

Health Care in the Balance

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Reassessing the roles of European governments and individuals in health care

Introduction

This study builds on the work of the Civitas Health Consensus Group for the UK, which brought together a range of experts to discuss future options for health policy¹. The current project has extended this approach across Europe, to Germany, Holland, and Denmark, each of which were studied by the Consensus Group during its analysis. Again a range of well-renowned experts have given their time to begin discussion of the most important issues in national health policy and options for reform.

Most health policy commentators acknowledge that there needs to be an open discussion of the changing role of the state in health care finance and provision. Nevertheless, the political obstacles to such a discussion are great. But the longer that this rethink of the role of the state is put off, the more difficult and urgent it will become. In the meantime state health coverage becomes a lottery, in which citizens discover only at their time of need that services that they fully expect to receive are, in fact, not available to them.

In the preparation of this report expert roundtable meetings were held in Cologne, The Hague, and Copenhagen, to consider the challenges facing health systems and options for change with regard to the relative roles of users and the state.

Although the specific challenges for each country differed, as does the cultural and political environment, common themes emerged from the discussions. The development of market-based health policy and an increasing role for the individual raises important issues relating to information provision, quality assurance, and risk

¹ Green D “A New Consensus for NHS Reform” Civitas, London, May 2003

selection that policy makers must address during the process of change that is already underway. As individual responsibility continues to grow alongside a relative diminution of state responsibility then new ways of meeting state responsibilities for health care, not least protection against catastrophic risk, need to be found. These need to support rather than suppress the role of the individual. During the roundtables potential uses for state-backed medical savings accounts (MSAs) were discussed. I shall give particular consideration to their potential role as part of a strategic solution for health systems in a state of flux. I have also given considerable space to pharmaceutical policy. The availability of medicines is usually the first area within which governments are willing to openly ration access, apply health technology assessment, and shift costs to individual users. This was, for example, the situation with the UK's National Institute for Clinical Excellence (NICE), that was originally created to deal with "postcode prescribing" of expensive new medicines, replacing a lottery that depended on where the patient lived within the UK with national post-licensing decisions on access to new medicines. The remit of NICE was subsequently extended to also cover non-pharmaceutical therapies. The focus on medicines has, of course, often led to a "silo" problem in health budgets, as the focus on one aspect of care undermines purchasers' ability to take rational decisions on care, taking into account global costs and benefits. At its most extreme, silo budgets can make hospitalisation a rational choice instead of taking a drug, or make the risk of future illness a rational choice over current prevention. Pharmaceutical policy is, therefore, some way ahead of the remainder of health care in terms of facing the problems that can come from regulated markets, particularly in situations in which information levels are poor.

I am extremely grateful to Marin Gemmill at the LSE for her assistance in gathering and analysing data on the pharmaceutical markets in the three countries, and to Chresten Anderson, Eline van den Broek, and Dr Robert Geursen for the considerable technical input respectively on Denmark, Holland, and Germany, and their invaluable practical help in bringing together the expert roundtables in these countries.

Trends across Europe

In recent decades the possibilities of health care have expanded, and European socialised health systems have struggled to produce the level of funding increases necessary to meet European citizens' desire to benefit from the best contemporary care, to maintain their ever-improving life styles and life expectancy. State-run systems have also striven to meet demands for “choices” in health care, although it can be less of an issue for insurance-based systems, including Germany and The Netherlands, than for tax-funded systems such as Denmark and the UK.

Since the mid-1970s the focus of most European governments in terms of health policy has shifted from pushing the boundaries of what is medically possible, to the achievement of cost containment and the suppression of public expectations. Indeed, the assessment of health reform policy proposals is often nowadays based on their impact on cost control rather than their impact on access to modern care and treatment. Many so-called “reforms” of European health systems are, in fact, simply austerity measures, designed to improve system efficiency rather than improve the quality of services.

The urgency of European governments' fiscal mission increased dramatically with the creation of Euro-land, and the new disciplines on public spending that this entailed. Even with the rather relaxed application of the new fiscal rules it has become increasingly clear that social spending in the future will never be as relaxed as in the past. Whatever becomes of Euro-land, the competitive pressures of globalisation guarantee that no country can fall out of line with global standards of tax and spending and still remain competitive. In the three countries covered by this project, this was particularly evident in Germany, which had been the post-war powerhouse of Europe, as it struggles to come to terms with the reductions in the welfare system that are essential to its sustainable economic recovery.

In every country the focus of policymaking for the public services is to contain the costs borne by direct and indirect taxation, including systems of compulsory social health insurance. Whilst health technology assessment is now common across all major purchasers of care, in the public sector it operates within an overall cash

constraint so that it can assist in the rationing of care, rather than simply assess the value of each item of care.

The trend of health funding is clear. The *relative* role of government will continue to diminish over time, as individuals take more responsibility for their own provision, as well as willingly taking more of a role in choices and decisions on the care for themselves and their families. This is often not an overt or planned process and few, if any, governments have encouraged discussion of their countries' future options in this context. Much of the process of change has been concentrated in the less visible aspects of the finance and provision of care; increasing restrictions on the range and cost of care, most notably pharmaceuticals; and increasing the scope and scale of patient payments at the point of use. Whilst these changes are rarely announced as part of a strategic change in health policy, they nevertheless amount to an ongoing process of privatisation in European health care.

Professor Hans Maarse has described European health care as being at the “crossroads”, beyond which state involvement will no longer grow². Whilst differentiating between privatisation that is largely demand-led (i.e the free choice of citizens) and that which is policy-driven (a concerted government strategy) in an analysis of data from 40 countries Maarse demonstrates that the majority of countries did see a marginal shift towards private financing in the decade to 2001³, due largely to the end of growth in the *public* share of health spending, except in Eastern Europe where the public share has actually been in decline.

The Outlook for Germany, Holland & Denmark

The health system of each country has until recently served its citizens well, but is each of them is looking increasingly unable to do so. The root causes of this change lie not only within the growing importance of pan-European and global competitiveness, imposing restraint on the tax burden on individuals and firms, but

² Presentation to Civitas Roundtable, Den Haag, 21 April 2005

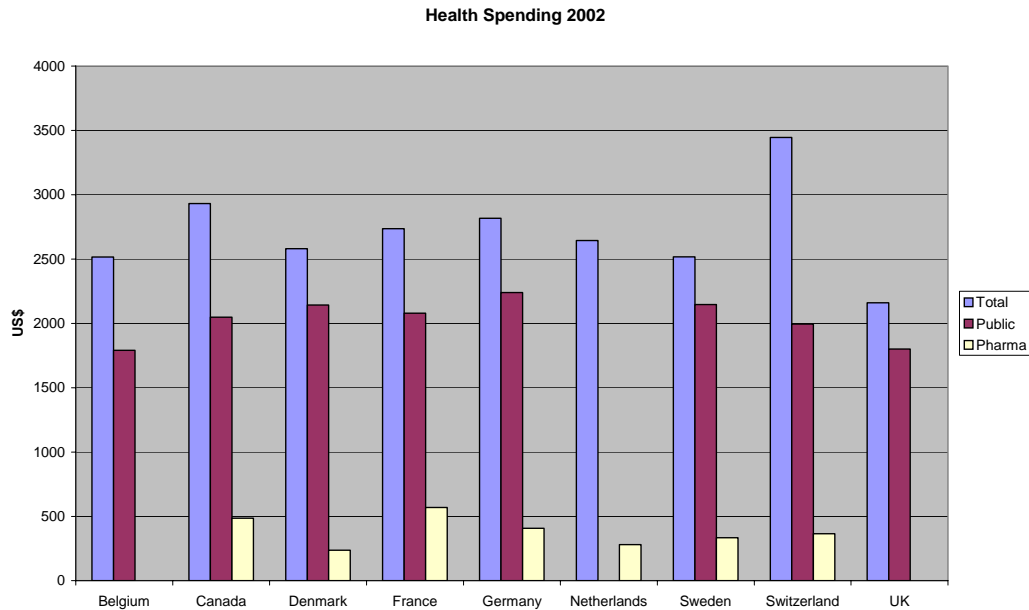
³ Maarse H (ed) *Privatisation in European Health Care* Elsevier gezondheidszorg, Maarssen, The Netherlands, 2004. Figure 11.5, p208

also in the new possibilities of modern health care and people's continuing aspiration to receive the best possible care.

During the twentieth century rise of modern research-based medicine advances took place in leaps and bounds, so that it was unquestionable that health systems should strive to make the advances available to all. Innovation in other technology-driven sectors took a similar course, whether in the development of the internal combustion engine for road transport, or the jet engine for flight. The lack of similar advances since these great technological leaps does not reduce public excitement around the launch of a new type of car, plane, or medicine. Instead, as the basic technology matures, people become more knowledgeable about it, and subsequently more demanding to benefit from the latest advances, whether in speed, comfort, or style. Because so much of European healthcare has been funded and provided by the state, however, welfare systems have proven to be slow, or even unable, to adapt to the process of cultural change. Systems that once did all they could to make the latest advances available to all, to often now operate in reverse, searching for reasons to exclude or limit access to modern care. The gulf between the aspirations of government policymakers and the aspirations of individuals can only widen as this process of cultural change continues, and governments fail to engage in fundamental reforms.

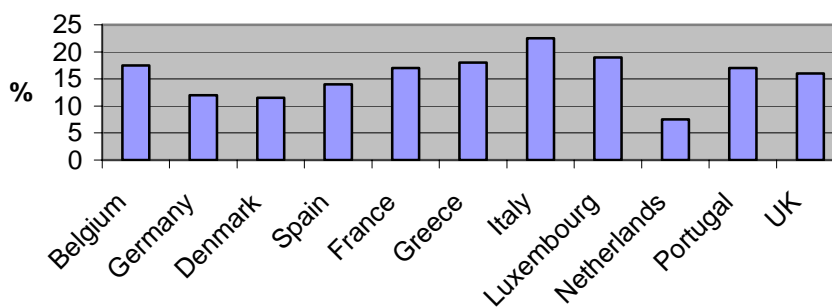
Financing

Although the systems of raising finance differ in the three countries, the overall burden of health funding is largely similar, and the similarities will increase as Denmark, which runs a tax-based rather than insurance-based system, implements the proposed hypothecated 8% health tax.. None of the countries has an exceptional level of total health spending, nor do they have exceptional share of spending financed by the public sector, or accounted for by the costs of pharmaceuticals.



In each country there has been a gradual but continuous shift of responsibility towards private funding, from low levels; a shift that is largely due to restrictions on the growth of public spending rather than overt policies to promote private alternatives, whether out-of-pocket payments or voluntary insurance.

Patients' Share of Health Spending
(Van Montfort 2002)

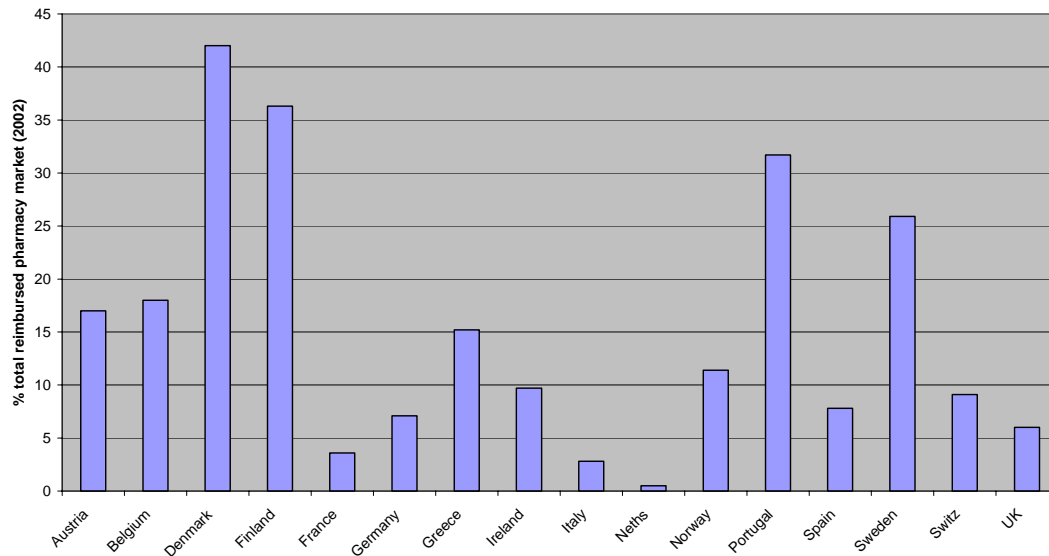


In Denmark and Germany out-of-pocket payments currently account for slightly more than 10% of total health spending, and in Holland these payments represent less than 8% of the total⁴. But these figures do not show how the burden of co-payments is spread. In Denmark, for example, patients themselves bear more than 40% of the total

⁴ Van Montfort A P *Public-Private: A Dilemma in Health?* Presentation to iFHP Biennial, (2002) Amsterdam.

cost of medicines within the reimbursed pharmacy market. Patients in Germany and Holland pay less than 5% of these costs themselves⁵.

Patients' Share of Drug Costs



Data for Holland are complicated by the fact that services that are “delisted” by the state system are not, however, officially counted thereafter as private expenditure, hence Maarse’s comment that Dutch privatisation is “below the water line”⁶. As co-payments and delistings increase, the relative attractiveness of insurances and private alternatives to restrictive state health systems increases. The increase in the take-up of critical illness insurance (paying cash benefits) in Denmark appears to be attributable to increases in out-of-pocket payments during the 1990s as well as to rising dissatisfaction with treatment waiting lists⁷.

Quality

According to the World Health Organisation none of the three health systems perform particularly well against international standards of service provision. Although controversial and very easily challenged⁸, these rankings do offer at least some basis of comparison against a selective range of criteria, although they are widely believed to oversimplify the impact of health systems on life expectancy. Separate attempts

⁵ (2002) European Federation of Pharmaceutical Industries and Associations (Efpia).

⁶ Maarse H (2004) *op cit* p114

⁷ Krasnik A *The strong public tradition in Danish health care* in Maarse (2004) *op cit* p57

⁸ Navarro V *Assessment of the World Health Report 2000*, The Lancet, The Lancet, Volume 356, Issue 9241, 4 November 2000, Pages 1598-1601.

have, however, been made to focus on premature mortality from conditions known to be amenable to health systems and policies (i.e preventable or treatable conditions).

Avoidable mortality

Despite advances in medicine there remains a considerable burden of premature death attributable to conditions that are widely accepted to be preventable or treatable. In Holland, for example, preventable mortality amongst women *increased* by one third in the decade to 2001, and there remains a substantial gap in mortality rates from Ischaemic Heart Disease between the old East and West Germany⁹. Whilst an assessment of system performance based upon avoidable mortality (before the age of 75 years) does improve the European-ranking of Denmark compared to the WHO analysis, it largely reaffirms the rankings of Germany and Holland¹⁰.

Access to New Technologies

Delays in access to approved new medicines can vary substantially. Whilst all three countries are by no means outliers in the European context of local bureaucratic delays before new medicines are available to patients, the averages mask the fact that the maximum delay can reach to almost two years in Holland and nine months in Denmark¹¹. As is being seen in the UK¹² there is now a real risk that the ongoing development of systems of *post-licensing* health technology assessment, for reimbursement purposes, may introduce new and additional delays before patients can benefit from new medicines and medical technologies.

Cost-Control

As can be seen from the discussion that follows, cost-control and cost-shifting (to patients) in health systems have focused intensely on pharmaceuticals, and the complexity and variety of systems that state health systems use to obtain reduced prices for patent-protected pharmaceuticals can have many knock-on effects. They inevitably affect patients' access to medicines, whether through unexpected out-of-

⁹ Newey C, Nolte E, McKee M and Mossialos E *Avoidable mortality in the EU* Institut des Sciences de la Santé (ISS), Paris (2004).

¹⁰ Nolte E, McKee M *Does healthcare save lives?* (2004), Nuffield Trust, London, Figure 15, p93

¹¹ *Delays in market access* (2002) Cambridge Pharma Consultancy

¹² CancerBACUP *Dossier of Delay* London, May 2005

<http://www.cancerbacup.org.uk/News/Press/Pressreleasesstatements/2005/84975716>

pocket costs, limits on use and availability, creating arbitrary incentives to resort to other forms of treatment or to deny early treatment, or in the longer term through the impact of parallel trade on pharmaceutical companies ability and willingness to invest in medicines research for European patients. This assessment of three important European health systems demonstrates the way in which pharmaceutical policy is often at odds with each country's wider health policy ambitions, particularly in the pursuit of high-quality cost-effective prevention, care, and treatment. If these ambitions are to be met then it is imperative that better ways are found of paying for pharmaceuticals, that recognise the core role that pharmaceuticals play within modern health care rather than treat them as a separate case from all other aspects of care.

Cost-shifting

The ways in which health systems are shifting costs to patients are of particular concern, as too often they appear to offer neither improved efficiency nor improved effectiveness, and can also contradict the claims of social solidarity that have so often been claimed as the heart of European health systems. In investigating three health systems we have sought to identify ways that the relative decline of the role of the state can be combined with the maintenance of social solidarity, as current *ad hoc* and isolated policies that achieve cost-shifting seem to be incompatible with this goal.

Germany

Introduction

Health reforms continue to be a major destabilising feature within German politics, which have created a difficult environment for successive governments. The system depends significantly upon employer contributions to social health insurance, and this direct burden on labour market costs has made welfare reform central to German attempts to regain global competitiveness.

Despite widespread recognition that welfare reform is essential, this does not translate into support for any specific cost-saving measures. In particular, German reunification extended the West German system to a population who always expected comprehensive healthcare to be provided without charge. They are, of course, set to be disappointed.

The German healthcare system is unusual inasmuch as individuals above a specified income level can choose whether or not to participate in the redistributive system of social health insurance or to go-it-alone and become privately insured. The sanction that once someone has opted out they must stay out, is evidently a significant deterrent, and even families with above-average incomes can become significant beneficiaries of the redistributive system as their dependent families grow, which acts as a brake on the young and healthy who would otherwise opt out. The civil servants and politicians who make health policy are also not required to join the social health insurance system. In all, some 88% of the population participate within the social health insurance system, although the number with private coverage has been growing steadily.

One of the most important questions for future reform of the financing of the German health system concerns horizontal equity; whether to maintain a system that redistributes from singles to families, from men to women, from the healthy to the sick, and from the wealthy to the less affluent, or to concentrate limited resources on the poor. Issues of redistribution and risk-equalisation are already central to the

current system, and the existing regulations severely limit the scale and operation of any “market” for private health insurance. Indeed, it is arguable that the way the system is regulated ensures that private insurers have no incentive to engage in competition. For example, ageing provisions that are required in insurance contracts, that essentially fix age-related premiums with regard to each customer’s age at the time of entry into the contract, mitigate against subsequent decisions to switch insurer.

It seems that whenever governments express an interest in the role of “competition”, their policy response is to introduce more regulation not less, thus further reducing the prospects for active competition. Most often strategic ambitions to allow competition to raise the quality of care, are lost due to short-term ambitions of cost control¹³.

Much of the political debate today relates to the forms of income on which social health insurance premiums should be levied, with some on the left wishing to include capital in the equation whilst some on the right favour a flat-rate levy mitigated by financial assistance for the poor. The arguments are between and within Germany’s political parties¹⁴. The debate also extends to considerations of whether premiums should be levied at a flat or variable rate. Despite the importance of this debate, however, it does not deal with the fundamental problem underlying the *Agenda 2010* analysis; that the German system relies too heavily on a “tax on jobs” that has made Germany uncompetitive. Recent analysis has demonstrated that without much more substantial reform contribution rates from earned income will need to increase from less than 15% today (and less than 8% in 1970) to at least 22%, and possibly more than 26% within the next 25 years¹⁵. Past experience has demonstrated that rising contribution rates within the statutory health insurance scheme raise the attractiveness of opting out of the scheme. When opting out increased noticeably in 2001, policymakers subsequently responded by increasing the income threshold below which participation is compulsory.¹⁶

¹³ Sauerland D *The German strategy for quality improvement in health care: still to improve* Health Policy 56 (2004) 127-147

¹⁴ *Doing their best to lose? Angela Merkel v Edmund Stoiber* The Economist 14th October 2004

¹⁵ Sauerland D, Presentation to the 5th European Conference on Health Economics, London, 2004. www.akad.de

¹⁶ Busse R and Wörz *The ambiguous experience with privatisation in German health care* in Maarse (2004) *op cit*, p82

Background

Germany is often credited with having been the first country to introduce a system of widespread health insurance, under Bismarck in the late 19th Century. Around 1890 less than 10 percent of the population of Imperial Germany (the working poor) was covered. What had previously been a voluntary system of employment-based coverage, was eventually transformed into a compulsory and heavily regulated system¹⁷.

The number of “sickness funds” has been declining in recent years, so that in 2005 there were 261 funds offering the package of statutory health insurance, covering 88% of the population¹⁸. A further nine percent of the population have opted for private health insurance, and most of the remaining three percent fall into categories of public employment that entitle them to supplementary coverage by a (free) government health care scheme¹⁹. In addition to those who opt for private insurance cover, voluntary supplementary insurance is also popular amongst those within the statutory health insurance scheme, to cover out-of-pocket expenses and other health costs.

The German system is employment-based, with coverage by the selected sickness fund extended to the employee’s family. Income-related contributions are due equally from the employee and employer within limits. Premiums cannot be risk-rated, and ever more complex equalisation systems are developed to deal with concerns regarding risk-selection. Premiums averaged 14.3% of income in 2003²⁰.

For the lowest-paid only (with a monthly income threshold of €400) the employer is required to contribute. In the case of the unemployed and retired, then state

¹⁷[1] For a discussion of these developments: Saltman R and Dubios H “*The Historical and Social Base of Social Health Insurance Systems*” in Saltman R, Busse R, and Figueras J (eds) “*Social Health Insurance Systems in Western Europe*”, Open University Press, 2004 pp21-32

¹⁸ *Gesundheitsministerin Schmidt: 30 bis 50 Krankenkassen reichen aus* Deutsches Arzteblatt Online 14 September 2005 <http://www.aerzteblatt.de/v4/news/news.asp?id=21384>

¹⁹[2] European Observatory on Health Care Systems: “*Health Care Systems in Transition – Germany*” 2000

²⁰ Grubert N *Health care reform in Germany promises few winners* Pharmaceutical, Pricing, and Reimbursement, DRI, 2:1-14, February 9 2005. www.decisionresources.com

unemployment and retirement schemes assume the role of “employer” with respect to sickness fund contributions.

The package of benefits that the German state requires sickness funds to cover is closely stipulated, and extends even to cash benefits to compensate for loss of income during periods of extended illness and coverage of taxi travel to hospital. In recent years the package has been variously extended and reduced, to include or exclude health promotion measures, as governments have come and gone. Certain aspects of coverage are closely detailed in the Social Code Book V (SGB V), but this excludes, for example, hospital care, which is negotiated directly between individual hospitals and sickness funds

Sickness Funds are able to compete on the contribution *rates* that they levy on employees income, but not on the package of benefits. Since the early 1990s the process of reform has been continuous, but to many commentators resembles a systematic rearrangement of deckchairs on the *Titanic*. Perhaps the most significant change was the 1996 introduction of free choice between sickness funds, tied to a risk-equalisation scheme, and the subsequent creation in 2002 of programmes of disease management in order to reduce incentives for risk selection²¹.

Some recent Reform Acts

1992 - Health Care Structure Act)

Introduced a range of spending caps; some restrictions into the system for reimbursing hospitals; co-payments for medicines; freedom to choose sickness funds, and a “risk compensation” scheme to equalise risks between funds.

1996 - Health Insurance Contribution Rate Exoneration Act

Co-payments

²¹ Busse R *Disease management programs in Germany's statutory health insurance system* (2004) Health Affairs Vol 23 No.3 p56-67

1997 – 1st & 2nd Statutory Health Insurance Restructuring Acts

Co-payments

1998 – Act to Strengthen Solidarity in Statutory Health Insurance

Removing co-payments

2000 Reform Act of Statutory Health Insurance

New health technology assessment (HTA) measures; new payment system for hospitals' quality measures; reduce inpatient/ambulatory care boundaries.

2003 Statutory Health Insurance Modernisation Act

Major supply-side reforms, including provision for GPs to act as “gatekeepers”. Variety of co-payments, including for GP visits, and benefit cuts.

“Agenda 2010”

The generosity of the German social insurance system, funded equally by employers and employees was viable for as long as the “German economic miracle” lasted, and was a central element of Germany’s social market economy. Since reunification and a significant downturn in the country’s relative economic position which brought levels of unemployment that had not been experienced for 60 years, the generous welfare system has become increasingly unsustainable. Successive governments of the past decade have faced the challenge of designing politically-difficult reforms to bring the social insurance system back into financial balance and ease the competitive burden of Germany’s high non-wage labour costs.

The most recent attempt was the 2003 announcement of the *Agenda 2010*²² reforms by the social democratic government led by Gerhard Schroeder, with (limited) support for its implementation if not its prescription from the opposition Christian Democrats. Perhaps unsurprisingly given this severe austerity drive, the social democrats suffered

²² *Agenda 2010: Questions & Answers* The Federal Government, Germany (2004)

<http://www.bundesregierung.de/Anlage613968/PKG34.pdf>

extremely heavily in several federal state elections and the European elections of 2004, only to be confronted by the challenge of parliamentary (Bundestag) elections the following year. Nevertheless, the vast majority of Germans appear to believe that health reform is necessary, and have a mixed opinion of the current system, even though they also disapprove of reforms led by politicians²³, thus limiting the opportunities for reforms that they themselves consider to be necessary.

Reform Proposals

Despite increasing debate around welfare reform following publication in 2003 of *Agenda 2010* this debate was later pushed to the background by both of the main parties, particularly in the run-up to the September 2005 elections, when their reformist rhetoric was both toned down and given a low profile in their election programmes.

In part, it seems, that their determination to pursue major cuts and reforms in the welfare system, was severely weakened by the rise of the new Left Party²⁴. The popularity of the Left Party and the timidity of both the Social Democrats and Christian Democrats as the election approached reflected widespread public pessimism for the Germany's economic prospects in general, and substantial opposition to *Agenda 2010* in particular. Some two-thirds of respondents to one TNS-Enmid opinion poll during the Summer of 2005 flatly rejected any further welfare cuts²⁵. Thus the prospects for strategic reform look to be rather weak.

More positively, several commentators have begun to develop strategic options for reform of German healthcare, based on increased personal responsibility and market competition. The German pharmaceutical industry, for example, has stepped beyond the usual European model for the industry to struggle from one ad-hoc agreement with the government to the next, and commission research on strategic change. Its proposals provide for better-informed patients to take more financial and decisionmaking responsibility for everyday care, and for the development of greater

²³ Disney H et al "*Impatient for Change: European Attitudes to Healthcare Reform*" The Stockholm Network, London, 2004

²⁴ Lindsey D *Will leftists and disenchanted voters kill reform in Germany?* Spiegel Online, 26 July 2005 <http://service.spiegel.de/cache/international/0,1518,366913,00.html>

²⁵ *ibid*

flexibility in statutory health insurance for more significant health needs²⁶. Separately Wilfried Prewo has produced a “consumer model” in which individual responsibility would become the cornerstone of the welfare state. Contributions towards social security would be paid into individual Social Savings Accounts, leaving individuals free to choose for themselves the services and providers that they want, subject to minimum core cover for catastrophic risks. The Prewo model has been developed to enable evolutionary change, in which current providers shift to become competing suppliers of social insurance products, and in which current cross-subsidies are maintained but become transparent – a “no loss” rule²⁷.

Pharmaceutical Policy

The *Agenda 2010* proposals include plans to establish a system of evaluation for medicines, to promote cost-effectiveness.

Germany is the third largest market for pharmaceuticals with a volume of about \$22 billion in 2003. The country also exhibits below-average growth. From 1998 to 2003, sales in the German pharmacy market increased by about 38 percent. In comparison, the U.S. market grew by almost 90 percent, while in Spain, Great Britain, and Italy, sales increases were 42 to 65 percent. Only France and Japan recorded lower sales increases than Germany²⁸.

In 2002 Germany spent \$236 (adjusted for purchasing power parity) per capita, an amount that was more than Spain and the UK but less than the USA, France, Japan, Switzerland, and Italy²⁹.

Pharmaceutical Regulation

The pharmaceutical market is partially under direct government supervision and partially regulated by self-governing and self-regulating institutions. Medicines licensing, purchasing, and market regulation are taken as Government responsibilities.

²⁶ *Self-determination, solidarity, competition – How to make the health care system future-proof* Verband Forschender Arzneimittelhersteller BV (VFA), Berlin (2002)

²⁷ Prewo W *From Welfare State to Social State* Centre for New Europe, Brussels (2004)

²⁸ VFA (2004)

²⁹ *ibid*

The official national licensing bodies for pharmaceuticals are the Paul-Ehrlich-Institute and the Federal Institute for Pharmaceuticals and Medical Devices (BfArM). The Paul-Ehrlich-Institute carried out drug licensing and supervision for blood, blood products, sera, and vaccines, while the Federal Institute for Pharmaceuticals and Medical Devices (BfArM) covers all other drugs. These institutions also supervise the safety of pharmaceuticals and medical devices.

Manufacturers are either required or can also choose to use the “centralised procedure” at the European Agency for the Evaluation of Medicinal Products (EMA) in London, which grants market authorization in all member states of the European Union. A third licensing possibility is through the European Union’s “mutual recognition” procedure, so that a drug that has been licensed in another EU country as a “Reference Member State” may then apply for simplified process in Germany. The BfArM can refuse market licensing in this case if a specific public danger exists in Germany.

Economic Evaluation

Currently, cost-effectiveness has no effect on the licensing procedure. However, the government has issued legislation for the introduction of a ‘*German Centre for Quality in Medicine*,’ similar to the National Institute of Clinical Excellence (NICE) in the UK. This new centre started work early in 2005 and is tasked to evaluate and classify new pharmaceuticals according to their degree of innovation and effectiveness. Thus, if a medicine’s effectiveness is deemed equal to products already on the market, the new product would be classified as a “me too” product with all consequences regarding its price level, including being “clustering” with other relevant medicines and inclusion in the reference price system.

Pricing

Manufacturers are at present free to set the prices of their patent-protected medicines, although Germany operates a set of demand-side controls that limit this freedom, not least provisions for patient co-payments with regard to their medicines for out patient care. Until 2003 the levels of these payments were fixed according to the package size, and in 2003 were

package size	co-payment (Euros)	
	small	4
medium	4.5	
large	5	

Some patients, however, benefited from full exemption or exemption for certain treatments: children below 18 years of age; pregnant women; low-income groups; and the chronically ill who have spent more than 1% of their annual income on treatment of their condition.

In 2004 the cost-sharing structure was changed, so that patients would be required to pay 10% of the retail price, with a minimum charge of five Euros and a maximum charge of ten. The exemptions were also reduced, so that the general exemptions were restricted to prescriptions for children below the age of 12, and those above the age of 12 only if the drugs are prescribed for treatment of developmental disorders or severe diseases. There are also still exemptions for expenditures over 1% of income for persons with chronic diseases, and anyone else spending more than 2% of their income also escapes further drug co-payments. Altogether some 3.2m people are exempt from co-payment.

In 2002 the Pharmaceutical Expenditure Containment Act imposed a requirement on pharmacists to operate a system of **generic substitution** for branded off-patent pharmaceuticals above a certain substitution “price line”. The price lines were developed with input from the “federal committee of physicians and sickness funds” and an association of sickness funds “Bundesverband der Betriebskrankenkassen (BKK). Physicians could only avoid subsequent substitution if they explicitly indicated their opposition to this on the prescription form. If the physician does not explicitly specify the drug on the prescription but only defines the active ingredient, then pharmacists were now required to choose a drug below the substitution price line. The substitution price line was updated every three months.

The cost containment legislation proved to be relatively unsuccessful in the eyes of policymakers, and further legislation was enacted in 2004. Calculating a price line was abandoned, and instead products deemed to have replaceable active ingredients

were grouped, with the substitution price line based on this grouping, and the reference price for all of the medicines within the group is set below the price line.

A **negative list** is produced containing all licensed pharmaceuticals that are not covered by the sickness funds for insured adults. The list includes drugs generally used for minor conditions e.g. cough and cold remedies, laxatives, travel sickness products and those for mouth and throat infections. The Minister of Health can also exclude “inefficient” drugs or those that combine more than three drugs and from which the combined effect of cannot be fully evaluated. The financial effect of this list has been marginal. Despite the existence of a negative list, a positive list does not yet exist.

- **Pharmaceutical guidelines** are also provided for in legislation, but have not yet been deployed. If and when they are, they would be regulated by the Federal Committee of Physicians and Sickness Funds and would be legally binding. Specifically, the guidelines would limit the prescription of certain drugs to specific indications, and determine that a drug may only be used after non-pharmaceutical treatments had been unsuccessful. In some cases the guidelines could even completely ban prescription by the physicians.

Pharmaceutical guidelines have not yet been implemented due to legal challenges from the pharmaceutical industry. According to the legislators the new German Centre for Quality in Medicine will remedy this situation of stalemate.

As a broader demand-side control mechanism **pharmaceutical spending caps** existed in various forms between 1993 and 2001. Until their abolition physicians faced either regional spending caps or practice-specific spending targets. In both cases there was a legal limit on prescribing costs, with a pay-back system for prescribing in breach of the targets.

Although cost-control measures have been focused on the demand side of the pharmaceutical market in Germany, supply-side measures have included:

- Reference pricing for the off-patent sector, for drugs

- containing the same active substance,
- with similar active substances, and
- with comparable efficacy.

New drugs with patent protection are not covered by the scheme. Patients co-payments also exert pressure on price-setting for all drugs, particularly as patients must pay any difference between the actual price of the drug and the reference or reimbursement price if the seller sets a price above this. This is in addition to the established co-payment system.

The variety of price-setting systems deployed by European governments creates substantial opportunities for cross-border traders to profitably engage in pharmaceutical **parallel trade**, particular when pharmacists are reimbursed at fixed prices for the drugs that they dispense, so that they too can benefit from buying more cheaply from traders who have bought their supplies in other price-regulated countries. There are no incentives for German pharmacists to use parallel imports, but there are strong disincentives for not dispensing them if they are available given their influence on the levels of reimbursement that pharmacists receive from the sickness funds.

The association of sickness funds and the German association of pharmacists agree upon a parallel import quota, based on the pharmacies' overall turnover with sickness funds. This quota is not product-related and describes the share that dispensed, imported pharmaceuticals account for in a pharmacy's revenue. As of January 2003, for example, the quota was 7%. The price advantage of parallel imports was assumed to be 10% of the pharmacy sale price.

If the pharmacist does not achieve the quota in a given month, the pharmacy's reimbursement bill is reduced for that month. If the pharmacist exceeds the quota, then he receives a credit, which can be used to settle the pharmacist's bill in future when the import quota is not reached. The credit is transferred to the following year if it has not been used. Overall, there should be no cash benefit to pharmacists.

The Netherlands

Current plans for a system of privately-provided compulsory universal health insurance from 2006 represent a continuation of attempts by Dutch policymakers to operate a managed market that provides *both* choice and solidarity.

Participating insurers will not only have to accept all applicants but will also have to provide a standard package of benefits and set premiums at a “community” level i.e. with no regard to each individual’s risk profile. Increasingly, however, the restrictions and requirements that such regulation places on private insurance providers appear to be incompatible with the European Single Market, particularly the *EC Third Non-Life Insurance Directive*. Under the plans insurers, for example, must offer open enrolment to all applicants, offer the government-dictated package of benefits, and must not risk-rate the premium charged to each individual. Additionally, the Government reserves the right to intervene and compensate or penalise insurers for apparent risk-selection.

The core challenge for Dutch policy makers is to define a limited core package for all insurers to provide, if insurance is to be compulsory, and to ensure that this package is limited to those items that are deemed essential for social solidarity. The greater the core package, then the less scope there is for a market to operate, providing choice to users. On the other hand, if the core package is well-defined, then there would be little reason for the state to intervene, as it currently does, in the market for voluntary coverage.

Background

The Dutch health insurance system is divided into three “compartments”:

- (1) Long-term care
- (2) Curative Care
- (3) Voluntary, supplementary care

The first compartment “**AWBZ**” provides universal coverage against “exceptional” risks from chronic needs e.g. illness and disability long-term residential or home care. The second comprises basic compulsory social health insurance (“**ZFW**”) for much of the population, notably employees with an annual income below €32,600 (2004), and with largely income-related premiums, for a standard package of coverage. Others are either free or compelled to select private coverage equivalent to the “ZFW” package, with an additional “solidarity supplement” on their premiums to cross-subsidise for the older age-profile of the compulsory system. About 64% of the Dutch population are covered by the ZFW³⁰. The third compartment consists of voluntary, supplementary insurance. In all there are about 80 insurers participating within the Dutch system³¹.

2006 Reforms³²

The Dutch Government’s insurance reforms of 2006 intend to replace the dual public and private curative care insurance structure (i.e. the second compartment) with a single insurance, and to subsequently integrate this curative cover with the system of long-term care cover (AWBZ)³³, so that each person would have a single insurer covering both their curative and long-term care needs.

The new Health Insurance Act comes into effect in January 2006, merging the existing public and private systems into a “basic” package insurance to which all citizens must subscribe, and which can be provided by any public or private insurer willing to do so. Initially at least, the basic package will resemble existing levels of cover for curative care under the previous ZFW system, that had been compulsory for much of the population, but with the addition of short-term mental health care (previously covered by the “exceptional expenses” AWBZ). Flat-rate nominal premiums (estimated to be €1300) paid by insured adults will be supplemented by income-related employer contributions. Contractual negotiations between insurers and

³⁰ *Pharmaceutical Pricing and Reimbursement 2003*, Chp 15. “Netherlands” PPR Communications Ltd 2003

³¹ Van der Wilk EA, Achterberg PW, Mac Gillavry E, Zwakhals L, Van Linden F *How do we do? Health in the EU from a Dutch Perspective* (2004) VWS, The Hague

³² *Reform of the healthcare system curative care and the General Law on Special Medical Expenses (AWBZ)*. Ministry of Health, Welfare, and Sport. Policy Items./2E July 2004

³³ *A Question of Demand: Outlines of the reform of the health care system in the Netherlands*. International Publication Series Health, Welfare and Sport no14E, Ministerie van Volksgezondheid, Welzijn an Sport (MVWS), The Hague, March 2002

employers will be heavily circumscribed by regulations, including a maximum possible discount, in an attempt to strengthen “solidarity” within the system³⁴. The net financial effect of this extension of compulsion (albeit to privately-provided insurance) is estimated to be a shift of €8.5bn from private consumption to public consumption in 2006³⁵, although this will almost certainly be a temporary shift against the trend of gradual privatisation in health care.

The Dutch government wishes to enhance patients’ own responsibility for their care, and are implementing a limited “no-claims bonus” system, by which anyone who incurs medical costs of less than €250 in a calendar year will receive the balance from this sum paid to their bank accounts. Patients will also be able to opt for an “own risk” excess on their compulsory insurance (but only up to a maximum of €500 a year) in order to obtain a reduction in their premium. They will also be able to switch insurer once each year.

Although insurers will be unable to compete on the package of care and will be forbidden from targeting or selecting their enrolees (“open enrolment”), they will be able to compete on the size of premium reductions they offer in return for a policy excess up to the €500 maximum, as well as on the quality of care that they provide. Insurers will no longer be obliged to contract with every provider.

Anyone with high medical expenses and a low income will be eligible for a “healthcare bonus” contribution from the State, in order to compensate them for the fixed premiums under the new system. Meanwhile reform of the AWBZ for exceptional expenses (long-term care for chronic or disabling conditions) is also underway, to reduce eligibility for membership and to shift costs to families where this is possible,

The success of the 2006 reforms in achieving the ambitions set for it depends upon politicians’ future ability to limit the basic package, and thereby keep compulsory premiums under tight control. High levels of opposition in Holland to “own

³⁴ *The New Health Insurance System in Brief* January 2005 supplement to second revised version of November 2004, MVWS, The Hague, January 2005

³⁵ Netherlands Bureau for Economic Policy Analysis (CPB)

http://www.cpb.nl/eng/cepmev/cep/2005/speciale_onderwerpen/stelselwijzigingen_eng.pdf

contributions” make this a difficult political task, as a basic compulsory package necessarily requires increased reliance upon co-payments and complementary insurances. The limit that has already been placed upon own payments places a severe restriction on the development of greater individual responsibility.

Pharmaceutical Regulation

The Ministry of Health, Welfare and Sport (MVWS) is responsible for implementing the government’s policy to obtain safe and affordable pharmaceuticals for all. The policy can be roughly divided into three sections. The first policy objective takes the quality, preparation, canalization and supply of medicines as its primary focus. The second policy objective is to control the cost of medicines. The third policy objective is geared towards encouraging responsible use amongst patients and stimulating a judicious and cost-conscious approach to the prescription and supply of medicines. No other aspect of medicine is subject to such intervention and control³⁶.

Separate to medicines licensing The Netherlands operates a specific authorization procedure for access to the **Drug Reimbursement System (DRS)**, operated by The National Healthcare Tariffs Authority.

The Medicine Price Act (1996) specifies that the price for prescription-only medicines may not exceed a set maximum level, and covers all prescription-only medicines purchased through pharmacies. The maximum is determined biannually through a calculation of the average price of comparable medicinal products (same active substance, same strength and same pharmaceutical dosage form) in four reference countries: Germany, France, Belgium and the UK. The product need be on the market in just two of these four countries for a maximum price to be calculated.

Both patented medicines and generics are treated in this way. The pharmacist may override the pricing level as determined by the Medicinal Products Prices Act (submit a price other than the level specified in the law) to the purchaser (patient or their insurance company), but subject to restrictions:

³⁶ Koopmanschap MA, Rutten FFH *The Drug Budget Silo Mentality: The Dutch Case Value in Health*, Vol 6 Issue s1 pS46, July 2003

- Under a temporary agreement with the pharmaceutical industry discounts of 8% for each single-source prescription and 40% for each multi-source prescription are returned to the insurance funds
- For generics, the lowest price listed for the same generic must be declared
- For parallel imports, the lowest listed price *per* country should be taken
- If the price of the delivered medicinal product is lower than the (reference) price of an (usual branded) equal medicinal product, the pharmacist can also charge one-third of the price difference

Added to this the pharmacist may charge a ‘dispensing fee’, which is a fixed sum *per* prescription.

“Positive annex 1a” lists products that are considered to be therapeutically interchangeable and which are, therefore, covered by the **reference price system**. These medicines are grouped into clusters, based on mode of action, range of indications, and route of administration, patient age group, and the absence of clinically relevant differences applying to the whole patient population (e.g. side effects). For each product cluster a reimbursement limit is calculated. If the price of a medicinal product exceeds the reimbursement limit, the difference has to be paid by the patient.

There is also a positive annex ‘1b’ on which reimbursed medicinal products that cannot be clustered are placed. In this case no reimbursement limit exists. The conditions for inclusion are both clinical and economic:

1. Assessment of therapeutic value: the product is compared with other reimbursed medicinal products for effectiveness (both in clinical trial or test environment and practical use), side effects, applicability, and user convenience. Higher, lower or equal value is concluded. A lower therapeutic value leads to a negative decision, and exclusion from annexe 1(b).

2. Assessment of (cost) efficiency: medicinal product costs for products seeking reimbursement are compared with the medicinal costs of comparable products already reimbursed. Since the end of 2000 “pharmacoeconomic” principles have been applied to this category of comparison.

Equal therapeutic value leads to a positive decision only if costs are not higher than those of the comparable products. If a higher therapeutic value is possible only at a higher cost, then the Minister of Health is responsible for a decision on reimbursement.

In some cases medicinal products are also placed within an ‘annex 2’ which applies more conditions before reimbursement is approved. These conditions relate to the particular patient population, the treatment protocol, insurer requirements for prior-approval, or restricting the prescribing authority to selected physicians.

Reimbursement decisions for pharmaceuticals are increasingly based on cost-effectiveness information. From 2005 onward, pharmaceutical companies will have to provide proof of the **relative efficiency** of their product when requesting reimbursement for new drugs.

There is little overt **co-payment** for pharmaceuticals, although patients would have to pay a surcharge if they opt for some drugs for which a less expensive alternative exists.

Cost sharing can, however, take other forms. Pharmacists can charge a fixed ‘dispensing fee’ per prescription, but not if a general practitioner manages the pharmacy or if the patient is covered by a public scheme.

GP’s are generally free to prescribe whatever medication they see fit for the patient without having to consider the cost-consequences of their choice, being free of fixed budgets and other such control systems. Although an **electronic prescription system** (EPS) exists, GPs have limited incentives to be constrained by it. Experiments with the EPS achieved little in terms of cost-savings; some 70% of Dutch general practitioners claimed to use the system, yet the estimated savings on drug costs

appeared to be modest: around 10% of the €139m expected³⁷. An evaluation of the EPS concluded that it may have a more positive impact on the quality of prescribing than on the cost of it.

Cost-effectiveness has played a role in the development of prescribing guidelines, and these guidelines exist for some disease areas. However, GP's often have limited direct incentives to strictly follow guidelines. The limited adherence to guidelines may be because the guidelines do not specify the specific brand of pharmaceuticals needed but instead offer more general guidance.

If the GP prescribes a **generic medicine**, the pharmacist can dispense either a branded version or a generic. But if the GP prescribes a specific brand, the pharmacist is obliged to deliver this. If the pharmacist dispenses a generic version of a branded medicine, he receives 33% of the difference between the brand-price and the generic price.

Since the beginning of 2004, all **non-prescription** medicines have been excluded from reimbursement. Prior to the new Medicines Law of 2005, all non-prescription medicines could only be sold in pharmacies and in drugstores (druggists), but these are now much more widely available in supermarkets and other retail outlets, as the new law sought to stimulate greater competition and ease the burden of regulation. Although non-prescription medicines available “over the counter” (OTC) can be freely priced, retailers typically still follow the advisory price list of the Royal Dutch Association of Pharmacy (KNMP).

As part of the 2005 legislation, the government has proposed a new reimbursement scheme, whereby all prescription medicines within a therapeutic group would be reimbursed at the level of the cheapest product in that group. Under the plan, reimbursement would still be by product group, as before, but would be based on the cheapest product in the group.

³⁷ Wolters H, Bakker D *Evaluation of Implementation of the Electronic Prescription System: Monitoring Phase, the Situation ...* Utrecht (2002)

Another aspect of recent reforms is that pharmacists may now be employed by other non-pharmacists (e.g. supermarkets) to run a pharmacy. Previously, only pharmacists could run pharmacies.

Additionally, hospitals can set up a hospital-related pharmacy for outpatient prescription drugs. Previously, hospital pharmacies were only permitted to dispense medications to patients who were admitted to their own hospital. This new legislation has resulted in a number of ‘polyclinic pharmacies’ instituted by hospitals alone and in tandem with community pharmacists.

Furthermore, another change allows insurers to run their own pharmacies based on the assumption that insurers are in a stronger position than local pharmacists to negotiate lower prices with the pharmaceutical industry). This reform may lead the way for the elimination of the strict institutional separation between health insurance and health care delivery.

In February 2004 a “**medicines covenant**” was agreed, which led to sharply reduced prices for generic drugs, and which the Dutch research-based pharmaceutical association (Nefarma) also signed up to later in the year. Estimates have suggested that this should lead to a 40 percent reduction in the prices of products marketed by Nefarma, if a generic variant is available, in addition to the agreed price freeze on other products. Amidst significant drug budget savings Ministers must now choose whether to continue with the Covenant after 2005 or pursue complete reform of the pricing and reimbursement system as originally intended. It seems that, for the time being, the pharmaceutical industry has held the new price regulation system at bay, through compliance with a temporary system of arbitrary price cuts and freezes. Nevertheless, the inevitable debate on the future operation of the Dutch pharmaceutical market will continue.

Denmark

Introduction

The Danish health system bears many resemblances to the UK, being largely tax-funded, publicly provided, with a peripheral private sector, and decisions dominated by providers. Also similar to the UK there is some limited experimentation with the supply-side privatisation, in public-private partnerships. In contrast to the UK, however, Denmark operates a remarkably decentralised system of political control and public finance, with service decisions often taken by municipalities most of whom cover populations of less than 15,000 inhabitants³⁸. Recent times, however, have seen moves to bring a degree of centralisation of control³⁹, based on a new system consisting of five regions with health care responsibilities, and enlarged municipalities with public health and social care responsibilities and legal obligations to co-operate with each other⁴⁰. This contrasts with the direction of policy in many other European countries, although Denmark is starting from a position of extreme decentralisation and will remain more decentralised than most.

Reforms to date have been incremental, cautious, and slow, often based in difficult negotiations between municipalities. The costs of healthcare and funding flows remain opaque, as is usual with tax-based systems, although recent proposals for a degree of hypothecation of tax funding, with the creation of an 8% “health care contribution”, would create some basic transparency. In addition, the reformed system will have a small degree of activity-related funding, although it will continue to rely mainly on Government block grants.

Critics of the system argue that it (like the UK) is based on a myth of quality, that is disseminated and maintained by self-interested politicians and providers. There are no

³⁸ *Recommendation of the Commission on Administrative Structure - Summary*, no 1434, (2004) Ministry of Interior and Health, Denmark. www.im.dk

³⁹ Vrangbaek K, Christiansen T *Health policy in Denmark: Leaving the decentralized welfare path?* *Journal of Health Politics, Policy & Law*, (2005) Feb-Apr, 30 (1-2) 29-52

⁴⁰ *Agreement on a Structural Reform* (2004) Ministry of Interior and Health, Denmark www.im.dk

plans, for example, for the new system for quality assurance that is being developed to undertake independent service inspections or audits of providers. It will operate solely as a reporting mechanism for information from providers and, unlike other areas of data collection in Denmark, it will have no power to fine providers that fail to present the required data.

Background⁴¹

The current Danish system of health care financing and provision dates back to the 1970s, providing universal access to tax-funded care for the country's 5.4 million inhabitants. The 14 counties are responsible for hospitals and primary care, working with each other and their constituent municipalities, and largely funded by local taxes levied at rates that average in excess of 30 per cent. Patient co-payments are focused on dentistry and medicines prescribed by GPs, and are substantial but subject to annual limits for each patient. Pharmaceutical co-payments have risen significantly in recent years.

Pharmaceutical Regulation

The *National Board of Health* and the *National Board of Medicines*, two agencies of central government, house the *Danish Center for Evaluation and Technology Assessment*, and the *Institute for Rational Pharmacotherapy*. Both of these latter two organisations aim to develop a broader understanding of the use of pharmaceutical treatment and choice, and both possess powers to make recommendations for central or level action. Other committees within the National Board of Medicines include the *reimbursement committee*, as well as others controlling drug licensing and other regulatory functions.

The local municipalities have some role in the pharmaceutical market, because they administer the Social Security Act and Social Assistance Act, which provides some

⁴¹ This sections draws heavily on the Civitas publication *Background Briefing – Health Care Lessons from Denmark*, (2002) available online at: www.civitas.org.uk/pdf/denmark.pdf

reimbursement for patients based on social and economic needs criteria. And counties have political and budgetary responsibilities for medicines use in primary and secondary care.

Policy implementation, however, largely rests with the *National Health Insurance Service* for primary care, and the *Hospitals* for secondary care. Furthermore, 12 out of the 14 counties have combined forces within a centralised pharmaceutical purchasing unit known as *AMGROS*. The individual budgets for the counties are negotiated with the central Ministry of Finance, with the counties represented in the negotiations by their association *Danish Regions*.

Denmark does not have a permanent price control system. Other than a temporary arrangement during the second half of the 1990s, manufacturers and importers in Denmark have been free to set the price of each individual medicinal product without prior approval from the Danish authorities. The only requirement has been that the Danish Medicines Agency (Lægemiddelstyrelsen; DMA) has to be notified of the pharmacy purchase price (known as the ‘notified pharmacy price’). Once notified, the price is binding, and wholesalers must use this price when selling the product to pharmacies.

From the mid 1990’s to 2001, there were some pricing arrangements that put restrictions on the price of pharmaceuticals such as price ceiling agreements between the Ministry of Health and the industry, and temporary price ceiling laws. At present, however, there is no compulsory price control and pharmaceutical companies are theoretically able to charge a price higher than the reimbursement level, if they chose to do so. For the past four years however, the member companies of the Danish Association of the Pharmaceutical Industry (LIF) decided on their own initiative to declare that the Danish price of the companies’ products would not exceed the average European price. The absence of formal price regulation is, however, heavily tempered by restrictions within the reimbursement system, based upon a **reference price** mechanism and a culture that deters manufacturers from confronting patients with prices higher than the reimbursement price, particularly as patient co-payments are already very high by European standards. The actions of LIF may have diverted

attention from prices and price-regulation, but they have not eased the debate on reimbursement as costs to the health system continue to increase.

For off-patent medicines the Government has for the past four years set a reimbursement price for each group of medicines containing the same molecule. Prior to April 2005, the reimbursement price of the group was either the price of the cheapest product in the group (if the group consisted of only products with Danish prices) or the lowest European price in the group (if a European price existed).

From April 2005 reimbursement prices has been based on the Danish price of the cheapest product available in a substance or reimbursement group. For the substance groups with generic competition, the generic is most likely to be the cheapest, while for patent-protected substances, the reimbursement price is likely to be based on the cheapest domestic supply or a parallel import. If there is only one product in a group, the drug is reimbursed at its retail price.

Patient **co-payments** are significant in Denmark. The percent of the price that is actually reimbursed depends on the patient's exemption status and the patient's sum of expenditures for that calendar year. All pharmacies are connected to a nation-wide database, The Central Reimbursement Register (Centrale Tilskudsregister, CTR), administered by the Danish Medicines Agency. The database ensures that patients receive the correct reimbursement when purchasing reimbursable products, by constant calculation of the amount the patient has paid for reimbursable products within the preceding twelve-month period.

If a pharmaceutical product is excluded from general reimbursement, the prescribing physicians is able to seek "single reimbursement" for the individual patient. The Danish Medicines Agency evaluates these applications for reimbursement and attaches importance in the application to whether:

- the medicinal product plays a special role in the patient's treatment
- the effect of the treatment on the patient has been seen
- other relevant methods of treatment have been found to be insufficient or inappropriate in this particular case

Reimbursement is granted as a fixed amount. This is calculated as 50%, 75%, 85% or 100% of the price of the cheapest product available in a substance or reimbursement group under consideration – the reference price. The reference price system, therefore, promotes the use of generics, since the lower the drug costs, the less the patient pays.

The **substitution** scheme, called the “G” scheme, was introduced in 1991. This scheme comprises most of the off-patent medicinal products for which pharmaceutical substitutes with the same active ingredients exist. The pharmacy can always dispense the cheapest product covered by the scheme unless the physician has explicitly stated on the prescription that the pharmacy should dispense the particular drug. Since June 2001 parallel imports have been included in the substitution scheme.

Unless the physician specifies otherwise by writing ‘ej S’ (not S) on the prescription, *substitution* is mandatory in the following circumstances:

- For medicinal products whose price is less than DKr 100, the pharmacist must substitute the cheapest alternative if the price is at least DKr 5 below the price of the product prescribed by the doctor.
- For medicinal products whose price is DKr 100 – 400 the pharmacist must substitute when the price is at least 5% below the price of the product prescribed by the doctor.
- For medicinal products whose price is more than DKr 400 the pharmacist must substitute when the price is DKr 20 below the price of the product prescribed by the doctor.

The Minister of Health may extend these substitution schemes to cover (a wider selection of) analogous⁴² medicinal products, at some future date. A patient may refuse substitution, but this will affect the amount that they themselves must pay.

The reimbursement rate for pharmaceuticals depends on the patient’s prior consumption of pharmaceuticals within an individual reimbursement period of one year. A new period of one year begins the first time the patient purchases

⁴² Any medicine that has the same active ingredient, formulation and dosage as the one prescribed

reimbursable medicinal products after the expiry of a preceding period 12-month period.

Reimbursement rates for pharmaceuticals in 2005

Annual expense per person on reimbursement-entitled medicine before the extraction of reimbursement*	Coinsurance rate for persons over 18	Coinsurance rate for persons over 18
0-520 DKr	100%	50%
520-1260 DKr	50%	50%
1260-2950 DKr	25%	25%
Over 2950 DKr	15%	15%

*The limits of the amount applies from 1 Jan 2005 and are adjusted every year on the 1 Jan

According to the reimbursement system, the health care system will not reimburse persons over 18 years of age for their expenses if their expenditure for reimbursable pharmaceuticals does not exceed 520 DKK within a year. If a patient's expenditure exceeds 520 DKK but is below 1,260 DKK within a year, 50% of the expenditure between 520 and 1,260 DKK will be reimbursed. If a patient's expenditure lies between 1,260 and 2,950 DKK, 75% of the expenditure between 1,260 and 2,950 DKK will be reimbursed. And if expenditure for reimbursable medicine exceeds 2,950 DKK, the amount exceeding 2,950 will be reimbursed at the rate of 85%. This scheme is also explained in the table.

Children under 18 years old benefit from reimbursement of 50% of their spending up to 520 DKK in a year. Above this level they are treated similarly to adults.

After an application from the treating physician, the Danish Medicines Agency may determine that for persons with an extensive, permanent, and professionally well-documented need for medicinal products, the reimbursement rate will be 100% of the part of the total *out-of-pocket payment* which is in excess of 3,805 DKK per year.

Additionally, after an application from the treating physician, the Danish Medicines Agency grants reimbursement of 100% of *all* medicinal products prescribed by a physician for patients who are terminally ill and who, according to a physician's prognosis, will not live much longer and will not benefit from hospital treatment.

The National Health Security Act allows the Minister for the Interior and Health to change the general cost limits and the ceiling on co-payment for persons with an extensive, permanent and professionally well-documented need for medicinal products, which is usually done annually.

There are schemes within the social security system that grant relief for medical expenses for particular patients such as pensioners in particularly difficult economic circumstances, people in financial need, and handicapped persons living in their own home.

A chronically ill individual can receive reimbursement through an application made by his general practitioner if:

- the patient has a prolonged and medically well documented consumption of medicinal products entitled to reimbursement,
- the patient's total annual expenses on medicinal products entitled to reimbursement (before reimbursement is subtracted) exceeds DKK 19,567 (DKK 21,300 for children under 18).

Terminally ill patients who wish to spend their last moments at home, or in a hospice, can get all expenses covered for medicinal products that are prescribed by a doctor and written on a prescription, regardless of whether or not the medicinal product is generally entitled to reimbursement.

Additionally, if a patient has to use a relatively expensive drug for medical reasons the physician can apply to the Danish Medicines agency for increased reimbursement. For example, the patient may have an allergy caused by additives. Increased reimbursement means that reimbursement is given at the actual price of the medicinal product instead of at the reimbursement price.

Most medicines are sold by authorised pharmacies, with the Ministry of the Interior and Health deciding both the number of pharmacies and their locations. In 2003 there were around 276 main pharmacies and 48 pharmacy subsidiaries (franchises attached to a main pharmacy and managed on behalf of the pharmacist) in Denmark. There are

also around 138 so-called pharmaceutical outlets and 705 regulated outlets for over-the-counter (OTC) medicines. These outlets are allowed to take prescriptions from patients, but must acquire the prescription medicines from pharmacies.

The total gross profits of the private pharmacies are fixed biannually by agreement between the Ministry of the Interior and Health and the Association of Danish Pharmacy Proprietors (Danmarks Apotekerforening).

Pharmacy retail prices to patients are fixed on a scale set by the Ministry of the Interior and Health. The retail price consists of the pharmacy purchase price, plus a fixed amount, a percentage profit, the dispensing fee (currently DKK6.15), and 25 percent VAT. At present the profit scale is:

To the pharmacy purchase price (PPP) 61.0% of the following amount is added:

PPP ≤ 30 DKK	60% of PPP + 1.80 DKK
30 DKK < PPP ≤ 60 DKK	40% of PPP + 7.80 DKK
60 DKK < PPP	20% of PPP + 19.80 DKK

The net result of this regulatory system is that a particular prescription-only medicine has the same price everywhere in Denmark. Once every fortnight the Danish Medicines Agency publishes price and reimbursement information for all marketed pharmaceuticals in the Price List of Proprietary Medicinal Products (Specialitetstaksten). Pharmacies are required to use this price information for patient sales. The information is also available for the general public on the Internet on www.medicinpriser.dk.

The pharmacy mark-up scheme changed on 1 April 2005, so that over the next three years cheaper medicines will become relatively more expensive, and more expensive products relatively cheaper. Moreover, a report on the liberalization of Danish pharmacies is currently under consideration by the Competition Authority. The market for pharmaceuticals may be deregulated to some extent by 2007.

Danish hospitals can choose either to buy pharmaceuticals through private pharmacies or through a hospital pharmacy. In fact, around 90 percent of their supplies come through the hospital pharmacies. When they do purchase from private pharmacies, the retail price is dependent on the hospital's purchase of medicinal products in the preceding year (OMS). The pharmacy retail price is calculated by adding the following amounts to the notified pharmacy price:

If OMS ≤ 2 million DKK	12.3% of PPP
If 2 million DKK < OMS < 9 million DKK	(13.4143 - (OMS/1,794,867 DKK)) % of PPP
If OMS ≥ 9 million DKK	8.4% of PPP

Many hospital pharmacies combined forces to form AMGROS I/S, a wholesale society that invites tenders for pharmaceutical contracts. Most hospital pharmacies now buy pharmaceuticals through AMGROS I/S.

Pharmacies are obliged to electronically report each sale to a central database run by the Medicines Agency. For prescription medicines, the pharmacy must report the number of the prescribing physician and the ID number of the patient. This information is used to monitor the consumption and prescription practices of healthcare professionals for cost control and the establishment of clinical guidelines.

The database can also be used to control prescriptions written by individual physicians. Prescription information may be passed on to the authorities (the counties) responsible for running the reimbursement system and to the National Board of Health (Sundhedsstyrelsen). The counties' 'Field Force'/ALKE use the information to monitor physicians' prescription practices.

Although Danish doctors are not obliged to use county (or national) guidelines, the Organization of General Practitioners has accepted responsibility for costs generated by their prescriptions and accepted financial liability if prescriptions are not shown to be cost-efficient. This means that GPs have some motivation to follow the counties guidelines.

In cases where the prescribing patterns of a physician differ considerably from average, steps are taken to bring pressure to bear to fall into line with their peers. Ultimately the county can withdraw the support of Sygesikringen, which would mean that patients are reimbursed at a much lower rate, but there is as yet no automatic reduction of payments to providers in the Danish system.

A Tale of Three Countries

Patients across the European mainland are becoming more assertive in their attitudes to their health care. Restrictions and problems in their state health system are driving them to seek care in other countries or in the private sector, and their decisions are now reinforced by European Single Market legislation.

Even in Denmark, the traditional taboo associated with the avoidance of waiting lists by “queue-jumping” is breaking down, as individuals take their own decisions to access faster care⁴³. Private health care and cross-border care are growing rapidly from their very low base.

An opinion survey by the Stockholm Network has demonstrated that people’s future expectations from state health systems are low⁴⁴, and are undoubtedly made worse by ongoing debates on cost-driven reforms.

Information

There are few incentives to patients to become better-informed when the direct price of their health care is either very low or zero. Even the *maximum* co-payment in Germany is still very low and following a policy reversal in early 2004 most travel costs are still reimbursed, costing the system around €2.7bn per annum. The only sector facing real cuts have been pharmaceuticals, which are often seen as a soft target; given the commercial and ethical imperative to make medicines available it is the pharmaceutical companies and not patients who bear the consequences of such policies⁴⁵, at least in the short term⁴⁶. The Council for Concerted Action in Health Care reported in 2002 that the:

⁴³ Appel M *Reforming the Danish Health Care System* A CNE Health Luncheon Transcript, March 2004, Brussels. www.cne.org

⁴⁴ Disney H et al *Impatient for Change: European Attitudes to Healthcare Reform* (2004) Stockholm Network, London. www.stockholm-network.org

⁴⁵ Grubert N *Pharmaceutical Pricing & Reimbursement* DRI, (February 2004)

⁴⁶ Ruol J et al *Health Policy* 60 (1992)

“sectorization of delivery, financing and regulation is a major barrier to adequacy and efficiency”

In Germany doctors are paid the same regardless of the quality of the service they provide, and regardless of the fact that many patients would willingly pay more for higher quality.

Improved information must be the first step of any reform process. Unless patients themselves are aware of the opportunities and costs of modern healthcare there cannot be a rational discussion of reform. An informed patient is also an informed elector, however uncomfortable this may be for politicians in the transition as patients become more aware of the failings and restrictions of their local health system. Transparency is the first essential step of a long process, whatever the path of future reform.

Attempts to maintain social solidarity in health systems are often seen to achieve the opposite. By taking regulation far beyond what is necessary, including complex systems of silo budgets that limit flexibility to reflect patient and physicians choices, policymakers are adding to the frustrations that reduce public support for socialised health care.

Compulsion is at the heart of much current debate on health reform in Germany and Holland, with considerable interest in the Swiss mandatory system of “citizens’ insurance” (in which private insurers can participate) with exemptions from additional lump-sum payments for those with very low incomes. The scope of compulsion and any remaining flexibility for individuals to act upon their own willingness to invest in their health care will determine the sustainability of European health systems in the years ahead.

Whilst co-payments are a sensitive topic in all European health systems, the expansion of the EU to include the former soviet republics has meant the incorporation into to the EU of countries for whom (informal) out-of-pocket payments have long been normal practice regardless of income levels. The difficulties associated with co-payments are demonstrated by the extensive exemptions that are put in place whenever co-payments are introduced or extended. Most countries find it

necessary to continuously tinker with their co-payment systems, in order to be seen to be doing something. Furthermore, there is the justifiable concern that patients will demand too little care, too late, in order to avoid co-payments; hence the widespread use of annual limits on co-payments.

Equity issues associated with out-of-pocket payments could be partly addressed through targeted support through medical savings accounts, rather than by perpetuating free-at-the-point of use systems that necessitate restrictions on access through waiting lists and other rationing mechanisms. In most countries the scope of out-of-pocket payments is based more on historical quirk than on any rational process in order to achieve the best levels of equity and efficiency within the health system. The burden of the payments, therefore, usually falls unevenly and haphazardly on users, thus necessitating compensatory systems (including exemptions) that also undermine the financial value of the co-payments. If co-payments are intended to induce some degree of user responsibility for their health and health care, then exemptions that free the most significant consumers of care from any financial responsibility, the poor and the elderly, make very little sense. Similarly, the focus of co-payments on pharmaceutical care alone is damaging to rational care, particularly as they increasingly play a significant part in preventative and chronic care.

Despite these flaws co-payments will continue to grow in European systems, as governments increasingly look for ways to limit their own financial responsibility for advancing technology and user expectations. Increasing reliance on health technology assessment is giving governments' rationing decisions a gloss of respectability, but it is ultimately imposing new limits on access to care at the population level, regardless of the circumstances of individual patients. The impact of the denial of care and out-of-pocket payments that result from these decisions require careful consideration, and mechanisms need to be devised to allow users to take their own rational decisions.

Recent research in Switzerland by Zweifel, Telser, and Vaterlaus⁴⁷ has shown high heterogeneity in people's willingness to pay to avoid exclusions and deductibles in their insurance coverage, including significant cultural differences. The research

⁴⁷ Zweifel P, Telser H, Vaterlaus S *Consumer resistance against regulation: the case of healthcare* (February 2005) Working Paper, SocioEconomic Institute, Zurich www soi.unizh.ch

suggests that co-payment systems would benefit from flexibility with regard to individual preferences. So-called “one size fits all” solutions are evidently inefficient. The analysis demonstrates, for example, that the poor would willingly accept restrictive policies, and hence significant co-payments at the point of use, in order to achieve premium reductions. This finding, largely related to an inverse relationship between income and the time-preference of money, is reinforced by experience in Denmark, where the voluntary insurance cover provided by Sygeforsikringen Denmark, which assists with out-of-pocket payments, is largely the preserve of the healthy and wealthy in the population⁴⁸.

Forthcoming Dutch reforms will provide important new data on attitudes on the relationship between co-payments and premiums, as this is one of the few areas within which participating insurers in the state system will be able to experiment and compete.

Insurance

In those countries in which competing insurers play a significant role, much still needs to be done to achieve open and “fair” competition, and the role of the state reassessed. If intervention in the market for supplementary insurance is deemed necessary, for example, then this is indicative that additional aspects should be within the compulsory package. Outside of any compulsory core package of care, market competition should be left to function. There is a very real risk that regulations to protect a few, will limit the healthcare options for all, whose only result will be welfare losses.

Experience in Germany and Holland with competing private insurance with a social health insurance system have demonstrated the immense complexities of designing and implementing risk-equalisation systems that are reliant upon explicit cross-subsidies, whether from high to low income groups, or high to low health risk groups. Research by Francesco Paolucci has demonstrated that the *range* of risk-rated premiums increases dramatically when the scope of voluntary health insurance (VHI)

⁴⁸ Christiansen T, Lauridsen J and Kamper-Jørgensen F *Demand for private health insurance and demand for health care by privately and non-privately insured in Denmark*. Odense, Health Economics Paper 2002/1 (2002). Cited in Krasnik (2004) *op cit*

increases, with more items transferred from the mandatory system. Whereas, within a limited VHI scheme insurers may find it beneficial to use a high degree of community-rating in premium setting, this is no longer the case as the package grows, thus increasing the potential role for explicit cross-subsidies in order to maintain social support for the system⁴⁹.

Medical Savings Accounts

Medical Savings Accounts (MSAs) have become a controversial topic in health policy, despite the belief of their proponents that they can build on the contemporary trend towards personal responsibility, and provide an incremental route to strategic reform.

The most substantial test of the MSA has been Singapore's *Medisave* scheme, introduced in 1984 and administered by the Central Provident Fund (CPF) Board. Singapore operates as a centralised state, with a population of over 3 million people. The Government was quick to recognise the need for reform of its health system; the population is young by international standards, but has the fastest ageing profile of any OECD country. The introduction of MSAs went hand-in-hand with other policies that recognised the challenge ahead. Not only was health financing changed, to offer a well-educated populace more choice and financial control, but the Government embarked upon aggressive preventative policies that have had a marked effect, for example, on smoking and childhood obesity levels. MSAs were introduced at a time of continuous and strong economic growth, but the system was tested by the "Asian Crisis" in the late 1990s, although Singapore weathered the crisis better than its Asian trading partners.

Singaporeans enjoy a comprehensive health system that is enviable by international standards, with access to advanced treatments much better than pertains in other developed countries with centralised health systems. The much-debated ranking of health systems by the World Health Organisation (WHO) places Singapore in sixth place on overall attainment and performance, compared to its placing of The

⁴⁹ Paolucci F (Erasmus University) *Presentation to Civitas Roundtable* 21 April 2005, The Hague

Netherlands in 17th place, Germany 25th, and Denmark 34th (just below Chile)⁵⁰. Despite this remarkable achievement, the Singaporean system is able to pay its doctors at levels that equate to those in the US and other advanced health economies whilst maintaining overall health care costs at less than 3% of GDP, about one-third of the level of restrictive European systems⁵¹.

The voluntary MSA in Singapore operates alongside a long-standing compulsory savings scheme for old age, also administered by the CPF Board, and schemes for catastrophic medical coverage and supplementary means-tested medical expenses assistance, known respectively as *Medishield* and *Medifund*. In essence an MSA is little different to a pension plan, in which individuals take their own decisions whether to trade off early spending, from a lump sum, and their potential future needs. An MSA completely decentralises the rationing decision from a central agency to the individual.

In the Singaporean system there is a maximum limit on the size of the MSA fund, which earns interest, and there is also a minimum level of saving that must be maintained by anyone of the age of 55. Investments into the account are made at three fixed monthly rates by employers and employees, increasing with age, and are tax-exempt. The account covers the employee's family, so that offspring have become the source of 55% of finance for healthcare needs of the elderly⁵². There is, therefore, substantial intergenerational risk-pooling, albeit limited to within each family unit.

The MSA in Singapore is very limited in scope, to cover items that have relatively inelastic demand, primarily inpatient surgery, and each usage is restricted to a Medisave Withdrawal Limit (MWL) related to the particular Diagnosis-Related Group (DRG). Nevertheless, even in these aspects of care patients can and do opt for "de luxe" hospitals in times of economic confidence (The Government directly

⁵⁰ World Health Organisation *World Health Report 2000 – Health Systems: Improving Performance*, Statistical Annexe, Table 1, WHO, Geneva, 2000

⁵¹ von Eiff W, Massoro T, Voo YO, Ziegenbein R *Medical Savings Accounts: a core feature of Singapore's health care system*, *European Journal of Health Economics* (2002);3:188-95

⁵² Chia N-C & Tsui AKC *Medical Savings Accounts in Singapore: How much is adequate?* SCAPE Working Paper Series Paper No. 2005/02, Department of Economics, National University of Singapore, 2005. <http://nt2.fas.nus.edu.sg/ecs/pub/wp-scape/0502.pdf>

subsidises hospitals on a sliding scale, so that the greatest subsidy is given to “C” class wards, and no subsidy for the highest “A” grade wards).

MSA experiments have also been underway in urban China, South Africa, and amongst some insurers within the US. In the latter case they are mainly an attempt to deal with the problem of the uninsured, particularly amongst employees of small businesses who are not offered corporate health insurance coverage. By 2005 health savings accounts in the US had gained more than one million enrollees, one-third of whom had previously been uninsured, and the figure is forecast to reach six million within three years⁵³. The Chinese and South African MSAs have been deployed more broadly, as a fundamental part of the development of modern health systems after analysis of the alternatives.

China now has a decade of experience with MSAs, in a compulsory system combined with a mechanism of social health insurance, covering in excess of 60 million people⁵⁴. All employer contributions and nearly a third of employee contributions to the health insurance scheme are put into the account which can be used to cover out-of-pocket payments for the deductible on the insurance system.

Conclusions

If one accepts the reality that publicly-funded health systems will continue to delist treatments and increase out-of-pocket payments then ways must be found in order to mitigate the impact of these changes on the efficient operation of health systems, the maintenance of solidarity in face of extraordinary health needs, and individuals’ access to necessary care.

The gradual retrenchment of socialised health care financing needs to take place in a much more coherent way than has become the norm. The focus on pharmaceuticals and dentistry will increasingly create perverse incentives in physician and patient

⁵³ Turner G-M *Consumerism in Health Care: Early evidence is positive* Health Issues, 11 August 2005, Galen Institute

⁵⁴ Dixon A *Are Medical Savings Accounts a Viable Option for Funding Health Care?* Croatian Medical Journal (2002); 43:408-416

behaviour that will undermine attempts to bring about necessary improvements in the quality of much European health care.

Medical Savings Accounts present a particularly interesting mechanism to help individuals cope with the financial consequences of their future, and largely predictable, health needs and could be a *quid pro quo* for a broadening of the scope of user charges and the delisting of particular forms of care. MSAs could sit easily alongside the core health system, whether funded by taxation or social health insurance, and would enable individuals to make their own choices over day-to-day care and ease the difficulties of policymakers in constantly striving to define and refine the state “package” of care. MSAs can raise many of the same issues of risk equalisation as systems of competing health insurance, but only if they are appropriate to more than a narrow aspect of care. It would remain for policymakers to decide whether to operate a system, using tax-incentives and/or overt subsidies to operate MSAs in a way that pursues certain goals relating to particular concepts of equity.

European experience has shown that when individuals face notable out-of-pocket payments many of them will resort to voluntary insurance to cover these payments. Insurance, however, has many of the same problems of needing to define and limit the package of benefits as state-funded care, thus limiting individual choice at the point of need. MSAs could offer a more flexible alternative, enabling individuals to take their own informed decisions when necessary rather than needing to check the small print in their policy documents or government circulars.

Expert Roundtable Participants

Cologne, Germany 22 February 2005

Prof Dr Friedrich Breyer	Universität Konstanz und DIW Berlin
Prof Axel Ekkernkamp	Unfallkranenhaus, Berlin
Dr Robert Geursen PhD MD	Geursen Consulting, Heidelberg
Andreas Mihm	Frankfurter Allgemeine Zeitung, Berlin
Dr Wolfgang Reuter MA	Deutsche Krankenversicherung AG, Köln
Christoph Rupprecht	AOK Rheinland, Düsseldorf
Prof Dr Dirk Sauerland	AKAD Wissenschaftliche Hochschule, Lahr
Dr Harry Telser	Socioeconomic Institut, University of Zurich
Ulrike Götting	VFA Verband Forschender Arzneimittelhersteller
Anne Zimmerman	Universität zu Köln

The Hague, Netherlands, 21 April 2005

Eline van den Broek	Edmund Burke Stichting
Dr Bart Jan Spruyt	Edmund Burke Stichting
Ad Antonisse	AstraZeneca BV
Peter de Bekker	Ministry of Health
Marco Kortleve	CDA Party
Frank Lafort	Lafort Public Affairs
Prof Hans Maarse	Universiteit Maastricht
Francesco Paolucci	iBMG Erasmus University, Rotterdam
Drs Edith Schippers	VVD Party, Tweedekamer
Ronald F Schreuder	Health Management Forum

Copenhagen, Denmark, 11 May 2005

Chresten Anderson	MarkedsCentret
Michael Appel	University of Southern Denmark
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Niels Bottger Rasmussen	Copenhagen Institute for Futures Studies
Prof Kjeld Moller-Pederson	University of Southern Denmark
Dr Michael Seitz	Hannover Chamber of Commerce & Industry
Prof Jes Sogaard	Danish Institut for Health Services Research
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Prof Karsten Vrangbæk	University of Copenhagen