Articles
Special Section – Policy Coordination in the EU: Taking Stock of the Open Method of Coordination

The OMC Processes in the Health Care Field: What Does Coordination Really Mean?

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Abstract: More than fifteen years after the introduction of the Open Method of Coordination (OMC), it is necessary to assess the practical implementation of this tool. It is a subject of major interest that has inspired numerous studies in the framework of the Lisbon Strategy, but the attention focused on the OMC has diminished during the past few years, particularly with the deepening of the economic governance of the EU. This trend needs to be addressed in order to understand the actual meaning of the OMC and its relationship to the main features of EU law. The policy field of public health is an appropriate approach for a retrospective assessment of the OMC. Originally conceived as a single method, designed to promote flexible convergence on general objectives concerning the sustainability and quality of care, policy coordination in the health care field has gradually become more complex. It has now become more appropriate to consider several processes of coordination, each one with its own rationale, rather than a single method which can be qualified as an "OMC". This *Article* discusses this evolution.

Keywords: open method of coordination – health policies – new modes of governance – policy coordination – economic governance – soft law.

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I. Introduction

The Open Method of Coordination (OMC) was gradually introduced in the health care field in 2004. Since then, its implementation has undergone substantial changes that reflect a more general evolution of the OMC within the EU legal system. To understand these changes, it is necessary to discuss the challenges raised by a legal analysis of the OMC (Section II), to assess the trajectory of the OMC in the field of health care within the EU legal system (Section III) and, finally, to consider the renewal of the OMC as a specific tool (or not) for the coordination of Member States' health policies (Section IV).

II. General challenges for legal analysis of the Open Method of Coordination

Among the community of European lawyers, the OMC is often seen as an enigma. At the dawn of the 2000s, the introduction of this new policy coordination tool gave rise to a substantial body of literature. The OMC's novelty, its link with the popularity of theories on new governance,[1] and its "softness" in comparison with the "traditional" community method can explain, among others, the bulk of studies on it.[2] These features can also explain the enthusiasm that characterized the first studies dealing with the OMC, which portrayed it as a "third way" between pure integration and the simple logic of cooperation[3] or as a suitable instrument for realizing "integration by cooperation".[4] The OMC was thus initially considered as an alternative tool to the formal harmonization of national laws, but its link to others features of the relationship between EU law and national law was unclear as several qualifications (coordination, cooperation, convergence) were concurrently used with regard to it. Moving beyond these initial assessments, two issues need to be raised: on the one hand, the discrepancy between the conceptualization of the OMC and the traditional features of EU law (II.1); and on the

[1] There is an obvious proximity between the conclusions of the Lisbon European Council in March 2000 and the presentation of the White Paper on Governance regarding the search for new forms of production of norms. See Commission, *European Governance – A White Paper*, COM(2001) 428 final.

[2] It would be impossible (and illusory) to list here the numerous articles on the OMC, but selected studies can be mentioned, such as: J. Scott, D.M. Trubeck, *Mind the Gap: Law and the New Approaches to Governance in the European Union*, in *European Law Journal*, 2002, p. 1 *et seq.*; C. de la Porte, Ph. Pochet (eds), *Building Social Europe through the Open Method of Co-ordination*, Brussels: PIE-Peter Lang, 2002; J. Zeitlin, D.M. Trubek, *Governing Work and Welfare in a New Economy: European and American Experiments*, Oxford: Oxford University Press, 2003.

[3] See, for instance, for the European Employment Strategy: J. Kenner, *The EC Employment Title and the Third Way: Making Soft Law Work*, in *The International Journal of Comparative Labour Law and Industrial Relations*, 1999, p. 33 *et seq*.

[4] P. Magnette, *L'intégration par la coopération. Un nouveau modèle de construction européenne?*, in P. Magnette, E. Remacle (eds), *Le nouveau modèle européen*, Bruxelles: Éditions de l'Université Libre de Bruxelles, 2000, pp. 25-29.

other hand, the significant decrease in references to the OMC in EU official documents (II.2).

II.1. The OMC and the specificities of the EU legal system

More than fifteen years after the implementation of the OMC, a retrospective look reveals a paradox, as if the significant number of studies on the OMC was inversely proportional to the degree of certainty in or knowledge of the topic. In fact, before examining the OMC in the light of EU legal considerations (such as its relationship with the principle of the distribution of competences, the relationship of hard law with soft law and the type of norms which are at stake, e.g. binding, non-binding), it is necessary to identify the relevant analytical framework. Initially, the OMC's analytical framework was deeply inspired by the methods of the sociology of law and law in context, with a specific focus on institutional discourse and the channels of influence of EU law on national policy-making. In itself, this theoretical framing can find strong justifications. Underlined by a broad conception of EU law, which contrasts with a purely normative and formal delimitation of EU law (perceived as the law of the treaties, the norms of secondary law and the case law of the Court of Justice of the European Union), such a theoretical framing allows for a dynamic understanding of European integration.

However, such an open conception of EU law raises substantial issues, related to unanswered and unavoidable questions on the boundaries of law and the delimitation of the scientific field to which the notions and concepts at stake (such as "coordination" or "convergence") belong. It is, therefore, useful to put some distance between the study of the OMC and the discourses linked to the theories on the so-called new modes of governance, at least to better identify the share of the law (*la part du droit*) that is contained in the OMC.[5] This assessment is consistent with a number of current studies dealing with the transformation of EU law in the context of the deepening of EU economic governance.[6] Paraphrasing the famous formula of the sociologist Pierre Bourdieu, such distance is also useful for understanding "what coordination means".[7]

[5] See, on the ebb and flow of theories on new governance, M. Dawson, *Three Waves of New Governance in the European Union*, in *European Law Review*, 2011, p. 208 *et seq.*; the general and retrospective study by D. Georgakaki, M. de Lasalle, *The Political Use of European Governance: Looking Back on a White Paper*, Opladen: Barbara Budrich, 2012, p. 193; F. Peraldi-Leneuf, S. de La Rosa (eds), *L'Union européenne et l'idéal de la meilleure législation*, Paris: Pedone, 2013, and especially S. de La Rosa, *Les significations évolutives du programme mieux légiférer*.

[6] See, M. Dawson, H. Enderlein, C. Joerges (eds), *Beyond the Crisis. The Governance of Europe's Economic*, in *Political and Legal Transformation*, Oxford: Oxford University Press; S. de La Rosa, F. Martucci, E. Dubout (eds), *L'Union européenne et le fédéralisme économique*, Bruxelles: Bruylant, 2015.

[7] Freely adapted from the well-known title, P. Bourdieu, *Ce que parler veut dire. L'économie des échanges linguistiques*, Paris: Fayard, 1982.

This need for clarification of the OMC and its legal share is not a superficial prerequisite, neither is it meant to establish divisions within European studies, which obviously require cross-analysis through the mobilization of different scientific fields: law, political science, economy or sociology. But, there is certainly a need to study and to assess the OMC from the perspective of the EU legal order, if only in order to understand whether this tool follows a different rationale from the general rules of EU law or whether it is consistent with them. According to settled case law, the EU legal system is conceived as an independent source of law, enjoying primacy over the law of the Member States, and the direct effect of a whole series of provisions that are applicable to the Member States and to their nationals. These elements are intrinsically linked with the preservation of fundamental rights, respect of which is a condition of the lawfulness of EU acts. They are requirements that are deeply established – from the *Costa* judgment to the most recent Opinion 2/13 on the accession of the EU to the European Convention on Human Rights – to identify the specificities of the EU legal order and to enable a common understanding of them.[8]

It follows from these classical features of the EU legal order that assessment of the OMC, including in the field of health care, must be conducted through processes such as identifying the relevant legal bases, their consistency with the principle of the distribution of competences, the articulation of the OMC with the principle of legal certainty and compliance with fundamental rights.[9] More broadly, the OMC must be examined through the requirements for a Union based on the rule of law, "inasmuch as neither its Member States nor its institutions can avoid a review of the question [of] whether the measures adopted by them are in conformity with the basic constitutional charter, the treaty".[10]

II.2. A trend toward fewer OMC references

In examining the incorporation of the OMC in to the EU legal system a gap must be acknowledged and considered. There is an obvious discrepancy between the number of studies on the OMC and the qualification and uses of the OMC in EU law, both in primary and secondary sources of law. An explanation can be found in the fact that a significant part of the literature on the OMC, consistent with the momentum of the European Commission's White Paper on Governance at the beginning of 2000, portrayed the OMC as excessively autonomous by disconnecting it from EU law and the requirements of

[8] Court of Justice, judgment of 15 July 2004, case 6/64, *Flaminio Costa v. Enel*; Court of Justice, opinion 2/13 of 18 December 2014.

[9] On this see S. de La Rosa, *La méthode ouverte de coordination dans le système juridique communautaire*, Bruxelles: Bruylant, 2007.

[10] Following the well-established formula since the landmark case *Les Verts*, Court of Justice, judgment of 23 April 1986, case C-23/83, *Parti écologiste les Verts v. European Parliament*.

the rule of law.[11] This favoured the formation and edification of an autonomous body of literature on the OMC, which is built on cross references and which is often detached from the reality of the qualification of the OMC by EU law itself.

A simple search in Eur Lex demonstrates this trend. It is widely recognized that the historical systematization of the OMC took place through the conclusions of the Lisbon European Council, which extended the legal rationale of the Treaty's provisions on employment (Art. 148 TFEU, formerly Art. 128 of the Treaty establishing the European Community (TEC))[12] to several policies with a link to the economy of knowledge (i.e. education, digital literacy, the promotion of small and medium enterprises, and so on).[13] At that time, in 2000, the OMC was broken into four phases: the definition of guidelines associated with specific timetables, the establishment of quantitative and qualitative indicators in order to analyze best practices, the translation of the guidelines into national and regional policies, and monitoring and evaluation organized through peer review.[14] Following the Lisbon Strategy, the wording "open method of coordination" can be found, through Eur Lex, in 29 references in 2000, 78 in 2001, 107 in 2002, 127 in 2003 and 112 in 2004. Of course, these results have to be qualified depending on the legal nature and function of the measures in which the selected references are made. If one excludes opinions and written questions by EU parliamentarians, the data are less regular, with, for example, 26 references to the OMC in Communications from the Commission in 2001, 33 in 2002 and 43 in 2004. What undoubtedly needs to be noted is the significant decrease in formal references to the OMC at the end of the 2000s, which become rare after the endorsement of the post-crisis legal framework, with the Six Pack

[11] White Paper on European Governance, cit.

[12] Introduced by the Treaty of Amsterdam, Art. 148 TFEU was initially the basis of the European employment strategy and provided the main features of the OMC process: endorsement of guidelines which the Member States shall take into account in their employment policies, preparation by the Member States of annual reports on the main measures taken to implement employment policy, annual examination by the Council and the Employment Committee of the implementation of the employment policies of the Member States, annual endorsement by the European Council of an annual report jointly prepared by the Council and the Commission.

[13] European Council Conclusions of 23-24 March 2000, especially paras 12 and 13 (Establishing a European area of research and innovation), paras 14 and 15 (Creating a friendly environment for starting up and developing innovative businesses), paras 25 to 27 (Education and training for living and working in the knowledge society).

[14] It is generally considered that the seminal definition of the OMC can be found in the conclusions of the Lisbon European Council, at para. 37, which states: "fixing guidelines for the Union combined with specific timetables for achieving the goals which [the Member States] set in the short, medium and long terms; establishing, where appropriate, quantitative and qualitative indicators and benchmarks against the best in the world and tailored to the needs of different Member States and sectors as a means of comparing best practice; translating these European guidelines into national and regional policies by setting specific targets and adopting measures, taking into account national and regional differences; periodic monitoring, evaluation and peer review organized as mutual learning processes".

and the Two Pack.[15] For instance, in 2016, only five documents made references to the OMC, with a single Commission Communication referring to it.[16]

This downward trend of OMC references in EU official documents can also be observed in the field of health care. In 2004, the Commission set up a specific process, designed as a kind of extension of the OMC for social inclusion, with the purpose of fostering convergence of national health policies on three main objectives: universal access to care, high quality of care and financial sustainability of care.[17] The process was essentially aimed at sharing experiences and comparing national practices to address common challenges such as the ageing of society, end of life care, the need for technology, and so on. In its Communication, the Commission insisted on the complementarity of Member States' policies and the ancillary actions of the EU, noting: "Responsibility for the organization and funding of the health care and elderly care sector rests primarily with the Member States, which are bound, when exercising this responsibility, to respect the freedoms defined and the rules laid down in the Treaty. The added value of the 'open method of coordination' is therefore in the identification of challenges com-

[15]The qualification "Six Pack" refers to a body of five EU regulations (Regulation (EU) 1173/2011 of the European Parliament and of the Council of 16 November 2011 on effective enforcement of budgetary surveillance in the euro area; Regulation (EU) 1174/2011 of the European Parliament and of the Council of 16 November 2011 on enforcement measures to correct excessive macroeconomic imbalances in the euro area; Regulation (EU) 1175/2011 of the European Parliament and of the Council of 16 November 2011 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies; Regulation (EU) 1176/2011 of the European Parliament and of the Council of 16 November 2011 on the prevention and correction of macroeconomic imbalances; Regulation (EU) 1177/2011 of the European Parliament and of the Council of 16 November 2011 on speeding up and clarifying the implementation of the excessive deficit procedure), and one directive (Directive 2011/85/UE of the European Parliament and of the Council of 8 November 2011 on requirements for euro area countries' budget). The expression "Two Pack" refers to two regulations: Regulation (EU) 472/2013 of the European Parliament and of the Council of 21 May 2013 on the strengthening of economic and budgetary surveillance of Member States in the euro area experiencing or threatened with serious difficulties with respect to their financial stability and Regulation (EU) 473/2013 of the European Parliament and of the Council of 21 May 2013 on common provisions for monitoring and assessing draft budgetary plans and ensuring the correction of excessive deficits of the Member States in the euro area.

[16] See, for instance, Joint Communication JOIN(2016) 29 final of 8 June 2016 from the Commission, *Towards an EU strategy for international cultural relations*, which refers to the OMC as applied in the field of culture, "in a light but structured way", as a possible source of inspiration for implementing partnerships with third countries in the cultural industries field (e.g. a European network of creative hubs or a network between young creative and cultural entrepreneurs from the EU and third countries).

[17] Communication COM(2004) 2004 of 20 April 2004 from the Commission, *Modernizing social protection for the development of high-quality, accessible and sustainable health care and long-term care: Support for the national strategies using the Open Method of Coordination*.

mon to all and in support for the Member States' reforms".[18] The aim was thus to create a common cognitive framework, which was sometimes portrayed as "neoliberal".[19]

After this first communication, the use of the OMC in the health care field was incorporated into a more general process of coordination, following a streamlined approach of policy coordination for social inclusion.[20] Member States reported on their national health policies with specific national health policy reports only for 2005; from 2006 to 2010, reporting of health policies with regards to common objectives and indicators was incorporated into the national social inclusion plans.

A central role was (and still is) played by the Social Protection Committee (SPC), established by Art. 160 TFEU.[21] The SPC quickly assumed the role of administrative leader, by organizing a concrete process for the exchange of experiences and the comparison of national practices. This committee constitutes a forum that combines political discussion on the main objectives pursued with technical expertise, for example in the definition of indicators. This kind of hybrid approach has favoured the creation of epistemic communities, with the participation of national experts, members of non-governmental organizations (NGOs) and members of the Commission deeply involved in improving the functioning and effectiveness of the OMC.[22]

Nevertheless, despite the attention paid to the OMC in the mid-2000s, references in official documents to the OMC with respect to health care have slowly decreased. In the last five years, coordination in health care appears to be a multifaceted process which can hardly be reduced to one method. Although there are still references to the OMC in

[18] *Ibid.*, p. 11.

[19] On the application of the OMC to care, see also, F. MARK, *The Open Method of Coordination on Health Care after the Lisbon Strategy II: Towards a Neoliberal Framing?*, in S. KRÖGER (ed.), *What We Have Learnt: Advances, Pitfalls and Remaining Questions in OMC Research*, in *European Integration Online Papers (EIoP)*, 2009, p. 1 *et seq.*, eiop.or.at.

[20] Communication COM(2005) 706 of 22 December 2005 from the Commission, *Working together, working better: A new framework for the open coordination of social protection and inclusion policies in the European Union*.

[21] According to this provision "The Council, acting by a simple majority after consulting the European Parliament, shall establish a Social Protection Committee with advisory status to promote cooperation on social protection policies between Member States and with the Commission. The tasks of the Committee shall be: – to monitor the social situation and the development of social protection policies in the Member States and the Union, – to promote exchanges of information, experience and good practice between Member States and with the Commission, – without prejudice to Article 240 [TFEU], to prepare reports, formulate opinions or undertake other work within its fields of competence, at the request of either the Council or the Commission or on its own initiative. In fulfilling its mandate, the Committee shall establish appropriate contacts with management and labour. Each Member State and the Commission shall appoint two members of the Committee".

[22] On the role of the Social Protection Committee, see K. JACOBSSON, A. VIFFEL, *Towards Deliberative Supranationalism? Analysing the Role of Committees in Soft Coordination*, in O. MEYER, W. WESSELS (eds), *Economic Government of the EU, a Balance Sheet of New Modes of Policy Coordination*, London: Palgrave MacMillan, 2005.

the legal provisions concerning the mandate and the mission of the SPC, it seems that the rationale and the general orientation of the OMC as a coordination tool (soft compliance, non-binding objectives, and convergence without formal obligations) have been extended in many directions.[23]

From this perspective, on the one hand it can be argued that the OMC for health care has followed the same trajectory that other OMC processes did, falling from light in to shadow, that is, from an ancillary process, designed to be self-maintained by regular reporting, to growing institutionalization through a number of links with existing processes of coordination. On the other hand, one can observe a proliferation of practices of coordination in health care that have borrowed key features of the OMC, such as the use of indicators, the use of guidelines and more generally soft convergence. This could be considered to be a renewal of the method in the health care field. Both aspects are discussed below.

III. The evolution of OMC in the European legal system: From light to shadow

To understand the trajectory of the OMC in the health care field, two main aspects need to be examined: the recognition of a specific legal basis for the operation of the OMC in the field of interest (III.1) and the dilution of the OMC within the normative framework that has followed the substantial recast of the rules applying to economic governance (III.2). A significant consequence of the latter is a diversification of the practices related to the OMC in health care.

III.1. Recognition of a legal basis for the OMC in the field of health care

While the OMC was initially portrayed as a "new mode of governance", marking "a shift" *vis-à-vis* the traditional Community method, it has been increasingly incorporated into the European legal system, with the recognition of specific legal bases in EU primary law.[24] Assessment of the OMC only through the conceptual framework of a "method" in EU law (e.g. method of coordination v. Community method, "soft method" v. "binding method") is somehow biased. In fact, the very general meaning which is attached to the qualification of "method" can lead to an overly broad perception of the decision-making process; it therefore can produce, as Jean-Paul Jacqué righty noted, a somehow "*ré-*

[23] In recent years, references to the OMC can only be found in internal documents of the Social Protection Committee, but with a link to the European Semester (see Council Decision 2015/773 of 11 May 2015 establishing the Social Protection Committee and repealing Decision 2004/689/EC).

[24] See for instance, J.S. Mosher, D.M. Trubek, *Alternative Approaches to Governance in the EU: EU Social Policy and the European Employment Strategy*, in *Journal of Common Market Studies*, 2003, p. 63 *et seq*.

ducteur" vision, in comparison with the complexity of the different forms of the policy-making processes.[25]

A debate on the legal grounds of the OMC occurred during the negotiations on the stillborn constitutional treaty. The working group on Social Europe suggested a horizontal provision to be inserted into the treaty, in order to define the OMC and its procedure and determine its scope of application *a contrario*:[26] the OMC would not apply in areas where sectoral coordination already existed (such as in economic and employment policy) and in areas where the Union had legislative powers. However, neither this provision nor any other efforts to constitutionalize the OMC have been successful, leading to its inclusion in the constitutional treaty.[27]

Despite the rejection of the constitutional treaty in 2005, the lack of agreement on the constitutionalization of the OMC had consequences for the drafting of the provisions of the Treaty of Lisbon related to health and social policies. The drafters of the Lisbon Treaty reiterated the wording of the constitutional treaty by using a general formula that establishes the main features of the OMC without qualifying them as elements of the OMC.

For health care, the relevant provision can be found in Art. 168, para. 2, TFEU, which lays down that "The Commission may, in close contact with the Member States, take any useful initiative to promote coordination, in particular 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. The European Parliament shall be kept fully informed". This formula can also be found in the Treaty provisions on cooperation in the fields of social policy, research and education.[28] Although these provisions do not specifically refer to the OMC, their wording points to its main features, such as the use of indicators, the non-binding nature of the process, the establishment of exchanges of best practice and the main role given to the Commission for fostering coordination.

The incorporation of such provisions in the Treaty provides consistency on the use of the OMC and the nature of the EU competence at stake. For social policy, for instance, the same formula is used in Art. 156 TFEU, which, since the Single Act, has been used as a horizontal provision for promoting coordination between Member States, but

[25] J.-P. Jacqué, *La Commission européenne après Lisbonne: déclin ou changement de paradigme*, in *Liber Amicorum en l'honneur du professeur Vlad Constantinesco*, Bruxelles: Bruylant, 2015, p. 241 *et seq*.

[26] Final Report of Working Group XI "Social Europe", pp. 17–20.

[27] G. de Búrca, J. Zeitlin, *Constitutionalising the OMC – What Should the Convention Propose?*, in *CEPS Policy brief*, 31 March 2003, www.ceps.eu. *A contrario*, several lawyers deny the necessity of having a specific provision within primary law. See, for instance, J.-V. Louis, *La MOC dans la Convention*, in J. Vandamme (ed.), *The Open Method of Coordination and Minimum Income Protection in Europe. Liber Memorialis Herman Deleeck*, Louvain: Acco, 2004, pp. 114-120.

[28] See, respectively, Art. 156, Art. 173 and Art. 181 TFEU.

without containing a legal basis for the adoption of harmonizing measures. On the contrary, there is no reference to the characteristics of the OMC in Art. 153 TFEU, which does serve as a legal basis for the adoption of the main directives in the field of social policy.[29]

The case is similar for health care. Art. 168 TFEU is the only provision in EU primary law that deals specifically with public health. It recognizes the possibility of adopting directives, in paragraph 4, but only for measures setting standards of quality and safety of organs, measures in the veterinary and phytosanitary fields and measures setting standards for medicinal products and devices. By enabling the adoption of binding measures, Art. 168, para. 4, TFEU is conceived as a derogation both to Art. 2, para. 5, TFEU (which defines the category of supporting or ancillary competences) and Art. 6 TFEU (which identifies the scope of such competences, including the "protection and improvement of human health").[30] Given this restrictive possibility of enacting binding secondary law, it follows that the reference to the features of the OMC in Art. 168, para. 2, TFEU is a concrete formalization of the types of actions and measures that shall be undertaken to substantiate the supporting EU competence in public health.

Provisions of this kind must be emphasized, as they allow for a better understanding of the relationship of the OMC with the formal distribution of competences, laid down in Arts 2 and 6 TFEU. With the Lisbon Treaty, the drafting of these provisions limits the OMC to the implementation of supporting (or ancillary) EU competences, which cannot include the harmonization of Member States' laws or regulations. At first glance, the OMC is thus disconnected from the scope of the EU's shared competences, which presuppose the co-existence of two legal bases (at Member States' and the EU level) to enact binding rules.

Besides use of the OMC in areas where the EU has supplementary competences, there is some space for using the OMC in policy areas where the EU has shared competences, especially when the treaty lays down a requirement of unanimity to enact

[29] For instance, directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 on working time; directive 98/59/EC of the Council of 20 July 1998 on the approximation of EU countries' law regarding collective redundancies and directive 2002/14/EC of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community.

[30] Art. 168, para. 4, TFEU reads: "By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k), the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures; b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; c) measures setting high standards of quality and safety for medicinal products and devices for medical use".

norms of harmonization. For instance, this could be the case for social policy, insofar as Art. 153 TFEU requires a special legislative procedure for adopting directives on such issues as social security, protection of workers when their employment contract is terminated, representation and collective defense of the interests of workers and employers and conditions of employment for third-country nationals legally residing in Union territory. In such cases, the key to understanding the use of the OMC lies in the discrepancy between the formal categorization of the EU competence as a shared competence and the limited powers that can be effectively exercised.

III.2. Dilution of the OMC in the context of deepening European economic governance

The EU legal response to the economic crisis that occurred at the end of the 2000s substantially changed the perception and use of the OMC. The Economic and Monetary Union has gone through an important process of transformation in the last six years. It has led to EU law becoming increasingly complex, with the adoption of international treaties (e.g. the Treaty on Stability, Coordination and Governance in the Economic and Monetary Union,[31] the Treaty establishing the European Stability Mechanism,[32] the Agreement on the Transfer and Mutualization of Contributions to the Single Resolution Fund in the Field of Banking Union), a deepening of the coordination of national policies (with the adoption of the so-called Six Pack on multilateral surveillance and Two Pack to assess Member States' draft budget plans) and a reinforcement of the monitoring of national policies.[33] Most of the tools endorsed in these frameworks raise a major difficulty concerning the discrepancy between the extent of powers given to the Union, including the intensity of economic and social policy coordination, and the nature of the legal competences of the EU as identified by the Treaty.

With respect to the coordination of national policies (including national policies in the field of health care), the creation of the European Semester diluted former processes of open coordination in the fields of employment, social inclusion and health.[34] From

[31] Treaty on Stability, Coordination and Governance in the Economic and Monetary Union (also known as the Fiscal Compact) of 2 March 2012. To stabilise the euro area, euro area governments have concluded an intergovernmental Treaty on Stability, Coordination and Governance in the Economic and Monetary Union. It has been in force since January 2013.

[32] Treaty establishing the European Stability Mechanism of 2 February 2012.

[33] Agreement between Belgium, Bulgaria, Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia and Finland of 21 May 2014 on the transfer and mutualisation of contributions to the single resolution fund.

[34] The European Semester was initially proposed by the European Commission in its Communication COM(2010) 250 of 12 May 2010 on reinforcing economic policy coordination. According to the communication, the European Semester "should encapsulate the surveillance cycle of budgetary and structural policies", relying on the common presentation by the Member States of the Stability and Convergence

a certain point of view, the European Semester can be seen as a gathering process: it brings together the implementation of several coordination procedures, such as those laid down in Art. 121 TFEU for economic policies and Art. 148 TFEU for Employment Guidelines but also procedures laid down in specific provisions introduced by the Six Pack. In this sense, the European Semester can be understood as a procedural tool which gathers measures founded on different legal bases. The machinery of the Semester relies on processes and tools which are not far from the semantic framework of the OMC: the adoption of an annual growth survey, the presentation of country reports with recommendations to the Member States, the endorsement of policy orientations by the Council, the submission by the Member States of national reform programs (and stability and convergence programs for the assessment of budgetary convergence), the evaluation by the Commission of national policies and so on.

At the same time, although the European Semester relies on similar mechanisms to those of the OMC, it has produced a shift in both the purpose and use of coordination by the Commission. Whereas coordination, within the several processes of the OMC, was initially conceived to ensure soft convergence and to exchange best practices between Member States, the implementation of the European Semester changed its purpose: coordination in this framework seeks to ensure the surveillance of national policies and their compatibility with budgetary requirements. This significant change can be observed in the sanctions that can be taken by the Council: although the content of the EU recommendations endorsed in the framework of the European Semester is not formally binding, Member States' lack of appropriation can lead to the launch of the procedure for macroeconomic imbalances, which can trigger financial sanctions.

This has produced significant changes in the coordination of national policies in the field of health care. Whereas up until 2010 the Member States reported their national health care policies through their national inclusion plans, the European Semester produced a kind of split.

On the one hand, the financial sustainability of health care has been incorporated into the national reform plans, which are part of the European Semester process. The national reform plans have thus become a tool to assess national health reform together with budgetary constraints. The French national reform plans, endorsed in 2015 and 2016, are illustrative of this tendency.[35] Their drafters insisted on reducing charges and

Programs and the National Reform Programs. Following this proposal, this process of surveillance was established by Regulation (EU) 1175/2011 of the European Parliament and of the Council of 16 November 2011 amending Council Regulation (EC) 1466/97 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies.

[35] See the *Programme national de réforme* of 13 April 2016, available at www.tresor.economie.gouv.fr, p. 33, which reads (in French): "La maîtrise des dépenses de santé est articulée autour de quatre piliers: l'amélioration de l'efficience de la dépense hospitalière avec la mise en place d'un programme national décliné au niveau régional, le développement de la médecine ambula-

costs, by pointing at several changes introduced by the latest national health law, such as the extension of third party payment, the expansion of compulsory consultation with a general practitioner before having the possibility to visit and be reimbursed for a consultation with a specialist or the merger of local hospitals through the setting up of general structures (*Groupements hospitaliers territoriaux*).[36]

On the other hand, the SPC pursues a specific mission of coordination by implementing a "soft" open method of coordination, which aims at establishing an overview of national health care policies, in light of three common objectives:

– to guarantee access for all to adequate health and long-term care, to ensure that the need for care does not lead to poverty and financial dependency, and to address inequities in access to care and in health outcomes;

– to promote quality in health and long-term care and adapt care to the changing needs and preferences of society and individuals, notably by establishing quality standards reflecting best international practice and by strengthening the responsibility of health professionals and of patients and care recipients;

– to ensure that adequate and high quality health and long-term care remain affordable and sustainable by promoting healthy and active lifestyles, good human resources for the care sector and rational use of resources, notably through appropriate incentives for users and providers, good governance and coordination between care systems and institutions.

Coordination in this context essentially aims at fostering cognitive convergence between Member States. To give an example, in the field of long-term care, in a 2014 report on "adequate social protection for long-term care needs in an ageing society",[37] the SPC assessed current challenges facing long-term care systems and identified national policy responses to address the need for prevention, rehabilitation and re-enablement.[38] In line with the traditional set up of the OMC, the report stressed national strategies considered sufficiently comprehensive, such as the New Medicine Service in the UK, the French policy for the prevention of loss of autonomy or, concerning pre-

toire et l'adéquation de la prise en charge en établissement, la baisse du prix des produits de santé et la promotion des médicaments génériques, l'efficience et le bon usage des soins et des médicaments".

[36] Law no. 2016-41 of 26 January 2016 (France), *Modernisation de notre système de santé*.

[37] Social Protection Committee Report 10406/14 of 18 June 2014, *Adequate Social Protection for Long-term Care Needs in an Ageing Society*.

[38] As defined in this Social Protection Committee Report 10406/14, prevention is understood as "[s]ervices for people with poor physical or mental health to help them avoid unplanned or unnecessary admissions to hospital or residential settings" which "can include short-term emergency interventions as well as longer term low-level support"; rehabilitation as "services for people with poor physical or mental health to help them get better" and re-enablement as "services for people with poor physical or mental health to help them accommodate their illness by learning or re-learning the skills necessary for daily living".

vention, the Buurtzog model in the Netherlands, which consists of small self-managed teams aimed at providing integrated care at home.[39]

For the coming years, the SPC seeks to preserve forms of coordination that seem to be consistent with the initial rationale of the OMC. This is actually one of the targets of the current proposal for a European Pillar of Social Rights,[40] aimed at establishing a transversal framework for putting employment and social protection (including health care) at the forefront of EU and national policy-making. For the implementation of this strategy (which is still pending), the SPC is clearly willing to draw upon previous models of coordination, such as the OMC. For instance, in a key note speech in June 2017, the SPC, together with the Employment Committee, stressed:

> "implementation of the Social Pillar should aim at reinforced action at EU and Member State level and build on the existing instruments and mechanisms which have proven to be effective, notably the Europe 2020 Strategy and the European Semester, the European Employment Strategy and the Open Method of Coordination for Social Protection and Social Inclusion, including the activities related to mutual learning and exchange of best practices. Further clarity is needed as to how the implementation will be linked to these and other existing processes and procedures such as the Macroeconomic Imbalance Procedure, and how duplication of instruments and processes will be avoided".[41]

This statement is important, as it shows that both Committees wish to preserve a specific (even if circumscribed in scope) type of coordination, within their mandate, which remains qualified as an "OMC".

IV. The revival of the OMC in health care

Several features of the OMC, such as the endorsement of common indicators, the setting up of common objectives and the exchange of good practices have been incorporated within a range of tools dealing with health care, even if such tools are not referred to as an OMC. Three main points will be considered from this perspective: the systematization of a set of indicators (IV.1), the integration of OMC features within secondary law (IV.2) and the development of a set of programs and strategies that have borrowed certain OMC characteristics (IV.3).

[39] See law no. 2015-1776 of 28 December 2015 (France), *Loi relative à l'adaptation de la société au vieillissement*.

[40] Communication COM(2017) 250 of 26 April 2017 from the Commission, *Establishing a European pillar of social rights*.

[41] Employment and Social Protection Committees Opinion 9498/17 of 2 June 2017, *European Pillar of Social Rights: Endorsement of the Joint SPC and EMCO*.

IV.1. Endorsement of common indicators

The SPC has gradually developed a proper methodology to establish a comprehensive framework of social indicators, in order to propose a Joint Assessment Framework of National Policies, together with the Employment Committee. This work on indicators consists of a first-step screening of country-specific challenges based on quantitative information and as a second step in-depth qualitative analysis to contextualize findings coming from hard data.[42] The latter involves the consultation of thematic reports, national-level publications and national data sets.[43] In this context, there is obviously a link with the OMC: before entering into a process of deep, refined coordination between Member States, it is necessary to agree on a common understanding of the challenges faced in the field of health. The adoption of common indicators is a preliminary and central step in this direction. In fact, the endorsement of common indicators faces conflicting requirements: on the one hand, the indicators must be considered sufficiently objective, neutral, robust and statistically valid; on the other hand, they need to avoid the risk of manipulation that could introduce bias.

For this purpose, the SPC carries out remarkable work. A substantial part of its activities covers the identification of indicators related to the three main objectives of EU health care policy: quality (e.g. concerning colorectal cancer survival rates, breast cancer survival rates, cervical cancer survival rates, vaccination coverage for children, influenza vaccination for people aged 65+, hospital mortality and so on), sustainability of resources (e.g. current expenditure on health care per capita, practicing physicians or doctors, practicing and professionally active nurses and midwives and so on) and general improvement of health (e.g. life expectancy, obesity rate, exposure to alcohol or tobacco). The aim is to provide through a country profile chart an initial screening of areas where Member States might be facing specific challenges. The framework allows for summary assessments of overall health outcomes and provides indications on what might be the underlying factors explaining these outcomes.[44]

IV.2. Incorporation of OMC features within secondary law

Another notable development over the past several years derives from the incorporation of tools inspired by the OMC into directives adopted in health care. A very good ex-

[42] Social Protection Committee Progress Report SPC/2015.2.2/4 of 17 February 20151on the review of the Joint Assessment Framework in the area of health.

[43] See European Commission, DG Employment, Social Affairs and Inclusion & Social Protection Committee, Work in progress: 2015 update of 22 November 2015, *Towards a Joint Assessment Framework in the Area of Health*.

[44] *Ibid.*, p. 44.

ample is Directive 2011/24/EU on cross border health care.[45] This Directive has a dual legal basis: it is based both on Art. 114 TFEU (the general legal basis for harmonization measures in the internal market) and Art. 168 TFEU (on public health). Its main justification was the need to codify the substantial case law dealing with the mobility of patients on the basis of the freedom to provide services. Through seminal cases such as *Kohll and Decker*,[46] *Geraets-Smits and Peerbooms*[47] and *Watts*,[48] the Court of Justice recognized the possibly for patients to make use of the fundamental economic freedoms contained in the Treaty (such as the freedom to provide services) in order to challenge national measures (enacted in the State of affiliation) that could restrict mobility for access to health care in another Member State. In line with these rulings, the Directive distinguishes between ambulatory care and hospital care. Although access to ambulatory care cannot be denied by the State of affiliation (where the patient is insured) for obtaining reimbursement from social security funds, for hospitals, a system of prior authorization may be justified when required for certain reasons, given the specific nature of the medical services provided in a hospital setting. This specification is due to the need to preserve the discretion of the Member State of affiliation to exercise its own health care policy and avoid the risk of seriously undermining the financial balance of its social security system.

Besides the codification of the case law on the freedom to provide services, the Directive also had to clarify the nature of the rights enjoyed by patients. One of the issues dealt with was the freedom to provide services within the existing framework on the coordination of Member States' social security systems, which is set up by Regulation (EC) 883/2004.[49] This considers the patient as an insured person in the State providing the care. Although the patient is legally covered by the social security of the State of affiliation, he is considered, under the scheme of this Regulation, as a patient on the grounds of the law of the state of treatment. On the contrary, under the system of the freedom to provide services, the patient is considered a user of a provided service – as if he had obtained it in his country of residence.

This issue explains the attention paid, in the Directive, to specific mechanisms of coordination and the exchange of information between Member States. Actually, the

[45] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[46] Court of Justice, judgment of 28 April 1998, case C-158/96, *Raymond Kohll v. Union des caisses de maladie*; judgment of 28 April 1998, case C-120/95, *Nicolas Decker v. Caisse de maladie des employés privés.*

[47] Court of Justice, judgment of 12 July 2001, case C-157/99, *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen*.

[48] Court of Justice, judgment of 16 May 2006, case C-372/04, *Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health*.

[49] Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

diversity of reimbursed care in the Member States, the differences regarding the coverage rate and the disparities of the quality of care, as well as the need to preserve patients' data are, among others, factors which explain the need to coordinate national practices, in order to avoid abuses by patients of cross-border care. In this regard, the Directive requires the Commission to foster cross-border cooperation using three main tools.

First, Art. 12 of the Directive sets up for the Commission a framework to support the development of so-called European Reference Networks of health care providers and centres of expertise (in particular on rare diseases) by: adopting the criteria that such networks, and providers wishing to join them, must fulfil; developing criteria for establishing and evaluating such networks; and facilitating the exchange of information and expertise within the networks. In March 2014, the relevant legal framework, which was adopted on the grounds of the delegated competence of the Commission, was introduced.[50] According to the 2015 Commission report on the operation of the Directive, the process of establishing these networks has begun.[51] Secondly, Art. 15 of the Directive creates a Health Technology Assessment network, implemented by a specific decision of the Commission.[52] This network aims at supporting cooperation between national authorities, including on the relative efficacy and short/long term effectiveness of health technologies. This network adopted a Strategy for EU cooperation on health technology in October 2014, and a reflection paper on national activities in April 2015.[53] It meets twice a year and is supported on scientific and technical issues by a joint action under the Health Program, called EUnetHTA. Thirdly, the Directive requires the Commission to encourage Member States to cooperate on cross-border health care provision in border regions. The relevant provision, contained in Art. 15 of the Directive, still needs to be implemented, as there are a limited number of existing cross-border projects that may provide valuable experience.[54]

To understand the specific structure of the Directive, the qualification of "hybrid governance" has been proposed with the aim of describing the combination of rules

[50] Commission Delegated Decision (EU) 2014/287 of 17 May 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil.

[51] Communication COM(2015) 421 of 4 September 2015 from the Commission, *Report on the operation of Directive 2011/24/EU on the application of patients rights in cross-border healthcare*.

[52] European Commission Implementing Decision (EU) 2013/329 of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the network of national authorities or bodies responsible for health technology assessment.

[53] See European Commission, DG Health and Food Safety, Consultation report Ares(2017)2455149 of 15 May 2017 *Strengthening of the EU cooperation on Health Technology Assessment*.

[54] Communication COM(2015) 421, cit.

and principles that the Directive contains.[55] These stem directly from EU primary law (the implementation of the freedom to provide services as interpreted, for health care, through case law) and flexible mechanisms and tools, which are underlined by the necessity to reconcile the preservation of national competences and policies in the field of care and the existing influence of EU law. Specific features of the OMC have been integrated in the Directive, in order to facilitate its implementation into national legal systems. This explains and gives consistency to the legal foundation of the Directive: Art. 114 TFEU, for the main rules, and Art. 168 TFEU, for the coordinating tools.

IV.3. The OMC's rationale within partnership programs

In the policy field of public health, one can further observe an increasing use of tools or so-called partnership programs, which are not formally qualified as an OMC but which include similarities to it. These appear as a specific use of soft law, as it is conceived as a finality in itself, with a form of disconnection from the enactment of binding rules. Two examples demonstrate this.[56]

First, the eHealth plan could be seen as the implementation of some features of the OMC.[57] This plan creates a network aiming at supporting cooperation between national authorities. It meets twice a year and is supported operationally by a joint action (led by the EU and Member States) under the Health Programme established by Regulation (EU) 282/2014.[58] The work of the eHealth Network is supported by a number of activities carried out under the eHealth Action Plan 2012-2020. Since its inception, the eHealth Network has formulated guidelines on patient summaries data sets and ePrescriptions, and it has adopted position papers on: electronic identification, interoperability, the proposed Regulation on data protection, and eHealth investment to be supported by the Connecting Europe Facility.[59] It is currently working on guidelines on effective methods for the use of medical information for public health and research. Specific EU funding has been allocated to implement the exchange of patient summaries

[55] L. Trubek, T. Hervey, *Freedom to Provide Health Care Services within the EU: An Opportunity for "Hybrid Governance"*, in G. de Búrca, J. Scott (eds), *Narrowing the Gap? Law and New Approaches to Governance in the European Union*, in *Columbia Journal of European Law*, 2007, p. 623 *et seq*.

[56] This is already a settled tendency, see, G. Vanhercke, *The Hard Politics of Soft Law: The Case of Health*, in *Health Systems Governance in Europe. The Role of European Union Law and Policy*, 2009, p. 186 *et seq*.; also T. Hervey, *The European Union and the Governance of Health Care*, in G. de Búrca, J. Scott (eds), *Law and New Governance in the EU and the US*, Oxford: Hart Publishing, 2006.

[57] Commission Implementation Decision of 22 December 2011 providing the rules for the establishment, management and operation of the network of national responsible authorities on eHealth.

[58] Regulation (EU) 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Program for the Union's action in the field of health (2014-2020) and repealing Decision 1350/2007/EC.

[59] EHealth Network, Guidelines on ePrescriptions Dataset for Electronic Exchange under Cross-border Directive 2011/24/EU of 18 November 2014, available at ec.europa.eu.

and ePrescriptions. In the period 2012-2014, this network established a set of common objectives to assess the added value and benefit of eHealth solutions and to promote interoperability between national practitioners' prescriptions.[60]

Secondly, the "*European Innovation Partnership on Active and Healthy Ageing*" also shares common features with the OMC. Formally launched in 2012, it can be seen as a platform for cooperation, which belongs to the general framework of European Innovation Partnerships.[61] It pursues a three-part goal: to improve the health and quality of life of Europeans with a focus on older people, to support the long-term sustainability and efficiency of health and social care systems, and to enhance the competitiveness of EU industry through business and expansion in new markets. On the whole, this partnership looks much more like an in-depth process of exchanges between experts rather than a proper process of coordination. It works through Action Groups, an assembly of partners committed to work on specific issues related to ageing, by sharing knowledge and expertise with their peers, giving added value to their national and local experience and identifying gaps that need to be filled at the European level. Six actions groups have been set up thus far on: adherence to prescription, fall prevention, functional decline and frailty, integrated care, independent living solutions, and age friendly environments.[62]

V. Conclusion

This brief and non-exhaustive presentation of the OMC in the field of health care leads to two conclusions. Given the diversity of coordination practices and the recognition of a specific legal basis for coordination in Art. 168 TFEU, it is no longer relevant to consider a single, proper "OMC" in the field of health care. It is more consistent with reality – and with actual institutional practice – to speak of several processes of coordination, which include some key features of the OMC as it was defined 15 years ago. Therefore, it is more relevant to consider the OMC as a general toolbox that can be used flexibly, in order to substantiate and to give a concrete enforcement to the EU's supporting competences, as defined in Art. 6 TFEU. This raises a more general issue, which remains un-

[60] These general objectives were identified in a Communication COM(2012) 736 final of 16 December 2012 from the Commission, *eHealth Action Plan 2012-2020. Innovative healthcare for the 21st century*. They refer to general considerations, such as improving chronic disease and multimorbidity (multiple concurrent disease) management and strengthening effective practices for prevention and promotion of good health, increasing sustainability and efficiency of health systems though innovation, enhancing patient/citizen-centric care and citizen empowerment and encouraging organizational changes, fostering cross-border healthcare, health security, solidarity, universality and equity and improving legal and market conditions for developing eHealth products and services.

[61] Communication COM(2012) 83 final of 29 February 2012 from the Commission, *Taking forward the strategic implementation plan of the European innovation partnership on active and healthy ageing*.

[62] See the general presentation on the dedicated webpage: ec.europa.eu.

solved: how can the EU formalize and substantiate its coordinating or ancillary competences that do not formally allow measures of harmonization (and therefore the enactment of binding legal norms) but which are nevertheless central to giving the EU a social dimension – a process still unfinished? There is certainly still a long and winding path before the values of social market economy – emphasized as a foundation of the EU, in Art. 3, para. 3, TEU – are translated into concrete rights for citizens.[63]

[63] Art. 3, para. 3, TEU reads: "The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance. It shall combat social exclusion and discrimination, and shall promote social justice and protection, equality between women and men, solidarity between generations and protection of the rights of the child. It shall promote economic, social and territorial cohesion, and solidarity among Member States".