

Leading and Coordinating Global Health: Strengthening the World Health Organization

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174

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ABSTRACT

The World Health Organization (WHO) should act as the directing and coordinating authority in global health but it has been steadily marginalized over time by design, through criticism as an inefficient organization, the reduction of assessed contributions and consequent impoverishment, and the proliferation of “new” international health agencies to which WHO has been compelled to cede operational space. This paper discusses how such marginalization of the WHO is in the interest of the dominant actors in global health, and leads to the neglect of health as a development issue. Today the global health system is more fragmented than it was when the WHO was established in 1948. Rich donor countries and corporations dominate multistakeholder governance structures in health partnerships, marginalizing most of the WHO membership and, notably, the Global South, in their decision-making. A consequence of this fragmentation in global health governance is that the space of the only multilateral organization where developing countries have an equal presence in terms of participation and decision-making as sovereign States –WHO– has been marginalized. Consequently, the development dimension of health is also marginalized and only the development assistance aspects of it receive major attention through vertical programmes and agencies addressing limited health needs without effectively addressing the basic need of strengthening health systems. Therefore, for developing countries it is imperative that WHO is effectively retooled to act as the leading and coordinating authority on global health with adequate legal powers, as well as institutional and financial capacities to do so without undue influence from donor countries and entities that have interests in the private sector. This would enable WHO to ensure that the interests of all countries are fairly addressed in its normative and operational activities. Such a transformation of WHO would require action both within and outside the organization. The paper proposes some suggestions in this regard.

La Organización Mundial de la Salud (OMS) debería actuar como autoridad directiva y coordinadora de la salud mundial, pero con el tiempo se ha visto marginada de forma constante y deliberada, a través de las críticas como organización ineficaz, la reducción de las contribuciones señaladas y el consiguiente empobrecimiento, y la proliferación de "nuevas" agencias sanitarias internacionales a las que la OMS se ha visto obligada a ceder espacio operativo. En este documento se analiza cómo esta marginación de la OMS favorece los intereses de los actores dominantes de la salud mundial y lleva a descuidar la salud como cuestión de desarrollo. Hoy en día, el sistema sanitario mundial está más fragmentado que cuando se creó la OMS en 1948. Los países donantes ricos y las empresas dominan las estructuras de gobernanza de las alianzas sanitarias, marginando en su toma de decisiones a la mayoría de los miembros de la OMS y, en particular, al Sur Global. Una consecuencia de esta fragmentación en la gobernanza sanitaria mundial es que se ha marginado el espacio de la única organización multilateral en la que los países en desarrollo tienen igual presencia en términos de participación y toma de decisiones que los Estados soberanos: la OMS. En consecuencia, la dimensión de desarrollo de la salud también está marginada y sólo los aspectos de ayuda al desarrollo reciben una atención importante a través de programas y agencias verticales que abordan necesidades sanitarias limitadas sin atender eficazmente la necesidad básica de reforzar los sistemas sanitarios. Por lo tanto, para los países en desarrollo es imperativo que la OMS se reorganice de forma efectiva para actuar como autoridad líder y coordinadora de la salud mundial con los poderes legales adecuados, así como las capacidades institucionales y financieras para hacerlo sin influencias indebidas de los países donantes y las entidades que tienen intereses en el sector privado. Esto permitiría a la OMS garantizar que los intereses de todos los países se tienen en cuenta de forma

equitativa en sus actividades normativas y operativas. Esta transformación de la OMS requeriría medidas tanto dentro como fuera de la organización. El documento propone algunas sugerencias a este respecto.

L'Organisation mondiale de la santé (OMS) devrait agir en tant qu'autorité directrice et coordinatrice dans le domaine de la santé mondiale, mais elle a été régulièrement marginalisée au fil du temps, à dessein, par les critiques formulées à son encontre en tant qu'organisation inefficace, par la réduction des contributions obligatoires et l'appauvrissement qui en découle, et par la prolifération de "nouvelles" agences internationales de santé auxquelles l'OMS a été contrainte de céder son espace opérationnel. Cet article examine comment une telle marginalisation de l'OMS sert les intérêts des acteurs dominants de la santé mondiale et conduit à négliger la santé comme enjeu de développement. Aujourd'hui, le système de santé mondial est plus fragmenté qu'il ne l'était lors de la création de l'OMS en 1948. Les pays donateurs riches et les entreprises dominent les structures de gouvernance multipartites dans les partenariats pour la santé, marginalisant la plupart des membres de l'OMS et, notamment, les pays du Sud, dans leurs prises de décision. Cette fragmentation de la gouvernance mondiale de la santé a pour conséquence de marginaliser la seule organisation multilatérale où les pays en développement ont une présence égale en termes de participation et de prise de décision en tant qu'États souverains - l'OMS. Par conséquent, la dimension développement de la santé est également marginalisée et seuls les aspects liés à l'aide au développement font l'objet d'une attention majeure par le biais de programmes et d'agences verticaux répondant à des besoins sanitaires limités sans répondre efficacement au besoin fondamental de renforcement des systèmes de santé. Par conséquent, pour les pays en développement, il est impératif que l'OMS soit restructurée pour agir en tant qu'autorité directrice et coordinatrice de la santé mondiale, dotée de pouvoirs juridiques adéquats, ainsi que des capacités institutionnelles et financières nécessaires pour le faire sans influence disproportionnée des pays donateurs et des entités qui ont des intérêts dans le secteur privé. L'OMS pourrait ainsi veiller à ce que les intérêts de tous les pays soient équitablement pris en compte dans ses activités normatives et opérationnelles. Une telle transformation de l'OMS nécessiterait une action au sein de l'Organisation et à l'extérieur. Le présent document propose des suggestions à cet égard.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ORIGIN, POWERS AND FUNCTIONS OF WHO.....	2
	<i>II.1 International Cooperation on Health Before the WHO</i>	2
	<i>II.2 Establishment of the WHO</i>	3
	<i>II.3 Powers and Functions</i>	4
III.	WHO IN ACTION	8
	<i>III.1 Limited Focus on Eradication of Specific Diseases</i>	8
	<i>III.2 Focus on Primary Health Care</i>	9
	<i>III.3 Essential Drugs, Intellectual Property and Access to Medicines</i>	12
	<i>III.4 Food Standards</i>	16
	<i>III.5 Selective Primary Health Care</i>	17
IV.	FRAGMENTATION AND SHARING OF LEADERSHIP IN GLOBAL HEALTH	20
	<i>IV.1 Increasing Engagement with Non-State Actors</i>	21
	<i>IV.2 Prioritizing Work on Global Epidemic Threats and Health Security</i>	23
	<i>IV.3 Financial Troubles</i>	26
V.	CONCLUSION	30

I. INTRODUCTION

The World Health Organization (WHO) is mandated as the United Nations (UN) specialized agency on health, among others, to act as the directing and coordinating authority on international health work, assist governments in strengthening health systems, and provide technical assistance and emergency aid upon request. One of the objectives of WHO is to promote international cooperation to improve public health globally. However, political, commercial, development, and security interests have influenced international cooperation on health,¹ which has limited the ability of WHO to effectively ensure that all States act in cooperation and solidarity through adoption and implementation of common strategies and mechanisms. In particular, as evidenced during the COVID-19 pandemic,² the organization lacks tools to ensure equity in addressing the global health problems, particularly for providing developing countries with the differentiated support they need to strengthen their health systems.

It is important to understand why the WHO has been unable over the years to enforce its writ even though it was established to become the leading and coordinating authority on global health. To this end, it is important to examine how the WHO was created, how it is structured, what its focus has been and how its functions have been performed in different periods, as well as the extent to which its members and non-state actors (NSA)³ influence the organization's work. Paradoxically, the WHO is expected to play a leading and coordinating role with limited resources, substantially smaller than those available to some of the other international health-related agencies.

This paper aims at contributing to the analysis of the global governance of public health with a focus on the role of the WHO. It suggests actions that would need to be taken to strengthen such a role as a leading and coordinating global public health agency. The paper explores the origin, powers and functions of the WHO as a UN specialized agency, the activities of the organization in different periods of its evolution, and the factors that influenced such developments. Section II provides a brief overview of the origin, powers and functions of WHO. Section III describes the work undertaken by WHO in different stages of its evolution and the global geopolitical and economic contexts in which these developments occurred. Section IV discusses how the WHO has been compelled to share and cede space to multiple partnerships leading to fragmentation and sharing of leadership in global health, and its implications for the global South. Section V draws conclusions.

¹ See Ole Petter Ottersen et.al., "The Lancet-University of Oslo Commission on Global Governance for Health: The political origins of health inequity: prospects for change", *The Lancet*, vol. 83 (February 15, 2014), p. 630. Available from <https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2813%2962407-1.pdf>.

² See South Centre Statement to the WHA 73 Session, November 2020. Available from <https://www.southcentre.int/covid-19/>; German Velasquez, *The World Health Organization Reforms in the Time of COVID-19*, Research Paper No. 121 (Geneva, South Centre, November 2020). Available from <https://www.southcentre.int/research-paper-121-november-2020/>; Nirmalya Syam et. al., "The 73rd World Health Assembly and Resolution on COVID-19: Quest of Global Solidarity for Equitable Access to Health Products", South Centre, Policy Brief No. 78, May 2020. Available from <https://www.southcentre.int/wp-content/uploads/2020/05/PB-78.pdf>.

³ A recent study on the participation of actors from the Global South in global health governance concluded that "... protection of public health in developing countries...in global governance remains a daunting challenge" and points to the need for more meaningful participation by developing country governments and non-state actors. See Sue-rie Moon, "How Much do Health Actors from the Global South Influence Global Health Governance? A Response", in Joost Pauwelyn et al. (eds.), *Rethinking Participation in Global Governance: Voice and Influence after Stakeholder Reforms on Global Finance and Health* (Oxford University Press, 2022), pp. 401-8.

II. ORIGIN, POWERS AND FUNCTIONS OF WHO

II.1 International Cooperation on Health Before the WHO

The roots of WHO lie in the development of international health as a systemic area of regulation and action since the mid-nineteenth century, primarily to safeguard western Europe from external pandemic threats originating in their colonies and other impoverished countries. The early international health cooperation was between western countries as the primary actors, and the focus was on modernizing and standardizing quarantine and other border health protocols.⁴ Goals of disease eradication were deprioritized to the primary goal of preventing the spread of disease in Europe. It is in this context that the early normative developments on international health occurred. The seventh International Sanitary Conference in Venice in 1892 adopted two normative principles which even today form fundamental principles of the International Health Regulations (IHR) administered by the WHO – that every government must notify other governments of specific disease outbreaks⁵ within their borders; and that there should be an international clearing-house mechanism for notification and exchange of information on epidemics.

Gradually, this cooperation led to the sprouting of several institutional arrangements between the participating countries. In 1902 the Pan American Sanitary Bureau, the predecessor of today's Pan American Health Organization (PAHO), was established.⁶ The International Sanitary Conference of 1907 in Rome led to the establishment of the *Office Internationale d'Hygiene Publique* (OIHIP) – with the objective of collecting and bringing to the participating governments (mostly from Europe) information of a general character relating to public health, particularly infectious diseases, notably cholera, plague and yellow fever, and measures taken to combat those diseases. In parallel, the first international private philanthropic programme on global health – the International Health Division of the Rockefeller Foundation – was established in the US in 1913. In 1924, the League of Nations Health Organization (LNHO) was established at the end of World War I,⁷ after unsuccessful attempts to merge the OIHIP with the Epidemics Commission of the League of Nations (the League).⁸

⁴ Between 1851 to 1885, the European powers organized six international sanitary conferences which essentially focused on the creation and strengthening of maritime quarantine measures to prevent the spread of cholera - a disease hitherto endemic to India - to western Europe.

⁵ The first pronouncement of this principle at the seventh International Sanitary Conference was limited to cholera. Subsequently, under the IHR the application of this principle has been expanded to cover other diseases.

⁶ "History of PAHO." Available from <https://www.paho.org/en/who-we-are/history-paho>.

⁷ The idea of a health organization as part of the League of Nations was discussed at the first meeting of the Council of the League of Nations in 1920 and plans for convening a conference for forming the organization were made. However, due to the immediate need of addressing the outbreak of typhus epidemic in Poland, an Epidemics Commission was established and subsequently, its role was expanded to respond to epidemic outbreaks in Russia and the Baltic States. In parallel, in 1921 the Council of the League appointed a Provisional Health Committee which later became a permanent committee, to work with the OIHIP, to perform the functions of the health organization until the organization of a permanent organization. In 1923, the Council of the League chose a committee comprised of equal number of members of the Health Committee and the OIHIP to plan a constitution of the permanent health organization. The new League of Nations Health Organization (LNHO) was established based on the recommendations of this committee and met for the first time in 1924. See Georgia Dill, "History of the health organization of the League of Nations" (1938), Graduate Student Theses, Dissertations and Professional Papers, The University of Montana. Available from <https://scholarworks.umt.edu/cgi/viewcontent.cgi?article=9686&context=etd>.

⁸ The United States (US) did not support the merger of the OIHIP of which it was a member with the League, which it never joined. See Patricia Anne Sealey, "The League of Nations Health Organization and the Evolution of Transnational Public Health", Dissertation, Ohio State University, 2011, pp. 28-9. Available from https://etd.ohiolink.edu/apexprod/rws_etd/send_file/send?accession=osu1306338169&disposition=inline.

The OIHIP remained the principal international organization in global health during the inter-war period. The Advisory Board of the OIHIP constituted half of the membership of the Health Committee of the League. It played the lead role in substantially drafting the revision of the International Sanitary Convention that was adopted in 1926 and was recognized therein as the coordinating agency, instead of LNHO, for receiving information from governments about epidemic outbreaks. In this context, the LNHO ventured into new areas of cooperation on international health including the exchange of sanitary information and statistics, the development of guidelines and standards, and the exchange of public health experts. The LNHO also focused on public health issues beyond epidemic challenges such as infant mortality, research on other diseases (e.g., leprosy, tuberculosis, malaria), and social determinants of health.⁹ These ventures were substantially facilitated through contributions from major American philanthropic organizations to the LNHO, particularly the Rockefeller Foundation. However, there was lack of political support for the LNHO to undertake direct action.¹⁰

II.2 Establishment of the WHO

The LNHO became dysfunctional with the outbreak of World War II and the OIHIP came under German influence following the occupation of France. In this context, the Allied powers, who referred to themselves as the United Nations following the adoption of the “Declaration by the United Nations” on 1 January 1942, established the United Nations Relief and Rehabilitation Administration (UNRRA) in 1943, which also became involved in medical and health operations. The UNRRA took over the functions of the OIHIP in 1944 on a temporary basis through the adoption of the UNRRA International Sanitary Convention, giving a period of 18 months for the OIHIP to be rebuilt.

However, supporters of the LNHO were resistant to the revival of the OIHIP and advocated for the establishment of a new international agency that would assume the functions of the LNHO.¹¹ The US was also opposed to the re-opening of the OIHIP.

At the United Nations Conference on International Organization in San Francisco (San Francisco Conference) in 1945 where the United Nations Charter was adopted, Brazil and China submitted a proposal calling for the establishment of an international health organization as part of the UN Economic and Social Council (ECOSOC) that would be responsible for establishing and defining the role of UN specialized agencies. The proposed declaration was adopted through a unanimous resolution which called for convening a general conference for establishing an international health organization. The declaration explicitly mentioned that “... in the preparation of a plan for the international health organization, full consideration should

⁹ Paul Weindling, “The League of Nations Health Organization and the rise of Latin American participation, 1920-40”, *História, Ciências, Saúde – Manguinhos*, vol. 13, No. 3, 2006, pp. 1-14. Available from <https://www.scielo.br/j/hcsm/a/yS4n8gK3MhC3H4BW8ktFG9v/?lang=en>.

¹⁰ Soon after the end of World War I, the League had established an Epidemics Commission to respond to the typhus epidemic in Eastern Europe. The Epidemics Commission implemented a policy of direct intervention through measures such as setting up hospitals, delousing, etc., across the affected regions in Europe. In later years, similar intervention outside Europe did not receive political support within the League.

¹¹ In 1943, Raymond Gautier, a Swiss official of the LNHO wrote a confidential report presenting an outline of a future post-war international health agency that would undertake the functions of LNHO as well as take initiative of intervening in emergencies without waiting for a government request. Similarly, Ludwik Rajchman, the first director of the LNHO, also advocated the establishment of a new international health organization under the United Nations. In 1944, Gautier and other medical leaders suggested principles on which the international health organization for the post-war period should be established and that the US should convene a conference on world health as soon as possible. However, the US was disinclined to reviving the League and its agencies.

be given to the relation of such organization and to methods of associating it with other institutions, which already exist, or which may hereafter be established in the field of health.”¹² The San Francisco conference also adopted specific provisions in the UN Charter which made the UN responsible for, among other socio-economic issues, promotion of solutions to international health problems,¹³ establishing official relations with specialized agencies in health,¹⁴ and initiating negotiations among States for the creation of new specialized agencies, including in health.¹⁵ In 1946 the ECOSOC established a Technical Preparatory Committee (TPC) comprised of 16 medical experts to prepare the draft constitution of the new health organization and the agenda of its first assembly.

An International Health Conference was convened in New York from 19 June to 22 July 1946, where the Constitution of the WHO was adopted based on the draft presented by the TPC. Following the adoption of the WHO Constitution, an Interim Commission was established to oversee international health work until the first World Health Assembly. The WHO was also recognized as a UN Specialized Agency through a relationship agreement with the UN that was approved by the UN General Assembly in July 1947.¹⁶ The WHO Constitution was adopted and ratified by 26 States at the first session of the World Health Assembly.¹⁷

II.3 Powers and Functions

The objective of WHO as stated in its Constitution is “...the attainment by all peoples of the highest possible level of health.” The meaning of this objective is clarified in the preamble. The preamble defines health in very broad terms as “... a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” The preamble further states that “The enjoyment of the highest attainable state of health is one of the fundamental rights of every human being ...” without discrimination. It also states that “The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.” Further, governments have the responsibility for the health of their peoples through the provision of adequate health and social measures. At the same time, it is recognized that “Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.”

The objectives in the WHO Constitution are very progressive and provide the foundations for the organization to address public health issues from a socio-economic and development perspective to strengthen health systems in countries that lack the same. Much before environmental degradation was recognized by the international community as a common danger, the WHO Constitution explicitly recognized unequal development in public health capacities as a common danger. In furtherance of these objectives, the Constitution mandates the WHO to “... act as the directing and coordinating authority in international health work.” However, as discussed in this paper in subsequent sections, since the 1980s this role of the WHO has been increasingly challenged in practice with the rise of new institutions and funding mechanisms in global health.¹⁸

¹² WHO, “Summary Report on Proceedings, Minutes and Final Acts of the International Health Conference held in New York from 19 June to 22 July 1946”, Official Records of the World Health Organization, No. 2, June 1948. Available from https://apps.who.int/iris/bitstream/handle/10665/85573/Official_record2_eng.pdf?sequence=1&isAllowed=y

¹³ UN Charter, Article 55(d).

¹⁴ Ibid., Article 57.

¹⁵ Ibid., Article 59.

¹⁶ WHO, *Basic Documents*, 48th edn., (Geneva, World Health Organization, 2014). Available from <https://apps.who.int/gb/bd/PDF/bd48/basic-documents-48th-edition-en.pdf>.

¹⁷ See WHO, History of WHO. Available from <https://www.who.int/about/who-we-are/history>.

¹⁸ Charles Clift, *What's the World Health Organization For? Final Report from the Centre on Global Health Security Working Group on Health Governance*, (London, Chatham House, 2014). Available from https://www.chathamhouse.org/sites/default/files/field/field_document/20140521WHOHealthGovernanceClift.pdf.

The WHO is also mandated to undertake certain promotional and educational activities and field operations.¹⁹ As discussed in the sections below, WHO operational activities have been marginalized with other international agencies such as the World Bank, multistakeholder partnerships such as the Global Fund, GAVI, etc., taking the lead in operational activities. WHO has been restricted to address normative functions. This is exemplified by the WHO coordinated response to COVID-19 in respect of access to medical countermeasures for developing countries (see box 1).

Box 1

In April 2020 the WHO Secretariat together with the European Commission, France and the Bill and Melinda Gates Foundation had launched the Access to COVID-19 Tools Accelerator (ACT-A) in response to a call from the G-20 leaders.²⁰ The objective of ACT-A is “to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.”²¹ It should be noted also that the ACT-A or initiatives within it were never proposed for formal endorsement by the World Health Assembly.

The initiatives that have been rolled out under ACT-A are partnerships between WHO and other multistakeholder entities,²² which do not have the WHO playing a leading role in their implementation. Donor countries, corporations and philanthropists seem to exert major influence to shape the initiatives launched for providing access to diagnostics, vaccines and therapeutics to developing countries.²³

As the lead agency under the ACT-A for vaccines, GAVI had launched the Gavi Advance Market Commitment for COVID-19 Vaccines (COVAX) with a seed funding of over USD 500 million at the time of its launch.²⁴ However, the COVAX facility proposal seemingly prioritized the needs of self-financing countries participating in the scheme: “once all countries in this group have received sufficient supply from the Facility to cover e.g., 20 per cent of their population, any additional supply of vaccines would be offered to countries in line with a needs-based allocation framework”.²⁵ The volumes specifically directed to these funded countries were to be allocated across them using guidance from a global allocation framework subsequently developed by the WHO Secretariat as a working document,²⁶ which also was never submitted for approval of the World Health Assembly.

¹⁹ The promotional functions concern maternal and child health and welfare, mental health, prevention of accidental (primarily household) injuries, and improvement of nutrition, housing, sanitation, recreation, economic or working conditions and other aspects of environmental hygiene, in co-operation with other specialized agencies (such as FAO and ILO). In respect of educational activities, the WHO is mandated to promote improved standards of teaching and training in health, medical and related professions; promote cooperation among scientific and professional groups which contribute to the advancement of health; assist in developing informed public opinion among all people on matters of health. The field operations are activities such as assisting governments, upon request, in strengthening health services; providing technical assistance and emergency aid; providing or assisting in providing health services and facilities to special groups upon request of the UN.

²⁰ It is reported that the original idea of ACT-Accelerator was conceived in a white paper by the Gates Foundation.

²¹ WHO, “Access to COVID-19 Tools (ACT) Accelerator”, 24 April 2020. Available from [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator).

²² WHO, “The ACT-Accelerator frequently asked questions”. Available from <https://www.who.int/initiatives/act-accelerator/faq>.

²³ See Priti Patnaik, “COVID-19 Vaccine Governance: Sidelining Multilateralism”, People’s Health Movement, January 2021. Available from https://phmovement.org/wp-content/uploads/2021/01/Final_PHM_COVID-AND-GOVERNANCE-compressed.pdf.

²⁴ Gavi, “The Gavi COVAX AMC: An Investment Opportunity”. Available from <https://www.gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf>.

²⁵ GAVI, “COVID-19 Vaccine Global Access (COVAX) Facility: Preliminary Technical Design”, Discussion Document, 11 June 2020. Available from <https://www.keionline.org/wp-content/uploads/COVAX-Facility-Preliminary-technical-design-061120-vF.pdf>.

²⁶ See WHO, “Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility”, 9 September 2020. Available from <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>.

The Constitution mandates the WHO to undertake three types of international norm-setting functions in relation to health matters: 1) make formal recommendations on international health matters; 2) propose international conventions or formal agreements for acceptance by governments in accordance with their constitutional processes; and 3) propose regulations on specific subjects which become effective for all Member States once adopted, subject to any expression made by a State not to be bound by that instrument.

The majority of WHO norms such as technical standards, guidelines and global strategies are adopted as soft law instruments through resolutions of the World Health Assembly. Regarding treaty instruments, the WHO Constitution provides for two kinds of treaty-making techniques. One technique is the negotiation and adoption of treaties or formal agreements by a two-thirds majority vote in the Assembly, subject to their acceptance or ratification subsequently by the Member States of the WHO. Another innovative approach in international treaty-making that the WHO Constitution adopted, drawing from a similar approach adopted in the Chicago Convention on International Civil Aviation,²⁷ was to allow the Assembly to adopt regulations on specific matters which would come into force for all WHO Member States upon being duly notified of such action by the Assembly, unless a Member State submits a rejection or reservation to the same, within the period stated in the notice.

The difference in the terms used to describe the instruments under article 19 (conventions or agreements) and article 21 (regulations) seems to be intended to distinguish the law-making technique to be followed in how these instruments would come into force for WHO Member States. However, this does not have a bearing on the formal status of these instruments as distinct treaties under international law. The Vienna Convention on the Law of Treaties (VCLT) clearly states that “a “treaty” means an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and **whatever its particular designation** (emphasis added).” Hence, an instrument adopted under article 19 or under article 21 of the WHO Constitution has the status of a treaty under international law. Indeed, both the WHO Framework Convention on Tobacco Control (FCTC) adopted through the process under article 19, as well as the International Health Regulations (IHR) adopted through the process under article 21, have been deposited with the UN Secretary-General as treaty instruments. Article 19 adopts the traditional treaty-making approach, wherein delegates to the Health Assembly are empowered to negotiate the final text of a treaty but are not assumed to have full powers to express the consent of the State to be bound by its terms without reservation, which is subject to the ratification or acceptance of the treaty by the State through its internal procedures. Conversely, the technique under article 21 assumes tacit approval of the member States to be bound in respect of instruments adopted on a limited range of matters and provides some flexibility to opt out of such instrument or make reservations within a notified period. As article 21 of the WHO Constitution itself is a treaty obligation it implies a tacit consent by WHO Member States to be bound by regulations adopted by the Assembly through the process under article 21. Article 11 of the VCLT states that the consent of a State to be bound by a treaty may be expressed by signature, exchange of instruments constituting a treaty, ratification, acceptance, approval, or accession, or **by any other means if so agreed** (emphasis added).

Another point to be noted is that the WHO Constitution envisages the use of traditional process of treaty making under article 19 on any matter within the competence of the organization, while limiting the technique of treaty approval by implied consent under article 21 to specific matters – sanitary and quarantine requirements and other procedures designed to prevent the

²⁷ Article 90 of the Chicago Convention states that the adoption of international standards relating to civil aviation by the ICAO Council by a two-thirds vote would come into effect for the contracting States within three months of submission of the same to the contracting States (or for a longer period prescribed by the ICAO Council), unless within this period a majority of the contracting States register their disapproval of the same with the ICAO Council.

international spread of disease; nomenclatures with respect to diseases, cause of death and public health practices; standards with respect to diagnostic procedures for international use; standards with regard to safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; and, advertising and labelling of biological, pharmaceutical and similar products moving in international commerce. In practice, regulations have been made under article 21 only about sanitary regulations and nomenclatures with respect to diseases and causes of death.

III. WHO IN ACTION

During the first decade of WHO, the US exerted predominant influence on shaping global health policies and the work of WHO.²⁸ The US vision for global health focused on the use of technological means for targeted eradication of specific diseases in developing countries. American financial aid and technologies provided by American corporations were extensively deployed in technical assistance provided through WHO to that end.

III.1 Limited Focus on Eradication of Specific Diseases

This approach led to the adoption of several vertical programmes targeting the eradication of specific diseases such as yaws, tuberculosis, leprosy, filariasis, trachoma, malaria, and smallpox.²⁹ The US actively supported such vertical programmes as a means of extending its development cooperation on health, complementing the broader interest of ensuring their alignment to the western sphere of influence in the cold war era.

The biggest of these vertical programmes was the Global Program for Malaria Eradication. WHO set up a special fund for national eradication programmes, wherein most of the funding came in the form of US bilateral cooperation. Technological tools such as insecticides, and medicines were also predominantly supplied by American companies. However, some countries from Africa were excluded from the global eradication programme on the grounds that it would be premature to attempt eradication in those countries due to poor health systems and communications. No attempt was made to strengthen health systems to enable such countries to benefit from malaria eradication. The exclusion of such African countries implied the need for less financial resources to support a "global" malaria eradication programme.

Despite a massive unprecedented global campaign aimed at spraying dichloro-diphenyl-trichloroethane (DDT), a synthetic insecticide, in homes in malaria-prone regions to kill the vector mosquitoes, by the 1960s it emerged that such interventions were having limited impact due to rising DDT resistance in mosquitoes and the realization that the effectiveness of the insecticides was considerably diminished in rural dwellings that were typically built with mud. Though this led to a growing consensus on the need for using antimalarial drugs more prominently for malaria eradication, the supply of such drugs was adversely impacted by logistical problems arising from precarious public health infrastructures. By the early 1970s, DDT was banned in many developed countries including the US. Funding for malaria eradication declined sharply and in 1969 the World Health Assembly acknowledged that many countries would not realize malaria eradication for the foreseeable future.

Of all the vertical eradication programmes pursued during this period in WHO, only smallpox was successfully eradicated.³⁰ However, the experience of all other vertical disease

²⁸ Theodore M. Brown et. al., "The World Health Organization and the Transition from 'International' to 'Global' Public Health", *American Journal of Public Health*, vol. 96, No. 1 (2006), pp. 62-72. Available from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1470434/>.

²⁹ For example, the massive spraying of DDT insecticide for eradication of the mosquito that acts as the vector for the malaria parasite was a major feature of the Global Program for Malaria Eradication. The WHO Executive Board adopted a decision in 1955 subsequently endorsed by the eighth World Health Assembly urging all countries threatened by malaria to undertake total eradication before mosquitoes developed resistance against the insecticide.

³⁰ Smallpox eradication was originally proposed by the Soviet Union in 1958 after it returned to the WHO in 1956. However, the programme really took off in the 1960s with the US coming around to support the work of WHO on smallpox eradication. In 1966 the World Health Assembly approved an item on smallpox eradication in the regular budget of WHO and allocated about 2.5 million USD to the item. In the following year, the Health Assembly formally

eradication programmes was very modest. These programmes also proved to be very expensive. At the same time, by diverting resources away, these programmes hindered the growth of integrated health services. This led to the realization within WHO and other agencies of the need for the development of integrated health services, including basic health services.

III.2 Focus on Primary Health Care

The 1960s was marked by the end of colonization and the emergence of newly independent States in Asia and Africa. These States began to assert themselves in the UN and its specialized agencies calling for a global order that adequately addressed their development aspirations. To that end they called for the establishment of a "New International Economic Order" (NIEO). Developing countries critiqued that the existing international order contributed to the consolidation and concentration of economic power in the hands of a few nations and the maintenance of more than two-thirds of mankind in poverty and dependence.³¹ In 1974, the UN General Assembly unanimously adopted a resolution titled "Declaration on the Establishment of a New International Economic Order." As stated in the NIEO Declaration, its objective was to "... correct inequalities and redress existing injustices, make it possible to eliminate the widening gap between the developed and the developing countries and ensure steadily accelerating economic and social development and peace and justice for present and future generations....".

While the NIEO Declaration did not specifically mention health as a development issue, the importance of addressing health in the context of NIEO was clarified in 1975 by another unanimous resolution on development and international economic cooperation that was adopted by the Special Session of the UN General Assembly. This resolution specifically stated that the WHO and competent organs of the UN system, particularly UNICEF, must "... intensify the international effort aimed at improving health conditions in developing countries by giving priority to prevention of disease and malnutrition and by providing primary health services to the communities, including maternal and child health and family welfare." ³²

The NIEO Declaration served as the moral and political backdrop for the movement in the WHO to pursue the goal of primary health care (PHC) and the goal of "health for all"³³ under the leadership of its Director-General Dr. Halfdan Mahler. In his 1976 report to the UN on the work of WHO, Dr. Mahler referred to the NIEO Declaration and the 1975 UN General Assembly resolution as "... a turning-point in the history of the United Nations and of international cooperation..." Acknowledging unequivocally the relevance of NIEO to the work of WHO, Dr. Mahler further stated:

approved the formation of the Smallpox Eradication Programme (SEP), which was headed by an American officer on secondment from the US Centers for Disease Control (CDC). The Soviet Union also acceded to the choice of leadership of the SEP and donated 75 million doses of the smallpox vaccine. Unlike malaria eradication, smallpox vaccination was conducted based on a strategy of surveillance and containment rather than an emphasis on absolute numbers of vaccinated populations. The cooperation between the superpowers allowed WHO to work with relative autonomy and smallpox vaccination was carried out by combining the medical and technical knowledge of WHO experts along with the participation of local populations in planning and implementation. This allowed the 33rd World Health Assembly to declare in 1980 that the global eradication of smallpox had been accomplished.

³¹ Mohamed Bedjaoui, *Towards a New International Economic Order* (New York, Holmes & Meier Publishers, 1979). Available from <https://unesdoc.unesco.org/ark:/48223/pf0000035806>.

³² UN General Assembly document A/RES/3362(S-VII). Available from https://digitallibrary.un.org/record/218608/files/A_RES_3362%28S-VII%29-EN.pdf?ln=en.

³³ Kiran R. Pandey, "From health for all to universal health coverage: Alma Ata is still relevant", *Globalization and Health*, vol. 14 (2018), p. 62. Available from <https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/s12992-018-0381-6.pdf>.

"Has the Organization a part to play in establishing and maintaining the New Economic Order? I believe that the answer must be an emphatic affirmative. I think it would be true to say that the General Assembly's deliberations and decisions have vindicated views that have long been expressed within this Organization.... we have made a start in reorienting the Organization's programmes towards fostering social and economic development rather than confining ourselves to health development at the purely technical level."³⁴

Indeed, around the same time as the NIEO movement was growing in the UN, a debate had ensued in WHO on the importance of PHC. The debate emerged as a critique of the vertical programmes. At the World Health Assembly in 1970, the Soviet Union proposed a resolution on scientific or rational principles for the development of national public health systems.³⁵ The Health Assembly adopted resolution WHA 23.61 on basic principles for the development of national health services.³⁶ In January 1971, the Executive Board agreed to undertake an "Organizational Study on Methods of Promoting the Development of Basic Health Services" which was submitted to the Executive Board in 1973. The 1975 World Health Assembly adopted a resolution welcoming the report and requested the Director-General to report to the Executive Board on a comprehensive long-term research programme with systems of health care organization on local and country-wide levels, and to report also on the steps taken to implement the conclusions and recommendations of the organizational study and their impact on future programmes of the WHO.³⁷

At the Executive Board session in January 1975, the Director-General submitted a report on "Promotion of National Health Services." This report advocated that primary health care services at the community level is the only way in which health services can develop rapidly and effectively and called for a radical departure from conventional health services approaches and fully integrate primary health care with other sectors of community development (agriculture, education, housing, public works, etc.).³⁸

In parallel, WHO and UNICEF issued a joint report in 1975 on "Alternative Approaches to Meeting Basic Health Needs in Developing Countries." This report heavily critiqued the focus on eradication of specific diseases under the vertical programmes and their assumption that expansion of Western medical systems would meet the needs of the common people in developing countries. The report pointed out that the principal causes of morbidity in developing countries were malnutrition and respiratory and diarrheal diseases, which were the result of poverty, squalor and lack of education.

In this context, the 1975 World Health Assembly adopted a resolution which urged Member States to develop and implement national plans of action on primary health care leading to the provision of a comprehensive health care system to the total population. It also requested the WHO Director-General to promote and assist the development of primary healthcare activities through the active participation of different socio-economic sectors, and continue consultations with member States and relevant national and international agencies in order to

³⁴ WHO, The Work of WHO, 1975: Annual Report of the Director-General to the World Health Assembly and to the United Nations, Official Records of the World Health Organization, No. 22 (Geneva, World Health Organization, 1976). Available from

https://apps.who.int/iris/bitstream/handle/10665/86025/Official_record229_eng.pdf?sequence=1&isAllowed=y.

³⁵ Socrates Litsios, "The Long and Difficult Road to Alma-Ata: A Personal Reflection", *International Journal of Health Services*, vol. 32, No. 4 (2002), p. 712. Available from <https://www.jstor.org/stable/45131243?read-now=1&seq=4>.

³⁶ WHO document WHA23.61, 22 May 1970. Available from https://apps.who.int/iris/bitstream/handle/10665/91739/WHA23.61_eng.pdf?sequence=1&isAllowed=y.

³⁷ WHO document WHA26.35, 22 May 1973. Available from https://apps.who.int/iris/bitstream/handle/10665/92123/WHA26.35_eng.pdf?sequence=1&isAllowed=y.

³⁸ WHO document EB55/9, 6 December 1974. Available from https://apps.who.int/iris/bitstream/handle/10665/148378/EB55_9_eng.pdf?sequence=1&isAllowed=y.

obtain assistance in the development of an expanded long-term programme on primary health care, including technical and financial aspects. In response to a proposal by the Soviet Union to organize an international conference to exchange experience on the development of primary health care as part of national health services, the resolution acknowledged that organizing such a conference would be desirable.³⁹ The following year the Executive Board agreed to organize such a conference. The only viable proposal to host the conference was submitted by the Soviet Union. Accordingly, as proposed, the International Conference on Primary Health Care was held in Alma Ata in 1978. The possibility of UNICEF co-sponsoring the conference was formally welcomed by the 1976 World Health Assembly through a resolution.⁴⁰

Meanwhile, in 1975 the WHO Director-General had issued a "Blueprint for Health for All by the Year 2000." The essential elements of the blueprint included adequate food and housing protected against insects and rodents, water for cleanliness and safe drinking, waste disposal, immunization against major infectious diseases of childhood, and prevention and control of locally endemic diseases. The priority programmes under the blueprint included primary health care, control of communicable diseases and locally important diseases, appropriate health technology, drugs, basic sanitary measures, and human resources to conceive and deliver these programmes and manage the systems. The Director-General was of the view that primary health care had to be part of a broader health system, and the components of that system had to be so organized as to support its needs. These elements were also elaborated in the Director-General's report to the UN on the work of the WHO in 1975.

III.2.1 The Alma Ata Declaration

The International Conference on Primary Health Care adopted a declaration which was endorsed by a resolution of the World Health Assembly in 1979. The Alma Ata Declaration specifically recognized the gross inequality in the health status of people from developed and developing countries, as well as within countries, as a matter of common concern for all countries. It emphasized that economic and social development based on NIEO is of basic importance for the fullest attainment of health for all and the reduction of the gap in the health status between developed and developing countries. The Declaration stated that a main social target of governments, international organizations and the world community in following decades should be the attainment by the year 2000 of a level of health that will permit all peoples of the world to lead a socially and economically productive life. It emphasized that primary health care is key to attaining this target as part of development in the spirit of social justice. The Declaration also enlisted the minimal elements of primary health care – education about health problems and their prevention and control, promotion of food supply and proper nutrition, adequate supply of water and basic sanitation, maternal and child health care including family planning, immunization against major infectious diseases, prevention and control of locally endemic diseases, appropriate treatment of common diseases and injuries, and provision of essential drugs.

The work of WHO on various initiatives relating to primary health care and "Health for All" continued for the next few years after the Alma Ata Declaration. Through resolution WHA32.30 that endorsed the Alma Ata Declaration, the 1979 World Health Assembly invited member States to act individually and collectively in formulating national, regional and global strategies for health for all. The Global Strategy for Health for All by the Year 2000 was adopted by the 1981 Health Assembly through resolution WHA 34.36.

³⁹ WHO document WHA28.88, 29 May 1975. Available from https://apps.who.int/iris/bitstream/handle/10665/86022/Official_record226_eng.pdf?sequence=1&isAllowed=y.

⁴⁰ WHO document WHA29.19, 13 May 1976. Available from https://apps.who.int/iris/bitstream/handle/10665/86029/Official_record233_eng.pdf?sequence=1&isAllowed=y.

III.3 Essential Drugs, Intellectual Property and Access to Medicines

An integral component of primary health care and "Health for All" was the consolidation of the concept of essential drugs in the work of WHO. During the 1970s developing countries began to pursue a vision of self-reliance in pharmaceutical manufacturing as a major component of their self-sufficiency in health. Several developing countries introduced innovative policies and management tools to meet the therapeutic needs of their populations and provide the most needed medicines. This was supported by the WHO by assisting countries in the process of selection of a list of essential medicines in the context of their health challenges and promoting rational use of drugs.⁴¹

The production and distribution of essential drugs was seen as an area in which implementation of the NIEO declaration could contribute to decreasing the dependency of the global South on developed countries.⁴² Thus, in the 1975 World Health Assembly the Director-General strongly advocated for the development of national pharmaceutical policies based on affordability, quality and availability of drugs. The Health Assembly adopted resolution WHA 28.66 which urged the WHO to assist Member States to formulate national pharmaceutical policies that meet the health needs of the people. The WHO began compiling national practices on lists of basic drugs and the first meeting of the Expert Committee on Selection of Essential Drugs was held in 1977. The Expert Committee adopted the first WHO Model List of Essential Medicines which contained 208 medicines.⁴³

The discussions at the Alma-Ata conference sowed the seeds for subsequent work, and debate, in the WHO for affordable and equitable access to medicines, vaccines and health technologies. The conference agreed unequivocally that "Primary health care requires the development, adaptation and application of appropriate health technology that the people can use and afford, including an adequate supply of low-cost, good-quality, essential drugs, vaccines, biologicals, and other supplies and equipment." In this context, the conference made the following recommendation:

"The Conference,

Recognizing that primary health care requires a continuous supply of essential drugs; that the provision of drugs accounts for a significant proportion of expenditures in the health sector; and that the progressive extension of primary health care to ensure eventual national coverage entails a large increase in the provision of drugs,

RECOMMENDS that government formulate national policies and regulations with respect to the import, local production, sale and distribution of drugs and biologicals so as to ensure that essential drugs are available at the various levels of primary health care at the lowest feasible cost;"⁴⁴

The 1981 World Health Assembly also requested the Director-General to establish a special programme on essential drugs and the same year the Action Programme on Essential Drugs

⁴¹For example, the ban on irrational drugs in Bangladesh led to the exit of multinational pharmaceutical companies and enabled the development of a local industry in finished simple pharmaceutical formulations. See Sudip Chaudhuri, "Evolution of the Pharmaceutical Industry Bangladesh 1982 to 2020", Centre for Development Studies, Working Paper 495. Available from <https://dx.doi.org/10.2139/ssrn.3767822>.

⁴² Oscar Gish, "Relation of the New International Economic Order to Health", *Journal of Public Health Policy*, vol. 4, No. 2 (1983), p. 215. Available from <https://doi.org/10.2307/3342434>.

⁴³ Zafar Mirza, "Thirty Years of Essential Medicines in Primary Health Care", *La Revue de Santé de la Méditerranée Orientale*, vol. 14, 2008, S.75. Available from <http://www.emro.who.int/emhj-volume-14-2008/volume-14-supplement/thirty-years-of-essential-medicines-in-primary-health-care.html>.

⁴⁴ WHO and UNICEF, Primary Health Care: Report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978 (Geneva, World Health Organization, 1978). Available from <https://www.unicef.org/media/85611/file/Alma-Ata-conference-1978-report.pdf>.

was established.⁴⁵ In accordance with the Alma-Ata Declaration, in 1985 the second meeting of the WHO Expert Committee on Selection of Essential Drugs produced a specific model list of essential medicines for primary health care by selecting 23 medicines from the list of essential medicines produced in its first meeting in 1977.⁴⁶ The 1980 session of the World Health Assembly also undertook discussions in six working groups on the contribution of health to the New International Economic Order.⁴⁷ Consistent with NIEO, the WHO leadership envisioned the Essential Drugs Programme to address local production of medicines and intellectual property (IP) rights.

IP protection and its implications for development of pharmaceutical industry received particular attention in this context. In 1980 the United Nations Conference on Trade and Development (UNCTAD) produced a study on "Technology Policies and Planning for the Pharmaceutical Sector in the Developing Countries" calling for the establishment of regulatory frameworks for transfer and development of technology for pharmaceuticals production. In the same year, the United Nations Industrial Development Organization (UNIDO) prepared a "Global Study of the Pharmaceutical Industry" which recommended that "Developing countries should consider the implementation of policies restricting the excessive privileges granted to patent holders...." In the same spirit, the WHO Director-General Dr. Halfdan Mahler said in an interview, "With essential drugs ... we are now moving straight into technology, production, patents, trademarks – all the elements of a new international economic order in the widest sense."⁴⁸

The possible implications of the lack of pharmaceutical capacity in a country are illustrated by the AIDS crisis. By the mid-1990s the international response scenario to AIDS had changed with the discovery of antiretroviral drugs. However, the World Bank along with USAID and the UK Department for International Development did not favour the promotion of antiretroviral treatment in developing countries due to the prohibitive cost of such drugs and instead preferred to focus on preventive measures in developing countries. Nevertheless, developing countries began to adopt measures to promote universal access to affordable generic antiretroviral drugs. For example, in 1996 Brazil enacted a law making generic and patented antiretroviral drugs universally available and encouraged the production of generic drugs. South Africa also enacted a law to enable the parallel importation of generic antiretroviral drugs, which was challenged in an infamous case by multinational pharmaceutical companies. This led to a global outcry and eventually led to the adoption of the Doha Declaration on TRIPS and Public Health in the World Trade Organization (WTO), reaffirming the scope of using flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for public health purposes.⁴⁹ During this period WHO produced a number of important publications pointing to the flexibilities⁵⁰ available in the TRIPS Agreement and their importance for public health.

The WHO Essential Drugs Programme produced a seminal publication on the implications of the TRIPS Agreement and the possible options available under the TRIPS Agreement to safeguard and promote access to medicines. In 1996 the World Health Assembly adopted

⁴⁵ WHO document EB95/INF.DOC./6, 12 October 1994. Available from https://apps.who.int/iris/bitstream/handle/10665/172278/EB95_Inf.Doc-6_eng.pdf?sequence=1&isAllowed=y.

⁴⁶ Zafar Mirza, *supra* note 43.

⁴⁷ WHO document A/33/Technical Discussions/5, 15 May 1980. Available from https://apps.who.int/iris/bitstream/handle/10665/155565/WHA33_TD-5_eng.pdf?sequence=1&isAllowed=y.

⁴⁸ James R. Phelps, "The New International Economic Order and the Pharmaceutical Industry", *Food, Drug, Cosmetic Law Journal*, vol. 37, No. 2, 1982, p. 207. Available from <https://www.jstor.org/stable/26658660?seq=8>.

⁴⁹ Carlos Correa and Duncan Matthews, "The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health", UNDP Discussion Paper, 20 December 2011, pp. 6-7. Available from https://www.undp.org/content/dam/undp/library/hiv/aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf.

⁵⁰ See South Centre, "A Public Health Approach to Intellectual Property Rights: Public Health Related Flexibilities in the TRIPS Agreement". Available from <https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf>.

resolution WHA 49.14 on the revised drug strategy, which requested the WHO produce a study on the implications of the TRIPS Agreement. This study — "Globalization and Access to Drugs: Implications for the WTO/TRIPS Agreement" — stressed that public health concerns should be considered when implementing the TRIPS Agreement.⁵¹

Several resolutions by the World Health Assembly since 1996 have addressed the role that the WHO and its Member States should undertake in the area of access to medicines. These resolutions have consistently called upon Member States of the WHO to make full use of the flexibilities under the TRIPS Agreement; requested the WHO Secretariat to monitor and analyse the pharmaceutical and public health implications of trade agreements; explore options under trade agreements to improve access to medicines; and provide guidance and technical support to Member States in their efforts in this regard.⁵²

The WHO has undertaken several initiatives on the basis of these resolutions. In 2006, a report by an independent commission established by the WHO to examine the interface between public health, innovation and intellectual property recommended, among others, that the WHO should develop a global plan of action to secure sustainable funding for developing new medical products and for making medical products that mainly affect developing countries more accessible. Based on this recommendation an intergovernmental working group of member states was established to develop a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) by the World Health Assembly in 2008.

The GSPA-PHI gave WHO the mandate to provide technical support to countries that intend to make use of the provisions of the TRIPS Agreement, including its flexibilities.⁵³ It also pointed to the need to examine the financing and coordination of research and development and consider proposals for new and innovative sources of financing to stimulate biomedical research and development. Pursuant to this a WHO Consultative Expert Working Group on Research and Development (CEWG) had recommended in 2012 to commence negotiations for a binding treaty on biomedical research and development (R&D treaty).⁵⁴

Since then, WHO activities in the area of access to medicines and IP have been sporadic and limited. The implementation of the GSPA-PHI has been underfunded and failed to create any impact.⁵⁵ Thus, even after the adoption of several resolutions, the WHO has played a limited role in the promotion of local production, technology transfer and in addressing health-related IP issues.⁵⁶ WHO Member States also failed to agree to the recommendation of the CEWG to negotiate a binding R&D treaty.

In 2018, the World Health Assembly requested the WHO Secretariat to prepare a roadmap on access to medicines and vaccines for the period 2019-2023. With regard to the work of WHO on IP and access to medicines the roadmap did not address the importance of use of TRIPS flexibilities though it mentioned that the WHO would offer technical assistance in this area

⁵¹ German Velasquez, *Seeking Remedies for Access to Medicines and Intellectual Property: Recent Developments* (South Centre, Geneva, 2019). Available from https://www.southcentre.int/wp-content/uploads/2019/11/Bk_2019_Seeking-Remedies-for-Access-to-Medicines-and-Intellectual-Property_EN.pdf.

⁵² See German Velasquez, *Medicines and Intellectual Property: 10 Years of the WHO Global Strategy*, Research Paper No. 100 (South Centre, Geneva, 2019), 14. Available from https://www.southcentre.int/wp-content/uploads/2019/12/RP100_Medicines-and-Intellectual-Property-10-Years-of-the-WHO-Global-Strategy-EN.pdf.

⁵³ German Velasquez, *supra* note 51.

⁵⁴ WHO document A65/24, 20 April 2012. Available from https://apps.who.int/gb/CEWG/pdf_files/A65_24-en.pdf.

⁵⁵ See Catherine Saez, "World Health Assembly Agrees to Reinvalidate Plan of Action to Boost R&D, Access", *Health Policy Watch*, 25 May 2018. Available from <https://healthpolicy-watch.news/wha-agrees-on-recommendations-to-reinstantiate-plan-of-action-to-boost-rd-access/>.

⁵⁶ See German Velasquez, *supra* note 52.

upon request of Member States. However, in comparison to the limited focus on TRIPS flexibilities the roadmap provided greater attention to management and licensing of IP rights and the trilateral cooperation of WHO with WIPO and WTO.

The marginalization of WHO activities in the area of access to medicines and IP has also been very evident in its response to the COVID-19 pandemic (see box 2).

Box 2

In the wake of COVID-19, the use of TRIPS flexibilities can be critical to enable governments to take adequate measures to ensure that the knowledge for manufacturing medicines and vaccines on a mass scale is made accessible for such purpose without being constrained by any IP right. A number of instances exist where IP rights have been a constraint to the use of health technologies required for COVID-19.⁵⁷ In this context, even though resolution WHA73.1 made a mention of TRIPS flexibilities, the US specifically disassociated from the paragraphs referring to the need to use TRIPS flexibilities.⁵⁸

Much of the focus of the multilateral response to the concerns around IP in the context of COVID-19 has been on exhorting actions by governments and the private sector to undertake voluntary licensing of technologies through use of patent pooling mechanisms. This preference for voluntary mechanisms that relies on the solidarity and goodwill of the patent right holders, essentially allows the boundaries of public policy in response to COVID-19 to be determined by business corporations that may own the patent rights over the needed medicines and vaccines.⁵⁹ However, even the call for voluntary action has not found sufficient support from developed countries and the pharmaceutical industry. For example, the US had reacted to the reference to voluntary pooling of patents in the WHO resolution on COVID-19 by stating that it should be narrowly tailored in scope.⁶⁰

In May 2020, WHO launched a COVID-19 Technology Access Pool (C-TAP) to compile the pledges of commitments made to voluntarily share COVID-19 health technology related knowledge, IP and data, in accordance with a solidarity call to action by the President of Costa Rica and the WHO Director-General. C-TAP has the overall objective of "promoting open science in order to accelerate product development and facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how'".⁶¹ However, the most important challenge for C-TAP has been to develop an operating model that could be sufficiently attractive for holders of proprietary knowledge, data and technology to waive their commercial interests and voluntarily share the same through C-TAP.⁶² C-TAP was able to secure its first licensing agreement — a global non-exclusive licensing agreement for a COVID-19 serological antibody test technology, nearly two years after its launch.⁶³ In May 2022, the Medicines Patent Pool (MPP) concluded two

⁵⁷ Nirmalya Syam, "Intellectual Property, Innovation and Access to Health Products for COVID-19: A Review of Measures Taken by Different Countries" South Centre, Policy Brief No. 80, June 2020, p. 2. Available from <https://www.southcentre.int/wp-content/uploads/2020/06/PB-80.pdf>.

⁵⁸ Nirmalya Syam, et. al., supra note 2.

⁵⁹ Sudip Chaudhuri, "Making COVID-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities", *SouthViews* No. 200, 16 June 2020. Available from <https://www.southcentre.int/wp-content/uploads/2020/06/SouthViews-Chaudhuri.pdf>.

⁶⁰ Nirmalya Syam et.al., supra note 2.

⁶¹ WHO, "Operationalising the COVID-19 Technology Access Pool (C-TAP): A Concept Paper". Available from https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true.

⁶² Biswajit Dhar and K.M. Gopakumar, "Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS", ARTNet Working Paper Series No.200, November 2020, Bangkok: ESCAP, pp. 8-9. Available from https://www.unescap.org/sites/default/d8files/knowledge-products/AWP200_Dhar.pdf.

⁶³ Priti Patnaik, "Policy Updates: WHO/Health: C-TAP", *Geneva Health Files*, 23 November 2021. Available from <https://genevahealthfiles.substack.com/p/whos-c-tap-wins-its-first-license?s=r>.

voluntary licenses under the auspices of C-TAP with the US National Institutes of Health for 11 technologies related to therapeutics, early-stage vaccines and diagnostics.⁶⁴

In April 2021 WHO and its partners announced the launch of one or more COVID-19 mRNA Vaccine Technology Transfer Hubs to expand the capacity of low and middle-income countries to produce COVID-19 vaccines and scale up manufacturing. It was also stated that the initiative will initially prioritize mRNA vaccine technology but could expand to other technologies in the future. The WHO invited expressions of interest from manufacturers of medical products which could host an mRNA hub and assemble the technology up to good manufacturing practices-grade, pilot lots for clinical trials and transfer the appropriate know-how and technology to existing or new manufacturers in LMICs to develop and produce mRNA vaccines. At the same time, WHO also invited expressions of interests from IP owners to voluntarily contribute their proprietary technology to an mRNA hub through the WHO.⁶⁵ Soon after the launch of the South African mRNA hub, in July 2021, Pfizer and its partner BioNTech entered into a contract manufacturing agreement with Biovac – the South African manufacturing spoke of the mRNA hub – under which Biovac would undertake "fill and finish" work (putting the vaccine into vials, sealing and shipping) to produce 100 million doses of the Pfizer-BioNTech mRNA vaccine annually for Africa. This fell short of the transfer of the technology and know-how for manufacturing mRNA vaccines that the WHO mRNA hub sought to do. Moreover, in August 2021, a consulting firm hired by BioNTech submitted to the Government of South Africa a "Mission Report to South Africa" which remarked that "The WHO Vaccine Technology Transfer Hub's project of copying the manufacturing process of Moderna's COVID-19 vaccine should be terminated immediately. This is to prevent damage to Afrigen, BioVac, and Moderna....".⁶⁶ Despite this, the mRNA hub in South Africa made significant progress in replicating the COVID-19 mRNA vaccine⁶⁷ while a new mRNA vaccine was developed in the Latin American hub.⁶⁸

III.4 Food Standards

The 1963 World Health Assembly approved the joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission (the Codex).⁶⁹ The Codex is funded through the

⁶⁴ WHO, US NIH licenses to C-TAP. Available from <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses>.

⁶⁵ WHO, "Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing", 16 April 2021. Available from <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

⁶⁶ Madlen Davies, "COVID-19: WHO efforts to bring vaccine manufacturing to Africa are undermined by the drug industry, documents show", *The BMJ*, vol. 376, 9 February 2022. Available from <https://doi.org/10.1136/bmj.o304>.

⁶⁷ Michael Dumiak, "Can mRNA manufacturing become more global?" IAVI, 21 June 2022. Available from <https://www.iavi.org/iavi-report/can-mrna-manufacturing-become-more-global>.

⁶⁸ Nurith Aizenman, "A dire moment in the pandemic ... was the chance he'd been waiting for", NPR, 18 July 2022. Available from https://www.npr.org/sections/goatsandsoda/2022/07/18/111985674/middle-income-countries-have-come-up-with-a-game-changing-plan-for-covid-vaccine?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social.

⁶⁹ In the 1950s WHO and FAO had established close collaboration to work on international food standards through joint expert meetings on nutrition, food additives, etc. In 1953 the World Health Assembly recognized the increasing use of chemical substances in the food industry as a health problem. During this time, Austria pursued the adoption of a regional food code for Europe known as the Codex Alimentarius Europeus leading to the establishment of the European Council of the Codex Alimentarius Europeus in 1958. In 1960 the FAO Regional Conference for Europe endorsed the desirability of an international agreement on minimum food standards and requested the FAO to submit proposals for a joint FAO/WHO programme on international food standards. The European Council of the Codex Alimentarius Europeus also proposed through a resolution that its work on food standards be taken over by FAO and WHO. The 1961 FAO Conference established the Codex Alimentarius Commission and a joint FAO/WHO Standards Programme, requesting the WHO to endorse the same. In 1962 WHO and FAO organized a joint Food Standards Conference which requested the Codex Alimentarius Commission to implement a joint

regular budgets of WHO and FAO, and its activities are subject to the approval of the governing bodies of the two organizations.

The purpose of the Codex is to adopt international food standards aimed at protecting consumers' health and ensuring fair practices in food trade. One hundred and eighty-eight countries and the European Union are members of the Codex. Though the standards adopted by the Codex are non-binding, they assume a de facto effect of binding standards as they are recognized as standards of reference under the WTO agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT).

The status of the Codex as the implementation arm of a joint programme of WHO and FAO, subordinate to their governing bodies, suggests that as far as the WHO is concerned, the standards should safeguard public health concerns. However, critics have pointed out that there is an imbalance between public health and fair-trade practices in the standards adopted by the Codex, with increasing involvement of national trade officials and the reflection of their commercial interests in its work.⁷⁰ In several instances, the Codex standards on commercial milk formula have been cited by exporters of dairy and milk formula products to challenge national laws implementing the WHO International Code of Marketing of Breast-Milk Substitutes (International Code).⁷¹

A major development in WHO through the 1970s and 1980s was the work on promotion of breast milk leading to the adoption of the International Code.⁷² This put WHO on a path of confrontation with the global artificial infant formula industry. In 1979 WHO and UNICEF began work on the International Code which was finally adopted by the World Health Assembly in 1981. Notably, however, the US openly opposed the Code and was the sole country voting against it. It is important to note that the US opposition also prevented the WHO from adopting the International Code as a binding regulation under article 21 of the WHO Constitution, like the IHR, and the International Code was adopted only as a recommendation. This made the International Code non-binding and consequently very few countries have implemented it in their national laws.

III.5 Selective Primary Health Care

The implementation of the Alma-Ata Declaration was impacted adversely by geopolitical developments, much like the implementation of NIEO. Developing countries were adversely impacted by the economic shock resulting from the oil crisis. The economic crisis compelled many developing countries to seek financial assistance from the International Monetary Fund (IMF) which provided such assistance based on conditionalities that included undertaking structural adjustment programmes involving drastic cuts in public health budgets. The forced withdrawal of the State from the health sector created health markets for the private sector. The election of Prime Minister Thatcher in the UK in 1979 and President Reagan in the US in 1980 marked the global revival of conservatism and assertion of neoliberal economic policies that sought to promote unregulated markets, limiting State welfarism, privatization of State

FAO/WHO food standards programme and create the Codex Alimentarius. The first meeting of the Codex Alimentarius Commission was held in 1963.

⁷⁰ Sam F. Halabi, "The Codex Alimentarius Commission, Corporate Influence and International Trade: A Perspective of FDA's Global Role", *American Journal of Law and Medicine*, vol. 41 (2015), p. 413. Available from <https://scholarship.law.missouri.edu/cgi/viewcontent.cgi?article=1648&context=facpubs>.

⁷¹ Kathryn Russ et. al., "What You Don't Know About the Codex Can Hurt You: How Trade Policy Trumps Global Health Governance in Infant and Young Child Nutrition", *International Journal of Health Policy and Management*, vol. 10 (No. 12), pp. 983-97. Available from https://www.ijhpm.com/article_4101_7d772b3450e87b15c49de5d03a91ea69.pdf.

⁷² In 1974 the World Health Assembly had adopted a resolution that urged member States to promote breast milk as part of balanced nutritional requirements of infants and as the best form of prevention of early childhood infections. In 1978, another resolution called for the regulation of sales promotion of artificial infant foods.

enterprises, and removal of restrictions on foreign investors. The IMF, the World Bank and the US Agency for International Development (USAID) promoted neoliberalism in all sectors, including health. Under the Reagan Administration, the US became vehemently critical of the UN system, including the WHO. The US complained of improper political debates occurring in WHO. In 1985, the US withdrew from the United Nations Educational, Scientific and Cultural Organization (UNESCO), creating strong suspicion that it might similarly withdraw from other international organizations.

In 1979, the same year that the World Health Assembly adopted the Alma Ata Declaration, the Rockefeller Foundation sponsored a conference in Bellagio, Italy with the participation of the heads of the World Bank, the Canadian International Development and Research Center (IDRC), the Ford Foundation, and USAID. The objective of the conference was to discuss identification of cost-effective and practical health strategies. In this conference, the broad definition of primary health care in the Alma Ata Declaration provoked an immediate challenge. The discussions were based on an article in the *New England Journal of Medicine* in 1979 that critiqued the concept of primary health care as impractical and advanced the concept of selective primary health care (SPHC), an approach that focused on diseases with the highest prevalence, greatest risk of mortality and highest possibility of control in terms of cost effectiveness.⁷³ After the Bellagio conference, the concept of SPHC was embraced and promoted in WHO and UNICEF by developed countries,⁷⁴ as a realistic alternative to implementation of the Alma Ata Declaration.

Another major advocate of primary health care and co-sponsor of the Alma Ata conference, the UNICEF, also began to prioritise a set of specific, low-cost interventions focused on growth monitoring of children, oral rehydration techniques for diarrheal diseases, breastfeeding and immunization (GOBI).⁷⁵ These interventions were supported by the World Bank and US bilateral agencies. UNICEF ventured further to make these interventions the basis for launching the "Child Survival and Development Revolution" (CSDR). Immunization was one of the principal pillars of CSDR, and universal child immunization by 1990 (UCI-1990) soon became the primary focus of UNICEF. UNICEF was instrumental in mobilizing global support for this goal that was originally articulated by the WHO in 1977 under the Expanded Programme on Immunization (to achieve universal child immunization for six antigens by 1990).⁷⁶

SPHC approaches have been criticized by scholars from developing countries on several grounds. First, such programmes inhibited self-reliance and encouraged dependency of developing countries on western countries for funds, vaccines and equipment. Second, such programmes were implemented at the country level without considering any data on the incidence rates of infectious diseases to be vaccinated against or the epidemiological trends of targeted diseases, lack of health workers to provide sufficient immunization coverage, the lack of cold storage facilities, and diversion of scarce administrative and financial resources to immunization and the consequent neglect of other areas of health services.⁷⁷

⁷³ J.A. Walsh and K.A. Warren, "Selective primary health care: an interim strategy for disease control in developing countries", *New England Journal of Medicine*, vol. 301, No. 18 (1979), pp. 967-74. Available from <https://pubmed.ncbi.nlm.nih.gov/114830/>.

⁷⁴ Debabar Banerji, "Reflections on the Twenty-Fifth Anniversary of the Alma-Ata Declaration", *International Journal of Health Services*, vol. 33, No. 4 (2003), p. 816. Available from <https://www.jstor.org/stable/45131322?seq=4>.

⁷⁵ Subsequently, food supplementation, female literacy and family planning were added to this, with expanded acronym GOBI-FFF.

⁷⁶ Richard Jolly, "Jim Grant: The Man behind the Vision", in Richard Jolly (ed.), *Jim Grant: UNICEF Visionary*. Available from <https://www.unicef.org/media/92481/file/Jim-Grant-LR.pdf>.

⁷⁷ See Debabar Banerji, "Hidden Menace in the Universal Child Immunization Program", *International Journal of Health Services*, vol. 18, No. 2 (1988), pp. 294-5. Available from <https://www.jstor.org/stable/45130560?read-now=1&refreqid=excelsior%3Ac450495f612dbbc84e2f3179ff1d5ed2&seq=3>.

Nevertheless, despite the criticism, the SPHC approaches continued. In 1988 the World Health Assembly discussed a report on the progress of primary health care and the goal of "Health for All by 2000." While the report acknowledged that the goal of "Health for All" had a strong impact, few practical commitments to primary healthcare had been made, especially in developing countries. In the same session the Assembly adopted a resolution on health promotion, public information and education. The resolution urged WHO Member States to develop strategies for health promotion and health education as an essential element of primary health care.⁷⁸ However, the health promotion work in WHO did not lead to a revival of primary health care, and health promotion itself became de-prioritized in the WHO after a new director-general was appointed in 1988.⁷⁹

⁷⁸ WHO document WHA42.44, 19 May 1989. Available from https://apps.who.int/iris/bitstream/handle/10665/172239/WHA42_R44_eng.pdf?sequence=1&isAllowed=y.

⁷⁹ Commenting on the concept of health promotion, a leading public health scholar from the South had observed that "People should not be asked to eat the cake of promotion of positive health when they do not have the bread of relief from the suffering caused by the diseases of poverty and oppression." Debabar Banerji, "Health Promotion: A personal view from the South", *Health Promotion*, vol. 1, No. 1 (1986), p. 82. Available from <https://www.deepdyve.com/lp/oxford-university-press/health-promotion-a-personal-view-from-the-south-VH44NpYD9r?key=OUP>.

IV. FRAGMENTATION AND SHARING OF LEADERSHIP IN GLOBAL HEALTH

Around this time, while the WHO was experiencing significant financial challenges that were impacting its operations, the World Bank emerged as a major financial institution playing an active role in health. In 1993, the World Bank published a report *Investing in Health*, the first annual report by the World Bank that focused on a specific sector. The report defined a package of essential health services that governments should assure to their populations. It also introduced a new indicator to measure the cost of disease interventions and define priorities to allocate resources – the Disability Adjusted Life Years (DALY). The World Bank advocated for health spending on cost-effective programmes and decentralizing and reforming health services to promote quality and competition. While the WHO had a zero growth budget since 1982 and budgetary deficit of USD 206 million in 1996, the World Bank held a USD 8 billion portfolio in health programmes in the same year and was the largest single financier of health activities in low-and middle-income countries. It promoted a neoliberal agenda of health sector reforms in such countries resulting in reduced access to health services for the poorest sections of societies. The WHO was unable to launch an alternative proposal for health reform even though the Director-General complained to the Executive Board that the World Bank approach was distorting the aim of free access to health care for all.

In this context, the WHO began to refashion itself as a coordinator, strategic planner and leader of global health initiatives. In 1992, the Executive Board appointed a working group to recommend how WHO could be most effective in international health work. The working group recommended that WHO must overhaul its fragmented management of global, regional and country programmes, diminish competition between regular and extrabudgetary programmes, and increase the emphasis on global health issues⁸⁰ and its coordinating role in that domain.⁸¹ The WHO Secretariat transmitted the recommendations of the working group to the regional committees and the initiative did not progress further thereafter.

In 1995, the World Health Assembly rejected the proposed budget of the WHO due to dissatisfaction with the lack of reforms in the organization. Donor countries called upon the WHO to limit itself to a normative role since other institutions such as the World Bank were already addressing operational functions including funding health programmes and technical cooperation. The donor countries expected WHO to share leadership in global health. In this scenario, some programmes in the WHO on their own initiative began to collaborate with other organizations.

In 1998 the World Health Assembly elected a new Director-General — the former prime minister of Norway Dr. Gro Harlem Brundtland, who initiated a process of "privatization of the WHO".⁸² In her first address to the World Health Assembly, she clearly outlined the vision of a WHO that was willing to share leadership in international health by reaching out to others. She expressed WHO's full support to the Joint United Nations Programme on HIV and AIDS (UNAIDS) — an agency that was created by taking the Global Program of AIDS out of the WHO (see below) — and the need to reach out to IMF, the World Bank and other regional development banks. She also stressed that WHO "must reach out to the private sector" and observed that the private sector had an important role to play in technology development and

⁸⁰ The reference to "emphasis on global health issues" in the report of the working group essentially meant that the WHO should work on emerging and re-emerging infectious diseases on a global scale that were perceived as a health security threat by developed countries, e.g., multidrug-resistant tuberculosis, avian influenza, Ebola, etc.

⁸¹ Theodore M. Brown, *supra* note 28.

⁸² German Velasquez, *Vaccines, Medicines and COVID-19: How can WHO be Given a Stronger Voice?* (Cham, Springer, 2022), p. 95. Available from https://www.southcentre.int/wp-content/uploads/2022/01/Vela%CC%81squez2022_Book_VaccinesMedicinesAndCOVID-19.pdf.

provision of services.⁸³ The seeds for partnerships between WHO and other international and multistakeholder initiatives were sown.

Two major priorities of the new Director-General were internal management reforms and direct engagement with donors like the Bill and Melinda Gates Foundation. Dr. Brundtland undertook substantial management reforms in the WHO which satisfied the donor countries and foundations. The Rockefeller Foundation announced a USD 2.5 million grant to create a Global Health Leadership Fund to be used for internal changes and recruitment of external personnel in WHO.⁸⁴ Dr. Brundtland set about refashioning WHO in her vision — a normative agency setting standards, developing guidelines and providing information to be used by governments instead of engaging in operating programmes. Programmatic operational work was to be carried out through partnerships involving WHO, private foundations, bilateral agencies, pharmaceutical companies, etc. Some of these partnerships have become influential actors in global health — the Global Alliance for Vaccines and Immunization (GAVI), the Roll Back Malaria Partnership, the Stop TB Partnership, and the biggest public-private partnership in global health — the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). Within a few years nearly 70 global health partnerships had been established.⁸⁵ A fragmented global health governance system was in place.

IV.1 Increasing Engagement with Non-State Actors

Alongside refashioning itself as a coordinator among multiple global health agencies and working with partnerships within and outside the WHO, since the 1990s the WHO has increasingly collaborated with non-state actors (NSA), including those that do not have an official relationship with WHO.⁸⁶ In 1999 the Director-General submitted a report to the Executive Board on “Public-Private Partnerships for Health.” The report cited the establishment of the UN Foundation Inc. in 1998 and the Bill and Melinda Gates Foundation with an endowment of USD 17 thousand million as major developments for the WHO, noting that both the foundations made substantial pledges to the WHO. The report noted that both foundations made partnerships and collaborations with the private sector a key feature of their grant giving. The report further noted the potential for WHO to collaborate with the private sector and the advantage of widening the reach of WHO to have more significant impact on global public health.

The Executive Board approved a policy on extrabudgetary resources, which emphasized on broadening the range of donors with more member States contributing as well as greater involvement of the private sector. The policy also stated that it would be implemented through partnerships with donors based on shared responsibilities and outcomes.

The WHO Secretariat had developed a set of “Guidelines on working with the private sector to achieve health outcomes” which was taken note of by the EB in 2001. Though the guidelines were not approved by the EB, the WHO Secretariat adopted the guidelines as a managerial

⁸³ WHO document A/51/DIV/6, 13 May 1998. Available from https://apps.who.int/gb/archive/pdf_files/WHA51/eadiv6.pdf.

⁸⁴ Barbara Crossette, “New Leader of W.H.O. Gets Big Grant to Hire Experts”, *The New York Times*, 21 July 1998. Available from <https://www.nytimes.com/1998/07/21/world/new-leader-of-who-gets-big-grant-to-hire-experts.html>.

⁸⁵ Theodore M. Brown et. al., *supra* note 28.

⁸⁶ Ayelet Berman, “Stakeholder Participation Reforms in Global Health Governance”, in Joost Pauwelyn et. al., (eds.), *Rethinking Participation in Global Governance: Voice and Influence after Stakeholder Reforms on Global Finance and Health* (Oxford University Press, 2022), p. 248.

tool, ignoring comments and concerns expressed by developing countries and public health groups.⁸⁷

Observers of WHO have pointed out that the private sector could be motivated to engage with the WHO and influence its policies for several reasons such as legitimizing unethical business practices, or shaping the development of WHO norms, policies and standards that offer distinct competitive and commercial advantages.⁸⁸

In view of the increasing engagement of the WHO with the private sector, in 2011 the WHO Director-General Dr. Margaret Chan advanced a number of proposals to increase stakeholder engagement as part of “WHO reforms”. These discussions ultimately led to the adoption of the WHO Framework of Engagement with Non-State Actors (FENSA) by the Health Assembly in 2016.

FENSA is comprised of an overarching framework, along with specific policies and operational procedures for engagement with NGOs, private sector entities, philanthropic foundations, and academic institutions. The overarching principles of FENSA addresses five types of interactions between WHO and NSAs – participation in WHO meetings, financial or in-kind contributions (such as donations of medicines) to WHO, contribution of information and knowledge to WHO, advocacy on health issues, and technical collaborations relating to product development, capacity building, emergency operations, or implementation of WHO policies. It also lays down general procedures to manage conflict of interest and other risks of engagement such as the requirement to conduct due diligence and risk assessment, establishment of a publicly available register of NSAs, and an electronic tool for management of individual conflicts of interest.

However, the implementation of FENSA has been compromised.

First, though FENSA identified conflict of interest as a key risk of engagement with NSAs and required due diligence, risk assessment and risk management to be undertaken by the WHO Secretariat before any engagement, it provided substantial discretion in these respects to the technical units of the Secretariat. Though the WHO does not have a comprehensive conflict of interest policy, the development of such a policy is not mandated by FENSA.

Secondly, while FENSA laid down specific provisions barring WHO engagement with the tobacco and arms industry, there was disagreement on specifically prohibiting other harmful industries such as fast food or alcohol. Instead, FENSA requires particular caution to be exercised when engaging with the private sector, including entities under the influence of the private sector. Such NSAs are also subject to strict conditions under the specific policy and operational procedures of FENSA relating to the private sector, particularly in respect of financial contributions. However, the WHO Secretariat has substantial discretion to determine whether an entity is a private sector entity or is under the influence of the private sector. Observers of implementation of FENSA have pointed out how such discretion has been exercised in apparent compromise to FENSA when engaging with entities such as the Gates Foundation to grant it observer status as a philanthropic foundation under FENSA, even though the Foundation does not appear to have an arm’s length relationship with the private sector in which it has substantial investments managed by a trust.

⁸⁷ German Velasquez, *Public-private Partnerships in Global Health: Putting Business before Health?*, Research Paper No. 49 (Geneva, South Centre, January 2014). Available from https://www.southcentre.int/wp-content/uploads/2014/02/RP49_PPPs-and-PDPs-in-Health-rev_EN.pdf.

⁸⁸ K.M. Gopakumar, “The World Health Organization’s Engagement with Non-State Actors: The Risk of Corporate Influence”, in Joost Pauwelyn et al., (eds.), *Rethinking Participation in Global Governance: Voice and Influence after Stakeholder Reforms on Global Finance and Health* (Oxford University Press, 2022), pp. 421-33.

Third, FENSA also prohibits secondments from the private sector. The resolution adopting FENSA also requested the WHO Director-General to develop in consultation with Member States a set of criteria and principles for secondments to the WHO from NGOs, philanthropic foundations and academic institutions, while complying with some conditions laid down in the resolution in relation to secondments. However, though the resolution mandated that secondments should adhere to specific technical expertise needed and exclude managerial and sensitive posts absolutely, the Secretariat developed a criteria and principles for secondment that was only taken note of by the World Health Assembly in 2017, which allowed secondments to be made to managerial and sensitive posts as long as they do not involve validation or approval of WHO norms and standards.

IV.2 Prioritizing Work on Global Epidemic Threats and Health Security

Since the mid-1980s, WHO became gradually involved in working on global epidemic challenges. This was marked by WHO starting its work on HIV/AIDS. The Global Programme of AIDS (GPA) was established in 1987 and in a very short span of time it became the best financed programme in WHO. The programme was started with a budget of USD 5 million but by 1989 it had a budget of USD 60 million, funded by donors and bilateral agencies from developed countries. The funding for this programme grew to such an extent that a WHO Trust Fund for the GPA was established to manage the donations. The Director of the GPA, Dr. Jonathan Mann reported directly to Director-General Dr. Halfdan Mahler. However, he resigned his position due to an untenable relationship with the succeeding Director-General Dr. Hiroshi Nakajima. After Dr. Mann left the WHO, the US and other donor countries decided to pull the GPA out of the WHO, leading to the establishment of the UNAIDS in 1996.⁸⁹

Besides AIDS, several new disease threats emerged in the 1990s alongside the re-emergence of bacterial, fungal, viral and parasitic diseases all over the world. A new strain of multidrug-resistant TB emerged across the globe. In 1997 WHO identified more than 60 significant disease outbreaks of both classic as well as unfamiliar diseases. Epidemics that were believed to be on the verge of extinction appeared in unexpected places e.g., diphtheria epidemic in Russia, cholera in Peru, bubonic plague in India, the mad cow disease in the UK, avian influenza in Hong Kong, Ebola in Zaire (now Democratic Republic of Congo), etc. There was also rising antimicrobial resistance to existing drugs. Globalization, environmental degradation, wildlife habitat destruction were factors attributed to the emergence or re-emergence of these diseases. These diseases were perceived as a health security threat by developed countries. In 1996, US President Bill Clinton issued a Presidential Decision Directive that identified infectious diseases as a threat to domestic and international security. Responding to international outbreaks of infectious diseases became a high priority issue for developed countries.

A consequence of these developments was a major emphasis by developed countries for WHO involvement in infectious disease surveillance. In 1989, WHO established a division on communicable diseases to improve the international surveillance system to monitor and rapidly inform on epidemic outbreaks and coordinate a coherent international response. In 1995, the World Health Assembly adopted a resolution mandating the WHO to work on identifying rapidly emerging and re-emerging diseases and the division of communicable diseases was expanded to the division of Emerging Viral and Bacterial Disease Surveillance (EMC). The division secured substantial extrabudgetary funding and became an important unit of WHO. In 1994, the division convened a scientific working group to examine drug-resistant bacterial infections, marking the launch of WHO work in antimicrobial resistance

⁸⁹ German Velasquez, *The World Health Organization Reforms in the Time of COVID-19*, Research Paper No. 121 (South Centre, Geneva, November 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/11/RP-121-rev2.pdf>.

(AMR). The Director of EMC, David L. Heymann, an American epidemiologist, strongly advocated the study of antibiotic resistance monitoring networks and the modernization of the International Health Regulations (IHR) to transform them into a real global alert system. In 1995 the World Health Assembly instructed the WHO Secretariat to revise the IHR and create mechanisms to make governments adhere to technical regulations. The process of IHR revision was expedited by the outbreak of SARS in early 2003. In 2005 the World Health Assembly adopted the revised IHR that empowered the Director-General to determine when an event constituted a public health emergency of international concern.

These developments in the WHO made it a leading actor in the process of development of global norms and initiatives for containment of the threat of infectious diseases. Scholars of securitization of global health observe that the consequence of this has been the development of international health cooperation mechanisms that place western fears of an outbreak reaching them above the prevention of such outbreaks.⁹⁰ The prioritization of containment of the international spread of an infectious disease implies that response efforts tend to lack sustained political commitment to address the complex underlying conditions that give rise to an infectious disease.⁹¹

Moreover, the health security perspective has also marginalized development dimensions in the design of policies or norms relating to health issues. An example of this is the WHO Global Action Plan on Antimicrobial Resistance. Though the AMR crisis affects developing countries the most, their interests and challenges in terms of the need for international cooperation for financing and technology to set up the institutions and mechanisms to undertake the required actions, are not sufficiently addressed in the WHO Global Action Plan. Similarly, the predominant focus of international cooperation is on ensuring restricting the use of antimicrobials without addressing, at the same time, the need for ensuring affordable access to existing and new antimicrobials for developing countries.⁹² Similarly, even though the threat of infectious diseases is more severe for developing countries, the health security framing of the threat tends to prioritize measures that are focused on surveillance, data collection, event reporting, and sharing of pathogen and sequence information as priority issues, marginalizing the need for health systems strengthening, developing epidemic intelligence analysis capabilities, laboratory capacities for genetic sequencing, sharing of vaccines and health technologies and know-how for developing countries. The IHR is glaringly silent on the needs of developing countries.

An evident consequence of the excessive health security focus has been vaccine nationalism by developed countries as has been experienced during past pandemics such as the swine flu and also the COVID-19 pandemic (see box 3).

Box 3

The experience of vaccine nationalism during recent pandemics such as the swine flu had made it evident that an equitable vaccine sharing mechanism was required to respond to the COVID-19 pandemic. However, the COVAX mechanism that was eventually launched gave precedence to the interests of developed countries. The level of ambition of COVAX to procure 2 billion doses by the end of 2021 that would cater for less than 15 per cent of the global demand⁹³ for COVID-19 vaccines was very low to begin with. Even so, COVAX was unable

⁹⁰ See Sara E. Davies, "Securitizing infectious disease", *International Affairs*, vol. 84, No. 2, (2008) p. 295.

⁹¹ See generally Eugene T. Richardson, *Epidemic Illusions: On the Coloniality of Global Public Health* (MIT Press, Cambridge, Massachusetts, 2020).

⁹² See Mirza Alas and Viviana Munoz Tellez, "Tackling Antimicrobial Resistance: Challenges for Developing Countries", South Centre, Policy Brief No. 29, September 2016. Available from <https://www.southcentre.int/policy-brief-29-september-2016/>.

⁹³ Priti Patnaik, "'Dose Donations are Proving to be a Good Medicine for Vaccine Nationalism' says UNICEF's Gian Gandhi", *Health Policy Watch*, 20 July 2021. Available from <https://healthpolicy-watch.news/dose-donations-are-proving-to-be-a-good-medicine-for-vaccine-nationalism-says-unicefs-gian-gandhi/>.

to meet this modest ambition and in fact reduced its procurement target to 1.5 billion doses. It failed to meet its own revised target. This failure is due to the voluntary nature of the initiative which depended fundamentally on the realization of the financial pledges made by rich countries and their willingness to share vaccine doses with COVAX.⁹⁴ As the world witnessed subsequently, COVAX was left wanting on both parameters as rich countries undertook unilateral action and pursued vaccine nationalism⁹⁵ to secure excess vaccine doses for their populations.⁹⁶

In a media briefing prior to the 2021 World Health Assembly, the WHO Director-General urged the rich developed countries that had brought up the majority of vaccine supplies to reconsider vaccinating lower risk groups and instead donate the vaccines to COVAX.⁹⁷ In this context the Director-General stressed that "Trickle down vaccination is not an effective strategy for fighting a deadly respiratory virus."⁹⁸ In his address to the 2021 World Health Assembly Dr. Tedros said, "The ongoing vaccine crisis is a scandalous inequity that is perpetuating the pandemic. More than 75 per cent of all vaccines have been administered in just 10 countries. There is no diplomatic way to say it: a small group of countries that make and buy the majority of the world's vaccines control the fate of the rest of the world."⁹⁹

However, these appeals by the Director-General have been absolutely disregarded by the developed countries that have hoarded the available global supply of vaccines. It is also noteworthy, that WHO has been unable to go beyond appealing to the sense of solidarity and goodwill of the donor countries and make use of existing legal instruments like the IHR to discipline countries that were disregarding its appeals.¹⁰⁰

The revisions of the IHR in 1995 and 2005 were shaped by health security considerations and were focused on prevention and containment of public health emergencies of international concern. While the underlying assumption in IHRs was that contracting Parties would be able to establish the core capacities required to be established in terms of the obligations under the IHR by 2012, 110 contracting Parties requested for extensions to establish core capacities as they struggled to overcome challenges that essentially arose from their fragmented and weak health systems. There is need for sufficient recognition of the fact that "... health security rests on universal and equitable health systems upon which sustained implementation of the IHR core capacities depend."¹⁰¹ WHO Member States have an opportunity to translate this principle into action through full and adequate recognition and reflection of the interests of developing countries in the process of negotiations that have been launched in the WHO in

⁹⁴ See Rohit Malpani and Alex Maitland, "Dose of Reality: How rich countries and pharmaceutical corporations are breaking their vaccine promises", The People's Vaccine Alliance, 21 October 2021. Available from <https://app.box.com/s/hk2ezb71vf0sla719jx34v0ehs0l22os>.

⁹⁵ See Muhammad Zaheer Abbas, *Practical Implications of "Vaccine Nationalism": A Short-Sighted and Risky Approach in Response to COVID-19*, Research Paper No.124 (South Centre, Geneva, November 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/11/RP-124.pdf>.

⁹⁶ See James Ducharme, "COVAX Was a Great Idea, But Is Now 500 Million Doses Short of Its Vaccine Distribution Goals. What Exactly Went Wrong?", *Time*, 9 September 2021. Available from <https://time.com/6096172/covax-vaccines-what-went-wrong/>.

⁹⁷ WHO, Director-General's opening remarks at the media briefing on COVID-19 – 14 May 2021. Available from <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-14-may-2021>.

⁹⁸ Ibid.

⁹⁹ World Health Organization, Director-General's opening remarks at the World Health Assembly – 24 May 2021. Available from <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-world-health-assembly---24-may-2021>.

¹⁰⁰ See K.M. Gopakumar, "WHO under DG Tedros: The Last Five Years", *Geneva Health Files*, 2 February 2022. Available from <https://genevahealthfiles.substack.com/p/guest-editorial-who-under-tedros?s=r>.

¹⁰¹ Sara E. Davies, "National Security and Pandemics", *UN Chronicle*, vol. L, No. 2 (2013). Available from <https://www.un.org/en/chronicle/article/national-security-and-pandemics>.

the aftermath of the COVID-19 pandemic for amendments to the IHR and the negotiation of a possible pandemic treaty.

IV.3 Financial Troubles

Since its establishment WHO has been financed through a mix of assessed contributions by its Member States and voluntary extrabudgetary contributions, with extrabudgetary funds used to supplement regular funds.¹⁰² However, the extent of extrabudgetary component of the budget was low. Since 1976 the extrabudgetary component has steadily increased and currently more than 80 per cent of the total budget of WHO is financed by the voluntary contributions of a small group of donors.¹⁰³ Currently, 88 per cent of all voluntary contributions are tightly earmarked to specific programmatic areas or geographic locations.¹⁰⁴ This implies that about 70 per cent of the total current budget of WHO is earmarked for specific programmes or geographical areas, leaving very little flexibility with regard to how the budget could be utilized.

As mentioned above, since the 1980s the WHO as well as other UN agencies had to function in a changed geopolitical context marked by the rise of neoliberalism and neoconservatism. WHO and other multilateral organizations were adversely impacted by the neoliberal perception that multilateral organizations were dysfunctional. This perception gained credence as the interests of developed countries which advanced the neoliberal agenda were challenged by developing countries in multilateral settings. This perception also impacted the financing of the WHO budget with the assessed contributions of the US representing approximately 25 per cent of the organization's budget in the mid-1980s. The US began to consistently lean in on the WHO to be more cost-effective and reign in its budget. In 1982 this pressure led the World Health Assembly to freeze the budget of the WHO. Even after that, in 1985 the US refused to pay its assessed contributions to WHO on the grounds that the WHO Essential Medicines List was contrary to the interests of the US pharmaceutical corporations. Developing countries were also adversely impacted by financial crises and structural adjustment programmes imposed on them, which in turn impacted their ability to effectively contribute to the budget of the WHO.

Even though the budget of WHO was frozen, in 1987 it still had the second largest budget in the UN system. However, another trend that went on to substantially impact the organization began to take root during this period – increase in voluntary earmarked contributions by donor countries to specific programmes. Even though such contributions constituted less than half of the regular budget at the time, the growing voluntary pledges were proving to be a menace to coherent governance in the organization. By the early 1990s the extra-budgetary contributions constituted 54 per cent of the entire budget of WHO. This generated several vertical programmes where decisions were made by donors and the programmes were effectively outside the organization's control.¹⁰⁵ By the 1990-91 and the 1992-93 bienniums, extrabudgetary contributions exceeded the regular budget of WHO.¹⁰⁶

¹⁰² Article 57 of the WHO Constitution bestows power on the Health Assembly or the Executive Board acting on its behalf to accept and administer gifts and bequests made to WHO, provided that the conditions attached to such gifts or bequests are acceptable to the Health Assembly or Executive Board and are consistent with the objectives and policies of WHO.

¹⁰³ Priti Patnaik, "Financing WHO: How much must countries pay & what are essential functions", *Geneva Health Files*, 2 July 2021. Available from <https://genevahealthfiles.substack.com/p/the-clock-is-ticking-on-securing?s=r>.

¹⁰⁴ WHO, How WHO is Funded? Available from <https://www.who.int/about/funding>.

¹⁰⁵ Gavino Maciocco and Angelo Stefanini, "From Alma-Ata to the Global Fund: the history of international health policy", <https://www.scielo.br/j/rbsmi/a/CRj5PggMmsDr97F4XwpDRbh/?format=pdf&lang=en>.

¹⁰⁶ J.P. Vaughan et al., "Financing the World Health Organization: global importance of extrabudgetary funds", *Health Policy*, vol. 35 (1996), pp. 231-2. Available from <https://www.sciencedirect.com/science/article/abs/pii/0168851095007865>.

The financial situation of the WHO worsened during the 1990s. Following the collapse of the Soviet Union and political transformations in the countries in eastern Europe, many of these countries stopped paying their contributions to WHO. In 1991 WHO depleted its working capital fund and borrowed USD 56 million against internal budget that was earmarked for other programmes. For the next budgetary biennium WHO froze implementation of 10 per cent of its budget and allowed extensive borrowing of funds within the agency. The budgetary deficit rose to USD 206 million by 1996. This increased the organizations dependency on borrowings and extrabudgetary voluntary contributions from donor countries and private philanthropies, at the risk of transforming it into a tool for donors and bilateral agencies. Ten countries provided 90 per cent of all extrabudgetary funds and financed more than half of the regular budget.

In this context, the WHO Director-General Dr. Brundtland tried to promote a vision of "one WHO" in contrast to two WHO's – one financed by assessed contributions and the other part financed by extrabudgetary contributions. However, while her reforms were successful in increasing extrabudgetary contributions, she was unable to increase the regular budget.¹⁰⁷ At the Executive Board meeting in January 1999, the Director-General called on Member States to augment their assessed contributions to the WHO and pledged to return to a policy of zero real growth. The proposal was intensely discussed at the World Health Assembly in 1999, but none of the donor States except France were prepared to increase their assessed contributions. Instead, the World Health Assembly called on the WHO Secretariat to compensate its declining income through budgetary discipline.¹⁰⁸ In this context, the WHO attempted to move to an integrated programme budget through results-based budgeting by including anticipated income which the Secretariat would attempt to raise from voluntary contributions through a strategy of decentralized fundraising by programmes. It was anticipated that donors would be attracted to invest in high profile priorities through special programmes and partnerships. This strategy implied that WHO had to sever control both at the Headquarters and with regard to health partnerships initiated by WHO.¹⁰⁹

Since then, WHO has been unable to reverse its reliance on extrabudgetary funds and the internal fragmentation that arose out of decentralized fundraising. Director-General Dr. Margaret Chan tried to introduce budgetary ceilings to bring about some control over the programmes, but these tools were bypassed through innovative approaches by channelling funds through regional or country offices. In 2013, the World Health Assembly adopted decision WHA 66(8) to establish a Financing Dialogue with Member States. Two forums of the Financing Dialogue were held in 2013. However, while the challenges confronting WHO and its financial situation were highlighted, nothing was achieved in terms of financial pledges from Member States.

The current Director-General Dr. Tedros has also stressed on the need for flexibility in how the WHO can utilize its financial resources. In a report to the Executive Board in January 2021 on sustainable financing, the Director-General pointed out that sustainable financing is a key challenge for WHO that must be addressed as part of the lessons learnt from the COVID-19 pandemic. The report stressed that "... only assessed contributions can be considered truly sustainable..." but only 17 per cent of the budget is funded from such sustainable sources. The report pointed to the challenges arising from the lack of adequate sustainable financing and requested the EB to establish a process aimed at finding a concrete solution to the problem of sustainable financing of WHO.

¹⁰⁷ Charles Clift, "The Role of the World Health Organization in the International System", Centre on Global Health Security Working Group Papers, Working Group on Governance, Paper 1, Chatham House, February 2013, pp. 8-9. Available from https://www.college-de-france.fr/media/dominique-kerouedan/UPL5808829414632481998_OMS_Chatham_House.pdf.

¹⁰⁸ Tine Hanreider, *International Organization in Time: Fragmentation and Reform* (Oxford University Press, 2015), p. 108.

¹⁰⁹ Ibid, pp. 108-11.

The Executive Board adopted decision EB 148(12) to establish a Member States Working Group on Sustainable Financing. The working group considered what should be an acceptable percentage range of the budget that assessed contributions should represent,¹¹⁰ when should an increase in assessed contributions (if agreed or recommended) begin, governance reforms that are within the Secretariat's control to which the WHO should commit alongside an increase in assessed contributions, and existing barriers before Member States from deciding for increasing assessed contributions. It recommended that the base segment of the WHO budget should be flexibly funded and the Health Assembly request Member States and other donors to strive to provide WHO with fully unearmarked voluntary contributions for financing the base budget as a pre-requisite for securing financial independence and increasing the efficiency of WHO. It recommended that the WHO Secretariat should develop budget proposals for an increase in assessed contributions with an "aspiration" to reach 50 per cent of the 2022-2023 base budget by the 2030-31 biennium. The 2022 World Health Assembly approved the recommendations of the working group through decision WHA 75(6).

While the decision to gradually increase assessed contributions with an aspiration to finance 50 per cent of the base budget is a welcome development,¹¹¹ it remains to be seen whether this aspiration becomes a reality and an equitable approach is adopted to increasing assessed contributions with developed countries committing to a larger increase in their assessed contributions. The African Group has suggested the need for designing a contribution model based on equity and considering each country's gross domestic product and its ability to honour its financial commitments. Another approach that the working group has considered is the adoption of a replenishment model by attracting major donors to fund the base budget. The WHA decision also accepted the recommendation of the working group to request the secretariat to explore the feasibility of a replenishment mechanism to broaden the financing base and report on this to the 2023 Health Assembly.

The Independent Panel on Pandemic Preparedness and Response that was commissioned to review the WHO coordinated response to the pandemic had recommended a mix of increased assessed contributions for two-thirds of the base budget and an organized replenishment process for the rest of the base budget.¹¹² The working group's recommendations suggest a lesser aspirational increase of assessed contributions than recommended by the IPPR, and consequently, a greater reliance on voluntary contributions through a replenishment process. Given that private sector and philanthropic foundations have preferred to contribute to special programmes instead of the base budget through specifically earmarked contributions, WHO will need to devise rules on the basis of which voluntary contributions from non-State entities may be received for the base budget.

Even as Member States consider increasing assessed contributions, it is a matter of concern that the extent of donor dependency has increased in WHO. The WHO response to the COVID-19 pandemic has been substantially shaped by the interests of donors. As donors such as the Gates Foundation have become major funders of the organization since the reforms in the mid-1990s, their influence has increased beyond mere financing to also influence staffing in the organization through innovative mechanisms such as secondments based on nil-remuneration contracts. Moreover, in apparent contradiction to the FENSA, WHO has created the WHO Foundation to receive funds from the private sector except for the

¹¹⁰ The Independent Panel on Pandemic Preparedness and Response had recommended that assessed contributions should be increased to two thirds of the base segment of the programme and budget, and the Bureau of the working group had proposed an incremental increase in assessed contributions to 50 per cent of the base segment.

¹¹¹ The base budget is the biggest segment of the WHO budget. Approximately 77 per cent of the current budget constitutes the base budget segment.

¹¹² The Independent Panel for Pandemic Preparedness & Response, "COVID-19: Make it the Last Pandemic". Available from https://recommendations.theindependentpanel.org/main-report/assets/images/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

tobacco industry, even though other industries could also have conflicts of interest about optimal policies and actions that WHO should promote. These developments underscore the need for robust rules limiting the extent of influence of non-State donor agencies in WHO. Such rules would be needed even more if WHO were to adopt a replenishment model for financing a part of the base budget.

V. CONCLUSION

The Euro-American origin of norms and institutions for international cooperation on health and their subsequent integration with the WHO demonstrates how their creation was driven by the health security and political interests of the Western countries. The history of WHO suggests that the organization had to constantly strive to establish its central leadership role in international health. When WHO was created, the international health system was fragmented with the presence of multiple health agencies such as the OIHIP and LNHO, as well as regional agencies like the Pan American Sanitary Board, which were established and acted under the influence of the western countries. The dominance and influence of western countries through these institutions were sustained by assimilating the existing institutions and norms such as the sanitary convention within the WHO.

The dominance of developed countries in the design and implementation of policies and norms in the WHO was overwhelming after its creation until the 1970s when WHO acted in support of the call for strengthening primary health care from developing countries leading to the adoption of the Alma Ata Declaration and undertook initiatives in pursuit of the same. These initiatives were resisted and marginalized by developed countries through criticism of WHO as an inefficient organization, reduction of assessed contributions and consequent impoverishment of WHO, and the proliferation of “new” international health agencies to which WHO has been compelled to cede operational space. Donor countries and corporations dominate multistakeholder governance structures in health partnerships, marginalizing most of the WHO membership and, notably, the Global South, in their decision-making. The governance of the global health system today is more fragmented than it was when the WHO was established in 1948.

In this fragmented global health system WHO is recognized as the leading and coordinating authority, but in effect, while this bestows responsibility on the WHO, the organization has little authority to implement its norms. On the other hand, the health partnerships and other agencies such as the World Bank exercise the real authority. It is important to recognize that this fragmentation is by design, and serves the interests of the dominant actors in global health.

A consequence of this fragmentation in global health governance is that the space of the only multilateral organization where developing countries have an equal presence in terms of participation and decision-making as sovereign States, the WHO, has been marginalized. Consequently, the development dimension of health is also marginalized and only the development assistance aspects of it receive major attention through vertical programmes and agencies addressing limited health needs without effectively addressing the basic need of strengthening health systems. For example, programmes to support procurement of drugs for AIDS, TB and malaria have received substantial support through partnerships such as the Global Fund, while strengthening local production of medicines has been marginalized.

The marginalization of the development dimension is also evident in how public health issues for multilateral discussion are increasingly framed from a health security perspective. This has resulted in utter neglect of issues concerning developing countries in how the policies and norms in response to the existing and emerging health threats are framed.

Therefore, for developing countries it is particularly important that the WHO is effectively retooled to act as the leading and coordinating authority on global health with adequate legal

powers¹¹³ and institutional and financial capacities to do so without undue influence from donor countries and entities that have interests in the private sector. This would enable the WHO to ensure that the interests of all countries are fairly addressed in its normative and operational activities. The Constitution of the WHO empowers it to take over the functions, resources and obligations of any agency whose purpose and activities lie within the field of competence of the WHO. It is an irony that the WHO instead has been conceding its functions to various agencies that have proliferated global health governance.

Such transformation of the WHO would require action both within and outside the organization. Within the organization, developing countries should strive to strengthen WHO financing by ensuring that the aspiration to increase assessed contributions of Member States agreed at the 2022 World Health Assembly is realized. This should lead to increased assessed contributions of Member States to reduce the reliance of WHO on extrabudgetary funding and provide it with sufficient flexibility in resource allocation. At the same time, necessary governance reforms must be undertaken to insulate the staffing and decision-making processes of WHO from being unduly influenced by business interests. In particular, developing countries should ensure that policies relating to financing, secondments, and appointments of experts complement and do not undermine the FENSA.

Moreover, Member States should ensure the primacy of WHO and oversight of its governing bodies over hosted and external partnerships; ensure full and effective representation of all WHO Member States in any such partnership; and introduce legally binding obligations on non-State actors engaging with WHO to act consistently with the decisions of WHO governing bodies. Member States should also consider exercise of the powers conferred on the WHO under article 72 of its Constitution to take over the functions of any agency that is involved in global health.

With regard to substantive norms, global strategies, policies and guidelines on health issues, developing countries should ensure that they recognize and address their needs and challenges with regard to measures proposed.

However, the quest for strengthening WHO must also be complemented through initiatives outside the WHO. The quest for a just and equitable global health order based on recognition of the challenges of the global South with regard to preparedness and response capacities for health threats, as well as the recognition of the primacy of health as a development issue rather than a business or security issue will be critical. Health must be addressed as a common global challenge, with the primary responsibility on the developed countries for redistribution of technological and financial resources to address these challenges. There is also the need for effective representation of the global South in decision-making in all global health agencies. These issues should be pursued by developing countries as a political agenda in the WHO governing bodies, the UN General Assembly, the Economic and Social Council and other fora such as the G20.

¹¹³ The negotiation on the “pandemic treaty” and on the eventual reform of the IHR may provide an opportunity to create new tools and achieve equity. See Viviana Munoz Tellez, *Can Negotiations in the World Health Organization Lead to a Just Framework for the Prevention, Preparedness and Response to Pandemics as Global Public Goods?* Research Paper No. 147 (Geneva, South Centre, February 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/02/RP147_Can-Negotiations-at-WHO-Lead-to-a-Just-Framework-for-the-Prevention-Preparedness-and-Response-to-Pandemics-as-Global-Public-Goods_Pandemic-Treaty_EN.pdf; Nirmalya Syam, “Mainstreaming Equity in the International Health Regulations and Future WHO Legal Instruments on Pandemic Preparedness and Response”, South Centre, Policy Brief No. 108, March 2022. Available from https://www.southcentre.int/wp-content/uploads/2022/03/PB108_Mainstreaming-Equity-in-the-IHR-and-Future-WHO-Legal-Instruments-on-Pandemics_EN.pdf.

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171	31 January 2023	Directives pour l'examen des demandes de brevet relatives aux produits pharmaceutiques	Carlos M. Correa
173	7 February 2023	Analysis of COVID-Related Patents for Antibodies and Vaccines	Kausalya Santhanam



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