Tamara K. Hervey, Calum Alasdair Young, and Louise E. Bishop (eds), Research Handbook on EU Health Law and Policy

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Jean Claude Juncker began his term as President of the European Commission at a time when enthusiasm for the European project was terminally low and the challenges facing it had reached an unprecedented high. Recognising the need to concentrate resources and regain support, he pledged to lead a reformed Commission that would be 'big on the big things and small on the small things', focusing on specific policy areas and reducing the burden of European Union (EU) law across the *acquis*.[1] This has led to a reduction in legislative output in policy areas not identified as priorities and an increase in evaluations of the 'fitness for purpose' of existing legislation, with the goal of reducing red tape and lowering costs for economic operators. Falling squarely in the category of 'small things', health is the epitome of the 'non-priority' experience. Health did not feature in any of President Juncker's 10 priority projects, no dedicated vice president was appointed, and no team has been established to forge progress on health objectives. The mission letter sent to the Health Commissioner, Vytenis Andriukaitis, confined health activity to a few, clearly delimited areas,[2] whilst DG Santé (the Directorate General for Health and Food Safety) has seen its human resources reduced.[3] As a result, there have been virtually no new legislative initiatives in this decade, and civil society actors concerned about the future of existing programmes and co-operation, recently launched a campaign to defend health as a 'core business' of the EU.[4]

These trends should not be taken to imply that EU health law and policy is no longer relevant, important, or under development. DG Santé is not the only DG to have had its resources reduced and it remains one of the busiest directorates in terms of legislative output, on account of the vast number of implementing and delegated acts that support its central *acquis*. Moreover, activity in some areas of the portfolio has increased – the State of Health in the EU exercise, for example, is a new initiative which seeks to strengthen the EU knowledge-base by gathering data on member states health systems,[5] and has seen resources transferred to it for this purpose. However, President Juncker's reforms imply that action on health should be limited to that explicitly prescribed in the treaties, serving one of the President's priorities, and/or deemed by the Commission leadership to represent genuine added value. The Brussels health community, in particular the NGO community, is thus concerned that whilst action on health systems data collection, such at the State of Health exercise,[6] has found renewed impetus as part of the macroeconomic governance framework, commitments in traditional areas of public health like alcohol, obesity and non-communicable diseases have dried up.[7] Even responses to pressing international health threats, such as antimicrobial resistance, have

[1] President Juncker *A new start for Europe: My agenda for jobs, growth, fairness and democratic change*, <https://ec.europa.eu/commission/publications/president-junckers-political-guidelines_en> accessed 30 August 2017.
[2] President Junker mission letter to Health Commissioner Vytenis Andriukaitis, 1 November 2014 <https://ec.europa.eu/commission/sites/cwt/files/commissioner_mission_letters/andriukaitis_en.pdf> accessed 30? August 2017.
[3] HR Key Figures data obtained directly from European Commission DG Human Resources in July 2017.
[4] Campaign for the EU to do more for health, <https://epha.org/eu-do-more-for-health-campaign/> accessed 30 August 2017.
[5] See State of Health in the EU, <https://ec.europa.eu/health/state/summary_en> accessed 30 August 2017.
[6] State of Health in the EU programme, see https://ec.europa.eu/health/state/summary_en accessed 30 August 2017.
[7] Data collected from my interviewees in Brussels in June and July 2017.

'fallen short'.[8] EU health law and policy has always been a patchwork of instruments and commitments rather than a coherent regime but now for the first time, perhaps in its history, there seems to be potential for elements of the patchwork to dissolve.

The story of EU health law and policy under the Juncker Commission – and to some extent in the longer post-crisis period – is a stark affirmation of the central thesis of Tamara Hervey, Calum Alasdair Young and Louise Bishop's timely *Handbook*, in that the current constitutional order of the EU is clearly not sufficient to guarantee, protect or promote health as an EU priority. Faced with an economic, social and democratic crisis, the EU has retreated to its market-facilitating origins, encouraging austerity and fiscal conservatism at the expense of the European Social Model. For health, two distinct trends can be identified in the post-crisis experience. The traditional fields of EU health law and policy, explored in a small but comprehensive body of existing literature[9] and updated in the *Handbook*, are, at best, in a holding pattern. This has been perceived as a decline because although the majority continue to operate in the status quo, there have been no new initiatives and some areas are even exhibiting signs of policy dismantling.[10] A small number of areas have, however, seen progression in recent years, on account of their relevance to President's Juncker's priority projects and the broader economic growth agenda of EU leaders. These include eHealth[11] and performance assessment and health technology assessment (HTA), marking a shift in the kind of EU health law and policy enabled and pursued under current constitutional settings, but not a redressing of the fundamental imbalance between health and market objectives.

The weak competence ascribed in the founding treaties[12] means that the pursuit of health objectives at EU level has always been difficult. Despite the breadth and variety of health topics explored by the *Handbook's* contributors, each chapter reveals the weaknesses, gaps and inconsistencies in prevailing EU health institutions, causing the editors to (rightly) remark on its durability in the face of fragility (p 9). The development of EU action on health is perhaps best thought of as a bell curve - building momentum during the 1990s, when an explicit treaty competence was first adopted[13], and through the 2000s to a 'peak' during the height of the economic crisis in 2010/11.[14] Early co-operation in areas of public health –

[8] European Public Health Alliance, 'New EU Action Plan on Antimicrobial Resistance advances One Health vision, but falls short on concrete action' (2017) <https://epha.org/eu-action-p an-amr-2017-no-concrete-action/> accessed 30 August 2017.

[9] See, for e.g., M McKee, E Mossialos, R Baeten, *The Impact of EU Law on Health Care Systems* (Peter Lang 2002); E Mossialos and M McKee, *EU Law and the Social Character of Health Care* (Peter Lang 2002); T Hervey and J McHale, *Health Law and the European Union* (CUP 2004); M Steffen (ed), *Health Governance in Europe: Issues, Challenges and Theories* (Routledge 2005); S Greer, *The Politics of European Union Health Policies* (OUP, 2009); E Mossialos et al., (eds.), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010).

[10] Based on data collected from my interviews with the Brussels health community in June and July 2017. Also see A Jordan et al. (eds) *Dismantling Public Policy: Preferences, Strategies and Effects* (OUP 2012); E Brooks, 'Post-crisis health policy: Dismantling at the EU level?', paper presented at the European Consortium for Political Research Annual Conference, September 2017, Oslo.

[11] Ch 10.

[12] Article 168 of the Treaty on the Functioning of the EU gives the EU powers to coordinate and support cooperation on issues of public health, but precludes harmonisation or exclusive EU competence, reiterating member states' autonomy over the organisation and delivery of healthcare.

[13] Article 129 EC, Treaty of Maastricht, 1991.

[14] Acknowledging that such chronologies can be cut a dozen different ways, a minor criticism of the *Handbook's* first substantive chapter might be made that the authors' choice of chronological structure – divided into the pre-Maastricht Treaty era, the 1992-2007 period leading up to the adoption of the Lisbon Treaty, and the post-Lisbon era – risks obscuring this peak and the oscillating momentum of EU health law and policy in this final period.

Cancer, HIV/AIDS, communicable disease – supplemented measures to facilitate the 'health market' in pharmaceuticals, tobacco, food and health professionals, all underpinned by the principles of free movement, competition and market efficiency. By the late 2000s, negotiations had begun on, for example, the revision of legislation on clinical trials,[15] the pharmaceutical package,[16] the action plan on health workforce,[17] the Joint Action on HTA,[18] the directive on human organs for transplantation.[19] A third public health action programme,[20] running from 2009-2013, expanded EU activity even further, emphasising health inequalities, health security and the need to generate health knowledge.[21] The peak of this integrative momentum was reached with the adoption of the Directive on Patients' Rights in 2010,[22] Although the body of the Directive addresses a relatively small and distinct set of circumstances, its impact was significantly amplified by the Commission's capacity to include supplementary provisions. The final text provides for new EU activity in eHealth, HTA and the establishment of reference networks for co-ordinating expertise in specific disease areas, as well as a strict application of free movement principles in healthcare services. The degree of expansionism in the Directive is largely unprecedented, marking the 'high water' point of EU health policy influence and integration.[23]

Since the adoption of the Patients' Rights Directive, the focus of health law and policy in the EU has shifted. The coverage of these new (or at least newly revived) foci is one of the primary strengths of the *Handbook*. In addition to providing no less than four in-depth and challenging contributions on health technologies,[24] it offers comprehensive introductions to some of the most recent developments in EU health activity in the chapters on macro-economic governance, trade and global health.[25] In doing so, it does not overlook the 'traditional' areas of EU intervention in health – those concerning public health and the 'health market' – but it contextualises them as among several facets of a broader EU health law and policy. Accordingly, the *Handbook* is divided into five principle sections – historical and institutional contexts, people and products, systems, public health, and the external dimension – which, to use a grossly rudimentary measure, reflect the degree of EU involvement in their size. With six and four chapters respectively, the sections on people and

[15] Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC OJ L 158/1.

[16] The Pharmaceutical Package was a set of three legislative proposals – tackling falsified medicines, pharmacovigilance and information to patients – issued by the European Commission in 2008. See <https://ec.europa.eu/health/human-use/package_en> accessed 12 October 2017.

[17] European Commission Staff Working Document on an action plan for EU health workforce, SWD(2012) 93 final, 18.4.2012.

[18] EUnetHTA, the EU's joint action on HTA, is now in its third iteration. See <http://www.eunethta.eu/activities/joint-action-3/jointaction31/eunethta-joint-action-3-2016-2020> accessed 12 October 2017.

[19] Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation, OJ L 207/14.

[20] Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020), OJ L 86/1.

[21] See K Anderson, *Social Policy in the European Union* (Palgrave Macmillan 2015) 175.

[22] Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, OJ L 88/45.

[23] M Peeters 'Free movement of patients: Directive 2011/24 on the application of patients' rights in cross border healthcare' (2012) 19 *European Journal of Health Law* 26; W Sauter 'Harmonisation in Healthcare: The EU Patients' Rights Directive' TILEC Discussion Paper No. 2011-030: See SSRN <https://ssrn.com/abstract=1859251> or <http://dx.doi.org/10.2139/ssrn.1859251> accessed 12 October 2017; E Brooks 'Crossing borders: A critical review of the role of the European Court of Justice in EU health policy' (2012) 105 *Health Policy* 33.

[24] Chs 7-10.

[25] Chs 12, 17, 18, respectively.

products and public health cover those 'traditional' areas of health law and policy where the EU has used its treaty mandate (sometimes very creatively) to develop a dense web of legislation and commitments.[26] Comprising a more modest two chapters each, the sections on health systems and the external dimension address the newer, less explicitly mandated and, in some cases, as yet under-developed areas of EU health intervention.[27] Exploring the complexities of each chapter in detail is not possible in a review of this length, but in the following I attempt to describe the central argument and general content of the contributions, before offering some reflections on the volume as a whole.

Mary Guy and Wolf Sauter's opening chapter, which reviews the history and scope of EU health law and policy, offers a thorough and clearly signposted outline of how the field has evolved.[28] It highlights key moments, actors and debates of relevance for the chapters and topics which follow, offering brief and enticing introductions to the parameters of the book and the field. The historical evolution of EU health competences and actions are presented in three phases: the pre-Maastricht Treaty era, the 1992 to 2007 period leading up to the adoption of the Lisbon Treaty, and the post-Lisbon era, dominated by 'political malaise with a persistent economic downturn' (p 32). The following chapter, written by Dorte Sindbjerg Martinsen, is emblematic of both the interdisciplinarity of the book and its challenge to the prevailing narrative of health in the EU.[29] It provides a solid and detailed overview of the actors and processes involved in EU health law and policy – important in itself and valuable as a foundation for subsequent chapters – introducing the political institutions, the legislative process and the network of agencies and other actors involved in health. It uses the Directive on Patients' Rights as a case study in the importance of legislative politics in the development of EU health law and policy, providing a political perspective on the adoption of a centrepiece of EU health law. In doing so, it makes the case for looking beyond the European Commission and the Court of Justice of the EU (CJEU) – long considered the dominant drivers – to the European Parliament, the Council of the EU and wider stakeholders as key actors in the shaping of EU health law and policy.

Interdisciplinarity is similarly evident in Clemens Rieder's chapter.[30] From the outset, he notes that the influence of the CJEU is likely to be less direct than that of national courts, which can shape policy by granting or refusing rights. By contrast, the process at EU level is 'dialogic and relational among the different stakeholders, rather than hierarchical' (p 61). This recognition serves as a starting point from which Rieder explores not only direct court intervention, but also the relevance of the 'shadow of litigation' for political outcomes and their negotiation. Reflecting elements of the political science literature on the 'shadow of hierarchy' and its influence over EU policy-making,[31] Rieder accounts adeptly for the reality that, since the EU's legal mandate in health is strictly curtailed, studying 'EU health law' in a comprehensive manner requires inclusion of many 'soft law' instruments and mechanisms. He also discusses the CJEU's relationship with three sets of institutions – the national courts of the member states, the member state governments and the European Court of Human Rights, concluding that the latter offers a viable 'direction of travel' – a key concept which the editors asked all contributors to speak to – for the future.

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[27] Part II, comprising Chs 5-10.

[28] Part III, chs 11-12; Part V, chs 17-18, respectively.

[29] 'The History and Scope of EU Health Law and Policy', ch 1.

[30] 'Governing EU Health Law and Policy – On Governance and Legislative Politics', ch 2.

[31] 'Courts and EU Health Law and Policies', ch 3.

See, for instance, A Héritier, M Rhodes (eds) *New Modes of Governance in Europe: Governing in the Shadow of Hierarchy* (Palgrave Macm

Taking up the conclusions of the previous chapter, Callum Alasdair Young makes a valuable contribution in an area of the field not currently well documented.[32] His chapter on the interaction, both existing and potential, between health and fundamental rights in the EU provides a comprehensive introduction to the topic and a well-reasoned opinion on its relevance for the future. He explores the EU's fundamental rights law, focusing in particular on the Charter of Fundamental Rights of the EU (CFREU) and instances of its interaction with health law and policy. Young concludes, following an assessment of the opportunities missed in its application to date, that the conceptualisation of EU health law and policy through a fundamental rights lens has 'frustrated potential' which 'remains undelivered' (p 108).

The second section of the book turns to perhaps the most visible and easily comprehended element of EU health law and policy, that applying to 'people and products'. Ellen Kuhlmann and colleagues open the section with a chapter on health professional mobility, one half of the health sector's 'people' constituency.[33] The story is one of fragmented decision-making and regulation – a central theme of the book – resulting from overlapping sectoral responsibility and dispersed competences between the national and European levels. They chart the evolution of health professional mobility in Europe (within the context of international trends), noting the relevance not only of free movement law, but of interactions with labour market policy, competition law and the EU's overarching commitment to fiscal discipline. Kuhlmann and colleagues present empirical data which shows that changing dynamics in the post-crisis era have seen professionals from poorer Southern and Eastern member states migrating to work in wealthier Northern and Western countries (pp 120-121). The inequalities that this creates and exacerbates are an inevitable result, they argue, of the market-oriented approach of EU law and policy on health professionals and poses a direct challenge to the principles of solidarity and universal access in the health system.

An emerging market-orientation is also recorded in Mark Flear's chapter,[34] which covers another under-researched area of EU health law and policy, and introduces the use and regulation of 'citizen science' – understood broadly as public participation in science via its funding, provision of data or analysis (p 148) – in EU biomedical research. In the intricate and multi-disciplinary discussion which follows, Flear offers an assessment of how the principles behind public participation in science interact with the priorities, norms and values of EU health law and policy. He highlights both the compatibilities which support the proliferation of citizen science – such as the EU's innovation union, the Digital Agenda and the broader commitment to advancing research – and the areas where the absence of an explicit EU policy will see citizen science 'harnessed and channelled' in ways which support market priorities (p 154).

Mapping another emerging area of EU health law and policy, Estelle Brosset and Aurélie Mahalatchimy address the regulation of new health technologies, charting the EU's latest attempt to balance the competing objectives of innovation and fundamental rights.[35] They approach this task by presenting the two phases of new health technology development in sequence: first discussing their funding and patenting (the 'research' phase) before exploring

[32] 'Fundamental Rights and EU Health Law and Policy', ch 4.
[33] E Kuhlmann, CB Maier, G Dussault, C Larsen, E Pavolini, M-I Ungureanu, 'EU Law, Policy and Health Professional Mobility', ch 5.
[34] 'European Union Biomedical Research Law and Policy and Citizen Science', ch 6.
[35] 'EU Law and Policy on New Health Technologies', ch 8.

the relevant medicinal product and medical device regimes which apply once an invention has been registered (the 'marketing' phase). In doing so, they piece together the web of complex secondary law which comprises the EU's 'policy' on new health technologies, covering the role of research funding, frameworks and infrastructure, patent and invention protection, and special provisions for orphan medicinal products and advanced therapy medicinal products. Brosset and Mahalatchimy conclude that, in addition to requiring ongoing legislative action that accounts for rapid technological development, this is a field where attention should also be paid to patients' ability to access the end result – the innovative new treatments available – or else risk ignoring the EU's commitment to ensuring a high level of protection of human health.

In contrast, Marcus Pilgerstorfer explores a well-documented area of EU health law and policy – the regulation of pharmaceuticals – but addresses a particular and important legal issue within it, namely the interaction between the market authorisation and liability regimes.[36] Essentially, he considers the relevance of the former for the latter – whether the fact that a pharmaceutical drug has market approval is relevant to the assessment of whether it is defective under EU law. Pilgerstorfer first walks through the complexities of the EU's procedures for marketing authorisation, labelling, packaging and advertising, and post-marketing responsibilities, before introducing the scope, structure and priorities of the Product Liability Directive.[37] The discussion which follows explores the interactions between these regimes and reveals a fundamental tension between the commitment to consumer protection and the promotion of research and innovation. Jean McHale and Aurélie Mahalatchimy present another story of patchwork regulation in the long-standing subfield of human materials law and policy.[38] Whilst the three sets of legislation governing blood,[39] tissues and cells,[40] and human organs,[41] have a virtually identical structure and approach, they do not represent a comprehensive framework. Taking a thematic approach, McHale and Mahalatchimy provide a detailed overview of the relevant provisions for legal classification, safeguarding of quality and safety, transfer across borders and ethical concerns for each group of materials. Along the way, they delve into specific points of interest, such as the complexities involved in governing a human material which has been altered sufficiently to become a medicinal product and thus be regulated by a separate regime. Their exploration of the ethical challenges involved highlights an interesting trend in the preference for common structures of research ethics, but also brings to the fore the limits of the EU in this area – able to make some inroads on patient safety but without inclusion of an ethical dimension, it seems EU legislation in this area is likely to remain a patchwork.

Closing the section on people and products, Andre den Exter's chapter explores the 'final frontier' of EU health law and policy, the emergence of electronic and mobile health technologies (eHealth and mHealth).[42] Mirroring the multi-disciplinary approach taken throughout the book, he combines perspectives from human rights law, competition law and

[36] 'EU Law and Policy on Pharmaceuticals Marketing and Post-Market Control Including Product Liability', ch 7.
[37] 85/374/EEC.
[38] 'EU Law and Policy on Human Materials', ch 9.
[39] Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, OJ L 33/30.
[40] Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L 102/48.
[41] Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation, OJ L 207/14.
[42] 'eHealth Law: The Final Frontier?', ch 10.

internal market law, and offers a detailed introduction to the status of electronic prescriptions, electronic health records and health or lifestyle 'apps' under existing EU health law and policy. In addition to the legal challenges around privacy, safety, liability and jurisdiction, den Exter touches on issues of equal access and the potential of eHealth to address or exacerbate prevailing health inequalities. He provides a detailed and comprehensive overview of an area of EU health law and policy which is constantly changing – the negotiation of the General Data Protection Regulation[43], uncertain application of the Medical Devices Regulation[44], the new eHealth network under the Patients' Rights Directive[45], and a number of other legislative fluctuations will all have an impact.

The third section of the book is a short one, containing just two chapters on EU health law and policy pertaining to 'systems'. Johan van de Gronden and Catalin Rusu open the section with a detailed and encompassing introduction to the role of EU competition law in health.[46] The beginning of the chapter contains an illuminating discussion of the term 'efficiency' and its relevance for the EU's legal frameworks, contrasting the expansive understanding of efficiency embodied in competition law to the narrower conception used in the following chapter on cost-efficiency. van de Gronden and Rusu go on to present an overview of EU rules on cartels, market dominance, concentration control and state aid, discussing their application to and implications for the health sector in each case. They highlight intricate but crucial repercussions of the existing legal regime; for instance, the autonomy retained by member states by virtue of the services of general economic interest derogation, which provides that any service a state wishes to deem 'universal' can be delivered by designated enterprises, exempt from state aid laws (pp 283-288). Such features, van de Gronden and Rusu argue, mean that EU law and policy in this area is likely to develop with a focus on pharmaceuticals, leaving national competition authorities and governments to decide upon the application of EU competition law to other areas of national health systems.

Tomislav Sokol and Nikola Mijatović's chapter marks a departure from the structure of the book to this point.[47] Rather than reviewing a particular subfield, they examine the impact of the economic crisis – and the crucial changes made to the EU's economic governance framework as a result – upon the whole of EU health law and policy. Starting from the premise that the crisis has forced member states to reduce spending on their health sectors (both through national financial necessity and EU legislative provision), they chart the impact of this trend upon three areas: access to care, healthcare professional mobility and the regulation of medicines. A case might be made that Sokol and Mijatović miss an important point of analysis, as they do not consider the fundamental difference between the latter two areas, where the EU has long-established legal competence and a range of hard law instruments at its disposal, and the area of access to care, which remains a member state competence and is thus targeted by the EU only indirectly and via soft law mechanisms. Notwithstanding this, Sokol and Mijatović provide a detailed account of how changes to the

[43] Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, OJ L 119/1 and Directive 2016/680 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, OJ L 119/89.
[44] Regulation (EU) 2017/745 on medical devices OJ L 117/1 and Directive 2017/746 on *in vitro* diagnostic medical devices, OJ L 117/176.
[45] Commission Implementing Decision 2011/890/EU providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth OJ L 344/48.
[46] 'EU Competition Law and Policy and Health Systems', ch 11.
[47] 'EU Health Law and Policy and the Eurozone Crisis', ch 12.

financing of care are affecting access, and how this varies between countries depending upon their fiscal stability and reliance upon supranational financial support. They also pick up a debate from Kuhlmann and colleague's chapter, discussing the impact of cost containment upon health professional mobility, and extrapolate a different aspect of pharmaceutical policy by focusing on medicines pricing, thus also complementing Pilgerstorfer's chapter.

The fourth section of the book covers the EU's public health policies, noted by the editors as '(arguably) the longest-standing area of EU health law and policy' (p 5). Fittingly, Markus Frischhut and Scott Greer open the section with one of the longest-standing areas of global health law and policy, and a field in which the EU has become increasingly involved as it has grown – communicable diseases.[48] They use integration theory to explore the paradox created in this field where the value of collective action is so clear, yet the legal competence ascribed to the EU remains weak. Frischhut and Greer review the historical development of EU action on communicable diseases, the main actors involved, and its interaction with food law, the free movement principles, liability regimes and fundamental rights. Among the above, they identify the precautionary principle, a core facet of EU law, as crucial for the trajectory of communicable disease law and policy, citing its relevance in the negotiation of trade agreements by way of illustration (p 345). Their conclusion also makes a strong case for the importance of soft law and new modes of governance, warning against their dismissal as 'not really like law' (p 345). Echoing the similar point made in Rieder's chapter (p 61), Frischhut and Greer cite instances of soft law's hierarchical nature and 'constitutive function', which give it power as both a precursor and an alternative to hard law solutions (pp 345-346).

Alberto Alemanno's chapter reviews the history and contemporary character of EU tobacco control.[49] Having described the evolution of a global level tobacco control regime, he introduces the parameters of EU action in this field, a classic case study in the use of internal market competences for public health imperatives. Alemanno explores the central question of tobacco law and policy, asking to what extent public health can be a justification for the harmonisation of EU rules on tobacco control. In the discussion he notes that a shift can already be seen in the approach taken by the EU when discouraging consumption, stating that 'They aim to achieve this not by informing individuals about how harmful smoking is but by changing the context within which all smoking choices are "made"' (p 367). Citing the recent example of plain packaging, Alemanno argues that this shift from a market-oriented to a public health approach might, conversely, call into question the EU's authority to harmonise – a painful irony for those health actors who have sought a public health approach for so long. He concludes that the 'nudging' strategy employed in recent instruments - such as standardised packaging and content regulations (pp 361-365) – whilst potentially effective, will prevail as one of a range of regulatory approaches required in the fight against tobacco.

Turning to the second major health determinant, Oliver Bartlett and Amandine Garde provide a critical overview of the EU's action on alcohol control.[50] In looking at how EU law and policy affects national adoption of alcohol control measures, they argue that the CJEU has not 'fully captured the complexity of alcohol control' (p 370) and that the European Commission does not take proper account of scientific evidence when constructing EU action. This case is supported not only by a review of the relevant EU provision for regulating alcohol matters, but also by an exploration of how these provisions come into

[48] 'EU Public Health Law and Policy – Communicable Diseases', ch 13.

[49] 'EU Public Health Law and Policy – Tobacco', ch 14.

[50] 'EU Public Health Law and Policy - On the Rocks? A Few Sobering Thoughts on the Growing EU Alcohol Problem', ch 15

conflict with international commitments made under the World Health Organisation (WHO). Citing a 'chronic lack of political will' (p 391), Bartlett and Garde conclude that the EU has 'hardly engaged' with the process of constructing an effective alcohol strategy – a view that is only reinforced by contemporary developments in the field (p 397).

Closing the section on public health issues, Iris Goldner Lang offers a detailed overview of the development of EU food law and policy.[51] After tracing its emergence from transnational food safety crises and free movement spillovers, she explores both the relevance of and the challenge posed by the distinction between food safety and food health. The EU's law and policy in this area has, to date, been developed on the basis of the former, Golder Lang argues, meaning that it addresses the risks inherent in producing and consuming food in the internal market. However, she presents two pressing contemporary concerns of the field – obesity/nutrition and antimicrobial resistance – and notes that the existing framework is not equipped to regulate these issues. Through closer examination of the definitions attached to 'food injurious to health' and food representing a 'hazard', Goldner Lang argues for a reformulation of these terms for use in promoting food *health* (p 405). A final section places this debate within the context of interactions between free movement and health/food law, drawing on lessons from the field of tobacco to conclude that further, strong legislative action might be expected (p 425).

The final substantive section of the book, comprising two chapters, addresses perhaps the 'newest', or at least the most recently recognised, elements of EU health law and policy. Holly Jarman and Meri Koivusalo open the section with their chapter on EU trade policy and how the EU's external trade policies impact upon internal EU policies affecting health.[52] This is a timely contribution because trade law and policy has entered a new era where its influence over public policy has increased significantly. Whereas the trade agreements of the past impacted health in narrow terms, usually limited to areas of food safety (such as hormones in beef, p 430), contemporary agreements have a much broader scope, covering trade in health services, investment protection and regulatory cooperation (p 431-2). As such, the potential to constrain the policy space for health is greater and affects more areas. To explore this changing context, Jarman and Koivusalo review existing EU trade laws and policies, before comparing these to contemporary and ongoing agreements. The discussion notes an 'ideological' (p 452) shift in recent negotiations on CETA (the EU-Canada Comprehensive Economic and Trade Agreement), TiSA (the Trade in Services Agreement) and TTIP (the Transatlantic Trade and Investment Partnership), favouring market-oriented principles and investment liberalisation. Though Jarman and Koivusalo find little reason to forecast a new direction for EU trade law and policy, they highlight some promising developments, such as increased transparency, scrutiny on the part of the European Parliament and greater civil society activism (pp 451-452).

In the final substantive chapter of the book, Tamara Hervey introduces and defines a comparatively new subfield of EU health law and policy.[53] Labelled the EU's '(emergent) global health law and policy' it comprises a patchwork of commitments and principles found at the intersection of EU and global provisions on human rights, trade and development. For the EU, these three areas make up its external relations law and policy, and though they do not always target health explicitly, their impact can be significant. Starting from the context of the EU's international legal personality, Hervey discusses the main institutional structures

[51] 'Public Health in European Union Food Law', ch 16.
[52] 'Trade and Health in the European Union', ch 17.
[53] 'The EU's (Emergent) Global Health Law and Policy', ch 18.

in which this fragmented body of law and policy is found – including the Global Health Forum, the International Health Regulations, the International Conference on the Harmonisation of Technical Requirements for pharmaceuticals, the Sustainable Development Goals, and the Global Fund to fight HIV/AIDS. She then looks in more depth at provisions on trade, development and human rights, and reviews how a global health agenda has and can be pursued in these settings. Much of the chapter is unavoidably spent pulling together the disparate strands of EU global health law and policy to illustrate its, as yet 'largely unrealised' (p 475), potential, but, in the conclusion, two concrete developments are identified. Hervey notes that both the territorial expansion of the EU to include more Eastern European countries and the influence of its regulatory and legal regimes beyond its borders to its trading partners and neighbours – each of which are an example of EU global health law and policy – are having significant effects upon health in the rest of the world, by inducing a 'race to the top' in regulatory standards which protect health (p 476). Though not widely recognised as a discrete facet of EU health law and policy just yet, the importance of such progress should not be underestimated.

In the book's concluding chapter, Anniek de Ruijter returns to the issue of legal competence.[54] The 'constitutional asymmetry' of the EU – whereby its market-making and economic competences drastically outnumber and outweigh its market-correcting and social competences – is the thread which runs through virtually all scholarship on European social and health law and policy. Within this context, the breadth and variety of health law and policy reviewed in the preceding chapters seems perhaps illogical. As the editors note, the fragility of EU health competence means that 'the very fact that EU health law and policy is under discussion at all is itself significant' (p 10). Taking the imbalance of EU competences as a starting point, de Ruijter explores the relationship between the resulting health law and policy, fundamental rights and 'health values'. Within the latter, four key principles are identified: solidarity, universal access, equality, and human dignity. de Ruijter explores the source and nature of values in the EU's constitutional order, pointing to trends of 'over-constitutionalisation' (p 490) and 'depoliticisation through science' (p 492), to explain why and how market-oriented principles come to dominate health-related values in the EU. Fundamentally, she concludes that the EU's current constitutional setting means that it 'is not able to promote and protect the values that are embedded in member states' national health law and policy fully' (p 481), and is more likely to prioritise economic, trade, competition and fiscal imperatives. In making this argument, this chapter is more than a traditional summary or collection of themes running through the chapters that precede it. Rather, it is an exploration of the crucial structures which underpin those debates and form common parameters for their future trajectory.

Though the editors and contributors could hardly have foreseen so when they undertook to write it, Hervey and colleague's *Handbook* is published at a critical time for the EU and the future of health law and policy at the supranational level. The introduction dedicates considerable space to discussion of the British vote to leave the EU and what implications this might have (pp 1-2; 11-12); whilst the foreword, offered by Professor Martin McKee co-founder of the *Healthier In* campaign for UK health actors to voice support for EU membership,[55] is a scathing account of how the referendum unfolded and the debate which accompanied it. Accounting for the *Handbook's* context amid the political tsunami of the day, is both important and understandable, but what the editors rightly conclude is that EU

[54] 'The Impediment of Health Laws' Values in the Constitutional Setting of the EU', ch 19.
[55] <http://www.healthierin.eu/> accessed 20 October 2017.

health law and policy will continue to evolve and to affect the health of Europeans far beyond any (increasingly uncertain) rescinding of UK involvement (p 1). As such, more important to the value and contribution of the volume is the reality that 'This moment represents an opportunity to revisit the tensions in the current constitutional arrangements of the EU' (p 13). The primary lesson drawn from the *Handbook's* contributions is that these arrangements are not sufficient for an EU health law and policy regime which exemplifies health values or fundamental rights. The prevailing period of flux presents fertile ground for discussing what can and should be done to address this imbalance. Such a discussion will doubtlessly be improved by the publication of a research handbook which goes beyond the brief usually associated with a volume like this to offer not only a comprehensive account of the major topics in EU health law and policy, but also a decidedly normative presentation of the strengths, weaknesses and desirable trajectories of EU action for health.