Introduction

Tamara K Hervey, Calum Alasdair Young, Louise E Bishop

As we complete and submit this manuscript, in early July 2016, it seems almost wrong for a book on EU health law and policy to be co-edited by three scholars in the United Kingdom. The referendum on the UK's membership of the EU reverberates across the EU, with some even interpreting it as a portent for the end of the European project as we know it.

Questions of health were among the key issues for the referendum debates in the UK. The now infamous claim on the 'Leave battlebus' that leaving the EU would release £350 million a week to be spent on the UK's NHS was one of the first 'promises' of Leave to be revealed as a total fabrication. Claims that EU membership meant privatisation of the NHS via the backdoor of TTIP were not far behind in being exposed as inaccurate scaremongering by Leave. Among the concerns of the subsequently regretful Leave voters is access to free health care while on holiday in other EU countries. Much more seriously, the position of the many UK nationals living and working in other EU countries quickly became a significant anxiety. As did the position of non-UK EU nationals in the UK – especially those working in the health system. Provision of nursing care, in particular, would be quite simply impossible without the many EU nationals who provide the backbone of such care in the UK. A debate in the House of Commons on protecting the 'acquired rights' of EU citizens in the UK attracted significant media attention. Noticeable were the abstentions from a very large number of Conservative MPs, along with the inevitable statement from the Government that no promises could be made.

Whatever the future relationship between the UK and the EU, and whichever way the EU itself develops, the EU's involvement with health law and policy will continue. Indeed, in some possible futures, much if not all of what we have written in this *Research Handbook on EU Health Law and Policy* will continue to apply in the UK. Even if it does not, there are 27 other Member States for which it will continue to be important. Health is one of the issues that concerns Europeans the most.

And so we are delighted to be able to offer this collection of analyses on EU health law and policy. Each chapter in the *Research Handbook* reflects

on the 'state of the art' in a particular aspect of the broad topic. Each chapter brings together an account of the legal position, including questions that remain unresolved, and reflects on the broader policy contexts. We asked each author also to consider the 'direction of travel': what are the current issues, and how might these unfold in the short and medium term? The result is more than a timely snapshot of where we are now – it is also an agenda for the future.

EU health law and policy is not a subject that can be readily understood from the perspective of any one discipline. Consequently, we count ourselves very fortunate as editors in having attracted a group of contributors whose interests and expertise across several disciplines: in particular, law, political science, policy studies and sociology. We also sought to include contributors from a range of stages in their careers. This allows the views of the 'old hands' or 'established names' to be balanced by fresh voices in the field: a blend of expertise significantly strengthening the *Handbook*. We are particularly grateful to our contributors for the open-minded and respectful way in which they approached the collaborative task we set for them.

Our contributors also come from many different countries: both within the EU and beyond. Bringing some degree of coherence into such a project is made easier when contributors are able to meet and discuss their work in progress face-to-face. With the support of the Observatoire Social Européen, the Society of Legal Scholars, the University Association for Contemporary European Studies, and the Health Law and Policy Research Group at the University of Sheffield, we were able to organise a round-table workshop. In January 2016 in Brussels, the majority of the papers were discussed and we are grateful to all our sponsors for facilitating this. This workshop followed directly after an open event, with a large audience, at which some of the contributors spoke. Hearing the views of a range of stakeholders enriched our own small workshop immeasurably. We would like to thank all the workshop participants, particularly our hosts Bart Vanhercke and Rita Baeten, as well as the excellent administrative support provided by Françoise Verri in Brussels and Sarah Beedham in Sheffield. We would also like to express our thanks to those who gave their time and expertise as discussants, especially Martin McKee, Bart and Rita, Katherine Fierlbeck and Eleanor Brooks.

THE 'STATE OF THE ART'

The *Handbook* is organised into five main parts, reflecting the broad divisions within EU health law and policy as we see them. We begin by considering the historical and institutional contexts. Mary Guy and

Wolf Sauter draw out the broad historical trends in EU health law and policy. Their analysis reveals three broad periods of its development: up to 1992; 1992–2007; and 2007 onwards. In so doing, they also define the scope of EU health law and policy, noting that it has moved beyond a 'patchwork' or 'interface' approach. It has emerged as both a legal and policy domain, and a subject for academic study in its own right. Dorte Sjindberg Martinsen uses the example of the Patients' Rights Directive to show how institutional structures and political preferences enable and constrain EU policy-making in health fields. The impact of the Directive on actual patient mobility is negligible. However, the ways in which different stakeholders were able to access and condition the law-making process nonetheless gives important insights into the past and future of EU health law and policy-making.

As EU health law and policy is often seen as a creation of courts, rather than legislatures or executives, two chapters follow in which the roles of national courts and the CJEU (under the powerful narratives of human rights) have played out in the unfolding of EU health law and policy. Clemens Rieder considers both the implications of actual litigation, and the 'shadow of litigation', which may indeed be more important. The relationships of the CJEU with national courts, the governments of the Member States, and the European Court of Human Rights in Strasbourg are all crucial institutional contexts for the development and future trajectory of EU health law and policy. The emergent and powerful narrative of human rights is taken up by Calum Young, who characterises this as an area of 'frustrated potential' for the future development of EU health law and policy.

The second part of the *Handbook* concerns people and products. Readers may be a little surprised to discover that there is no stand-alone chapter on free movement of patients, either on the law or on its practical impact. In a book of this nature, coverage cannot be exhaustive, and as editors we made some difficult choices of exclusion. The actual numbers of mobile patients within the EU are so small as to have led to Martin McKee describing EU patient mobility as a 'solution without a problem'. That is the principal reason for our decision: other areas of EU health law and policy have much more significant effects than patient mobility. Moreover, we have provided for readers who want to learn more about that particular topic through the information in Chapters 2, 3, 4 and 19.[1] Ellen Kuhlmann

[1] For further information, see N Azzopardi-Muscat and others, 'The impact of the EU Directive on patients' rights and cross border health care in Malta'; (2015) 119 *Health Policy* 1285; H Nys, 'The Transposition of the Directive on Patients' Rights in Cross-Care Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered' (2014) 21(1)

and others explain the effects of EU health law and policy on health professionals. Drawing on new empirical data, they show how the EU's free movement law, combined with its fiscal disciplines (considered further in Chapter 12), have challenging effects on sustainability of healthcare systems, reinforcing negative implications for equality and solidarity. Both people and products – as 'citizens' and 'science' – appear in Mark Flear's chapter on EU biomedical research law and policy. Flear shows how the spaces created for biomedical research by EU law and policy embody a particular type of citizen, and play on narratives of hope and promise. The result is an obfuscation of the dominant drivers of market-oriented norms and values.

The ways in which EU health law and policy protects consumers – through regulation and litigation – are the subject of Marcus Pilgerstorfer's chapter on pharmaceuticals. Interactions between those two regimes leave uncertainties in the legal position, with implications for policy. The development and regulation of, as well as potential liabilities for, new health technologies are also the subject of Estelle Brosset and Aurélie Mahalatchimy's chapter. They consider both EU pharmaceuticals and medical devices law, as new health technologies may occupy either space, even though a separate body of EU law and policy, with its own logics, has developed for each. The theme of novelty in health products is continued in the chapters by Jean McHale and Aurélie Mahalatchimy, and Andre den Exter. McHale and Mahalatchimy note insufficient attention to the ethical dimensions of EU human materials law. Den Exter's chapter shows how EU law and policy on innovative health technologies raise similar legal and ethical concerns. The complexities of legal liabilities alone, in the context of a market for e-health technologies spanning over 28 legal systems, provide ongoing challenges for health lawyers.

A short part 3 of the *Handbook* focuses on the implications of EU health law and policy for health systems. Johan van de Gronden and Catalin Rusu investigate the extent to which EU competition law and policy may improve, or worsen, the efficiency of national health systems. The application of EU competition law to the behaviour of powerful market actors,

---

European Journal of Health Law 1; S Olsena, 'Implementation of the Patients' Rights in Cross-border Healthcare Directive in Latvia' (2014) 21(1) *European Journal of Health Law* 46; H Vollaard and DS Martinsen, 'Bounded Rationality in Transposition Processes: The Case of the European Patients' Rights Directive' (2014) 37(4) *West European Politics* 711; W Palm and R Baeten, 'The quality and safety paradox in the patients' rights Directive' (2011) 21(3) *European Journal of Public Health* 272; D Delnoij and W Sauter, 'Patient information under the EU Patients' Rights Directive' (2011) 21(3) *European Journal of Public Health* 271.

such as the pharmaceutical industry, (social) health insurance providers or hospital chains, certainly has the potential to do so. But this may be at the cost of health-specific values – a point which is taken up in Chapter 19. For Eurozone Member States, the requirements of economic and fiscal governance are even more challenging than competition law for health systems and the values they embody. Tomislav Sokol and Nikola Mijatović show how the consequences of these rules, enforcing austerity economics, are felt unevenly across EU Member States. The resulting negative effects on access to medical care raise important questions of equality.

Public health is (arguably) the longest-standing area of EU health law and policy. It is covered in part 4 of the *Handbook*. Markus Frischhut and Scott Greer explain how EU communicable disease policy is intertwined with EU law on communicable diseases, particularly as embodied in the 'precautionary principle'. There follow a trio of chapters on products which pose threats to public health: tobacco, alcohol and food. Alberto Alemanno's review of the constitutional debates surrounding the EU's tobacco law shows how a direction of travel (to significantly constrain the freedom of operation of the tobacco industry) may have reached its limits in recent developments. These align more with soft regulatory approaches ('nudging') than with hard EU-level restrictive laws. From a different direction, Oliver Bartlett and Amandine Garde reach a similar conclusion. The limits of EU law create significant constitutional imbalances, which impede national evidence-based policies seeking to constrain alcohol consumption. At the same time, EU-level alcohol control measures are hortative only. Iris Goldner Lang tracks the development of EU food law and policy from an original focus on food safety (where public health concerns were encapsulated in EU-level regulatory measures, and significant institutional structures) towards a focus on the key public health challenge of obesity. Here again, the consequences of the EU's free movement rules and limited Member State discretion to protect public health, combined with the lack of political will to adopt EU-level binding measures, leave public health protections embodied in 'soft' rather than 'hard' norms.

The final substantive part of the *Handbook* turns from the internal aspects of EU health law and policy to the external context. Holly Jarman and Meri Koivusalo consider the health implications of the EU's external trade policies and law. From the narrow focus (essentially on food) of the past, the EU's trade agreements now concern a very wide range of matters concerning health. Included are pharmaceuticals, insurance and even the provision of healthcare services themselves. If health ministers are not 'at the table' of these negotiations, Jarman and Koivusalo warn that the values associated with European health systems will be 'on the menu'. Similar conclusions are arrived at concerning the fragility of health in EU

external relations law and policy. Here Tamara Hervey broadens the focus to include the EU's development law and policy, as well as its external human rights work. Echoing Young's chapter, the overall analysis reaches a conclusion of unfulfilled potential and missed opportunities.

Anniek de Ruijter's concluding chapter is a powerful discussion of the values of solidarity, universal access, equality and human dignity, in the context of EU health law and policy. De Ruijter assesses the extent to which such values are – and could ever be – promulgated through EU health law and policy, given the EU's constitutional arrangements. She shows how the EU's infamous 'constitutional asymmetry' leaves solidarity, universal access, equality and human dignity – more often than not – in a non-equal relationship with free trade, free competition, competitiveness, the knowledge economy, and above all, fiscal austerity. Fundamental (human) rights represent a possible future site for constitutional realignment, allowing 'the constitutional order of the EU to be changed or set up in a manner in which EU health laws' values will not have to compete so hard with EU economic values'. This is – at present – the 'road not taken' by the EU and its health law and policy.

THE 'STATE OF THE ART': THREE THEMES

Overall, from the detailed analyses in the *Handbook*, we discern three broad themes.

1. Fractured Decision-Making, Leading to Policy Ineffectiveness or Incoherence

We are not the first to observe that the pursuit of health agendas within the EU's institutional structures is complicated by the actors and the decision-making processes involved. The need to secure agreement from multiple parties or bodies, often with conflicting interests, sometimes with no expertise in health, damages the pursuit of policies with a central focus on health and its protection and improvement. This fracturing is evident in Martinsen's chapter (legislative institutions); Rieder and Young's chapters (courts and litigation); and de Ruijter's chapter (the 'constitutional asymmetry' of EU health law and policy) and what this means for health values. It is also either evident or implicit in the detailed accounts of specific health policy areas in the other chapters of the book. For instance, McHale and Mahalatchimy are critical of the lack of a coherent EU policy for human materials, leading to an inconsistent approach to its regulation. The ways in which the EU's laws and policies on novel health technologies

are similarly dispersed among different institutional settings is reflected in Pilgerstorfer's, Brosset's and Mahalatchimy's, and den Exter's chapters.

Health law and policy does not 'belong' and has never fitted within a single law or policy-making space in the EU's institutions. As Martinsen's chapter shows, the governance of health for the sake of health, and especially law and policy affecting health systems, are areas of law and policy that the EU has found difficult to enter. Where the EU does adopt law and policy affecting health systems, the effects may be undesirable, as van de Gronden and Rusu, and Kuhlmann et al. demonstrate. The difficulties are present even in the area of public health, where the EU has significant formal competences. Alemanno's, Bartlett's and Garde's, and Goldner Lang's chapters show how the EU is still searching for the right set of tools to solve a series of public health problems through different institutional settings, none of which is squarely concerned with public health protection or promotion per se.

Further, law and policy-making competences are shared between the EU and its Member States in virtually every health policy area discussed in this *Handbook*. Even in areas where the movement over time is for policy to be increasingly made at EU level, as, for instance Frischhut and Greer argue is the case for communicable diseases, significant powers remain with national bodies. Those policy areas where the EU has 'exclusive competence' (for instance, trade deals concerning goods, marketing authorisation for novel pharmaceuticals) are very much the exception. Distribution of policy competences between different institutional actors, within the EU and at national level, makes for fractured decision-making with discernable consequences for responsibilities and effectiveness. The EU's Eurozone governance arrangements have unplanned effects on health systems, as shown by Sokol and Mijatović. Moreover, the dispersion of powers between the EU, its Member States and the IMF means it is impossible to use traditional accountability mechanisms, such as judicial review of executive decisions. Regulatory vacuums can emerge, as Kuhlmann et al. demonstrate, where neither EU nor national institutions are sufficiently able to control unwelcome developments. Yet shared decisions between EU and national institutions are impossible to reach. None of this institutional context is good for hammering out legal and policy settlements that are good for health.

2. The Place of 'Science' and 'Innovation' in EU Health Law and Policy

Innovation is a significant challenge for EU health law and policy. The balance between enabling novel technological developments and securing protection for patients, health systems and others, is a theme that

emerges in several chapters of the book. It is most evident in the chapters by Flear, Pilgerstorfer, Brosset and Mahalatchimy, McHale and Mahalatchimy, and den Exter. All of these chapters, along with those in the part of the *Handbook* on public health, consider the extent to which the EU institutions have secured a fair and effective compromise between competing interests. The EU's 'scorecard' in this regard is mixed, at best. In particular, McHale and Mahalatchimy consider that the ethical dimensions of innovation have been insufficiently accommodated in the EU's regulation of human materials.

The ways in which litigation (or the mere threat of litigation) interacts with legislation and other regulatory measures, including executive decision making, are an important institutional context here. This theme is taken up by Rieder, Pilgerstorfer and, in particular, by Frischhut and Greer, who explore how the legal concept of 'the precautionary principle', based on the idea of 'scientific evidence', is articulated in various policy contexts. The notion of 'science-based' policy making thus imbues EU legislation and litigation alike.

De Ruijter argues that 'good science' should be a value that plays an important role in health policy. Where the EU's policies incorporate 'good science', these are often said to encapsulate nuanced and balanced settlements between competing interests. They are also considered to be effective, in that they express the state of the art in terms of technological innovation, and seek to regulate it. Elements of the EU's food, tobacco, clinical trials, pharmaceuticals, medical devices and e-health technology laws and policies may be said to meet this description. But the EU does not always meet the health policy community's standards of such 'science-based' decision making, as, for instance, Bartlett's and Garde's chapter demonstrates, in their argument that the EU has failed to engage with the scientific evidence on alcohol. Likewise, Frischhut and Greer argue that the EU's communicable disease policy is not simply a product of 'science-based' decision making.

Nonetheless, as Flear reminds us, 'good science' is not a 'scientifically' determined concept. The social construction of 'science', and indeed also of 'innovation' forms a crucial vector in understanding the EU's health law and policy. 'Innovation' can be an opportunity for the EU institutions to become involved in health law and policy making in unexpected ways. For instance, by supporting health technology industries through Horizon 2020, itself part of the EU's economic governance mechanisms. The notion of the 'knowledge economy' as the future for the EU includes the health knowledge economy. Here, the imbalances between different parts of the EU (as Sokol and Mijatović show) cannot themselves be corrected by 'science-based' decision-making alone. The benefits of health

innovation will not be evenly enjoyed across the EU without some kind of redistributive policies. And – of course – the EU lacks redistributive competences. This brings us to our final theme.

3. The Fragility and Frustrated Potential of EU Health Law and Policy, and Yet its Remarkable Durability

The EU institutions have been involved in health policy for a considerable period of time – arguably from the inception of the EEC. We see the temporal aspect of EU health law and policy in Sauter's and Guy's historical chapter, but also in the timelines de facto considered in all the substantive chapters of this *Handbook*. There is hardly a chapter which does not reach back to at least the 1980s, if not earlier, in its substantive scope. In that sense, therefore, EU health law and policy has proven remarkably durable through time.

However, although EU health law and policy may be seen as long-standing, it is also seen as precarious. Many commentators on EU health law and policy frame their analysis in terms of a 'clash' between the values of the market and the values of health – with health in a suboptimal position in that conflict of values. The majority of the contributors to our *Handbook* follow this approach. This 'standard narrative' sees the EU's market orientation (free movement of factors of production, free competition) in conflict with a wide range of public interests. Health is such a public interest. What is good for businesses (or more accurately for private capital) can be damaging to individual human beings or wider society.

The classic articulation of this dynamic in EU law is known as 'constitutional asymmetry'.[2] Where EU law applies, the logic of the market stands in a hierarchical relationship above other logics. It follows that where health goals can be successfully aligned with economic goals, health can be improved through EU law and policy. But the converse is also true: EU market law and policy can be detrimental to human health.

In this *Handbook*, these ideas are expressed in their purest form in van de Gronden's and Rusu's chapter. Their analysis shows that, where Member States choose to shelter their healthcare systems from competition, the effects of EU law are significantly different from the effects of EU law

[2] F Scharpf, 'The European social model: coping with the challenges of diversity' (2002) 40 *Journal of Common Market Studies* 645; F Scharpf, 'The Asymmetry of European Integration or Why the EU Cannot be a "Social Market Economy"' (2010) 8(2) *Socio-Economic Review* 211.

on those Member States which seek to bring competition within their healthcare systems. In the latter case, the EU approach in general does not protect healthcare-specific values. In this instance, bringing EU law into healthcare – with all that entails – is a *choice* for governments of Member States.

But in many instances, once a country is a Member State of the EU, and even more so if it is a Eurozone Member State, any such choice is removed. Health stands in a non-equal relationship to market-based, or fiscal-austerity-based, values, with negative consequences for health systems (Sokol and Rusu); public health protection (Frischhut and Greer, Alemanno, Bartlett and Garde, Goldner Lang); securing professional care for patients (Kulmann); and global health (Jarman and Koivusalo, Hervey). EU law's entitlements for healthcare professionals to move throughout the EU undermine an approach to healthcare capacity-building based on accountability to national populations. This approach leads to growing inequalities between patients in different EU countries. In the Eurozone, the pursuit of macroeconomic stability through a narrow approach to austerity affects the de facto provision of healthcare in crisis-hit economies. EU law on free movement of products prevents Member States from enacting legislation to tackle (childhood) obesity or alcoholism. In the EU's global trade and development policies, economic liberalism is pursued over and above increasing health protection in the global South.

The idea that health is in a non-equal relationship to market-based values such as free trade also features strongly in Young's and de Ruijter's chapters. Those chapters, along with Sjindberg Martinsen's, and several other chapters, also explore the ways that litigation based on the logics of EU market law is fundamentally disruptive of health policy. The ability of individual market actors (usually powerful companies) to rely on their rights to trade in EU law is a crucial feature of the highly fragile position of health within the EU's law and policy.

And yet, there is nothing *inherent* about the place of health (or other non-market) values within EU law. It is a matter of law and policy-making *choice*. For courts, and administrative authorities, it is a matter of *interpretation*. Specific considerations and concrete choices can be made to ensure the promotion and protection of health. The place of 'services of special economic interest' in EU competition law is a case in point. The EU's approach to tobacco regulation is another. These examples show how in many ways what is remarkable about EU health law and policy is its very durability in the face of such fragility. The very fact that EU health law and policy is under discussion at all is itself significant.

Here, our *Handbook* offers a potential direction of travel – an increased focus on human rights – which would see the protection and promotion

of health as a central value of EU law and policy. Human rights – as an embodiment of EU law and policy value in itself, as part of the EU's 'constitutional settlement' – offer a value system for the EU's general law and policy-making orientation (de Ruijter). They also offer a strategy of judicial interpretation (as Young's discussion of AG Opinions shows), or a policy goal (eg Frischhut and Greer). We do not have space here to explore the problems with such a human rights-based approach. As this was not our agenda for the *Handbook*, we simply note here that we are not in agreement (as contributors or as editors) as to the desirability of this potential future for EU health law and policy.

What we do agree on is that rather than the frustrated potential, or missed opportunities (Hervey), inherent in the standard narrative, a health-values-based future for the EU may be within reach. A systemic approach to values would fundamentally change EU health law and policy. For instance in the regulation of human material (McHale and Mahalatchimy, Flear); the sharing of the benefits of novel medical technologies (Pilgerstorfer, Brosset and Mahalatchimy, den Exter); the deployment of human (Kulmann et al.) and other (van de Gronden and Rusu, Sokol and Mijatović) resources; and the protection of human health in the spaces occupied by powerful global industries (Pilgerstorfer, McHale and Mahalatchimy, Brosset and Mahalatchimy, den Exter, Frischhut and Greer, Alemanno, Bartlett and Garde, Goldner Lang). If the reasons for the EU institutions not having pursued health agendas in the past, despite formal legal competence and sufficient resources, lie in the political preferences of governments of powerful Member States, an EU without the UK may offer altered possibilities.

THE 'DIRECTION OF TRAVEL'

These themes are, in our view, likely to influence the overall direction of travel for the EU's health law and policy. It seems presumptuous to say that EU health law and policy as a whole has a single direction of travel. Of course, we recognise that each area of EU health law and policy progresses at its own pace and following its own logics. We respect the different conclusions on the trajectory of a particular area reached by each of our contributors. Nonetheless, as editors, we offer some final thoughts, drawing together the threads of analysis which we hope our readers will explore through the rest of the *Handbook*.

As editors located in the UK, we expect that the EU without the UK will be a different forum for health law and policy making, and to the extent to which we are able, we reflect on that future EU in the remaining paragraphs.

The British referendum of June 2016 represented an opportunity for various calls to reshape the EU as a whole. If such reshaping takes place, it could include a dramatic change for EU health law and policy. We note that, looking across European integration as a whole, periods of centralisation involve many areas of EU law and policy-making developing at the same time, at a significantly faster pace than at periods of stagnation or sclerosis. Key to these periods of centralisation are questions of legitimacy: in whose name is the European project being carried out, and how are the voices of European populations heard in the integration process? The movement over time from an EEC which was a governance space for technical elites, to an idea of a EU in which citizens feel allegiance, may be continued more readily without a Member State 51.9% of whose population does not share that allegiance. We note that calls for similar referenda in other supposedly 'Eurosceptic' countries, such as Denmark, have been significantly muted as the effects of the UK's referendum are beginning to be felt. To the extent that the UK government represents a barrier to the transfer of competences to the EU, the EU's powers in the future might be significantly enhanced in many areas that are important to European populations, including health.

In the alternative, of course, the UK leaving the EU could be taken as a signal that the EU has become too centralised. We might see the 'repatriation' of legal and policy-making competences to national or regional levels, returning the EU to a more inter-governmental era. With the exception of areas where a clear inter-governmental mandate is present (for instance, regulation of pharmaceuticals or communicable disease control), in that scenario we would expect much less in the way of EU health law or policy. Even those areas might revert to non-EU international fora, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use or the World Health Organisation. A possible future sees the end of the EU as we know it, including as a site for health law and policy.

In either future, we see the possibility for the articulation of the core values of the EU (or whatever it becomes) to include health – and not just health as a factor of production or a contribution to economic growth and prosperity. Human health will remain a significant consideration for the legitimacy of any government. This is also true for any inter-governmental or supranational arrangements, through which national governments and other institutions cooperate to create law and policy. There is scope for the European project to be given greater legitimacy to include a re-articulation of health values – whether through a human rights frame, or in another way such as within equality policies concerned with redistribution. The 'health in all policies' approach of the current position, along with the

idea of the EU as a 'social market economy',[3] and the EU's constrained competences over national welfare settlements, are good places to start. This moment represents an opportunity to revisit the tensions in the current constitutional arrangements of the EU, and to articulate more clearly which are inherent and which are the product of choices of the EU's institutions and those of its Member States.

The effects of economic integration, even when they translate into increased overall prosperity, are not equally felt in all parts of an economy or society. Equality and dignity – including in health contexts – requires redistribution, not growth alone. Legitimated constitutional arrangements respect that insight. When the balance between the powers and capabilities of international, EU, national and local institutions reflects this position, whatever the EU becomes, it can contribute to the health of Europe, and of the world.

[3] Article 3(3) TEU.