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GLOBAL HEALTH LAW

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THIRD REPORT OF THE COMMITTEE

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I. The COVID-19 Pandemic and International Law

1. The Biennial Conference of the ILA was to take place in Kyoto, Japan in August 2020. A global public health emergency caused the postponement of this Biennial and transition to an online forum. The international community is confronting an extraordinary situation. The COVID-19 pandemic has resulted in the untimely death of more than 1,234, 800 individuals worldwide,¹ and has resulted in significant parts of the world economy being effectively shut down. Travel within and between countries has been sharply curtailed. And as if these consequences were not enough, accusations between governments regarding responsibility for containing the virus have resulted in a troubling deterioration in international relations with spillover affecting the World Health Organization (WHO).

¹ Data from WHO Coronavirus Disease (COVID-19) Dashboard, <https://covid19.who.int/>, visited November 7, 2020, 2020, and; Johns Hopkins COVID-19 Dashboard, <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6> (November 7, 2020) (showing a higher total global deaths at 1,245,446) .

2. International law and legal systems more generally are secondary actors in addressing the COVID-19 pandemic and similar public health emergencies. Science is in the forefront as bringing an end to the pandemic requires the development and deployment of new vaccines, treatments and diagnostics, as well as improvements in the production and distribution of medical equipment. The strengthening of national health systems more generally, including (but not limited to) establishing capacity to address outbreaks is likewise a primary element of emergency response.

3. While acknowledging a secondary role, it is nonetheless evident that international law is important in addressing the COVID-19 pandemic. The WHO is an international institution established by a treaty (the “WHO Constitution”), the decision-making bodies and Secretariat of the WHO operate under rules established by the treaty and subsidiary decisions, and the International Health Regulations (IHR) that are followed by member states in situations of emergency are binding. Actions taken by the WHO in the course of the COVID-19 outbreak have been the subject of controversy and will be subject to a review once the crisis subsides.²

4. Certain states have asserted claims that other states failed to provide timely information and appropriate warning of the nature of COVID-19, and that by failing to do so they substantially exacerbated the injury suffered in consequence of the pandemic. This has raised the question whether there might in principle be some basis for a claim of responsibility under international law, whether under the International Health Regulations (IHR), some other international instrument, or customary international law.³

5. Prior to the COVID-19 outbreak, the Committee selected the theme of Access to Medicines for this Report. As the scientific community begins to introduce new vaccines, treatments and other health products to address the pandemic, the issue of access becomes critical. Will innovations be owned and controlled by private sector companies who will make the determinations regarding who produces them, where and at what price they are sold? It will take some time before there is adequate global production capacity to address all individuals needing a vaccine or treatment. How will those public health goods be allocated? Legal issues surrounding Access to Medicines are present in the broader context of issues raised by the pandemic.

6. We recall that the Committee in its 2016 Report to the Johannesburg Biennial discussed the results of a meeting on Global Health Security it convened in Geneva in March 2015. At that meeting many of the gaps in pandemic preparedness that have created severe difficulties in the current crisis were identified. The Committee was not alone in identifying these gaps, but it highlights that the COVID-19 pandemic was not an unforeseeable event. It raises the serious long-term question how public policy should cope with low probability, high risk events. Perhaps of even greater concern is whether there has been some change in the international environment - such as crowding in cities, increased international travel, and growth of traffic in exotic wildlife - that the possibility for pandemic events has risen such that pandemic events may become more common.

² See World Health Assembly (WHA) Resolution, COVID-19 response, A73/CONF./1 Rev. 1, 18 May 2020.

³ See, e.g., Jacques deLisle, *Pursuing Politics through Legal Means: U.S. Efforts to Hold China Responsible for COVID-19*, Foreign Policy Research Institute, May 12, 2020, <https://www.fpri.org/article/2020/05/pursuing-politics-through-legal-means-u-s-efforts-to-hold-china-responsible-for-covid-19/>.

7. The Committee adopted a Statement regarding the COVID-19 pandemic of April 5, 2020, in which it addressed legal issues arising out of this global public health emergency. That Statement is attached to this report as Annex 1. The Committee has updated and revised that Statement principally to take account of developments at international institutions taking place following its adoption and the Committee proposes that the Statement be adopted as a Resolution of the International Law Association at this 79th Kyoto Conference. The proposed Resolution and revised Statement is attached to this report as Annex 2.

8. This Committee Report is not specifically directed to the COVID-19 pandemic, but many of the elements of the Report are relevant. The main theme of this report is Access to Medicines, and the COVID-19 pandemic is highlighting the importance of this issue. By Access to Medicines, we principally refer to the ability of individuals to obtain vaccines, treatments and diagnostics that are needed to prevent and treat disease. We are generally referring to pharmaceutical products that already are on the market. The issues concern where they are distributed, to what individuals and groups of individuals, and whether at an affordable price. Of course, the question of access does not arise if the necessary vaccines and treatments have not been developed. This is the innovation side of the equation. In the first part of the Report we focus on cutting-edge issues in the innovation sphere. Specifically, we discuss the role that Artificial Intelligence is playing in the development and deployment of new health products, and legal issues that arise in that connection. In the second part of the Report we consider some of the policy options and related legal mechanisms that are available to governments to assure access for their citizens. In the third part of the Report we address whether Access to Medicines is a human right and, if so, how individuals may enjoy that right.

9. As exemplified by the Statement on the COVID-19 pandemic adopted by the Committee, there are fundamental values underlying the Committee's work. These include the rights to life and health as key human rights, non-discrimination among individuals and groups in respect to the protection and promotion of health, access to adequate healthcare for all, the necessity for international cooperation, respect for individual privacy, and government and private sector transparency and accountability. These values are supported by international agreements, customary international law, principles of equity, and international soft law standards, as well as by soft law instruments in the form of governmental and non-governmental guidelines, statements and best practices.

II. Artificial intelligence, drug development and access to medicines

10. The application of artificial intelligence (AI) tools in drug discovery has the potential to deliver innovative medicines at affordable costs. An introductory section of this report summarizes advances in the development of AI applications for pharmaceutical and health innovation. Afterwards, three major areas of legal discussion are addressed: (i) data sharing and AI for health; (ii) legal challenges in drug development and AI; (iii) intellectual property and AI.

A. Health outcomes and the broader context

11. The application of AI technologies to large amounts of data increases the opportunities for the prevention, diagnosis, treatment and management of diseases.⁴ The impact on healthcare arising from emerging technologies and advances in data processing is so profound that it seems right to claim that public health is undergoing a structural change.⁵ At the same time, the application of AI technologies to large amounts of data is modulated by diverse factors such as law, data access and ownership conditions, and technological capabilities. It is important, hence, to consider both the impact of AI tools on healthcare and the framework that allows or hinders such impact.

12. Health diagnostics is a good example of how the 4th Industrial Revolution (4IR) technologies impact health. The diagnosis of disease and ailments can be improved if patterns in data are identified, an objective that machine learning and predictive analytics intend to achieve.⁶ AI systems applied to genomic sequencing, digital pathology imaging⁷ and radiology⁸ promise important advances in health diagnoses in multiple areas, notably oncology.⁹ For example, in the US and UK alone, 42 million breast cancer screenings are performed per year and AI researchers have now developed algorithms that reduce both false positive and false negatives in these exams, surpassing even expert human interpretation.¹⁰

13. In this new environment, the role and activity of health actors evolve, and new actors emerge. Tech giants acquire prominence and capabilities, explained by their capacity to perform large investment in expanding AI tools and the importance that data has acquired to manage healthcare and to develop health research. Researchers themselves also change roles and part of their activity moves from the lab to the computer. Likewise, the activity of doctors is modified by new tools that assist their work and algorithms that can predict what clinicians would only diagnose.¹¹ Patients also experience the

⁴ B Norgeot, BS Glicksberg, AJ Butte, “A call for deep- learning healthcare” *Nat. Med.* 2019;25(1):14–15.

⁵ See, more broadly, A Esteva et al. “A guide to deep learning in healthcare”, *Nat Med* 2019;25(1):24–9; EJ Topol, “High-performance medicine: the convergence of human and artificial intelligence”, *Nat Med* 2019;25(1):44–56; C Krittanawong et al, “Artificial intelligence in precision cardiovascular medicine”, *J. Am. Coll. Cardiol.* 2017 (69) 2657–2664.

⁶ V Gulshan, L Peng, M Coram, et al. Development and validation of a deep learning algorithm for detection of diabetic retinopathy in retinal fundus photographs. *JAMA* 2016;316(22):2402–10; A Esteva et al. “Dermatologist-level classification of skin cancer with deep neural networks. *Nature* 2017; 542(7639):115–8; De J Fauw, JR Ledsam, B Romera-Paredes, et al. “Clinically applicable deep learning for diagnosis and referral in retinal disease” *Nat Med* 2018;24(9):1342–50.

⁷ T Olsen et al. “Diagnostic performance of deep learning algorithms applied to three common diagnoses in dermatopathology”, *J. Pathol. Inform* 9, 32–32 (2018).

⁸ A Lezzi et al., “Artificial Intelligence in Interventional Radiology: A Literature Review and Future Perspectives”, *Journal of Oncology*, vol. 2019, Article ID 6153041; RK Tripathy et al. “Artificial intelligence-based classification of breast cancer using cellular images, *Cell, RSC Adv.* 2014; 4: 9349-9355.

⁹ S M McKinney, M Sieniek, V Godbole, et al. “International evaluation of an AI system for breast cancer screening”, *Nature* 577, 89–94, 2020; D Ardila, AP Kiraly, S Bharadwaj, et al. “End-to-end lung cancer screening with three-dimensional deep learning on low-dose chest computed tomography”, *Nat Med* 25, 954–961 (2019). <https://doi.org/10.1038/s41591-019-0447-x>

¹⁰ S M McKinney, M Sieniek, V Godbole, et al. op. cit.

¹¹ N Tomašev et al., “A clinically applicable approach to continuous prediction of future acute kidney injury”, *Nature* 2019 572: 116-119.

change, for instance when monitored by wearable devices,¹² or when interacting with online health smart assistants.¹³

14. When it comes to pharmaceuticals, the impact of 4IR technologies is also systemic and can be observed in a vast number of areas, from the medicines' supply chain¹⁴ to consumption.¹⁵ In the context of pharmaceutical innovation, AI-assisted drug discovery has the potential to develop medicines faster than conventional small-molecule drug design, and may be an opportunity for the development of medicines that, without AI, would not exist. Fueled by a profusion of digitized data, rapidly advancing computational processing power¹⁶ and wide availability of new computer software and hardware such as graphical processing units,¹⁷ AI techniques and functional applications¹⁸ give rise to new opportunities for drug discovery, thus they make more efficient the drug development process, improve already existing drugs, and even assist in developing new drugs. Similarly, data analytics and modeling have the capacity to inform clinical trial design and ensure trials are appropriate to answer the clinical questions at hand.¹⁹

B. Artificial Intelligence, Big Data, and Distributed Ledger Technologies in pharma R&D

15. The massive use of data and AI techniques and functional applications in drug discovery and clinical development transforms the way health innovation is produced. AI can help at understanding diseases, shorten the duration of research and development (R&D) processes, decrease failure rates, increase the accuracy of predictions regarding efficacy and safety of drugs, and lower drug discovery and development costs. AI can contribute in all stages of pharmaceutical R&D, from early drug discovery to pre-clinical and clinical development. Successful applications of machine learning to drug discovery include target identification and validation, compound screening and lead discovery, preclinical development, and clinical development.²⁰

¹² EJ Topol, SR Steinhubl, A Torkamani, "Digital medical tools and sensors", *Jama* 313, 353–354 (2015).

¹³ D K-h Ho, "Voice-controlled virtual assistants for the older people with visual impairment", *Eye* (2018) 32, 53–54; doi:10.1038/eye.2017.165.

¹⁴ The distribution and control of medicines changes thanks to distributed ledger technologies. See DHL Trend Research, *Blockchain in logistics*, Troisdorf: DHL Customer Solutions & Innovation, 2018.

¹⁵ Think for instance about the intake of pills with ingestible sensors. See P Belluck, "First digital pill approved to worries about biomedical 'Big Brother'". *The New York Times* <https://go.nature.com/2yDBbSm> (13 November 2017); L Cosgrove, IA Cristea, AF Shaughnessy, et al "Digital aripiprazole or digital evergreening? A systematic review of the evidence and its dissemination in the scientific literature and in the media", *BMJ Evidence-Based Medicine* 2019, 24:231-238.

¹⁶ WIPO, *Artificial Intelligence*, WIPO Technology Trends, Geneva: WIPO, 2019, p. 13.

¹⁷ J Vamathevan, et al, "Applications of machine learning in drug discovery and development" *Nat Rev Drug Discov*. 2019 Jun;18(6):463-477. doi: 10.1038/s41573-019-0024-5, p. 463.

¹⁸ Artificial intelligence techniques include machine learning, deep learning, fuzzy logic, logic programming, neural networks, latent representation and unsupervised learning. Artificial intelligence functional applications include computer vision (including image recognition and biometrics), natural language processing (including semantics and sentiment analysis), speech processing (speech-to-speech and speaker recognition), robotics, control methods. See WIPO, *above*, p. 31.

¹⁹ M Woo, "An AI boost for clinical trials" *Nature* 573, S100-S102 (2019)

²⁰ J Vamathevan, et al, op. cit. See, in particular, Fig 1 at p. 464.

16. Algorithms and computational power are used to identify new disease-associated targets by mining the information originating from basic research. In order to identify novel targets, AI is capable of conducting a massive literature review in a fraction of the time traditionally devoted to this activity.²¹ Gene-disease associations, target druggability predictions, and identification of alternative targets are among the successful applications of machine learning to drug discovery.²² AI technologies enhance prediction and matching when screening small molecules libraries to identify new drug candidates. In this same area, next generation sequencing allows to predict success rates based on biological factors²³ and machine learning enables to predict organic reaction outcomes.²⁴

17. Even more complex is designing new drug candidates, an objective that AI-based approaches try to achieve by matching new drug candidates with the structure of the target (which is the only information initially known²⁵), or embarking in *de novo* design of molecules with desired properties employing deep and reinforcement learning approaches.²⁶ In this context, the capacity of deep neuronal networks to increase predictive power when inferring the properties and activities of small molecules becomes of particular relevance.²⁷

17. While different from the design of new drug candidates, reference can also be made to the optimization of already existing compounds. Insights gained from computational power²⁸ and machine learning are instrumental to identify a better use, or even new uses, of already existing drugs.²⁹

19. In a different context, AI can also be instrumental to improve preclinical and clinical testing. Thanks to AI, advances are made in preclinical modelling and in the identification of animal models that permit conducting tests in a more accurate manner. Tissue-specific biomarker identification and prediction of biomarkers of clinical endpoints are among the successful applications of machine learning

²¹ V Tshitoyan, J Dagdelen, L Weston, *et al.* Unsupervised word embeddings capture latent knowledge from materials science literature. *Nature* 571, 95–98 (2019). <https://doi.org/10.1038/s41586-019-1335-8>

²² J Vamathevan, *op. cit.*

²³ S Odell, Machine learning in the pharmaceutical industry, 5 October 2016, <http://blogs.royalsociety.org/in-verba/2016/10/05/machine-learning-in-the-pharmaceutical-industry>.

²⁴ CW Coley *et al.*, “Prediction of Organic Reaction Outcomes Using Machine Learning”, *ACS Cent. Sci.* 2017, 3, 5, 434-443.

²⁵ See F Properzi *et al.*, *Intelligent drug discovery Powered by AI*, Deloitte, 2019.

²⁶ M Popova, “Deep reinforcement learning for de novo drug design”, *Science Advances*, 25 Jul 2018: vol. 4, no. 7, eaap7885, DOI: 10.1126/sciadv.aap7885; M Olivecrona, T Blaschke, O Engkvist, H Chen, “Molecular de-novo design through deep reinforcement learning”, *J. Cheminform.* vol .9, 48 (2017).

²⁷ J Ma, RP Sheridan, A Liaw, GE Dahl, V Svetnik, “Deep neural nets as a method for quantitative structure–activity relationships”, *J. Chem. Inf. Model.* 55, 263–274 (2015).

²⁸ J Achenbach, “Computational tools for polypharmacology and repurposing”, *Future Med Chem.* 2011 Jun;3(8):961-8. doi: 10.4155/fmc.11.62.

²⁹ A Aliper, *et al.*, “Deep learning applications for predicting pharmacological properties of drugs and drug repurposing using transcriptomic data”. *Mol. Pharm.* 13, 2524–2530 (2016); N Fleming (2018) “How artificial intelligence is changing drug discovery”. *Nature* 557(7707):S55–S57.

to drug discovery.³⁰ AI also helps at identifying possible safety issues, accelerating decisions regarding whether to maintain or to pursue a concrete target.

20. The efficacy of clinical trials can also be enhanced thanks to advanced predictive analytics,³¹ identifying the right subjects to participate in clinical trials, generating hypothesis to understand features which impact trial delays, and using a much wider range of data than at present, including genetic information, clinical history, and social media. Safety of participants to a clinical trial can also be improved thanks to monitoring tools and real-time control of participants. In a related context, AI allows to identify the advances in knowledge that are most likely to translate into clinical research.³²

C. Legal challenges

21. AI has the potential to develop “data-driven, implicit model-building processes to navigate vast datasets”³³ and, by doing so, improve the accuracy and velocity of drug discovery. With technological change, however, also comes the need of legal adaptation. Innovative legal responses are needed to translate present potential into needs-driven pharmaceutical innovation and access, capable of delivering affordable products. Critical questions relate to research choices, legal tools for innovation and the regulation of the data fueling new technologies.³⁴ Similarly, the lack of an integrated global frameworks and norms for data use, ownership and informed consent undercuts the full potential of these technical advances.

22. If the pharmaceutical development chain is observed from the sequential point of view, the identification of new diseases-associated targets is the first area of drug discovery where AI technologies are applied. Such identification is possible thanks to the existence and access to large databases³⁵ which enable the automatization of literature review and the analysis of basic research. The search can be done focusing on specific areas or can also be disease-agnostic.

23. Ethical and legal implications are clear. The coders of the algorithm can choose targeting diseases with unmet medical needs or diseases for which treatment already exists, as has traditionally happened. When choosing diseases with unmet medical needs, the coders can also choose diseases

³⁰ J Vamathevan, et al, op. cit.; Deep Knowledge Analytics, *AI for drug discovery, biomarker development and advanced R&D landscape overview 2019 / Q2*, available at <https://ai-pharma.dka.global/quarter-2-2019/> (accessed 30 December 2019).

³¹ CH Wong, KW Siah, AW Lo, “Estimation of clinical trial success rates and related parameters”, *Biostatistics* <https://doi.org/10.1093/biostatistics/kxx069> (2018).

³² For instance, a machine learning system detects whether a paper is likely to be cited by a future clinical trial or guideline. This way, the rate at which scientific discoveries lead to successful treatment of human disease increases. BI Hutchins, TM Davis, RA Meseroll, GM Santangelo, “Predicting translational progress in biomedical research”, *PLOS Biology*, October 10, 2019 <https://doi.org/10.1371/journal.pbio.3000416>.

³³ P Schneider et al at “Rethinking drug design in the artificial intelligence era”, *Nat Rev Drug Discov.* 2019 Dec, doi.org/10.1038/s41573-019-0050-3.

³⁴ For example, in the context of the current Corona19 pandemic, many countries are lessening regulations such as by reliance on emergency use authorizations and acts such as the US Public Readiness and Emergency Preparedness Act (PREP Act) <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> (accessed 15 April 2020).

³⁵ See Nature, *Scientific data*, at <https://www.nature.com/sdata/policies/repositories> (accessed 15 April 2020).

affecting populations that can pay for drugs once they have been developed, or diseases impacting populations that most likely will not be able to pay by themselves. A related aspect, also with important ethical and legal implications is transparency of algorithms. Such transparency is necessary to identify the logic behind research choices and research outcomes, and also to meet drug development regulations.

24. The more the information about a specific patient, the more precise future drugs and treatments for that patient can be. Monitoring devices, microsensors, clinical records, and mobile apps are effective in the field of personalized medicine, impacting positively both on patients’ situation and cutting healthcare costs. AI can also drive medicine towards personalized products and treatments, and poses new questions regarding genetic differences and the potential for genetic-based discrimination. Indeed, the interest in developing treatments targeting human collectives that are identifiable from a genetic standpoint may vary in light of, among others, market considerations. Thus, not health needs, but aspects such as costs and technical difficulties of medicines targeting specific genetic characteristics could become central criteria, increasing the risk of discrimination.

1. Ethical considerations in data sharing and AI for health

25. While the potential of AI and machine learning (ML) applications described above are in various states of maturity, a unifying principle applies. The quality, quantity, and veracity of the data inputs to these systems can be the difference between accuracy or inaccuracy, bias or objectivity, benefit or harm. It is long understood that AI/ML can yield unintended consequences.³⁶ Yet in consideration of the potential benefits to human health – the ability to analyze information and identify patterns beyond the capabilities of the human mind - under what rubric should these competing considerations weigh on our ethical scale?

Table 1: Factors for/against data sharing for AI/ML in health

Supporting	Disfavoring
<ul style="list-style-type: none"> ● Increase in quality diagnosis/treatment/ prevention ● New pattern recognition ● Context for medical decision making ● Deidentified data as public good ● Increased access to medical care through telemedicine ● Global economic drivers – ability to focus resources on most poignant GH/public health needs & most efficacious diagnostics and therapeutics 	<ul style="list-style-type: none"> ● Infringement on privacy ● Inaccuracy/risk of failure ● Exploitation/misuse ● Commercial interests ● Lack of benefit sharing to data owner ● Risk exposure of PHI ● Unconscious bias/data bias ● Lack of control on recall of data ● Lack of measurement of all pertinent factors

³⁶ A recent report indicates that “25% of organizations worldwide that are already using AI solutions report up to 50% failure rate.” See R Jyoti, Artificial Intelligence Global Adoption Trends and Strategies”, Jun 2019 - IDC Survey - Doc # US45120919, <https://www.idc.com/getdoc.jsp?containerId=US45120919>.

<ul style="list-style-type: none"> ● Continuous improvement through ML ● Decrease in misdiagnosis 	
Neutral but required for use of data	
<ul style="list-style-type: none"> ● Informed consent ● Framework for data standards, collection and use 	

1.1 Factors in Favor of Sharing - Is it ethical to withhold data?

(i) *Improved Health Outcomes.* The potential for more accurate diagnosis, treatment and prevention of disease is a prominent factor supporting data sharing. The examples provided above of advantages arising from image recognition to fight cancer are a good case in point of the relevance of data sharing, thus AI/ML provides the ability to compile the ‘experience’ of millions of images and thousands of doctors.³⁷

(ii) *Personalized Medicine.* AI/ML empowers phenotypic and genotypic tailoring of medical interventions called *personalized medicine*.³⁸ Personalized medicine and AI play an innovative role in treatment regimens based on the observation that genetic and individual factors contribute to disease and could allow for an ability to tailor (‘personalize’) diagnosis, treatment and prevention to individual patients.³⁹

(iii) *Telemedicine.* Consideration must be given to the potential for increase in access availed to millions of medical providers to make informed and contextualized medical decisions with the advent of AI/ML which is capable to tracking a magnitude of factors. Not only does telemedicine increase access to health information, it has the potential to reduce costs in the provision of care. To maximize impact, an enabling legal framework for cross-border provision of healthcare, however, should be developed.

(iv) *Global Health Economic Drivers.* The ability to continuously improve upon vast amounts of data creates the ability to inform data driven decision making so that limited resources can be focused on country priorities most poignant to their public health needs. Similarly, data driven assessments can be made as to the most efficacious diagnostics, therapeutics and prophylactic interventions.

(v) *Need for Data.* AI/ML for health is highly dependent on data inputs, including appropriate application of AI algorithms that are supervised.⁴⁰ Obtaining appropriate datasets is one among ‘grand

³⁷ See above I.1.

³⁸ R Abbott and D Chang, A Harris Eyre, et al, “Pharmacogenetic Decision Support Tools: A New Paradigm for Late-Life Depression?,” 26(2) *Am J Geriatr Psychiatry* 125–133 (2018).

³⁹ NJ Schork (2019) “Artificial Intelligence and Personalized Medicine”, in D Von Hoff, (eds) *Precision Medicine in Cancer Therapy. Cancer Treatment and Research*, vol 178: 265-283, Springer; NJ Schork, C Chan et al. (2017), “Novel Strategies on Personalized Medicine for Breast Cancer Treatment: An Update” *Int J Mol Sci.* 18(11): 242-3.

⁴⁰ i.e. trained on known inputs and outputs so that quality correlations are made. J Couzin-Frankel, “Artificial intelligence could revolutionize medical care. But don’t trust it to read your x-ray just yet”, *Science* 2019, Jun.

challenges' in drug discovery.⁴¹ Difficulties for such access may arise because of logistic and organizational aspects, and also because of legal constraints, such as inconsistent consents and permissions. In respect of the former, while ML relies on the intensive use of vast datasets, which must be “accurate, curated, and as complete as possible in order to maximize predictability”,⁴² data in reality frequently found in heterogeneous and federated formats, may not be comparable and often includes information of bad quality. Regarding legal constraints, data publicly available is just a fraction of useful information actually existing. Companies and institutions may keep information confidential if such health data offers them a competitive advantage or a legal barrier exists to sharing. Some legal regimes explicitly provide for confidentiality of data of relevance to drug discovery, notably regulatory test data protection, yet others call for disclosure of clinical trial information.⁴³

26. Data types relevant to drug discovery and health include “images, textual information, biometrics, and other information from wearables, assay information and high-dimensional omics data”,⁴⁴ and can be both structured and unstructured.⁴⁵ Among other sources, data can be extracted from clinical trials records, electronic medical records,⁴⁶ insurance providers records, conference abstracts, grant applications, chemical structures, human transcriptomic, proteomic and metabolomic profiling, scientific literature,⁴⁷ and public data banks. For instance, natural language processing enables to identify drug-disease, gene-disease and target-drug associations in Medline abstracts, and relies on the European drug reactions database and the Genetic Associations Database.⁴⁸ There are, as well, valuable unpublished datasets for drug development and health purposes, such as the records of all drug development projects that have failed and that companies and research centers gather. Such information includes valuable insights to prevent the repetition of failed projects, safety concerns, and also promising leaps for alternative projects.⁴⁹

27. If AI algorithms with robust data are capable of increasing the accuracy of diagnosis, treatment and prevention – which could decrease global Disability Adjusted Life Year (“DALY”) burden - should health data be considered a public good that should be broadly shared for this purpose? If so, what controls should be associated with this data.

1.2 Factors disfavoring sharing – What protections would be needed to enable sharing?

doi:10.1126/science.aay4197; M Uddin, Y Wang, W Smith, “M. Artificial intelligence for precision medicine in neurodevelopmental disorders” *npj Digit. Med.* 2, 112 (2019). <https://doi.org/10.1038/s41746-019-0191-0>

⁴¹ P Schneider et al “Rethinking drug design in the artificial intelligence era”, *Nat Rev Drug Discov.* 2019 Dec, doi.org/10.1038/s41573-019-0050-3.

⁴² J Vamathevan, et al, op. cit.

⁴³ <https://www.who.int/ictrp/results/en/> and <https://clinicaltrials.gov/ct2/manage-recs/background>

⁴⁴ J Vamathevan, et al, op. cit.

⁴⁵ F Properzi et al, *Intelligent drug discovery Powered by AI*, Deloitte, 2019, p. 3.

⁴⁶ Z Yang, et al. Clinical assistant diagnosis for electronic medical record based on convolutional neural network. *Sci. Rep.* 8, 6329 (2018).

⁴⁷ The “primary source of knowledge on target association and disease”. See J Vamathevan, et al, op. cit.

⁴⁸ A Bravo, J Pinero, N Queralt-Rosinach, M Rautschka, LI Furlong, “Extraction of relations between genes and diseases from text and large- scale data analysis: implications for translational research” *BMC Bioinformatics* 16, 55 (2015).

⁴⁹ F Properzi et al, op. cit., p. 4.

28. Fundamentally, the factors disfavoring sharing commonly relate to privacy, judgment and the potential for error.

(i) *Privacy, Misuse & Consent.* A key concern motivating privacy regulation is the potential for unconsented use of personal data. Informed consent is a critical pillar of medical ethics.⁵⁰ The lack of uniformity in informed consent standards, however, presents a unique challenge to data integration for AI/ML. Regulations related to human subject research include over 1000 laws and regulations across 131 countries with data privacy and informed consent often determined on a country-by-country basis.⁵¹ Yet the ability of a patient to consent to all or a limited set of requested uses (such as performance of medical treatment only or permission for secondary research or commercial purposes) is a central concern. Even the most sophisticated data companies struggle with the real-world implementation of the General Data Protection Regulation (GDPR) to enable the ability to erase, correct, port and exclude automated processing of personal data.

(ii) *Errors.* AI/ML error is another concern that, while unintentional, can have consequential implications. Improperly trained or validated algorithms can produce erroneous results as contemplated in the application of self-driving cars.⁵²

Similarly, training data can create implicit bias and higher error rates in certain populations. Algorithms trained in facial recognition, for example, may have higher error rates based on differences in skin tone if the primary training data did not adequately represent a diverse population⁵³. Errors of this type could have significant consequences, including for health.

(iii) *Judgement.* While the potential benefits of AI/ML for health are high, it has been aptly noted that qualitative data may exclude inputs that are difficult to measure. Empathy, compassion, unique practitioner-experience, unconscious bias, and morality are not yet factored into the AI-based algorithmic results.⁵⁴ These qualitative inputs call for judgement from a uniquely human perspective.

29. In order for AI/ML to enhance data-driven decision making one must consider frameworks that guide data collection with the end goal in mind – integration of data for improved health outcomes while balancing privacy and misuse concerns.

2. Legal challenges in drug development and AI

⁵⁰ Global Clinical Practice Network, *Informed consent of trial subjects*, available at <https://ichgcp.net/48-informed-consent-of-trial-subjects/>, accessed April 2020.

⁵¹ Office for Human Research Protections U.S. Department of Health and Human Services, *International Compilation of Human Research Standards*, available at www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf, accessed April 2020.

⁵² R Calo “The Courts Can Handle the Deadly Uber Self-Driving Car Crash”, <https://slate.com/technology/2018/03/the-deadly-uber-self-driving-car-crash-is-just-the-beginning.html>

⁵³ T Simonite, “The Best Algorithms Struggle to Recognize Black Faces Equally”, *Wired magazine*, July 22, 2019.

⁵⁴ J Kerr et al., “Digital Diabetes Data and Artificial Intelligence: A Time for Humility Not Hubris”, *Journal of Diabetes Sci & Tech*, 13:1, pp. 123-127.

30. Despite the variety of informed consent procedures, there is a need for establishing a central mechanism for securing agreement for secondary uses of health data in drug development research. When it comes to informed consent, patients should be provided with a detailed explanation of the basic way in which the AI program or system works, of the risks versus potential benefits of the AI technology (e.g. compared to human accuracy), of the human versus machine roles and responsibilities in diagnosis, treatment, and procedures and of the safeguards that have been put in place, such as cross-checking results between clinicians and AI programs. Special attention should be paid to confidentiality of patient's information and any data privacy risks.

31. A key element of any major legal intervention in the field of control of AI-based systems should be the establishment of accountability and explainability schemes in algorithmic decision-making and the formulation of regulatory oversight and legal liability of all those involved. Explainability should focus not only on how the system simply works but, more importantly, on how it behaves including design/code review, input data analysis; statistical analysis of outcomes; analysis of sensitivity to inputs. Explainability should be seen as part of a process for meaningful transparency that is required to be installed in all medical AI-based systems. It should be one of the principles inspiring the responsible development of AI, along with beneficence, non-maleficence, autonomy and justice.

32. Accountability schemes may need to take the form of redress in cases of unfair treatment. Redress committees can operate in the form of ethics review committees that examine issues such as re-identifiability, given that unidentified data may be re-identified and reconnected to the individuals concerned through the use of AI. Input data, target values, and envisaged consequences are also of major legal importance. Law should provide procedural opportunities to citizens to engage in 'black box tinkering' and resort to the so-called dynamic consent that entails an update on the use of data in a continuous way so that the individual can opt out for specific uses of data while allowing the use for other purposes via consent portals.

33. The principle of transparency as a fundamental principle of good governance of new and emerging technologies should also incorporate the legal obligation of unpacking the black box of algorithms that are used to generate the outputs. These algorithms should be adapted to all levels of development, so as to enhance the required benefit-sharing requirements and to ensure that low- and middle-income countries are able to reap the benefits of drug-development findings. The type and level of inclusiveness, the inclusion-exclusion criteria and the quality of data sets used for self-learning artificial intelligence algorithms are important parameters that need to be looked at very carefully.

34. In addition, secondary use of data should be conditioned to a positive evaluation by a Research Ethics Committee and adequate technical procedures in order to prevent researchers and third parties from accessing personal data. The benefits of data processing via AI should be harnessed through fair data-sharing practices and benefit-sharing agreements and development of compliance and ethics follow-up and fair research contracts tools. Two additional areas of concern have been identified, and relate to "the difficulty of providing meaningful access rights to individual data subjects that lack necessary resources" and "Big Data Divides" created between those who have or lack the necessary resources to analyse increasingly large datasets." Next section introduces intellectual property aspects of relevance in this context. Last but not least, all AI developers should be required to conduct an ethical

context-specific assessment prior to deployment of an AI system for public health reasons. Such an assessment should rate ethically relevant characteristics of an AI system on the basis of a classification of different AI application contexts and the risks they pose to the individuals affected and society overall, the intensity of the system's potential harm and the dependence of the affected person(s) on the respective decision. The precautionary principle, well-known in areas such as environmental protection, along with the principles of justice, accountability, transparency and privacy should find adequate translation in the context of such an ethics risk-matrix of health-related innovation arising from AI functional applications. Such an assessment could take the form of or even compliment algorithmic impact assessments and take into account, among others, the accuracy and reproducibility of the system's outcomes. It should be conducted prior to the commercial deployment of an AI system whereas its outcomes should be evaluated by independent ethics committees and regulatory bodies. The assessment could be based on standards issued by national standardisation organisations and international standards bodies such as the International Standards Organization (ISO) and the IEEE (the Institute of Electrical and Electronics Engineers).

35. Additionally, there is a need for independent and effective oversight of the development, deployment and use of AI systems by public authorities from a human rights perspective. Various forms of ex ante assessment models can be designed such as human rights impact assessments and mandatory consumer protection impact assessments. Cross-jurisdictional rules for specific AI applications, systematic monitoring and periodic ex-post evaluation of regulatory measures and the introduction of regulatory sandboxes may be some additional options for controlling AI in the drug-development sector.

3. Intellectual Property Standards

36. Changes brought by AI to the intellectual property (IP) domain will significantly impact substantive law, administration of IP law, and enforcement related standards. In terms of substantive law, for example, long standing questions about the extent to which AI can be patented remain important and controversial. AI is generally software, and in most jurisdictions software per se cannot be patented.⁵⁵ However, most jurisdictions do allow for some form of AI software protection. For instance, under European Patent Office (EPO) guidelines "computer-implemented inventions" can be patented so long as they provide a technical solution to a technical problem.⁵⁶ Both the EPO and the United States Patent and Trademark Office have recently updated their guidances on patents involving software.⁵⁷ The U.S. Congress has also recently held a series of hearings on significantly changing subject matter restrictions to patentability so as to more broadly permit patents on software. Even without patent protection for software, patents on AI may be possible through patents on use of software or patents on AI-related hardware.

⁵⁵ European Patent Office, "Guidelines for Examination" https://www.epo.org/law-practice/legal-texts/html/guidelines2018/e/g_ii_3_3_1.htm.

⁵⁶ European Patent Office, "Index for Computer-Implemented Inventions, Guidelines for Examination" www.epo.org/law-practice/legal-texts/html/guidelines/e/j.htm.

⁵⁷ USPTO, Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (Berkheimer v HP, Inc), 2018, www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF.

37. AI software can also be protected by copyright and trade secret protection. Both source and object code receive copyright protection as a “literary work”. Beyond that, copyright protection varies by jurisdiction, for example with respect to preparatory design work. AI software may be protected as a trade secret if it is kept confidential and if software code cannot be accessed by competitors. This may be the case with some AI-as-service business models where only the AI’s output is shared outside of an organization.

38. Intellectual property protections for AI will have a significant impact on health given the increasing importance of AI in fields such as research and development, diagnostics, and clinical patient management. On the one hand, the absence of adequate IP laws may fail to encourage the development and use of AI, promote secrecy, and discourage the development of new products and services that will improve public health. On the other hand, excessive protections may interfere with research and development, limit information sharing, and create unnecessary barriers to entry for competitive and disruptive offerings.⁵⁸

39. AI will also impact IP protections afforded to data, given the importance of data to training some forms of AI and AI’s ability to generate value from big data. Big data has particular relevance in the area of health, where AI can be used to generate novel insights from clinical databases, including with respect to new uses of existing drugs and pharmacovigilance. Whether data should be “owned” as a form of property in its own right is controversial, although there does not appear to be any jurisdiction that recognizes data ownership per se. Nevertheless, data can be protected by a variety of intellectual property rights (IPRs) such as copyright, trade secret, and database protection. The extent to which data and its use by AI can be protected by these IPRs varies by jurisdiction. For example, Japan was the first country to explicitly exempt text and data mining (TDM) from copyright infringement. TDM may involve the use of AI techniques to analyze data for useful information, and usually requires copying of data that may have copyright. Unlike many subsequent jurisdictions that have developed TDM exceptions, Japan’s exception applies to both commercial and non-commercial uses.⁵⁹ More broadly, in addition to intellectual property laws, a host of laws such as the GDPR in the EU impact data governance. Privacy is of particular concern with health-related big data where there is a risk of disclosure and of reidentification of deidentified data.

40. Another major issue with AI and IP involves the subsistence of IPRs in works generated by AI without a traditional human creator.⁶⁰ For example, because most jurisdictions require the existence of an author or inventor for copyright or patent protection, it is not clear whether the absence of a human author or inventor (AI-generated works) would prohibit IPRs for AI output. There have been claims of AI-generated works for decades, but relatively little attention has been paid to this phenomenon legally.

⁵⁸ F Abbott, T Cottier, F Gurry, *International Intellectual Property in an Integrated World Economy*, 4th ed., Kluwer/Aspen Publishers 2019.

⁵⁹ Future TDM, *Baseline Report of Policies and Barriers of TDM in Europe*, https://www.futuretdm.eu/wp-content/uploads/FutureTDM_D3.3-Baseline-Report-of-Policies-and-Barriers-of-TDM-in-Europe-1.pdf.

⁶⁰ R Abbott, “I Think, Therefore I Invent: Creative Computers and the Future of Patent Law”, 57 *B.C. L. REV.* 1079 (2016).

41. In 1988, the United Kingdom was the first jurisdiction to adopt a copyright law to deal with AI-generated works. The Copyright, Designs and Patents Act 1998 (CDPA) deems the “person by whom the arrangement necessary for the creation of the work are undertaken”⁶¹ as the author and the work receives protection for a limited term—50 years. A similar scheme exists with respect to design rights. By contrast, the US Copyright Office has operated a Human Authorship Requirement since 1973 that prohibits the registration of “works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human author.”⁶² Neither jurisdiction has a law or policy specifically about an AI-generated invention.

42. The growing involvement of AI in the inventive process, whether augmenting human researchers or automating invention, has resulted in considerable discussion in institutional, industrial, and academic circles. For example, both the USPTO and WIPO in late 2019 issued requests for comments for new policies on AI and IP.⁶³ The impact of AI on substantive IP law will be significant, and also impacts issues such as patentability criteria (inventive step, novelty, and industrial application) and infringement.⁶⁴ This is of particular relevance to health given the increasingly important role played by AI in both R&D and clinical care.⁶⁵

43. In the area of administration of IP, the work of IP offices experiences a process of modernization and optimization thanks to AI technical applications. For example, WIPO has recently opened an AI division focused on the use of AI by patent offices.⁶⁶ Enforcement related norms and institutions also experience an important change, in particular in areas relating to border and civil enforcement. In this last respect, the necessity to enable collaboration instead of exclusion of multilayered, interconnected and patented technologies -think for instance about a medical device- makes it doubtful that IP remedies, notably injunctions, should maintain exclusion and not compensation as its main objective.⁶⁷

44. For instance, any invention the commercial exploitation of which would be contrary to ‘ordre public’ or morality is excluded from patentability. The purpose of this rejection is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behavior.⁶⁸ In the same way algorithms have already been designed to predict whether a patent will be

⁶¹ CDPA, s 9(3).

⁶² Compendium of US Copyright Office Practices, s 306, s 312.2, <https://www.copyright.gov/comp3/chap300/ch300-copyrightable-authorship.pdf>.

⁶³ <https://www.federalregister.gov/documents/2019/09/30/2019-21190/request-for-comments-on-patenting-artificial-intelligence-inventions>; <https://www.wipo.int/about-ip/en/artificial-intelligence/call-for-comments/wipo-ai-ip-call-for-submissions.pdf>.

⁶⁴ R Abbott, *Everything is Obvious*, 66 *UCLA. L. REV.* 2 (2019).

⁶⁵ See F Properzi et al, *Intelligent drug discovery Powered by AI*, Deloitte, 2019.

⁶⁶ https://www.wipo.int/about-wipo/en/activities_by_unit/index.jsp?id=1030

⁶⁷ X Seuba, “Global trade flows, big data and customs enforcement of intellectual property rights”, M Burri (Ed.), *Big Data and Global Trade Law*, Cambridge University Press, 2020.

⁶⁸ EPO, Guidelines for examination, Matter contrary to "ordre public" or morality, available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm (accessed January 2020).

issued⁶⁹ or whether it will be invalidated,⁷⁰ and patent offices have already started to deploy machine learning in the area of prior art search and classification,⁷¹ it is also possible that at some point algorithms are to be placed in the position to decide whether an invention abides to ‘ordre public’ or morality.

D. Conclusions

45. AI/ML has potential to accelerate improvement of health outcomes. While proposals have been made to “enable the community to share specific parameters without disclosing proprietary information”,⁷² the relevance of such information requires systemic and structural approaches.

46. Preparing data sets that have been curated and are of high-quality needs investment, thus it has been recommended to set up pre-competitive consortia of private and public institutions to meet these data demands, develop shared and federated data resources and metadata, collaboration to aggregate and generate large data resources of corporate and non-corporate bioactive data sets of investigational compounds and historic clinical test data.⁷³

47. International law may need to ensure individual access to justice. An international AI ombudsman could handle individual complaints associated with the use/misuse of AI. Such an oversight structure, eventually within the United Nations, should have the power and the resources to look at all models used to support decision making. Legal and ethical oversight is needed thus unreliable predictions could cause more harm than benefit in guiding clinical decisions if the relevant algorithms have been trained with unfit and insufficient data.

48. AI plays a vital role in both life sciences R&D and in the provision of clinical services. For AI to provide the most social benefit, it is critical for appropriate IP frameworks to be in place. Determining what the appropriate frameworks are is a complex and often controversial matter, and requires input from a broad range of stakeholders, including regulators, public health professionals, industry, academics, and non-profits. There is an important role also for multilateral efforts, recognizing that national situations differ and that what is right for one jurisdiction may not be right for another. Recent efforts by WIPO and by the USPTO to solicit public comments on issues associated with AI and IP are a positive development in this respect. More national offices should be pursuing similar efforts with a focus on national impact, and there is a need for more research and consultation with professional

⁶⁹ R Lee, M Torres, “Predicting Patent Outcomes with Text and Attributes”, CS230: Deep Learning, Winter 2018, Stanford University, CA, 2019, available at [cs230.stanford.edu > projects_spring_2019](http://cs230.stanford.edu/projects_spring_2019) (accessed January 2020).

⁷⁰ D Winer, “Predicting Bad Patents: Employing Machine Learning to Predict Post-Grant Review Outcomes for US Patents”, Technical Report No. UCB/EECS-2017-60, May 11, 2017, available at <http://www2.eecs.berkeley.edu/Pubs/TechRpts/2017/EECS-2017-60.html> (accessed January 2020).

⁷¹ AK Rai, “Machine Learning at the Patent Office: Lessons for Patents and Administrative Law”, *Iowa Law Review*, Vol. 104, 2019, p. 2617.

⁷² See the examples of Salt Knowledge Share Consortium, EU Innovative Medicines Initiative projects and the ATOM Consortium’s projects at P. Schenider, op. cit.

⁷³ J Vamathevan, et al, op. cit., pp. 475-476.

bodies. This issue should also be taken up in the context of the WHO/WTO/WIPO trilateral collaboration.

49. Ultimately, IP frameworks should incentivize the use and development of AI-based goods and services in the life sciences, while at the same time not inhibiting access. Clear rules are needed to provide guidance to both industry and consumers, and clarity is also needed with respect to how those rules interact with issues such as consumer privacy, data governance, and public health. In light of the close connection between patents and regulatory exclusivities, and the relevance for research purposes of health data found in pharmaceutical dossiers, it may be worth considering the development of a test and data mining exception applicable wherever regulatory test data protection impedes access to data.

III. Access to Medicines Policy Options

A. Investment in Research and Development

50. As the scientific process of developing new drugs is mired with uncertainty, there is no full guarantee of reaching expected outcomes at the initial stage of research.⁷⁴ The pharmaceutical sector is a particular example, since the overall process from setup to regulatory approval lasts ten years on average.⁷⁵ Investing in research thus entails a degree of risk-taking. The prospect of obtaining patent protection is one way through which an incentive is granted. Assuming these economic incentives are present, it still leaves open the question of where investments are undertaken and by whom.

51. In light of cost-benefit calculus, private investments in research will be mostly oriented towards areas with a higher likelihood of success. An initial bottleneck in research and development is found in the distinction between basic research, on one hand, and applied research, on the other. Basic research aims at the production of knowledge in general regardless of its application. Applied research, in turn, also aims towards acquiring new knowledge, but directed at a specific aim or objective.⁷⁶ Due to its reduced potential for profitability, basic research is rarely funded by the private sector.⁷⁷ Instead, existing regulatory models of patent protection provide incentives to invest in safer options, leading *inter alia* to the development of new drugs which have multiple similar traits to existing ones.⁷⁸ The public sector often assumes the costs of the riskier side of research.⁷⁹ Further steps by states in order to improve access could involve taking public funding in early research stages into account in drug pricing, and not just the phase directly leading to the patent protection.⁸⁰

⁷⁴ Organization for Economic Cooperation and Development, *Frascati Manual 2015. Guidelines for Collecting and Reporting Data on Research and Experimental Development*, 47.

⁷⁵ United Nations Industrial Development Organization, *Emerging trends in global manufacturing industries*, 2013, 40.

⁷⁶ Definitions found in *ibid.*

⁷⁷ Stuart Schweitzer and Z. John Lu, *Pharmaceutical Economics and Policy*. Third Edition, Oxford University Press, 2018, 39.

⁷⁸ Also known as “me too” drugs. Ellen t’Hoen, *The Global Politics of Pharmaceutical Monopoly Power*, AMB Publishers, 2009, 87.

⁷⁹ UNITAID/World Health Organization, *An economic perspective on delinking the cost of R&D from the price of medicines*, Discussion paper, 2016, 13.

⁸⁰ Lancet Commission on Essential Medicines Policies (Veronika Wirtz, Hans Hogerzeil, Andrew Gray et al), *Essential medicines for universal health coverage* (2017), 389 *The Lancet* 389, 454.

52. The scientific process is not necessarily linear, since basic research may not always lead to any future application. However, there are notable instances where it does.⁸¹ Publicly funded basic research may be used afterwards by the private sector to engage in applied research.

53. From a business perspective, patent-protection is a goal in itself in order to yield returns. Investment in research may be shaped by the requirements of regulatory agencies for granting patent rights and marketing authorization. Even if research eventually leads to regulatory approval for marketing a drug, the subsequent manufacturing process may not always be able to meet demand in countries where purchasing power is generally low.

54. Against this backdrop, the World Health Organization (WHO) approved in 2008 the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA).⁸² The elements of the GSPA were more recently reinstated at the 61st World Health Assembly in 2018.⁸³ Its implementation is ongoing and scheduled to be reviewed again in 2022. Notably, the GSPA recognized the need for states to support both basic and applied research, as well as de-linking research and development costs from drug pricing.⁸⁴ The latter also sets a goal of creating economic incentives for under-researched diseases. The need for public policies providing for alternative funding schemes for research and development has been stated elsewhere.⁸⁵

55. Guaranteeing access to good quality medicines raises huge challenges on the part of States. In terms of availability and affordability, the high prices of drugs cause barriers to treatment, as well as the lack of research and development for treatments that are not considered profitable by the industry.⁸⁶ In terms of quality, poor-quality medicines present a serious public health problem, particularly in emerging economies and developing countries,⁸⁷ while WHO reports growing threats from substandard and falsified medicines.⁸⁸

B. Transparency in Drug Pricing

56. The need to achieve an equilibrium between affordable drug prices and incentives to innovation underlies the discussions on fair drug pricing.⁸⁹ typically, depending on the healthcare system, patent

⁸¹ E.g. the discovery of the double helix DNA structure and the sequencing of the human genome, leading to countless medical products. Bhanu Neupane, A more developmental approach to science, UNESCO Science Report. Towards 2030, second revised edition, 2016, 6.

⁸² World Health Assembly, Global strategy and plan of action on public health, innovation, and intellectual property, Resolution WHA 61.21, 2008.

⁸³ World Health Assembly, Global strategy and plan of action on public health, innovation and intellectual property: overall programme review, Decision WHA 71(9), 2018.

⁸⁴ World Health Assembly, para. 4.

⁸⁵ Lancet Commission, 452-454, below n. 86.

⁸⁶ Lancet Commission on Essential Medicines Policies (Wirtz VJ, Hogerzeil HV, Gray AL, et al.), Essential medicines for universal health coverage. The Lancet. 2017 Feb 3;389(10067):403-76. See also Ellen F.M. 't Hoen, TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, ANRS Collection Sciences Sociales et Sida, Le Publieur, 2003; 39-69.

⁸⁷ E.g. A. Johnston A and D.W. Holt, Substandard drugs: a potential crisis for public health. Br J Clin Pharmacol. 2014;78(2):218-243. doi:10.1111/bcp.12298.

⁸⁸ WHO, see <https://www.who.int/bulletin/volumes/88/4/10-020410/en/>.

⁸⁹ Maria Angelica Borges dos Santos et al, Factors influencing pharmaceutical pricing – a scoping review of academic literature in health science (2019), 12 Journal of Pharmaceutical Policy and Practice 1.

holders may set prices either by negotiating with public authorities or with private healthcare providers. Alternatively, governments regulate the price of drugs more directly, such as by establishing price ceilings through reference pricing.

57. Negotiations related to drug pricing often do not include information on how much of the costs derived from public financing. Under the concept of “business confidential/sensitive information”, pharmaceutical companies are able to maintain non-disclosure of certain items. As a result, full information on the relationship between production costs and pricing is not available to the public at large. In universalized and single-buyer healthcare systems where prices are directly negotiated with suppliers (i.e. pharmaceutical companies), the non-disclosure leads to asymmetry of information. However, it has also been argued more transparency might not necessarily lead to lower prices by itself.⁹⁰

58. A draft resolution at the World Health Assembly of 2019, presented by the government of Italy, aimed at promoting transparency in drug pricing. However, the resolution was revised after a refusal by the representatives of other Member States. In particular, the paragraph on transparency of R&D cost met resistance from some high-income countries. The resulting resolution toned down the initial wording. At the same time, it led to the dissociation by countries such as Germany, Hungary and the United Kingdom.

59. Debates on what degree of transparency would guarantee fair pricing are still open, namely regarding exactly which elements should be considered to be commercially sensitive material, thus remaining undisclosed.⁹¹

C. Beyond Compulsory Licensing: Strengthening Manufacturing Capacity

60. Compulsory licensing, as provided in Article 31 of the TRIPS Agreement, can be an essential tool in lifting barriers to accessing data. Yet even in non-compulsory license settings, patent-holders of pharmaceutical products, such as medicines, are not necessarily end producers. Some companies invest mostly in research in order to obtain patent protection. Afterwards, they may sell the licensing rights to other companies for manufacturing purposes.⁹² This is also because only a handful of companies possess the capacity to produce sufficient drugs in order to satisfy demand.⁹³

61. Thus, granting a compulsory license, while overcoming an initial regulatory barrier, needs to be coupled with a manufacturing capacity. Most low-income countries without a considerable presence of local drug manufacturing capacity will depend on foreign companies to meet supply requirements. This logic was expressly incorporated in Article 31bis of the TRIPS Agreement,⁹⁴ as entered into force on 23 January 2017. From the adoption of this solution as a waiver on 20 August 2003 question has been

⁹⁰ Lancet Commission, 424.

⁹¹ Brendan Shaw and Jorge Mestre Ferrandiz, *Talking About a Resolution: Issues in the Push for Greater Transparency of Medicine Prices (2020)*, 38 *PharmacoEconomics*, 130.

⁹² On this business model, Christopher Cotropia, *The Folly of Early Filing in Patent Law (2009)*, 61 *Hastings Law Journal* 65, 67-68.

⁹³ Rick Mullin, *COVID-19 is reshaping the pharmaceutical supply chain (2020)*, 98 *Chemical and Engineering News*, <https://cen.acs.org/business/outsourcing/COVID-19-reshaping-pharmaceutical-supply/98/i16>.

⁹⁴ Frederick Abbott & Jerome Reichman, *The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions (2007)*, 10 *Journal of International Economic Law* 921, 939-942.

raised whether it adequately addresses the circumstances of countries without adequate manufacturing capacity.

62. The challenge remains how to foster either the creation of local pharmaceutical capacity, or to provide incentives for foreign manufacturers to establish subsidiaries in countries with little to no capacity.⁹⁵ Such developments are needed for fulfilling the potential provided by the removal of regulatory barriers of patent protection. Yet overall trends in industrial policies related to the pharmaceutical sector do not show this is currently the case. Moreover, in extraordinary situations where demand will be overwhelming, as is the case with potential vaccines and antivirals for COVID-19, countries with higher purchasing power and national drug manufacturing capacities will have prioritization. The immense global demand is projected to create a strain for even the most developed economies. The major existing concern is that the impact of a limited access to new medicines for COVID-19 will likely be much more dire in low- and middle-income countries.

D. Safeguarding access to essential medicines during public health emergencies

63. Given the nature of pharmaceutical innovation as a global public good, the question of how to strike a balance between the private interests of producers and those of access to the public at large comes to the fore. There is a constant tension between human rights-based public health goals, on one hand, and international norms for the protection of intellectual property, on the other hand. At the outset, the right to health includes the obligation to develop general plans of immunization for disease control.⁹⁶ This obligation could be interpreted as having both an individual and a collective dimension, whilst keeping in mind they are not mutually exclusive. In addition, the element of availability in the right to health includes “the provision of essential medicines”.⁹⁷ The formulation inserts a direct cross-reference to the WHO’s Model List of Essential Medicines. Although most of the medications in the list are not patent protected, the potential for clashes with the intellectual property regime is present and likely to increase because new medicines, including for non-communicable diseases such as cancer, are added to the list.

64. In light of the ongoing COVID-19 pandemic, emergency declarations are proliferating around the globe. The race between multiple pharmaceutical companies for developing a vaccine and antiviral medications has led to a geopolitical contest where states’ national interests are at the forefront. Moreover, questions related to states’ obligations to guarantee access to medicines for COVID-19, if and when they are available, will depend to a high degree on the capacity to find manufacturers. Past experiences with the 2009 H1N1 influenza pandemic showed how certain states may rely upon advance purchase agreements (APA) with manufacturers in order to secure priority access. The two pandemics are not comparable in terms of both magnitude and of the existing pharmaceutical production chain. It nevertheless serves as a comparative framework for different policy strategies.

⁹⁵ Ibid, 975-976; World Health Organization, *Local Production and Access to Medicines in Low- and Middle-Income Countries. A literature review and critical analysis*, 2011, 2.

⁹⁶ Article 12 (2)(c) International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) and UN Committee on Economic, Social and Cultural Rights (CESCR), *The Right to the Highest Attainable Standard of Health*, UN General Comment No 14 (2000), UN Doc E/C12/200/4, 11 August 2000, para 36.

⁹⁷ General Comment 14, para 43 under (d).

65. Depending on how developments in the production and supply chain take place, the resulting vaccination and antiviral medications may be subjected to a series of intellectual property protections, namely through patents. This will allow a patent-holder to either have exclusivity over the production of the vaccine, or to grant a third-party the rights to manufacture and distribute the medicine. The protection of intellectual property rights related to medicines take place both at the international and the national levels. On 29 May 2020, the WHO established the Covid-19 Technology Access Pool to facilitate the voluntary sharing of IP, data and knowledge related to therapeutics, diagnostics and vaccines needed in the response to the Covid-19 outbreak.⁹⁸

66. Both the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Paris Convention for the Protection of Industrial Property are directly at stake in international law issues of pharmaceutical patents. The TRIPS Agreement falls under the concept of single undertakings, entailing that all WTO Members - currently 164 - accept the covered agreements. As a result, the domestic patent regimes of all WTO Members must comply with the contents of the TRIPS Agreement and integrated instruments, although least developed WTO Members have been granted extensions with respect to IP obligations in general, and with respect to pharmaceutical patents more specifically.

67. The dichotomy between obligations under the right to health and intellectual property led to the adoption in 2001 of the Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration"), which principally affirmed flexibilities provided for by the TRIPS Agreement. Some of these flexibilities relate to Articles 30 and 31 TRIPS Agreement, which provide for exceptions to obligations by states to protect patent rights. Article 31 specifically allows for the grant of compulsory patent licenses, including government use licenses, to producers other than the patent-holders without the latter's authorization, effectively lifting the existing patent protection. Article 31 of the TRIPS Agreement allows for the export of a non-predominant part of production under compulsory license. Addressing an issue deferred by Paragraph 6 of the 2001 Doha Declaration, WTO Members adopted a 2003 waiver that in 2005 was transformed into Article 31*bis* of the TRIPS Agreement (an amendment that entered into force in 2017 for the Members accepting it, with others remaining subject to the 30 August 2003 waiver). Article 31*bis* provides flexibility for Members to issue compulsory patent licenses predominantly for the export of pharmaceutical products to countries lacking adequate manufacturing capacity.

68. Lifting the protection provided by patent law may not be sufficient in itself to enhance access. The existing global disparity in production capacities needs to be taken into account. If a certain country aiming to issue compulsory licensing does not find a manufacturer with the possibility and willingness to undertake required production, the issue of authorization is moot. The underlying economic context in least-developed and developing countries, where there is a limited presence of local pharmaceutical manufacturers, may yet hamper a broader access to essential medicines in emergency settings notwithstanding the extension of TRIPS Agreement flexibilities.

⁹⁸ See <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>.

69. Questions on whether and how compulsory licensing may contribute to enhance access are apposite in light of the ongoing 2019-2020 coronavirus (SARS-CoV2) pandemic. At the moment of writing, the race for the development of an effective vaccine has already begun. The future pharmaceutical product(s) will need to undergo clinical trials before achieving marketing authorization by regulatory bodies and the ensuing patent protection. Estimations on the potential duration until the final outcome vary. At this point, it is already possible to assert that a pandemic caused by a novel infectious agent fits the definition of public health emergency for the purposes of the Doha Declaration and Article 31bis of the TRIPS Agreement. The patent protection granted to future pharmaceutical products for coronavirus will become a matter of concern not only for developing countries, but also for the international community of states as a whole.

E. Data Exclusivity

70. Assuring efficacy, safety and quality of medicines, be it innovative products or generic medicines is an important public service meant to protect consumers and patients. This service is performed by national or regional medicines regulatory agencies, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), using the data that is submitted to them by companies that seek to obtain a marketing authorisation for a new medicinal product.

71. Medicines regulatory agencies require drug companies to submit test data that show efficacy, safety and quality of a new medicines they want to put on the market. Generating such data can be time-consuming and costly particularly when it involves a new chemical entity. Therefore, test data is often protected from use by others than the originator.

72. Data exclusivity means that the use of the test data is exclusive to the originator company for a certain period of time. In practical terms this means that during the data exclusivity period, a generic version of the product cannot be registered by the regulatory agency.

73. The data exclusivity was first introduced in the US in 1984 with the adoption of the "*Drug Price Competition and Patent Term Restoration Act of 1984*," also known as the "*Hatch-Waxman Amendments*". The act provided several types of exclusivities to innovators, in addition to patents, as a trade-off for provisions to make market entry of generics easier and quicker.⁹⁹ The US provides five years of exclusivity for small molecule new chemical entities, three years for a new indication of a previously approved medicine and four years for biologics (complemented by a parallel 12-year market exclusivity).¹⁰⁰

74. The EU introduced data exclusivity in 1987. Directive 87/21/EEC initially provided for six years of data exclusivity for most medicines from the first marketing approval and ten years for biotech

⁹⁹ <https://pdfs.semanticscholar.org/2fdb/0784f6fb314cf99063933cb6bfbfae6a7091.pdf>.

¹⁰⁰ In 2009, the US Federal Trade Commission (FTC) concluded that a lengthy exclusivity period (12 to 14 years) is unnecessary to promote innovation by biologic drug manufacturers. The FTC considered existing incentives (patents and market-based pricing) to be sufficient to support biologic innovation. See: U.S. Federal Trade Commission, 'Emerging Health Care Issues: Follow-on Biologic Drug Competition' (FTC, June 2009), <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

products. Member states could extend data exclusivity to 10 years if they considered this was “in the interest of public health.” In 2004 the EU data exclusivity rules were further harmonised and extended to eight years of data exclusivity, plus two years market exclusivity during which generic companies can prepare and apply for their marketing approval but not market the product. An additional one year of market exclusivity can be obtained by the originator company for a new indication with significant added clinical benefit. The new EU exclusivity regime became known as the 8+2+1 rule and is globally the most generous.¹⁰¹

1. Rationale

75. The rationale behind data exclusivity is similar to the rationale behind patents and other pharmaceutical market exclusivities such as those provided in the orphan drug act: the assumption that the protection of the research and development investments companies make by providing exclusive rights, stimulates innovation.

76. There are, however, important differences with patents. For example, data exclusivity is granted automatically and enforced through the regulatory system. The holders of the rights, mostly drug companies, do not have to apply or provide evidence of eligibility. Data exclusivity rights exist independently of patents, can overlap with patents and can also exist where patents do not. Data exclusivity is also different from patents in that there is no international obligation to provide data exclusivity.

2. WTO and data protection

77. The World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)¹⁰², contains an obligation of WTO members to protect certain kinds of test data against unfair commercial use. TRIPS Article 39(3) requires the following from WTO members:

1. To protect data on new chemical entities, the collection of which involved considerable effort, against unfair commercial use;
2. To protect such data against disclosure, except where necessary to protect the public;
3. To protect such data against disclosure, unless steps are taken to ensure that the data is protected against unfair commercial use.

78. The WTO rule does not establish the obligation to provide exclusive rights to the use of the data and does not create new IP rights.¹⁰³ It also does not preclude the use of the data for the approval of a product, which, as some have argued, does not fall within the definition of 'unfair commercial use'.¹⁰⁴ The obligation to protect undisclosed data does not yet apply to least developed country members (LDCs) of the WTO.¹⁰⁵

¹⁰¹ Directive 2004/27/EC on the Community code relating to medicinal products for human use [2004] OJ L136/34.

¹⁰² WTO TRIPS Agreement, Article 39.3.

¹⁰³ <http://www.iphandbook.org/handbook/ch04/p09>

¹⁰⁴ Jerome H Reichman 'The International Legal Status of Undisclosed Clinical Trials Data: From Private to Public Goods?' (2009) 13 Marquette Intellectual Property L Rev 17.

¹⁰⁵ World Trade Organization IP/C/73.

3. Data exclusivity in free trade agreements (FTAs)

79. Both the US and the EU seek, in trade agreements, including in WTO accession agreements introduction or expansion of data exclusivity from their trading parties. However, there has been recent roll back of data exclusivity in FTAs. In 2018, after the withdrawal of the US, the 11 remaining parties to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP, formerly the TPP) suspended parts of the IP chapter that include various market exclusivity obligations. The US-Mexico-Canada Agreement (USMCA) initially contained five-year exclusivity for small molecules, three years for new clinical information - which refers to the new use of a known medicine and 10-year exclusivity for biologics. In 2019, driven by the debate on high drug prices in the US, the provision for 10-year exclusivity for biologics was removed from the USMCA.

4. Data exclusivity and TRIPS flexibilities

80. Data exclusivity can form a barrier to effective use of flexibilities in patent law, in particular compulsory licensing or government use of medicines patents. This was recognised in the New Trade Policy in the US (2007) which authorized a public health exception to data/market exclusivity in the event of a compulsory licence or other public health need. Implementation flexibility to that effect was included in several US developing-country free-trade agreements (FTA), including FTAs with Colombia, Panama, and Peru.

81. Some countries have introduced waivers to data exclusivity in their law that can be invoked in case of a compulsory license. Countries that have data exclusivity waivers include Malaysia, Chili and Colombia.¹⁰⁶

82. In the EU, a waiver to data exclusivity is only foreseen in cases of compulsory licensing for manufacturing a product for export outside the EU but not to enable effective use of compulsory licensing or other measures to protect public health.^{107 108} Even in case of an urgent need or an emergency situation, the EU law does not provide a safety valve to data exclusivity to allow registration of a competitor product.¹⁰⁹

5. Conclusion and recommendations

¹⁰⁶ Ellen FM 't Hoen, Pascale Boulet, and Brook K Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation (2017) 10 JOPPP. DOI: [10.1186/s40545-017-0107-9](https://doi.org/10.1186/s40545-017-0107-9).

¹⁰⁷ Regulation 816/2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems [2006] OJ L157/1.

¹⁰⁸ This regulation implements the WTO 'August 30, 2003 decision', which provided a waiver to the TRIPS Article 31(f) requirement that production under a compulsory licence be predominantly for the domestic market. This restriction hampered the use of compulsory licensing by countries that were dependent on the importation of medicines. The 30 August 2003 waiver became a permanent amendment of the TRIPS Agreement in 2017 (see: WTO, 'WTO Members Welcome Entry Into Force of Amendment to Ease Access to Medicines' (30 January 2017) <https://www.wto.org/english/news_e/news17_e/heal_30jan17_e.htm>).

¹⁰⁹ European Commission, 'Letter from the European Commission to Mr Greg Perry, EGA-European Generic Medicines Association on the subject of Tamiflu application and data exclusivity in an emergency compulsory license situation' (Brussels, 2006).

83. Since data is becoming more important for the commercial sector as a source for new therapy development, safeguards to ensure that data remains available for legitimate public health functions including the assessment of efficacy and safety of needed products are important.

84. Countries should consider replacing the data exclusivity regime with a data protection regime that acknowledges the investment made to generate data but does not allow the investor to exclude others from using the data. The TRIPS Agreement leaves much flexibility for WTO members to design data protection regimes and such a *data compensation regime*. Under a *data compensation regime*, the registration of a generic medicine or biosimilar medicine is considered fair commercial use. The originator company that made the investment that was needed to generate the data will receive adequate remuneration for the use of the data but cannot prevent its necessary use by the medicines agency to perform its public health duties.

85. Countries should have the option to use waivers to data exclusivity for effective use of measures to protect public health and making needed treatments available to all. Further it would be useful if the WTO TRIPS Council offers a clarification that Article 39.3 of the TRIPS Agreement does not constitute the obligation to provide data exclusivity.

F. Using Competition Law to Promote Access to Medicines

1. Anticompetitive Abuse in the Pharmaceutical Sector

86. Over the past two decades competition law has been increasingly used as an instrument to promote equitable access to medicines. The purpose of competition law is to defend, restore and maintain the integrity of markets by addressing anticompetitive behavior, and to promote and protect the welfare of consumers by taking action against abusive economic conduct.¹¹⁰

87. There is a wide range of anticompetitive practices that can and do take place with respect to pharmaceuticals, and health products and services more generally. These include practices involving agreements between undertakings, and abusive practices engaged in by a dominant actor in a relevant market.

88. Anticompetitive agreements between undertakings involve matters such as price-fixing, output restraints and geographic allocations of territory. Abuse of dominant position involves matters such as the imposition of oppressive selling or licensing conditions, refusals to deal and excessive pricing.

89. In the pharmaceutical market, a significant amount of enforcement activity has addressed efforts by patent owners to unfairly foreclose entry of generic products onto the market, for example, by paying generic producers to drop patent infringement challenges that would otherwise allow early market entry.¹¹¹ Competition authorities in the European Union and the United States have prosecuted

¹¹⁰ See generally, UNDP, *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* (ed F. M. Abbott 2014), and *Supplement to UNDP 2014 Guidebook* (forthcoming 2020).

¹¹¹ These are often called “reverse payment” cases because the patent owner is paying an accused infringer, while in the ordinary patent enforcement case the infringer is expected to pay the patent owner. See generally, Commission, *Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector* European competition authorities working together for affordable and innovative

a substantial number of competition actions against patent-owning pharmaceutical companies for abusing patents in various ways, including by obtaining and seeking to enforce patents that should not have been granted (sometimes called “sham patent litigation”), and for extending patent terms based on false information.

90. Anticompetitive abuses in the pharmaceutical sector are by no means limited to owners of patents and other IP. Producers of generic (i.e. off-patent) pharmaceuticals are prosecuted for various types of price-fixing arrangements, such as through agreements setting the minimum selling price of products, agreements restricting the supply of products, and agreements to “rig” bidding on procurement tenders (such as those issued by government pharmaceutical purchasing agencies).

91. A major sphere of enforcement activity over the past several years has involved prosecution against “excessive pricing”. Excessive pricing is a form of abuse of dominant position in which a party that has dominance in the market for a particular drug(s) (patented or not) charges a price that is unreasonable or unfair in the circumstances. For example, a pharmaceutical company may charge a price that is not reasonably related to the economic value of the drug (as that value may be established by, e.g., the cost of producing it). When generic products are involved, the cost of production may be relatively easy to establish as the technologies involved are known. When innovative patented products are involved, determining a reasonable price is a more complicated exercise because the costs associated with research and development (R&D) must be taken into account, along with a risk premium. So far, successful competition prosecutions against pharmaceutical companies for excessive pricing have involved generic products¹¹² (although an investigation into excessive pricing regarding patented HIV drugs in South Africa resulted in a favorable settlement).

92. There is interest by competition authorities in the role that intermediaries play in the process of taking drugs from the manufacturer (originator and generic) to the patient, whether that be through wholesalers, pharmaceutical benefit managers or others. One of the principal tasks of the competition authority traditionally is conducting investigations that bring to light the way that prices are established in the marketplace. The movement for greater transparency should help in the work of the competition authority.

93. In addition, mergers and acquisitions have been used to stifle market entry in ways that have had some dramatic effects on prices and access to key medicines.

medicines (European Union 2019), <https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf>, published also with document identification Brussels, 28.1.2019 COM(2019) 17 final, https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf [hereinafter “European Commission 2019 Enforcement Report”], and; Markus H. Meier, Bradley S. Albert & Kara Monahan, Overview of FTC Actions in Pharmaceutical Products and Distribution, Health Care Division Bureau of Competition Federal Trade Commission Washington D.C., Sept. 2019, available at: https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf.

¹¹² There are several decisions on excessive pricing under appeal in the EU, in addition to those in which final decisions already have been taken. See *Aspen Italia et al. v. Italian Competition and Market Authority*, Council of State (Italy), Section Six, N. 01832 / 2020 REG.PROV.COLL., N. 08447/2017 REG.RIC., 13/03/2020, and; *Competition and Markets Authority v. Flynn and Pfizer*, Court of Appeal (Civil Division), Case No: C3/2018/1847 & 1874, Neutral Citation Number: [2020] EWCA Civ 339, date: 10/03/2020.

2. Competition law and intellectual property rights (IPRs)

94. IPRs are generally intended to promote innovation -- in the pharmaceutical arena through the development of new therapeutic treatments -- by offering a reward to the innovator in the form of a protected market position for a limited duration. By their nature IPRs are exclusionary and tend to limit access because they provide the basis for maintaining supra-competitive prices.

95. Debate concerning the proper balance between IPRs protection and access to medicines has gone on for a long time, and the push and pull in favor of one preference or another appears likely to continue for the indefinite future. National governments are torn between interests in pursuing industrial policies (e.g., championing home-based pharmaceutical originators) and assuring equitable access to medicines for individuals at home and abroad.

96. Competition law is not intended to solve the policymakers' dilemma of balancing the interest in promoting innovation, on one side, and establishing access, on the other. What competition law is intended to do is make sure that the ground rules established for participating in the pharmaceutical market are not abused. Exactly what constitutes abusive conduct or conduct taking unfair advantage is not answered the same way across national (or regional) jurisdictions, nor is it prescribed in a specific way by international law. On the other hand, international law does mandate, mainly through rules established at the WTO (including the TRIPS Agreement), but increasingly also through rules incorporated in more geographically limited trade and investment agreements (TIAs), that national jurisdictions allow for the grant of pharmaceutical patents and comply with certain minimum standards regarding those grants. In addition, the TRIPS Agreement requires that WTO members provide certain assurances regarding potential unfair commercial use of certain regulatory data submitted to authorities, and such requirements also appear in various forms in TIAs.

97. There have been some notable trends in terms of policy concerns and ways to address them. One of the most notable involves increasing demands for "transparency" regarding the way the pharmaceutical market works.¹¹³ This interest in transparency is wide-ranging, including demands for better information regarding the costs of R&D for new drugs and delivery devices, and the way that prices are established taking account of those costs.

98. Another recent trend implicating the balance between IPRs and access to medicines involves an expansion of trade secret protection. Trade secret protection has been invoked by pharmaceutical companies to deny public access to pricing information, and this has hindered better understanding of pharmaceutical markets. A more recent trend involves use of trade secret protection to inhibit access to processes used in the production of biologic medicines, including by denying access to samples of biological materials that may be important to creating generic biological products. And, enhanced protection for trade secrets is being embedded in new trade and investment agreements and this may raise additional obstacles for competition authorities.

99. Of course, much of the protection against competition in the pharmaceutical sector is based on exclusive marketing rights granted on the basis of commercial marketing approvals from drug regulatory authorities. Again, as with patents, it is not the role of competition law to establish the appropriate period of regulatory market exclusivity (or data exclusivity). That is the role of the legislator. On the

¹¹³ See *discussion*, above at paras. 57-59.

other hand, a significant amount of anticompetitive abuse takes place in connection with drug regulatory approval processes, including by the filing of frivolous objections that slow down the work of regulators.¹¹⁴

100. The world of biological drugs brings new potential avenues of anticompetitive abuse. The regulatory pathway for introduction of biologic drugs and follow-on bio-generics is complex. When companies actively seek to improperly impede the pathway, introduction of bio-generics may be pushed back for years.

3. Competition Rules in Trade and Investment Agreements

101. Up until the past several years, many governments were reluctant to negotiate international rules on competition law. This is the result of several factors. While the European Union for a long time advocated such negotiations, the United States competition authorities resisted this to maintain flexibility with respect to domestic policy, and also out of concern over international “least common denominator” solutions. US-based multinational companies were not interested in promoting competition enforcement abroad. For a number of low- and middle-income countries (LMICs) there was interest in maintaining flexibility, including to treat locally based enterprises on a different basis than foreign enterprises with respect to competition law scrutiny. Reluctance to entertain international rules has diminished somewhat. One reason was changed perspective in the United States where concerns grew over more active enforcement by non-US competition authorities, with minimal legal basis for US pushback. As US-based companies faced increasing attention from non-US competition authorities, these companies were more inclined to view international rules as constraints on competition authorities as opposed to threats to their own behavior. But the US was not alone. The willingness to entertain international competition rules has involved a fairly broad range of countries and regions, with such rules mainly embodied in competition chapters in preferential trade and investment agreements (TIAs).¹¹⁵ The focus of the competition rules in TIAs has largely been on process or procedural matters, and cooperation among competition authorities, rather than on establishing detailed substantive rules. There remain reasons for LMICs to be cautious about accepting competition-related commitments in TIAs.¹¹⁶ LMIC competition authorities may ultimately face trade-based pressures that affect their independence and efficiency. It is relatively early days for these TIA competition chapters in terms of assessing their utility and consequences.

IV. Human Rights as a Foundation

A. States’ human rights obligations to guarantee access to medicines

¹¹⁴ In the United States, for example, originator companies have used “citizens petitions” that were designed to allow the public to bring information to the attention of the FDA as a way to delay decisions by the US FDA, and in several cases the companies have been found to have abused that mechanism.

¹¹⁵ See Robert Anderson, et al., *Competition Policy, Trade and the Global Economy: An Overview of Existing WTO Elements, Commitments in Regional Trade Agreements, Some Current Challenges and Issues for Reflection*, Dec. 5, 2019.

¹¹⁶ See Frederick M Abbott, *Let Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity*, *IIC - International Review of Intellectual Property and Competition Law*, March 2018, Volume 49, Issue 3, pp 259–266, <https://doi.org/10.1007/s40319-018-0683-5>.

102. States, as the formal parties to the human rights treaties, carry primary responsibility for guaranteeing the rights of everyone residing on their territory. Given that access to essential medicines is a core component of the right to health,¹¹⁷ States are under an obligation to guarantee the availability, accessibility, acceptability and quality ('AAAQ') of medicines.¹¹⁸ State obligations under human rights law fall into obligations to *respect*, to *protect* and to *fulfill* human rights. This tripartite typology is firmly established under international human rights law.¹¹⁹ While an obligation to 'respect' is a negative (state) obligation to refrain from action, an obligation to 'protect' is a positive (state) obligation to protect individuals from harmful acts of third parties, and the obligation to 'fulfill' is a positive (state) obligation to ensure access to or provide a certain service.

B. Vindicating the Human Right to Essential Medicines through Litigation

103. Individuals and groups have increasingly gone to court to hold governments accountable for the lack of available medicines. There are ample examples of such court cases in low- and middle-income countries, with perhaps the most extensive examples in Latin America. The main feature of health litigation in Latin America consists of plaintiffs who, acting separately and represented by private or public attorneys, use the courts to claim the provision of specific drugs or treatments. This type of litigation concentrates on the right to health downstream, when patients are already sick and have to file a lawsuit to demand access to a specific drug that is being refused by national health systems or private insurers.¹²⁰ However, this downstream approach based on litigation would be incapable of transforming the upstreaming determinants of the right to health, such as regulatory, institutional, economic, environmental, and social ones, which actually produce the violation of rights of vulnerable people.¹²¹

104. The right to health, as enshrined in General Comment 14,¹²² entails a direct link to the WHO's Model List of Essential Medicines as a starting point for ensuring access. Many domestic authorities devise their medicines policies by referring to the contents of this list.¹²³ This shows the authoritative weight of the list as a policy tool used to concretize states' obligations in the matter. In this sense, international litigation has also taken place when public authorities have not fully guaranteed the

¹¹⁷ Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14, The Right to the Highest Attainable Standard of Health, UN Doc. No. E/C.12/2000/4 ((2000), para 43 (a 'core obligation').

¹¹⁸ General Comment 14, para 12 ('AAAQ').

¹¹⁹ First introduced by Henry Shue, *Basic Rights, Subsistence, Affluence and U.S. Foreign Policy*, (New Jersey: Princeton, 1980); refined by Asbjørn Eide, 'Economic, Social and Cultural Rights as Human Rights', in Asbjørn Eide, Catarina Krause, Allan Rosas (eds.), *Economic, Social and Cultural Rights: A Textbook*, (New Jersey: Princeton, 1980), 21-41; G.J.H. van Hoof, 'The Legal Nature of Economic, Social and Cultural Rights: a Rebuttal of Some Traditional Views', in Phillip Alston and Katarina Tomaševski (eds.), *The Right to Food* (Utrecht: SIM, 1984), 97-111.

¹²⁰ Everaldo Lamprea (2017) *The judicialization of health care: a global south perspective*. *Annual Review of Law and Social Science*, v. 13, p. 431-449.

¹²¹ Paul Farmer (2003) *Pathologies of Power: Health, Human Rights, and the New War on the Poor*. Berkley: University of California Press.

¹²² Committee on Economic, Social and Cultural Rights (CESCR), *op. cit.*

¹²³ Already introduced in Global Health Law Committee (2016), *First Report*, International Law Association, Johannesburg, 7.

provision of a medication deemed to be essential.¹²⁴ At the regional level, the Inter-American Court of Human Rights referred to the list of essential medicines as part of a directly actionable right to health, particularly regarding antiretroviral drugs for HIV/AIDS.¹²⁵ It is, to this date, the only example of a direct justiciability of the right to health and access to medicines by a regional human rights court. The European and African counterparts have so far resorted to an “indirect approach”, where health is subsumed as a component of the right to life, dignity and physical integrity of persons.¹²⁶

105. At the national level, the WHO’s Model List of Essential Medicines is included as part of an overall series of policies related to basic healthcare services. While this is not a universal strategy, direct linkages may provide a basis for litigation in national courts, particularly in countries where the respect of the right to health is deployed as a direct basis for constitutional adjudication.¹²⁷

106. In India, popularly deemed as the “pharmacy of the developing world” due to its manufacturing capacity,¹²⁸ there have been landmark rulings in the field of access to medicines. The Indian Supreme Court has considered health to be a part of the constitutionally-enshrined right to life as early as in 1987, including policies aimed at enhancing the availability of drugs at reasonable prices, as derived from the WHO’s Model List of essential medicines.¹²⁹ In the same vein, failure to observe this Model List was directly cited by the Karnataka High Court as one of several grounds for striking down drug pricing policies.¹³⁰ Later, the Indian Supreme Court would also mandate through a series of orders an increase in the availability of antiretroviral treatments for HIV/AIDS.¹³¹ Given how public interest litigation in India lowers procedural requirements for standing, it has been argued that this has allowed for a broader impact of rulings on access to medicines beyond individual complainants.¹³²

¹²⁴ José Luis Cárdenas T., “Algunas reflexiones sobre judicialización y acceso a medicamentos: el caso de Brasil y México”, in Manuel Becerra Ramírez and Roberto Martínez Olivera (eds.), *Industria farmacéutica, derecho a la salud y propiedad intelectual: el reto del equilibrio*, Mexico: UNAM, 2018.

¹²⁵ IACTHR, *Caso Duque Vs Colombia. Excepciones Preliminares, Fondo, Reparaciones y Costas*. Ruling of 26 February, 2016, Serie C, No 310, para. 174; more directly, IACTHR, *Caso Cuscul Pivaral y otros vs Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas*, Ruling of 23 August, 2018, Serie C, No 359, paras. 108-114.

¹²⁶ Olasupo Owoeye, *Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access*, Abingdon, Routledge, 2019.

¹²⁷ Hans V. Hogerzeil et al, “Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts?”, in Michael Grodin (ed), *Health and Human Rights in a Changing World* (New York, Routledge, 2013), 139-150; Alicia Ely Yamin, “Taking the Right to Health Seriously” (2017), 39 *Human Rights Quarterly*, 341-368.

¹²⁸ S. Srinivasan and Malini Aisola, *Access to Pharmaceuticals. Role of State, Industry and Market*, in Purendra Prasad, Amar Jesani and Sujata Patel (eds.), *Equity and Access: Health Care Studies in India* (New Delhi, OUP, 2018), 154-156.

¹²⁹ *Vincent Panikurlangara v Union of India*, 1987 AIR 990, Judgement of 03 March 1987.

¹³⁰ *KS Gopinath v Union of India*, Karnataka High Court, 21618/2002, Judgement of 12 November 2002, para. 19.

¹³¹ *Sahara House v Union of India and others*, Writ Petitions 535 of 1998, 512 of 1999, 61 of 2003 and 311 of 2003, Order of 02 December 2013. See also Anup Surendranath, *Life and Personal Liberty*, in Sujit Choudhry, Madhav Khosla and Pratap Bhanu Mehta, *The Oxford Handbook of the Indian Constitution* (Oxford, OUP, 2016), 2016, 770.

¹³² Anand Grover, Maitreyi Misra and Lubhyathi Rangarajan, *Right to Health. Addressing Inequities through Litigation in India*, in Colleen Flood and Aeyal Gross (eds.), *The Right to Health at the Public/Private Divide. A Global Comparative Study* (New York, CUP, 2014), 449-450.

107. The South African Constitutional Court ruled, on the basis of the right to health care in the South African Constitution, that governmental restrictions to access to the antiretroviral medication nevirapine were not “reasonable”.¹³³ In Nigeria, the Federal High Court ruled that the rights of prisoners with HIV/AIDS were violated due to lack of access to medical treatment.¹³⁴ Although more limited in terms of its reach,¹³⁵ the Court based its reasoning directly on the right to health enshrined in Article 16 of the African Charter on Human and Peoples’ Rights.¹³⁶

108. The figures found especially in Colombia and Brazil are due in some extent to the low threshold to accessing courts.¹³⁷ Other Latin American countries do not present health litigation figures as high as in these two countries.¹³⁸ Nevertheless, high courts in other jurisdictions have also tackled the issue of access to medicines, notably for HIV/AIDS. The Constitutional Chamber of the Costa Rican Supreme Court of Justice issued two rulings in 1997 incorporating antiretroviral treatment as mandatory for the social security system.¹³⁹ This court’s legal grounds included several international human rights treaties.¹⁴⁰ Similarly, when ruling on access to healthcare, the Mexican Supreme Court included the provision of antiretrovirals in the national equivalent to the List of Essential Medicines, as part and parcel of the constitutionally enshrined right to health.¹⁴¹

109. The major part of expenditure with health litigation in Colombia and Brazil is invested in paying for costly drugs, leading some authors to call this the “pharmaceuticalization” of health rights

¹³³ Minister of Health et al. v. Treatment Action Campaign et al, Constitutional Court of South Africa, Case CCT 8/02, Judgement of July, 2002, paras 34-36 and Order of the Court. See also Hurst Hannum, Dina Shelton, James Anaya and Rosa Celorio, *International Human Rights. Problems of Law, Policy, and Practice*, 6th Edition, New York, Wolters Kluwer, 2018, 539-540.

¹³⁴ Festus Odefe and Others v Attorney-General and Others, Federal High Court of Nigeria, Port Hartcourt judicial division, Suit FHC/PH/CS/680/2003, Decision of 23 February 2004.

¹³⁵ Failure by the Nigerian Supreme Court in this decision to condemn discrimination of persons infected with HIV/AIDS is criticized in Ebenezer Durojaye, *Discrimination based on HIV/AIDS: A comparative analysis of the Nigerian court’s decision in Festus Odaife & Ors v Attorney General of the Federation & Ors with other Commonwealth jurisdictions* (2007), 11 *Law, Democracy and Development*, 150.

¹³⁶ Remigius N Nwabueze, *The Legal Protection and Enforcement of Health Rights in Nigeria*, in Colleen Flood and Aeyal Gross, (eds.), *op. cit.*, 391.

¹³⁷ 3,289 in Colombia and 206 in Brazil/ lawsuits per one million individuals Ottar Mæstad, Lise Rakner and Octavio L. Motta Ferraz (2011), *op. cit.*

¹³⁸ In Chile, the Supreme Court has interpreted in a restrictive way, arguing with the constitution’s lack of explicit mention of an enforceable right to health and thus barring the litigation and adjudication of health rights, including access to medicines. Jorge Contesse; Domingo Lovera Parmo (2008) *Acesso a tratamento médico para pessoas vivendo com HIV/AIDS: êxitos sem vitória no Chile*. *Sur, Rev. int. direitos human.* vol.5 n.8, pp. 151-169. In Mexico, the writ of amparo, used for the judicial enforcement of basic rights, presents high-opportunity costs and a technical intricacy of the procedural arguments which contrast with the particularly easy access to courts for litigants in Colombia and Brazil. Everaldo Lamprea (2017), *op. cit.*

¹³⁹ Luis Guillermo Murillo Rodríguez et al v Caja Costarricense de Seguro Social, Sala Constitucional, Decisión 6096-97, 1997; William García Álvarez v Caja Costarricense de Seguro Social, Decisión 5934-97, 1997.

¹⁴⁰ Canadian HIV/AIDS Legal Network/UNAIDS, *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV*, 2006, 55-56; Hans Hogerzeil et al, *op. cit.*, 146.

litigation.¹⁴² In a similar vein, some authors have argued that in Colombia a collusion between pharmaceutical companies, doctors and judges has led to the judicial concession of expensive drugs.¹⁴³ Moreover, some pharmaceutical companies in this country have given financial incentives for doctors or health providers to use branded drugs in the place of generics.¹⁴⁴

110. This scenario of intensive health rights litigiousness has led countries as Brazil and Colombia to implement strategies aimed at containing litigation. These strategies included, in Brazil, new forms of dialogue between the Judiciary and the Executive powers and the implementation and improvement of health technology assessment processes.¹⁴⁵ In Colombia, by contrast, the adoption of Law 1751 of 2015 has brought institutional changes to the health system, as the government had to design a new health benefit plan consistent with a set of categories of excluded medications and treatments that the health system is not obliged to provide to patients.¹⁴⁶

C. The responsibility to respect human rights of the pharmaceutical industry

111. UN bodies, scholars and practitioners increasingly maintain that corporations have complementary human rights responsibilities.¹⁴⁷ Given the influence that they exert over our health and wellbeing, corporations should also carry duties under international human rights law.¹⁴⁸ Specifically, it is argued that pharmaceutical corporations have a responsibility to contribute to the realization of the

¹⁴² In Brazil, for instance, the federal government spent around US\$ 519 million between 2007 and 2018 with the acquisition of one single medicine claimed by individual litigants, called eculizumab. This humanized monoclonal antibody used to treat atypical hemolytic uremic syndrome, a rare chronic blood disease, was registered with the American Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in 2007. In Brazil, Alexion Pharmaceuticals Inc. required its registration with the Brazilian Health Regulatory Agency (Anvisa) in 2015. Registration was granted in March 2017, but the incorporation by the Brazilian Health Technology Committee (CONITEC) occurred only in December 2018. This example shows how litigation can be used as a strategy to access non-registered expensive drugs. Rosângela Caetano et al. (2020) O caso do eculizumabe: judicialização e compras pelo Ministério da Saúde. *Rev Saude Publica*, vol 54, n. 22, pp. 1-11.

¹⁴³ Alicia Ely Yamin; Oscar Parra-Vera (2010) Judicial protection of the right to health in Colombia: from social demands to individual claims to public debates. *Hastings Int'l & Comp. L. Rev.*, v. 33, n. 2, pp. 101-129

¹⁴⁴ Angela Acosta et al. (2019) Judicialización del acceso a medicamentos en el contexto suramericano. *R. Dir. sanit.*, São Paulo v.20 n.1, p. 32-62, mar./jun. 2019.

¹⁴⁵ Fabiola Sulpino Vieira (2020) *Direito à saúde no Brasil: seus contornos, judicialização e a necessidade da macrojustiça*. Texto para discussão/Instituto de Pesquisa Econômica Aplicada - Brasília; Rio de Janeiro: Ipea.

¹⁴⁶ Everaldo Lamprea (2017), *op. cit.* Additionally, national authorities from Colombia previously attempted to invoke a public interest clause in order to lift patent restrictions. In 2016 the Ministry of Health issued Resolution 2475, which deemed the production of imatinib, a medication for the treatment of patients with leukemia, a matter of public interest. The purported goal was to stem the high costs of the existing patent-protected product, Glivec®, through the production of a generic brand. The policy ultimately did not lead to the issuing of a compulsory license, rather only led to a maximum-price fixation. The ensuing threats of international litigation by the pharmaceutical industry shows how this is a factor to take into account. Conde, C. (2018) El Ministerio de Salud como parte legítima para realizar oposiciones en trámites de patentes farmacéuticas: Una alternativa a las licencias obligatorias. *Innovation and Entrepreneurship*, <https://bit.ly/2Qna7jA>.

¹⁴⁷ *Inter alia*, General Comment 14, para 42.

¹⁴⁸ Brigit Toebes, 'Direct corporate human rights obligations under the right to health: from mere 'respecting' towards protecting and fulfilling', in J. Letnar Černič and T. Van Ho, *Direct Human Rights Obligations of Corporations*, The Hague: Wolf Legal Publishers, 2015, 263-278.

right to access to medicines.¹⁴⁹ An important basis for this position are the UN Guiding Principles on Business and Human Rights, developed in 2008 by former Special Representative on Business and Human Rights, John Ruggie ('Ruggie Principles').¹⁵⁰ These Guidelines were endorsed by the UN Human Rights Council in its resolution 17/4 of 16 June 2011. Generally seen as an authoritative standard, they present a three-pillar framework for corporate accountability for human rights, which includes the state duty to *protect* against human rights violations by or involving corporations; the corporate responsibility to *respect* human rights; and effective access to *remedies*.

112. It is clear that States and corporations do not have the same obligations.¹⁵¹ As mentioned above, States have legal obligations to respect, protect and fulfill human rights, which includes a legal undertaking to ensure access to good quality medicines.¹⁵² Based on the Ruggie Principles, corporations have *responsibilities* toward human rights rather than legal obligations, which suggests something less binding, potentially in the sphere of soft law. Furthermore, corporations merely have responsibilities to 'respect' human rights, and not to 'protect' and to 'fulfill' human rights.

113. According to Ruggie, respecting human rights means that, throughout their operations, businesses should 'avoid infringing on the human rights of others and should address the adverse human rights impacts with which they are involved'.¹⁵³ Yet, according to the report, 'doing no harm' is not merely a passive responsibility for firms but may entail positive steps – for example, a workplace anti-discrimination policy might require the company to adopt specific recruitment and training programmes.¹⁵⁴ The responsibility to 'respect' may thus still require positive measures.¹⁵⁵

114. Moon asserts that transparency is central to the Ruggie Principles and important for due diligence and effective remedy.¹⁵⁶ More substance to this transparency undertaking is given in the 2008 Guidelines for Pharmaceutical Companies in relation to Access to Medicines, advanced by then-UN Special Rapporteur on the Right to Health, Paul Hunt. These Guidelines contain three principles on transparency: 6) 'There is a presumption in favor of the disclosure of information, held by the company, which relates to access to medicines (...)'; 7) 'The company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines (...)'; and 8) '(...) the company should establish an independent body to consider disputes that may arise regarding

¹⁴⁹ For a thorough analysis see Suerie Moon, *Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry, Health and Human Rights*, Volume 15, No. 1, June 2013, pp. 32-43.

¹⁵⁰ J.C. Ruggie, Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, *Protect, respect and Remedy: A Framework for Business and Human Rights*, UN Doc. A/HRC/8/5 (2008). Regarding the efforts that pharmaceutical companies currently make, see also *Access to Medicines Index*, available at <http://accesstomedicinefoundation.org/>. See also the efforts of the open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights, UN Doc A/HRC/RES/26/9, 14 July 2014, with drafts for a treaty available at <https://www.ohchr.org/EN/HRBodies/HRC/WGTransCorp/Pages/IGWGOnTNC.aspx>. Accessed 8 November 2020.

¹⁵¹ Moon, 2013, p. 35.

¹⁵² See above, paras. 102-05.

¹⁵³ Ruggie's 2011 Report, para 13 (and Chapter II for the corporate responsibility to respect human rights).

¹⁵⁴ *Ibid.*, para 42.

¹⁵⁵ Moon, 2013, p. 35.

¹⁵⁶ Moon, 2013, p. 38.

the disclosure or otherwise of information relating to access to medicines'.¹⁵⁷ Clearly, these principles suggest negative as well as limited positive obligations for pharmaceutical companies to ensure that there is transparency around the development, production and sale and pricing of medicines.

115. Whether such human rights claims against the pharmaceutical industry can be adjudicated successfully in domestic courts will much depend on the nature of domestic legal systems, and on the willingness of courts to impose human rights obligations on non-state actors. Cases that have been litigated successfully can set important precedents for other potential countries in other parts of the world. A potential court case could address a lack of transparency by a pharmaceutical company about the composition of the price of a certain medicine, the cost of R&D and patenting policy.¹⁵⁸ Furthermore, expensive medicine eat up a large proportion of the overall domestic health budget, thus exerting pressure on the realization of the right to health of society at large.

V. Beyond the COVID-19 Pandemic

116. The global pandemic of 2020 will have public health, social and economic consequences for years. It should transform the way governments think about health systems. Ideally it would cause policymakers to think globally and holistically, recognizing that the welfare of people in each country is dependent on adequate safeguards in other countries. It should lead to greater cooperation in disease outbreak monitoring and the sharing of information regarding the character of infectious agents. It should promote global approaches to assuring adequate production and distribution of vaccines, treatments, diagnostics and medical equipment. It should recognize the crucial role of multilateral agencies such as the WHO in the response to infectious disease outbreaks.

117. Regrettably, the COVID-19 pandemic has not brought out the “better angels” of human nature. It raises our awareness that situations of global health emergency cannot be approached without taking into account human psychology and tendencies to react to insecurity with fear and aggression.

118. The Global Health Law Committee will continue its work toward identifying legal approaches that will promote innovation and equitable access to health products and services.

¹⁵⁷ See UNGA, sixty-third session, UN Doc A/63/263, 11 august 2008, Annex; Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.

¹⁵⁸ The WHA Transparency Resolution refers to these three elements. See Improving the transparency of markets for medicines, vaccines, and other health products, WHA72.8, 28 May 2019.

ANNEX 1

Statement of the Global Health Law Committee of the International Law Association regarding the COVID-19 pandemic

adopted by the Committee on 5 April 2020

The Global Health Law Committee of the International Law Association observes that the potential for virus-based pandemic outbreaks has long been anticipated by public-health specialists as well as by the World Health Organization (WHO). During the 2014-2016 Ebola outbreak attention was drawn to gaps in the preparedness of local health systems, to the scientific challenges of developing new treatments, vaccines and diagnostics in a sufficiently rapid manner to effectively confront large-scale virus outbreaks, and to the special difficulties confronted by low-resource environments in addressing pandemic outbreaks. In February 2015 the Committee convened a meeting on Global Health Security in Geneva at which a substantial number of interested stakeholders shared concerns about these gaps. Following detailed preparatory work, the World Health Assembly met in May 2015 and decided that additional resources should be directed toward prevention of and response to pandemic outbreaks. Although the precise contours and the magnitude of the COVID-19 outbreak could not be foreseen at that time, the potential for such an event was widely understood, as was the need for further advance investment to address it.

Taking note of the global COVID-19 pandemic, the Global Health Law Committee wishes to restate fundamental principles and rules of international law important to containing and ending the pandemic, safeguarding the rights of individuals and groups, and ultimately returning international society to a normal functioning state:

1. **Cooperation.** The Committee stresses the importance of cooperation among states and international institutions in addressing pandemic outbreaks. A pandemic outbreak is an opportunity to demonstrate the value of pooling scientific ingenuity and of open cooperation among scientists and research institutions, for coordinating logistic and manufacturing capacity, for making available the financial resources necessary to purchase and distribute necessary health products (including vaccines, diagnostics, treatments and personal protective equipment), and for attempting to assure that individuals throughout the world have access to life-sustaining support, including adequate nutrition. A pandemic outbreak is not an occasion for seeking political or economic advantage. Uncoordinated travel and trade restrictions and, more generally, the perception that states can effectively protect themselves from a pandemic in isolation or competing with other states for limited resources, are counterproductive. Actions taken on such premises threaten to destabilize the existing multilateral regime and its institutions with long-term adverse consequences. The world needs more cooperation, coordination and solidarity at this critical time. The Committee therefore welcomes the United Nations General Assembly resolution of 2 April 2020 affirming its commitment to international cooperation and multilateralism.
2. **Support to the World Health Organization.** The WHO was established in substantial measure to provide a forum where the world community could meet and agree on the processes and substantive measures necessary to address international public health emergencies. It is critical that states support the central role of WHO in addressing the COVID-19 pandemic and in preparing for and confronting future public health crises. To this end, respecting the

independence of the Secretariat and of the experts and enhancing financial support for WHO in a sustainable, predictable and flexible manner through voluntary contributions as well as a long-term increase of its assessed contributions are crucial. Even though the current state of the pandemic arguably exceeds the scope of the International Health Regulations (2005) (IHR), it still has an important role to play as the global legal framework to channel data and information and facilitate the coordination of response measures. States parties should avoid weakening the IHR through the proliferation of unilateral uncoordinated measures and comply with their obligations, in particular with regard to notifications, provision of information, mutual assistance and cooperation and refraining from restrictive measures not supported by a proper risk assessment.

3. **Fundamental human rights.** The rights to life, to health and to food are fundamental. As treatments, vaccines and diagnostics are introduced to address the COVID-19 pandemic, it is critical that the international community focus on assuring equitable access to all people, at all levels of income, wherever they may be located. The response to this pandemic must be grounded in the principle of nondiscrimination.
4. **Food security and trade.** The Committee applauds the joint statement by the heads of the UN Food and Agriculture Organization (FAO), the WHO and the World Trade Organization (WTO) of 31 March 2020 calling on states, as they move to enact measures aiming to halt the accelerating COVID-19 pandemic, to minimize potential impacts on the food supply or unintended consequences on global trade and food security. The Committee also welcomes the declaration by the G20 leaders to avoid unnecessary disruptions and interferences in international trade.
5. **Pooling and availability of technologies.** Exclusive rights to technologies such as those afforded by patents and regulatory-based market exclusivity may be useful in ordinary circumstances to promote the aggregation of capital necessary for private enterprise to engage in research and development (R&D). The higher prices facilitated by such exclusive rights may in ordinary times be acceptable as a trade-off between future research and prompt access, though in ordinary times prices must be reasonable. In the extraordinary circumstance of a global pandemic, however, where rapid access to treatments, vaccines and diagnostics is vital, technologies must be shared so that production, distribution and access are maximized. Technology should be pooled and made available at low cost. Exclusive intellectual property rights must not act as a constraint on access. On 22 March 2020, the Committee joined with other stakeholders in supporting a proposal from Costa Rica to the WHO Director General to create a broad technology pooling and licensing arrangement to address the COVID-19 pandemic. The Committee will continue its role in developing and supporting proposals to further innovation and to assure equitable access.
6. **Temporary restrictions to rights and freedoms.** Some measures to curb the COVID-19 pandemic, including quarantines, are inherently at tension with a range of rights and freedoms guaranteed under human rights law, including the right to privacy and physical integrity, and freedom of movement. These measures must have a legal basis and be proportionate. They should be designed to minimize interference with human rights. Should a State decide to temporarily 'derogate' from human rights, such derogation requires careful monitoring to ensure that rights are not set aside unnecessarily. These extraordinary restrictions and derogations should be temporary and great caution and attention must be taken to assure they are lifted as soon as they become unnecessary and do not persist after the public health emergency has passed. A pandemic must not provide an ongoing basis for heightened and indefinite government intrusion in personal spheres of activity. International monitoring bodies should hold states accountable for how they have implemented limitations and derogations to

their human rights obligations as part of their fight against the COVID-19 pandemic, while fully taking into account the exceptional nature of the situation.

7. **Humanitarian assistance.** The Interagency Standing Committee (IASC) is the humanitarian coordination forum of the UN system. It brings together the executive heads of 18 UN and non-UN organizations and programs (including WHO, FAO, UNICEF and UNHCR) to ensure the coordination of humanitarian assistance during emergencies. After the Ebola outbreak in West Africa, IASC adapted its procedures to ensure a more effective response to infectious disease events. We welcome the adoption of the COVID-19 Global Humanitarian Response Plan launched on 25 March 2020. This plan is to be implemented by the IASC partners in selected vulnerable States already facing humanitarian crises because of conflict or natural disasters. It is thus essential that all member states of the United Nations, especially developed states, fully support the COVID-19 Global Humanitarian Response Plan through additional funding that should not be diverted from ongoing humanitarian operations. As requested in the plan, donor funding should maximize flexibility (across the board rather than project by project) to enable rapid adjustments of the response. The Committee notes that funding for the COVID-19 Global Humanitarian Response Plan will be complementary to the financing instrument launched by the UN Secretary General on 31 March 2020 for responding to the socio-economic impacts of the pandemic.
8. **Ongoing conflicts.** Parties to ongoing conflicts, whether internal or international, should immediately pursue ceasefires as requested by the UN Secretary-General so as to avoid magnifying the scale of human suffering. The United Nations organs such as the General Assembly and the Security Council, as well as the UN Secretary General, should demand that hostilities be suspended to stem the spread of the pandemic. Health has historically served as a humanitarian consideration during armed conflicts, including “days of tranquility” agreed between opposing combatants to allow for child vaccination. WHO, the UN, the ICRC and other international institutions should build on the value of health at this moment both to enable urgent health operations as well as to pursue de-escalation of current conflicts.
9. **Limitations to economic sanctions.** As part of the elementary considerations of humanity, unilateral and collective countermeasures (“sanctions”) should not interfere with access to food and should not prevent the circulation, export, import and purchase of goods required for humanitarian needs, such as medicines and medical devices.
10. **UN Security Council role.** The United Nations Security Council has discussed in the past the possible implications of certain diseases on international security, notably HIV-AIDS and Ebola. Given the unprecedented magnitude of the current crisis, the Committee believes that the Security Council has a role to play in managing the political effects of the COVID-19 pandemic. In particular, it could monitor and address the impact of the pandemic on current crises and conflicts, peacekeeping operations and request cooperation and coordination among states and other actors when warranted by health considerations.
11. **International financial institutions.** International financial institutions are positioned to attenuate the more vulnerable situation of developing countries facing economic shocks due to the pandemic. The Committee welcomes the recent announcements by the International Monetary Fund (IMF) and the World Bank to authorize additional funding to developing countries aimed at mitigating the multidimensional economic impact of the COVID-19 pandemic. In the case of the IMF, the Committee takes note of its close collaboration with the WHO, which resulted in doubling the amount of available emergency response funds for strengthening healthcare systems. The Committee also notes the authorization by the World Bank of multiple projects for Emergency Health Support. The Committee encourages review of

existing mechanisms such as the World Bank's Pandemic Emergency Financing Facility to identify gaps in pandemic response, and to address those gaps as appropriate.

Global Health Law Committee of the International Law Association

Frederick Abbott, Co-Chair, Edward Ball Eminent Scholar Professor, Florida State University College of Law, USA

Brigit Toebes, Co-Chair, Professor and Chair, Health Law in a Global Context, Faculty of Law, University of Groningen, The Netherlands

Ellen 't Hoen, Co-Rapporteur, Director Medicines Law & Policy and University Medical Centre, Groningen, The Netherlands

Including the following Members:

Ryan Abbott, Professor of Law and Health Sciences, University of Surrey, United Kingdom and Adjunct Asst. Prof. of Medicine, David Geffen School of Medicine at UCLA, USA

Pia Acconci, Full professor of international law, Faculty of Communication Science, University of Teramo, Italy

Gian Luca Burci, Adjunct Professor of International Law, Graduate Institute of International and Development Studies, Geneva, Switzerland

Wang Chenguang, Professor of Law, Tsinghua University, China, and Member of the National Expert Committee of Covid-19 Emergency in China

Hélène De Pooter, Senior Lecturer in Law at Bourgogne Franche-Comté University, France

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Pedro Villarreal, PhD (UNAM, Mexico), Senior Research Fellow, Max Planck Institute for Comparative Public Law and International Law, Heidelberg, Germany

Tania Voon, Professor, Melbourne Law School, University of Melbourne, Australia

ANNEX 2

Resolution

Resolution No. []/2020

GLOBAL HEALTH LAW

The 79th Kyoto Conference of the International Law Association, held online, 29 November-13 December 2020:

HAVING CONSIDERED the Statement of the Global Health Law Committee of the International Law Association regarding the COVID-19 pandemic adopted by the Committee on 5 April 2020;

OBSERVING that developments since the adoption by the Committee of that Statement have reinforced the importance of its subject matter and recommendations;

TAKING NOTE of the Work Program and Reports of the Global Health Law Committee addressing preparedness and response to global health emergencies;

ADOPTS this Statement regarding the COVID-19 Pandemic.

Statement regarding the COVID-19 pandemic

The potential for virus-based pandemic outbreaks has long been anticipated by public-health specialists as well as by the World Health Organization (WHO). During the 2014-2016 Ebola outbreak attention was drawn to gaps in the preparedness of local health systems, to the scientific challenges of developing new treatments, vaccines and diagnostics in a sufficiently rapid manner to effectively confront large-scale virus outbreaks, and to the special difficulties confronted by low-resource environments in addressing pandemic outbreaks. In February 2015 the Global Health Law Committee of the International Law Association convened a meeting on Global Health Security in Geneva at which a substantial number of interested stakeholders shared concerns about these gaps. Following detailed preparatory work, the World Health Assembly met in May 2015 and decided that additional resources should be directed toward prevention of and response to pandemic outbreaks. Although the precise contours and the magnitude of the COVID-19 outbreak could not be foreseen at that time, the potential for such an event was widely understood, as was the need for further advance investment to address it.

Taking note of the global COVID-19 pandemic, the International Law Association wishes to restate fundamental principles and rules of international law important to containing and ending the pandemic, safeguarding the rights of individuals and groups, and ultimately returning international society to a normal functioning state:

- 1. Cooperation.** The International Law Association stresses the importance of cooperation among states and international institutions in addressing pandemic outbreaks. A pandemic outbreak is an opportunity to demonstrate the value of pooling scientific ingenuity and of

open cooperation among scientists and research institutions, for coordinating logistic and manufacturing capacity, for making available the financial resources necessary to purchase and distribute necessary health products (including vaccines, diagnostics, treatments and personal protective equipment), and for attempting to assure that individuals throughout the world have access to life-sustaining support, including adequate nutrition. A pandemic outbreak is not an occasion for seeking political or economic advantage. Uncoordinated travel and trade restrictions and, more generally, the perception that states can effectively protect themselves from a pandemic in isolation or competing with other states for limited resources, are counterproductive. Actions taken on such premises threaten to destabilize the existing multilateral regime and its institutions with long-term adverse consequences. The world needs more cooperation, coordination and solidarity at this critical time. The International Law Association therefore welcomes the United Nations General Assembly resolutions of 2 April 2020 ([A/RES/74/270](#)), 20 April 2020 ([A/RES/74/274](#)) and 11 September 2020 ([A/RES/74/306](#) and [A/RES/74/307](#)) affirming its commitment to international cooperation and multilateralism. The International Law Association stresses the importance of universal participation in the United Nations system. Universality and inclusive dialogue are essential to comprehensively addressing the global transboundary threat posed by COVID-19.

- 2. Support to the World Health Organization.** The WHO was established in substantial measure to provide a forum where the world community could meet and agree on the processes and substantive measures necessary to address international public health emergencies. It is critical that states support the central role of WHO in addressing the COVID-19 pandemic and in preparing for and confronting future public health crises. To this end, respecting the independence of the Secretariat and of the experts and enhancing financial support for WHO in a sustainable, predictable and flexible manner through voluntary contributions as well as a long-term increase of its assessed contributions are crucial. Even though the current state of the pandemic arguably exceeds the scope of the International Health Regulations (2005) (IHR), it still has an important role to play as the global legal framework to channel data and information and facilitate the coordination of response measures. Member states must pay due consideration to the recommendations made by WHO's Director-General on the advice of the IHR Emergency Committee and should avoid weakening the IHR through the proliferation of unilateral uncoordinated measures and comply with their obligations, in particular with regard to notifications, provision of information, mutual assistance and cooperation and refraining from restrictive measures not supported by a proper risk assessment.
- 3. Independent evaluation.** The International Law Association welcomes the establishment of the Independent Panel for pandemic preparedness and response as called for by [World Health Assembly Resolution WHA73.1](#), and it commends the Panel Co-Chairs for the steps already taken, as detailed in their report to the WHO Executive Board ([EBSS/5/3](#)). The International Law Association also welcomes the establishment by the WHO Director-General, further to WHA73.1, of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response. This Committee is reviewing the functioning of the IHR during the COVID-19 response, as well as the status of implementation of the relevant recommendations of previous IHR Review Committees. The results of the work of the IHR Review Committee, including its recommendations, should be the subject of in-depth consideration by WHO member states as potential improvements in the functioning of the IHR are important to containing and addressing future disease outbreaks. The International Law Association reaffirms that the independence and impartiality of the Independent Panel and the IHR Review Committee must be guaranteed,

that they must be permitted to pursue their duties without external political interference, and that their work should be undertaken in as transparent a manner as possible.

4. **Fundamental human rights.** The rights to life, to health, to an adequate standard of living and to food are fundamental. As treatments, vaccines and diagnostics are introduced to address the COVID-19 pandemic, it is critical that the international community focus on assuring equitable access to all people, at all levels of income, wherever they may be located. The response to this pandemic must be grounded in the principle of nondiscrimination. The International Law Association calls attention to the need for governments and international organizations to address violence against women that has intensified as a consequence of the pandemic, constituting a deprivation of the human rights to personal security and equality, among others. It further affirms the importance of maintaining adequate funding and support for mental health services that have been severely disrupted during the course of the pandemic.
5. **Food security and trade.** The Committee applauds the joint statement by the heads of the UN Food and Agriculture Organization (FAO), the WHO and the World Trade Organization (WTO) of 31 March 2020 calling on states, as they move to enact measures aiming to halt the accelerating COVID-19 pandemic, to minimize potential impacts on the food supply or unintended consequences on global trade and food security. The Committee also welcomes the declaration by the G20 leaders to avoid unnecessary disruptions and interferences in international trade.
6. **Pooling and availability of technologies.** Exclusive rights to technologies such as those afforded by patents and regulatory-based market exclusivity may be useful in ordinary circumstances to promote the aggregation of capital necessary for private enterprise to engage in research and development (R&D). In the extraordinary circumstance of a global pandemic, however, where rapid, general and equitable access to treatments, vaccines and diagnostics is vital, technologies must be shared so that production, distribution and access are maximized. Technology should be pooled and made available at low cost. Exclusive intellectual property rights must not act as a constraint on access, especially as regards COVID-19 in a circumstance of ongoing international emergency. On 22 March 2020, the Global Health Law Committee joined with other stakeholders in supporting a proposal from Costa Rica to the WHO Director General to create a broad technology pooling arrangement to address the COVID-19 pandemic. The International Law Association recognizes that there are a number of collaborative projects underway directed toward the financing, development and testing, acquisition and distribution of health technologies and products needed to protect against, diagnose and treat COVID-19, including the ACT-Accelerator, the COVAX Facility and the C-TAP initiative. The International Law Association encourages strong support for these initiatives, including financial support from governments with adequate resources, as well as support for other initiatives being made by governments and groups to promote and assure timely and affordable access to health technologies and products to address COVID-19. The Global Health Law Committee should continue its role in developing and supporting proposals to further innovation and to assure equitable access.
7. **Temporary restrictions to rights and freedoms.** Some measures to curb the COVID-19 pandemic, including quarantines, are inherently at tension with a range of rights and freedoms guaranteed under human rights law, including the right to privacy and physical integrity, and freedom of movement. These measures must have a legal basis and be proportionate. They should be designed to minimize interference with human rights. Should a State decide to temporarily 'derogate' from human rights, such derogation should be formally proclaimed and notified to the competent international organizations and treaty

bodies. Derogation requires careful monitoring to ensure that rights are not set aside unnecessarily. These extraordinary restrictions and derogations should be temporary and great caution and attention must be taken to assure they are lifted as soon as they become unnecessary and do not persist after the public health emergency has passed. A pandemic must not provide an ongoing basis for heightened and indefinite government intrusion in personal spheres of activity. International monitoring bodies should hold states accountable for how they have implemented limitations and derogations to their human rights obligations as part of their fight against the COVID-19 pandemic, while fully taking into account the exceptional nature of the situation.

- 8. Humanitarian assistance.** The Interagency Standing Committee (IASC) is the humanitarian coordination forum of the UN system. It brings together the executive heads of 18 UN and non-UN organizations and programs (including WHO, FAO, UNICEF and UNHCR) to ensure the coordination of humanitarian assistance during emergencies. After the Ebola outbreak in West Africa, IASC adapted its procedures to ensure a more effective response to infectious disease events. We welcome the adoption of the COVID-19 Global Humanitarian Response Plan launched on 25 March 2020. This plan is to be implemented by the IASC partners in selected vulnerable States already facing humanitarian crises because of conflict or natural disasters. It is thus essential that all member states of the United Nations, especially developed states, fully support the COVID-19 Global Humanitarian Response Plan through additional funding that should not be diverted from ongoing humanitarian operations. As requested in the plan, donor funding should maximize flexibility (across the board rather than project by project) to enable rapid adjustments of the response. The Committee notes that funding for the COVID-19 Global Humanitarian Response Plan will be complementary to the financing instrument launched by the UN Secretary General on 31 March 2020 for responding to the socio-economic impacts of the pandemic. The International Law Association acknowledges that the scale of financing needed for emergency humanitarian response to the COVID-19 pandemic reflects a wider struggle to end poverty everywhere to secure economic and social rights and to achieve UN Sustainable Development Goal (SDG) 1. The pandemic has set back meaningful progress already made toward SDG 1. Sustained increases in financial and other support will be needed to move efforts to end poverty back in the direction of achieving that goal.
- 9. Ongoing conflicts.** Parties to ongoing conflicts, whether internal or international, should immediately pursue ceasefires as requested by the UN Secretary-General so as to avoid magnifying the scale of human suffering. The United Nations organs such as the General Assembly and the Security Council, as well as the UN Secretary General, should demand that hostilities be suspended to stem the spread of the pandemic. Health has historically served as a humanitarian consideration during armed conflicts, including “days of tranquility” agreed between opposing combatants to allow for child vaccination. WHO, the UN, the ICRC and other international institutions should build on the value of health at this moment both to enable urgent health operations as well as to pursue de-escalation of current conflicts.
- 10. Limitations to economic sanctions.** As part of the elementary considerations of humanity, unilateral and collective countermeasures (“sanctions”) should not interfere with access to food and should not prevent the circulation, export, import and purchase of goods required for humanitarian needs, such as medicines and medical devices.
- 11. UN Security Council role.** The United Nations Security Council has discussed in the past the possible implications of certain diseases on international security, notably HIV-AIDS and Ebola. Given the unprecedented magnitude of the current crisis, the International Law Association considers that the Security Council has a central role to play in managing the

political effects of the COVID-19 pandemic. In particular, the Security Council can and should monitor and address the impact of the pandemic on current crises and conflicts, peacekeeping operations and request cooperation and coordination among states and other actors when warranted by health considerations. The International Law Association welcomes adoption by the Security Council on 1 July 2020 of Resolution 2532 (2020) ([S/RES/2532 \(2020\)](#)) that acknowledges likely threats to international peace and security associated with the COVID-19 pandemic and demands the cessation of hostilities that jeopardize human health and humanitarian operations and that impose exceptional hardship on the most vulnerable populations.

12. Combatting corruption. The International Law Association takes note that weakened governmental oversight and inadequate transparency during the COVID-19 pandemic regrettably has presented opportunity for corruption that is diverting substantial resources from those in need, undermining public trust and interfering with protection of fundamental rights. It supports the UN Secretary General’s Statement of 15 October 2020 on Corruption in the Context of COVID-19 urging “all governments and all leaders to be transparent and accountable, and to use the tools provided by the United Nations Convention against Corruption”.

13. International financial institutions. International financial institutions are positioned to attenuate the more vulnerable situation of developing countries facing economic shocks due to the pandemic. The International Law Association welcomes the recent announcements by the International Monetary Fund (IMF) and the World Bank to authorize additional funding to developing countries aimed at mitigating the multidimensional economic impact of the COVID-19 pandemic. In the case of the IMF, the International Law Association takes note of its close collaboration with the WHO, which resulted in doubling the amount of available emergency response funds for strengthening healthcare systems. The International Law Association also notes the authorization by the World Bank of multiple projects for Emergency Health Support. It encourages review of existing mechanisms such as the World Bank’s Pandemic Emergency Financing Facility to identify gaps in pandemic response, and to address those gaps as appropriate.