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HEALTH POLICY GOVERNANCE IN THE EU: COMPOSING A JIGSAW PUZZLE?

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Abstract. *This paper aims to analyze the impact of the economic and the political integration and also the Europeanisation on health policies and health systems in the EU. How European Union objectives can affect policies places under exclusively national competence? Health policy appears to be an enclave within the European integration, because health is perceived as an area with firm member state control, with a minimal EU role in the incremental and irresistible process of harmonization and Europeanisation. Although, health systems in the EU share common values and different health priorities and backgrounds the question that arises is : can we talk about market integration of health policies? I argue that the impact of European integration on national healthcare and the ways in which governments adjust their institutionalized healthcare governance do it – in terms of regulation of access, funding, membership entitlements, and management can be an interesting analysis of the evolution of health care systems and policies in the European Union.*

Keywords: *Health policy, Europeanisation, EU, Governance, European single health market*

1. European Union: a Particular System of Governance

1.1. Introduction

How do European Union legislation and policies affect the health sector? This question seems to be paradoxical since, at first glance, there is no such thing as a common European health policy. This paper argues that health

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policy is a good example to demonstrate the impact of Europeanisation of healthcare market. EU health policy is a relatively new policy area with a distinctive history (Abel-Smith, 1995; Geyer, 2000; Greer 2005) Influenced by the 1996 bovine spongiform encephalopathy (BSE) crisis in the United Kingdom and a blood contamination crisis in France (Coleman, 2004), health became a major issue at the European level in the run up to the Amsterdam treaty negotiations. In consequence, Article 152 of the 1997 Amsterdam Treaty laid the foundation for mainstreaming health policy in stating that: "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities." In 1999 the Prodi Commission created the new DG Health and Consumer Protection (DG SANCO). In 2000, health policies were integrated into the Lisbon Strategy for Jobs and Growth and health programmes were financed trough EU public health action programmes.

1.2 EU Governance

Governance is a system of rules, norms, and institutions that govern public and private behavior across national boundaries (UN Commission on Global Governance, 1995), and it occurs at different levels within the international system (Krahman, 2003). Scholars had divided the compartmentalized governance structure within the EU into three levels, depending on whether Member States had federal or unitary domestic political structures (Hooghe and Marks, 2001; Marks, 1993). The relationships between these levels of governance are complex and amorphous as local units/governments have been venues for policy innovation as well (Cairney, 2007). The literature on governance, in particular that applied to the European Union, it is predominantly descriptive and normative, and rarely rigorously analytical (Pierre, Peters, 2005). From the point of view of the actors involved, governance is a means for achieving goals. It promises to guarantee the effectiveness of policy implementation not assured by mere coercion (Héritier, 2002/ 2003). Governance is therefore a system of coproduction of norms and public goods where the co-producers are different kinds of actors (Bartolini, 2011: 8).

Multilevel governance in the EU refers to how EU institutions, the Member States, and the interaction between substate entities. International relations theories such as institutionalism, which emphasizes cooperation through common interests (Keohane, Martin 1995; Pollack, 1996), or critical

theory, which emphasizes cooperation through norms (Wendt, 1992), do not explain how established institutions incrementally share authority with their constituent Member States. The venue-shifting approach to policymaking, where policy entrepreneurs try to move decision making to favorable institutions for their goals (Baumgartner, Jones 1993; Leibfried, Pierson, 1995) cannot explain how the EU has gained authority in health policies, because EU states and substate entities have been prominent venues for national health programmes. Sovereignty has been conceptualized in three major ways: (1) international legal sovereignty, (2) Westphalian sovereignty, and (3) domestic sovereignty (Krasner, 2005; Lake, 2003). Health public policies are governed in terms of "shared soveranity". "Shared sovereignty" involves the engagement of external actors in some of the domestic authority structures of states for an indefinite period of time (Jamison, Frenk and Knaul, 1998; Krasner, 2005; Lake, 2003). According to Stephen Krasner (2005), shared-sovereignty institutions require three pre-conditions: (1) there must be international sovereignty, (2) the agreement must be voluntary, and (3) the arrangement must not ask the third party to contribute large resources. Under this arrangement, state actors have the authority to enter into agreements that would compromise their Westphalian sovereignty, with the goal of improving domestic sovereignty. While states preserve their authority to enter voluntary agreements, they cede their autonomy by pooling their resources into a multilateral organization or their commitments into an international treaty, which then become vehicles for international collective action (Jamison, Frenk and Knaul, 1998). Krasner argues that shared sovereignty could be limited to specific issue areas. States become bound by adherence to international norms developed as a result of this collective action or cooperation. In this respect, the state does not have the sole authority over policy but is disaggregated, composed of state officials, nongovernmental organizations (NGOs), judges, commissions, and concerned citizens coming together to foment change (Vaughan and Kilcommins, 2007). Phenomena such as globalization, interdependence, and regional integration have diminished the ability of states to be self-reliant, and as a result international institutions have emerged to deal with many issues that transcend national boundaries, leading to shared sovereignty. European governance is not just determined by the structural properties of the European Community system but also influenced by actor's perceptions of legitimate organising principles. (Kohler-Koch, 2005: 15) To understand the main characteristics of the European social policy governance it is important to analyse the original

procedural patterns under the EEC Treaty. The social chapter of the 1957 EEC Treaty (EECT) was based on national competence and on hierarchical relations between public and private actors, the Member States had almost exclusive competence in this area. The Commission was assigned "the task of promoting close co-operation" between Member States (Art. 118 EECT).

The EU legitimacy to act is stated in the Treaty on the European Union but it faces two major challenges: 1) the multitude and diversity of actors (at national and global level, different government departments, different organisations, different sectors, public/private, etc. and 2) different Member States health agendas (security, economic, political, social justice, soft power/philanthropy). The EU has a Treaty obligation in Art. 168 to "foster cooperation with third countries and the competent international organizations in the sphere of public health", with a particular emphasis on the regional dimension and on candidate, potential candidate and the European Neighbourhood Policy countries. The EU is committed to create better outcomes for health through "sustained collective leadership in global health". Thus, coherence between internal and external health policies, as well as the sharing of values, experience and expertise, is essential in attaining the EU's global health goals. EU's new governance system involves "a shift in emphasis away from command and-control in favour of "regulatory" approaches, which are less rigid, less prescriptive, less committed to uniform approaches, and less hierarchical in nature (Búrca, Scot, 2006: 2.3). According to the subsidiarity principles the Union has to act only "if the objectives of the proposed action cannot be sufficiently achieved by the Member States". Subsidiarity iterates that public policies should be handled by the lowest (vertical subsidiarity) or closest (horizontal subsidiarity) possible level to where they will have their effect. Regional authorities should perform only those tasks which cannot be carried out effectively at a more immediate or local level, and undertake only those initiatives which exceed the capacity of lower communities, individuals or private groups acting independently (Brugnoli et all, 2007: 64).

In conclusion, EU's action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization 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. Health policy is a

polymorphic and complex sector, a cross-cutting policy field as aspects of health policy are regulated in other policy sectors.

1.3 Health in the European Union: legal framework

"Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices". This is how the right to "Health Care" is described in the "Charter of Fundamental Rights of the European Union" agreed in Nice on 7 December 2000. One of the tasks of the Community is "by establishing a common market and a monetary union to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of social protection, the raising of the standard of living and quality of life and social cohesion and solidarity among Member States" (art. 2 of the Treaty of Amsterdam). According to Article 3 of the EC Treaty, the European Community has a broad policy mandate for health ("the activities of the Community shall include… a contribution to the attainment of a high level of health protection...") including specific tasks which are set out in Article 152. Member States health systems comprise many components all of which form sub-markets which are subject to Treaty provisions governing the free movement of goods and services. These include the market for medical manpower and the markets for pharmaceuticals, medical devices and production of healthcare services.

1.4 Member States under allocation and mediation

The state's role has moved from "authoritative allocation and mediation above to the role of partner and mediator" (Krohler – Koch, 1996: 371) regarding health issues. The recent Reform Treaty (agreed in Lisbon in October 2007) has not changed this; on the contrary, what belongs to national competence is now explicitly laid down in the new provision on health. Nevertheless, the EU has a considerable impact on health care and health law. First of all, the development of the internal market and the subsequent harmonization of law to remove obstacles to cross border traffic of goods, services and persons has had substantial consequences for several parts of health law, sometimes even marginalizing the role of national legislation. Secondly, EU policies in other fields such as fair competition, insurance law,

and consumer protection continue to have their own side-effects on the health policies. Finally, there is the potentially far reaching influence of the European Court of Justice, with its sometimes revolutionary application of the free movement principles of the EU Treaty to the health care sector.

Health issues were found as derogations for the Member States in relation to the free movement principle in the old Article 36 and Article 46 EC. The Treaty of Maastricht[1] (1992) introduced a new Article 129 EC (renumbered Article 152 EC after the Treaty of Amsterdam 1997) setting out the limited competence of the then Community to regulate the area of public health. Essentially the involvement of the EU was to complement the activities of the Member States, encouraging and promoting the coordination and cooperation between the Member States on issues which may have a cross-border effect. The former Article 152(5) EC stated that any action by the Community in the field of public health should fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care. Following Maastricht, the Commission moved quickly to develop EU public health policy. Examples included: a 1991–93 action programme against AIDS, the 1992 European drug prevention week and the 1993 public health action programme (COM (93) 559) that focused on eight main areas - cancer, drug dependence, AIDS, health promotion, health monitoring and research, pollution-related diseases, injury prevention and rare diseases. In general, by the mid-1990s, EU public health policy issue areas in almost every DG in the Commission (Abel-Smith et al., 1995: 127).

Article 168(7) TFEU (The Consolidated Version of the Treaty of the Functioning of the European Union), which is now in place since the Treaty of Lisbon 2009, also acknowledges these responsibilities, although in different wording. The Protocol [9] on Services of General Interest annexed to the TEU and TFEU by the Treaty of Lisbon 2009 emphasizes, in Article 2, that the Treaties do not in any way affect the competence of the Member States to provide, commission and organize non-economic services of general interest. The role of health care as a national responsibility in what Ferrara (Ferrara, 2005) has termed a "bounded space" with defined membership and territorial

[1] The Treaty of Amsterdam 1997 raised the profile of public health issues by adding it to the list of activities of the Community in Article 3(1) (p) EC. The new Article 152 EC also mainstreamed a "high level of human health protection" through Community policies.

scope has been challenged. The limited EU competence to legislate in the field of health care was lost in the use of the fundamental free movement provisions to create a new citizenship right to travel abroad for health care and have the costs reimbursed by the State of affiliation. Above that a process of "EU competence creep" (Van De Gronden, Szyszczak, Neergaard, Krajewski, 2011: 484) into the national health care systems is taking place. In 2002, the health action programme was developed and passed that consolidated earlier health actions and allocated €312 million to a new *2003–08 EU Public Health Action Programme* (Decision No. 1786/2002/EC). The subsequent 2007 Commission White Paper, *Together for Health: A Strategic Approach for the EU 2008–2013* (COM (2007) 630 final) and the second health action programme (2008–13) (Decision No 1350/2007/EC) was similar to the first with only a slight rise in overall funding to €321 million, averaging just over €50 million a year for public health policy for the entire EU.

The proposed Constitution for Europe promises to extend the health competency further, offering a EU competency in public health shared with member states and justified by the real problems of controlling infectious diseases and public health risks at the member state level. Article 13.2 creates a shared competence in "common safety concerns in public health matters" (shared competencies, it appears, will not put ceilings on EU activity but will allow state activity). Article 16.1 establishes the European competency for "supporting, coordinating, or complementary" action over "protection and improvement of human health.", but in practice Member States have shown little desire for EU involvement in their health services (Jorens, 2002; Hatzopoulos, 2002: 106).

The "EU competence creep" raises the question of a constitutional nature: how is at the present stage of the European integration process a balance struck between the EU and national health care powers. Resolving this question starts with pointing out that incrementally, the European Court of Justice of the European Union (ECJ) is seen as the central Institutional actor exercising considerable influence on the health care systems of the Member States. The ECJ has repeatedly stated as "a mantra" that the responsibility over the organization and delivery of health care services is the responsibility of the Member States (seen in ECJ, Case 238/82, Duphar [1984] ECR 523). In an increasingly complex environment, health has become the business not only of health ministries but of a vast range of stakeholders including purchasers of health services, professional organizations, educational institutions, donors,

industry, advocacy groups, citizens and users of health services. Governments are becoming increasingly aware of the importance of broad public participation in policy-making and the demand for duly considering public values, priorities and concerns. Good governance for health enhances the performance of health systems by improving transparency and accountability. Informing policies and programmes through evidence on the performance of health systems and the effects of implemented action are key instruments of good governance Health 2010 (Draft – WHO, Regional Office for Europe, 2011: 86).

EU Member States have chosen different ways to organize their health systems reflecting different social and economic backgrounds as well as health policy goals. Different policy instruments are used for health systems integration hard law or soft law. (Greer, 2008), but there is value in collaborating, sharing experience and information EU Member States explicitly stated that equitable, effective and high quality healthcare systems are a means of promoting both economic growth and social cohesion in the EU. The nature of the policy instruments (binding/ non-binding decisions) is modified by using soft law in particular. The growing use of soft law has been widely identified as a way of steering without coercion, leaving broad ranges of autonomy to EU institutional actors, member states and private actors with regard to the implementation of measures and to their individual adjustment to common objectives. (Diedrichs; Reiners; Wessels, 2011: 24).

According to Stoker (1998) national governance could be described with five broad characteristics:

1. It refers to a complex set of institutions and actors that are drawn from but also beyond government;
2. It recognizes the blurring of boundaries and responsibilities for tackling social and economic issues;
3. It identifies the power dependence involved in the relationships between institutions involved in collective action;
4. It is about autonomous self-governing networks of actors;
5. It recognizes the capacity to get things done which does not rest on the power of government to command or use its authority. It sees government as able to use new tools and techniques to steer and guide.

EU Member States health systems have evolved individually over a long period of time and are based on very different organisational patterns and

principles. According to the OECD classification heath systems are referred to as Bismarckian where they involve social insurance and third party payers providing reimbursement insurance (Luxembourg, France, Belgium) or benefits-in-kind (Germany, Netherlands); or as Beveridge systems where funding is predominantly through taxation (Central and Eastern Europe).

Health is an good example of the interconnected policy-making required in the 21st century, not only because of the need to address the health determinants but also because it is clearly a so-called "wicked problem" (Kickbusch; Bucket, 2010: 16-18). Health policy is characterised by an explicit concern for health and equity in all areas of policy and by accountability for health impact. The main aim of healthy public policy is to create a supportive environment to enable people to lead healthy lives. The European Union, is facing a particularly complex governance challenge, has made explicit its notion of good governance in general terms. In the health arena the EU has being accumulating a number of "genetic" and "developmental" difficulties: an artificial distinction between "public health" and the other components of the health system, an ambitious treaty obligation to assess the impact on health of other policies with very limited practical application this far, a European Court of Justice driven policy on patient mobility. The political sensitivity of EU institutions might explain why the EU is taking a less than active role in contributing to monitoring and evaluation of health governance. (Kickbusch, Bucket 2010) The roots to considering the health aspects of the Community policies go back to the 1950s, when occupational health and safety were put on the agenda of the European Coal and Steel Community.

Governance in the European Union is "multi-level", in the sense of involving interactions between sub-national, national, EU, and transnational institutions and actors. The EU's constitution operates in a "top-down" mode, with distinct spheres of competence between EU institutions and those of the Member States and regional or local actors. According to Flinders (2002), the notion of governance refers to the challenge to take on the direction and coordination of a complex ensemble of organizations through a control system built upon many links. The key elements for good governance could be presented as follows: (Louise St-Pierre, 2005:14).

- The inclusion of several actors from both inside and outside the government;
- The use of horizontal and vertical management;

- Accountability and control mechanisms;
- High-level political commitment;
- Financial and human resources support;
- Skills development;
- The existence of knowledge production systems.

2. Europeanisation of Health Policies

2.1 Institutionalization of policy styles

Academics have focused increasing attention on the nature of European institutions and their impact on those of Member States, they to tend to disagree over whether the EU is a collection of unitary states (Taylor, 1991; Moravscik, 1991; Garrett, 1992), or as a quasi-federal state (Sbragia, 1993: 28; Schmidt, 1997; Kohler-Koch, 2005). Europeanisation will be defined as: Processes of (a) construction, (b) diffusion, and (c) institutionalization of formal and informal rules, procedures, policy paradigms, styles, 'ways of doing things', and shared beliefs and norms which are first defined and consolidated in the making of EU public policy and politics and then incorporated in the logic of domestic discourse, identities, political structures, and public policies. (Radaelli, 2003: 30).

By exploring the Europeanisation of health policy I follow the assumption that the system of governance in the EU serves as an institutional setting to maintain governmental autonomy regarding societal actors, including the control over which other actors will be granted access in given functional contexts, there would obviously be limitations to more horizontal modes of governance in the EU. Under the conditions of globalisation and growing economic interdependence, Member States lose their problem-solving capacity, which they try to redress, on a higher level of aggregation, by establishing new forms of joint governance in the form of integrated policy-making structures. Healthcare integration is characterized by a fragmented degree of coerciveness.

As a field of integration, healthcare is institutionalized in a scattered way, in the sense that it lacks the binding knots of political commitments. However, it is a field of integration which demonstrates the powerful role of law in transcending high spirited, but inconcrete, principles, such as the free

movement of services and Union citizenship, into effective tools of governance. (Martisen, 2008: 171).

Europeanisation has developed many facets (Olsen, 2002/2003) and has been used to explain a confusing range of heterogeneous phenomena and processes of change (Radaelli, 2000). Despite a possible risk of "conceptual stretching" (Sartori, 1970) The case under study illustrates at least four (interrelated) perspectives of the Europeanisation of health policy, that is, Europeanisation: (1) as supranational institution building; (2) as affecting domestic politics, polities, and public policies, and as such changing domestic opportunity structures; 3) as a dynamic intertwining of top-down and bottom-up processes including two tiered games, feedback loops, and unintended outcomes; and finally, (4) as a diffusion of European policy paradigms and integration requirements throughout national policy debates and arenas by shaping problem perceptions and framing policy solutions. European integration is characterized by a fundamental asymmetry which can be described as a dualism between supranational European law and intergovernmental European policy-making.

Health policy is a dazzling and complex policy sector: it is a service sector (personal services, and health professionals, service providers, purchasers) It is a highly regulated market for goods (pharmaceuticals, remedies, medical equipment). It is a cross-cutting policy sector, 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" (Lamping; Steffen, 2004). 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 been affected by European policy-making: single market compatibility, coordination, and harmonisation. Although it is clear that the national health care systems are not immune for EU law, the Europeanisation process, which these systems are subject to, have a sophisticated nature: as the famous Echternach procession two steps forwards are followed by one step backwards. (Gronde; Szyszczak, 2011: 448). How can Member States shape national health care systems in a way that they could ensure the proper reception of the EU rules on free movement, procurement, harmonisation, competition and European citizenship? In other words how should the second pillar of governance (EU law) be placed on the first pillar of governance

(national health care system)? First, the competent national authorities must base their interventions on strong and logic ("consistent") causal links between the measures to be taken (such as planning) and the objectives to be attained (such as universal coverage). Europeanisation of health policy it is "chaordic," a term borrowed from Hock (Hock, 2000) denoting a combination of chaos and order. The Europeanisation of health policy, this particular combination of chaos and order results from at least three factors: the existence of both national and European authority over various aspects of the health policy field; particular characteristics of the health sector; and rather ambiguous treaty provisions**.**

Regarding the treaty, Hervey (Hervey, 2007: 1) concludes that, at first glance, there is "nothing [that] would touch national health policies or their fundamental values and principles" (Martinsen, 2005: 1036), argues that health policy is the "less likely policy field" for discussing Europeanisation effects. Greer analyzes the EU impact on national health-care systems as "uninvited Europeanisation" (Greer, 2006). He identifies specific "critical junctures" (Greer, 2008) for the development of EU policies in the health-care sector. Treaties provide the EU with only restricted responsibilities and competencies in marginal areas of health policy, member states have exclusive policy rights: Article 152 of the Treaty Establishing the European Community (TEC) and the Treaty of Lisbon concede that "European Union action in the field of public health shall fully respect the responsibilities of the member states for the organization and delivery of health services and medical care" (TEC, Art. 152 No. 5 and Treaty of Lisbon, Art. 152 No. 7). Direct influence of the EU on financing and delivery of medical care, that is, on the core of the national "health-care states" (Moran, 1999), has thus been formally excluded from the policy mandate of the EU. There are, however, explicit exceptions: cross-border social security rules are under the competence of the EU (TEC, Art. 42), and Article 3 of the TEC raises the protection of health to the rank of a Community objective. The EU Charter of Fundamental Rights states that "everyone has the right of access to preventive healthcare and the right to benefit from medical treatment." The EU also has to perform specific tasks foreseen by Article 152 of the TEC (and extended by the Treaty of Lisbon) in the broad field of public health. Furthermore, the European Court of Justice (ECJ) confirmed on several occasions that health systems are part of the "single market." The internal market regime is therefore basically applicable to them,

although Member States try to keep the EU out of social policy and particularly to protect their health policy competency. Finally, the Commission has clarified the issue as follows: "Respecting national responsibility for health systems does not mean doing nothing at European level" (Communication of the Commission (COM) 2004/301:16).

The Treaty explicitly introduces monitoring and evaluation approach as an integral part of health policy emphasizing the need for systematic collection and analysis of information on processes and impact of public health actions. Having a more robust legislative basis will enable the European Commission, in close contact with the Member States, to promote initiatives aiming at the establishment of guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. Collaboration between European countries in activities aimed at:

- fostering elaboration of common indicators for assessing outputs and outcomes;
- establishment of frameworks for systematic
- reviewing needs; and regular monitoring of activities and periodic evaluations of outcomes in areas of health promotion and prevention and control of diseases.

Achieving a whole-of-government approach to intersectoral working requires more than a simple mandate. Evidence indicates clearly that institutional mechanisms are required. A clear shared strategic societal narrative on health is needed, with the objectives of embedding health and health equity into the main government strategies and financial mechanisms; stimulating debates in parliament and in cabinet committees and the mass media; and ensuring clear and multiple-stakeholder mechanisms for accountability. The available possibilities here include arms-length independent bodies, formal consultative groups and making documents and decision-making processes and outcomes widely available for debate. (Health 2020, 2010) National health ministries coordinate different types of activities as part of their health system stewardship capacity: they define a vision for health, and strategy and policies to achieve better health; they exert influence across all sectors of government and advocate for better health; they ensure good governance supporting the achievement of health system goals; they ensure the alignment of the health system design with goals pursued; they make use of legal, regulatory and policy

instruments to steer health system performance; and they collect, disseminate and apply appropriate health information and research evidence. (WHO, 2000)

The Europeanisation process in this policy field is direct and mainly crisis driven in the area of public health, where the EU now holds a clear mandate and is actively engaged in institution building, with DG SANCO as a key player. It is indirect and mainly law driven in the area of healthcare and services, where most of the EU interventions borrow legitimacy from other policy fields and mandates, mainly from the four freedoms (for the circulation of goods, services, capital and labour within the European Union) and the European competition regime, with the Commission and the ECJ as leading actors. It is politically driven in the newly Europeanised areas of health expenditure, coverage, and access, where the OMC (Open Method of Coordination) is sought to constitute a forum and procedure of cooperation and coordination. It is also politically driven, but under the leadership of professionals and scientific expertise, in sensitive areas with important national differences and trans-sectoral implications, such as bioethical policy. During the European Council of Lisbon, in March 2000, OMC was introduced in the context of the long-term aim to develop the knowledge-based economy, in tandem with increased social cohesion and employment, both qualitatively and quantitatively (Council of the European Union, 2000: 4) The OMC it is a post-regulatory approach to governance, in which there is a preference for procedures or general standards with wide margins for variation, rather than detailed and non-flexible rules and legislation.

EU Treaties which are the definitive statements on the scope of European law state explicitly that health care is a responsibility for Member States. Thus, health systems involve interactions with people (staff and patients), goods (pharmaceuticals and devices) and services (health care funders and providers), all of whose freedom to move across borders is guaranteed by the same Treaty, it is increasingly apparent that many of their activities are subject to European law. The European Union (EU) has both economic and social goals and, since the Treaty of Maastricht, it has been required to "contribute to the attainment of a high level of health protection".

In order to resolve this apparent puzzle, it is necessary to examine the underlying constellation of interests among governments represented in the Council of Ministers? Unanimous or qualified-majority voting rules institutionalize veto positions - and it is analytically true that, ceteris paribus, the

existence of multiple veto positions reduces the capacity for political action (Tsebelis, 1995) The Europeanisation process is thus developing as an issue-specific, fragmented, and incremental process, necessarily technocratic and patchy, but quite consistent. Some authors are more sensitive to the fragmented aspects of the process or to the absence of explicit policy decisions. Daly insists on "what seem at best loosely connected fields" (Daly, 2007: 1), while others, such as Ferrera, stress out the constant process of "incremental social supra-nationalism" (Ferrera, 2005: 239).

Article 152 of the TEC specifies that actions in the public health area should contribute toward ensuring a "high level of health protection throughout the Union" by preventing human illness and disease, eliminating sources of danger to health, and ensuring that all European policies are compatible with health protection (Hervey, 2002). Since the mid-1990s, the Commission has promoted an EU-wide dialogue on health issues. In May 2000, it proposed a new health strategy based on the "Programme of Community Action in the Field of Public Health," including a precise schedule covering first the period 2001–2006 and then, in a renewed plan, the period of 2003–2008. The expansion of powers and provisions has often been a crisis-driven and haphazard process of competence accumulation at the Community level. In this process, the Commission, particularly the restructured DG "Health and Consumer Protection" (DG Sanco), has provided political leadership. Outbreaks of communicable diseases, like AIDS (Steffen, 2004), CJD, SARS, and BSE1 (Krapohl, 2004; Vincent, 2004), and other potential threats to public health on a European scale, including "bioterrorism" (COM 2003/320), opened up temporary windows of opportunity. They gave the Commission the chance to actively organize cooperation among Member States, which eventually allowed it to further centralize competencies and to establish intervention capacities at the EU level. The cross-cutting nature of public health issues provides room for the "treaty based game" (Rhodes, 1995). According to Rhodes (1995) "treaty base game" describes the process of transferring topics and borrowing legitimization from other treaties, as illustrated by the avian flu case, when public health legislation (2005/94/EC) was based on the EU common agricultural policy.

The establishment of a comprehensive EU-wide regulatory framework for the collection, manufacture, and supply of blood, plasma, and blood products has become a significant part of growing EU competence and influence in public health governance. Health policy is a striking example of the

Commission's capacity to turn "constraint into opportunity by becoming a "network" organization, working with and through public and private bodies within the member states and at EU level" (Laffan, 2002: 123).

2.2 Health without borders: Health in all policies?

The EU Health Strategy adopted in 2007 "Together for Health: A Strategic Approach for the EU 2008-2013" sets out the EU principles for global health policy. The principles include recognizing the links between health and economic prosperity, taking a value-driven approach, integrating health in all policies, and strengthening the EU's voice in global health. The need for a new approach to health governance in 21st century that builds on intersectoral action and health in all policies. Health-in-all-policies is a horizontal, complementary policy-related strategy with a high potential to contributing to population health. The core of health in all policies is to examine determinants of health, which can be influenced to improve health but are mainly controlled by policies of sectors other than health. This concept clearly builds on the first two waves of collaborative approaches highlighted in primary health care and health promotion, drawing on their strengths and learning from their shortcomings. It is an innovative policy strategy that responds to the critical role that health plays in the economies and social life of 21st century societies in ways that take it beyond intersectoral action and healthy public policy. Horizontal health governance has become a dynamic and partnership-based policy process that is no longer driven only by the health sector but by a larger agenda that includes the contribution by health to other sectors. (WHO: 1997) HIAP is a concept that already underpins work on health at the European level. Under article 168 of the Treaty, the EU is required to make sure that "a high level of health protection [is] ensured in the definition and implementation of all Policies and Activities of the Union". Health-in-all-policies (HIAP) approaches will be further encouraged and promoted at all levels, including through giving Member States new opportunities to network, share experience and best practice, with the aim of supporting increased intersectoral cooperation in the field of health. The use of HIA (Health Impact assessment) and HSIA (Health Systems Impact Assessment), is already recognised as part of the Commission's Impact Assessment mechanism also in reference to encourage health-in-all-policies in third countries. Health impact assessment

merits particular attention in this section dealing with governance tools, because it is considered one of the most structured approaches to integrate health in all policies (HiAP) (Lock, 2000; Sim, Mackie, 2003) The health impact is "a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population" (WHO European Centre for Health Policy, 1999) in other words can be considered a governance tool, since it fosters interaction between public administration sectors and encourages "boundary works" (Bekker, 2007).

Important examples of the whole-of-government approach for health in all policies in Europe can be found in England, Finland, France, the Netherlands, Norway and Sweden. These countries use combinations of governance tools such as policy formulation, target setting, public health laws, cabinet level coordination, interdepartmental committees, horizontal and vertical coordination mechanisms, public hearings, cross-departmental spending reviews and new forms of intelligence provision in a relatively coherent government framework. A study showed (WHO, 2005) that 40 out of the 52 WHO European Region Member States had formulated HFA-style policies by 2004. Although the organisation and delivery of health services remains primarily a responsibility of the Member States, the EU also has a range of responsibilities in the field of global health. The EU's role is to complement national policies although in some specific areas it has explicit authority to legislate (early warning and response to communicable diseases, quality and safety of substances of human origin, organs, blood and blood derivatives, food and product safety, veterinary and plant health measures directly aimed at public health). The European Commission has a Treaty obligation in Article 168 to "foster cooperation with third countries and the competent international organisations in the sphere of public health".

Healthcare is viewed as a as part of the services provided in the (national) general interest, and is a public good. (Ostrom, 1990) Free movement, competition and public procurement law are the main areas which invite clashes between national health care policies and EU law, but the potential range is even wider, touching upon citizenship and discrimination issues, human rights and data protection. Health policy in the European Union raises important arguments: first, is the self-interest of the 27 Member States: for the EU to exercise a wider role in health policy would require a new Treaty provision. It would necessarily be one that recognised public health as a

multidimensional concept – both in theory and practice – rather than a "low" policy field, limiting it only to tackling specific diseases and "taking health into account in other Community policies" (Mosalios, 2001: 21) On other hand, the duality or competence-sharing between the EU and Member States where health policy is concerned is captured in the understanding of European law as supranational and European policy-making as intergovernmental.

3. Health Market a Double Dynamic?

Health is not a typical market and health care systems carry in themselves economic as well as social elements. The importance of health to the individual, and the need for Member States to ensure equitable access to health care across their populations, gives rise to a form of market which is not easily subject to the competitive model. The internal market shall comprise an area in which the free movement of persons, services, goods and capital shall be assured in accordance with the Constitution (Article III - 14).

Health care is considered an economic activity (transaction against remuneration) falling under the scope of free movement. The specific nature of (statutory) health care does not remove it from this ambit. The free movement and competition requirements of the internal European market may sometimes conflict with national interests around these high-employment and export-orientated industries, and around the setting of prices and reimbursement rates for social security schemes. Consequently, case studies by Permanand and Mossialos (2005) and Kotzian (2002) show a complex picture. This deadlock "stem[s] primarily from a dissonance between the principle of subsidiarity, which enables national governments to determine healthcare policy, and the free movement goals of the single market, under which medicines are treated as an industrial good" (Permanand; Mossialos, 2005: 49). The creation of the single market has a dual role in the development of an EU health policy framework. First, as it enables the Community to regulate only in areas such as: patient movement across borders within the EU, the establishment of a system for the mutual recognition of professional qualifications or pricing, reimbursement of pharmaceuticals and voluntary health insurance. Second, the European single market has served as an

important magnet securing intergovernmental agreement on the economic aspects associated with health policy in Europe.

According to European Union's legislation patient mobility and cross-border healthcare cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued (Directive 2011/24/EU). Even if Member States have sought to limit cross-border usage in order to limit its potential for health tourism (Hervey, 1998: 147–150) patients have Treaty-based rights to a treatment anywhere in the EU, funded by the home member state if the treatment would have been funded at home by the member state of residence and the reimbursement of medical costs.

Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. Furthermore, the trans-position of the European directives into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation. The obligation of reimbursement of cross-border healthcare, it is limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation. The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several rulings. For example, the Kohll and Decker cases[2] created a second avenue of cross-border health care in addition to Regulation 1408/71, patients could from then on seek medical treatment in another Member State at will, rather than at the discretion of their domestic insurance institutions. Discussion about access to health care abroad has traditionally been based on the principle of free movement of people within the EU, but in 1998 the ECJ was required to assess the rules regarding access to health care abroad in the light of the free movement of goods and services. In refusing to reimburse Kohll and Decker for the treatment received abroad, the Luxembourg government had relied

[2] The Kohll and Decker rulings of the ECJ concerned two persons insured under the Luxembourg social security system who had obtained orthodontic treatment in Germany (Raymond Kohll) and spectacles in Belgium (Nicolas Decker) and wanted to be reimbursed by their health insurance fund in Luxembourg, even though the fund had not previously authorised their treatment abroad (135), (136). (EC Treaty).

upon the national rules incorporating EC Regulation 1408/71 into Luxembourg law. The Kohll and Decker rulings established clearly, for the first time, that the economic rules regarding the free movement of goods and services within the EU can be applied to social security systems.

Under the Lisbon process[3] newer forms of governance have emerged. Like the Single Market Programme these were linked to a deadline and an objective but unlike that programme, the governance methods, captured under the umbrella term "the open method of coordination" (OMC) were primarily based on policy learning, reporting and the issuance of guidelines all firmly within the realm of soft law which may or may not result in binding legal measures.

Post regulatory approach, the open method of coordination, is applied in health policy only very carefully and gradually from 2004 onward, the OMC has above all enabled the Commission to switch from "aggressive leadership" (Wendon, 1998: 59), unlikely to work in the health sector, to a softer and somewhat ideational political leadership. This type of political leadership has in any case been developing generally, as Borras (2009) argues, since the reform of the Lisbon strategy in 2005. The OMC strategy helps the Commission to circumvent many of the obstacles to supranational regulation of the health-care sector identified in this article. These obstacles range from weak official legitimacy, a vague policy mandate, and lack of political consensus (Member State interest in own health policy), to weaknesses in policy coherence and policy formulation resulting from the intergovernmental system of negotiation as well as the internal structure of the health policy sector.

The main objective in health policy field is enhancing the governance of health systems to improve accountability and performance (Health 2020, Draft – WHO, Regional Office for Europe, 2011), therefore, the Health 2020 programme sets up strategic orientations:

[3] The objective articulated by the European Council in Lisbon in 2000 was to make Europe the most competitive and dynamic knowledge-based economy in the world, capable of sustaining economic growth with more and better jobs and greater social cohesion with a deadline of 2010. This has now been reduced to growth and jobs and the deadline has been dropped, generally EC Commission, *Delivering on Growth and Jobs: A New and Integrated Economic and Employment Co-ordination Cycle in the EU*, SEC(2005) 193, 3 February 2005.

- Working together for health and wellbeing in the European Region – Member States, international strategic partners, public health constituencies;
- Committing to a whole-of-government approach for health and wellbeing;
- Strengthening leadership for health and wellbeing and ensuring that all sectors understand and act on their responsibility for health;
- Upholding the right to health and a value-based approach to action for health and wellbeing;
- Tackling the health divide between and within countries;
- Investing in governance for health and wellbeing that reflects the realities and needs of the 21st century;
- Investing in solutions that work and are appropriate for Member States in different circumstances, to address the public health challenges of the European Region;
- Integrating strong evidence-based economic arguments to advocate for and support action on disease prevention and inequalities;
- Mobilizing action at country, inter-country and European levels for tackling the chronic diseases epidemic;
- Preparing and dealing effectively with emergencies;
- Ensuring high-performing, outcome-oriented and transparent health systems.

Since the late 1990s, DG Sanco[4] has shown determination in agenda setting and problem framing, and in confronting governments with elaborate policy proposals. Success depends on DG Sanco's ability to build supra- and transnational supporting coalitions in order to increase both its legitimacy and its political influence.

Regarding the Europeanisation of public health single market I my argue about a double dynamic. First, a positive integration - the Member States harmonisation of secondary legislation (Directive 36/2005 on the recognition of professional qualifications; Regulation 883/04 on the coordination of social security systems; Third non-life insurance Directive 49/92; Transparency

[4] Health benefited from a two-fold shift of competences within the Commission: the transfer of competence for food from the Agriculture and Fisheries Directorate to the Directorate for Health and Consumer Protection, and the internal reorganization of the latter.

Directive 89/105 on the pricing and reimbursement of medicinal products), and second, a negative integration by the direct application of Treaty rules. Positive integration requires the introduction of an active, supranational policy. Typically, the EU has negotiated a policy template, and the task is to put it into operation in the Member States (Radaelli, 2003). The Commission has to ensure that legislation is properly implemented, and it can refer governments to the ECJ if necessary, thus the supremacy of European law is indicator of the hierarchical nature of arrangements. By contrast with positive integration, negative integration relates to sectors where the removal of national barriers suffices to create a common policy.

The four freedoms and the single market competition law (negative integration) define the conditions for market access and market functioning and aim at abolishing legal prohibitions against national regulations that might function as barriers to the free movement, or as distortions of competition between Member States within the EU. 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, "Europe of Health"[5], although one not politically created.

4. Conclusion

This paper argued that the health governance it is as a contested mechanism of coordination, therefore we acknowledged a double discrepancy: economic policies and single market regulations are now decided at the European level when social policies are still formally decided at the national one; economic policies are now based on a neo-classical, supply-side approach when national social policies and programmes are still linked with demand-side approach. The contradictory picture is related to the existence of national and EU competency over different domains of the health policy field. This paper identifies a growing European health policy compound characterized by new,

[5] Byrne, Commissioner for Health and Consumer Protection, at the European Health Forum, Bad Gastein, 3 October 2003 (SPEECH/03/443).

complex, and often overlapping responsibilities between the national and supranational levels. It conceptualizes the Europeanisation of health policy as a differential, multiple, but accidental process. The evolution of modes of governance in the health sector reveals a complex and multifaceted picture characterized by overall systemic dynamics. Summing up, the impact of major Treaty reforms and European recommendations in the healthcare field affect the European Union on its legal and living architecture. It is also clear that there are not two distinct processes at work here, but that domestic health law influences European health governance and that European health governance influences domestic health law. Even though European healthcare systems still formally appear to be national, European integration has reduced the policy margin Member States can effectively use when regulating their healthcare sector. Up to now the integration of health policies in the EU policy framework has been a juristic process (negative integration) and Member States remain hesitant to actively shape European health policies.

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