Chapter 7
Healthcare regulation: an obstacle to cross-border trade in services? On the muffled application of the EU Single Market Strategy and CETA

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Introduction[1]

European Union (EU) policies to create an internal market for services initially focused on the adoption of sectoral directives establishing EU-wide principles and minimum standards, for example in the fields of safety and quality, designed to replace national norms. This approach, however, was considered too slow for removing obstacles to the cross-border provision of services. Since the internal market of services remained to a large degree fragmented within the EU, these policies were supplemented with an approach based on mutual recognition of national norms and the removal of unjustified restrictions on trade in services. Such restrictions mainly relate to national requirements which must be met by service providers - in other words, regulation. This approach was to a great extent codified in the Serv136ices Directive, adopted in 2006 (European Parliament and Council of the European Union 2006).

The inclusion of health services in the European Commission proposal for the Services Directive in 2004 (European Commission 2004) was the subject of heated policy debates. The application of general rules on the free movement of services and freedom of establishment to health services, thus handling them like any other commercial service, was considered inappropriate by policymakers and stakeholders alike. They were afraid that the removal of unjustified restrictions on free movement could cripple the steering instruments used by health authorities, leading to Member States losing control over areas such as healthcare priority setting and capacity planning (Baeten 2005). Fear of legal uncertainty ultimately led to healthcare being excluded from the scope of the Services Directive.

Ten years after the adoption of the Services Directive, the EU again launched a number of policy initiatives aimed at removing barriers to trade in services. According to the Commission, the Services Directive is delivering only a fraction of its potential (European Commission 2015a). In this chapter we will discuss three policy developments in 2016 that apply to health services and in particular to health professions. In these initiatives, as in the EU policies to create an internal market and to promote trade more generally, regulation of healthcare providers is seen as an obstacle to the operation of the market,

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rather than as a way of ensuring access to healthcare, quality of care or the financial viability of health systems.

First, as part of the roadmap set out in the Single Market Strategy, the European Commission launched its 'Services Package' with several proposals aiming to simplify procedures for service providers and to subject regulation in the service sectors to EU scrutiny (European Commission 2017a). It included a proposal for a Directive on a proportionality test before adoption of new regulation of professions (Proposal for a Proportionality Test) (European Commission 2017b). According to the European Commission, the proposal should 'help Member States identify overly burdensome or outdated requirements on professionals operating domestically or across borders' (European Commission 2017a). The bulk of the regulated professions falling under the scope of this proposal are health professions.

Second, the European Committee for Standardization (CEN), one of the three European standardisation organisations (ESOs), established a Healthcare Services Focus Group (HSFG) to make proposals on 'an overall approach and methodology towards standardisation in the area of healthcare services'. This initiative is to be seen in the larger context of the European Commission's recent policy to prioritise and incentivise the development of voluntary European service standards (European Commission 2016a). The development of such standards was already encouraged in the 2006 Services Directive to compensate for the lack of legal rules on service supply, due to the deregulatory construct of the Services Directive (Delimatsis 2016). According to the Commission, this approach had been unsuccessful since voluntary service standards account for only around 2% of all European standards. Since the fragmentation of standards acts as a barrier to the cross-border provision of services, the Commission wants to complement its 2016 initiatives facilitating the cross-border provision of services under the Single Market Strategy with the targeted development of voluntary European service standards (European Commission 2016a).

Although standard-setting is largely industry-driven, and the European Commission claims not to be involved in the initiative to set up a Healthcare Services Focus Group, our findings suggest its active behind-the-scenes involvement as the initiative's agenda-setter.

Third, the 2016 initiatives for removing obstacles to trade in services were not limited to the accomplishment of the internal market, but also included important developments in external trade policies. The EU is negotiating a series of multilateral and bilateral trade agreements with a very broad focus on services, investment, government procurement, intellectual property rights and regulatory cooperation (Jarman and Koivusalo 2017). The first of this new generation of international trade agreements, the Comprehensive Economic and Trade Agreement between the EU and Canada (CETA) was signed on 30 October 2016. It is, as stated by the European Commission, 'by far the most far-reaching agreement ever concluded by the EU in the area of services and investment' (European Commission 2017b). Since this agreement is considered by many as a template for future trade deals, its importance cannot be underestimated. Despite the claims of the European Commission, many CETA provisions apply to the regulation of healthcare providers and in particular to rules relating to healthcare capacity planning.

For the purpose of this chapter, it is important to understand that these developments in EU internal and external trade policies, through removing (regulatory) obstacles to the free movement of services on the one hand and encouraging standardisation on the other hand, are interlinked. According to the European Commission, 'a more complete internal market for services and more systematic regulatory cooperation with major third countries will facilitate international trade in services and the dismantling of behind-the-border barriers'. The Commission argues that the EU needs to 'strengthen the mutual links between internal and external regulatory actions and to explore how to improve coordination between the two in areas like government regulation and international standards, with a particular focus on future legislation' (European Commission 2010).

We will show how EU internal and external developments promoting cross-border trade create substantial legal uncertainty and put pressure on the capacity of health authorities to regulate healthcare providers, despite the fact that each of these frameworks includes, at least on first sight, certain legal clauses exempting health services from their scope or safeguards to ensure a specific approach for health services.

Nevertheless, many specific healthcare features require strong regulatory frameworks. These can be summarised as follows. *First*, the right to the highest attainable standard of health is commonly accepted as a fundamental human right.[2] This right includes timely access to comprehensive, quality healthcare services.[3] Universal healthcare coverage, requiring large investments of collective resources, is a means to promote the right to health. To ensure such universal coverage, health systems in the EU provide a specified package of benefits to all members of a society. *Second*, from an economic perspective the healthcare sector is characterised by significant externalities and market failures, making it impossible to achieve an efficient market for healthcare (Hsiao and Heller 2007). Indeed, patients in general lack the necessary background knowledge to make informed decisions about the care they need and the quality and effectiveness of the services they receive. Since healthcare providers may have other interests than those of their patients, this information asymmetry makes the relationship very precarious. Healthcare providers have unique power to induce demand and set prices. Furthermore, since healthcare in the EU is mainly publicly financed, both patients and healthcare providers might seek to respectively receive and supply more healthcare (moral hazard), due to the fact that the cost is mainly borne by a third public party. For all these reasons, health systems are highly complex and the activities of healthcare providers require extensive regulation to bring them fully in line with the goals of public health and social policy and to ensure the most cost-effective use of limited public financial resources.

The remainder of this chapter is organised as follows. Section 1 discusses how EU internal market legislation applies to the regulation of healthcare providers. The next three sections each discuss one of the 2016 EU policy initiatives that include provisions having an impact on national regulation of health services. These are: the proposal for a proportionality test before adoption of new regulation of professions; proposals for

2. See e.g., Art 1 of the Constitution of the World Health Organisation.
3. See e.g. Art 35 of the Charter of the Fundamental rights of the European Union OJ C 326, 26 October 2012, 391-407.

the voluntary standardisation of health services; and the CETA agreement. For each of these policies we present the aspects of the initiative able to put pressure on regulation of health services, the positions of institutional actors and the reactions of stakeholders. In the last section, we discuss our findings.

The chapter will not deal with other important aspects of the impact of the EU internal and external trade rules on healthcare systems, such as rules on state aid, medical products and the impact of the legal frameworks on statutory health insurers.

1. Background: EU internal market law applied to the national regulation of healthcare providers

The variety of national regulations across the EU can create de facto barriers for healthcare providers coming from abroad, and can thus potentially obstruct the freedom of healthcare providers to establish themselves in another Member State or temporarily provide services there.

Given the unique role of health professionals in protecting human life and health, they have been singled out for special treatment in the Treaty on the Functioning of the European Union (TFEU) (European Union 2012 and Lonbay 2000), with Article 53 (2) specifying that 'in the case of the medical and allied pharmaceutical professions, the progressive abolition of restrictions shall be dependent upon coordination of the conditions for their exercise in the various Member States'. The EU has since established a regulatory framework ensuring the mutual recognition of professional qualifications, including health professions, based on either a minimum harmonisation of training requirements or the coordination of access conditions and licensing rules – the so-called Professional Qualifications Directive (PQD) (European Parliament and Council of the European Union 2005).

It gradually became clear that the free movement principles also applied to healthcare institutions such as hospitals, medical laboratories or pharmacies. In this respect, the Court of Justice of the European Union (CJEU) plays a central role as it interprets EU law and ensures it is applied in the same way in all EU Member States. The CJEU has applied the fundamental freedoms enshrined in the TFEU directly to healthcare providers, ruling that the principles of free movement apply to both regulations governing access to a national (health) services market, and to regulations governing the exercise of the healthcare activity itself. Moreover, the Court has made it clear that not only rules discriminating against health providers from another Member State, but also measures that equally apply to domestic healthcare providers and providers from abroad were liable to be seen as restricting free movement (Gekiere *et al.* 2010). Consequently, almost any regulatory or institutional aspect of healthcare provision can be challenged as a potential obstacle to the free movement of services (Davies 2006). This is particularly important for healthcare, a field characterised by a plethora of regulations, such as rules on professional behaviour, patient access, quality, effectiveness and pricing, none of which specifically relate to cross-border situations (Gekiere *et al.* 2010).

The Court does however not intend to create a completely deregulated internal market, nor does it give healthcare providers unconditional access to a particular domestic healthcare market (Gekiere *et al.* 2010). Member States are allowed to maintain barriers to free movement provided that these are justified by public interest. In this respect, three conditions — known as the proportionality test — apply: it must be proven that the measure is necessary to protect the public interest objective, that it does not exceed what is necessary to attain this objective, and that the result cannot be achieved by a less restrictive measure.

Member States' ability to regulate healthcare providers thus became subject to a general proportionality requirement. In doing so, they face a relatively high burden of proof. The grounds for exempting the regulation of healthcare providers do not give Member States broad discretion to preserve national policies (Hervey and McHale 2015), and in fact it may be a challenge to demonstrate the wider effect of an individual measure on the sustainability of the entire system or on any other general interest objective it is pursuing (Gekiere *et al.* 2010).

The proportionality test was codified in the Services Directive. Article 15 obliges Member States to engage in a major screening exercise of their legislation on services. The requirements to be assessed include quantitative or territorial restrictions, requirements fixing a minimum number of employees, and fixed minimum and/or maximum tariffs. If a listed requirement is found to be discriminatory, or if its necessity and proportionality cannot be justified, Member States are required to simplify or abolish the authorisation or licensing procedures.

The application of this article in the original proposal of the Services Directive (European Commission 2004) to the regulation of healthcare providers was one of its most controversial aspects. A systematic and pre-emptive screening of all healthcare regulations was considered undesirable by many stakeholders, as it would have led to legal uncertainty: it could turn out to be difficult in some cases to sufficiently substantiate certain measures and could therefore disrupt the consistency of the health system as a whole (European Health Policy Forum 2005). This ultimately led to healthcare services being excluded from the scope of the adopted Services Directive.

After this exclusion, Member States called for more clarity on how much room for manoeuvre they had to justify regulations — in the general interest — even if they represented an obstacle to free movement. They were however unable to find a consensus on this sensitive topic, mainly because any legal proposal addressing this issue at EU level would inevitably encroach upon national powers regarding the organisation of health systems. Moreover, the European Commission was not in favour of providing a specific approach for the application of the internal market principles to healthcare services.

In the absence of clear political guidance, the Treaty provisions on free movement of services continued to be interpreted by the CJEU. In its more recent case law, the Court seems to acknowledge the specificity of healthcare, ruling that, when assessing whether restrictions on free movement are appropriate, Member States have, in the absence

of common or harmonised rules, the power to determine the level of protection they wish to afford to public health and the way in which that level is to be achieved. Since the level of protection may vary from one Member State to another, Member States must be allowed discretion[4] and, consequently, the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate.[5] The Court furthermore noted that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent[6], for instance without having to wait for the shortage of health professionals to materialise. The Court also took the view that, when there is uncertainty about the efficacy of alternative or less restrictive measures to protect public health, the inherent risks can be invoked to justify the maintenance of a measure[7]. The Court thus applies the precautionary principle in the field of healthcare (Baeten and Palm 2011). According to this principle, in the absence of scientific consensus that a policy is not harmful to the public, the burden of proof that it is not harmful falls on those initiating the policy. It could thus be argued that the Court, in this more recent case law, takes into account the political message sent out by the exclusion of healthcare from the 2006 Services Directive.

Given that the Court can only rule on the very specific national cases brought before it, it remains unclear how the principles established by the Court are to be applied to other specific provisions in other healthcare systems in other Member States. The Court is thus unable to provide the much-needed legal certainty.

This background on how the free movement principles apply to healthcare services is important for understanding the developments discussed below, and in particular the proposal for a proportionality test before adoption of new regulation of professions, which we will now consider.

2. A proportionality test before adoption of new regulation of (health) professions

2.1 The policy initiative

The first 2016 policy initiative impacting the regulatory capacity of health authorities focuses on regulation of health professions.[8] In January 2017, the European Commission came up with a proposal for an EU Directive obliging Member States to conduct an ex-ante proportionality assessment of any new provisions / amendments to existing ones that were likely to restrict access to or the pursuit of regulated professions (European

4. Case C-169/07 Hartlauer, Case C-141/07 Commission v Germany, Joined Cases C-171/07 and C-172/07 Apothekerkammer des Saarlandes and Others, Case C-531/06 Commission v Italy.
5. Case C-141/07 Commission v Germany, Joined Cases C-570/07 and C-571/07 José Manuel Blanco Pérez and María del Pilar Chao Gómez.
6. Case C-531/06 Commission v Italy, Joined Cases C-570/07 and C-571/07 José Manuel Blanco Pérez and María del Pilar Chao Gómez, Case C-73/08 Bressol and Chaverot.
7. Case C-531/06 Commission v Italy.
8. For a more detailed analysis, see Baeten 2017.

Commission 2017b). The proposal requires Member States, when reviewing existing rules on regulated (health) professions or introducing new ones, to assess whether the provisions are necessary to attain a public interest objective, are suitable for securing the attainment of the objective pursued, and do not go beyond what is necessary to attain that objective (the proportionality principle). Before introducing a measure, other Member States and interested parties have to be informed and should be given the possibility to express their views. They may submit comments to the Commission or to the notifying Member State. As is the case with the Services Directive, if the Commission considers that the proportionality of a measure is inadequately justified, it can start an infringement procedure against the Member State concerned.

The bulk of the regulated professions falling under the scope of this proposal for a proportionality test are health professions. According to the European Commission, the health and social services sector accounts for 42 percent of the 6,000 professions regulated across the EU (European Commission 2015b). Regulation makes access to or the pursuit of a profession conditional upon the possession of specific professional qualifications, or protects the use of a specific title. It aims to reduce the information asymmetry between service providers and consumers, and to protect the public from unqualified practitioners.

The type of regulations referred to in the proposal for a proportionality test include: continuous professional development; language knowledge; reserving specific activities for professionals with a particular professional title; rules relating to the organisation of the profession, professional ethics and supervision; compulsory chamber membership, registration or authorisation schemes; requirements limiting the number of authorisations to practise, or fixing a minimum or a maximum number of employees, managers or representatives holding particular professional qualifications; and finally territorial restrictions, in particular where the profession is regulated in a different manner in different parts of a Member State. These kinds of measures are indeed applied in all European healthcare systems.

Many of the requirements to be assessed under the Commission proposal for a proportionality test are almost copy-pasted from Article 15 of the Services Directive. In its impact assessment, the Commission clarified that the proposal for a proportionality test was complementary to the Services Directive and in particular that, 'in terms of scope the Services Directive relates to only legal persons and does not cover the medical professions' (European Commission 2017d). This suggests that an important driver for the current proposal is the desire to extend the principles enshrined in Article 15 of the Services Directive to healthcare services.

The proposal stems from the Commission's assessments of a mutual evaluation exercise which Member States carried out in the course of 2015-2016, based on a 2013 revision of the Professional Qualifications Directive. This revision introduced a new Article 59, obliging Member States to list the professions they regulate and to explain why regulation is necessary. They had to enter all regulated professions into an EU database

together with all regulatory measures implemented for each profession notified.[9] Member States were required to examine whether their regulatory requirements were compatible with the principles of non-discrimination, necessity and proportionality and had to justify any decisions taken as a result of this analysis to maintain or amend professional regulations[10]. Other Member States and stakeholders were invited to submit their observations on these assessments. To this end, the Commission organised a public consultation (27 May to 21 August 2016) [11] and a conference (on 18 May 2016)[12]. Furthermore, 12 professions were chosen as examples of different regulatory approaches, including four health professions: physiotherapist, psychologist, dental hygienist and optician. The Commission published a sector report on each of these professions (European Commission 2015c, 2016b, 2016c and 2016d), drawing on information communicated by the Member States and discussions which took place during a meeting in 2015 on mutual evaluation for each sector. These sector reports call on Member States to assess in greater depth the necessity and proportionality of specific requirements, most of which were subsequently listed in the proposal for a proportionality test. According to the Commission's impact assessment on the proposal, Member States did not provide sufficient arguments in the mutual evaluation exercise as to the proportionality of their professional regulations, and produced only scarce evidence to suggest that regulatory decisions are currently being based on sound and objective analysis (European Commission 2017d).

A proportionality test in itself could be an instrument of good governance and could be used to improve the general interest objectives of regulating health professions, whilst countering corporatist private interests as well as protectionist national interests. However, the lack of clarity in the draft directive as to the extent to which a specific approach for health professionals could be justified leads to substantial legal uncertainty on regulation that can be crucial to preserve high-quality health services and universal access to healthcare.

2.2 Positions of institutional actors and stakeholders

The Council gave the Commission a mandate to provide an analytical framework for a comprehensive proportionality assessment of professional regulations (Council of the European Union 2016a) and reached, surprisingly quickly and without much debate, a 'general approach' on the proposal (Council of the European Union 2017), which will serve as a basis for negotiations with the Parliament. It should be noted that this proposal is being discussed in the Competitiveness Council and that health ministers are thus not involved. It is nevertheless striking that public authorities, i.e. those primarily responsible for ensuring that the general interest objectives in healthcare are

9. Regulated professions database. http://ec.europa.eu/growth/tools-databases/regprof/index.cfm?action=homepage

10. Mutual evaluation of regulated professions: National Action Plans. http://ec.europa.eu/DocsRoom/documents/20581

11. Consultation on the regulation of professions: Member States' National Action Plans and proportionality in regulation. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8827

12. Reforming regulation of professions: results of mutual evaluation and way forward. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8592&lang=en

preserved, did not voice any reservations over the inclusion of health professionals in this horizontal proposal for a directive.

In the European Parliament, there was initially little controversy on the proposal. The ENVI Committee (Environment, Public Health and Food Safety), the prime forum for investigating any EU initiative affecting public health, initially even decided not to issue an opinion on the proposal. However, positions have since shifted. The ENVI Committee revoked its initial decision and is now preparing an opinion. The draft opinions of both the ENVI and the JURI (Legal affairs) Committees are proposing the exclusion of health professions from the scope of the proposal. Also, several national parliaments have meanwhile adopted reasoned opinions stating that the draft does not comply with the principle of subsidiarity. In a resolution, the German Bundesrat calls for an exemption for health professions or, alternatively, a greater focus on patient protection. Whilst finalising this chapter, Andreas Schwab, the rapporteur on the proposal in the Committee responsible for the proposal, the IMCO Committee (Internal Market and Consumer Protection), has also proposed in his draft report to exclude health professions from the scope of the Directive[13].

The most vigorous stakeholder reactions to the proposal so far have come from the EU-level organisations of some key healthcare professions. In a joint position statement, the Standing Committee of European Doctors (CPME), the Pharmaceutical Group of the European Union (PGEU) and the Council of European Dentists (CED) have called for the exclusion of the regulation of health professions from any EU-wide framework for a proportionality test. They express concerns about the lack of specificity in addressing the overall issue of health profession regulation, and are convinced that health professions should be considered distinct from other professions. They argue that policy decisions relating to the regulation of health professions must serve the objective of attaining the best possible quality of care for every patient, and that under no circumstances should quality of care, access to care or patient safety be put at risk by policies driven by other agendas, in particular economic concerns (CED *et al.* 2017). The European Public Services Union, EPSU, the recognised European social partner organisation for workers in the healthcare sector, also calls for the exclusion of the health professions from the scope of the proposal. EPSU fears that the Directive will have a 'chilling' effect on Member States' regulation and that they will be less inclined to give full weight to social concerns and objectives of health, social, employment and professional training policies and measures[14].

13. All documents available at: http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2016/0404(OLP)#tab-0

14. EPSU intervention at the S&D Group Hearing on 1 June 2017.

3. Voluntary standards for health services

3.1 The policy initiative

The second EU-level initiative potentially impacting the capacity of health authorities to regulate healthcare providers aims to establish voluntary standards for healthcare services.

Standardisation aims to ensure interoperability and to reduce costs for the cross-border provision of services, notably by defining technical or quality specifications. These specifications are voluntary and are developed by industry and market players. Funding for standardisation comes from the stakeholders themselves. Although the use of standards is voluntary in nature, they may have legal effect when referenced in the context of legally binding agreements, such as contracts, accreditation processes or similar, when used in public procurement, or when referenced in legislation or in judicial proceedings.

European standardisation in the healthcare sector has traditionally been mostly limited to medical devices and e-health applications. European standards in these areas support the implementation of European legislation on safety and quality of medical devices and the interoperability and effectiveness of healthcare ICT applications and information.

By contrast, a number of initiatives were taken in 2016 with the aim of establishing standards of healthcare provision. Market-driven convergence through healthcare standardisation allows physicians to work in another country, hospitals to open branches overseas and patients to travel for surgery (Cortez 2009).

In June 2016 CEN established a Healthcare Services Focus Group (HSFG) tasked with making proposals for an overall approach and methodology moving towards standardisation in the area of healthcare services. This HSFG will prepare future activities in this field (CEN and CENELEC 2016). Furthermore, CEN established two new technical committees (TC) in 2016, one for the development of standards on 'Quality of care for older people'[15] and the other on 'Minimum requirements of patient involvement in person-centred care'[16].

According to a preliminary draft strategy of the HSFG, standardisation activities may cover primary healthcare, non-specialized and specialized healthcare, ambulatory and hospital care, emergency services, ambulance services, nursing homes, hospices, preventive healthcare, mental health services, dental services, physiotherapy, occupational health services, rehabilitation and pharmacies[17]. In sum, all types of healthcare services could become the subject of voluntary standardisation.

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15. CEN/TC 449 - Quality of care for older people. https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:2130749&cs=16605FFC2C3DD055E0211682B6C062AA4

16. CEN/TC 450 - Patient involvement in person-centred care. https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:2151116&cs=1D44A19AFA1BBECA019313BDB1377FF73

17. CEN strategy on standardisation, 21 February 2017, unpublished document.

The draft document proposes, in an annex, an extremely far-reaching structure for healthcare service standards, going far beyond 'technical' specifications (such as the interoperability of ICT applications) and covering many core elements of health systems. It indeed includes requirements related to healthcare facilities and premises, patients' rights, insurance cover, pricing, billing, measurement, evaluation of clinical outcomes. It furthermore deals with core requirements related to access to and the exercise of health professions. It proposes to define elements such as:

— The description of the healthcare service, including who provides it, where and how it is provided;
— The human competences, awareness, training, knowledge, skills and attitudes necessary for providing the healthcare service. In this context, reference is made to professional qualifications and competences required by physicians, nurses, midwives, radiologists, medical imaging practitioners, medical engineers, etc.;
— The service structure, including the professionals, departments, support services, communication and capacity planning. For capacity planning, reference is made to clinical laboratories, pharmacies, blood banks, radiology and other clinical services;
— Issues related to liability and insurance;
— Continuous learning and peer review.

This list includes many aspects on which Member States would have to screen their national rules under the proposal for a proportionality test. Taken together, the two developments – standardisation and the proportionality test – thus increase pressure on public authorities to remove nationally set norms on healthcare providers and to refer instead in their policies to standards set by market players and stakeholders at European level.

Box 1 **European Standardisation Organisations (ESOs)**

The three European Standardisation Organisations (ESOs) are the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI). They have been officially recognized by the European Union and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at European level. They bring together the National Standardisation Bodies of 33 European countries. If European standards are adopted, they replace corresponding national standards in all 28 Member States.

The equivalents at the international level are the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

The initiative aims to establish standards on elements of health systems that are heavily regulated at (sub) national level and that are core tasks of public policies. Such standards may be used by business to push towards lower-cost norms, possibly putting pressure on health authorities to lower their requirements, for instance when contracting out health services. It could lead to legal uncertainty when the standards differ from nationally-set legal norms. Cortez (2009) has shown that such convergence is dynamic and self-reinforcing.

3.2 Positions of institutional actors and stakeholders

The role of the European Commission in this initiative deserves particular attention. Most standardisation projects are initiated by national standard-setting institutes on behalf of interested parties. Standards can also be commissioned by the European Commission to be used in the implementation of EU law. EU companies that choose to use these harmonised European standards benefit from a 'presumption of conformity' to the requirements set out in EU legislation and are protected from liability.

The power of the European Commission to mandate the standardisation bodies to establish standards on healthcare is restricted, with the Regulation on European Standardisation (recital 11) stipulating that the Commission should 'fully respect the exclusive competence of the Member States to define the fundamental principles of their health systems when mandating the standardisation bodies to draft European standards' (European Parliament and Council of the European Union 2012). In spite of the fact that European Commissioner for Health Vytenis Andriukaitis denied that the Commission was involved in the current CEN initiatives on healthcare (Bulletin Quotidien Europe 2016), there are strong indications that the Commission acted as an agenda setter for the initiatives taken by the CEN. *First*, in its annual Union work programme (UWP) for 2015, the Commission included the development of European standards on healthcare services (European Commission 2014), suggesting that developing such standards is a Commission priority. *Second*, the CEN Strategic Advisory Group on Services (CEN/BT/WG 214-SAGS) and the Advisory Board for Healthcare Standards (ABHS)[18] jointly set up an ad-hoc group on healthcare services in 2014 to develop the first draft of the strategy on healthcare services. The European Commission is a member of both these advisory groups. *Third*, the first preamble of the document on the decision of the CEN Technical Board (BT) to establish the HSFG, in June 2016, refers to the outcomes of a workshop, held on 20-21 October 2015, on healthcare services.[19] This workshop was organised jointly by DG GROW (Internal Market, Industry, Entrepreneurship and SMEs), the European standardisation bodies and other actors. DG SANTE was indirectly also involved[20].

Since healthcare was excluded from the scope of the 2006 Services Directive, and the Commission has no legal competence to mandate the ESOs to standardise health services, it is thus plausible for the Commission to use other avenues to encourage healthcare standardisation as part of its internal market strategy.

As for the Council, the Polish delegation at the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council meeting of June 2016 expressed its concern over the CEN's work programme for 2016, arguing that the process initiated by CEN in the field of healthcare services might create a regulatory system with the potential to impact

18. Advisory Board for Healthcare Standards (ABHS). https://www.cencenelec.eu/standards/Sectors/healthcare/Pages/ABHS.aspx

19. BT 20/2016 of 16 June 2016, unpublished document.

20. European Commission, Putting Science into Standards: Evidence-based quality assurance – an example for breast cancer. https://ec.europa.eu/jrc/en/event/conference/putting-science-standards-evidence-based-quality-assurance-example-breast-cancer

healthcare professionals' ability to exercise their judgement under domestic regulatory systems. Poland called upon the Member States and the Commission to prevent further CEN actions in this area (Council of the European Union 2016b). According to Agence Europe, around ten Member States, including Germany and the United Kingdom, expressed similar concerns and called on the European Commission to support them in their approach. By way of response, Commissioner Vytenis Andriukaitis indicated that the Commission had no say in the matter (Bulletin Quotidien Europe 2016).

Various stakeholder groups also reacted to the developments.

Social health insurance organisations, organised in the European Social Insurance Platform (ESIP), and the International Association of Mutual Benefit Societies (AIM) expressed their concern over the development of market-driven standards in the field of healthcare and social services, arguing that introducing European standards in this domain could lead to legal uncertainty, since relevant guidelines covering the quality of these services had already been developed at national level. If European standards were to contradict these existing guidelines, they would reduce rather than improve the quality of services and lead to legal uncertainty (ESIP and AIM 2016a).

Also, the healthcare providers organised in the European Hospital and Healthcare Federation (HOPE), the Standing Committee of European Doctors (CPME), the Council of European Dentists (CED), the European Federation of Public Service Unions (EPSU) and the European Trade Union Confederation (ETUC) expressed in a joint open letter their concern over the increasing efforts at European level for standardising healthcare and social services. According to them, the voluntary and market-driven nature of European standardisation was not an appropriate mechanism for ensuring the realisation of public service principles and objectives. They argued that the 'pay to play' principles governing the process for developing European standards fell short of ensuring transparency, representativeness and accountability towards the general public. The letter stressed that professional autonomy was fundamental to ensuring both quality of treatment and patients' rights[21].

4. Regulation of healthcare providers subject to CETA

4.1 The policy initiative

The third 2016 policy initiative we discuss in this chapter is the Comprehensive Economic and Trade Agreement between the EU and Canada (CETA). Several chapters of this agreement are particularly relevant with regard to their impact on the capacity of health authorities to regulate healthcare providers. Whereas the first two initiatives proposing certain reforms were in their initial stages in 2016, CETA is nearly finalised.

21. Letter of 6 July 2016. http://www.epsu.org/sites/default/files/article/files/HOPE%2BCPME%2BCED%2BEPSU%2BETUC-Letter-Standardisation-06.07.16.pdf

On 30 October 2016, the EU (the European Council and European Commission) and Canada signed this agreement, and it was ratified by the European Parliament on 15 February 2017. However, since CETA was declared to be a mixed agreement (July 2016) (see Barbier in this volume), this means that it will not be fully implemented until the parliaments in all Member States have ratified it according to their respective domestic constitutional requirements.

The European Commission claims that 'CETA fully protects public services' and that 'the system of investor protection enshrines the right of governments to regulate in the public interest' (European Commission 2017c). However, as a detailed analysis by Thomas Fritz (2016) shows, the exclusion of health services from the agreement is not clear at all. CETA contains no general exemption of health services. Instead, the EU introduced specific reservations limiting the applicability of selected provisions on cross-border trade in services and investment. Furthermore, some of the exemptions only apply to EU Member States that expressly requested them. This targeted approach opens the door to various types of actions which could reduce the legal power of EU Member States to regulate healthcare providers. Although a comprehensive analysis of the potential impact of CETA on regulating healthcare providers is not possible within the scope of this chapter – the agreement covers 1,600 pages –, in the following sections we will highlight some of the main provisions potentially problematic for healthcare regulation.

Firstly, the CETA market access rules prohibit specific measures imposing limitations on service suppliers. Fritz (2016) concludes from his analysis that the prohibition of monopolies, exclusive rights granted to private operators and economic needs tests do not apply to health services. The agreement also preserves the right for authorities to adopt or maintain requirements to obtain a license, be a member of a professional organisation or speak a national language. Other requirements, such as rules limiting the number of service suppliers, the total number of service operations or the total quantity of service output, are prohibited. These are all crucial instruments, particularly for national planning policies on health services and professionals. Crucially, whereas under EU law regulating authorities have the possibility to justify such measures in the general interest by submitting them to a proportionality test, such possible justifications are much more limited under CETA. The latter only contains a narrow exception ground for the adoption or enforcement of measures necessary to protect human health.

Secondly, health services are exempted from some of CETA's investment rules, with the exclusion of privately funded hospitals and ambulance services. The definition of 'privately funded' is, however, unclear, potentially leading to substantial legal uncertainty.

Thirdly, the investment chapter includes the controversial investor protection mechanism (Investment Court System – or ICS). This mechanism could be used by foreign investors against any service regulations regardless of the exemptions ('reservations') made in the agreement, if they consider that the government is breaching their 'legitimate expectation' of a stable business environment (Fritz 2016). Jarman and Koivusalo (2017) argue that, whereas foreign investors so far have often been deterred by the strength and complexity of healthcare regulation, giving them

extra-territorial means to challenge regulations could change this. According to many stakeholders and scholars critical of international trade agreements, such an ICS could constrain European governments when it comes to introducing public policy measures that threaten corporate bottom lines, and thus could have a so-called 'chilling effect' (Health and Trade 2016).

Fourthly, CETA includes a specific chapter providing a framework for mutual recognition of professional qualifications, to be negotiated between the EU and Canada, which fully covers health professions. The recognition of professional qualifications is a precondition for both temporary service supply and permanent establishment on the other side of the Atlantic.

Fifthly, various categories of professionals are allowed to stay temporarily (for up to four and a half years) in the EU (Fritz 2016). This includes employees of transnational corporations (e.g. commercial hospital chains). For some of these employee categories, including health professionals, the host countries cannot limit the number of posted senior personnel, and may not subject them to any specific requirements concerning evidence of their qualifications (Fritz 2016).

The agreement furthermore includes a number of mechanisms which make future regulation particularly difficult. *First*, market access provisions apply to all investments and services except to those specifically excluded by governments by means of reservations. This means that under this so called 'negative list' approach, future new health services are not excluded from the agreement. *Second*, it contains a so-called 'ratchet clause' implying that, if a country decides in the future to further open up its market in a specific sector, such an opening would be 'locked in' - i.e. there can be no step backwards. *Third*, it contains a 'standstill clause' implying that the countries commit to keep the market at least as open as it was at the time of the agreement. This means that if a Member State has decided (now or in the future) to liberalise certain aspects of its health system, it will not be able to reverse this decision if this liberalisation fails to meet the public interest goals of health systems. These mechanisms might limit future efforts by governments to extend regulation or renationalise services.

4.2 Positions of institutional actors and stakeholders

The CETA negotiation mandate, awarded by the Council to the Commission in 2009, asked for the agreement to provide, with regard to the liberalisation of trade in services, 'the highest level of market access opportunities, without any a priori exclusions'. Nevertheless, the exclusions of 'audiovisual and other cultural services' and 'services supplied in the exercise of governmental authority' were explicitly mentioned. The mandate asked the Commission to 'establish the necessary steps for the negotiation of agreements providing for the mutual recognition of requirements, qualifications, licenses and other regulations' (Council of the European Union 2015a). Only in 2010 did the Council add a mandate on investment protection (Council of the European Union 2015b). The Council thus did not request a specific approach or exemption for health services.

In its resolution of 8 June 2011 on EU-Canada trade relations, the European Parliament considered that a state-to-state dispute settlement mechanism and the use of local judicial remedies were the most appropriate tools for addressing investment disputes. The Parliament considered that the 'public utilities exemption remains the most appropriate tool to guarantee universal access to public services to citizens'. There was no specific mention of an exemption for health services (European Parliament 2011). Nevertheless, more recently, in February 2016, the Parliament adopted a resolution on the negotiations for another trade deal, the Trade in Services Agreement (TiSA), in which it asked 'to exclude current and future services of general interest and services of general economic interest from the scope of application of the agreement, including health services' (European Parliament 2016). Despite these positions, the European Parliament voted on 15 February 2017 in favour of CETA.

Whilst the initiatives on the proportionality test and standardisation of health services have a clear focus on services, and in particular health services, the CETA agreement has a comprehensive scope, and thus touches on many policy areas. Within the wide range of stakeholders reacting to the agreement, organisations representing healthcare providers and professionals seem to have been less proactive.

On 22 September 2016, a broad group of organisations including Friends of the Earth Europe, the European Trade Union Confederation (ETUC), the European Consumer Organisation (BEUC), the European Public Services Union (EPSU), the European Anti-Poverty Network (EAPN), the Health and Environment Alliance and the CEE Bankwatch Network called on the EU's trade ministers to reject signing CETA, arguing that it 'threatens public policies through its investment dispute resolution mechanism, brings no benefits to Europe's citizens, and endangers the delivery of high quality public services' [22], i.e. including health services.

Both the ETUC and EPSU are primarily concerned about the deregulation of standards protecting the public interest. In this context, they criticise the investor-state dispute settlement system, the use of a 'negative list' in the area of services, the fact that public services (including health services) are not categorically excluded from CETA and that those public services which are excluded remain subject to the so-called 'standstill' and 'ratchet' clauses, which will prove to be an obstacle to future governments (EPSU 2016; ETUC and CLC 2016). EPSU points explicitly to the risk that market access rules might interfere with planning procedures in the health and social care sector.

The European Public Health Alliance (EPHA), a grouping of not-for-profit organisations working on different aspects of public health, has called on members of parliaments to reject CETA and in particular the Investor Protection Provisions (Investment Court System-ICS) (EPHA 2016). It argues that CETA promotes the further liberalisation of healthcare, because the reservations in CETA only apply to publicly-funded healthcare, because it is the first agreement with a 'negative list' approach, and because the scope of the reservations has been limited.

22. Civil society groups call on European governments to reject the CETA agreement, 22 September 2016. http://www.epsu.org/article/civil-society-groups-call-european-governments-reject-ceta-agreement

The social health insurance organisations ESIP and AIM have called for a clarification of the exemption on health services, arguing that there are grey areas that could lead to legal uncertainty. They point out that publicly-financed professional health services are still bound by the chapters on cross-border trade in services, and have asked for an EU reservation that excludes all services delivered and paid for by statutory and complementary systems of social security, as well as at least an additional exemption for the area of social security in the investment protection chapter (AIM 2016; ESIP and AIM 2016b).

Discussion and conclusions

In this chapter, we have explored three 2016 EU-level developments aimed at promoting the cross-border mobility of services, all of which explicitly include or target healthcare providers. This is the case despite the fact that several legal frameworks underpinning these developments either explicitly exclude healthcare services from their scope or provide for a specific approach to healthcare provision.

Such provisions include:

— The specification in Article 53 (2) of the TFEU that the removal of restrictions on the cross-border exercise of health professions is conditional 'upon the coordination of the conditions for their exercise in the various Member States'.
— Article 168 (7) of the TFEU stipulating that Union action shall respect the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.
— The exclusion of healthcare from the scope of the Services Directive.
— The Regulation on European Standardisation preventing the European Commission from mandating the standardisation bodies to elaborate standards related to health systems.
— The many exclusions of health services and public services from the application of aspects of the CETA agreement.

We have shown how the CJEU has played a driving role in subjecting regulation of healthcare providers to EU free movement principles. Nevertheless, the Court has acknowledged the specificity of healthcare by providing Member States with a relatively wide margin of discretion to determine the level of protection they wish to afford and the way in which that level is to be achieved, and by applying the precautionary principle when there is uncertainty about the existence of a risk to human health or the efficacy of alternative or less restrictive measures to protect public health.

Box 2 **Requirements under scrutiny in one or more of the 2016 policy initiatives or in CJEU case law**

- The reservation of certain kinds of health services for professionals with particular qualifications;
- training and continuous professional development requirements;
- rules relating to the organisation of health professions, professional ethics and supervision;
- compulsory chamber membership;
- registration or authorisation schemes;
- rules requiring health professionals to have sufficient language skills;
- requirements concerning insurance cover;
- rules limiting the number of service suppliers;
- rules on the territorial distribution of healthcare providers;
- rules on the total number of service operations or the total quantity of service;
- rules on the legal form of the health provider;
- requirements to have a specific professional qualification in order to manage a company providing specific health services;
- requirements fixing a minimum or maximum number of employees; managers or representatives holding particular professional qualifications;
- an obligation on the provider to supply other specific services jointly with his service;
- requirements restricting the exercise of a regulated profession jointly or in partnership;
- the ban on a professional having more than one place of operation.

Despite this, the proposal for a proportionality test in no way points to the specificity of health professions, nor does it apply the precautionary principle. What is more, whereas the EU internal market principles provide for the possibility of justifying restrictions on free movement in the general interest, as long as they are proportionate, in CETA such possibility is strictly limited (Jarman and Koivusalo 2017; Krajewski 2015). As a result, the prohibition under CETA on establishing rules limiting the number of healthcare providers, the number of health services or the quantity of service output fully applies.

Both the proposal for a proportionality test and CETA target future regulation. Numerous stakeholders and critical scholars voice the fear that such procedures could result in 'regulatory chill' (Jarman and Koivusalo 2017; De Ville and Siles-Brügge 2015), possibly dis-incentivising authorities from taking new measures in the general interest to protect public health or social objectives. The effects are therefore likely to be subtle, entrenching institutional machineries and processes that are likely to have a deregulatory impact in the longer term (De Ville and Siles-Brügge 2015).

The three developments in 2016 discussed in this chapter show how EU internal and external developments promoting cross-border trade in services are interrelated, and

how all three create substantial legal uncertainty and put pressure on the capacity of health authorities to regulate healthcare providers. As argued by Hervey and Mc Hale (2015), regulation of healthcare providers, rather than being seen as a way of protecting patients, or inherent to the proper functioning of national healthcare systems, is instead viewed as an obstacle to the operation of the market.

The European Commission, mandated by the (Trade and Competitiveness) Council, is the main agent for these policies. Health ministers are concerned about some of the developments but are barely involved in the debates. The European Parliament has voiced critical concerns on some of these policy initiatives, but seems to be in a rather weak bargaining position. Stakeholders actively involved in the provision or financing of publicly funded healthcare, such as health professionals, social insurers and trade unions, are the most critical. These are to a large extent the same categories of stakeholders reacting to the three 2016 policy initiatives, although for the proportionality test reactions have so far been mainly voiced by health professional organisations, a category less proactive with regard to CETA.

The first two initiatives, on the proportionality test and standardisation, are further examples of the asymmetry between the EU's weak powers in the field of social policies and its strong powers in economic issues. National welfare states are legally and economically constrained by European rules on economic integration, whereas efforts to adopt European social and health policies are politically impeded by the diversity of national welfare states (Scharpf 2002). By extension, the same asymmetry applies to EU external trade policies. Whereas in EU internal trade policies, the pressure for creating markets in the healthcare sector is somewhat tempered by democratic negotiation processes, in particular on secondary legislation, this safeguard is absent from EU external trade policies. In this way, EU external trade policies could be used by the proponents of greater cross-border market integration in healthcare to circumvent restrictions on the liberalisation of healthcare in the EU internal market.

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