

eurohealth

*Minister Andrea Fischer on the
German Presidency of the European Union*



editorial

As this is the first edition of a 'new look' *eurohealth*, it provides a timely opportunity to thank readers for their continued support of our aim to provide a unique platform for policy-makers, academics and health policy experts to present their own views on European health policy issues.

eurohealth is a unique publication which has bridged the divide between the wider policy-making community and academia. Rarely are the views of these two communities brought together in a single forum which is accessible to all. We recognise that busy policy-makers are often dissuaded from writing at length in peer-review journals, yet we have also succeeded in balancing the needs of contributors from academic circles. We are pleased to see that *eurohealth* is being cited increasingly in both peer review journals and government policy documents as a visible sign of our success in reaching out to both constituencies.

Although Paul Belcher (former editor and now senior editorial adviser) and I have regularly received your views and comments over the years, I would like to ask for your assistance in responding to some specific questions so that *eurohealth* can continue to respond to your needs in the future. Please take time to fill in and send back the enclosed questionnaire. Your time in responding to these questions will be greatly appreciated. Having been editor for over a year now, I hope you are pleased with the direction *eurohealth* is taking.

Rob Wood
Editor

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German Presidency of the European Union

- 1 New beginning and continuity: the health agenda for the German EU Presidency
Andrea Fischer



A new approach to pharmaceutical policy in Europe?

- 23 The Single Market in pharmaceuticals
Jörn Keck
- 25 Towards the Single Market in pharmaceuticals: DG III's hopes and suggestions
Andrew Herxheimer
- 26 Development of the Single Market in pharmaceuticals
Brian Ager

The EU Presidency conference on public health policy

- 2 A new public health policy in the European Union
Andrea Fischer

Working Group Reports

- 5 Improving information for the development of public health
Hugh Markowe
- 6 Reacting rapidly to threats to health
Fritz Tiemann
- 7 Tackling health determinants through health promotion and disease prevention
Tapani Piha
- 8 The impact of the internal market on health systems in the Member States
Philip C. Berman
- 9 Contribution of research to European public health policy
Jussi Huttunen
- 11 EU enlargement – the influence on the EU health agenda
Magdalene Rosenmüller

Health and social inequalities

- 29 Tackling inequalities in health: how can we learn what works?
Michaela Benzeval
- 31 Socioeconomic inequalities in health in Europe
Johan P. Mackenbach and Anton E. Kunst
- 35 Inequalities in health
Walter W. Holland

Health technology assessment in Europe

- 37 Health technology assessment in the European Union
David Banta and Wija Oortwijn
- 39 Health technology assessment: a European Community perspective
Bernie Merkel
- 42 European health technology assessment: time to change gear?
Franco Sassi

Health systems and reform

- 43 UK health reforms: a threat to doctors' autonomy
Ann Widdecombe
- 45 New reform of the Italian NHS: structural changes or fine-tuning?
Giovanni Fattore
- 47 The development of the French health system
Serge Skanavi

- 50 European Union news
Govin Permanand

The EU budget and health

- 12 How to build a better EU public health budget
Doeke Eisma

The European Court, the Single Market and health

- 14 The Kohll and Decker rulings: revolution or evolution?
A. P. van der Mei
- 16 National reactions to Kohll and Decker
Jens Gobrecht
- 18 Health as a tradable service: a prospective view of the European Union
Panos Kanavos
- 20 Kohll and Decker: a new hope for third-country nationals
Jason Alan Nickless

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New beginning and continuity: the health agenda for the German EU Presidency

————— *Andrea Fischer, German Federal Health Minister* —————

New beginning

A key aspect of the current German Presidency of the EU Council of Ministers will be the difficult task of breathing life into the new Article 152 of the Amsterdam Treaty. As we are now going through a transition period this will be no easy task as the Commission will only be able to submit new proposals on the basis of this article when the Treaty has been ratified. As a result, no precise dates can be fixed. Moreover, the European Parliament will be newly elected this year and will not be in a position, before the end of the year, to make a statement on the Commission's proposal. Structural and organisational changes regarding health policy are also likely to take place in the newly constituted Commission in the year 2000.

Notwithstanding these difficulties, elaborating the future EU health strategy must be one of the focal points of this EU Presidency's work. My thoughts on this important area are covered in a separate article in this issue of *eurohealth*, written on the occasion of the working conference of health experts and policy-makers, held by the German Presidency at the end of January in Potsdam.

With regard to the health implications and problems associated with the accession of new Member States to the EU, the Commission will be submitting a report on this subject which is to be discussed with the new Member States. The Council of Health Ministers could adopt a resolution outlining the steps which need to be taken at its meeting in June. The further development of EU public health policy will definitely have to take into account the consequences of enlargement and the situation in the health sectors of the acceding countries. It is incumbent upon the Community – also in its own legitimate interest – to lend its active support.



Continuity

There seems to be agreement among the Member States on the proposal for a Council Recommendation on the limitation of exposure of the general public to electromagnetic fields and this could be adopted at the meeting of the Council of Ministers in June. Another important health topic for which we could consider the possibility of a Council Recommendation is the microbial threat from overuse of antibiotics. The Council has requested a report from the Commission on the public health repercussions as well as economic and legal consequences by June 30th 1999. The Health Council in forming its Recommendation will take this into account.

The fight to control tobacco consumption has always been one of the focal points of EU health policy. Despite the differing positions in the Member States on individual issues – such as the prohibition of tobacco advertising – the Council has always drawn attention to the fact that tobacco consumption cannot be fought by means of individual measures alone but required instead a comprehensive strategy. The Commission should revive the proposals it put forward in its

Communication of December 18th 1996 and submit them to the Council for adoption.

The Commission reports on the state of health in the European Community, the integration of health protection requirements in Community policies as well as on TSEs and BSE are important instruments for the further development of the Community's health strategy. Therefore, it is particularly important that these reports are submitted in the immediate future so that their findings can be taken into consideration in developing this new strategy.

The efforts undertaken by the European Commission and the Member States in the area of safety of blood products and self-sufficiency in blood should be continued. The work that needs to be done on those issues, which the Health Council has singled out in various resolutions over the past few years, is still not complete. I have asked the Commission to be more expeditious in the pursuit of these activities. A conference on the 'Optimum Use of Blood Products' will be held by the German EU Presidency. The purpose of this conference will be to elaborate the basis for Commission proposals on increasing therapeutic safety and making rational use of blood and blood products.

Cooperation between the EU and international organisations in health matters, in particular the WHO, is in need of urgent improvement. Although this wish is long standing and has often been reiterated, it has not been fulfilled in a sufficiently concrete way.

At the moment, my statements are but declarations of intent. Transforming them into reality will require, at many levels, close cooperation with the Commission, the European Parliament, the next Presidency and with all the Member States.

A new public health policy in the European Union

Policy Statement from Andrea Fischer

“There will not be... any harmonisation of national health care systems in the EU. What we cannot escape from, though, is the continuous convergence of these health systems.”

To forward the debate on the implementation of the new Article 152 on public health, a key priority for the German EU Presidency, I convened a meeting of national health officials and experts at Potsdam, Germany in January. This was purposely at the beginning of the Presidency so that the results can be utilised at the next meeting of the Council of Ministers for Health in June. Summary conclusions by the rapporteurs of the six working groups at this meeting are contained at the end of this paper

Even today, health has not yet come to be an intrinsic, formative element of European integration. Public health policy has not until now secured an established status on the regular European agenda. What is lacking are clear-cut European health targets, contents, forms and structures. However, the opportunities and options for organising and shaping European public health policy as required are now better than ever as the extended European Community competence enshrined in Article 152 of the Treaty of Amsterdam provides the necessary legal prerequisites. This calls for suggestions for the identification, arrangement and formulation of contents and a strong political will. Aspects I consider to be especially important for the future are the following:

Greater visibility

European health policy must become more visible and comprehensible for the general public. It must be responsive to the citizens' needs and concerns. It must move away from the current high level of abstractness. European health reporting – however important it is – does not mean very much to the

people. Hence it must be made sufficiently clear why European health policy is also important for each individual person. That will not be an easy undertaking. The EU does not build hospitals. Nor does it pay for medical services. But it can improve the requirements that guarantee the necessary quality of care provision everywhere.

Given the lack of proximity to the citizens, I find it deplorable that a visible instrument of European health policy, the ‘European emergency health card’, in fact one of the first European initiatives in the public health field, should have met with such a poor response from the Commission. We should give serious thought to how, in the age of telematics, instruments of high external visibility can be created that strengthen the citizens' interest in and awareness of European health policy.

“Even today, health has not yet come to be an intrinsic, formative element of European integration.”

Another means of taking European policy closer to the citizens might be a ‘European Patients’ Charter’. In his speech before the European Parliament on January 12th 1999, the President of the Council of the European Union, the German Minister for Foreign Affairs, Mr. Joschka Fischer, proposed that a European Charter of Basic Rights be drawn up in an effort to strengthen the rights of citizens. A patients’ charter would fit well into this picture.

European ‘added value’

EU public health policy is far more than just the continuation of national policy at the European level. It very much differs, also as far as quality is concerned, from the possibilities for action available to the World Health Organisation or the Council of Europe. It has a clear, legally established mandate for action spelled out in Article 152, paragraph 1 of the Treaty of Amsterdam. Specifically, it must – I quote “ensure a high level of human health protection in the definition and implementation of all Community policies and activities.” This wording alone implies that it has all instruments available at the EU level at its disposal.

This comprehensive mandate starts from the premise that there is hardly any domain of community policy that exerts no influence on human health or the health care systems. Particularly striking examples are: the internal market, industrial policy, agricultural and research policies.

It is obvious that the task set out above is an extremely difficult one to accomplish since it very soon runs up against opposing interests. We will only be able to cope with this challenge if we face up to it together and jointly demonstrate the political will required.

Certainly it is important and necessary to provide for the requisite structures and mechanisms. ‘Health impact assessments’ for entire fields of policy are highly unlikely to be in place anywhere in the world. Here we are indeed breaking new ground. Here the new EU health programme can afford possibilities, but I reiterate: without the firm political will to implement and enforce health tar-

gets, mechanisms and structures are nothing but technical aids.

An inclusive health policy

As a consequence, European health policy must be inclusive by definition. It cannot and may not exclude any political field from the outset. However, it can never be universal in coverage, nor can it even make such a claim. It cannot pursue every issue that might be desirable, indeed necessary and meaningful on the European level, if for no reason other than that the human and financial resources of the Member States and the Commission are finite and cannot be multiplied at will.

More funds are not synonymous with more health policy. We must economise. That goes for the Commission, just as it goes for the Member States. But we must economise in ways that make sense. This is what the Council of Ministers did in a general form in its Resolution of 26 November 1998 but the general statements it made then have yet to be redrafted in a far more concrete manner. This work will be promoted during the German EU Presidency and the expert meeting convened in Potsdam is part of this process.

Enlargement and health

The further development of the EU's health policy will have to take into consideration the consequences of EU enlargement and the public health situation in the acceding countries.

The majority of these countries are confronted with serious public health problems that are very hard to solve for a number of reasons – among them the lack of resources and health care systems that need to be reformed and rendered more efficient. Here, the EU must find an appropriate strategy that allows a continual harmonisation to European Community legislation and EU standards.

There is broad consensus that highly developed social standards are an integral element of the EU's productivity and competitiveness. These standards certainly include, in the public health field, not only the areas

of competence that are stipulated in the Treaty but also well-functioning and adequately equipped health care systems overall.

The objective is the development of health care systems that are financially and socially acceptable and deliver high-quality health care in conformity with EU standards accessible to all citizens, regardless of their social and economic status. It is here that the EU must provide assistance – which, by the way, also serves its own legitimate interests.

“... Europe is gaining influence over the structures and contents of our health care systems to an ever greater degree ”

European health policy can only succeed in accomplishing the tasks set if it takes into political and formal consideration four mutually complementing framework conditions:

- Public health policy is not the exclusive responsibility of the Community. The latter's public health competence is limited. The national responsibility of the Member States for their health care systems is not lessened by the European Union; it is only supplemented by it.
- The differences between the national health care systems of the Member States.
- The application of the principle of subsidiarity.
- The different public health situations in the Member States.

The Member States will continue to retain full and undiminished responsibility for their national health care systems. There cannot be and will not be a European standardisation or even harmonisation of the national differences, the peculiarities of the traditionally evolved structures specific to each individual Member State. These are the results of decades of development. They are a direct response to a country's social situation and profile.

In the process of European unification, the social and cultural traditions of the various social security systems must be taken into account and secured. Safeguarding the pluralism of the national health systems existing in Europe is a valuable asset in itself.

Nevertheless, the Member States still fear – a fear we must take seriously – that the Commission might aspire to competencies in the health field it is not entitled to hold. After all, next to everyone seems reluctant to give the Commission an inch, since doing so would be to risk it taking a mile.

This mistrust might even be comprehensible in view of past experiences, but as long as it prevails, it will be difficult to encourage the Member States and all those working in their national health systems to take an active part in shaping European health policy.

And yet it is precisely this type of active, forward-looking participation by the Member States that is indispensable. We must make every effort to dispel the mistrust on both sides. I am very grateful to Commissioner Flynn who, in his speech before the European Parliament on October 28th 1998 at the public hearing on the future of public health policy, said, “Let me be blunt. The European Union has neither the desire nor the ability to run national health systems. Nor do we wish in any sense to tell Member States what to do.” This position is also in line with all the statements on this subject laid down in a multitude of Commission documents. Thus, we should realise that nobody in Brussels or Luxembourg is earnestly pursuing the harmonisation of the social protection and health care systems.

But – and this is a highly important but – we must recognise, acknowledge and take into consideration that Europe is gaining influence over the structures and contents of our health care systems to an ever greater degree and at an ever faster rate particularly in the creation of the Single Market.

The increasing economic interdependency, i.e. globalisation; the changes in the technological environment including ultra-fast, ubiqui-

tous information technologies; the financing problems of the health care systems that are also due to demographic and labour market factors; the changing value patterns of society; the growing mobility of the populations; the changing spectrum of diseases that brings new hazards to health with an often world-wide incidence – are all challenges confronting all health systems to a similar degree.

These problems must be solved by the Member States within the framework of their national competence to organise their systems, but – and this is decisive for European health policy – the European Union can assist them in these endeavours.

European health policy will make it easier to identify and detect problems and risks at an early stage. It will also provide much needed guidance.

It is our job to make active use of these possibilities: evidence-based medicine, health technology assessment, disease management, quality assurance – these tasks are topical in the European setting, whatever the health care system.

There will not be – a point on which I am repeating myself quite deliberately – any harmonisation of national health care systems in the EU. What we cannot escape from, though, is the continuous convergence of these health systems. How far this convergence can actually go, how fast and how comprehensively it is going to take place, is a difficult issue that has to be approached primarily by political decisions in the Member States, and it may only be accomplished step by step.

If the Member States rightly want to maintain the current level of quality and basic principles of their national systems, they must actively contribute to this already ongoing process and do so at an early stage.

It is an uncontested fact that has become quite evident through judgments of the European Court of Justice, that tension exists between the free movement of goods and services on the one hand and the Member States' competence for the organisation and regulation of their

national health care systems on the other.

It is feared – primarily in Germany – that the application of European Community law, especially along the lines of the decisions by the European Court of Justice, might eventually erode the national responsibility of the Member States for their own health care systems.

This indisputably problematic situation must be defused by means of political decisions. It would be fatal and a political *testimonium pauperitatis* if the development of health policy in the EU were left mainly to the jurisdiction of the European Court of Justice.

“We should give serious thought to how, in the age of telematics, instruments of high external visibility can be created that strengthen the citizens' interest in and awareness of European health policy.”

I believe it is ultimately unavoidable that the existing EU economic constitution, the European competition law, and also the further development of the freedoms afforded by the internal market – not least on the strength of the judgements of the European Court of Justice – will gradually but inevitably make the individual areas of health care provision work together more closely.

This trend, emerging in many other areas, is not going to spare the health care systems. The important thing is for public health policy at the national and Community levels to face up to this challenge, to accept it and turn it into an advantage.

In this context, reference is often made to the subsidiarity principle. Regardless of the fact that this principle is frequently misunderstood and not exceedingly popular at the EU level, it must be applied without restriction. This is the position which the new German Federal Government, too, will continue to uphold unchanged.

This subsidiarity principle applies, of course, also to public health policy. It very much depends on whether this basic European principle is abused in a resisting and negative context as a ‘bludgeon’ to defend certain interests or whether it is used in a positive way – as a ‘dynamic concept’ as it is called in the Subsidiarity Protocol to the Amsterdam Treaty – to attain the objectives set out in this Treaty.

For European health policy, this means not focusing too much on identifying areas that must be protected against Community influences, but rather turning to the issues and areas in which Community initiatives can contribute to improving the health of its citizens.

The health status of the population in the Member States of the Community is often reported to be better than ever before, which it indeed is. Child mortality is on the decline, people live longer, a large part of what were deadly diseases in the past are no longer the appalling threats they used to be. But, the number of unnecessary premature deaths is still too high, new hazards to health have arisen, and new diseases have been emerging. Moreover, wide differences in health status persist not only across, but also within Member States, between one population group and another. Differences also exist between the mortality rates that are often linked to the socioeconomic status of the specific population group. Finally, there are inequalities in the EU that need not be. The remarkable thing about this situation is the fact that the Member States with the highest annual health expenditure per capita – with amounts for 1994 ranging from DM 1,307 to DM 4,238 – are not the same as those whose populations enjoy the highest life expectancy.

As new Member States accede to the EU, these differences are set to widen dramatically. One objective of the EU is to ensure the highest quality of life for all citizens. This objective also covers health. As long as the differences mentioned prevail, the EU will be obliged to take public health policy action.

Improving information for the development of public health

Report of Working Group 1: The new public health policy of the European Union, Potsdam, January 27-29th 1999

— *Hugh Markowe* —

A range of factors have been identified which make the development of a European Community health information system a high priority: the development of a Community public health policy; the increasing use of health objectives and strategies in Member States; the increased use of comparative information by Member States and the general demand for good quality comparable information relating to health determinants and outcomes, together with the attention which is now increasingly focused on a range of health care issues. All have information implications. At the same time there is a boom in the availability of health information and a growing need for information at various geographic levels: European, Member State and regional. The technology to provide easy access to this information is now becoming widely available.

A Community Health Information System is needed to exploit relevant health-related data and information for policy purposes, including meta-information and for it to be made available to all who require it in the form most appropriate for their needs.

The Community health information system

A diverse range of information is recognised to contribute towards a 'comprehensive' system, including traditional measures of health status and determinants but also socioeconomic health determinants and information relating to health care utilisation, quality and costs.

A Community health information system has been identified as comprising a number of elements including:

- The database: perceived as a distributed (set of) database(s) with an associated network, with a

major role for each Member State in the establishment and running of its node(s).

- The organisation/coordination/facilitation of the system.
- The strategic direction of the system: including catalysing activity and identifying priorities, this needing to be organised within some form of central capacity.
- Analysis.
- Output: i.e. dissemination of meta-information and Community health reports, with a need for a Community health reporting agenda.

Different approaches to establishing this 'capacity' are considered possible including the development of some form of health observatory.

It is necessary to establish a process which results in a permanent system so that continuity will be ensured and a strategic and long-term plan may be properly supported. Additionally the system must be designed to be flexible and responsive to changing needs.

Different countries are at different stages of development in this field and efforts have to be directed to the development of suitable capacity within Member States (both current and future).

The balance of the work

There is a substantial new agenda which must be developed in the field of health care information at both national and regional levels.

The whole area of health impact assessment – including assessment of EU policies – also needs to be properly integrated into the Community health information system.

The system must enable issues relating to health inequalities to be addressed and must encompass a

range of socioeconomic determinants of health and health inequalities. However, the more traditional areas of health promotion, disease prevention and health status must also be given suitable priority as key elements of the system.

There is a need to ensure that alongside information centred on systems and routine data collection systems, information derived from individuals (e.g. via health surveys) is also included.

The user perspective

Development of the system needs to be driven by interaction between data providers, policymakers, 'practitioners' and other users (including the general public). There is a need for better understanding of the needs of the users so that systems, information content, analysis and presentation (dissemination) can all be user-centred.

Accessibility is a critically important issue. Depending on the user, access might be required to data, indicators or in some cases 'meta-data' (e.g. specific databases/ information sources; information about information). The Internet will offer substantial opportunities to facilitate rapid access to databases and to enable the 'signposting' of key information sources.

Research and development

There is an important interface and overlap between information, information collection and research and development. The links relate to a wide spectrum of areas such as the need for research to underpin the health information requirements, the use of the health information system to disseminate and aid better access to health research, and the use of the information system to define research needs.

The system must stimulate and offer the opportunity to exploit comparative information analyses. This should be built around a specific programme that is structured and prioritised in accordance with Member States' experience and needs. Examples might include the variability in health care organisation and utilisation, screening information, or specific health status issues.

Generally the R&D agenda and information agenda need to be well coordinated and exploited in tandem with suitable transparency.

The way forward

The Group has identified the need to:

- Exploit available data/networks/expertise including that available from WHO and other organisations (e.g. OECD, Eurostat).
- Pursue a long-term agenda to build a permanent, continuous, flexible and evolving system.
- Ensure that a short-term agenda – including the work of the Health Monitoring Programme – is being developed to underpin longer term aims.

- Resource properly – the system itself and any support structures (e.g. a capacity).
- Ensure that the Commission receives the support necessary to fulfil appropriate functions in relation to the system (ability to 'hire' expertise).
- Be practical/realistic (if necessary consider doing 'less better')
- Exploit, but avoid being driven by, technology.
- Require full Member State commitment and involvement as well as Commission action.

Reacting rapidly to threats to health

Report of Working Group 2: The new public health policy of the European Union, Potsdam, January 27–29th 1999

— Fritz Tiemann —

While early warning and rapid reaction to threats to health are not unique to the field of infectious diseases they are especially important in this area. The EU decision on surveillance and response to communicable disease threats provides a new legal basis to discuss this topic.

The creation of a European 'network of networks' would be a method to implement a 'rapid alert'/'early warning' system if certain conditions are met.

All surveillance networks which fulfil the following criteria must be part of the network.

The threat to public health of the diseases covered by the network should be demonstrated at a European level by looking at factors such as mortality, contagiousness, long-term harm to health, expected expenditure for treatment and for long-term compensation measures.

At the same time it is necessary that:

The efficiency of a European early warning system can be demonstrated because the European dimension:

- improves international coordination to identify outbreak clusters where more than one Member State is affected or;
- makes it more likely that an out-

break/cluster can be identified at European level when the number of cases observed in each national context does not indicate a cluster or;

- delivers an adequate database for epidemiological analysis where the incidence in different Member States is too small or when an epidemiological development follows a geographic pattern.

An extra early warning network for new and/or rare syndromes has to be developed. Adequate facilities for laboratory diagnosis, treatment and care needed to deal with rare/new syndromes may not be available in each Member State.

A specific early warning system for this particular field could include greater cross border cooperation between institutions of different Member States.

Surveillance of communicable diseases is an ever changing field. Epidemiological situations and challenges are changing, therefore the 'network of networks' needs continuous updating. All parts of the network of networks must have appropriate evaluation strategies to institutionalise this process.

A network is as good as its weakest link. Therefore, all Member States

and the European Commission have to commit themselves to providing a substantial, material and financial contribution to each network.

A network of networks is the best way to use and improve what already exists. A centralised structure in a decentralised, heterogeneous social and legal landscape cannot utilise surveillance resources as efficiently as a network and it cannot provide for adequate intervention measures as long as the centralised institution is unable to overrule national institutions in Member States. Moreover, the EU decision on surveillance of and response to communicable diseases does not cover the field of intervention and favours the 'network-philosophy' for surveillance and early warning.

National authorities are responsible for intervention. But decisions to intervene should be evidence based and justified to other Member States and the EU by using an evidence based approach. Since surveillance and early warning deal with objectives which cannot be confined within borders, intervention has to be coordinated on a transregional and European level. Efficient coordination is not possible without a comprehensive and rapid exchange of information about what has been

done and to what effect. Therefore, all Member States have to provide for such an information exchange. Coordination itself remains a matter of bargaining between the technical and political factors of the different Member States who are involved in an early warning procedure.

A lot of networks dealing in some way with communicable diseases and early warning already exist within the EU. Most of them are funded by EU institutions other than European Commission DGV. These networks have to be taken into consideration when the network of networks is designed. The core-set of networks must be constructed with proper links to these existing networks.

Early warning is also a feature of international networks, especially those coordinated by WHO. Duplication of effort has to be avoided. Existing early warning systems can provide experience and knowledge of the most efficient procedures. Therefore the network implementation has to integrate and improve existing infrastructures and not re-invent them.

A network of networks has the best opportunity to integrate and use what already exists, but in order to guarantee efficiency and effectiveness, work is needed at regional, national and EU levels.

Capacity building has to focus on intervention epidemiology and

laboratory diagnosis to provide for comparable approaches and methods executed by different nodes of a network. Capacity building also has to build an adequate central organisation which is able to prepare, implement and manage the transnational components of the network.

Modern management approaches favour decentralisation and networking. The variety of health care and prevention systems in Europe have been developed not just by chance but according to different needs and conditions and they cannot be assessed as singly insufficient or inefficient. Therefore the road to strict centralisation should be avoided.

Tackling health determinants through health promotion and disease prevention

Report of Working Group 3: The new public health policy of the European Union, Potsdam, January 27-29th 1999

— *Tapani Piha* —

The concept of health in all Community policies was emphasised throughout the discussion as a cross-cutting issue of major importance. Health in all policies should be an element in all strands of the future framework. It must be stressed that both financial and human resources are needed for its implementation.

Target of action: health determinants

Consideration of determinants, risk factors, settings, and target population groups should be combined in broader themes each of which can form a basis for the development of a mix of measures in all relevant Community sectors.

The selection of priority themes for action should be based on opportunities for influence through Community measures. We know a lot about some determinants and how Community policies may influence them, for others we need to know much more. A good example of how the most important determinants can be identified can be found in a recent Swedish study (see Table).

A list of themes from which priorities can be selected should include:

- food and nutrition;
- inequalities: no simple solutions exist how to address them;
- addictions: tobacco, alcohol and narcotics;

- living conditions and other social factors: unemployment, work, social exclusion;
- healthcare;
- mental health as a broad concept;
- oral health: an example of multi-sectorial approach was given;
- genetic factors;
- life cycle, from pregnancy and early life to old age.

The mix of multisectorial measures, or the strategy for each theme, could be further defined in Commission communications or Council recommendations. Thematic task forces could be a useful mechanism to act upon different themes.

Prerequisite for successful action: health impact intelligence
Community policies and actions under each theme must be based on evidence of their effectiveness.

A component of Community action for each theme must include the development of methodologies with direct policy implications, such as health impact analysis, better under-

PROPORTION OF TOTAL DISEASE BURDEN IN THE EU ATTRIBUTABLE TO MAJOR RISK FACTORS IN RANK ORDER		
Rank	Risk factor	Attributable fraction (%)
1	Tobacco smoking	9.0
2	Alcohol consumption	8.4
3	Overweight	3.7
4	Occupational risks	3.6
5	Low vegetable/fruit diet	3.5
6	Relative poverty	3.1
7	Unemployment	2.9
8	Drug addiction	2.4
9	Traffic injuries	—
10	Other unintentional injuries	—
11	Physical inactivity	1.4
12	High saturated fat diet	1.1
13	Air pollution (outdoor)	0.2

Source: National Institute of Public Health. Determinants of Burden of Disease in the European Community. Stockholm: National Institute of Public Health, 1997.

standing of risk factors and risk perception among professionals and the population.

The evidence base for actions and policies must be made available and accessible for European actors. The Community must put mechanisms and resources in place for active promotion of relevant knowledge.

Action tool: networking

Community networks can serve as tools for:

- knowledge management (information and experience sharing, modelling the best practice);
- advocacy and effecting change (“we know that tobacco subsidies are bad, we need to produce the political majority to act”);
- policy development.

A network for health impact analysis was mentioned as an example in the working group.

Networks can also build a wider European dimension (European added value) into action, enhance civil dialogue, serve as a bottom-up element, and create partnerships for health.

Networks need clear objectives and outputs to justify their funding from Community sources. Their success and outputs need to be regularly evaluated.

Finally, networking of networks is important to prevent fragmentation of Community action.

Development of the European health strategy

The Community strategy for health will in the future consist of a new public health action programme and a broad approach to health issues in the Community. The action programme will serve as a funding mechanism.

The development of a broad strategic approach to health issues needs time. Its development is a continuous process and the future programme should provide resources for it.

An essential element in such a Community strategy is to detail how a high level of health protection can be ensured in the definition and implementation of all Community policies and activities.

The public health programme could include support for a European forum on health policy involving non-governmental organisations, Community institutions as well as member states. It would provide for better transparency, form a democratic element and create an opportunity for a civil dialogue.

As the dialogue between the EU and WHO develops mutual benefits will become also available in policy development.

The impact of the internal market on health systems in the Member States

Report of Working Group 4: The new public health policy of the European Union, Potsdam, January 27-29th 1999

Philip C. Berman

Working Group 4 noted that, contrary to the position in recent years, there is now widespread acceptance that the internal market does have an impact on health services, and that the impact is likely to grow.

The group clearly endorsed the views of the Federal German Minister of Health, Ms. Andrea Fischer, that “there will not be any harmonisation of national health care systems in the EU”. But there was also agreement with her subsequent remark that “a relationship of tension exists between the free movement of goods and services on the one hand, and the Member States’ competence for the organisation and regulation of their national health care systems on the other”.

The following comments and recommendations were made:

There is a need for greater

clarity on the impact of the internal market on health systems of the member states

The boundaries delineating the responsibilities of Member States vis-à-vis the European Community’s role need to be clarified – a clearer definition about what needs to be retained. Politicians in the Member States are concerned about retaining control over two principal dimensions of healthcare:

- the manner in which healthcare is organised in the countries (access to health services; capital planning; workforce planning), and
- the financing of healthcare systems (insurance or tax financed; who pays for what and when; what proportion of the public purse should be spent on health)

If there could be a clearer definition along these lines, then politicians

would be more inclined to cooperate on the impact of the internal market on health services.

Recommendation:

Agreement between Member States to be reached on those powers which are retained by the Member States.

The impact of the internal market on health services has been inadequately studied, and policy-makers are thus in danger of developing policy with inadequate evidence. The nature and the extent of the impact requires systematic evaluation.

Recommendation:

(a) Analysis is needed to identify the extent and nature of EU cross-border care:

- The types of care, and the number of cases, that are currently being provided on a cross-border basis, and future trends.

– The types of formal or informal arrangements that exist between health authorities for cross-border care.

(b) Analysis is needed to identify the Directives and Regulations affecting healthcare; the likely impact on health services; and future Directives and Regulations which may have an impact on health services.

(c) Europe-wide manpower analysis/monitoring is needed to identify the impact that the free movement of professionals will have in the light of growing healthcare manpower shortages and/or surpluses.

(d) Analysis is needed to understand the impact that the free movement of capital may have on public health services.

(e) Analysis is needed to understand the impact of the internal market on the relationship between public health, health services and social services.

When drafting EU treaties, directives, instruments etc. Member States should carefully consider the consequences in terms of the impact of the internal market on health services

There is a widespread misunderstanding that the European Court of Justice is making law. In fact it only interprets the Treaties. It was suggested that, in order to avoid further unexpected developments like Kohll and Decker, Member States should analyse every Directive, Regulation etc. – especially those of a generic nature – to assess the potential impact on health and healthcare.

Recommendation:

(a) Member States should be proactive, rather than reactive, in managing the impact of the internal market on healthcare services. This can best be achieved by working together – pooling knowledge – to influence Community policies, directives etc.

(b) To be successful, proactive Member State and Community collaboration will have to be inter-sectoral (e.g. involving different ministries/departments such as Commerce and Industry, Social Affairs, Employment etc.).

(c) The Commission should be requested to undertake a monitoring role in assessing the impact of the internal market on health services

The internal market is currently working imperfectly in health care

It is apparent that the internal market is not operating effectively in some healthcare areas. For example, oversupply of physicians has not had the expected consequence of reduced pay scales, nor have there been the movements of doctors from one Member State to another that might have been expected.

Recommendation:

Member States should be proactive in determining whether or not they wish to see a more effective internal market, and should then take the requisite action.

It is not only the EU's internal market that is affecting health services of the Member States

It was pointed out that major EU

economic policies have had substantial impacts on healthcare in the Member States. Most obviously, the overall EU economic targets – the convergence criteria – have significantly affected public expenditure and especially the national budgets for healthcare. The adoption of the Euro will certainly create price transparency which will surely have an impact on the purchasing of pharmaceuticals, medical devices and even health services.

Recommendation:

Member States should assess the impact of EU macro-economic policies on their own health services.

The internal market will have consequences in terms of evaluation of cost effectiveness and accreditation

There are enormous variations in health, healthcare and health services between Member States. The internal market involves the free movement of citizens, some of whom will require treatment when in another Member State. While in another Member State, they may reasonably expect to receive treatment of a similar quality and at a reasonable price. This may lead to demands for accreditation of hospitals on a Europe-wide basis, and evaluation of the effectiveness (and possibly cost-effectiveness) of treatments, pharmaceuticals, physicians (reaccreditation) etc.

Recommendation:

The Commission and Member States should consider if and how Europe-wide assessments, evaluations and accreditations should be established.

Contribution of research to European public health policy

Report of Working Group 5: The new public health policy of the European Union, Potsdam, January 27-29th 1999

————— *Jussi Huttunen* —————

Health research has brought knowledge that people can use to adopt healthier behaviours and technological solutions for a range of pressing health problems. Advances in biolo-

gy and in the technologies of research also promise advances in the future. But, in order to hold on to the improvements of the past and build on them in the future, the

European Union Member States must maintain a strong research base and build assessments of health needs into their decisions about research allocation for strategic and

applied research.

Target of action

The health of European nations will be influenced by several major issues during the next ten years. These include the following.

- The ageing of the population
- Increasing population mobility
- Changes in the environment and in the work setting
- Rising expectations for improved health
- General socioeconomic problems
- Rapid development of advanced medical technology
- Increasing need for cost containment of health systems

The responses to these challenges must be on many fronts, of which public health research is one. To underpin the New European Health Policy, public health research should be seen as a priority area in the research policy both at Member State and Community level.

Public health research as a part of European research policy

The focus of the European Union research programmes has remained centred on biomedical disciplines, and the influence on public health policy has been minor. Resources allocated to public health research and health services research have been limited, although the BIOMED I and II Programmes of the Third and Fourth Framework Programmes for RTD contained activities for public health research.

It is noted with satisfaction that the Fifth RTD Framework Programme of the European Union emphasises a number of public health issues. Theme 1 'Quality of Life and Management of Living Resources' contains six actions many of which are closely associated with public health policy e.g. food, nutrition and health, environmental health, and the ageing population. Furthermore, the RTD activities of a generic nature of Theme 1 include public health and health services research as one of the priority areas.

In its communication the Commission has proposed three strands of

action for the New Public Health Policy of the European Union:

- Improving information for the development of public health
- Reacting rapidly to threats to health
- Tackling health determinants through health promotion and disease prevention

It is of utmost importance that these actions are taken into account in the preparation of the work of the Fifth RTD Framework Programme. The instruments for promotion of high-quality public health research in Europe do not differ from those of other research disciplines. Apart from funding high-quality research projects, emphasis should be placed on creation of networks, promotion of exchange of scientists and other ways of stimulating European collaboration.

The research projects supported at the European level should always fulfill three criteria: scientific excellence, relevance for public health and public health policy, and European added value.

Priorities of public health research

Public health problems vary from one Member State to the other, and, therefore, it is difficult to identify definite priorities for public health research at the European level. Areas of major importance both for the European health policy and for the Member States include at least:

- Health policy research (including effects of other policies on health)
- Health systems research (including health services research and tools for cost containment)
- Development of methods and standards for health technology assessment
- Efficacy and effectiveness of different approaches to health promotion and prevention
- Development of indicators and systems to monitor population health and its determinants
- Research on dissemination and implementation of research results.

Coordination of health actions including public health research

Better coordination of public health research and other health actions at Member State and at European level would greatly improve the quality of research and the implementation and dissemination of its results. Work aiming at formulation of a common European public health research strategy was initiated by the BIOMED II Programme committee in 1994. This work should have been completed taking into account the priorities of the New European Health Policy. New structures for coordination and collaboration should include WHO and international science organisations such as the European Science Foundation.

The Commission should be more active in initiating public health research projects underpinning the new European Health Policy. Thus, DGV should commission research projects needed for development of European Health Policy. Similarly, DGXII should leave reserve funds for emerging research needs in the area of public health.

Implementation and dissemination of research results

Public health research, as any other research, is useless unless its results are disseminated and implemented. Every effort should be taken to improve the integration and implementation of public health research in the decision making processes both at the European and at the Member State level. Action includes research on dissemination of research results, development of interfaces between science and health administrators, and training of scientists, administrators and politicians to promote communication and collaboration.

EU enlargement – the influence on the EU health agenda

Report of Working Group 6: The new public health policy of the European Union, Potsdam, January 27-29th 1999

— *Magdalene Rosenmüller* —

Issues and challenges around health and enlargement

Important gaps exist between candidate countries and EU Member States concerning the most common indicators for health status: life expectancy and infant mortality. The rise in communicable and chronic diseases is related to risk factors like smoking, unbalanced diet, lifestyle, environmental factors and rising drug abuse. The effects of the transition: increase in social inequalities, widening income gap, social exclusion and an increasing dependency ratio aggravates the situation.

Challenges of the candidate countries health systems are related to economic viability, social acceptability, management capacity, institutional development and poor communication. Resources dedicated to the health sector are scarce: an average 4.5% of a generally low GDP.

Consequently there are important concerns about the ability of the candidate countries to fully participate in the European social security convergence, to assume the challenges related to the internal market and to actively contribute to health policy and issues at Community level. The effects on Member States' health systems, together with possible migration pressures, created by low motivation of health professionals, could put a severe strain on the public mood in Europe in the future.

Actions proposed and discussed to respond to these challenges

More involvement of candidate countries and exchange of experience

- Ways should be found for increased cooperation of candidate countries in the public health programmes, delayed by compulsory financial contribution, a complicated process, and with the European institutions related to health.

- Additional meetings around specific topics like the health reform process, priorities related to resource and investment allocation, cross-border cooperation, supra national issues, information systems and health technologies would foster exchange of experience.

Better information for the candidate countries

- More active transparency would allow easier acclimatisation of the candidate countries to the 'European arena' (e.g. the Pre Conference Workshop for Candidate Countries, organised by the German Presidency and DGV).
- Priority topics for better information would be the introduction to the 'European Health Arena' in general, European health policy, health related activities and the effect of European law on national health policy and health systems.
- More information should be channelled to the relevant institutions on the participation in public health and research programmes, the latter now open to the candidate countries with support from EC-Phare. Here learning could be assured through an initial consortium with an experienced Member State institution, before submitting own projects.

Give health more priority in the enlargement process

- Good health is a prerequisite for economic development and a well functioning system a prerequisite for social security coordination in the Community. The improvement of health systems would allow candidate countries to devote more attention to public health aspects.
- Even though in the field of health

only a few explicit *acquis* exist, there are many obligations like the ones related to compulsory reporting of data. With the Amsterdam Treaty more emphasis will be put on health in the Accession Agreements and a Commission document on health and enlargement is expected to give a basis for action. This would support the health ministries in putting health higher on the agenda in their country's accession process, especially related to priorities for funding.

Better assistance to the candidate countries

- For bilateral and international programmes, a facilitation mechanism would allow better information and organisation of different cooperation efforts, avoid overlapping and find synergies.
- Consensus, a Phare specific social programme, dedicates a very small part to health, and the twinning programme does not yet have health included in its priorities. This could change, with health given a higher priority in the accession agreements.
- The new Phare 2000 programme, which is in the conception phase, will dedicate more resources to health. An individual Phare 2000 health programme could address the specific health and enlargement related issues with tailor made programmes in each country, where issues are better solved at national than at the regional level.
- The idea has been forwarded and largely supported, that a consultation mechanism, including Member States, Commission, candidate countries and international organisations, could help identify priorities for Phare health intervention and corresponding actions and review them periodically.

How to build a better EU public health budget

— Doeke Eisma —

The key to the future success of the EU health policy is not only a matter of more funding. The core of the EU's future efforts should be the integration of health into the other policy areas. Furthermore, it is imperative that EU public health funds be used more efficiently.

As the draftsman for the 1999 EU budget on behalf of the Committee on the Environment, Public Health and Consumer Protection I was responsible for the health budget. In my report I suggested an increase of the EU health budget up to 50 million Euro. Compared to the 37.8 million Euro of last years budget for health this seems quite a lot but compared to the whole EU budget (97 billion euro) it is still minuscule.

The EU budget for 1999 was fixed during the plenary session last December. Although I am satisfied that the Council accepted some of my remarks to support patient groups and organisations for handicapped people, it is disappointing that Parliament and Council accepted only a moderate increase of the health budget (42.7 million Euro) and put a part of the budget in the reserve because of a lack of legal base. When we consider that the total health budget from the EU is less than 5% of the EU premiums paid for tobacco (more than 999 million Euro) one cannot proclaim that the EU takes the EU health policy seriously.

For me there are enough reasons to justify an increase for the EU public health budget.

Firstly, although in general terms the health of the Community population is better than ever before, this does not prevent the continued prevalence of serious illness and emerging diseases. The health problems facing the Community are too urgent and too large in scale to allow complacency.



Every year in Europe millions of people die prematurely or suffer ill health from serious conditions that could have been prevented. There are still high levels of premature death from diseases related to lifestyle, such as tobacco, drugs and alcohol. Health budgets of EU Member States are under intensive strain simply because people are living longer and people's expectations for better care and treatment are higher than ever. In addition there are new risks to health notably from the emergence of new communicable diseases, such as AIDS and the growing problem of resistance to antibiotics.

Secondly, although health care is recognised as something which should be carried out at national, or even regional level, much can be gained from the cooperation and the exchange of experience between Member States. The EU has a role to fulfill, namely to help Member States by improving the collection, analysis and dissemination of information so that European citizens' health will be improved.

Inequalities in health status between and within the Member States are worrying in a European Union which is committed to raising the

quality of living and ensuring a high level of health protection to its citizens. These inequalities are mainly caused by differences in lifestyle (e.g. smoking), socioeconomic conditions (e.g. housing) and environment.

Thirdly, the Treaty of Amsterdam calls on the Commission to prepare for new areas of public health and demands that the EU shall not only 'complement' the individual action of Member States, and 'encourage cooperation and support', but also aim at improving public health.

Fourthly, the development of public health policy has to take into account the consequences of enlargement of the Community towards Central and Eastern Europe. The health situation in these countries is poor compared to the EU. Most of the candidate countries face serious problems such as communicable and pollution-related diseases. With the exception of Cyprus fewer resources than in the EU are spent on health. Enormous resources are needed to improve the existing health systems and to improve their overall effectiveness and to bring them in line with European standards. Enlargement will also have implications for the health systems in the existing Member States, especially due to the free movement of people and the free circulation of products, notably certain pharmaceuticals and blood products. It is clear that there is a need to assist the applicant countries to adapt to the EU health policy, but without an increase in budget it is difficult to see how.

Although I am convinced of the need to increase the EU health budget it does not mean that funding alone is the key to future success. It is more important that the money is spent in an effective and coordinated way. Programmes need to make better use of existing budgets in the first

instance.

The existing EU health policy structure lacks this flexibility. In 1993, the Commission decided to put forward proposals for eight separate action programmes. Five have been implemented namely Cancer, AIDS and Communicable Diseases, Drugs, Health Promotion and Health Monitoring. The remaining three programmes, on Pollution-related Diseases, Injury Prevention and Rare Diseases, are in preparation but have not yet formally started.

In addition to the action programmes, the Commission proposed the establishment of a European Community network for the control and surveillance of communicable diseases (but without budget). Furthermore, initiatives have been taken on smoking, such as a Communication on combating tobacco consumption and a Council decision on tobacco advertising. A strategy has been agreed on blood safety and self sufficiency, reports have been produced on health status in the EU and health research is being proposed under the Fifth Framework Programme for Research and Technological Development.

This EU framework on health has given rise to unforeseen problems. The division among eight separate programmes and a lack of an overall strategy has led to an administrative burden, owing to the fact that each programme has its own committee, rules and structure. Since the available budget for each of these programmes is relatively small, one can question whether the use of funds is being maximised.

The fact that all funds have been dedicated to programmes for special purposes means a limited flexibility. For DG V/F (directorate for public health) it is therefore very difficult to respond to developments not covered by the present programmes as there is no money left for policy and analysis, preparation of new legislative proposals, studies, new initiatives and reaction to emergencies. Since each programme develops its own independent strategy and work plan, coordination between the programmes is difficult to achieve in practice with the risk of duplication

and overlap of activities. Furthermore, there is a considerable confusion for organisations supplying projects and also within the management committees about the respective roles of DGXXII (research) and DGXXIV (consumer health) DG XI (environment and health) and DGV (public health). Another problem with the funding for health research is that it lacks strategic management of the available budgets to determine funding priorities.

“The total health budget from the EU is less than 5% of the EU premiums paid for tobacco”

Furthermore, one can question whether some of these programmes have a European value-added at all. For example direct health education is unsuitable to be undertaken at EU level because it is a culturally specific activity which can better be implemented at the national level. ‘Europe against Cancer’ weeks, for example, are not the best way of spending the EU health budget since it is not effective at the local level.

In general one could say that the EU should not so much seek to increase its health budget only, but should spend the existing budgets more selectively on programmes and projects which really have a European added value and have been assessed for cost-effectiveness.

EU funding should become highly selective, involving fewer and larger projects. These projects should have clear, policy-oriented objectives and must be transparently evaluated.

However, the key to the future success of EU health policy is not just a matter of more funding. As many commentators have said already, the EU’s future efforts should be based around the integration of health into other policy areas. The BSE crisis has demonstrated the need for such an approach. A disease-based approach alone is too restrictive but must incorporate health determinants, such as lifestyle factors (e.g. tobacco, nutrition).

Many threats to human health are

also environmental, like waste, water quality, air quality, ozone depletion and ionising radiation. Therefore it seems logical to combine these two factors in the same exercise of integration. That means that we should not only ‘green’ the budget, but that we should also ‘cure’ the EU budget to ensure that environment and health are well taken into account.

The idea of integration builds on the Amsterdam Treaty which states that a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. But this means that the EU should put its own house in order through the integration of health into other sectors.

Besides budgetary reforms we need institutional reforms which implies a health section in the other Directorates-Generals and the transfer of the health department from Luxembourg to Brussels in order to bring to an end the geographical and political marginalisation and to stand any chance of integration with other policy areas. But an increase in the influence of EU public health can only be achieved by expanding administrative budgets.

It is therefore clear that the existing EU public health framework needs to be reviewed not only because of the drawbacks of the current approach, but also to deal with new challenges such as emerging health threats and increasing pressures on health systems, as well as the enlargement of the Community and the new public health provisions in the Treaty of Amsterdam. Moreover, such a review is particularly urgent as most of the existing programmes will be coming to an end in or about the year 2000 and proposals have to be put forward in the near future.

On the eve of the Millennium the EU has the opportunity to upgrade EU health policy. Now there is an occasion to clearly demonstrate that the EU can have real meaning for the lives and well-being of its citizens. For that we do not need just a gesture of cosmetic additions, but increased resources for highly selective funding and a real integration of health into other sectors.

The Kohll and Decker rulings: revolution or evolution?

The rulings in Kohll and Decker [Case C120/95 – Nicolas Decker v. Caisse de Maladie des Employés Privés; and Case C-158/96], Raymond Kohll v. Union des Caisses de Maladie] which the Court of Justice of the European Communities delivered on April 29th 1998,^{1,2} have caused a stir in the European health care and health insurance sectors.

A. P. van der Mei

In these rulings the Court concluded that national rules which make the reimbursement of the costs of medical treatment or medical products obtained in other Member States subject to the prior authorisation of sickness funds are in principle incompatible with the provisions of the EC Treaty on the free movement of goods (Articles 30) and services (Article 59).

The rulings are expected to increase patient mobility among the Member States and have significant implications for the organisation, financing and administration of the Member States' health care and insurance systems. From a health care perspective, Decker and Kohll can be classed as a revolution. The same does not hold true, however, from the perspective of European Community law. Even a short survey of the jurisprudence of the Court of Justice could have made clear that prior authorisation rules are hard to compare with the principles governing the free movement of goods and services and that the chance that the rules would not be able to withstand judicial scrutiny was, at the very least, present. In fact, it is remarkable that it took so long before the questions on the compatibility of prior authorisation rules with Articles 30 and 59 were submitted to the Court.

The prohibition of national rules hampering the free movement of medical goods and services

Articles 30 and 59 prohibit in principle all national rules which burden the free inter-State movement of medical goods and services. The prohibition contained in these two provisions are far reaching. Not only rules which directly and actually hamper freedom of movement but also rules which do so indirectly or even only potentially

are covered. In previous case-law the Court had already indicated that medicines and other medical products are to be regarded as goods for purposes of Article 30 and that medical care may be classed as a service in the sense of Article 60 of the Treaty. In addition, the Court had recognised that the free movement of goods and services includes a right to move to other Member States in order to obtain (medical) products or to receive (medical) services. Prior authorisation rules discourage patients from obtaining medical products or care in other states; the rules burden the free movement of goods and services. Therefore, one could already have foreseen that the Court would hold in Decker and Kohll that prior authorisation rules are at odds with Articles 30 and 59.

The financial stability of health insurance schemes

This did not necessarily imply that (the Luxembourg) rules were indeed inconsistent with the Treaty. National rules which burden the free movement of goods or services may possibly be justified either through Articles 36 and 56 or the so-called rule of reason. The two Articles leave room for national rules which are necessary for the protection of a number of public interests among which is the protection of (public) health. The rule of reason is a judge-made exception according to which Member States may apply rules which are necessary for protecting a number of "overriding reasons in the public interest".

In the proceedings in Decker and Kohll it was argued that prior authorisation rules would be necessary for protecting the financial stability of their insurance schemes. The prices of medicines, medical products and medical care differ considerably in the various Member States. If insurance organs would be obliged to reimburse the costs of all medical benefits obtained abroad, health expenditures could increase and this could possibly affect the financial stability of health insurance schemes. The chance that prior authorisation rules could be justified on this ground seemed small. It is settled case-law that Articles 36 and 56

“The rulings are expected to increase patient mobility among the Member States and have significant implications for the organisation, financing and administration of the Member States' health care and insurance systems.”

do not leave room for national rules which are applied for economic reasons and the rule of reason can only be relied upon as regards non-discriminatory measures, i.e. rules which apply equally to 'foreign' and 'national' goods and services.

Generally, however, prior authorisation rules apply only to 'foreign' medical products and care. Moreover, prior authorisation rules do not seem necessary for keeping health expenditures under control. Expenditures do not increase solely because medical care or medical products are obtained abroad. 'Foreign' medical benefits may also be cheaper than at home and as regards more expensive foreign benefits, no additional expenditures are incurred when sickness funds limit reimbursement to the maximum provided for under their 'own' price regulations. In *Decker* and *Kohll* the Court accepts the need to secure the financial stability of health insurance schemes as a possible ground for justification, but it concludes that reimbursement of the costs of 'foreign' medical products or care cannot have a significant effect on the financing of insurance schemes.

The infrastructure of health care systems

In *Kohll* it was further claimed that prior authorisation rules would be necessary for maintaining "a balanced medical and hospital service open to all". In order to provide adequate care, Member States must ensure that there are enough doctors, medical facilities and hospital beds available in their territory. Waiting-lists and other problems of undercapacity limit the accessibility of the health care system and are to be avoided. At the same time, the number of doctors, facilities and beds should also not be too large. Overcapacity implies an unnecessary waste of human and financial resources. Capacity planning would be virtually impossible if patients were free to choose in which State they wish to obtain medical treatment. In order to protect the infrastructure of the care systems a distinction must be made between care provided "at home" and care provided abroad.

The chance that this 'infrastructure-argument' could save the (Luxembourg) prior authorisation rules did not seem very big either. Firstly, the rules did not seem able to fall under either one of the two exceptions to the free movement of services. The protection of the infrastructure of health care systems could possibly be regarded as an "overriding reason in the public interest" for purposes of the rule of reason. Yet,

because they are discriminatory, prior authorisation rules did not seem justifiable under the rule of reason. Article 56 does not exclude the justification of discriminatory measures, but this provision only leaves room for national rules which are necessary for the protection of public health. The protection of the infrastructure of health care systems is not mentioned. It could have been argued that the existence of an adequate "health care system open for all" is a prerequisite for protecting public health and that, in spite of the economic factors involved, national rules necessary for securing the infrastructure of health systems could be justified through Article 56.

In *Duphar*, however, the Court had rejected such a line of reasoning as regards the equivalent provision contained in Article 36. Secondly, even if one of the two exceptions could be applied, prior authorisation rules did not seem justifiable. Increased patient mobility may cause capacity problem in the field of intramural care, but this does not seem so likely as regards extramural care. Prior authorisation rules generally apply to all types of 'foreign' medical care; from the perspective of protecting the infrastructure of medical care systems, the rules seem overinclusive.

The Luxembourg rules could not withstand scrutiny. The Court concluded that Article 56 does allow Member States to restrict the freedom to provide medical and hospital services, but only in as far as necessary for maintaining medical services and facilities which are essential for the public health and the survival of their population. Prior authorisation rules only seem necessary for this purpose in as far as applied to intramural care. In order to reach this conclusion the Court was even willing to extend the scope Article 56 and to come back from the line of reasoning which it initially had rejected in *Duphar* (as regards Article 36).

Conclusion

The precise meaning and implications of the *Decker* and *Kohll* rulings are still far from clear. Yet, long before April 28th 1998 one could have known that prior authorisation rules are at odds with the main principles governing the free movement of goods and services and that the rules as applied in Luxembourg and virtually all other Member States, were not likely to be able to withstand judicial scrutiny. The two rulings seem to have caught the health care and health insurance sectors by surprise, but in light of the case-law of the

"The two rulings seem to have caught the health care and health insurance sectors by surprise, but in light of the case-law of the Court of Justice the conclusions of Decker and Kohll could more or less have been predicted."

Court of Justice the conclusions of Decker and Kohll could more or less have been predicted. From the perspective of European Community law, Decker and Kohll are not so much to be regarded as a revolution, but above all as an evolution.

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National reactions to Kohll and Decker

Synopsis of a German EU Presidency preparatory meeting held in Bonn on November 23th-24th 1998, prepared by Jens Gobrecht.

The judgements of the European Court of Justice in the Kohll and Decker cases pronounced on April 28th 1998 caused a major stir and sparked intensive discussions on all political and scientific levels within the European Union. The tension between the right of the Member States to organise their national systems of social security and the freedoms of the internal market became clear.

The German Federal Ministry of Health organised a working meeting with other Member States and the Commission on the implications of these judgements in Bonn November 1998. The results of this meeting are to be summarised as follows.

German opinion

Up to now, there is no official statement of the new German Federal Government on these judgements. The German participants see no case for a transferability of the these. From the German viewpoint, they solely concern the Luxembourg health system, based on the principle of reimbursement. Therefore, the judgements are only transferable to systems that also operate on the cost reimbursement principle. Consequently, Germany will implement them only with respect to the reimbursement of costs; bilateral agreements, however, are not affected. Nevertheless, Germany expects that the basic freedoms will have massive

impacts on the national social security system that might substantially erode the right to freely organise it and restrict its manageability if the European Court of Justice were to extend its jurisdiction to cases in which state run institutions provide the necessary insurance services and benefits.

Dutch opinion

The Netherlands regard the judgements as inevitable. Therefore, health insurance legislation on the European level has to be reconsidered. The Netherlands are of the opinion that even after the judgements, the authority of the Netherlands to maintain the benefits-in-kind principle is not destroyed. In the Netherlands, as in Germany, both the territoriality principle and the right of the insured to receive benefits in kind exist. While relevant agreements have been concluded between the health insurance funds and the service providers, these do not explicitly stipulate that

service providers must be based in the Netherlands. So, foreign service providers cannot be refused contracts with Dutch health insurance funds. Although contract policies might have to change now, this may not lead to a situation where contracts are concluded with all service providers throughout the European Union. For the Netherlands, the question of whether concerted action needs to be considered within the European Union is still open.

French opinion

There is no official French position on the judgements. Concerning their quantitative effects, France expects only minor consequences in the short and medium term. France is of the opinion that the judgements must be followed and translated into action. The question is, however, how this can be accomplished without calling into question either the national systems or the financial balance. The French approach consists of minimum norms and standards. Subsidiarity has to be preserved so that the European Union does not take over the organisation of the health insurance system. The systems should be opened up without losing their distinctive character. Measures should be taken to avoid

the European Court of Justice regulating the health systems of the Member States. Countries with 'closed' health systems (e.g. Spain and Great Britain) must open up to the judgements.

Austrian opinion

Under the liberal Austrian health insurance system, the insured can choose between benefits in kind and the reimbursement of costs, where 80% of the rate that the health insurance funds would have had to pay to the contracting parties, is reimbursed. Demand comes mainly from patients with higher earnings or an additional private health insurance. Under this arrangement, there is no impact on the health insurance funds. Moreover, the 20% discount in the case of cost reimbursement acts as an incentive for the insured to make use of the services at home. In Austria, a specific problem is posed by Hungarian dentures offered at dumping prices. After all, Austrian courts of law have found these dentures to be comparable to domestic ones in terms of quality and stability. There is no need to amend the EC Treaties in order to exempt the social security systems from the basic freedoms of the internal European market. Problems might only arise with regard to the enlargement of the European Community.

Opinion of the United Kingdom

The United Kingdom, with its tax-financed and residence-based National Health System (NHS), does not fear that the judgements might call the NHS into question, but, nevertheless, wants to participate in solving the problem together with the other Member States. Under the NHS, the insured pays merely a lump sum, yet all services are available free of charge, regardless of the patient's nationality, provided the insured is resident in the United Kingdom. The general practitioner has the task of the gatekeeper and the provision of services is the subject of a contract concluded between her/him and the State. In the British opinion, the NHS is not an enterprise within the meaning of the EC Treaty, nor does it directly offer services which would come under Article 60 of the Treaty.

Regulation 1408/71 governs the use of services abroad with prior permission from the NHS. Permission is not granted if the service is available under the NHS.

Finnish opinion

Finland has a dual health system, similar to that of the United Kingdom. No negative effects of the judgements are feared. The health services are organised by the government and all citizens are covered by that national health system. Primary and hospital care are organised at the local level. Up to now, patients seeking treatment abroad without obtaining permission from the local authorities have not had the costs incurred reimbursed. Since this arrangement contradicts the Luxembourg judgements, an amendment is planned under which these patients would be eligible to a partial reimbursement of expenses. If, however, a patient is referred for treatment abroad by the local authorities, the costs are borne completely.

Italian opinion

Up to now there is no official Italian response to the judgements and the Italian health system does not feel to be affected by them. In the Italian health system the physician has no monetary claims on the patient. Remuneration is negotiated between the service providers and the public authority and fixed in contracts. Hospital-based services are classified and fees agreed on, with maximum amounts being fixed for services. Treatment abroad is handled in line with the provisions of Regulation (EEC) 1408/71. Italy shares the position that the judgements should not automatically be extended to other fields of the health systems as e.g. the benefits-in-kind principle which would cause problems concerning quality assurance including minimum standards, a fair billing of services with fixed maximum costs and the different levels of costs. If it is accepted that some of the patients are treated abroad, this can lead to a two-tier medicine, which contradicts the basic principle of equal treatment for all patients. If there will be more cross-border health care in future, the health systems will be thrown off balance.

Danish opinion

In Denmark, service providers do not conclude contracts with the State, but there is a public health care provision system in place. Up to now, the Danish Government has not commented on the judgements in the Kohll/Decker cases. While Denmark will accept them, it reserves the option to further analyse and evaluate the judgements and their consequences. At the moment, the principle of benefits in kind is not legally covered by either the EC Treaty or by the judgements and therefore, the judgements have not given rise to any fears in Denmark. Cause for concern is, however, the possibility of further decisions by the European Court of Justice with greater areas of application. Difficult political problems would arise if these decisions were to affect the right of the Member States to decide on their social security systems. Therefore, Denmark would prefer to have no further judgements by the European Court of Justice. Denmark sees a possible solution in a more flexible organisation of Regulation (EEC) 1408/71.

Conclusions

The meeting gave the participants a synopsis of the various positions held by the Member States concerning the judgements and their implications and heightened the awareness of the tension between the freedoms of the internal market and the right of the Member States to organise their national social security systems. All attending Member States shared the will to continue the political and legal discussions over this explosive issue. Therefore, the understanding of the judgement by the Member States had to be more clearly identified and structured. Any potential advantages, in particular, those that the internal market might bring for the public health system should be identified. In addition, the question of what direction future joint action may take needs to be answered. The participants were unanimous in that their countries seek to avoid the health sector being fashioned by judicial decisions that have already been taken without the political will of the Member States being reflected or endorsed.

Health as a tradable service: a prospective view of the European Union

Health treatment of EU citizens in a Member State other than that in which they pay social security contributions was until recently regulated by EU law^{1,2} and required prior authorisation and approval. The Decker & Kohll cases [Case C120/95 – Nicolas Decker v. Caisse de Maladie des Employés Privés; and Case C-158/96, Raymond Kohll v. Union des Caisses de Maladie], however, are likely to have considerable implications for the future provision of health services and the purchase of health-related goods and services across borders between Member States. Both cases relate to patients' rights to acquire medical goods and services in Member States other than those in which they pay social security contributions without prior authorisation.



Panos Kanavos

Likely implications

The principle of subsidiarity empowers national governments to determine all aspects of health policy within their jurisdiction, including pricing of medical goods and services, levels of reimbursement, and types and levels of patient co-payments. The Court's rulings have made mainstream health services subject to the free movement of goods and the free movement of services and have therefore introduced a transnational aspect to health policy-making. The freedom to choose goods and services effectively empowers consumers and patients or their agents to shop much more widely for the best available deal and potentially increases choice.

Health as a tradable good

The Decker case concludes that the free movement of goods should not be compromised, even in 'sensitive' areas such as pharmaceuticals and prostheses. The Court ruling builds on a previous case concerning consumer health care products available in different Member States over-the-counter.³

Applying the principle of the free movement of goods in health can potentially have significant implications for a range of products, including the cost of medicines and their rationing across Member States. For medicines that are reimbursed by (tax- or social insurance-based) health systems, there are potential benefits to payers, providers and patients, although for the latter, these may be negligible for reimbursable drugs and the benefits are focused on co-payment differentials.

Payers in some countries, including health authorities and social insurance funds, may benefit considerably. Faced with increased

medical costs, payers may be interested in taking advantage of price differentials with neighbouring countries, and, through the free movement of goods, exercise arbitrage favouring the supply of final products from countries in which prices are lowest. This may be the case in pharmaceuticals where price differentials are quite significant between Member States due to price regulation. In this case, payers in high price countries (e.g. Germany, the UK, Denmark) may benefit from prices prevailing in low-price countries (Spain, France, Italy, Greece) through parallel importing. The more decentralised the process of decision-making is in national health policy-making, the more intensive this is likely to be. This would be the case in tax-financed systems with a purchaser-provider split, as in the UK, Denmark and Sweden, but also in social insurance systems with multiple insurers, of the kind that exists in Germany or the Netherlands. In the former case, payers are interested in saving on their centrally allocated budgets and in the latter, the incentive is to reduce pressure to pass higher costs to insurees through higher premia. Although this may appear to defy national policies regarding the pricing of medicines, it would be in line with national and EU law regarding the free movement of goods and parallel trade.

Providers may also be interested in acquiring their medicines from cheaper sources since pharmaceuticals consumed in hospitals are a significant proportion of total hospital costs. Tendering procedures may therefore acquire an international dimension, in accordance with EU legislation on public procurement.

For manufacturers, the potential medium- to long-term response might be to discon-

"There is... a clear clash between the principle of subsidiarity and the freedom of movement of goods and services."

“Assuming that patients as well as payers have access to improved information and demand quality and value for money, the two cases suggest that, within a single market, health care will be freely available and at wider choice regardless of national frontiers.”

tinue their activities in countries where prices of medicines are heavily regulated and shift their production to high-price countries, where there is absolute or relative freedom in price-setting. This would mean an over-concentration of industry in countries such as Germany or the UK and less so in Denmark and the Netherlands. Intra-EU trade would then satisfy demand from the original low-price countries.

If, on the other hand, the medicine in question is rationed (no reimbursement or selective reimbursement), patients would be able to acquire it more cheaply in a low-price Member State on a private prescription. The current pharmaceutical price differentials between EU countries may justify such transactions along border areas. Target products include new and expensive treatments, which are rationed by the health service of one Member State. The next step may be for payers to re-negotiate reimbursement levels within their jurisdiction and set these in line with price levels prevailing in neighbouring countries.

Health as a tradable service across borders

The Kohll case rendered health services available to all EU citizens regardless of their country of residence or their health insurance status or insurance fund. While the ruling allows citizens of one Member State to seek medical treatment in another, it also gives due consideration to the reimbursement of the services delivered. Such reimbursement will take place according to the rules prevailing in the patient's country of residence.

To the extent that patients are allowed to obtain health services freely across borders without prior authorisation, the ruling improves on existing regulations involving paperwork for transnational patients, who fall ill whilst visiting other countries, or specifically request treatment in a country other than their own. Given that cross border movements to obtain health services are well documented,⁴ particularly between France and Belgium, between France and Italy, and between Germany and France,⁵ the ruling could increase the volume of services provided across borders not only in these regions but also in others (e.g. Spain-Portugal, Spain-France, UK-France, UK-Ireland).

An increase in the volume of patients seeking care in another Member State may occur for a number of different reasons: firstly, due to differences in the perceived

quality of the services between countries. This has been the case of Northern Italians seeking treatment in France.

Secondly, due to capacity shortage or implicit rationing through a waiting list in the insuree's own country. In this case, local payers, using local capacity control as a mechanism for rationing and cost control will have to reimburse patients who travel abroad for treatment. This will involve increased expenditures by local payers. The losers are not only local payers, but also local providers since care provided abroad would imply loss of income for them.

Finally, patients may wish to receive treatment overseas because the service they require may not be reimbursed in their own country. In this case, they may wish to do so once it has been established that it would be cheaper to have the service delivered abroad, since they are paying out-of-pocket. In the UK, for instance, dental treatment and optical care have over time been excluded from reimbursement for the majority of the population.

What does the future hold?

Assuming that patients as well as payers have access to improved information and demand quality and value for money, the two cases suggest that, within a single market, health care will be freely available and at wider choice regardless of national frontiers.

The rulings introduce an indirect, but definite, element of transparency that challenges the way systems are financed in different EU Member States, and which has fiscal implications for those systems that deliver less satisfactory services. There is thus a clear clash between the principle of subsidiarity and the freedom of movement of goods and services. Cross-border movements put health care under a new scrutiny particularly where services or goods are reimbursed in some Member States but rationed in others. In the latter case, governments are likely to encounter growing public dissatisfaction. This may, in turn, stimulate a debate about whether there should be a standard package of care offered across the EU, and, if so, what such a package should be, how should it be defined, and how should it be financed.

Although the principle of social solidarity still holds in all EU Member States, clearly the breadth of coverage differs. This generates a series of questions regarding patient reimbursement levels, co-payments, issues relating to the pricing of goods and ser-

vices, but also the whole issue of 'social' insurance across borders and its portability across borders. In sum, the two cases pose several fundamental issues that would require collaboration and a gradual shift from the island mentality in the provision of health services.

While the Treaty of Rome arguably paid little attention to health care provided at European level across borders, receiving health care in a Member State other than one's country of residence is not uncommon. The empirical literature suggests that cross-border movement by patients seeking health care is rising and is likely to continue to do so in the near future. While significant barriers and costs are associated with cross-border transactions, particularly for tangible health goods, such as drugs and prostheses, the recent European Court rulings may be the beginning of a process that will ultimately create a European health policy.

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Kohll and Decker: a new hope for third-country nationals

The European Court of Justice (ECJ) decisions in the Kohll and Decker cases have confirmed the existence of two distinct procedures by which to obtain medical goods and services in another EU Member State at the expense of one's social health care system.



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Two distinct procedures

Firstly, the ECJ confirmed the legality of the 'authorisation procedure' contained in Article 22 of the EC Social Security Coordination Regulation 1408/71.¹ This procedure allows EU nationals to apply for authorisation for foreign health care from their social health care system, if authorisation is granted they are treated abroad and their social health care system reimburses the foreign health care provider directly. Secondly, the ECJ described a 'new' procedure based on the EC Treaty provisions on the free movement of goods and services,² which enables patients to purchase medical goods and services in another Member State without the permission of their social health care system. Under this new procedure the patients pay their foreign health care provider themselves and then claim a reimbursement of their expenses from their social health care system as if the treatment

had been provided in their own state.

A closer inspection of the legal grounds behind these procedures reveals that they are not just different as regards their substance but also their personal scope. Regulation 1408/71 only applies to EU nationals and their families and expressly excludes third-country nationals. The EC Treaty provisions concerning the free movement of goods and services on the other hand are not concerned with the nationality of the recipients but with the origin of the goods or nationality of the service provider. The free movement of goods and services are rights reserved to the EU supplier and there are no nationality-based restrictions placed on the consumer. As third-country nationals are free to consume goods and services from other Member States they are also (theoretically) capable of benefiting from the procedure laid down in Kohll and Decker. These decisions have thus effectively extended the right to foreign medical goods and services to any third-country national who is covered by the health care system of an EU Member State and is allowed to travel across the internal borders of the EU. Before taking a closer look at which third-country nationals can benefit from the new

procedure, some more attention should be given to the social security situation of third-country nationals.

Third-country nationals and regulation 1408/71

A third-country national is someone who is not a citizen of one of the EU Member States. EU law in general distinguishes between various categories of third-country nationals:

Third-country nationals who are family members of an EU national

Free movement would be severely hampered if migrating workers and self-employed persons could not bring their families with them and so EU provisions exist to protect the rights of non-EU family members.

Nationals of the European Economic Area

The EEA agreement extends the entire *acquis* (including the provisions on free movement to Norway) Iceland and Liechtenstein. The nationals of these states are thus placed on a par with EU nationals.

Nationals of states that are party to agreements with the EU

The EU has entered into agreements with many third countries that dictate the rights and obligations of their nationals regarding entry, residence and employment in the EU. These agreements are extremely complex* and as none of them include the right to social health care in another Member State I shall not look into them in detail.

Others

This residual category includes all those third-country nationals who are neither related to EU nationals nor subject to an EU agreement.

Regulation 1408/71 expressly applies to EU nationals and the members of their family, which thus includes third-country family members who are entitled to the same treatment as EU family members.⁴ As the EEA states are now subject to the EU *acquis* this means that EEA nationals benefit from exactly the same rights as those provided in Regulation 1408/71, including the right to health care in another Member State. All other third-country nationals are unable to rely upon Regulation 1408/71 to receive health care in another Member

State, not even in cases of emergency.

There are 12.5 million third-country nationals legally residing in the EU today. They are comprised of workers and their families, they include children who have been born, raised and educated here and yet most of them are still excluded from the ambit of Regulation 1408/71. The EC Commission has attempted to rectify this situation. In 1995 a proposal was submitted to extend emergency treatment to third-country nationals legally resident in one Member State who are injured whilst visiting another. However, the Member States rejected the proposal because they did not believe the EC was competent to take this step, this was the case despite very convincing arguments to the contrary.⁵

Following the rationale of the ECJ in Kohll and Decker there is no reason why a third-country national who is injured during a stay in another Member State can not take the bill for his/her emergency care back to his/her social health care system. In this respect the ECJ has extended the personal scope of foreign health care up to and beyond that envisaged in the Commission proposal. This brings us on to the question of which third-country nationals will benefit from the ECJ extension and what will be the effect on the national social health care systems.

Which third-country nationals can benefit from Kohll and Decker?

In order to benefit from the ECJ decisions third-country nationals must, firstly, be covered by a Member State's social health care system and, secondly, be allowed to travel to other Member States.

Covered by the social health care system

Generally speaking most national social security systems will base their coverage on residence or employment and not on nationality.⁶ This means that national law will cover legal residents or legal workers (and their legally resident family members) and will not exclude third-country nationals per se. If a Member State should discriminate against non-nationals the person concerned may be entitled to equal treatment according to an EU agreement which includes equal access to national social security systems.** Failing this, a person who is not covered by a specific EU agreement or whose agreement does not provide a clear right to non-discrimination may be able to argue that s/he is entitled to join the national system on the basis of the European Convention on Human Rights,

“... it is clear that the ECJ has created a ‘hope’ of medical treatment abroad for legally resident third-country nationals but first these people must be covered by social health care, entitled to travel and have enough money to pay for their treatment up front.”

* For a more detailed introduction to these EU agreements see Peers S, 1997.³

** For example, see the Turkish Association Agreement as interpreted in ONEM v Kziber [1991] ECR 199.

as interpreted in the *Gaygusuz* decision.⁷ Of course, to be affiliated to the national social health care system the third-country national will have to fulfil all the same contribution conditions as nationals.

Entitled to travel within the EU

At present third-country nationals are not free to travel anywhere they like within the EU. The Member States are still free to demand visas before they admit third-country nationals. The free movement of goods and services does not provide third-country nationals with a right to enter a different Member State even if they do intend to purchase goods and services there. Therefore the right to travel must pre-exist under EC law.

The Schengen Agreement represents the clearest right of travel for third-country nationals as they will be allowed to cross the internal borders of the Schengen states for a limited period of three months, which is certainly long enough to purchase medical goods and services. EU service providers are allowed to take their non-EU employees to another Member State in order to provide a (temporary) service there.⁸ Should one of these employees need emergency treatment s/he shall certainly fall within the ambit of *Kohll* and *Decker*. A proposal has been made for a Directive that would extend the right to cross internal borders for short periods to all third-country nationals, should this Directive be passed it should enable any third-country national to travel abroad for medical goods and services.⁹

The actual impact of this extension of personal scope

The ECJ has once again used its interpretative powers to step in and fill a social gap that could not be plugged by the more democratic institutions of the EU. There are around 3 million Turks, 3 million Central and Eastern Europeans, 2.5 million Asians and 1.5 million Africans legally resident in the EU today. Germany and France have the highest concentration of third-country nationals. Germany contains around 2 million Turks and substantial numbers of Eastern Europeans, in 1991 of the 91,000 Turks to enter the EU nearly 75,000 went to Germany. France has a sub-

stantial population of Moroccans and Algerians and contains over 36% of the 4.8 million immigrants from the twelve non-EU states surrounding the Mediterranean (the 'MED 12'*). Other States with extensive third-country populations include the Netherlands and Belgium.¹⁰

Given that both Germany and France are members of the Schengen Agreement and that Turkish, Algerian and Moroccan workers enjoy clear rights of equal access to social security coverage according to EU Agreements, the extension of the personal scope of foreign medical treatment is likely to be heavily felt in these states. As Germany does not operate a reimbursement system similar to that in Luxembourg this might be an added reason for it to attempt to restrict the application of *Kohll* and *Decker* to such systems.

Despite the many uncertainties surrounding the decisions of *Kohll* and *Decker*, it is clear that the ECJ has created a 'hope' of medical treatment abroad for legally resident third-country nationals but first these people must be covered by social health care, entitled to travel and have enough money to pay for their treatment up front.

The author would welcome any comments or feedback from readers.

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The European Union Single Market in pharmaceuticals

————— Jörn Keck —————

“To date, the debate on the Single Market in pharmaceuticals has, arguably, been characterised by considerable caution on the part of both the Member States and the industry... But it is increasingly clear that – in practical as well as legal terms – the Single Market will not somehow ‘stop at the front door’ of the Member State health systems.”

One of the more memorable analogies that has been drawn about the debate on the Single Market in pharmaceuticals was made about ten years ago and was an analogy with the Echternach procession. Echternach is a small village that nestles in the hills alongside the Moselle. Once a year, pilgrims join in a procession which requires them to take two steps back for every three they advance.

The debate on the Single Market in pharmaceuticals has been around for considerably less time than the Echternach tradition. Nevertheless, we are fast approaching the twentieth anniversary of the first judgements by the European Court of Justice affirming pharmaceuticals are part of the Single Market – which helped to bring this issue onto the agenda of those working in this field. The debate has developed from there with two broad impetuses:

- Firstly, a series of judgements from the European Court of Justice. One notes in passing that a considerable amount of the case law relating to the general operation of the Single Market has been developed through cases brought in the pharmaceutical sector;
- Secondly, an uncertainty, particularly on the part of the Member States and the industry, about the implications of a Single Market on their respective interests.

The Round Table process

It was against that background that Commissioner Bangemann launched his initiative to address some of these concerns. It was perhaps inevitable that this process would have a large weight of hopes and expectations loaded upon it – for much was, and is, at stake in the eventual outcome of these considerations. In view of these expectations, the process was launched under the heading of “*completing* the Single Market in pharmaceuticals”.

There have now been three Round Table meetings – two in Frankfurt and a third last December in Paris. Contributions have come into the process – notably in the form of two reports by the ‘Frankfurt working groups’ that were set up after the first Round Table to prepare the discussion in the second Round Table and in the form of Council Conclusions agreed by ministers from the Member States in the Internal Market Council in May 1998. This ministerial policy statement prepared the way for the Commission to set out its own policy stance on these issues which it did in the form of a Communication on the Single Market in Pharmaceuticals which was agreed at the end of November 1998. The papers relating to the process, including the written proceedings of the Round Tables themselves, are all available on the

DGIII pharmaceuticals web site (<http://dg3.eudra.org>).

The Communication has received a broadly favourable response from some parts of the pharmaceutical industry, notably the sectors that deal with older, generic, products and those dealing with products delivered without prescription (‘over-the-counter’); together, these interests account for substantial parts of the pharmaceutical market in Europe. However, no-one who follows these issues regularly will be unaware that the Communication has raised strong concerns in certain other parts of the pharmaceutical industry – notably those with interests in research and development. A number of criticisms have been made by this part of the industry, notably that the Communication was just “a collection of cost-containment measures” with no concern for innovation. These concerns were vociferously expressed at the Paris Round Table.

Those who attend the Round Tables feeling a little like the pilgrims at Echternach might be forgiven for thinking that little progress appears to have been made in the process. Summing up at the end of the third Round Table, Commissioner Bangemann highlighted a number of key principles that all participants can sign up to. But it was clear that the Commissioner was right to observe that, the moment the debate moves beyond such broad statements of intent, points of contact and consensus between the parties to the debate are still few and far between. But one should be cautious about judging that the absence of progress against one set of expectations constitutes failure for the whole process – not least because of the considerable contribution that

the process has made to developing greater understanding of the interests and positions of all its participants.

The Commission Communication on the Single Market in pharmaceuticals

Much of the Communication itself had been designed to bring out what the Commission perceives as the consensus in the views that have been developed in the discussions over the past couple of years. The Communication also sought to set out why a Single Market was important in this sector – not just in order to meet Treaty obligations but also to improve the innovative and competitive base for this sector within Europe. The Communication highlighted the balance that has to be drawn between industrial interests and health care interests in this sector and established that the pressures that are growing in Member State budgets in this sector mean that the industrial interest cannot be credibly addressed by simply arguing for a massive increase in expenditure on pharmaceuticals. The Communication identified some key dynamics to the pricing debate, notably that, because aggregate expenditure has both a price and a volume element, the setting of low prices does not necessarily mean a lower aggregate expenditure on pharmaceuticals – indeed, one of the fundamentals that we are dealing with in these discussions is that certain parts of the European Union spend about as much, or even more, per person on pharmaceuticals as is spent even in the United States and yet have had relatively low prices for pharmaceuticals. Finally, the Communication – for the first time – establishes a clear distinction between the Member States' legitimate interests in ensuring aggregate expenditure control and the risk that they rely excessively on price-fixing as the means for achieving this. Perhaps most radically, the Communication broached for the first time the issue of pricing liberalisation in this sector – setting out the view that this was readily achievable in the over-the-counter sector but noting that, subject to an effective competitive structure, it could be considered as a policy direction also for the prescription sector.

The Single Market project was thus put into its full context in the Communication. There has been considerable progress in developing the best systems for protecting intellectual property and in providing the potential for speedy access to the market through the new systems for issuing marketing authorisations – and I am sure that the industry does not begrudge us this! But the agenda has still to be completed on the market side where the Communication notes that we still seem to be some way from a Single Market which all parties are comfortable with – but that further developments have to be in the integrating direction of the Single Market, not moving further from it.

In preparing the Communication, the Commission had identified two key issues that would benefit from clarification at this stage. The first was on parallel trade in pharmaceuticals; the second was the value of proposing some realistic policy parameters for these discussions, ensuring that the debate focuses on developments that will be both credible to the regulators and relevant to the innovation interest.

On parallel trade, the Council conclusions in the Internal Market Council specifically asked the Commission to address in its Communication “the question of the price differentials between Member States and the issue of parallel trade in this sub-sector”. This the Commission did, setting out some of the convergence effects that parallel trade can be expected to have – positive convergence effects in the Commission's view and effects that are reinforced by the increasing use by Member States of techniques of international reference pricing. It is clear that, as far as prices are concerned, these convergence effects are two-fold – restraining at the higher-priced end of the market, but making it increasingly difficult to have very low prices at the other end of the market (this latter point is of crucial importance as we look towards the forthcoming Accessions negotiations). The Commission tried to make the presentation of parallel trade balanced: in acknowledging its potential benefits, it in no way chal-

lenged that it can be disruptive – and that, in a situation of static prices, a relatively small amount of the value of parallel trade itself seems to accrue to the consumer or health care system. But the fundamental of the Commission's position has been reconfirmed: parallel trade is part of the pressures for change and for integration within this sector.

On the issue of parameters for this debate, the Communication has helped to confirm that the Commission is not arguing that it should take over control of the management of their health care systems, nor is it arguing that the “answer” lies in major increases in aggregate levels of expenditure on pharmaceuticals. However, the Communication does set out that there are a range of measures to improve the functioning and transparency of the market that, in different ways and in different health care systems, can contribute to more rational approaches to the regulation of this sector and that such an approach can help to address legitimate concerns about the competitiveness and long-term development of this sector.

Next steps

Communications are not the last word in any policy debate: it is unlikely that the Commission's Communication on the Single Market in pharmaceuticals will mark the end of this debate – it certainly was not intended to. The European Parliament has announced its intention to prepare a report on the Communication; the Commission hopes that the Council will wish to return to this issue, possibly in the context of the German Presidency. The Commission has also signalled its sense that a re-examination of the Transparency Directive (the major piece of Community legislation in this area) appears to be becoming timely.

The Single Market agenda – in any sector – is as radical as the interests in that sector wish it to be. However, because it is a Treaty obligation, it is not a *negotiable* part of the regulatory infrastructure. The “trick” is, therefore, to ensure that the Single Market is harnessed to help to deliver the fundamental

objectives in this sector and to maintain thereby the international competitiveness of the European pharmaceutical industry. The Commission's Communication clearly acknowledges these objectives – fundamental for both the Member States and industry – that have to be met if patients are to get the pharmaceuticals they need, if genuine innovation and added-value is to be promoted and if budget constraints are to be met.

To date, the debate on the Single Market in pharmaceuticals has, arguably, been characterised by considerable caution on the part of both the Member States and the industry. This is understandable – both Member States and industry face strong pressures to deliver demanding short-term objectives. But it is

increasingly clear that – in practical as well as legal terms – the Single Market will not somehow ‘stop at the front door’ of the Member State health systems. Pressures are also growing on pharmaceutical budgets and yet there are signs that sometimes new products appear to be taking a long time to get to patients after being licensed. The question that all participants in this debate perhaps might now start considering carefully is whether a less cautious, more strategic, engagement in this debate is needed. The realisation, and acceptance, on the part of all interests in this debate that the competitive forces of the Single Market are necessary for the long-term survival of an innovative, high-tech pharmaceutical industry in Europe. In the process, this will create winners and losers within the industry,

could get us into the next stage of a productive discussion. Such a discussion may be an inevitable part of promoting innovation and added-value whilst at the same time helping to meet budgetary constraints and to ensure patient access. In the view of the Commission, it is a discussion that will have to be complemented by a sustained effort by the Member States to examine the extent to which their purchasing functions might be better aligned with competitiveness objectives: the Commission has undertaken to be helpful in this endeavour. The twentieth anniversary of the first ECJ judgement affirming that pharmaceuticals are part of the Single Market gives us good reason to pause and think about these possibilities more thoroughly.

Towards the Single Market in pharmaceuticals: DG III's hopes and suggestions

— *Andrew Herxheimer* —

The European Commission has long been worrying that “parts of the pharmaceutical industry in the EU” may be losing global competitiveness, and therefore wants to get on with establishing the Single Market in pharmaceuticals. The Communication it issued on November 25th is a discussion paper describing the needs and the problems, and outlining possible approaches to them. The completion of the internal market is seen as essential for “establishing a stable and predictable environment [for the industry] in order to protect the health of patients, to ensure rapid access to the market and to encourage rapid innovation.”

The Commission wants to ensure that “patients and consumers have access to the pharmaceuticals they need, at affordable cost, and that appropriate incentives are available for innovation and industrial development.” That does not sound at all controversial, but two points raise thorny questions. First, how are

needs for particular pharmaceutical products to be judged? The industry has been spectacularly successful in persuading consumers, patients and health professionals that they need products in many cases where this need is far from clear. The marketing skills and efforts of the industry are enormous, while controls of promotion are weak.

Second, what are appropriate incentives for innovation? Up to now any innovation has been regarded as a good thing, but we really want to encourage only useful ones, that is products providing a significant advantage over existing ones in effectiveness, safety, acceptability or cost. The current licensing system does not require any such advantage to be demonstrated, and the great majority of patented pharmaceutical innovations have not been shown to have one.

The most interesting and constructive idea put forward by the

Commission is its distinction between the three different sectors in the pharmaceutical market: the medicines available without prescription; the out-of-patent prescription medicines; and the in-patent medicines.

For non-prescription products the removal of price controls would be logical and easy, and would increase competition. It “could reduce marketing costs considerably by allowing companies to benefit from the economies of scale and scope that could come from cross-border marketing.” In the UK the Government's proposal to end retail price maintenance has predictably led community pharmacists to protest that many would be bankrupted. The obvious remedy would be to pay them properly for their contribution to the NHS in advising people about medicines, provided that steps are taken to ensure a high standard of advice.

For out-of-patent products, espe-

cially those sold by their generic names, price competition already exists; price control is unnecessary. But transparent information about the competing products is essential. The Communication does not mention generic non-prescription products (the most important are paracetamol and aspirin), presumably because the self-medication industry considers them commercially trivial and hates them.

For patented products there is a tension between rewarding the innovator and paying over the odds. To make the product affordable and accessible, the price should be related to its likely therapeutic benefit. Other aspects to be considered include the scale of the need for the product, and the prices of other therapies for the same condition. The Communication discusses reference pricing and the possibility of de-listing or greater patient co-payment for certain products. Perhaps public purchasers might also ask themselves what further research is needed to establish how the product is best used, and how that research will be funded. Contractual arrangements could be made for the supply of a range of drugs for several years between a health service and a phar-

maceutical company. This could help both sides by providing lower prices in exchange for long-term stability.

“The marketing skills and efforts of the industry are enormous, while controls of promotion are weak.”

The paper was developed by DG III with input from Commissioner Bangemann’s Frankfurt Round Tables – tripartite meetings between “Member States, industrial interests and the Commission.” It is not clear whether any of the participants knew much about health issues, but the text of the Communication suggests that none did. References to health amount to no more than superficial generalities, whereas industrial and economic issues are discussed in detail. The conclusion does suggest that the next steps might include dialogues “between Member States and the major stakeholders, including patients and consumer associations”; but health pro-

fessionals are present only between the lines.

The conclusion also cites the Commission communication on the development of public health policy in the EU [COM(1998)230], which recommends that “future work should address and promote cooperation on the evaluation of the therapeutic value of pharmaceuticals, in particular in comparison to alternatives, as well as the systematic collection and analysis of data on the utilisation of drugs and brands, especially prescription and consumption patterns.” These points seem to have been stuck on at the end: they have not been integrated into the rest of the document. One wonders whether DG V was even shown the draft.

Finally the Communication notes that the Commission could arrange a discussion conference this year with the current applicant countries on the pharmaceutical market aspects of accession “to ensure full understanding of the challenges ahead”. If this conference takes place, will it be another industry-centred meeting with no one competent to address health issues? I very much hope that will not be allowed to happen.

Development of the Single Market in pharmaceuticals

Innovation, competitiveness and access should be the drivers of an integrated health and industrial policy for Europe



Brian Ager

Pharmaceuticals, one of Europe’s most heavily regulated products, contribute hugely to human health and economic growth. Yet in the last decade, Europe’s pharmaceutical research capability has been progressively eroded, as leading edge research and development (R&D) outfits relocate to third countries.

Up to early 1990, the European pharmaceutical industry was the world leader in R&D and innovation. It then gradually lost ground to the US until, in 1997, large US corporations not only launched more new chemical entities than EU ones, but also, on average, had more products about to emerge from the development pipeline. To take the stark example of biotechnology-derived medicines, 63% are now being developed in the US, but only 25% in Europe. In 1997, US firms in this field employed 140,000 people compared to 40,000 in Europe.

The best incentive for innovation remains a competitive environment, free from state intervention in the market. The mainstay of the European pharmaceutical industry's long-term competitiveness is its ability to pay for research and development. This ability largely depends on the success of products already on the market, and in particular on the attitude that Europe takes towards innovative new products. In many European countries, the launch prices of patented products are constrained to a level which, in some cases, makes it difficult to generate a sufficient return to enable companies to recoup all their research costs before the patent expires. This is a root cause of the steady erosion of European pharmaceutical industry competitiveness.

The European pharmaceutical industry faces a patchwork of national laws on pricing and reimbursement that act as a disincentive to innovation. Europe is slow to take up new medicines, and access to them is unequal: it varies from country to country and thus from citizen to citizen. A recent study shows that there are three or even four years' delay before new medicines are available on some markets. Prices are being forced into a downward spiral within Member States, and this is then exacerbated further downwards by arbitrage, where the lowest price fixed in one country is exported to the others.

Whilst acknowledging the legitimacy of measures taken by national governments to contain pharmaceutical spending, Commissioner Bangemann, anxious that the consolidation of pharmaceutical industry competitiveness could suffer, three years ago initiated a Round Table tripartite dialogue bringing together representatives from EU Member States, European institutions, and industry.

At the heart of the process was the very fact that the European pharmaceutical industry was caught between two contradictory approaches. On one side, the pharmaceutical market remains fragmented by

divergent Member State policies and heavy regulation on the industry, which prevents the completion of the Single Market in pharmaceuticals. On the other, the Commission defends the free movement of goods principle as the priority objective of the Treaty and applies it unconditionally to the pharmaceutical market.

The three key issues to be discussed within the tripartite process could be summarised as follows: to what extent could the European pharmaceutical market be considered as a Single Market, driven by market forces? What should be done to make Europe an attractive place for R&D and innovation? What should the next steps towards completing the Single Market be?

At the third tripartite Round Table on Completing the Single Market in Pharmaceuticals, on December 7th 1998, the research-driven pharmaceutical industry in Europe expressed its disappointment that these fundamental issues no longer seem to be driving the political agenda. Participants took note of the lack of progress towards the pharmaceutical market deregulation required to secure the competitiveness of the EU industry. Industry's comments come against the background of the European Commission's Communication on Completing the Single Market for Pharmaceuticals, which was approved in haste in the last week of November 1998, without giving interested parties the opportunity to comment on its policy orientations.

It is no secret that the industry considers that the Communication is unsatisfactory as an industrial policy document and is therefore an unsuitable platform for continuing the dialogue within the tripartite process started back in 1996. In fact, it even seems to endorse added regulation by Member States, which is not within the Commission's competence.

An earlier version of the text was widely circulated in October 1998. Industry welcomed this in as much as it sought deregulation in all areas where market forces make it possible to attain interested parties' objectives. It also paved the way for possible solutions (as requested in the May 18th 1998 Internal Market Council mandate), to existing tensions in those segments where deregulation cannot be implemented overnight. The industry considers that liberalisation should precede, or at least be introduced simultaneously with, any safe-

“... the launch prices of patented products are constrained to a level which...makes it difficult to generate a sufficient return to enable companies to recoup all their research costs before the patent expires. This is a root cause of the steady erosion of European pharmaceutical industry competitiveness.”

guard measures that may prove necessary to avoid slip-ups and also that solutions should be outlined to reduce existing tensions for the market segments where price controls cannot be relaxed overnight.

Neither the Communication nor the 1998 Round Table conclusions proposed initiatives which would support R&D leading to innovation, a process which would liberalise the market and make the pharmaceutical industry more competitive, and ensure speedy and equal access to innovative medicines for all European patients.

The industry reiterates the importance it attaches to the dialogue. It supports the creation of a Single Market in medicines, which can only function successfully if competitive mechanisms play their proper place in delivering value to the healthcare providers. No industry can compete successfully in global markets unless conditions in its domestic market support competitiveness. Not only do the lack of such conditions undermine industry, but they invariably lead to additional public expenditure burdens.

The experience of more competitive mechanisms in sectors such as energy, telecommunications, and transport has proven to be successful. Not only do European citizens have more rapid access at 'lower' cost to basic necessities, but progressive liberalisation has enhanced the competitiveness of Europe in these fields. We should apply the lessons learnt to the pharmaceutical sector.

As clearly stated by EFPIA President, Jorge Gallardo, at the Round Table: "Industry accepts that it must shoulder the responsibilities for social solidarity, which is part of the social charter in European health care. It is though in the interest of no one that this industry becomes a public utility. It is a source of frustration for this industry that, in the midst of evidence of the benefits of liberalisation in many other sectors, policy in pharmaceuticals remains driven by over-regulation".

The pharmaceutical industry strongly believes that time has come for Europe to act to foster new technologies, if Community and national authorities genuinely wish to make Europe a more attractive investment location for pharmaceutical R&D. At this very moment this industry has the opportunity to benefit from revolutionary advances in basic research underpinning the discovery of new medicines. There is nothing in the current national and Community policy framework that

"The industry considers that future discussions should be oriented towards an industrial policy strategy which enhances innovation, competition and patient access to medicines. This is the only way to secure the global competitiveness of the European pharmaceutical industry."

encourages this innovative wave, and yet it is vital that Europe is part of these developments. It is not enough to spend money on basic sciences; it is necessary to create a market place which recognises the value of innovation.

The objective of the discussions should be to reconcile the question of affordable access to medicines with the need to secure sufficient funding for research and development on the one hand, and on the other the need to meet Member States' public health and social security objectives. Although the Round Table participants confirmed their commitment to these three fundamental principles, the Round Table conclusions did not give full consideration to these fundamental principles in the sense that they do not clearly recognise the need to address the tensions as identified by the May 1998 Internal Market Council. The industry considers that future discussions should be oriented towards an industrial policy strategy which enhances innovation, competition and patient access to medicines. This is the only way to secure the global competitiveness of the European pharmaceutical industry.

The scope of future discussions should include topics that effectively address the following issues:

- Market access and delays in making new products available to patients;
- The liberalisation of the OTC market and the impact of e-commerce in this segment;
- How to exercise flexibility for managed price products, within the law, to inhibit the most distortive effects of arbitrage;
- Bring forward plans for progressive liberalisation of the pharmaceutical market, recognising the different patterns and pace of development in the different sub-sectors as identified in the May 18th 1998 Internal Market Council conclusions.

Tackling inequalities in health: how can we learn what works?

The British Labour Government came to power in May 1997 with a manifesto commitment to tackle inequalities in health. Within a few months of the election there was clear evidence of a significant change of direction from the previous Government.



*Michaela
Benzeval*

“... the Government has made tackling inequalities in health a key aim of the NHS.”

In June the Prime Minister acknowledged the link between poverty and health and announced an ‘Independent Inquiry into Inequalities in Health’. In July the new Minister for Public Health set out her vision for a new health strategy for England with tackling health inequalities at its heart. The resulting Green Paper ‘Our Healthier Nation’ was published in February 1998. It had two central aims, one of which was “to improve the health of the worse off in society and to narrow the health gap”. It emphasised the social causes of ill health and acknowledged that “tackling inequalities in general is the best means of tackling health inequalities in particular”. Two sets of policies are therefore vital to this endeavour: general social policies to tackle social exclusion and poverty, and specific local health policies aimed at further reducing health inequalities.¹

New Labour’s strategy

Labour’s strategy to tackle social exclusion ranges across a wide spectrum of policies, coordinated and reinforced by the work of the new Social Exclusion Unit. In their first 18 months in Government, they introduced policies that aim to: improve education and child care; create employment opportunities; tackle low wages; invest in new and improved social housing; regenerate and rebuild local neighbourhoods; reduce crime and disorder; increase benefit levels for families with children and pensioners; and improve the uptake of benefits. Obviously Labour’s strategy is not without its problems.¹ Nevertheless, they have introduced a range of policies that previous research suggested should be a central part of any agenda for action to tackle inequalities in health.²

At the local level, it has been argued that the NHS (UK National Health Service)

needs to develop policies in three main areas² to play its part in tackling health inequalities, by:

- ensuring resources are distributed in relation to need;
- responding appropriately to the health care needs of different social groups;
- taking the lead in encouraging a wider and more strategic approach to healthy public policies.

Again, New Labour has made progress in all of these areas. In relation to resource allocation they have addressed some of the more immediate problems with the formula to allocate resources to hospital and community services, and announced a major review of all resource allocation mechanisms across the health care sector. The ‘New NHS’ White Paper introduced a much broader approach to performance management that emphasises the importance of both fair access and health improvement alongside concerns about efficiency and effectiveness. Finally, and perhaps most importantly, the Government has made tackling inequalities in health a key aim of the NHS.

The ‘New NHS’ White Paper gave health authorities the lead responsibility for working with other agencies to tackle health inequalities. ‘The National Priorities Guidance for 1999 to 2001’ made tackling inequalities in health one of three share priorities for action between health and local authorities. In addition, the Government established ‘Health Action Zones’, initially in 11 areas, now extended to a further 15, to act as ‘trail blazers, leading the way in modernising services and tackling health inequalities’. While in their infancy, ‘Health Action Zones’ are setting themselves tough goals in relation to reducing health inequalities and introducing a range of innovative initiatives in housing, employment, education, access to healthy lifestyles, transport, neighbourhood regeneration, community empowerment and health and social care to achieve these.

Independent Inquiry into Inequalities in Health

Simultaneously with this rapidly moving policy agenda, Sir Donald Acheson was asked, in July 1997, to chair an Independent Inquiry into Inequalities in Health to "identify priority areas for future policy development...to reduce health inequalities".³ The Inquiry's report, which was published in November 1998, is a comprehensive synthesis of the latest scientific evidence on a wide range of topics that affect people's health, with 39 main recommendations – see box for examples. From these, the Inquiry Committee argued that three were crucial:

- All policies likely to have an impact on health should be evaluated in terms of their impact on health inequalities;
- A high priority should be given to the health of families with children;
- Further steps should be taken to reduce income inequalities and improve the living standards of poor households.

The general thrust of the Inquiry's recommendations is broadly consistent with those in the Black report,⁴ the King's Fund's 'Agenda for action'² and the current Government's strategy. The Inquiry, therefore, confirmed the main areas of policy development required to reduce health inequalities. However, the scope of the Report was very broad and most of the recommendations were specified at a high level of generality and not directly related to the current Government's activities, making it difficult to translate it quickly into specific policy action. Further analysis is required, therefore, to identify the key gaps in New Labour's strategy, to assess the investment required to fill them and to debate the relative priorities and opportunity cost of doing so. Alongside this analysis, however, there also needs to be a much greater emphasis on developing a new evidence base to inform policy makers about which particular interventions are most effective in reducing health inequalities.

New policy learning

In every area that policy development is required a range of interventions are possible. Much more focused research is needed to identify which particular interventions are most effective in different situations. For example, what kinds of pre-school education, crime prevention, housing improvements, neighbourhood regeneration schemes, healthy workplace initiatives, employment generation activities and

health services are most appropriate for which groups of the population in what circumstances? Such questions require a new approach to evaluation that aims to maximise the potential for policy learning from the introduction of community-based social programmes in different contexts.

Social programmes operate in complex open systems and frequently evolve and adapt with changing circumstances. Yet traditional forms of evaluation are ill equipped to learn from interventions when the external environment cannot be held constant, suitable controls are unavailable and the interventions change over time. What is required is a new approach to policy evaluation that addresses these problems by studying the interaction of specific mechanisms with different contexts which together result in particular outcomes.

In the North American literature⁵ such an approach is based on identifying the theories of change or logic models that underpin the rationale for introducing a particular intervention in a specific context. In the UK, this approach to realistic evaluation⁶ requires the *a priori* specification of context-mechanism-outcome configurations to assess what works for whom in what circumstances. By prospectively identifying

SELECTED RECOMMENDATIONS FROM THE ACHESON REPORT³

- ✘ The provision of additional resources for schools serving children from less well off groups.
- ✘ The further development of high quality pre-school education so that it meets, in particular, the needs of disadvantaged families.
- ✘ Policies which improve the opportunities for work and which ameliorate the health consequences of unemployment.
- ✘ Policies to improve the quality of jobs, and reduce psychosocial work hazards.
- ✘ Policies which improve the availability of social housing.
- ✘ The development of policies to reduce the fear of crime and violence, and to create a safe environment for people to live in.
- ✘ The further development of a high quality public transport system.
- ✘ Policies which will increase the availability and accessibility of foodstuffs to supply an adequate and affordable diet.
- ✘ Policies which promote the adoption of healthier lifestyles particularly in respect of factors which show a strong social gradient in prevalence or consequences.
- ✘ The needs of minority ethnic groups are specifically considered in the development and implementation of policies aimed at reducing socio-economic inequalities.
- ✘ Policies which reduce disability and ameliorate its consequences in older women.
- ✘ Providing equitable access to effective care in relation to need should be the governing principle of all policies in the NHS.

“There is real commitment and enthusiasm around the country to put substantial effort into tackling inequalities in health. This must be supported by appropriate investment in developing an evidence base to learn what works.”

the detailed steps that key stakeholders expect to occur between their chosen intervention in their context and their final outcomes, evaluators are better able to attribute the observed impact to particular policy interventions. Evaluators can observe whether activities are implemented as expected and early outcomes are achieved, and whether other contextual shifts can account for observed changes. While not proving causal relationships, such analyses allow constructive policy learning to be generated by gaining a much better understanding of how interventions interact with contexts to change relevant outcomes. Moreover, if a programme deviates from its expected goal, the reasons for this can be explored and used to refine the intervention and generate more effective policy action in the future.

There is real commitment and enthusiasm around the country to put substantial effort into tackling inequalities in health. This must be supported by appropriate investment in developing an evidence base to learn what works. Only in this way can we make real progress in reducing health inequalities.



Johan P.
Mackenbach

Socioeconomic inequalities in health in Europe

Socioeconomic inequalities in health, i.e. systematic differences in morbidity and mortality rates between those with a lower and a higher socioeconomic status, have been found in all countries with available data. Most studies, however, have focussed on the situation in one particular country and/or for one particular health measure, and an overall picture of the situation in Europe has until now been lacking.



Anton E. Kunst

A Concerted Action funded by the Biomed-programme of the European Union has produced an overview of socioeconomic inequalities in morbidity and mortality in 13 Western European and three Central and Eastern European countries, based on comparable data and standard methods of analysis: Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Hungary, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland. For comparative purposes the United States of America have been added to some of the analyses as well. The analyses cover the period

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1985–1992 (morbidity) and the period 1980–1990 (mortality).

The results of this study have been reported in a four-volume report, 13 published scientific papers (with several more in the pipe-line), and two doctoral theses. In this contribution to *eurohealth* we will highlight some of the most notable findings.

Socioeconomic inequalities in morbidity

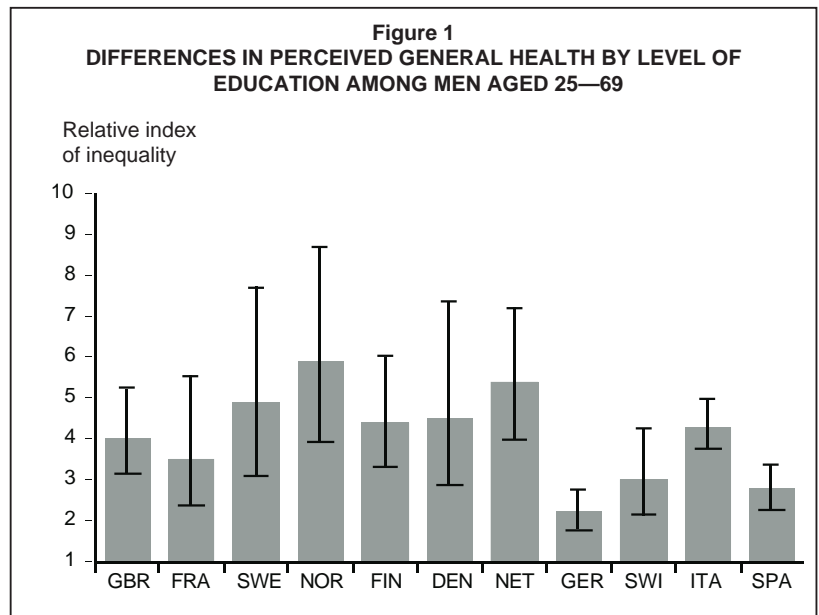
All countries participating in this study have health interview, level of living or multi-purpose surveys with questions on

both socioeconomic status (education, occupation, income) and health (e.g. self-assessed health, chronic conditions, disability). Analysis of these data shows that inequalities in self-reported morbidity are substantial everywhere and always in the same direction: persons with a lower socioeconomic status have higher morbidity risks.

Within Western Europe the risk of ill-health is 1.5 to 2.5 times higher in the lower half of the socioeconomic distribution as compared to the upper half. For example, in Sweden the risk of chronic conditions is 1.85 times higher among men with primary or lower secondary education as compared to men with higher secondary or tertiary education. When the extremes of the socioeconomic distribution are compared, as in Figure 1, the size of the inequalities becomes even more dramatic. Substantial inequalities in health are found in all countries participating in this study, from Spain to Finland and from Great Britain to Italy, underscoring the tremendous importance of this public health problem.

Surprisingly, inequalities in self-reported morbidity are not smaller in the Nordic countries, with their long histories of egalitarian socioeconomic and health care policies, than in other European countries. On the contrary, there is a tendency for inequalities to be relatively large in Sweden, Norway and Denmark, although there are some exceptions to this general pattern. For example, Sweden has relatively large inequalities in self-reported morbidity by educational level and by occupational class, but relatively small inequalities by income level, suggesting that welfare policies may affect one dimension of socioeconomic inequalities in health while leaving others untouched.

In the Czech Republic, Estonia and Hungary, similar results were found: in many cases, survey respondents with a low socioeconomic status had a two-times higher risk of morbidity than respondents with a high socioeconomic status. Socioeconomic inequalities in self-reported morbidity were about equally large in these Central and Eastern European countries as in most Western European countries. These data are the first to show the relative position of these former socialist countries on the health inequalities league, and are therefore an important addition to our knowledge. It is important to note, however, that the data reflect the situation shortly before and around the fall of the Soviet

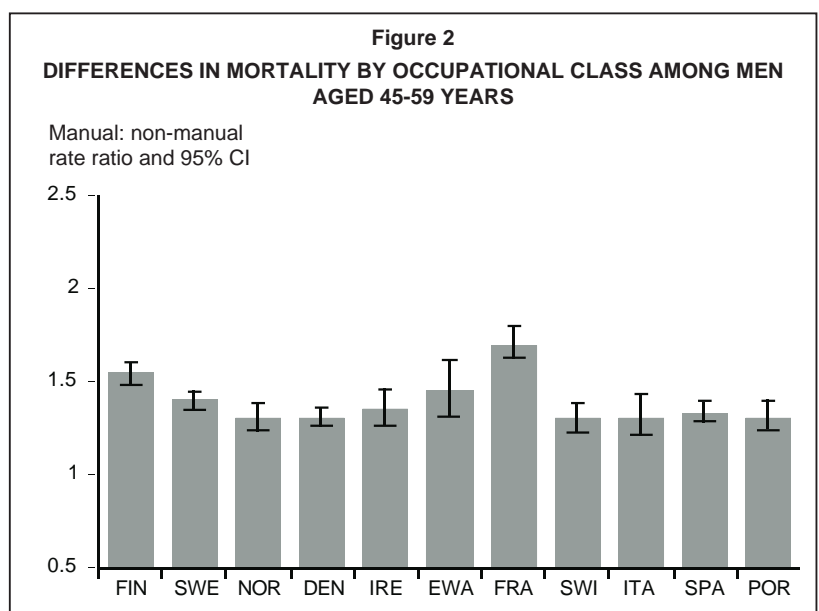


empire and there may well have been increases in the size of health inequalities since then.

Socioeconomic inequalities in mortality

For mortality, the harder but rarer outcome measure, similar results were obtained. Socioeconomic inequalities in mortality of considerable magnitude were found in all Western European countries with available and comparable data. For example, the excess risk of premature mortality among middle-aged men in manual occupations as compared to non-manual occupations ranged between 33 and 71%. Inequalities in mortality were largest in France, followed by Finland (Figure 2). Again, there is no evidence for smaller inequalities in the Nordic countries,

“Substantial inequalities in health are found in all countries...from Spain to Finland and from Great Britain to Italy, underscoring the tremendous importance of this public health problem.”



“Surprisingly, inequalities in self-reported morbidity are not smaller in the Nordic countries, with their long histories of egalitarian socioeconomic and health care policies, than in other European countries.”

although Sweden has rather low absolute inequalities in mortality, due its low average death rates.

One of the advantages of mortality data is that they permit a breakdown by cause of death, which may help in identifying possible backgrounds of inequalities in mortality. An analysis by cause of death reveals a striking north-south pattern within Western Europe. In the Nordic countries and in England/Wales and Ireland, socioeconomic inequalities in mortality are largely due to an excess risk of cardiovascular diseases in the lower socioeconomic groups. In France, Switzerland, Italy, Spain and Portugal cardiovascular diseases account for a small fraction of the higher risks of premature mortality in the lower socioeconomic groups only, while cancers (except lung cancer) and gastrointestinal diseases (such as liver cirrhosis) have a very large share in these excess risks. These data suggest that explanations are likely to be different in the north and in the south of Europe: cardiovascular risk factors such as smoking and intake of animal fat are likely to be important in the north, excessive alcohol consumption in the south.

In the Czech Republic and Estonia inequalities in mortality tended to be larger than in most Western European countries. The real outlier, however, is Hungary which had by far the largest inequalities in mortality among the countries included in this study. The risk of dying among middle-aged men was 165% higher in manual than in non-manual occupations. These very large relative differences combine with

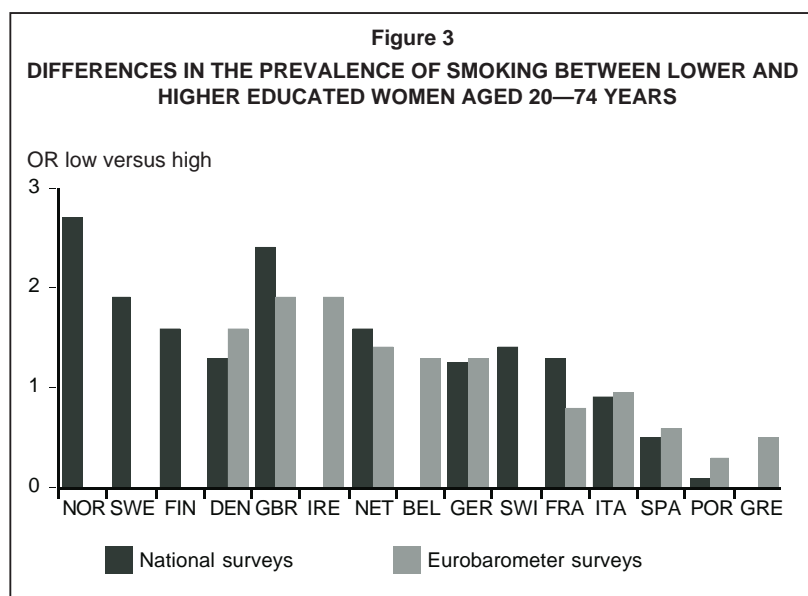
the high average death rates in Hungary to form extremely large absolute differences in mortality between the higher and lower socioeconomic groups. These elevated risks of dying apply to a wide range of causes of death.

In the United States, substantial inequalities in mortality were seen as well, but the size of these inequalities was not clearly different from those observed in Western Europe. In view of the variations observed within Europe, it is tempting to speculate that the heterogeneity of the United States population, with its immigrants from all parts of Europe as well as from many other parts of the world, has averaged out the experience of subpopulations with larger and smaller inequalities in mortality.

Explanations

Although most of the Concerted Action focussed on the analysis of morbidity and mortality data, a limited attempt was made to obtain data on socioeconomic inequalities in risk factors for morbidity and mortality as well. Many health interview, level of living and multi-purpose surveys contain questions on smoking, alcohol consumption, body weight and other risk factors. The Eurobarometer surveys also turned out to be a useful source of information.

The most striking results were obtained for smoking where a clear north-south gradient was observed. In the north of Europe, e.g. Great Britain, Norway and Sweden, large inequalities in smoking were found, both among men and among women, with the highest rates of smoking invariably in the lowest socioeconomic groups (Figure 3). In the south of Europe, however, e.g. France, Italy, Spain and Portugal, inequalities in smoking were smaller and less consistent. Among younger men, higher rates of smoking were generally found in the lower socioeconomic groups, but not so for middle-aged men; for women inverse patterns, with higher rates of smoking in the higher socioeconomic groups, were found. We found a strong correlation between inequalities in smoking on the one hand, and inequalities in cardiovascular disease mortality on the other hand. This suggests that the larger inequalities in cardiovascular disease mortality in the north of Europe are at least partly due to larger inequalities in smoking. If this is true, then the same reasoning applies to the relatively large inequalities in total mortality in the north of Europe: these may also be partly due to the stronger social patterning of smoking



Source: Cavelaars AEJM. *Cross-national Comparisons of Socioeconomic Differences in Health Indicators*. Rotterdam: Erasmus University, 1998.

behaviour.

Of course smoking is not the whole story. One of the main findings in this study is that inequalities in mortality may not have the same explanation in all countries. Smoking is likely to be important in the north of Europe, while excessive alcohol consumption is likely to be an important contributor to socioeconomic inequalities in mortality in the south of Europe. But these are only 'downstream' causal factors: the higher rates of smoking or excessive alcohol consumption in the lower socioeconomic groups also ask for an explanation. The truly remarkable finding is that despite the different roles of specific risk factors, the higher socioeconomic groups manage to have lower death rates both in the north and in the south of Europe. This suggests that there are other, 'upstream' causal factors, such as material living conditions or psychosocial factors, which operate similarly everywhere.

Smoking is not the whole story, and it is also an unfinished story. There is evidence, both from the age-patterns of smoking in our study and from findings in national studies of the 'smoking epidemic', that the higher socioeconomic groups are simply ahead of the lower socioeconomic groups in their smoking behaviour. Decades ago, the higher socioeconomic groups started the habit, and during the 1960s and 1970s they were also the first to stop. That is, in the north of Europe, not in the south where the epidemic still seems to be in its early phases. It is likely that the large inequalities in smoking in the north of Europe represent a later stage in the smoking epidemic, and that in the course of time similar inequalities in smoking will develop in the south. The same may apply to other cardiovascular risk factors.

If this is true, it is also unfair to judge the effectiveness of egalitarian socioeconomic and health care policies on the basis of a cross-sectional comparison of inequalities in health in different countries. Such a comparison is likely to be biased by the different stages of epidemiological development countries find themselves in. In the north of Europe, the effect of egalitarian policies may have been undone by the advanced stage of the smoking epidemic (and similar developments for other cardiovascular risk factors). Similarly, the south of Europe may have been relatively protected from larger inequalities in health because cardiovascular risk factors had not yet become strongly socially patterned.

Perhaps one should study the effect of egalitarian policies on inequalities in health taking data applying to the same 'epidemiological time', instead of to the same calendar time.

Conclusions

This study, of which only a few highlights could be presented, clearly shows the potential for comparative studies within Europe – a huge population laboratory which, as long as some diversity exists, may help us to understand the determinants of complex phenomena like socioeconomic inequalities in health as well as many others. We hope that the Fifth Framework Programme will support and stimulate such comparative work as did its predecessor, and that it will be possible to update and refine these analyses as soon as data for the 1990s become available.

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“... it is... unfair to judge the effectiveness of egalitarian socioeconomic and health care policies on the basis of a cross-sectional comparison of inequalities in health in different countries.”

Inequalities in health



Commentary by Walter W. Holland

For the past 30 years there have been many reports and research papers on inequalities in health. This has been of particular concern in

Britain and in Scandinavia. Despite the provision of free health care and improvements in welfare benefits, inequalities persist.

The paper by Mackenbach and Kunst (see pages 31–34) documents clearly these inequalities in health in several European countries, as well as the United States. It is particularly welcome as they include the findings in three former Eastern European countries (Czech Republic, Estonia and Hungary), and include the former German Democratic Republic. Such research was unacceptable in these countries before 1989. The European studies explore some of the possible underlying reasons for the differences in levels of health (measured by morbidity and mortality) and demonstrate widely varying differences between regions as well as different causes of illness.

Benzeval (see pages 29–31) comments optimistically on the changes in policy which have occurred in Britain since the changes in government in May 1997. It is too early to show whether a change in rhetoric can produce results.

It is regrettable that so much of current research and policy relies on current work and philosophies without references to experience in the past. The connection between poverty levels and health was

obvious in the 19th century. In the inter-war period (1918–1939) the problem was still with us – but different and more difficult to disentangle. The effects of deprivation were not so obvious. Although there were some attempts by the Chief Medical Officer, at that time Newman, to undertake a variety of studies, these led to little progress.¹ It was left to a local Medical Officer of Health, Dr. G.C. M'Gonigle, in Stockton-on-Tees, to address this issue in a consistent, thorough way. His study concluded, “that the increased mortality was associated with dietary deficiencies”.² This is not the place to describe this in any detail, but it is noteworthy that this local study was sufficiently persuasive to influence policy on nutrition and rationing during the Second World War – which is considered, by some, to have been the major reason for health improvements in Britain.^{3,4}

Benzeval, in her article, comments that current policies of NHS Resource Allocation are an advance because they include a ‘deprivation factor’. I differ from this view as it illustrates the policy problem. The original RAWP formula deliberately did not include such a factor because it was not considered that clinical service redistribution would have a great effect on disease incidence – all it could do would be to improve access. It was considered that it would be used as a ‘sticking plaster’ by governments – investment in housing, environment, employment etc. are far more expensive and are the underlying causes of health inequalities. If health service allocations included a deprivation factor governments could claim that they were addressing the problem.^{5,6} How right we were!

“In spite of the improvements in standards of life and in state provision for those in greatest need, the inequalities that exist are unacceptable at the end of the twentieth century.”

It is true that there has been a major change in rhetoric – but even that is ambiguous. In considering what needs to be done the word “may” is used in the government’s Green Paper on Health – not “will”. Although many activities and special units have been created, it is unfortunate that the lessons of the past have not been learnt.

There are several examples which illustrate this discrepancy between rhetoric and possible action.

Most people believe that actions during childhood are particularly important in reducing health inequalities. Health visitors were specifically recruited and trained in order to help families to have optimal services during childhood. But it is this group of professionals, which continues to be at risk from cuts, rationalisation and reorganisation – without any consideration of what they can contribute to the health of children, or the elderly, particularly in inner city areas. Similarly there are discrepancies between ‘central’ rhetoric and local action in the provision of family planning services. In the 1970s it was found that large, poor families could not utilise the centres provided, but were helped greatly by domiciliary family planning services. I have seen no sign of this being revived.

All reports on health inequalities are concerned with smoking habits. Obviously there are two possible strategies – to help people give up, which is being addressed, but more importantly to stop children from starting to smoke. There are references to healthy schools, which are very worthy, but there appears to be little appreciation that in order to stop children from starting to smoke, education has to begin in primary schools, and in order to have any likelihood of effect this involves a change in the curriculum – which must help in the development of self-reliance, decision making and biology – rather than role learning or the threat of doom in later years.^{7,8}

The disparity between words and action is also illustrated at older ages in relation to specific clinical policies. In early documents from the present government, stroke, the commonest cause of disability and the third commonest cause of death was specifically mentioned. Services for this group of the population can be effective both in prevention (particularly blood pressure control in those aged more than sixty-five) as well as treatment, including rehabilitation, if provided in an organised manner. Yet current policies exclude

those aged more than sixty-five, and the priorities for stroke have been dropped. Cynics consider that this is because of the costs, but at least 50% of the population do not receive optimal, effective services for this condition.

To tackle the problems of inequalities in health we do not need more national working parties or research projects. We need specific investigations at local levels to tackle the inequalities, barriers and problems that exist, reinforced by national initiatives that actually do something rather than promise action. Current policies and actions at all levels appear to be more concerned with rationalisation and reorganisation of services and structures leading to reduction of services at local level, particularly for those in greatest need, and to less coordination. Only if we heed the call for action which has been shown effective have we any hope of reducing these inequalities in levels of health. Above all we must act to reduce poverty which stands out as a factor of major impact on health. In spite of the improvements in standards of life and in state provision for those in greatest need, the inequalities that exist are unacceptable at the end of the twentieth century.

“We need specific investigations at local levels to tackle the inequalities, barriers and problems that exist, reinforced by national initiatives that actually do something rather than promise action.”

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Health technology assessment in the European Union

Recognising that critical health policy issues needed to be faced, in November 1991 the Ministers of Health of the European Union countries adopted a resolution on fundamental health policy choices. They indicated that closer cooperation and collaboration between Member States was both desirable and necessary. The Ministers identified one important issue: "value for money in health care." They also identified health technology assessment (HTA) as a key tool to improve the management of scarce health care resources. Within this field, clinical health care technology is defined broadly as the pharmaceuticals, devices, and medical and surgical procedures offered by the health care system, including such complex technologies as intensive care.



David Banta



Wija Oortwijn

Health policy challenges in Europe

To quote Commissioner Flynn of the European Commission, health policies in Europe are "at a critical juncture. On the one hand, there are enormous challenges to be overcome: demographic changes, increasing population mobility, growing social exclusion, costly new therapeutic techniques and rising public demands and expectations are all combining to place mounting pressure on service provision, and are doing so at a time when public spending is under tight constraints."

Perhaps demographic changes, with the ageing of the population of Europe and associated rising rates of chronic disease and dependence, is the greatest policy challenge to policy makers and managers in Europe. Hand in hand with ageing, the demands of the population for accessible and effective health care are increasing. Such demands are fuelled by rapid developments in health technology, including those in biotechnology and genetics, more reliable and smaller medical equipment and devices, and health care informatics and telematics. These factors and others have stimulated rising expenditures for health care, putting severe pressure on health budgets.

While health care has become increasingly effective during recent decades, evidence has gradually emerged of substantial ineffective technology, as well as overuse and

inappropriate use of health technology. This evidence has stimulated a debate on health care reforms and has also stimulated development of the field of health technology assessment (HTA). HTA can help policy makers, managers, clinicians, and the general public to make difficult choices in health care.

Health Technology Assessment

Now about 20 years old, the HTA field developed as a tool for policy makers to help shape the course of technological change in health care.

HTA began to develop in Europe in the early 1970s, with studies of expensive medical devices in several European countries, notably Sweden.¹ The Swedish Planning and Rationalization Institute (SPRI) began studies of the then-new computer tomography (CT) scanner in 1972, then developed a series of studies of the implications of health technology. Other countries also studied the CT scanner and other technologies. By the mid-1980s, Catalonia (Spain), France, the United Kingdom, the Netherlands, and Denmark had all begun to carry out such studies and to use the term 'technology assessment' to describe their work. By early 1998, six of the fifteen EU Member States had formal national programmes in HTA, and other countries were planning or considering the establishment of such programmes.

At the same time, other approaches have been evolving to address problems of ineffective and cost-ineffective health care. The Cochrane Collaboration, a worldwide network of centres and people, is critically reviewing the literature concerning a wide variety of health care interventions to produce the evidence needed to improve health policy and practice. The evidence-based medicine (EBM) movement, led by clinicians and clinical epidemiologists, is linking evidence to health care practice, with the aim of improving the quality and effectiveness of individual patient care.

The present situation with health care in Europe

One of the most visible health policy issues in Europe for the past decade has been the problem of quality of care. The health care system abounds with ineffective and overused health technologies.

Another visible health policy issue in Europe for the past two decades has been cost-containment. Health technology has become a very visible issue, mainly because

of rising costs and questions that technologies engender concerning cost-effectiveness and value for money in health care. Experience has shown that the establishment of overall budgets for health care, or for each of its main parts, are the most effective means for containing costs. Most of the EU Member States have implemented, or are implementing, such budgets. Prospective budgets certainly can contain costs, but they are unselective with regard to technology, simultaneously limiting effective and ineffective technology. Therefore, specific policies related to technology are also necessary.

The organisation of health care has a strong effect on technology. A regionalised system of hospital care such as that found in Sweden tends to assure that technology is appropriately sited, and it also encourages appropriate use. A number of European health care systems have formally regionalised systems, while others directly regulate technology to prevent excessive services furnished from inappropriate sites. The general practitioner gate-keeper is also a method of discouraging specialist care.

These mechanisms generally do not directly affect health care quality. Although many approaches to improving quality are being developed, successful approaches are hard to find and document. Improving quality remains a critical challenge for health policy.

As indicated, the health care systems of European countries are under increasing pressure and such pressure does not seem likely to diminish during the next years. Critical health policy analysis and HTA are more than ever needed to assist policy makers in making difficult decisions and choices.

The 'internationalisation' of HTA

In the early 1990s, a number of European HTA agencies and programs joined together to develop a proposal to promote coordination of HTA in Europe. Directorate General XII of the European Commission approved a proposal for what became the EUR-ASSESS project from 1994 to 1997.² The project sought to promote coordination of HTA in Europe mainly by improving methods of assessment, priority-setting, and use of HTA results through such means as better dissemination and use of HTA in insurance coverage decisions.

Still, HTA activities were not coupled to health policy aims at the European level. Funding by the Research Directorate did

not promote such aims. The partners in EUR-ASSESS realised that it was important to develop relationships with Directorate General V, which has the responsibility for developing European Commission activities in the area of public health policy.

A number of factors led DGV to become increasingly interested in HTA. One of those was a report commissioned by DGV oriented to improving health policy at the European level. Improving coordination of HTA was highlighted in this report, which made several recommendations relevant to HTA stating that the Community should coordinate technology assessment throughout the Union.³

Development of the HTA-Europe project

Discussions with staff of DGV of the Commission were held during 1997. One question was "What would be useful for improving the coordination of HTA in Europe?"

The Steering Committee of the EUR-ASSESS project had considered this question, and had formulated several recommendations. One concerned the value of bringing those involved in HTA in different countries together. Another concerned the need for more efficient methods of sharing information. The third became the main basis for the proposal:

"While there is certainly value in diversity, the existing diversity is not understood or documented. The relationship between HTA and the health system in different countries has hardly been examined. Resources should be devoted to studying the relationships between HTA and health systems in the Member States of the European Union."

The proposal outlined a plan for commissioning papers in line with this recommendation from all EU members (with the addition of Switzerland), under the supervision of a steering committee representing those countries. In addition, several workshops were proposed on subjects of interest to the general issue of HTA in Europe, such as identifying new technology, the general relationship between health systems and HTA, and models for international assessment. The plan was followed as outlined in the proposal and the report presented to the European Commission in April 1998. It is presently in preparation for publication as an official publication of the European Union.

"The main conclusion of the report is that it would be beneficial for the health care systems of Europe for the European Commission to assist the establishment of a coordinating mechanism for HTA at the European level."

The steering committee considered all of these materials and assisted in a general synthesis of all materials from the project. After considering all issues raised in the project, the steering committee concluded the European Commission could carry out a number of actions to stimulate and encourage HTA:

- Collecting, collating and disseminating information on emerging technology issues.
- Collecting and disseminating information on priorities in HTA.
- Collecting, collating and disseminating information on emerging plans and programmes for HTA.
- Ensuring that the findings of HTA from across the world are readily available across the European Union.
- Organising possibilities for joint assessments and supporting joint assessments agreed on.
- Providing opportunities for developing, defining and sharing best practice in undertaking and reporting assessments.
- Providing opportunities to analyse and discuss methods of connecting HTA more closely to health policy and practice.

- Organising and funding training for assessors and decisions in the European Union in assessment methods, particularly (but not exclusively) for countries with relatively undeveloped HTA activities.
- Supporting those seeking to develop HTA in European countries not actively involved in HTA.
- Organising cooperative periodic meetings of partners to discuss all of these issues.

The main conclusion of the report is that it would be beneficial for the health care systems of Europe for the European Commission to assist the establishment of a coordinating mechanism for HTA at the European level. It should be quite clear that what is being proposed is not a new European Agency.

There are four interdependent needs for an effective mechanism:

1. A board or steering body representing all Member States, in addition to a smaller executive committee or board for continual oversight.
2. An administrative centre to support all activities of the network.
3. A mechanism to ensure full use of

the relevant expertise and commitment of different programmes and individuals in Europe. In summary, this would mean a system in which important substantive functions are decentralised to different sites in Europe.

4. Funding to cover the added activities inherent in a European programme of work.

The objective is to utilise and help strengthen the existing network under the principle of subsidiarity. The main recommendation of this report is that the European Commission assist in the establishment of such a coordinating mechanism.

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Health technology assessment: a European Community perspective



Bernie Merkel

Not so very long ago, if the term 'health technology assessment' (HTA) had been included in a speech to a general audience of people involved in public health, a good number would have been scratching their heads wondering what on earth was meant. This reflects the fact that HTA was, if not exactly an underground activity, hardly a central pillar of public health policy.* But in the last few years it has achieved a high level of visibility and European governments and

health authorities have become aware of its potential utility and importance. Indeed, it is now becoming one of 'the flavours of the month' as more and more European countries (inside and outside the European Union) are engaged in establishing their own national and regional HTA structures.

The rapid rise in official interest in HTA that we are now seeing is no doubt due in part to the authorities' efforts to reform

* It is open to question whether the choice of the name 'health technology assessment' was very helpful in spreading the understanding of the kind of work actually being undertaken and of the potential scope and value of the techniques employed. Similarly, the work and aims of 'The Cochrane Collaboration' are hardly transparent for those health professionals who have not been involved in the evidence-based medicine movement, let alone policy-makers and the general public, to whom the name of the late Archie Cochrane cannot be expected to mean very much.

their health systems to make them more efficient and effective, and particularly to their growing concerns about the control of health costs. In all EU countries health expenditure has been rising for decades and most governments have in consequence been engaged in a delicate balancing act between taking action to contain costs at the same time as trying to improve the quality and effectiveness of care. Today, many States are becoming more than ever concerned that, in spite of their efforts at cost containment, they will face real difficulty in the future in financing services. In particular they are fearful about the potential impact on future costs of the combination of rising public expectations fuelled by the explosion in readily-accessible health information, the ageing of the European population which will lead to a great expansion of those over retirement age, and in particular of those over 80, and the introduction of new technology into the health sector, such as the new 'blockbuster' drugs that are now becoming available.

Against this potentially very difficult economic background, governments have concluded that HTA has an important role to play in the process of making decisions about priorities and the choice of health interventions. It would be misleading to suppose that the use of HTA techniques necessarily leads to reductions in expenditure. Indeed the opposite can be the case. This is because a particular HTA study might conclude that the cheapest option was not necessarily the best one. But the great advantage and attraction of HTA is that it offers a way of thoroughly evaluating actual or potential health interventions and can thus help to ensure that available resources are well spent, i.e. that they are allocated to measures that can be shown to work, and not wasted on those for which there is scant, or no, evidence of effectiveness.

At the level of the European Community, attempts have been made for a number of years to stimulate the growth of HTA in the Member States. Two particular aims have been pursued: first to encourage the growth of HTA and the for-

mation of HTA organisations in those countries where there has been no significant tradition of work in this field; and second to ensure that there is the maximum cooperation between the various agencies that have been set up. For several years the BIOMED research programme of DGXII of the Commission supported actions in this field. More recently DGV, responsible for public health, has been involved in encouragement and support of the cooperation between the various HTA centres in the EU.

More important, the interest of the European Community in HTA, and in evaluation of health interventions more broadly, can be expected to grow in the future as an important part of the new public health policy that is currently being developed. To put the possible future developments in relation to HTA into a more general context, it is necessary to consider the main thrust of future Community public health policy as a whole. In a communication of April 15th 1998² the Commission presented its ideas for a reorientation of public health policy. This communication was intended to stimulate a wide-ranging debate on the way forward.

The communication begins by reviewing the general health situation in the Community. It then considers the existing strategy which was put forward in 1993 following the coming into force of the Maastricht Treaty which gave the Community an explicit competence in public health. The framework of action developed then includes eight public health programmes. Of these, five are currently being implemented. These are on: AIDS and other communicable diseases, cancer, drug dependence, health promotion, and health monitoring. The remaining three (on pollution-related diseases, injury prevention, and rare diseases) are still being discussed by the Council and the European Parliament, and they should be agreed very shortly.

The communication concludes that the present strategy needs fundamental revision to reflect new developments in health and health sys-

"...the present strategy needs fundamental revision to reflect new developments in health and health systems..."

tems, such as the impact of demographic change and the emergence of new threats to health, to take account of the potential enlargement and to respond to the strengthening of public health provisions in the Treaty of Amsterdam.

It sets out the lines of a possible new Community public health policy, which would be based upon three strands of action.

Improving information for the development of public health, through the development of a comprehensive Community system for collecting, analysing and disseminating information. The intention is that this information should cover not only the areas of health status, morbidity, mortality and health determinants, but also include developments in health systems, such as trends in expenditure and reforms. This reflects the view that the Community has a major role to play in the exchange of ideas about how to address the problems that all Member State are facing and in the provision of information about the approaches and actions that have worked, and those that have not.

Reacting rapidly to threats to health, by means of a Community surveillance, early warning and rapid reaction capability. The network for the monitoring and surveillance of communicable which was recently agreed is a first step towards this end. The network should provide the instruments by which coordinated responses will be put in place. It

also offers a model for possible response mechanisms for non-communicable diseases and other threats for which counter-measures need to be taken quickly (e.g. environmental health problems).

Tackling health determinants through health promotion and disease prevention. This will build upon the Community's experience from the existing public health programmes in these fields. Many premature deaths are preventable. Some are connected to unhealthy living and working environments, and issues such as pollution, poor housing and living conditions and inequalities have to be tackled. Community provisions in other policies, can complement local, regional and national actions in this area.

Actions in relation to HTA would fit within the first strand on information. The communication devotes a whole paragraph (para. 48) to this point, and this is worth quoting in full.

"A major emphasis within the information strand covering both health status and health systems would be placed on best practice in health care, i.e. the current best evidence as regards the safety, efficacy, effectiveness and cost-effectiveness of different approaches to health promotion, prevention, diagnosis and treatment; for instance the cost-effectiveness of

"... it is important that those who believe that action on HTA should be a component of the future programme make their views known to Member States' governments and to the European Institutions."

screening programmes, health education programmes, emergency services and new pharmaceutical products. The work would aim to promote and bring together activities in the Member States in the fields of evidence-based medicine, quality assurance and improvement, appropriateness of interventions, and health technology assessment. Coordination of work in these fields would be supported and set on a formal footing in order to pool the expertise of the centres in the Member States, to gather and exchange information, stimulate international studies, and improve the dissemination of findings."

This wording gives some indications of the issues that need to be taken into account in considering proposals for action on HTA at Community level. These include:

- The need to consider possible developments in HTA in the Community alongside work in other related areas. The Communication uses the concept of best practice in health care as a way of bringing together the various activities that are underway. But it is of course one thing to link these various activities together at the conceptual level, quite another to find sensible ways of undertaking practical actions on them which are complementary and to establish links between them at the Community level.
- The necessity of involving the various national authorities in taking the work forward. The objective would be to go beyond loose, informal systems and networks relying on personal contacts and voluntary cooperation between centres in exchanging information by gradually working towards the establishment of an enduring structure involving the active participation of all the Member States. This would mean developing some formalised arrangements for continuing cooperation and coordination between all the various centres in the EU, as well as for disseminating information and expertise to those countries with a less developed tradition in HTA.

- A formal structure for the EU could be set up in a number of ways. There are already examples in other areas that show what can be achieved and how added value can be provided. For instance, there is the European Medicines Evaluation Agency, set up in 1995, which licenses pharmaceutical products. A system using a centralised agency like the EMEA can be valuable in reducing duplication of work between the different countries, in offering a clear focus of expertise and advice, in collecting and disseminating data and in helping to guarantee that all countries benefit from the best expertise that exists in the EU. Another rather different model would be based on building up links between a network of centres, as is being done for the monitoring and control of communicable diseases. This avoids the need to set up a whole new organisation in one physical location and ensures that the different centres and national authorities are fully involved in the developmental process and share a sense of ownership of the outputs of the system.

After the Amsterdam Treaty comes into force (probably in the first half of 1999), the Commission intends to come forward with proposals for an overall programme to implement the new policy. Any proposals on HTA would therefore form an integral part of this programme. But the Commission has also stressed that the ideas in the communication on public health were intended to stimulate a wide debate, not to stifle it. The exact contents and shape of the future programme will thus depend upon the responses and reactions that the ideas provoke. In this light it is important that those who believe that action on HTA should be a component of the future programme make their views known to Member States' governments and to the European Institutions.

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European health technology assessment: time to change gear?

— Franco Sassi —



It is now widely recognised that technological progress is the leading cause of the pressures on health care expenditure that all European countries experience.¹ This is not because new technology increases the cost of health care (which it does not), but because it increases the capabilities of medicine and allows health systems to treat more patients and to treat them better. However, the willingness of governments to sustain further increases in health expenditure is limited; new technology does not always improve health outcomes; and new technology is sometimes used inappropriately. Health technology assessment (HTA) seeks to address these issues by providing evidence on the impact of technologies and on whether the additional benefits they produce are worth a possible expenditure increase.

As pointed out in other contributions to this issue of *eurohealth*, significant changes have taken place in the 1990s. Despite having a relatively long tradition in Europe, HTA was still new to most policy makers (particularly at the European level) in 1993, when we carried out a study that revealed to the European Commission (DGV) the key aspects of HTA in Europe.² HTA activities were concentrated in half of the Member States. The existing studies were too narrow in scope, and the circulation of information was very limited. Five countries had parliamentary agencies, but these played a very limited role in HTA. Governmental agencies (central or local) seemed more active and were mostly concerned with the synthesis of existing evidence. Most technology assessment activities, and almost all primary research programmes, were undertaken by academic or independent institutions. HTA was highly dispersed and few attempts had been made to coordinate

research and facilitate the concentration of resources on larger projects.

A number of changes have taken place since then. Firstly, initiatives aimed at improving the coordination of HTA activities have been promoted by members of HTA agencies and programmes, and these have been at least partially supported by the European Commission. Examples of such initiatives are the EUR-ASSESS and HTA Europe projects illustrated in the previous articles, the ASTEC project (Analysis of the Scientific and Technical Evaluation of Health Interventions in the European Union) funded by DGV and led by a research team at the London School of Economics, and the development of the International Network of Agencies for Health Technology Assessment (INAHTA).

Secondly, there has been a decline in the role of parliamentary agencies. These never took off in Europe and the US Congress Office of Technology Assessment was shut down after the Republican Party won the majority in the 1994 elections. Efforts towards the development of HTA in the public sector in Europe were mostly focused on governmental programmes.

Thirdly, HTA activities in the private and independent (including academic) sector and within health insurance organisations had a further significant increase. Research methods have been developed further and a large number of technologies have been evaluated.

These developments clearly indicate that there is a need to take stock of the progress made so far and rapidly move forward to a new scenario. Public agencies and programmes need to establish themselves in a new role, being committed exclusively to setting priorities for HTA, monitoring the quality of assessments, and establishing links with potential users (dissemination and implementation). This applies to national programmes as well as to a possible future European HTA organisation. The task of undertaking research should be left to the private and independent sector, which has been shown to be far more effective and efficient. Moreover, now that communication channels between HTA agencies and programmes have been established, and information is starting to circulate, the emphasis in HTA should be put on avoiding duplication and ensuring that the studies undertaken are not too narrowly focussed. This may require some additional effort on individual projects, but will be greatly beneficial for European HTA as a whole.

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UK health reforms: a threat to doctors' autonomy

The current UK Health Bill combined with the other reforms following from the White Paper will place unprecedented powers in the hands of the Health Secretary to impose central control over our Health Service. This, along with new structures to rationalise clinical decision making, will lead to an increase in covert rationing and a reduction in choice for patients.



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“The result will be less autonomy for doctors, and a great deal more centralisation of power around the Secretary of State.”

Professor Glennerster argues that the UK Government's health reforms have in many ways continued the spirit of changes made by the Conservative Government during the 1990s (*Eurohealth*, Autumn 1998). To the extent that the purchaser provider split – the internal market – remains, this is indeed the case. The changes that will be made as a result of the current Health Bill, however, will actually achieve the opposite effect. Decisions on prioritisation within the health service will be obfuscated by new structures such as primary care trusts, the National Institute for Clinical Excellence (NICE), and the Commission for Health Improvements (CHIMP). The result will be less autonomy for doctors, and a great deal more centralisation of power around the Secretary of State.

The Health Bill combined with the other reforms following from the White Paper will place unprecedented powers in the hands of the Health Secretary to impose central control over our Health Service. This, along with new structures to standardise clinical decision making, will lead to an increase in covert rationing and a reduction in choice.

After the publication of the Government's White Paper over a year ago, the Health Service was expecting a substantial bill and a clear agenda. This, however, appears not to have occurred; the Health Bill actually sets out a deeply ambiguous series of discretionary powers for the Health Secretary with the really big issue of rationing left unresolved.

Looking at the Health Bill immediately after the White Paper gives one the overall impression that the Government has lost its

way. What started out as an ambitious programme, albeit a misguided one, to reform totally the structure of our Health Service has actually turned into a muddled series of new powers for the Government. What has become clear is that whilst much of the old structure of the Health Service will remain, there will be the potential for far more regulation, interference, and control.

The most obvious omission from the Health Bill is the absence of any definition of a primary care trust (PCT). Apparently this is because the Government has no clear idea as to how PCTs will develop, or what scope they will have. In fact, it appears that a mechanism has yet to be agreed regarding how a primary care group (PCG) on stage 2 of the ladder and wishing to become a primary care trust will proceed. This is far from being a trivial omission – regardless of the fact that Parliament is being asked to approve a measure that has not been adequately defined. GPs will be compelled to join up to organisations controlling their budgets and contracts, whose structure is not properly outlined in legislation.

There are, however, more practical problems with PCGs and PCTs. They will be highly bureaucratic; it has been estimated that the total annual cost of running PCGs will be £150 million, according to Professor Alan Maynard of York University and the King's Fund. Former health minister Alan Milburn argued that this was “recycled bureaucracy” and that money would come from the abandonment of fund-holding. This, however, is incorrect. The money to be ‘saved’ from fund-holding has already been spent or accounted for. Even if this were not so, Alan Milburn, appearing before the Select Committee on Health stated that the cost of fund-holding was £135 million – considerably less than the cost of PCGs.

PCGs will be structured to give GPs control of the chair and all committees if they

desire, although this is unlikely to be the case with PCTs. This, however, could lead to interminable disagreements as to planning of services and placing of contracts with Trusts. Given the size and scale of PCGs, the decision making process is likely to be cumbersome and committee orientated, leading to even more delays and bureaucracy. The streamlined structure of fund-holders' decision making process, by contrast, led to quick and focused decision-making. It also seems likely, given that PCGs are seen as interim bodies, that the 'deal' between the BMA and Alan Milburn over PCG bodies was struck without GPs realising that they would only have control over a temporary arrangement. Once GPs on the ground realise this, there could be further disillusionment.

PCGs will also lead to incentive problems. With fund-holding, GPs were responsible for their own budgets and hence had a direct incentive to be as efficient and effective as possible. PCGs, however, will contain between 50 and 100 GPs. This may result in a 'free-rider' effect, where poor performance from a small number of GPs could drag down the entire PCG. Other efficient GPs may feel that there is little incentive for them to look for new ways of working more efficiently at practice level, when the rest of the PCG would swallow up their gains.

Furthermore, with fund-holding, GPs were free to move their patients from one hospital to another in order to secure the shortest waiting times for their patients. Under PCGs and PCTs they can only do so with the agreement of the Board, and after protracted negotiations with the Health Authority and Trusts. This will lead to a worse deal for patients, and inflexibility in the referrals process. There also seems to be a built in pressure to remain with the same Trust, barring all but disaster. This could mean that the only positive outcome to GPs wishing to move their patients will be slow improvement in services after months or even years of negotiation.

For the first time ever in the history of our Health Service, GPs will have cash limited drugs prescription budgets, as they are set to be lumped together with the rest of the budget for PCG/PCT services. The Government has argued that this will lead to better cost effectiveness in prescribing, but have also argued that no patients will ever be denied prescriptions merely because their PCG/PCT has spent up to the limit. These aims are contradictory. If

the budget is limited at a realistic level, then theoretically it can be used up and patients denied drugs. If, as the Government claims, patients are never to be denied drugs, then presumably it will be set at a level where it could not be spent up thus making the whole exercise futile.

GPs and clinicians are also becoming increasingly worried at the Government's increasingly interventionist stance into professional autonomy. NICE can be seen in part as an extension of the role of political decisions on rationing into the surgery. It is likely that GPs and clinicians wanting to prescribe drugs, or carry out procedures that do not have the approval of NICE will be placed under extreme pressure not to do so, both professionally (through CHIMP) and financially.

It is also the case that the PRODIGY prescribing system may well focus far more on the cost effectiveness of drugs than on their clinical effectiveness. GPs and clinicians must, in most cases, retain the autonomy to prescribe the drugs, or carry out the procedures that they feel are clinically necessary for the well-being of their patients. The combination of these new measures, however, could pose a real threat to clinical autonomy. Doubts have also been expressed as to the suitability of an 'expert' system in handling the complexity of a general practitioner's prescribing decisions.

Whilst controlling expenditure is of vital importance, this must not be achieved at the expense of clinical freedom or treatment on the basis of clinical need. The combination of cash-limited drugs budgets and NICE will bear down upon GPs freedom to prescribe, and could result in increased rationing of advanced new drugs. This has been seen most recently in the fact that many Health Authorities are having to ration the latest psychoactive drugs for patients with mental health problems.

It can, therefore, be argued that the overall focus of the Health Bill and the measures outlined in the White Paper will be to extend the powers of the Department of Health to direct and influence decisions that have previously been the preserve of clinicians alone. The fact that the Bill is a messy piece of legislation, concerning itself mainly with the transfer of powers to the Secretary of State reflects the fact that it is impossible to legislate directly to control clinical decisions, but comparatively easy to place overall powers in the hands of ministers.

"... the overall focus of the Health Bill and the measures outlined in the White Paper will be to extend the powers of the Department of Health to direct and influence decisions that have previously been the preserve of clinicians alone."

New reform of the Italian NHS: structural changes or fine-tuning?

The Italian National Health Service is to be reformed in the next few months. New legislation will probably try to fine-tune the system, so to improve accountability chains in the NHS and to alleviate some of the shortcomings introduced by the 1992/93 'quasi-market' reform. However, whether a 'fine-tuning' strategy will suffice to secure more stability and more public satisfaction with the NHS is difficult to predict.



Giovanni Fattore

The Italian NHS

The Italian health care system is to be reformed in the next few months. In November 1998, Parliament delegated the Government to reform the way the Italian NHS is structured and financed. It is the third important reform of the Italian health care system in 20 years.

In 1978, the old system based on compulsory social insurance was replaced with a National Health Service. This transformation had few precedents in the history of Italian social policy and was the most concrete result of the 'Compromesso Storico', a search for agreement on basic social issues between the two dominant social and ideological movements in Italy at that time: the Communists and the Christian Democrats. With the new legislation, Italy adopted the 'Beveridge' model for health care. Coverage was made universal; sickness funds were abolished, and all financial resources for public health care were channelled into the national Government's budget and then allocated to regions and from them to Local Health Units (LHUs – the basic entities of the NHS providing a whole range of services for a determined geographical area). From an organisational point of view, political and administrative responsibilities to run the NHS were allocated to the three main tiers of the Italian Government: the State, the regions and the communes.

The health care system which emerged in the 1980s had various shortcomings. The institutional arrangement was 'baroque'. Accountability chains in the NHS were not clear, conflicts between the three institutional levels were very frequent and, rather than being democratically controlled, the

system was over-politicised, even at local level. Also, unlike the British NHS, the Italian system resulted in a public-private mix in the provision of health services with private providers playing an important role, particularly in the central and southern regions of the country that lacked public hospitals. In addition, although NHS workers were made civil servants, public employment and private practice (outside the NHS) were not made legally incompatible. As a result, the Italian NHS always had problems in making private organisations consistent with NHS strategic goals and to assure full accountability of health professionals to public health care organisations. Finally, the Italian NHS was not under financial control. To a certain extent, during the 1980s the national Government could be viewed as a third payer with only limited control over the expenditure process.

Cost-containment and the 1992/93 reform

These shortcomings and the need for more incisive cost-containment action became clear in the early 1990s. A drastic cost-containment policy was undertaken in the period 1992–1996. Through various measures including stricter control over increases in health personnel costs and a revision of the main regulatory tools to manage pharmaceutical expenditure, NHS expenditure was stabilised in nominal terms and it was reduced as a percentage of the Gross National Product. Parallel to actions aimed to reduce public expenditure, a radical reform was approved in 1992 and amended in 1993. The reform introduced three major changes that are re-shaping the public system: devolution of power to regions, managerialism and a quasi-market in health services provision. Originally, the reform also included a measure that allowed patients to opt out of the NHS. However, this measure was later withdrawn.

Regionalisation

According to the 1992/93 reform, the national Government maintains a central role in financing the system and in assuring

uniform availability of health services across the country. Each region is funded by the central Government and is kept accountable to provide an “essential list of services”. Regions have direct control over NHS providers and the role of municipalities was greatly reduced. Regions were enabled to issue legislation to re-group LHUs, to transform hospitals into self-governing public entities, to fund providers, to implement, consistently with national guidelines, accreditation procedures. Also, regions were put in charge of guidelines on the organisational structures, accounting systems and managerial development of public providers.

Managerialism

Coupled with other reforms regarding the public sector in general, the 1992/93 reform also aimed at strengthening management in the NHS. Various barriers to effective decision making and human resources management were eliminated; accountability chains in NHS organisations were simplified and management systems were upgraded.

The Italian ‘quasi-market’

Consistent with a general trend in Europe, the national Government decided to introduce competitive mechanisms in the provision of secondary and tertiary services. However, compared to other countries, the Italian ‘quasi market’ appears unique. It is based upon three main elements: (i) in-patients and outpatient specialist care is funded according to a prospective per-case payment system; (ii) patients are free to choose where to receive care, provided that the delivering organisation is accredited; (iii) both public and private organisations can be accredited. This ‘quasi-market’ is more extreme than that experienced in the UK or Sweden (see Figure 1).

In fact, at least three potential risks of this model can be identified:

- i Per-case payment systems coupled with patients’ choice create incentives to increase volume and hence may lead to loss of control over total costs;
- ii regions may have limited strategic control over providers (especially those that are privately owned);
- iii given structural difference between public and private providers, fair competition appears difficult to implement.

Since the introduction of this piece of legislation, regions have been relatively cautious in implementing national legislation. Many regions still fund providers on an historical

basis, and the regions that have really implemented a per-case-payment system have also promoted contractual arrangements with providers and have introduced volume targets and other incentives to keep public expenditure under control. However, despite the usefulness of these measures, it is unclear whether closed-ended funding at regional level and per-case payment of providers can coexist.

1999: a new radical reform?

By May 1999 the Government is expected to issue new legislation according to a general framework recently approved by the National Parliament. The general framework is a long list of specific issues on which the Government intends to introduce changes. However, it is framed in such a way that, at this stage, it appears difficult to predict exact changes. Nevertheless, the direction of changes can be guessed. First of all, the framework clearly re-states the basic idea of the Italian NHS: the universal right to health and health care. The Italian NHS aims to guarantee uniform access to health care to all Italian citizens, despite the explicit statement that the process towards the ‘regionalisation’ of the system will be completed. Universal access seems to be in safe hands. However, the framework explicitly recognises, consistently with the National Health Plan released last summer, that the NHS is mandated to provide only a “list of essential services” and that regions and communes can decide to fund additional services. The Italian Government appears serious in attempting to define clearly (and limit) the extent of NHS coverage, although it probably underestimates the technical and political difficulties of pursuing this strategy.

In various parts of the framework the national Government supports the enhancement of management in the NHS and the regionalisation process. In the last five years the NHS has dramatically

“... whether a ‘fine-tuning’ strategy will suffice to secure more stability and more public satisfaction with the NHS is difficult to predict.”

Figure 1
QUASI-MARKETS IN SECONDARY AND TERTIARY HEALTH CARE

Purchasing arrangement	Provider institution capital ownership	
	Public	Private
Consumer led	Some Swedish counties	Italy
Agent led	British NHS (in practice)	British NHS (in theory)

“The Italian Government appears serious in attempting to define clearly (and limit) the extent of NHS coverage, although it probably underestimates the technical and political difficulties of pursuing this strategy.”

changed its attitude towards management ideas, and now many providers are really implementing new management systems. It is thus likely that forthcoming legislation will try to provide more scope for further enhancement of management capabilities in the NHS. As far as the regionalisation process is concerned, the picture appears less clear. From one side, the national Government seems to accept and even support the regionalisation process; on the other it seems concerned with a fragmentation of the system into 20 regional systems and with the risk that the present arrangements cannot assure full regional accountability. Various elements of the framework suggest that the Ministry of Health will try to strengthen its monitoring activities and its powers concerning the definition of the accreditation systems, the way providers are funded and the criteria to identify hospitals that can become self-governing organisations. In addition, the regionalisation process is threatened by the ‘return’ of

the third tier of the NHS: the communes. The framework re-introduces a role for communes in planning and programming services at local level.

The Government was also delegated by the Parliament to issue legislation on various important aspects, including new rules to eliminate dual practice (physicians working for the NHS and private providers at the same time), the ‘privatisation’ of the labour contract for health professionals, new arrangements to develop primary care and new powers for the National Agency for regional health care services.

The present Minister of Health appears committed to the basic principles of the Italian NHS founded in 1978. Legislation to be issued soon will probably reflect this commitment and thus will not introduce structural changes. However, whether a ‘fine-tuning’ strategy will suffice to secure more stability and more public satisfaction with the NHS is difficult to predict.

The development of the French health system

Towards a structure guided by priority targets and better management coordination

Serge Skanavi

In the summer 1998 edition of eurohealth, P. Lancry and S. Sandier analysed the 1996 ‘Juppé plan’ reforms of the French health system, focusing on the economic perspective. The measures, which were the result of a nationwide consultation process started in 1991, aimed to make the health service more responsive to the needs of the population, and to improve its organisation. Following on from the earlier article, we want to consider these reforms by re-examining them in the context of the health problems from which they originated, and to look at their contribution to the definition of a health policy in France.

The health context

There are still many health problems in France which give rise for concern.

The 1994 report on health in France, published by the High Level Committee on Public Health, notes the continuing existence of a number of health problems which give rise for concern.

The level of premature death is far higher in France than in other countries of the European Union. The figures indicate 120,000 premature deaths per year, or around one quarter of all deaths. Two thirds of the deaths considered as premature and avoidable relate to risk taking behaviour. The two main causes are well known; these are alcohol and tobacco. The second noteworthy aspect of the health situation in France is the existence of important differences in health status marked by social and regional variations. This excessive rate of premature deaths, and the degree of social and regional inequalities, are indicators of a health system which is not working to the highest standards.

The problems of the French health system are clear

The working group on Perspectives for the Health System of the Commissariat

Général considering the new plan, published a report in 1993 outlining its analysis of the reasons for the failure of the health system.

The administrators and finance managers are unable to provide strategic guidance for the health system

A lack of medical expertise and political legitimacy on the part of the financing systems has led to a situation in which the negotiation process between the health insurers and health professionals has been unable for several years to come to compromises which are both substantial and practical. Consequently, this leads to a continual increase in the level of expenditure resulting from a persistent unequal balance between the providers and financiers of health services.

Budgetary control is not precise, and tends to promote the status quo without providing for real control in the growth of expenditure. As a result of this, historically, the logic of health expenditure is to fund services currently available rather than to respond to the needs of the population.

The split between the decision-maker, in the form of the state, and the financier, in the form of the health insurance organisations, leads to distortions in the service. These two actors do not have the same priorities, with distinctions made, for example, between health of the population versus health of the individual, or health in the broadest sense versus curative services. In the absence of a clear definition of the roles of the state and the health insurer, the objectives of public health are not clearly communicated and are not placed high on the agenda of either the financiers or planners of the health system. The planning of services is guided mainly by the requirements of local politics and the filling of beds. Changes in training are inflationist. The structures of organisation of work and distribution of doctors across a geographic area are ill adapted to needs and are often dictated by corporate interests.

Preventive medicine is starved of resources, and health professionals do not take a coordinated approach

The association of curative medicine with undeniable therapeutic progress and the stress laid on this field in financial terms, at the expense of other areas of health, has gradually led the general public, following health professionals and politicians, to consider the curative approach to be the best

or indeed the only means of improving health status. Other approaches such as prevention and health education, which target problems at a much earlier stage, have been marginalised.

Within the provision of care itself, the strict demarcations between health professionals of different specialities leads to difficulties in the coherent management and follow up of patients (an approach which becomes even more important as the impact of chronic illnesses increases). The every increasing number of persons involved leads to a breakdown in coordination of care which is the responsibility of several different providers of services. This also has an impact on the relations between hospital services and services of care in the community. In addition, the notion of evaluation is still very limited in France. The reason for this is the lack of information systems, and the absence of clear objectives, but also a resistance on the part of health professionals. The absence of any objective other than the control of expenditure is the main flaw which explains the deficiencies of the health system and the lack of information and evaluation systems. There is now a need to bring to all of this a sense of coherence, to infuse the providers, financiers and users of the health system with a new impetus. This will only be achieved through public health goals which are published and accepted, having been established by a democratic system.

A new system for planning and implementing a policy for health

As a result of this very critical report, the 'Juppé plan' established in 1996 a structural reform of the French health and social protection system.

Regional health conferences: a debate to identify answers to health needs

Regional health conferences have been established in all 26 regions of France. These provide a forum of reflection, analysis and debate, to establish a definition of health, as uniform as possible, of needs and of responses required to fulfil these. These conferences had been preceded in 1996 by a general consultation of all interested parties as to the problems or determinants of health which they considered to be a priority in their region.

The national health conference: priorities for public health

The national health conference has drawn on the contributions of the regional health

“This excessive rate of premature deaths, and the degree of social and regional inequalities, are indicators of a health system which is not working to the highest standards.”

“The absence of any objective other than the control of expenditure is the main flaw which explains the deficiencies of the health system and the lack of information and evaluation systems.”

conferences as well as the work of the High Level Committee on Public Health. Its role is to analyse data relating to the existing health status and the evolution of health needs, and to propose priorities for public health policy and the broad outlines for the organisation of health services. The first national conference, held in 1996, identified ten national priorities, each of which was given equal weight (see table). The 1997 and 1998 national conferences, which also drew largely on the preparatory work of the regional conferences, put forward recommendations relating to two of the priorities identified in 1996: child, adolescent and youth health in 1997 and inequalities in health, diabetes and iatrogeniatry in 1998.

Parliament approves the broad line of health policy and establishes a budget

The process of national consultation, as established through the health conferences, is a system of support for decision-making destined to clarify the decisions of Parliament. Indeed, Parliament must now approve the broad outlines of health and social security policy before setting a national target for the expenditure on health insurance (ONDAM) and an objective for the annual evolution of expenditure.

A better distribution of responsibilities between state and health insurers

Another objective of the ‘Juppé plan’ originated from the need to clarify the distribution of responsibilities between state and health insurers. This was achieved by formalising a partnership between the relevant organisations in the form of a multi-annual Convention on Objectives and Management. The first of these was agreed in 1997 for a period of three years. One of the aims of this convention is to direct the options open to the decision-makers towards the priority themes as identified in the broad lines of health policy voted by Parliament.

Regional health programmes: a partnership between decision-makers and providers in the health system

The 1996 reforms also created new institutional instruments which aim to ensure the transfer of health priorities into concrete and

structured actions. The role of individual regions has been confirmed, not only at the decision-making and prioritisation stage, but also for the implementation of health policy. The regional health programmes are to be the primary instrument used for the practical implementation of regional health priorities which were identified at the regional health conference. In addition to the statutory services, organisations responsible for social care, health and social workers and users’ organisations will all have a role in the definition and delivery of health programmes. The Regional Agency for Hospital Care will be responsible for ensuring that health priorities are taken into account in hospitals, while the Regional Union of Health Insurers and the Regional Union of Doctors will also have their role to play in supporting public health, prevention and health education activities. These activities, now the subject of a new focus, will benefit from coordination between all the different actors at the regional level.

The National Agency for Accreditation and Evaluation of Health has the aim of promoting quality in the health service

The 1996 reform sought not only to bring health care funding under control but also to reaffirm the fundamental aim of the health system, namely to allow an access to quality health care for all, with the belief that it is possible to provide better care while spending less, and therefore spending more sensibly. Thus the measures taken have aimed to promote the quality of care provided in both the hospital and community and primary care sectors. An organisation has therefore been created to provide an evaluation of the quality and safety of care, the National Agency for Accreditation and Evaluation in the Health Sector (ANAES). Several tools have been put in place to ensure that medical activities take up the concept of ‘right care’: accreditation, access to second opinions, continuing medical education. Consideration is being given to this through analysis and pilot projects in the different sectors and networks of care.

Conclusion

Since the early 1990s, there has been a greater inclusion of public health activities in the management of the French health system. This considers the aims of the health system at the highest level, and seeks to link the management of health professionals’ individual actions to the problem of broader priorities.

RESULTS OF THE NATIONAL CONFERENCE ON HEALTH IN 1996

Ten priorities for health identified in France (in no particular order)

1. **Provide greater resources for health promotion and the evaluation of results**
2. **Coordinate child health in order to ensure better continuity from post-natal to adolescence**
3. **Provide immediate reinforcement for actions and programmes of prevention/education targeted at adolescents aimed at reducing dependencies (of alcohol, tobacco, drugs, mind altering medicines)**
4. **Assist older people in need of support to stay in their own environment if they so choose**
5. **Improve results for and prevent the ghettoisation of structures for the fight against cancer**
6. **Prevention of suicide**
7. **Obtain more information on accidental death (excluding road accidents and deaths in the workplace)**
8. **Reduce the level of iatrogeniatric accidents, whether linked to medicines or not**
9. **Access to quality health care guaranteed for all**
10. **Reduce health inequalities between and within regions**

FURTHER AGREEMENT ON INJURY PREVENTION

Within the context of the European Community injury prevention programme, the European Parliament and the Council of Ministers have agreed – via committee procedure – on the establishment of a data pool to enable Member States to exchange and compare each other's health information. A budget of 14 million Euro has been decided upon, with the data pool expected to be a natural spin-off from the current European Home and Leisure Accidents Surveillance System (EHLASS). Also agreed upon was the need for a Committee comprised of national representatives to assist the Commission in implementing this new data-bank.

The new system has been named the European Union Public Health Information Network, and is expected to be designed in such a manner as to facilitate the comparison of statistical information on health across countries with not only differing information collating tools, but also national health care systems. As with the EHLASS procedure, all data will be coded in order to protect the privacy of individual citizens, and international collaboration with countries such as Malta, Cyprus and those of Central and Eastern Europe is to be encouraged.

The European Commission is not, however, entirely pleased with this development. Prior to agreement being reached by the Parliament and Council, the Commission had criticised the Council over its decision (on November 12th 1998) to employ the committee procedure for the oversight of the injury prevention programme.

The Commission argues that the procedure is too bureaucratic for such a programme, and that the use of an Advisory Committee would have been preferable. Furthermore, in a formal statement sent to the Committee of Permanent Representatives (COREPER), the Commission took issue with the fact that some of the amendments it originally tabled were left out by the Council in its common position agreed at the November 12th Health Council Meeting in Brussels.

NETHERLANDS FAILS TO TRANSPOSE FRAMEWORK DIRECTIVE ON WORKERS' HEALTH

On December 18th 1998, the European Commission agreed to send a reasoned opinion to the Netherlands regarding its failure to transpose the provisions of Framework Directive 89/391/EEC into national law.

The Directive concerns measures aimed at improving the health and safety of workers in the Member States. The Commission cited the following reasons for its decision:

- The Directive requires employers to involve external health and safety services only if they cannot be provided for 'in-house' because of a lack of qualified personnel. Current Dutch provisions enable the employer to choose freely between external and internal services.
- Dutch provisions do not currently ensure that employee health and safety representatives – where workers councils do not exist – are guaranteed access to lists of occupational accidents and readings of reports prepared for national authorities on occupational accidents in the workplace.
- Employers are not obliged to contact health and safety representatives regarding information pertaining to numbers and lists of accidents in the workplace, and the numbers of staff designated responsibility for first aid, fire-fighting and evacuation procedures.

AGREEMENT ON RARE DISEASES AND POLLUTION-RELATED DISEASES

Meeting in Conciliation Committee on February 2nd 1999, the European Parliament and the Council of Ministers finally reached agreement over the two outstanding programmes within the Community's framework policy for public health – those for rare and pollution-related diseases.

After its second reading of each proposal, the Parliament tabled 20 changes to the former and 14 changes to the latter. Despite agreement between the Parliament and the Council over the majority of these issues prior to the Conciliation proceedings, disagreement over two issues remained a sticking-point. The first related to the budgets to be allocated to the programmes, and the second to the scope of actions to be undertaken within each framework.

Regarding the budgetary disagreement, sums of 6.5 million Euro for the rare diseases programme (1999-2003) and 3.9 million Euro for the pollution-related diseases initiative (1999-2001) were finalised through the conciliation meeting. A condition was however, attached. Namely, that within the broader context of the future framework on public health, the Parliament, Council and Commission "will pay particular attention to rare diseases and pollution-related diseases and will give careful consideration to the budgetary consequences".

Within the scopes of the two programmes, it was decided that the sharing of information on the adverse effects of major pollutants – as required under each agenda – would be directed at policy-makers and professionals rather than the general public. It was also specified that the Commission will have to "endeavour as a priority to support initiatives integrating Member State competent authorities and concerned professionals."

BIRTHS CONTINUE TO FALL IN EUROPE

The preliminary findings of a Eurostat (the Luxembourg-based EU statistical office) report released on February 12th 1999 predicts that the number of babies born in the EU will have fallen to 4.01 million in 1998 – this is down from 4.05 million the previous year.

The report says that the number of live births in the Community is down by a third on those recorded during the mid-1960s. Between 1965-1975, fertility rates are said to have 'dropped dramatically', and the trend – despite modest increases in the 1996 and 1997 – is expected to continue. The reason for this is that the large numbers of women born during the 'baby-boom' period of the 1960s are now moving out of the peak childbearing years, and are being replaced by the smaller number of women born between 1965 and 1975.

The pattern in 1998 was not, however, predicted to be uniform across all EU Member States. For instance, whilst in Austria, Finland, Germany and Greece the fall in births is expected to be quite dramatic, in France and the Netherlands, significant increases are in fact forecast. The highest crude birth rate is in Ireland (14.1 per thousand population), and the lowest in Italy (9.2 per thousand population). The EU average meanwhile is predicted to be 10.7 per thousand population.

**BIRTHS, DEATHS AND NATURAL POPULATION CHANGE —
NOW-CASTS FOR 1998**

	Live births (1,000)	Deaths (1,000)	Natural change (1,000)	Natural change per 1,000 population
Austria	81.6	78.7	2.9	+0.4
Belgium	114.2	103.9	10.3	+1.0
Denmark	66.2	58.3	7.9	+1.5
Finland	57.4	49.8	7.5	+1.5
France	743.0	542.5	200.5	+3.4
Germany	776.5	848.0	-71.5	-0.9
Greece	98.3	99.6	-1.2	-0.1
Ireland	52.0	31.5	20.5	+5.5
Italy	530.1	569.5	-39.4	-0.7
Luxembourg	5.4	3.8	1.6	+3.8
Netherlands	199.0	137.2	61.8	+4.0
Portugal	114.6	107.7	6.9	+0.7
Spain	364.7	350.7	14.0	+0.4
Sweden	89.2	92.6	-3.4	-0.4
United Kingdom	715.3	613.9	101.5	+1.7
EU 15 Totals	4,007.5	3,687.7	319.9	+0.9

Source: Eurostat (1999). *Statistics in focus, Population and social conditions, No1/99, Slightly fewer births and deaths in 1998.*

Two other points raised by the survey relate to a fall in mortality rates and growth in population in the Community. The former is, however, expected to be tempered by the continuing ageing of the population – with Denmark having the highest death rate at 11.0 per thousand, and Ireland, at 8.5 per thousand, the lowest. The total number of deaths is predicted to have fallen from 3.71 million in 1997 to 3.69 million in 1998. Despite a fall in natural population growths in 1998, overall population growth is expected to continue rising in the EU, due to a "substantial net inflow of international migrants."

Special measures for women's health in the Community

A report drafted by Finnish MEP Heidi Hautala (Green) and adopted by the European Parliament Committee on Human Rights on January 18th 1999, argues that specific health measures for women are required in the Community.

In highlighting health problems particular to women, the report specifies that free and regular testing of women for breast and cervical cancer, and the need to establish a code of practice for all feminine hygiene products manufacturers, are measures which, amongst others, could be introduced across the Community. In the report, the Committee also addressed the issue of violence against women. In defining such violence as a public health problem, the report appeals to the Commission to include the health aspects associated with it in other Community campaigns designed to counter the incidence of violence in the EU.

Brundtland calls for increased WHO-EU cooperation

On January 7th 1999, Dr Gro Harlem Brundtland, Director-General of the World Health Organization (WHO), met with European Commission officials in Brussels. In a speech, she called on the EU, and Social Affairs Commissioner Padraig Flynn in particular, to increase the levels of cooperation between the two organisations. Citing the provisions of Treaty Article 129 which require the EU to increase its role in Community public health matters, Dr Brundtland said that the cooperation agreement originally signed between the WHO and EU in 1983 ought to be strengthened. This was particularly in light of the EU-membership hopes of several Central and East European countries. Specifically, she explained to Commissioner Flynn that at the WHO, "We know how policies work. You are telling applicant countries what to do in the health field, but you can't show them how to do it. Bad health means bad economics."

NEW CALL FOR PROPOSALS UNDER THE FIFTH FRAMEWORK

On 6th March 1999, the European Commission announced its first calls for proposals under the 'Quality of Life and Management of Living Resources Programme' (LIFE) of the Fifth Framework.

The LIFE programme "aims to unlock the resources of the living world and improve the quality of life" within the changing economic and social environment in the EU. It focuses on establishing and fostering the links "between discovery, production and end-use", where "the needs of society and the requirements of the consumer are paramount and research must lead to quantifiable future wealth and job creation, while respecting the principles of sustainable development." The programme carries a particularly strong public health focus, and six key areas for action have been identified:

1. Food, nutrition and health.
2. Control of infectious diseases.
3. The 'cell factory'.
4. Environment and health.
5. Sustainable agriculture, fisheries and forestry, and integrated development of rural areas including mountain areas.

6. The ageing population and disabilities.

Other generic research activities will be undertaken within the following areas:

- Cardiovascular diseases, rare diseases, chronic and degenerative diseases, cancer and diabetes.
- Research into genomes and diseases of genetic origin.
- Neurosciences.
- Public health and health services research (including drug-related problems).
- Research relating to persons with disabilities.
- Biomedical ethics and bioethics in the context of respect for fundamental human values.
- Socioeconomic aspects of life sciences and technologies.

Further calls will follow, and for more information contact the programme website: <http://www.cordis.lu/life/src/overview.htm>.

European Parliament report on 1998 Commission Public Health Communication

At the March Strasbourg plenary session of the European Parliament, MEPs overwhelmingly approved the Parliament's final response to the Commission's April 1998 Communication of the Development of Public Health Policy in the EU (COM[98] 230 final).

The Parliamentary report, prepared by the European Parliament Committee on the Environment, Public Health and Consumer Protection (rapporteur, Clive Needle, UK) endorsed the Commission's three-strand policy on: improving information for the development of public health, rapid reaction to health threats, and tackling health determinants, as well as making a series of further recommendations.

The report emphasises the need for a commissioner with responsibilities for health, a Community role in promoting quality in health across the EU, and the greater involvement of other international agencies, NGOs, and professional health and research networks in the policy process.

NEWS IN BRIEF

DURING a speech delivered on January 29th to a conference in Potsdam on public health in the EU, Social Affairs Commissioner, Pdraig Flynn, expressed the view that national health systems can no longer expect to be "completely insulated" from the "natural consequences" associated with the development of the internal market (specifically the single currency), and the increasing internationalisation of the health sector.

UNDER a joint effort with the European New Care Programme (EuroNCAP), the European Commission announced in January 1999 the first results of the most recent series of tests into car safety in the Community. With particular manufacturers and models of car being singled out, the more general findings of the report reflect a changing automotive industry attitude towards road safety in the EU. Neil Kinnock, the Transport Commissioner, greet-

ed the results with optimism and said that within the context of 123 deaths a day on Europe's roads (45,000 per annum) EuroNCAP is "an important component in the fight to cut that carnage".

DURING their February 12th 1999 plenary session in Strasbourg, MEPs adopted the report by British Socialist David Bowe approving the Commission's proposal to amend Directive 90/220/EEC on the voluntary release of genetically modified organisms (GMOs) into the environment. In agreeing with the Commission's draft Directive which changes the rules for granting market authorisations for transgenic products or those containing GMOs, MEPs emphasised that safety and health must be the primary concern.

AT the first meeting of the Council of Ministers' Working Party considering the draft regulation on orphan drugs, representatives agreed with the Commission's proposed incen-

tive measures to be offered those companies willing to research and develop such products (proposal made July 28th 1998 - see *eurohealth* Vol. 4 No. 3). Italy, Greece, the Netherlands, Portugal and the United Kingdom did, however, table certain reservations.

ON March 1st 1999, the European Commission announced its conditional approval for the planned merger between pharmaceutical giants Astra and Zeneca. Should it go ahead, at Euro 58 billion, the deal would be the largest pharmaceutical sector merger to date. Based on research indicating that the merger would give the combined undertaking too dominant a market position in the anti-hypertension, anti-asthmatic, and anaesthetic drugs markets, the Commission stipulated that only if the two companies were to sell off exclusive distribution rights and interests in the three sub-sectors, would it grant complete approval.