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EUROPEAN UNION GLOBAL HEALTH LAW

Abstract. The European Union is an important player in global health issues. This paper firstly explains the concept of EU global health law and then examines a number of areas where the EU acts and may influence, directly or indirectly, global health issues (eg, trade, public health, health migration, development aid, and health security). What follows is an attempt to tie up the threads more systematically by advocating a Global Health Convention, based on human rights principles. Such a shared vision on global health law may help the EU and Member States to respond more effectively to global health challenges such as international trade, public health security and health threats.

In line with EU Council Conclusions 2010, the focus is on four dominant areas of EU law, explained in more detail. The variety of measures and activities embodies: external trade and global health; EU health law and external relations; health migration and development initiatives; global health security: the emerging health/security nexus.

Author conclude that examining the EU's role in the global health debate, has revealed a 'hodgepodge' of legal issues, rather than a distinct body of rules reflecting a coherent framework of EU law. As a result, its role in the global health is largely influenced by other policy areas than health. What is missing is a common global health policy. Communication 2010 provided key elements of what reflects a fragmented, highly compartmentalised approach. Balancing international trade and other economic interests with global health issues requires a shared vision and strategy what is global health. Here, it is argued that the EU should take the lead in drafting such a common policy based on previous experiences in close collaboration with the key global health actor: the WHO. Formulating and implementing a global health treaty at Member State level, a Framework Convention on Global Health could respond to trade, in a more systematic and coherent manner, reflecting international health law principles and specifying State obligations.

Keywords: EU global health law; international trade; public health security and health threats; health workers' migration; Global Health Convention.

1. Introduction

Inherent to major health threats such as HIV/AIDS, SARS and Ebola is that they do not respect national and regional borders, and may spread globally. International co-operation among national states and supranational organisations is therefore crucial to resolve public health problems. Traditionally, the World Health Organization (WHO) is the leading actor involved in global health operations, aiming at isolating risk factors and preventing the border-crossing spread of infectious diseases. Its main instrument is the new set of International Health Regulations (2005), which aims to offer protection against a wide range of public health threats.

But the WHO is not the only player in global health issues. In 2010, the European Union (EU) acknowledged its role as a global health actor by publishing its communication on "The EU role in Global Health"[1]. This Communication presented an EU vision on global health, defined the guiding principles that should apply to all relevant policy sectors and presented a number of areas where the EU could act more effectively. In line with the WHO approach, the Commission document confirms that 'public health policies need to go beyond the national level and require strong global institutions and co-ordinated efforts'[2].

The EU as a global partner in health raises several questions, such as: what exactly is the role of the EU in global health, what are the global health activities or mechanisms, and what is the legal basis for such interventions? But also, how successful is it in improving global health? These questions trigger a more fundamental debate on an emerging field or branch of law: the concept of European Union global health law. What does it mean, and what are the legal implications of such a relatively new branch of law at Union level? Instead of analysing the 'success rate' in improving global health, which involves disciplines other than law, this paper will provide clarity on such a novel concept of law and will examine the role of the EU in global health, to increase understanding of the underlying principles and body of rules relating to global health.

Strengthening the EU's global health role, it is argued that apart from improving coherence in trade and other external policies, the EU should take the lead in a coordinated effort with WHO to strengthen comprehensive health care systems based on equitable and universal coverage worldwide.

[1] European Commission. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions 'the EU Role in Global Health', Brussels, 31.03.2010, COM(2010)128 final. The Communication is accompanied by Commission staff working documents dealing with respectively: 'Global health – responding to the challenges of globalisation SEC(2010) 380 final; 'European research and knowledge for global health 'SEC(210) 381 final; and 'Contributing to universal coverage of health services through development policy' SEC(2010) 382 final.

[2] Ibid 2.

At the same time, it is recognised that other actors, such as non-governmental organisations, also play an additional role in strengthening global health.

2. What is EU global health law?

The concept 'EU global health law' has strong links with the recent debate on international or global health law. Global health law focuses not upon individual patients, but on the health of different populations in the world; more specifically, protecting the health of populations and addressing global health challenges. A key element of global health law is therefore the border-crossing dimension, as health problems transcend national boundaries, and the need for an international approach. Global health law is historically understood to be part of international law: i. e. the set of rules explaining the relationship between nation states and international organisations such as the WHO[3]. A more modern approach to global health law, however, also recognises the role of non-state actors, such as transnational corporations (eg, pharmaceutical companies) and non-governmental organisations influencing public health (eg, Médicins sans Frontières and the Bill and Melinda Gates Foundation).

Global health law is aimed at the protection and promotion of a population's health and prevention of global health concerns (obesity, cardiac diseases, malnutrition, etc.). In line with the broad 'health concept' – defined as 'not only the absence of infirmity and disease but also a state of physical, mental and social well-being' – one may even argue that global health provides support for the determinants of physical and mental health (eg, nutrition, shelter, education) and even so-called 'third generation' or group rights (solidarity rights, such as peace and development, etc.). Such an all-inclusive approach to global health law aims to both protect global health and to improve health inequalities worldwide. In the legal doctrine, Lawrence Gostin is one of the proponents of such a broad approach, by defining global health law as:

> <…> the study and practice of international law – both hard law (eg, treaties that bind states) and soft instruments (eg, codes of practice negotiated by states) – that shapes norms, processes, and institutions to attain the highest attainable standard of physical and mental health for the world's population[4].

Ultimately, such an established international legal framework will help 'to empower the world community to advance global health, consistent with the values of social justice'[5]. By referring to the social justice dimension, Gostin is

[3] A L Taylor, 'International Law, and Public Health Policy' in Kris Heggenhougen and Stella Quah ed, *International Encyclopedia of Public Health,* Vol 3 (Academic Press 2008) 667–78; B Toebes, 'International health law: an emerging field of public international law' (2015) 3 Ind J Intern Law 299–328.
[4] J Gostin, *Global Health Law* (HUP 2014) 59.
[5] Ibid 60.

viewing global health from an all-inclusive perspective encompassing 'multiple legal regimes outside the health sector that intersect with the health sector' (eg, food, labour, housing)[6].

Nowadays it is generally accepted that human rights are interrelated and interdependent, but Gostin's approach goes even further, i. e. *incorporating* other human rights into the health concept to strengthen and improve (community) health. Though attractive, there is the risk that such a holistic approach makes global health a hollow phrase that covers a wide range of rights. Therefore, a more pragmatic approach is limited to the subject of global health law: the protection and promotion of a population's health, irrespective of other human rights interdependencies. Excluding the social justice component, what remains is the variety of a distinct and coherent system of international legal norms, including soft law, improving the health of populations[7].

As EU health law addresses the *internal* dimension, i. e. the influence of the internal market on national health systems (eg, public health, patient mobility, mutual recognition of health professions' diplomas, pharmaceuticals, health data protection, competition law in healthcare, and human rights in health care), EU global health law approaches the *external* dimension of EU law on health issues[8]. The EU as a global actor negotiates bilateral trade agreements with so-called third countries, including health exceptions to improve health. In addition, the EU collaborates with UN-based and regional organisations, such as the World Intellectual Property Organization (WIPO), to facilitate access to key medicine patents, the WHO in the field of the International Health Regulations (IHL 2005) and the Council of Europe on human rights in health care issues (privacy, non-discrimination, quality of care, etc). Also at non-state level, the EU collaborates with multinational corporations (eg, the pharmaceutical sector) and NGOs in facilitating research and funding global health initiatives, etc. EU global health law therefore examines the legal role of the EU in global health issues, covering several areas: international trade, public health security and health threats, international migration and development aid (supporting developing health systems, universal coverage, HIV/AIDS, preventing a 'brain drain') and the role of transnational corporations in improving health. Essentially, EU global health law is a response to trade,

[6] Gostin (n 4).

[7] D Fidler, 'Global Health Jurisprudence: A Time of Reckoning' (2008) 96 The Georgetown Law Journal 399–400.

[8] At the same time, it is recognised that both the external and internal dimensions interact, therefore, EU global health law may influence EU internal health law and reverse. For instance, the International Health Regulations (IHR 2005 rules) have been transformed into EU law. Reserve, internal market rules have been 'exported' to reduce the spread of communicable diseases (hereafter). Hervey and McHale: "extraterritorial impact of the EU's internal market rules" (at T Hervey & J McHale, 'The global context: Opportunities and threats; health knowledge; communicable diseases, global food and tobacco law' in *European Union Health Law: Themes and Implications* (2015 Cambridge University Press) 531–2).

health (security) threats, mobility, and a new understanding of the role of transnational corporations and health rights. So, despite the missing conceptual unity – even a missing shared 'vision' with the Member States[9] still, EU global health law examines a wide range of areas affecting global health.

3. EU global health law: the quest for a legal framework

With growing acknowledgement that the role of the EU in global health law is expanding, explaining the main legal instruments will help to clarify the scope and strengths of this new branch of law. In line with EU Council Conclusions 2010, the focus is on four dominant areas of EU law, explained in more detail. The variety of measures and activities embodies:

3.1. External trade and global health

The EU is known as an international actor in several policy areas. The oldest form of external policy is on trade, known as the common commercial policy (CCP) under Article 207 TFEU, which allows the EU to conclude international trade agreements with the WTO and third countries worldwide. These agreements are aimed at '<…> harmonious development of world trade, the progressive abolition of restrictions on international trade, <…> and the lowering of other barriers' (Article 206). In terms of substance, such agreements primarily deal with the trade in goods and services, intellectual property rights, foreign direct investments, etc. These trade agreements have been concluded since the 1970s, and renewed on various occasions. One of the most prominent examples is the EU/Canada Comprehensive Economic and Trade Agreement (CETA), a comprehensive trade deal on goods, services and investments[10]. Governing free trade and tariffs, these agreements apply to medicines, medical devices, food products, sanitary measures, services, IPRs and dispute settlement. For instance, the EU/Singapore trade and investment agreement aims – amongst other points – to eliminate non-tariffs barriers in the fields of pharmaceuticals and medical devices, and, simultaneously, 'to ensure consistency with the Public Health Declaration on the TRIPS Agreement (2001)'[11]. As a result, it will open up the pharmaceutical market while allowing general exceptions as under the GATT regime (public health). In addition, the agreement follows the safety measures set out under the Sanitary and Phytosanitary (SPS) agreement, allowing restrictive measures necessary to protect health[12]. Trade liberalisation of (health) services and electronic

[9] As argued by L Steurs and others, 'The Global Health Policies of the EU and its Member States: A Common Vision?' (2018) 5 IJHPM 434.
[10] OJ L11, 14 January 2017, p. 23–1079, signed on 30 October 2016 and provisionally entered into force on 21 September 2017.
[11] Signed 19 October 2018, Ch.2, Annex 2-C, Art 1(a)(c).
[12] Ch. 5, Art 5.13 (1) "emergency measures".

commerce is another key area regulated under the agreement (Chapter 8), allowing the transnational supply of (electronic) health services in line with national requirements[13]. For instance, hospital providers in EU Member States may therefore outsource diagnostic test services to laboratories located in Singapore. Alternatively, an EU-based medical specialist can be invited for a tele-consultation by his/her colleague in Singapore. This kind of international offshoring and outsourcing – subcontracting foreign providers for providing health services – is raising controversial questions on legal issues such as securing information privacy, contractual requirements and informed consent, since it happens 'behind the scenes', with patients unaware that certain services will be delivered by foreign providers[14]. And although the options are endless, national standards concerning safety requirements, professional requirements, and data protection rules may raise additional legal barriers.

Finally, the chapter on 'Intellectual property' under the Singapore free trade agreement is of direct relevance to health care, as it follows the pharmaceutical patent rules under the TRIPS Agreement (Chapter 10). Of particular relevance is the confirmation of the so-called 'patent flexibility' incorporated by the Doha Declaration, i. e. restricting patent rights based on the public health exception ('compulsory licensing', Article 10.30)[15]. Otherwise, the Singapore agreement allows for a patent extension for a maximum of five years to compensate the patent holder for the reduction in the effective patent life as a result of the administrative marketing approval process (Article 10.31). The all-inclusive attitude to commercial relations, including not-trade values (eg, equal access and accessibility of medicines) characterises the new generation trade agreements (eg, with Japan, Mexico, Vietnam, South Korea, etc)[16] based on what can be referred as 'trade integration' or 'deep trade'[17].

A special type of bilateral agreement includes the Association Agreements with neighbouring countries in Eastern Europe, providing for an association including 'reciprocal rights and obligations' without offering EU membership[18]. Apart from liberalising trade, it also addresses political co-operation on, for example, the rule of law and fundamental rights, environmental protection, migration, public health, etc. In return for

[13] Art 8.5 on market access, except when market access commitments were stipulated; and Art 8.6 (National treatment clause).

[14] In more detail, see S Singh and R Wachter, 'Perspectives on Medical Outsourcing and Telemedicine – Rough Edges in a Flat World?' [2008] 358(15) The New England J Medicine 1625, quoted by: A. den Exter, 'E-Health law: the final frontier?' in T Hervey and others, *EU Health Law and Policy* (Elgar Publishing 2017) 245.

[15] Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Ministerial Conference of the WTO.

[16] EU-Japan Free Trade Agreement (released text, 8 December 2017); EU-Mexico negotiations textual proposal, October 2017; EU-Vietnam Free Trade Agreement, released text January 2016); Free Trade Agreement with the Republic of South Korea OJ L 127, 14 May 2011.

[17] As discussed by B. A. Melo Araujo, *The EU Deep Trade Agenda: Law and Policy* (OUP 2016).

[18] The EU has concluded more than 20 of such association agreements (AAs) under Art 217 TFEU, in particular with its neighbours in Eastern Europe (Armenia, Georgia, Moldova and Ukraine).

(partial) access to the internal market, the association country is required to comply progressively with EU legislation, rules and standards. How this affects health can be illustrated by the EU/Ukraine Association Agreement[19]. The agreement foresees in, for example, the protection of (health) data (Article 15), the conditional mobility of (health) workers (Article 18), progressive market access of goods, including pharmaceuticals and medical devices (Article 25), technical co-operation and full approximation of technical regulations (standardisation, market surveillance, accreditation, etc, Articles 55, 56), compliance with EU sanitary and phytosanitary measures (Article 59(1)(b), progressive liberalisation of (health) services (Article 85), mutual recognition of qualifications (Article 106), transparency and disclosure of confidential information (Article 107), pharmaceutical patent protection rights (Article 219), compliance with EU competition rules in healthcare (Article 256), consumer protection (Article 415), public health (eg, gradual integration of EU public health networks, approximation of public health legislation on blood, tissues and cells, and tobacco, etc, Articles 426–428)[20].

What becomes clear so far, is that the comprehensive and ambitious nature of these "new generation" trade agreements have the potential to limit regulatory leeway in the health sector, directly and indirectly. Of particular interest is then when and how the so-called 'public health-related flexibilities' for medicines will be triggered, justifying patent infringements.

3.2. EU Health Law and external relations

Nowadays, the European Union and health are inextricably related[21]. Under the current treaty, the 'Treaty on the Functioning of the European Union' (TFEU), the EU and its member states have shared competencies in the area of common safety concerns in public health matters, and the EU is required to take health protection into account in all of its policies[22]. But the most explicit health commitment has been made by the public health provision, Article 168(1): 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities', followed by more specific EU competencies in this area.

The history of the European Union's health policy can be characterised as a 'creeping competence'[23]. Since its establishment (1952), the role of

[19] OJ L 161/3, 29.5.2014.
[20] Confirmed by Annex XLI to Chapter 22.
[21] As illustrated by A. den Exter and T. Hervey, *EU Health Law: treaties and legislation* (Maklu Press Antwerp 2012).
[22] Consolidated version, Official Journal of the European Union C 83/47, articles 4(2)(k), 6 (a) and 9.
[23] Derived from M A Pollack, 'Creeping competence: The Expanding Agenda of the European Community' (1994) 2 J Pub Pol 95–145.

what is now the EU in the field of health has gradually grown in terms of competencies, and has become more explicit. Prior to the Treaty of Maastricht (1992), health regulations were based on agricultural policy, medicine and food safety and the internal market (public health exemptions on free movement and co-ordinating social security entitlements). Confronted with border-crossing health threats (HIV/AIDS, SARS, BSE, bioterrorism, etc), the Maastricht Treaty introduced a specific treaty-based competence aimed at public health protection (Article 129). During subsequent treaty revision, EU public health competencies have gradually increased, including standardising quality and safety of organs and substances of human origin, blood products and blood derivatives, adopting measures to combat major cross-border health threats and fostering co-operation with international organisations such as the World Health Organization and third countries in the sphere of public health.

As formal EU competence in the field of public health developed, whether or not combined with the general harmonisation provision (Article 114 TFEU), newly-established entities such as the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Monitoring Centre for Drugs and Drug Addiction became responsible for, respectively, the protection of human health through the evaluation and supervision of medicinal products, fighting infectious diseases, and providing information for drawing up informed drug laws and strategies. These, and other agencies, have an impact on the way the EU protects the health of its citizens, and supports its large health industry.

Conceptualising EU health competencies, the main focus is on Article 168 TFEU[24]. Though understandable, this is, however, not the entire story. Other legal bases have also been lawfully applied to ensure a high level of health protection (eg, free movement provisions, consumer and environmental protection, social policy, competition policy, etc). For instance, under the consumer protection policy, the general product safety directive (2001/95/EC) established general safety requirements for all consumer products, including medical devices. Combined with the 'horizontal' liability directive for defective products (89/374/EEC), these directives are aimed at protecting consumers' (patients') health against defective products. Additionally, EU social and employment law – aimed at protecting workers and fighting discrimination – had some unintended consequences in health care settings. A clear example is the Working Time Directive's applicability to medical professionals, which, it is claimed, has hampered the planning and organisation of medical

[24] Read for instance, A de Ruijter, *EU 'Public Health' and 'Health-care' Law and Policy* (Oxford Scholarship on line 2019) chs. 3 and 5.

care[25]. Furthermore, the co-ordination of social security law and the mutual recognition of diplomas of regulated health professions, combined with the harmonisation of pharmaceutical law, as well as the impact of European competition law, have a clear health dimension. At the same time, we will be confronted with new challenges, since the EU is becoming increasingly involved in human rights and health care. The EU Charter of Fundamental Rights and Human Rights Agency may influence EU law on health and health care in the member states[26]. For instance, courts may consider the Charter as the basis of judicial review of the activities of EU institutions[27]. Relevant rights may include the right to conduct a business, non-discrimination, life, equal access to health care, human integrity and informed consent.

Given the increased role of EU measures protecting health, and in line with the rationale of the internal market, extending such an approach towards a European health care market may seem quite logical. However, under the current Treaty provision Article 168(7), that idea has been explicitly rejected. '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 <…>'. Even the directive on patients' rights in cross-border health care does not change this, although this directive does define common principles and standards on quality and patients' rights (eg values of universality, access to good quality care, equity, solidarity, eligibility criteria, informed choice, personal data protection, measures for seeking remedies, etc.)[28]. However, the most essential elements (material scope, benefit package ('basket of care') and reimbursement decisions) remain the exclusive competence of the member states. Although constrained, health law is firmly on the map as an area of EU competence.

At the same time, EU health law may also affect the EU's relationships with third countries and health institutions[29]. For instance, in the field of public health, the European Centre for Disease Prevention and Control

[25] Directive 2003/88/EC, ECJ rulings Case C-303/98, *SIMAP* [2000] ECR I-7963 and Case C-151/02 *Jaeger* [2003] ECR I-8389. See A J Maxwell et al, 'Implementation of the European Working Time Directive in neurosurgery reduces continuity of care and training opportunities' (2010) 7 Acta Neurochirurgica 1207–10.

[26] See as reference, the FRA Handbook on European data protection law (medical data paragraph) 2014, 2018 edition, and the Handbook on European law relating to the rights of the child (right to health paragraph) 2015 (*Handbook on European data protection law, 2018 edition)* <https://fra.europa.eu/sites/default/files/fra_uploads/fra-coe-edps-2018-handbook-data-protection_en.pdf>; *Handbook on European law relating to the rights of the child* <https://fra.europa.eu/sites/default/files/fra_uploads/fra-ecthr-2015-handbook-european-law-rights-of-the-child_en.pdf> (accessed: 10.02.2020).

[27] See eg, the labelling of food stuffs and the protection of health under Art. 35 FCHR in *Deutsches Weintor* C-544/10; a licensing system for establishing private pharmacies based on public health under Art. 35 FCHR, Susisalo C-84/11; idem *Sokoll Seebacher* Case C-637/12 (Art. 16 FCHR); *Léger* C-528/13 on the prohibition of discrimination based on sexual orientation (Art. 21(1); Case C-220/17 questioning the validity of certain Tobacco restrictive measures under the Charter's rights 17 and 34.

[28] 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 [20011] OJ L88/45.

[29] Either based on Art 168 (3) or 216 (1) TFEU.

(ECDC) network collaborates with neighbouring countries and the WHO, focusing upon epidemiologic surveillance (developing standards, improving data quality, sharing best practice in surveillance, strengthening capacity in surveillance)[30]. This 'early warning and response system' has been a model of neighbouring epidemiological surveillance systems[31].

Apart from the ECDC, the European Medicines Agency (EMA) also operates in close co-operation with Member States and partners at international level to promote the convergence of regulatory requirements, sharing of information and addressing common health challenges[32]. On the globalised pharmaceutical market, EMA has concluded several agreements with different countries (Australia, Canada, Japan, United States, the WHO) to exchange confidential information and ensure regulatory co-operation, including marketing authorisation and good clinical practice (GCP) inspection findings[33]. In addition, the EU has signed a number of mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of medicinal products. These agreements facilitate market access while protecting consumer safety, and encourage the international harmonisation of compliance standards[34]. As such, the overall objective of such bilateral agreements is to 'foster international collaboration and information-sharing and to reduce unnecessary duplication'[35].

Another example, illustrating the "territorial extension" of EU law[36], concerns the process of clinical trials conducted in third countries. Due to growing concern with respect to ethical and scientific standards required of clinical trials, as well as the available framework for the supervision of these trials conducted outside the EU (e. g., 'clinical trial dumping' in African countries), a system of regulatory inspections in third countries has been

[30] ECDC Long-term Surveillance Strategy 2014-2020 (revised), ECDC 2018, under the direct mandate Reg. 851/2004/EC establishing a European centre for disease prevention and control, OJ L 142/1, 3 April 2004.

[31] Alternatively, ECDC incorporated international surveillance standards, see in case of the Zika virus transmission: 'ECDC adaptation of WHO's Zika virus country classification scheme', news 21 December 2017, ECDC (publications).

[32] 'International agreements' *(European Medicines Agency)* <https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements> (accessed: 10.02.2020).

[33] Ibid, see eg, Confidentiality arrangement Letter from EMEA TGA of the Australian Government Department of Health (1/1/2012), reference EMEA/490079/2009; Letter on the working arrangement to exchange non-public information on medical products between the European Commission's DG Sante, EMA and WHO, ref. EMA 512920/2015, based on Reg. 726/2004/EC establishing a European Medicines Agency OJ L 136/1 30 April 2004.

[34] These MRAs are trade agreements and allow EU authorities and their counterparts to: rely on each other GMP inspection system; share information on inspection and quality defects, eg, Council Decision (2012/837/EU) of 18 July 2011. Agreement between the EU and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and marketing between the European Community and Australia, OJ L 359/2 29 Dec 2012; Decision 1/2017 of the joint committee established under Article 14 of the Agreement on mutual recognition between the European Community and the United States of America, 1 March 2017 amending the sectoral annex for pharmaceutical GMPs (C(2017)1323 final Annex.

[35] Programme to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers, 20 February 2012 EMA/INS/GMP/129953/2012, 2.

[36] As explained by J Scott, 'The New EU "Extraterritoriality"' (2014) 51 CMLR 1343–80.

introduced for GCP compliance in the context of marketing approval (Union controls)[37]. EMA inspections in third countries concern various aspects of CTs (infrastructure of CTs, measures implemented to protect volunteers' interest and safety, adequacy of the sponsor system and the verification of compliance with the principles of GCP, as well as local regulations). These inspections, therefore, ensure the 'ethical equivalence of CTs in third countries'. A similar approach concerns the manufacturing of medicinal products in third countries, supervised by Union inspections[38]. In the end, these Union inspections directly or indirectly influence the domestic regulatory framework on research and development and manufacturing of medicinal products in developing countries incorporating European 'ethical equivalence' standards and confirming the global reach of EU law.

3.3. Health migration and development initiatives

According to recent ILO estimates, there are more than 150 million migrant workers on a global level[39]. In the area of health, WHO found that 6 percent of physicians and 5 percent of nurses were living outside their country of birth (mid 1970s)[40], and most of them are working in sub-regions such as North America, Western Europe and Australia[41]. These and other studies show a significant outflow of highly-skilled professionals ('brain drain') to – among others – EU member states. Equally, data shows that the workforce mobility of health professionals is unequally distributed among Member States[42]. It is expected that shortages of health professionals in the EU will further increase due to the ageing of the EU health workforce[43], thus increasing the loss of human capital from developing countries, most likely the 'best and brightest'. Being confronted with shortages of health professionals and the high outflow of health professionals from low-income countries, the EU plays a role in

[37] Arts. 78, 79 CT Regulation 536/2014 OJ L 158, 27.5.2014 verifying the equivalence of rules underlying the Regulation as regards the rights and safety of the subject and the reliability and robustness of the data generated in the CT, Art 25(5).

[38] Art. 16. In case a holder of a marketing authorisation fails to comply with good manufacturing practice as set out in Union law, the competent authority can suspend the authorisation from a third country, Art 25 Commission Delegated Regulation 2017/1569/EU supplementing Regulation 538/2014 OJ L 238, 16.9.2017.

[39] ILO global estimates on migrant workers. Results and methodology, Special focus on migrant domestic workers, International Labour Geneva Office 2015.

[40] A Meija and H Pizurki and E Royston, *Physician and nurse migration: analysis and policy implications* (World Health Organization 1979).

[41] International Organization for Migration (IOM), 'Mobility of Health Professionals to, from and within the European Union' (2014) 48 IOM Migration Research Series 36.

[42] Most of the 'external' and 'internal' migrants (physicians and nurses) migrate to the United Kingdom. Sending countries are both former colonies and former Eastern European and Mediterranean countries: J Buchan and others (eds), *Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses, European Observatory on Health Systems* (2014) 71.

[43] In 2012, the European Commission estimated a potential shortfall of around 1 mln. Healthcare workers by 2020, in Commission staff working document on an Action Plan for the EU Health Workforce, Strasbourg 18.4.2012 SWD (2012)93 final, 5.

the process of global migration. But what exactly is the EU's role in health migration?

In 2005, a European Commission Communication recognised that the global health workforce crisis required a comprehensive and coherent EU approach[44]. As a result, the 'programme for action to tackle the critical shortage of health workers in developing countries' defines actions at country, regional and global levels, supported by the EU[45]. At *national level*, the EU agreed with a number of countries to strengthen national health workforce capacity (eg, providing technical assistance on planning and recruitment to overcome critical shortages, expanding 'north-south' training capacity for individual health professionals, improving their qualifications, stimulating institutional collaboration by linking health professional associations and health agencies addressing the quality of health care services, etc.)[46]. The EU also (financially) supports WHO training programmes responding to the fight against communicable diseases (TB, AIDS, etc.) and to building an effective health care system to respond to national health priorities[47].

EU actions at *regional level* emphasise technical and political dialogue on human resources in health at regional platforms (Africa, Asia, etc)[48]. More concretely, regional observatories were also launched, collecting and analysing data on human resource capacity, training skills, best practice, etc, whereas in the African region such actions are combined with economic partnership agreements, addressing migration issues, such as limiting the 'brain drain' from south to north and 'skill-sharing'[49].

At *global level,* the EU has recognised the need for *internal* EU action, reducing health migration to EU Member States. Here, the underlying idea is that concerted action on planning, training and recruitment of the health workforce and promoting EU 'brain circulation' will reduce internal shortages of health personnel, thus reducing the outflow from third countries. At the same time, the EU has accepted the principles of the ethical recruitment of the health workforce from third countries in the labour migration Directive: the so-called "Blue Card Directive"[50]. Without doubt, the Blue Card Directive

[44] 'EU Strategy for Action on the Crisis in Human Resources for Health in Developing Countries' COM (2005) 642 final, 8.

[45] Communication from the European Commission to the European Parliament and the Council, European Programme for Action to tackle the critical shortage of health workers in developing countries (2007–2013), COM(2006) 870 final, Brussels, 21.12.2006.

[46] Ibid 3–4.

[47] Ibid 5.

[48] Ibid 6.

[49] Ibid 7.

[50] WHO code of conduct minimising the negative effects on health workforce capacity in third countries, partially incorporated in the "Blue Card Directive", Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment OJ L 155/17 Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment OJ L 155/17.

shows some overlap with the EU health migration policy (eg, preventing a brain drain and promoting 'circular and temporal migration')[51]. However, the Directive is first of all aimed at boosting economic growth *in Europe* by attracting highly-qualified workers from all around the world, whereas the health migration policy focuses on preventing detrimental effects of the health workforce migration on third countries. In 2014, a Commission report confirmed the risk of brain drain, reviewing the initial effects of the Directive: it was relatively successful in admitting highly-qualified (health) professionals and no ethical recruitment clauses were activated or reported by the Member States[52]. More recent evidence on the application and effects of the ethical recruitment principles is limited, and therefore the effectiveness of EU global immigration policy actions on limiting the outflow of highly qualified health professionals from third countries remains largely unknown[53].

Reducing the outflow of health professionals from third countries is closely related to the need for sustainable health care systems in developing countries. Investing in universal health coverage for all citizens, will contribute to improve the health of the population, strengthen human and financial resources in health care, and may bring economic progress in developing countries. EU development cooperation and humanitarian aid policy is therefore a key pillar supporting third countries to achieve the health-related Sustainable Development Goals (SDGs 2015). According to Article 208(1) TFEU, the main objective of EU development cooperation (EUDC) is 'the reduction of poverty in the world'[54]. In addition, it will contribute towards the development and consolidation of democracy and the rule of law, including respect for fundamental rights[55]. Since the EU Global health communication (2010), health-related development cooperation initiatives have shifted towards universal coverage by investing in more efficient and accessible health systems in low-income countries, subsidizing global health initiatives (fighting HIV/AIDS, malaria and tuberculosis, and supporting the global alliance for

[51] Arts. 3(3) and 8(4) of the Directive provide a clause specifically requiring ethical recruitment in sectors experiencing a lack of personnel.

[52] Commission Communication on the implementation of Directive 2009/50/EC on the conditions of entry and residence of third-country nations for the purpose of highly qualified employment, Brussel 22.5.2014 COM(2014) 287 final, 5. Although it concerns preliminary results since the Directive was not timely implemented in more than 20 MS (mid June 2011).

[53] The 2015 stakeholder report shows that several countries have implemented the principles of ethical recruitment but the risk of brain drain of health professionals remains present: 'HealthWorkers4All. Practices of WHO Code of Conduct implementation in Europe: the role of non-governmental actors', 2015; see also, Report of the second meeting of the expert advisory group on reviewing the Relevance and Effectiveness of the WHO Global Code of Practice on the International Recruitment of Health Personnel, 27-28 April 2015, Geneva, Switzerland, p. 4; Disappointing results were presented by A. Siyam and others, 'Monitoring the implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel' 2013 (91) Bull World Health Organ 816–23.

[54] Development cooperation (Arts. 208-211), closely intertwined with Economic, financial and technical cooperation with third countries (Arts 212–213), and Humanitarian aid based on Article 214

[55] H. de Waele, *Legal Dynamics of EU External Relations. Dissecting a Layered Global Player* (Springer 2017) 132.

vaccines and immunisation), and promoting and protecting human rights and gender equality in health care[56]. Examples of such actions with varying degrees of success have been reported by the Commission's website, supporting both health system development, as well as public health actions tackling infectious diseases outbreaks (eg, Ebola) in West Africa[57]. These, and other EUDC actions may show some overlap with CCP trade measures, but more often trade liberalisation agreements contradict the idea of poverty reduction[58], and development actions' underlying values, including promoting equal access and solidarity in health care. These so-called coherency problems or conflicts can arise from conflicting expectations, decision-making procedures and divergent policy objectives[59]. To overcome these conflicts, several mechanisms have been suggested and applied such as setting priorities, better coordination with member states' own bilateral support actions, and common strategies to remove contradictions between different areas of external policies and increase the impact (more synergy) and reduce fragmentation[60].

3.4. Global health security: the emerging health/security nexus

Since the International Health Regulations (IHR 2005) came into force, several public health crises have occurred, testing its relevance and effectiveness in responding to health threats around the globe (the influenza pandemic, SARS, Ebola and Zika)[61]. Despite its shortcomings[62], the IHR is generally considered to be a unique tool for controlling border-crossing health threats[63]. But since the 2001 anthrax attacks, biotoxins causing biohazards, chemical and environmental threats and, more recently, the proliferation of antimicrobial resistance (AMR) and vaccine shortages may also constitute a public health emergency of international concern. These developments seem

[56] EU Role in Global Health Commission staff working document SEC(2010)382 final, 31 January 2010.

[57] 'International Cooperation and Development' (European Commission website) <https://ec.europa.eu/info/departments/international-cooperation-and-development_en> (accessed: 10.02.2020).

[58] Despite Article 21 TEU, De Waele, at 140.

[59] Th. Bodenstein and Jörg Faust and Mark Furness, 'European Union Development Policy: Collective Action in Times of Global Transformation and Domestic Crisis' (2017) 4 Development Policy Review 444, 451.

[60] Ibid 445.

[61] Some authors argue that substandard and falsified medicines can also be considered as a threat to global health security, justifying 'mechanisms of action that span national boundaries', see: L Gostin and others, *Substandard and falsified drugs: a threat to human and global security* (Lancet 2015) 385.

[62] Notably implementation gaps at national level as it remains difficult to implement in federated countries, see K Wilson and C McDougall and R Upshur, 'The new International Health Regulations and the federalism dilemma' (2006) PLoS Medicine 3: e1. But shortcomings cover more than only implementation issues. It provides opportunities for the politicization of epidemic responses (J E Suk, 'Sound science and the new International Health Regulations' (2007) Global Health Governance 1: 1–4); moreover, the failure to specify how national governments are actually supposed to collaborate with one another (D Bhattacharya, 'An exploration of conceptual and temporal fallacies in international health law and promotion of global public health preparedness' (2007) 35 Journal of Law, Medicine and Ethics 588–98), derived from S J Hoffman, 'The evolution, etiology and eventualities of the global health security regime' (2010) 25 Health Policy and Planning 514.

[63] Confirmed by the GHS Conference Lyon 2016.

to widen the scope of IHR, focusing on transnational communicable diseases only. Initiated by the United States, and driven by the threat of bioterrorism, a newly conceived 'global health security' emerged. At European level, the EU responded with a framework of health security to threats to health across borders and across Europe. But what is this global health security about? And is that the role of the EU?

The concept of global health security remains a highly contested concept, as it combines different approaches to health and security with different perceptions, priorities and agendas[64]. The narrow approach emphasises the population health dimension of infectious diseases (WHO)[65]. Others have questioned the collective health focus of global health security since the Ebola outbreak highlighted the individual health security aspect: '<…> substandard infection control and inadequate access to effective health products and services has demonstrated a wider notion of health security – the intertwining of collective and individual health security'[66]. As security comes from access to safe and effective health care services, this would call for a re-adjustment of priorities in global health security activities.

But even before the Ebola pandemic, policymakers argued about the importance of the direct connection between health issues and security concerns and preparing for and responding to bioterrorist threats (Global Health Security Initiative GHSI, 2002)[67]. This initiative is an international collaboration between various countries 'to strengthen health preparedness and respond globally to threats of biological, chemical, radio-nuclear terrorism and pandemic influenza'. The EU is one of the partners, whereas the WHO is the expert advisor to the GHSI. Subsequently, global health security 'incorporates a diverse range of policy concerns under that heading – ranging from bioterrorism through to infectious diseases with pandemic potential'[68].

At EU level, the Health Security Committee (HSC) follows the same approach as the GHI at global level, functioning as an informal advisory group on health security issues at European level[69]. The HSC plays a crucial

[64] W Aldis, 'Health security as a Public Health Concept: A critical analysis' (2008) 23 Health Policy and Planning 370.

[65] WHO narrow concept: global health security is defined narrowly as the collection of preventative and response activities that minimize the vulnerability of populations to communicable disease transmission across geographical, national or regional boundaries. WHO, World Health Report 2007: A Safer Future: Global Public Health Security in the 21st Century. Geneva: World Health Organization, p. ix.

[66] Eg, D L Heymann, 'The true scope of health security, global security' in *Global health security: The wider lessons from the West African Ebola virus disease epidemic* (The Lancet 2015) 385.

[67] GHSI Ministerial Statement Mexico City, December 2002. Since then, various statements have extended emerging health security 'events'.

[68] S Elbe, *Security and Global Health. Towards the Medicalization of Insecurity* (Polity Press 2010) 5.

[69] Established on the basis of Presidency Conclusions of 15 November 2001 on bioterrorism. The HSC is one of the mechanisms within the EU health security framework. Essentially, the key objectives of EU global health security are: managing and controlling health threats on a global level (preventing avoidable outbreaks irrespective the nature of that threat); to detect threats early (preparedness), and to respond rapidly and

role in the co-ordination of recent health crises and was given formal status by Decision 1082/2013/EU, avoiding duplications with other Union entities responsible for risk management[70]. Decision 1082/2013/EU also extended the network of surveillance and control of communicable diseases with other related threats (biological or chemical agents or environmental events (volcanic ash clouds), endangering the health of citizens in the entire Union). With the 'all-hazards approach', the EU has incorporated a broad notion of global health security[71]. The international dimension of Decision 1082/2013 has been reflected in the co-operation and exchange of information option with third countries and international organisations such as the WHO (preamble 26)[72]. More specifically, co-operation and exchange of information may include participation in relevant epidemiological surveillance networks and alert systems on serious cross-border health threats ('Early Warning and Response System', EWRS), and the exchange of good practice in the areas of preparedness and response planning, as well as the exchange of information on measures taken pursuant to this Decision. Facilitating such international co-operation initiatives, the Decision shows the EU's preparedness to contribute to global health security.

This supportive role of the EU in global health security issues has been confirmed by the mandate of the European Centre of Disease Control (ECDC) under Regulation 851/2004. Article 9(2) includes: '<…> *to provide scientific and technical assistance in any field within its mission*' upon request of '<…> third countries and international organisations (WHO)'[73]. The most concrete examples of such assistance were the mobilisation and co-ordination of EU experts fighting the Ebola outbreak in Guinea (2015)[74], as well as monitoring the course of Zika outbreaks in the Pacific region, providing updates on cases of Zika outbreaks, including an assessment of the risk of importation of the disease into EU territory, etc.[75].

The Regulation finally calls upon the European Centre for Disease Control (ECDC) to develop 'close co-operation with the competent bodies of third countries, the WHO and other international organisations' (Article 11(2)), to collect data and to 'be open to the participation of countries

effectively, Commission Staff working document. Health security in the European Union and Internationally, Brussels 23.11.2009, SEC(2009) 1622 final 3.

[70] Decision 1082/2013/EU of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293/1, 5.11.2013, preamble 4 and Art 17.

[71] Art 2(1) Decision 1082/2013.

[72] Art 168 (3) of the TFEU confirms cooperation in the sphere of public health.

[73] Regulation 851/2004 of 21 April 2004 establishing a European centre for disease prevention and control, OJ L 142/1, 30.4.2004.

[74] ECDC 'reinforcing the fight against Ebola in Guinea, ECDC in the field, 15 January 2015, calling for epidemiologists willing to work in Guinea; ECDC international relations policy 2020, Stockholm 2018.

[75] ECDC, communicable disease threats report, weekly bulletin on active public health threats, search for publications, CDTR.

which have concluded agreements with the Community by virtue of which *they have adopted and apply legislation of equivalent effect* to Community legislation' in the field of public communicable diseases (Article 30(1)). So, apart from promoting good practice on early warning systems (i.e. technical assistance), ECDC will share data with other countries when complying with the EU communicable diseases acquis! This is a clear example of exporting EU public health standards in order to fight infectious diseases and global health threats.

4. Discussion: Structuring EU policies from a global health perspective

Given the variety of EU policies affecting (elements of) global health, one of the main questions is whether there is an overall direction of EU global health policy and law[76]? Starting with the Commission's Communication (2010), it appeared that the various pillars (trade, health, mobility, security) have different legal starting points, rationales and objectives, and directly or indirectly affecting global health. Despite the promoted 'all-inclusive approach', EU action seems more fragmented then reflecting a well-considered global health strategy. As a result, coherency problems emerge between trade liberalization and development aid/cooperation initiatives (patent protection rules and the seizure of generic medicines in transit or triggering health flexibilities in case of 'public health emergencies'); outsourcing clinical trials to low-income countries and reducing health risks; and, facilitating third country-labour migration vs. humanitarian aid policies fighting the 'brain drain'. Moreover, diversity in national strategies on global health further complicate a European approach. Steurs and others therefore conclude that the existence of a common 'European' vision on global health is questionable[77].

To tackle these major challenges requires a more systematic approach. Although the Commission's Communication 2010 is an important step – to identify relevant policies addressing global health, clarify and examine common goals and perspectives, as well as potential impact on global health- it is not sufficient. Taking the EU's role as a global health actor seriously requires a shared policy on global health based on shared values and 'beyond the national level and require strong global institutions and co-ordinated efforts'[78].

Such a shared and coherent policy should be aimed at the protection and promotion of a population's health and prevention of global health concerns (obesity, cardiac diseases, malnutrition, etc.), i. e., based or subject of global

[76] Steurs and others (n 9).
[77] Ibid 440.
[78] Communication (n 1) 2.

health law. This would urge the EU to take the lead in defining a legally binding international document: a Framework Convention on Global Health (FCGH). The idea of such a framework Convention has been advocated by leading scholars such as Gostin and others[79].

Fostering cooperation with the WHO (Article 168(3)) such a Framework Convention would enable to conceptualise EU's global health law founded on human rights in health care (the right to health; universal health coverage; non-discrimination and equal justice in quality health care) responding to trade, patents, migration and health (security) threats (Communication 2010).

Conceptually, the Framework Convention would formulate clear obligations on establishing an equitable financing system for the entire population, covering essential health services and public health facilities and medicines, based on transparency rules in budgeting, allocating and providing health services, as well as effectuating accountability mechanisms in health care (monitoring, reporting, evaluation of action towards compliance, and effective remedies in case of non-compliance)[80].

More than the Commission's Communication, such a legally binding document formulates a common ground of underlying values and principles, building on international human rights law State obligations (to respect, protect and fulfil) regarding the right and other rights, promoting positive health determinants (education and housing) and effectuating policy coherence through health impact assessments, and ensuring compliance with the Framework Convention. As such, the Convention would contribute to more coherent understanding and a straightforward conceptualisation of Europe's role in global health. At the same time, the EU could place itself in the centre of global health by leading the coalition with WHO, using its expertise of European health agencies in the field of public health, medicines, and epidemiology.

Using its treaty-making authority, the Global Health Framework Convention could be based on Article 168(3) TFEU, fostering the cooperation with WHO and confirming the successful cooperation in the field of public health. Similar as under other WHO treaties (e.g., the Framework Convention on Tobacco Control, FCTC), the so-called "regional economic organization" (REIO) clause used in international conventions, will make the EU a contract party as any other country and therefore bound to fully implement the new

[79] L Gostin and others, 'Towards a Framework Convention on Global Health' (2013) 10 Bull. World Health Organ 790–3; G Ooms and others, 'Great expectations for the World Health Organization: a Framework Convention on Global Health to achieve universal health coverage' (2014) 2 Public Health 173–8.

[80] K Buse and L Gostin and E Friedman, 'Pathways towards a Framework Convention on Global Health' in *Political Mobilization for the Human Right to Health, in Law and Global Health* (Freeman M and Hawkes S and Bennett B eds, OUP 2014) 43–6.

Framework Convention[81]. In addition, the development cooperation frame (Article 208 TFEU) confirms the need for a coherence drive of external action and legitimizes an all-inclusive approach towards poverty reduction, eliminating global health inequities.

5. Conclusions: from a fragmented to structured approach?

Examining the EU's role in the global health debate, has revealed a 'hodgepodge' of legal issues, rather than a distinct body of rules reflecting a coherent framework of EU law. As a result, its role in the global health is largely influenced by other policy areas than health. What is missing is a common global health policy. Communication 2010 provided key elements of what reflects a fragmented, highly compartmentalised approach. Balancing international trade and other economic interests with global health issues requires a shared vision and strategy what is global health. Here, it is argued that the EU should take the lead in drafting such a common policy based on previous experiences in close collaboration with the key global health actor: the WHO. Formulating and implementing a global health treaty at Member State level, a Framework Convention on Global Health could respond to trade, in a more systematic and coherent manner, reflecting international health law principles and specifying State obligations.

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Андре ден Екстер

ПРАВО ЄВРОПЕЙСЬКОГО СОЮЗУ ПРО ГЛОБАЛЬНУ ОХОРОНУ ЗДОРОВ'Я

Анотація. Європейський Союз (ЄС) відіграє важливу роль у питаннях охорони здоров'я на світовому рівні. У статті роз'яснюється концепція ЄС з охорони здоров'я на світовому рівні, розглядаються певні галузі, в яких ЄС діє і може прямо або опосередковано впливати на питання охорони здоров'я у світовому масштабі (наприклад, торгівля, охорона здоров'я населення, міграція у галузі охорони здоров'я, допомога в цілях розвитку та безпека охорони здоров'я). Зроблено спробу більш систематично пов'язати ці напрями на підставі Конвенції про глобальну охорону здоров'я, яка базується на принципах прав людини. Таке спільне бачення законодавства в галузі охорони здоров'я на світовому рівні може допомогти ЄС і державам-членам більш ефективно реагувати на глобальні виклики щодо охорони здоров'я населення світу, такі як міжнародна торгівля, безпека охорони здоров'я населення та загрози для здоров'я населення.

Відповідно до Висновків Ради ЄС 2010 р. основна увага приділяється чотирьом основним галузям законодавства ЄС, які пояснюються більш детально. Різноманітні міри та заходи охоплюють: зовнішню торгівлю й охорону здоров'я у світовому масштабі; законодавство ЄС у галузі охорони здоров'я і зовнішні відносини; ініціативи в галузі міграції та розвитку галузі охорони здоров'я; безпеку охорони здоров'я населення світу: утворюваний зв'язок між здоров'ям і безпекою.

За результатами вивчення ролі ЄС у світовій полеміці з питань охорони здоров'я автор доходить висновку, що законодавство ЄС можна охарактеризувати радше як "вінегрет" із правових питань, аніж чіткий звід правил, що відображають узгоджену структуру. Як наслідок, його роль щодо охорони здоров'я на світовому рівні значною мірою перебуває під впливом інших, ніж охорона здоров'я, галузей політики. Загальна політика щодо охорони здоров'я на світовому рівні відсутня. В офіційному повідомленні Комісії за 2010 р. представлені ключові елементи того, що відображає фрагментований і надзвичайно роздрібнений підхід. Для забезпечення збалансованості міжнародної торгівлі та інших економічних інтересів із питаннями охорони здоров'я населення на світовому рівні потрібне загальне бачення і стратегія стосовно самого поняття здоров'я населення світу. Автор вважає, що ЄС має взяти на себе провідну роль у розробленні такої загальної політики на основі попереднього досвіду та в тісній співпраці з ключовим суб'єктом охорони здоров'я населення світу – Всесвітньою організацією охорони здоров'я. Формулюючи і реалізуючи глобальну стратегію охорони здоров'я на рівні держав – членів ЄС, Рамкова конвенція про глобальну охорону здоров'я може забезпечити більш систематичне й узгоджене реагування на пов'язані з торгівлею питання, відображаючи принципи міжнародного права у галузі охорони здоров'я та конкретизуючи зобов'язання держав.

Ключові слова: право Європейського Союзу про глобальну охорону здоров'я; міжнародна торгівля; безпека охорони здоров'я населення та загрози для здоров'я населення; міграція медичних працівників, Конвенція про глобальну охорону здоров'я.