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Conceptualising Multilevel Regulation in the EU: A Legal Translation of Multilevel Governance?

*Nupur Chowdhury and Ramses A. Wessel**

Abstract: *How should we conceive of regulation in the European context? This paper attempts to answer this by developing multilevel regulation as a theoretical concept. The basic aim of the paper is to explore the difference and convergence between regulation and governance and develop multilevel governance and multilevel regulation as two individual heuristic concepts. We suggest that it is useful to frame multilevel governance in the context of regulatory spaces. As an example, we undertake an exploratory investigation of multilevelness of the regulatory space of marketing authorisation of medical devices. This allows us to help focus on certain aspects of the regulatory process by acknowledging that it is no longer located in the hand of a single (governmental) actor and highlighting the necessity of considering interventions beyond the state in addressing regulatory effectiveness problems that may crop up in this context. Ultimately, we assess whether multilevel regulation is a legal translation of the concept of multilevel governance.*

I Introduction

Since more than three decades, regulation has emerged as an exciting area of social science research, drawing primary from the disciplines of economics, political science and law.[1] In the US, the 1960s and 1970s witnessed an explosion of regulatory research flowing from the new structures of health safety and environment regulation.[2] The setting up of a number of independent institutions, saw the shift away from control through bureaucracy to technocrats operating through independent federal regulatory commissions. Typically, these commissions subsumed the powers of rule making, monitoring and enforcement and sanctioning.[3] Scholars focussed at the level of the

* Respectively Doctoral Fellow of Law and Professor of the Law of European Union and other International Organizations at the Section Law & Regulation group and the Centre for European Studies of the University of Twente, the Netherlands. Both authors are also fellows of the university's Institute of Innovation and Governance Studies (IGS).

[1] R.G. Noll (ed.), *Regulatory Policy and the Social Sciences* (University of California Press, 1995).

[2] See J.Q. Wilson, *The Politics of Regulation* (Basic Books, 1980); E. Bardach and R.A. Kagan, *Going by the Book: The Problem of Regulatory Unreasonableness* (Temple University Press, 1982); E. Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (Cambridge University Press, 1990).

[3] P. Selznick, 'Focusing Organization Research on Regulation', in R. Noll (ed.), *Regulatory Policy and the Social Sciences* (University of California Press, 1985), at 363. See on the history of regulation, R. Rabin,

agency on aspects like architecture, institutional setting and rule specificity.[4] Across the Atlantic, the UK, legislatures retained rule-making authority, and delegation was limited to enforcement or sanctioning operations that was given to central bodies such as the Health and Safety Executive or utilities regulators (viz. electricity and railways). This underlined the importance of regulatory cultures in the design of institutions and choice of enforcement tools.[5] The French school of regulation theory scholars in the 1970s[6] chose to focus on the conflictual dynamics of capitalist markets embedded in an understanding of the different phases of capitalist development and types of capitalist formation. Since the early 1990s with the hastening of the European project, studies on regulation within the political entity of the EU, also emerged.[7] Diffusion of regulatory authority to supranational bodies private institutions and their undermining of modes of democratic control and legislative accountability has also been explored.[8]

Current research has focussed on several aspects of regulatory theory. The research team at The Australian National University (ANU) led by Professor Braithwaite has focussed on the challenges of regulatory enforcement, in their graduated scale of enforcement paradigm and pioneering study on responsive regulation.[9] Responsive regulation does not suggest a certain regulatory type, it supports the opening up of a discursive space, wherein regulators can consider a range of outcomes taking into consideration the specific characteristics of the regulated industry. Specific regulatory interventions for networked industries like energy, electricity and telecommunications has been pursued by researchers at the EUI.[10] A more systemic perspective on risk as the central organising principle underlying regulation has been adopted by others in explaining the varieties of enforced self-regulation and risk management practiced

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'Federal Regulation in Historical Perspective', in P.H. Schuck (ed.), *Foundations of Administrative Law* (Oxford University Press, 1994), at 39–50.

[4] See S. Breyer, *Regulation and its Reform* (Harvard University Press, 1982); S. Peltzman, 'The Economic Theory of Regulation after a Decade of Deregulation', (1989) 1989 *Brookings Papers on Microeconomics* 1–59. and, C. Diver, 'The Optimal Precision of Administrative Rules', (1983) 93(1) *Yale Law Journal* 65–109.

[5] E. Meidinger, 'Regulatory Culture: A Theoretical Outline', (1987) 9 *Law and Policy* 355–386.

[6] M. Aglietta, *A Theory of Capitalist Regulation* (Verso, 1979). Also, R. Brenner and M. Glick, 'The Regulation School: Theory and History', (1991) 188 *New Left Review* 45–119. A. Lipietz, 'Behind the Crisis: The Exhaustion of a Regime of Accumulation. A Regulation School Perspective on Some French Empirical Works' (1986) 18 (1-2) *Review of Radical Political Economics* 13–32. R. Boyer, *The Regulation School. New York* (Columbia University Press, 1990).

[7] See G. Majone, 'The Rise of the Regulatory State in Europe', (1994) 17 *West European Politics* 77–101; G. Majone, 'From the Positive to the Regulatory State. Causes and Consequences of Changes in the Mode of Governance', (1997) 17 *Journal of Public Policy* 139–167; J.D. Vogel, 'The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe', (2003) 33 *British Journal of Political Science* 557–580 and, D. Coen, and C. Doyle, 'Designing Economic Regulatory Institutions for the European Network Industries', (2000) 9 *Current Politics and Economics of Europe* 83–106.

[8] H. Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing, 2005), at 407. G. Teubner, 'Breaking Frames: The Global Interplay of Legal and Social Systems', (1997) 45(1) *American Journal of Comparative Law* 149–169.

[9] See I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1992); N. Gunningham and P. Grabosky, *Smart Regulation: Designing Environmental Policy* (Oxford Clarendon Press, 1998) and, J. Braithwaite, *Restorative Justice and Responsive Regulation* (Oxford University Press, 2002).

[10] See for instance, D. Bauknecht, *Incentive Regulation and Network Innovations* 2011, RSCAS Working Papers; F. Bickenbach, *Regulation of Europe's Network Industries: The Perspective of the New Economic Theory of Federalism* (2000) Kiel Working Papers 977, Kiel Institute for the World Economy.

at the firm level and how that connects to the systemic level as steered by public regulators.[11]

Both policy makers and academic scholars from law and politics have come to accept the fact that the process of regulation has undergone a dramatic change over the last two decades. It has gone from being a limited political activity of the State—that of managing the market to secure public interest goals, to that of a more open-ended process by which an independent public (technocratic) authority interacts with a host of public and private actors (regulatees) in norm formation, norm enforcement and norm adjudication within a specific public policy area.[12] This de-coupling of the state from its regulatory activities has been widely analysed and commented by political scientists.[13] Scott most famously termed it as the 'rise of the post-regulatory State.'[14] This process has been characterised as open-ended, since both the rationale and the manner in which regulation is conducted has increasingly come to resemble a negotiated outcome resulted from the interaction between multiple actors.

This phenomenon has now come to characterise regulation in a number of policy sectors[15] in most countries and (given the nature and distribution of political authority in Europe) those in Europe in particular. As mentioned above, one of the rationales that have acted as a catalyst for cooperation of international regulation has been the probability of negative externalities that could result from activities carried out within national boundaries. The objective of free trade has also been a key driver of regional and international regulation efforts that focus on harmonisation in standard setting. Similar rationales have also driven efforts for the 'Europeanisation' of public policy issues in Europe.[16] This trend refers to the extending mandate of European institutions to cover hitherto national public policy issues. With this, more and more sectoral regulation has seen the emergence and active participation of both private and public actors operating at the European level. Regulatory mandates reflecting the shared competences between

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[11] See the Centre for Analysis of Risk and Regulation (CARR) at the London School of Economics. See for instance, M. Benzer, *Quality of Life and Risk Conceptions in UK Healthcare Regulation: Towards a Critical Analysis* (2011) Discussion Paper no. 68, CARR; J. Etienne, *Self-reporting Untoward Events to External Controllers: Accounting for Reporting Failure by a Top Tier Chemical Plant* (2010) Discussion Paper no. 66, CARR.

[12] This would include both hard and soft norms.

[13] De-coupling refers to the distancing of the State from its functions as a regulator (including that of norm formation, norm enforcement and norm adjudication). Julia Black refers to this as a process of de-centering. J. Black, 'Decentering Regulation: The Role of Regulation and Self-regulation in a Post-regulatory World', (2001) 54 *Current Legal Problems* 103–147.

[14] C. Scott, 'Regulation in the Age of Governance: The Rise of the Post-regulatory State', in J. Jordana and D. Levi-Faur (eds), *The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance* (Edward Elgar Publishing, 2004), at 145–176. See also M. Loughlin and C. Scott, 'The Regulatory State', in P. Dunleavy *et al*. (eds), *Developments in British Politics 5* (London:Macmillan, 1997), at 205. See generally, G. Majone (ed.), *Regulating Europe* (London: Routledge, 1996), F. McGowan and P. Seabright, 'Regulation in the European Community and Its Impact on the UK', in M. Bishop, J. Kay and C. Mayer (eds), *The Regulatory Challenge* (Oxford: Clarandon, 1995) M. Moran, 'Review Article: Understanding the Regulatory State', (2002) 32 *British Journal of Political Science* 391–413.

[15] This is especially true for those sectors—environment, finance, and health policy—where negative externalities are enormous and regional and global regulatory initiatives are well developed.

[16] A. Lenschow, 'Europeanisaton of Public Policy', in J. Richarsdon (ed.), *European Union: Power and Decision making* (Routledge, 3rd edn, 2006) at 55–71. S. Princen, 'Agenda-setting in the European Union: A Theoretical Exploration and Agenda for Research', (2007) 14(1) *Journal of European Public Policy* 21–38; D. Dimitrakopoulis and J. Richardson, 'Implementing EU Public Policy', in J. Richardson (ed.), *European Union: Power and Policy-making* (Routledge, 2nd edn, 2004), at 335–356.

the Member States and the European Commission have made a direct impact in opening up the regulatory space[17] to include a wide variety of actors operating at multiple administrative levels. Another important driver fuelling this expansion of the regulatory space (to include actors operating at multiple levels) has been the regulatory expertise deficits that have seemed to emerge in high technology areas.

Depending on the nature of the public policy field, these actors may include a range of public and private actors not only operating nationally but also at the subnational, European and even international level. Certain kinds of public policy issues, *viz*. environment that have enormous potential negative externalities are ideal candidates for regional and international regulation. Others like specific aspects of health systems (pharmaceuticals and service delivery) are increasingly subject to EU regulation due to the freedom of movement provisions in the EU Treaties.[18] The actors that play a critical role in the regulatory process (design, implementation and enforcement of norms) may therefore be drawn from more than one administrative level (subnational, European and international)—and this phenomenon is referred to as multilevel regulation. Multilevel regulation essentially refers to the nature of regulatory activity in a specific sector/on a specific issue—and by definition it involves a range of actors that may be operating at different administrative levels—but who come together to interact and negotiate both substantive and procedural norms that regulate all activities in that sector. We understand 'regulation' in a broad sense here, referring to the setting of rules, standards or principles that govern conduct by public and/or private actors. Whereas 'rules' are the most constraining and rigid, 'standards' leave a greater range of choice or discretion, while 'principles' are still more flexible, leaving scope to balance a number of (policy) considerations.[19] However, it is important to note that the interaction between norms may occur within well drawn out institutionalised settings and through formalised processes or could be more informal in nature and therefore prone to inequitable outcomes for the regulatory actors and may also result in compromise or even negation of public interest. Thus, a relatively new phenomenon emerged: 'informal' international regulation or law making. The type of rules these bodies produce is 'informal' in the sense that they deviate from traditional law making in relation to three aspects: *output*, *process* or the *actors involved*.[20] Hence, Pauwelyn defined informal

[17] Here, we use the concept of 'regulatory space' as developed by Hancher and Moran, The term 'regulatory space' has been used as referred to by Hancher and Moran within regulatory theory—in that regulation involves a mixture of private and public characteristics that involve dynamic relationships between and within organisations and actors who may come together to occupy a shared space that is characterised by a number of regulatory issues subject to public decision making. While they have developed the term to characterise national level regulatory processes, herein we use it in a limited sense to denote the nature of norms (hard and soft norms), process of norm creation, implementation and enforcement and also the various public private actors involved in this process within a specific regulatory sectors that may be integrated vertically across international, regional, national and subnational levels. L. Hancher and M. Moran (eds), *Capitalism, Culture and Regulation* (Oxford: Oxford University Press, 1989), specifically the chapter, 'Organising Regulatory Space.'

[18] Articles 18, 39, 43, 28 and 49 of the Treaty on the Functioning of the European Union (TFEU).

[19] See R.A. Wessel and J. Wouters, 'The Phenomenon of Multilevel Regulation: Interactions between Global, EU and National Regulatory Spheres', in A. Føllesdal, R.A. Wessel and J. Wouters (eds), *Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes* (Martinus Nijhoff Publishers, 2008), at 9–47.

[20] See J. Pauwelyn, 'Informal International Law-making: Framing the Concept and Research Questions', in J. Pauwelyn, R.A. Wessel and J. Wouters (eds), *Informal International Lawmaking* (Oxford University Press, 2012, forthcoming), chapter 1.

international law making as: 'Cross-border cooperation between public authorities, with or without the participation of private actors and/or international organisations, in a forum other than a traditional international organisation (process informality), and/or as between actors other than traditional diplomatic actors (such as regulators or agencies) (actor informality),and/or which does not result in a formal treaty or legally enforceable commitment (output informality).'[21]

We develop the concept of multilevel regulation to capture several developments within the general process and functioning of regulatory regimes in Europe.[22] First is the move away from the state as the primary actor within the regulatory process, to that of a more fluid regulatory space which is populated by both private and public actors that play critical roles in the design, implementation and enforcement of norms. Second, these actors may be drawn from different administrative levels—ie they may include international organisations, European regulators, national industry associations, multinational companies, competent authorities of Member States, private standardisation organisations, to name just a few. Together, these actors may constitute the regulatory space for a specific sector—medical products for instance. Third, the regulatory space may or may not be reflected in the formal legal/regulatory framework that governs that sector. In other words, the regulatory space may be populated with actors that do not have formal legal roles but play a critical role in the regulatory process. Thus norm formation, norm implementation and norm enforcement may happen at different administrative/governance levels with little or no reference to each other and more critically without reference to the formal legal systems that are in place at the national and European level. The danger of regulatory overlap and dissonance as an outcome of lack of cohesiveness and fragmentation may lead to regulatory uncertainty and may in the process undermine legal certainty in a regulatory space that is characterised by such multilevelness.

The concept of regulatory space is primarily used here as a framing device or an analytical tool[23] to carry out a mapping of relevant actors, the distribution of resources and competences between them and the process of interactions between them. Regulatory space also allows for flexibility in the delimitation of a regulatory sector/regime in terms of the specific aspects to be studied. Thus for instance, it is possible to distinguish intellectual property regulation of pharmaceutical products as a separate regulatory space from that of product safety regulation of such products. It therefore allows researchers to undertake an in-depth study of a specific aspect of the regulatory regime. The concept of focussing on different kinds of regulatory power enables us to identify a range of actors that inhabit the regulatory space. On the basis of their actions within the entire regulatory life cycle, it is possible to identify the relative importance of the actors in terms of principals (who are involved in rule formulation), participants (who are receivers of rules and are involved in the rule implementation and enforcement) and 'residual actors' (who may only play a reactive role in terms of following the rules). This is admittedly a simplification; it is of course possible that some of the actors could also

[21] *ibid*, at 4.

[22] For instance, an argument supporting the EU as a multilevel polity; see; A. Benz, *Restoring Accountability in Multilevel Governance*, Paper prepared for the ECPR Joint Session Workshop (2007) Workshop 5 'Governance and Democratic Legitimacy'; R. Brownsword and H. Somsen, 'Law, Innovation and Technology: Before We Fast Forward—A Forum for Debate', (2009) 1 *Law, Innovation and Technology* 1–73.

[23] Similar applications of this concept in socio-legal studies include, J. Kaye and S.M.S. Gibbons, 'Mapping the Regulatory Space for Genetic Databases and Biobanks in England and Wales', (2008) 9 *Medical Law International Home Contents* 2.

play multiple roles. However, it is necessary to underline that by focussing attention on the diversity of (and unequal in terms of regulatory resources) actors inhabiting this space, the concept provides us with a theoretical avenue for a better analysis of functions and capacities of actors. We use the concept of regulatory space as against policy spaces,[24] regimes[25] or sites of governance[26] because, we want to focus on a specific aspect within a policy field/space (in our case marketing authorisation of medical devices). We find the other three alternatives to be broader and more loosely defined in terms of the relationship between the constituent units. Within a regulatory space, the constituents are actors, and they are the primary drivers of regulatory actions.

Ultimately, multilevel regulation allows us to focus our attention within a regulatory space that is operating vertically. Meaning, there are regulatory actors functioning at different administrative levels who are not in hierarchical relationship with each other but who may take cognisance of each other. Globalisation has reconfigured most regulatory spaces in a vertical fashion, wherein national legal systems function as another administrative level rather than as a separate legal system. It highlights the explicit or indirect relationships between the different actors within a specific regulatory space and how this affects rule making, rule enforcement and rule adjudication activities. The central assumption of a legal systems approach to regulation is that higher level structures shape lower level entities. We explicitly abandon this assumption for the possibility of regulatory actors being motivated not only by their location within that administrative level but also by their membership of specific networks which may operate at other administrative levels (an obvious example being the European Committee for Standardization (CEN) as a member of the International Organization for Standardization (ISO) network also has rule making authority under the *New Approach* regulatory sectors). Thus, a specific regulatory space that may be concomitantly existing as an enclave across several independent but interconnected legal systems.

Robert Ahdieh's vision of intersystemic regulation[27] as a current legal reality and his attempts to interpret interactions between multiple regulatory authorities as hierarchic, dialogic or 'dialectical regulation' form an inspiration for multilevel regulation. Paul Schiff Berman built on Ahdieh's research, to also non state actors. He has argued for the need to study plural law-making communities, and by implication, the deterritorialisation of legal effects.[28] Francis Snyder, in his work on sites of governance for understanding global legal pluralism[29] resulting from globalisation, also seems to challenge the territorial obsession that a legal systems approach has always propounded. Do the 'levels' in multilevel regulation represent this obsession with territoriality? No, they do not. We believe that the locus of the national state cannot be given primacy. We believe that regulatory spaces represent much more useful units of analysis. We locate actors involved in rule making, rule enforcement or rule adjudication activities at the various 'administrative levels.' Our manner of using levels does not give primacy to one

[24] H. Wallace, M.A. Pollack and A.R. Young, 'An Overview', *Policymaking in the European Union* (Oxford University Press, 6th edn, 2010).

[25] S.D. Krasner, 'Structural Causes and Regime Consequences: Regimes as Intervening Variables', (1982) 36 *International Organization* 185–205.

[26] F. Snyder, 'Sites of Criminality and Sites of Governance', (2001) 10 *Social and Legal Studies* 251.

[27] R. Ahdieh, 'Dialectical Regulation', (2006) 38 *Connecticut Law Review* 863.

[28] P. Schiff Berman, 'Dialectical Regulation, Territoriality, and Pluralism', (2006) 38 *Connecticut Law Review* 929.

[29] F. Snyder, *The EU, the WTO and China: Legal Pluralism and International Trade Regulation* (Hart Publishing, 2010).

administrative level over another but is more of a descriptive tag to capture the location of different regulatory actors. In that sense, the concept is not a normative project but simply a descriptive tool to capture current regulatory processes.

The paper proceeds in four steps. In section II, we investigate the literature on the use of the neighbouring concept of multilevel governance highlighting the different disciplines and policy studies that have used the concept of multi-level governance to capture a wide variety of governance developments within Europe. Given that multi-level regulation and multilevel governance has been interchangeably used within such studies,[30] it is important to explore whether at the conceptual level there are certain similarities or whether the two can be separated and what is the implication of that for evolving a conceptual definition of multilevel regulation. In Section III, we propose a definition of multilevel regulation and discuss the key features which such a definition should capture. Given the multidimensional and largely fluid nature of social science concepts that capture phenomena as evolving in reality—the family resemblance structure is more appropriate than the essentialist structure of necessary and sufficient condition. We also investigate how legal scholars have responded to these debates on regulation and assess the theoretical debates on legal pluralism to highlight the ways in which multilevel regulation builds on them. In Section IV, we analyse the regulatory space of marketing authorisation of medical devices in Europe and determine whether it is multilevel in character. We explain the development of legal rules, the primary regulatory actors and the nature and specificity between these actors.

II Multilevel Governance as an Inspiration for Multilevel Regulation

Current usages of the term 'multilevel governance' seems to be widespread and prolific amongst both political scientists as well as policy makers. However, there are significant differences between multilevel governance as a descriptive concept developed to theorise decision making within European policy processes and multilevel governance as a policy goal underlying the European integration project in general. Although the currency of these two conceptions have in some senses fed off each other, it is important to study them as separate, given that each has different functions, and therefore their substantive implications are distinct. Our focus here is on excavating the contours of the descriptive concept to then investigate whether it is possible to whittle down (in a rather reductionist manner) certain core features of the concept. Nevertheless, the political foundations of this concept have to a large extent also moulded (and to some extent have limited) the applicability of this concept; the debate on whether this concept primarily characterises a European political phenomenon is still ongoing. We will revisit this issue in the following paragraphs.

Most accept Gary Marks' study of European structural policy making in the early 1990s as one of the first expositions of the concept of multilevel governance.[31] The initial definition was therefore necessarily broad and referred to multilevel governance as:

> . . . a system of continuous negotiation among nested governments at several territorial tiers—supranational, national, regional, and local – as a result of a broad process of institutional creation and decisional allocation.

[30] European styles or approaches to regulation as being distinctive and reflecting the distinctive politico-institutional structures of Europe, L. Hancher and M. Moran, 'Introduction', in L. Hancher and M. Moran (eds), *Capitalism, Culture and Regulation* (Oxford University Press, 1989).

[31] G. Marks, 'Structural Policy and Multilevel Governance in the EC', in A. Cafruny and G. Rosenthal (eds), *The State of the European Community* (Lynne Rienner, 1993), at 391–410.

Subsequently, this definition was refined further by Marks and Hooghe in 2003 as implying 'reallocation of authority upwards, downwards and sideways from central states.'[32] Others like Kohler-Koch and Rittberger have also highlighted the role of private actors in these governance arrangements and the interdependence between them and other actors.[33] Shared decision making by actors operating across different administrative levels have been split into horizontal and vertical multilevel governance The former highlights the shift in responsibility within governance arrangements from government actors to a host of private actors (both non-profit and others).[34] While the latter refers to governance shifts away from the nation state to other administrative levels (subnational, regional and international).[35] Multilevel governance processes simultaneously make accessible European governance arrangements to a wide range of actors operating at different levels, and thereby making it more complex and therefore difficult to map.

Marks and Hooghe tried to address this problem by distinguishing between Type I and Type II versions of multilevel governance. They contended that Type I resembled federal arrangements and intergovernmental arrangements and is characterised by general purpose jurisdictions, where functions are bundled, and there are multiple (but limited) levels of government within a system-wide architecture. The Type II version is characterised by functionally specific jurisdictions, operating at different territorial levels in a flexible manner. They gave the example of such kind of arrangements operating at the local level in Switzerland (where *Zweckverbände* operate as goal-oriented jurisdictions). They also underline that such governance arrangements have also been variously referred to in scholarship as polycentric governance,[36] and FOCJ (functional, overlapping and competing jurisdictions).[37]

Various scholars have attempted to define the concept of multilevel governance. Phillipe Schmitter defined it:

> As an arrangement for making binding decisions that engages a multiplicity of politically independent but otherwise interdependent actors – private and public – at different levels of territorial aggregation in more or less continuous negotiation/deliberation/implementation, and that does not assign exclusive policy competence or assert a stable hierarchy of political authority to any of these levels.[38]

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[32] L. Hooghe and G. Marks, 'Unraveling the Central State, but How? Types of Multi-level Governance', (2003) 97(2) *American Political Science Review* 233–243.

[33] B. Kohler-Koch and B. Rittberger, 'The "Governance Turn" in EU Studies', (2006) 44 *Journal of Common Market Studies* 27–49, Annual Review.

[34] K. Eckerberg and M. Joas, 'Multi-level Environmental Governance: A Concept under Stress?' (2004) 9(5) *Local Environment* 405–412.

[35] M. Watson, H. Bulkeley and R. Hudson, 'Vertical and horizontal integration in the governance of UK municipal waste policy' (2004) paper presented Homeyer/Knoblauch: EPI and Multi-Level Governance—State-of-the-Art Report 15 at the IDHP Berlin Conference on the Human Dimensions of Global Environmental Change 'Greening of Policies—Interlinkages and Policy Integration', Freie Universität Berlin, December 3–4, 2004, draft paper.

[36] The foremost proponents being Vincent and Elinor Ostrom; V. Ostrom, 'Polycentricity', part I, in M. McGinnis (ed.), *Polycentricity and Local Public Economies* (University of Michigan Press, 1999), Readings from the Workshop in Political Theory and Policy Analysis, at 52–74. Also See K.P. Andersson and E. Ostrom, 'Analyzing Decentralized Resource Regimes from a Polycentric Perspective', (2008) 41 *Policy Science* 71–93.

[37] B. Frey and R. Eichenberger, *The New Democratic Federalism for Europe. Functional, Overlapping, and Competing Jurisdictions* (Edward Elgar, 1999).

[38] P. Schmitter, 'Neo-functionalism', in A. Wiener and T. Diez (eds), *European Integration Theory* (Oxford University Press, 2004), at 45–74.

This definition highlights the nature of engagement of multiple actors within such arrangements. The nature of engagement is not passive but active and also substantive in terms of shaping and steering decision making. Peters and Pierre's study zeroes in on a set of descriptions of multilevel governance: (1) it is governance (as opposed to government); (2) 'refers to particular kinds of relationships between several institutional levels' not hierarchically ordered but more contextually defined; (3) 'denotes a negotiated order rather than an order defined by formalised legal frameworks,' and (4) 'frequently conceived of as a political game.'[39] This again underlines the highly flexible nature of such arrangements and their decoupling from the statist administrative arrangements.

It has been stressed by Bach and Flinders that there is no one definition of Multilevel governance that enjoys consensus across academic disciplines.[40]

Although the development of multilevel governance as a concept is closely connected with the European political integration process, there have been several studies that have explored specific sectors like environmental policy. One such excellent empirical study was by Walti, in which she investigated whether multilevel governance structures affect environmental policy in industrialised countries. The study used two theoretical strands: functional federalism; which underlines the efficiency enhancement capabilities of decentralised governance, and the actor-related theory of federalism that stresses the potential for fragmentation and multiple veto points in such a system.[41] The study concluded that 'multilevel structures do play a role in environmental policy, albeit often an indirect one: to the extent that multilevel governance variables have a direct impact on environmental performance, their effect appears to be positive.'[42] This would seem to suggest that regulatory structures and distribution of competences ensuring subsidiarity will have a positive impact in the context of sectors wherein regulatory actions are influenced greatly by local factors.

If we were to provide for a tightly bound concept of multilevel governance (for instance like the Pattoni list of features) then it would seem that multilevel governance could be used to characterise any policy field within or outside the EU that displays those particular features—and this policy field can operate at the national, European or international level. Indeed this seems to be the presumption in studies of specific policy fields like energy efficiency,[43] environment,[44] food safety[45] and even development aid[46] in the context of multilevel governance. Part of the reason why there is a lack of consensus relates to the wide range of definitions of multilevel

[39] B.G. Peters and J. Pierre, 'Multi-level Governance and Democracy: A Faustian Bargain', in I. Bache and M. Flinders (eds), *Multi-level Governance* (Oxford University Press, 2004), at 75–89.

[40] I. Bache and M. Flinders (eds), *Multi-level Governance and Environmental Policy* (Oxford University Press, 2004).

[41] S. Walti, 'How Multilevel Structures Affect Environmental Policy in Industrialized Countries', (2004) 34(4) *European Journal of Political Research* 599–634.

[42] *ibid*, 624.

[43] International Energy Agency. 2009. Innovations in Multi-level Governance for Energy Efficiency. Information Paper, OECD/IEA: Paris Cedex.

[44] C.J. Paraskevopoulos, *Adapting to EU Multi-level Governance: Regional and Environmental Policies in Cohesion and CEE Countries* (Ashgate, 2006).

[45] T. Bernauer and L. Caduff, *European Food Safety: Multilevel Governance, Re-Nationalization, or Centralization?* (ETH Zurich, 2004).

[46] E. Patrick, Develtere Hertogen and F. Wanyama, *The Emergence of Multilevel Governance in Kenya*. Working Paper no. 7, Interdisciplinary Research Group on International Agreements and Development, LIRGIAD (KU Leuven 2005).

governance, which scholars[47] have worked with leading to what Sartori termed as 'conceptual stretching.'[48]

Other perspectives on European governance have also come from within the legal discipline. One of the earlier examples of this investigation was Markus Jachtenfuchs work on European governance[49] and the plea to refocus attention on the effects of globalisation and functional differentiation instead of addressing exclusively the question whether the national Member States will be replaced or overtaken by the European polity. In that sense, the European governance was reconceived as dynamic arena through the nation states, negotiated the pressures of globalisation and functional differentiation as propounded in the systems theory.[50] Another key focus driving studies of European regulation has been the issue of legitimacy of the EU.[51] The shift from law-based to nodal (network-based) governance within the EU by focussing on such processes as the open-method of coordination (OMC) has been highlighted.[52] Legitimacy deficits could also be addressed via multilevel control.[53] Others have sought to reveal the negative implications of having multilevel governance within the EU as a normative project.[54] Where the *demos* is sought to be replaced with expertise and technical knowledge, this then forms the basis of new public management. Scholars like Charles F. Sabel and Jonathan Zeitlin have characterised European regulatory processes as 'new architecture of experimental governance' highlighting a set of distinct features of European governance like framework goals that are set jointly by Member States and European institutions, autonomy to local bodies within Member States to device strategies and mechanisms to implement those rules and also to participate in a peer review process that regularly reviews their performance. They refer to this as direct deliberative polyarchy (DPP) and argue that it does promote new forms of democratic accountability which is not akin to representative democracy.

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[47] See E. Gualini, *Multi-level Governance and Institutional Change: The Europeanisation of Regional Policy in Italy* (Ashgate, 2004). P. Stubbs, 'Stretching Concepts Too Far? Multi-level Governance, Policy Transfer and the Politics of Scale in South East Europe', (2005) 6(2) *Southeast European Politics* 66–87.

[48] G. Sartori, 'Compare Why and How: Comparing, Miscomparing and the Comparative Method', in M. Dogan and Kazancigil (eds), *Comparing Nations: Concepts, Strategies, Substance* (Blackwell Publishers, 1994), at 14–34.

[49] M. Jachtenfuchs, 'Theoretical Perspectives on European Governance', (1995) 1(2) *European Law Journal* 115–133.

[50] In systems theory, subsystems based on functionality develop self-logic to a degree to which they become immune to external influence and become self-referential in action. Here, the state is not seen as the primary basis for social organisation—as the political arena is just one of the many arenas of functional differentiation. And, therefore reflection and not hierarchy becomes the new medium of governance. See G. Teubner (ed.), *Juridification of Social Spheres* (De Gruyter, 1987), at 3–48.

[51] C. Carter and A. Scott, 'Legitimacy and Governance Beyond the European State: Conceptualising Governance in the European Union', (1998) 4 *European Law Journal* 429–445.

[52] D. Radaelli, *The Open Method of Coordination: A New Governance Architecture for the European Union* (Swedish Institute for European Policy Studies, 2003); K.V. Kersbergen and F.V. Waarden, '"Governance" as a Bridge between Disciplines: Cross-disciplinary Inspiration regarding Shifts in Governance and Problems of Governability, Accountability and Legitimacy', (2004) 43 *European Journal of Political Research* 143. More generally, see, G. de Burca and J. Scott, 'Introduction: New Governance, Law and Constitution', in G. de Burca and J. Scott (eds), *Law and New Governance in the EU and US* (Hart Publishing, 2006), at 1–14.

[53] C. Scott, 'The Governance of the European Union: The Potential for Multilevel Control', (2008) 8 *European Law Journal* 59.

[54] C. Shore, '"European Governance" or Governmentality? The European Commission and the Future of Democratic Governance', (2011) 17 *European Law Journal* 287–303.

We do not use multilevel regulation as a normative concept, and in that sense not resemble multilevel regulation as it has been developed by European policy makers. Multilevel regulation is developed as a frame of reference to capture developments that are vertically linked across administrative or territorial levels within a specific regulatory space. Therefore, two important assumptions underlying this concept: first, regulatory actions like rule making, rule enforcement and rule authorisation is dispersed vertically across administrative levels, and in that sense, we eschew the horizontality of networks and sites of governance; second, multilevel regulation also assumes a dispersion of authority amongst public and private actors. These actors may be acting concomitant or in competition with each other. In the following section, we draw a distinction between regulation and governance in order to also highlight the differences between multilevel governance and multilevel regulation. Looking at multilevel regulation as a legal translation of multilevel governance would be a simplification and, that which has limited explanatory power.

III Defining Multilevel Regulation

A How is Multilevel Regulation Different from Multilevel Governance?

It may not come as a surprise that the differences between the concept of multilevel regulation and multilevel governance primarily lie in the distinction between what is known as governance and regulation in academic literature. As a heuristic category, 'governance' refers to the shift in nature and process of policy making within the modern nation state, in which, the government is a relationship of negotiation and cooperation with private actors from the public sectors, in setting up and implementing binding rules which may be implemented beyond the realm of the nation state, and also in some form of societal self-regulation.[55] In reductionist terms, one of the most important contexts of the usage of the term 'governance,' has been in the delivery of public goods and services, in the post-privatisation era[56]—in which the state is transformed into a gatekeeper ensuring that public goods are distributed in a fair and effective manner. And, on the other hand, 'regulation' refers to the control of private behaviour by public agencies to ensure that public interest is not violated within specific fields of delivery of goods and services.[57] This control is effected via a body of administrative rules. The term is also used in the context of self-controlling behaviour by private entities—self-regulation. As is apparent from the exposition of these two ideal type concepts, 'regulation' brings with it more of a statist[58] implication than 'governance.' Scholars have also argued that regulation is a small species action within the broader field called governance, based on its functionality.[59] The purposes of regulation are limited to that of steering private action with the aim of achieving a public good/goal. Therefore, multilevel governance

[55] R. Mayntz, 'New Challenges to Governance Theory' Jean Monnet Chair Paper 50 (Robert Schuman Centre of the European University Institute, EUI: Florence 1998).

[56] M.M. Atkinson and W.D. Coleman, 'Policy Networks, Policy Communities and the Problem of Governance', (1992) 5 *Governance* 154–180.

[57] C. Scott, 'Organizational Variety in Regulatory Governance: An Agenda for a Comparative Investigation of OECD Countries', (2001) 3(3) *Public Organization Review* 301–316.

[58] J.J. Laffont, 'The New Economies of Regulation Ten Years After', (1994) 62 *Econometrica* 507–537.

[59] Governance is about providing, distributing and regulating; See J. Braithwaite, C. Coglianese and D. Levi-Faur, 'Can Regulation and Governance Make a Difference', (2007) 1 *Regulation and Governance* 1–7.

refers to a range of policy-making activities both within and outside the nation state. Multilevel regulation on the other hand refers to the dispersed nature of rule/norm making, rule implementation and rule enforcement activities across different administrative levels both within and beyond the nation state. It is clear from the above that the primary point of difference between multilevel governance and multilevel regulation is the nature of outcome of such processes. Since multilevel regulation is closely connected with statist processes, the process of regulation has a direct or indirect (for instance self-regulation is often initiated in the shadow of formal legal requirements)[60] reference to formal legal processes either at the national, European or international level. In any case, the outcome of such a process will have an effect in terms of influencing or shaping the legal relationship[61] between the producers and enforcers,[62] and the followers of such norms and also the regulatory behaviour of individual actors[63] operating within the sector. This is not contingent on the quality of the norms—hard or soft norms—this holds true for both kinds of rules. Given that multilevel regulation shares a referential relationship with law, the entire range of activities covering the lifecycle of regulation[64] is reflected within multilevel regulation. Thus, multilevel regulation includes the process of creation, implementation and enforcement of regulation. To reiterate an earlier point, the key point of difference between multilevel regulation and multilevel governance is the question of legal/regulatory effect of the activities. Given that multilevel regulation will cover only such activities which would directly or indirectly have a legal effect—the scope of activities are much narrower than those which are covered under the multilevel governance concept. Therefore, only those activities which directly or indirectly affect the regulatory behaviour of the regulator or the regulatees are included within the definition of multilevel regulation.

B Towards a Definition of Multilevel Regulation: An Analysis of Key Features

Multilevel regulation is a term used to characterise a regulatory space, in which the process of rule making, rule implementation or rule enforcement[65] is dispersed across more than one administrative or territorial level amongst several different actors, both public and private. The relationship between the actors is non-hierarchical and may be independent of each other. Lack of central ordering of the regulatory lifecycle within this regulatory space is the most important feature of a multilevel regulation.

In order to understand the substantive import of the above definition of multilevel regulation, it is important to clarify some of the aspects of this description. First, we

[60] A. Heritier, and S. Eckert, 'New Modes of Governance in the Shadow of Hierarchy: Self-regulation by Industry in Europe', (2008) 28 *Journal of Public Policy* 113–138.

[61] In making this argument, we may be accused by what John Griffith referred to as 'the ideology of legal centralism'—exclusive focus on state law. We do not focus on only state law—but only rules that intend o create some regulatory effect—in terms of shaping behaviour.

[62] P. Grabosky, 'Counterproductive Regulation', (1995) 23 *International Journal of the Sociology of Law* 347–369.

[63] See, for a discussion of factors that influences regulatee behaviour towards compliance. A. Hopkins, 'Compliance with What? The Fundamental Regulatory Question', (1994) 34(4) *British Journal of Criminology* 431–443.

[64] L. Camacho-Romisher, 'The Regulatory Life Cycle and Regulatory Concerns for the Utilities of the Northern Mariana Islands', (2000) 40 *Natural Resource Journal* 569–601.

[65] Therefore, we extend it to the entire regulatory lifecycle, See C. Hood, H. Rothstein and R. Baldwin, *The Government of Risk: Understanding Risk Regulation Regime* (Oxford University Press, 2001).

have defined multilevel regulation as feature of a regulatory space. Herein, we draw on the concept of regulatory space[66] developed by Hancher and Moran. The primary theoretical assumption underlying this concept is the de-centring of the process of regulation from the state apparatus, and in which the state or public actors are just one of many regulatory actors (who are widely varied in nature and size) that interact with another to produce certain regulatory effects within the space. Thus, formal legal authority is just one of many sources of regulatory power. Monopoly over technical expertise can be another resource.[67] The presence of different sources of regulatory power, also leads to an uneven distribution of that power amongst the various actors. Regulatory power in this context refers to the ability of influencing and shaping substantive and procedural rules that govern regulatory outcomes within the specific regulatory space. The process of interaction between these regulatory actors is through both formal and informal networks, which as Scott puts it is characterised by 'negotiated interdependence and bargaining.'[68] This concept has, however, been criticised by Black,[69] because it considers too many variables that may lead to obfuscation rather than illumination of the reality. We think this criticism would stand when the concept is used in an isolated manner. However, as an analytical tool, it is just a useful first order framing device that allows us to focus on certain specific aspects of the regulatory regime and the micro-level dynamics within that aspect, and in enabling us to identify certain regulatory trends and contextualise macro-level developments that may be an outcome of such micro-dynamics.

Other characteristics seem to include the distribution of these rule making, rule implementation and rule enforcement activities across a diverse number of actors operating at different levels. The idea is to draw attention on two aspects. First that the regulatory process can be divided into these three aspects, rule formation/making, rule implementation and rule enforcement. Second, rules in this context mean both substantive and procedural norms that may or may not have legal sanction. Thus, it will also include private industry standardisation codes that may be followed by a number of manufacturers and receive informal recognition by enforcement agencies and therefore indirect sanction under law. Thus the quality of rules—whether they are soft or hard law—is not relevant to their identity—as long as they influence and shape regulatory behaviour of the actors operating within that regulatory space. Another aspect of this definition is that the sources of these rules and the actors that take part in the processes of rule making, implementation and enforcement could operate at different administrative or territorial levels. We have used the words administrative *or* territorial to convey sub-national levels as well as regional or international levels. In this case, within national states, regional authorities may be administratively constructed—for instance like subnational entities (eg Notified Bodies that oversees enforcement of medical devices regulation within EU Member States[70]) and outside nation states,

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[66] L. Hancher and M. Moran, 'Organizing Regulatory Space', in R. Baldwin, C. Scott and C. Hood (eds), *A Reader on Regulation* (Oxford University Press, 1998), at especially 148–172.

[67] D.W.P. Ruiter and R.A. Wessel, 'The Legal Nature of Informal International Law: A Legal Theoretical Exercise', in Pauwelyn, Wessel and Wouters, *op cit.*

[68] C. Scott, 'Analysing Regulatory Space: Fragmented Resources and Institutional Design', (2001) (Summer) *Public Law* 329–353.

[69] J. Black, 'Decentering Regulation: The Role of Regulation and Self-regulation in a Post-regulatory World', (2001) 54 *Current Legal Problems* 103.

[70] C. Scott, 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance', (2002) 29 *Journal of Law and Society* 56–76.

regional players—*viz*. EU and internationally, organisations like the UN, operate and may play important roles within a regulatory space.

It is important to note that the relationship between the actors involved within the regulatory space are necessarily non-hierarchical in nature. This is so because the actors are not self-identified members operating within a well-defined and well-ordered regulatory system, which is based on legal rules. In this case we specifically use the concept of regulatory space because it allows us the flexibility to focus on a specific aspect of the system that is not operating within a defined institutional system of rules—with clear hierarchy of order wherein each actors has been given a specific task within the system and operate in full knowledge of that competence. In this case, the actors operating within the regime may not have formal authority and therefore cannot be said to be in any hierarchical or even a well-defined relationship with other actors. The relationship between the actors is not defined by an ordered system of legal rules but is contingent on their control of resources, and in that sense it could well be a competitive or a collaborative relationship between actors at different points within the regulatory process and is therefore more pluralistic in nature. Another implication of such a construction is that there is a possibility that each of these actors could operate in dissonance with each other. In other words, the lack of hierarchy and therefore the absence of any presumption of central ordering means that the actors playing identical and even similar functions could operate concomitantly and independently of (and therefore also at crossroads with) each other. In fact, within specific regulatory sectors, it is a two-way process, wherein national regulators participate in European and transnational regulatory networks that make rules for domestic markets.[71]

The primary hook on which this construct of a regulatory space operates is how it responds to the question of delimitation. In other words, how do you limit the boundaries of a regulatory space and how do you therefore distinguish one regulatory space from another? The primary issue of difference between two regulatory spaces is the objective or subject of regulation. Thus, the regulatory space for pharmaceutical pricing is different from marketing authorisation of pharmaceuticals. This, to an extent, helps to distinguish between two analogous but different regulatory spaces. Another mode of delimiting a regulatory space is in terms of the legal rules that construct or operationalise that regulatory space. Certain rules will be of primary importance, and others will only regulate certain minor or residual aspects of the regulatory space. Of course this does not preclude a certain degree of overlap between two regulatory spaces. Hancher and Moran chose to focus on the 'range of issues' that define or are *sui generis* to that regulatory space. This is similar to the object/subject of regulation argument which we referred to earlier. The underlying assumption is that each regulatory space can be differentiated in terms of the range of issues that is specific to it.

C Multilevel Regulation: Response from Legal Scholars

Globalisation and its impact on the role of law has been an important arena of legal research that has provided the impetus to re-engage with the idea of legal pluralism. The acceptance that there are coexisting normative orders that challenge state-led law making in several areas has been explored by lawyers[72] and other researchers from

[71] See footnote 17.

[72] F. Maitland, 'A Prologue to the History of English Law', (1898) 14 *Law Quarterly Review* 13.

social sciences and anthropology.[73] Pluralists have sought to record spaces characterised by multiplicity of norms functioning in the absence of a meta-norm and of complex overlapping institutional norm production authorities. Francis Snyder's idea of global legal pluralism includes two aspects; the structural and the relational. The former, relates to the several sites that may be structurally different—comprising of legal institutions, binding norms and dispute resolution processes. And the latter, refers to the diversity of relation types between these sites, ranging from autonomy to independence.[74] Braithwaite and Drahos have argued that increasingly in a number of policy areas, transnational private regulation is being adopted by nations (referring to them as rule takers rather than rule makers).[75] They identify policy areas such as environment and financial security, where global regulation has driven down standards. And, contrast it to general economic regulation. Structural coupling is the term suggested by Larry Catá Backer is what is taking place between private governance systems and public governance systems transnationally leading to a 'coordinated metagovernance.'[76]

The global administrative law project[77] led the movement on highlighting the enormous growth of transgovernmental regulation across a diverse number of sectors—banking and financial regulation, environmental protection, public health and safety, labour standards, humanitarian issues and consequently the upward delegation of regulatory decision-making authority. This growing integration of hitherto national policy sectors with global regulatory processes is a reality in a number of policy sectors and poses a challenge to the national structure of constitutional checks and balances which were built to safeguard such decision-making processes. Within European studies, legal scholars like Pernice and De Witte have developed the multilevel constitutionalism as a framework to describe the uniquely *sui generis* relationship between two supreme legal institutions functioning nationally and regionally.[78] Lastly, as mentioned earlier, Berman's approach to globalisation is first to accept that there are hybrid legal spaces, where the actor is regulated by multiple normative frames. This may result in conflict, although this, he contends, should not be seen as negative—pushing the utility of legal pluralism from just being a descriptive concept to one that can provide

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[73] H. Berman, *Law and Revolution: The Formation of the Western Legal Tradition* (1983); W. Ullmann, *The Medieval Idea of Law* (1969). S. Engle Merry, 'Law and Colonialism', (1991) 25 *Law & Society Review* 889. S. Engle Merry, 'Global Human Rights and Local Social Movements in a Legally Plural World', (1997) 12 *Canadian Journal of Law and Society* 247. W.W. Burke-White, 'International Legal Pluralism', (2003–2004) 25 *Michigan Journal of International Law* 963.

[74] F. Snyder, *The EU, the WTO and China: Legal Pluralism and International Trade Regulation* (Hart Publishing, 2010).

[75] J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge University Press, 2000). Another example being the entire area of international standardisation led by ISO; See H. Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing, 2005), at 407.

[76] L.C. Backer, 'Private Actors and Public Governance Beyond the State: The Multinational Corporation, the Financial Stability Board and the Global Governance Order', (2011) 17 *Indiana Journal of Global Legal Studies* 751–802.

[77] B. Kingsbury, N. Krisch and R.B. Stewart, 'The Emergence of Global Administrative Law', (2005) 68 *Law and Contemporary Problems* 15–61.

[78] I. Pernice, 'Constitutional Law Implications for a State Participating in a Process of Regional Integration: German Constitution and "Multilevel Constitutionalism"', in E. Reidel (ed.), (1998) 40 *German Reports on Public Law*; I. Pernice, 'Multilevel Constitutionalism and the Treaty of Amsterdam: European Constitution-Making Revisited', (1999) 36 *Common Market Law Review* 703–750.

important clues to the design of institutional structures and mechanisms that allow for a sort of peaceful coexistence of normative structures.[79]

In the second place, scholars have argued for a multilevel regulatory regime in the case of specific policy issues such as climate change, which requires a multilevel and multi-actor approach.[80] The primary aspects of this phenomenon being of interest to legal scholars, is the multiplication of formal and informal fora wherein regulation formation is taking place. There is a great diversity in the nature of fora—and that also includes those that focus on developing technical regulations within a specific context—for instance the International Civil Aviation Organization (ICAO) on aircraft engine emissions.[81] Herein, it is necessary to underline that over the past decade there has been have been a spurt in the activity of technical fora set up internationally to develop technical norms (some perhaps soft). Most of these forums operate under the aegis of one or the other intergovernmental body—ie they draw substantial amount of legitimacy for their activity by being associated with them. However, they are usually independent in terms of their own membership and functions from these intergovernmental bodies. Their basic claim to the legitimacy of their activity, and therefore for the norms they are generating, is via their technical expertise. The production of norms therefore has been dispersed across a number of forums which may be only tenuously linked to intergovernmental organisations.[82] This means that constitutional checks which were practiced within such organisations are not in force and therefore may not inhibit norms being produces in such non-governmental forums. This is possibly the primary legal puzzle which legal scholars have to address within this context: how to ensure that international norms are constitutionally valid.[83]

IV An Example from Practice: The Regulatory Space of Marketing Authorisation of Medical Devices in Europe

In this section, we explore the authorisation of medical devices in Europe as a separate regulatory space and investigate the usefulness of the term multilevel regulation in allowing us to highlight specific features of this regulatory space. The European regulatory framework for medical devices is unique. It is based on the *New Approach* legislations that envisage a distinct form of law making and implementation of law.

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[79] H. Berman and P. Schiff, 'Global Legal Pluralism', (2007) 80 *Southern California Review* 1155; Princeton Law and Public Affairs Working Paper no. 08-001.

[80] K. Kern, 'Climate Governance in the EU Multi-level System: The Role of Cities', Paper prepared for presentation at the Fifth Pan-European Conference on EU Politics, University Fernando Pessoa and Faculty of Economics of Porto University, Porto (Portugal), June 23–26, 2010. B.G. Rabe, 'Beyond Kyoto: Climate Change Policy in Multilevel Governance Systems', (2007) 20(3) *Governance* 423–444.

[81] Annex 16—Environmental Protection, Volume II—Aircraft Engine Emissions to the Convention on International Civil Aviation, Third Edition, 2008. http://www.icao.int/environmental-protection/Pages/environment-publications.aspx.

[82] E. Chiti and R.A. Wessel, 'The Emergence of International Agencies in the Global Administrative Space: Autonomous Actors or State Servants?' in N.D. White and R. Collins (eds), *International Organizations and the Idea of Autonomy: Institutional Independence in the International Legal Order* (Routledge, 2011), at 142–159.

[83] P. Weil, 'Towards Relative Normativity in International Law?' (1983) 77 *American Journal of International Law* 413–442. R.A. Falk, 'To What Extent are International Law and International Lawyers Ideologically Neutral?' in A. Cassese, J.H.H. Weiler (eds), *Change and Stability in International Lawmaking* (1988), at 137; and C.M. Chinkin, 'The Challenge of Soft Law: Development and Change in International Law', (1989) 38 *International and Comparative Law Quarterly* 850.

Law making in the field is limited to providing essential requirements, implementation to which can be fulfilled through conformity with 'harmonised' standards. The standards are developed by CEN/CENELEC, ETSI, either on demand through a mandate issued by the European Commission or independently, and are then included in the list of harmonised standards if the commission deems them to be useful for ensuring compliance with regulatory obligations. Private entities referred to as notified bodies are also involved in law implementation. These bodies perform conformity assessment of companies in order to see compliance with regulatory obligations. Expert involvement in the standardisation process and those in notified bodies performing conformity assessments therefore characterise rule making and rule implementation in medical devices regulation in Europe. As a regulatory space, it is therefore an ideal case to test the utility of the concept of multilevel regulation.

It is important to underline that the concept of multilevel regulation is in a sense a kind of glasses that we put on in order to make sense of specific functional features of that space. This would necessarily have to be followed up by looking at the implications or the effects of such a multilevel regulatory structure on legal certainty for instance. However at this stage, we are content to limit our analysis to explaining two primary aspects of our contention. First, to define marketing authorisation of medical devices in Europe as a separate regulatory space—our aim is to discuss the critical hooks on which we develop this analytical notion—building largely from Hancher and Moran's work. Second, following the definition of multilevel regulation that was developed in the previous section, we elucidate on two factors that form the basis of multilevel regulation—the distribution of rule making, rule enforcement and rule adjudication authority across multiple actors operating at different administrative levels and the authority for rule interpretation being shared amongst these actors. We examine the operational dynamics in this particular regulatory space so as to elucidate the application of multilevel regulation.

Hancher and Moran, while developing the concept of a regulatory space, specify that;

> Dimensions and occupants can be understood by examining regulation in any particular national setting, and by analysing that setting in terms of its specific political, legal and cultural attributes.

They also demarcate a regulatory space with reference to a

'range of regulatory issues in a community.'

We choose to focus on two benchmarks that help us delimit a regulatory space: first is the regulatory objective—which in every sense is intimately connected to the range of regulatory issues referred to by Hancher and Moran. The regulatory objective will help in determining which is the larger arena being carved out as a regulatory space and will also provide unity to the issues included within that regulatory space. Second are the rules—we refer to the legal rules within the EU that shape this legal space and determine the architecture, general principles and the actors that perform important regulatory functions under the legal rules. We are of course aware that there may be other actors as well that may not be mentioned within the legal rules but may also perform an important function—however, as a first step—we select actors based on their role and functions as provided under the legal rules—because law does provide formal legitimacy to the function of these actors. In the second step we will also focus our attention on those actors who may derive their legitimacy from other factors such as access to regulatory information, etc.

Here, we focus on regulatory objective of marketing authorisation. Marketing authorisation takes very different regulatory pathways in the case of devices and medicinal products. In the case of the latter, the manufacturer or the applicant has to *ex ante* prove the safety and efficacy of the product as well as reduce risks as much as possible before the product is granted a marketing authorisation and placed on the market. For medical devices, the burden of proof is that of compliance with quality systems and conformity assessment to specified product standards—this assures a CE marking—thereafter, the product can be launched in the market. However, marketing authorisation of medical devices is similar to that of medicinal products; in as much as for both, it acts as the main regulatory doorway through which all other regulatory obligations are fulfilled. The grant of marketing authorisation presupposes the completion of other regulatory obligations along the product development cycle. Marketing authorisation is the pre-eminent part of the regulatory landscape of medical products in general, and therefore for our purposes an important regulatory space to be investigated.

The regulatory space of marketing authorisation of medical devices within the EU is in the first place shaped by the European rules that regulate this process in this sector. The three main European rules regulating this space are; three directives—90/385/EEC (active implantable medical devices), 93/42/EEC (general medical devices) and 98/79/EC (*in vitro* diagnostic medical device) and five other modifying and implementing directives. These three primary directives were based on the 'new approach' to technical harmonisation and standards that was adopted by the Council in 1985. At its crux, it allows legislations to be adopted at a level of generality reflecting certain regulatory principles and which then can be achieved by conforming to voluntary standards that are harmonised at the European level by bodies such as the CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization). The idea behind is to disincentivise member countries from adopting standards nationally and thereby resulting in fragmenting the European internal market. It was also a solution to the mounting number of legislative documents for each product specification. Therefore the choice of general requirement directives to be supplemented by voluntary standards—following which will ensure a presumption of conformity—will also allow the legislative framework to keep pace of scientific and technical progress driving product developments.

The first question put forward is the nature of distribution of regulatory authority—rule making, rule enforcement and rule adjudication. It is important to understand the unique nature of rule making activities in the context of medical devices. As mentioned, there are two kinds of regulations in this sector—one is more in the nature of general principles or essential requirements laid down within the directives and the other, being the harmonised technical standards that are developed by the CEN and CENELEC. The European Commission Directorate General for Heath and Consumers (DG SANCO) and the Competent Authority of the Member States are the primary actors in charge of the rule making. The latter essentially provides input and has been closely involved in the rule-making process—especially in the drafting of the three directives that form the crux of the rules. Further because these rules, which are in the form of directives have to be transposed into national legislation—it gives the competent authorities of the Member States room to play a more active role in rule making—by legislating additional requirements on top of the primary requirement under the European directives. DG SANCO, the primary rule maker has walked the extra mile—in terms of taking up measures—which may not have the support of the competent authorities of the Member States. The recast (RECAST is the term officially used by the

European Commission to refer to the process of legislative changes that was under discussion with references to the medical device directives. However since then, the European Commission in the end of 2011, has stated that the term RECAST creates an incorrect allusion to the nature of amendment of the directives, They preferred using the term "revision", since the changes being considered could lead to fundamental changes in the regulatory structure of medical devices in Europe) process has been one such example in which both these actors has taken contrarian positions. The standardisation process on the other hand is dominated by industry actors who have used the open and facilitative processes that underlie such activities—to take a proactive role in suggesting and lobbying for standards.

In the case of rule enforcement, marketing authorisation of medical devices adopts the principle of third party assessment. So we have the regulators, regulatees and then compliance checks or rule enforcement is undertaken by private bodies—notified bodies. Each of the Member States notifies to the European commission (therefore the term notified bodies) the number of such bodies functioning in its territory—and has the responsibility of overseeing the functioning of such bodies. It is the notified bodies that are tasked with undertaking conformity assessment of companies and in giving permission to companies to use the CE marking before placing the products on the market. The competent authorities of the Member States have the responsibility of ensuring that all the notified bodies have the necessary competence to perform the functions that it has been notified for and also to oversee the conformity assessment activities that it undertakes. With the exception of certain kinds of high risk medical devices, a manufacturer could approach any of the notified bodies for their services in assessing conformity assessment and subsequently and directly market their products within the internal market. It is important to note that although enforcement is a function performed by notified bodies, it is the competent authorities that have the oversight over them. This is an important authority especially because a manufacturer can use the conformity assessment services of any notified body and not necessary those established in the nation in which they would like to market their device.

Rule adjudication refers to the competence and authority vested in a single actor to adjudicate a dispute between two regulators on any issue that is addressed within that regulatory space. This is different from legal adjudication wherein the regulator and regulatees are usually seen on opposing sides and where the court of law steps in to adjudicate. To give a concrete example, Recital 12 of the Directive 2001/83/EC provides that in case of a difference of opinion between Member States on the quality, the safety or the efficacy of a medicinal product under the decentralised (mutual recognition) procedure of marketing authorisation of medicinal products, it will be referred to the Committee for Medicinal Products for Human Use (CHMP), which was established by Regulation (EC) no. 726/2004 and which replaces the former Committee for Proprietary Medicinal Products (CPMP). No such similar procedure or body to adjudicate exists in the case of marketing authorisation of medical devices in Europe, therefore giving credence to the problem of lack of uniform enforcement that has been discussed in the context of this regulatory space.

The proposal for the recast of the directives[84] states; 'uniform implementation of the directives has been hampered by national variation in areas of definition of a medical device, national registration procedures, classification and interpretation of

[84] European Commission, Roadmap 2011, April 2010.

guidance. The variation threatens not only the smooth functioning of the internal market, but also in this case, the health and safety of patients.' There are essentially three aspects of the regulatory regime that these criticisms allude to. First is the question of product classification regulatory channels that each of them will follow—the determination of what constitutes a pharmaceutical product or a medicinal device although defined by European directives—primarily it is the intended use of the product as well as the primary mode of action (in case of physical/chemical then a product and in case of mechanical then a device)—there are many exceptions. For instance in Germany, tissue-engineered products are considered pharmaceutical products, whereas in France and the Netherlands and UK, they are considered medical devices. Therefore, given the radically different character and regulatory pathways of medical devices and pharmaceutical products, this variance in product definition may affect the quality of compliance. This also highlights that despite valiant efforts at harmonisation via standardisation, Member States reserve important legislative powers which may limit the objectives of the European legislations.

The next issue is that of rule interpretation of the legislation. As mentioned in the previous paragraphs, the legislative framework for medical devices was deliberately structured towards general principles—the compliance with which could be achieved through conformity with voluntary standards. However, what was not envisaged was the large body of explanatory or guidance documents that would be required to interpret those standards for ensuring compliance. The foremost amongst them are the MEDDEV (Guidelines relating to medical device directives), which explain and interpret all aspects of the directives for manufacturers and notified bodies—these are not legally binding and are issues by the European commission. The commission web site on the guideline states that:

> They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the documents. Therefore, they reflect positions taken in particular by representatives of Competent Authorities . . . and Commission Services, Notified Bodies, industry and other interested parties in the medical devices sector.

In addition, we have 'consensus statements' which are again endorsed by the European commission and drafted by the Medical Devices Expert Group (MDEG)—a loose conglomeration of experts representing all interests within the field. Then, we have interpretive documents that are issued directly by the European commission in the event of any amending directives or international treaties that will affect the functioning of the regulatory regime. Lastly, we have the standards themselves, which are issued by CEN/CENELEC and which represent consensus between different interests—primarily driven by private actors—such as manufacturers. Apart from this, the notified bodies group (NBG) has also published guidance documents, as well as competent authorities of Member States—for instance the Medicines and Healthcare products Regulatory Agency (MHRA) of UK has been extremely active in developing guidance for manufacturers. Thus, there are multiple actors which participate within the process of rule interpretation. *Prima facie* one may distinguish between the legal values of each of these kinds of documents; however, it is important to realise that the existence of multiple actors that have the power of rule interpretation and operating at national and European levels may lead to heterogeneity in regulatory responses and the concomitant regulatory uncertainty.

In conclusion, if we were to provide an overview of the regulatory space of marketing authorisation of medical devices, we would find that the primary activities of

rule making and rule enforcement are being performed by multiple actors at both the European and national levels. Further, there is no specific authority for rule adjudication—unlike in the medicinal products sector—and this contributes to the non-hierarchical nature of relationship between these actors. Most importantly on the aspect of rule interpretation, there are various kinds of guidance documents that are being issued by different actors—*viz*. European Commission, MDEG, NBEG, as well as by national competent authorities of Member States. Through their rule enforcement functions, both the competent authorities of Member States, as well as the notified bodies, have extensive rule interpretation authority. These characteristics make this regulatory space *prima facie* multilevel in nature. The following question would naturally be, 'what are the implications of this finding?' In this paper, we do not focus on investigating the implications of multilevel regulation. However, *prima facie*, the discussion in this section does point out to specific developments in this sector that are critically different from the way national legal systems functioned. One of the most immediate problems that have arisen in this regulatory space (and referred to in previous sections)—a direct consequence of the architecture of multilevel regulation—has been the lack of uniformity of enforcement and the fragmentation. These reasons have been widely referred to in the proposal for recast and also have been largely accepted by the actors.[85] Rise in regulatory uncertainty is a logical consequence of such fragmentation and lack of uniformity within this regulatory space. Regulatory uncertainty could adversely contribute to the lack of legal certainty.

As mentioned in the earlier section, the aim of this paper is not to discuss the 'implication' of multilevel regulation—this is the later task. The limited aim of this paper is to establish the 'utility' of the concept of multilevel regulation. As discussed in the context of the regulatory space of marketing authorisation of regulatory devices, the concept highlights the regulatory architecture, the functions and the actors operating within this space, and the fissures and fragmentation that may result from this architecture. This may lead to increasing regulatory uncertainty, which seems to be the primary concern of the European Commission proposal to recast the medical devices regulations at the European level. Another important aspect is that once we accept that a specific regulatory space is multilevel in character, and that this may lead to fragmentation and create legitimacy and effective challenges, we also need to design responses or checks and balances that go beyond those traditionally embedded within the constitutional framework of the national state. The changed architecture and the roles of the actors, within the multilevel regulatory structure will also provide the first clues as to the points at which such effectiveness and legitimacy deficits should be addressed.

Thus, the utility of the concept is three-fold. First, its descriptive function allows us to capture the current processes of regulation as they occur within specific regulatory spaces; and second, it allows us to assess whether significant aspects of this changing regulatory architecture itself results in legitimacy and effectiveness deficits that may arise from structural fragmentation and dispersion that is synonymous with multilevel regulation. And third, in addressing these deficits, it enables us to look beyond traditional constitutional mechanisms that are nationally embedded to a more hierarchically sensitive mechanism that are more suited to address leakages in system operating at various administrative levels—both above and below the nation state (Table 1).

[85] One of the actors—the competent authorities of the Member States have also reacted to this problem and sought to address this by setting up the Central Management Committee to meet more regularly—4 times in a year—in order to enable more coordination between the functioning of the competent members.

Table 1. Regulatory pace of marketing authorization of medical devices

Regulatory lifecycle	Administrative levels	Actor responsibility	
		Primary	Oversight
Rule making	International — Guidance documents	GHTF (global harmonization task force)	
	European — Directives — MEDDEVs — Standards	DG SANCO MDEG (medical devices expert group) CEN(European committee for standardization)	— DG SANCO
	National — Implementing national acts	National competent authorities	— DG SANCO
Rule enforcement	International	None	
	European		— DG SANCO — Central management committee (national competent authorities) — NBOG (notified body operations group)
	National — Conformity assessment of individual products	Notified bodies	National competent authorities
Rule adjudication	International	None	
	European	— ECJ — MDEG	
	National	— National courts	

V Conclusion

Our focus here was to understand the several meanings and the contexts in which the concept of multilevel regulation has emerged. In this endeavour, we first focussed on providing a brief historical overview of the development of the concept of multilevel governance. Although these two concepts have sometimes been used interchangeably by scholars, we have argued that they are distinct from each other. The point of difference between multilevel regulation and multilevel governance is the question of legal/regulatory effect of the activities. We have argued that that multilevel regulation will cover only such activities which would directly or indirectly have a legal effect—the scope of activities are much narrower than those which are covered under the multilevel governance concept. Therefore, only those activities which directly or indirectly affect the regulatory behaviour of the regulator or the regulatees are included within the definition of multilevel regulation. We have also argued that the European context within which the concept evolved does not primarily limit the application of the concept to study European regulatory activities. Given the definition that was presented in this paper, it is possible to have regulatory spaces characterised by multilevel regulation in other countries/regions as well.

We have also sought to develop multilevel regulation as a characteristic of a regulatory space, which would allow for a wider and more specific usage of the concept. Indeed that has been one of the hallmarks of its present usage where it has been used to illustrate specific international processes that can also be subsumed under different and other competing labels such as the 'post-regulatory state.' We have also developed the concept with the assumption that the multilevelness of a regulatory space may vary over time (depending on the nature of the regulatory process or the shift of competences from the national to the EU level), and therefore a regulatory space can be characterised by high or low multilevelness. In that sense, a negative concept of multilevel regulation would refer to hierarchical bound public regulation of a regulatory space within nation states, wherein there is a clear difference between a regulator and a regulatee, and all regulatory activity can be traced inside the chain of public actors aligned together within the government and functionally responsible to one single public actors within the state.

With the continuing blurring of boundaries between legal orders, the notion of multilevel regulation may be helpful in explaining newer forms of regulation, which in many regulatory spaces are increasingly in the hands of a variety of actors at different levels of governance. Accepting and defining this phenomenon is the first step, but more importantly, the possible consequences open a new research agenda in which many of the foundations of legal science (concerning the sources of law, the rule of law and the binding nature of norms) need to be re-assessed.

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