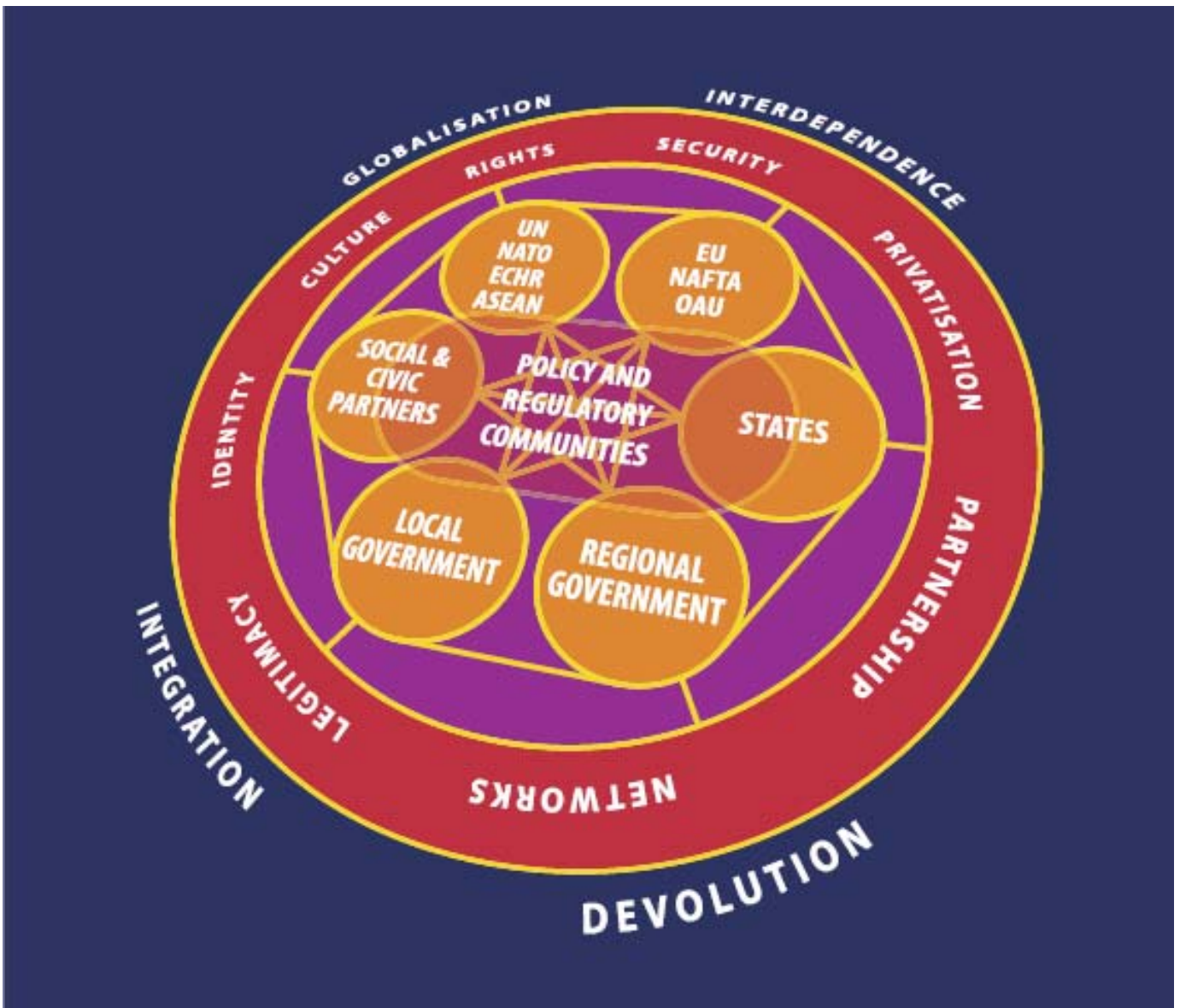


*EU Policies and Programmes Concerning Health:  
A Short History*

**Robert Coleman**

Working Paper QU/GOV/5/2004

May 2004



**Institute of Governance,  
Public Policy and  
Social Research**  
Queens University Belfast  
Belfast  
BT7 1NN

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# **EU POLICIES AND PROGRAMMES CONCERNING HEALTH: A SHORT HISTORY**

**Institute of Governance, Public Policy and Social Research  
Queen's University Belfast**

**Briefing Paper Gov/BP/2004/2**

## **Foreword**

This paper is the latest in a series of briefing papers on policy published by the Institute of Governance, Public Policy and Social Research. In the convention of all the Institute's publications, this paper reflects the views of its author.

The Institute was set up to serve two equally important purposes - to enhance the quality of research in QUB and to make a significant contribution to the policy community in Northern Ireland. We do so by being both interdisciplinary and cross-sectoral and by working in partnership with others.

We are able to publish this particular paper because of our good fortune in attracting to the Institute as a Senior Fellow, Dr Robert Coleman who, until he came here, was Director General for Health and Consumer Protection in the European Commission. Dr Coleman has made many important contributions to the work of the Institute and the wider university. His paper on this important EU policy is being published in the run-up to the elections to the European Parliament and we hope that it will be a contribution to information and debates in Northern Ireland.

**Elizabeth Meehan  
Director, Institute of Governance, Public Policy and Social Research  
May 2004**

## **Introduction**

The purpose of this short paper is to recount as concisely as possible the story of the EU's involvement in health issues since the beginning of the Coal and Steel Community<sup>1</sup>. It is accompanied by a short selected bibliography of works that also give an overview of the subject or large parts of it. Specific issues can be further researched most easily in the first instance by accessing health related pages of the Europa web site, in particular, [http://europa.eu.int/comm/health/index\\_en.html](http://europa.eu.int/comm/health/index_en.html).

For the material on developments from the 1970s to the early 1990s in the third section, I am particularly indebted to the briefings that I received from Marianne Lauridsen. She was a senior Danish health official working as a seconded national expert in the Commission's Directorate for Health and Consumer protection when I arrived there in 1999. Her untimely death in 2002 deprived the EU of an enthusiastic servant of better health policy for Europe's citizens, including an appropriate role for the EU itself. This article will serve, I hope, to celebrate her contribution as well as those of the many other individuals who have worked to that end over many years.

## **The founding Treaties: no broad, explicit mandate but narrow or implicit bases for action**

Under the Coal and Steel Treaty (1951), Rome (1957), Euratom (1957) and the Single European Act (1986), health protection, promotion and care did not figure as explicit, general objectives. As regards workers, occupational health issues were addressed but at first only implicitly as part of the goal of harmonising working conditions with a view to a general raising of standards. Specific measures were foreseen on protecting workers and the general public against the dangers of ionizing radiation. Also provision was made for action to address obstacles to the movement of migrant workers arising from differences in social security provisions. Finally, the protection of health figured as one of the grounds on which Member States can derogate from the fundamental provisions on free circulation of goods, persons and services provided they do so in a proportionate manner and without discrimination on grounds of nationality. Accordingly, scope existed for legislation to address obstacles to the proper functioning of the internal market arising from national measures to protect human health.

On these apparently modest bases, much was built, with a notable widening and deepening of activity as a major political effort was made to complete a genuine single market by 1992. The main realisations included basic standards on radiation protection applicable in all Member States, such as limits on exposures in diagnostic radiation and

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<sup>1</sup> In this article, "EU" is used as shorthand for the different legal entities that it has over the years comprised: the Coal and Steel Community, the Atomic Energy Community, the European Community or Communities.

treatment. In the field of pharmaceuticals first came harmonisation of national approval systems and then an EU authorisation and pharmacovigilance regime. On medical devices, a harmonised regime was adopted to ensure the safety of such products when they are in free circulation. Harmonisation and recognition of professional qualifications for certain medical professions, including doctors and nurses, was pursued progressively.

In the field of occupational health, "soft" approaches to promoting convergent developments in occupational medicine, including responses to occupational diseases and surveillance in the work place, gave way first to binding directives on specific threats arising from particular chemical, physical and biological agents and then to a framework directive as the basis for a comprehensive regulatory approach under the much more explicit provisions of Article 118a of the Single European Act. In the social security field, coordination provisions were adopted to ensure that persons exercising their rights of free movement are not placed in a worse position than those who do not, including those seeking sickness benefits during a temporary stay. Finally, in the environmental field, the first measures contributing to the protection of human health were taken, again on the basis of a more explicit provision in Article 130r of the Single Act.

The free circulation provisions of the Treaties also constituted the foundation for an internal market in health services though it would be some years before this became a reality, except for migrant workers and tourists.

### **Growing political and institutional recognition of the need for a more global approach**

The steady, if sometimes unspectacular, growth in specific health related measures taken by the EU began to be accompanied in the late 1970s by a growing feeling of some within its institutions that health policy as a whole merited a different kind of approach. Certain health Ministers and senior officials began to reflect on the need for them to meet together in the Council to consider issues of common concern which would benefit from more convergent approaches. In 1977, under the Belgian presidency, at the particular initiative of the Belgian health Minister Halter and with the influential support of the French Minister Simone Veil, the first such meeting was held. It was followed by others in subsequent years with most presidencies holding one meeting during their six-month period of office until the Health Council was merged into the combined Council on Employment, Social Policy, Health and Consumer Affairs in 2002.

In the early '80s, the interest of certain Health Ministers, in developing convergent even common approaches to important shared problems, received high-level political support in the form of President Mitterand's personal interest in seeing action taken in relation to cancer. At the Milan European Council in 1985, the Heads of State and Government emphasised the importance of launching a programme of action against cancer, which led in 1986 to the adoption of a Council Resolution and appropriate follow-up by the Commission and the Member States in the following years. In the same period, the European Parliament was also beginning to manifest an interest in health related matters, for example, by asking in 1982 for a report on the medical and public health aspects of the Community's research activities.

Given these manifestations of political interest, health concerns unsurprisingly also emerged during the intergovernmental conference that led in 1986 to the Single European Act. The need to address the health dimension of other policies was given new, explicit recognition, for example, in relation to legislation to realise the single market (Article 100a), protection of workers' health and safety (Article 118), research (Article 130f to q) and environment (Article 130r to t). However, a general mandate to develop a EU health policy or protect public health was not seriously discussed. Indeed, it was becoming clear that for every advocate of increased EU involvement in health policy, there were those who viewed such a development with suspicion and strongly resisted any attempt to broaden its powers, especially in an open-ended manner. This ambivalence in the expressions of political opinion on the subject continues to this day, reflecting the importance and sensitivity of health policies and care provision for the citizen, for the responsible authorities and for public budgets.

Despite these reservations in certain quarters, the health Ministers continued to meet regularly and the implementation of the cancer action programme was carried forward, including legislative proposals to address the harm caused by tobacco. Requirements on labelling and tar content were adopted relatively quickly but the proposal to restrict advertising proved much more difficult, despite the ban on television advertising introduced by the directive on television without frontiers adopted in 1989. Adoption of the proposal for a general directive on tobacco advertising and sponsorship in 1998 took over eight years to achieve and in 2000 it was set aside after a challenge made by the German government in the European Court of Justice. It argued, as much of the tobacco industry had done, that the directive's provisions exceeded the scope of the legal basis on which it was adopted, namely legislation shown to be necessary to realise an internal market, in this case, in tobacco products (Article 95, the successor to Article 100a). An action programme on AIDS was also developed, endorsed by the Council in 1991 and then put into effect. This was followed by an action programme on demand reduction for drugs. Like the cancer programme, these programmes had no specific basis in the Treaty but relied on the Treaty as a whole, including its general objectives such as the constant improvement of living and working conditions mentioned in the preamble.

Despite these achievements, there was a growing dissatisfaction about the way in which the EU was addressing health issues on the basis of the Treaty as it then stood. An increasing number of health Ministers, their senior officials and some interest groups felt that the approach was too fragmented, did not address many issues of fundamental importance and was distorted by the limited legal bases for action which might subordinate health objectives to other considerations such as the promotion of free circulation, while in any case leaving even adopted measures open to legal challenge. These currents of opinion led at the beginning of the '90s to the creation of a High Level Committee on Health made up of senior officials from the Member States and the Commission. Officials from Denmark, the United Kingdom and Germany as well as from the Commission played a leading part. The basic idea was to see whether a process of high level reflection and discussion could establish a more comprehensive and coherent approach to policy making on health, while fully respecting the responsibilities of the Member States for health care provision. The process could also provide the necessary in-put on health policy to the intergovernmental conference getting under way that would lead to the Treaty of Maastricht.

The state of opinion prevailing in health Ministries at the time can be fairly well assessed by the content of a Council Resolution concerning fundamental health policy choices adopted at the end of 1991 on the basis of discussions at an earlier informal meeting organised by the Dutch presidency. In careful language influenced by the limitations on the EU's powers, Ministers took note of certain topics warranting joint consideration, discussion or efforts. These included the drawing up of comparative data, for example, on the state of health of the population in the Member States and the efficiency of medical services; continued application of specific EU programmes; the development of strategies to facilitate choices and the setting of priorities in the health policies of the Member States; analysis of the probable impact of the completion of the internal market on national health policies and the medical sector; and also analysis of the EU's possible contribution to removing prevailing disparities in supply and demand owing to shortfalls of various kinds, for example, in areas such as transfrontier supply of health care. At the same time, the Resolution emphasised that it was for the Member States to determine the organisation and funding of their health care systems and to make fundamental health policy choices. Their desire to see EU activities contribute in a direct and coherent manner to the development of their responses to the central challenges of health care provision in an ever more integrated regional economy was not to be regarded as in any way calling into question their power to decide autonomously and individually what those responses should be.

The High Level Committee on Health continued to meet as the intergovernmental conference addressed changes to the EU's powers and responsibilities, including a draft provision which would for the first time give it a more generally defined mandate concerning health while at the same time setting limits designed to prevent developments which might disrupt sensitive national approaches or interfere with the

Member States' responsibilities for providing health care. This balanced, or possibly ambivalent, approach was an accurate reflection of prevailing attitudes in most health Ministries.

### **New Treaty objectives**

Nevertheless, the Maastricht (1992) and subsequently the Amsterdam (1997) Treaties effected a fundamental change in the EU's constitutional framework as regards health. For the first time, a Treaty provision consecrated a high level of human health protection as a general and free-standing goal and also specified certain means by which the goal should be pursued. Maastricht put the emphasis on soft approaches like promotion of research, information, education, coordination among Member States, international co-operation, incentive measures and Council recommendations but "excluding any harmonisation" (Article 129). Only a few years later, Amsterdam took the regulatory plunge by not merely permitting but calling for EU legislation on high standards of safety of organs and substances of human origin, blood and blood derivatives. It also shifted veterinary and phytosanitary measures for the protection of human health from the title on the common agricultural policy to public health. These changes were both a result of the challenges emerging from a highly integrated internal market and a political response to growing public sensitivity to health problems, no doubt stimulated by major affairs like BSE and blood contamination in France as well as chronic problems of health care delivery in many Member States. At the same time, the Member States were reluctant to give the EU an open-ended role and the Amsterdam text underlined in somewhat Delphic language the need for EU action to "fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care" (Article 152).

### **From specific action programmes to a health strategy and a single programme**

On the basis of the new Treaty provisions, the EU in a first phase developed eight action programmes:

- cancer
- communicable diseases, including AIDS
- drug dependence
- health promotion
- health monitoring
- pollution related diseases
- injury prevention and
- rare diseases.

A fairly common feature of these programmes was the creation of networks among actors in the Member States for exchange of information and personnel, joint analysis of common problems, training, and sharing best practice. Some of these developed into highly effective instruments that will in all probability make major contributions into the future.

The most important example is to be found in the field of communicable diseases. The relatively informal constitution during the '90s of a set of largely disease specific networks involving health authorities and other actors led in 1999 to a formal Council and Parliament Decision (2119/98/EC) providing a solid legal basis for a permanent, overarching network of national health authorities and the Commission to manage epidemiological surveillance of communicable diseases and an early warning and response system. The Decision includes provision for the adoption of guidelines on protective measures to be taken at the external frontiers of the EU in emergencies. This machinery has proved its worth on a number of occasions, notably in connection with the SARS outbreak in 2003. It was used intensively throughout the epidemic and ensured that the Member States acted in a consistent and effective fashion, largely resisting the temptation to divergent responses which, if they escalate, can undermine public confidence and misallocate scarce resources, energy and attention.

The successful functioning of the communicable diseases networks strongly influenced the EU's policy response to the events of 11 September in the field of planning for acts of terrorism involving biological, chemical and physical agents. An action programme on health security was decided at the level of the Council in November 2001 and pursued as a high priority. Given the importance of speedy detection and transmission of information about alerts, the Member States have been improving their surveillance and alert systems. At EU level, a rapid alert system for biological and chemical attacks (BICHAT) has been put in place, building on the existing communicable diseases network. The programme and the rapid alert system have been implemented since 2002 with the support of an *ad hoc* task force under the guidance of a Health Security Committee. Close co-operation has been developed with the WHO and the Global Health Security Action Group consisting of the USA, Canada, the UK, France, Germany, Italy, Japan and Mexico.

The experience gained in developing coordinated responses to communicable diseases and other shared threats to health facilitated the discussion and rapid adoption in 2004 of the proposal made by the Commission on the creation of an EU Centre for Disease Control to provide a more centralised and robust agency at the heart of the EU's networks for surveillance, alert and response concerning health threats in general.

Experience gained in managing the eight specific health programmes enabled the Commission to propose in 2000 a health strategy for the EU including a single integrated programme based on three complementary themes or strands: health information, health threats and health determinants. This programme of €312 million was adopted in 2002 and runs from 2003 to 2008. While an activity like "health information" or "monitoring" can sound rather anodyne, it is important to note that it covers matters like differences in health status in the Member States as well as, and increasingly, comparative analysis of the effectiveness of health care systems and even specific treatments. Such work is likely to generate discussion and controversy but also, and more importantly, promote convergence in health care policy making, management and even clinical practice based on those experiences that have proved themselves most effective.

## **Legislation**

The health strategy also includes the use of legislative instruments, hard and soft.

On the basis of the relatively narrow mandate in the Public Health Title, legislation was adopted in 2002 on the safety regime to apply to blood and blood products and in 2004 on tissues and cells. Legislation on organ transplants is also foreseen but will take longer to develop. The main problem in this field at the moment is not the safety regime but the chronic shortage of donated organs, which limits the scope of the activity in general, and certainly cross-border operations.

As indicated above, while the mandate for legislation on human health protection in its own right is limited, health related legislation is an important aspect of the realisation and management of the internal market (Article 95). In this context, in 2004, the pharmaceuticals framework was thoroughly revised including a broadening in the scope of application of the EU authorisation procedure, in particular, to make it compulsory for all new active substances, not just those resulting from the application of high technology processes such as biotechnology. The system to allow health professionals to provide services in other Member States is also being revised, in particular, with a view to making temporary or occasional service provision easier.

Legislation on tobacco has continued to be an important priority, despite the legal campaign of attrition that sections of the tobacco industry continue to wage against it. Following the decision of the Court of Justice to set aside the general directive on advertising and sponsorship to which reference has already been made, the Commission in 2002 made a new proposal designed to respect fully the limits of legislation justified as measures needed to realise the internal market. The directive was adopted relatively quickly in 2003 but is again being challenged in the Court. The latest,

rather visible development is the compulsory use of unambiguous, large letter health warnings in accordance with the up-dated provisions on labelling contained in another directive also decided in 2003. The year 2004 will see the entry into force of rules on the use of dissuasive images. In the meantime, the legal skirmishing goes on and unfortunately so does smoking. A 2003 Eurobarometer survey shows that since 1995, both the percentage of the population that smokes and average consumption rates of smokers have increased, the former by a substantial 5%. Declines in Denmark, the Netherlands and Belgium have been offset by increases elsewhere. Health professionals and policy makers will be watching attentively to see if the recent measures can change this deadly trend.

Soft, that is, non-binding, legislative instruments are also used in the public health field, not least to give political expression to the results of certain projects from the health programme. The most recent development is a proposed recommendation on cancer screening based on the experience gained under the successive Europe Against Cancer campaigns in the '90s and the work of the Advisory Committee on Cancer Prevention. The 2001 Recommendation on alcohol and young people and the 2002 Recommendation on prevention of smoking and measures to improve tobacco control are other important examples.

In the agriculture and food sectors, of course, the legislative machine continues to consolidate, review and up-date the whole regulatory framework for protecting human health on the basis of scientific risk assessment, now provided by the newly created European Food Safety Authority. A recent example is the new Commission proposal for a Regulation on the addition of vitamins and minerals to foods, the so-called "fortified" foods. And in this field too, soft law is likely to find a place as the emphasis shifts from essential safety requirements to nutrition. Obesity and other problems associated with poor diet, like growing "type 2" diabetes in children, are of increasing concern as regards the health status of certain social groups in many Member States. An effective policy response will need to combine both compulsory requirements, for example, on labelling with other techniques designed to ensure that consumers are aware of the risks and have the understanding necessary to manage them.

### **An emerging internal market in health services**

In a series of judgements in recent years, the European Court of Justice has affirmed the right of citizens resident in one Member State to obtain health care in another and still be compensated by the authorities of their home State<sup>2</sup>. The Court has begun to define the limits of this right, recognising the need for conditions that will enable the Member States to plan for the provision of health services, avoid undermining the

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<sup>2</sup> Kohll and Decker 1998, Smits/Peerboms and Vanbraekel 2001 and Müller-Fauré/Van Riet 2002.

finances of the social security system and control costs. The Member States themselves have reacted with a mixture of enthusiasm and anxiety. On the one hand, they appear to see possible advantages in a more open system which would allow available capacities to be better matched to patient needs, provide greater patient choice and allow concentration of scarce resources and expertise in certain areas. At the same time, they are of course concerned that this new freedom should not destabilise their systems or make more difficult their already complex task.

Starting in 2002, a high-level reflection process was undertaken involving certain health Ministers themselves and other key actors. Their report, adopted in December 2004, recommended a number of policy responses to the challenges created by an internal market in health care services. These address four main themes: European cooperation to permit better use of resources; improved information requirements for patients, professionals and policy makers; access to and quality of care; and means of reconciling national health policy objectives with European obligations. The report is likely to have a major impact on future developments and could well mark the beginning of a real EU health care policy to be decided by its political institutions in instruments including new legislation rather than by the judges of the Court.

In the meantime, in 2004, a new Regulation was agreed by Council and Parliament to modernise the social security rules by improving the rights of insured persons in the context of the introduction of a single health insurance card to replace the different paper forms currently in use. Ultimately this card should function entirely electronically.

### **The research and technology vectors**

In parallel to the initiatives taken under the Treaties' various provisions on health and on the internal market, important activities related to health have been under way, particularly over the last decade, in the context of the EU's programmes on research and technology. The framework programmes on research developed steadily throughout the '90s with life sciences playing a large and growing role. As to the promotion of advanced technologies, the programmes on IT merit a mention, particularly the e-health programme to develop an intelligent environment for health managers and professionals.

A quick browse through the relevant data-bases immediately impresses by the scope of the activities completed, under way and continuing into the future. What is harder to do is to make any kind of overall evaluation of the activities in the real world of health care. Happily, that should be easier in the not too distant future. An impact evaluation concerning health is to be included in the revised work programme for the sixth framework. Also, better coordinated technology assessment is certain to figure as a major feature of future activities.

## **Enlargement**

Enlargement poses a considerable challenge in the health field. While implementing the legislative "acquis" is unlikely to give rise to major difficulties, with the possible exception of food safety and animal health, differences in health status and care provision are very significant. On average, the accession States spend in real terms about a quarter of what is spent per citizen in the existing Member States. Life expectancy is significantly shorter and there are some particular causes of concern like growing levels of disease resistant to antibiotics including tuberculosis. And there is also the issue of the impact on their health professionals of new opportunities in the west. A major effort will be needed to address these problems for which fortunately there is a precedent in the use of structural funds in Portugal in the period 1994 to 1999.

## **The external dimension**

The steady expansion in the health related activities of the EU has inevitably been reflected at the international level. Its role within the World Health Organisation had been developing over many years, leading in 2000 to the conclusion of a new cooperation agreement between the Commission and the Organisation aimed at promoting closer cooperation and establishing a framework for their relations adapted to current circumstances. During the negotiation in 2003 of the WHO's Framework Convention on Tobacco Control, the EU played a key part in ensuring the adoption of an international instrument sufficiently rigorous to combat the effects of tobacco use world-wide, especially in the developing world. It has also been active to give an international dimension to its efforts to combat communicable diseases and bioterrorism.

## Political drivers

To conclude, EU policy on health and health care provision, from very modest beginnings in the Coal and Steel Community, has grown significantly, especially in recent years. It will continue to do so driven, in particular, by the continuing integration of Europe's economy, scientific and technological advances; the Member States' interest in meeting the challenges of better health care provision; new challenges like those of enlargement; and last but by no means least voters' concerns and aspirations as regards the quality of their lives. Recent Eurobarometer opinion surveys show particular public concern about radioactivity, chemicals and food quality, with air quality, indoors and outdoors, and noise cited as the factors believed by respondents to be the top three environmental factors causing ill health in their families.

At the same time, the Member States' ambivalence about EU involvement in health policy is still apparent. At one point in 2003, it appeared that discussions within the Convention on the future of Europe were favouring a Treaty amendment that would broaden the EU's legislative competence so that, independently of other Treaty powers, it would be able to address common concerns, especially threats to health. Unfortunately, at the last minute, without serious debate and for reasons that have not been clearly explained, those guiding the complex process preferred to continue with an approach which leaves the objectives and the limits of the EU's role far from clear.

The next eighteen months will not be a typical period in the history of the EU. The current political cycle is entering its last phase with a Parliamentary election in June 2004 and a new Commission in the autumn. The new Member States will join and, in the second half of the year, begin to make their presence felt. And the Intergovernmental Conference may yet have delivered a draft Constitution for ratification. In the remainder of 2004, the emphasis in the health field is thus not likely to be on major new initiatives but on delivering what is already under way or announced. However, past experience suggests that a period of consolidation and execution will be followed by renewed innovation once the institutions are in place in their new compositions. A consultative document on pandemic planning, particularly to address the threat posed by influenza and a proposal for a new action programme to address the environmental causes of ill-health have been announced for the middle of 2004. They are likely to give a firm push to the start of the next political cycle.

All of this suggests that, whatever the Treaty provisions in force and despite the probable continuing ambivalence of Member State attitudes to further development of its legislative powers, health policy will continue to be a field in which the EU continues to innovate as a response to the deeply felt concerns of its citizens.

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