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Geneva Jean Monnet Working Papers 01/2022

CENTRE D'ÉTUDES JURIDIQUES EUROPÉENNES
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Elisabet Ruiz Cairó

(University of Geneva)

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UNIVERSITÉ DE GENÈVE

With the support of the Erasmus+ Programme of the European Union

ISSN 2297-637X (online)

Université de Genève – Centre d'études juridiques européennes
CH-1211 Genève 4

The Geneva Jean Monnet Working Papers Series is available at:
www.ceje.ch

Publications in the Series should be cited as:
AUTHOR, TITLE, Geneva Jean Monnet Working Paper No ./YEAR [URL]

Elisabet RUIZ CAIRÓ, The EU and the Global Fight Against Cross-border Health Threats: From the International Health Regulations to an International Pandemic Treaty, Geneva Jean Monnet Working Paper No 01/2022, pp. 1-29

The EU and the Global Fight Against Cross-border Health Threats: From the International Health Regulations to an International Pandemic Treaty Goods

by

Elisabet Ruiz Cairó*

Abstract

The opening of the negotiations on an International Pandemic Treaty under the auspices of the World Health Organization opens an opportunity for the European Union to play a more significant role in the global fight against cross-border health threats. The Union's ability to seize that opportunity will largely depend upon the legal instrument that will be negotiated and the material scope of the agreement. The Union should argue in favour of negotiating a convention under Article 19 of the WHO Constitution and incorporating preparedness and response measures that go beyond public health to cover trade, human rights, environmental concerns or economic matters.

Keywords: European Union; World Health Organization; global health; cross-border health threats; multilateral agreement; mixed agreement

* Elisabet Ruiz Cairó, PhD, Researcher and Programme Coordinator, University of Geneva (Elisabet.RuizCairo@unige.ch).

This paper has been presented in November 2021 in Geneva within the activities of the EUDIPLO Jean Monnet Network.

The EU and the Global Fight Against Cross-border Health Threats: From the International Health Regulations to an International Pandemic Treaty

Global health law is at a turning point. Up to this date, it was characterized by a limited attention from States and international organisations, as well as by weak legal instruments. The COVID-19 pandemic has completely changed this landscape. For the past couple of years, the world's attention has turned towards public health. Much of that attention has focused on the weaknesses of the current legal framework to address cross-border health threats.[1] These are threats of biological, chemical, environmental or unknown origin that spread from one person to the other, including communicable diseases, antimicrobial resistance, healthcare-associated infections, and biotoxins or other harmful biological agents not related to communicable diseases.[2]

At the global level, cross-border health threats are currently governed by the International Health Regulations (IHR) of 2005.[3] This international agreement was adopted in the aftermath of the Severe Acute Respiratory Syndrome (SARS) outbreak and significantly contributed to improve the global response to cross-border health threats. However, its weaknesses have become increasingly apparent over the years and COVID-19 has reinforced previous criticisms. Many gaps have been noted in the prevention of and the response to this pandemic. States, civil society and academia have raised their voices and requested a strengthening of this system.

The European Union has been a strong advocate for reform and it has been at the origin of the idea of negotiating a global pandemic treaty. In November 2020, the President of

[1] Public health emergencies and cross-border health threats are often used interchangeably by international organisations and the doctrine. The International Health Regulations refer to public health emergencies (see, among others, Article 12 IHR), whereas the European Union rather refers to cross-border health threats (see Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2014 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293 of 5 November 2013, p. 1). The term 'pandemic' is also used in the media, although in scientific terms this notion is not equivalent; the International Pandemic Treaty should define the threshold under which a cross-border health threat becomes a pandemic.

[2] Article 2(1) Decision 1082/2013/EU.

[3] Although the International Health Regulations are named in plural, they constitute a single international agreement.

the European Council raised the need to negotiate a new international agreement on pandemic preparedness and response,[4] an idea that was subsequently promoted at the global level and sponsored by the World Health Organization (WHO).[5] This proposal was adopted by consensus at the World Health Assembly Special Session of 29-1 December 2021.[6] The World Health Assembly resolution of 1 December 2021 established an Intergovernmental Negotiating Body (INB) in view of the negotiation and adoption of an international instrument on pandemic prevention, preparedness and response. The first full draft of such instrument should be ready by August 2022 and the instrument should be submitted for consideration by the World Health Assembly in May 2024.

The negotiation of an International Pandemic Treaty raises questions regarding the negotiating procedure, the content and scope of the agreement, or its relationship with other international agreements. The ability of parties to find answers to these questions will determine their leadership during the negotiation and implementation of the treaty. As one of the sponsors of the International Pandemic Treaty, the European Union has an opportunity to play a leadership role. The Council decision on the negotiation of the International Pandemic Treaty confirms the Union's ambition to become a key player in these negotiations.[7] The goal of this paper is thus to determine the current weaknesses of the international legal framework for the response to cross-border health threats (I) and explore the opportunities that an International Pandemic Treaty offers (II). Although weaknesses and opportunities at the global level will be briefly addressed, the paper essentially focuses on the role of the European Union at the global level. It is argued that the choice of legal instrument and the material scope of the International Pandemic Treaty will determine the status of the European Union under this agreement.

There are strong expectations on the potential of an International Pandemic Treaty to strengthen the global response to cross-border health threats. Such expectations are even greater for the European Union, an actor that has, so far, played an accessory role in this area and that could become much more active in the future. More significantly, a strengthened role of the EU in the global fight against cross-border health threats could lead to a more significant role of the EU as a global health actor more generally.

[4] European Council, "Towards a world better prepared for shocks" – Speech by President Charles Michel at the Paris Peace Forum, 12 November 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/11/12/intervention-du-president-charles-michel-au-forum-de-paris-sur-la-paix/ (last accessed 11 October 2021).
[5] European Council, Press release by President Charles Michel on an international Treaty on Pandemics, 3 December 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/12/03/press-release-by-president-charles-michel-on-an-international-treaty-on-pandemics/ (last accessed 11 October 2021); World Health Organization. Global leaders unite in urgent call for international pandemic treaty, 30 March 2021, available at https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty (last accessed 7 September 2021).
[6] World Health Organization, The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response, 1 December 2021, SSA2/SR/5. The World Health Assembly is the decision-making body of the World Health Organization; it is attended by delegates from all WHO Member States and regular sessions take place on a yearly basis.
[7] Council Decision 2021/1101 on the position to be taken on behalf of the Union in the special session of the World Health Assembly, OJ L 238 of 6 July 2021, p. 79.

I. State of the art: current gaps in the global response to cross-border health threats and the role of the European Union

The current framework to respond to cross-border health threats revolves around the IHR of 2005.[8] This international agreement presents several gaps that became obvious in the aftermath of the COVID-19 outbreak (A). The European Union holds an observer status at the WHO and has not ratified the IHR. Both elements limit its role at the global level (B). The legal framework for the global response to cross-border health threats is thus unsatisfactory, leading to growing calls for reform both at the EU and at the global levels.

A. Weaknesses of the International Health Regulations

The IHR are the modified version of the International Sanitary Conventions of 1892, 1897 and 1903 and of the International Sanitary Regulations of 1951.[9] The first IHR were adopted in 1969, but the current version dates from 2005 and entered into force on 15 June 2007. The IHR are a binding international legal instrument. Together with the Framework Convention on Tobacco Control,[10] these are the only two international agreements adopted by the WHO so far.[11]

The purpose of the IHR is 'to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade'.[12] Previous versions of the IHR limited the scope of application to an exhaustive list of diseases. In the most recent version of the regulations prior to the adoption of the IHR of 2005, the list included cholera, plague and yellow fever. However, with the emergence of HIV/AIDS and the advent of SARS, it became obvious that a revision of the scope of application was needed. An 'all-hazards' strategy was embraced by the revised version of the IHR.[13] The IHR of 2005 do not limit the scope of application to specific diseases or forms of transmission, but instead cover 'illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans'.[14] This

[8] International Health Regulations, Geneva, 23 May 2005, 2509 UNTS 79.
[9] Gian Luca BURCI, 'The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations' (2020) 11 *Journal of International Humanitarian Legal Studies* 204, p. 206.
[10] WHO Framework Convention on Tobacco Control, Geneva, 16 June 2003, 2302 UNTS 166; Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213 of 15 June 2004, p. 8 (Decision 2004/513).
[11] Apart from the Nomenclature Regulations; see Gian Luca BURCI and Claude-Henri VIGNES, *The World Health Organization* (The Hague/London/New York, Kluwer Law International, 2004), pp. 132-134.
[12] Article 2 IHR.
[13] Lawrence O. GOSTIN and Rebecca KATZ, 'The International Health Regulations: The Governing Framework for Global Health Security' (2016) 94(2) *The Milbank Quarterly* 264, pp. 266-267.
[14] Article 1(1) IHR.

formulation aimed at allowing the text to be relevant in the long term despite the continued evolution of diseases.[15]

One of the most important elements established in the IHR is the determination of public health emergencies of international concern (PHEIC). These are extraordinary events constituting public health risks to other States and requiring a coordinated international response.[16] Since 2007, the WHO Director-General has declared six public health emergencies of international concern: during the 2009 H1N1 influenza pandemic; for polio in 2014; for Ebola in 2014 and in 2019; in the case of the Zika virus in 2016; and during the COVID-19 outbreak in 2020. However, in all those cases the WHO was criticised either for over-reacting or for under-reacting.[17] For example, the declaration of COVID-19 as a PHEIC has been considered too slow. The WHO declared a public health emergency on 30 January 2020 despite numerous warnings from experts for several weeks.[18] It can be questioned whether the procedure to declare a PHEIC is properly addressed in the IHR. When a PHEIC is declared, the WHO issues temporary recommendations,[19] but many States refuse or fail to follow such recommendations. This weakness was made apparent during the COVID-19 pandemic, where States did not follow WHO's recommendations on border closures, travel restrictions or trade limitations.[20] It is interesting to note that the IHR provide for rules to address public health emergencies of international concerns but do not mention pandemics. Pandemics are thus not defined under the IHR although the WHO qualified COVID-19 as a pandemic in March 2020.[21]

The IHR also provide preventive measures to be adopted by all parties. These include the obligation for States to develop the capacity to respond to emergencies within five years since the entry into force of the IHR,[22] hygiene measures at the borders,[23] and public health measures for travellers.[24] However, compliance with these measures is low. Most States have not developed strong health capacities.[25] Despite collaboration duties being present

[15] Foreword IHR, p. 2.
[16] Articles 1(1) and 12 IHR.
[17] Lawrence O. GOSTIN, Mary C. DE BARTOLO and Eric A. FRIEDMANN, 'The International Health Regulations 10 Years On: The Governing Framework for Global Health Security' (2015) 386 *The Lancet* 2222, p. 2222; Belinda Benett and Terry Carney, 'Public Health Emergencies of International Concern: Global, Regional and Local Responses to Risk' (2017) 25(2) *Medical Law Review* 223, p. 229.
[18] David N. DURRHEIM, Laurence O. GOSTIN, Keymanthri MOODLEY, 'When Does a Major Outbreak Become a Public Health Emergency of International Concern?' (2020) 20(8) *The Lancet Infectious Diseases* 887; Gian Luca Burci, 'The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations' (2020) 11 *Journal of International Humanitarian Legal Studies* 204, p. 211.
[19] Articles 15 and 18 IHR. Recommendations are health measures regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of diseases while avoiding unnecessary interference with international traffic. These include medical examinations, vaccination requirements, quarantines, tracing of contacts, entry restrictions, inspections, etc.
[20] Gian Luca BURCI, 'The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations' (2020) 11 *Journal of International Humanitarian Legal Studies* 204, p. 213; Lawrence O. GOSTIN, Benjamin MASON MEIER and Barbara STOCKING, 'Developing an Innovative Pandemic Treaty to Advance Global Health Security' (2021) 49 *The Journal of Law, Medicine and Ethics* 503, p. 504.
[21] Jamie DUCHARME, World Health Organization declares COVID-19 a 'Pandemic'. Here's what that means, *Time*, 11 March 2020, available at https://time.com/5791661/who-coronavirus-pandemic-declaration/ (last accessed 11 October 2021).
[22] Article 13 IHR.
[23] Articles 19-22 IHR.
[24] Articles 23 and 30-32 IHR.
[25] Giulio BARTOLINI, 'The Failure of 'Core Capcities' under the WHO International Health Regulations' (2021) 70(1) *International and Comparative Law Quarterly* 233.

in the IHR, the lack of global cooperation during the COVID-19 among parties has revealed some significant weaknesses in this area. [26]

The impact of the lack of compliance with IHR provisions is amplified by the ineffective dispute settlement mechanism.[27] Such mechanism is based on mediation or conciliation, the referral of the dispute to the Director General, who should try to settle the dispute, and, ultimately, arbitration if the parties have accepted it. Up do this date, no party has accepted arbitration under the IHR system.[28]

The IHR are based on the assumption that States will act transparently, diligently, cooperatively and in good faith, and that the WHO will base its functions exclusively on public health considerations and science-based risk assessment.[29] However, COVID-19 has highlighted how politicised the IHR are. Whether we take the deferential attitude of the WHO Secretariat towards China when investigating the origins of the pandemic, or the United States decision to freeze WHO's funding in 2020, there are many indications of politics influencing decision making in this organisation.[30]

The IHR are an important and necessary instrument in the fight against cross-border health threats. However, COVID-19 has highlighted some significant gaps weakening the application of this international agreement and has revealed the strong need for reform.

B. The unsatisfactory position of the European Union in the global fight against cross-border health threats

The European Union has a limited role in the global fight against cross-border health threats, resulting from its coordinating competence in public health (1), its position at the World Health Organization (2), and its status in the International Health Regulations (3). The role of the European Union in the global fight against cross-border health threats should however not be underestimated, as it can play a role beyond the WHO and the IHR. The current pandemic has made apparent the significance of informal economic bodies, such as the G20, or public-private partnerships, such as the COVAX initiative, to promote global health (4).

[26] Lawrence O. GOSTIN, Sam F. HALABI, Kevin A. KLOCK, 'An International Agreement on Pandemic Prevention and Preparedness' *JAMA Network*, 15 September 2021, available at https://jamanetwork.com/journals/jama/fullarticle/2784418?resultClick=1 (accessed 17 September 2021).
[27] Article 56 IHR.
[28] Steven J. HOFFMAN, 'Making the International Health Regulations Matter: Promoting Compliance through Effective Dispute Resolution' in Simon RUSHTOn and Jeremy YOUDE (eds), *Routledge Handbook of Global Health Security* (Routledge, 2014), p. 242.
[29] Gian Luca BURCI, 'The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations' (2020) 11 *Journal of International Humanitarian Legal Studies* 204, p. 207.
[30] Ibid., p. 212.

1. EU powers to fight against cross-border health threats

EU public health powers are defined under Article 168 TFEU. In accordance with this provision, Union action 'shall complement national policies'[31] and 'the Union shall encourage cooperation between the Member States'.[32] As a result, 'Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes'.[33] Article 6(a) TFEU confirms the coordinating nature of the EU public health competence. Article 168(4) TFEU provides three exceptions to this limited competence: the European Union has a shared competence to adopt measures on the quality and safety of organs and substances of human origin, blood and blood derivatives,[34] measures in the veterinary and phytosanitary fields,[35] and measures on the quality and safety of medicinal products and medical devices.[36] Measures to combat cross-border threats to health are however not included in this derogation and Article 168(5) TFEU explicitly provides that the Union may only adopt 'incentive measures' to combat serious cross-border threats to health. Such incentive measures should exclude 'any harmonisation of the laws and regulations of the Member States'.

The role of the European Union in the fight against cross-border health threats is therefore limited, as the COVID-19 pandemic has revealed. Although the European Union has been very active throughout the outbreak, its role has essentially been one of coordination. The European Centre on Disease Prevention and Control (ECDC) has shared daily risk assessments and epidemiological updates whereas the Health Security Committee has organized regular coordination meetings with Member States and the European Commission.[37]

The support competence of the Union in cross-border health threats does not fully ban any response measure in case of a public health outbreak. However, where the European Union plays a more substantial role, it does so on the basis of other legal bases. For example, the Union adopted important internal market, competition or trade measures throughout the pandemic.[38] Consequently, the Union uses all its competence catalogue to respond to cross-border health threats and adopts measures based on a variety of provisions, but the overall EU response to cross-border health threats remains weak and, most importantly, fragmented.

[31] Article 168(1), second paragraph, TFEU.
[32] Article 168(2), first paragraph, TFEU.
[33] Article 168(2), second paragraph, TFEU.
[34] Article 168(4)(a) TFEU.
[35] Article 168(4)(b) TFEU.
[36] Article 168(4)(c) TFEU.
[37] Elisabet RUIZ CAIRÓ, *The Promotion of Public Health in EU External Relations* (Geneva/Zürich, Schulthess, Studies in European Law No 35), pp. 151-154.
[38] Ibid., pp. 158-159.

2. EU status at the World Health Organization

Cooperation between the WHO and the EU dates back to 1982. Bilateral relations between the two organisations were established through an exchange of letters in which the two parties underlined the importance of effective coordination on matters of common interest and agreed on the reciprocal participation in their meetings and the exchange of information.[39] Another exchange of letters of 2000 settled the principles, objectives, areas of cooperation, priorities and procedures for the conduct of the parties' activities.[40]

The WHO Constitution restricts membership to States, so regional economic integration organisations cannot apply for membership.[41] The Union therefore holds an observer status at the WHO.[42] As an observer, its rights and duties at the World Health Assembly are governed by Rules 19 and 44 to 47 of the Rules of Procedure of the World Health Assembly.[43] Observers can attend plenary meetings of the World Health Assembly and of the Executive Board. They can sometimes make statements on the subjects under discussion. Observers have access to non-confidential documents and are allowed to submit memoranda to the Director-General.[44] The participation of the Union in those bodies has improved over time. In January 2006, the European Union wrote a letter to the Executive Board of the WHO informing about its intention to participate fully in the deliberations of the Board's 117th session. The Union also asked for an invitation to attend all meetings of the World Health Assembly in May 2006.[45]

The Memorandum attached to the 2000 exchange of letters specifies the institutional relationship between the WHO Director-General and the European Commission. The two parties consult each other on questions of mutual interest. They participate once a year in an exchange of views and review relevant activities and future plans of work. They also take measures to ensure close liaison and cooperation between officials of the two parties.[46]

[39] Exchange of letters between the European Communities and the World Health Organization (WHO) laying down the procedure for cooperation between the two organizations – Memorandum defining the arrangements for cooperation between the World Health Organization and the European Communities, OJ L 300 of 28 October 1982, p. 20.
[40] Lourdes CHAMORRO, 'Coordination Between the European Union and the Member States: An EU Perspective' *in* Christine KADDOUS (ed), *The European Union in International Organisations and Global Governance: Recent Developments* (Oxford/Portland, Hart Publishing, 2015), p. 144; Exchange of letters between the WHO and the Commission of the EC concerning the consolidation and intensification of cooperation and Memorandum concerning the framework and arrangements for cooperation between the WHO and the Commission of the EC, OJ C 1 of 4 January 2001, p. 4.
[41] Article 3 WHO Constitution.
[42] Paragraph D.1.1 Memorandum.
[43] World Health Assembly, Rules of Procedure of the World Health Assembly, available at https://www.who.int/governance/rules_of_procedure_of_the_wha_en.pdf (last accessed 15 December 2021). The WHO Constitution does not contain express rules on participants or observers.
[44] Rule 45 Rules of Procedure of the World Health Assembly; para. 1 (4) Memorandum.
[45] Barbara EGGERS and Frank HOFFMEISTER, 'UN-EU Cooperation on Public Health: The Evolving Participation of the European Community in the World Health Organization' *in* Jan WOUTERS, Frank HOFFMEISTER and Tom RUYS (eds), *The United Nations and the European Union: An Ever Stronger Partnership* (The Hague, TMC Asser Press, 2006), p. 162.
[46] Paragraph D.2 Memorandum.

The European Union can therefore be considered a 'privileged' observer at the WHO, as it has acquired some additional rights to those of traditional observers.[47] However, its influence at the WHO remains limited, as it has a restricted access to documents, it cannot always make statements, and it cannot vote.

3. EU status in the International Health Regulations

As a unique international agreement in the area of communicable diseases, the IHR were the perfect opportunity for the European Union to shape international rules in the field and to promote its own standards at the global level. Yet, the Union did not seize this opportunity. The participation of the European Union in the negotiation and conclusion of the IHR was limited by the rules applicable to that international agreement. The WHO Constitution provides that regulations adopted by the World Health Assembly shall come into force for all WHO members except for those that notify their rejection or that make reservations.[48] As a general rule, only WHO members may become contracting parties to a WHO regulation. Exceptionally, States that are not members of the WHO but that notify the acceptance of the IHR may also become contracting parties to this agreement.[49] The European Union is neither a member of the WHO nor a State, and thus could not become a contracting party to the IHR. This situation constituted a significant limit, as the scope of the IHR could overlap some areas of EU competence.[50]

While the European Union could not become a contracting party to the IHR, the memorandum attached to the exchange of letters between the EU and the WHO opens the door to the participation of the Union in the negotiation of international agreements.[51] In accordance with this possibility, the European Union was allowed to participate in the negotiation of the IHR. The Resolution of the World Health Assembly on the Revision of the International Health Regulations provided that 'regional economic integration organizations constituted by sovereign States, members of WHO, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into international legally binding regulations, may participate, in accordance with Rule 55 of the Rules of Procedure of the World Health Assembly, in the work of the intergovernmental working group referred to under paragraph (1)'. [52]

[47] Namely the full participation in the WHO Executive Board's deliberations, attendance to all WHA meetings, and the establishment of yearly exchanges of views as well as cooperation mechanisms between the European Union and the World Health Organization.
[48] Article 22 WHO Constitution, read in conjunction with Article 21.
[49] Article 64 (1) IHR.
[50] Gian Luca BURCI, 'The European Union and World Health Organization: Interactions and Collaboration from a Governance and Policy Perspective' *in* Christine KADDOUS (ed), *The European Union in International Organisations and Global Governance: Recent Developments* (Oxford/ Portland, Hart Publishing, 2015), p. 167.
[51] Para. D.1.4 Memorandum.
[52] World Health Assembly, Revision of the International Health Regulations, 28 March 2003, Resolution WHA56.28 (Resolution WHA56.28), para. 2(2).

In the EU side, the European Commission adopted a communication in September 2003 on the revision of the IHR.[53] As several areas of Union activity overlapped with the objectives of the revised IHR, the Union needed to be involved in the negotiation.[54] Some of the areas concerned with Union activity were food safety, restrictions to trade, transport or civil protection.[55] The revised IHR should also be compatible with the Early Warning Response System (EWRS) and the European Centre on Disease Prevention and Control (ECDC).[56] The European Commission concluded that the Union and the Member States should work in close cooperation and in a coordinated manner.[57] That communication provided that the European Commission and EU Member States should take part in the deliberations and play an active role in the revision process to obtain an international agreement in accordance with the Community *acquis*.[58] The European Commission should coordinate with the technical experts from Member States in the areas of EU competence.[59] It should coordinate with Member States and participate alongside with them during the regional meetings organised by the WHO to ensure a coordinated position.[60] Despite these arrangements, the role of the European Union during the negotiation phase has however been described as essentially one of facilitation and coordination between EU Member States, rather than a leadership one.[61] Moreover, only WHO members could vote on the final agreement under Articles 2 (k) and 21 of the WHO Constitution. Accordingly, the Council authorised Member States to accept the final text in the interest of the Union.[62]

While the European Union did not ratify the International Health Regulations, it has declared to fully implement this international agreement.[63] The International Health Regulations are regularly mentioned in EU legislation.[64] The ECDC has signed a memorandum of understanding and an administrative arrangement with the WHO Europe office, and the procedures to declare a public health emergency under the EU and the global systems have been made compatible to avoid the duplication of tasks. These examples reveal the autonomous application of the International Health Regulations by the European Union. It can therefore be argued that the International Health Regulations have had a greater influence

[53] European Commission, Communication from the Commission to the Council on the revision of the International Health Regulations under the framework of the World Health Organization, 19 September 2003, COM(2003) 545 final.
[54] *Ibid.*, para. 11.
[55] *Ibid.*, para. 24.
[56] *Ibid.*, paras. 25-27. The ECDC did not exist yet at the time but its establishment was provided for in Decision No 2119/98 and a regulation on its creation was proposed by the Commission precisely in 2003; see European Commission, Proposal for a Regulation of the European Parliament and of the Council establishing a European Centre on Disease Prevention and Control, 16 September 2003, COM(2003) 441 final.
[57] European Commission, COM(2003) 545 final, p. 10.
[58] *Ibid.*, p. 10, para. 1.
[59] *Ibid.*, p. 10, para. 3.
[60] *Ibid.*, p. 10, paras. 4-5.
[61] Didier HOUSSIN, 'The EU's Role in the International Health Regulations and the Pandemic Influenza Preparedness Framework Agreement' *in* Thea EMMERLING, Ilona KICKBUSCH and Michaela TOLD (eds), *The European Union as a Global Health Actor* (Singapore, World Scientific Publishing, 2016), p. 275.
[62] *Ibid.*, p. 168.
[63] European Commission, The International Health Regulations, 26 September 2006, COM(2006) 552 final.
[64] See Recital 6 Decision 1082/2013/EU; Recital 8 and Articles 2 and 11 Proposal for a Regulation on cross-border health threats, 11 November 2020, COM(2020) 727 final.

in the European Union than the influence reached by the European Union in the text of the International Health Regulations.[65]

The role of the European Union during the negotiation of the IHR was weak and the influence of the Union in the final text of the agreement has been limited. Although its participation was allowed, the EU mostly filled a coordination role among Member States. The inability of the Union to obtain a stronger position in the negotiations and to conclude the agreement have resulted in an inability to shape international rules in accordance with EU positions. Accordingly, the influence of the Union at the multilateral level is insufficient and an increased leadership should be sought. The International Pandemic Treaty provides the perfect opportunity to strengthen that position.

4. The EU and the global fight against cross-border health threats beyond the WHO

Although the role of the European Union at the WHO and the IHR is not fully satisfactory, its position in global health should not be underestimated. The role of the European Union during the COVID-19 pandemic is revealing in this regard. The Union has used informal institutions to promote its objectives in the fight against the pandemic, as illustrated by the two following examples.

The European Union has been a key actor in the promotion of the Access to COVID-19 Tools Accelerator (ACT-Accelerator) and the COVAX initiative associated to it. The ACT-Accelerator is a global collaboration of governments, scientists, business, civil society, philanthropists and global health organizations. It aims at facilitating the development, production and equitable access to COVID-19 tests, treatments and vaccines.[66] The European Commission and France participated in the launch of this mechanism, together with the World Health Organization and the Bill & Melinda Gates Foundation.[67] With $ 3.9 billion in pledges by November 2021, team Europe (the EU and its Member States) constitutes the largest donor to this instrument, followed by the United States with $ 3.5 billion.[68]

The European Union has also played a significant role to promote global heath at the G20. On 21 May 2021, the European Commission and Italy, as chair of the G20, co-hosted the Global Health Summit, which led to the Rome Declaration.[69] This declaration defines some

[65] Elisabet Ruiz Cairó, *The Promotion of Public Health in EU External Relations* (Series in European Law No 35, Schulthess, 2021), pp. 180-182.
[66] ACT-Accelerator is composed by four pillars of work: diagnostics, treatment, vaccines and health system strengthening; COVAX constitutes the vaccines pillar of this mechanism.
[67] World Health Organization, What is the ACT-Accelerator, available at https://www.who.int/initiatives/act-accelerator/about (last accessed 10 October 2021).
[68] Gavi, COVAX AMC donors table, 6 August 2021, available at https://www.gavi.org/sites/default/files/covid/covax/COVAX-AMC-Donors-Table.pdf.
[69] European Commission, Rome Declaration, available at https://global-health-summit.europa.eu/rome-declaration_en (last accessed 10 October 2021).

common principles to fight against COVID-19 and prevent future pandemics with the view of achieving the Sustainable Development Goals (SDGs).

The success of global health discussions in institutions unrelated to health reveals that the fight against pandemics goes well beyond health discussions, and that a more comprehensive approach is required. The European Union has overcome its weak position at the WHO by promoting global health through such institutions. The use of informal governance structures is an effective mechanism for the Union to promote global health. However, in parallel, it has still attempted to strengthen tools available at the WHO, as the proposal for an International Pandemic Treaty reveals.

II. The International Pandemic Treaty as an opportunity for the European Union

The negotiation of an International Pandemic Treaty constitutes an opportunity to fill in some of the gaps of the IHR evidenced during the COVID-19 crisis (A). It could also provide the Union with the perfect setting to strengthen its role in the global fight against cross-border health threats. The institutional features of the International Pandemic Treaty (B) and its material scope (C) could contribute to that result.

A. Main features of the International Pandemic Treaty under discussion

The negotiation of an International Pandemic Treaty will raise the issue of the best legal instrument to achieve the goals pursued. The WHO constitution provides for three possible instruments: recommendations, regulations, and conventions. Recommendations are the weakest instrument that can be adopted.[70] This instrument was used, for example, for the adoption of the WHO Code of Practice on the International Recruitment of Health Personnel, which is a voluntary instrument providing for ethical principles when hiring health workers from other countries.[71] Regulations can only be adopted in a limited number of areas.[72] They come into force for all WHO Member States once adopted by the World Health Assembly, except if rejected.[73] This legal instrument was the preferred one for the International Health Regulations of 2005. Lastly, the World Health Assembly can also adopt conventions.[74] Conventions can cover any matter within the competence of the WHO. They only come into force for parties that accept them, whether they are WHO

[70] Article 23 WHO Constitution.
[71] Article 2 WHO Code of Practice on the International Recruitment of Health Personnel.
[72] Article 21 WHO Constitution. Regulations can concern: (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.
[73] Article 22 WHO Constitution.
[74] Article 19 WHO Constitution.

members or not. Unlike regulations, WHO conventions can incorporate a Regional Economic Organisation clause (REIO clause), allowing regional organisations, such as the European Union, to become contracting parties. This legal instrument was used for the adoption of the Framework Convention on Tobacco Control.[75] The resolution adopted on 1 December 2021 for the negotiation of an International Pandemic Treaty seems to prioritise the adoption of a convention, but it does not rule out the possibility of adopting another sort of legal instrument.[76]

State parties also need to define the material scope of the future International Pandemic Treaty. While it will build on the IHR and complement those, it should be much broader in scope and incorporate international human rights, environmental or trade law issues. The International Pandemic Treaty should not be exclusively about the response to infectious diseases but should rather aim at preventing outbreaks.[77] This would mean strengthening surveillance and regulating laboratory safety to prevent the release of pathogens. However, this agreement should also go much further in defining response mechanisms to pandemics. An International Pandemic Treaty should look beyond the public health consequences of a cross-border health threat. It should enhance cooperation in research, ensure adequate supply of medical countermeasures, address intellectual property concerns, look at the economic and social disruptions that might result from a pandemic, and examine the potential effects of pandemic response in human rights.

A future International Pandemic Treaty should also address some of the procedural shortcomings of the IHR of 2005. It should define sanctions for members not complying with their obligations. Such sanctions should apply to members not notifying a public-health threat, not collaborating with the WHO in investigations, and not complying with preventive measures, such as obligations to strengthen healthcare capacities. The strengthening of sanctions would require enhancing WHO authority to investigate health events and adopt measures, and providing an effective dispute settlement mechanism. The establishment of a peer and/or expert review mechanism, similar to the one applicable to human rights, has been proposed.[78]

The Intergovernmental Negotiating Body will therefore look at the institutional features and the material scope of a potential International Pandemic Treaty. Both aspects of the

[75] Framework Convention on Tobacco Control, Geneva, 21 May 2003, 2302 UNTS 166.
[76] World Health Assembly, The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response, 1 December 2021, SSA2(5): '(1) to establish, in accordance with Rule 41 of its Rules of Procedure, an intergovernmental negotiating body open to all Member States and Associate Members2 (the "INB") to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the INB'.
[77] Jorge VIÑUALES, Suerie MOON, Ginevra LE MOLI and Gian Luca BURCI, 'A Global Pandemic Treaty should aim for Deep Prevention' (2021) 397(10287) *The Lancet* 1791.
[78] Haik NIKOGOSIAN, 'A guide to Pandemic Treaty: Things you must know to help you make a decision on a Pandemic Treaty', *The Graduate Institute - Global Health Centre*, available at https://www.graduateinstitute.ch/sites/internet/files/2021-09/guide-pandemic-treaty.pdf (last accessed 12 October 2021), p. 14.

international agreement provide an opportunity for the European Union to play a strengthened role in the fight against cross-border health threats.

B. Institutional setting of the International Pandemic Treaty

The European Union pursues a leadership role in the global fight against cross-border health threats, as evidenced from its role since the beginning of the COVID-19 outbreak. As previously mentioned, the Union participated in the launching of the COVAX initiative and brought the COVID-19 pandemic to the attention of the G-20. The European Union has also used WTO mechanisms to address COVID-19 concerns.[79] All those measures reveal that the European Union supports global cooperation to fight against future pandemics and the International Pandemic Treaty could contribute to that goal.

The European Union supports the negotiation of a convention for the International Pandemic Treaty.[80] This choice of legal instrument does not come as a surprise. Regulations and conventions, under the WHO system, provide very different opportunities to the European Union. While the European Union cannot become a party to WHO regulations, it can become a party to conventions, as illustrated by the WHO Framework Convention on Tobacco Control (FCTC).[81] The role of the European Union in the negotiation and implementation of the FCTC has been considered an example of EU leadership in global health.[82] That success story suggests that the European Union should promote the adoption of public health conventions in other areas. The fight against pandemics provides the perfect opportunity for ensuring the *effet utile* of the WHO treaty-making powers and strengthening the role of the European Union in the field of cross-border health threats. The European Union should therefore seek the adoption of a convention and the incorporation, in the wording of such convention, of a REIO clause.

Beyond the potential accession of the European Union to the International Pandemic Treaty, conventions have other advantages over regulations that need to be considered in this case. Regulations can only be adopted for the limited number of concerns provided for

[79] For example, the European Union presented a communication at the World Trade Organization requesting State parties to notify all trade-related measures adopted to fight against the pandemic; see World Trade Organization, *Communication from Australia, Canada, Chile, European Union, Japan, Korea, New Zealand, Norway, Singapore, Switzerland – Covid-19: Transparency of trade-related measures*, 24 July 2020, available at https://trade.ec.europa.eu/doclib/docs/2020/july/tradoc_158904.pdf (last accessed 12 October 2021). The European Union is also the second largest exporter of COVID-19 vaccines after China; see Lionel GUETTA-JEANRENAUD, Niclas POITIERS and Reinhilde VEUGELERS, 'A world divided: global vaccine trade and production', *Bruegel,* 10 July 2021, available at https://www.bruegel.org/2021/07/a-world-divided-global-vaccine-trade-and-production/ (last accessed 12 October 2021). More generally on the EU trade response to COVID-19, see Christine KADDOUS and Elisabet RUIZ CAIRO, 'Politique commerciale commune' in Fabrice PICOD (ed), *Annuaire de droit européen 2020* (Paris, Editions Panthéon Assas, 2021).

[80] Article 1 Council Decision 2021/1101 on the position to be taken on behalf of the Union in the special session of the World Health Assembly, OJ L 238 of 6 July 2021, p. 79.

[81] Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213 of 15 June 2004, p. 8; Article 35 FCTC.

[82] Elisabet RUIZ CAIRÓ, 'Follow the leader! The EU as a global health actor after the negotiation of the Framework Convention on Tobacco Control' (2017) 2 *Geneva Jean Monnet Working Papers* 1.

under Article 21 of the WHO Constitution. The list includes rules to prevent the international spread of disease, which constituted the legal basis for the IHR.[83] However, an International Pandemic Treaty should be broader in scope than the IHR and cover topics that could hardly be considered within the scope of Article 21. The next paragraph addresses the material scope of the International Pandemic Treaty and the opportunities it provides for the European Union.

C. Material scope of the International Pandemic Treaty

The COVID-19 pandemic revealed the narrow scope of application of the IHR and the need for a more comprehensive agreement to fight against pandemics. A broader material scope would constitute an opportunity for the European Union, as it would imply that the future agreement could revolve around areas of EU competence and affect existing EU rules (1). The broader material scope of the agreement would however result in the International Pandemic Treaty being ratified as a mixed agreement, which would raise a number of questions under EU law (2).

1. The opportunities provided by the material scope of the International Pandemic Treaty

The International Pandemic Treaty would not apply to any cross-border health threat, but rather to those that reach the 'pandemic' level, which ought to be defined.[84] The International Health Regulations and the International Pandemic Treaty would therefore coexist.[85]

The IHR provide response mechanisms to limit the spread of cross-border health threats, but they do not deal with all the consequences that come with such response mechanisms. For example, travel and mobility restrictions during the COVID-19 pandemic resulted in a reduction of economic activity that had deep economic consequences all over the world. The limitations observed during the past few months have brought countries to realise that a more comprehensive set of measures needs to be established. The potentially broad scope of application of the International Pandemic Treaty is an advantage for the European Union. The EU has strong competences in many of the areas that should be covered by this agreement and has extensively legislated in such sectors, as the following examples reveal.

Current discussions on the International Pandemic Treaty highlight the need to agree on mechanisms to ensure production and equitable access to protective equipment, medicines,

[83] Article 21(a) WHO Constitution.
[84] Haik NIKOGOSIAN and Ilona KICKBUSCH, 'How would a pandemic treaty relate with the existing IHR (2005)?', 23 May 2021, *The British Medical Journal*, available at https://blogs.bmj.com/bmj/2021/05/23/how-would-a-pandemic-treaty-relate-with-the-existing-ihr-2005/.
[85] The World Health Assembly Special Session also led, in fact, to the decision to amend the International health Regulations. Both negotiations will be conducted in parallel.

treatments, and vaccines against pandemics. The management of supply chains, the conditions under which export restrictions can be applied, or intellectual property rights are some of the elements that could be included in the agreement. The European Union has an exclusive competence in the Common Commercial Policy.[86] Hence, the European Union should be involved in the negotiations if these were to address trade matters. The EU trade competence has extensively been exercised during the COVID-19 pandemic. The EU has adopted export restrictions on protective equipment and vaccines,[87] it has removed custom duties for the import of essential products,[88] and it is an active member at the WTO regarding the debate on the TRIPS waiver for COVID-related products and vaccines.[89] The European Commission has also recently proposed a regulation on a framework of measures for ensuring the supply of medical countermeasures in the event of a public health emergency.[90] Thus, the European Union has a strong expertise in the use of trade measures as a response to pandemics that could be used in international negotiations.

The International Pandemic Treaty should also address the impact of pandemic response measures on human rights.[91] Social distancing, tracing apps, lockdowns, curfews, isolation and quarantines have an impact on human rights.[92] Although States can restrict certain human rights to protect public health, limitations need to be necessary, proportionate, non-discriminatory, and subject to review.[93] Restrictions can thus be justified, but must be strictly framed. During COVID-19, response measures inequitably affected vulnerable groups and resulted in violations of civil and political rights.[94] The European Union should be able to participate in such discussions since the rights contained in the Charter of Fundamental Rights of the European Union can be affected by those measures. The Charter indeed applies to measures to contain a pandemic taken by EU institutions and to those taken by EU Member States linked to the implementation of EU law. For example, an EU measure advising against traveling might affect the freedom of movement within the EU,[95]

[86] Article 207 TFEU.
[87] See Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorization, OJ L 21I of 30 January 2021, p. 1; see also Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorization, OJ L 104 of 25 March 2021, p. 52 and its subsequent amendments. The latest amendment if of 29 September 2021 and extends the restriction until 31 December 2021. The export authorization scheme has now been transformed into a surveillance scheme; see Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021 subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance, OJ L 421 of 26 November 2021, p. 52.
[88] Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020, OJ L 103I of 3 April 2020, p. 1.
[89] European Parliament, World Trade Organization TRIPS waiver to tackle coronavirus, September 2021, available at https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf (last accessed 14 October 2021).
[90] European Commission, Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, 16 September 2021, COM(2021) 577 final. Note that this proposal is not based on Article 207 TFEU but on Article 122(1) TFEU.
[91] Sara (Meg) DAVIES, 'An International Pandemic Treaty must centre on human rights', 10 May 2021, *The British Medical Journal*, available at https://blogs.bmj.com/bmj/2021/05/10/an-international-pandemic-treaty-must-centre-on-human-rights/.
[92] For a parallelism with the response to the swine flu outbreak in 2009-2010, see Anniek DE RUIJTER, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press, 2019), pp. 141-149.
[93] Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights (1984).
[94] Judith BUENO DE MESQUITA, Anuj KAPILASHRAMI and Benjamin MASON MEIER, 'Strengthening Human Rights in Global Health Law: Lessons from the COVID-19 Response' (2021) 49 *The Journal of Law, Medicine & Ethics* 328, p. 330.
[95] Article 45 Charter.

whereas the obligation to provide a COVID certificate might restrict the right to data protection.[96]

Considering the increase of zoonotic diseases, negotiations should also concentrate on the links between pandemics and environmental concerns. The loss of biodiversity, climate change, and gaps in food legislation are some of the causes that can lead to increased zoonotic diseases. All these are areas where the European Union has significant powers. The European Union has a shared competence in environmental matters.[97] It is an increasingly active member in this field, as evidenced by the most recently adopted strategies in these areas.[98] Moreover, the European Union aims at promoting its environmental rules at the global level. For example, it regularly includes provisions on food safety and biodiversity in its Free Trade Agreements. [99] Both its internal legislation and provisions contained in its bilateral agreements could easily be proposed in multilateral negotiations.

The COVID-19 pandemic has revealed the lack of cooperation among States. Although the International Health Regulations require State parties to assist each other, this obligation has hardly been followed.[100] The International Pandemic Treaty should provide stronger rules on global cooperation and assistance. The European Union has a strong development and cooperation policy, which has been thoroughly used during the COVID-19 pandemic, but also in the response to other cross-border health threats. The EU Civil Protection Mechanism plays a particularly relevant role in this regard.[101] This mechanism was used during the Ebola outbreak to deploy emergency supplies and experts in the countries concerned, whereas during COVID-19 it was used within and outside the European Union to repatriate EU citizens and to assist affected countries.[102]

Cooperation obligations could include a global financial mechanism.[103] The European Union could contribute to the development of such a global instrument, based on its expertise in this area. The EU Solidarity Fund constitutes a financial instrument to support Member States or accession countries stricken by a natural disaster; its scope was extended in 2020

[96] Articles 7-8 Charter.
[97] Article 192 TFEU.
[98] Notably the From Farm to Fork strategy of 2020, the Biodiversity strategy for 2030 of 2020, and the European Green Deal of 2019; see European Commission, A European Green Deal: Striving to be the first climate-neutral continent, available at https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en (last accessed 14 October 2021).
[99] For example, CETA contains a chapter on sanitary and phytosanitary measures that concerns food safety; the agreement in principle between the EU and Mercosur contains a provision on trade and biodiversity.
[100] Article 44 IHR.
[101] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, OJ L 347 of 20 December 2013, p. 924.
[102] Elisabet Ruiz Cairó, *The Promotion of Public Health in EU External Relations* (Geneva/Zürich, Schulthess, Series in European Law, 2021), pp. 157-158.
[103] Such mechanism already exists under other international agreements; for example, the Montreal Protocol established an 'Ozon Fund' whereas the UNFCCC has a 'Green Climate Fund'; see Haik NIKOGOSIAN, 'A guide to a pandemic treaty: Things you must know to help you make a decision on a pandemic treaty', Global Health Centre – The Graduate Institute Geneva, 2021, available at https://www.graduateinstitute.ch/sites/internet/files/2021-09/guide-pandemic-treaty.pdf (last accessed 14 October 2021), p. 14.

to cover COVID-19.[104] The EU also has an emergency support mechanism that can be activated in case of an ongoing or potential disaster occurring within the Union, such as a public health emergency.[105] The EU recovery instrument, Next Generation EU, could also serve as a useful example in this regard.[106]

More traditional rules on pandemic response that should also be included in an International Pandemic Treaty concern travel restrictions, quarantines, or inspections at the border.[107] The European Union has a competence in those areas, as they essentially concern the internal market and the Common Commercial Policy.[108] The EU competence in those areas had already been acknowledged prior to the negotiation of the IHR and justified the participation of the European Union in the negotiation of that agreement.[109]

An International Pandemic Treaty should identify the economic and social measures that can minimize the impact of measures adopted to fight against pandemics, such as travel restrictions, the suspension of trade, or the impossibility to work from the office. The European Union can also act in this area under Article 107 TFEU. For example, during the COVID-19 pandemic it has adopted State aid rules aimed at alleviating economic operators of the consequences that reduced economic activity had upon them.[110] The European Union has also adopted the SURE mechanism as a response to COVID-19, which aims at supporting Member States that need to mobilise significant financial means to fight the negative economic and social consequences of the coronavirus outbreak on their territory.[111]

The previous paragraphs highlight the number of areas potentially covered by an International Pandemic Treaty that belong to EU powers. Current discussions underline that the response to public health emergencies goes well beyond public health concerns. The broad approach that is being followed has strong implications for the European Union since many of the potential rules that could be incorporated to an International Pandemic Treaty could affect EU legislation and policies. This potential impact fully justifies EU participation in

[104] Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund, OJ L 311 of 14 November 2002, p. 3; European Commission, COVID-19 – EU Solidarity Fund, available at https://ec.europa.eu/regional_policy/en/funding/solidarity-fund/covid-19.
[105] Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70 of 16 March 2016, p. 1. The proposal for a regulation to ensure the supply of medical countermeasures adopted in September 2021 explicitly refers to this instrument; see Article 13 of the Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, 16 September 2021, COM(2021) 577 final.
[106] Council Regulation (EU) 2020/2094 of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis, OJ L 433I of 22 December 2020, p. 23. This regulation is based on Article 122(1) TFEU.
[107] Such rules are already provided for in the IHR.
[108] Articles 114 and 207 TFEU.
[109] European Commission, Revision of the International Health Regulations under the Framework of the World Health Organization, 19 September 2003, COM(2003) 545 final, paras 28 and following.
[110] European Commission, Temporary framework for State aid measures to support the economy in the current COVID-19 outbreak, 19 March 2020, C(2020) 1863 final, last amended on 28 January 2021. The list of Member State measures approved under this framework is available at https://ec.europa.eu/competition-policy/document/download/fd113a0a-9c99-4405-aa4c-4ed52134f657_en (last accessed 14 October 2021).
[111] European Commission, The European instrument for temporary Support to mitigate Unemployment Risks in an Emergency (SURE), available at https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/financial-assistance-eu/funding-mechanisms-and-facilities/sure_en (last accessed 20 December 2021).

the negotiation of such an agreement and the subsequent ratification of the treaty. However, the ratification of the International Pandemic Treaty by the European Union would raise a number of questions under EU law, as it would imply that the International Pandemic Treaty is to be ratified as a mixed agreement.

2. The challenges provided by the material scope of the International Pandemic Treaty

The previous paragraphs reveal areas of EU exclusive competence, such as trade matters, and areas of shared competence where extensive EU legislation exists, such as food safety concerns. However, the International Pandemic Treaty would also cover areas of national competence, for example public health measures to fight against pandemics, and areas of shared competence for which the European Union has not legislated so far. Consequently, should the European Union be allowed to conclude the International Pandemic Treaty,[112] it should be concluded as a multilateral mixed agreement.[113] There are several consequences to mixity under EU law, as the following paragraphs reveal.[114]

Mixity requires delimiting areas of EU competence from areas of national competence.[115] Such delimitation is not specified in the agreement itself nor in the Council decisions on the signature or conclusion of the agreement. Yet, the delimitation of competences is necessary to define the role of the Union and its Member States in the multilateral setting (competence to negotiate, voting rights, or responsibility issues, for example). The delimitation of competences would also be necessary in case of provisional application of the international agreement under Article 218(5) TFEU.[116]

Mixity also results in the principle of sincere cooperation playing a significant role.[117] This principle has a special significance in mixed agreements, where both the Union and its Member States are represented, to ensure the unity in the international representation of

[112] The possibility for the European Union to conclude the International Pandemic Treaty does not only depend on EU competences but also on the international agreement allowing regional organisations to become contracting parties. The International Health Regulations also covered areas of EU competence but only allowed States to become contracting parties.
[113] Allan ROSAS, 'The European Union and Mixed Agreements' in Alan DASHWOOD and Christophe HILLION (eds), *The General Law of EC External Relations* (Sweet & Maxwell, 2000), pp. 203-204.
[114] See Christophe HILLION and Panos KOUTRAKOS (eds), *Mixed Agreements in EU Law Revisited – The EU and its Member States in the World* (Hart Publishing, 2010); Nicolas LEVRAT, Yuliya KASPIAROVICH, Christine KADDOUS and Ramses A. WESSEL (eds), *The EU and its Member States' Joint Participation in International Agreements* (Hart Publishing, forthcoming 2022).
[115] For the time being, such delimitation has not been done yet as it will depend on the exact scope of the international agreement; see European Commission, Recommendation for a Council Decision authorizing the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005), 1 December 2021, COM(2021) 766 final. In multilateral agreements, the delimitation of competences between the Union and its Member States is often done through declarations of competence; see Andrés DELGADO CASTELEIRO, *The International Responsibility of the European Union: From Competence to Normative Control* (Cambridge University Press, 2016), p. 110 and ff.
[116] For a multilateral agreement, provisional application could only arise once the required number of ratifications has been reached at the international level. At that moment, if all EU Member States have not ratified the international agreement yet, the Union could decide to provisionally apply provisions of exclusive EU competence.
[117] Christophe HILLION, 'Mixity and coherence in EU external relations: The significance of the 'duty of cooperation''(2009) 2 *CLEER Working Papers* 1.

the Union as well as the coherence of the EU external action.[118] The Court has emphasized the relevance of the principle of sincere cooperation in mixed agreements.[119] The principle of sincere cooperation is however not only applicable to mixed agreements. It plays an even greater role in multilateral agreements covering areas of EU exclusive competence that the Union cannot ratify, such as the International Health Regulations. Such agreements need to be ratified 'through the medium' of the Member States.[120] Member States have to represent EU interests in areas of EU exclusive or shared competence and the principle of sincere cooperation ensures that such outcome is properly reached. Consequently, a mixed agreement would actually be an improved outcome for the Union compared to the situation in the International Health Regulations.

One of the problems traditionally associated with mixed agreements is the lengthy procedure before their entry into force, as they need to be ratified both by the Union and all its Member States.[121] However, this risk seems low in the case of the International Pandemic Treaty. First, as a multilateral agreement, the entry into force of the International Pandemic Treaty does not depend upon the ratification by the Union and all its Member States, but rather upon the ratification by a minimum number of parties in general.[122] Thus, the agreement can enter into force even if some Member States do not participate, as long as the minimum number of ratifications has been reached. The consequences of having an 'incomplete agreement', that is one which has not been ratified by all EU Member States, would thus not be as problematic as in bilateral agreements.[123] Second, the debate surrounding EU free trade agreements is less likely to materialize in this case, and the ratification procedure is thus less likely to be hindered.[124] A parallelism with the Framework Convention on Tobacco Control can be drawn. When the European Union ratified this agreement in 2005, most EU Member States had already ratified it and the remaining did so in the following months.[125]

Consequently, the conclusion of the International Pandemic Treaty as a mixed agreement is not perceived as a threat; instead, it can be seen as an opportunity, as it would imply that

[118] Opinion of the Court of 15 November 1994 in Opinion 1/94 *Agreements annexed to the WTO Agreement*, EU:C:1994:384, para. 108; Opinion of the Court of 6 December 2001 in Opinion 2/00 *Cartagena Protocol*, EU:C:2001:664, para. 18; Judgment of the Court of 2 June 2005 in Case C-266/03 *Commission v Luxembourg*, EU:C:2005:341.
[119] Judgment of the Court of 30 May 2006 in Case C-459/03 *Commission v Ireland (MOX Plant)*, EU:C:2006:345.
[120] Opinion of the Court of 19 March 1993 in Opinion 2/91 *ILO Convention No 170*, EU:C:1993:106; Markus KLAMERT, *The Principle of Loyalty in EU Law* (Oxford University Press, 2014), p. 189.
[121] Guillaume VAN DER LOO and Ramses WESSEL, 'The Non-Ratification of Mixed Agreements: Legal Consequences and Solutions' (2017) 54 *Common Market Law Review* 735, pp. 737-738.
[122] Article 19 WHO Constitution.
[123] Guillaume VAN DER LOO and Ramses WESSEL, 'The non-ratification of mixed agreement: Legal consequences and solutions' (2017) 54(3) *Common Market Law Review* 735, pp. 742.
[124] The debate on mixity is very much centered around EU free trade agreements, where the Union and its Member States disagree on the scope of the Common Commercial Policy and, therefore, the extent to which the Union has an exclusive competence to conclude such agreements.
[125] United Nations Treaty Collection, WHO Framework Convention on Tobacco Control, available at https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=_en (accessed 14 December 2021).

the Union has the possibility to ratify this international agreement and, therefore, to play a meaningful role in the negotiation and implementation of this instrument.

III. Conclusions

The negotiation of an International Pandemic Treaty opens many possibilities at the global and EU levels. It is an opportunity to complement the IHR of 2005 by strengthening prevention and covering areas that go beyond stopping the spread of disease. For the European Union, the possibility to negotiate and ratify the International Pandemic Treaty could significantly strengthen its role in the global fight against cross-border health threats. Such role has already increased during the COVID-19 pandemic through informal channels and institutions not related with health. However, the International Pandemic Treaty would formalize a deeper involvement of the European Union in this area.

The potential role of the European Union will ultimately depend on the areas that are covered by the agreement. However, current discussions indicate that it should address trade, intellectual property rights, economic affairs, and human rights. All of these are areas where the European Union has strong powers and has developed a significant expertise. It is now for the Union to push for all those topics to be included in the future agreement and, later, to provide the leadership that will be required during these negotiations.

The International Pandemic Treaty will cover a very specific topic, namely pandemic preparedness and response, but the role of the European Union during these negotiations should not be underestimated. Following the EU success in the Framework Convention on Tobacco Control, EU leadership in the International Pandemic Treaty would underline the prominent role of the Union in the two major international agreements negotiated under the auspices of the WHO. Consequently, EU leadership in this negotiation would influence EU leadership in the global fight against cross-border health threats but it could also, eventually, influence EU leadership in global health.

* * *

List of abbreviations

COVID-19	Coronavirus disease 2019
ECDC	European Centre on Disease Prevention and Control
EU	European Union
EWRS	Early Warning and Response System
FCTC	Framework Convention on Tobacco Control
G-20	Group of 20
IHR	International Health Regulations
INB	Intergovernmental Negotiating Body
PHEIC	Public Health Emergency of International Concern
SARS	Severe Acute Respiratory Syndrome
SDGs	Sustainable Development Goals
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade-Related aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization

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