2005 the Programme for Supplementary Pharmaceutical Provision (DLO) was implemented in the Russian Federation, enabling, for the first time, uniform, free access to medicines to the most vulnerable social groups in need of extensive pharmaceutical care due to poor health status or disability (federal eligibles). Attitudes towards the programme show increasing levels of satisfaction; utilisation of needed medicines has increased several-fold, particularly in under-provided regions and predominantly for expensive medications, including those for cancer, mental illness, haematology and cardiovascular disease. In order to ensure financial sustainability, further reforms will be implemented aiming at improving efficiency and cost-effectiveness, whilst maintaining quality and equity.

Keywords: Russian Federation, pharmaceutical policy, health care reform, health insurance coverage, access to medicines

Background

Current economic policy in the Russian Federation has become increasingly focused on four priority national projects, Health, Education, Housing and Agriculture.¹ As part of 'Project Health', a new programme enabling prescription drug coverage for the weaker segments of society commenced on 1 January 2005 following Federal Law No. 122-ФЗ. This Programme for Supplementary Pharmaceutical Provision (Dopolnitelnogo Lekarstvennogo Obespecheniya – DLO) aims to provide prescription drug coverage and free access, at the point of use, to

Ramil Usmanovich Khabriev is Head, Federal Service of Health Care and Social Development, Moscow, Russian Federation;

Panos Kanavos is Lecturer, LSE Health, London School of Economics and Political Science.

Elena Telnova is Deputy Head of the Federal Service of Health Care and Social Development; and

Gilea Gildeeva is Deputy Head of the Department of Medicines and Medical Devices Registration of the Federal Service of Health Care and Social Development.

Email: p.g.kanavos@lse.ac.uk

quality medicines within ambulatory care (polyclinic) level (in part also inpatient care, up to a limit) to the most vulnerable social groups of the Russian Federation, namely those who need extensive pharmaceutical care because of poor health status or disability. In this respect, the DLO programme is a major step in the direction of modernising publicly funded health services in the Russian Federation.

The programme established a mechanism for the equalisation of the conditions under which pharmaceutical care is provided to the eligible population, in that it applies throughout the Russian Federation in accordance with uniform principles (thereby avoiding prior significant regional variations and taking into account regional differences), provides pharmaceutical care in as sufficient a quantity as required by medical need and ensures the provision of pharmaceutical products of high quality.

Programme provisions

The DLO programme initially enrolled nearly sixteen million eligible citizens in the Russian Federation comprising people of all ages (children, retirees and those aged between 16 and 60). Eligibility is based either on disability status with the 'disabled' defined as those severely or

chronically ill (more than 90% of all eligible groups), or special social status such as war veterans. The key objective has been to enable access to pharmaceutical treatments for this population at no cost to these insurees.

The key actors in the DLO programme include the Ministry of Health Care and Social Development, which coordinates the activities of all other stakeholders, sets the main rules for programme regulation, including those governing the budget, medications, and flows of funds, as well as establishing the list of reimbursable products. Other actors include the Federal Foundation of Obligatory Medical Insurance (FFOMI), which holds the budget from which it pays for pharmaceutical products supplied and the Federal Service of Health Care and Social Development (Roszdravnadzor), which supervises the implementation of the DLO programme and is also responsible for oversight, pricing policy and overall policy reform. Physicians, pharmacies and regional warehouses, who prescribe, dispense and store and deliver, respectively, pharmaceuticals to the eligible population, as well as pharmaceutical distributors at the federal level, who purchase and supply pharmaceutical products in the Russian Federation are also key actors.

The implementation of the DLO programme has required the mobilisation of a substantial number of resources and manpower including:

- 233,698 participating physicians
- 26,064 polyclinics, hospitals, and other institutions
- 6,000 pharmacies initially, subsequently increasing to 12,813 pharmacies by the beginning of 2006
- 23 pharmaceutical distributors at federal level, selected through an initial competitive process
- 86 regional warehouses working together with federal level pharmaceutical distributors
- 61 national and 110 foreign pharmaceutical manufacturers

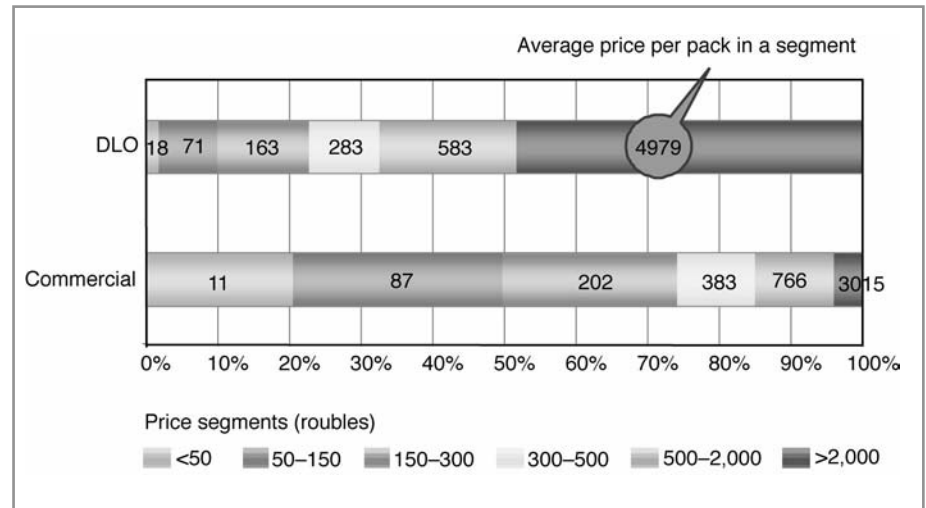
Evaluating programme performance

Undoubtedly, the most important achievement of the DLO programme is that, for the first time, it has enabled free access to essential medicines for the most vulnerable and under-provided segment of the Russian population. Patients have been able to obtain medications on a sustainable basis, without the necessity of having to make any out-of-pocket contribution. Provision has remained, therefore, co-payment-free at the point of use for all eligible patients. Figure 1 illustrates the difference that the DLO programme has made to those who needed to make more intensive use of pharmaceutical care. Prescribed drug provision increased from 87% (April 2005) to 99.5% (January 2006), with the share of prescriptions waiting to be filled decreasing from 11% (April 2005) to less than 1% (January 2006).

The vast majority of medicines (over 75%) consumed by DLO eligible patients in the first half of 2006 were contained within the more expensive medicines categories, costing more than 500 roubles each (\$US 18); about 50% of these medicines were very expensive, each costing the system in excess of 2,000 roubles (\$US 72) (Figure 1). Prior to the implementation of the programme, patients would either need to purchase these on the commercial market, paying the entire cost out-of-pocket, or obtain some pharmaceutical coverage through in-patient settings, or, simply, forego treatment.

There was also a regional reimbursement system, which provided drugs to so-called 'regionally eligible citizens', but the reimbursement list, eligibility criteria, and the

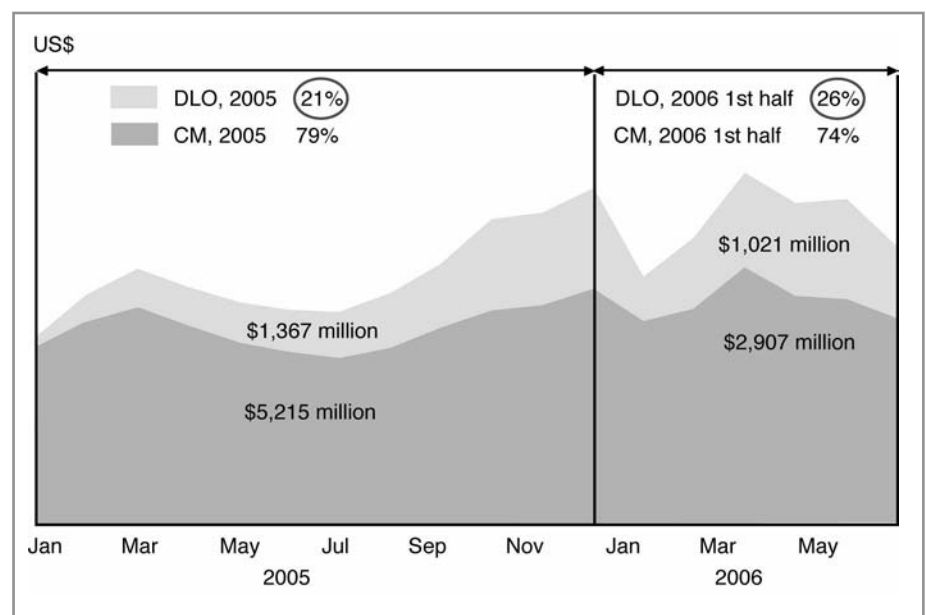
Figure 1: Expenditure in the commercial and the DLO markets by type of drug (January – June 2006)



Source: Adapted from Kuzin A, 2006..³

Note: 1 US\$ = 28 roubles.

Figure 2: Pharmaceutical market structure in 2005 and first half of 2006, at public prices including VAT (CM:Commercial market + DLO)



Source: Adapted from Kuzin A, 2006..³

level of co-payment required differed greatly from region to region, depending on budgetary constraints. Moreover, no regional reimbursement list could be compared with the current federal reimbursement list. The latter is far more comprehensive, in terms of both the number of INNs (international non-proprietary names) and the new and innovative medicines reimbursed. By contrast, the commercial market has been dominated by lower cost medicines; only about 15% fall into the expensive medicines' categories.

Receiving its budget direct from the Ministry, the DLO programme immediately became an important player in a system dominated hitherto by a commercial market that experienced regular price instability and price hikes. Indeed, the DLO's total market share increased from 0% in 2004, to 21% in 2005 and 26% by the first half of 2006 (Figure 2).

Satisfaction surveys conducted at the start of the programme in January 2005 and also towards the end of that year showed improvements in the perception of the programme by eligible individuals; the

Box 1: DLO programme – thresholds for satisfactory performance

1. Level of provision of drugs relative to number of prescriptions submitted to pharmacy at first request (needs to be >90%).

2. Proportion of prescriptions filled (within 10 days) relative to monthly average number of submitted prescriptions (needs to be <10%)

3. Proportion of prescriptions waiting to be filled (for more than 10 days) relative to the monthly average number of submitted prescriptions (needs to be <1%)

4. Proportion of inappropriately issued prescriptions (needs to be <1%)

5. Compliance with licensing requirements by organisations participating in the DLO programme.

Source: Ministry of Health and Social Development of the Russian Federation, 2006.²

proportion of respondents indicating that they were very, or generally, satisfied rose from 38% to 45% over this time period. This is hardly surprising given that the implementation of the programme resulted in a significant increase in the number of prescriptions successfully filled by eligible insurees. On average the number of prescriptions filled in Russia increased two and a half to threefold in 2005 compared with 2004.

In some regions, particularly those which were previously under provided, the increases were even more striking. These included a fourfold increase in Mordovia, fivefold in Amur, more than sixfold in Kaluga and sevenfold in North Ossetia. The average cost per prescription nearly doubled, from 180 roubles (\$6.4) to 340 roubles (\$12), between the first quarter of 2005 and the same period in 2006. This was not, however, the result of price hikes, as prices had stabilised and even fallen by 10% across 118 molecules, but rather an indication that more expensive medicines were being prescribed more frequently.

Additionally, in order to monitor and evaluate the programme's performance, a number of key indicators to be used as benchmarks were developed by the Russian Ministry of Health Care and Social Development and the Federal Service. (The most important are shown in Box 1). These tied in with a series of problems impacting on patients, physicians, pharmacies and manufacturers that arose during the implementation of the DLO programme.

Patients were mainly concerned about the duration of waiting times to see a physician or to fill a prescription at a pharmacy, as well as the shortages at pharmacy level in terms of filling the prescription with the prescribed medicine first time, resulting in delay. Government-led surveys suggested that 27% of all patient-related complaints related to medicines not being in-stock at a participating pharmacy and a further 27% related to (excessive) waiting times in order to see a physician and receive a prescription. 23% of all complaints related to (excessive) waiting times at the pharmacy, whereas in 16% of all cases, patients experienced problems due to a lack of information.

Physicians were mainly concerned with having an excessive workload, seeing many patients without necessarily having the relevant supporting infrastructure. Pharmacists were also sometimes overwhelmed by having to service an increased number of patients, whilst at the same time experiencing shortages in a number of drugs on the reimbursement list. An additional problem was the requirement to prepare dispensing and activity reports; this led to a disproportionate amount of time being spent on administration.

Efficiency measures

While the DLO programme has undoubtedly had a significant positive impact on improving access to essential medicines, it has continued to operate within a fixed budget determined by the federal government. This implies that resources have to be used cost-effectively

to maximise both programme impact and value for money. To that end, significant policy changes have occurred during the first two years of the programme [4]. These are intended to ensure that funding is adequate to guarantee continued access to medicines. Of particular attention in the second half of 2006 was a policy shift from simply focusing on the delivery of pharmaceutical products to eligible patients, towards managing resources more rationally.

At the beginning of 2006, INN prescribing was introduced, although it remains to be seen how the policy will be taken up by prescribing physicians. A further policy measure, introduced in April 2006, was a new reimbursement list, comprising 2276 trade names and which reduced the prices of 178 trade names. In addition to these selective price reductions, 103 branded products were excluded while 46 new branded products added to the list. The Ministry of Health Care and Social Development anticipates that the total efficiency savings from this fine tuning measure will be in the region of 14% of total spend.

“If manufacturers refused to decrease prices, their products would be automatically delisted”

Subsequent reforms on the operational side of the programme have included the introduction of further restrictions to the list of reimbursable products in October 2006. Some 74 INNs and 62 product formulations, mainly products financed from other programmes within the health care system (HIV, tuberculosis, some oncology drugs), as well as INNs and product formulations for in-patient use, were excluded from the list. In addition, prices for the most frequently prescribed INNs were reduced to the level of the lowest generic price, plus a supplement of 20%. If manufacturers refused to decrease prices, their products would be automatically delisted. In total, these price cuts affected 122 individual products. As a result, a total of 834 positions (both INNs and product formulations) were affected (due to both INN list shortening and demands for price cuts for individual products or product formulations).

A new tender system was announced for

four groups of the most expensive INNs, (three each from oncology, haemophilia and multiple sclerosis and eight for diabetes (insulins)). These seventeen INNs put together account for 40% of total DLO spend. The objective was to decrease wholesale markups from the current per-region fixed rate (35% on average) to a significantly lower rate. The 2007 tenders are now being published by FFOMI.

Total anticipated savings from these measures, calculated on the basis of next year's projected DLO budget, have been estimated at 15% of DLO total spend, or \$230 million. 7.2% and 7.8% respectively will be saved by the exclusion of INNs and branded products (Figure 3). This is expected to be achieved without adversely affecting the level of access to medicines, or the quality of products supplied. It should also allow room for innovative products to be included in the 2007 DLO programme.

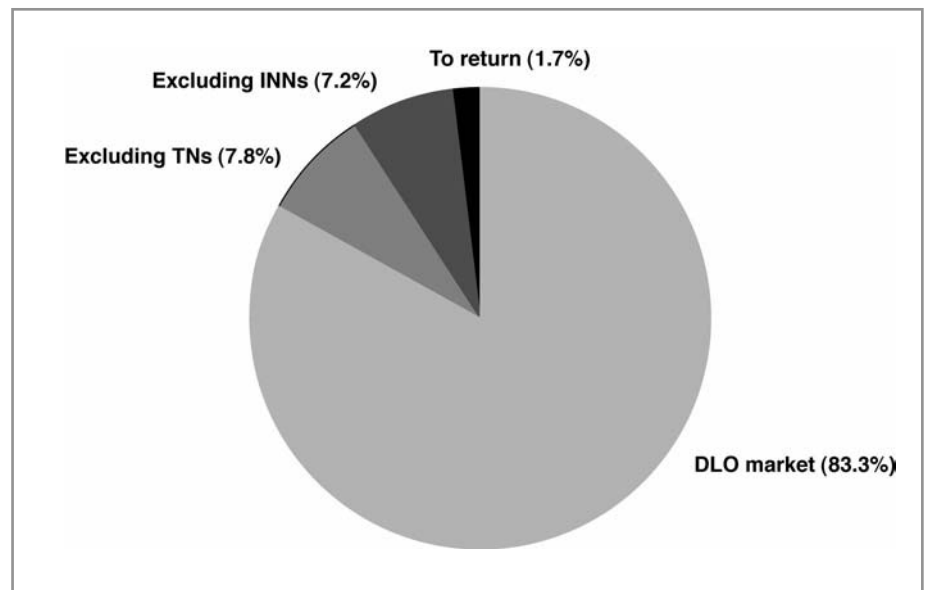
Future policy directions

While the Federal Government remains committed to providing continued access to essential medicines and improving the health status of the population, it must also ensure that the DLO programme provides coverage in a rational and cost-effective way. In order to do this, a number of reforms are necessary. In addition to the already existing INN prescribing, the Federal Government has requested that options such as internal reference pricing and cost-sharing also be considered. Reference pricing would imply that patients would have to pay out-of-pocket if a medication's price were in excess of the reference price. This might encourage physicians to prescribe cheaper, but equally efficacious alternatives.

“There has been an increase in the confidence of patients in the health care system”

While some of these reforms, such as INN prescribing and, if introduced, reference pricing, are aimed at rationalising both physician prescribing habits and patient utilisation patterns, others are aimed at rationalising the programme's type of coverage. To date, the DLO programme, being a prescription drug insurance scheme, covers both outpatient and some inpatient use drugs. However, proposals

Figure 3: Expected savings on 2007 DLO budget due to product delisting, as a percentage of market share



Notes: INN = international non-proprietary name; TN = trade name

Source: The authors based on data from the DSM Group, 2006.

are already in place to shift certain categories of medications to other programmes. For instance, HIV and tuberculosis drugs, which were included in the DLO controlled list until September 2006, and available to patients with doctors' (specialists or heads of polyclinics) authorisation, will now be shifted to other parts of 'Project Health' and reduce the burden on available DLO funds.

In addition, products for oncology, psychiatry, diabetes and hypertension patients intended for in-patient care, may be shifted, for example, to the 'Federal Dedicated Programme', which aims to provide integrated care for patients requiring these interventions; this will also include pharmaceutical care. Finally, the 'High Technology Medical Care' project, being part of the President's 'Project Health', is intended to improve access to hospital and high technology medical care, including hospital drugs reimbursed under the project.

Suppliers will compete to provide medicines via a tendering mechanism. This measure should reduce the demands placed on DLO resources. It should also provide an opportunity for the programme to expand its outpatient coverage and tackle the potential under-use of medications in key diagnoses, whilst at the same time, generally enhancing access to improved pharmaceutical care.

To date, the DLO programme has provided free access and comprehensive coverage to the federally eligible population. Its first two years have been accompanied by an increased confidence in the system from a patients perspective while there has also been an accumulation of expertise in terms of establishing infrastructure, administering the programme, addressing its shortfalls and initiating policy changes aimed at a rational and efficient use of resources.

REFERENCES

1. World Bank. *Russian Economic Report*. Moscow: Economic Unit, World Bank Moscow Office, April 2006. (<http://www.worldbank.org.ru>)
2. Ministry of Health and Social Development of the Russian Federation. *Results of DLO programme implementation in 2005*. Moscow: Federal Service for Health Care and Social Development, 2006.
3. Kuzin A. *DLO and Commercial Market – Mutual Influence* (presentation). Moscow: DSM Group, 15 October 2006.
4. Telnova EA. *Expected Future Implementation of DLO Programme and its Impact on the Pharmaceutical Market in Russia in 2005–2006*. Moscow: Federal Service of Health Care and Social Development, 2006.

European junior doctors who work at night

Roy Pounder

Summary: In 2007, the Working Time Directive expects every junior doctor to work a maximum of 13 hours in every 24 and have 11 hours rest, with a weekly average of 56 hours. This has driven European junior doctors from working on call to becoming shift workers. Shift working at night increases errors, but the length of shifts and the number of shifts worked in succession are also safety factors. Preparation for shift work, in terms of sleep patterns and design of rotas, improves safety. Only four European countries comply with the existing regulations, and ministers should consider delaying further implementation.

Key words: European Working Time Directive, junior doctors, rotas, safety, shift work.

Health care is a 24-hour business in every European general hospital. There are roles and responsibilities that can only be performed by a licensed doctor, and these skills may be required on demand, and immediately. Thus, there is a need to have doctors present in hospitals day and night.

Until 2004, most hospitals had junior doctors resident in the building, who were resting and sleeping when not actively caring for patients. This 'on call' system, if unregulated, could result in exhausted doctors, but it provided a pool of doctors available at short notice. The European Working Time Directive is a health and safety measure designed to protect workers, but it has made life more difficult for many junior doctors.

The Directive was applied to all European junior doctors in 2004, and it will be applied with increasing stringency in the coming few years. In 2007, the regulations expect every junior doctor to work a maximum of 13 hours in every 24, and consequently have 11 hours rest in the same period. In addition, each trainee doctor may only work an average of 56 hours each week. But there are 168 hours in every week, and it is clear that devising a roster of junior doctors, all of whom have the relevant skills and training is quite

a challenge. A group of seven to twelve doctors is needed just to provide the presence of a single trainee doctor, available 24 hours every day, throughout the year.

The SiMAP judgement* of the European Courts of Justice has caused the greatest problem – because it decided that a junior doctor sleeping on call in a hospital is still working – that is, every hour is deducted from the weekly average of 56 hours. This is not only an economic disadvantage for the employer – that is, paying for essentially no output – but these are trainee doctors, and whilst losing working hours during sleep, they are also losing their training.

The implementation of the Working Time Directive has driven a sudden change in the pattern of work of European junior doctors from working on call, to full-shift workers – there is no other way to staff a hospital 24/7. Thus, if they obey the Directive, a hospital has one team of doctors working in the day and evening, and an entirely new team coming on the late evening to work the night shift until the morning.

My evidence, from informal surveys in 2005 and 2006 of colleague gastroenterologists throughout Europe, is that the Directive is only being followed in Sweden, Denmark, the Netherlands and

the United Kingdom. All the other EU Member States appear to disobey the rules, by rostering their doctors to work continuously for 24 to 36 hours.

What's so bad about a night shift?¹

Working at night is harder than working during the day, because this is the time when the human body is programmed to be asleep. It also results in loss of sleep and increased fatigue, which directly impacts on performance. Working at night involves trying to function when one's alertness, vigilance and cognitive reasoning are all at their lowest, making it easier to make mistakes without noticing. Tired junior doctors in the USA and Denmark did exactly this, and were shown to lose concentration more often and make more clinical errors compared to when they were able to get more sleep.²⁻⁴ Of particular relevance to junior doctors in training, exhaustion also impairs recent learning and can decrease their ability to make correct diagnoses and perform technical procedures.⁵

Importantly, because working a night shift involves trying to sleep in the day, the lack of sleep can quickly become excessive. Sleeping during the day is much harder than sleeping at night, because it is not what humans are designed to do. Bright sunlight, temperature, and noise can all keep night workers awake during the day,

Professor Roy Pounder is Lead for the European Working Time Directive, Royal College of Physicians, London.
Email: roy.pounder@rcplondon.ac.uk

* Sindicato de Médicos de Asistencia Pública (Simap) v Conselleria de Sanidad y Consumo de la Generalidad Valenciana, ECJ Case C303/98 Judgment of 3 October 2000.

but perhaps most importantly, the body's internal clock, which regulates sleep-wake patterns, acts to maintain alertness and wakefulness. This means that daytime sleep is not of such good quality or duration as sleep at night;⁶ shift workers who work several consecutive night shifts can become progressively more tired over the course of their duty. Inevitably this can then lead to further reductions in performance and an increased likelihood of accidents or mistakes.

Night shifts and safety

While working at night does contribute to an increased risk of making errors, it is not the only factor to consider. Evidence collected from a range of industries where shift work is common shows that the length of individual shifts and the number of shifts worked in succession are also very important (see Figures 1 and 2).^{7,8} The more shifts that are worked consecutively, the greater the relative risk compared to the first shift worked. Likewise for the length of each shift – the longer each shift, the greater the chance of an accident. Interestingly, if two otherwise identical shifts in terms of length and number of previously worked shifts are compared, the risk of an accident is always greater on the night shift than during the day.

Shift length and the number of consecutive shifts must always be considered when designing new rotas. Furthermore, because of the increased risk with working at night, it is essential to remember that what is an acceptable rota for working during the day may not be sensible when planning night shifts.

Getting home after a night shift

Designing safe rotas does not just involve considering the doctor at work. After the shift, doctors must also be able to travel home safely, and often this will mean driving. Just as with performance on duty, driving ability is strongly affected by fatigue and lack of sleep. There is clear evidence that this is a particular hazard for American junior doctors working very long hours.⁹ While this should be less of a problem if doctors work two or three shorter night shifts at time, appropriate napping and preparation are nonetheless necessary. Driving while tired becomes an increasing potential hazard as shift length and the number of nights worked in succession rise, particularly if the recommendations in *'Working the night shift: preparation, survival and recovery – A guide for junior doctors'*¹ are not followed.

Figure 1: The estimated risk of accidents in shift workers, related to length of shift.^{7,8} An 8-hour shift has been set to have an estimated risk of 1.0, with all other shifts relative to this

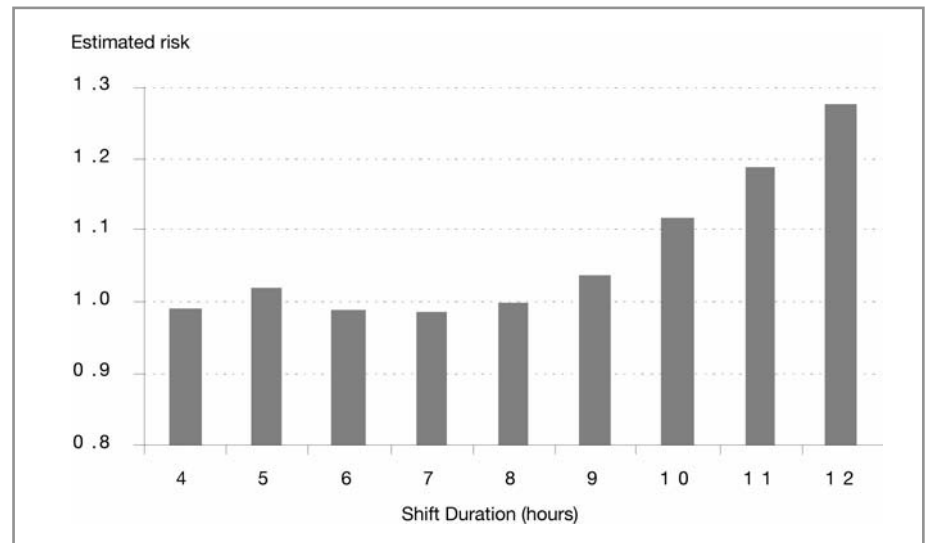
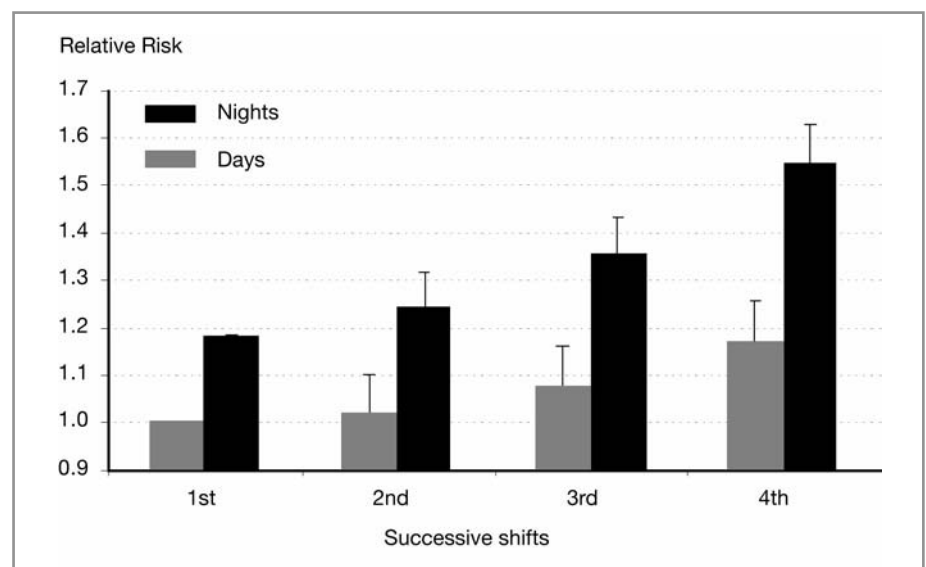


Figure 2: The estimated risk of accidents in shift workers, related to the number of successive shifts and whether they are day or night shifts^{7,8} The first day shift has been set to have a relative risk of 1.0 and all other shifts are relative to this



Shift patterns that don't work, and some that should

When the Working Time Directive Regulations were implemented in the United Kingdom in August 2004, the most common pattern of shift work was for an individual doctor to work a 13-hour night shift for seven nights in succession. This made design of the roster easy – one week of nights, followed by some leave for recovery and then some weeks of day shifts. It also seemed to 'get rid' of the stressful period in one sharp, unpleasant week of nights. But it meant that the individual worked seven 13-hour shifts in one week – that is, a 91-hour week, which would be daunting if worked in the daytime, and clearly wrong if associated with an acute change of diurnal body rhythm.

A working group from the Royal College of Physicians has published a document that discusses different solutions to this rostering problem; it recommends an innovative pattern of three overlapping nine-hour shifts to provide cover across the 24 hours.¹⁰

What's the future for European junior doctors?

In 2009, the average working week is scheduled to be reduced from 56 to 48 hours, to come into line with all other workers in the European Union. This demands an approximate 20% increase in daytime productivity (daytime, because most hospitals already roster the absolute minimum number of juniors at night, and no more reductions can be achieved at

night). This increased productivity is needed for not only work output, but also training. Only four countries have achieved compliance with the existing regulations, and it seems sensible for Ministers to consider a delay in further implementation.

REFERENCES

1. Horrocks N, Pounder R, RCP Working Group. Working the night shift: preparation, survival and recovery – a guide for junior doctors. *Clinical Medicine* 2006;6:61–67. Also freely available at http://www.rcplondon.ac.uk/pubs/books/night_shift/night_shiftbooklet.pdf
2. Lockley SW, Cronin JW, Evans EE et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *New England Journal of Medicine* 2004; 351:1829–37.
3. Landrigan CP, Rothschild JM, Cronin JW et al. Effect of reducing interns' work hours on serious medical errors among interns in intensive care units. *New England Journal of Medicine* 2004;351:1838–48.
4. Eastridge BJ, Hamilton EC, O'Keefe GE et al. Effect of sleep deprivation on the performance of simulated laparoscopic surgical skill. *American Journal of Surgery* 2003;186:169–74.
5. Stickgold R. Sleep-dependent memory consolidation. *Nature* 2005;437:1272–78.
6. Knauth P, Rutenfranz J. Duration of sleep related to the type of shift work. In: Reinberg A, Vieux N, Andlauer P (eds). *Advances in the Biosciences, Vol 30. Night and shift work: biological and social aspects*. New York: Pergamon Press, 1980:161–8.
7. Folkard S, Tucker P. Shift work, safety and productivity. *Occupational Medicine* 2003;53:95–101.
8. Folkard S, Lombardi DA, Tucker PT. Shift work: safety, sleepiness and sleep. *Industrial Health* 2005;43:20–23.
9. Barger LK, Cade BE, Ayas N et al. Extended work shifts and the risk of motor vehicle crashes among interns. *New England Journal of Medicine* 2005;352:125–34.
10. Horrocks N, Pounder R, RCP Working Group. *Designing Safer Rotas for Junior Doctors in the 48-hour Week*. London: Royal College of Physicians, 2006. Freely available at <http://www.rcplondon.ac.uk/pubs/content/s/09446ffc-7f46-4f18-a1d0-fb5b8607b0c4.pdf>

Is Denmark prepared to meet future health care demands?

Martin Strandberg-Larsen, Mikkel Bernt Nielsen, Allan Krasnik and Karsten Vrangbæk

Summary: One consequence of the decentralised nature of the Danish health care system, characterised by a high degree of patient satisfaction and expenditure control, has been the somewhat uneven level of access to health care resources across the country. A series of interventions to gradually strengthen coordination and centralised control of the system have been introduced in recent decades, culminating in major structural reform being implemented from January 2007. This article presents a brief analysis of this reform process, its policy goals, key elements and potential to prepare the system to meet future health care challenges.

Keywords: Health care reform, administration, decentralisation, recentralisation, health care financing, Denmark.

Introduction

The predominantly tax-based Danish health care system has traditionally been highly decentralised politically, financially and operationally; public regional and local authorities are responsible for the provision and delivery of health care services. The system has also been characterised by strict expenditure controls and a high level of patient satisfaction.¹ One consequence of decentralisation however, has been the somewhat uneven access to health care resources across the country. Danish politicians have, until now, given more weight to the importance of local self governance (and its potential to achieve innovation) than geographical equity. This has led to differences in waiting times, the availability of medical technologies and rates of specific diagnostic and curative activities, such as systematic breast cancer screening or the use of expensive drugs for ovarian cancer.¹

The demands for ever more comprehensive primary care services, in addition to highly specialised secondary health care services, have not always been helped by the fragmented structure within this decentralised system. It has been argued that this structure with three political/administrative levels has led to suboptimal decision-making and management. As a consequence, a series of interventions to gradually strengthen the coordination and centralised control of the system have been introduced during recent decades, culminating in a major reform of administrative structures that came into effect on 1 January 2007.

The reform measures radically change the administrative and geographical boundaries of the health care system. Simultaneously, a centralisation and decentralisation process has been initiated, where both the state and the municipalities obtain new responsibilities and tasks. One of the goals

Martin Strandberg-Larsen is a doctoral research student, Mikkel Bernt Nielsen is Research Fellow and Professor Allan Krasnik is Director of the MPH-programme, Institute of Public Health, University of Copenhagen, Denmark. Karsten Vrangbæk is Associate Professor, Department of Political Science, University of Copenhagen, Denmark.

of the reform process is to ensure equal standards of care throughout the country by increasing the power of state bodies in planning and quality management. Another goal is to improve the structural conditions needed for primary care services that better meet needs, with an emphasis on preventive services and health promotion, in addition to the provision of high quality specialist secondary health care services.^{2,3} This article presents a brief analysis of this reform process, policy goals, key elements, and potential to prepare the system to meet future health care challenges.

Changing structure

The health system has been characterised by path dependent and incremental changes since major administrative reforms created the decentralised (county-based) system in the early 1970s. As a result of the growing debate on the structure of the public sector, the government appointed a Commission on Administrative Structure in October 2002. This Commission was charged with the task of assessing the “advantages and disadvantages of alternative models for the structure of the public sector and on this basis to make recommendations for changes that would remain sustainable for a number of years”.⁴⁻⁶

In January 2004, this Commission concluded that reforms to public sector structures were required. This conclusion was partly based on the assessment that counties and municipalities were of insufficient size for proper task performance and also because the distribution of tasks in the public sector was inappropriate. The Commission presented six different alternative public sector models, describing their advantages and disadvantages but without making any recommendation.⁴⁻⁶

After a public hearing, the central government proposed large scale structural reform that deviated somewhat from the models put forward by the Commission, particularly in regards to financing mechanisms and the number of regional units. The government proposal, which became the basis for the final political decision, maintained the three political/administrative levels but introduced new divisions of labour. The larger regions would retain responsibility for most treatment-related health tasks, while the municipalities would gain a greater role in terms of prevention, health promotion and rehabilitation. The agreement also included

Figure 1: Post reform structure of the statutory health system in Denmark



* The Danish Regions and the National Association of Local Authorities are not part of the formal political and administrative system. They are interest groups for the municipalities and regions. They represent the decentralised authorities in discussions and negotiations between regional and municipal politicians, professional organisations and central government but cannot enter into legally binding agreements on behalf of their members.

financing and resource allocation measures, with the regions losing the right to finance health expenditure via regional taxation, instead relying on a combination of state block grants, activity-based contributions as well as municipal co-financing (see section on key elements of new system).

“One of the goals of reform is to ensure equal standards of care across the country”

Free choice of hospital remains a key feature of the system. The reform reduces some of the administrative issues related to choice of services across regional borders. They are also expected to increase the administrative and legal capacity of the regions to enter into contracts with private providers. This is likely to become more important, as the government intends to lower the general waiting time guarantee from referral to treatment from two months to one month as of 1 October 2007. Patients will have access to a range of private contracted providers if the regions are unable to offer treatment within this time limit.

The legislation for reform passed through parliament in 2005 and was implemented in January 2007; 2006 being a transition year. The reform bill was passed by a small majority; this is unusual in Denmark,

where typically major structural reforms have achieved a broad consensus between the government and opposition parties. In this case, two of the parties behind the reform, including the ruling Conservative party, had been in favour of dismantling the counties for a number of years.²

Policy goals and principles behind reform

The main arguments in favour of reform were broadly related to a reduction in bureaucratic costs and taxation levels. The government further stated that the purpose of the reform was to maintain and develop a democratically governed public sector on a sound basis for continued development of the Danish welfare society. Therefore, the decentralised public sector needed to be designed in such a way that it could meet future requirements by creating sustainable structures with a clear responsibility to provide high quality welfare service to the population. Larger municipalities were expected to be able to provide more specialised and integrated solutions for welfare tasks, whilst maintaining local democratic accountability.

The government also set out two underlying principles governing reform. The first was that funding should be linked to tasks. This meant that the authorities taking on new tasks would be compensated by those authorities relinquishing these activities. The parties behind the reform measures agreed that this should not result in higher taxes nor increased public expenditure.

The second linked principle was that while these structural measures, in general, should be neutral in terms of expenditure, this did not mean that there would be no costs involved in merging municipalities and creating new regions. These costs however, would very much depend on how the individual municipalities and regions planned the process. The municipalities had to bear these costs, which the government argued would ultimately be outweighed in the long run because of potential synergy effects and economies of scale.^{3,6}

Key elements of the new system

Organisation

Structural measures within the reform have changed the political and administrative landscape by dramatically reducing the number of regional and local units and changing their division of responsibilities. The number of regional authorities have been reduced from fourteen counties to five regions (0.6-1.6 million inhabitants) and the number of municipalities from 271 to 98 (37% of the new municipalities have more than 50,000 inhabitants, 38% have 30,000-50,000, 18% 20,000-30,000 and 7% have less than 20,000). Both administrative levels are governed by directly elected politicians.^{2,6} (See Figure 1 for an organisational overview of the new administrative structure).

The purpose of establishing larger units within the health care sector is to improve the quality of patient care, as well as health promotion and preventive services, by creating opportunities for grouping treatments and services, thus exploiting the advantages of specialisation which ensures the best possible utilisation of resources.^{2,6}

With reform, municipalities have gained overall responsibility for rehabilitation that is not provided during hospitalisation. Previously, this responsibility was shared with the counties. In addition, the municipalities now have primary responsibility for prevention and health promotion, with the goal of integrating these activities into other local responsibilities, i.e. day care, schools, centres for the elderly, etc. Treatment of alcohol and drug abuse, as well as specialist dental treatment for people with learning difficulties, are likewise now the responsibility of the municipalities.^{2,6}

The chief responsibility of the regions is to run hospitals, including psychiatric and prenatal care centres. Environmental and

regional development tasks have also been maintained at this level. Most other tasks have been moved to the state or municipality level.^{2,6} In order to ensure coordination between regional and local activities within the health care system, regions and municipalities will have to enter into binding partnerships within health coordination committees. Furthermore, they must make health agreements on procedures for the discharge of frail and elderly people from hospital, social services for people with mental disorders as well as preventive treatment and rehabilitation.^{2,6}

“Co-financing may incentivise municipalities to invest in prevention”

The role of the central government is almost exclusively concentrated on regulating, supervising and financing. Following reform, the influence of the National Board of Health on hospital planning has been strengthened, with the intention of ensuring more equal provision of hospital treatment across the country.^{2,6}

Financing

Until 2007, the Danish health care system was financed through progressive general income taxation at the national level supplemented by proportional income and property taxes at the regional level. National level tax revenue was redistributed to the counties via block grants based on objective criteria and some activity-based financing for hospitals. The system was designed to support solidarity in financing and equity in coverage.^{7,8}

With reform, several important financial changes have been implemented. The independent right to raise taxation at regional level was abolished. Health care activities are now financed largely through a national earmarked health tax (8% of income), redistributed in terms of block grants to regions and municipalities. The earmarking of health taxes is a new feature in Denmark and is intended to create greater transparency within this sector. However, it also reduces the potential for redistribution between health and other sectors.

80% of all health care activities in the regions are financed through these block grants in addition to some activity-based

payments (approximately 5%). The size of these block grants are calculated using a formula where expected need for health care in the population is a central component. This level of need is assessed by combining the distribution of age and socioeconomic status in the region. The purpose of activity-based payments is to encourage the regions to increase activity levels within hospitals.

The remaining funding comes from a combination of per capita and activity-based payment contributions by municipalities. Co-financing it is thought will incentivise municipalities to invest in prevention activities, as their activity-related contributions will primarily reflect the number of hospitalisations and outpatient treatments at hospitals, as well as the number of services from general practitioners. In this way, municipalities that are successful in reducing the need for hospitalisation will be rewarded.^{2,6}

Discussion

One key argument for reform has been the cost of bureaucracy and the multiple tiers of taxation. However, it is not clear whether it will lead to any major reduction in administrative costs. Moreover, significant implementation costs are being incurred. With the continuation of three administrative/political levels, now with just two tiers where taxes are levied, the stage is set for a blame-game between the newly empowered state and the regions. Some observers question the sustainability of the new organisational structures and predict that the regional tier of administration will in turn be removed due to the separation of funding from the provision of services. This could lead to a new structure, with the state also responsible for the provision of hospital services.

Another key driver behind reform was the perceived need for larger catchments areas to support future specialisation and sustainable structural adjustments. Many observers have pointed to the ambiguous evidence on economies of scale and specialisation in health care, while several independent observers have pointed out that the former counties were already performing well in terms of controlling expenditure, increasing productivity and making gradual structural adjustments. Most observers agree that strengthening the role of the municipalities is beneficial; however, there is some fear that they lack sufficient competence to plan and implement their newly acquired responsi-

Box: Reform research initiatives in Denmark

The structural reform measures to the Danish health care system are highly complex which makes evaluation of their effects challenging.

However, health services research initiatives have been initiated in order to disseminate empirical findings on their impact to policy-makers and health system planners in Denmark and abroad.

Such research initiatives have been established within a Danish multi-institutional research network.

The network is assessing the impact of this reform, with a focus on administrative and managerial changes, impact on the health economy, influence on coordination of care, and the redistribution of activities regarding health promotion, preventive services, and rehabilitation

See www.sundhedsreform.ku.dk

bilities and that they might instead give priority to activities directly reducing hospital admissions rather than long-term prevention programmes.

The challenges imposed by fragmentation in the system have probably not been solved through these measures. The newly established formal tool for achieving coordination between the different administrative levels of health care has been shown to be inadequate.⁹ The fragmentation of the system is further challenged by the increasing use of public-private partnerships.⁹

To date, no independent experts have spoken out in favour of the financing changes.^{1,2} Municipal co-financing for regional health services, for example, hospital admissions and consultations with general practitioners, have been based on two assumptions. First, that incentive structures will only be effective if use of regional health services can in fact be prevented. This is not likely for a large amount of hospital services. Second, that prevention or alternative services offered by the municipalities have to be less expensive than the municipalities' contribution to the total costs of the given service otherwise provided by the region.

This is also not very likely due to the relatively limited municipal co-financing contributions. Since many municipalities are currently developing substitute services, one unintentional consequence of the new financial system could be that the total cost of municipal and regional health services will increase, especially in the short run.

Another important radical change in the financial arrangements is that the level of activity-based financing in hospital budgets will increase from 20% in 2006 to 50% in 2007.¹⁰ The government has actively sought to use activity-based financing to create incentives for increased activity when redistributing funds.² So far, the relative limited use of activity-based financing seems to have led to increases in activity level at hospitals, but possibly also bias against some areas where activity levels are harder to measure and influence (for example, geriatrics or internal medicine).^{11,12}

The implementation of such large scale reform will not be without obstacles and a significant challenge still lies in ensuring a system that all groups of patients and their families can access and navigate easily. Careful ongoing evaluation of these reform measures, such as those by the Sundhedsreform network will be required (See Box).

However, if these challenges can be handled appropriately, the structural changes will likely make the Danish health care system better prepared to meet the future demands of modern health care. On the other hand, the changes in financing arrangements are not without their difficulties and the likelihood of unintentional consequences is present. With the new organisational structures in place, the logical next step would be to go deeper into the core of problems that have much to do with the need to strengthen the culture of trust between health professionals within the system. This might possibly be achieved through skilled stewardship at all levels, with an emphasis on a whole-system approach towards health care services.

References

1. Pedersen KM, Christiansen T, Bech M. The Danish health care system: evolution – not revolution – in a decentralised system. *Health Economics* 2005;14(Suppl 1):S41-S57.

2. Strandberg-Larsen M, Nielsen MB, et al. *Health Systems in Transition: Denmark*. Copenhagen: European Observatory on Health Care Systems, unpublished work.

3. Ministry of the Interior and Health. Agreement on a Structural Reform. Copenhagen: The Ministry of the Interior and Health, 2007. Available at <http://www.sundhedsministeriet.dk/publikationer/agreement/index.html>

4. The Commission on Administrative Structure. Analysis of the health care sector [In Danish]. Copenhagen: Ministry of the Interior and Health, 2003.

5. The Commission on Administrative Structure. Recommendation of the Commission on Administrative Structure, Vol.III, Recommendation no. 1434. Copenhagen: Ministry of the Interior and Health, 2004. Summary available at <http://www.im.dk/publikationer/strukturuk/SummaryGB.pdf>

6. The Ministry of the Interior and Health. The local government reform – in brief. Copenhagen: Ministry of the Interior and Health, 2005. Available at http://www.im.dk/publikationer/government_reform_in_brief/Kommunal_UK_screen.pdf

7. Gundgaard J. Income-related equality in utilization of health services in Denmark: Evidence from Funen County. *Scandinavian Journal of Public Health* 2006; 34(5):462–71.

8. Wagstaff A, van Doorslaer E, van der Burg H, et al. Redistributive effect, progressivity and differential tax treatment: Personal income taxes in twelve OECD countries. *Journal of Public Economics* 1999;72(1):73–98.

9. Strandberg-Larsen M, Nielsen MB, Krasnik A. Sundhedsaftaler som nyt styringsredskab til at sikre sammenhæng i sundhedsvæsenet [Health plans as a new management tool]. *Tidsskrift for Dansk Sundhedsvæsen* 2006;82(10):334–37.

10. The Ministry of Finance. Agreement on the municipal and regional economy 2007 [in Danish]. Copenhagen: Ministry of Finance, 1 June 2006.

11. Ankjær-Jensen A Rath MB. Takststyring af sygehuse. Copenhagen, DSI - Institut for Health Services Research, 2004. Available in Danish at http://www.dsi.dk/publikationer/DSI-rapporter/2004.08/Rapport_2004_08.pdf

12. Ministry of the Interior and Health. Evaluering af takststyring på sygehusområdet. Copenhagen: Ministry of the Interior and Health, 2005. Available in Danish at http://www.im.dk/publikationer/eva_takststyring/Evaluering.pdf

Institutional change or political stalemate?

Health care financing reform in Germany

Kai Mosebach

Summary: After its inauguration in Autumn 2005, the second Grand Coalition in German post-war-history announced a major reform of health care financing. The public and the media were curious to see how the governing CDU/CSU and SPD coalition would overcome their differences on health care financing. To date, the parties have not fully agreed on the final institutional design of the future system. However, the Grand Coalition will introduce some institutional innovations that nonetheless will alter the overall structure of health care financing in the country.

Key words: Germany, health care financing, health policy, regulated competition, health insurance

On 24 October 2006, the German government agreed a proposal that would alter the structure of both statutory (SHI) and private (PHI) health insurance, if approved by the lower (*Bundestag*) and upper house (*Bundesrat*) of parliament in 2007. The parties representing the Grand Coalition between the Christian Democrats (*Christlich Demokratische Union – CDU*), their sister party the Bavarian Christian Social Unionist (*Christlich-Soziale Union in Bayern – CSU*), and the Social Democrats (*Sozialdemokratische Partei – SPD*) struggled to get their diverse factions to support this proposal. Moreover, these reforms have been faced by nearly unanimous opposition from the sickness funds, physicians, pharmacists and hospital managers, as well as the media and public.

As a result of lengthy rounds of negotiations, the original draft proposal, the SHI-Competition-Strengthening Act (*GKV-Wettbewerbsstaerkungsgesetz, SHICS-Act*) has been revised, thus making it extremely difficult to assess what the final outcome will be prior to the conclusion of

parliamentary deliberations in March 2007.¹ However, this overwhelming level of dissent and ongoing debate obscures the fact that an evolutionary process of health system change is already under way; the most recent health care reform proposals are a further step in that direction.

'Back to the future': regulated competition and managed care in Germany

Since the early 1990s, German health care policy has been changing course. In 1992, the governing CDU/CSU and the Free Democrats (*Freie Demokratische Partei – FDP*) agreed, in consensus with the opposition SPD, the Health Care Structure Act (*HCS-Act*). In hindsight, the most important structural change that the HCS-Act introduced was the implementation of regulated competition between, what by then had become, regionally and/or branch-organised sickness funds. Following the implementation of a risk-adjustment mechanism, from 1997, insureds could choose between most sickness funds. One consequence of this new policy of 'choice' was that the young, male, healthy and wealthy insured in particular, changed sickness funds, leading to rising levels of redistribution between funds.²

The notion of regulated competition meant that sickness funds could offer different packages of service provision. Initial steps

in this direction were taken under the two Statutory Health Insurance Restructuring Acts (*SHIR-Acts*) by the CDU/CSU and FDP government in 1997. These Acts enabled sickness funds and health care providers to contract selectively for the first time. However, due to the political links between doctors and the FDP, as well as factions of the CDU/CSU, selective contracting still depended on the approval of regional physicians' associations.

This obstacle was overcome by the SHI Modernisation Act (*SHIM Act*), enacted by the first red-green SPD/Green government with support from the opposition CDU/CSU in 2003. From 2004, sickness funds could contract selectively with individual or groups of individual health care providers without requiring the formal approval of a physicians' association. Furthermore, to overcome financial constraints on selective contracting, the SHIM-Act decided to fund integrated health care at the expense of collective reimbursement schemes for physicians and hospitals. Ever since, the number of new forms of health care provision making use of selective contracting has risen constantly. These new 'networks of care' range from gate-keeping models and disease management programmes to integrated care – the German model of preferred provision, integrating providers from different health care sectors.

Kai Mosebach is a Health Policy Analyst, Institute of Medical Sociology, Johann Wolfgang Goethe University, Frankfurt, Germany.
 Email: mosebach@em.uni-frankfurt.de

All these developments have meant that a new regulatory model has been emerging since the 1990s; one that, in line with international trends, focuses on regulating incentives instead of relying on cost-containment alone.³ The new shape of the health care system has been labelled 'competitive corporatism'. This combines competition between sickness funds and among health care providers with the preservation of a common regulatory framework through corporatist bargaining procedures.⁴ However, the political dynamics of competitive corporatism are both contradictory and conflict-driven. In essence, a dual structure has emerged, placing selective contracting into an environment where traditionally block contracts have been the norm.

Debating health care financing reform: red-green agenda and beyond

One motivation behind the introduction of regulated competition has been the desire for efficiency gains, which consequently would imply lower social insurance contributions. This would help support the international competitiveness of the German economy. This policy has been accompanied by higher levels of co-payment first introduced through the SHIR-Acts at the end of the CDU/CSU and FDP government in 1996. This was the only significant change in health care financing after the introduction of open enrolment in the 1990s.

Eventually, the red-green coalition put health care financing reform onto its political agenda in summer 2003. It established an expert Commission on Social Insurance Financing, which laid the conceptual groundwork for the ongoing political debate seen today. While focussing on several pillars of the German welfare state, the Commission's recommendations regarding health care financing rested on two commonly shared premises.⁴ First, that the financial foundations of the income-related health care insurance had been eroding because of economic globalisation, European integration and rising unemployment. Second, in order to preserve the international competitiveness of the German economy, health care insurance contributions must not rise excessively. However, due to a lack of consensus, the Commission's reform proposals ended up consisting of two competing models of health care financing: a nation-wide citizen's health insurance (ending the co-existence of SHI and substitutive PHI by integrating the latter into the

former), or alternatively a flat-rate health insurance limited to the SHI.

From a political perspective, the SPD and Greens favoured the citizen's insurance, while the CDU/CSU (the latter by no means unanimous) preferred a flat-rate insurance. This citizen's insurance would subject all individuals and all forms of income to health insurance contributions. By preserving the income component of the SHI, the citizen's insurance would lead to a significant increase in funds for health care. Additionally, it would make redistribution within the health care system more progressive.

However, the federal SPD/Green government had to contend with a CDU/CSU-led majority of state governments in the *Bundesrat*. Their conservative model of health care financing would imply a capital-funded health care insurance shifting the mechanism of income redistribution out of health insurance and towards tax based subsidies. As a consequence of this political stalemate, health care financing reforms were postponed, leaving only a new system of co-payments in place.⁵

After the end of the red-green government in early autumn 2005, the newly established Grand Coalition, under Chancellor Angela Merkel (CDU), agreed to bring in health care financing reforms. The proposed *SHICS-Act* will strengthen the role of the federal state in regulating the health care system at the expense of the traditional (corporatist) regulatory system. With regard to health care financing, this means on the one hand the introduction of a federal fund to pool financial flows, and on the other, a change in the relationship between SHI and the (substitutive) PHI system.

'Bringing the state in': federal fund, sickness funds and competition

Currently, sickness funds compete through different health insurance contribution rates paid by employers and employees. From 2009, the federal government will set (on an annual basis) income-related and uniform (for all sickness funds) health insurance contribution rates through legal regulation. The resulting revenues will be pooled centrally into a new federal fund on health care financing, managed by the Federal Insurance Office (*Bundesversicherungsamt*). This federal fund will also receive tax subsidies which should rise from €1.5 billion (2008) to €3.0 billion in 2009. However, due to political pressure

from the Federal Ministry of Finance the current (2006) tax subsidy of €4.3 billion will be reduced by €1.8 billion to €2.5 billion in 2007.

The proposals to channel funds from the PHI into the SHI and to construct a standardised reimbursement scheme for SHI and PHI were debated, but eventually abandoned. The SPD (especially its left wing) favoured both measures, but the CDU and CSU blocked these proposals, thereby reflecting their close links with PHI-companies and physicians that have the option of billing their services for private insurees at rates several times higher than those for statutorily insured patients. Furthermore, the implementation of the already concluded (SHIM-Act) morbidity-based and standardised reimbursement system for SHI physicians has been postponed to 2011.

After pooling the revenues, an amount of money consisting of a per capita amount, plus a risk-adjusted extra payment which balances the different risk structures of sickness funds, will be directed to the individual sickness funds. In contrast to the current risk-adjustment mechanism, in the future the total sum of health and administrative expenses of one sickness fund should be balanced with all others. In addition, the new system will redistribute health care expenditures according to the sickness fund's relative burden of morbidity.

At the start of the new health care financing system in 2009, sickness funds will be relieved of (recently accumulated) debt. If revenues are not sufficient to pay their health care expenditures, an individual sickness fund will be obliged to charge an additional levy on their members (but not their employers) – either through income-related or flat-rate payments. These charges should help incentivise funds to make further efficiency savings through the expansion of selective contracting. The reforms also aim to support selective contracting through strengthened outpatient and integrated care.

The federal government will also determine (by legal regulation) the overall distribution rate of funding from health insurance contributions, as well as the level of additional funding to be raised by individual sickness funds. In 2009, the share of funds from the income-related health insurance contribution will be 100%. However, the scale of additional charges could rise to as much as 5% of the overall

health care costs in the SHI, possibly reducing the share from health insurance contributions to 95%. Consequently, the level of additional charge should act as a signal of the efficiency of the sickness funds' operations.

However, due to a proposed hardship clause, sickness funds with an unfavourable risk structure (for example, many chronic ill and low-income insurees) may face funding problems. Under the terms of the hardship clause additional charges are individually limited to a maximum of 1% of the income of the member. The charge will in fact be collected without respective income testing up to an amount of €8, meaning that poor and low-income households (i.e. the working poor) will suffer the most if this additional charge is applied by their sickness funds.

Funds with a high concentration of low income households may face the additional problem of having to charge their more affluent members at a much higher level than low income members because of the restrictions on charges set by the hardship clause. One scenario where this might be the case would be if the government decides to raise the scale of any additional charges to more than 5% of total health care costs. Therefore many, but by no means all sickness funds, fear that if financial pressure on the SHI persist, in future the hardship clause might lead to a loss of competitiveness in some funds in comparison to those with a more favourable 'risk structure'. Eventually, many funds may face bankruptcy and/or have to merge with their competitors; the latter is in fact a political goal of the current reform proposals.

Regulating the boundaries between voluntary SHI and PHI

In Germany, the structure of health care financing currently consists of both SHI and (substitutive) PHI. High income earners above a specific income ceiling can choose between SHI and (substitutive) PHI. In fact, competition exists (albeit limited) between SHI and PHI for high income earners. Since the early 1990s, the number of privately insured individuals has continuously risen. There are however increasing restrictions for solidarity related reasons. These for example, prevent high income earners who are privately insured from insuring their children without any cost through the SHI contributions of their low paid spouses, thereby pulling

insurance contributions out of the SHI-system and shifting the health care costs of children onto the solidarity based system of SHI. Moving from SHI to PHI will now also be more difficult than in the past.

Consequently, while the regulation of the boundaries of SHI and PHI has been the subject of contention, there has nevertheless been some convergence, leading first to the introduction of a standardised health insurance scheme within the PHI, covering mainly low income older people (*Standardtarif*) in 2000. In addition, some PHI-measures were implemented into SHI, for example deductibles and no-claim refund schemes if insurees did not make use of health insurance benefits within a given period. The *SHICS-Act* will also expand the scope of PHI-type regulations in the SHI by enabling all SHI-insurees to choose (reduced) health insurance schemes with deductibles and to opt for reimbursement schemes instead of benefits-in-kind.

Although the 'Great Coalition' did not agree to integrate the PHI into the SHI as proposed by the Social Democrats, the *SHICS-Act* will change the rules of the game for (substitutive) PHI. In order to establish a more competitive framework, the *SHICS-Act* will introduce new regulations. First, the federal government will oblige PHI to offer a (revised) standardised insurance scheme, similar to SHI, which is prohibited from applying individual health risk-adjusted premiums (*Basistarif*). The original draft regulation which required PHI funds to accept every insured person from SHI and PHI schemes to this standardised insurance scheme (as favoured by the Social Democrats) was however abandoned during consensus negotiations in early January 2007. This was due to pressure from PHI companies channelled through the CDU/CSU.

Now SHI-insured individuals can switch to PHI (probably to the *Basistarif*) if they have an income in excess of a specified income ceiling for at least three years. The window of opportunity for those already PHI-insured individuals to change to the new standardised insurance scheme (*Basistarif*) will now be limited to a six month period in 2009.

The government will also make old age reserves in the PHI transferable in order to establish a higher level of competition within PHI. At the moment, capital funded old age reserves are not transferable even if the privately insured would like to

change their PHI provider. Competition between PHI companies has thus been severely limited for this group until now.

Finally, as a step towards counteracting the recently growing numbers of the non-insured, the government wanted to introduce a regulation stating that every (legal) resident will have the legal right to return to the system from whence he/she had been insured previously, before becoming ineligible for health care insurance (be it either SHI or PHI). Concerning this regulation, the Association of PHI Companies has highlighted the potential perverse incentive that privately insured persons could decide to opt-out of health insurance and return to the *Basistarif* if they were to become ill and need expensive health care (*Vorteilshopping* – health-insurance-free-riding). To counter this would require additional funds within the PHI through comparatively higher insurance premiums, because it would be possible that especially high income earners would opt-out of PHI. In order to avoid such health-insurance-free-riding the Grand Coalition has decided to make health insurance compulsory for SHI and PHI.

Institutional change: health care financing at the crossroads

The *SHICS-Act* will introduce several innovations into the German health care system. Most prominently, will be the establishment of a federal fund, thus reducing the power of sickness funds. Furthermore, the boundaries between SHI and PHI will be both more closed and more open. While it will be more difficult to switch from SHI to PHI, the probable implementation of a standardised health insurance scheme (*Basistarif*) as well as the transferability of capital funded old age reserves will intensify competition within the PHI system and between (voluntary) SHI and PHI. However, both the original proposals and final agreed regulations underline the highly contested boundaries of SHI and PHI. In addition, most reform proposals within the *SHICS-Act* (concerning health care financing) are to be implemented only in 2009.

Furthermore, the basic problems of health care financing are still to be addressed. The proposed reform will not counteract the erosion of the financial foundations of health care insurance, nor will it prevent the social insurance contribution from rising steadily. Therefore, critics argue that in effect there has been no health care

financing reform at all, only the extension of a political stalemate.

Nevertheless, it is clear that some initial steps that will change the institutional foundations of health care financing have been taken. The introduction of the federal fund and the (however limited and contested) convergence between SHI and PHI point to an evolutionary change from competitive corporatism to the marketisation of health care (financing), accompanied by a changing role for state regulation. However, the *SHICS-Act* also represents a political stalemate in respect of the final design of health care financing (be it citizen's or flat-rate-insurance) in Germany. Health care financing reform, no doubt, will be a key issue in the electoral campaign of 2009.

REFERENCES

1. Mosebach K. *Money for Nothing? Discourse, Power, and the Politics of Health Care Financing Reform in Germany During the Governmental Period of the Grand Coalition of CDU, CSU and SPD (2005–2007)*. Frankfurt: Institute of Medical Sociology at the Hospital of the Johann-Wolfgang-Goethe-University, Frankfurt, Discussion Paper 2/2007
2. Busse R. Risk adjustment in social insurance systems. Risk structure compensation in Germany's statutory health insurance. *European Journal of Public Health* 2001;11:174–77.
3. Saltman R. Regulating incentives: the past and the present role of the state in health care systems. *Social Science and Medicine* 2002;54:1677–84.
4. Gerlinger T. Vom korporatistischen zum wettbewerblichen Ordnungsmodell? Ueber Kontinuität und Wandel politischer Steuerung im Gesundheitswesen. [From a corporatist to competitive model? Beyond continuity and change in the steering of health policy] In: W Gellner, M Schön, Markus (eds). *Paradigmenwechsel in der Gesundheitspolitik?* [A Paradigm Shift in Health Policy?] Baden-Baden: Nomos, 2002.
5. Mosebach K. Transforming the welfare state. Continuity and change in social policy since 1998. In: S Beck, F Klobes, C Scherrer (eds). *Surviving Globalization? Perspectives for the German Economic Model*. Dordrecht: Springer, 2005.
6. Mosebach K. The politics of health care financing reform in Germany. *Euro Observer* 2005;7(1):3–6.

Pharmaceutical policy reform in Spain

Joan Costa-Font and David McDaid

Summary: There are many deficiencies in the operation of pharmaceutical policy in Spain. This article provides a brief overview of the way in which the market functions and highlights some structural problems. We describe and provide some insights on the main economic policy problems to be faced in the regulation of the Spanish market. Key measures introduced as part of new 2006 legislation intended to address some of these deficiencies are then discussed.

Keywords: Spain, pharmaceutical policy, generics, reference pricing, medicines, regulation

Spain has traditionally faced serious problems in containing pharmaceutical expenditure. Compared to other European Union countries, she has historically relied heavily on pharmaceutical treatments.¹ The pharmaceutical market has struggled with a number of deficiencies related to quality and performance including variability in clinical practice and limited use of clinical guidelines in prescribing. There are also inefficiencies at the provider level, including limited use of generics with few incentives to switch to generics, while at consumer level there is a high level of self medication and limited impact of co-payments.

Traditionally mark-ups to reimburse the pharmaceutical distribution chain have neither fostered cost-containment nor generic substitution; instead there have been subtle incentives including non-transparent discounts that benefit retailers and wholesalers but do little for the tax payer. The mechanism for distributing pharmaceuticals also heavily restricts competition between retail pharmacists, for instance by requiring the owner of the business to have a degree in pharmacy. Wholesalers are also linked to groups of pharmacies, rather than subject to wider

competition. This system, compounded by strict price regulation based on unclear indexation and costs-plus formulae, leads to low average prices and explains why the country is involved in the parallel export of drugs.²

Physicians traditionally have had very few incentives to prescribe efficiently. Moreover generic prescriptions do not guarantee that the cheapest generic will be dispensed; economic incentives are not in place. There is also only a very limited role for cost-effectiveness analysis in guiding drug reimbursement and pricing.

While the responsibility for health generally has been decentralised to the 17 Autonomous Communities (ACs), pharmaceutical policy and regulation remains one of the few areas much less affected by this process; although some steps have been taken to involve the ACs in quasi-federal decision making boards that look at pricing and coordinate some policies. Consequently, pharmaceuticals are a high priority for health policy reform.

There have been some recent attempts to break the cycle of stagnation in the pharmaceutical market through modest reforms that strive to accommodate all

Joan Costa-Font is Research Fellow in Health and Pharmaceutical Economics, LSE Health, London School of Economics and Political Science and Associate Professor of Economics, University of Barcelona. David McDaid is Research Fellow, LSE Health and European Observatory on Health Systems and Policies, London School of Economics and Political Science. Email: j.costa-font@lse.ac.uk

Table 1: Pharmaceutical expenditure in Spain (1990–2005)

	1990	1995	1996	1997	1998	1999
Drug Expenditure						
NHS Drug Expenditure (€m)	2,524	4,389	4,887	5,155	5,700	6,268
NHS Share of Total Drug Expenditure	68%	72%	73%	73%	73%	72%
Drug Expenditure Per Capita (€)	63.3	110.6	123.2	129.9	143	155.9
Drug Expenditure Drivers						
Price per NHS prescription (€)	5.63	9.17	9.68	9.99	10.99	11.88
Number of prescriptions	532,231	525,316	551,696	562,716	561,716	569,526
Population per pharmacy	2,172	2,101	2,098	2,084	2,073	2,068
% Patients who make co-payments	13.00%	8.90%	8.50%	8.20%	7.70%	7.30%
% Drug expenditure for older people	61.50%	68.30%	68.90%	69.30%	70.10%	71.00%
	2000	2001	2002	2003	2004	2005
Drug Expenditure						
NHS Drug Expenditure (€m)	6,800	7,462	7,996	8,962	9,530	10,075
NHS Share of Total Drug Expenditure	72%	73%	73%	74%	74%	75%
Drug Expenditure Per Capita (€)	167.9	181.5	191.1	209.8	220.6	228.4
Drug Expenditure Drivers						
Price per NHS prescription (€)	12.26	12.9	13.36	14.08	14.43	14.55
Number of prescriptions	596,891	621,593	661,402	706,737	728,722	764,884
Population per pharmacy	2,062	2,080	2,082	2,099	2,111	2,143
% Patients who make co-payments	7.10%	6.90%	6.80%	6.80%	6.40%	6.20%
% Drug expenditure for older people	71.90%	72.20%	72.10%	72.00%	72.10%	72.40%

Source: Consejo General del Colegio de Farmacéuticos, 2006³ and own calculations.

stakeholders' interests involved. One significant measure implemented from July 2006 was the introduction of a law guaranteeing the rational use of pharmaceuticals and health care products (*Ley de Garantías y Uso Racional de Medicamentos y Productos Sanitarios – Ley 29/2006*). This law replaces the old 1990 Pharmaceuticals Act and contains a number of ambitious measures. This short article looks at the context for this legislation and highlights some of the recent innovative steps taken.

Pharmaceutical expenditure

Pharmaceutical expenditure has continued to grow between 1990 and 2005 (see Table 1). The price per prescription rather than the number of prescriptions has been responsible for much of this increase. The

market strategy of the industry has been to concentrate their promotional efforts on new and sometimes highly innovative products that command higher prices. This is one reason for the increasing share of pharmaceutical revenues enjoyed by manufacturers (see Table 2). On the other hand, from the turn of the millennium there has also been some increase in the number of prescriptions; this may be due to greater penetration by generics, as well as the introduction of a reference price system; this might foster the expansion of more intensive treatment. This also opened up the market to competition between generics.

The data also indicate that there have been few changes in the geographical concentration of pharmacies. This is consistent

with the protected and highly regulated retail pharmacy market. Co-payments for medications have reduced; older people who are exempt from such payments and represent 18% of the population account for 72% of drug expenditure.⁴

Market structure

Prescription drugs account for approximately 85% of total volume and 92% of total sales in the pharmaceutical market. Generics only represented 9% of total volume in 2003. Locally based industries have only a limited research and development capacity. Research and development expenditure relative to sales declined from 8.6% in 1987 to 7.9% in 2001. Only 10% of employees work in this area compared with 43% engaged in marketing.⁵

Table 2: Average share of revenues for pharmaceuticals 1991–2005

	1991–1992	1993–1994	1995–1996	1997–1998	1999–2000	2001–2003	2004–2005*
Ex-factory price	58.2	59.9	59.3	61.7	62.7	63.3	64.2
Wholesaler's margin	7.9	8.2	8.1	7.6	6.6	6.5	5.9
Retailer's margin	28.2	29	28.8	26.8	26.8	26.4	26.1
VAT	5.7	2.9	3.8	3.9	3.9	3.8	3.8

Source: Farmaindustria, 2004⁵

* After 1 March 2005 a non-linear margin system is in place so that products with a price below €89.62 had a wholesale margin of 8.62% and a retail margin of 27.9%. Products priced above €89.62 had a wholesale margin of €8.43 and a retail margin of €37.94.

The share of revenues from pharmaceuticals for each of the principal stakeholders is shown in Table 2. Interestingly, whilst reforms that were put in place in the early 1990s did not have any significant impact, those introduced after 1996 under conservative administrations appear to indicate that a greater share of revenues have accrued to product manufacturers compared with distributors, both retail and wholesale.

Generics market

The market for generic drugs in Spain has been practically nonexistent over the last two decades. Until 1992, the country only recognised process (rather than product) patenting. The 13/1996 General Budget Act and the 66/1997 Regulation Act, which opened the door to the introduction of generic drugs, modified the 1990 Pharmaceuticals Act. The first generic brands were registered for commercial distribution in July 1997 and generic penetration has risen steadily (although leisurely) ever since. In 2000, generics accounted for just 3% of total national health service sales. This increased to 6.4% by 2003 and 7.5% (13.8% in volume) by 2005. This compares with an average 27% shares of sales volume across the EU as a whole, although this varies markedly with rates well over 40% reported in the Netherlands, Poland, Slovakia, Slovenia and the UK.⁶

The market for generics is typically dominated by local manufacturers, with few international players operating in the market. This implies that there are very few incentives for competition. Generic prescriptions depend heavily on information being provided to general practitioners and patients; initiatives in this regard remain small. In 2001 whereas 12–15% of total prescriptions (8–10% of sales) in Madrid and Catalonia were for

generics, in Galicia the figure was less than 3%.⁷ Policies to promote the greater use of generics have taken the form of promotion and advertising campaigns for physicians, as well as subsidies and requirements to only dispense generics when the prescription is based on such an active ingredient. Since the approval of the most recent General Health Act reforms (so called Cohesion and Quality Act), pharmacists should play a wider role in the promotion of the rational use of drugs by working in collaboration with other health professionals to promote generics. However, both the enforcement of these requirements and incentives to promote generic substitution fall short compared with other European countries such as France.

Key reforms

A number of measures set out in the new pharmaceuticals law are intended to address some of the deficiencies in the current system. In some areas there is a paradigm change, but in others the regulations offer the prospect of reform of measures that have already worked in the past.

A new system of reference pricing will come into operation from March 2007. This is slightly more transparent than its predecessors though it in essence follows similar rules. It essentially brings together all off patent drugs financed for more than ten years by the national health service. These are grouped by form and active ingredient and include at least one generic equivalent. The reference price for each group of drugs is computed as the average of the three cheapest products regardless of market share. This is an improvement on previous requirements which were dependent on the market share obtained by these products or the overall cost of treatment.

To improve the efficiency of the reference pricing system, the new system has slightly expanded the number of therapeutic groups to 135. No significant reform though has been introduced to promote competition with innovative drugs. Indeed, drugs that are considered to be 'innovative' can be exempted from the system. Reference prices can be revised as regularly as every year. All, in principle, must be revised every three years.

“incentives to promote generic substitution fall short compared with other European countries”

To promote generic competition, the new law also has put in a place a 20% reduction in the price of products that after ten years of registration have a generic equivalent in another European country. The so-called 'bolar provisions' will also be implemented. Clinical trials for the development of new generic drugs will be able to start eight years after drug authorisation.

One paradigm change has been the introduction of a contribution, in the form of a tax on manufacturers based on their sales volume. This will be used to help fund the national health service. Through this mechanism, the system ensures that some of the proceeds of pharmaceutical companies are shared with the state and thus stands as a form of ex-post regulation.

The new law does not, contrary to some expectations, have a significant impact on the way in which pharmaceuticals are dispensed. As a concession to pharmacists it introduces the concept of 'pharmaceutical care' services that are to be provided

within pharmacies. The law also permits drug substitution by pharmacists in some circumstances and prohibits the sale of most drugs without a prescription. High levels of self medication have been a particular problem in the country.⁸ Under the new law penalties of up to €90,000 can be imposed on those pharmacists who ignore this prohibition. At the same time, the law permits electronic prescriptions for people living with chronic conditions; this will reduce their need to travel to a health care centre in order to obtain a prescription.

The new regulation has also sought to reform the distribution system by enforcing a product traceability system throughout the whole product distribution chain (at the manufacturer, wholesale and retail level). The main rationale for this has been to eliminate the shortages that have often been commonplace in pharmacies in the past and reduce the continuing expansion of the parallel trade market.⁹ Agreement was reached after one company proposed setting up its own distribution network so as to avoid the further development of a parallel distribution chain. Spanish wholesalers argued that they should still have a right of access to manufacturers' products. The new regulations enshrine this right and in exchange the industry will have some control over the distribution network and most likely will be able to apply differential prices; that is a discounted price upon justification of local sale and a European price for all others.

Discounts on products from wholesalers have also been banned, other than those related to early payment or sales volume. They can no longer be used to encourage the purchase of any one specific product. Prior to the law, discounts that effectively meant 'buy one get one free' (and variants thereof) were commonplace. However, from prior experience, the interpretation of the law always ends up allowing some flexibility to maintain discounts of some sort. Indeed, one of the problems of Spanish decision making is the frequent recourse to the courts to interpret policy set out in legislation. This is already happening in respect of discounting. New obligations have also been imposed upon the pharmaceutical industry with respect to pharmacovigilance; in addition to maintaining the system they must report any adverse events to the Ministry of Health, thus enhancing the information system with regards to medicines.

Discussion

Given the nature of the pharmaceutical market in Spain and the extent to which it is subject to regulation, changes in the regulatory environment are critical to achieving improvements in practice. The market in Spain has been shown to react significantly to changes in incentives; however until now there was no significant paradigm change. The shape of regulatory measures have always been an issue for bargaining and lobbying between the different stakeholders, the Ministry of Health and the ACs. Such measures are then typically enshrined in law, as in the case of the new Act and resemble a rent-seeking process where the final equilibrium typically implies only modest change.

“Another key issue to be addressed is the lack of transparency in the way drugs are initially priced and reimbursed”

The new legislation has undoubtedly introduced reforms intended to improve the efficiency of the distribution system as well as foster competition in the generics market. However, how this regulation is finally implemented will be the key to its success. Careful evaluation of the reforms will in time be required but clearly limitations remain. Retailers, nonetheless, continue to control roughly 70% of the wholesale market, limiting competition. While there are now some incentives in place to promote the use of generics, as well as support for innovative products, one continuing challenge will be to design a system that makes, once and for all, the reference price efficient. This implies devoting particular attention to preventing unjustified substitutions from products included in the reference price to those exempt from the system.¹⁰

Co-payments can be an obvious way of containing drug expenditure, yet the use of such cost sharing measures in Spain has not changed in the last twenty years; possibly due to a lack of political support and the unpopularity of such reforms. An increasing share of total drug expenditures now fall on groups that are exempt from such co-payments, which creates significant equity concerns (a rich older person will be exempt from co-payments whilst a

poor middle age woman with children would have to pay 40% of their costs). This may be an issue for further reform, whilst being mindful of efficiency and equity concerns. Another key issue yet to be addressed, and one which is a bone of contention for the European Commission, is the lack of transparency in the way that drugs are initially priced and reimbursed. Ultimately, the best way to reduce rent-seeking behaviour and prevent government from being captured by vested interests of any sort is by defining clear rules and enforcing them.

REFERENCES

1. Costa-Font J, Puig J. The pharmaceutical market regulation in Spain is drug cost-containment under question? *Journal of Pharmaceuticals Finance, Economics and Policy* 2004;13(4):33–49.
2. Kanavos P, Costa-Font J. Pharmaceutical parallel trade in Europe: impact on stakeholders and competition effects. *Economic Policy* 2005;20(44):753–98.
3. Consejo General del Colegio de Farmacéuticos. *Información Estadística* [Statistical Information]. Consejo General del Colegio de Farmacéuticos, 2006. Available via <http://www.portalfarma.com>
4. Puig-Junoy J. Incentives and pharmaceutical reimbursement reforms in Spain. *Health Policy* 2004;67:149–65.
5. Farmaindustria. *La industria Farmacéutica en Cifras* [The pharmaceutical industry in statistics]. Madrid: Farmaindustria, 2004.
6. Perry G. The European generic pharmaceutical market in review: 2006 and beyond. *Journal of Generic Medicines* 2004;4(1):4–14.
7. Asociación Española de Productores de Genéricos, Madrid. Data provided from annual reports. Website <http://www.aeseg.es>
8. Costa-Font J, Kanavos P, Rovira, J. Determinants of out-of-pocket pharmaceutical expenditure and access to drugs in Catalonia. *Applied Economics* 2007 (in press).
9. Costa-Font J, Kanavos P. Drug parallel imports: the case of Simvastatin in Germany, Netherlands and the United Kingdom [in Spanish] *Gaceta Sanitaria*, 2007 (in press).
10. Puig-Junoy J. *The Impact of Generic Reference Pricing Intervention in the Statin Market*. Barcelona: Departament d'Economia I Empresa, Universitat Pompeu Fabra, 2005.

Corporate lifelines: a new approach to making poverty history

David McDaid

Summary: Traditionally government aid, supplemented by the actions of non-governmental organisations, have been the mainstay of actions to tackle global poverty and improve health. Some argue that there are inefficiencies in this model and advocate for a more business orientated approach to the promotion of sustainable development. This article looks at some of the issues raised and highlights some of the development work undertaken by the commercial sector.

Keywords: Poverty, economic development, foreign aid, private sector

Making poverty history

Much has been said about the need to eradicate poverty and avoidable disease to improve the life chances of all those living in the developing world. The first of the United Nations' eight Millennium Development Goals (MDG) agreed in 2000 was to halve extreme poverty and hunger by 2015. Responding to the world's main development challenges and to the calls of civil society, the MDGs also promote education, maternal health, gender equality, and aim to combat child mortality, HIV/AIDS and other diseases. They are the most visible indication of a global partnership that has developed from commitments and targets established at various world summits in the 1990s.

Certainly some progress has been made in terms of poverty reduction. The most recent estimate from the World Bank suggests that 21.7% of developing country populations were living on less than \$1 per day in 2002 compared with more than 29% in 1990; they project this will reduce to 10.2% by 2015, thus attaining the MDG target on poverty.¹ This still leaves an enormous number of people in abject poverty, while others who may see some

growth in income will have very limited aspirations beyond their daily struggle to survive.

Governments, civil society organisations and others recognise the need to do much more. One immediately can think of the 'Make Poverty History' campaign and the lobbying at the 2005 G8 Summit in Scotland by the Live 8 coalition on the need for more debt relief and a level playing field for international trade. It is also clear that positive actions were taken in response both by the G8 and the broader international community.

For instance, the G8 pledged a further \$50 billion in aid to developing countries, including the doubling of aid for Africa to \$25 billion by 2010. It also agreed to cancel all \$40 billion in debts of some eighteen eligible heavily indebted poor countries to the International Development Association, the International Monetary Fund and the African Development Fund. A further twenty countries would also become eligible for debt cancellation if they met certain structural conditions and made progress to tackle corruption.

The need to drive growth and boost incomes across the world has also been recognised as a necessary element of work to reduce global poverty; trade distortions, the G8 concluded, need to be reduced and, in the case of agriculture, eliminated by some as yet to be determined credible end

date. At the United Nations World Summit later in 2005, further commitments were given on attaining the MDGs and "promoting the development of the productive sectors in developing countries to enable them to participate more effectively in and benefit from the process of globalisation."²

Trade not aid

Traditionally, there has been a heavy reliance on governmental development aid, supplemented by the actions of non-governmental organisations (NGOs) of all shapes and sizes, to help in global efforts to address the need to promote better health, tackle some of the terrible but eminently treatable diseases that are commonplace in low income countries and alleviate poverty. This model of aid has come under increased scrutiny in recent years; there have been questions about the merits of donations rather than efforts to create self-sustaining solutions – as perhaps best captured by the slogan 'trade not aid'. Some have suggested that NGOs based in developed countries might not be the most efficient way of helping individuals to get out of poverty.

Certainly the 2005 UN General Assembly recognised that intervention must not be confined to the NGO and public sectors alone but that "the private sector can play a vital role in generating new investments, employment and financing for devel-

David McDaid is Research Fellow, LSE Health and European Observatory on Health Systems and Policies, London School of Economics and Political Science. Email: d.mcdaid@lse.ac.uk

opment.”² Further recognition of the importance of private sector involvement was also forthcoming in the award of the 2006 Nobel Peace Prize to Muhammad Yunus and the Grameen Bank for their work in providing access to micro-credit to help individuals lift themselves out of poverty. Some of the limitations in the traditional approach to aid and development, as well as examples of innovative approaches undertaken by the business community to tackling global poverty, which in turn can have a positive impact on health, are illustrated in this article.

Does the aid community have all the answers?

NGOs have undertaken much valuable work to both save and improve the quality of life across the world; in some cases, as for instance can be seen in the ongoing tragedy in Darfur, aid workers have ultimately paid with their own lives for their efforts.³ In some instances however, it is not always clear that the NGO model alone can best alleviate poverty. Partnership with business may have merit, yet many in the aid community have historically been distrustful of the private sector.

Kurt Hoffman, director of the Shell Foundation, an independent London based charity that adopts a business orientated approach to promoting sustainable development, has called for reform in the aid community. He wants it to apply fundamental business principles to enhance performance and accountability.⁴ He notes that “big injections of official aid (for example, nearly \$600 billion to sub-Saharan Africa since 1960) have not generated economic growth in the past. So without fundamentally changing the aid industry’s ‘business model’ why would past failures miraculously morph into successes?”

While there was a quadrupling of aid as a percentage of gross domestic product (GDP) in Africa between 1970 and 2000, he observes that GDP decreased on average by 0.6% every year over the same period. It is perhaps unsurprising therefore that he has been critical of the G8’s decision to give more money to the aid community, calling this “apparently throwing good money after bad” and something that “paradoxically leads not to the support of initiatives that will make poverty history, but to the creation of a vastly inefficient delivery system of outcomes that have at best, limited short-term benefit.”

Clearly there are issues about the ways in which the performance of NGOs are evaluated. To what extent are there sufficient incentives to ensure that funds are invested in such a way as to generate maximum social benefit? Criticisms can also be made of governmental partners. One recent Parliamentary report in the UK, looking at private sector development, also was critical of the UK’s Department for International Development for not having specialist expertise in property rights. Having property rights guaranteed is essential to help promote business investment and more might be done on this.⁵

Clearly there are challenges, widely acknowledged, in terms of corruption and poor governmental infrastructures within countries, that will undoubtedly hamper NGO and government performance; these cannot be ignored – but are NGOs doing enough to overcome these obstacles? How would any performance assessment measures, if used, affect the donating preferences of those living in the high income world.

Perhaps more importantly who should determine how such donations should be used? NGOs, which may be restricted to very specific types of investment and project under their terms of incorporation, or might a better alternative be to involve individuals in low income countries in a much more pro-active way in this resource allocation process? If one was thinking about funding health policy priorities using public money, good practice would involve making use of mechanisms such as needs assessment as well as involving local stakeholders in this process.

Hoffman draws attention to the fact that, unlike aid agencies, investors in new business ventures are careful to look at the track record of any entrepreneur seeking capital, as well as the market potential of any product, before making any investment decision. Those seeking investment will need to their homework carefully, to make a strong business case for any proposed project; such incentives do not necessarily exist for those seeking money from NGOs. Moreover because entrepreneurs are willing to share in the risk, investors may be more confident that they will also take steps to ensure that the venture is a success.

Reform of aid agencies, Hoffman argues, should therefore allow those in the developing world to have a genuine choice over

the providers of aid financed services; introduce targets and incentives that reward those agencies that create sustainable pro-poor enterprises; and increase accountability among aid actors by getting those agencies on the ground to bear some of the risk and invest their own personal resources in projects. He also has called for the same standards of risk assessment and due diligence seen in the business community to be applied to investment decisions taken by NGOs. Such measures are more often seen in charitable organisations that have been influenced by business practices. Take, for example, the Bill and Melinda Gates Foundation, which has a system of key performance indicators for all its projects.

Enterprise solutions

Business solutions do not need to be driven by the profit motive alone; it is possible to create social business entrepreneurs seeking to achieve social objectives through the creation and support of sustainable business enterprises.⁶ They can help introduce a greater level of competition and choice into the market helping to foster innovation and drive down prices. The performance of such businesses might ultimately be assessed using some set of objective criteria, thus helping potential investors/donors decide which initiatives are likely to generate a good social return.

Such social business can benefit enormously from advice and support from the business community in the developed world. This support may be vital to nurturing business to survive and compete with developed country competitors. Completing the World Trade Organisation’s Doha round and promoting fair trade will be insufficient to allow southern business to flourish. Getting products to consumers is critical; capacity in developing countries in this respect may be limited, but there is much expertise in managing the supply chain in companies in the developed world.

Here again Kurt Hoffman has argued that new initiatives in developing countries will not simply appear if trade barriers come down; they are unlikely to have the business acumen to compete against long established competitors. “What can’t be fixed is what does not exist, the widespread presence of scalable, self-sustaining enterprise that forms the backbone of a diversified growing economy. Poor countries need to create more enterprise of all kinds if they are to escape poverty and take

advantage of freer trade. But enterprise doesn't just pop up; it has to be nurtured en masse.... Success or failure will be determined by how good enterprise is at producing, delivering, distributing, managing and innovating. This is the missing half of trade justice.”⁷

Emergence of new players

How have business sector approaches developed? Looking at Hoffman's Shell Foundation, (www.shellfoundation.org) this was set up in 2000, as an independent charity, initially receiving an endowment of some \$250 million from Shell, the energy company. This has been invested until 2012 after which time the annual income is projected to be sufficient to sustain the Foundation's activities. Currently it is receipt of an annual grant of approximately \$12 million from Shell.

Working in partnership with local African banks, it has provided a mixture of commercial and development expertise to over 120 pro-poor small and medium-sized enterprises (SMEs), together with the finance and business support needed to help them grow. Projects are also being developed in India and Eastern Europe exploring how community enterprises can access national and international markets and adapt to the rigours of competition.

Sustainability and scalability of projects is important. According to the Foundation's Communications Advisor, Simon Bishop, “if the Foundation invests in a project, it is investing in a model which should be capable of being replicated. The model needs to be proved to work, so that others, including the private sector will also buy in to this approach elsewhere.” He points to one of its current investments in clean, smokeless cooking technology to replace the old wood burning stoves used in many homes.

Smoke in the home, it has long been known, can have a major detrimental impact on health. NGOs and governments have, however, largely failed to come up with sustainable answers to this problem, or have simply given away clean technology to small population groups. The private sector may be interested in product development, but only if there is a commercially viable market, something not really achieved to date. As Bishop says, “our solution is to bring the two sectors together, with a part commercial approach, which may need some seed capital to get it going.” NGO partners and community groups might then play a key role in the

distribution of new stoves, selling them at affordable rates at a local level.

Similar ventures are developing all the time. Well known players include the Grameen Bank and its sister Grameen Foundation, helping to provide loans, financial services and technology to help the poor develop self-sustaining businesses to escape poverty. The work of this Foundation on microfinance alone reaches 2.7 million families in 22 countries.

The founders of the internet search engine Google, have also recently set up a foundation, Google.org, providing an endowment of some \$1 billion and charged with a mandate to tackle poverty, disease and global warming. Their approach is different from many existing foundations, in that it will be a for profit enterprise. It will help budding entrepreneurs and may work in partnership with that much maligned element of capitalism, the venture capitalist. The for profit status of the company it is argued allows greater flexibility, but says executive director Larry Brilliant, the “emphasis is on social returns, not economic returns.”⁷ Already Google.org has made over \$7 million in grants and investments across a range of projects including support for research in western Kenya to identify ways to prevent child deaths caused by poor water quality and to better understand what works in rural water supply and literacy initiatives in India.

Google.org is also one of a number of corporate foundations that support the Acumen Fund, a not for profit organisation that amongst its activities looks for market solutions to help improve access to health care products and services. The Fund, like many structures that make use of business expertise, seeks to reduce cost structures, making health care products more affordable or alternatively may look at new pricing structures involving micro-financing or cross subsidisation of health care products. Improved mechanisms for distribution can also help improve the accessibility of health care products.

For instance, this Fund has invested in A to Z Textile Mills, a Tanzanian manufacturer that produces bednets impregnated with a long-lasting insecticide, making them effective for up to five years instead of the usual six months, with no need for re-treatment.⁸ The Fund claims that A to Z has already found a more cost-effective way to weave the bednet, which is expected to decrease the cost of production

from \$7 to \$5 and provide even more access to the life-saving bednets. Expertise from the Fund is also being used to help in the distribution of this net.

The impact is significant: these nets already protect more than five million people in the country, with more than ten thousand nets sold privately. Moreover the mill has created over two thousand better paid jobs primarily for women, helping to raise the standard of living for these workers and their families. Other investments made by the Fund include support for a company producing low cost solar powered hearing aids across the developing world and a retail micro-franchise distribution network promoting better access to essential drugs and basic health services in Kenya.

Conclusions

There is potentially much to be gained from ensuring that development policy puts more emphasis on economic growth, alongside traditional developmental aid. Historically there has been some distrust of private sector involvement; this appears to be changing with genuine partnerships between the public and private sectors developing.

Business must however also be more proactive in recognising its social responsibilities, and making use of what it knows best – i.e. logistics and the supply chain to help promote economic development. Good examples can be seen, for instance the Accenture Development Partnership, a non profit organisation where consultants from Accenture take time off from their core business and a substantial pay cut in order to work with international agencies such as UNICEF and the World Bank. Despite such examples, the involvement of the business community remains all too limited.

The European Union can play an important role in terms of fostering greater contributions from the European business community. In March 2006, the European Commission published a new Communication on Corporate Social Responsibility (CSR), and through it, launched the European Alliance for CSR – an umbrella network for discussion and debate on new and existing CSR initiatives by large companies, SMEs and their stakeholders.⁹ This Communication recognises the importance of the international dimension of CSR and has a goal of maximising the contribution of enterprises to the achievement of the UN Millennium

Development Goals. The Commission will also strengthen its cooperation with the International Labour Organisation to promote decent work, including through a pilot project on trade and decent work indicators in developing countries.

One other recent positive development was the first EU-Africa Business Forum under the Finnish Presidency in November 2006. As Aapo Pöhlö, Director General, Department for Africa and the Middle East, Ministry for Foreign Affairs, Finland, said in closing the conference, "from the perspective of broad-based development as well as business, it is of utmost importance to involve African countries so that they are genuinely able to participate in and benefit from the international commerce. We should support African countries in strengthening their overall trade capacity both in their North-South and South-South commerce."¹⁰

Not all private sector involvement however is to be encouraged. One unwelcome development has been the emergence of so-called 'vulture funds'. These are private sector companies that buy up the debt of poor nations cheaply when this is about to be written off and then sue for the full value of the debt plus interest – which might be many times more than what they paid for it. There are growing concerns that such funds are wiping out the benefits which international debt relief was supposed to bring to poor countries. One recent court action saw one of these vulture funds suing Zambia for \$42 million for a debt that the fund bought from Romania for less than \$4 million. The English High Court ruled in favour of the applicant, although it is expected that the

judge will order Zambia to pay no more than half of what was demanded. Nonetheless, this is still equivalent to half of all the debt relief received by Zambia in 2006.¹¹ Coordinated international actions to promote partnership with business to help make poverty history, while curtailing the activities of the unwelcome elements of capitalism, are urgently needed.

REFERENCES

1. World Bank. *Global Monitoring Report 2006*. Washington D.C: International Bank for Reconstruction and Development/World Bank, 2006. Available online via www.worldbank.org
2. United Nations General Assembly. Resolution adopted by the General Assembly. 60/1 World Summit Outcome. New York: United Nations, 2005. Available at <http://daccessdds.un.org/doc/UNDOC/GEN/N05/487/60/PDF/N0548760.pdf?OpenElement>
3. Nichols M. UN says surge in attacks on Darfur aid workers. AlertNet, 5 February 2007. Available at <http://www.alertnet.org/thenews/newsdesk/N05476653.htm>
4. Hoffman K. *Aid Industry Reform and the Role of Enterprise*. London: Shell Foundation, 2005. Available at http://www.shellfoundation.org/news_rel/Aid_industry_reform_and_the_role_of_enterprise.pdf
5. House of Commons International Development Committee. Private sector development. Fourth report of session 2005–2006. Volume 1. London: The Stationery Office, 2006, HC-921-I. Available at <http://www.publications.parliament.uk/pa/cm200506/cmselect/cmin>
6. Yunus M. Social business entrepreneurs are the solution. Washington D.C: Grameen Foundation, 2006. Available at <http://www.grameenfoundation.org/pubdownload/~pubid=26>
7. Hoffman K. *Trade Your Way Out of Poverty*. London: Shell Foundation, September 2004. Available at <http://www.shellfoundation.org/index.php?articleID=28>
8. Hafner K. Philanthropy Google's way: not the usual. *New York Times*, 14 September 2006.
9. Acumen Fund. A to Z Textile Mills – Long Lasting Anti-malaria Bednets. Acumen website, 2007. Available at <http://www.acumenfund.org/Work/HealthTechnology/Investments.asp>
10. Commission of the European Communities. Implementing the partnership for growth and jobs: making Europe a pole of excellence on corporate social responsibility. Brussels: Commission of the European Communities, 2006 COM (2006) 136. Available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0136en01.pdf
11. Pöhlö A. *Connecting Two Continents: Opportunities for the EU's Africa Strategy*. Speech to EU-Africa Business Forum, 17 November 2006. Available at <http://forin.finland.fi/public/default.aspx?contentid=83700&nodeid=15317&contentlan=2&culture=en-US>
12. Jones M. *Vulture Fund Threat to Third World*. BBC Newsnight. London: BBC, 14 February 2007. Available at <http://news.bbc.co.uk/1/hi/programmes/newsnight/6362783.stm>



Health Economics, Policy and Law

International trends highlight the confluence of economics, politics and legal considerations in the health policy process. HEPL serves as a forum for scholarship on health policy issues from these perspectives, and is of use to academics, policy makers and health care managers and professionals.

HEPL is international in scope, and publishes both theoretical and applied work. Considerable

emphasis is placed on rigorous conceptual development and analysis, and on the presentation of empirical evidence that is relevant to the policy process.

The most important output of HEPL are original research articles, although readers are also encouraged to propose subjects for editorials, review articles and debate essays.

HEPL invites high quality contributions in health economics, political science and/or law, within its general aims and scope. Articles on social care issues are also considered. The recommended text-length of articles is 6–8,000 words for original research articles, 2,000 words for guest editorials, 5,000 words for review articles, and 3,000 words for debate essays.

Instructions for contributors can be found at www.cambridge.org/journals/hepl/ifc

All contributions and correspondence should be sent to: Anna Maresso, Managing Editor, LSE Health, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK. Email hepl@lse.ac.uk

The impact of smoke-free hospitality venues in Norway

Karl Erik Lund and Marianne Lund

Summary: In June 2004, Norway introduced an absolute ban on smoking in all hospitality venues. The main purpose of the ban was to protect employees in the hospitality business from harmful exposure to tobacco smoke. This article focuses on the economic consequences of this policy for the hospitality industry and the public's attitudes towards smoke-free hospitality venues. Evaluation suggests that the smoking ban has had a small positive effect on business. In addition, employees in the industry report better compliance with this total ban on smoking compared with previous regulations which required the provision of smoke-free areas. Among the general public, three quarters now support the ban, with the most rapid increase in support observed in smokers.

Keywords: Smoking ban, hospitality industry, economic impact, public attitudes, Norway.

After sixteen years of exemptions from section six of the Act on the prevention of the harmful effects of tobacco, an amendment to this so-called 'Tobacco Act' introduced a smoke-free regime to all hospitality venues in Norway from 1 June 2004.¹ The previous regulations regarding the provision of smoke-free areas within bars, pubs, cafes and restaurants were thereby superseded by an absolute ban on smoking indoors. The authorities' most important reason for revoking these exemptions was to afford employees in the hospitality industry the same protection against passive smoking as other employees had enjoyed since section six of the Tobacco Act came into effect in 1988. Furthermore, hospitality venues, night clubs and the like were seen as an important recruitment arena for smoking among young people. Importance was also attached to the fact that numerous individuals with asthma and allergies could not make use of hospitality venues because of the problems they suffered as a result of the smoky atmosphere. Moreover, the hospitality industry was having difficulty complying with existing regulations on smoke-free areas.

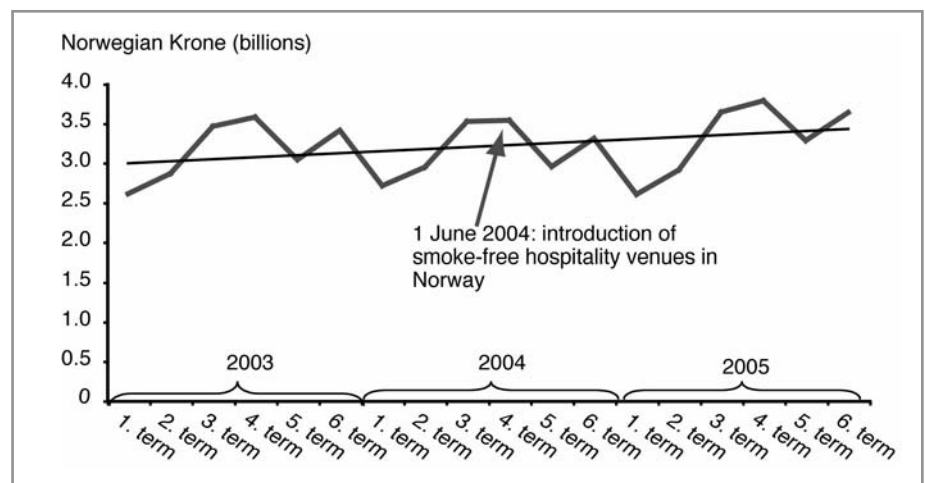
Karl Erik Lund is a Researcher and Marianne Lund an Adviser at the Norwegian Institute for Alcohol and Drug Research (SIRUS), Oslo, Norway.
Email: kel@sirus.no

The Standing Committee on Health and Social Affairs in the Storting (Parliament) augmented by subsequent parliamentary debate, expressed a desire for an evaluation of the smoking ban. The ban had been controversial and there was doubt with regards to the economic consequences for the hospitality industry, as well as uncertainty associated with the general public's compliance and satisfaction. The evaluation was to present results within three years and the Norwegian Institute for Alcohol and Drug Research (SIRUS) charged with its conduct. This would be linked to a broader evaluation of the State's tobacco prevention work in Norway.

Commercial impact on the hospitality industry

According to the evaluation, value-added tax (VAT) collected from the hospitality industry (restaurants, pubs and bars) increased by 5% in the first sixteen months after the ban compared with same period prior to its introduction.² In the restaurant segment of the industry, sales went up by 6%, while typical taverns such as bars and pubs, which have significantly lower sales than the restaurant industry, reported a small downturn of 1%. VAT registrations have seasonal variations, but there is a slight upward trend in taxes collected (Figure 1) in the period from 2003 to 2005.

Figure 1: Reported VAT from the hospitality industry, 2003–2005



Source: Statistics Norway. One term = 2 months.

No major changes have been observed in the breweries' sale of beer to food retailers following the ban. This may indicate that the small decline in the licensed sale of alcohol has not led to more consumption of beer in private settings. Nor was any pattern observed regarding regional differences in the sale of beer between the northern and southern parts of the country. The decline in beer sales was however somewhat higher during the coldest periods of the year.

Many conditions can affect the volume of beer served to guests at hospitality venues. These include price, customers' purchasing power, the weather, the price of beer from alternative sources (retail price) and availability (number of bars and business hours). The Norwegian Meteorological Institute reports that the first summer with smoke-free dining was colder and wetter than normal – except in the northernmost regions of the country. On the other hand, the summer before was warmer than usual in large parts of the country. It is therefore surprising that the sales in the hospitality business went up. This may indicate that the ban on smoking has had a more positive impact on sales than shown in our results.

In addition to sales statistics, data are also available from surveys (undertaken before and after the ban) on the public's frequency of patronage at hospitality venues. No significant differences were observed in self-reported frequency of patronage among smokers or non-smokers during the periods before and after the ban.

A longitudinal survey among hospitality industry staff indicated that no less than 70% were of the opinion that the ban had led to no (39%) or minor change (31%) in the frequency of patronage at their place of work. Thus, these responses do not quite support what the sales statistics indicated, i.e. an increase of 5%. In fact, nearly one-third of the employees contended that the ban had meant far fewer customers. The responses to this question were however strongly influenced by the attitude of employees to smoke-free hospitality venues prior to the ban. Thus, similar to information on frequency of patronage, such data have limited validity. This survey also reported that the perception that jobs would be endangered were correlated with attitudes towards the ban.³

The number of bankruptcies in the hotel and restaurant industry increased moderately during the first two quarters after the

ban and then subsided. This increase occurred during a season in which the number of bankruptcies had already been rising over previous years. Accordingly, it is not clear whether the observed increase was related to the introduction of smoke-free hospitality venues. Employment in the hospitality industry displays seasonal variations. A slight decrease in the number of employees was observed in the final quarter of the year in which the ban was introduced, compared with the same quarter in the two preceding years. Employment has however since returned to its normal level. It is also difficult to say whether the temporary dip can be related to the ban.

A 5% increase in the revenues of the Norwegian hospitality industry subsequent to the ban is however in line with the results of a number of foreign surveys. The literature has consistently shown that the introduction of smoke-free hospitality venues has had positive or little impact on retail sales in the industry. Most of these surveys have, nonetheless, been performed in locations (countries, states, cities) where the percentage of smokers has been lower than in Norway and where the climate is warmer. With the somewhat less favourable starting point, it was therefore perhaps rather surprising that the ban on indoor smoking has had such a limited impact on the revenues of the Norwegian hospitality industry.

Changes in satisfaction with hospitality venues

One reason for the increase in sales may be due to the fact that smokers failed to experience their anticipated reduction in satisfaction. Prior to the ban, of those who smoked on a daily basis, 69% and 55% respectively felt that their satisfaction would be reduced when visiting smoke free pubs/bars and restaurants. Only a mere 38% and 32% respectively, reported an actual reduction in satisfaction eighteen months after the introduction of the ban. This indicates that the ban did not turn out to be as bad as smokers initially feared. The results must be seen in the light of moves by many in the hospitality industry to pave the way for outdoor smoking through several initiatives to raise satisfaction levels. Among non-smokers, 81% and 82%, respectively, reported a higher level of satisfaction with pubs/bars and restaurants after the ban. One year after the ban, no fewer than three out of four respondents stated that they would retain smoke-free hospitality venues if given a

hypothetical choice.

Changes in attitudes

The general public's attitude to passive smoking has changed since the Tobacco Act was implemented in 1988, effectively banning smoking in all workplaces (but not the hospitality business) and enclosed public areas. By the time hospitality venues became smoke-free in 2004, far more people perceived passive smoking as a health hazard compared to the situation in 1988. Support for the ban has increased steadily. The most recent survey (June 2006) indicated that three out of four people were positive towards smoke-free hospitality venues.

The views of smokers and non-smokers were largely in harmony about the Tobacco Act in 1988, but by 2004 there appeared to be considerable differences in views on smoke-free hospitality venues. In 2005, 84% of non-smokers were positive towards smoke-free hospitality venues, while just 45% of those who smoked on a daily basis shared the same opinion. Two years earlier, however, only 25% of smokers were positive towards the idea, so support for smoke-free hospitality venues has grown quickly, not least among those in the most sceptical group. Steadily growing support for smoke-free hospitality venues has also been observed in a number of international attitude surveys.⁴⁻⁶

Changes in air quality

While just one out of ten guests reported very good indoor air quality in pubs/bars prior to the ban (when smoke-free areas were provided), six out of ten reported very good air quality after its introduction. Similarly, the percentage reporting very good indoor air quality at restaurants has increased from about 40% to 75%. Employees in the hospitality industry also report a significant reduction in air quality problems at work, with reported problems due to second-hand smoke declining from 44% to just 6% five months after the ban was enforced.⁷

Compliance and enforcement

Before it came into force, smokers had already suggested that they would have a high degree of compliance with the ban. Subsequently customers have not observed many problems with the new smoke-free hospitality venues. Among those individuals with the highest frequency of patronage to pubs/bars, a mere 3% observed any serious enforcement

problems during the regulation's first eighteen months. The comparable figure for restaurants was just 2%. Even among smokers, only a very small percentage had observed or experienced any type of enforcement problems. Staff reported fewer unpleasant incidents and better compliance in enforcing a total smoking ban compared with smoke-free areas.³

Other consequences

Nearly half of all employees contended that one consequence of the ban was more noise outside premises. However, this has not led to more complaints from neighbours. There were also reports of more cigarette butts on the street near the front entrance to premises, but it was not clear whether this represented a serious and unexpected problem. Employees pointed out that the advantages of the ban included easier cleaning of premises, a better state of health, better air quality and work clothes that did not reek of smoke.⁷

The evaluation has however shown that since the ban, the hospitality industry has become a sales channel for snus (a Scandinavian type of moist smokeless tobacco) and an arena for its use. It is likely that the ban has accelerated the use of snus in Norway. It is also likely that the ban has accelerated the decline in the percentage of smokers among the general public, although it is difficult to isolate one particular effect. Among smokers, nearly half those between the ages of eighteen to twenty reported that the ban had caused them to cut back on cigarettes, but the responses were biased by the attitude young people had to the ban on smoking and are thus not entirely valid. However, a survey from the USA showed that the progression from experimentation to becoming a regular smoker was significantly lower in regions with a ban on smoking in hospitality venues.⁸ Our data are however, not appropriate for determining whether the ban has contributed to the reduction in taking up smoking observed in Norway in recent years.

REFERENCES

1. Directorate of Health and Social Affairs. Ot.prp.nr.23 (Proposition to the Odelsting) 2002–2003. Concerning act regarding changes in Act No.14 of March 1973 relating to Prevention of the Harmful Effects of Tobacco. (Smoke-Free Food and Drink Establishments). Oslo: Directorate of Health and Social Affairs, 2003. Available at: http://www.shdir.no/vp/multimedia/archive/00000/Whitepaper_

Proposition_655a.pdf

2. Lund KE. The introduction of smoke-free hospitality venues in Norway. Impact on revenues, frequency of patronage, satisfaction and compliance. Oslo: Norwegian Institute for Alcohol and Drug Research (SIRUS), 2006: Series 2 (updated version). Available at: <http://www.sirus.no/cwobjekter/SIRUSskrifter0206eng.pdf>

3. Hetland J, Aarö LE. Smoking habits, attitudes to and enforcement of the ban on smoking in eating and drinking establishments – a prospective panel study. Oslo: Norwegian Institute for Alcohol and Drug Research (SIRUS), 2005: Series 2. Available at <http://www.sirus.no/cwobjekter/SIRUSskrifter0205eng.pdf>

4. Friis RH, Safer AM. Analysis of responses of Long Beach, California residents to the smoke-free bars law. *Public Health* 2005;119(12):1116–21.

5. Kottke TE, Aase LA, Brandel CL, et al.

Attitudes of Olmsted County, Minnesota, residents about tobacco smoke in restaurants and bars. *Mayo Clinic Proceedings* 2001;76(2):121–23.

6. Miller C, Wakefield M, Kriven S, Hyland A. Evaluation of smoke-free dining in South Australia: support and compliance among community and restaurateurs. *Australian and New Zealand Journal of Public Health* 2002; 26(1):38–44.

7. Hetland J, Aarö LE. Smokefree restaurants and pubs: Air quality, self reported health and job satisfaction. Oslo: Norwegian Institute for Alcohol and Drug Research (SIRUS), 2005: Series 3. Available at: <http://www.sirus.no/cwobjekter/SIRUSskrifter0305eng.pdf>

8. Siegel M, Albers AB, Cheng DM, Biener L, Rigotti NA. Effect of local restaurant smoking regulations on progression to established smoking among youth. *Tobacco Control* 2005;14(5):300–6.

Improving access to health care in Armenia

Erica Richardson

An increasing body of research indicates that ongoing health care reforms in the countries that have emerged from the Soviet Union have had an impact on access to health care in some parts of the region, including Armenia.¹ Despite a declared political commitment and policy efforts to improve access to health care for those most vulnerable groups, a recent survey by the Armenian National Statistical Service indicates that there are still significant financial barriers to access for poor households.² According to household survey data, only 40% of individuals from households in the poorest quintile on the income scale consult a doctor anywhere in the health system when they are very ill, compared with 80% of households in the

richest quintile.² This low level of access has remained stable since independence was gained in 1991.³

Falling utilisation rates

Health care utilisation rates in Armenia remain some of the lowest in the post-Soviet region, with only Georgia experiencing lower levels of utilisation. Inequalities in health service utilisation are significant. Estimates in 2001 indicate that the poorest 20% of the population consumed just 16% of primary health care service resources and 13% of hospital care resources, compared with 28% and 43% respectively by the wealthiest 20%.³

Before independence, when Armenia was still a part of the Soviet health care system, it is likely that there was significant over-utilisation of health services, because excessive use of inpatient care was one feature of the Semashko system – with funding dependent on a high level of activity and bed occupancy. However,

Erica Richardson is Research Officer, European Observatory on Health Systems and Policies, London School of Hygiene and Tropical Medicine.
Email: erica.richardson@lshtm.ac.uk

current utilisation rates in Armenia are now significantly lower than in the rest of Europe, for example, in 2002 outpatient contacts per person per year in Armenia were 2.06, while the Commonwealth of Independent States (CIS) average was 8.84 and that of the EU 6.68.⁴ This would suggest that the low utilisation rates are due to problems in accessing services rather than merely a 'balancing out' following reforms to the Semashko system.⁵

Provisions for vulnerable groups

Armenia suffered acute economic problems following the collapse of the Soviet Union. State funding for health care all but ceased and service provision was essentially privatised as hospitals and doctors were allowed to generate revenues by selling services to the public.⁵ The fee-for-service nature of the system was formalised in 1997 with the introduction of social health insurance with a state financed Basic Benefits Package (BBP) to cover most health care for vulnerable groups (such as military or labour veterans, orphans, lone-parents or large families, disabled children, etc.) as well as specific public health concerns including tuberculosis, sexually transmitted infections and HIV/AIDS).³

However, the BBP does not yet function as an adequate safety net for these vulnerable groups, partly because eligibility criteria have not remained stable; moreover the means of demonstrating eligibility has also changed on an almost annual basis.³ This confusion meant that neither patients nor providers knew who was covered or for what, so charges were levied on patients anyway, particularly as the BBP does not cover the full service costs for providers.³

The problem of informal payments

In Armenia approximately 65% of health care expenditure is made through out-of-pocket payments.³ These can be formal co-payments, from which especially vulnerable groups are exempt or straightforward fee-for-service charges for 'private' care. However, many out-of-pocket payments in Armenia take the form of informal payments, including bribes and gratuities, which are levied at all levels of the system and by the full range of health care personnel.

Informal payments have arisen from a specific set of circumstances, which are by no means unique to Armenia. In addition

to costs not being fully reimbursed meaning that patients pay the difference, medical personnel receive such low wages as to necessitate supplementary income. The informal payment system has grown out of the common practice in the Soviet health care system of giving gratuities – partly as an acknowledgement of this low pay of health care personnel, but also as a simple way of thanking staff.

Greater political commitment needed

There is evidence that the introduction of the BBP and subsequent changes to improve coverage have had a positive impact on the level of out-of-pocket payments – both formal and informal – that very poor families have to pay. However, this has not significantly improved access rates as out-of-pocket payments for services are only part of the financial burden; the cost of pharmaceuticals at all levels of the system is also prohibitively expensive for the very poor.⁵

There is no shortage of policy documents to address the problem of access to health care and there has been considerable international assistance in developing pro-poor strategies.³ However, policy implementation remains a serious problem. Forthcoming elections for both the Parliament

(May 2007) and the Presidency (February 2008) are likely to mean that the attention of political actors will be elsewhere.

REFERENCES

1. Balabanova D, McKee M, Pomerleau J, Rose R, Haerpfer C. Health service utilization in the Former Soviet Union: evidence from eight countries. *Health Services Research* 2004;39(6):1927–50.
2. National Statistical Service of the Republic of Armenia, World Bank. *Social Snapshot and Poverty in Armenia*. Yerevan: National Statistical Service of the Republic of Armenia, 2006. Available at: http://www.armstat.am/Publications/2006/PV_04/index.html
3. Hakobyan T, Nazaretyan M, Makarova T, Aristakeysan M, Margaryants H, Nolte E. Armenia: health system review. *Health Systems in Transition* 2006;8(6):1–180. Available at: <http://www.euro.who.int/Document/E89732.pdf>
4. World Health Organization. *Health for All Database*. Copenhagen: WHO Regional Office for Europe, 2006.
5. Angel-Urdinola DF, Jain S. *Do Subsidized Health Programs in Armenia Increase Utilization Among the Poor?* Washington: World Bank, Policy Research Working Paper 4017, September 2006.

Ireland's grey vote grows bolder

Anne Dempsey

The run up to the May 2007 general election in the Irish republic has galvanised many of the usual suspects into action. Both sitting and aspiring parliamentarians have been jostling for media space, constituency clinics are being assiduously managed, and candidate leaflets are dropping on hall mats round the country.

Anne Dempsey is a writer and journalist specialising in health and social issues. She also a counsellor and a trainer in health promotion and is based in Greystones, Co Wicklow, Ireland.

Email: annedempsey@eircom.net

Amidst this traditional clamour, a new voice has emerged. The 'Older & Bolder' campaign, launched in November 2006, brings together a number of organisations who work in the ageing sector, aiming to seek from all parties and candidates a commitment for a National Strategy for Older People.¹ It is the first such coordinated campaign, and a timely one when older people in Ireland, as elsewhere, are living longer than ever before, providing opportunity and challenge in equal parts.

While Ireland is normally portrayed as a young, thrusting country, our ageing figures are compelling. According to the

2002 Census,² there are 436,000 people aged 65 and over, representing 11% of the population. The National Council on Ageing and Older People (NCAOP) predicts this will rise to 15% by 2021,³ with other research anticipating the over-65s being one in four by 2050. Set against the 1900s when older people in Ireland numbered one in 25, this represents a huge demographic change in 100 years.

This increased longevity is a result of improved living conditions and medical advances. However, many people see the greying population as a demographic time bomb rather than demographic bounty. Ireland is no different from other western countries in being ageist.

Ageism characterises older people as a problem to be solved, rather than a resource to be celebrated. Ageism assumes that somehow people are worth less as they age, and is based on fear, myth and inaccurate assumptions about what it may be like to be older. One of ageism's most worrying aspects is that it is socially acceptable. Discrimination on the basis of age is rarely challenged because many people either don't think about it, or regard it as the natural order of things.

Age-related barriers

Such ageist attitudes are translated into public policy in terms of income, employment, discrimination and, of course, in access to health services. While holistic health at all ages is also affected by living conditions, income levels, social connectivity and feelings of being valued, the NCAOP's 2005 'Perceptions of Ageism in Health and Social Services in Ireland'⁴ identified a series of age-related barriers. These include:

- The upper age limit of age 64 for access to Breastcheck, a cancer-screening service, despite the fact that post-menopausal women may be more at risk of contracting breast cancer.
- The lack of stroke rehabilitation services for the over 65s in some Health Service Executive (HSE) areas – when again strokes are more prevalent in the older population.
- The limit of age 82 in one health area for access to cardiac services, while in others, the suspicion of rationing by age.
- An unwritten policy of prioritising younger people for intensive care.
- An absence in one health area of

aggressive oncology treatment for older people with cancer.

Campaign

Older & Bolder is spearheaded by five national organisations – Age Action Ireland, Age and Opportunity, the Irish Hospice Foundation, the Irish Senior Citizen's Parliament and the Senior Help Line – coming together under a unified banner. The campaign began with a national billboard initiative. It showed the head and shoulders of an older person pictured large, with a similar figure of a younger person in the background. The slogan reads 'Ageism: We're both getting older. But which one of us have you just written off?'

A key campaign aspect is giving older people a voice. Accordingly, awareness meetings were organised round the country with groups of older people. Thousands of postcards were distributed inviting them to sign, stamp and return to campaign headquarters for presentation to the Irish parliament – another media event in early January which made the front pages. Older people have received media training supporting them to talk publicly about their own experiences and concerns.

During winter 2007 a series of public meetings are being held between groups of older voters and their public representatives, with mutual listening and discussion. In a particularly imaginative move, a laminate card with questions for canvassers who call to the door looking for votes have been made available to householders. Sample questions include:

1. What are your views on the rights of older people?
2. What are your party's policies in relation to older people?
3. What do you plan to do for older people in this constituency?
4. Will you consult with older people on their issues?
5. Will your party support the development of a National Strategy for Older People if you get into government?

Position paper

In a position paper commissioned by the campaign, Professor Eamon O'Shea, of the Irish Centre for Social Gerontology, National University of Ireland at Galway,⁵ set out a sense of what a New Strategy for Older People in Ireland might look like. An important goal should be to increase

healthy life expectancy for the over 65s, with an expanded role here for a proactive health promotion programme aimed at older people.

Prevention and early disease protection in primary care settings would include action on falls prevention, pain relief for arthritis sufferers, early intervention for people with sensory disabilities, early diagnosis of dementia, support for carers, and equal access to relevant screening programmes.

Specifically, he suggested it should ensure that:

- All government policies are age-proofed to remove discrimination against older people.
- Clear and consistent legislation on the rights and entitlement of older people is developed.
- Equality legislation is developed and strengthened.
- A proactive programme of information and provision is put in place to ensure that older people know what their rights and entitlements actually are.

A central aim of the Strategy should be to promote independent living of older people in their own communities for as long as possible, with the consequent implications for social care provision, access to public transport, social connectedness, and more research on technology supported-housing.

REFERENCES

1. Older and Bolder website: <http://www.olderandbolder.ie>
2. Central Statistics Office. *Census 2002: Volume 2, Ages and Marital*. Dublin: Stationery Office, 2005.
3. National Council on Ageing and Older People. *An Age Friendly Society: A Position Statement*. Dublin: National Council on Ageing and Older People, 2005.
4. National Council on Ageing and Older People. *Perceptions of Ageism in Health and Social Services in Ireland*. Dublin: National Council on Ageing and Older People, 2005.
5. O'Shea E. *Towards a National Strategy for Older People in Ireland. Position Paper*. Galway: Irish Centre for Social Gerontology, National University of Ireland, Galway, 2006.

Mythbusters

Myth: Managed care = mangled care

Mention managed care to a Canadian, and he may tell you that it's one of the best reasons to stick with public medicare. Large, impersonal health maintenance organisations (HMOs) loom large in the Canadian imagination, and American style managed care often brings to mind only the bad — reduced choice of physicians, limits on what services are covered, and delays in or denial of care being prime examples.

But it turns out managed care is getting a bit of a bad rap. While no health care system is perfect, some American managed care organisations have made strides in many areas, such as improving chronic and preventive care, reducing hospital use, and improving physician practice.

Managed care 101

Managed care refers to a wide variety of health care systems, some of which control costs largely by contracting with physicians for reduced fees and by restricting the patient's choice of physicians. Managed care includes health maintenance organisations, which either directly employ doctors or contract with groups of clinicians to provide services.

Patients are usually required to have one primary care physician or physician group to pre-authorise tests, visits to specialists, and other services for care to be covered by insurance. Particularly in HMOs, savings achieved through more efficient use of services like hospitals and magnetic resonance imaging (MRI) tests can be shared with the clinicians.

Managed care organisations often put a

strong focus on managing chronic illnesses and providing preventive care, in the hope of avoiding costly acute care later on. For example, in 1996 Kaiser Permanente, the largest health maintenance organisation in the United States,¹ created an integrated diabetes care management programme. Kaiser used the best evidence available to develop treatment guidelines and, working collaboratively with its physicians, implement a plan that improved screening and control of blood sugar levels for its diabetic patients.²

Another innovation that is becoming widely used is the 'chronic care model' developed by Group Health Cooperative, a non-profit HMO based in Seattle. The model identifies six 'pillars' of good chronic care, including having health care organisations link with community resources and teaching patients good self-management skills. Studies of health care organisations that have implemented components of the model show improvements in the care provided to chronic patients.^{3,4}

Finally, studies of the American Veterans Affairs health system have found dramatic improvements in treatment for chronic care since it reorganised itself along the lines of a managed care organisation in the mid-1990s. Examples include treating diabetes and high blood pressure and screening for and treating depression.⁵⁻⁷

Some managed care organisations also do well in preventive care. Studies have looked at health maintenance organisations, the Veterans Health Administration, and Medicare's managed care option, which allows senior citizens to use their Medicare benefits to enrol in a managed care health plan and typically receive more benefits than they would under the traditional fee-for-service option. They show higher levels of

Mythbusters are prepared by Knowledge Transfer and Exchange staff at the Canadian Health Services Research Foundation and published only after review by a researcher expert on the topic.

The full series is available at www.chsrf.ca/mythbusters/index_e.php. This paper was first published in 2005. © CHSRF, 2005.

preventive services, such as vaccinations, counselling to quit smoking, screening for various cancers, and regular blood pressure checks.⁶⁻¹¹

Show me the money

Since a hospital is usually the most expensive place to treat someone, managed care organisations (and indeed all health systems) look for ways to care for patients in non-acute settings while still giving them the best care possible. While it is always difficult to compare different hospital populations, the Veterans Affairs system reduced bed-day rates by 50% over four years after its reorganisation, with no change in patient mortality, and bed-day use in the English National Health Service is three and a half times that of Kaiser's rate.^{12,13} Finally, an extensive study of the American health system found more inappropriate hospital admissions among fee-for-service patients than among patients of Group Health Cooperative.¹⁴

Improving performance

One final aspect of managed care that is worth noting is its focus on providing doctors with feedback on their performance. While this information is used to determine which physicians cost the system the most (in terms of ordering tests, sending patients to specialists, etc.) and for bonus payments, it is also used for quality management. Doctors know if they are meeting benchmarks for the proportion of patients screened for cancer or given a flu vaccine, for example.^{2,15} Those working in managed care organisations are far more likely to receive this information than physicians in other types of practice.¹⁶

Conclusion

Managed care organisations want to get the most out of every dollar, as do purchasers in other health care systems. While this can sometimes result in undesirable strategies that are well-documented in the popular media, it also

means managed care organisations primarily offer services that have strong evidence of effectiveness. While requirements to see only one physician or physician group and less hospital use are seen as negatives by many patients, innovative managed care organisations find creative and effective ways to prevent illness and complications, enhancing their patients' health while at the same time being financially responsible.

REFERENCES

1. Baumgarten A. *California Healthcare Market Report 2005*. Oakland: California HealthCare Foundation, 2005. Available via <http://www.chcf.org/topics/download.cfm?pg=hospitals&fn=CAHealthCareMarketRep2005%>
2. Stiefel M, Rothert K, Crane, R, Caplan W, Pettay H. Kaiser Permanente's national integrated diabetes care management programme. In: *Informing judgment: Case studies of Health Policy and Research in Six Countries*. New York: Milbank Memorial Fund, 2001. Available at <http://www.milbank.org/2001cochrane/010903cochrane.html>
3. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *Journal of the American Medical Association* 2002;288(14):1775-79.
4. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: The chronic care model, part 2. *Journal of the American Medical Association* 2002;288(15):1909-14.
5. Kerr EA, Gerzoff RB, Krein SL, et al. Diabetes care quality in the Veterans Affairs health care system and commercial managed care: The TRIAD study. *Annals of Internal Medicine* 2004;141(4): 272-81.
6. Jha AK, Perlin JB, Kizer KW, Dudley RA. Effect of the transformation of the Veterans Affairs health care system on the quality of care. *New England Journal of Medicine* 2003; 348(22):2218-27.
7. Asch SM, McGlynn EA, Hogan MM, et al. Comparison of quality of care for patients in the Veterans Health Administration and patients in a national sample. *Annals of Internal Medicine* 2004;141(12):938-45.
8. Rizzo JA. Are HMOs bad for health maintenance? *Health Economics* 2005;14(11):1117-31.
9. Weinick RM, Beauregard M. Women's use of preventive screening services: A comparison of HMO versus fee-for-service enrollees. *Medical Care Research and Review* 1997;54(2):176-99.
10. Wilson NJ, Kizer KW. Oncology management by the 'new' Veterans Health Administration. *Cancer* 1998;82(10 supplement):2003-9.
11. Landon BE, Zaslavsky AM, Bernard SL, Cioffi MJ, Cleary PD. Comparison of performance of traditional Medicare vs Medicare managed care. *Journal of the American Medical Association* 2004;291(14):1744-52.
12. Ashton CM, Soucek J, Petersen NJ, et al. Hospital use and survival among Veterans Affairs beneficiaries. *New England Journal of Medicine* 2003;349(17):1637-46.
13. Ham C, York N, Sutch S, Shaw R. Hospital bed utilisation in the NHS, Kaiser Permanente, and the US Medicare programme: Analysis of routine data. *British Medical Journal* 2003;327(7426):1257-61.
14. Newhouse JP, Insurance Experiment Group. *Free for all? Lessons from the RAND Health Insurance Experiment*. Cambridge: Harvard University Press, 2003.
15. Kizer KW. The 'new VA': A national laboratory for health care quality management. *American Journal of Medical Quality* 1999;14(1):3-20.
16. Rittenhouse DR, Grumbach K, O'Neil EH, Dower C, Bindman A. Physician organisation and care management in California: From cottage to Kaiser. *Health Affairs* 2004;23(6):51-62.

Evidence-based health care



Bandolier

What is Evidence-Based Medicine?

The primary purpose of the English NHS is "... to secure, through resources available, the greatest possible improvement in the physical and mental health of the [population]"¹. To achieve this, decisions about the delivery and provision of healthcare are increasingly being driven by evidence of clinical and cost-effectiveness as well as systematic assessment of actual health outcomes.

*Jonathan Belsey,
Independent
Medical Adviser
and
Tony Snell, Medical
Adviser, East Kent
Health Authority*

Evidence-Based Medicine (EBM) is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.²

Increasingly, purchasers are looking to the strength of scientific evidence on clinical practice and cost-effectiveness when allocating resources. They are using this information to encourage GPs and NHS trusts to adopt more clinically effective and cost-effective practices.

EBM forms part of the multifaceted process of assuring clinical effectiveness, the main elements of which are:

- Production of evidence through research and scientific review.
- Production and dissemination of evidence-based clinical guidelines.
- Implementation of evidence-based, cost-effective practice through education and management of change.
- Evaluation of compliance with agreed practice guidance and patient outcomes – this process includes clinical audit.

The logic behind EBM

To make EBM more acceptable to clinicians and to encourage its use it is best to turn a specified problem into answerable questions by examining the following issues:

- Person or population in question.
- Intervention given.
- Comparison (if appropriate).
- Outcomes considered.

For example: Is an elderly man given nicotine patches more likely to stop smoking than a similar man who is not?

Next, it is necessary to refine the problem into explicit questions and then check to see whether the evidence exists. But where can we find the information to help us make better decisions? The following are all common sources:

- Personal experience, for example, a bad drug reaction.
- Reasoning and intuition.
- Colleagues.
- Bottom drawer (pieces of paper lying around the office, etc).
- Published evidence.

It is only by concentrating on the final category that ineffective, dangerous or costly interventions can be reduced.

Analysing information

In using the evidence it is necessary to:

- Search for and locate it.
- Appraise it.
- Store and retrieve it.
- Ensure it is updated.
- Communicate and use it.

Every clinician strives to provide the best possible care for patients. However, given the multitude of research information available, it is not always possible to keep abreast of current developments or to translate them into clinical practice. One must also rely on published papers, which are not always tailored to meet the clinician's needs.

Forms of evidence

Evidence is presented in many forms, and it is important to understand the basis on which it is stated. The value of evidence can be ranked according to the following classification in descending order of credibility:

I. Strong evidence from at least one systematic review of multiple well-designed randomised

Bandolier is an independent monthly journal about evidence-based healthcare, written by Oxford scientists. Articles can be accessed at www.jr2.ox.ac.uk/bandolier

This paper was first published in 2001. © Bandolier, 2001.

controlled trials.

II. Strong evidence from at least one properly designed randomised controlled trial of appropriate size.

III. Evidence from well-designed trials such as non-randomised trials, cohort studies, time series or matched case-controlled studies.

IV. Evidence from well-designed non-experimental studies from more than one centre or research group.

V. Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees.

Critical appraisal

For any clinician, the real key to assessing the usefulness of a clinical study and interpreting the results to an area of work is through the process of critical appraisal. This is a method of assessing and interpreting the evidence by systematically considering its validity, results and relevance to the area of work considered.

The Critical Appraisal Skills Programme, based at the Oxford Institute of Health Services, helps health service professionals and decision-makers develop skills in appraising evidence about clinical effectiveness. Its process uses three broad issues that should be considered when appraising a review article:

- Are the results of the review valid?
- What are the results?
- Will the results help locally?

Meta-analyses

Sometimes research findings may contradict each other and obscure the true picture – this is particularly the case with small trials. However, by pooling together all the results of various research studies, the sample size can, in effect, be increased. This is known as meta-analysis.

Although pooling together the results of a number of trials will provide a greater weight of evidence, it is still important to examine meta-analyses critically:³

- Was a broad enough search strategy used? MEDLINE, for instance, covers only about a quarter of the world's biomedical journals.
- Do the results all or mostly point in the same direction? A meta-analysis should not be used to produce a positive result by averaging the results of, say, five trials with negative and ten trials with

positive findings.

- Are the trials in the meta-analysis all small trials? If so, be very cautious.

Practical examples of EBM

EBM is not a purely academic or financial exercise – its implementation has major clinical implications that can save lives.

1. Deep vein thrombosis and pulmonary embolism

Deep vein thrombosis (DVT) of the lower limb and pulmonary embolism are major causes of death and disability; clinically recognised DVT and/or pulmonary embolism occurs in about 2/1,000 persons each year. It is estimated that postsurgical DVT and pulmonary embolism cost the NHS in excess of £200m each year. Despite the fact that the major risk factors for DVT (age, immobility and certain forms of surgery) are well known, only 46% of high-risk patients receive any form of peri-operative prophylaxis.⁴

Subcutaneous heparin has, in recent years, become the prophylactic treatment of choice for surgical procedures, based in part on the findings of a systematic review of the evidence.⁵ By comparing results from over 70 clinical trials of heparin, the authors were able to demonstrate a substantial benefit in patients undergoing general, orthopaedic and urological surgery. Based on this calibre of evidence, the Thromboembolic Risk Factors (THRIFT) Consensus Group⁶ recommends the following measures for prophylaxis:

All hospital inpatients: should be assessed for clinical risk factors and overall risk of thromboembolism; should receive prophylaxis according to degree of risk before discharge.

Low-risk patients: should be mobilised early.

Moderate- and high-risk patients: should receive specific prophylaxis; should be mobilised early.

Clinicians, units and hospitals: should develop written policies for prophylaxis; should include prophylaxis in clinical audit and patient care plans.

Efficacy of prophylactic methods: should be assessed in outpatients; more recently, studies have suggested that the use of low molecular weight heparin (LMWH) could be associated with an improved outcome, compared with unfractionated heparin. The higher unit cost of LMWH, however,

means that healthcare purchasers have queried whether this benefit is real and its magnitude sufficiently great to warrant the additional investment.

A further systematic review⁷ has confirmed not only that LMWHs are effective prophylactic agents in postoperative thromboembolic disease but that they are significantly more effective in preventing DVTs than standard forms of heparin. Indeed, an economic evaluation of the use of one LMWH (enoxaparin) in elective hip replacement⁸ estimates that a net saving of £20 could be made for every patient treated prophylactically with the LMWH. This increased efficacy, combined with ease of administration on an outpatient basis, promises considerable savings in secondary care expenditure.

2. Influenza vaccination

Significant hospitalisation and 3–4,000 deaths are attributed to influenza each year in the UK. More than 85% of these deaths are people over 65 years, and in epidemic years the death toll is even higher. In addition, people with underlying chronic conditions are at higher risk of serious illness or death through influenza.

A comprehensive review,⁹ based on a comparison of 8,000 vaccinated and 20,000 unvaccinated patients, indicated that the influenza vaccine is highly effective and that cases of respiratory illness, pneumonia, hospitalisations and mortality were reduced by over 50% in institutionalised elderly people. It recommends that people over 65 should be considered for influenza vaccination and that, in particular, those with chronic disease and resident in nursing and residential homes should be targeted.

Sources of information

There are many sources of information to inform clinical practice, and a full reference pack has been produced by the NHS Executive.¹⁰ Some sources are listed here:

The Cochrane Collaboration

An international endeavour in which people from many different countries systematically find, appraise and review available evidence from randomised controlled trials (RCTs). There are two components of the Cochrane Collaboration: Cochrane Centres (currently ten worldwide) and Collaborative Review Groups. The UK Cochrane Centre issues four regularly updated databases on CD-Rom, available from BMJ Publishing: The Cochrane Database of Systematic Reviews

(CDSR); The York Database of Abstracts of Reviews Of Effectiveness (DARE); The Cochrane Controlled Trials Register (CCTR); The Cochrane Review Methodology Database (CRMD).

The NHS Centre for Reviews and Dissemination

CRD is based at the University of York, produces:

- Effective Health Care bulletins, based on a series of systematic reviews and synthesis of research on clinical and cost-effectiveness.
- Effectiveness Matters bulletins, summarising the results of important systematic reviews of research on specific clinical topics.
- Systematic Reviews of Research Evidence – CRD reports.

The National Research Register

A database of information about research and development projects relating to the NHS. Available to all through the Department of Health and on the DH website.

The NHS R&D Programme standing group on Health Technology Assessment

This group reports on the effectiveness of the latest health technologies. Each regional office has a brief to set up advisory groups and implement the R&D priorities identified as part of the national

programme.

The Centre for Evidence Based Medicine at the University of Oxford, the Clinical Effectiveness Group for Wales based in Cardiff and the Clinical Resources and Audit Group (CRAG) at the Scottish Office in Edinburgh provide advice on various effectiveness matters.

MEDLINE and EMBASE

Electronic databases drawing data from key publications worldwide. Available at most medical libraries, on CD-Rom or via the internet.

An increasing range of journals and periodicals

These include Bandolier, British Medical Journal, Journal of Evidence Based Medicine and Health Trends.

The National Primary Care Research and Development Centre

Based in Manchester, this is a collaboration between the Universities of Manchester, Salford and York disseminating research on primary care policy and practice.

problem solving. *British Medical Journal* 1995;310(6987):1122–26.

3. Oxman AD et al. Users' guides to the medical literature, VI. How to use an overview. *Journal of the American Medical Association* 1994;272(17):1367–71.

4. Griffin J. *Deep Vein Thrombosis and Pulmonary Embolism*. London: Office of Health Economics, 1996.

5. Collins R et al. Reduction in fatal pulmonary embolism and venous thrombosis by perioperative administration of subcutaneous heparin. *New England Journal of Medicine* 1988;318:1162–73.

6. Thromboembolic Risk Factors (THRIFT) Consensus Group. Risk of and prophylaxis for venous thromboembolism in hospital patients. *British Medical Journal* 1992;305:567–74.

7. Leizorovicz A et al. Low molecular weight heparin in prevention of perioperative thrombosis. *British Medical Journal* 1992;305:913–20.

8. Drummond M et al. Economic evaluation of standard heparin and enoxaparin for prophylaxis against deep vein thrombosis in elective hip surgery. *British Journal of Surgery* 1994;81:1742–46.

9. NHS Centre for Reviews and Dissemination, University of York. Influenza vaccination and older people. *Effectiveness Matters* 1996;2(1).

10. Department of Health Reference Pack. *Clinical Effectiveness*. London: DH, 1996.

REFERENCES

1. Department of Health. *Promoting Clinical Effectiveness: A Framework for Action in and through the NHS*. London: Department of Health, 1996.
2. Rosenberg W, Donald A. Evidence-based medicine: an approach to clinical

New publications from the Observatory



Decentralization in health care

Edited by Richard Saltman, Vaida Bankauskaite, Karsten Vrangbaek

Open University Press, December 2006

352 pages

£25.99 Softback, £70.00 Hardback

This new book explores the capacity and impact of decentralisation within European health care systems. It examines both the theoretical underpinnings as well as recent practical experiences, and assesses the appropriateness of management processes within health systems for implementing a successful decentralisation strategy.

More information at

http://www.euro.who.int/observatory/Publications/20070223_1



Mental health policy and practice across Europe

Edited by Martin Knapp, David McDaid, Elias Mossialos, Graham Thornicroft

Open University Press, December 2006

488 pages

£25.99 Softback, £70.00 Hardback

This new book maps the current state of policy, service provision and funding for mental health care across Europe, taking into account the differing historical contexts influencing the development of services and the ways in which they are delivered. A holistic approach is adopted, looking not only at mental health care services, but also at the influence of environmental factors such as housing, poverty, employment, social justice, and displacement on mental health.

More information at

http://www.euro.who.int/observatory/Publications/20070209_1

NEW PUBLICATIONS

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

Halting the brain drain. Why we need to tackle global mercury contamination

Génon Jensen and Karolina Ruzickova



Health & Environment Alliance and Health Care Without Harm, December 2006

40 pages

Freely available at:

<http://www.env-health.org/r/145>

This report published by the 'Stay Healthy, Stop Mercury' campaign explains the relationship between mercury and health; where mercury pollution comes from; the measures that are already in place in Europe to control mercury; and what else needs to be done. The campaign is coordinated by two international health non governmental organisations, the Health & Environment Alliance and Health Care Without Harm. The campaign aims to raise awareness of a potential 'child brain drain' taking place in Europe and around the world as a result of environmental mercury pollution. It calls on the European Union to show leadership in efforts to control environmental mercury pollution by securing a global ban on mercury.

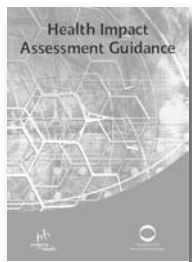
The report provides the results of a small-scale study in 21 countries that suggests

one in six women has a level of mercury above a widely-accepted recommended safety dose. This safety dose has been revised downward over the years and some studies indicate that it should be much lower. The campaign has also produced a series of fact sheets that examine the implications of mercury in health care and issues including vaccines, dental amalgams, and fish consumption. Each fact sheet provides recommendations to address the problem, and are available free for download.

Contents: Preface; Executive summary; 1. How does mercury affect our health?; 2. Mercury pollution – where does it come from?; 3. Mercury control – how far have we come?; 4. Conclusion and recommendations; Annex 1: The testing protocol; Annex 2: Hair sample results, mean values per country; References.

Health Impact Assessment Guidance

Owen Metcalfe, Claire Higgins, Cathal Doyle and Stephen McDowell



The Institute of Public Health in Ireland, April 2006

ISBN 0-9542316-2-7

44 pages

Freely available at:

http://www.publichealth.ie/getFile.asp?FC_ID=424&docID=581

Developed by the Institute of Public Health in Ireland on behalf of the Ministerial Group on Public Health (MGPH) in Northern Ireland, this document describes Health Impact Assessment (HIA) and the steps involved in HIA. It gives advice based on the experience of HIA practitioners and provides tools to help carry out these steps and adapt HIA to local circumstances. It aims to provide a user friendly and practical framework to guide not only policy-makers, but those developing specific proposals through the HIA process and to enable them to undertake a HIA.

The Investing for Health Strategy, launched in March 2002, sets out how the health and well-being of all the people of Northern Ireland can be improved, and in particular, how the unacceptable inequalities in health can be reduced by taking action to tackle the factors which impact on health.

The Strategy was developed by all government departments through the MGPH. Investing for Health contained a commitment to develop a methodology to enable all departments to identify and evaluate the health impacts of new policy developments as they emerge in order to ensure that any positive impacts on health

can be maximised and negative impacts minimised.

A small number of policy areas have been put forward by departments on which to pilot HIA and findings have been incorporated into this guidance document. The development of methodology is an iterative process and this document will be reviewed in the light of feedback from users and ongoing developments in HIA.

Contents: 1. The Purpose of this Document; 2. Overview of HIA; 3. Guidance on the Methodology; 4. Statement of Influence on Policy/Programme/Project; 5. Monitoring and Evaluation; 6. Further Information and Advice on HIA; Appendices: Screening Tool, Checklist of items to consider when establishing and managing the Steering Group, Checklist of possible HIA resource items, Tool for Framing Recommendations, Examples of Recommendations from Case Studies, Reporting Format for Statement of Influence, HIA Case Studies, Overview of Health Impacts of Transport Policies and Projects, Overview of Health Impacts of Employment, The Health Impacts of Housing, Information Sources on HIA, Documents and other Sources of Information for this Publication.

German Presidency of the EU News and information on the German Presidency of the European Union.
<http://www.eu2007.de/en>

ERAWATCH
<http://cordis.europa.eu/erawatch>

Launched in January 2007 by the European Commission, this new online information platform offers comprehensive and timely information on research systems in thirty seven countries covering the EU, as well as China, Croatia, Iceland, Israel, Japan, Liechtenstein, Norway, Switzerland, Turkey, and the United States. It contains information on recent policy documents, research programmes, funding agencies, research performance, and major indicators such as expenditure, publications and patents. The service is kept up-to-date by a network of national contact organisations. Users can access and customise the way information is presented and downloaded.

The Canadian Best Practices Portal for Health Promotion and Chronic Disease Prevention
<http://cbpp-pcpe.phac-aspc.gc.ca>

This portal originates from the work of health promotion practitioners and experts in the field who identified the need to build capacity among those working in chronic disease prevention by providing relevant and accessible best practices information to enhance decision making. Its ongoing mission and goals are to develop and disseminate best practice information for chronic disease prevention and control interventions; provide decision-makers with a comprehensive and standardised resource about best practices; provide a centralised access point for best practices approaches; coordinate activities that increase their uptake and utilisation; and enhance the evaluation of effective interventions at community and population levels. There are currently 97 best practice interventions contained in the database. It is available in English and French.

Mental Health Foundation of Armenia
<http://www.mentalhealth.am>

Founded in 1996, the Armenian Mental Health Foundation works to improve mental health in the country. Since 1999, the Foundation has provided a wide range of community-based services, including supported employment, self help, and a day centre hotline. The website contains an overview of activities, including a legislation and policy programme, advocacy training project, community-based service programmes, and a list of relevant publications. A limited number of publications, including some in English, can be accessed on-line.

Portalfarma
<http://www.portalfarma.com>

Portalfarma, developed by the Official Colleges of Pharmacists in Spain and the Spanish General Council of Official Colleges of Pharmacists, provides a wide range of information targeted at both pharmacists and the general public. This includes market statistics, price data and the national health service share of total sales. There is also a detailed archive of press releases commenting on developments in pharmaceutical policy and practice in Spain. Publications include access to a regular newsletter, *Farmacéuticos*, as well as much information on new products and their indications. Information on relevant legislation and links to other useful sites are provided. There is a detailed English language version of the website, although links to information on statistics and publications are more limited.

Commission of the Bishops' Conference of the European Community
<http://www.comece.org>

COMECE, established in 1980, is made up of Bishops delegated by the Catholic Bishops' Conferences of the European Union and has a permanent Secretariat in Brussels. It meets twice a year in plenary session. The Apostolic Nuncio to the European Communities also participates in these plenary meetings. The group raises awareness of the development of EU policy and legislation within the Church and sets out views on many health policy related issues including human rights, bio-ethics (including the use of human tissues and cells) and social affairs. There is a detailed press archive, while working papers and position statements on a range of issues are available for download. Written by independent contributors, a monthly review of developments, *Europe Infos*, can also be accessed. The website is available in English, French and German.

News

EUROPEAN MONITOR

Schmidt outlines health priorities under the German Presidency

German Minister of Health, Ulla Schmidt set out the German Presidency's priorities for health in a speech to the European Parliament's Environment, Public Health and Food Safety Committee on 22 January 2007. The Minister emphasised the importance of health as a way of demonstrating the role that the EU can play, stating that "a smoothly functioning cross-border health care system and safe medicinal products make Europe's added value into something palpable."

There are three main elements to the programme: innovation, prevention and access to health care services. All have been developed in cooperation with the subsequent Portuguese and Slovenian presidencies who will be "taking up the baton and furthering the work"

The Minister emphasised the role that scientific innovation in health can play, both in meeting patient needs, and providing a valuable contribution towards achieving the EU's Lisbon goals on economic growth. She highlighted events where these issues will be explored further. "We will be demonstrating this in our conference programme with two conferences. The 'ehealth week' from 16 to 20 April in Berlin, for example, will be presenting the diverse telematics activities conducted by the Member States. The aim here is to identify possible solutions for cross-border, interoperable processes and Europe-wide electronic services." A conference on pharmaceutical innovation will also be held in Bonn in June 2007.

The Minister recognised the importance of investing in prevention, stating that "preventing disease takes precedence over the treatment of disease and is the necessary response to the challenges our health care systems will be facing

in the future. The rising costs brought on by demographic change can only be controlled by Europe's health care systems if we manage – with the aid of a successful prevention policy – to permanently change people's attitudes and behaviour."

A high level conference on the promotion of healthy lifestyles is taking place in Badenweiler. The control of communicable diseases was also highlighted. A ministerial conference in Bremen on 12–13 March will focus on the question of how civil society can be more effectively involved in AIDS prevention.

Under the theme of access to health care services, envisaged regulations on cross-border health care services in Europe constituted, in the opinion of the minister, "the most important (legislative) project in the area of European health policy to be undertaken in the years to come." It will be discussed at the Informal Council of Health Ministers in Aachen on 19 and 20 April 2007.

Ms Schmidt spoke in detail on a number of issues including the revision of the Medical Device Directives. She noted that "the envisaged improvements in the area of clinical trials and the authorisation procedures, will increase patient safety. Here, too, we see an opportunity to achieve a political agreement with the European Parliament in the first reading. However, this will require a high degree of willingness to compromise on the part of all who are involved." She added that "the German Presidency will discuss the compromise proposals elaborated in the Council working group on topics that remain controversial such as 'the re-processing of single-use medical devices' and the 'prohibition of dangerous substances in medical devices', in informal tri-partite talks with the European Parliament and the Commission."

Turning to the Community Framework for Health Care

Services announced by the Commission for 2007, she said that "Germany has set its sights on contributing to having the Member States arrive at a clear stance in the coming months." The Minister also made clear her own personal interest in the prevention and control of HIV/AIDS. Speaking of the upcoming Bremen conference she said that "I am very optimistic – after numerous preliminary talks – that, in Bremen, the Health Ministers of the European Union and the neighbouring countries will be endorsing their shared will to tackle the spread of this scourge at the highest political level and help to mitigate its destructive consequences." She also recognised the challenge in ensuring that there is access to medications needed to treat HIV/AIDS, stating that "the existing systems to prevent trade diversions must be further refined with a view to making the distribution channels safe and enabling more medicines to be available at a reduced price." The Minister also, in referring the Green Paper on Mental Health, welcomed the intention of the European Commission to draft a Community Strategy on this topic.

The full text of the Minister's speech can be accessed at http://www.eu2007.de/en/News/Speeches_Interviews/January/0126BMGPraesprogramm.html

Green Paper: Towards a Europe free from tobacco smoke

According to the European Commission, tobacco is the single largest cause of avoidable death in the EU. The economic burden of tobacco is also high, such that the annual cost of smoking-related diseases in the EU-25 is between €98–€130 billion (equivalent to 1–1.4% of GDP in each country). The Commission is committed to exploring both legal mechanisms and health-promotion initiatives to promote the goal of a "smoke-free Europe", as stated in its Environment and Health Action Plan (2004–2010).

Press releases and other suggested information for future inclusion can be e-mailed to the editor David McDaid d.mcdaid@lse.ac.uk

Presented on 30 January 2007, the Green Paper, *Towards a Europe Free from Tobacco Smoke: Policy Options at EU Level*, launched a public debate on the best way to tackle passive smoking in the EU. The Commission now wants to know what role it is expected to play and what policy options are preferred by the different stakeholders. The policy options range from the current status quo to the introduction of “binding legislation”. More moderate options include voluntary measures and self-regulation, the use of coordination to converge national smoke-free legislations, and Commission or Council recommendations. The Green Paper concludes that of these options, a “comprehensive smoke-free policy would bring the greatest health benefit to the population”.

The consultation on the Green Paper is open until 1 May 2007, after which time the Commission will analyse comments received and report back on the consultation's outcome. A Commission Communication is expected in 2008 and dependent on the outcomes of Council discussions, the Commission will bring forward relevant proposals.

More information at: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/gp_smoke_en.pdf

Commission welcomes new agreement on pharmaceutical free-trade

The European Commission has welcomed the adoption by EU Member States of an international agreement which will make it easier to trade in pharmaceuticals. The third revision of the Pharma-GATT (Global Agreement on Tariffs and Trade) Agreement, the Commission believes, will eliminate customs duties among the main pharmaceutical trading nations and territories and will improve the competitiveness of EU pharmaceutical companies. Over the last few years, the European Commission assumed a leading role in the negotiations towards the conclusion of this Agreement and its revision.

The agreement, reached on 12 January 2007, eliminates customs duties between the EU, Switzerland and the USA on finished pharmaceutical products and on the chemical intermediates used in their production. Japan is expected to apply this revision later this year. The Agreement is also open to additional members.

It replaces a previous agreement, from 1994, which already enabled many pharmaceuticals to benefit from zero-tariffs, but did not cover any of the more recent products. With this review, 1,290 additional products are added to the 7,329 currently benefiting from duty-free treatment.

EU Trade Commissioner, Peter Mandelson, said “this agreement puts free trade at the service of European businesses and consumers. It is a show of confidence in the global competitiveness of the EU pharmaceutical industry, and a signal of our commitment to ensuring that the modern trading environment is in step with innovation”. The European Chemical Industry Council (CEFIC) has also estimated the savings generated by the Agreement for EU pharmaceutical companies to be approximately €230 million in 2007.

More information at http://ec.europa.eu/trade/issues/global/medecine/pr120207_en.htm

EU regulation on paediatric medicines

On 26 January 2007, the EU Regulation on Paediatric Medicines (No 1901/2006) came into force. The main aims of the Regulation are to increase research and development of medicines for use in paediatrics, ensure that such medicines are appropriately tested and authorised and improve the information available to patients and prescribers, for example in respect of clinical trial data. Another key element of the Regulation is the establishment of a new Paediatric Committee of the European Medicines Agency (EMA). The main focus of the Committee will be to assess and provide opinions on the content of paediatric investigation plans (PIPs). It will also review applications for deferrals and waivers.

From 26 July 2008, all new medicines must include in their application for marketing authorisation the results of studies performed under a PIP, the scope of which should be agreed in advance with the new Paediatric Committee of EMA. From 26 January 2009, this regulation will also apply to new indications, new pharmaceutical forms and new routes of administration for existing medicines. In some instances, it will be possible to defer the studies or apply for a waiver in relation to studies, for part or all of the paediatric population.

There are also new incentives for pharmaceutical companies through patent extensions. After completion of a PIP and submission of the appropriate information to the relevant regulatory authority, a medicine's patent may be extended for six months through the product's Supplementary Protection Certificate. To receive the extension, the medicines must be authorised in all EU Member States. Also, for off-patent products, the regulation has created a new category – the Paediatric Use Marketing Authorisation (PUMA). This category is intended only for medicines for paediatric use and encourages the development of off-patent medicinal products for use in children. The successful applicant will benefit from ten years of data and market exclusivity.

More information at: <http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/L378/L37820061227en00010019.pdf>

Mental health: Commission releases report about Green Paper consultation and publishes Eurobarometer survey

In December, the European Commission published a report on the results of its consultation on the Commission's Green Paper on Mental Health, launched in October 2005. It also presented the results of an Eurobarometer survey on mental wellbeing. The survey indicated that 13% of respondents have sought psychological help over the last twelve months. 7% of EU citizens have been treated for psychological or emotional problems with medications, while those in psychotherapy and hospital respectively account for 3% and 1%. Most respondents to the consultation called for an EU mental health strategy, to foster mental health prevention and promotion and combat stigma.

Mental health problems affect every fourth European citizen at least once during life and are one of the major public health challenges in the EU. The economic and social consequences are significant: very conservatively estimated to be equivalent to 3–4% of the EU's Gross Domestic Product. As many as four-fifths of those with enduring mental health problems are economically inactive compared with one third of those with physical disabilities.

Speaking on the publication of the report, Markos Kyprianou, European Commissioner for Health and Consumer Protection said that “the

importance of mental health needs to be better recognised. Good mental health of the population is a precondition for the EU's success in the knowledge economy. The situation of those with mental health problems is an indicator of the level of inclusiveness of EU societies."

In the Green Paper, *Improving the mental health of the population. Towards a strategy on mental health for the EU*, the Commission proposed the development of a comprehensive strategy on mental health at the EU level. The report now published summarises the 234 responses received. The responses welcomed the Green Paper and called for increased attention and priority for mental health. Most respondents supported the development of a mental health strategy.

They advised that the emphasis be put on mental health promotion and prevention, as well as on enhancing the situation of those with mental health problems through reducing stigma and discrimination. To do that, the implications of other sectors' policies on mental health should be better considered in policy making and implementation, and appropriate tools further elaborated. It was also noted that there were substantial needs for improvement in mental health care. Increased exchange and collaboration between Member States was recommended. Many research needs were identified, as well as the need for improved links between research and policy-making.

The report on the consultation is available at http://ec.europa.eu/health/ph_determinants/life_style/mental_health_en.htm

The Eurobarometer on mental wellbeing is available at http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm

Launch of European Charter to Counter Obesity

Half of all adults and one in five children in the WHO European Region are overweight. A third of these are already obese and numbers are increasing rapidly. Obesity reduces the length and quality of people's lives. The epidemic causes one million deaths a year in Europe and seriously hampers economic development.

In response to this problem, on 20 February, the European Charter on Counteracting Obesity, the first of its kind in this area, was launched in Copen-

hagen, in the presence of Her Royal Highness, Crown Princess Mary of Denmark, Patroness of the WHO Regional Office for Europe. The Charter was officially adopted by Member States of the WHO European Region in November 2006 at the European Ministerial Conference on Counteracting Obesity in Istanbul.

It provides political guidance and a strategic framework for strengthening action against obesity stating that "visible progress, especially relating to children and adolescents, should be achievable in most countries in the next four to five years and it should be possible to reverse the trend by 2015 at the latest". Reaching this goal requires specific, targeted action across many sectors.

The Charter identifies key areas of action including; reducing marketing pressure, particularly towards children; promoting breastfeeding; reducing free (particularly added) sugars, fat and salt in manufactured products; adequate nutrition labelling of foods; and promoting cycling and walking through better urban design and transport policies.

Speaking at the launch, Crown Princess Mary said that she believed the Charter to be "an important milestone in addressing the challenge of obesity" and hoped that "the action it produces will serve as a turning point to adapt the environment we live in and ultimately enable everyone in the WHO European Region to make healthy choices". WHO is supporting these efforts further by facilitating the development of a European action plan, covering nutrition and physical activity, and internationally comparable monitoring mechanisms. The action plan is expected to be released in late 2007.

The Charter is available at <http://www.euro.who.int/Document/E89567.pdf>

WHO: Encouraging progress on avian influenza vaccines

Experts meeting at the World Health Organization (WHO) in Geneva on 16 February to discuss advances in pandemic influenza vaccine development reported encouraging progress. This was the third such meeting in just two years and more than 100 influenza vaccine experts, from academia, national and regional public health institutions, the pharmaceutical industry and regulatory bodies throughout the world, attended

the meeting convened by the WHO Initiative for Vaccine Research and the WHO Global Influenza Programme. Information on more than twenty projects was presented and discussed.

Sixteen manufacturers from ten countries are developing prototype pandemic influenza vaccines against H5N1 avian influenza virus. Five of them are also involved in the development of vaccines against other avian viruses (H9N2, H5N2, and H5N3). At present, more than forty clinical trials have been completed or are ongoing. Most of them have focused on healthy adults. Some companies, after completing safety analyses in adults, have initiated clinical trials in older people and in children. All vaccines were safe and well tolerated in all age groups tested.

For the first time, results presented at the meeting have convincingly demonstrated that vaccination with newly developed avian influenza vaccines can bring about a potentially protective immune response against strains of H5N1 virus found in a variety of geographical locations. Some of the vaccines work with low doses of antigen, which means that significantly more vaccine doses can be available in case of a pandemic.

In spite of the encouraging progress noted, the WHO stresses that the world still lacks the manufacturing capacity to meet potential global pandemic influenza vaccine demand as current capacity is estimated at less than 400 million doses per year of trivalent seasonal influenza vaccine.

In response to this challenge, the WHO launched the Global pandemic influenza Action Plan (GAP) in 2006 to increase vaccine supply. This is a US\$10 billion effort over ten years. One of its aims is to enable developing countries to establish their own influenza vaccine production facilities through the transfer of technology, providing them with the most sustainable and reliable response to the threat of pandemic influenza. The WHO is currently working with several vaccine producers, mainly in developing countries affected by H5N1, to facilitate establishment of in-country influenza vaccine production.

More information on avian flu can be found at http://www.who.int/csr/disease/avian_influenza/en/index.html

COUNTRY NEWS

Kyrgyzstan: Integrated household survey to include health module

From Baktygul Akkaziiev*

A health module will form part of the Kyrgyz Integrated Household Survey in March 2007. The survey will contribute to ongoing monitoring efforts on health system performance and includes indicators on financial protection, equity in access, responsiveness and awareness of rights to the State Guaranteed Benefit Package (SGBP). All of these can contribute to National Health Reform Programme measures between 2006-2010 (*Manas-Taalimi*). The survey will be conducted by the National Statistical Committee (NSC) with the technical and financial support of the World Health Organization and the UK Department for International Development. The population sample will be the same as that for the general survey, which provides national and oblast (regional) level representative data. 5,016 households are participating (approximately 21,000 individuals).

The survey instrument is composed of five sections covering: (i) general demographic information; (ii) utilisation and expenditure on outpatient services in the last thirty days (including the consumption of prescribed and non-prescribed medicines); (iii) utilisation and expenditure on hospital services in the last twelve months; (iv) self-reported health status of each adult household member, as well as some objective measurement of cardiovascular disease risk-factors; (v) knowledge of the head of household regarding entitlements to the SGBP.

The survey instrument follows international best practice and has been widely discussed with local experts from the Ministry of Health, Mandatory Health Insurance Fund, and NSC to ensure it meets the monitoring needs of Manas-Taalimi. The new questions on assessing knowledge of the SGBP have been extensively field-tested. This led to marginal modifications to the questionnaire from 2001/04 in order to allow

comparative analysis over time.

There are several innovations in this health survey. Firstly, measuring blood pressure will help establish the prevalence of hypertension and link this to the quality of health service delivery. Cardiovascular disease generally is an under-researched priority area in Manas-Taalimi and this survey will provide important new information. The survey will use the global positioning system to accurately pinpoint the locality of households in relation to service providers. It will also be the first time that households' awareness of their rights within the SGBP have been measured. Draft findings are expected by October 2007.

Russia: Muscovites live seven years longer than other Russians

The Russian daily, *Rossiiskaya Gazeta*, reported on 19 February that life expectancy for Muscovites increased by nine years over the last twelve years. This compared with an average of eighteen months for Russia as a whole.

The survey conducted by the Russian Science Academy found that those living in the centre of Moscow had the greatest life expectancy: on average men living to 70 and women 78. In the Zelenograd-suburb, however, the comparable rates are just 65 and 75.5 respectively.

Apart from the centre, the northern, south-western and north-western regions of Moscow proved rather favourable in terms of life expectancy, while the eastern, south-eastern and southern regions of the city turned out to be not so advantageous. Here education levels are lower and it is speculated that the more educated are more aware of health risks and thus follow healthier diets.

There are however some anomalies. The death rate for able-bodied Muscovites (from 20 to 39) went up. The principal reasons for this were cardiovascular disease, as well as injuries and poisonings. Moreover, non-residents accounted for more than 10% of all deaths. Their social status is typically lower than that of Muscovites.

Overall, the researchers attribute longer lives of Muscovites to economic growth and stable medical care. Yet while deaths from cancer are decreasing across Russia and Moscow as a whole, the peak cancer rates are to be found among city centre

residents. Some Russian commentators have argued that the marked increase in life expectancy may be somewhat erroneous and due in part to poor statistical collection which in fact previously underestimated life expectancy over the last decade.

Kremlin unveils measures to counter avoidable mortality

On 25 January, Russia's First Deputy Prime Minister, Dmitry Medvedev, unveiled a host of measures to tackle Russia's shrinking population. These include moves to cut the road traffic deaths that account for almost 5% of the decline. The population of the world's biggest country is falling by around 750,000 people a year and President Vladimir Putin has ordered a national programme to reverse the trend. Medvedev said a key part of the programme would be to cut accidental deaths on Russia's roads that number around 36,000 annually.

"In order to reduce deaths from preventable causes, including traffic accidents, we are proposing a series of measures, first and foremost providing fast, high-tech and qualified medical aid to victims," he said. One of the first measures is to provide an additional six hundred ambulances equipped with resuscitation equipment to travel to the scene of accidents. Independent member of the Duma (Parliament) and chair of the Russian Motorist Movement, Viktor Pokhmelkin, commenting to journalists on the measures also said that there was a need for more rapid access to medical care, stating simply that "a lot of people die on the roads because they do not get help in time."

Medvedev said his national programme would also try to reduce mortality by improving treatments for cardiovascular disease and acute poisoning (often a result of drinking tainted alcohol). Russia's demographic crisis is alarming the Kremlin. Birth rates in Russia are now rising slowly but mortality levels remain high. The average Russian man lives for just 58 years, 17 years less than the average German man.

Netherlands: Electronic medication records introduced

Health care providers in the Netherlands began working with an electronic medication record system (EMR) from January 2007. Authorised individuals are

* Baktygul Akkaziieva is a Consultant, WHO-DFID Health Policy Analysis Project, Center for Health System Development, Bishkek, Kyrgyzstan. Email: baktygul@manas.elcat.kg

now able to use this EMR system to gain access to a patient's medication history. According to the Ministry of Health, Welfare and Sport, this system should mean that medication errors can be avoided, as authorised health care staff will be supplied with the information they need through an on-line environment. Only if patients object, would such information not be available to service providers. Health care providers should therefore be able to avoid prescribing drugs that might otherwise lead to dangerous interactions with medications that the patient might already be taking on the advice of another doctor.

The EMR is one component of a nationwide system known as the Electronic Patient Record (EPR), intended to facilitate the exchange of patient information. The EPR will be a virtual medical record. Data from different health care information systems will be brought together for doctors who have authorised access. They will then be able to form a more complete overall picture of the patient's medical history, including drugs prescribed.

This national EPR system will be built up in step by step fashion connecting various regional systems to the new nationwide infrastructure. In addition to the EMR now in place, the EPR will also include individual patient identification through a Citizen Services Number; care provider identification and verification with the Unique Healthcare Provider Identification Register; and secure and reliable exchange of information through a 'national switch point.'

Further information at

<http://www.minvws.nl/en/nieuws-berichten/meva/2006/january-launch-for-electronic-medication-records.asp>

Sweden: PM rejects call for cut in alcohol taxes

On 19 February Swedish Prime Minister, Fredrik Reinfeldt, rejected a call put forward by members of his own party to reduce taxes on wine and beer. A number of Moderate Party members of the government's taxation committee had called for taxes to be reduced as a means of tackling the illegal import of beer and spirits for sale on the Swedish market. Public health minister Maria Larsson, a Christian Democrat, had already distanced herself from the proposal.

According to Swedish English language on-line daily *The Local*, the Prime Minister said "we have not yet reached an agreement with our alliance partners and we should not do anything in this area if we are unsure of the budgetary effect. It is very important at the moment that we underline that we want to reduce tax on employment, which means that there will not be as much room for all other types of tax cuts."

The Prime Minister said he was aware of his party colleagues' view that the proposal would have no budgetary effect if balanced by higher taxes on spirits but added that he wanted "to be sure that we have evidence that this really is budget neutral." Prior to the election, Reinfeldt's Moderate Party had argued in favour of reducing alcohol taxes, with the Prime Minister himself critical of the previous government for not cutting alcohol taxes. The latest developments come in the wake of a recent ruling by the European Court of Justice which led to more than thirty websites selling cheap foreign alcohol being closed down. EU regulations state that any reduction in taxes on beer must be followed by similar reductions for wine.

Ireland: Shake up in private health insurance

On 14 December, BUPA Ireland announced that it 'had no option but to commence its withdrawal from the health insurance market.' The decision followed the recent judgement of the High Court on the introduction of the risk equalisation payments scheme. The scheme came into effect from 1 January 2006. BUPA estimated that under the scheme they would "be required to pay €161 million in Risk Equalisation payments over the next three years to the dominant market insurer, the VHI. This would be far in excess of its estimated surplus of €64 million in this period." Thus they claimed that the scheme would make their business unviable. Commenting on the announcement, BUPA Ireland Managing Director Martin O'Rourke said "Irish consumers are the real losers as the market will be restored to a virtual monopoly. Irish consumers have benefited from the choice, innovations and quality of service we have brought to the market over the past ten years and it is with great sadness that we must begin the wind-down of our business."

Subsequently however, at the end of

January 2007 it was announced that the Quinn Group would purchase BUPA Ireland Ltd. Unlike BUPA, as a new insurer the Group would have been exempt from risk equalisation payments for three years. Emergency legislation was however passed in the Irish Parliament on 21 February to ensure that any insurer could not seek to avoid risk equalisation provisions altogether by changing their underwriter every three years.

Quinn Group Chairman, Sean Quinn, said that their entry into the market was significant for the group. "We believe our agreement with BUPA presents an opportunity for real competition in the Irish health insurance market. In all of our businesses, we operate in an open and competitive environment and we trust that the report of the review group established by the Minister for Health, Mary Harney, [on the private health insurance market], and other initiatives, will lead to a more open and competitive landscape in this market."

The Minister for Health and Children, Mary Harney, has welcomed the news. She said that the government believes there is still significant potential for reform of the market, stating that she 'will continue to pursue the government's policies of supporting a community rated market and fair competition. It is important that health insurance remains affordable to older people and those with illnesses, and also that consumers benefit to the greatest degree possible from competition and innovation in the market.' She added that the Quinn Group is a significant player in the general insurance market and was confident that they could play a similar role in sustaining competition in the health insurance market.

Report on competition in the Irish private health insurance market

The Health Insurance Authority published a report on competition in the private health insurance market on 16 February. This report was commissioned by the Minister for Health and Children to look at "further measures to encourage competition in the private health insurance market and the strategy or strategies which might be adopted in order to create greater balance in the share of the market held by competing insurers."

Many of the conclusions and recommendations in the Health Insurance Authority's report's are similar to those in a corresponding report issued earlier in the week by the Competition Authority.

The Irish private health insurance market is community rated. The community rating system is supported by regulations concerning lifetime cover, open enrolment, minimum benefit and risk equalisation. While the regulations also impact on competition, the HIA judged that its impact is fair and proportionate and the regulations facilitate competition between insurers. Nevertheless, it noted that the Irish market is highly concentrated (with only three significant players) and there are a number of measures recommended in the report that should be taken in order to benefit consumers by encouraging greater competition in the market.

A primary objective of the report's recommendations is to bring about a situation as soon as possible that all health insurers operate under the same regulatory framework. To this end, a number of recommendations are made with the aim of VHI Healthcare, the dominant provider of health insurance, becoming an authorised insurer, regulated by the Financial Regulator and required to achieve solvency levels specified in insurance legislation.

The HIA also noted that the absence of risk equalisation in a community rated market gives a regulatory advantage to insurers with lower risk profiles. The Risk Equalisation Scheme it stated "is designed to reduce but not eliminate this advantage and insurers with lower risk profiles will continue to have a significant advantage, even with risk equalisation payments." The HIA came to the conclusion that such payments are essential and that any attempt to end such payments "would involve significant risks for the current community rated health insurance framework and would not be in the interests of health insurance customers generally."

The HIA report on competition in the health insurance market can be downloaded at <http://www.hia.ie/docs/reports/Competition-Report-2007.pdf>

Scotland to get annual check up

There is to be an annual public review of the state of Scotland's health. First Minister, Jack McConnell, made the

announcement on 4 December as the first annual Health Improvement Report was published by Health Minister, Andy Kerr.

The report was commissioned last year and approved by Scotland's Cabinet for publication at a World Health Organization conference that took place in Edinburgh in December. It will be the first of a new form of annual reports to the First Minister covering all actions on health improvement.

At the WHO conference, the First Minister explained that the report will now form part of a new systematic annual process to examine Scotland's health needs and to identify priorities for the year ahead. The new approach is aimed at enabling better co-ordination and prioritisation of initiatives already taking place to improve Scotland's health record.

Mr McConnell pointed to the impact poor health has on people's quality of life, economic growth and the cost to the NHS as "reasons why improving our health matters and it matters to all of us, not just those in the NHS". The First Minister made it clear that, for this reason, the new public review will engage expertise from outside the health service and harness a more rounded approach to addressing health needs.

The report also measures progress being made across government to improve Scotland's health with the aim of bringing it up to a par with the best in Europe. It highlights initiatives such as the ban on smoking in public places, improved school meals and the alcohol test purchasing pilot as examples of how all parts of government are working together, in addition to stressing the role of the NHS in more preventative and proactive care.

The First Minister said "my vision for a healthier, happier more productive Scotland is one shared by the vast majority of Scots. For that reason I feel confident that we can open up our work on health improvement to a wide range of partnership organisations, experts and influential stakeholders. The annual health report we have published today will be sent for comment and engagement to the widest range of stakeholders – here in Scotland and beyond – to encourage them to play a full part in a healthier Scotland. Their input will be even more important in future years.

And to monitor progress and create a shared national agenda, there will be an Annual Public Review based on the report and what needs to be done. This new, very public, annual check up will be a way to rigorously examine what has been done, so that our health improves and our economy grows. Our poor health impacts not just on individual lives but on the NHS, our economic growth and our international reputation. These are just a few of the reasons why improving our health matters and it matters to all of us, not just those in the NHS. But to turn around the reality and the perception of the personal health of Scots, we need to step up our efforts, create a shared national purpose and check against progress each year. While we recognise that Government cannot force people into lifestyle choices, we do believe that there is enormous scope for individuals in Scotland to make more of their lives."

The first annual health report, Delivering a Healthy Scotland can be downloaded at <http://www.scotland.gov.uk/Publications/2006/11/29141927/0>

Scotland: Report on eyecare services

On 14 December the results of a review of eyecare services, written under the chairmanship of Gareth Davies, Medical Director NHS Forth Valley, were published. The review had been commissioned in March 2004 by the Scottish Executive government with the charge of reviewing arrangements for the provision of eyecare services in the community in Scotland, and to provide recommendations on good practice for effective models of care. Another aim of the review was to encourage the development of integrated eyecare services to ensure patients receive a good quality and efficient service in a convenient setting without undue delay.

Among the key recommendations of the review were that an integrated, patient-centred approach should be taken to the design of eyecare services, both for children and for adults. It also suggested that the planning of services should be based on a broad definition of visual impairment, so as to include those who have additional disabilities or impairments. The particular needs of members of minority ethnic groups should be taken into account. Minimum service standards should also be established to ensure that patients receive a consistent

quality of service across Scotland.

As a result of the review, the Scottish Executive government are committed to an additional £2 million investment to aid closer working between eyecare providers. Speaking at the launch of the report, Deputy Health Minister, Lewis Macdonald said that future eyecare services will focus on better support, enhanced preventative and quality of care: "we have already made significant progress in the introduction of free eyecare examinations in April this year. This review will bring even greater benefits to the people who need eyecare."

Mr Macdonald added that "our wide-ranging recommendations set and maintain national standards that can be adapted and implemented locally, establish better integration between communities, hospitals, social work and general practice and make better use of optometrists, orthoptists and ophthalmic nurses."

John Legg, speaking on behalf of the Royal National Institute for the Blind Scotland, said "we welcome the Scottish Executive's proposals to provide integrated patient-centred services to support people on the sight loss journey. Properly funded and with robustly enforced standards, these proposals have the potential to provide Scotland with world-class eye care services."

The review can be accessed at <http://www.scotland.gov.uk/Publications/2006/12/13102441/0>

UK: New rules on television advertising of food to children

On 22 February the UK's independent regulator and competition authority for the communications industries, Ofcom (Office of Communications), completed its review of the rules on the television advertising of food and drink products to children, and published its final statement on the introduction of restrictions in this area.

Ofcom's co-regulatory partners, the Broadcast Committee on Advertising Practice (BCAP) and the Advertising Standards Authority, are now responsible for implementing the new scheduling and content rules and securing compliance respectively. The new rules will form part of the BCAP Television Advertising Standards Code.

Ofcom's final statement follows the

conclusion of its additional consultation (published 17 November 2006). This proposed to extend restrictions on the television advertising of food and drink products high in fat, salt and sugar (HFSS) to include programmes and channels aimed at children aged under sixteen.

After a detailed analysis of the evidence, including a full impact assessment, Ofcom concluded that it would be appropriate and necessary to adopt restrictions intended to reduce significantly the exposure of children under sixteen to HFSS advertising.

The new restrictions will be phased in, so that from 1 April 2007, HFSS advertisements will not be permitted in or around programmes made for children (including pre-school children) or that are likely to be of particular appeal to children aged four to nine. From 1 January 2008, this restriction will be extended to children aged four to fifteen.

Children's channels will be allowed a graduated phase-in period, with full implementation required by the end of December 2008. Existing advertising campaigns, or those in the final stages of creative execution, can still be broadcast until the end of June 2007. However, from 1 July 2007 all advertising campaigns must comply with the new content rules.

In addition to the scheduling restrictions, content rules will also apply to all food and drink advertising to children irrespective of when it is scheduled. These rules include banning the use of celebrities and characters licensed from third parties, promotional offers and health claims in HFSS product advertisements aimed at primary school children or younger. All restrictions on product advertising will apply equally to product sponsorship. A review of the effectiveness and scope of new restrictions will take place in autumn 2008, one year after the full implementation of the new content rules.

The full Ofcom statement can be accessed at http://www.ofcom.org.uk/consult/condocs/foodads_new/statement

UK: Historic changes for the pharmacy profession

The Chief Pharmaceutical Officers from England, Scotland and Wales came together on 21 February to reveal plans for historic changes to the regulation of

the pharmacy profession. The measures, which form part of the Government White Paper on professional regulation, will see the formation of two separate bodies to oversee pharmacy. One organisation would act as a regulator and a second would be responsible for leading the profession. It is envisaged that the two new bodies will take the form of a General Pharmaceutical Council (GPC) to regulate the profession and a Royal College to provide leadership.

Chief Pharmaceutical Officer for England, Dr Keith Ridge, said "I truly believe this is a good deal for pharmacy. Pharmacy is changing and so professional leadership is vital. We envisage a GPC that takes regulation forward and a Royal College which is sustainable, underpins the science and practice of pharmacy, and commands the respect the profession deserves.

This is about ambition, consolidation, and leadership. It will put pharmacy into the position it has earned and deserves. If we do not seize this opportunity, we will, in my view, have failed pharmacy and our profession at a vital time; consigning it to a wilderness isolated from other healthcare professions."

Chief Pharmaceutical Advisor for Wales, Carwen Wynne Howells, said that "pharmacy is a rapidly changing profession and, as greater responsibilities are placed on it, the public needs to be assured of excellence in its governance arrangements. Whilst the creation of a GPC will move the regulation of the profession forward, the establishment of a Royal College will promote excellence in clinical practice, innovation and leadership within the profession. A historic moment, certainly, but one which presents the profession with huge opportunities."

Chief Pharmaceutical Officer for Scotland, Professor Bill Scott, said "the evolution of pharmacists from a product and technical based focus to one of clinical practitioner continues to gather pace. The most recent independent prescribing powers are a prime example of how the Government is ensuring pharmacists and pharmacy practice will be fit for the 21st century. It is therefore essential that the underpinning regulatory functions and professional leadership are also fit for the 21st century."

The Chief Pharmaceutical Officer for Northern Ireland, Dr Norman Morrow,

who was unable to attend, said that “good governance at both regulatory and professional development levels is at the heart of these proposals, and I believe they offer the profession considerable opportunity for advancement, given the importance of the pharmaceutical contribution to the provision of health care. The [Northern Ireland] Department of Health, Social Services and Public Safety and the Pharmaceutical Society of Northern Ireland are positively engaged in consideration of the future arrangements which will pertain in Northern Ireland.”

This announcement comes as the safe and effective prescribing and dispensing of medicines becomes more complex and greater clinical responsibilities are placed upon the pharmacy profession. It is in accord with the Government commitment to ensure that healthcare professionals will be independently regulated.

Unusually, the Royal Pharmaceutical Society of Great Britain (RPSGB) is both the regulator and the professional body responsible for leading the pharmacy profession. In addition, it has an important role in inspecting pharmacy premises and legislation will soon be in place to enable it to take on the role of regulating pharmacy technicians. The new move will require the RPSGB to separate its regulatory system from its system of professional and clinical leadership, allowing each distinct function to focus solely on its core role.

Northern Ireland has its own professional body, the Pharmaceutical Society of Northern Ireland, and existing arrangements are broadly parallel to those in Great Britain. The White Paper provides the opportunity for a more integrated approach across the UK and this is for Northern Ireland to consider.

The Department of Health in England will present proposals for legislating on professional regulation at the earliest opportunity, on behalf of all health administrations. To help take this work forward a short-term working party will work collaboratively with the broader pharmacy profession, the Pharmaceutical Society of Northern Ireland and other key stakeholders, on agreed proposals for implementation. The working party will be led by Lord Carter of Coles and includes the Chief Pharmaceutical Officers for England,

Scotland, Wales and Northern Ireland. Its work will also help inform future decisions about the regulation and leadership of pharmacy in Northern Ireland. It will report to ministers with recommendations by the end of March 2007. It is anticipated that the necessary legislation to establish the new GPC should be in place by mid 2008.

The government White Paper, Trust, Assurance and Safety, The Regulation of Health Professionals in the 21st Century can be accessed at via <http://www.dh.gov.uk>

Spain: health and beauty go hand in hand

On 23 January, an agreement was reached between Spain’s biggest fashion retailers and design houses and the Ministry of Health and Consumer Affairs to work together on standardising clothing sizes in order to promote a healthy and realistic body image for women. The Minister said that “it was not appropriate in a modern society to have stereotypes of beauty. It is the agreement of all that beauty and health go hand in hand.”

One of the fundamental objectives of the accord is the need to provide more accurate and understandable information on clothing sizes. In reality, there is no agreed standard on clothing sizes, either in Spain or in the European Union as a whole. Sizes differ between manufacturers, causing confusion and problems for consumers; this situation affects the majority of women. In addition to manufacturers agreeing to conform to a current European voluntary standard, Health Minister, Elena Salgado-Mendez, announced that the National Consumer Institute will, over a period of eighteen months, measure 8,500 women between twelve and seventy years of age, with the aim of “defining standard patterns and redefining and normalising sizes.”

A second fundamental objective is to promote healthy body images. The ideal picture of beauty sometimes advocated by the fashion industry can put pressure on women to be too thin, which in some cases can lead to health problems such as anorexia nervosa. Major retailers such as Inditex, which owns the fashion retailer Zara, as well as El Corte Ingles, Mango and Cortefiel are all behind the agreement. Shop dummies will now be at least a European size 38, while size 46 will no longer be considered outside.

This is the latest measure taken to curb weight-related disorders and follows the prohibition of models below a certain weight from Madrid catwalks. Similar measures have been taken in other European countries. The plans for reform will not stop with women. According to the Minister “if everything goes well as we expect then of course we will continue with (a resizing) for men – but it seems that men’s sizes are more advanced.” Once the study is completed, retail sizes will be unified over an eighteen month period.

The text of the accord in Spanish only is available at <http://www.msc.es/gabinetePrensa/notaPrensa/pdf/TextoAcuerdo.pdf> while information on the survey of body sizes is available at <http://www.msc.es/gabinetePrensa/notaPrensa/pdf/DossierEstudioAntropometrico.pdf>

German Länder to introduce limited smoking ban

On 23 February, Germany’s sixteen regional states (Länder) agreed to a limited smoking ban in restaurants and cafes. Meeting in Hannover, regional health ministers agreed on rules that would protect restaurant customers and employees from second-hand smoke, but still allow designated closed-off smoking areas. The ban would cover restaurants and cafes, nightclubs, theatres, cinemas, museums and play centres for children as well as public buildings. Two regions, Lower Saxony and North Rhine-Westphalia, insisted on retaining the right to create legislation that would allow businesses to specifically cater to smokers. The agreement must now be approved at a meeting of the regional heads of government on 22 March.

Consumer Affairs Minister Horst Seehofer said the measure was “long overdue.” The federal government had been forced in December to abandon proposals for a nationwide ban on smoking in public places which would have included restaurants and schools although not bars. The interior and justice ministries feared that such a ban would contravene the constitution which gives broad legislative powers to the country’s regional states.

European Parliament lights up

This move in Germany comes at a time when European parliamentarians have

been criticised for voting to set up sealed smokers' rooms in their Strasbourg and Brussels buildings after a voluntary ban failed. A spokesman said that "a complete ban started on 1 January. In practice, this was not working too well, people were not obeying it." Green MEP, Gerard Onesta, a member of the parliament's administrative office, was outvoted twelve to one on the issue. He said that MEPs would be sending a "horrible political signal" at a time when smoking bans are spreading throughout the EU, as evidenced by France's recent ban on smoking in public places. He also noted that the step could be costly as the rooms would require special air filters.

The vote comes on the heels of the call from EU's Health Commissioner, Markos Kyprianou, for a comprehensive ban on smoking in public places across the EU. "It certainly is an odd message. Everywhere else in the world, smoking bans are respected," said a second parliament official.

Germany: agreement reached on health reform plan

On 13 January, German Health Minister, Ulla Schmidt, said that a compromise had been reached on plans to reform the country's €140 billion (\$181.3 billion) health care system, ending months of haggling in the Grand Coalition government. "All those who are sick are winners with this reform," Minister Schmidt told reporters, describing the multi-party compromise as a "break-through" in the months-long impasse inside the grand coalition.

Health insurance will become obligatory for all German citizens if the reforms come into effect as planned by April 2007. The Minister said that "as a result of rising health costs even the more affluent Germans have no longer been able to pay treatment costs without insurance, and an obligatory health insurance scheme is also the best protection against abuse, because individual health costs can no longer be passed on to society as a whole."

Obligatory health insurance was the Minister's suggestion to break the deadlock in the talks over the future of private insurance companies. In contrast to public health insurance funds in which the majority of Germans are insured, the wealthiest 10% of the population can get private insurance which has traditionally been viewed as offering better services. It

is estimated that between 200,000 and 300,000 people in Germany do not have health insurance.

There had been much dispute on whether private insurance companies must open themselves to uninsured people without being allowed to check on an applicant's health status. The Social Democrats (SPD) were strongly in favour of the plan, saying it was a contribution to national solidarity. The Christian Democrats rejected it, arguing that it would ruin private insurance companies. As part of the compromise the SPD dropped this condition.

The controversial plan for an overhaul of the healthcare regime has divided Chancellor Angela Merkel's power sharing coalition for months, hitting popular support for her government. Several conservative state leaders, including Bavarian premier, Edmund Stoiber, and Baden-Wuerttemberg premier, Guenther Oettinger, had led opposition to the reform and initially refused to drop this, even after a government study demonstrated that the burden on rich states like theirs would be limited.

Portugal : abortion to be legalised

Prime Minister, Jose Socrates, has said abortion will be legalised in Portugal despite the turnout for a referendum being too low to be legally binding. Turnout in the traditionally Catholic country was about 40%, far less than the 50% required, but of those who did vote, 59.3% backed a proposed change to the current law. The proposal allows all women abortion until the tenth week of pregnancy.

Currently, abortions are only allowed in cases of rape, a health threat to the mother or serious foetal abnormality. Under the current system, women who have an abortion can go to prison for up to three years. Those aiding women undergoing terminations can also be prosecuted.

One high profile case in recent times was that where the main defendant, midwife Maria de Ceu Ribeira, was sentenced to more than eight years in jail. In total forty-nine people went on trial alongside seventeen women who had aborted at a clinic in the town of Maia in the north of the country. Doctors, pharmacists, and even taxi drivers who had transported them, faced the judges and several were convicted. Many thousands of

Portuguese women therefore have gone to Spain for terminations or resort to illegal abortions.

The "yes" campaign had focused on the estimated 23,000 secret abortions carried out every year. Jose Socrates, the prime minister, called them "Portugal's most shameful wound" and argued that legalising abortion would end such back-street operations and allow women to obtain proper treatment. In a referendum held in 1998, voters upheld the existing abortion law by 51% to 49%, but the result was declared void as nearly seven out of ten voters stayed away. The Socialists made holding another referendum part of their election platform in 2005.

The leader of the conservative Partido Popular, Jose Ribeiro e Castro, who campaigned against the change, said the prime minister was acting too hastily. "Socrates will be responsible for this sad chapter in Portugal's history, for insisting on a political move that has split Portuguese society," he said adding that "low voter turnout has confirmed that (abortion) was not a critical issue."

The Catholic Church were at the forefront of opposition to any change in the law, with church radio stations telling listeners that they still had "time to save lives" and reminding them that the unborn were "children of God". Cardinal Jose Policarpo, the patriarch of Lisbon, declared abortion to be "an attack on civilisation" and in his televised Christmas Eve address to the nation said that "whatever the motives that justify this dramatic act in the eyes of a woman, it is always the denial of a place in the world for a human life that was conceived." In a final move, Portuguese bishops gathered at Fatima, one of the holiest shrines in Catholicism, where the faithful believe the Virgin Mary appeared to three children in 1917. They set up an information desk at the shrine during the final week of the campaign handing out leaflets asking people to vote against the new law.

The Prime Minister did not indicate when a bill to legalise abortion would be sent to parliament. He can however rely on the support of the main opposition party, the centre-right Social Democrats, which should ensure there will be no obstacles to legalise abortion for the Socialists, who already have a parliamentary majority. When the ban is lifted,

Portugal will join most European countries in allowing abortions, except a small group with strict abortion laws: Malta, Ireland and Poland.

Italy: Police raids expose major hospital hygiene and safety concerns

Health Minister, Livia Turco, ordered a nationwide investigation into the state of Italy's hospitals following raids by special health units from the Carabinieri paramilitary police on 321 of Italy's 672 public medical centres during early January. The police reported some grave lapses in hygiene and safety including expired pharmaceuticals, unlicensed nurses, stray cats and scuttling rats.

The raids followed an undercover investigation by a journalist for *L'Espresso* magazine who worked for a month as a cleaner at Rome's Policlinico Umberto I. His report contained photographs of piles of rubbish in the hospital's corridors and unguarded labs containing radioactive and bacteriological material. A spokesman for the Policlinico, which treats more than 80,000 patients a year, said that they were aware of these problems but did not have the funds to address the situation.

However, Ignazio Marino, a surgeon and president of the Health Committee of the Italian Senate, said that "the situation at the Umberto I General Hospital as described by the *Espresso* investigation is intolerable, however unfortunately not surprising. There are only two possible routes to take regarding the Umberto I hospital, it can either be razed to the ground and rebuilt according to modern criteria or it can be given to the Cultural Heritage ministry and used for other purposes".

Francesca Moccia, the National Coordinator of the Patients' Rights Court-Cittadinanzattiva, added that "the dreadful condition of the Umberto I General Hospital of Rome is not an isolated case. The problem comes from the scarce attention paid to controlling hospitals by all levels of staff. This is a problem common in many Italian hospitals."

The police investigation found that some 17% of hospitals, mostly in southern and central Italy, had problems serious enough to recommend possible judicial investigations against 111 people. They found that in Calabria, some nurses were unlicensed, while some hospital workers

in Sicily had friends or family clock them in and out of work while they were earning extra money elsewhere! Italian newspapers also reported that police found a colony of stray cats in the basement of Milan's San Carlo hospital, while rats were found in a Naples hospital, where bulldozers had to be called in to remove piles of garbage and medical refuse left in underground corridors.

General Saverio Cotticelli, head of the unit that made the inspections, confirmed these reports but insisted the problems were limited and didn't affect patient care. "The problem of stray animals is one that returns periodically, you exterminate and after a month they are back," he said. "We found disorder and lack of maintenance ... there are some modest changes to be made, often it's simply an issue of mentality."

Minister Turco insisted that Italians could still trust their health system, noting the problems affected a minority of the country's hospitals. "Citizens can trust the Italian health system, there are cases of negligence that must be dealt with firmly, there are problems of neglect that must be solved, but there is a lot of good health work being done," she said at the presentation of the inspection's results.

Despite the Minister's assurances, it has not gone unnoticed that several high profile figures, including former Prime Minister Silvio Berlusconi who recently had a pacemaker fitted, have received treatment abroad. Opposition leader Umberto Bossi went to Switzerland to recover from a stroke and members of the Agnelli family, owners of the Fiat car group, have gone to the United States regularly for medical treatment. These decisions to receive treatment abroad have been met with much criticism in the Italian press.

The Ministry will now launch an investigation to know if Italian hospitals are respecting the rules and protocols relative to safety and hygiene. The announcement was made by Minister Turco during an inquiry of the Parliamentary Social Affairs Committee of the Chamber of Deputies. The investigation will be conducted independently from the Carabinieri inspections, which will continue in the private accredited hospitals and health facilities in Italy.

According to the first European

Barometer on European Health Systems and Citizen Evaluation, approximately 70% of Italians have a negative opinion of the National Health System. 76% think assistance given to the elderly is under par. The result is that 68% of the Italians are ready to go abroad for treatment because they think there are better services in other countries and that foreign countries are more technologically advanced (75%). The Ministry are keen to point out that despite the recent revelations, between 4.5 and 7% of patients in Italy contract an infection while staying in hospital, a rate in line with that of other European countries.

Latvia: Ban on junk food sales in schools

In November 2006 Latvia became the first EU country to ban the sale of soft drinks, confectionery, crisps and chewing gum from schools and nurseries. The move banned products containing artificial additives such as colouring and flavouring agents, preservatives, amino-acids and caffeine. The ban is part of the government's attempt to improve children's diets and also covers foods containing excessive levels of salt and sugar.

School shops and cafeterias are no longer be able to sell sugary drinks sodas, chocolates, sweets and crisps. However, pupils can still bring their own confectionery to school. Healthy alternatives including dried fruit, unsalted nuts, unsweetened fruit juice, yoghurt, whole-grain snacks, mineral water and milk are now being provided.

The move highlights the increasing pressure on soft drinks and snack food producers in the EU to restrict the availability of their products amongst children. The move by Latvia is just one of a number of steps taken by European countries. In September 2006, Russia also introduced a similar ban in schools while vending machines are also being removed from French schools. In January 2007 the Union of European Beverages Associations announced that they would voluntarily ban advertising to children across the European Union and also pledged to provide unbranded vending machines in secondary schools and that there would be "no engagement in any direct commercial activity" in primary schools.

News in Brief

A sporting chance for health

The European Union has no direct competence for sport, however, European policies in a number of areas have a considerable and growing impact. The European Commission has therefore launched a public consultation on a planned White Paper. This will focus on the role of sport in European society, its economic impact and the way in which it is organised. The consultation, which runs until 3 April 2007, includes reflection on health and social inclusion impacts.

More information at http://ec.europa.eu/yourvoice/consultations/index_en.htm

2007 public health call announced

The 2007 call for proposals in the field of public health has been announced by the Health and Consumer Protection Directorate General. The deadline for applications is 21 May.

Further information is available at http://ec.europa.eu/phea/calls/call_for_proposals_en.html

Update to Health For All Database

The January 2007 updates of both the World Health Organization's European Health For All database (HFA-DB) and the European Mortality Database (MDB) are now available. HFA-DB provides fast and easy access, in graphical form, to a wide range of basic health statistics on the 53 countries of the WHO European Region. The MDB provides the same user-friendly access to mortality statistics by 67 causes and for several age groups.

The database can be downloaded at <http://www.euro.who.int/hfadb>

Report: Future funding of health care in England

In order to help inform the debate about funding health in England over the next five to ten years, the independent health policy think tank, the King's Fund, organised a meeting of senior NHS managers, Department of Health officials, Prime Ministerial policy advisers and academic health economists. It set out to consider not just the immediate question of what level of public funding is feasible and desirable in the immediate future and beyond, but also the process by which such decisions should be reached and the framework that ought

to guide and inform policy-makers. The report includes presentations on key aspects of current system reforms in the NHS and a summary of the discussions. It also includes a chapter on international trends in funding.

More information at http://www.kingsfund.org.uk/resources/publications/funding_health.html

Health care reform in Russia: problems and prospects

This working paper, written by William Tompson at the Organisation for Economic Cooperation and Development, examines the prospects for reform of Russia's health care system. It begins by exploring a number of fundamental imbalances that characterise the current half-reformed system of health care provision before going on to assess the government's plans for going ahead with health care reform over the medium term. The challenges it faces include strengthening primary care provision and reducing the current over-reliance on tertiary care; restructuring the incentives facing health care providers; and completing the reform of the system of mandatory medical insurance.

The report is available at [http://www.oecd.org/olis/2006doc.nsf/linkto/eco-wkp\(2006\)66](http://www.oecd.org/olis/2006doc.nsf/linkto/eco-wkp(2006)66)

Masterfoods to stop advertising to the under 12s

In February 2007, Masterfoods, the maker of Mars and Snickers chocolate bars, announced that it would stop marketing confectionery to children younger than twelve by the end of the year. The self-imposed ban will apply to all advertising, including online and new media. Masterfoods already has a policy of not advertising to children aged under six. It is the first time a major food company has set such a high global age threshold for confectionery products. Writing to Robert Madelin, the European Commission Director-General for Health and Consumer Protection, the company stated that they had "decided to make an official policy change to a cut-off age of twelve years for all core products." Some have speculated that the move has been made in anticipation of regulatory measures. In the UK the broadcast regulator Ofcom recently

announced plans to introduce a ban on junk food advertising to those under sixteen (see article in main news section). This is the latest in a series of voluntary moves by the food and drink industry. The Union of European Beverages Associations last year agreed to stop advertising to children under twelve in Europe. Coca-Cola does not market its carbonated drinks to children under twelve globally.

DG names senior team and revised structure

On 22 February, Dr Margaret Chan, Director-General of the World Health Organization (WHO), named her senior team to lead the health programmes, or 'clusters' at WHO headquarters in Geneva. Dr Chan also announced a revised structure including three new clusters, in order to realign WHO's structure with the six core areas she has identified to take WHO's work forward: health development, health security, health systems capacity, evidence and information, partnership, and performance.

More information on the new structures at <http://www.who.int/mediacentre/news/notes/2007/np08/en/index.html>

Home safety campaign launched

The European Child Safety Alliance launched its home safety campaign at the end of November in Brussels. For the campaign the Alliance has made some home injury fact sheets and parent tip sheets and has also produced a Child Safety Product Guide. The Alliance defines home injuries as those occurring in or around the home, including the garden, garage and driveway, and excluding the pavement, street or community playground.

Presentations and fact sheets are available at <http://www.eurosafe.eu.com/csi/eurosafe2006.nsf/wwwVwContent/14homesafetycampaign.htm>

Additional materials supplied by

EuroHealthNet

6 Philippe Le Bon, Brussels.

Tel: + 32 2 235 03 20

Fax: + 32 2 235 03 39

Email: c.needle@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