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competition cooperation solidarity

Health: A vital issue for Europe

Health is one of European citizens' foremost concerns. Although this is still not widely known, the EU intervenes in many different ways in the field of health, whether it is fighting communicable diseases, guaranteeing drug and food safety, limiting the harmful effects of unhealthy lifestyles, or even building a community healthcare space. At a time when EU intervention in this area is expanding, we may well question about the latter's forms and motivations. In fact, Community action in the health sphere is only marginally related to the desire of building a Europe of Health; it is above all a secondary effect of the process of European integration. Taking full advantage of the Community's added value means breaking free of this logic by acknowledging the role of the EU in this sector and streamlining its efforts. At a time when European integration is more than ever in pursuit of meaning and legitimacy, the EU could, in such a way, draw decisively closer to its citizens.

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Research

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by Sébastien Guigner

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Executive Summary

Health is one of European citizens' foremost concerns. Although this is still not widely known, the EU intervenes in many different ways in the field of health, whether it is fighting communicable diseases, guaranteeing drug and food safety, limiting the harmful effects of unhealthy lifestyles, or even building a community healthcare space. At a time when EU intervention in this area is expanding, we may well question about the latter's forms and motivations. In fact, Community action in the health sphere is only marginally related to the desire of building a Europe of Health; it is above all a secondary effect of the process of European integration. Taking full advantage of the Community's added value means breaking free of this logic by acknowledging the role of the EU in this sector and streamlining its efforts. At a time when European integration is more than ever in pursuit of meaning and legitimacy, the EU could, in such a way, draw decisively closer to its citizens.

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Introduction

If there is one precious asset among the rest that we all unceasingly strive to safeguard and augment, for ourselves and those close us, it is undoubtedly "health." Beyond our borders, irrespective of nationality, religious belief or political ideology, we all have one common concern: "mankind." Mankind as such in his fragile condition, exposed since birth in every part of the world and in every climate, to disease, to suffering and to death…. I am therefore asking you to undertake a generous task […]: the creation and organisation of a "EUROPEAN HEALTH COMMUNITY."

Paul Ribeyre, 24 September 19521

1 Statement by Paul Ribeyre, the French Minister of Health and Population, at the Council of Ministers. This document can be consulted at the following Internet website: http://www.ena.lu

A few months after treaties were signed concerning the European Coal and Steel Community (ECSC) and the European Defence Community (EDC), several European States met to create a "European Community for the fight against suffering and illness," a European Health Community. In the mind of its founders, its aim was to increase interdependency between European peoples and, above all, to legitimise, in public opinion, the emerging process of European integration. Indeed, health appeared to be not only one of the few areas which concerns all citizens but one of those which preoccupies them the most.

However, after the swift failure of this project, the European integration process seems to have carefully avoided the topic of health. Invoking the diversity of health systems and practices, and eager to retain control over an area essential to their legitimacy, the governments which successively headed the various Member States proved reluctant to renounce their prerogatives concerning health. The latter is thus widely considered to be one of the last domains reserved to Nation-States, and the majority of citizens, as well as stakeholders in the field, are still of the opinion that the European Union (EU) is not an actor in this field.

Yet even if most laws stipulate that health policies should remain under national control, the EU's involvement in this area is now growing rapidly. Recent events attesting to this include the creation in 2005 of a European Centre for Disease Prevention and Control, the adoption of a "Programme of Community action in the field of health" at the end of 2007, and, in the summer of 2008, the Proposal for a Directive on cross-border healthcare regulation. However, because the Union's intervention in the health field can assume unconventional forms, it remains unrecognised, undervalued and sometimes denied.

First, the EU's health policy is centred around public health (for a definition, see the box below), an area in which it obviously brings added value to initiatives taken on a national level. This sub-field generally plays a minor role in the Member States' health policies, which are focused on healthcare. Therefore, health policies are assumed to primarily deal with healthcare and disease control. This view naturally tends to devalue the EU's health-related activities. Public health has nonetheless been reassessed in Member States. The latter are gradually rediscovering the old adage, "an ounce of prevention is worth a pound of cure," even if their motivation is primarily to reduce health system costs. Moreover, the Union has not been totally unconcerned about health systems; it has been involved with them to some degree for a long time, but lately has significantly broadened its involvement (I).

By definition, *public health* is a field which concerns groups or populations, not individuals. According to this definition, healthcare, inasmuch as it is provided to individuals, would not be a matter for public health. Healthcare organisation, on the other hand, is not individualised and therefore *is* a public health matter. This approach is all rather ambiguous, and even more so when a standard definition of "public health" does not exist. Public health policies sometimes refer to actions related to promoting, preventing and restoring health, while at other times they merely refer to health insurance schemes and exclude healthcare and all associated activities. It is the latter approach that will be adopted here. In fact, it is the one which the EU has implicitly adopted, inasmuch as according to the Treaty, it does not have the authority to intervene in the organisation and delivery of health services and medical care—i.e., in health and healthcare systems—when it is carrying out public health activities (see Article 152 of the Treaty in Appendix 1).

Second, the inadequate knowledge and devaluation of Community intervention in the health field stems from the way in which the latter is expanding. Health integration is very often primarily not motivated by health concerns, the EU's intervention being merely consequential to other activities—particularly the construction of the Common Market—and still relatively unofficial. Furthermore, often it is only under the pressure of public health crises, or when confronted with a major threat to population health, that governments agree to delegate health competences to the Union. Also, building the "Europe of Health" often appears to be a "directionless, erratic, reactive, and not always the most suitable, process" (II).

The streamlining of Community health intervention therefore calls for a two-pronged effort. On one hand, it requires a (re)structuring of European Commission agencies responsible for implementing the Community's health policy, which are weak and scattered. This change is underway and it has already made it possible to develop a more strategic approach to Community action in health matters. On the other hand, without an appropriate revision of its legal basis, the latter approach cannot be totally effective, either in the areas in which its added value is evident, or in controlling the EU's involuntary interferences with health-related issues. Despite some progress made, the Lisbon Treaty has shown that many governments do not yet seem prepared to take a decisive step in this direction (III).

Today, health is more of a priority than ever for the general public, which is worried about the resurgence of epidemics and the threats looming over health systems. The EU has certain assets which clearly can help Member States to resolve these problems while at the same time improving its relations with its citizens. Paul Ribeyre certainly had the right idea: what better means is there to unite European peoples than to collectively address their health concerns? What better way to make European integration meaningful to the EU's citizens than to infuse it with an area which directly concerns, and means a great deal, to all of them? In short, as David Byrne, the first European Commissioner for Health and Consumer Protection, more recently stated: "After all, what more positive contribution can Europe make to the lives of its citizens than to improve their health?1 It will still be up to the EU to acquire the means to effectively handle such issues and ensure that its citizens are aware of its activities in this area.

1 David Byrne, the Enabling health- Empowering citizens Conference of the European Health Management Association, Potsdam, 23 June 2004, SPEECH/04/234.

I - A sphere in which the EU is already considerably invested

Although Community intervention may still seem erratic, currently the Union is extensively involved in the health field and contributing several forms of added value to the initiatives taken by the national governments. Before providing an overview of the latter, it may be helpful to briefly review the structural framework of the Union's health-related activities: the Programme of Community action in the field of health.

1.1 The Community Action Programme in the field of health (2008-2013)

Until the early 2000s, Community action in the field of health was implemented on a case-by-case basis. For example, there was a cancer prevention programme, another to promote health, and still another for health surveillance. This segmented approach actually reflected the reticence of certain States to expand Community activities. This inevitably led to regrettable administrative burdens and overlapping activities. Tapping into a new form of legal basis—Article 152 of the Treaty, as

will be pointed out later on[2]—"the Public Health Programme" (2003-2008) made it possible to streamline these activities by offering a horizontal approach centred around transversal objectives, rather than specific problems.

Later, the Community Action Programme in the field of health (2008-2013)[3] set out three key objectives, accompanied by several sub-objectives. Community action in the health sector must therefore (1) "improve citizens' health security," for example, by strengthening Member States' capacity to fight epidemics by formulating emergency plans and immunisation programmes and by adopting measures and standards to ensure patients' safety; (2) "promote health," for example by encouraging a healthier lifestyle through prevention campaigns or by implementing measures which limit the negative impact of certain factors on health; (3) "generate and disseminate health information and knowledge," for example by creating health indicators, or by expanding the Internet website 'health portal.'"[4]

As the Treaty limits the Union's ability to regulate within this field, meeting these objectives will be minimally done through legislation; it will be mainly accomplished by way of projects primarily implemented by national stakeholder groups. For the 2008-2013 period, the European Commission has at its disposal a budgetary envelope of EUR 321,500,000, which it distributes jointly with the Member States through the agency of several mechanisms. This notably involves joint funding of projects designed to meet a Programme objective, or co-funding the operating costs of NGOs or specialised networks. Some 300 projects have thus been funded within the framework of the preceding Programme, most of which have concerned prevention and health promotion, as well as disease control.

2 See also Appendix 1.
3 The Programme text is available at the following address : http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF
4 A clearer and simpler version than the official DG Health and Consumer Protection website (http://ec.europa.eu/health/index_en.htm), this general public website has a thematic structure (food, long-term care, etc.) focused on European activities, but also informs users about national policies pursued in the various areas covered. It also provides practical information. For example, it explains how healthcare professionals can work in another Member State, and informs patients of their rights and duties in case they should wish, or be obliged, to receive treatment abroad (http://ec.europa.eu/health-eu/).

1.2 Disease prevention and control: The core focus of Community action

After the "Europe Against Cancer" campaign was launched in 1987, prevention and health promotion activities, along with those concerning disease control, for many years officially constituted the sole component of "Community health policy" and still represent the substance of it. The Member States' governments have gradually agreed, less reluctant to confer jurisdiction to the Union in this area, which to them appears to be less politically profitable than healthcare and in which the Union is equipped to contribute obvious added value to the actions undertaken at the national level. As a result, the Union currently appears to be a key actor in this area. Without claiming to cover all Union activities, this paper outlines the types of added value, often cumulative, which the EU contributes to national intervention.

Managing cross-border problems: The EU and communicable diseases

The micro-organisms that cause communicable diseases and epidemics do not stop at national borders, which all the more applies when controls have been lifted, which is the case in the EU. The potential spread of disease is amplified by the free movement of persons, goods and animals, which increases flows and reduces the options for controlling communicable diseases. The actions undertaken at the European level have appeared relevant for treating communicable diseases and avoiding disorderly national responses with potentially disastrous consequences. Community intervention seems all the more indispensable in that certain communicable diseases (such as tuberculosis) which were more or less under control in the Europe of Fifteen are still thriving in some "new" Member States. The worldwide context is equally threatening. We need only consider SARS, the avian influenza (A-H5N1), or the growing risk of an influenza pandemic which, according to WHO,[5] could kill several million, or even dozens of millions, of people throughout the world.

5 The "WHO Handbook for Journalists: Influenza Pandemics," updated in December 2005 (available at this website link: http://www.who.int/csr/don/Handbook_influenza_pandemic_dec05.pdf).

As early as in 1991, the EU was already involved in the fight against AIDS through the "Europe Against AIDS" programme, which mainly strives to stimulate the exchange of knowledge in the areas of prevention, training and research. After the trauma brought on by the mad cow crisis, it extended its activities to further the fight against communicable diseases by creating a surveillance network and an alert system. Most importantly—based on America's Atlanta model made famous by "disaster" films—in 2005, the Union created a European Centre for Disease Prevention and Control (ECDC). Close to 200 people based in Stockholm are working to strengthen the fight against communicable diseases by supplying scientific data, monitoring health risks, launching alerts, and by coordinating national alert networks, as well as national policies aimed at responding to epidemics or bio-terrorist attacks.

Tapping into European diversity: The EU and health determinants

While the Union's diversity can challenge its ability to offer a coordinated response to certain public health issues, it constitutes an asset in understanding a number of health problems. A European scale system is clearly an advantage in the fight against non-communicable diseases relating to lifestyles—particularly after the enlargement, during which disparities in the prevalence of this type of disease rose within the EU—as well as in accident-related matters. Action at the European level makes it possible to conduct broad epidemiological studies and to make comparisons by introducing new explanatory variables.

The EU has thus funded numerous projects to sustain the development of actions and networks aimed at gathering, supplying and exchanging information in order to better understand certain health issues. For example, the Union is currently funding a project (POL-MARK) involving ten research institutes in various Member States, of which the aim is to better grasp what effects marketing has on children's diets. The objective is to obtain information which will allow the EU to more effectively fight obesity. Among hundreds of other possible examples, the EU provided most of the funding for the European Prospective Investigation into Cancer and Nutrition (EPIC) in cooperation with the WHO. Launched in 1992, this was the most extensive study ever done on the relationship between food and cancer. It was based on 500,000 people in ten countries and was designed to identify causal links between the appearance of certain cancers and diets, anthropometric data, physical activity, and hormonal and genetic factors. This study notably demonstrated the protective effect of fruits and vegetables against certain cancers and, conversely, the devastating effects of tobacco and alcohol. The data thus collected are allowing not only local, but also national and European-wide prevention policies to be improved. Among the latter are the 2002 "Feel free to say no" radio and television anti-smoking campaigns directed at young people, and the recent campaign, "Help – For a life without tobacco."

Profiting from a European-scale effort: The EU and rare diseases

Lastly, the Union clearly appears to operate on a government scale suited for low-prevalence diseases—namely, rare diseases. The rarity of diseases impedes the production of medicines for two reasons. First, it compromises experimentation and restricts knowledge on the subject. Secondly, it compromises the return on capital potentially invested by the pharmaceutical industry. It is for this reason that the medicinal products used to treat, prevent or alleviate the effects of these diseases are called "orphan drugs."

The Union has rallied to fight against this phenomenon by taking advantage of its size. The European-scale effort has been reducing disease rarity: according to the European Commission, 27 to 36 million Europeans are currently suffering from a rare pathology. The Union became involved in this field in the late 1990s. Most of its actions have consisted of promoting the structuring of networks (of patients, caregivers and researchers), identifying rare diseases and funding research. To sustain these activities, the EU formulated legislation aimed at facilitating the fight against this type of illness. On 16 December 1999, a regulation was adopted to induce the industry to develop and market orphan drugs. Its aim is to make it possible for the industry to turn a profit on its investments should the drugs prove successful (by extending patent rights, introducing a simplified market authorisation, etc.) and to facilitate its access to public funding. Similarly, in 2006, the Union adopted a Regulation on Medicines for Children, inasmuch as the develop

ment of such medicines was confronting the same obstacles as those intended for the treatment of rare diseases[6].

1.3 Healthcare and health systems: Increasingly important fields for Communication Action

Although the final paragraph of Article 152 in the Treaty deliberately calls on the EU to "fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care," the Union did not completely stay away from these issues. It recently increased its initiatives to support national policies. It is moreover significant that the "Community Action Programme in the field of *public health*" (2003-2008) was succeeded by a "Community Action Programme in the field of *health*" (2008-2013). The right to medical care was also recognised by the European Union Charter of Fundamental Rights. Here too, the Union is able to lend its support at the national level in order to deal with challenges and issues which are, or will be, confronting health systems.

The EU: A think tank for the preservation of health systems

In a context of demographic ageing, global increase in demand for healthcare, acceleration of technological developments, and shrinking human and financial resources, the issue of health system reform is on every European country's agenda. It is even more important in the "new" Member States, where there is a chronic lack of resources.

In order to meet these challenges, the Union has, over the last few years, increased the number of discussion documents and mechanisms by which to compare national experiences and exchange good practices. As with epidemiological studies, the key objective is to capitalise on the Member States' cultural, political and institutional differences, as well as on the diverse solutions adopted at their level. Among such mechanisms is the "OMC in Healthcare" initiated in 2004 and integrated into an expanded "OMC in Social Protection and Social Inclusion" in 2006. "To ensure that adequate and high quality health and long-term care remain affordable and financial sustainable" is therefore one of the key objectives of the new "OMC in Social Protection." The OMC (Open Method of Coordination) is an instrument designed to stimulate training. It relies on the setting of objectives and assessment of national strategies adopted in order to reach them. This instrument therefore supports the action of Member States without encroaching upon their competences or compelling them to abandon their own mechanisms. The "Community Action Programme in the field of health" (2008-2013) is not to be outdone—it is also calling for the exchange of good practices and knowledge with respect to healthcare and health systems. Similarly, the Seventh Framework Programme for Research (2007-2013)—the main Community research-funding tool—makes health the number one theme of research and places the emphasis on health system sustainability and the optimisation of medical care. It provides funding of up to EUR 6 billion for research devoted to both medical sciences (mainly based on treatment effectiveness and patient safety research) and to the social and economic sciences (notably based on research on organisational, financial and regulatory aspects).

The EU: A solidarity and medical care space

In matters concerning health and health systems, the Union is more and more determined not to be merely a think tank. It is also initiating very concrete interventions and is daily affecting the medical care of numerous European citizens.

First, the Union serves as a solidarity space by contributing material support to European regions less well-equipped in terms of healthcare. For example, during the period 2007-2013, the European Regional Development Fund (ERDF), which strives to correct regional imbalances, plans to focus on investments in infrastructures and health human resources. Solidarity also calls for development of a European medical care space. Another goal of this same Fund is therefore to expand the sharing of health infrastructures and human resources, primarily in border regions.

6 Grave illnesses rarely affect children, who, moreover, should be considered in at least three different age brackets as far as prescriptions and drug development are concerned, which reduces the targeted public. At the same time, clinical trials involving children are long, difficult and particularly costly. The specific dosage, routes of administration and packaging also give rise to added industrial costs, with the result that the paediatric medicine market is limited in terms of commercial profitability.

The Union has thus already funded a large number of so-called "cross-border" projects. Notable examples include the cooperation established between the hospitals of Tourcoing (France) and Mouscron (Belgium). This cooperation began with an agreement allowing French and Belgian patients needing haemodialysis, and AIDS patients, to travel across the border in order to benefit from medical care in which the establishments reciprocally specialised. As more Community programmes were successively implemented, what resulted was a genuine sharing of medical resources through a quadrilateral Mouscron-Tourcoing-Roubaix-Wattrelos partnership which allowed several hundred thousand citizens to receive treatment under better conditions by streamlining the supply and access to healthcare on both sides of the border.

The Union is not merely building a medical care space for border regions: it is increasingly facilitating the mobility of all patients. The European Health Insurance Card, available in all Member States since January 2006, attests to this trend, and is helping to bring Europe closer to the daily life of its citizens, just like the euro now found in every pocket.[7] This Card, issued by the user's affiliated health insurer, contains no medical data. Its sole purpose is to facilitate access to medical care while the user is in another Member State, inasmuch as presenting it assures that the latter will receive care, and that his(her) medical expenses will be reimbursed.

Authorising and promoting access to healthcare abroad guarantees patients a broader range of choices in terms of costs and quality of care and can help to reduce the long waiting lines found in some of the Union's Member States. It can also help to streamline the costs of European health systems. Taking advantage of these opportunities raises a few questions. For example, it is advisable to first make sure that the quality of care, patient safety and the provision of care is adequate throughout the Union's territory. To that end, in July 2008, the Commission issued a Proposal for a Directive "on the application of patients' rights in cross-border healthcare," which will be discussed further on.[8]

7 This card is also modelled after the euro: one side is common to all Member States and contains the European symbol and some obligatory information, while the content of the other side is left to the discretion of each Member State (some of them have reproduced their pre-existing national card on it).
8 See paragraph 2.2. of this study.

The Community Action Programme in the health field for 2007-2013, another sign of the EU's incorporation of healthcare and health systems in its health policy, provides that the latter will strive to improve its health capacity and promote practical cooperation between health systems.

II - Community action in the health sector: A secondary effect of European integration

It is obvious that the Union is already broadly involved in the health field and that its influence is growing rapidly. Despite these activities and the evident added value that the Union can contribute to actions undertaken at the national level, the original national governments' reservations about EU intervention in the health field persist, as do those of European citizens—which is regularly confirmed by Eurobarometer survey findings.[9] The first refuse to lose their grip over an area essential to the exercise of their power, while the second are worried about seeing their beloved and vital health systems dismantled and replaced by less favourable alternatives. This latter fear is mainly sustained by the image of a Union which—rightfully or wrongfully—is often judged indifferent to its citizens' concerns and essentially motivated by economic considerations.

Due to the lack of a firm political will to build a "Europe of Health, most of the initiatives developed by the EU are only "interstitial." Caught in a "spill-over effect," the EU either finds itself obliged to initiate activities in the health field because that has proven necessary in order to meet other more fundamental objectives—par-

9 In 2007, for example, only 31% of Europeans—29% in the Europe of Fifteen and 38% in the new Member States—were of the opinion that "health and social security" was an area in which decisions should be made jointly within the EU. Only the integration of "taxes" and that of "pensions" received less support (Eurobarometer "Standard" 67 of November 2007, fieldwork of April-May 2007; http://ec.europa.eu/public_opinion/archives/eb/eb67/eb67_fr.pdf)

ticularly the construction of the common market—or a consequence of a double-bind effect, intervenes in health matters without directly intending to do so and finds itself forced to react. Or it may be conferred with more or less adequate prerogatives to deal with a health crisis. Under such conditions, the Union's often erratic intervention cannot benefit health policies as much as it should be able to

2.1 The Single Market-Health spill-over effect

Most Community actions relying on "legally binding" standards concern health safety. Such European activities always combine two objectives which they strive to reconcile in order to ensure that they do not adversely affect each other: to safeguard Europeans' health and to optimise the Common Market, in other words to ensure the free movement of goods, services and persons. However, the driving force behind the growth in health activities is above all the EU's determination to meet its internal market objectives, which implies considering certain health protection requirements, a nuance that is not inconsequential in the event of political conflict or legal conflict between these goals.

Ensuring the free movement of workers: The harmonisation of health professions

The harmonisation of health professions provides an initial example of this Single Market-Health spill-over effect. In the 1970s and 1980s, the media often reported on the creation of a "White Europe." The expression refers to the harmonisation of training and of conditions for access to the health professions (medical, paramedical and pharmaceutical). Doctors were the first among liberal and regulated professions to be affected by the mutual recognition of diplomas. This profession was deemed to be the most sensitive in view of the human and economic issues involved, and of the national disparities in training and regulations. For these reasons, it needed to serve as a model for other health professions, as well as for architects and lawyers, among others. After the first strides were made in 1975 in the form of two directives on medical specialists and general practitioners, all liberal and regulated health professions soon followed suit. The principle behind the "doctor directives" was subsequently applied to the nurse (1977), dentist (1978), mid-wife (1980) and pharmacist (1985) professions. On each occasion, a directive was adopted aimed specifically at the mutual recognition of diplomas—each State must recognise the qualifications listed in the directive, and a diploma earned in another Member State by a European national entitles the holder to the same rights as a diploma obtained on national territory—as well as a directive whose purpose was to coordinate national statutory laws on the subject (particularly the duration of classroom training).

Since then, these sectoral directives have been revised several times. Despite a certain number of limitations, regulations are now such that, in short, most health professionals are free to set up office and practice anywhere in the Union, as long as they have been trained in a Member State. In other words, Community legislation has dictated that "a doctor is a doctor and a nurse is a nurse."[10]

An essential point to be made is that the construction of this "White Europe" was based on a legal basis (Article 57 of the Treaty Establishing the European Economic Community) as part of the chapter devoted to right of establishment. It therefore referred to the elimination of the "restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State" (Article 52). At the onset of European integration, health professionals were not excluded from the scope of free movement principles. To the contrary, they are even mentioned as one of the targets for the principles of freedom of establishment and provision of services. However, inasmuch as access to such professions is based on regulations specific to each Member State which the latter was expecting to maintain for public health reasons, specific provisions were slated for adoption in order to harmonise these professions at the Community level. Otherwise stated, the goal of harmonising the health professions was to eliminate obstacles to their free movement. The aim of constructing "the White Europe" was not to improve the training of doctors, nurses or pharmacists, but, more simply, to allow them to exercise their profession in another Member State, while at the same time avoiding the possibility that inadequately trained professions could carry on their practices anywhere in Europe that they wished. In addition, from an administrative viewpoint, the measures in

10 Greer S. (2006), Uninvited Europeanisation: Neofunctionalism and the EU in Health Policy, *Journal of European Public Policy*, Vol. 13, No. 1, p.142.

question, like most provisions relating to medical products, do not fall under the Community's health policy.

Ensuring the free movement of medical goods: The harmonisation of health products

The EU is also dedicated to the harmonisation of standards relating to medical products, starting with medicinal products. Since 1965, there has been a progressive development of a genuine "Pharmaceutical Europe" which can only be briefly described here.[11] This space is represented by European-level stakeholders and by specialised structures and specific rules. The structures and institutions of "Pharmaceutical Europe" are indeed numerous, whether committees, workgroups, specific units within the European Commission or, first and foremost, the European Medicines Agency (EMEA), which employs 400 people. The EMEA is responsible for the scientific evaluation of marketing authorisation applications for medicinal products. Without describing the various procedures in great detail, it should simply be pointed out that the EMEA's authorisation is mandatory for many medicines.[12] Once it is granted, the medicine is automatically authorised to be marketed in all of the Union's Member States. In addition to the role which it plays upstream of their commercialisation, the EMEA monitors the safety of medicines on the market through a pharmacovigilance network. The Agency also plays a role in stimulating innovation and research in the pharmaceutical sector by offering scientific advice and protocol assistance to companies for the development of new medicinal products.

Although European regulations pertaining to medicines are the most widely known, medical equipment and devices—which are equally necessary for patient care and can harm patients if incorrectly used or if their quality is inadequate—are also regulated at the European level. Here, too, regulations are first based on the legal authority to create a common market and not to improve citizens' health. Each time, a regulation must be established at the European level to ensure the safety of health products prior to allowing their circulation. The Member States are authorised by the Treaty to invoke a so-called "opt-out' clause, which allows them to prohibit the importing of products proven to be dangerous to public health.

Preventing "social dumping": Legislation on health and safety at work

The health and safety at work sector offers another example of the Single Market-Health spill-over effect. It is generally considered to be the social area in which national regulations are the most affected by Community standards. The EU has been clearly involved in this issue since it was created. This involvement intensified with the adoption in 1986 of the Single European Act. This treaty laid the grounds for legislation to be enacted at the Community level without a unanimity requirement, which, in 1992, led to the creation of the European Agency for Safety and Health at Work, which is responsible for advising the European Commission and Member States on this subject.

According to the European Commission itself, its involvement in the health and safety at work sector directly originated from the aim of completing the internal market: "to facilitate the free movement of workers within the European internal market [and] in order to ensure competition, productivity and protection of workers on an equal footing, the Single market had to be complemented by minimum requirements for health and safety at work."[13] To use a common expression, European legislation on public health and on health at work is first and foremost aimed at preventing "social dumping"—in other words, at unfair competition between businesses in the Common Market.[14] Nonetheless, this motivation has obviously not prevented Community legislation from setting particularly progressive standards for certain Member States and from going beyond the minimal common denominator in matters concerning health and safety at work.

11 On this point, see Hauray B. (2006), *L'Europe du médicament. Politique - Expertise - Intérêts privés*, Paris: Presses de Sciences Po.
12 This also concerns all drugs for human and veterinary use derived from biotechnology and other advanced technologies, all drugs for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative diseases, as well as all drugs for the treatment of rare diseases. Similarly, this authorisation is mandatory for all veterinary medicines which act to improve animal performance in terms of promoting their growth or output.

13 European Commission (DG V) (1994), "L'Europe pour la sécurité et la santé sur le lieu de travail," *Europe Sociale* 3/93, OPOCE, pp. 7 and 10.
14 More specifically, the expression "social dumping" refers to "a scenario in which businesses operating in areas in which payroll taxes are low would be able to sell their products at a lesser price than those practiced by their competitors, thereby forcing businesses subject to higher payroll taxes to go bankrupt, to relocate [...], or even to, in turn, pressure their governments in order to obtain a reduction in payroll taxes," Rhodes M. (1998), "Une énigme pour les théories de la régulation : relations sociales et relations professionnelles," in Leibfried S., Pierson P. (dir.), *Politiques sociales européennes entre intégration et fragmentation*, Paris: L'Harmattan, p. 80.

2.2 The indirect results of European integration on healthcare and health systems

Although the EU's efforts in the health sector are increasingly focused on healthcare and health systems by virtue of the Treaty, they still pertain to supporting national policies, although they are never substituted for the latter. Despite these legal precautions, the management of such issues is now increasingly influenced by the Community. In fact, the latter is able to sway certain decisions choices by means of other policies.

The same holds true with EU policies relating to health products or to the harmonisation of health professions, which primarily stem from internal market provisions. Europe's influence may be felt even more indirectly. Community decisions made in one sector may involuntarily generate indirect consequences on healthcare and health systems, thereby forcing the Union's political institutions to react in order to moderate these effects via ad hoc decisions. Such a scenario is the main driving force behind recent Union involvement in healthcare and health systems.

Two recent examples stemming from the case law of the Court of Justice of the European Communities (CJEC) illustrate this trend: one concerns working time—notably that of hospital doctors—the other, patient mobility."[15] Although the alarmist interpretations which accompanied court decisions on these two points lack credibility because they overestimate the mobility potential of health professionals and patients, they did induce the EU to directly intervene in healthcare systems in order to regain control over the indirect effects produced on them.

15 These two cases exemplify the effects of indirect consequences on healthcare systems. Other noteworthy examples are the economic convergence criteria which limit the level of public debt and therefore of policy choices, especially with respect to healthcare system funding. Moreover, these indirect effects of European integration on the health sector are not limited to medical care and healthcare systems; they also affect public health policies. For example, the quantitative limits on alcohol importation have been eliminated for intra-Community travellers by virtue of the free movement of goods. Some States therefore had to lower their customs duties on alcoholic beverages in order to remain competitive, which put an end to alcoholic beverage taxation as an instrument of public health policy (Ugland T. (2000), "Impact of Europeanisation on Nordic alcohol control policies: A discussion of processes and national differences," *Journal of European Social Policy,* Vol.10, no. 1, pp. 58–67).

Healthcare and health systems, and European working time standards

- The "Working Time Directive" and its interpretation by the CJEC

The aim of this directive is to protect the health and safety of workers against the adverse affects of inadequately organised working time by setting a maximum number of working hours and minimal rest periods. "Working time" is defined as "any period during which the worker is working, at the employer's disposal and carrying out his activities or duties, in accordance with national laws and/or practice" and a rest period is defined as "any period which is not working time" (Article 2).

Thus, the main provisions of the Council Directive (93/104/CE) of 23 November 1993 concerning certain aspects of the organisation of working time and of its amended version (2003/88/EC), more commonly known as the "Working Time Directive" provides that:

the average weekly working time, including overtime, should not exceed 48 hours (Article 6);

- the possible calculation of an average maximum weekly working time is based on a reference period not to exceed four months (Article 16);
- a minimum daily rest period of 11 consecutive hours is allowed per 24-hour period (Article 3);
- a minimum weekly rest period of 24 hours is allowed in addition to the 11 hours of daily rest (Article 5);
- best breaks are allowed when a working day is longer than six hours (Article 4);
- night work hours do not exceed an average of eight hours per 24-hour period (Article 8);
- Member States have the option not to apply Article 6 on the maximum average weekly working time of 48 hours; this is the so-called "opt-out" clause (Article 18)[16];

16 Certain conditions must nonetheless be met:
the employer must obtain the worker's consent for such a derogation; the employee must not suffer any prejudice by refusing to consent; and these agreements and their implementation must be recorded by the employer and such records made available to the authorities.

- the option to depart from the preceding provisions is granted for services relating to the reception, treatment and/or care provided by hospitals or similar establishments, as long as the workers are afforded equivalent periods of compensatory rest except when that is not possible, for objective reasons (Article 17).

In 2000 and in 2003, after several complaints were filed by hospital doctors in Germany and Spain, the CJEC specified that a collective agreement cannot be substituted for an agreement between individuals to allow for derogation. More importantly, the Court rued that on-call time performed by hospital medical personnel must be considered as working time, even when such staffs are not called upon to perform a job-related activity. Lastly, the Court stipulated that the derogatory compensatory rest authorised by the Directive must immediately follow the working time. Furthermore, for each of these points, the Court found that the economic and organisational consequences underscored by several governments were not to be considered as a possible derogation to the rules applied to hospital personnel—nor, moreover, to those of other health, social and medico-social institutions. In short, the Court ruled that the Directive shall apply to health personnel and must be so applied as strictly as possible inasmuch as its aim is to protect the health and safety of all workers.

- The potential impact of the Court's decisions on health systems

Judging from the actions of the various policy and hospital stakeholders involved in this case,[17] if case law were applied, it could pose some significant challenges for health systems and health care administration.

First, it would imply a reorganisation of hospital staffs' work, to the extent that the work is generally organised according to the principle of long periods of work comprised of on-call time and rest time. Moreover, it would no longer be possible to use interns as an adjustment variable, inasmuch as the latter are subject to the same rules as their elders. In addition, European legislation would imply making doctors and other health personnel work fewer hours, and therefore mean that interns would have to work more hours. Many European countries are already confronted with a declining healthcare workforce, and the drain of doctors from "new" EU member countries towards Western European countries, which lack medical personnel, is likely to increase. What is more, the inclusion of on-call time in working time may trigger a drain of doctors from certain (mainly Mediterranean) countries—where on-call time is viewed as hidden compensation—to other Western countries in which the status of hospital doctors is more advantageous and, at the same time—by causing a reduction in salaries—reduce the profession's appeal. Lastly, case law is often perceived as a threat to the financial viability of health systems. Indeed, the application of the directives would lead to more paid working time, which would jeopardise the financial equilibrium of hospitals—especially that of small, and often rural, hospitals.

In a context of a shrinking medical workforce and a generalised difficulty to finance health systems—at least in terms of cost control—case law seems to encourage resorting to the use of the "opt-out" clause. However, besides the fact that it greatly reduces the social advances spearheaded by the Directive, reckless recourse to opting out could give rise to "social dumping" by allowing some service providers to reduce their costs, as compared to those of their foreign counterparts which would not have the opportunity to use this option. As a result of more attractive prices, the former would attract more patients, without being able to totally guarantee their safety. Ultimately, the service providers which would find themselves compelled to apply the standards set by the Directive may find it challenging to remain profitable. If they had to close, this would pose a threat to the members of the population who are unable to travel to seek treatment. If, to the contrary, the care providers threatened by the social dumping were to choose to raise their prices, the principle of universal access to healthcare would be threatened.

According to the most pessimistic stakeholders and observers, the health system Directive and case law could give rise to three types of potential issues or negative repercussions with respect to healthcare quality and accessibility as well as health system viability.

- *Struggling policymakers*

Although all actors agree on the need to revise this Directive, particularly because of its involuntary effects, the revision begun in 2003 has yet to be completed.

17 See, for example, the reports: *The healthcare workforce in Europe: Problems and solutions*, Final report of the European Hospital and Healthcare Federation's study group on workforce issues, Brussels, 12 May 2004; Hassenteufel P. et al. (2007), *Le temps de travail des médecins hospitaliers : quelle européanisation de la santé ? Une étude comparative européenne (Allemagne, Danemark, Espagne, Lituanie, Royaume-Uni)*, a study submitted to the DREES [Directorate for Research, Studies, Assessment, and Statistics].

This attests to how difficult it is to reconsider past decisions, above all when they comprise the Court's case law.

One sign of a new awareness of the Directive's implications is that, since 2003, healthcare staffs have been the focus of deliberations on the revision of this piece of legislation, even though the latter is intersectoral and interprofessional in scope. This is a reversal of the approach that had prevailed during the first negotiation of the Directive. At that time, the Member States had in effect refused to consider the specific case of health staffs, inasmuch as the Union was not supposed to interfere with healthcare and health systems. Taking a step back is now difficult due to the mobilisation of hospital doctors, who benefit from the Court's decision, and from the divergent positions of the EU's political institutions. The European Parliament's main policy groups categorically want the CJEC's case law to be upheld, the opt-out clause to be repealed, and the core standards set out in the original Directive to be maintained. For its part, the European Commission wants to maintain the opt-out clause, while limiting the conditions for resorting to it. The Commission also suggested introducing the concept of "inactive on-call time" to limit the economic and organisational impact of the Directive and of its case law. As for the Member States, they have long been unable to reach a consensus on the issue. Taking advantage of political majority shifts in some of the EU States, the Council finally reached a common—though tenuous—position in June 2008. Against the advice of several States, which saw the latter as a form of social regression,[18] the Council opted for the inactive on-call time (called "inactive working time") not to be considered as working time unless otherwise provided under national law. Moreover, it decided to uphold the opt-out clause, though supplementing it with several framework measures[19] and a ceiling of 60 to 65 working hours per week.[20] The Council's position is directly opposed to that which the European Parliament expressed in June 2005 and confirmed by a second reading in December 2008. The European Parliament clearly voted against (421 vs. 273) the Council's proposals (and those of the Commission) and demanded that on-call time be included in working time and that the opt-out choice be gradually eliminated. As long as an agreement—increasingly less probable—has not been reached on the revision of the Directive, the latter, like the related case law, will remain in effect, thereby leaving unresolved the challenges to health systems which it has raised.

18 Spain and Greece voted against this common position. Belgium, Cyprus, Hungary, Malta and Portugal abstained.
19 Among these, specific provisions have been made for short-term contracts and options by which the wage earner may withdraw his(her) consent.
20 More precisely, the 60-hour ceiling per week for workers choosing to opt out is based on an average estimate over a three-month period, and may be exceeded under a collective agreement. The 65-hour ceiling per week is also estimated over a three-month period and is valid only if the inactive working time is included in the working time, and there is no contrary collective agreement.

Healthcare and health systems, and European case law on patient mobility

- *CJEC case law*

Citizens would no doubt be reluctant to travel beyond their country's borders if they had no assurance that they would receive healthcare abroad if they needed it. The EU has therefore adopted a certain number of technical provisions aimed at providing access to healthcare abroad and its reimbursement, without in so doing harmonising the services provided and the health systems, which would have constituted an infringement on national sovereignty in this matter. Therefore, prior to the Court's intervention, two situations anticipated by two regulations (1408/71 and 574/72) adopted in the 1970s should be distinguished:

1) If a person happened to need healthcare during a temporary stay in another Member State, he had the right to receive on-site care, to be covered by his medical insurer, provided that the latter's competent authorities had issued to him a specific form (different forms exist, depending upon the reason for the stay);

2) If the person had planned to travel to another country to benefit from health services there, he should have obtained pre-authorisation from his medical insurer so that the latter would assume the cost of his care according to the rates in effect in the country visited.

These provisions have been considerably amended on the basis of Community case law. With the Kohll and Decker rulings of 1998, the Court of Justice decided that healthcare qualifies as a service and, as such, falls under the Treaty's provisions on the free movement of services. Therefore, the Court found that the provisions subordinating the reimbursement of expenses incurred in another Member State to a pre-authorisation constitute obstacles to the free movement of services.

In summary, two situations now remain to be distinguished:

1) All non-hospital care to which a citizen may be entitled in his Member State may also be provided to him, without pre-authorisation, in any other Member State. The cost of the care will be reimbursed to him up to the maximum amount reimbursable under his insurance scheme;
2) All hospital care to which a citizen may be entitled in his Member State may also be provided to him in any other Member State, provided that he has obtained the pre-authorisation from his medical insurance scheme. In such case, the insured person will at least be reimbursed up to the maximum reimbursement amount provided for under his insurance scheme.

In terms of reimbursement, the Court has established subtle case law, considering that the aim of Community law is to facilitate patient mobility. The Court has therefore set out the principle of a patient's right to benefit from the most advantageous coverage for his cross-border hospital care. Although Regulation 1408/71 provided for the cost of the care to be reimbursed—actually paid directly by the subscriber's insurance scheme—according to the rules of the system under which the healthcare had been provided, the Court found that "the fact that a person has a lower level of cover when he receives hospital treatment in another Member State than when he undergoes the same treatment in the Member State in which he is insured may deter, or even prevent, that person from applying to providers of medical services established in other Member States […]."[21] Therefore, when the level of cover is lower in the visited State than it is in the State in which he is insured, the latter scheme must provide a supplementary reimbursement of up to an amount equal to the coverage level which exists in its territory.

As for pre-authorisation, the Court finds that it must automatically be granted when the insurance scheme cannot provide the care which the patient needs within a medically acceptable time limit. Conversely, it can be refused for imperative reasons of general interest, when:

1) there is a risk of serious prejudice to the financial equilibrium of the social security system;
2) the maintenance of a balanced medical and hospital service accessible to all, affording a high level of health protection, is threatened;
3) the maintenance of treatment capacity and medical competence essential to public health on the national territory, or even to the survival of its population, is threatened.

However, the Court has been very strictly interpreting these restrictions on patient mobility. Therefore, none of the individual cases litigated to date has fulfilled the conditions that would allow the national authorities to deny coverage of expenses incurred abroad for imperious reasons of general interest.[22]

- Potential impact of the Court's decisions
As with the Working Time Directive, this case law raises important questions about healthcare accessibility and quality, and the financial viability of health systems. According to some—notably most Member States[23] who fear massive patient movement—this presents numerous destabilisation risks.

First of all, the cost control measures achieved through supply management could, in this scenario, be affected by such case law. The most striking example concerns the rationing policy based on the creation of waiting lists. In the United Kingdom, "the bypassing of waiting lists by applying for healthcare abroad, to be reimbursed afterwards […]," would totally undermine this policy and render it ineffective, or even unfair, for those who lack the knowledge and the mobility."[24] Moreover, patient mobility could create a competitive environment in which healthcare supply, and therefore demand, would increase to such a degree that it would place more financial pressure on health systems.

21 The Vanbraekel Case, C-368/98, of 12 July 2001, item 45.

22 The European Commission has produced an educational video which explains how to access cross-border healthcare and some of the challenges this entails. It is available from the following link: http://ec.europa.eu/health/ph_overview/co_operation/healthcare/cross-border_healthcare_en.htm
23 See the reactions compiled in the following report: Palm W. et al. (2000), *Implications de la jurisprudence récente concernant la coordination des systèmes de protection contre le risque de maladie*, Brussels, Association Internationale de la Mutualité.
24 Palm W. et al. (2000), *Implications de la jurisprudence récente concernant la coordination des systèmes de protection contre le risque de maladie*, Brussels, Association Internationale de la Mutualité, p. 105.

In addition, it might be advantageous for some hospitals to attract a foreign clientele. This may improve their financial viability, and enable them to acquire costly state-of-the-art equipment, attract the best specialists or even maintain an on-going flow of business. On the other hand, hospitals left behind would experience the opposite: accessibility to, and the quality of, their healthcare services would be reduced. For reasons of profitability, some hospitals might even give priority to healthcare offered to foreigners—especially if the subsidised rates do not apply to them—over that offered to nationals.

In other words, from this alarmist viewpoint, Community case law might indirectly call into question aspects of the health system's national management and territorial hospital planning framework.

Overly pessimistic interpretations act as catalysts for Community action

This interpretation of the effects of case law on patient mobility, like that of the effects of the Working Time Directive, sounds logical when reasoning in purely abstract terms. In reality, however, both seem very improbable. Impacts of this sort on European health systems would actually imply a massive mobility of health professionals and patients, which is highly unlikely.

The possible disruption of the national systems was already raised when the plan for a European Health Community was first proposed, some thirty years ago, when the directives on the harmonisation of health professions were adopted. The facts have put most of these concerns to rest. Until the Union's most recent wave of accessions, the mobility of health professionals has remained negligible.[25] The inclusion of Eastern European countries has somewhat changed the situation. Health professionals from some of the "new" member countries do seem to be emigrating towards a certain number of Western European countries.[26] In the short-term, there is a risk of "medical desertification" in certain specialities in the Union's least-advantaged countries. Yet health professional mobility should decline as those countries' standard of living reaches the level of those of the other EU Member States. It is already apparent that the wealthiest European countries have been employing many more extra-Community personnel in order to deal with problems resulting from their own medical workforce drain.[27] Of course, this merely shifts the problem to the world's poorest countries.

As for the threat which patient mobility would cause for health systems, it appears to be greatly exaggerated. However, it has been confirmed that a growing number of patients are seeking healthcare abroad. According to the former European Commissioner for Health and Consumer Protection, Markos Kyprianou, even though cross-border healthcare represented 1% of the total volume of treatments in 2001, in 2006, they represented 5%.[28] The number of treatments provided abroad is expected to level off fairly soon, despite the fact that certain businesses—and even certain States—are playing the medical tourism card by advertising the availability and quality of local healthcare, or by offering treatment tours-sightseeing-hotel packages. Even when setting aside travel expenses and information access issues, it is common knowledge that the criteria patients use to select healthcare facilities directly conflict with opting for treatment abroad. Patients want to be able to communicate with their doctors, and thus speak the same language, have easy access to them before and after treatments, and make sure their relatives and friends can visit them easily during periods of hospitalisation, which implies a certain geographic proximity. It is also no coincidence that the majority of disputes giving rise to the CJEC's case law involve patients who are natives of a country—such as Luxembourg, Belgium and the Netherlands—whose borders are never far away.

Nonetheless, CJEC's case law has produced pressure in favour of Community initiatives in the health service sector, which have actually expanded.

The Court's decisions have thus been incorporated into Regulation 883/2004, which repealed Regulation 1408/71 on the coordination of compulsory social security schemes. The part played by the Court of Justice has also been decisive in creating the aforementioned European Health Insurance Card, which the European

25 On this matter, see Roland Ries' "Rapport sur l'Union européenne et les services de santé" on the European Union and its health services, written on behalf of the French Senate, Information Report no. 186, Ordinary Session of 2006-2007.
26 See the report, "Quelle Europe médicale pour demain ?" in *Le Bulletin de l'Ordre des médecins*, No. 3, March 2006.
27 See the World Health Organisation's 2006 edition of *The World Health Report*.
28 Statement in the 9 November 2006 issue of *Libération*. It should be noted, however, that in its communication entitled "Consultation regarding Community action on health services" (SEC (2006) 1195/4 of 26 September 2006), the Commission included only the 1% figure.

Parliament had ardently sought since 1981.[29] However, the political reactions to the Court's case law have not only given rise to its codification but also to the development of a new Community-level sector of activity.

In order to address the issues raised by this case law, and after the mobilisation of various European committees on this question, on 26 September 2006, the European Commission launched a "Consultation regarding Community action on health services."[30] This consultation, which stirred much debate inasmuch as it heralded the Union's full-fledged involvement in healthcare and health system issues, was primarily focused on two objectives. The first was to seek advice on ways to ensure that the Court's case law was implemented while preserving the quality of healthcare provided abroad, as case law had left a certain number of questions unanswered. For example, what rights do patients treated abroad have in the event that a problem arises at the time the service is provided and afterwards? How can patient follow-up be assured and dysfunctions be detected? How can a national system verify the quality of healthcare provided abroad? Would the medical protocols, prescriptions and medical records need to be harmonised? The second aim of the consultation was to identify the areas in which the Member States' patients and health systems could take advantage of EU-wide cooperation. The consultation suggested several options, such as forming and networking reference centres—each of which would offer resources for certain pathologies such as rare diseases requiring specific medical expertise, or particularly costly equipment that all national health systems are not able to provide for their nationals; improve the comparability of data on national health policies; and facilitate cooperation in border areas or between countries in which there is a supply deficit, or inadequate demand.

This consultation resulted in close to 300 responses, primarily from national governments, regional authorities, representatives of public and private interests, patients and social security institutions. In 2007, the Commission published a summary of these findings.[31] Although opinions were widely divided according to the respondents' national origin, or the interests represented, this consultation undoubtedly proved that the majority of the respondents were in favour of Community intervention in health services.

The initiatives set out in the "Community Action Programme in the field of health (2008-2013), and the Seventh Framework Programme for Research (2007-2013) mentioned above, are the first concrete results of this new momentum.

More recently, in July 2008, the European Commission issued a "Proposal for a Directive on the application of patients' rights in cross-border healthcare,"[32] which is explicitly "based on [related] case law" (Explanatory Memorandum, item 2) and follows it overall by providing, for example, that coverage of non-hospital cross-border healthcare not be conditional upon pre-authorisation. Conversely, such an authorisation can be required for hospital care, provided that such care can be dispensed in the country in which the scheme covers the patient, or if there is a risk of causing prejudice to the equilibrium of the social security system or hospital planning concerned. What is more, when the States set time limits for recourse to cross-border healthcare, they must take into account several criteria, including the severity of the patient's pain. This proposal is all the more remarkable in that it is not only codifying the Court's case law, but is strengthening the EU's involvement in healthcare matters. In order to ensure the safety and quality of cross-border healthcare, for example, the proposal requires that Member States define clear standards for the quality and safety of all types of healthcare, "taking into account international medical science and generally recognised good medical practices" (Article 5.1). The State in which the treatment is provided must furthermore guarantee recourse options in the event of problems associated with the medical treatment, and extend the same rights to both foreign, and their own, nationals. The recognition of prescriptions enforced in another Member State constitutes another measure provided for in this Proposal for a Directive. The latter also imposes a "Duty of cooperation"(Article 13) according to which Member States must render

29 Nonetheless, the Member States have opted for a minimalist version of the Card. It is actually a health insurance card and not a health card. The card only replaces the administrative paper forms previously required for reimbursement of healthcare provided abroad. Because of national differences with respect to the privacy of medical data and their content, Member States remain free to print, or not to print, such data.

30 The Commission's communication on the "Consultation regarding Community action on health services," SEC (2006) 1195/4 of 26 September 2006, which is available at the following address:
http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm_health_services_comm2006_en.pdf

31 Health and Consumer Protection Directorate General, European Commission, Summary report of the responses to a "Consultation regarding Community action on health services' (SEC (2006) 1195/4) of 26 September 2006. The document may be consulted at the following address:
http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_rep_en.pdf

32 The Proposal for a Directive on the application of patients' rights in cross-border healthcare COM(2008) 414 final reading of 2 July 2008. It is available at the following address:
http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf

whatever mutual assistance necessary for the Directive's implementation and facilitate cooperation on cross-border healthcare provision at the regional and local levels. The Proposal also calls for the setting up of European reference networks to achieve economies of scale. As a final example, the latter provides for the creation of national contact points to inform citizens about cross-border healthcare access procedures and about reimbursement and compensation terms.

This Proposal for a Directive has already aroused many hostile reactions. Certain governments believe that the aim of this plan, based on Article 95 of the Treaty, is to ensure the proper operation of the internal market, a breach of Article 152, which protects national sovereignty in matters pertaining to health services—the provisions of which were reiterated by the Lisbon Treaty (see the last part of this study and Annex 2). Several of the European Parliament's policy groups and various health sector actors also complain that it requires patients to pay the cost of care before being reimbursed, which might prevent the less affluent from enjoying equal access to healthcare abroad.[33] Although still far from being implemented, this Proposal is a strong symbol of the emergence of a new Community-level activity sector in reaction to the CJEC's decisions.

2.3 A Community action taken in a crisis situation

Health protection is all the more necessary in order to perpetuate the Common Market inasmuch as a health problem can sow panic and untimely reactions among Member States which, invoking economic, political or public health concerns, could compromise the EU's fundamental principles. This functional link between the Common Market and health which we stressed above is even more striking in the field of communicable diseases. Indeed, although most diseases do not recognise borders, the latter can constitute key weapons in the fight against communicable diseases. Conversely, as mentioned above, the lifting of barriers to the free movement of goods, persons and animals increases the risks of epidemics. First, it naturally stimulates exchange, and thereby the flow of vectors that propagate infectious agents. Secondly, by setting out the principle of lack of systematic controls, it complicates the fight against the spread of infectious agents.

Some may have thought that the EU would very soon undertake to fight against the spread of epidemics on its territory. Yet it took the "mad cow" disease crisis before it visibly began to make serious headway in this sector. This crisis suddenly made the States aware of the fact that the free movement of products is intensifying the spread of health risks and diseases, and that the "exercise of Community competencies in public health matters [was] not yet a deeply rooted practice."[34] In the absence of an administration dedicated to health and endowed with a solid legal basis and the political will to balance health imperatives with the sacrosanct principles of free movement, the Community institutions—which are confronting States divided as to which solutions to adopt—have been slow to react. This delay allowed the epidemic to spread to such a degree that, at the height of the crisis, in 1996, BSE disrupted the entire Community's political and institution system, which induced Franz Fischler, the then European Commissioner for Agriculture and Rural Development, to say that "the BSE crisis was the worst the European Union has ever known."[35] Still fresh in people's memory is the British decision, by way of reprisal against the embargos finally initiated by the Union following several unilateral decisions made by the Member States, to launch a policy based on systematic obstruction of European affairs. For its part, the European Commission was accused of practicing disinformation as far as the general public was concerned, after confidential documents leaked in the press. These events induced the European Parliament to form a committee of inquiry on managing this crisis, the final report of which caused it to threaten the European Commission with a motion of censure.

The "mad cow" crisis has had a major impact on the institutionalisation of the "Europe of Health" and has exposed the need for a genuine European policy on the subject. It nonetheless took additional food scandals—such as the "dioxin-fed chicken" and the growth hormone scandals—as well as the latest threats of increasingly dangerous epidemics such as foot-and-mouth disease, the emergence

33 All the more likely in that the Directive provides that the reimbursement will be made within the limits of the coverage provided by the patient's insurance scheme, therefore supplemental costs will remain the patient's responsibility, and the latter will no longer be able to benefit from the most advantageous coverage. See the summary of the reactions to the Directive Proposal available on the *Euractiv* news website: http://www.euractiv.com/en/health/patient-mobility/article-148956

34 Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts, Temporary Committee of Inquiry into BSE, Parliament document A4-0020/97, Part 4.1.

35 *The Financial Times,* 24 September 1996.

of bio-terrorism, SARS and avian influenza—to convince the Union to deepen and expand its activities in these areas. Thus, even though the idea had been tossed about since the middle of the 1990s, the creation of the European Centre for Disease Prevention and Control (ECDC) was only completed in April 2004 because of the opposition of several governments.

This illustrates the reluctance on the part of the Union's Member States to allow the Union to become involved in the health field—an opposition that often only major crises can eliminate, if only partially.[36] The Union's intervention in the field of public health often occurs under emergency conditions, without a genuine long-term strategy.

36 It should be noted that it was only in the aftermath of an accident causing the death of 264 people in a Belgian mine in 1956 that European cooperation on health and safety at work truly got underway. Similarly, Community efforts to harmonise drug standards were launched following the scandal over pregnant women's use of thalidomide, which resulted in thousands of deaths and birth defects in the early 1960s. Community regulations on blood and products of human origin were formulated after the contaminated blood scandal that affected several European countries in the 1990s.

III - From "Europe and health" to "Europe of health": Stressing Community added value

It is obvious that the Community is now intervening in every area of the health sector. Today, the EU is a major actor in healthcare and disease control policy-making. Yet a substantial part of Community efforts in the field of health is not primarily motivated by a health objective and remains rather implicit. Moreover, these activities are often developed in an unpredictable and inconsistent way.

Formulating a health policy suited to the realities of this already Europeanised field, and thereby maximising the benefits to be derived from European-level action opportunities in the health sector, calls for two reforms: that of the European health administration and that of the legal basis which provides for health-related interventions. These two elements are a cause, a consequence and a reflection of the current limits of Community involvement in health matters.

3.1 Strengthening the European Health Administration

To date, the European Commission has not yet fully assumed the guidance and leadership role that is expected of it in health matters. At present, however, it seems

to be increasingly aware of the scope of the challenge that this field represents for Europe, and to be getting better organised so as to deal with it more effectively. This means undergoing a sectoral and cross-sectoral restructuring, by establishing a structure devoted to health within the European Commission and by developing instruments capable of integrating health into all Union policies.

Pursuing the emancipation of health within the Commission's organisation chart

Until the "mad cow" crisis, the Commission's health-related services were scarcely visible, and their activities marginal.[37] The BSE crisis triggered a major redeployment, which caused the Directorate General for Agriculture and Rural Development's monopoly over the food sector to be broadly criticised. In response to these attacks, the Commission decided to the legislative and scientific advisory bodies from those responsible for control. In order to lay the organisational groundwork for these changes, the scientific committees concerned, as well as those in charge of inspections and phytosanitary, veterinary and food product control, were placed under the responsibility of the European Commissioner for Consumer and Health Protection and therefore—at the operational level—within a new "DG for Health and Consumer Protection." The movement aimed at giving health more visibility later led to the setting up of the Prodi Commission in 1999. It was then that the DG for Health and Consumer Affairs (SANCO) was created, which became the DG for Health and Consumer Protection in 2008. The latter integrated the services responsible for public health previously attached to the DG for Employment, Social Affairs and Equal Opportunities— which retained the services responsible for health and safety at work—raising them to the rank of a Directorate.

The creation of DG SANCO marked a decisive turning point in that it allowed health matters to gain a material and symbolic visibility within the Commission, thereby establishing that health was one of the Union's objectives. It also meant a substantial increase in the number of staffs qualified to work on health objectives, and lastly strengthened the clout of health within the Union's political system, thanks to the appointment of a Commissioner almost exclusively responsible for health matters.

This structure, however, cannot be deemed sufficient. First, it is perceived more as a "Consumer Protection DG" rather than a "Health DG." In fact, food safety and consumer are over-represented in it, occupying four Directorates—even though it is not the most critical issue in health policy—while public health is represented by only one. After the BSE crisis, food safety overshadowed all other health issues to such an extent that, for many years, the Commissioner in charge of DG SANCO was called the "BSE Commissioner."

The end of this crisis, compounded by the fact that, since January 2007, DG SANCO has been reporting to a Commissioner for Consumers and a Commissioner for Health, has allowed this DG to deal with other health issues (such as smoking). Also, the 2006 launching of an Executive Agency for Health and Consumers (EAHC) responsible for managing the Community action in the health sector has made it possible for the DG SANCO's Public Health and Risk Assessment Directorate, with its scant human resources, to dispense with certain administrative tasks which had encumbered it.[38] Recently, this Directorate has managed to focus more on analysis and strategic activities aimed at improving the effectiveness and consistency of the Union's actions in health-related matters.

Notwithstanding, until DG SANCO becomes a genuine DG for Health, it is questionable whether its services will be capable of formulating a uniform and totally relevant policy. In fact, a number of activities which are, or should be, health-related, are still not being handled under DG SANCO's full responsibility. Such is the case for some of the problems associated with healthcare and health services, as well as pharmaceutical products, which nonetheless are an inseparable part of public health issues. The former are being handled by the DG for Employment, Social Affairs and Equal Opportunities and the DG Internal Market and Services, and the latter by the DG for Enterprise and Industry. Both assignments of responsibility speak volumes about the motivations of Community intervention in these

37 These services, which scarcely employ fifty people, used to be part of the Directorate General for Employment, Social Affairs and Equal Opportunities, but was merged into the Directorate of Public Health and Safety at Work, in which the second activity was given much greater priority and resources than the first until the mid-1990s.

38 This agency, formerly called the Public Health Executive Agency (PHEA) primarily manages the launching of tender offers aimed at implementing Community action programs in the health sector, the drawing up of contracts, distribution of funds and the monitoring of funded projects. Since June 2008, the PHEA has become the Executive Agency for Health and Consumers (EAHC), and also oversees the implementation of the Programme of Community action relating to consumers.

matters. DG SANCO has unquestionably become gradually involved in each of these sectors. Yet without any formal plan for the distribution of competences within the European Commission, DG SANCO's role will be limited to influencing decisions that are key to any health policy. The appointment of the new Commission in 2009 will provide an opportunity to endow the European health policy with a more solid administrative foundation.

Integrating health into other Union policies

While it would make sense to combine the activities most closely related to health within the same DG in order to expand the latter's political clout and to make the Union's health activities more consistent, this would not be sufficient. Health is a highly cross-sectoral field: it has an impact on most activity sectors and most of those have an impact on it—as shown above. The key is to create synergies and to integrate health into all Union policies, as mandated by the Treaty.

The Commission has already set up several instruments to accomplish this, including the "Health Inter-Service Group", chaired by DG SANCO's Public Health Director, which regularly meets with other Commission directors when their projects may conflict with the health objectives. Similarly, the Commission also makes use of several tools designed to assess the impact of Community policies on health and health systems, based on indicators.[39] However, neither DG SANCO, nor any future DG for Health or independent external body such as the European Agency, will ever be capable of assessing *a priori* the impact of all Community policies and decisions. The best move would therefore be to rely on the services which formulated these policies and decisions to integrate health concerns into the latter and even the most precise indicators will be inadequate to ensure that these requirements have been taken into account.

Integrating health into all Union policies must therefore be achieved by promoting the idea that health protection is not only a key concern of European citizens, but also a moral imperative and a sphere of intervention which should be the core focus of the Union's activity. Efforts to emancipate health within the Commission and to create a DG for Health might be a major step in this direction. At the very least, the transfer of the Public Health Directorate from Luxembourg to Brussels appears unavoidable for obvious operational and symbolic reasons. As heir to the Directorate of Health and Safety at Work, and later to the Directorate of Public Health and Safety at Work, both located in Luxembourg, the Public Health Directorate continued to be partially based there for diplomatic reasons, while the other DG SANCO services are located in Brussels—clearly illustrating this DG's "patchwork" nature. Thus, the main agencies which supervise it are located far away from the other DGs with whom they should, however, be closely cooperating.

3.2 Revising the legal basis for Community action in health matters

Provided that the European Commission pursues the streamlining efforts in which it is now engaged, it may become the driving force behind the Europe of Health. However, without the proper engine—which is to say without a revised legal basis—part of the Community's action in the field of health is bound to remain residual and contingent. Currently, the legal basis for Community action for health does seem unsuitable in two ways neither of which are affected by the Lisbon Treaty. First, this legal basis does not permit the adoption of restrictive measures in the public health areas where they might prove beneficial, or even necessary. Secondly, it does not yet clearly recognise the added value which the Union can contribute in healthcare and health system matters, and therefore prevents optimal benefits from being derived from the European level, nor does it offer any satisfactory solutions to health problems which may stem from European integration. Despite certain strides that are being made, the Lisbon Treaty has confirmed the Member States' reluctance to let the EU intervene in the field of health.

A legal basis which reflects today's public health challenges

In keeping with the way in which health is being managed at the EU level, Article 152 of the Treaty—the only article to deal with public health (see Appendix 1)—seems to be a last-minute text, hastily written to no definite purpose. It evolved as

39 A description of these mechanisms can be found at the following address: http://ec.europa.eu/health/ph_overview/other_policies/impact_health_fr.htm

events took place and Community health activities developed, sometimes without any specific legal foundation. The "Europe Against Cancer" and "Europe Against AIDS" programmes were launched even before the Maastricht Treaty introduced for the first time a Public Health Article (ex Article 129), promoting health to the status of a Union objective (Article 3). These provisions appear first and foremost to be legal regularisations of activities already initiated. The "mad cow" and contaminated blood cases were, for the most part, responsible for the revision of the "Public Health" article set out by the Treaty of Amsterdam, and for the possible adoption of stringent standards in the veterinary and phytosanitary fields and in the quality and safety of organs and substances of human origin, such as blood and blood derivatives. The Member States considered that it was important to guarantee the safety of products circulating in the EU and which could directly or indirectly harm the health of its populations.

While these two areas are now the only ones in which the Union is authorised to adopt legally binding measures in order to ensure public health, the Member States added a new one to the Lisbon Treaty (Article 168)—that of medicinal products and devices for medical use. This development marks a change in the priority in terms of European legislation, which is no longer solely aimed at permitting free movement, but at protecting citizens' health. Should this trend be sustained, it would mark a significant turning point.[40]

The Lisbon Treaty also expanded the legal foundations by prompting the Union to fight against major cross-border health scourges (such as communicable diseases) and other critical public health concerns. The Union is expressly authorised to adopt measures which are directly aimed at protecting public health against tobacco and the abuse of alcohol. Great strides have been made in these areas, inasmuch as these provisions reinforce the grounds for actions already undertaken by the Union in these various spheres. Furthermore, by clearly designating alcohol abuse and tobacco as elements harmful to health, they are symbolically and legally providing support to health policy advocates against their opponents.

40 Even more so in that this change will allow the Commission's health services to claim competency in such matters, which could facilitate a regrouping of health activities and promote the emergence of a DG for Health. If the public health services were capable of handling medicinal products and medical devices, they should be able to reach the critical threshold of activity that would allow the creation of a DG.

However, these changes are still not fully satisfactory. The Union is only authorised to implement incentive measures to deal with these public health concerns. It is prohibited from adopting measures aimed at harmonising the Member States' legislation and regulatory provisions. Naturally it does not have the authority to harmonise through legislation all national health protection policies. Lifestyles which produce health problems and health risks mainly depend on cultural, geographical, and even local, climate considerations. Public health policies must be primarily formulated at the national, or even territorial, level in order to be appropriate—and therefore effective—for widely diverse situations. The Union's key role must continue to be that of a think tank and a space for the comparison of policies and practices. However, by prohibiting *a priori* the Union from harmonising national provisions, Europe is depriving itself of instruments which may, if only on occasion, bring wide-ranging support to public health protection initiatives undertaken at the national level. Some decisions are, indeed, easier to get adopted at the European, than at the national, level. The best example is undoubtedly that of the Community legislation partially prohibiting tobacco advertisements and regulating the labels and contents of tobacco products. The powerful economic interests which were blocking the adoption of such measures in several Member States were circumvented thanks to efforts at the national level. Despite the lack of adequate legal foundations, the Union had to nonetheless ostensibly circumvent the treaties and base this legislation on Article 95 of the Treaty, which was initially intended to ensure the proper operation of the internal market, and which has prevented it from purely and simply banning any form of advertising for tobacco products.

The fact that the Union has been prohibited from adopting legally binding provisions in its fight against cross-border health scourges is even more regrettable. As the BSE crisis clearly proved, the Member States can very effectively collaborate in order to coordinate their responses and agree on minimum standards and measures in case of an epidemic, but all it would take to jeopardise the health of the entire European population would be the refusal of one State to cooperate. This sort of defection could easily occur, considering the swift negative effects which the epidemic control measures have on the economy.

Acknowledging the Union's crucial role in healthcare and health systems

As for healthcare and health systems, Member States have always showed themselves to be particularly eager to preserve their unique national legacy of history, culture, needs and traditions. As already pointed out, this led to the inclusion in the Treaty of a provision which provides that "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care" (Article 152.5).

Nonetheless, healthcare and health systems are sometimes targeted by Community action in other areas. Such indirect involvement, particularly with respect to patient mobility, prompted the Union to react, notably by expanding cooperative efforts in the regions most likely to be affected by such movements. Healthcare and health systems have thus started to integrate the Union's health policy. The Lisbon Treaty could sanction this trend by way of legislation. Its Article on "Public Health" (see Appendix 2) calls for the Union to promote "cooperation between the Member States to improve the complementarity of their health services in cross-border areas" (Article 168.2).

While European citizens stand to gain much from this cooperation, which should be applauded, the EU's intervention in healthcare and health systems is yet to be fully acknowledged. First, it is limited to cross-border areas—even though other citizens could promptly benefit from European-level cooperation, especially in countries with waiting lists and in "new" Member States in which infrastructures are still inadequate. Next, the new Treaty confirms the restrictions of the former Treaty. In fact, it even expands them by providing that, in the future, it is all of the Union's actions—and not just those in the health sector—which must not interfere with the Member States' responsibilities. Yet that will not put an end to the indirect effects of European integration on health systems. By opposing any direct Community intervention, these effects will be challenging to control without a clear legal foundation. For example, Article 95 of the Treaty on which the Proposal for a Directive on the enforcement of patients' rights in cross-border healthcare is based is merely a stop-gap measure whose legitimacy, if not legality, is already being challenged. A less strict formulation of the Article on "Public Health" would no doubt have been preferable, without venturing so far as to open the door to an undue centralisation at the European level. Ultimately, because of its unsound basis, the current compromise could place the health of European citizens—or even health systems—in jeopardy.

Conclusion

Obviously, despite persistent allegations to the contrary, the European Union is an essential actor in the health field. Explicitly and implicitly, through the agency of other policies, it intervenes in the area of public health as well as in that of healthcare and health systems.

In each of these areas, the Union is in a position to contribute genuine added value to the actions undertaken at the national level to protect and improve the health of European citizens. In matters concerning the control of epidemics, the fight against rare diseases and the regulation of problems relating to cross-border health service mobility, it is obvious that it can be more effective than action taken at the national level, hence the need for the Union to make these areas the core focus of its activities. Yet in doing so, it should not neglect actions which tap into European diversity to expose the causes of health problems and propose ways to maintain one of the key components of the time-tested European social model: viable, accessible and quality health systems.

Refusing to acknowledge Europe's role in the health field for the purpose of preserving national autonomy in such matters is not only simplistic, but it may force the EU to assume a role in this field devoid of consistency, strategic vision, and sometimes even of genuine health objectives. Ultimately, this would mean discrediting the Union's action and undermining its capacity to protect and improve the health of its citizens.

At a time when European integration is more than ever in pursuit of meaning and legitimacy, the EU could draw decisively closer to its citizens by playing a positive role in this sector. Health is a daily concern of all citizens; it worries them all the more in that health threats have been on the rise—whether in the form of risks of epidemics or the funding of health systems. Without question, Europe has a great deal to gain in becoming more involved. Conversely, any inaction or inappropriate action on its part could very well undermine its legitimacy.

Appendices

Appendix 1: TREATY OF AMSTERDAM (currently in force)

TITLE XIII: PUBLIC HEALTH

Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.
Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases and obviating sources of dangers to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.
The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.
Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251, and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States..

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Appendix 2: LISBON TREATY

TITLE XIV: PUBLIC HEALTH

Article 168 (ex Article 152)

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases and obviating sources of dangers to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k), the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

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