

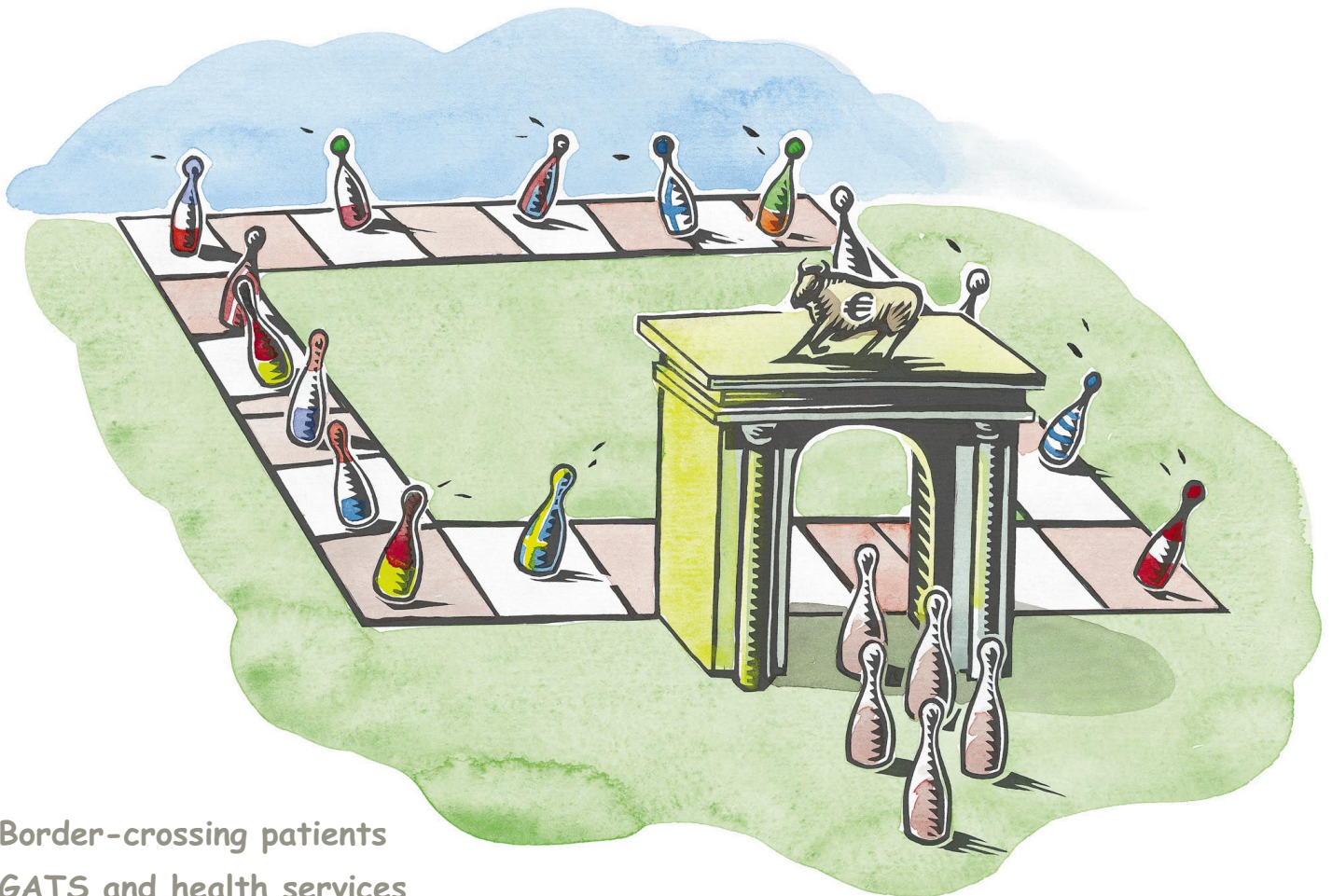
eurohealth

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GATEWAY TO THE EUROPEAN UNION: HEALTH AND EU ENLARGEMENT

Guest editors: Laura MacLehose & Martin McKee



Border-crossing patients

GATS and health services

Fair trade: health and safety

Movement of health professionals

Beyond the candidate countries: health and the stability pact countries

A joint publication between LSE Health & Social Care and the European Observatory on Health Care Systems

LSE Health & Social Care,
London School of Economics &
Political Science, Houghton Street,
London WC2A 2AE, United Kingdom
Tel: +44 (0)20 7955 6840
Fax: +44 (0)20 7955 6803
Website: www.lse.ac.uk/Depts/lsehsc

EDITORIAL TEAM

GUEST EDITORS

Laura MacLehose & Martin McKee

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DESIGN & PRODUCTION

Sarah Moncrieff
Westminster European

EDITORIAL TEAM

Josep Figueras, Walter Holland,
Julian Le Grand, Elias Mossialos &
Richard Saltman

SUBSCRIPTIONS

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

For further information

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

Paul Belcher: Senior Editorial Adviser
+44 (0)20 7955 6377
email: p.belcher@lse.ac.uk

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The Impact of EU Law on Health Care Systems

Martin McKee, Elias Mossialos, Rita Baeten (eds.)

The expanding scope of European law in areas that impinge on health care, coupled with a greater awareness by individuals and organisations within the European Union of the rights that this confers on them, has created new tensions. It throws into relief the challenge of ensuring that progress in developing an internal market enhances rather than undermines consumer safety and social protection. Resolving this challenge has become more important as the social dimension of what was first conceived as primarily an economic union has become more prominent.

In December 2001 the Belgian presidency of the European Union convened a conference in Ghent on the implications of European law for the social nature of health care. Two complementary books emerged from this process. This volume provides an in-depth analysis of some of the most important issues facing health policy makers in Europe. Leading commentators present a range of perspectives from the legal profession on the current situation and prospects for the future, providing a detailed map of the often-labyrinthine body of European law and how it impacts on health care.

About the Editors:

Martin McKee is Research Director of the European Observatory on Health Care Systems and Professor of European Public Health at the London School of Hygiene and Tropical Medicine.

Elias Mossialos is Research Director of the European Observatory on Health Care Systems and Brian Abel-Smith Reader in Health Policy, Department of Social Policy, London School of Economics and Political Science.

Rita Baeten is Researcher at the Observatoire Social Européen. She worked for several years as a policy advisor on health care issues at the Cabinet of Belgian ministers of Public Health and Social Affairs.

Series: *Work & Society* Vol. 39

General Editor: Pochet Philippe

The series Work & Society analyses the development of employment and social policies, as well as the strategies of the different social actors, both at national and European levels. It puts forward a multi-disciplinary approach – political, sociological, economic, legal and historical – in a bid for dialogue and complementarity.

The series is not confined to the social field stricto sensu, but also aims to illustrate the indirect social impacts of economic and monetary policies. It endeavours to clarify social developments, from a comparative and a historical perspective, thus portraying the process of convergence and divergence in the diverse national societal contexts. The manner in which European integration impacts on employment and social policies constitutes the backbone of the analyses.

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CONTRIBUTORS

TIT ALBREHT is Head of the Centre for Healthcare Organisation, Economics and Informatics at the Institute of Public Health of the Republic of Slovenia in Ljubljana.

IVANA BOZICEVIC is researching her Doctorate in public health at London School of Hygiene and Tropical Medicine, United Kingdom.

JAMES BUCHAN is Professor of Health Care Employment Policy at Queen Margaret University College, Edinburgh, United Kingdom.

REINHARD BUSSE is Professor of Health Care Management at the Technische Universität Berlin, Germany.

JOHN M CACHIA is Director of the Department of Institutional Health, Ministry of Health, Malta.

EVGENIA DELCHEVA is Head of the Department of Financial & Economic Analysis and Prognosis at the National Health Insurance Fund in Sofia, and Associated Professor of Health Economics at the University of National and World Economy, Sofia, Bulgaria.

ANNA GILMORE is Research Fellow at the European Centre on Health of Societies in Transition, London School of Hygiene and Tropical Medicine, United Kingdom.

PANOS KANAVOS is Harkness Fellow in Health Care Policy, 2001–2002 at Harvard University, Massachusetts, USA.

KIRSI KÄRKKÄINEN is an administrator in Policy Analysis and Development, Public Health Directorate, Directorate General for Health and Consumer Protection, European Commission.

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DEBRA LIPSON is a Health Policy Consultant.

MANUEL LOBATO is Commercial Law Professor at the Universidad Autónoma de Madrid, Spain.

LAURA MACLEHOSE is Research Fellow at the European Observatory on Health Care Systems, London School of Hygiene and Tropical Medicine, United Kingdom.

MARTIN MCKEE is Professor of European Health at the London School of Hygiene and Tropical Medicine, United Kingdom.

BERNARD MERKEL is Head of Unit for Policy Analysis and Development, Public Health Directorate, Directorate General for Health and Consumer Protection, European Commission.

SALLIE NICHOLAS is Head of the International Department, British Medical Association.

ELLEN NOLTE is Lecturer in Public Health at ECOHOST, London School of Hygiene and Tropical Medicine, United Kingdom.

ESA ÖSTERBERG is Senior Researcher at the National Research and Development Centre for Welfare and Health, Finland.

MAGDALENE ROSENMÜLLER is a Lecturer at the IESE Business School in Barcelona and Madrid, Spain.

ALISON WRIGHT-REID is a Health and Safety Consultant in the United Kingdom.

MONIKA ZAJAC is a Public Health Specialist in Poland.

WITOLD ZATONSKI is Professor of Medicine in the Department of Cancer Epidemiology and Prevention, M. Skłodowska-Curie Memorial Cancer Centre and Institute of Oncology, Warsaw, Poland.

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Looking forward, looking back



Laura MacLehose



Martin McKee

“Accession will clearly have profound consequences for citizens of the countries concerned as they go about their everyday lives. But what will it mean for policies on health and healthcare?”

Even at the time it was apparent that the revolutions that shook central Europe in 1989 would have profound consequences for the post war political structures of Europe. The division of Europe into two – communist and capitalist – had been decided arbitrarily more than forty five years earlier, as Churchill, Roosevelt and Stalin sketched out their respective spheres of influence on the back of a menu at Yalta. It was inevitable that, as soon as they were free to decide for themselves, some of the countries that had found themselves on the wrong side of that divide would want to become an integral part of the developing European idea.

As a consequence, in 1998, the European Union initiated formal negotiations with six countries: Cyprus, the Czech Republic, Estonia, Hungary, Poland and Slovenia. A seventh, that had previously applied, was Malta, although after a change of government it had frozen its application in 1996. The following year, at the Helsinki Council, negotiations were extended to include Bulgaria, Latvia, Lithuania, Malta, Romania, Slovakia and Turkey, with Romania, Bulgaria, and Turkey subject to certain specific conditions.

The initial concept of a first and second wave of candidate countries, as they became known, was abandoned and negotiations became subject to the principle of differentiation, in other words that different countries would move at different speeds. Transition was in two phases, involving first those issues pertaining directly to the single market, the second to

the other issues arising from EU membership. The prerequisites for accession were set out as the achievement of stability of institutions guaranteeing democracy, the rule of law, human rights and protection of minorities, the existence of a functioning market economy with the ability to cope with market forces within the European Union, and the ability to take on obligations of membership including adherence to economic and monetary union.

Each country was also required to create the conditions for integration through adoption of European Community legislation (known as the *Acquis Communautaire*, the accumulated body of European legislation since the creation of the European Communities). Each candidate country would have to sign up to this in its entirety and to accept that European law would take precedence over national law. Accession will clearly have profound consequences for citizens of the countries concerned as they go about their everyday lives. But what will it mean for policies on health and healthcare?

This special issue of *Eurohealth* explores some of the issues that will arise. Its examination is not confined to the current group of candidate countries, which are the most obvious focus of attention, but also to possible future candidates. As Laura MacLehose notes, current candidate countries, at least those that have undergone the transition from communism, stand out from the existing Member States because of their far poorer health, although in some cases, such as the Czech Republic, Slovakia and Poland this has already improved rapidly. This improvement is largely a consequence of the opening up of markets, with increased access to year round fresh fruit and vegetables and to modern pharmaceuticals.

However, a single market for people could have profound consequences for both

Laura MacLehose is Research Fellow at the European Observatory on Health Care Systems, London School of Hygiene and Tropical Medicine. Email: laura.maclehose@lshtm.ac.uk

Martin McKee is Professor of European Health at the London School of Hygiene and Tropical Medicine. Email: martin.mckee@lshtm.ac.uk

“Concerns about a rapid, uncontrolled ‘brain drain’ to western European countries may be overstated.”

candidate countries and existing Member States. Sallie Nicholas and James Buchan write from a British perspective about the opportunities and challenges arising from the increasing mobility of healthcare staff. They conclude that concerns about a rapid, uncontrolled ‘brain drain’ to western European countries may be overstated. On the other hand, John Cachia, writing from Malta, has particular concerns, in part reflecting the vulnerability of a small country many of whose physicians have received postgraduate training abroad. A different perspective is offered by Tit Albreht, writing from Slovenia, who sees opportunities for his country to attract patients from elsewhere in the European Union, providing high quality care at lower prices.

It is not, however, only with regard to migration that governments must address the issue of health professionals. Monika Zajac shows how Poland has had to make wide ranging changes to its regulatory system to comply with European law.

Free movement is not, however, confined to people, and also covers goods, services and capital. As a consequence there are many other health related issues that need to be taken into account. Alison Wright-Reid highlights the significant challenges in approximating very different approaches to health and safety, made even more difficult by the shortage of skills in this area. Panos Kanavos outlines the extremely complex procedures that must be complied with in relation to the market in pharmaceuticals.

And what of health? Unfortunately, not all things that are traded internationally are ‘goods’. Some, such as tobacco, are unequivocally ‘bads’. What will a single market mean for countries such as Poland that have been in the forefront of efforts to reduce the toll of premature death caused by smoking? Will they have to water down their policies to harmonise with less effective policies in existing Member States? Anna Gilmore and Witold Zatonski show how complex this situation is but caution for extreme vigilance. On the other hand, as Evgenia Delcheva notes, countries where policies have been less effective so far may find that accession provides a means to strengthen them.

The process of accession is clearly extremely complex, so what is the European Union doing to help? Bernard Merkel and Kirsi Kärkkäinen describe the activities of DG Sanco and Magdalene Rosenmöller describes the activities undertaken within

the PHARE and related programmes.

Given the risks of prediction, it is important to learn lessons from the past. This is not the first time that new members have joined the European Union. Indeed, it is not the first time a country that had recently undergone a transition from authoritarianism to democracy has joined. Greece in 1981 and Spain and Portugal in 1986 had all made just such a transition.

It is not even the first time that a former communist country will have joined, as is shown by Ellen Nolte’s exploration of the somewhat unusual circumstances surrounding the accession of the former German Democratic Republic in 1991, on its unification with the Federal Republic. For this reason we have asked experts from some of the more recently acceding countries to offer their perspectives. Manuel Lobato describes the challenges that faced Spanish pharmaceutical policy and how they were resolved. As if to emphasise the caution voiced by Anna Gilmore and Witold Zatonski, Esa Österberg describes how Finland was required to modify its policies on alcohol, with results that were not entirely encouraging.

What next? It is unlikely that the current wave of accession will be the last, although the parlous state of the remaining post-Soviet countries such as Ukraine or Belarus will put a brake on expansion in that direction for many years. On the other hand, peace in south east Europe raises the prospect of a further round of accession, bringing in countries such as Croatia and possibly some of its former-Yugoslav neighbours. Ivana Bozicevic examines the prospects for the countries in this region, looking in detail at the role of the stability pact.

Finally, European Union accession is only the beginning of a long and complex process of change but, as Debra Lipson shows, this does not just mean harmonisation with European Union law. All of the candidate countries are also members of the World Trade Organisation and all but three have made commitments to open up their health sectors to global competition to a greater or lesser extent. Yet the World Trade Organisation is a very different entity from the European Union, with much fewer restraints on the adverse social consequences of free trade. As Lipson shows, the combination of European Court of Justice rulings and World Trade Organisation provisions could have many unexpected consequences.

Public health aspects of accession



Bernard Merkel



Kirsi Kärkkäinen

“The Commission is taking steps to ensure that the candidate countries can be involved in the new public health programme as soon as it begins.”

Maintaining and improving public health requires considerable resources. The health systems in the European Union are having to cope with the consequences of ageing populations, the introduction of new technologies and the rising expectations of citizens about the quality of services and standards of care.

For the Member States of the EU these pressures are certainly serious. Yet, because EU countries have well developed economies and strong infrastructures and benefit from long standing expertise in health services, the problems are manageable. And in fact year on year the overall health of the population is improving; people are living longer and in better health.

Transition

In most of the candidate countries, however, not only is population health status significantly lower than the EU average, but the resources devoted to health are very limited.

The unwanted effects of the transition to a market economy such as fiscal problems and the widening of social and economic inequalities have adversely affected health status in most candidate countries.

If we take two basic health indicators, infant mortality and life expectancy, most candidate countries lag well behind the EU. And the difference in life expectancy between most of the candidate countries and the EU is actually greater now than it

was some decades ago.

Major chronic diseases, such as cancer and cardiovascular diseases also have a high incidence in the candidate countries. This is probably linked to higher prevalence of risk factors such as smoking, alcohol abuse and poor nutrition. Drug abuse is a growing problem, and severe environmental pollution remains a major concern.

In addition, there are indications in some candidate countries of a rapid increase in sexually transmitted diseases and HIV infection rates, as well as increases in prevalence of other communicable diseases, such as tuberculosis.

However, spending on health has not kept pace with the challenges to be faced, and in some candidate countries it has actually declined, reflecting the decrease in the GDP and competing priorities in the transition phase.

The level of spending on health, both in absolute and in percentage terms, is therefore significantly less than in the EU. Health's share of GDP is on average around 4.5 per cent (with considerable variation between the countries), whereas the EU average has been rising and is about 8.5 per cent. In terms of real spending per head on health, the picture is even worse: some candidate countries spend less than one quarter of the average EU amount.

Modernisation

Candidate countries are also striving to modernise and reform their health care systems to make them economically viable and responsive. This involves the replacement of the previous vertically integrated health care systems, with the objective of producing high quality health services geared to the evolving needs of the population.

Undertaking such major reforms in a

Bernard Merkel is Head of Unit for Policy Analysis and Development, Public Health Directorate, International Questions, Directorate General for Health and Consumer Protection, European Commission.

Kirsi Kärkkäinen is an administrator in the Unit for Policy Analysis and Development, International Questions, Public Health Directorate, Directorate General for Health and Consumer Protection, European Commission.

difficult economic environment has not surprisingly led to very variable results.

It is against this background that we need to shape the EU's approach towards health and enlargement. A key part of this is to help the candidate countries to prepare themselves for entry into the EU, by adapting their structures to meet Community norms and taking on board the Community's health-related legislation. There is relatively little legislation in the area of public health as such, but a huge amount in various health related fields, for example pharmaceuticals, medical devices, qualifications of health personnel, health insurance and cross border movements of goods and services.

“The difference in life expectancy between most of the candidate countries and the EU is actually greater now than it was some decades ago.”

Assistance

The EU is doing what it can to assist the candidate countries in tackling the major health problems they face. The Commission has taken action in areas such as health sector reforms, health policy formulation, health financing, health care provision, human resource development and training, the pharmaceutical sector, and developing economic evaluation and quality assurance techniques and expertise.

With regard to public health, candidate countries are being involved in Community activities, such as projects in the framework of the Community network on surveillance and control of communicable diseases. They have been participating in programmes on cancer, health promotion, drug abuse and AIDS, and they are involved in the preparation of the proposed directives on blood safety and tissues and cells.

More generally, they are involved in the development of the Community's overall

health strategy. Representatives from all candidate countries participate in various meetings of high level officials. This gives them the opportunity to discuss strategic issues and express their concerns and needs. It also provides a means for them to see how the Community works in practice, and how policy is made, as well as enabling them to set up new collaborative arrangements and joint projects with other countries.

Similarly, the Commission is also taking steps to ensure that the candidate countries can be involved in the new public health programme as soon as it begins. This major programme will focus on three areas: improving health information, developing the capacity to respond rapidly to threats to health, and tackling the underlying determinants of health. All these areas are of key concern to the candidate countries and the programme will provide them with valuable support and tools. Their early involvement in the programme will help them to shape its priorities and future work plans, and also ensure that they benefit fully from the results of the actions undertaken.

Benefit

But it is not just a question of the EU providing assistance to the candidate countries. The EU also stands to gain a great deal from their full involvement. They bring with them new ideas and innovative approaches which will add to the wealth of expertise available. In the last few years they have gained a huge amount of knowledge and experience on how to change and improve health systems and on how to strengthen provision and tackle health issues in a cost-effective way – in short, on which approaches work, and which do not. Their unique experience will offer valuable insights to the Community.

It is also evident that many of the health problems we face are inherently transnational. Communicable diseases, food-borne illnesses, and environmental threats do not respect national borders. They have to be tackled across Europe as a whole. The involvement of the candidate countries is crucial. Their active partnership with existing Member States will thus enable the EU to develop the concrete actions needed to help safeguard public health across Europe.

This paper reflects the personal views of the authors and not necessarily those of the European Commission.

Health trends in the EU and the candidate countries

Common challenges?



Laura MacLehose

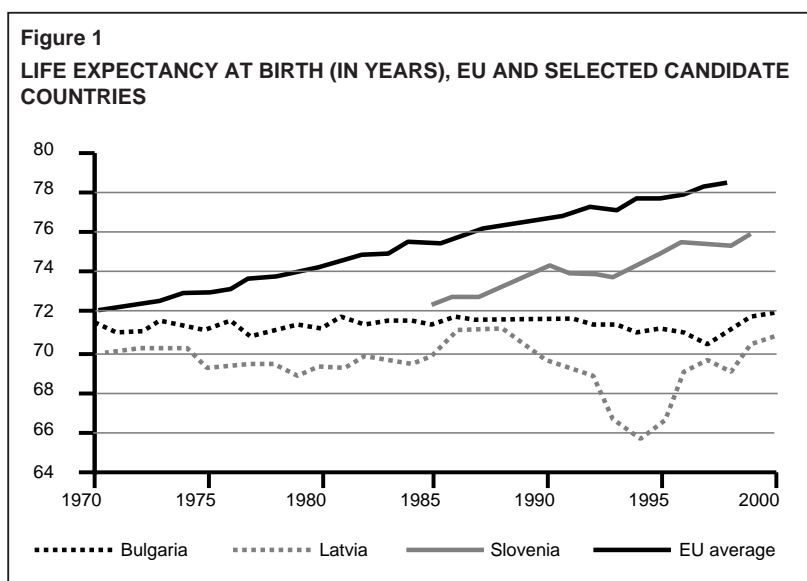
“The challenge for public health professionals is to grasp the opportunities for health improvement arising through the enlargement process.”

The enlargement of the European Union will increase the current population of 375 million by 170 million, thus bringing together 545 million people within a new political and economic trading zone. Background information gathered over the last three decades and current health data show that this new grouping will unite a population with not only a diverse range of health profiles, but also 28 quite different health systems. From infant mortality to overall life expectancy rates, countries differ quite substantially: indeed in some cases the trends over the last decade have shown a widening in some key health indicators. The relative importance of different causes of death varies between countries. The underlying causes and the role of health-care in explaining these trends continue to be debated. In this paper, some of the health trends in the candidate countries and the current EU Member States are outlined.

The so called ‘health gap’ between the east and west of Europe has been well documented.¹ The gap refers to the sharp divide in mortality patterns between the two regions. This is a major issue for the EU as, despite considerable diversity among candidate countries, there remains a substantial, and clearly avoidable, health gap between Member States and the candidate countries. In 1998, overall life expectancy in the EU was 78.2 years compared to 72.5 in the candidate countries as a whole (not including Cyprus).

The overall improving trend in life expectancy in the WHO European region in the last three decades masks some striking regional variations. Figure 1 shows life expectancy for the European region as a whole, the average EU pattern, and that for some of the candidate countries. The EU as a whole has experienced a steady rise in life expectancy, from around 72 years to the current level of over 78 years. In contrast, the candidate countries have experienced extremely diverse trends in life expectancy with some, mainly in central and eastern Europe and the Baltics, experiencing reversals during the early 1990s.

At the highest end, candidate countries such as Slovenia have mirrored, to a large extent, the EU’s steady progress in reducing mortality. Slovenia has shown a relatively steady increase in life expectancy, from just over 72 in 1985 to today’s levels of around 76 years. In contrast, countries such as Slovakia, Poland and Bulgaria have generally shown stagnation or even some reversal in the improvement of life expectancy throughout the 1970s and 1980s, but started to improve during the 1990s. Life expectancy in Bulgaria in 1998 was almost equal to that of 1970 but some overall improvement could be found by 2000. Furthest from the EU levels of life expectancy, the Baltic countries have



Laura MacLehose is Research Fellow at the European Observatory on Health Care Systems, London School of Hygiene and Tropical Medicine.
Email: laura.maclehose@lshtm.ac.uk

“In 1990, men in eastern Europe had the highest risk in the world of dying from cancer.”

experienced a range of dramatic patterns in life expectancy since the collapse of the former Soviet Union at the start of the 1990s. The Baltic States experienced major falls beginning around 1988. In Latvia, for example, the population experienced a drop of over four years in life expectancy from 1988 to 1994. From this low point in the mid 1990s, in each of the Baltic countries there was an improvement to current levels. Although Turkey has the lowest life expectancy of the candidate countries, it has shown an impressive and steady rate of progress over the last three decades. Life expectancy at birth increased from 54 years in 1970 to almost 70 years by 1999. Romania's improvements in maternal mortality rates following the collapse of the Ceausescu regime and its strict pro-natalist policies contributed to overall improvements in Romanian life expectancy.²

The differences in health patterns begin early. Looking at infant mortality patterns, there is around an eight-fold difference between the lowest and the highest rates within the candidate countries (40 per thousand in Turkey compared with 4.56 in Slovenia in 1999). At the best end, Slovenia and the Czech Republic have achieved lower rates than the EU average (5.07 in 1998).

Causes of mortality and morbidity

As in the EU, the main causes of mortality in the candidate countries are non-communicable diseases. The three leading causes of

death are: cancer, cardiovascular disease and injuries (including poisoning). Although not a major cause of death, in a number of the candidate countries communicable diseases have increased making an additional contribution to the burden of ill health.

Cancer

In 1990, men in eastern Europe had the highest risk in the world of dying from cancer (205 deaths per 100,000 population compared to 180 deaths in all other developed regions).³ Lung cancer is the main cause of male cancer deaths followed by stomach cancer. For women, breast and colon cancer are the two main causes of cancer mortality. High levels of smoking across most of the candidate countries contribute a large part to the premature mortality of men in the region. According to the estimates, smoking attributable deaths may constitute around 40 per cent of all male deaths for the year group 35–69.⁴

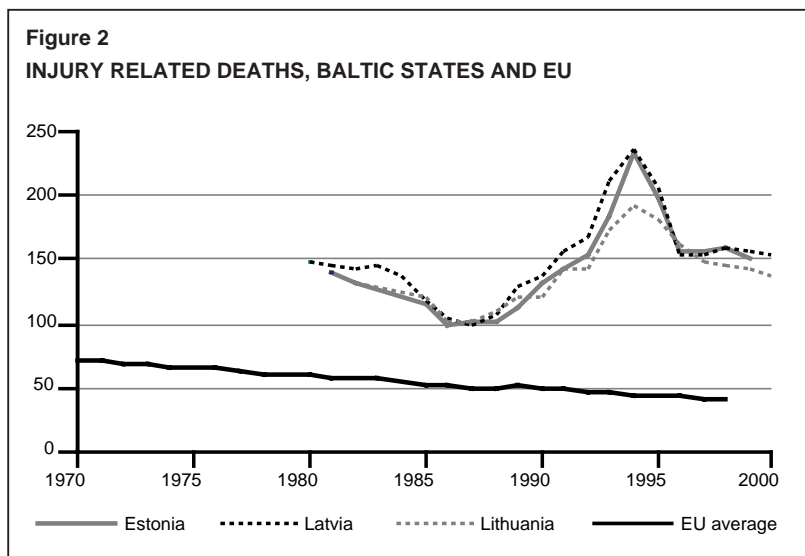
Cardiovascular disease

Countries such as the Czech Republic have made great progress in moving from being one of the countries with the highest ischaemic heart disease mortality (in the mid-1980s) to one of the lower levels in the region. Factors such as the dramatically decreased consumption of animal fats following price liberalisation of food may be linked to this improvement.⁵ However, CVD remains a big killer in countries such as Poland and Hungary: mortality rates range from around double that of the EU

Table 1
HEALTH INDICATORS, 1999

| | Life expectancy at birth | Infant mortality rate | TB incidence | Standardised death rate (0–64 years) for | | |
|----------------|--------------------------|-----------------------|--------------|--|-------------------------------|---------------------------------------|
| | | | | circulatory system diseases | trachea/bronchial/lung cancer | external causes of injury & poisoning |
| Malta | 77.31 | 7.20 | 5.80 | 51.35 | 12.41 | 20.38 |
| Slovenia | 75.77 | 4.56 | 21.40 | 61.06 | 22.00 | 59.20 |
| Czech Republic | 74.94 | 4.62 | 15.61 | 92.35 | 27.37 | 45.28 |
| Slovakia | 73.24 | 8.31 | 20.39 | 119.10 | 23.53 | 51.59 |
| Poland | 73.17 | 8.85 | 31.48 | 113.99 | 27.83 | 58.52 |
| Bulgaria | 71.67 | 14.62 | 42.99 | 166.67 | 21.37 | 45.81 |
| Hungary | 70.75 | 8.43 | 35.08 | 148.56 | 41.98 | 66.08 |
| Lithuania | 72.43 | 8.65 | 75.68 | 122.85 | 20.27 | 136.68 |
| Estonia | 71.05 | 9.49 | 50.75 | 155.50 | 19.44 | 142.85 |
| Latvia | 70.18 | 11.29 | 77.76 | 165.16 | 22.77 | 149.27 |
| Romania | 70.60 | 18.58 | 116.25 | 157.01 | 23.12 | 59.86 |
| Turkey | 69.50 | 40.00 | 34.33 | — | — | — |
| Cyprus NDA | NDA | NDA | — | — | — | — |
| EU average | *78.2 | *5.07 | 12.29 | 49.42 | *17.41 | *31.09 |

* 1998 Source: WHO Health for All (HFA) database, 2002.



(in Poland, Hungary) to over three times as high in Bulgaria.

Injuries

In the WHO European region, injuries and other external causes of death (such as accidental poisoning, suicide and homicide) are thought to account for a substantial proportion of all deaths. They also account for a large part of the overall burden of disability and ill health in the region. The three Baltic candidate countries underwent dramatic increases in deaths related to injuries (including suicide and poisoning) from the mid 1980s to the mid 1990s (see Figure 2). Contributing to this high level of injuries in the Baltic region are very high levels of deaths associated with motor vehicle traffic accidents. These were over twice as high in Latvia as in the EU in 1998, at 27 against 10.7 SDR (Standardised Death Rate) per

100,000, respectively. Motor vehicle deaths increased quickly and steeply following independence. Childhood injuries are an important contribution to the overall injury burden in both EU and candidate countries. From 1991 to 1995, had childhood injury death rates been at the EU average level,⁶ there would have been over 2,000 fewer deaths per year among children aged one to 14 (not including Malta, Cyprus and Turkey).

Communicable disease

Mortality due to communicable disease represents a relatively low part of overall mortality in both EU and candidate countries. However, it remains an important contributor to the morbidity burden, particularly for conditions such as tuberculosis and, increasingly, HIV.

Health systems and health trends

Although the relative contribution of healthcare to mortality rates in general has been debated, it is likely that in the central and eastern European region the health systems partly explain some of the current situation.^{7,8} Dramatic changes in available resources combined with a period of virtual collapse of health systems post-independence in the early 1990s and subsequent health reforms have contributed to some of the mortality trends seen in the region today. Table 2 shows the current resources available to health systems in candidate countries and the EU.

The health expenditure in the candidate countries is approximately 35 per cent of the average EU health expenditure but

Table 2
HEALTH CARE RESOURCES INDICATORS

| | Real health exp PPP\$ | | % GDP alloc to health | | Number per 100,000 population in 2000 | | | Avg LOS* 2000 |
|----------------|-----------------------|--------|-----------------------|--------|---------------------------------------|--------|------------|---------------|
| | 1990 | 2000 | 1990 | 2000 | doctors | nurses | hosp. beds | |
| Malta | — | **1262 | — | 8.8 | 263 | — | 542 | 4.63 |
| Slovenia | 311 | **1230 | 5.6 | **7.7 | **215 | **693 | **555 | **7.6 |
| Czech Republic | 576 | 1023 | 5.0 | 7.3 | 337 | 920 | 855 | 8.8 |
| Slovakia | — | **710 | 5.4 | 6.5 | 323 | 748 | 797 | 9.4 |
| Poland | 258 | **535 | 5.3 | **6.2 | **226 | — | **581 | — |
| Bulgaria | 244 | — | 5.2 | 337 | 462 | 741 | — | — |
| Hungary | 510 | 830 | 6.1 | 6.8 | **361 | 286 | 841 | 6.7 |
| Lithuania | 162 | **413 | 3.3 | 6.2 | 380 | 758 | 924 | 8.3 |
| Estonia | — | **543 | — | 6.1 | 322 | 633 | 718 | 7.3 |
| Latvia | 161 | **326 | 2.5 | 4.8 | 320 | 518 | 873 | — |
| Romania | 79 | ***147 | 2.8 | — | 189 | 402 | 744 | — |
| Turkey | 171 | ***316 | 3.6 | ***4.8 | **127 | **240 | 264 | **5.4 |
| EU average | 1267 | **1922 | 7.7 | **8.5 | 387 | — | 596 | ***8.2 |

* Average length of stay in days **1999 *** 1998 Source: WHO Health for All (HFA) database, 2002.

varies widely between the countries. Real health expenditure translates into levels of service provision for the population, access to pharmaceuticals and salaries of health care staff. Given the relatively low health budgets in some countries, a number have introduced some form of fee for service ele-

ment. At the same time in some countries, increasing 'informal payments' have been requested of patients by health staff in an effort to make up health staff salaries.⁹ Concerns have been raised about how such formal and informal charges will affect equity in accessing health services, particularly by the poorest and the most seriously ill.

Conclusions

While several candidate country populations have a health status similar to the EU average, some have a way to progress before matching indicators such as life expectancy. There remains a wide disparity in available resources for health between the Member States and all candidate countries. As healthcare remains the preserve of national governments rather than the EU, accession will not directly address this aspect of the health gap. However, other aspects of EU legislation will have implications for health, such as tobacco control laws and health and safety regulations. The much hoped for, and anticipated, increasing prosperity and stability in the newly enlarged EU, together with increased international professional cooperation within the health sector should also go some way in bringing health benefits to all. The challenge for public health professionals is to grasp the opportunities for health improvement arising through the enlargement process.

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Opportunities and challenges in the provision of cross border care



Tit Albreht

View from Slovenia

Sharing a border with two European Union members and at the crossroads of two major transportation routes in Europe, Slovenia occupies an important geopolitical position. There has been continuous movement of people and goods across the borders, despite changing political contexts. A

shared historical experience with its neighbours, having been linked at different times to both Austria-Hungary and Yugoslavia, has caused Slovenia to seek effective solutions through cooperation in many areas, including healthcare. The process of accession to the European Union brings new opportunities and challenges for the development of healthcare provision. As a small country, Slovenia desires to participate equally in a transparent and regulated market.

Tit Albreht is Head of the Centre for Healthcare Organisation, Economics and Informatics at the Institute of Public Health of the Republic of Slovenia in Ljubljana. Email: tit.albreht@telemach.net

Opportunities for the cross border provision of healthcare

Slovenia began the process of deregulation and de-monopolisation of healthcare provision in 1992 with two key legal acts defining the principles of a new national healthcare system and health insurance system.^{1,2} Throughout the past fifty years, Slovenia has experienced cross border cooperation in healthcare through agreements with Italy enabling movement of people and services across the border.* These were concerned primarily with the care of visitors from one country to the other and accession to the EU is expected to facilitate provision of healthcare to other EU nationals.

Given Slovenia's geographical position, with its proximity to neighbouring countries, easy access to the main healthcare providers should not present a problem. These are evenly distributed throughout the country, several lying conveniently close to national borders.

Slovenia could provide services competitively to citizens of EU Member States in several areas. The following specialties seem to offer the most opportunities and have had the greatest international experience so far:

- Plastic surgery, vascular surgery, orthopaedic and gynaecological care.
- Dental services (which are more competitively priced than in neighbouring countries).
- Rehabilitation and medically supervised spa treatments.

Both public and private providers participate in the provision of healthcare services. All but two hospital providers are public. Of the two private facilities, one performs treatment while the other is a diagnostic centre. There is more variation in outpatient provision, especially in dental care. About 70 per cent of dentists are private providers and about 15 per cent provide services for direct payers only.³ Many have surgeries in the areas close to the Italian and Austrian borders and already treat patients from these countries, although exact numbers are difficult to establish.

Adoption of the *acquis* related to the 'four freedoms' (free movement of people, goods, capital, and services within the EU) will certainly enable and enhance the possi-

* Gorizia, Trieste and Udine Agreements between the Socialist Federative Republic of Yugoslavia and the Republic of Italy, 31 March 1955, Rome, Italy.

Box 1

FACTORS THAT SHOULD FACILITATE CROSS BORDER PROVISION OF HEALTHCARE SERVICES

1. **Positive past experience**
2. **Introduction of private provision of care and diversification of provision (supply side of reforms)**
 - (a) **Introduction of private provision per se**
 - (c) **Possibility of foreign investments in healthcare facilities, including joint ventures**
 - (d) **Marketing of services**
3. **Health insurance system and its modifications (demand side of reforms)**
4. **Potential for cross border division of responsibilities and treatments**
5. **European Union regulations for cross border movement of patients**

bility of foreign investors seeking opportunities in Slovenian healthcare, especially inpatient and rehabilitation services. Such processes will require a different approach to marketing health services.

The cross border movement of patients represents not only an opportunity but also a challenge to insurers. So far the health provision market has been controlled by various means, including rather well defined catchment areas. Insurers might have difficulty preventing the insured from seeking treatment abroad when facing long waiting lists at home, especially when treatments are of comparable price and quality.

Cross border cooperation and the division of responsibilities and treatments could help to manage competition. Certainly there are several important regional healthcare providers that could, with a rational approach, split the responsibilities and treatments amongst them. One of the consequences of this might be the professional development of highly trained and skilled health professionals in narrow, sub-specialist fields.

Within EU legislation the precise definition of cross border patient movement rights remains unclear in terms of reimbursement of patients from national health funds. Thus the wider implications of any such future decisions for cross border provision of care remain unknown. In spite of this, it remains important for Slovenia to know how to attract patients even when they are only partly reimbursed for the use of services abroad. If eventually there is full reimbursement across the EU, this will open the door to competition and the marketing of healthcare provision far beyond immediate neighbours.

“Patients from other countries should have full confidence that they will receive treatment at the highest level, compared to that provided by their own healthcare system.”

Box 2

CHALLENGES FOR CROSS BORDER PROVISION OF HEALTHCARE SERVICES

1. The need to enter accreditation and standardisation procedures with contracting countries
2. Competition as an external pressure on the internal market
3. Existing health care providers and their competence
4. Workforce mobility
5. Trends that could reduce international competitiveness
6. Foreign patients as competition to the local patients

“Following years of a tightly controlled medical workforce, Slovenia is beginning to experience a significant deficit of physicians.”

Challenges for cross border service provision

Slovenian hospitals will need to enter accreditation and standardisation procedures at the level of the EU. At that level, to date, there are no common accreditation procedures. A number of initiatives are looking at accreditation issues, such as work undertaken within the European Union of Medical Specialists (UEMS)⁴ and most current EU Member States have authorised national agencies for this purpose.⁵ Alternatively, such processes are possible at a bilateral level. Patients from other countries should have full confidence that they will receive treatment at the highest level, compared to that provided by their own healthcare system. The hosting country will have to be able to ensure this, although such a process could result in some hospitals not gaining accreditation.

Widespread cross border service provision will introduce challenges of competition for local healthcare providers and in the development of health policy and facility planning. Management of providers (in this case mostly regional hospitals) will need

different approaches in order to protect the interests of the community that they serve, while still enabling patients to move freely to different facilities. With the forthcoming internal challenges and opportunities given by the opening of borders, existing healthcare providers will need to re-think their strategies and seek to rationalise services and optimise inputs. Their competence will be valued on the basis of business excellence and adoption of other international standards.

Workforce mobility is a particularly interesting issue where Slovenia hopes to gain benefits. Following years of a tightly controlled medical workforce, it is beginning to experience a significant deficit of physicians: approximately 700 (17 per cent of the total medical workforce). Physicians' salaries have increased greatly in real value, too. Manpower costs now represent almost 60 per cent⁶ of hospital treatment costs, double that of 40 per cent in 1993.⁷ This increase is largely the result of industrial action by all health professionals which began about a decade ago, and subsequently pushed vigorously by physicians and dentists. It is estimated that the upper limit to manpower costs has been reached, as any further increases might endanger the funds dedicated to direct provision of healthcare and its material costs. Furthermore, these costs could push up the gross prices in healthcare delivery to such a degree that competitiveness with certain other neighbouring Member States (existing or future) might be lost.

Conclusions

To a candidate country, the accession process poses several opportunities and challenges in healthcare. Most of these must be addressed at national level. Public providers, still dominant in the provision of hospital care, will have to adopt new strategies to be able to compete successfully for patients. Specialities and services that have been successful at attracting foreign patients could serve as examples to others. Competitiveness might be hampered by the significant increase in workforce costs over recent years. Workforce mobility is one of the ongoing processes that have required regulatory measures in order to standardise professional proficiency criteria. International agreements on shared services will be necessary for the rational development of specialist in- and out-patient treatment. This is particularly true of sophisticated, tertiary-type care procedures, which require extensive investments.

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Movement of health professionals

Trends and enlargement



Sallie Nicholas

“In eastern Europe nursing associations are worried about retaining qualified nurses.”

When the candidate countries join the European Union (EU), they will sign up to legislation allowing free movement of health professionals and mutual recognition of their qualifications. What impact will this have on them and on the current Member States? Imminent enlargement has sparked debate among policy makers and opinion formers and seems to be acting as a catalyst for review.

The law

Shortages in the UK health workforce and the English Department of Health's international recruitment campaign have made free movement a news story during the last year, but the EU has always been about the free movement of goods, services and people. Those who signed the Treaty of Rome in 1957 committed themselves to the mutual recognition of qualifications. In 1975 two directives provided legislation for doctors, supplemented in 1986 by a further directive on specific training in general practice. All three were amalgamated in a single text in 1993. Similar directives followed for nurses in general care, dentists, midwives and pharmacists. These have been known as the “sectoral” directives, as they cover individual professions.¹

During the 1980s the approach changed. In 1989 Member States adopted a directive that set out a framework for the mutual recognition of qualifications involving three years or more of higher (18+) training. This covers those in regulated professions moving to countries where their professions are also recognised and regulated. Health professionals within its scope include specialist nurses, physiotherapists and clinical psychologists. This and a second directive for those with two or more years training are known as the ‘general system’ directives.²

The sectoral directives lay down a system based on mutual trust. Member States agree to recognise each other's qualifications,

provided they are listed in the relevant directive and as long as those holding them are EEA (European Economic Area) citizens. Training programmes in all Member States must meet minimum standards. Until recently, each was backed by an advisory committee to ensure the maintenance of comparable standards. The general system involves case-by-case scrutiny of applications for registration but with a built-in assumption that qualifications will normally be accepted. Aptitude tests or adaptation periods can be imposed in some circumstances. A coordinating group of one member per country monitors the system's operation.

Each system has advantages and disadvantages, but those with sectoral directives and advisory committees have fought hard to keep them. With enlargement looming, however, the Commission is looking for a system that will be simpler and cheaper to run and facilitate free movement. It has published a proposal for a single directive bringing together in one text both systems and all professions and abolishing the advisory committees.³

How much movement has there been?

While most available information is informal, anecdotal or based on UK registration data, the overall impression is of low migration levels. Much of the movement has been across neighbouring borders, probably influenced by cultural and linguistic factors. The UK has bucked the trend by taking in migrants from a wide range of countries. It also appears to be one of the smallest exporters, its migrating doctors mainly choosing other, anglophone destinations. The General Medical Council's figures show that the largest groups of European doctors registering in the UK are German, Greek, Irish, Italian and Spanish. EU registrations increased by 75 per cent between 1989 and 1997, peaked in 1996 and have been in gradual decline since. In dentistry, by contrast, numbers of EU registrations have continued to rise year by year.

Sallie Nicholas is Head of the International Department, British Medical Association. Email: snicholas@bma.org.uk

There are many factors influencing movement. Two of the most significant are language and labour market conditions. English is widely taught and increasingly considered the language of scientific discourse, giving the UK a wide base from which to recruit. Perhaps even more significant are levels of unemployment or underemployment in the health professions. There is no EU-level workforce planning and wide variations in national planning strategy. Where there is free movement, one country's over- or underproduction may distort, or relieve, the employment situation in others. In recent years, Germany, Spain and Italy have experienced high levels of medical unemployment and large numbers of their doctors have migrated to the UK. The Permanent Working Group of European Junior Doctors (PWG), has warned that this surplus may turn into a deficit,⁴ and there are signs that the trend is reversing in some countries.

Other significant factors include:

- Disparities in training – many consider the minimum standards to be too minimal, and the 'one size fits all' approach of the sectoral system fails to take account of different systems and career structures. Equally, the reputation of a particular country's training may prove an attraction.
- Bureaucracy – there is no centralised registration procedure and anecdotal evidence suggests that red tape may act as a barrier.
- Lack of comprehensive information and advice: for migrants about opportunities, and for registration bodies about other countries' training.

Income levels do not seem to have been a significant factor.

Impact of accession

The European Commission points out that "research in general suggests that there will be no dramatic increases in migration".⁵ It goes on to suggest that the main factors influencing migration will be the income gap between the countries concerned and the labour market situation in the country of destination. Other factors include geographical proximity, culture and language. The highest number of migrant workers would be expected to go to Germany, the second highest to Austria. The governments of these countries have taken the lead in enlargement negotiations by calling for transitional measures to delay the full application of free movement rules.

Recent studies have indicated that there is no oversupply of doctors in the candidate countries,⁶ and in eastern Europe nursing associations are worried about retaining qualified nurses.⁷ 'Brain drain' is a potential problem, and income gaps might be a significant factor. Talking to doctors from the candidate countries, however, one often hears the response "those who wanted to go have gone already." While anecdotal evidence suggests that England, Norway, Sweden, France and some parts of eastern Germany are already recruiting from some candidate countries, doctors' representatives at least do not seem to be expecting a seismic shift. And patients may also move. At a recent European meeting, one delegate referred to the large numbers of Austrians in border regions who go to Hungary for dental treatment – presumably because of the lower costs.

Those operating the general system expect little change in their workload post-accession. Because of the way in which the sectoral directives operate, far more detailed preparation is occurring in this area.

The Internal Market and Enlargement Directorates General, together with the Office for Technical Assistance and Information Exchange (TAIEX) have launched a major programme of 'expert mobilisation' whereby teams of experts from the professions concerned have been visiting the candidate countries. They report on progress in implementing the relevant *acquis communautaire*, action still needing to be taken and timetables for the latter. The scrutiny programme for health professions is very detailed and covers two main areas: training and practice of the profession.

Conclusions

Will there be overall winners or losers? There is a fierce debate raging about agriculture, where there is much to win or lose for many countries. The debate about the health care sector is somewhat lower key and most indications are that there will be no major changes. One doctor from a central European country suggested, however, that the candidate countries would gain from the general impetus to reform triggered by EU accession.

Enlargement is a challenge, because it will change the scale at which we all operate, but it offers an opportunity to reflect on experience so far, to identify what has worked well and what could be improved. If we use this opportunity to improve the system for everyone, we could all be winners.

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EU Accession

Implications for Poland's healthcare personnel

"Given the shortages of healthcare staff in many EU countries, a supplementary health workforce that does not incur education costs will be a key advantage for the EU15."



Monika Zajac

In 1999, 14.6 per cent of the total workforce in Poland was employed in the health sector.¹ The overall number of health professionals has decreased during the last four years and there are shortages among physicians and nurses in some specialities.^{2,3} The general situation is difficult for healthcare staff already affected by healthcare reforms launched in 1999. The adoption of the European Union (EU) *acquis communautaire* regulations ('*the acquis*') concerning health professionals, and the process of enlargement may pose further challenges, as well as benefits, for the health sector. This paper outlines the main changes made, or being made, in Polish legislation aimed at bringing the training and performance of health professionals into line with EU Council Directives, including the potential implications of the free movement of health professionals.

Alignment of Polish legislation with EU law

Throughout the twenty-nine 'negotiation areas' of *the acquis*, none is solely devoted to health. Rather, health related laws are found throughout. In the Polish negotiation papers, Ministry of Health responsibilities can be found in 11 different chapters and require 191 separate legal acts to be screened and/or revised.⁴

On 21 December 2001 Poland announced that it was closing negotiations with the EU under the chapter '*Free movement of persons*'. This meant that Poland had aligned its relevant laws on the issue of professional movement with those of the EU, including the free movement across borders of specified health professionals. At accession, EU citizens will have equal rights in the Polish labour market and Polish citizens will be entitled to employment in EU Member States after a flexible transition period.⁵ Transitional arrangements vary in particular countries from two years (with the possible extension of

another three years) to a maximum of seven years. Legislation now guarantees an automatic equalisation procedure for people with recognised qualifications from other EU Member States. A maximum of three months wait and automatic 'temporary' registration in the chamber of physicians will now be available to such health professionals. However, professionals with non-Polish qualifications will have to show that they are proficient in the Polish language at the level necessary to provide services.

Training programmes in Poland for most health professions already complied generally with EU standards. However, the exception was training for nurses, where major changes were implemented, expanding and upgrading training. In dental healthcare, Poland agreed to change the title of 'doctor of dentistry' to 'dentist'.

Implications of enlargement

The labour market

Future implications of accession for health professionals should be considered as a part of the global change in the labour market in Poland and the European Union. A recent analysis by Eurostat concludes that there has been no clear, common or consistent relationship between the changing patterns of population and labour stocks or immigration, and the accession of Greece, Spain and Portugal. There are concerns about the impact of the free movement of workers based on considerations such as geographical proximity, income differentials, unemployment rates and workers' propensity to migrate. Staff from Poland have already been sought by existing Member States with shortages. For example, palliative care and operating theatre nurses from Poland have been recruited by Italy and Germany, respectively.

Advantages and disadvantages of accession

The overall influence of the accession process can be discussed in terms of advantages and disadvantages for Poland and current EU Member State healthcare labour markets.

Monika Zajac is a public health specialist in Poland.

Email:
zajac_monika@hotmail.com

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| | POLAND | EUROPEAN UNION |
|----------------------|--|--|
| ADVANTAGES | The process of EU accession itself | Provision of highly qualified professionals with little cost |
| | Equal status with the EU labour market (following a transition period) | Supporting the EU labour market with professionally active human resources |
| | Upgrading education for nurses | Improved access to health services |
| | Increasing knowledge of international healthcare systems among health professionals | |
| | Revenue to national budgets from taxes and consumption paid by legally employed immigrants | |
| | Enhanced international collaboration and transfer of knowledge in both directions | |
| | Competition in the healthcare services market (quality improvement) | |
| DISADVANTAGES | Brain drain | Lowering of wages |
| | Competition in the healthcare market | Taking over EU citizens' job opportunities |
| | Taking position for which healthcare professional is overqualified | Increasing unemployment pressure in the EU15 |

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The process of EU accession has been very beneficial for Polish healthcare. It has forced a review of Polish health-related legislation and updated it, not only to European but to global standards. The new nurse training is the clearest example of this. However, the equal status of health professionals in the EU labour market (after a transition period) is seen as the major advantage. It will result in new career opportunities and qualification improvement. Moreover, returnees bringing skills to their home countries may positively affect the development of the health sector.*

Given the shortages of healthcare staff in many EU countries, a supplementary health workforce that does not incur education costs will be a key advantage for the EU15. Moreover, with newly created competition in the market, access to some services might be improved for the current EU Member State citizens. Benefits for both Poland and the EU15 include competition in the healthcare market leading to quality improvement and international collaboration and knowledge transfer.

* A survey by the International Organisation for Migration in 1998 revealed that only 7–26 per cent of potential migrants are interested in permanent emigration; 18–57 per cent of them would choose to work a few years abroad. Candidate countries located close to economic centres in the EU have a particular preference for short term work.

A major disadvantage for Poland is the potential 'brain drain' of health staff, particularly amongst both the youngest and more highly qualified nurses and doctors. Furthermore, there is a danger that Polish professionals might be employed at lower positions than those for which they are qualified. The inflow of doctors to Poland from other EU Member States might also become a problem (current estimates suggest that around eight per cent of physicians in Europe are unemployed).

Conclusions

As part of the accession process, Poland has made great progress in adopting the legislation of the EU. As a result of health related legislation, a number of practical changes have been made in areas such as nurse training, bringing benefits to the health system and assuring equal status for health professionals in the labour market of the enlarged Community. While there are concerns that professional migration to other Member States may result in the loss of some of the youngest and most highly trained healthcare staff in Poland, increased investment in Poland is already attracting back Polish health professionals working in other countries. With more effective mechanisms to support temporary movement amongst countries within the EU, and encouragement of the common development of high healthcare standards amongst all EU Member States, EU accession offers benefits both to candidate countries, such as Poland, and existing EU Member States.

What's the connection?

British nurse recruitment in an enlarged EU



James Buchan

The UK is not alone in facing nursing shortages, and like other developed countries it has become increasingly reliant on international recruitment of nurses to help solve staffing problems.¹ But recruitment to date has been largely from countries such as the Philippines, South Africa and Australia. Why has the UK not been more active in recruiting from Europe, and what are the implications for the candidate countries?

The importance of other countries as a source of 'new' nurses for the UK has increased significantly. In the early/mid 1990s about one in ten new nurses registered in the UK was from a non UK source; by 2000/01 this had risen to almost four in ten. This upward trend is likely to continue. An estimate for 2001/02 suggests that nearly half of new registrants will be from overseas.² Figure 1 shows the trend in the annual number of non-UK trained nurses accepted onto the UK nursing register. Without registration, a nurse cannot practice in the UK, so the data gives a broad indication of trends in nurses' inward mobility to the UK.

Applications to the UK

In 2000/2001 a total of 9,694 entrants were recorded in the Register as entering from overseas (provisional data); of these, 8403

(87 per cent) were from non-EU/EEA countries. The three most important source countries were the Philippines (3396), South Africa (1086) and Australia (1046). An estimate for 2001/02 suggests that these admissions will have increased further, to almost 15,000.²

The number of nurses from EU sources has plateaued. In the mid 1990s they accounted for between 25 per cent and 33 per cent of annual total overseas admissions, but by 2000/01 this had dropped to only 13 per cent. In 2000/01 the total number of nurses registering from *all* EU countries was 1291 – few more than from either Australia or South Africa, and far fewer than from the Philippines.

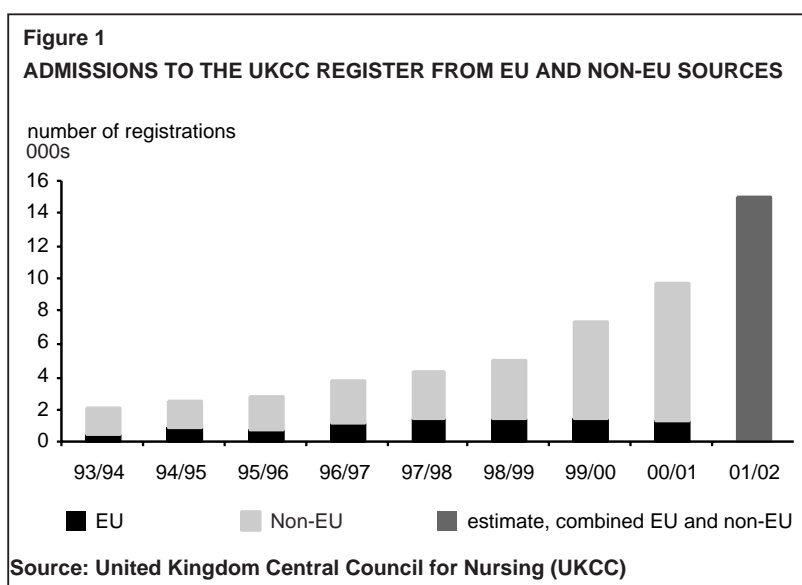
Despite the EU directives guaranteeing mutual recognition of nursing qualifications for first level registered nurses, relatively few EU based nurses have exercised this freedom to move to the UK, compared to the inflow of nurses from other countries (whose entry is complicated by the need to apply for a work permit).

Cross country initiative

One EU related initiative deserves some attention. The Department of Health in England has reached agreement with the Spanish Government to undertake structured recruitment of cohorts of Spanish nurses to designated NHS employers. Reportedly, Spain has a surplus of nurses, so there is an apparent 'win-win' situation.

Although initial projections were to recruit several thousand nurses from Spain, there is little sign of an inflow of this magnitude. Media coverage has suggested that some of the Spanish nurses already recruited to the UK have experienced language difficulties.³ Under EU law a language test cannot be applied to EU nationals, but it is reported that potential recruits from Spain will now be assessed on their language capabilities prior to travel to the UK. The UK nurse regulation council has also announced that all non-EU nurses (including those whose first language is English) will now have to pass a Standard English test administered by the British Council.⁴

While there is an increase in the number of



James Buchan is Professor of Health Care Employment Policy at Queen Margaret University College, Edinburgh. Email: JBuchan@QMUC.ac.uk

“Under EU law a language test cannot be applied to EU nationals.”

Spanish nurses registering in the UK as a result of the NHS recruitment initiative, the number of registrants from some other EU countries has fallen. For example, in the late 1990s some UK employers were active in recruiting Finnish nurses at a time when there was a relative oversupply of nurses in Finland. This situation has now adjusted, and the inflow from that country has reduced. The traditional flow of nurses from Ireland to the UK has not only ceased but also reversed as the Irish Government attempts to solve nursing shortages by recruiting in the UK and elsewhere.

Recruiting practice

The level of recruitment of nurses from some developing countries has caused controversy. In response, the Department of Health in England has published a Code of Practice on the recruitment and employment of international nurses.⁵ This Code covers issues of working with recruitment agencies, working in developing countries, advertising, fair recruitment, and English language proficiency. Whilst it will put pressure on NHS employers to comply with national policy, it is not intended to end the practice of international recruitment but to make it more effective.

Language is one key reason why the EU does not figure more prominently in the UK's international recruitment drive. The UK has tended to recruit from countries where English is the first language, primarily from other Commonwealth countries. There are insufficient 'pull factors' because pay, career opportunities and working conditions do not vary significantly across EU countries. 'Push factors' have been more important. Low standards of living in the Philippines, South Africa and the West Indies have been an incentive to leave; so too have cultural links such as the tradition

of young Australians visiting the UK for a year to explore Europe.

The accession states

Where do the accession states fit into this picture? Currently there are only small numbers of nurses moving to the UK from the candidate countries. Within the candidate countries nurses are generally paid much lower salaries and have more limited career opportunities than those in most EU countries and may be more motivated to move west. Additionally, the younger ones may have some English language capability. This suggests a potential for increased recruitment to the UK from these states once they have entered the EU.

Any growth in UK recruitment of nurses from candidate countries would be from current base of almost nil. It would have to overcome concerns about the adequacy of training in some of these states. Unless they are experiencing difficulties in recruiting from their current 'preferred providers' (such as the Philippines or Australia), it is unlikely that UK employers will invest heavily in opening up these new nursing labour markets in eastern Europe. It is more likely that UK employers would target individual qualified nurses with good English capabilities and advanced nursing skills. This is in contrast to the bulk recruitment from the Philippines, where a UK employer will recruit 50 or 100 nurses at a time.

Improving supply

The main policy message from this analysis is that the provision of an EU framework for freedom of movement of nurses does not necessarily mean that nurses will exercise that freedom. Other factors: language skills; cultural and post-colonial ties; and 'push/pull' imbalances are the main drivers. The short term needs the UK has in meeting NHS staffing targets is likely to continue to be an important dynamic in the interaction between the UK and international nursing labour markets. New UK government policy initiatives aimed at increasing the number of nursing students and improving retention and return rates should have a positive effect on supply, but the ageing of the UK nursing profession will lead to a growth in retirement of nurses, particularly from mid decade onward.⁶ This suggests that the UK will continue to be active in international nursing labour markets, and that there may be an increasing focus on some candidate countries as a source of small numbers of specialist nurses.

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Human resources in Maltese healthcare

Solutions for common needs



John Cachia

“The greatest challenge is to keep the health service attractive to its own professionals.”

In the long term, it is anticipated that joining the European Union (EU) will be very beneficial for Maltese healthcare staff. However, there are a number of short and medium term issues, which must be evaluated, assessed, quantified and remedied in the context of the country's health service. This is critical because the availability of appropriately trained and skilled human resources is the cornerstone for the delivery of healthcare services. Failure to act can also negatively affect further progress and development of healthcare services.

The benefits of enlargement

An immediate benefit of enlargement for Malta has been the review and subsequent revision of national registration and licensing procedures for healthcare staff to ensure that they are in line with EU directives. EU legislation covers regulation of professional qualifications, the definition of basic training programmes and specialist accreditation schemes, and the recognition of training institutions. In candidate countries such as Malta, undertaking this process has resulted in a deep soul searching exercise within all health professions and specialities to define clearly and transparently the competence and responsibilities of the various professionals within the healthcare team.

Another benefit for Malta was the consolidation of training programmes for healthcare professionals. The Department of Primary Care was set up at the University of Malta in 2000, which is organising training courses for primary care, so that formal vocational training for general practitioners can begin. Local public health training is being consolidated. Due to Malta's small size, we have always upheld a policy of exposing specialist trainees to a significant training period beyond our shores. Nearly all of our specialists have appropriate qualifications from EU countries.

In order to increase the professional profile of our nurses and paramedical staff the various hospital based schools of training were transformed into University of Malta programmes at Diploma and Degree level and has been upgraded to levels equivalent to EU standards. Moreover, postgraduate training and specialisation in health service

management and specialised fields such as adult and neonatal intensive care nursing, coronary care nursing and neurological rehabilitation is now also provided for Maltese health professionals.

Membership of the EU will also bring about significant changes in the working conditions of staff. The application of the EU Working Time Directive will require greater flexibility of health staff as average working hours are decreased. The main challenge will be to improve alignment of staffing requirements to service provision. At the same time, as a result of the directive staff can expect greater free time and it is likely that there will also be pressure to increase salaries to bring them closer to the EU average.

Malta has always been very active in international health, particularly within WHO and the Council of Europe. The accession process is also bringing benefits to Malta through wider international collaboration on health issues. Information exchange and collaboration are taking place through the European Commission, through several initiatives at the individual country level and through participation in non-governmental organisations, standing committees, and pan-European professional organisations and associations.

The challenges of enlargement

The EU accepted the negotiation position adopted by Malta concerning free movement of workers. Our concern was that the local labour market could come under pressure from a sudden influx of workers into the country. A safeguard clause, which will run for seven years, was accepted. There is however no barrier for Maltese professional staff to access jobs in other Member States.

Provisions have been taken to exempt persons already engaged in providing healthcare from EU rules governing the classification and registration of professionals (known as 'grandfather clauses').

Regulated professions impose stringent criteria on prospective trainees in the healthcare professions. It takes six to seven years to produce an accredited medical specialist. Enrolled nurses are becoming a rari-

John M Cachia is Director of the Department of Institutional Health, Ministry of Health, Malta.
Email: john.cachia@gov.mt

“The local labour market could come under pressure from a sudden influx of workers into the country.”

ty as we move to graduate nurses. In a situation of stiff competition for the same brainpower with other sectors of the economy, particularly information technology, business and financial services, the regulated professions may suddenly become less attractive to our youth, leading to an inability to recruit adequately.

In order to ascertain quality of training programmes, we have to apply benchmarks already widely available and applied in the EU. The approach towards attaining these benchmarks may pose problems for Malta which, owing to its size, can only have a limited postgraduate training programme. Our medical specialists undergo specialised training abroad at considerable personal expense and sacrifice. Quality requires well trained leaders and teachers supported by a solid infrastructure to provide clinical placements, bedside teaching and supervision. Implementing the EU benchmarking is likely to be very costly and will require considerable time for implementation.

Competition

The largest issue that candidate countries such as Malta will face is the competitive edge that EU Member States have in working conditions and salaries for healthcare staff compared to all candidate countries. There are lacunae in healthcare personnel, particularly nurses and doctors across the EU. Although population movement within the EU has been small and mainly restricted to border areas to date, this may cease to be so in an enlarged EU at least where healthcare is concerned. Better trained young professionals with poor or blocked career prospects may be attracted to move to other EU Member States. Losing the best professionals means that there is a lack of expertise to develop new, better and more advanced services. Another result will be lower quality healthcare and longer waiting lists.

Malta, like a number of other candidate countries, is also concerned about the implications of rulings of the European Court of Justice on the free movement of patients. It is not unrealistic to predict free movement of health services in the EU in the coming years. Candidate countries could be placed in a vicious circle: having to reimburse their citizens seeking services in other EU countries because of failure to develop their own services due to a loss of young motivated staff.

Future action

Healthcare is a reflection of the overall

development and economic status of a country. Beyond the absence of conflict and despite political stability, health frequently only becomes a policy priority when basic human needs such as adequate housing, safe food, water and sanitation, and education have been satisfactorily addressed.

Following the granting of Independence in 1964, Malta invested first in its human resources and in the 1980s and 1990s moved to develop more specialised services. A balance had to be struck between costs of referring patients abroad for treatment and developing specialised care locally, through investment in technology and challenging our staff to train and specialise further. As a small island state, it is more difficult to apply healthcare provision standards driven by economies of scale. The risk is under provision, rationing and inequality together with failure to attract and retain staff.

In candidate countries, the greatest challenge is to keep the health service attractive to its own professionals. Salaries cannot be drastically and suddenly increased. A phased and holistic approach to healthcare reorganisation and reform is necessary. Support staff such as care workers and clerical staff are vital so that nurses can focus on patient care. Specialised nurse training and extending the role of nurses in the healthcare team broaden nursing status and present nurses with fresh professional challenges.

For medical staff the introduction of new technologies at the local level can help them feel equal to their colleagues abroad. For some eminent professionals, a more attractive remuneration package has to be considered or else the country may run the risk of losing their services. Transition clauses negotiated by candidate countries for free movement of persons are only as long as it takes to train a healthcare professional: it is clear that we are operating within a very tight time frame.

EU Member States and candidate countries must strive to find solutions, which can be adapted to address common needs. It is important to meet, to share ideas, to exchange views and to learn from other countries' experiences. It is however the concerted action to which each individual must contribute, that will allow countries in an enlarged European Union to move quicker and together towards the integration of healthcare professions across Europe.

Border-crossing patients in the EU



Reinhard Busse

“Knowledge of the actual cross border movement of persons receiving healthcare services remains rather limited.”

Consumer choice for healthcare services across borders is a relatively new topic of research. Until 1998, attention focused on the free movement of persons and their potential healthcare needs when travelling to the ‘other side of the border’. This was particularly relevant for frontier workers who lived in one country but worked in another on a regular basis. But with the growing movement of workers from southern European countries to those further north, the issue of how to ensure their right to healthcare services while visiting their country of origin became an issue. The advent of mass tourism added a third group of persons to those in need of access to healthcare services in other countries.

It was with these groups in mind that, building on previous regulations as well as bi-lateral agreements, Regulation 1408/71 on the coordination of social security systems was passed. The original intention for Regulation 1408/71 was not to facilitate the free movement of services or goods but rather to facilitate the free movement of persons, more specifically that of workers. As the European Union (EU) is set to embark on its greatest enlargement to date, there is now additional interest in cross border provision of care.

EU legislation on cross border care

From its inception, Regulation 1408/71 also contained an element of the free movement of services, namely the procedure of pre-authorised care with the E112 form. Under this procedure, people cross national borders specifically to receive healthcare services in the other country. In economic terms, services are imported to the country which authorises the patient to go abroad while the country providing the service is exporting it.

The famous Kohll ruling (as well as the concurrent Decker ruling) first challenged and then changed the general perception: in brief, Raymond Kohll had argued that a

restriction of consumer choice for healthcare services across borders – under Regulation 1408/71 and the respective procedures in Luxembourg – would violate Articles 49 and 50 of the Treaty Establishing the Community which regulate the free movement of services. As this conflict was new, the Luxembourg court referred it to the European Court of Justice which agreed with the plaintiff’s interpretation of the Treaty, basing consumer choice of healthcare services across borders directly on the Treaty:

“The fact that national rules fall within the sphere of social security cannot exclude the application of Articles 59 and 60 of the Treaty. While Community law does not detract from the powers of the Member States to organise their social security systems, they must nevertheless comply with Community law when exercising those powers, i.e. the fact that a national measure may be consistent with a provision of secondary legislation, in this case Article 22 of Regulation 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty.”

Trends in cross border provision of care

Knowledge of the actual cross border movement of persons receiving healthcare services remains rather limited. In quantitative terms, it is mainly based on one study on the amounts and flows of financial transfers for cross border care within the EU,¹ which has been updated to 1998.²

According to these figures, the total amount for claims for reimbursement of cross border healthcare rose from €461 million in 1989 to €1103 million in 1993, but then fell to €894 million in 1997 and €758 million in 1998. In relation to public spending on healthcare in the European Union, these values are in the 0.1–0.2 per cent range of overall expenditure. The study carried out research into the flow of the three most important forms for cross

Reinhard Busse is Professor of Health Care Management at the Technische Universität Berlin. Email: rbusse@tu-berlin.de

border mobility: E106 (migrant workers), E111 (temporary stay, for example, tourism and business travel) and E112 (pre-authorized care). Pre-authorized care accounted for nearly 60 per cent of the total cost of cross border care, while the transfer for temporary stay and migrant workers were financially less important with 25 per cent and 16 per cent respectively of the total expenditure. In terms of the number of forms submitted the ranking was in reverse order. With a share of 53 per cent, the E106 form (migrant workers) was most applied, while E111 (temporary stay) accounted for 33 per cent and E112 (pre-authorized care) for only 14 per cent. Only nine per cent of the forms referred to hospital care.

“After the accession of new Member States, areas such as the Czech-German-Polish border region could become the focal point for new Euregios.”

Luxembourg consistently had the highest per capita expenditure for cross border care (€150 per capita in 1993; EU average €3) but this fell in line with the EU average after 1993. Other countries with above average expenditures are Belgium (up to €9), Italy (€8) and Portugal (€7). Low expenditure figures can be seen particularly in the Nordic countries with less than €1 per capita and year.² According to the same study, France is the main exporter of services (= importer of patients) with a share of over 40 per cent in 1993. It receives its money from the other Member States exclusively through invoiced credits, i.e. does not use lump sum payments. The latter method is, for example, favoured by Spain.

The EU candidate countries are faced with a dilemma: On the one hand, they could attract (especially private) patients by providing cheaper services, on the other hand their statutory health insurance systems might be in financial difficulties if they have to pay for treatments in the current Member States (which, due to the price differentials, are reluctant to sign waiver agreements).³

Improving access to care across borders

The Kohll and Decker rulings of the ECJ established, probably unintentionally, a new type of cross border access to healthcare in the EU. European citizens covered by a statutory social protection scheme in one country now have, in principle, three ways to receive healthcare services in another EEA country. However, consumer choice across borders remains quite restricted under the two main options provided by Regulation 1408/71, mainly as a result of administrative hurdles. The Regulation covers access to immediately necessary care during short term stays using the E111 form and pre-authorization to receive care in another Member State using the E112 form.

The new ‘Kohll/Decker’ procedure also has its limitations. One such potentially serious one is that direct payment is required and that a lower rate of reimbursement in the country of insurance affiliation may lead to a co-payment which would otherwise not arise (and which does not arise under the E111 and E112 procedures due to the benefit-in-kind principle). In addition, the range of available benefits is not only limited to those covered in the country of insurance, but is even limited to a subset of benefits, namely ambulatory services.

Two promising options to improve access to healthcare services across borders are therefore to ease the administrative procedures and to extend contracts for providing benefits-in-kind across borders. Both options have been and are used in certain border regions within the EU, most notably in the context of the ‘Euregios’. These are regions divided by borders between EU Member States which benefit from EU’s INTERREG initiative to improve their economic and social situation.

Euregios that have included health services arrangements in their activities include Meuse-Rhine (Belgium, Germany and the Netherlands), Rhine-Waal (Germany and the Netherlands), Scheldemond (Belgium and the Netherlands), Hainaut/Nord-Pas-de-Calais (Belgium and France), Schleswig/Südjylland (Denmark and Germany), Eems-Dollart and Rhine-Eems-Ijssel (Germany and the Netherlands).²

Classical examples of easing the administrative burden for patients can be found in the Euregios Scheldemond and Hainaut/Nord-Pas-de-Calais. In the for-

mer, a simplified E112 procedure using a form called 'E112+' was developed. This idea was then adapted in the latter region where an 'E112TF' form can be printed using the French insured person's *Vitale* card or the Belgian insured person's S/S card. Form E112TF is then filled out by the hospital where the insured person seeks treatment and is sent directly with the request for payment to a sickness fund in the country of the hospital.

All these activities, with the exception of Scheldemond, involve rather small numbers of patients, usually not exceeding a few hundred. Evaluation of their work reveals some, important lessons: firstly, waiting lists are cited as the major force contributing to cross border care which might become an even more relevant factor in the future.⁴ Secondly, proximity of the provider to the place of residence of the patient is another major factor stimulating cross border care.

Beyond the Euregios

The subject of easier access to healthcare services across borders is gaining increasing attention outside the Euregios. In Germany, the Working Group of Federal Associations of Sickness Funds, which comprises all groups of sickness funds, is urging the government to amend social legislation in order to allow German sickness funds to contract selectively providers in the EEA. The reasons for this are threefold. First of all, the sickness funds do not desire a 'Decker/Kohl solution' since this would entail the abolition of the benefit-in-kind principle. The benefit-in-kind principle establishes a close link between payers and providers not only on prices and volumes but also on quality.

The price issue is not of primary concern since reimbursement would be limited to the domestic level. And the volume issue does not matter much, since cross border care still occurs in rather small numbers. The quality issue seems to be more tricky because it assumes that quality abroad is lower than in Germany, an assumption which is difficult to base on evidence. The political reason for the contracting solution is to evade the collective contracts sickness funds hold with providers inside Germany. Provider associations, especially associations of physicians affiliated to statutory health insurance, would lose power if German sickness funds could contract providers abroad.

The Federal Chamber of Physicians (representing all physicians in Germany) is also

supporting a more liberal approach to cross border care according to a resolution ratified at the annual congregation in 2000. German physicians (or at least their representatives) do not seem to be afraid of cross border patient mobility. On the contrary, they seem to expect a net win since Germany has a very comprehensive healthcare basket and no severe capacity problem.

The first three British pilots of sending patients overseas confirm this hope: except for one French hospital, all EU providers treating British patients during the period 2001/02 were based in Germany.⁵ After the accession of new Member States, areas such as the Czech-German-Polish border region (around the divided town of Görlitz) could become the focal point for new Euregios. Candidate countries may also benefit from British patients if they provide good quality services at a lower cost than in Germany.

Accession therefore poses new challenges and opportunities for both current and new Member States. Before the likely effects can be predicted, however, better data on current movements, their financial implications and patient preferences are essential.

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"Consumer choice across borders remains quite restricted."

Health and safety in the workplace

Ensuring fair trade in the enlarged European Union



Alison Wright-Reid

“The Framework Directive makes no mention of enforcement, yet without policing, the law has no value.”

Within the EU15, failures of health and safety cost between 2.6 and 3.8 per cent of GNP.¹ Each year official accidents at work cause 6,000 deaths; the loss of around 150 million working days;² and injuries to around 150,000 people (sufficient to prevent employment in their chosen work). Work-related ill health is greater; one single example, asbestos, currently kills five times as many workers as all occupational accidents. In total, 500 million working days a year are lost to the EU as a consequence of poor health and safety.³

Why is health and safety legislation important?

In a perfectly free market, employers transfer most safety costs to their employees and society: they themselves bear only the costs of interrupted production. In practice, dangerous employers must offer higher wages to attract workers, but most costs are externalised. Employers in a free market have an economic advantage over those with responsibilities. Within the EU, fair trade requires that employers meet minimum health and safety standards, but any Member State wishing to set higher standards for its citizens may do so. Maximum standards apply to the safety and testing of equipment (CE marking) only, not to working conditions.

Until voting procedures in the Council changed from unanimity to qualified majority in 1986, there were few EU health and safety directives, and these could reflect awkward compromises made in the development of the legislation (for example, the multi-tier dose limits for noise). There are now about 30 directives, which still contain compromises to accommodate the differing safety systems in Member States (the French medical model; the UK's occupational hygiene model; Sweden's internal control model). Thus blended, EU

law assumes effective 'tripartism' (collaboration between government/experts, employers and employees) and usually sets objectives rather than detailed requirements. Dependence on objectives is partly philosophical, partly pragmatic: overly detailed legislation cannot keep pace with change. It is not universally popular because knowledge is necessary to work out what the law requires and whether such requirements have been met. Small and medium sized enterprises (SMEs) struggle with this style of law and would prefer to be told what to do.⁴

Health and safety in the candidate countries

Ten years ago, many candidate countries had surprisingly effective health and safety systems, but cuts in resources during transition often inflicted damage. While Malta and Cyprus have systems not dissimilar to those in the EU15, central and eastern European (CEE) countries typically had 'top-down' systems with trade unions functioning as inspectors (officials ensuring implementation of health and safety legislation). Often different ministries were responsible for managing occupational health and safety, with little cooperation between them. Managers were relatively powerless and employees were frequently conditioned to take neither initiative nor responsibility. Today new foreign owned enterprises typically offer safer working conditions, but tend to recruit a non-unionised workforce. Thus, in spite of support through twinning arrangements, tripartism is extremely weak in some candidate countries.

As to working conditions, protection of the environment came a poor second to employment. Monitoring of the working environment was sometimes manipulated to prove either that the safe standard was observed or that hazard pay was due; high levels of unemployment in some regions led to the acceptance of risk. Established practices persist and the proportion of

Alison Wright-Reid is a Health and Safety Consultant in the UK.
Email: alison.wright_reid@virgin.net

workplaces offering hazard pay ranges from 89 per cent in Bulgaria to 25 per cent in Hungary.⁵ Clearly, some trade unionists might have a stake in promoting, rather than preventing, dangerous working conditions as a means of improving workers' salaries.

Enlargement

The EU's preference for tripartism is no political whim: effective input from employers and employees makes for better law, greater commitment to it, and more effective implementation. In addition, effective trade union input to safety significantly lowers accident rates.⁶ Most candidate countries adopted the *acquis* without worker or employer input, and many have changed their law without changing their systems.

Some assume that EU Law is better, but pressure from new members, as well as SMEs, may provoke a reappraisal of the existing (low detail, high collaboration) legislation. The exclusion of the self employed is perhaps the most important deficiency in EU law. As the EU expands, there will be increasing need to remedy this as, overall, about 22 per cent of people working in candidate countries (33 per cent in Poland) are self employed, compared with 17 per cent in the Member States. This is doubly important as the self employed are more likely to be hurt at work. EU15 accident statistics exclude the self employed; their inclusion would increase the annual death toll from 6000 to 9000.

The Framework Directive makes no mention of enforcement, yet without policing, the law has no value and employees have no protection. It is hard to determine whether this is a problem because EU monitoring addresses only transposition and accident statistics (revealing more about reporting rates than compliance). However, equipment safety provides a useful example. A study of CE marked machines (marked to indicate conformity to EU safety standards) found that less than a sixth was properly marked or even safe.⁷ Criticisms have been made that some Member States fail to comply with the *acquis* which candidate countries are required to adopt upon accession. The EU intends to address compliance,³ but it is unclear how the small number of Commission staff will cope. Furthermore, the lead role is given to the Senior Labour Inspectors Committee – the only EU health and safety body which is not tripartite.

EU Law necessitates a different style of inspection than prescriptive law: employers and employees need detailed guidance and inspectors must consult them, along with experts. For the inspectors this will demand new attitudes, knowledge, skills and structures. The retraining demand is considerable and the 'reformed' inspectors have few suitably experienced colleagues from whom to seek advice.

Enforcement resource is also a challenge – even in some Member States. Romania has 1 inspector per 80,000 workers compared to 1:47,500 in Spain; about 1:10,000 in the UK, Denmark and Sweden; and 1:6,000 in Finland.³ While Commission employees are not inspectors, their numbers are clearly relevant to any discussion of EU legislation or compliance. It is, therefore, startling to discover that the Commission's Health and Safety Unit has dwindled to just 24. After enlargement there will be only one Commission professional per 10 million workers.

Whilst some candidate countries set out with reasonable safety challenges and compatible safety systems, most must compress thirty or more years of change into as many months, with fewer resources. If there is open, honest and meaningful evaluation of the safety performance of all the members of the enlarged EU, then each can learn from and support the others to the benefit of 225 million workers. Without it, the health and safety of workers is at risk.

“Overly detailed legislation cannot keep pace with change.”

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EU pharmaceutical policy

The challenges and opportunities of enlargement



Panos Kanavos

“Candidate countries argue that they are being treated more harshly than current Member States.”

In the longer term, eastward enlargement of the European Union presents considerable opportunities for pharmaceutical businesses and for consumers. However, there are also short term challenges, for the key stakeholders: Member States, candidate countries and the pharmaceutical industry. Intellectual property rights and regulatory issues are two areas that continue to be the subjects of intense negotiations. Despite considerable achievements, there remains much to do.

Intellectual property rights protection

Six aspects of intellectual property rights protection have been the subject of intense negotiations:

1. *Overall framework of intellectual property standards, particularly the patent type and the patent protection term:* The key principle is that intellectual property standards and their enforcement in the candidate countries must be compatible with the obligations of the European Union in relation to the World Trade Organisation Treaty on trade-related aspects of intellectual property rights (TRIPs). There has been significant progress in upgrading national legislation through negotiations with a number of candidate countries. Nevertheless, many pharmaceutical products due to be launched over the next few years in several candidate countries will have ‘process patents’ only, despite product patent protection having been introduced in all candidate countries. A process patent protects the process through which a specific product is derived, but not the final product itself, thereby allowing production of an identical product derived by a different manufacturing process.

2. *Supplementary protection certificates (SPCs), which effectively lengthen the period of patent protection beyond the original term:* Currently only Slovenia has this provision. The Czech Republic recently amended its patent legislation to include an SPC provision, and Poland will introduce SPCs once it becomes a full EU member.

3. *The application of ‘Bolar provision’ in several of the candidate countries:* Bolar provisions permit manufacturers of generic drugs to test their products before the

patent on the original product has expired (so-called on account of their elaboration in the Roche-Bolar case). Hungary has an explicit Bolar provision and Poland a prospective exemption; in Slovenia work on generics prior to patent expiry does not constitute patent infringement although there is no specific provision in law. The intensity of negotiations around SPCs and Bolar provisions reflect, in part, the pressures from industry. ‘Innovative’ industry in the EU favours strong patent protection with retrospective maximum duration SPCs and no Bolar exemptions. ‘Generic’ industry, which is especially strong in the majority of candidate countries, opposes SPCs and welcomes the freedom to conduct trials prior to patent expiry. The current policy direction suggests that candidate countries should all implement an SPC provision (but not one that is retro-active), but maintain Bolar provisions already in place. EU law does not include a Bolar provision, but several Member States have incorporated it in their national legislation.

4. *Regulatory data protection:* Regulatory data protection, whereby companies can keep confidential the information used to obtain marketing authorisation, is an issue of intense debate in the current round of accessions. An increasing number of eastern European countries are requiring publication of the full dossier of data used in marketing authorisations, before they have introduced a data exclusivity period. This leaves proprietary data vulnerable to copying without protection. An exclusivity period similar to that prevailing in the other Member States (six to ten years) seems to be the current consensus.

5. *‘Compulsory licensing’ and the ‘working’ of a patent:* Under compulsory licensing, a government can issue a licence for generic manufacture of a product in case of a public health emergency. National patent laws in each candidate country should be harmonised with the established TRIPs provisions that set out the circumstances when this is permitted. If a product is manufactured elsewhere and imported, this should be sufficient to prevent compulsory licences being granted to local companies.

6. *‘Parallel trade’:* Parallel trade, in which

Panos Kanavos is Harkness Fellow in Health Care Policy, 2001–2002 at Harvard University, Massachusetts.

products are imported from a low price country to a high price country to exploit price differentials, is an issue provoking great debate as part of the accession process but also on a global scale. Industry argues that accession of many relatively poor countries will, in principle, stimulate parallel imports from candidate countries to the high price Member States, thereby eroding companies' national market shares in the latter. Such fears may be exaggerated. Recent evidence from a WHO study suggests that price differentials between East and West actually may be minimal, and some prices may be higher in Eastern Europe.

Nonetheless, the Spanish and Portuguese experience has defined the current tough EU stance regarding candidate countries on this issue. On 3 March 2000, the Council of Ministers agreed to take a 'common position' whereby candidate countries should agree to provide a 'specific mechanism' under which the holder of a patent or SPC filed in a Member State at a time when a product patent or SPC could not be obtained in the candidate country, could rely on the rights granted by that patent or SPC to prevent the import and marketing of that product in the Member State where the product enjoys patent or SPC protection. This implies that a proprietary company could litigate to prevent the parallel trade of specific products patented in the EU, but not fully protected in the candidate countries at the time of accession; and candidate countries potentially agree to a free trade derogation, the duration of which is subject to intense negotiation.

Regulatory issues

The PERF initiative

In July 1999 the European Commission set up the Pan European Regulatory Forum (PERF) for regulators in both EU and candidate countries. This aims to bridge the cultural gap between east and west and promote good scientific practice by identifying practical arrangements for the implementation of EU pharmaceutical legislation ahead of the next enlargement. The formal agenda includes discussions of how a system of pharmacovigilance would work in an enlarged EU and how the candidate countries will assess quality, safety and efficacy in dossiers of human and veterinary products; implement EU directives for products already on their national markets; and make decisions on new products more transparent.

Dossier updates

Dossier updates have been a contentious issue in the accession talks. Pharmaceutical products must typically receive marketing authorisation every five years. Whilst this is not a problem for new products, it is a huge issue for existing products that received their marketing authorisation in the country of sale. This includes copy products, generics, and so on, which were licensed under national procedures that may have been considered inadequate. The Commission argues that candidate countries must make marketing authorisations for existing products comply with current EU law on the day of accession, or withdraw them from the market. The candidate countries claim the timetable for dossier updates is too tight and five have asked for a transitional arrangement (Cyprus to 2005, Slovenia and Malta to 2007, Poland and Lithuania to 2008). They also argue that they are being treated more harshly than current Member States that have had more time to conduct similar exercises.

A solution to the problem of updating pharmaceutical dossiers lies in EU Directive (99/83/EC) on 'well established medicinal use' which includes an abridged procedure for updating pharmaceutical dossiers. In principle, the Directive would enable regulators to use bibliographic references to satisfy requirements for pharmacological and toxicological information although a full quality dossier would still be required.

The EU centralised procedure in Eastern Europe

Since 1 January 1999, Eastern European regulatory agencies have been experimenting with an entirely new procedure for vetting medicines. It is an abbreviated form of the EU's centralised procedure involving the use of the European Medicines Evaluation Agency's (EMEA) scientific assessments to speed medicine approvals. The procedure is voluntary, initiated by the relevant company and has been implemented under an agreement among CADREAC agencies.* Between January 1999 and April 2000, CADREAC member agencies handled 211 procedures relating to 54 EU marketing authorisations: giving 130 positive decisions. For legal reasons, the agencies can issue only national marketing authorisations, but, significantly, the products generally have the same summary of product characteristics (SmPC) as those in the EU

As the abbreviated centralised procedure has worked so well, CADREAC is consid-

"Candidate countries' own pharmaceutical industries should profit from greater access to the enlarged EU market."

* CADREAC is the Collaboration Agreement between Drug Regulatory Authorities in European Union Associated Countries and consists of regulators from Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Cyprus and Turkey.

Table 1

STATUS OF REGULATORY AND INTELLECTUAL PROPERTY ISSUES IN CEE CANDIDATE COUNTRIES, 2002

| | REGULATORY ISSUES | | | | INTELLECTUAL PROPERTY ISSUES | | |
|------------|-------------------|--------|--------------------|------------------------|-------------------------------------|------------------|------------------------------|
| | Transparency | Delays | Fully EU compliant | Post-mktg surveillance | IPR* system compliant with treaties | SPC in operation | Bolar provision in operation |
| Czech Rep. | Yes | Yes | No | Yes | Yes | Yes | No |
| Estonia | Yes | No | Yes | Yes | — | — | — |
| Hungary | No | Yes | No | Yes | Yes | Yes | Yes |
| Latvia | Yes | Yes | No | Yes | Yes | — | — |
| Lithuania | Yes | No | Yes | Yes | No | No | — |
| Poland | No | Yes | No | No | No | No | Yes |
| Slovakia | No | Yes | No | Yes | No | Yes | Yes |
| Slovenia | Yes | No | No | Yes | No | Yes | Yes |
| Bulgaria | Yes | No | Yes | Yes | No | No | No |
| Romania | No | Yes | No | Yes | No | No | No |

* IPR = Intellectual Property Rights. — indicates not known or not available.

Source: Author's own research.

“The cost of new medicines may be disproportionate to the resources available in some candidate countries.”

ering extending the procedure to products approved before 1 January 1999. It is also looking at introducing a simplified system for vetting products approved in the EC under mutual recognition. In so doing, it would build on the experience of the Czech and Slovak Republics that have been running pilot mutual recognition projects since Spring 2000.

In anticipation of the enlargement, CADREAC is also trying to move toward common pharmacovigilance procedures, including how to format and deliver adverse drug reaction (ADR) reports and encourage more spontaneous ADR reporting.

The EU mutual recognition process in Eastern Europe

Support has also been given to a simplified procedure for reviewing pharmaceutical products approved through the EU's mutual recognition procedure (MRP). The simplified MRP could be applied to reviews of new chemical entities (NCEs) or to generics. Individual countries would decide how to use it, but many authorities are expected to seize the opportunity to speed up generic approvals. In a parallel move, the Slovak Republic launched its own pilot procedure for shortened MRP reviews on 1 April 2000. The Czech Republic started a pilot procedure in March 2000.

Within the EU, the MRP is the only way for generic companies to gain approval for

their products in more than one national market at a time. While CADREAC members broadly support the concept of simplifying regulatory reviews, there is concern in some agencies that multinationals could use the procedures to jump the regulatory queue.

Conclusions

Most, if not all, candidate countries have introduced legislation incorporating elements of the *acquis communautaire* on pharmaceuticals such as packaging, labelling, advertising, pharmacovigilance, inspections, GMP, GCP, transparency, and authorisation procedures. As the fields of intellectual property and regulation have demonstrated, there is still work to be done and the focus of both sides is in the detail. The proprietary industry is interested in achieving the highest possible protection standard in order to be able to sell its products in the new Member States. Candidate countries' own pharmaceutical industries should profit from greater access to the enlarged EU market. Patients should benefit from safe and efficacious products that meet EU-wide manufacturing and approval standards. However, as recent evidence suggests, the cost of new medicines may be disproportionate to the resources available in some candidate countries. If insurance systems do not, or only partly, reimburse certain expensive medicines, this will certainly create access problems for certain segments of the population.

NOTE

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Pharmaceutical policy

Lessons from Spanish accession



Manuel Lobato

“Parallel trade was a lucrative business for those involved with little, if any, gain to the end consumer.”

Spain joined the European Union (EU) in 1986. As part of the accession process a number of amendments were made to its pharmaceutical policies. This experience may offer lessons for candidate countries facing similar issues in their current negotiations and national health planning.

The necessity for reform

It was clear to all that Spanish legislation should be amended in order to match the standards of European Community Law. The steps to be taken for the protection of intellectual property (IP) were outlined by the Accession Act.

The Spanish position during the accession negotiations was extreme resistance to the introduction of tighter intellectual property protection. Spain wanted to exhaust all possibilities available to delay the implementation of a strong IP system based on EU legislation. This aim was fulfilled but it damaged both the image of Spain and accession negotiations on other issues such as agriculture and fisheries. As a result of the negotiations, Spain delayed the introduction of pharmaceutical, chemical and agrochemical product patent protection until October 1992. Supplementary Protection Certificate (SPC) legislation was not in place at EU level at the time of Spanish accession. However, when such SPC Regulation was approved to become part of EU law, Spain was granted a delay in implementing this legislation.

Impact of the new IP rules

The protection afforded by the 1986 Spanish patent law on medicines had a limited impact on the health system. Spain did not accept pipeline protection (retroactive patent protection afforded to old products). This meant that protection afforded by the new law did not extend to old products (which lacked the patentability requirement of novelty).

For new products, effective product patent protection was delayed until 7 October 1992 so only patent applications filed after this date could benefit from the new legal environment. However, new products filed at this date would not be available on the market until an average period of ten to twelve years had elapsed, so these patents

would appear in the Spanish market only after 2002. The Spanish National Health System will not finance many of these approved new products. The implementation of the Supplementary Certificate of Protection will have an even weaker effect. Although it came into force in January 1998, its real effects will not be felt until 2007 when it comes into force in Spain.

Pharmaceutical expenditure

Figures show that Spanish pharmaceutical expenditure increased continuously throughout the period 1982–2000. An obvious explanation for the rise in health care expenditure was the introduction of universal health care provision in the 1980s; the needs of the ageing population; and related costs of personnel and new premises. Another factor was the relatively high price of new drugs (drugs approved after Spanish accession to the EU), since they tended to be priced in line with other European countries.

The number of approved medicines was more or less constant in the years 1994–1998. Data from Farmindustria (the national trade body for the industry) shows that 8088 prescription and over-the-counter medicines were approved in 1994 and 8024 in 1998. In 1998, more than a fifth of total marketed medicines were new, since they had obtained their marketing authorisation in the previous five years. This situation had an obvious impact on prices, because new medicines were more expensive than older ones.^{1,2}

The proportion of publicly financed pharmaceutical expenditure as part of overall general public health expenditure rose from 15 per cent at the time of Spanish accession to 20 per cent by 1998.³ This is the highest in the EU. While relative price harmonisation for new approved medicines may explain the increase, it is remarkable that pharmaceutical expenditure as a proportion of overall national health expenditure is higher in Spain than in other Member States where full patent protection for medicines has been available for over twenty years. With roughly the same number of approved medicines there was a rise in overall pharmaceutical expenditure, in part because of the number of new medicines.

Manuel Lobato is Commercial Law Professor at the Universidad Autónoma de Madrid.
Email: mlobato@gomezacebo-pombo.com

“The exceptional lack of intellectual property protection in Spain did not help the Spanish national industry.”

“Mistrust of intellectual property is short sighted and incompatible with international obligations.”

Pharmaceutical law

Before 1986 the situation for the authorisation of medicines in Spain was unsatisfactory. The main regulatory provision was an administrative order (decree) of 1973, which, for obvious reasons, did not take account of EU Directive 65/65/EEC. This provision was very vague and allowed a considerable margin of discretion for health authorities dealing with pharmaceutical authorisation. There was no possibility of challenging a Health Administration decision, because courts held that they were unable to control technical decisions of the Administration. There was no data protection so many innovative products delayed launching in Spain, in order to avoid the disclosure of know-how.

As a result the Spanish market contained a mixture of original products; ‘me-too’ products (copies of original products, applied without the consent of the holder of the original authorisation, which were authorised by the Administration); false generics (copies with no proof of bioequivalence); licensed products; and others. This situation clearly posed problems for both consumers in terms of efficacy and safety and pharmaceutical developers and retailers.

The reform of Spanish pharmaceutical law began with the introduction of the EC Pharmaceutical Directives (Real Decreto 767/1993). The new legislation had consequences for the determination of prices (Transparency Directive), dossier data protection and other aspects. The new rules meant greater legal certainty for pharmaceutical producers as they limited the discretion of the national health authorities.

A particular complication of pharmaceutical law is that of parallel trade. Parallel trade refers to imports of medicines, within the European Economic Area, that happen without the authorisation of the holder of patents or other intellectual property rights related to these medicines. They are legal because they are supported by the principle of free movement of goods.

Parallel imports from Spain were prevented up until 7 October 1995. In fact, parallel trade to other European countries was harmful for the Spanish National Health System: in some cases medicines intended for the Spanish market were difficult to find as wholesalers diverted them to more profitable European markets. Parallel trade was a lucrative business for those involved with little, if any, gain to the end consumer in other states. The Spanish Authorities eventually realised that parallel imports

damaged the system and approved ‘double pricing’ for medicines in December 1999.

Consequences of Spanish policy

An obvious consequence of Spanish reservations towards strong intellectual property protection was research-based pharmaceutical companies’ unwillingness to invest in Spain. It was also clear that the exceptional lack of intellectual property protection in Spain did not help the Spanish national industry. Some existing industries disappeared, because their portfolios were poor, and there were new entrants in the market including foreign generics companies. Other companies had to change their policy. Many of them concentrated on generics (and copies), which was inefficient for the National Health System. While small and middle-sized companies concentrated on marketing, the most modern Spanish industries concentrated on licence agreements with the patent owners of original medicines. Doctors and pharmacists have faced difficulties keeping pace with the increasing number of approved medicines following accession.

A new approach

Spain now has a patent system in which all applications are fully examined regarding patent requirements (novelty, inventive activity, industrial application). This system is being established gradually and will be fully in place by December 2003. Since November 2001 Spain has been an International Preliminary Examination Authority in the PCT (Patent Cooperation Treaty, or ‘Washington Treaty’), and hopes to become the Reference Office for Spanish and Portuguese speaking countries.

Conclusions

Mistrust of intellectual property is short sighted and incompatible with international obligations, including EU Membership, the TRIPs Agreement (Trade Related Aspects of Intellectual Property Rights) and so on. Spain is a remarkable example of a State that showed clear reticence towards intellectual property protection, but has changed, because it did not obtain any profit from a situation of comparatively less protection than other European Member States.

The pharmaceutical field needs an environment of clear rules for marketing authorisations, data protection and prices. The harmonisation of such provisions is an essential part of the European integration process.

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Is EU accession always healthy?

Implications of EU accession for alcohol policy in Finland



Esa Österberg

“EU membership required Finland to abolish the comprehensive alcohol monopoly system.”

This paper examines the clash between EU free trade legislation and the protection of public health, specifically the issue of alcohol control in relation to Finland's accession process. Finland joined the EU in 1995 after preparations, which included the modification of Finland's strict alcohol legislation. The possible public health implications of these modifications to national legislation are described and discussed below.

Following the repeal of the Prohibition Act in 1932 the cornerstones of Finnish alcohol control were restricted physical availability of alcoholic beverages and enforced high alcohol taxes. Until 1995 the Finnish state alcohol monopoly, Alko, was a crucial part of the control machinery. It had a monopoly on the production, import, export, wholesale and retail sale of alcoholic beverages (defined as containing more than 2.8 per cent alcohol by volume). Alko also decided both off- and on-premises prices of alcoholic beverages.¹ The 1932 Alcohol Act allowed Alko to entrust private enterprises with beer and wine production and the serving of alcoholic beverages. However, Alko tightly controlled these activities as all licensed private alcohol producers and retailers were legally Alko's agents.

In 1968 Finland put in place new alcohol legislation that increased alcohol availability in a number of ways. The Medium Beer Act gave Alko the right to grant licences to ordinary grocery stores and cafés to sell beer containing less than 4.7 per cent alcohol by volume. Alko retained the power to set retail prices for medium beer as well as the profit margins for retailing the product. The 1968 Alcohol Act also allowed Alko to open liquor stores and licence all kinds of restaurants in rural municipalities. Age limits on buying alcoholic beverages off the premises were lowered.¹

The most important amendments between 1968 and 1995 concerned the introduction

of a total ban on alcohol advertising in 1977. From 1979 Alko closed its stores on Saturdays during the summer months. This policy was, however, discontinued in 1991. In the late 1980s and early 1990s increases in alcohol availability emerged. There were increases in the number of off- and on-premises outlets, the Alko stores changed from counter to self-service stores and the opening hours became longer in both Alko stores and licensed restaurants.

The 1994 Alcohol Act

In 1994 Finland participated in the European Economic Area (EEA). The new Finnish Alcohol Act (1994) was, for the most part, put in place as a reaction to the EEA agreement and for preparation for EU membership. It repealed alcohol monopolies on production, import, export, and wholesale. This was a direct outcome of the EU legislation under which quantitative restrictions on imports and exports, and all measures having an equivalent effect, are prohibited amongst Member States.¹ The 1994 Alcohol Act, however, left the monopoly almost intact on off-premises retail sale of alcoholic beverages.²

The Directive 92/83/EEC harmonises alcohol excise duty structures in the Member States by defining the products covered and how product categories should be taxed. It also defines the principles by which excise duty rates should be set. The Directive 92/84/EEC sets minimum excise duty rates for all alcoholic beverages and a target rate for distilled spirits but does not force countries with high alcohol taxation to lower their duty rates. The restructuring of the Finnish excise duty system in 1994, therefore, was realised so as to keep the average alcohol duty rates and alcohol prices constant while moving from value based alcohol taxes to excise duties based on alcohol content.²

EU membership increased travellers' allowances for duty free importation of alcoholic beverages with implementation delayed until 2004 (Table 1). These

Esa Österberg is Senior Researcher at the National Research and Development Centre for Welfare and Health, Finland. Email: esa.osterberg@stakes.fi

Table 1
TRAVELLERS' DUTY FREE ALLOWANCES OF ALCOHOLIC BEVERAGES
FROM OTHER EU MEMBER STATES IN FINLAND (litres)

| From | Distilled spirits | Intermediate products | Wine | Beer |
|-------------|-------------------|-----------------------|------|------|
| 1.1.1995 | 1 | or 3 | 5 | 15 |
| 1.1.1998 | 1 | 3 | 5 | 15 |
| 15 1.7.2000 | 1 | 3 | 5 | 24 |
| 24 1.1.2001 | 1 | 3 | 5 | 32 |
| 1.1.2003 | 1 | 3 | 5 | 64 |
| 1.1.2004 | 10 | 20 | 90 | 110 |

allowances have already put some pressure on alcohol excise duty levels.³ Thus far, excise duty rates for wine and intermediate products have been lowered by 17 per cent since the beginning of 1998. The 1999 abolition of tax free sales in the traffic between EU Member States has held down travellers' alcohol imports to some degree.

The 1994 Alcohol Act also included changes related to purely domestic interests. For instance, from the beginning of 1995, ordinary grocery stores, kiosks, gasoline stations and medium beer cafés could, for the first time, sell all alcoholic beverages produced by fermentation that were under 4.7 per cent alcohol by volume. From the same day the advertising of alcoholic beverages with an alcohol content between 1.2 and 22 per cent alcohol by volume was legalised.⁴

Alcohol consumption and EU membership

In 1994 total alcohol consumption in Finland (recorded and unrecorded) was

estimated at about 8 litres per capita. In 1995 it increased to 8.8 litres, mainly due to increases in travellers' alcohol imports. Since then unrecorded alcohol consumption has decreased somewhat while recorded alcohol consumption has increased to 7.4 litres giving an estimated total consumption figure of 9.2 litres alcohol per capita in 2001.

As there is a close connection between total alcohol consumption and alcohol related problems, it is likely that the increase of about 15 per cent in total alcohol consumption between 1994 and 2001 has contributed to the growth in alcohol related problems found. The number of violent crimes increased from 401 per 100,000 inhabitants in 1994 to 548 in 2000. From 1994 to 1999 deaths due to alcohol related liver cirrhosis increased from 8.1 to 9.9 per 100,000 inhabitants and the total number of deaths from alcohol related illnesses increased from 14.5 to 20.3 per 100,000 inhabitants.^{5,6} It is anticipated that the increase in travellers' duty free allowances to the common EU level, in connection with Estonia becoming a member of the EU, will further increase both total alcohol consumption and alcohol related problems. Figures up to 20 and 30 per cent have been suggested. Alcohol prices in Estonia are on average about half, for vodka only one third, of the Finnish prices. Travel between the Finnish and Estonian capitals takes only two hours by ferry, and the majority of Finns live in the southern part of Finland, near the capital city, Helsinki.

Conclusions

Since the 1950s there has been a more or less continuous trend of reduced alcohol control in Finland. Even in the mid-1990s domestic factors affected alcohol control legislation as the 1994 Alcohol Act also included liberalisations that were not required by the EU. Yet the 1994 Alcohol Act was enacted specifically because of EU membership, and which thus opened the field and gave different domestic actors the possibility to change all kinds of alcohol regulations. EU membership required Finland to abolish the comprehensive alcohol monopoly system and to relax the policy concerning travellers' duty free alcohol imports. These changes were a direct outcome of the EU membership because Finland had wanted to abolish the monopoly system more gradually and indeed received a derogation with regard to travellers' import quotas on alcoholic beverages.

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Free trade v. the protection of health

How will EU accession influence tobacco control in Poland?



Anna Gilmore



Witold Zatonski

Smoking prevalence in Central and Eastern Europe (CEE) has traditionally been high, particularly among men, but the entry of the tobacco multinationals in the early 1990s with their aggressive marketing campaigns propelled levels still higher.¹ Male smoking rates are now amongst the highest in the world and the rates for women and young people are rising rapidly.

The health impacts of this tobacco use are devastating. Tobacco is the single largest cause of avoidable death in the region and lung cancer rates, which provide the best indication of the health impact of tobacco, have reached higher levels in CEE than ever observed in the West.²

Tobacco control and accession

Despite pressure from the tobacco multinationals, the Polish government has enacted comprehensive tobacco control legislation. A 1995 law included bans on television, radio and some print advertising, smokeless tobacco, sales to minors, vending machines and smoking in workplaces and required health warnings to cover 30 per cent of the cigarette pack. In 1999, the regulations were strengthened, most notably with a comprehensive ban on advertising and sponsorship. Smoking rates are now declining and health indicators improving.³

European Union (EU) tobacco control legislation covers a number of areas⁴ (Table 1) including advertising, taxation and labelling, but following the annulment of the 1998 Advertising Directive, is less comprehensive than the Polish legislation described above.

If Poland joins the EU, it will have to sign up to the *Acquis*, the body of European legislation, and in areas where European

law exists, it will take precedence over national law. The question arises therefore, will accession to the EU complement or compromise Polish tobacco control?

Tobacco subsidies

Although EU subsidies have been widely criticised and described by the European Court of Auditors as “a misuse of public funds”⁵ Polish tobacco farmers have used the subsidies to argue their own need for funding and their government, keen to gain the farmers’ support for EU accession, obliged. Tobacco subsidies, previously unknown in Poland, were introduced two years ago and already account for a greater proportion of the state budget than the tobacco control programme.

It is unclear what will happen to the Common Agricultural Policy (CAP) with accession but the option of extending current subsidies to the more agriculturally orientated candidate countries is unaffordable and it seems inevitable therefore that the policy will be reformed. The Commission recently produced a Communication on sustainable development in preparation for this year’s World Summit, which recommended a phasing out of tobacco subsidies and the identification of alternate sources of income and economic activity for tobacco workers and growers.⁶ With the CAP due for review in 2003 and pressure from the World Trade Organisation for reform, an end to tobacco subsidies may finally be possible.

Tobacco advertising

A comprehensive EU ban on direct and indirect tobacco advertising and sponsorship was passed in 1998 but following a challenge by the German Government and four British tobacco companies, was annulled in October 2000 in the European Court of Justice (ECJ). The Advocate General’s opinion⁷ and the subsequent Court ruling⁸ concluded that the Directive had exceeded its legal base as an internal market measure: it did not facilitate trade but prohibited it, to an extent disproportionate to that needed to ensure the proper functioning of the internal market. It was also noted that, partly due to the so called

Anna Gilmore is Research Fellow at the European Centre on Health of Societies in Transition, London School of Hygiene and Tropical Medicine. Email: anna.gilmore@lshtm.ac.uk

Witold Zatonski is Professor of Medicine in the Department of Cancer Epidemiology and Prevention, M. Skłodowska-Curie Memorial Cancer Centre and Institute of Oncology, Warsaw. Email: zatonskiw@coi.waw.pl

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“Tobacco subsidies already account for a greater proportion of the state budget than the tobacco control programme.”

safeguard clause, which allows Member States to introduce their own more stringent legislation, that the Directive neither harmonised national rules nor removed distortions of competition.

This ruling has led the Commission to draft a much weakened directive which only bans cross border promotions, namely advertising (via print media, radio and internet) and sponsorship, but does not restrict indirect advertising. It also omits the safeguard clause which some argue will have little impact, as cover is provided by other clauses in the Treaty*. Others however fear that it will leave member states vulnerable to challenge for having or (as is more likely) attempting to introduce more

stringent advertising bans. Theoretically at least, candidate countries could face similar problems when attempting to accede. And, should Poland have to defend its legislation, the ECJ ruling on the tobacco advertising ban, by highlighting the subordinate nature of public health to trade in the EU treaties, suggests that arguments over the health impact of tobacco will hold little weight.

If the revised Directive fails, only the 1989 ban on television advertising will stand (see Table 1), leaving Member States free to enact their own legislation in areas other than television advertising. Whilst this would safeguard Polish legislation, it would leave Poland, as a member of the EU, powerless to prevent the entry of products bearing tobacco advertising from other Member States.

Tobacco regulation

The 2001 Tobacco Products Directive includes maximum tar yields; greatly enlarged warnings covering 30 per cent of the front surface and 40 per cent of the back surface of each pack; the disclosure of ingredients and additives and a ban on misleading product descriptions such as ‘light’ or ‘mild’. The size of the health warnings specified in the 2001 Directive was based on Polish warnings so that these would not be jeopardised when Poland accedes and the other measures in the Directive, in particular the ban on product descriptors, would strengthen Polish tobacco control.

The British Tobacco Manufacturers Association and the German Government have challenged the Directive along similar lines to the advertising ban challenge and a separate challenge is being mounted by Japan Tobacco International. If the Directive falls, the 1989 and 1992 Directives specifying warnings of at least four per cent would stand. Unlike the 1998 Advertising Directive, these Directives do not contain a safeguard clause and the large Polish warnings would therefore be threatened. In such a situation, even if Poland were to succeed in keeping its warnings, the import of cigarettes with smaller health warnings would indirectly threaten Polish

* Although other treaty clauses confer almost the same protection on Member States as the safeguard clause, there are slight differences. Article 95(4) refers to the right to maintain existing legislation (not introduce it) and Article 30 permits health protection measures which are not the subject of an existing directive as long as they are proportionate.

Table 1

PRINCIPAL EU TOBACCO CONTROL DIRECTIVES

| Directive No. (Active Directives in bold) | Provisions |
|--|---|
| Labelling Directives (& Smokeless Tobacco), 1989,1992 | |
| 89/622/EEC | Tar and nicotine yield to be printed on side of packet so four per cent of packet covered. Health warning to cover at least 4 per cent of pack front. |
| 92/41/EEC | Amended Directive 89/662 by introducing warnings for packaging of tobacco products other than cigarettes and banning the marketing of certain tobacco products for oral use. |
| Advertising Directive, 1989 | |
| 89/552/EEC (minor amendments made by Directive 97/36/EC) | Bans on all forms of television advertising for tobacco products. |
| Tar Yield Directive, 1990 | |
| 90/239/EEC | Sets a maximum tar yield of 15mg per cigarette by 31st December 1992 and 12mg per cigarette from 31st December 1997. |
| Tax Directives, 1992, 1995 &1999 | |
| 92/78/EEC 92/79/EEC 92/80/EEC 95/59/EEC 99/81/EC (amends earlier Tax Directives) | Set minimum levels of duty on cigarettes and tobacco. Requires an overall excise duty (specific and ad valorem combined) of at least 57 per cent of the final retail selling price of the price category most in demand, plus a VAT rate of 13.04 per cent. |
| Tobacco Advertising and Sponsorship Directive, 1998 | |
| 98/43/EC Annulled October 2000 | A comprehensive ban on tobacco advertising and sponsorship. |
| Tobacco Products Directive, 2001 | |
| 2001/37/EC (replaces 89/662/EEC, 92/41/EEC & 90/239/EEC) | Specifies a reduction in tar yield from 12 to 10mg, nicotine and carbon monoxide limits, health warnings to cover 30 per cent of the pack front, additive and ingredient disclosure, a ban on misleading product descriptors such as ‘light’ and ‘mild’. Currently being challenged in the European Court of Justice. |

tobacco control.

Preliminary results are however hopeful. The Advocate General recently found that the directive was valid and whilst the European Court of Justice ruling is awaited, it is likely to follow the Advocate General's opinion.

Taxation

The position on taxation appears more straightforward. EU Directives specify a minimum taxation rate of 70 per cent. This comprises an overall excise duty of at least 57 per cent plus 13.04 per cent VAT. The Polish government has been steadily making increases in taxation, partly in anticipation of accession and estimates that total excise taxes currently constitute 46 per cent of cigarette price and VAT stands at 22 per cent. Thus whilst accession would require at least an 11 per cent rise in excise tax, it would allow a drop in VAT of nine per cent. With income increasing in Poland, the two per cent overall increase in taxation required, could pass largely unnoticed. Nevertheless, as a result of industry pressure, a temporary delay in tax harmonisation has been granted.

Discussion

This brief overview illustrates not only that EU accession presents both opportunities and threats to tobacco control in Poland but that the situation regarding tobacco control is complex and uncertain. Once the new Advertising Directive is passed or rejected and the challenges to the Products Directive resolved, the situation will become much clearer. At present however, the threats outweigh the opportunities as the only certain advantage to Polish tobacco control is a small (and delayed) increase in tobacco taxation.

The Tobacco Products Directive, if it holds, will also offer benefits, particularly in its important ban on misleading descriptors. However, if overturned it could threaten the Polish health warnings. A further concern, and one the EU could still address, is the omission of the safeguard clause in the current draft of the revised Advertising Directive.

Two overall principles are clear. First, the need for effective supranational tobacco control policies. Not only would the import of cigarettes with smaller health warnings or products bearing advertising undermine Polish tobacco control, they would enable Polish manufacturers to argue that national legislation should be

weakened in order to ensure fair competition. Second, the EU is above all an economic entity where trade trumps health. Real reassurance to Poland and other candidate countries that value their public health legislation can only be achieved by giving public health a greater status in the EU treaties. There is a growing movement to have such treaty changes considered at the 2004 Inter Governmental Conference on treaty revision. In the meantime, Poland will have to monitor carefully the progress of the Advertising and Tobacco Products Directives and be prepared to negotiate its case if it wishes to retain its comprehensive tobacco control legislation. It should also ensure its voice is heard at the upcoming and final negotiations for the WHO's Framework Convention on Tobacco Control (FCTC), an international tobacco control treaty that is currently being negotiated.⁹ Understandably, political pressure is driving the accession countries to tow the EU line, a line that seems set to undermine the FCTC. Yet, if a strong FCTC (including for example a comprehensive advertising ban) is agreed and signed by the EU, it could be the very thing needed to protect Poland from the risks that accession poses to its tobacco control laws.

"The EU is above all an economic entity and trade trumps public health at every turn."

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Implementing EU tobacco legislation in Bulgaria



Evgenia Delcheva

Challenges and opportunities

The implementation of effective legislation and successful regulation of smoking prevention and reduction are important targets for a country with one of the highest rates of smoking in Europe. Progress in adopting tobacco related EU legislation is central to the strategy to reduce tobacco use.

High levels of smoking

Over 35 per cent of the Bulgarian adult population are smokers.¹ This contrasts with the overall decrease in smoker numbers in the EU (Figure 1).

Men smoke more than women (Figure 2), while among young people aged 15–24 years, the number of smokers has risen from 38.8 per cent in 1996 to 41.3 per cent in 2001.

Such increases in smoking are reflected in the national health indicators. Since 1980 there has been a 20 per cent increase in lung cancer cases, of whom more than 90 per cent of the men and 20 per cent of the women are smokers. It is estimated that smoking is responsible, directly or indirectly, for 21.6 per cent of general mortality in the country. Rapid introduction of anti-smoking legislation is therefore one of the key public health measures for Bulgaria.

Challenges

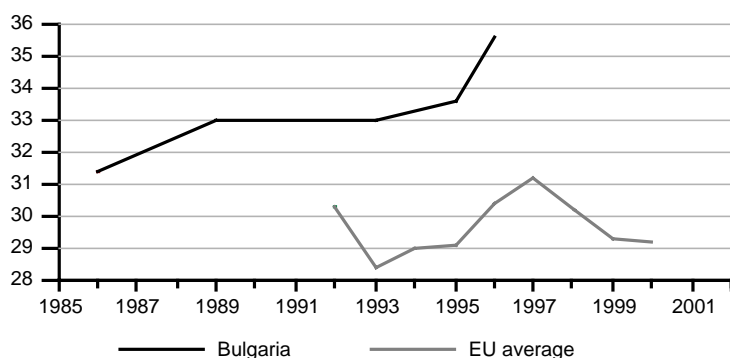
Bulgaria faces considerable challenges in passing EU health legislation, especially tobacco control directives. Aside from widespread smoking and anticipated resistance to stricter legislation, there is the economic importance of tobacco production. A key challenge is the poor standard of living and social instability of the population in the current period of economic transition. Bulgaria has one of the highest unemployment rates of the candidate countries, at 16–19 per cent in the last five to six years. Poorer people smoke more of the cheapest cigarettes that have the highest nicotine and tar yield. This sector of the population would be very resistant to enhanced tobacco controls, such as increases in prices, that are likely to arise as part of EU accession.

Another related challenge is the experience of failure in implementing national anti-tobacco legislation and anti-smoking campaigns over the last decade. Although Bulgaria has a several pieces of tobacco control legislation already in force,

Figure 1

SMOKING TRENDS IN BULGARIA AND THE EU

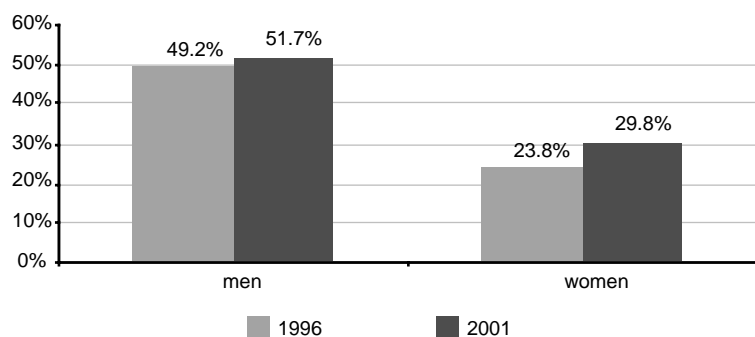
% of regular daily smokers, age 15+ years



Source: WHO HFA database, 2002

Figure 2

BULGARIAN SMOKERS BY SEX



Source: Survey of Health Status of the Bulgarian Population, NSI, March 2001

Evgenia Delcheva is Head of the Department of Financial & Economic Analysis and Prognosis at the National Health Insurance Fund in Sofia, Bulgaria and Associated Professor of Health Economics at the University of National and World Economy, Sofia, Bulgaria.

implementation of these laws has been less than satisfactory. In 2002 the Ministry of Health concluded that the anti-tobacco legislation and anti-smoking campaigns had been a failure and that more effective tools and policies were needed.

The importance of local tobacco production as a traditional and lucrative sector of the Bulgarian economy is a serious challenge to the rapid implementation of tobacco legislation. Bulgaria produces about 0.5–0.7 per cent of world tobacco. Since 1990 the tobacco sector in Bulgaria has been in recession: tobacco output in 2000 to 2001 fell 20 per cent on the previous year.² The collapse of former socialist markets, oversupply and international pressure against smoking have contributed to the worsening market. Bulgarian tobacco producers have sought a delay in the implementation of some parts of EU legislation until 2011. A transition period for legislation concerning the maximum tar yield of cigarettes and other products has been requested.

The Bulgarian Government has paid particular attention to stabilising the tobacco sector and improving its trade balance. In 2002, the privatisation of the leading tobacco producer in Bulgaria (currently state owned Bulgartabac Holding AD) will transfer about 80 per cent of tobacco production to the private sector. As a result, there will be a greater focus on profit and increasing sales.

Another challenge for implementing EU tobacco control directives in Bulgaria is perceived resource insufficiency to adapt local procedures necessary to support the new legislation. In particular, the state needs additional time and resources to put in place and establish monitoring for international standards (ISO): ISO 4387 for tar yields, ISO 10315 for nicotine yields, ISO 8454 for carbon monoxide yields and ISO 8243 for verification.

Progress

Despite the challenges outlined above, according to the 2001 Accession Report,³ Bulgaria has been making good progress in adopting health and agriculture related EU legislation as a whole. Over the last two years Bulgaria has made a great advance in tobacco control and the adoption of relevant EU legislation. In October 2000, the Bulgarian National Health Care Strategy 2001–2010 was launched. This includes strategic objectives, targets and interventions for the reduction of smoking.

Table 1
BULGARIAN COMPLIANCE WITH EU TOBACCO LEGISLATION

| LEGISLATION | PROGRESS IN IMPLEMENTATION |
|--|--|
| Labelling Directives (& Smokeless Tobacco) 1989,1992 89/622/EEC & 92/41/EEC | Transposed into Bulgarian law with the adoption of Government Directive (Requirements for Labels, Contents and Labelling on Consumer Tobacco Products Package) (26 October 2000, in force since 1 January 2001). |
| Advertising Directives 1989, 1997,1998 89/552/EEC & 97/36/EEC | Most advertising issues addressed by the 1997 changes in the 1973 Act of Public Health and through the 1998 Radio and Television Act which prohibits the advertising of tobacco products on the radio and television, near children and educational establishments or in ways encouraging smoking by the young. Since 2000 with the last changes in the Tobacco and Tobacco Products Act the advertising of tobacco products is banned outside factories, where tobacco is manufactured, and outside tobacco shops. The issues on sponsorship by tobacco companies have not yet been addressed. |
| Tar Yield Directive 1990 90/239/EEC | Not yet transposed into Bulgarian legislation but some local producers apply the tar yield to most brand name cigarettes. However, local producers want a transition period for EU legislation related to the maximum tar yield of cigarettes and other products. |
| Taxation on Manufactured Tobacco Directives 1992, 1995, 1999 92/79/EEC, 92/80/EEC, 95/59/EEC, 1999/81/EEC | The mechanism of taxation of cigarettes with excise duty is close to Directive 92/79/EEC. The mechanism for taxation of tobacco products with excise duty, with the exception of cigarettes, is in line with Directive 92/80/. Some recent amendments in the Excise Act are close to the requirements of Council Directive 95/59/ and Directive 99/81/EC. Overall minimum excise duties for cigars, cigarillos and tobacco-pipes, tobacco for chewing and sniffing are in line. The taxation on cigarettes is less than EU minimal norms. The structure of the excise duties on cigarettes is contrary to the <i>acquis</i> as it provides different duty rates for filter and non-filter cigarettes. The retail prices of tobacco products are cheaper than EU minimum levels outlined. |
| Resolutions on Smoking in Public Places 1989, 1996 | With the changes in the Act of Public Health, voted in 1997, the smoking in offices with non-smokers is now prohibited, and smoking in public places is allowed only accruing to a Regulation Note of the Ministry of Health. |
| Tobacco Regulation Directive 2001 2001/37/EEC | Requirements for the labelling, setting of lower maximum tar and nicotine yields in cigarettes and for the first time a maximum carbon monoxide yield have not yet been finalised. The Ministry of Health will prepare an amendment to the Government Directive (Requirements for Labels, Contents and Labelling on Consumer Tobacco Products Package) in 2002–2003. |

In further support of this, parliament passed 'A National Programme for Reduction of Smoking 2002–2005' in January 2002.⁴ This included a number of institutional, legislative, price and organisational changes, aiming at better coordination of anti-tobacco measures. Support for the WHO's proposed Tobacco Convention is being given.

In the last few years the government has been active in developing new tobacco control legislation or adopting EU tobacco control related sections of the *acquis communautaire*. A summary of the progress made in adopting EU tobacco legislation is given in Table 1.

Conclusions

The trends in smoking prevalence in Bulgaria highlight the need for a rapid implementation of EU anti-smoking legislation and a targeted and more effective approach towards smoking prevention. The popularity of tobacco, the importance of tobacco to the economy and resistance to

control by private producers are among the serious challenges to effective tobacco control in Bulgaria. Over recent years, however, Bulgaria has made efforts to develop strategies to tackle these problems and put in place related EU legislation. The next challenge for Bulgaria, together with other candidate countries and Member States, is to focus on the implementation and enforcement of these laws.

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Health and support for EU accession

Phare and other initiatives



Magdalene Rosenmöller

At the end of the 1980s the breakdown of communism set off a transition process of unprecedented extent. This paper examines the support given to the complex transition and accession process in central and eastern Europe (CEE) focusing on the health sector.

In retrospect the breakdown of communism was unavoidable, but at the time (1989) was so sudden that the development agencies were taken by surprise. Very soon, however, development assistance was largely orientated to making transition irreversible by fostering democracy and a free market economy. Health system reforms

undertaken in the adverse context of the wider political and economic transition had to compete for attention at national level and for the necessary external technical assistance and investment support.

EU Phare

The European Commission was quick to launch the Phare programme in 1989. Phare originally stood for 'Poland Hungary Assistance for the Reconstruction of the Economy' and, as the French word 'phare' (lighthouse) indicates, was meant to be a sign of hope, a light in the storm. The Phare programme became the single most important source of assistance to the candidate countries. In 1999 it accounted for 36 per cent of total development assistance to CEE.¹

Magdalene Rosenmöller is a Lecturer at the IESE Business School in Barcelona and Madrid.

At a time when enlargement was only an incipient vision, Phare responded to the most urgent needs in the transition process. For the first half of the 1990s funding was 'demand driven', aimed at system development and knowledge transfer. From 1990 to 1998 Phare committed a total of €105 million to the health sector in CEE, supporting health system projects such as sustainable financing, hospital management, primary care development, information systems, pharmaceutical sector regulation, and human resource management.

At the 1993 Copenhagen summit the basis of accession was laid out, prompting the redefinition and subsequent reorganisation (1995) of the Phare programme. At that point it became 'accession driven', a tool to support countries in their preparations for joining the European Union. The key focus was on transposing the *acquis communautaire* into national legislation. Phare concentrated on the development of institutional capacity and infrastructure investments, increasingly using twinning arrangements (between similar institutions in candidate countries and EU Member States). Twinning fostered the adoption of health related *acquis* such as occupational health and phyto-sanitary control. Additionally Phare supported the participation of candidate countries in EU public health and research programmes.

Because health care is not a competence at Community level and thus not a central issue in the accession process, effective Phare health sector support was discontinued. Funds devoted to the sector dropped from three per cent of the total Phare budget in 1990 to 0.5 per cent in 1998, while the need for technical and investment assistance in the health sector remained high.²

Other international support

In 1991 the EU established the European Bank for Reconstruction and Development (EBRD) with a mandate to facilitate the development of a market economy in CEE. It became the largest single investor in the region, investing a total of €9 billion during the 1990s. Although no direct support was granted to the health sector, the EBRD played an important indirect role by improving the overall economic context for the operation of health systems.

The World Bank has also played an important role in supporting health reform in CEE.³ Besides the provision of vital technical analysis at the beginning of the

transition, the World Bank lent an overall US\$561 million supporting health services development; hospital restructuring; primary health care; decentralisation; and the pharmaceutical sector. Projects have taken accession related issues very seriously, in particular strengthening institutional capacity. A memorandum of understanding signed in 2000 allows for co-financing of programmes between the Commission and the International Financing Institutions in view of accession. The International Finance Corporation (IFC), the private sector arm of the World Bank Group, committed a total of US\$40 million over the 1990s in health care projects such as diagnostic imaging, haemodialysis centres, medical services companies and distribution of medical supplies. This trend is increasing.

The Bank's support is likely to continue beyond the official accession date. The Bank's 'graduation policy' foresees a review of borrowing countries in light of their per capita income. Earlier accessions show that some countries (for example, Italy, Netherlands, Ireland and Portugal) continued to borrow from the World Bank even after becoming EU members, with a then much higher per capita GDP than the present candidate countries.⁴

The European Investment Bank (EIB) provides long term investment for closing the income gap between rich and less advantaged regions in Europe. The EIB started to invest in CEE in the early 1990s with a total of €15 billion. Its increasing focus on the public sector encompasses health, where capital requirements are high, especially in CEE.⁵ It is hoped that the large minimum threshold required of EIB projects will not jeopardise the badly needed smaller, specific health sector investments.

Other international organisations gave valuable technical assistance rather than financial aid: the OECD supported the development of national accounts including health expenditure surveys, often in cooperation with Phare. The World Health Organisation (WHO) Europe 'liaison officers' in CEE health ministries link the policy making function to the resources of the WHO Europe office. The frequently updated WHO HITs (Health Care Systems in Transition reports) provide a regular account on each country's progress. CEE officials are integrated in the different WHO Europe networks, partly with financial support from Phare, the World Bank or bilateral donors.

“Although individual initiatives may have been well directed, overall coordination has been lacking.”

“Developing institutional capacity should be a priority for support.”

Bilateral support

EU Member States and others have also provided substantial bilateral support with the aim of transferring know-how and fostering economic development. More specifically, bilateral aid has supported health system development and public health activities as an important factor in the social sustainability of transition. Aid often followed regional or cultural preferences; for example, the Scandinavian countries were very active in the Baltic region; France in Romania. Following historical patterns, Germany and Austria have been closely involved in supporting those countries with a pre-War ‘Bismarckian’ type of health system, such as the Czech and Slovak Republics and Hungary.

The support from those Member States most recently to acceded to the EU has been of particular interest. Austria has shared its general experience of European integration with a series of countries; Finland has supported health and safety at work initiatives; and Sweden has promoted direct cooperation between research institutions. Other smaller donor countries have followed a niche policy. Belgium has supported anti-drug policies in Romania and Poland; and Ireland has contributed to WHO Europe nurse and midwifery projects.⁶ Aid from smaller, donor countries was sometimes preferred, as was the case with Dutch support for the Czech health reform, coming from a small country rather than from their more powerful neighbour, Germany.

For some countries, such as Spain, language barriers have proved challenging. Although one of the leading health donors world wide,¹ Spain has never been very active in CEE and is orientated more towards Latin America. Political preferences, too, play a role in aid decisions: although Japan and the United States are both important international health donors, their role in the region has been somewhat limited in comparison to that of EU Member States.

Work still to do

Health aid in CEE as a percentage of available health aid is well below the worldwide average of four to six per cent,¹ not so surprising given the high health needs in developing countries. Nevertheless, the region’s health sectors have benefited from a fairly broad range of funding sources over the past decade. Yet, although individual initiatives may have been well directed, overall coordination has been lacking, each donor following its own strategies and

preferences. Especially in view of accession and the known challenges health care is facing at Community level, more coordination of support would be beneficial. This role could be assumed by the EC’s Directorate General for Health (DG ‘Sanco’). Developing institutional capacity should be a priority for support, especially in view of the countries’ aspirations to participate in the EU’s new public health programme.

With accession approaching, overall assistance to the region is decreasing as donors start to shift attention to the CIS countries, and elsewhere. Phare, other EU funds and the EIB will take on increasingly important roles in supporting the region’s development, including, it is hoped, the health sector as an important element for successful EU membership.

Conclusions

Health system reforms in central and Eastern Europe received vital support in the early transition phase. Yet accession has crowded out much of the crucial Phare health sector support, and even though support has come from other institutions and countries, it has often remained uncoordinated. Further coordinated support is needed to assist countries to continue strengthening their health sectors as part of the wider process of becoming fully functioning Members of the European Union.

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GATS and health services

Implications for EU candidate countries



Debra Lipson

“Recent rulings by the European Court of Justice suggest that trade agreements can have unintended consequences for health policy.”

In 1994, when national governments agreed to include international trade in services within the framework of World Trade Organisation (WTO) agreements, they linked a set of activities that had been largely disconnected. They defined four modes of international trade in services:

1. Cross border supply.
2. Consumption abroad.
3. Commercial presence.
4. Temporary movement of natural persons.

Each mode has a correlate in the health service sector:

1. Cross border delivery of health services, e.g. telemedicine.
2. Patients travelling abroad to obtain care.
3. Commercial health enterprises establishing or investing in foreign branches.
4. Health professionals temporarily migrating to deliver care in other countries.

Together these activities comprise trade in health services. International agreements affecting health services trade are now included within the framework of multilateral rules on cross border trade in services under the WTO's General Agreement on Trade in Services (GATS) – as well as the European Community's treaties governing the free movement of goods, services and people. This makes it important to understand the effects of trade agreements on national health policies and objectives, a task rendered more urgent by the launch of a new round of GATS negotiations, scheduled to end by January 2005. Because these negotiations are intended to further liberalise trade in services through deeper and wider sectoral commitments, the health system implications deserve careful consideration.

This article compares the WTO commitments concerning trade in health services by 13 candidate countries applying for membership in the EU* with those of the

EU. It highlights differences between the two and discusses the implications of EU accession for the WTO health services trade policies of the candidate countries. It concludes with suggestions for balancing the health related trade policies of new EU members with their capacity to regulate health services trade.

The GATS Agreement

The WTO General Agreement on Trade in Services (GATS) obliges all WTO member countries, which now includes all 13 candidate countries, to grant the same trading preferences to all other WTO members – called the most favoured nation (MFN) principle. This means that if a country permits health services trade, such as by allowing foreign companies to invest in the health sector, it must grant the same market access privileges to providers from all WTO member states. If a country prohibits trade in health services in a particular mode, it must do so for providers from all WTO member states. Exceptions to the MFN principle have been negotiated, which in theory are supposed to last no more than ten years. Under certain conditions, MFN exceptions are also permitted to participants in regional integration agreements, such as the EU, that grant more favourable terms of trade to its members.

Beyond the MFN obligation, GATS grants WTO members the flexibility to decide which service sectors and modes to open to trade via specific commitments regarding market access and national treatment. Market access concerns the ability of foreign providers to enter and consumers to leave the country. National treatment concerns whether foreign and domestic suppliers are treated equally. Full commitments have no limitations, while partial commitments place some limitations on market access or national treatment. Each country's GATS schedule contains the commitments negotiated with regard to market

* The candidate countries applying for EU membership are: Bulgaria, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia and Turkey.

“The differences between EU and candidate country GATS commitments in health related service sectors raise questions about the fate of candidate countries’ trade policies when they join the EU.”

access and national treatment for each mode of service in its chosen sectors.

Health related GATS commitments

As of July 2000, 64 WTO members made full or partial commitments in health professional or health related services, as defined by WTO and based on the UN Central Product Classification system.¹ At least 80 WTO members also made full or partial commitments in life insurance, which usually includes health insurance.

All 13 candidate countries now belong to the WTO. Through their GATS commitments, they have pledged to open their health service sectors and refrain from discriminating between domestic and foreign providers to a greater extent than WTO members as a whole. Ten of the 13 (77 per cent) candidate countries made commitments in either health professional or health related services (primarily confined to hospital services), a higher percentage than WTO members overall (45 per cent). GATS commitments by the candidate countries fall into five groups:

- No commitments for either sub-sector – Cyprus, Malta and Romania.
- Commitments for hospital services, but not health professionals – Estonia and Turkey.
- Commitments for health professionals, but not hospital services – Bulgaria, Czech Republic, Slovakia.
- Full or partial commitments for both health professionals and hospital services, but restricted to the private sector – Latvia, Poland and Slovenia.
- Full or partial commitments for both health professionals and hospital services – Hungary and Lithuania (and the EU).

Differences between the EU and candidate countries’ commitments in two modes are noteworthy. In mode 2, the EU’s commitments in the health services sector are full commitments, allowing EU citizens to travel freely to other countries to obtain health care. However, several candidate countries, including Bulgaria, Latvia, Lithuania, Poland, and Slovenia, limited this right by stating that public medical insurance plans and programmes would not cover services obtained abroad: a limitation that the EU did not include in its GATS schedule. It could be argued that such a provision is unnecessary since GATS commitments do not necessarily imply an

obligation to reimburse services obtained abroad under public insurance. However, recent rulings by the European Court of Justice granting this right to EU citizens in certain circumstances, suggests that trade agreements can have unintended consequences for health policy.² Thus, the five EU candidate countries may have been prudent to clarify the scope of their commitments.

In mode 3, Lithuania, Poland and Slovenia also limited, or made exceptions to, commitments to national treatment of foreign providers of hospital services by specifying that neither foreign private hospitals nor their customers may be entitled to receive financial support from public insurance programmes. The EU did not make a similar exception or limitation in its commitments.

Regarding health insurance, mode 3, the establishment of foreign operations or investment is the most important mode of trade in insurance. All the candidate countries, like the EU, scheduled GATS commitments in mode 3 for the financial services life insurance subsector, which covers health insurance unless explicitly excluded. But the Czech Republic and Slovakia explicitly prohibited foreign suppliers from offering compulsory health insurance, while Estonia specified that their commitments do not apply to compulsory social security services. Nonetheless, these exclusions still leave room for foreign suppliers to offer private health insurance to cover health care benefits supplementary to those included in mandatory insurance plans, or to people not covered under them.

As with similar provisions in mode 2 of health services, one could argue that such exclusions are technically unnecessary, since Article I.3 of the GATS agreement excludes from its scope “services supplied in the exercise of government authority”. Perhaps due to uncertainty about the interpretation of this phrase,³ three candidate countries opted for an unambiguous statement about the scope of their insurance commitments. These countries, which are moving from central planning to insurance based systems of health financing, may have wanted to limit the entry of private health insurance until adequate regulatory systems are in place. Without such regulation, private insurance may siphon off the richest or healthiest groups, thereby eroding the broad based risk pooling on which public insurance relies for financial sustainability and social solidarity.

Trade and health regulatory systems

The role of regulation in managing trade in health services is critical. Trade, by definition, involves commercial transactions. The introduction of commercial, for-profit, forces into the health systems of western and eastern Europe, is relatively recent and controversial. Experience of the introduction of market forces into health systems in western Europe has shown that free enterprise has increased economic efficiency in hospitals, and to a lesser degree in social and home care and primary care.⁴

But the value of private enterprise in the health sector, whether by domestic or foreign owners, depends on a regulatory system that can prevent anti-competitive practices, protect consumers, and safeguard social objectives. For example, in the Russian federation and in central and eastern Europe, "entrepreneurialism without adequate regulation has led ... to widespread instances of informal payments and official corruption."³

Recent studies from other service sectors suggest a complementary lesson about the sequencing of trade liberalisation and the introduction of market forces in any given sector. Countries most successful in achieving universal service or other development goals in the telecommunications sector were those that instituted a strong regulatory framework *prior* to privatisation and opening the sector to foreign investors.⁵ This suggests that it may be wise to limit trade liberalisation in health services until strong regulatory systems, comparable to those in western Europe, are in place in new EU member countries.

EU accession and trade negotiation

While there is general consistency between the EU's WTO commitments in health related service sectors and those of candidate countries, the differences between them raise questions about the fate of candidate countries' WTO commitments when they join the EU.

According to the EU, candidate countries relinquish their right to make their own choices regarding WTO-GATS commitments. "As a future [EU] Member State, each candidate country will have to renounce its own trade and economic agreements with third countries, adhere to the agreements concluded by the Community and its Member States and take over the commitments taken by the Community in international trade fora such as the WTO. After enlargement, the Community shall

also speak and negotiate on behalf of its new Member States in the WTO."⁶

If this requires that GATS commitments by candidate countries be withdrawn or modified, Articles V.5 and XXI of GATS oblige the candidate countries (and/or the EU) to negotiate compensation or concessions with affected trading partners. On the other hand, since the EU by and large allowed its most recent members (Finland, Sweden and Austria) to keep their own GATS commitments and limitations, the EU may allow the eastern European candidate countries to retain their GATS schedules even if they differ from those of the EU.

What of this round of GATS negotiations, planned to conclude in January 2005, at least one year *after* 10 applicants are expected to join the EU? In the short term, candidate countries appear to be more concerned with harmonising trade and investment policies with those of the EU, than seeking market access for services exports in WTO member countries via GATS negotiations. This is because the most promising markets for services trade are either EU countries or their neighbours to the east, which are not yet WTO members (e.g. Russia, Ukraine, Belarus). However, during the last phase of GATS negotiations, the 10 countries expected to join the EU would be bound by the sectoral commitments negotiated by the EU on their behalf. The EU would probably prefer few exceptions to its overall GATS negotiating positions by Member States but whether, and how, they will allow the newest EU members to specify their own sectoral limitations remains uncertain.

Conclusion

Trade agreements are no longer solely the concern of trade professionals. The scope of multilateral trade and integration agreements has expanded to cover a wide array of industries and sectors, and health is no exception. Health professionals must become more familiar with trade agreements to advise trade officials on how to avoid the risks to health from the liberalisation of trade in services, and ensure that health regulations are adequate to address such risks. The EU and its candidate countries should heed the lessons from the introduction of market forces into health systems, and from the sequencing of regulation and market opening in other sectors, in developing their positions on health services and health insurance in the current GATS negotiations.

"It may be wise to limit trade liberalisation in health services until strong regulatory systems are in place in new EU member countries."

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The transformation of the East German healthcare system

Lessons for enlargement?



Ellen Nolte

In 1989 the fall of the Berlin Wall ended the post war division of Germany. In a decade of immense social and political transition in Europe, the experience of the people of the former German Democratic Republic (GDR) was unique. Unlike its eastern neighbours, from 1 July 1990 it became a fully fledged market economy: part of the West German monetary system, and part of the Federal Republic of Germany from 3 October 1990. Upon unification, East Germany also became part of the European Union: a crucial step in the process of enlargement as it was the first former communist state to join. These developments made East Germany's prospects different from all other former communist countries, especially as this new market of 16 million people was financially guaranteed by West Germany.

German unification and European integration

The transition was also qualitatively different. Other countries were engaged in a

major process of state building, enacting new constitutions and establishing new institutions and laws on health and safety, while these already existed in the Federal Republic and were simply extended to the territory of the former GDR that became the new Länder. This also meant that from the date of German unification European Community law would be fully applicable to this territory as stipulated by Article 10 of the Unification Treaty. Importantly though, simultaneously with intra-German negotiations on the Unification Treaty, the European Commission worked on strategies to integrate the former GDR into the EU. In April 1990, a common approach was agreed on German unification and Community relations with central and eastern European countries at a special European Council in Dublin.

Recognising the particular situation of the former GDR, the Commission subsequently passed an exceptional decision to introduce transitory measures relating to the unification of Germany.¹ This authorised Germany provisionally to maintain in force in the former GDR legislation that did not comply with certain specified Community Acts. These included legislation related to workers' health and safety; environmental protection and the harmonisation of technical rules (see Box 1). However, almost 80 per cent of Community law came into force in the former GDR immediately after unification: the remainder to be incorporated by the end of 1992 or 1995.²

Unifying healthcare in Germany

Within this context of a 'ready-made state'* the Soviet style healthcare system

Box 1

INTEGRATING EAST GERMANY INTO THE EUROPEAN UNION: HEALTH LEGISLATION

Directive 90/657/EEC represented a particularly interesting set of transitional measures that affected a wide range of products manufactured in the former GDR.³

It required the Federal Republic to take all measures necessary to ensure that products not complying with [specified Directives] are not placed on the market in the territory of the Community other than the territory of the former [GDR].

Directives thus specified included those on labelling of tobacco products and maximum tar yield of cigarettes (89/622/EEC and 90/239/EEC) as well as Directive 75/319/EEC on proprietary medicinal products.

While these measures would give manufacturers in the former GDR at least a two year transition period to conform with EC regulations, they were not allowed to market their products anywhere within the EC except the territory of the former GDR.

* The notion of a "ready-made state" was introduced by Richard Rose and Christian Haerpfer. The Impact of a Ready-Made State: East Germans in Comparative Perspective. *German Politics* 1997;6(1):100-21.

Ellen Nolte is Lecturer in Public Health at ECOHOST, London School of Hygiene and Tropical Medicine. Email: ellen.nolte@lshtm.ac.uk

was replaced by a pluralist insurance-based system of medical care.⁴ The process of reforming the GDR's healthcare system during transition is looked at here using the framework for health policy analysis proposed by Walt and Wilson,⁵ to provide a better understanding of the role of specific contextual elements, processes and actors in the reform and to highlight some general lessons to be learnt for EU enlargement.

In the specific case of Germany one outstanding factor affecting the shape of health reform was the strong dynamic of the process of political unification.^{4,6} The speed with which the unification of the two states was driven required pragmatic solutions with virtually no space for innovative or experimental steps in reforming East Germany's healthcare sector. Also, the political developments following the resignation of the GDR's former leader Erich Honecker in October 1989 led to continuing disintegration of political authority, which in turn resulted in considerable inequality in the process of bargaining resources, competence, expertise and power between East and West.^{6,7}

The almost complete discrediting of the GDR administrative (civil) service accompanying this process also contributed to the weak negotiating position of East Germany, and to the inability of the healthcare sector to take part in the negotiating process.^{6,7} The previously rigid hierarchy and party discipline meant that institutions in almost all areas of GDR society were politically contaminated, causing deep mistrust in the administrative bodies. Thus, in the negotiations leading to the Unification Treaty, GDR politicians were of only secondary importance⁴ and the resulting, more or less complete, transfer to the East of the West German model seemed almost inevitable.⁶

Actors

In both East and West Germany there was consensus amongst actors in the field of social and health policy that the social insurance system of the former GDR was in need of reform. Thus, Lothar de Maizière, Minister President of the first democratic government of the GDR declared in the first governmental statement in Spring 1990 that the "centralised administration of the social insurance run by the FDGB [Free German Trade Union Association] does not meet the demands of a democratic welfare state". Whilst reorganisation was perceived as essential, the structure and content of this reorganisa-

tion, especially in relation to healthcare, were less clear. In fact, there was controversy among West German government and non-government actors, interest groups and even the administration itself about the structure of the health insurance system, funding mechanisms and the survival of the outpatient polyclinic system.⁴

Importantly, however, although the proposed reorganisation was of the East German healthcare system, those shaping the reform were exclusively West German. Initially, the Social Democratic Party and the Federal Association of Local Sickness Funds (AOK Bundesverband) were very successful in introducing their proposals into the coalition agreement of the newly elected GDR government in spring 1990.⁸

However, their suggestions to preserve some basic features of East Germany's healthcare sector, namely some form of unified health insurance and the polyclinic system as the main institutional setting for providing outpatient care, faced strong opposition. The associations of substitute funds lobbied hard for transferring the highly fragmented West German health insurance system to East Germany, an effort supported by the chambers of physicians who traditionally favour a pluralist health insurance structure.⁷ This alliance gained decisive support not only from the governing coalition party but also from the Federal Republic's Chancellor Helmut Kohl, who then had strong negotiating power.⁴ As a result of the negotiations on the Unification Treaty, the East German healthcare system was to be put on the same financial and organisational basis as that of the West by early 1991. Thus, with the exception of a five year period of grace for the maintenance of polyclinics and related facilities, East Germany's healthcare reform was an almost unmodified transfer of West Germany's institutional structure.⁸

Process

There have been three main stages in the process of reform of healthcare in East Germany:⁸

Fall of the Berlin Wall (Autumn 1989) – State Treaty on Monetary, Economic and Social Union (May 1990)

The first phase was characterised mainly by the negotiation processes concerning the general contents of healthcare reform, eventually leading to the decision to export the West German health insurance system to the East as outlined above.

“East Germany’s healthcare reform was an almost unmodified transfer of West Germany’s institutional structure.”

“The context of unification had a substantial impact on the content of reform.”

Treaty (May 1990) – Unification Treaty (October 1990)

This stage was characterised by negotiating the controversial ‘polyclinic issue’ (whether ambulatory care should be transferred to the private sector). A compromise was eventually reached that firstly granted every East German physician the freedom to practice privately and secondly authorised polyclinics and related facilities to provide services at least until the end of 1995. However, this time limit was removed later through the Healthcare Reform Structure Act (GSG) in 1992.⁴

Implementation of the Unification Treaty

The content of the Unification Treaty, already strongly biased against polyclinics, was further strengthened by a variety of successful interventions by professional and governmental bodies in the West. The West German Associations of Sickness Funds physicians, for instance, began to train their colleagues in East Germany in setting up private practices and establishing professional associations. The federal government supported establishment of private practices through special loans.⁹ The time limit set for the continuation of polyclinics and, more importantly, the remuneration

method that was agreed put substantial pressure on physicians to become self employed.⁸ Regional and local governments in the East, now owning the majority of polyclinics and fearing substantial deficits in their budgets, placed additional pressure on physicians to set up private practices.

As a consequence, more than 80 per cent of outpatient physicians had become office-based by the end of 1991; by 1998, 96 per cent of all physicians in East Germany were established in private practices whereas only four per cent were based in polyclinics.⁹ The establishment of the health insurance system in East Germany was also actively supported by the West, with both local and substitute sickness funds being able to start work in the East by January 1991.

Integration and enlargement

The process of political, economic and societal transition in central and eastern Europe led to the reform of healthcare systems by most countries in this region. But, as Wasem has pointed out, “whereas all these countries have to find answers to a huge catalogue of strategic questions, in East Germany these questions were answered through unification.” Indeed, reforming the healthcare sector in the former GDR was part of the greater enterprise of unification and did not rank highly on the reform agenda. However, this analysis demonstrates that the context of unification had a substantial impact on the content of reform by preventing the consideration of alternative solutions. This is also reflected in the relative power of the actors who shaped the content of reform. A uniform health insurance or a polyclinic system in East Germany would have been not only a “fundamental break with the principles of West Germany’s healthcare system since 1945”⁴ but also posed considerable threat to vital interests and corporate identities of West German actors. Their East German counterparts were of minor importance in shaping the reform due to their weak position, largely determined by the political circumstances of the time.⁷

As noted earlier, the process of reform in East Germany is a special case within the framework of European integration. Many aspects of transforming the former GDR were unique, not only the healthcare sector, and will not apply to the situation of candidate countries. Nevertheless, integrating East Germany into the EU represents an important step towards enlargement.

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Looking beyond the candidate countries

The Stability Pact countries and health



Ivana Bozicevic

As the current round of candidate countries progress towards European Union (EU) membership, further changes to the shape of the EU must be considered together with the implications for health and health systems. This paper discusses the new Stability Pact in south eastern Europe (SEE) in relation to these issues.

The Stability Pact for South Eastern Europe was initiated in 1999 with the aim of strengthening peace, encouraging respect for human rights, and fostering reconstruction and economic growth in the region. The Pact is a partnership between south eastern European countries, the EU, with Norway and Switzerland, the G8 and international organisations (Table 1).¹ At the same time the EU began a new stage in its relationship with the five countries of

south eastern Europe: Albania, Bosnia and Herzegovina, Croatia, Federal Republic of Yugoslavia (FRY) and Former Yugoslav Republic of Macedonia (FYRM) through the Stabilisation and Association Process (SAP). The SAP recognises these countries as potential candidates for EU accession and emphasises the improvement of regional cooperation as the main condition of potential EU membership. Integration to the European structure is provided through the Stabilisation and Association Agreements (SAA), which are similar to the Europe Agreements for the current candidate countries in central and eastern Europe.

The Stability Pact acts through three working tables: Working Table I (Human Rights and Democratisation), II (Economic Reconstruction, Development and Cooperation) and III (Security and Defence Issues).

The first Stabilisation and Association Agreements were signed between the EU and the FYR of Macedonia in April 2001 and Croatia in October 2001. The signing of these agreements provided 'potential candidate' status for EU membership. It is expected that SAA entry will come into force in approximately two years, as all the EU Member States need to be involved in their ratification. Since June 2001, negotiations have been underway for a SAA between the EU and Albania.

Health and the Stability Pact

South eastern Europe is Europe's poorest region. It is also heterogeneous in its socioeconomic development and population health status. The total population of the five countries is 24.5 million. The GNP per capita in 1999 ranged from US\$849 in FR Yugoslavia to US\$4530 in Croatia – 43 per cent of average for the central and east European countries (CEECs). While the macroeconomic situation largely stabilised for the CEECs in the mid-1990s, most of the SEE countries are struggling to achieve economic growth and stability. The

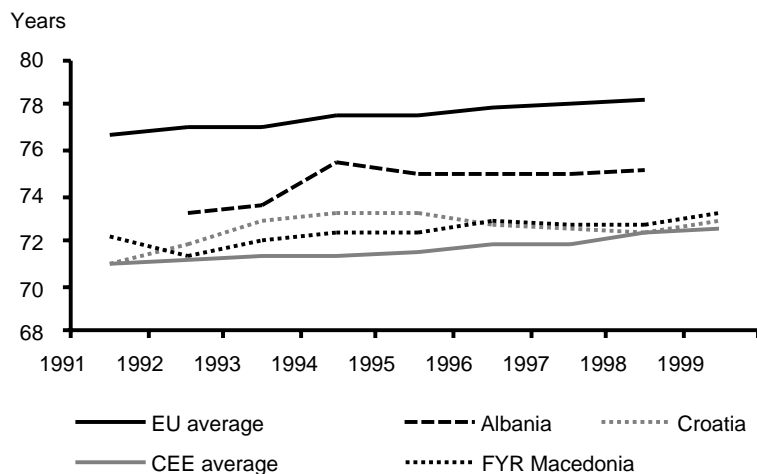
Table 1

STABILITY PACT PARTNERS

| | |
|--|---|
| Stability Pact countries and other countries in the region | Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Federal Republic of Yugoslavia, Former Yugoslav Republic of Macedonia (FYRM), Hungary, Poland, Turkey, Romania, Slovakia, Slovenia, Moldova |
| The European Union Member States and the European Commission | Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom |
| Non-EU members of the G8 | USA, Canada, Japan, Russia |
| Other countries | Norway, Switzerland |
| International organisations | UN, OSCE, Council of Europe, UNHCR, NATO, OECD |
| International financial institutions | World Bank, International Monetary Fund, European Bank for Reconstruction and Development, European Investment Bank, Council of Europe |
| Regional initiatives | Black Sea Economic Cooperation, Central European Initiative, South East European Cooperative Initiative, South East Europe Cooperation Process |

Ivana Bozicevic is researching her Doctorate in public health at London School of Hygiene and Tropical Medicine.

Figure 1
LIFE EXPECTANCY IN ALBANIA, CROATIA, FYR MACEDONIA, EU AND CEE COUNTRIES



proportion of GDP spent on healthcare in 1999 was 5.5 per cent in FYR Macedonia, 7 per cent in FR Yugoslavia, 9 per cent in Croatia, and only 3.1 per cent in Albania (1997), compared with the EU average of 8.5 per cent.²

The population health of former Yugoslavia and Albania is inadequately researched. Compared to EU standards the quality of information on health indicators during the 1990s was not satisfactory.³ This was due partly to large population movements because of war, and partly to outdated data monitoring systems and inadequate capacity in data analysis in these countries. For some countries, most figures for international comparison have not been available since 1991,⁴ although the 2001 census will help to provide a more accurate picture of population health status in the region. Figure 1 shows the life expectancy at birth for countries for which data is available.

Within the framework of the Stability Pact, the health sector is addressed in the Initiative for Social Cohesion (Working Table II), which recognises the need for strengthening institutions and building capacity in the health and social sector. In areas of health policy, it states that "relative legislation will be amended to comply with European Union standards".⁵ While the SAAs already signed with the FYRM and Croatia do not specifically mention health or healthcare, articles within them relate to relevant areas, such as consumer protection, environmental protection and work safety. The Social Cohesion Initiative provides financial assistance in each of the SEE countries for a number of projects that are considered to reflect their priorities for

public health and healthcare.

Future EU integration and health?

The links between the current Stability Pact projects and the requirements for the EU integration process in terms of health legislation are not very clear, although the Action Plan for Health, which funds and approves these projects, aims to enable the future compliance with the relevant EU *acquis communautaire*. It recognises that "restructuring of public health functions and infrastructures can be achieved by reviewing, reformulating and harmonising health legislation and standards in line with international conventions and recommendations, as well as the EU *acquis communautaire* in all relevant public health areas".⁶ Current discussions aim to clarify these issues and propose guidelines on linking the projects within the Social Cohesion Initiative with the requirements of the SAP.

The success of the Initiative depends greatly on improvements in the institutional, research and management capacities in the region's health sector, particularly in public health. As a starting point, comparable demographic and social statistics data are needed to allow identification of population health needs, planning and evaluation of health sector performance, and more accurate international comparisons. Investment in the professional development of public health personnel is also of great importance in modernising public health systems as the EU integration process requires the development of a substantial amount of multisectoral and multiagency work.

Conclusions

The SEE countries' successful integration into the EU structures depends on the implementation of the Stabilisation and Association Agreements in which health sector issues are addressed through policies in other sectors. The Stability Pact addresses health issues to a much larger extent through the Social Cohesion Initiative.

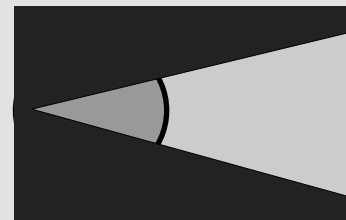
It may be beneficial to link Stability Pact health programmes more explicitly to the requirements of the SAP. If the projects funded reflect the south eastern European countries' priorities for health development in general, and the process of the European Union integrations in particular, it seems likely that the Stability Pact can bring improvements to the health of their populations and support the harmonisation of health sector legislation as part of early preparations for EU accession.

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- bringing together a wide range of academics, policy-makers and practitioners to analyse trends in health care reform
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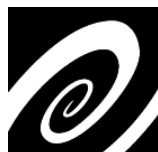
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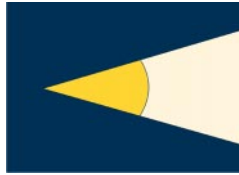
If you would like more information about the Observatory please contact:

*European Observatory on Health Care Systems,
WHO Regional Office for Europe, 8 Scherfigsvej,
DK-2100 Copenhagen Ø, Denmark.
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HEALTH AND EU ENLARGEMENT

