Chapter 15
Health Systems and Policy Space for Health in the Context of European Union Trade Policies

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Abstract European Union trade policies have been evolving towards more emphasis on bilateral agreements and addressing non-tariff barriers to trade with an increasing number of trade negotiations with focus on services, government procurement and investment. Maintaining national policy space is a challenge for governments due to negotiation focus, practices and priorities. This is further affected by the changing relationship between national health systems and European Union law. While national health systems have become commercialised, this has not been recognised as part of trade negotiations. The variety of health systems within the European Union also creates challenges for Member States wishing to maintain full policy space for cost-containment and regulation, and return to public provision of services. This paper explores emerging concerns regarding maintaining policy space from a Member State perspective in the context of evolving European Union law, and priorities and practice in trade negotiations.

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15.1 Introduction

The relationship between health and trade arises from a contested ground and is likely to remain so in the foreseeable future. This is due to three concerns and conflicts of interest with respect to health and trade policies: (1) epidemics and the spreading of infectious diseases; (2) contrasting policy priorities between health and commercial industries (e.g. tobacco), and (3) governance and management of national health systems to achieve universal coverage and solidarity, and ensure the sustainability of financing for health systems.

This chapter focuses on the third concern and argues why health services need to be considered a "sensitive" sector, where protection of essential policy space in publicly funded services is necessary but not sufficient for national health care systems. It then discusses how this aim relates to European Union trade policies, politics and practice of multilevel governance.

15.2 Health Systems and European Union Policies

The perceived and actual relevance of European Union policies to national health care systems was still negligible into the 1990s. While the first internal market-related cases at the European Court of Justice date back to the 1980s and health was present as part of the Maastricht Treaty (1992), the idea that European Union policies would be of major relevance to national health systems was neither discussed nor recognised broadly until key European Court of Justice cases emerged in the late 1990s. Indeed, when new member states Finland, Sweden and Austria joined the European Union in the mid-1990s, the Finnish government and policymakers were of the opinion that this would not have an impact on the national health care system, its organisation and financing.

The relevance of health was a public health issue for the European Union, in particular, due to the potential threats of epidemics and negative impacts of public health crises to the functioning of internal markets. This overall concern over public health was at the core of the public health Article 152 in the Amsterdam Treaty (1997) and the Nice Treaty (2001). Article 152 reiterated the requirement to ensure a high level of health protection in all policies, but kept any European Union competence complementary and strictly limited to public health.[1]

The Treaty of Amsterdam was important in making public health-related responsibilities part of broader European Union competence; however, the focus

[1]Article 152:5 of the Treaty establishing the European Community (Nice consolidated version) states that "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in para 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

on health services became more prominent as a result of key decisions by the European Court of Justice. The role of ECJ decisions was crucial for further engagement of the European Commission with health services. Hatzopoulos has described this as judicial activism in the creation of a European Union institutional role and presence in an area which, on the basis of Treaty, should have been preserved for Member States.[2] The first cases, known as the Kohll[3] and Decker[4] cases, were related to Luxembourg, Belgium and Germany, and it was initially considered that the problems were not applicable to national health services—NHS-type health systems (UK, Sweden, Finland). However, the subsequent Watt[5] case made it clear that this was not the case.[6] In addition to further court cases,[7] the changing context between national health systems and European Union policies was reflected on several fronts over the following 10 years:

(1) General economic and financial policies and concern over health and long-term care as a driver for high public spending as health and long-term care cover a substantial part of public spending[8]

[2]Hatzopoulos 2013, p. 125.

[3]CJEU, Case C-158/96 *Raymond Kohll v. Union des caisses de maladie* [1998] ECR I-1931.

[4]CJEU, Case C-120/95 *Nicolas Decker v. Caisse de maladie des employés privés* [1998] ECR I-1831.

[5]CJEU, Case C-372/04 *Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325. In these healthcare systems access to services is defined on the basis of residence and free (or mostly free) at the point of use.

[6]Nedwick 2006, pp. 1645–1668 has brought up a number of difficulties with the ECJ approach to healthcare, whereas Hatzopoulos 2002, pp. 683–729 has emphasised how the ECJ had prioritised individual rights over governance of health care in the decisions and created a market in health care. See also, Brooks 2012, pp. 33–37.

[7]See e.g. CJEU, Case C-368/98 *Abdon Vanbraekel a.o. v. Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363; CJEU, Case C-157/99 *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473; CJEU, Case C-385/99 *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; CJEU, Case C-444/05 *Aikaterini Stamatelaki v. NPDD Organismos Asfaliseos Eleftheron Epangelmation* [2007] ECR I-3185.

[8]The control of costs of health and pension systems has been part of economic policy focus for a longer time. See, for example Council of the European Union, The 2004 Update of the Broad Guidelines of the Economic Policies of the Member States and the Community (for the 2003–2005 period), 10676/04, 21 June 2004. However, after economic crisis health is increasingly an important part of European Semester process with European Commission providing guidance as part of Health 2020 and European Semester for Member States due to importance of health and long-term costs for public spending, see e.g. European Commission, Thematic summary on health and health systems, available from: http://ec.europa.eu/europe2020/making-it-happen/key-areas/index_en.htm. Accessed 27 November 2014 ; Council of the European Union, Conclusions on the sustainability of public finances in the light of aging populations, Press Release, 15 May 2012, para 3.

(2) Open coordination process with emphasis on health care and long-term care[9] and high level process of reflection on patient mobility[10]
(3) Services of general interest[11]
(4) Constitutional treaty negotiations and changes to the Treaty of Lisbon (2007)
(5) Services directive[12] and Directive on patient rights and mobility in cross-border care
(6) Changes in the focus of the European Union Health Programme with explicit engagement with health services and pharmaceutical policies as part of the European Union Health Programme[13]

The economic case with respect to the public funding of health care can be seen as providing legitimacy and relevance for the introduction of an open method of coordination, in particular, for long-term care. The high-level reflection process on patient mobility can be seen as paving way to the inclusion of health under the services directive and the later development of the directive on patient rights and mobility in cross-border care. The Open Method of Coordination on long-term care can also be seen as a means of legitimating the European Union's role in health services as this was later reflected in the Lisbon Treaty through Article 168 of the Treaty on the Functioning of the European Union (TFEU), opening up scope for European Union engagement with health services. The incremental and increasing engagement with health services building first on European Court of Justice decisions, but later on commission initiatives, was not left unobserved by the Member States. Perhaps the clearest and strongest statement was made in 2006

[9]European Commission, Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for national strategies using the 'open method of coordination', COM(2004) 304 final, 20 April 2004, p. 11 makes an interesting interpretation on how responsibilities for the organisation and funding of the health care and elderly care sector rests primarily with the Member States, which are bound, *when exercising this responsibility, to respect the freedoms defined and rules laid down in the Treaty.*

[10]European Commission, High level process of reflection on patient mobility and health care developments in the European Union, HLPR/2003/16, 9 December 2003.

[11]See e.g. European Commission, Green paper on Services of General Interest, COM(2003) 270 final, 21 May 2003; European Commission, White paper on Services of General Interest, COM(2004) 374 final, 12 May 2004.

[12]Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, *OJ* 2006 L 376/36; Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border health care, *OJ* 2011 L 88/45.

[13]See European Commission, Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014–2020, COM(2011) 709 final, 9 November 2011. Pharmaceutical policies were moved from DG enterprise to Health and Consumer affairs in 2009, see European Commission, President Barroso unveils his new team, Press Release, IP/09/1837, 27 November 2009.

in the Council conclusions and Statement on Common Values and Principles, which made it clear that[14]:

> This is a statement by the 25 Health Ministries of the European Union, about the common values and principles that underpin Europe's health systems. We believe such a statement is important in providing clarity for our citizens, and timely, because of the recent vote of the Parliament and the revised proposal of the Commission to remove health care from the proposed Directive on Services in the Internal Market. We strongly believe that developments in this area should result from political consensus, and not solely from case law.
>
> We also believe that it will be important to safeguard the common values and principles outlined below as regards the application of competition rules on the systems that implement them.
>
> This statement sets out the common values and principles that are shared across the European Union about how health systems respond to the needs of the populations and patients that they serve. It also explains that the practical ways in which these values and principles become a reality in the health systems of the EU vary significantly between Member States, and will continue to do so. In particular, decisions about the basket of health care to which citizens are entitled and mechanisms used to finance and deliver that health care, such as the extent to which it is appropriate to rely on market mechanisms and competitive pressures to manage health systems must be taken in the national context.

The fact that health services were carved out from the services directive has had implications for European Union commercial policies in relation to what is taken for granted for the negotiation of bilateral trade agreements, as internal markets and the services directive are often used to imply reference to European internal powers that entitle the Commission to act on behalf of Member States. This remains a broader concern in the context of the European Commission's increasing involvement in health, although the specific carve out of health services by the European Parliament made it more explicit that health is not just "any service" governed by the service directive as part of internal markets.[15]

The Lisbon Treaty, however, has enabled the definition of health services as an area of complementary action in Article 168 TFEU, building on engagement with the open method of coordination in para 2, and also removed explicit references to Community action on public health in para 7:

> 2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

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[14]Council conclusions on common values and principles in European Union Health Systems, *OJ* 2006 C 146/1, Statement paras 1–3.

[15]This is to some extent compromised by the fact that in spite of initial concerns the new proposal was not based only or, in particular, on the TFEU public health Article 168, but essentially on TFEU Article 114 (95 TEC) on functioning of internal markets, which was claimed as the "appropriate" article based on the claim that "functioning of internal markets on the basis of Article 114(3) requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.", Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, *OJ* 2011 L 88/45.

> Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in para 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.
>
> 7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in para 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

The implications from changes to Article 168 TFEU can be interpreted in different ways. On the one hand, it can be argued that the role of the EU has become now legitimately mentioned as this relates to health services, and that restriction of community action on public health has been changed, opening scope for increasing EU involvement in health services.[16] On the other hand, it can be emphasised that it includes a stronger reference to Member States' responsibility for definition of their health policies and management of health services.[17] What has taken place since would support the former interpretation of the shift of competence to the European Commission more strongly, as since the Lisbon Treaty negotiations the European Commission has engaged increasingly with health services on the grounds of expressed necessities with respect to patient mobility and cross-border care. While the White Paper on the strategic approach for the European Union discussed public health further, its title now focused on health rather than public health.[18] However, in spite of the strategic focus on public health, major efforts were geared towards health services as part of separate consultation.[19] Indeed, the new health programme for the years 2014–2020 has a substantial focus on health services.[20] The result of these changes is that while Member States still have responsibilities for the financing of health care, the role of the European Commission in the regulatory context of health systems governance has been

[16]Article 152.5 ECT (Nice version) had a clear and explicit focus on public health: "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in para 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

[17]Foreign and Commonwealth Office 2008, p. 14.

[18]European Commission, White paper, Together for Health: A Strategic Approach for the EU 2008–2013, COM(2007) 630 final, 23 October 2007.

[19]European Commission, Consultation regarding Community action on health services, SEC(2006) 1195/4, 26 September 2006.

[20]European Commission, Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014–2020, COM(2011) 709 final, 9 November 2011.

increasing in the field, both in the context of DG5 responsible for Health and Consumer Affairs and in the requirement that Member States follow Treaty obligations, requirements for economic and financial policies, and the broader regulatory framework established as part of internal markets and commercial policy.[21]

The carve out of health from the service directive resulted in consequent communication and a proposal for a directive on patient rights and cross-border care.[22] This was, however, approved only in late 2011 after substantial amendments in Parliament and substantial delays. The views of several Member States have been described by the term animosity,[23] but the proposed directive was (finally) approved by a vote, with Austria, Poland, Portugal, and Romania voting against approval and Slovakia abstaining, in 2011.[24] In Austria national legislation was in compliance with the directive, but the background was the federal organisation and financing of hospitals.[25] In this context, the active engagement of the European Commission in bringing health systems under internal markets was reflected in a Court of Justice case on free movement against the requirements of prior authorisation for reimbursement of costs in a case against France.[26] The ability to require prior authorisation for mobility of patients was a major sticking point between Member States and the European Commission, as Member States argued this would make planning and allocation of resources within health systems impossible, in particular, for major health care costs, even if these were applied to services outside national hospitals as was the case with France.

Thus, while European Court of Justice decisions were initially the "cause" for Commission engagement with health, decisions by the European Court of Justice have now come full circle in support of Member States policy space to ensure the financial sustainability of health systems against the Commission.

The financial sustainability of health systems is of interest, in particular, due to the use of intra-European Union investment agreements to challenge governments, such as Poland and Slovakia, which backed away from health care privatisation programmes.[27] Poland refused to privatise the majority of its health insurance system and backed off from further privatisation after the government changed.[28]

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[21]See e.g. Van de Gronden et al. 2011; Mossialos et al. 2010; Tritter et al. 2009, pp. 76–94; European Commission, A Quality Framework for Services of General Economic Interest in Europe, COM(2011) 900 final, 20 December 2011.

[22]European Commission, Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, COM(2008) 414 final, 2 July 2008; Koivusalo 2010, pp. 263–280.

[23]Hatzopoulos 2013, p. 126.

[24]Council of the European Union, Directive on cross-border care adopted, Press Release, 7056/11, 28 February 2011.

[25]Kostera 2013, pp. 149–156.

[26]CJEU, Case C-512/08 *European Commission v. French Republic* [2010] ECR I-8833.

[27]See Hall 2010.

[28]See e.g. FACTBOX-Poland, Eureko meet to settle PZU dispute, Reuters, 17 January 2008, available at: http://www.reuters.com/article/2008/01/17/pzu-idUSL174991720080117.

In Slovakia a similar story of overambitious liberalisation of the public health insurance system was followed by more restrictive action by the next government.[29] A key aspect was limiting mobility of capital through the requirement of non-profit status. Slovakia refused to pay and in May 2013 its assets were frozen at the value of 29.5 million euros on the basis of information provided by the Dutch insurance company Achmea, involved as a claimant in the case.[30]

There is a broader question of the applicability of intra-European Union investment agreements, where the case has been a landmark case confirming the scope for application of intra-EU BITs.[31] The reality is that arbitration cases within Europe have created scope for investment arbitration in the field of health care and health insurance services, including against such measures that governments use to constrain costs. It is not surprising that the focus has been on new Member States as these have undertaken more market-oriented health care reforms and there has been international interest in prospective health care markets in CEE markets as the result of changes in legislation.[32] On the other hand, as the case has not so far been judged by the European Court of Justice, we do not have evidence as to whether consideration of the financial sustainability of health systems would have in practice weighed more than Treaty obligations regarding free mobility of capital.

Emphasis in European Court of Justice cases that health services are services in the context of internal markets has meant that they have often been more part of the problem than the solution in efforts to ensure the financial sustainability of health systems. Furthermore, the particular trail of European Court of Justice decisions on health services has been complemented by judgements on freedom to provide services, government procurement and state aid in the area of social security and, in particular, services of general interest.[33] For example, European Court of Justice decisions on the AOK and Oymanns cases have been seen as controversial in terms of their further influence on the German health system as this relates to competition and government procurement law.[34] However, while it is and would

[29]See case *Eureko B.V. v. the Slovak Republic*, PCA Case No. 2008-13, Award on Jurisdiction, Arbitrability and Suspension, 26 October 2010. While this case applies to the intra-EU issue it has some discussion with respect to the case itself.

[30]See Achmea, Dutch insurer Achmea seizes Slovak assets. http://news.achmea.nl/dutch-insurer-achmea-seizes-slovak-assets. 22 May 2013. Accessed 24 February 2014.

[31]*Eureko B.V. v. the Slovak Republic*, PCA Case No. 2008-13, Award on Jurisdiction, Arbitrability and Suspension, 26 October 2010.

[32]See e.g. Koivusalo 2013, pp. 93–117.

[33]See e.g. Deutsche Sozialversicherung, Social Security as 'social service provision' in the Internal Market: not an appropriate concept for Europe, Joint Position Paper of the Umbrella Organisations representing the German Social Security System. http://www.deutsche-sozialversicherung.de/en/europe/documents/verweis_healthcare/Konzept_fuer__Europa_englisch.pdf. April 2005, p. 1. Accessed 24 February 2014.

[34]Welti 2011, p. 320; CJEU, Case C-264/01 *AOK Bundesverband a.o. v. Ichthyol-Gesellschaft Cordes, Hermani & Co.* [2004] ECR I-2493; CJEU, Case C-300/07 *Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik v. AOK Rheinland/Hamburg* [2009] ECR I-4799.

be a matter of European policies to address a lack of balance within European Union social and economic treaty obligations, changes are more difficult to make if the current state is bound further on the basis of trade and investment agreements.

Trade and services negotiations also broadly affect national health systems through what is negotiated in the context of professional services and mode 4 negotiations. These areas are also reflected in the European legal framework as it concerns the mobility of people. In the European Union, free mobility of workers is laid down in Article 39 TFEU and has been further developed in regulation 1612/68. Mutual recognition of qualifications was initially provided for in Directive 2005/36/EC. A further revision of the regulation on mutual recognition of qualifications was approved in 2013, allowing more policy space to tackle language requirements as well as to address concerns over rogue professionals moving from one country to another.[35] The Green Paper on the European workforce for health further established the role and presence of the European Union in the field.[36]

15.2.1 Services of General Interest and Health Systems

Services of general interest have been important in the definition of limits of internal markets and part of European discourse since the Treaty of Rome.[37] Broader debate on services of general interest was initiated on the basis of green and white papers with respect to the role, nature and scope of services of general interest.[38] Health and social services have also become explicitly defined as part of services of general interest.[39] A further process of clarification and guidance has taken

[35]Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No. 1024/2012 on administrative cooperation through the Internal Market Information System, *OJ* 2013 L 354/132.

[36]European Commission, Green paper on the European Workforce for Health, COM(2008) 725 final, 10 December 2008.

[37]See the original Rome Treaty of 1957, Article 90 EEC.

[38]See e.g. European Commission, Green paper on Services of General Interest, COM(2003) 270 final, 21 May 2003; European Commission, White paper on Services of General Interest, COM(2004) 374 final, 12 May 2004; European Commission, Services of general interest, including social services of general interest: a new European commitment, COM(2007) 725 final, 20 November 2007; European Commission, Staff Working Document, Progress since the 2004 White Paper on services of general interest, SEC(2007) 1515, 20 November 2007; European Commission, Staff Working Document, Biennial Report on social services of general interest, SEC(2008) 2179, 2 July 2008.

[39]See e.g. European Commission, Services of general interest, including social services of general interest: a new European commitment, COM(2007) 725 final, 20 November 2007; European Commission, Staff Working Document, Progress since the 2004 White Paper on services of general interest, SEC(2007) 1515, 20 November 2007.

place and is continuing, in particular for social services.[40] However, while there have been substantial discussions concerning the definition of services of general interest, the key problem for health systems is how a distinction between services of general interest and services of general economic interest is made. The most recent report on services of general interest clarifies the relationship with state aid, emphasising that state aid rules apply to the financing of social services of an economic nature, even if the body providing the service has non-profit status.[41]

As long as services of general interest (SGI) remains a more residual category in the context of internal markets in practice,[42] a substantial part of health services will become defined as services of general economic interest and subject to internal market regulations and competition law. This implies that SGI is not a sufficient basis for exclusion from trade and investment negotiations. Furthermore, Article 2 of the Lisbon Treaty Protocol on services of general interest (Protocol No. 26) makes it explicit that: "The provisions of the Treaties do not affect in any way the competence of Member States to provide, commission and organise *non-economic services* of general interest."

On the other hand, debates and discourse on services of general interest have been a channel for major discontent regarding the implications of single markets, in particular with provision of social services.[43] In European policies the role of SGI has been followed and promoted by nongovernmental organisations with substantial public scrutiny. The danger is that while rhetorics would emphasise the values and the role of SGI and the contribution of Social Europe to the trading partners of the rest of the world, this is not associated with adequate consideration of how this can be achieved, with the consequence of SGI becoming merely a replacement for GATS Article I:3 (see below).

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[40]European Commission, Staff Working Document, Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest, SEC(2010) 1545 final, 7 December 2010; European Commission, Staff Working Document, Second Biennial Report on social services of general interest, SEC(2010) 1284 final, 22 October 2010; European Commission, A Quality Framework for Services of General Economic Interest in Europe, COM(2011) 900 final, 20 December 2011; European Commission, Staff Working Document, Investing in Health, SWD(2013) 43 final, 20 February 2013; European Commission, Staff Working Document, Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest, SWD(2013) 53 final/2, 29 April 2013.

[41]European Commission, Staff Working Document, Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest, SWD(2013) 53 final/2, 29 April 2013, p. 9.

[42]This is reflected, for example, in CJEU, Case C-309/99 *Wouters a.o. v.* Algemene Raad van de Nederlandse Orde van Advocaten [2002] ECR I-1577.

[43]This is also reflected in formal reports on the Single Market, such as in M. Monti, A new strategy for the single market. At the service of Europe's economy and society. Report to the President of the European Commission Jose Manuel Barroso, 9 May 2010. http://ec.europa.eu/bepa/pdf/monti_report_final_10_05_2010_en.pdf, p. 73. Accessed 1 March 2014, where, according to Monti: 'Since the nineties, the place of public services within the single market has been a persistent irritant in the European public debate.'

15.2.2 Commercial Policy and Health Systems

European Union competence on health remained complementary and restricted to public health during the intergovernmental conference and negotiations of the Treaty of Nice. This provides the background as well as context for the way in which this relationship was reflected as part of European Union commercial policy in the Treaty of Nice, where a specific carve out was left for particular services: cultural and audiovisual, educational, social and human health services were carved out from shared majority voting to unanimous decision-making and shared competence in these fields:

Article 133. 6 ECT stated:

> An agreement may not be concluded by the Council if it includes provisions which would go beyond the Community's internal powers, in particular by leading to harmonisation of the laws or regulations of the Member States in an area for which this Treaty rules out such harmonisation.
>
> In this regard, by way of derogation from the first subparagraph of para 5, agreements relating to trade in cultural and audiovisual services, educational services, and social and human health services, shall fall within the shared competence of the Community and its Member States.
>
> Consequently, in addition to a Community decision taken in accordance with the relevant provisions of Article 300, the negotiation of such agreements shall require the common accord of the Member States. Agreements thus negotiated shall be concluded jointly by the Community and the Member States.

In health services the articulation of the problem during Treaty of Nice negotiations was relatively straightforward. As Member States had competence for organisation and financing of health care, they should have been able to maintain policy space within the sector in relation to commercial policy negotiations. Cultural, audiovisual, educational, social and health services became known as "sensitive services" in the context of European Union commercial policy. However, while international trade negotiations on services were stalled, the situation with respect to health services started to change more prominently in relation to European Union internal policies, services and health.

The Lisbon Treaty version of the Article on common commercial policy (Article 207 TFEU) has further limited the scope for carve out on services, but is still relevant to current trade negotiations as it gives support to arguments concerning "sensitive services" as well as, ultimately, a right to veto if there is a concern over the financial sustainability of health services in a member state as expressed in Article 207(4):

> 4. For the negotiation and conclusion of the agreements referred to in para 3, the Council shall act by a qualified majority.

> For the negotiation and conclusion of agreements in the fields of trade in services and the commercial aspects of intellectual property, as well as foreign direct investment, the Council shall act unanimously where such agreements include provisions for which unanimity is required for the adoption of internal rules.
>
> The Council shall also act unanimously for the negotiation and conclusion of agreements:
>
> (a) in the field of trade in cultural and audiovisual services, where these agreements risk prejudicing the Union's cultural and linguistic diversity;
>
> (b) in the field of trade in social, education and health services, where these agreements risk seriously disturbing the national organisation of such services and prejudicing the responsibility of Member States to deliver them.

The carve out represents in many ways the concern of Member States of maintaining policy space in a context where European Union engagement in the sector is increasing. A reservation for unanimity only for those areas where unanimity is required for internal rules was thus not sufficient to ensure policy space for these services, which required a specific carve out. On the other hand, it applies not only to services, but also to negotiations on foreign direct investment and commercial aspects of intellectual property rights. In light of the existing arbitration cases, as well as pressures from trade, this is of importance to national pricing policies and cost-containment in the field of medicines.[44] The scope for Article 207(4) TFEU carve out is thus broader than was initially assumed necessary to ensure policy space arises in a greater proportion from the existing, more contested relationship between national health systems and internal markets.

An interesting element in this is that Article 207 TFEU uses almost the same language as the initial Court of Justice case C-120/95, Decker, in para 39, which states:

> It must be recalled that aims of a purely economic nature cannot justify a barrier to the fundamental principle of the free movement of goods. However, it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind.

This "emergency brake" provision has potential to both a help and a hindrance in taking health services better into account as part of trade negotiations (see Sect. 15.2.5). There is also a risk that some of these services are considered "more sensitive" than others. While audiovisual services were excluded from services and establishment chapter in the directives for EU-USA negotiations, there was only a minor reference to recognising the "sensitive nature" of certain sectors[45]:

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[44]For example, Finland is already on the United States 301 pressure list due to reference to pricing and promotion of generic medicines; see United State Trade Representative, 2013 Special 301 Report. United States, Washington D.C. http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf. May 2013, p. 48. Accessed 1 March 2014.

[45]Council of the European Union, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 17 June 2013, para 15.

> The aim of negotiations on trade in services will be to bind the existing autonomous level of liberalisation of both Parties at the highest level of liberalisation captured in existing FTAs, in line with Article V of GATS, covering substantially all sectors and all modes of supply, while achieving new market access by tackling remaining long-standing market access barriers, recognising the sensitive nature of certain sectors. Furthermore, the US and the EU will include binding commitments to provide transparency, impartiality and due process with regard to licensing and qualification requirements and procedures, as well as to enhance the regulatory disciplines included in current US and EU FTAs.

The narrow application of GATS I:3 as discussed elsewhere in this volume[46] implies that, in principle, where governments have outsourced services with a liberal legislation allowing market access to foreign providers, this will not provide sufficient protection for policy space. Furthermore, the language regarding sensitivities is reduced to recognising sensitivities while "tackling remaining long-standing market access barriers".

From the perspective of a European Union Member State seeking to maintain necessary policy space for health, further Commission engagement on negotiation of bilateral treaties has not been straightforward, and in health services has led to the incremental inclusion of new areas for all Member States. For example, the European Union did make commitments with respect to privately funded mobility of patients in the CARIFORUM (2012) agreement,[47] which has formed the basis and precedent for new negotiations on health services in bilateral agreements including mode 2 in health services to BITs since the CARIFORUM agreement. The precedence factor is important as it is increasingly difficult for a Member State to back down from compromises made in one BIT in negotiations of another, unless further arguments on the matter can be made with respect to the particular country.

As the Lisbon Treaty increased the rights of the European Parliament with respect to the conclusion of trade agreements, this was accompanied by diminishing powers of national parliaments in relation to trade agreements.[48] Health and social policies are at the core of this problem as national parliaments remain responsible for the financing of health within countries, whereas financing of health care or the sustainability of financing of health care is not at the core of European Parliament concerns.

15.2.3 Policy Space for Health

The understanding of national health systems is often based either on an assumption that trade and investment issues do not matter at all, or that there are no issues that would imply that the health sector is different from any other sector. In practice both

[46]See Chap. 2 by Arena in this volume.

[47]CARIFORUM-EC Economic Partnership Agreement 2012, available at: http://ctrc.sice.oas.org/Trade/CARIFORUM-ECEPA/CARIFORUM-ECEPA_e.asp, accessed 5 January 2012.

[48]See e.g. Krajewski 2012, p. 311.

of these assumptions are wrong. In reality national health systems are based on and engage with commercial sector operators more than is usually assumed, but health services cannot be seen as equal to consumer or more "market" driven services due to substantial market failures in health services markets.

The term policy space for health is functional and can be defined as "the freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfil their aims".[49] It draws on an understanding of and discussions on economic policy space, which has been taken up in the context of UNCTAD and the Accra declaration.[50] However, it is particularly feasible for addressing trade negotiations on non-tariff barriers to trade, domestic regulation, government procurement, regulatory cooperation and investment liberalisation and protection, which are more likely than tariffs to have an influence on **how** governments regulate both public and private services in particular sectors. The issue is thus not only about the right of governments to set standards at a level they desire, but also the ways in which trade agreements change the process of how and on what basis governments can regulate.

Policy space for health is useful in this context as it extends from public health-related measures, health-related standards and standard setting to the scope and measures that governments can use to contain costs within health systems, to ensure universal provision of services, equity and affordable access to services. In many ways this would imply, in particular, government interventions of the type that are required for the purpose of services of general interest. In health care these types of activities include cross-subsidisation across services provided for the rich and healthy and those provided for the sick and poor. Statutory social security systems do this through insurance funds, whereas in NHS-type services this is done through pooling of funding and provision of services.

A particular trend in current health policy developments in a number of European Union Member States has been to introduce more contractual and competitive arrangements to health care provision. In some countries, such as Germany, hospitals have been privatised.[51] In others, such as the Netherlands, active measures have been implemented to achieve regulated competition within health care, but so far this has not reduced overall costs.[52] In Finland municipalities have contracted out primary health care services to private sector companies.[53] In Sweden consum-

[49]Koivusalo et al. 2009, p. 105.

[50]The Accra Declaration states in para 16 that: " While development is the primary responsibility of each country, domestic efforts should be facilitated and complemented by an enabling international environment based on multilaterally agreed and applied rules. It is for each Government to evaluate the trade-off between the benefit of accepting international rules and commitments, and the constraints posed by the loss of policy space…/…". http://unctad.org/en/Docs/iaos20082_en.pdf. Accessed 27 February 2014.

[51]Mosebach 2009, pp. 65–98.

[52]E. Schut, S. Sorbe and J. Hoj, Health care reform and long-term care in the Netherlands. OECD Economics Department Working Papers, No. 1010, 2013. OECD Publishing.

[53]Tritter et al. 2009, pp. 132–151; Eronen et al. 2013.

ers are allowed to choose between private and public providers.[54] The United Kingdom government has introduced competition to the NHS as part of the new health and social care bill with substantial criticism over the process and likelihood of compounding economic pressures.[55]

While commercialisation and reliance on choice and markets have been sought as a means for cost-containment, this does not imply that government intervention is not required in order to achieve benefits and ensure equity and quality of services. Furthermore, there remain concerns that expectations from more "consumer driven care" have been too high.[56] It has long been known that, depending on incentive mechanisms, service providers in competitive markets tend to cream, dump and skimp when it comes to patients.[57] In Finland a substantial number of local governments moved back to provision of their own health care as result of cost increase.[58] It is not surprising that Poland and Slovakia have engaged with more market restrictive initiatives, as before accession the major players in the CEE/CIS countries were the World Bank and the USAID with a predominant American influence via World Bank and US government-funded programmes in the region.[59] Backing off from health care markets, for example, in the United Kingdom could result in investment arbitration.[60] As a result health care systems have been more commercialised with a more substantial role for private insurance companies and private hospitals than in other European Union health care systems.

The problem with respect to health care systems, commercialisation and choice as a means to lower costs is that on the basis of OECD comparison (Fig. 15.1),[61] more commercialised and private insurance-based health care systems tend to have higher costs. Furthermore, there are not, as one may expect, more medical doctors per head of population in the United States, where there are relatively few medical doctors per head of population in spite of the high costs, in comparison to many European Union Member States.[62] The interface between internal market regulations and broader public interests within national health systems is likely to face increasing tensions in the future as a result of patient mobility. The economic crisis and subsequent concern over public spending is likely to impose further financial and reform pressures on the health care sector. While moves towards further

[54]See e.g. Blomqvist 2004, pp. 139–155; Dahlgren 2008, pp. 697–715; Tritter et al. 2009.

[55]Reynolds et al. 2012, pp. 213–217; N. Timmins, Never again? The story of the health and social care act 2012. Kings Fund and Institute of Government, London. http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/never-again-story-health-social-care-nicholas-timmins-jul12.pdf. Accessed 2 March 2014; Klein 2013, p. 237.

[56]Okma and Crivelli 2013, pp. 105–112.

[57]See Ellis 1998.

[58]Eronen et al. 2013.

[59]See e.g. Shakarashvili and Davey 2005, p. 15.

[60]Koivusalo and Tritter 2014, pp. 93–111.

[61]OECD 2013.

[62]OECD 2013.

commercialisation of health services provision do not usually create problems with respect to commercial policies, investment and markets, it is likely that further restrictions or shifts towards public or non-profit provision of health care would do so. It is this policy space for cost-containment measures that is particularly at stake as part of trade negotiations as it would constrict and affect services trade and the expectations of investors from European health care markets.[63]

Measures for ensuring the financial sustainability of health systems is an area where the context of European internal markets differs from the context of international trade agreements due to the fact that the European Court of Justice has clearly judged that the financial sustainability of national health care systems is a valid reason for government intervention. Furthermore, the Article 207 TFEU carve out for health and social services is based on the same concern.

The paradox of the health care sector and commercial policy is that for regulatory purposes there is no need to articulate policy space if health services and their operation are strictly under direct public "command and control". The more commercialised the provision of health services becomes, the more important it is to ensure sufficient policy space for regulation and cost-containment. It is also about priorities for government action. It is necessary for governments to decide whether their priorities with respect to the health care system are those related to commercial opportunities, foreign investors and export prospects for services or for access and quality of services that citizens receive within the country, as these are unlikely to coincide. There remains a major discrepancy between requirements for a well-functioning publicly funded service and a highly profitable commercial industry both in terms of the aims and focus of these services.

15.2.4 Policy Space for Health in the Context of Trade and Investment Agreements

In terms of policy space the largest scope can be achieved through broad exemption for health systems in a way that would be extensive enough to also apply to

[63]This is often impeded by restrictions and limits on the use of competition to lower costs of medicines as a result of trade-related measures in the field of intellectual property rights. Particular attention needs to be paid in this regard to the negotiations of the Transatlantic Trade and Investment Partnership (TTIP), where European technology assessment measures, reference pricing and price controls in the field of pharmaceutical policies have already been raised as a potential concern for the United States. As national health systems—and those who are ill—will, to a large extent, pay for pharmaceuticals (OECD 2008), it is not entirely clear how much of the share of the estimated gains for pharmaceutical markets as result of addressing non-tariff measures in the field of pharmaceuticals would actually be spent on jobs in the EU and what it would imply for prices of medicines paid for by national health systems and consumers in European Union and United States (Ecorys Nederland BV, Non-Tariff measures in EU-US Trade and Investment—An Economic Analysis. http://trade.ec.europa.eu/doclib/docs/2009/december/tradoc_145613.pdf, pp. 99–106. Accessed 2 March 2015.

social care and care for the elderly as these cannot necessarily be separated.[64] A generic exemption covering all aspects of trade and investment agreements would be simplest from the perspective of national health policies. Furthermore, from the perspective of policy space, it should cover not only services with **any public funding**, but also privately funded services. Publicly and privately funded services also rely on the same pool of expertise and professional work-force.

It is not always feasible to make a strict separation between publicly and privately funded services. Government obligations include regulation of privately funded health services and the quality of care that is provided. Lack of oversight or regulation of private practice can also become a burden for the publicly funded services. Failures of private sector providers to follow guidelines or provide adequate quality of care can result in serious consequences, which then need to be treated under publicly funded care.

For example, European Commission negotiators' assumptions of the non-problematic nature of liberalising health tourism in the form of the privately funded mode 2 in trade in health services can be easily challenged by cases where patients have contracted a multi-resistant hospital bacteria in a privately financed operation in another country and brought it to—publicly funded—hospitals in the home country.[65] Promotion of trade in privately funded services is often considered as irrelevant if not beneficial to publicly funded services. However, if this trade brings in an epidemic of multi-resistant hospital bacteria or results in the need for correctional operations, the costs of it can easily far outweigh the benefits.

Health policies will require the right to exclude and ban provision, establishment or advertising of particular services, even if these could be claimed to put foreign providers at a disadvantage or disproportionately affect foreign providers. The GATS dispute settlement case on gambling is a case in point in this respect. Government action to ban—without discrimination—the provision of online gambling services was considered a matter of restriction of market access and setting a quota of zero for services.[66]

One crucial question with respect to trade agreements is whether governments would have the right to regulate for cost-containment through, for example, restriction of patient choice to a limited number of providers. According to Luff,[67] cost-containment mechanisms have an unclear status in the GATS and, in principle, full commitments in the health sector could render the granting of special or exclusive rights to hospitals untenable in health care systems.

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[64] See Chap. 10 by Krajewski in this volume.

[65] See e.g. Kumarasamy et al. 2010, pp. 597–602, Another ethical dilemma relates to trade and trafficking of organs.

[66] *United States—Measures affecting the Cross-Border Supply of Gambling and Betting Services*, Report of the Appellate Body, WT/DS285/AB/R, para 5.67.

[67] Luff 2003, p. 213.

Issues with respect to the impact of domestic regulation on health systems have been raised and discussed in WTO consultations on domestic regulation.[68] Licensing procedures, technical standards and recognition of qualifications remain important means of regulation in practice. Member States have already responded to emerging problems with mobility of health professionals within the European Union; for example, the UK NHS Federation has been engaged in lobbying to correct problems with language skills, training requirements and clinical competence.[69]

The scope to tighten qualifications or introduce new qualifications is also a matter of health and safety when these measures focus on private providers. For example, a UK Department of Health report on cosmetic interventions emphasised the need to tighten regulation, including with respect to qualifications required for those using dermal fillers in accordance with several other governments considering or already engaged in tightening regulations.[70]

Government procurement requirements have allowed some flexibility and limitation in implementation within the European Union. However, it is not certain that flexibilities gained as part of European Union internal policies will remain as these elements become subject to international trade disputes. The change from GATS provisions on services to separate chapters on investment liberalisation and protection are perhaps the most problematic for policy space and regulation of health systems. The case with respect to Slovakia implies that there is a real risk of a "one way street" when further liberalisation is introduced to a health system. Concerns with respect to investment arbitration apply also to health promotion and public health-related services and measures, as has been the case with respect to the known investment arbitration case on plain packaging legislation between Philip Morris and Australia.[71]

15.2.5 Governance Challenges to Health Systems and Trade in the European Union

The governance challenge with respect to national health systems and health priorities in the context of European commercial policies includes both intended and unintended consequences of the increasing number of negotiated agreements and

[68]See e.g. WTO Working Party on Domestic Regulation, Regulatory Issues in Sectors and Modes of Supply, Note by the Secretariat, S/WPDR/W/48/Add.1, 30 April 2013.

[69]See e.g. NHS European Office, New EU law on mobility of health professionals across Europe, briefing October 2013, Issue 15. http://www.nhsconfed.org/Publications/briefings/Pages/New-EU-law-health-professionals-move.aspx. Accessed 24 February 2014.

[70]See Department of Health, Review of the Regulation of Cosmetic Interventions. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf. April 2013. Accessed 24 February 2014.

[71]*Philip Morris v. Australia*, Notice of Arbitration, 21 November 2011, available at: http://www.ag.gov.au/internationalrelations/internationallaw/pages/tobaccoplainpackaging.aspx. Accessed 24 February 2014.

their expanding and more complex nature, as well as changes and combinations of negotiation tactics geared towards more extensive inclusion of services and sectors. The large number of bilateral negotiations results more easily in mistakes and omissions in country schedules and often leads to incremental liberalisation in practice. The increasing depth and simultaneous expansion to investment and government procurement negotiations also creates a lack of focus and understanding of details on which commitments have been made and where. Investment agreements and, to some extent, bilateral agreements have been and, to some extent, remain negotiated under different governance practices with less public consultation than in multilateral negotiations on the General Agreement on Trade in Services.[72] As commitments made in one bilateral agreement are then used as precedence for the negotiation of the next one, it is difficult for Member States to back down from commitments made.

As commercial policy negotiators engage, in particular, with "barriers" to trade, it is likely that they are more informed about "protectionist" practices and problems that multinational industries face in different countries. This "bias" becomes more prominent in European Union level negotiations as these concern trade and health. Multinational industries within the health sector have an incentive to negotiate at European level for access to 27 different markets. On the other hand, due to assumptions of the "complementary" role of European Union and limited interest in trade, governments may not realise where and how health-related priorities should be defended as part of negotiations.

National governments may or may not consult with health ministries regarding their policies, and health ministries may or may not have sufficient understanding of the potential implications of negotiations. European negotiators are likely to be more informed of the need to exclude audiovisual services than health services. The lack of adequate consultation on negotiation mandate is reflected also in the European Parliament in the resolution on the opening of negotiations on a plurilateral agreement on services where para 5 makes it known that it "regrets the fact that the Council granted a mandate without having taken Parliament's view into consideration".[73] This contrasts with the claimed powers that the European Parliament were given as part of Lisbon Treaty negotiations and also potentially undermines the scope of the European Parliament to block processes, as was the case with ACTA negotiations. Indeed, the rejection of ACTA was the first time the European Parliament used powers from Article 207 TFEU.[74]

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[72]R. Adlung, Trade in health care and health insurance services: the GATS as a supporting actor(?), WTO Staff Working Paper ERSD-2009-15.

[73]European Parliament, Opening of negotiations on plurilateral agreement on services, 4 July 2013, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-325. Accessed 1 March 2014, para 5.

[74]See e.g. European Parliament, European Parliament rejects ACTA, Press Release, 4 July 2012, available at: http://www.europarl.europa.eu/news/en/news-room/content/20120703IPR48247/html/European-Parliament-rejects-ACTA. Accessed 24 February 2014.

The lack of consideration of health applies also to consultations and other practices, such as sustainability impact assessments, where health system or health policy considerations are not a main concern and broader public policy interests, such as maintaining regulatory policy space, are not necessarily brought up by those participating in consultations on impact assessments.[75] This would of course imply that impact assessments had relevance for decisions made. The European Parliament resolution on the opening of negotiations on a plurilateral agreement on services notes that[76]:

> The EU's negotiating mandate was proposed by the Commission and adopted by the Council *without any impact assessment*; insists that the Commission follow up on its intention to prepare a sustainability impact assessment and that it must do so in consultation with the relevant stakeholders as regards social, environmental and other concerns; demands that the Commission publish the sustainability impact assessment with a view to taking its conclusions into account in the negotiations.

The reality of European trade negotiations is that audiovisual services are better protected than social security, health and social services—or services of general interest. The potential for the use of Article 207(4) powers through a veto if the negotiated agreement does not fulfil the requirements of adequate consideration of these services can, nevertheless, be useful in ensuring that policy space for regulation is prioritised. Whether a government will want to use the "emergency brake" clause to turn down the whole agreement when substantial political capital has been invested in the process is another issue. However, it is important to recognise that there is always scope for using this as leverage in order to secure adequate consideration for "sensitive" services.

15.2.6 Policy Space and Negotiation Processes

A key challenge to ensure that a service sector is kept outside a trade agreement is the "normalisation" of liberalisation in the context of trade negotiations. The assumption that market access or a lack of non-conforming legislation implies that

[75]Representation of health interests in the context of trade in the European Union has been traditionally based more on trade unions and development-oriented nongovernmental organisations, although nongovernmental organisations working on public health have now followed TTIP and TiSA more. Participation in sustainability impact assessment consultations has been limited, where inclusion of health considerations has been weak or lacking. In the European Union–Canada (CETA) agreement sustainability impact assessment health was taken up, in particular in the Canadian context, but gained little focus due to expectations that services negotiations would not cover health. See e.g. Kirkpatrick C et al., A trade SIA related to the negotiation of a Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada. Trade 10/B3/B06. http://trade.ec.europa.eu/doclib/docs/2011/september/tradoc_148201.pdf. June 2011, p. 125. Accessed 1 March 2014.

[76]European Parliament, Opening of negotiations on plurilateral agreement on services, 4 July 2013, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-325. Accessed 1 March 2014, para 19 (emphasis by author).

a service or a sector can be included as part of a trade and investment agreement is particularly problematic. This may be a result of recent liberalisation and "under-regulation" or merely a reflection of the major role of public sector operators and professional associations within the sector. This is why policy space to undertake regulatory measures and tighten oversight can be the particular reason why governments have not included health services as part of trade agreements in the first place. For example, in Finland legislation on health is liberal and foreign investors are allowed into the sector, which lead to the initial inclusion of health services as part of the EU-Mexico FTA in 2001. However, the government had not intended to include health services as part of the agreement.

Another challenge is anticipating and understanding where commitments have been made. While the General Agreement on Trade in Services (GATS) offered governments and their ministries scope to assess where to make commitments and how, the focus on negotiations on the basis of "negative" listing changes this context profoundly. In contrast to knowing what they want to liberalise, governments now need to know what not to liberalise. Furthermore, when inclusion of services is done on the basis of existing legislation on market access it can suddenly imply inclusion of services and sectors which governments did not intend to include as part of a trade agreement. There are negative listing elements in the GATS in relation to broader sectoral coverage of different types of services; for example, the dispute settlement case on gambling made it clear how online gambling was included in GATS commitments as part of much broader group of "other recreational services" at a time when online gambling was not yet as prominent as it currently is.[77] The problem is a lack of flexibility to react to "market failures" in the most efficient way as part of national policies or to limit the scope of markets where unanticipated problems or practices emerge.

The focus on negative listing forces governments to anticipate their future regulatory needs, which is usually impossible, in particular, for such sectors which have been recently liberalised. This also makes the ratchet effect a problem as newly liberalised sectors are automatically included as part of agreements. If a government makes a mistake in liberalising a service with adverse consequences, the flexibility to move back is very difficult or in practice no longer a possible option. The focus on standstill assumes that there is no need to tighten regulation or introduce new non-conforming measures. This is particularly challenging to the newly liberalised sectors, more likely to be under-regulated or be prone to problematic trading practices or a lack of competition, which may have influenced government engagement in the field in the first place. Allowing for policy space does not imply that a government should introduce non-conforming measures, but provides scope for doing so, in particular, to achieve cost-containment, universal service provision and equity in access to services, the key values emphasised as part of Lisbon Treaty protocol on services of general interest.

[77]See *United States—Measures affecting the Cross-Border Supply of Gambling and Betting Services*, Report of the Appellate Body, WT/DS285/AB/R, para 5.67.

While it would be meaningful to seek broad and extensive European Union level exclusion for both publicly and privately funded health and social services and health and social insurance services, it is more likely, on the basis of prior European Union level measures, that a European level of exclusion would cover only public utilities or publicly funded services. In this context, as discussed elsewhere in this book, the most extensive form of exclusion would be any publicly funded services. Furthermore, in order to maintain policy space it should be part of negotiations for cross-border trade in services and investment liberalisation, and also apply to public procurement. Exclusions should also cover professional services and negotiations concerning mutual recognition of qualifications, even if these were to be negotiated separately from other services. Any carve out of health and social services would need to apply also to horizontal provisions affecting policy space, such as provisions on domestic regulation, regulatory cooperation, performance requirements and subsidies. Removal of investment protection provisions from negotiations would provide the most policy space. If this is not possible, it is necessary to ensure that exemptions made apply both to investment liberalisation and investment protection provisions and that adequate scope for health promotion and protection is ensured. This is a challenge if investment protection is negotiated separately from investment liberalisation, leading easily to a situation where governments may assume false security of policy space on the basis of excluding services from investment liberalisation when these could still be subject to investment protection provisions.

Governments have choice and flexibility in what is included under government procurement obligations of services within Europe. However, this may be lost or not appropriately secured in the context of trade agreements. For example, the TTIP negotiation directives are ambitious, seeking to cover all sectors, thresholds and services contracts and markets at all administrative levels with rules and disciplines to address local content or local production requirements for contracts.[78] Government procurement obligations can affect both health insurance and NHS-type health systems and are likely to have implications for any publicly funded services and their outsourcing in health and long-term care, as well as measures to cross-subsidise provision of services across regions.

While those inclined towards preference of free markets might assume that there is no need to return to public provision once services are outsourced, this is, of course, not always the case in practice. Indeed, a neutral position would support flexibility. For example, a recent survey found that in Finland around a third of local governments have returned from outsourced health services to public provision due to lower costs and administrative simplicity.[79] The problem of commitments made with respect to investment agreements is that if a government moves out of contractual markets or more liberalised insurance markets, multinational investors may call for compensation as a result of loss of potential income from outsourced services.

[78]Council of the European Union, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 17 June 2013, para 24.

[79]Eronen et al. 2013.

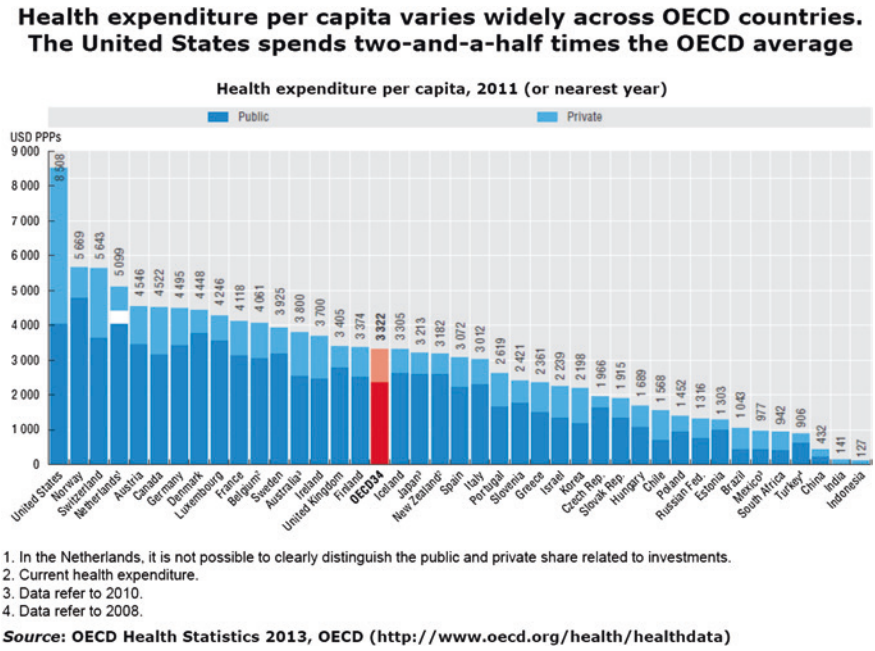

Fig. 15.1 Health expenditure per capita

The paradox of national health systems is that the more commercialised and liberalised governments wish their health systems to be in terms of service provision, the more important is to maintain regulatory policy space for cost-containment, equity and quality of services. Experiences of commercialisation in the field of health care provision in Finland would suggest that liberalisation and concentration takes place quite quickly in health and social services, with the danger of moving from public to private sector monopolies and market dominance.[80] Indeed, the question of the dominant position in health insurance markets can be seen as one of the issues in the Polish arbitration case.

From the perspective of policy space for health and safeguarding future regulatory policy space on the basis of health policy needs and priorities, the issue is not whether existing standards or legislation can be maintained, but whether legislation can be made more market restrictive and how the sustainability of financing of national health systems can be maintained. The comparison of "like services" can also be deceptive as there is, for example, a major difference in spending on health between European Member States and the United States[81] (see Fig. 15.1).

[80]In Finland markets for private contractors of publicly funded services have developed in the last 5 years with increasing involvement of large actors in service provision, as well as elements of concentration in the field of provision. See e.g. Eronen et al. 2013; Tritter et al. 2009.

[81]See OECD 2013.

Furthermore, while investment protection might not make the return from markets impossible, it can make it very expensive and represents unwise use of public funds. European Member States may not be delighted to find that the European Commission has negotiated excellent operational context for multinational health services industries, the pharmaceutical industry and trade in health professionals, with potential for commercial sector growth, if this takes place at the cost of the public purse, quality, safety and scope for regulation of services.

15.3 Conclusions

The deepening of trade negotiation agenda regarding regulatory cooperation and non-tariff barriers to trade, utilisation of expansive negotiation practices, and inclusion of government procurement and investment liberalisation and protection in negotiations all add to the complexity of current trade negotiations. The new generation trade agreements require a broader assessment and analysis, in particular with respect to services, investment, government procurement and horizontal rules negotiations so as to understand their implications upon health and social security systems financing, organisation and functioning. Trade in health services is also likely to bring new and mostly unexpected challenges and demands for a review in relation to mobility of health professionals and mobility of patients, which have not been adequately discussed or addressed as part of trade negotiations. The changing scope and complexity of trade negotiations puts particular pressure on European Union multilevel governance and the division of obligations and competences within the European Union.

Maintaining national policy space for health has been important for public health and health promotion measures, but also needs to be recognised in the context of services and investment negotiations and in relation to health systems. This is not only a matter of the number of personnel, quality, public health and safety within services, but applies, in particular, to cost-containment, cross-subsidisation and wise use of public funds.

The commercialisation of national health systems in European Union Member States has brought up a new regulatory context, where old assumptions of what public services entail are no longer adequate in ensuring sufficient policy space for European Member states to govern their health systems adequately.

Furthermore, the current context of trade negotiations with an emerging number of bilateral agreements, changing context and basis of negotiations, and increasing tendency for more ambitious and comprehensive trade agreements with focus on investment, services and government procurement poses a challenge for cost-containment, equity and quality of care within health systems. Furthermore, they have a risk of leading to commitments which are made without adequate consideration or full understanding of their future implications.

The division of competences and responsibilities between the European Union and Member States creates a void of accountability, as multinational health

care-related industries have an interest in ensuring their priorities become reflected in trade agreements, while there is limited understanding and focus in ensuring that Member States, responsible for the financing of health systems, will have sufficient means for ensuring cost-containment, equity and quality within health systems.

The new negotiations with high-income countries with focus on regulatory cooperation, domestic regulation and investment liberalisation and protection have particular relevance for maintaining policy space for health and capacities of governments to tackle issues emerging from recently commercialised services, unethical practices, novel trends in health care provision or challenges by multinational health care industries and investors.

Trade and investment agreements are negotiated on the basis of expected benefits rather than products of natural laws. It is important that all implications, including those for public policies, are adequately assessed. There are grounds for requiring policy space for health systems if governments seek to provide and finance theses services in the long-term. Securing policy space for health, social and education services—or audiovisual services—is a matter of governments' values and political priorities.

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