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(paper to be presented at the second annual ESPAnet conference, Oxford, 9th-11<sup>th</sup> September 2004, stream title: New health care policies for a new Europe)

## European Union and Health Policy

(Draft – not to be quoted without the authors' permission)

### 1. Introduction

Why and how do EU objectives and policies affect the health sector? This question seems to be paradoxical since – at first glance – there is no such thing as a EU health policy. To date, the Treaties have been rather modest on healthcare issues, formally conceding Member States exclusive health policy rights, whilst Art. 3 TEC<sup>1</sup> raises health protection to the rank of a Community objective, thus providing the EU with a policy mandate: the Union has to contribute “to the attainment of a high level of health protection”, including specific tasks formulated in the Treaty. Yet, rather unambiguously, both the Treaty establishing the European Communities (TEC) and the new Convention concede that “European Union 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” (Art. 152 No. 5 TEC and Article III-174 of the Convention<sup>2</sup>).

Consequently, direct influence of the EU on national institutions, has been widely excluded from the mandate of the Union, with the only exception of cross-border social security rules (Art. 42 TEC). Despite the Commission's ambitious blueprints, the EU, which is an economic and a political Union but apparently not yet a social one, has no genuine legal right to create legislation which would impact on the institutionalisation of health services and health systems in the member states. Thus, is health policy an appropriate example for exploring the impact of European integration?

This paper argues that health policy is one of the best examples possible to demonstrate how the EU and its institutions have successfully transformed a non-topic

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<sup>1</sup> Consolidated Version of the Treaty Establishing the European Community (TEC), Official Journal of the European Communities C 325/35.

<sup>2</sup> “Draft Treaty establishing a Constitution for Europe” of July 2003 (CONV 850/03).

into one of Community's most important future policy fields. It has become obvious since the 1990s that Art. 152 No. 5 TEC is one of the most misinterpreted and misunderstood articles of the European Treaty. In fact, and this might be the reason of such erroneous perceptions concerning health policy, the EU is not a provider of services or an agency of distribution and re-distribution, rather it primarily rules by regulation (cf. especially Majone 1993; 1994; 1996). This paper deals with the question why a policy sector such as health policy has become part of EU policy-making and subject to considerable regulation at supra-national level. Since the impact of European integration in general and the EU in particular is rather differential, we discuss which parts of the 'borderless' policy sector are concerned by European impact and in which direct and indirect ways they gradually become European policies. The purpose of this paper is to analyse the multiple ways in which health policy is Europeanised, and to gain a more complete picture of what might be called European health policy.

Health policy is a dazzling and complex policy sector: it is a *service sector* (personal services, employees and health professionals, service providers, purchasers, etc.) It is a highly regulated *market for goods* (pharmaceuticals, remedies, medical equipment, etc.). It is a *cross-cutting policy sector*, i.e. health-policy aspects are part of and regulated in a multitude of policy sectors, such as environmental policy, consumer protection, industrial safety standards, and EU single market policy. Compared to other welfare-state and social policies, health policy has traditionally more 'market traces'. Given the fact that health policy and health care is an intrinsic and considerable part of the European market of goods and services, it is not surprising that large parts of it have meanwhile been affected by European policy-making via single market compatibility, co-ordination, and harmonisation.

The paper, first, discusses theories and conceptual tools. Since both "Europeanisation" and "health policy" are stretchable concepts, we discuss how the different conceptions of health and health policy interact with the different conceptualisations of Europe and Europeanisation (section 2). Subsequently, three distinct sources of change and pressure for Europeanisation are identified:

- market integration and compliance,
- public health "crises",
- and policy diffusion and discourse.

We then provide empirical evidence from various areas of health policy. These field studies, which are based on the contributions in a forthcoming book on “The Europeanisation of Health Policies” (Steffen 2005) document the different manners and ways of European intervention and the feed-back effects in a wide scope of subjects, ranging from EU institution building in public health, such as food safety, drug abuse, blood safety, and bio-ethics (section 3), market regulation for pharmaceuticals and other medical goods (section 4), the effects of the EU competition and “four freedoms”-policies on health systems (section 5), to the domestic effects of European discourses and policy diffusion (section 6). The conclusion defines the Europeanisation process is gradual – but sustainable - move away from single medical issues and problem framing towards a twofold policy field that combines concrete consumer protection policies and the offensive creation of a borderless European health care market. The multiple facets of European health policy integration result from an indirect impact, deriving from other Community provisions and policies, rather than from a direct Treaty-based mandate. We therefore argue that European health policy should best be understood as an *intersection* between health policy and other policy fields: the Europeanisation process develops as an *issue-specific, fragmented* and *incremental* process, still *patchy* rather than systematic and consistent. The result is still a complex mosaic the logic of which will be analysed in this paper.

## **2. What is Europeanisation? What is the Europeanisation of health policy?<sup>3</sup>**

Europe and consequently Europeanisation have different meanings. In geographic terms, ‘Europe’ usually means the territory, including the islands, between the Atlantic Ocean and the Ural Mountains. In historical and cultural terms, it is generally defined through common cultural and religious inheritances. In political terms, Europe has more than one meaning. It may refer to the EU-25. It may refer to Western Europe which also includes Norway and Switzerland, or to Western Europe plus Central Europe which means the EU plus potential future accession countries, or to Western Europe, Central Europe and Eastern Europe, including an undefined ‘European’ part of Russia. A number of international organizations apply even broader definitions. The World Health Organisation (WHO) includes not only all the Asian countries of the former Soviet Union but also Israel in their “European Region”. In economic terms, “Europe” is perceived as one of the world’s three rich competitors, the others being the USA and Japan. In this

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<sup>3</sup> This section is based upon the conclusions drawn by Steffen/Lamping/Lehto (2005).

perception, Europe normally refers to the EU or the EU plus a group of 'rich' countries around it.

Furthermore, Europe covers a stretchable social and political reality, which inevitably reflects on an equally expandable concept of Europeanisation. This is well illustrated by the contrast between single market regulations – for example, for pharmaceutical products or medical devices –, on the one hand, and public health regulations – for instance for food safety, blood safety or in respect of bioethics –, on the other. The latter field in particular addresses issues that are clearly linked to the Europe of common cultural traditions and values, where 'Europe' is perceived not only through the EU and market freedoms but also through the Council of Europe striving to represent a larger European community of human rights and democratic values.

In political science the concept of Europeanisation, which has become an "extremely fashionable term" (Olsen 2003, 334) in the literature on Europe, has developed "many faces" (Olsen 2002). There are various potential meanings of what can be described and analysed with such an open concept. It can be used to explain a "confusing range of heterogeneous empirical phenomena and processes of change that may somehow have something to do with European integration and the penetration of the European dimension in national arenas of politics and policies" (Radaelli 2000: 3). The term Europeanisation, inherently endangered by a tendency of "conceptual stretching" (Sartori 1970) and ambiguity, is used in different ways to describe a variety of phenomena and processes of change. This paper illustrates at least five possible perspectives of Europeanisation, all implying different modes, mechanisms and driving forces of change and all operating in the health policy sector.

The first and most traditional perspective is to conceptualise Europeanisation as *institution building* at supra-national level and to focus on EU-level policy-making, via formal institutions, established networks, and guiding norms, and on its direct output in terms of collectively binding European policies. Compared to many other policy fields, health policy seems to be little or less concerned by this perspective. Member governments still perceive it as a genuinely national policy field which is of utmost importance in terms of public perception and electoral issues. Yet, as shown in this paper, health policy has *incrementally* become a major EU policy field, and probably one of the most challenging concerns of future European activity. In fact, and this could explain the bias in perceptions, European health policy remains a divided policy field,

because policy integration is marked by the traditional cleavage between *public health* (management of collective health risks) on the one hand and *health care* (treatment of individual illness) on the other. The policy areas of, e.g., medical devices, blood policy, food safety, bioethics or the pharmaceutical sector document the ongoing process of establishing and extending public health as a genuine EU policy field, and of institutionalising a robust EU mandate in this area. Though to a much lesser extent, this is also observed for the politically sensitive healthcare sector, in which a sustainable process of integration via case law can be witnessed.

This classical conceptualisation of Europeanisation as EU-level polity and institution-building has been challenged by a complete change of perspective in which European integration impacts on all sectors and dimensions of *domestic politics, polities and public policies*. In this perspective (see Cowles, Caporas and Risse 2001), Europeanisation is conceptualised as an adaptive process at national level. This research agenda is best captured by the broad definition of Hix and Goetz (2000: 27), who define Europeanisation as “a process of change in national institutional and policy practices that can be attributed to European integration”. The perspective treats European-level developments “as the explanatory factors, and changes in the domestic systems of governance as the dependent variable” (Olsen 2003: 343). This approach analyses changes that can be attributed to EU membership and European integration impacts, and that affect Member States internally: their political systems, political routines, political parties and sectoral policies in fields which have become subject to European attention. While some authors, like Börzel (1999), focus on the direct institutional effects of European integration on Member States, others, like Radaelli (2003) draw attention to the more indirect manners in which ‘Europe’ affects domestic politics and policies, sometimes “to the degree that EC political and economic dynamics become part of the organizational logic of national politics and policy-making” (Ladrech 1994: 69). Whatever one’s perspective, the final research challenge is to explain the variations in European impacts, and the varying responses or non-responses of national actors and institutions to the European pressures. The health sector seems particularly fertile for these questions, especially when it comes to actually implementing EU regulatory policies

From a third, i.e. a political perspective, Europeanisation is a multi-causal phenomenon. It is the result of a complex and dynamic intertwining of top-down and bottom-up

processes in a given policy area: EU-level activities and initiatives strongly affect domestic policies and politics (top down), while national actors interpret these ‘impulses’ and translate them into domestic political games (bottom up). At the same time, they tend to shift domestic issues to the supra-national level and actively seek to influence these processes at the European level according to their economic interests and policy traditions (Héritier 1997; Putnam 1988). The process resembles a cycle rather than any linearity. This understanding of ‘Europeanisation’ is restricted neither to the study of European institutions, institution-building and policies in the sense of EU-output or EU-driven constraints on Member States, nor to the direct domestic impact of EU politics and policies in the sense of implementation, change of domestic policies, and intended or unintended policy outcomes. It analyses the various and confusing *feedback-loops*, interactions, games, and specific dynamics linking *both* levels. In this perspective, Europeanisation is a mutual process of influencing, negotiating and adjusting at both EU and Member-State level. The process is most obvious in the wake of public health catastrophes like AIDS (Steffen 2004): the epidemic was a catalyst for both an intensification of cross-national health management and co-operation, and the organization of public health capacities at EU level. The EU regulation of medical devices and drug abuse or blood safety policies exemplify these reciprocal processes of policy development, norm diffusion and policy adoption and reform.

A fourth perspective of Europeanisation emerges as a soft variant, a transfer of ideas and of the way problems are perceived rather than European rules leading directly to structural or policy change at domestic level. European values, integration requirements and policy paradigms diffuse into national policy debates and arenas, shaping or influencing national policy formulation and strategic choices from within. This triggers a processes of institutional and “social learning” (Checkel 2001) and normative re-orientation. Most prominent examples are the Economic and Monetary Union (EMU), the Single European Market (SEM) and the Stability and Growth Pact. The concept is understood as both the creation of shared frames of reference by framing common sets of beliefs and ideas, and the inducement of actors in Member States to frame domestic structures and activities in ways that incorporate a European dimension. Both can have a major impact on domestic policy discourses in which national actors ‘communicate Europe’, and on the content of domestic politics in a growing number of policy issues. In the health sector, the process is illustrated by “cost containment”, “risk reduction” or

“equal access”. The effect is also dependent on the intellectual influence of “epistemic communities” (Haas 1992). In the health policy area, such epistemic communities have been considerably reinforced through the establishment of stabilized networks of issue-interested groups and the direct institutionalisation of problem-solving capacities, mainly through the creation of European agencies and observatories, comprehensive databases and comparative information systems, diffusion of best practise and incremental extension of regulatory competencies. They encompass individual health policy experts, representatives of European and national research units, selected officials from Member States and, most important in this sector, specific interest groups and non-governmental organizations (NGOs), such as patients’ organisations.

The fifth perspective on Europeanisation documented in this paper is that of changing domestic opportunity structures. In this respect European health policy integration has a (differential) impact both on domestic policies (institutions, instruments, problem-solving approaches, etc.) and on domestic politics (political influence, interest formation, coalition building, etc.). EU regulatory policy as well as the perceived or real European integration requirements primarily affect the domestic distribution of power and resources and re-define the domestic rules of the game: new constellations of actors emerge whilst traditional veto players are weakened; new norms and challenges are formulated; and new opportunities open up for pushing previously marginal policies forward. Therefore, without going to much into detail, our argument is that the internal market regime could – in a positive way – shake up rigid health-care structures in favour of patients’ interests, more cost-effectiveness and more efficient provision and at the same time increase the political feasibility of health policy reform. European integration is an opportunity for countries whose welfare states have been described as “frozen” (see Hering 2002 and 2003; Palier 2000), i.e. countries with fragmented political institutions, multiple veto points and strong, vested interest groups. In these countries, European integration could provide new opportunities to circumvent political (political competition, electoral risks, interest groups, etc.) and institutional barriers (institutional separation of powers, etc.) that make health policy reform so difficult in most countries. Furthermore, from the public management point of view, European integration might actually provide opportunities to break free of national ‘paralyses’ in health policy (conceptualisation and implementation of reforms; opposition of professionals) and to set towards probably more rational resource management, such as the establishment of

a borderless European health care market; introduction of EU-wide competition among health care providers; liberalisation of the health care service market in general and of contractual law in particular; new contractual relationships with purchasers and domestic providers from abroad; abolition or at least questioning of monopolistic and oligopolistic structures; purchase of cheaper goods or services in other Member States (see Lamping 2004). Moreover, European integration provides national actors – both governmental representatives and interest groups – with the opportunity to play the European card by shifting issues and blame to the European level and/or to build up new strategic domestic and trans-national coalitions. In this case domestic actors no longer rely exclusively on their national networks and resources, but participate in European politics and exploit European policies.

Like the terms 'Europe' and 'Europeanisation', health and health policy can be understood and conceptualised in a number of different ways. Generally, the term health policy refers to policies that focus on the development of medical care and the organization of healthcare systems. Analyses concentrate on how people are provided with diagnosis, cure and care for disease. This part of the subject may be called '*medical care policy*'. In a broader context, the focus tends to be on the social security system and the regime of social protection in the case of sickness. In this frame, the question relates to how different systems of social insurance cover the costs of buying medical care and temporarily remaining out of the labour market during a period of sickness. This may be called '*social security policy covering sickness*'. Most of the comparative literature on health policy and on welfare-state reforms are in fact limited to discussing this particular field of medical care and social security policies.

Health policies may also be viewed from the perspective of health determinants such as work and living conditions, environment, traffic safety, nutrition, smoking and physical exercise, in addition to health education, vaccinations and screenings. Such analyses concentrate on prevention policies and health promotion. The term 'public health' refers in general to policies related to these foci of health policy developing at the margins or even outside the institutional borders of the healthcare sector. Epidemiological surveillance and expertise systems form part of this particular type of *public health policies*. In some contexts the term 'public health', or the more recent concept 'health system' introduced and diffused by the WHO, are used for all the policies and institutions with health as their primary and main goal (WHO, 2000). They refer to a

combination of healthcare and promotion, the sickness branch of the social security, and prevention. Following the new WHO terminology, this global public health approach could be called *'health system policy'*.

The realm of health is also a significant arena for private enterprise, economic growth, employment and profit as well as industrial and commercial competition between the EU, the USA and Japan. The pharmaceutical and the medical devices industries as well as the agrifood and other assumedly health consumer-product industries, all seek to optimise their market and economic interests, particularly via the rapidly growing biotechnology industries. In this respect they are comparable to other public- or private-sector services, such as telecommunication or energy, and to more traditional economic sectors like the chemical or the car industry where safety issues constitute a major part of the business. From the perspective of the economic interests related to this arena, health policies may also be seen as *'policies creating growth potential for health-related industries'*.

These different aspects of health policy are related to Europeanisation in different ways, which compounds the existing complexity of integration processes. The "Draft Treaty establishing a Constitution for Europe" (CONV 850/03) is still unable to clear up these health policy ambiguities. It sticks to the rhetorically tricky path of conflict avoidance and competence sharing, whilst simultaneously whenever possible implementing points of reference for future Europeanisation and harmonization. Regarding the public health Article III-179 of the Draft, the Union is still restricted to "complementing national policies" and to "encouraging cooperation between the Member States". All in all, the Treaty restricts the mandate of the EU, differentiating it particularly clearly from the *medical care sector* and *social security covering sickness*. Yet there are many indirect ways in which the EU may have a considerable impact on the evolution of health policy in the Member States, including in the medical care sector.

### **3. European governance by crises: public health regulation at supra-national level**

It were especially the broad public health area and specific other cross-cutting issues that opened the backdoor to member states' health policies and incrementally put health at the forefront of the European political agenda. In the wake of new challenges and new concerns related to public health per se and to cross-border public health risks, the

limited resources of the Community (in Art. 129 of the 1993 Maastricht Treaty) were expanded in the Treaty of Amsterdam (now renumbered Art. 152) through the addition of several new provisions. According to Art. 152 TEC, actions in the public health area should contribute towards ensuring the attainment of a high level of health protection; improve health; prevent human illness and disease; eliminate sources of danger to health and ensure that all European policies protect health. Since the mid-1990s the Commission has strategically promoted a Union-wide dialogue on health issues. In May 2000, it proposed a new health strategy (see Commission 2000): the “Programme of Community action in the field of public health” (2001-2006, and the new programme 2003-2008) that replaces the fragmented eight European health action programmes within the framework put in place in 1993 in the wake of the Maastricht Treaty. It explicitly seeks to work towards co-ordination among Member States and to integrate public-health related issues into a more coherent supra-national framework. With hindsight, this expansion of powers and provisions has often been an accidental, crisis-driven and inadvertent process of cumulative competence accumulation at Community level – but it has been a process in which the Commission has demonstrated considerable political leadership. Not surprisingly, it was mainly communicable disease outbreaks (like AIDS, CJD, SARS – and especially BSE) or severe threats to public health (like “bio-terrorism”; see Commission 2003a) which pushed the Commission to actively organise co-operation among Member States (like the Communicable Diseases Network since 1999), to take policy initiatives, and finally to institutionalise the surveillance and control of communicable diseases and other serious health threats at EU level via the creation of a new European agency, the ‘European Centre for Disease Prevention and Control’ (ECDC), which will start work in 2005. This new Centre demonstrates the step-by-step transformation of the institutional landscape of European health care. Furthermore, as the European integration moves forward into discussions of technical details, the necessity and importance of EU agencies will grow in integration politics. This is especially evident with respect to the Commission’s regulatory initiatives and to the ‘technocratic’ matters affecting European health care with which supra-national bodies are concerned. The establishment of the European Agency for the Evaluation of Medicinal Products (EMA), described as a “revolutionary step” (Bassi/Bertele/Garattini 2003) in European public health, is a case in point. These EU agencies are not only functionally and politically important institutions, responding to the need of market regulation by professionals (market integration and market functioning

via standardisation and harmonisation), they also have a high inherent potential for vertically and horizontally integrating the EU as a political and administrative entity.

The public health article of the Treaty and the competence for the 'borderless' consumer protection policies provide the EU with a considerable policy mandate in a wide range of policy areas, especially when free-market issues coincide with potentially high risks for human health. To give but two examples:

i) Food safety has progressively become a key component of EU health and consumer protection policy. The EU has not only adopted comprehensive food laws in which the general principles, standards and procedures of food safety regulation are defined. It has also succeeded in institutionalising a considerable administrative and scientific apparatus at EU level (Clergeau 2005). This case demonstrates the crisis-driven history of EU food safety policy, marked by the complex relationship between food and health protection in Community policies. Food policy was gradually detached from the narrow liberal single market perspective and incorporated into the EU's health politics and policies. Despite such important changes, Community action in the field of food safety appears to be not yet coherent or sufficiently coordinated. It remains often limited to support for national policies and continues to be subject to incidental controversy between the EU and Member States. Food as a public health subject and will remain a politically salient issue in the enlarged Union and therefore an important policy on the future EU agenda.

ii) The EU's gradual involvement in blood safety since the 1990s, in the aftermath of the political fall-out from the HIV-blood contamination demonstrates both the catalysts of supra-national competence accumulation and the use of burden-shifting from Member States to the EU level. The crisis<sup>4</sup> led to the development of a complex, diverse and politicised European blood policy community in which scientific experts on blood-related matters in EU play an important role in policy formulation (Farrell 2005). The establishment of a comprehensive EU-wide regulatory framework for the collection, manufacture and supply of blood and blood products has become a significant part of the EU's growing competence and influence in public health governance.

#### **4. Regulating markets and promoting consumer protection**

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<sup>4</sup> Although the *political* crises were of national nature, most important in the French case, the *programmatic* crisis was of international and European nature, extent and dimension (cf. Boven/t Hart/Peters 2001).

The Commission, a highly self-interested political actor, has variously proven to be successful in grasping rare opportunities, such as public health crises, and thus in integrating heterogeneous sectoral policies into a more coherent public health strategy, under the mandate of the Union. These processes are in general accompanied by an internal re-organisation and a shift of competences within the Commission. The competence for food, for example, was transferred from the Agriculture and Fishery Directorate to the Public Health and Consumer Protection Directorate. The growing public health mandate of the Union implies a continuing shift from classical free market-policies to the institutionalisation of a broad and substantial legal public-health framework. This development does not necessarily contradict the EU single-market building and market-compatibility impetus – quite on the contrary: standardisation and harmonisation of safety policies are yet another constitutive building bloc for an integrated market combining consumer and trade interests. This holds true for food, blood and bioethical policies as well as for the regulation of pharmaceuticals and medical goods.

The consumer protection/public health mandate of the Commission has allowed for some important Community regulations although the EU's scope for 'positive' initiatives remains limited. Apart from the food sector where EU policy-making was largely crisis-driven, the most visible example and directly concerned sector is the construction and integration of a European market for medical goods (market making and market integration). This ambitious project comprises the common regulatory framework for medical and medicinal products in the area of manufacturing, safety and quality surveillance, market access authorization, and the free movement of pharmaceuticals within the Single Market (Feick 2002; Permanand/Mossialos 2005); the certification and registration of medical devices (Altenstetter 2002 and 2005); and the mutual recognition of *professional qualifications* for medical and pharmaceutical staff within the Single Market.

It is in particular the considerable market of pharmaceuticals and medical devices, tradable goods in the true sense, that witnesses a high level of integration and centralisation of competence. These areas are marked by a clash between subsidiarity claims of Member State governments and EU policies. National authority and self-interests to set prices and reimbursement rates and to pursue regional economic policy conflict with the free movement requirements of the internal market of goods. Case

studies conducted by Permanand/Mossialos (2005) however show a more complex picture: on the one hand, specific parts of the European market for pharmaceuticals are *highly harmonized* due to a high level of basic interest congruence (particularly between the Commission and the European pharmaceutical associations) and highly centralised from the point of view of competences. On the other hand, the European market as such is still marked by a striking imbalance and deadlock, which so far has precluded any completion of the single pharmaceutical market to date. The evolution of EU regulatory governance in the field of medical devices was examined by Altenstetter (2005) with a particularly close look at the conceptualisation of the “In Vitro Diagnostic Device” Directive and its domestic implications in the UK, France and Germany. Altenstetter concludes that European *and* national initiatives continue and will continue to exist. Whilst national variations in responses to EU regulation, in terms of implementation and outcome, are inevitably bound to increase with the 2004 enlargement, comparative results show that the regulatory harmonisation has lowered neither the safety standards nor the requirements for market authorisation. On the contrary, the common requirements of performance and the evaluation system have raised the safety threshold in the EU and even beyond. This finding suggests that a market-oriented Europeanisation can go hand in hand with consumer and patient protection objectives.

## **5. Indirect EU impact on health care institutions and patients’ rights**

Via the fundamental “four freedoms” and the SEM competition law negative integration policies define conditions for market access and market functioning and aim at abolishing legal prohibitions against national regulations that otherwise might function as obstacles and barriers to the free movement, or as distortions of competition between Member States within the Community. In this respect the four freedoms regime allows for cross-border market transactions irrespective of domestic regulations, while the competition law, directed at private actors and Member States, likewise basically aims at liberalizing the Single Market. Even though European healthcare systems still formally appear to be national, European integration has steadily reduced the policy margin Member States can effectively dispose of when regulating their healthcare sector. The spillover effects from the EU competition and four freedom regimes provide a further example for backing this argument.

It was especially the delivery of health services and medical care to patients that was previously thought to be unaffected by European integration politics. The ECJ, the European ersatz-legislator, however made it perfectly clear that market freedoms are *basically* also applicable to those areas of public policy that most national governments have explicitly excluded from the market and from the Treaty. As a consequence it is no longer possible to ignore the fact that health care is part of the single market and that the influence of the ‘four fundamental freedoms’ is effective, in particular a) the freedom of movement for *persons* (EU-wide labour market for professionals; mutual/automatic recognition of national qualifications and diplomas, especially in the health professions; Union-wide access of EU citizens to medical care services), b) the freedom of movement for *goods* (single market for pharmaceutical products and medical goods), and c) the freedom of movement for *services* (cross-border delivery of services and the choices available to patients; freedom of establishment). Several momentous ECJ rulings, following courageous actions of individuals to enforce their individual (social) rights as European citizens and consumers, pointed the way ahead for healthcare systems and future health policy.<sup>5</sup>

These internal market rulings, particularly those on patient mobility which were a step forward in the rights of European citizens (wider choice), set in motion a dynamic which governments and health policy actors cannot escape and with which they have to grapple. Even though the Court confirmed Member States’ ability and responsibility to freely organize their healthcare systems, it recalled at the same time that whatever Member State governments do, they have to comply with Community law. This is not a paradox but the logical consequence of the Treaty’s *political* imprecision and *legal* uncertainty concerning social policy. Inter alia, the ECJ explicitly stated that in- and out-patient care are “services within the meaning of the Treaty”, i.e. by no means different from purely economic services even though, in national contexts, they are usually part of public services which are regulated by social law. The ECJ has clarified several times to which extent and under which conditions patients have to be reimbursed for health care provided in another Member State than the state of his or her affiliation. In fact, the extension of patient mobility and patient rights has become one of the core concerns of EU activity in health policy (see e.g. Commission 2004). EU citizens are now entitled to travel *intentionally* to receive medical goods and to seek health care within the EU and,

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<sup>5</sup> See in particular case-law C-120/95; C-158/96; C-169/96; C-157/99; C-368/98; C-385/99; C-326/00; C-8/02.

thus, to outpass the exclusive institutional arrangements of their home welfare states in which they are embedded by social law. According to Threlfall's (2003) concept of "single social areas", citizens can experience the EU as if it was a single country. In this 'single healthcare area', national welfare-state frontiers are increasingly becoming legally insignificant for national citizens and making way to new European social citizenship boundaries. The EU is on the way to become one "Europe of Patients" (DGV 1999: 1) or, more emphatically, one "Europe of Health"<sup>6</sup> – although one created mainly via case-law, not politically.

The increasing *mobility* in the health sector has and will have major repercussions on national systems, on their 'permeability', and their traditional steering instruments because of the impact of a potentially Europe-wide competition among providers, the free flow of goods and services, and EU citizens' right of access to healthcare irrespective of national borders. It is above all the legally confirmed individual right of patients, as citizens and consumers, to quasi-unconditional access to healthcare abroad, which constitutes the new challenge to Member States' systems. The consequences, though still emerging, are already visible: European citizens have carefully started to compare healthcare and healthcare systems and to demand equal and high quality treatment and protection everywhere. Differences in health status, health outcomes and even in financial burdens for equal or similar treatment will increasingly become unacceptable and an important topic on the national and European agendas. This will trigger new processes of harmonization and policy convergence (benefits, prices, access etc.). The most probable result will be new an intensification of policy-learning via subtle processes of 'naming and shaming'.

Furthermore the complex and often contradictory EU competition law<sup>7</sup> might effectively pressurise the institutional, regulatory, financial and normative health policy frameworks of health policy in Member States in case of incompatibility with the liberal single market regime.<sup>8</sup> Whilst there is undoubtedly no general pressure to liberalise or privatise institutional healthcare arrangements, governments basically have to respect the momentum of open competition across borders and – depending on the specific features and institutional configurations of each health system – probably have to adjust

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<sup>6</sup> Byrne, Commissioner for Health and Consumer Protection, at the European Health Forum, Bad Gastein, 3 October 2003 (SPEECH/03/443).

<sup>7</sup> See Articles 81, 82, 86 (1) and 87 (1) TEC as well as the possible 'counter-articles' 16 and 86 (2).

<sup>8</sup> See the discussion in Lamping 2004 and 2005.

to a greater “market conformity” in certain sectors. The logical consequence is that the EU competition regime will lead to a *regulatory dichotomy* and differentiation in the regulation of health care: While the national level is basically responsible for and free to regulate health care protection, coverage, and funding within the country and through its own legislation, EU competition law will increase its liberalising impact on the “production of health”. Domestic supply and delivery structures of health services and respective institutional frameworks will have to adapt in order to respond to increasing EU pressure.

The compatibility of health systems with the EU competition and four freedom regimes have triggered far-reaching processes of adjusting to internal market requirements and of implementing a European dimension into national health systems and health care policies. Finally the regulatory competence for social security is divided: while member states still have the *specific* competence to regulate their systems of social security, the EU holds a *general* – and strong - policy mandate to implement national compatibility with the single market and competition law. Three major consequences are evident. The Court rulings imply a significant loss of Member States’ *sovereignty* in the key policy area of social security, and considerably weaken *territorial* and – which is crucial for social policy – *nationality* principles in healthcare.

## **6. Adjusting to Europe by policy discourse and diffusion**

Discourse and diffusion refer to the *indirect* effects of European integration on health policy and health-care systems. In the following, three examples which highlight different policies and different ways and levels of adjustment will be discussed:

*First*, the conceptualisation of cost containment policies which can be attributed to *both* the adjustment to the EMU and the Stability and Growth Pact *and* the domestic perception of single market requirements (competition, competitiveness, etc.). These inherently political pressures to adjust domestically to the common market and to the explicit economic EU self-bindings are a multi-dimensional and therefore – in terms of causal causalities - extremely complex phenomenon. It is essentially the combination of Economic and Monetary Union (the so-called Maastricht-criteria) and the internal market competition that challenges political scientists because its potential economic and political consequences for national health systems are so diverse and difficult to measure. The new economic and monetary framework places governments under

pressure to bring macro-economic policies in line with the – perceived or real – functional demands of the euro zone. At the same time, it gives member governments an external justification for doing so by making the SEM and EMU the scapegoats for unpopular decisions in order to push forward domestically blockaded cost containment reforms and to overcome the opposition from doctors, patients, and the pharmaceutical industry. Growing public budget deficits, especially those resulting from the deficits of social security institutions, interfere with the new obligations derived from the Maastricht criteria and the 1996 Dublin Stability and Growth Pact. In addition to that the dynamics of *regulatory competition* within a liberalized market, so this popular arguments goes (see Scharpf 1998 and 1999), forces Member States into a downward spiral with regard to social standards in order to attract investment and to increase national competitiveness (mutual adjustment). Health policy and health systems in Europe are thus facing considerable macro-economic constraints that may impact on the ability of health systems to keep pace with rising healthcare costs in the near future. The high importance of health within the state budgets has increased the temptation to reduce public sector deficits in general. In the complicated health sector this has been done, mainly and so far, through budget ceilings and the shift of financial burdens to the patients/insured, and, unfortunately less often through intelligent managerial policies which could increase the efficiency and effectiveness of institutional arrangements. Most probably, cost containment policy has been or will become more intensive in healthcare reforms than would have been the case in the absence of EMU constraints. Though it is conceivable that most of the health policy reforms would have emerged anyway, independently of EU membership European integration often further strengthens an already existing initiative or consensus for reform. This holds true for countries like Germany: Even though retrenchment in social policy has been fairly smooth to date, especially when compared to the economic and financial state of affairs, there is reason to expect that current EU initiatives will make Germany consolidate its public budgets. This might have a substantial impact on the statutory health insurance that accounts for an important and growing part of the German budget deficit. The harsh conflicts between ‘Brussels’ and the German government over the violation of the Maastricht deficit criteria put health authorities under an enormous reform pressure.

The joint constraints are in general regarded as considerable making governments, reduce social expenditure and implement austerity measures. These indirect effects of European integration imply considerable difficulties for national governments which are bound to maintain country-specific levels of social protection. Therefore, it is not surprising that empirical studies document very different reactions among and in the EU Member States. In some countries European integration and especially meeting the EMU criteria “was portrayed as a force that imposes welfare cutbacks and restructuring, and was used as a justification for social policy restructuring by domestic actors” (Timonen 1999: 259f), whilst others did not or only with hesitation engage in this discourse.<sup>9</sup> In this respect, the communication of ‘Europe’ sometimes plays an important role in national politics of cost containment.<sup>10</sup>

The *second* way European integration impacts on health policy refers to the establishment of a growing number of European health-care information and evaluation systems. The European Observatory on Health Systems and Policies as well as the important role of the Statistical Office of the European Communities (Eurostat) illustrate this. This goes hand in hand with the growing political influence of EU-level epistemic communities, which promote and diffuse EU policy ideas and pave the ground for future EU regulation (see, among others, the High Level Group on Health Services and Medical Care). The rapidly growing information infrastructures, aiming at data collection, rankings, transparency about health systems’ performance, etc., draw up and diffuse problem definitions, contexts elements, technical solutions and policy alternatives, the impact of which on national political debates and problem perceptions cannot be underestimated.

The Commission is a master craftsman in initiating and fostering EU-level policy discourses between experts, professionals, public administrations and governments from all Member States: it establishes health-policy networks, helps building supporting coalitions, exchanges knowledge and institutionalises expertise. This accumulation of expertise capacities at EU level is of utmost importance for the understanding of health

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<sup>9</sup> There is evidence that in some countries European integration, and especially meeting the EMU criteria, was actually used as a legitimization and a crisis scenario alike in order to facilitate welfare state retrenchment – as in France (see the 1995 ‘Plan Juppé’ which met widespread resistance from workers and unions), Italy (see e.g. Della Sala 1997; Ferrera/Gualmini 2000), or Austria (see Tálos/Badelt 1999). Without the external pressure of EMU it is highly unlikely that these various political decisions would have been taken in these countries. In other countries – such as Finland (see Timonen 1999) or Germany – (de facto or proclaimed) adaptation pressures played a minor role in social policy reform debates.

<sup>10</sup> For a general perspective on welfare state adjustment, see Schmidt 2000/2001/2002.

policy integration: it involves independent and pro-EU health policy experts; it pools high-level scientific knowledge and institutionalises sectoral forums. Such processes have proven to be effective vehicles in gradually introducing a European dimension into national policy discourses and in trans-nationalising the policy debates. These epistemic communities construct and diffuse a common perception of problems and solutions. This collection, exchange and diffusion of *knowledge* and ideas is comparable to the health-policy work of the OECD and the WHO and will have an increasing intellectual impact on domestic reform discourses and effective reform activities.

The work and political influence of, and even the conflicts inside such epistemic communities, as well as the institutionalisation of expert capacities at supra-national level can be observed in the health-policy area by both the efforts to settle bioethical norms and to promote risk reduction strategies linked to drug abuse. Lafond (2005) analyses the process of Europeanisation in the vast field of bioethical politics. Access to artificial insemination, cloning, research on the human embryo and, most importantly, patentability of the human genome, all of which present huge potential market interests and trigger political conflict over the legitimacy and content of norms. Policy responses in this field are heavily charged with symbolic values and root in different national traditions. However, their European dimension is of utmost importance and relevance since the rapid progress in biomedical science and technology entails major market implications as well as questions of public health and consumer protection, which all fall within the competence of the EU. The EU and the European Council have taken a stand on most biomedical ethical issues, although both actors sometimes pursue different objectives and policy initiatives. Both are loci of permanent trans-national discussions, compromises, learning processes and policy diffusion, although not to the same extent. While the EU's intervention has initially been marginal and reactive to date, in the absence of precise competences in this delicate policy field, the European Council has gradually become an important political actor and point of reference for national and international political initiatives. The policies to combat drug abuse provide another interesting example of how national public policies converge in the wake of European integration, even though the Union has barely any competence and little, if any experience in the policy field, and even though these public policies are politically salient and extremely sensitive issues in most Member States. Bergeron's study (2005) provides empirical evidence for both a steady convergence of national policies and,

simultaneously, the gradual extension of Community activities, although there still is no comprehensive or consistent EU drug policy. This part of public health policies demonstrates how, despite limited competence and much political controversy, the EU progressively establishes European information and problem-solving capacities and provides a forum for policy discussions between professional experts, governments and public administrations from Member States.

Similar mechanisms can be observed in a *third* arena of institutionalised policy discourse and policy diffusion, provided by the Open Method of Co-ordination (OMC) whose aim is to initiate both a competition of 'better practices' and a process-driven convergence of national policies and institutions (Lamping 2004). Though still in the preparatory stage in health policy and politically still contentious, the OMC, once effectively institutionalised, could substantially modify the political environment in which domestic social politics take place. The OMC, as a new mode of soft policy co-ordination, can be analysed as the "third way" in EU governance, to be used when direct harmonization would prove unworkable and the politics of mutual adjustment via regulatory competition within the internal market too risky (Eberlein/Kerwer 2002). The OMC does not aim at institutionalising common structures and models across the EU, rather it aims at achieving common results without officially interfering with Member States' competences in the respective policy areas. In contrast to the *legal* co-ordination of Member States' social security policies in support of workers' mobility, the OMC is a *political* co-ordination based on the concept of 'management by objectives'. Voluntary engagement and "gentlemen's agreements' instead of directives" (Begg & Berghman 2002: 191) are the price the Commission has to pay in order to motivate Member States to take part in these new procedures. The Commission, however, is fully aware of the fact that once the OMC has proved to be an effective instrument, voluntariness will turn into moral and political obligation. The shadow of hierarchy, effective only in terms of sanctions, has been replaced by the shadow of mutual control, resulting from group-pressure which might serve as an antidote against the pursuit of mere symbolic politics. Moreover, non-participation, failure to implement the fixed guidelines in national action plans, and ignorance of the recommendations will then have to be publicly justified in what may turn into an awkward situation for reluctant Member States.

This new method can be seen as part of the Commission's new and strategic experimentalism, particularly in the complex and politically salient area of social and

health policy. It involves Member States in a complex procedure of external and self-evaluation, in the wake of which strengths and weaknesses ought to become transparent and comparable, via monitoring, performance indicators, benchmarking, peer-reviews, rankings, self-commitment, implementation of best practices, etc. Since the 2000 European Council in Lisbon, this post-regulatory governance mode has been extended stepwise from – inter alia – social exclusion and pension policy to healthcare and health and safety at work. In its Communication on “streamlining open coordination in the field of social protection” (2003b), the Commission outlined its ambitious project of integrating the current disparate actions and various strands of work on social protection into a coherent framework within the OMC. The OMC will probably function as a new market of ideas and information and as a catalyst of a smooth, but steady policy convergence.

## **7. Conclusion: Health policy and European integration**

Different and contradicting assessments have so far prevailed concerning the role and impact of the EU and its economic and political integration process on health policy. The contradictory picture is partly related to the existence of both national and European competency over different domains of the health policy field. It is equally linked to different conceptualisations of health policy and to different conceptualisations of Europe and Europeanisation. Furthermore, any step towards European health policy integration is a complex and conflict-loaded venture, impacting on politically sensitive and traditionally national core domains with deep-rooted institutional configurations. Health systems have grown incrementally and therefore are unique institutional and socio-cultural entities, each with a specific role distribution between the state, the medical professions and the various socio-economic partners, with specific internal logics, purchaser-provider relationships, financing and remuneration systems, and well-entrenched influential interest groups.

Nevertheless, our paper has demonstrated that whilst politicians and health professionals still think in terms of national health policy, specialists of this policy field are fully aware that European integration has definitely begun a new chapter in the history of health policy. The ‘Europe of health’ is progressively taking shape, even though its contours are still confusing: core areas of health policy and health regulation have inevitably become subject to an incremental, though asynchronous process of Europeanisation and institutional harmonization. Obviously still “underdeveloped”

compared to economic integration and still far from the institutionalisation of a comprehensive regulatory regime, the process has nonetheless been on the way for many years. It has been a pragmatic, technocratic and juristic process rather than a political one because member governments remain hesitant to actively shape European health policies.

The European health policy arena, which is a highly fragmented one, proceeds by regulation and/or political compromise in the public health sector as well as in the medicinal products sector, and by case-law and legal compliance in the medical or health care sector. Both, the public health and the medicinal products arena comprise heterogeneous policy fields, several of them being discussed in this paper. Both are marked by different levels of integration, varying with the political sensitivity attached to the given areas and with the particular constellation of interests prevailing in the Member States. Moreover most of the EU health-policy regulation as well as the jurisdiction of the ECJ stem from other policy fields and goals and have to be legitimised by Treaty articles which, originally, have little or nothing to do with health care (like the single market law). Therefore the EU impact on health policy and health systems has often been, and will continue to be mainly indirect and often unintended.<sup>11</sup> Since there is neither a precise definition of EU health policy nor any clear separation of supra-national and national competences, it is unsurprising that EU health policy making is full of surprises, and even crises, which finally grants the supra-national actors a large scope for strategic activities.

European health policy is gradually and incrementally taking shape. This paper draws three major conclusions. First, the legal absence or weakness of direct EU health-policy competences does *not* mean that the Union's impact on Member States' health systems and policies is negligible. Second, European social and health policy integration has to be conceptualised as a parallel and intertwined process of deregulation and liberalisation on the one hand, and re-regulation and harmonization on the other. Third, the Europeanisation of health policy is an ambivalent and extremely complex phenomenon operating on various levels, in different forms and with diverse and sometimes contradictory effects. Different types of pressure result from the integration process and produce varied impacts on national "health care states" (Moran 1999). We

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<sup>11</sup> Therefore Mossialos et. al. (2001: 3) rightly state that "much of the relevant European law has emerged from rulings that have either arisen from considerations in other sectors or by addressing only the issues in a single case, leaving major issues of applicability unresolved".

propose the Europeanisation of health policies as a dynamic, but still rather unsystematic process of policy harmonisation and policy adaptation. It offers an example of effective and inspired 'muddling through', rather than of a consistent and clear-cut European or concerted strategy.

Health policy should no longer be discussed exclusively in terms of national autonomy and sovereignty. The constantly growing power and influence of the Union changes the institutional and political environment in which future national health politics will take place. To give but one last example for this argument: Besides the traditional agencies established at EU-level, the organisation and development of European centres of reference constitute an effective step towards a common definition of needs and requirements and a common planning of health-care capacities as well as medical facilities across the EU. We therefore conclude that a EU health regime has already emerged which considerably reduces the policy margin of Member States in regulating their health-care regimes. Supra-national and national level are manifoldly interwoven, but there is evidence that EU and Member States are on the way to forming a more systematic and reflected institutional *compound* of health policy. The term 'compound' is used here to simultaneously stress the two main characteristics of European health policy, marked by a dynamic dispersion and distribution of competences between Member States and Community institutions: this European health policy regime consists of shared competences and separated responsibilities, with an issue-specific division of labour between the supra-national and the national level. Both levels usually complement one another, despite the recurrent conflicts with each other.

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