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World Health Organization Reforms in the Time of COVID-19

Germán Velásquez

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Germán Velásquez[1]

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[1] Dr. Germán Velásquez is Special Adviser, Policy and Health at the South Centre, Geneva. The author thanks Dr. Carlos Correa and Dr. Viviana Muñoz for their valuable comments. The views presented in this paper are however the sole responsibility of the author.

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NOTE

South Centre
Chemin de Balexert 7-9
1219 Vernier
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

During its 70-year history, the World Health Organization (WHO) has undergone various reforms led by several Directors-General, including Halfdan Mahler at the Almaty Conference on primary health care in 1978, Gro Harlem Brundtland with her “reach out to the private sector” in 1998, and Margaret Chan with her unfinished debate on the role of “non-state actors” in 2012. The organization’s fragility is once again being highlighted, as the COVID-19 pandemic has revealed that WHO does not have the legal instruments and mechanisms necessary to enforce its standards and guidelines, and that its funding is not sustainable and adequate to respond to the challenge. This paper seeks to identify the main problems faced by WHO and the necessary measures that a reform of the organization would have to take.

A lo largo de sus 70 años de historia la OMS ha pasado por varias reformas lideradas por varios directores generales, como Halfdan Mahler en la Conferencia de Alma ata sobre la atención primaria de salud, 1978, Gro Harlem Brundtland con su « reach out to the private sector » 1998, Margaret Chan con su inconcluso debate sobre el rol de « los autores no estatales » 2012 . Una vez mas, y de forma contundente la crisis sanitaria del 2020 pone en evidencia la fragilidad de la Organización y nos revela que la OMS no tiene los instrumentos y mecanismos legales necesarios para aplicar sus normas y orientaciones y que su manera de financiamiento no es sostenible y adecuada para responder al desafío de la COVID-19. Este documento trata de identificar cuales son los problemas principales de que sufre la OMS y cuales serian las medidas necesarias que una reforma de la Organización tendría que abordar.

Tout au long de ses 70 ans d'histoire, l'OMS a connu plusieurs réformes dirigées par plusieurs directeurs généraux, tels que Halfdan Mahler à la Conférence d'Almaty sur les soins de santé primaires, 1978, *Gro Harlem Brundtland avec son "reach out to the private sector" 1998, Margaret Chan avec son débat inachevé sur le rôle des "acteurs non étatiques" 2012. Une fois de plus, la crise sanitaire de 2020 a mis en évidence la fragilité de l'organisation et révélé que l'OMS ne dispose pas des instruments et mécanismes juridiques nécessaires pour mettre en œuvre ses normes et lignes directrices et que son financement n'est pas durable et adéquat pour répondre au défi de la COVID-19. Ce document cherche à identifier les principaux problèmes rencontrés par l'OMS et les mesures nécessaires qu'une réforme de l'Organisation devrait prendre.*

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INTRODUCTION

The World Health Organization (WHO) has undergone many reforms and attempts at reform since its creation in 1948. These reforms have been largely driven by various Directors-Generals who, throughout the existence of WHO, have sought to leave a mark on the achievements of its administration.

The reform under discussion in 2020 has been prompted by the unprecedented health crisis caused by the COVID-19 pandemic. The international community has acknowledged the legal and financial structural inadequacies of WHO to meet its expectations.

Since the creation of WHO, its Member States have not always been supportive of the organization. At different times in its history, some countries have weakened it, rather than strengthened it.

In 1986, Jonathan Mann, Director of the WHO Global Programme on AIDS (GPA), organized a direct action strategy; to provide treatment and undertake/coordinate research by a team of 200 scientists and an expenditure of 70 million USD per year, and this led to a confrontation with the then Director-General, Hiroshi Nakajima of Japan.[2] Because of this confrontation, Mann left WHO, and the United States of America and other countries decided to pull out GPA from WHO.[3,4] After some years of discussion and debate, UNAIDS was founded in 1994–1995 under the leadership of Peter Piot.[5]

The Global Fund to Fight AIDS, Tuberculosis and Malaria ('the Global Fund'), was created in 2002 as an innovative financing mechanism that seeks to rapidly raise and disburse funding for programs that reduce the impact of HIV/AIDS, tuberculosis and malaria in low- and middle-income countries.[6] The idea of the Global Fund came from the Brundtland administration, which conceived it as an innovative mechanism to fund WHO. In this context the Brundtland administration called for a "Massive Attack on Diseases of Poverty" in December 1999.[7] The Global Fund was finally established in January 2002, outside WHO, following negotiations involving donors, country governments, non-governmental organizations (NGOs), the private sector, and the United Nations.[8]

The Expanded Programme on Immunization was launched by the World Health Assembly in 1974. Gavi, an alliance of public and private sector organizations, institutions and governments, the Bill & Melinda Gates Foundation, UNICEF, the World Bank, WHO, vaccine manufacturers, NGOs, and research and technical health institutes, was established at the

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[2] Jonathan M. Mann, "The World Health Organization's Global Strategy for the Prevention and Control of AIDS," *West J Med.*, 147(6): 732–734 (December 1987).

[3] Mathilde Krim, "Jonathan Mann 1947–1998", *Nature Medicine*, vol. 4 (October 1998), page1101. DOI https://doi.org/10.1038/2592.

4 See also, Michael Merson and Stephen Inrig, "End of the Global Programme on AIDS and the Launch of UNAIDS", in *The AIDS Pandemic: Searching for a Global Response*. (Springer, 2018). Available from https://doi.org/10.1007/978-3-319-47133-4_16.

5 Fee, Elizabeth, Parry Manon, "Jonathan Mann, HIV/AIDS, and Human Rights," *Journal of Public Health Policy* vol. 29 (2008), pp. 54–71. Available from https://link.springer.com/article/10.1057/palgrave.jphp.3200160#citeas.

6 Celina Schocken, "Overview of the Global Fund to Fight AIDS, Tuberculosis and Malaria". Available from https://www.cgdev.org/sites/default/files/archive/doc/HIVAIDSMonitor/OverviewGlobalFund.pdf.

7 WHO Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development*. Report of the Commission on Macroeconomics and Health (World Health Organization, 2001). Available from https://apps.who.int/iris/handle/10665/42435.

8 Every CRS Report, "The Global Fund to Fight AIDS, Tuberculosis, and Malaria: Background 2003 – 2006". Available fromhttps://www.everycrsreport.com/reports/RL31712.html.

Proto-Board Meeting in Seattle on 12 July 1999. Again, an initiative developed within WHO to support the global immunization program was created outside WHO.

Unitaid, an initiative of the Governments of France and Brazil, was created in 2006 with the support of Chile, Norway and the United Kingdom. This innovative financing initiative is hosted by WHO, but is an independent agency that operates autonomously.

COVAX is the vaccines pillar of the WHO Access to COVID-19 Tools (ACT) Accelerator, formally known as "the COVID-19 Vaccines Global Access Facility". It was created in April 2020 and is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO. Funding and the power to act are, once again, outside WHO.

It seems that at every health crisis, whether it is AIDS, vaccines, or COVID-19, WHO member countries opted to allocate the funding and the power to act outside WHO.

In the current unprecedented health crisis caused by COVID 19, some industrialized countries seem to have become aware of the structural problems of WHO, as set out in a "non-paper" presented in August 2020 by France and Germany,[9] or as reflected in the intervention of the president of Switzerland at the World Health Assembly in May 2020.[10] Other suggestions were presented in September 2020 by Chile (together with Uruguay, Paraguay and Bolivia) and the United States of America. These last two proposals will not be analyzed in this paper as they only refer to the process and methodology for the review of the International Health Regulations (IHR) and of the scope and transparency of the WHO pandemic declarations of a public health emergency of international concern (PHEIC).

This paper seeks to identify the main problems faced by WHO in the light of the COVID-19 crisis, and to suggest key elements that a reform of the organization would need to consider, based on some pertinent proposals of the non-paper presented by France and Germany and in view of the concerns and needs of the countries of the South.

[9] "Non-Paper on Strengthening WHO's leading and coordinating role in global health. With a specific view on WHO's work in health emergencies and improving IHR implementation" 1 August 2020. Available from http://q2h2.org/wp-content/uploads/2020/08/Non-paper-1.pdf.

[10] Swiss Federal Council press release, 18 May 2020. Available from https://www.admin.ch/gov/en/start/documentation/media-releases.msg-id-79150.html.

BACKGROUND

The first major reform of WHO was led by Halfdan Mahler (Director-General 1973–1988). The Declaration of Alma-Ata, proclaimed at the International Conference on Primary Health Care on 12 September 1978, underlined the urgency of promoting primary health care and access to an acceptable level of health for all.[11] Mahler's objective to reach "Health for All by the Year 2000" significantly changed the orientation of the organization.

The Director-General of WHO from 1998 to 2003, Gro Harlem Brundtland, made the most important reform of the organization after the change of direction brought about by the Alma-Ata conference (1978). A reform described by many as neoliberal, Brundtland initiated what has been termed the "privatization of the WHO".[12,13] The call "We must reach out to the private sector" was launched by Brundtland at her first World Health Assembly.[14]

In May 2011, a few months before the end of her first mandate, Margaret Chan (Director-General, 2007–2017) launched, in her own words, "the most important reform in the history of the WHO."[15] An ambiguous and disjointed reform that in the five years of her second and last mandate did not manage to conclude on the most urgent and controversial issues such as the issue of non-state actors. Tedros Adhanom Ghebreyesus, elected Director-General of WHO in 2017, announced in his opening speech to the first Executive Board (January 2018) a plan to transform WHO. The transformation plan was interrupted by the arrival of COVID-19 in December 2019.

On 31 December 2019, Chinese authorities reported several dozen cases of pneumonia from an unknown cause. On 20 January 2020, WHO reported the first confirmed cases in China, Thailand, Japan and South Korea, and on 30 January 2020, the Director-General declared the novel coronavirus outbreak a public health emergency of international concern (PHEIC), the highest WHO alarm level.[16]

In a context of criticism, mainly from the US Government, of the WHO handling of the pandemic, particularly on the reasons for an alleged delay in announcing the highest level of alarm and the USA complaint about China's influence on the announcement of the pandemic, President Trump announced the departure of the United States from the WHO.[17]

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[11] OMS, Déclaration d'Alma-Ata. Conférence internationale sur les soins de santé primaires, Alma-Ata (URSS), 6-12 septembre 1978, https://ireps-ors-paysdelaloire.centredoc.fr/index.php?lvl=notice_display&id=25123#.X3WE_2gzabg.

[12] Nitsan Chorev, "Restructuring neoliberalism at the World Health Organization," *Review of International Political Economy* 20(4) (August 2013). DOI: 10.1080/09692290.2012.690774.

[13] Germán Velásquez, "Qué remedios para la Organizacion Mundial de la Salud", *Le Monde Diplomatique* No. 253 (November 2016).

[14] Gro Harlem Brundtland Director-General Elect, The World Health Organization, "Speech to the Fifty-first World Health Assembly Geneva", 13 May 1998, A51/DIV/6 13.Available from https://apps.who.int/gb/archive/pdf_files/WHA51/eadiv6.pdf.

[15] Margaret Chan, "Introductory remarks on programs and priority setting at the Executive Board special session on WHO reform", (Geneva, Switzerland 1 November 2011). https://www.who.int/dg/speeches/2011/reform_priorities_01_11/en/.

[16] Timeline of WHO's response to COVID-19. Available from https://www.who.int/news-room/detail/29-06-2020-covidtimeline.

[17] BBC News Mundo, "Estados Unidos se retira de la OMS: Trump notifica oficialmente a Naciones Unidas de la salida de su país", 7 July 2020. Available from https://www.bbc.com/mundo/noticias-internacional-53329647.

SECTION 1

COVID-19 AND THE WHO REFORM

The COVID-19 pandemic has highlighted the need for a strong and independent global health governing body capable of managing a global health crisis. During the first six months of the pandemic there was much talk of what the WHO does or does not do and what it could or could not do. As recently pointed out by Gostin, Moon, and Mason Meier, "[t]he world is facing an unprecedented global health threat, and the response is highlighting structural limitations in the ability of international organizations to coordinate nationalist States".[18]

Faced with the US Government's irresponsible announcement of its withdrawal from WHO, Germany and France decided to start a process to "reform the WHO from outside" by presenting, as noted above, a document entitled "Non-Paper on Strengthening WHO's leading and coordinating role in global health. With a specific view on WHO's work in health emergencies and improving IHR implementation." (hereafter "the non-paper").[19]

The non-paper is based on the resolution adopted by the 73rd World Health Assembly (May 2020) requesting the Director-General to "initiate, as soon as possible and in consultation with Member States, a gradual process of impartial, independent and comprehensive evaluation, including by using existing mechanisms, as appropriate, to review the experience gained and lessons learned from the international health response coordinated by WHO to, inter alia, COVID-19:

i) the effectiveness of the mechanisms available to WHO;
ii) the functioning of the IHR and the status of implementation of relevant recommendations of previous IHR Review Committees;
iii) the contribution of WHO to the efforts of the United Nations system as a whole;
iv) and WHO actions and timetables in relation to the COVID-19 pandemic, and make recommendations to improve global pandemic prevention, preparedness and response capacity, including through strengthening, as appropriate, the WHO Health Emergency Programme."[20]

In the midst of the most intense health crisis in the last hundred years, WHO, as the United Nations specialized agency for health, stands at what probably is the greatest challenge in its history. It is a profound crisis of identity as the Secretariat in Geneva is weakened by the imbalances in international relations reflected in confrontations between some governments of the North and the South, the United States' withdrawal from the organization, and the decisive influence of the private and philanthropic sectors in setting its agenda. All this unfortunately leads to an unprecedented loss of credibility in the eyes of the public opinion. This is the challenge facing WHO today, and countries should see COVID-19 as an opportunity to build a stronger members led agency, rather than to attack it or allow for a greater influence by the private sector and philanthropy.

In the first half of 2020, the WHO Secretariat was particularly active in providing information, recommendations and guidelines for the management of COVID-19. More than 400 guidance documents for individuals, communities, schools, businesses, industries, health

[18] L. Gostin, S. Moon, and B. Mason Meier, "Reimagining Global Health Governance in the Age of COVID-19", *American Journal of Public Health* 110(11):615-619, (October 2020). DOI: 10.2105/AJPH.2020.305933.
[19] Gostin, Moon, and Mason Meier, "Reimagining Global Health Governance".
[20] WHA 73 Resolution: COVID-19 Response, May 2020, https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf.

workers, health facilities and governments related to different aspects of the COVID-19 pandemic were produced by the WHO Secretariat in the first six months of 2020.[21] What happened and what is continuing to happen is that some countries did not follow WHO, however timely and relevant the recommendations were. What is needed today, on the eve of the arrival of a possible vaccine, is a strong, independent organization capable of supporting countries in tackling problems such as those currently being caused by COVID-19.

Today more than ever, it is necessary to form a strong coalition of countries willing to defend the public character, authority and independence of WHO, so as to allow it to set public health rules at a global level with the capacity and the instruments necessary to put those rules into practice.

According to the non-paper, expectations regarding the mandate of WHO are immense. The organization must set health norms and standards, promote monitoring and implementation in a wide range of health areas, set the research agenda, articulate evidence-based and ethical health policies, react to disease outbreaks around the world, and finally monitor the global health situation.

Unfortunately, to fulfil this mandate WHO currently does not have the required legal, financial or structural instruments, says the non-paper. More precisely, it is not that WHO does not have the instruments to implement its mandate, but rather that it is unable to use them. The high imbalance among Member States assessed financial contributions and the high level of voluntary (public and private) and philanthropic financing, contributes to the problem.

The most logical way to approach a reform process is to start by identifying the problems, so that we know exactly what we want to reform and how we are going to reform it. There are three major problems/issues that a WHO reform would have to address, as explained in the following three points.

Problem 1: The Public-Private Sector Dilemma

WHO was created in 1948 as a specialized public agency of the United Nations System to improve and maintain health around the world.

For many years, this agency was financed by public funds from regular mandatory contributions by the 194 member countries. Over the past 20 years, voluntary contributions (private or public) have grown rapidly.

The biggest problem of WHO today, and at the same time the cause of many other ills, as stated in the non-paper, is the loss of control over the regular budget. This has led to a progressive "privatization" of the agency. "At the time when WHO's 194 Members States, after lengthy negotiations, adopt the program budget, it is only partly predictably financed (by roughly 20 per cent of assessed contributions)".[22] Approximately 80 per cent of the budget is in the hands of voluntary (public and private) contributors, including philanthropic entities such as the Bill & Melinda Gates Foundation and a small group of industrialized countries, which make donations for specific purposes chosen often by them in a unilateral manner.

[21] WHO Director-General's opening remarks at Executive Board Meeting. Special Session on the COVID-19 Response, 5 October 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-executive-board-meeting.

[22] "Non-Paper on Strengthening WHO's leading and coordinating role in global health. With a specific view on WHO's work in health emergencies and improving IHR implementation". Prepared by the Governments of Germany and France, August 2020.

Over-reliance on voluntary contributions (private or public) results in an inability to set priorities based on the global public health priorities. Member States try to set priorities, but funds come for specific issues, selected by a small number of donors who have a decisive role in deciding what the organization does or does not. As the German-French non-paper makes clear: "... the funding coming in is largely based on individual donor interests (...). The current way of funding WHO has led to a high risk of donor dependency and vulnerability..."[23]

It is surprising that specialized agencies of the United Nations System could be increasingly dependent on voluntary contributions (private or public) that make it impossible for the members states to define global priorities. There is an urgent need for the UN General Assembly to define clear criteria and principles for financing the whole system. Why not define, as a mandatory standard, that at least 51 per cent of the budget must come from assessed contributions by governments? And in order to preserve the multilateral and democratic nature of the agencies, it would also be urgent to define the maximum percentage (10 or 15 per cent, for example) that a single contributor (private or public) can contribute to the organization. Currently, there do not seem to be any obstacles preventing a single entity from contributing a large part, even more than 50 per cent, of the WHO budget.

In her speech to the World Health Assembly in May 2020, the Swiss President Simonetta Sommaruga explained that WHO, which currently depends on voluntary contributions for 80 per cent of its budget, requires sustainable funding in order to be able to fulfil its important role. She added, "Let us ask ourselves – is it fair to expect so much from the WHO while funding it in such an arbitrary manner?"[24]

The most urgent reform of the organization which should be addressed by Member States is not the lack of funding, as some industrialized countries suggest,[25] but how and by whom this agency is funded. It is a question of how to progressively recover the public and multilateral character of the institution. This is a fundamental condition for effectively putting WHO at the service of the global public health. An increase in the regular public budget will enable WHO to devote itself to the priorities set by all the Member States without having to constantly follow the priorities of an agenda set by the donors.

Closely related to the public/private role of WHO, is the debate known as FENSA (Framework of Engagement with Non-State Actors) "WHO collaboration with non-State actors" that the Margaret Chan reform left unfinished.

After five years of complex and slow negotiations on WHO reform, the 69th World Health Assembly (2016) approved a resolution on "WHO Collaboration with Non-State Actors" as part of the reform initiated by the then Director-General Margaret Chan in 2011. The FENSA process was essentially a debate/negotiation on the nature of the organization and the role that the private sector would play in it. Talking about the "private sector" in the context of WHO is complicated because "non-state actors" working in health include non-profit non-state actors such as NGOs like Médecins Sans Frontières. However, WHO also defines non-state actors as private for-profit entities, such as the pharmaceutical companies, as well as philanthropic foundations and there are questions whether some of the latter are for-profit or not.[26]

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[23] "Non-Paper on Strengthening WHO's Leading and Coordinating Role In Global Health".
[24] Ibid.
[25] See Germany intervention on behalf of EU, Executive Board special session on the COVID-19 response, 5 October 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-executive-board-meeting.
[26] Lionel Astruc, *L'art de la fausse générosité* : *la fondation Bill et Melinda Gates"*, (Paris, Actes Sud Editions, 2019).

The major point of controversy for the adoption of FENSA was the debate on the definition of a clear policy and mechanisms to avoid the conflicts of interest that could arise in the interaction of WHO with the private sector, a point on which unfortunately no clear conclusion was reached. A consensus was only achieved to totally exclude funds from the arms and tobacco industry, but the door was left wide open for money from the pharmaceutical industry or certain "less healthy" industries.

In May 2020, the WHO Director-General announced the creation of the WHO Foundation,[27] an independent grantmaking entity that will support the budget of the Organization's efforts to address global health challenges. Based in Geneva, legally separate from WHO, the foundation will accept contributions to WHO from the general public, individual major donors, and corporate private partners. The WHO Foundation will simplify the processing of philanthropic contributions in support of WHO and will accept contributions in support of every aspect of the agency's mission.[28] With the creation of the WHO Foundation as an independent and flexible way to finance WHO, the imbalance between private and public in WHO risks getting worse.

Problem 2: The Dilemma Between Voluntary Recommendations and Binding Instruments in the Health Field

A fundamental and historical responsibility of WHO has been the management of the global action against the international spread of diseases. Under Articles 21(a) and 22 of the WHO Constitution,[29] the World Health Assembly is empowered to adopt regulations "for the prevention of the international spread of disease", which, once adopted by the Health Assembly, become effective for all WHO Member States "except those which expressly reject them within the time limit."[30]

The International Health Regulations (IHR) were adopted by the WHA in 1969 and revised in 2005 due to the limitation of the number of mandatory reporting diseases (yellow fever, plague and cholera). The 2005 IHR, while not limiting the number of diseases, placed a limitation on measures that may affect international traffic or trade. The purpose of the IHR (2005) is "to prevent the international spread of disease, to protect against such spread, to control it and to provide a public health response that is proportionate and restricted to public health risks, while avoiding unnecessary interference with international traffic and trade."[31]

In this context, it could be said that in the first half of 2020 many countries acted in violation of the IHR,[32] and the fact that the non-paper and a large part of the interventions of the countries in the Executive Board Special session on the COVID-19 response on 5 October

[27] "WHO Foundation Established to Support Critical Global Health Needs", (WHO, Geneva, 27 May 2020). Available from https://www.who.int/news-room/detail/27-05-2020-who-foundation-established-to-support-critical-global-health-needs.
[28] "WHO establishes foundation to help address global health challenges », PND, (31 May 2020). https://philanthropynewsdigest.org/news/who-establishes-foundation-to-help-address-global-health-challenges.
[29] WHO Constitution Article 21: "The Health Assembly shall have authority to adopt regulations concerning: (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures of diseases, causes of death and public health practices; (c) uniform standards of diagnostic procedures for international use; (d) uniform standards of safety, purity and potency of biological, pharmaceutical and similar products in international trade; (e) advertising and labelling of biological, pharmaceutical and similar products in international trade." WHO Constitution Article 22: "These regulations shall come into force for all Members after due notice of their adoption by the Health Assembly, except for those Members which shall inform the Director-General of their rejection or reservation within the period specified in the notice."
[30] Ibid.
[31] WHO, International Health Regulations (2005).
[32] Bussard Stéphane, "La plupart des Etat ont violé le texte fondamental de l'OMS", *Le Temps*, 15 June 2020.

2020 called for urgent revision of the 2005 IHR,[33] serves as recognition that the tools currently available to WHO are insufficient.

Paradoxically, while the international trade rules of the World Trade Organization (WTO) are binding, WHO does not have the legal means to enforce disciplines that are vital for the protection of global health.

Article 19 of the WHO Constitution

Article 19 of the WHO constitution states: "The Health Assembly shall have authority to adopt conventions or agreements in respect of any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes".[34]

In May 2012, the World Health Assembly adopted a resolution that sought to change the dominant WHO model of "recommending".[35] This resolution aimed to introduce an alternative model to the Research and Development (R&D) model for pharmaceuticals by calling for the initiation of negotiations for a binding international treaty as a means of funding research for medicines.

A binding global treaty or convention, negotiated in WHO, could enable the sustainable financing of research and development of useful and safe drugs at prices affordable to the population and public social security systems. The adoption of such a convention within the framework of WHO, based on article 19 of its constitution, could also make it possible to review the way in which WHO operates in a broader sense. The negotiation of "global and binding instruments on health matters of global concern"[36] is perhaps the most promising avenue for the role that WHO could take on in the future.

In its entire history, WHO has only once used article 19 of its constitution to negotiate a convention of a binding nature. In May 2003, after three years of negotiations and six years of work, the World Health Assembly unanimously adopted the WHO Framework Convention on Tobacco Control, which has now been signed by 177 countries. This was the first –and so far, the only– time that WHO exercised the power to adopt an international treaty in a substantive area to provide a legal response to a global health threat.

The Framework Convention on Tobacco Control enabled the 177 signatory countries to progressively approximate their legislation to address the problem of smoking. The treaty does not set out agreed standards but also encourages the parties to adopt stricter measures through laws and regulations passed by the parliaments or other competent national bodies. This is undoubtedly one of the greatest achievements of WHO in its entire history. Why not to build on this successful example?

The recommendation to launch negotiations on an agreement on R&D for medicines has not been able to move forward because lack of a wide support among WHO members and the opposition from the industrialized countries where the powerful pharmaceutical industry is

[33] "WHO´s Executive Board assesses current COVID-19 response and requests to be more involved in the review processes", Cfr. SOUTHNEWS, No. 346, South Centre (20 October 2020). Available from https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=a2e651d8f1.
[34] Article 19 of the WHO Constitution. Available from https://www.who.int/governance/eb/who_constitution_en.pdf.
[35] Carlos Correa, "Una Resolución de la Asamblea Mundial de la Salud. Curar la enfermedades de los pobres?" *Le Monde Diplomatique*, February 2016. https://mondiplo.com/curar-por-fin-las-enfermedades-de-los-pobres.
[36] Ibid.

located. The crisis caused by COVID-19 is a historic opportunity to revisit this issue and help to recover the credibility of the organization.

Problem 3: The Dilemma Between Regulations and Humanitarian Aid

Another important issue that needs to be addressed is the dilemma between a standard-setting body responsible for the formulation and creation of standards and instruments, including of a binding nature, and for the administration of international health regulations, versus an agency responsible for providing humanitarian assistance in cases of health emergencies, thereby competing with and duplicating the efforts of other agencies such as the Global Fund, Gavi (including the COVAX facility), Unitaid, other UN agencies such as UNICEF, UNAIDS or UNDP, and large NGOs such as MSF.

In fact, the WHO handling of global health emergencies has not been the most brilliant in recent years. Was H1N1 an industry operation, a false pandemic as Director-General Margaret Chan herself asked, reflecting the criticisms that many observers and countries made at the time: "First, did the WHO make the right call? Was this a real pandemic or not? And second, were WHO decisions, advice, and actions shaped in any way by ties with the pharmaceutical industry? In other words, did the WHO declare a fake pandemic in order to line the pockets of industry?"[37]

As a result of the mistakes made by WHO in managing the H1N1 influenza epidemic, Zika and Ebola, there has been a trend in recent years to strengthen the role of WHO in emergency and humanitarian work. The French-German non-paper also suggests strengthening work in emergencies. This would give the organization a dual mission: a normative one and a humanitarian one. However, there are many[38,39,40] who believe that WHO should prioritize its normative functions and leave humanitarian health work to other agencies.

The coordination by WHO of actors such as Gavi (including the COVAX facility), CEPI, and the Global Fund, with significantly larger budgets and managed with the participation of the private sector, is illusory, as the difficulties in organizing the arrival of future vaccines for COVID-19 are showing.

Member countries of WHO and its Secretariat will have to choose between a management office for projects primarily financed by the private and philanthropic sectors, or the reconstruction of an independent public international agency to promote, preserve and regulate health by recommending or setting norms, strategies and standards. This is a key dilemma for WHO.

A choice will have to be made between what a few donors want WHO to be or do, and what the world needs today from a United Nations agency dedicated to health. For those who still

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[37] Margaret Chan, Director-General of the World Health Organization, Address to the 64th World Health Assembly Geneva, Switzerland 16 May 2011. Available from https://www.who.int/dg/speeches/2011/wha_20110516/en/.

[38] Gostin, Lawrence O. and Sridhar, Devi and Hougendobler, Daniel, "The Normative Authority of the World Health Organization", Public Health, Forthcoming, (2015). Available from SSRN: https://ssrn.com/abstract=2634181.

[39] Yach, D. World Health Organization Reform—A Normative or an Operational Organization? *Am J Public Health*, 106(11): 1904–1906. (November 2016). Available from https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2016.303376.

[40] 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, (London, Chatham House, 2013). Available from https://www.chathamhouse.org/sites/default/files/publications/research/2013-02-01-role-world-health-organization-international-system-clift.pdf.

believe that the United Nations has to play a leading role in the area of health, and even more so for those who want to offer solutions and contribute to the reform of WHO, the COVID-19 pandemic will perhaps be the last chance for this agency.

SECTION 2

THE INTERNATIONAL HEALTH REGULATIONS (IHR)

The IHR (2005) is an international agreement signed by 196 countries,[41] including all Member States of the World Health Organization (WHO). Its aim is to help the international community prevent and respond to serious public health risks that may cross borders and threaten the world's population. The purpose and scope of the IHR (2005), which entered into force in 2007, is "to prevent and protect against the international spread of diseases, to control them and to provide a public health response to them, all in proportion to the risks they pose to public health and to avoid unnecessary interference with international travel and trade".[42]

The purpose of the revised IHR (2005) is to "prevent, protect against, control and provide" a response to any public health emergency of international concern (PHEIC) (art. 2 IHR).

Ebola in 2014 and Zika in 2016 were both regarded as PHEICs: they were considered extraordinary events which created public health risks for other states and required a coordinated international response (art. 1 IHR). COVID 19 is the most recent and severe case of PHEIC ever dealt with by WHO. During a PHEIC, the WHO Director-General may issue temporary recommendations. However, due to their character as "non-binding advice" (art. 1 IHR), States may follow them or not. The temporary recommendations issued during the Ebola crisis, for instance, were widely ignored with devastating effects.

Taking a Straightforward Approach: Modifying the IHR

The easiest way to address one of the problems that need to be addressed by WHO reform is, obviously, to modify the IHR. Only one single word needs to be cut: "Art. 1 IHR could be modified to the extent that temporary recommendations are defined as 'binding' measures. In light of recent state practice this approach seems, however, to be out of question."[43]

The non-paper rightly points out that "While other global legally binding instruments include incentive mechanisms for implementation and reporting, the IHR does not currently provide for such mechanisms."[44] This means that the capacity of the WHO Secretariat is quite limited and depends on the goodwill of countries to cooperate. Other binding legal frameworks, such as the WTO trade agreements, include specific notification and transparency procedures that allow its members to monitor the extent to which other members comply with their obligations. In addition, the WTO rules provide that a member that fails to conform its conduct to any of the obligations of the agreements covered by the organization may suffer suspension of trade benefits. In common parlance, this consequence is called "trade sanctions".[45]

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[41] The 194 Member States plus two non-member states of the WHO – The Holy See and Liechtenstein.

[42] WHO, "¿Qué es el Reglamento Sanitario Internacional?". Available from https://www.who.int/features/qa/39/es/.

[43] Robert Frau, "Creating Legal Effects for the WHO's International Health Regulations (2005) – Which way forward?" *Völkerrechtsblog,* 13 April 2016. DOI: 10.17176/20171201-133647.

[44] "Non-Paper on Strengthening WHO's leading and coordinating role in global health. With a specific view on WHO's work in health emergencies and improving IHR implementation". Prepared by the Governments of Germany and France, August 2020.

[45] CEPAL "Tipologia de instrumentos internacionales" LC/L.3719, 2013 https://www.cepal.org/rio20/noticias/noticias/1/50791/2013-861_PR10_Tipologia_instrumentos.pdf.

Article 21 of the WHO Constitution states that the Health Assembly has the authority to adopt regulations concerning, inter alia, sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease. Article 22 stipulates that "Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice". However, there are no mechanisms to enforce the adopted regulations if not complied with by members that have not rejected them or made reservations. This is the gap that needs to be addressed in order to empower WHO to effectively protect the global public health in case of a PHEIC.

NON-PAPER PROPOSALS OF ACTION

The reform proposed in the non-paper contains 10 actions, of which several are highly relevant.

Action 1: Consider a general increase of assessed contributions. This proposal by France and Germany is a major step in the debate on WHO reform. Admitting that the organization must be a public entity is the first condition for any coherent reform of the WHO. For more than 20 years, the regular budget of WHO has been frozen by the United States and other industrialized countries that demanded zero growth.

In the early 1980s, the WHA introduced a "zero-real growth policy" for the regular budget. This policy froze membership dues in real dollar terms so that only inflation and exchange rates would influence members' assessed contributions. In 1993, the WHA voted for a more stringent budgetary policy, moving the organization from "zero real growth" to "zero nominal growth" for assessed contributions. This policy shift made the organization increasingly reliant on extra budgetary funds.[46]

Action 2: Strengthen the normative role of WHO. In the face of the multiplication of international actors in the health field, strengthening the normative capacity of WHO is a way to give it back its identity and specificity and to allow other public-private actors, philanthropists, to continue to act, while respecting and applying WHO standards. This second action proposed in the non-paper does not go far enough, as it does not mention what the instruments will be to ensure compliance with the standards that should logically be via Article 19, and developing rules under articles 21 and 22 of the WHO Constitution.

Action 3: Establish strong and sustainable governance structures that enable WHO Member States to provide adequate oversight and guidance to the work of WHO in health emergencies. A clear lesson from COVID-19 is that WHO must have "strong and sustainable governance structures," but this action is insufficient if strong governance structures are not identified. The non-paper merely mentions that a subcommittee of the Executive Board should be established to monitor health emergencies and crises.

Declarations of the highest level of health crisis (PHEIC) should be accompanied by effective compliance mechanisms to be activated in times of global health crises, e.g., in order to ensure that pandemic-related diagnostics, treatments and vaccines are accessible and affordable to all.

Actions 8 and 9 of the non-paper refer to the reform of the PHEIC and the transparent implementation of the health regulations at the national level. As already mentioned, the declaration of a PHEIC should be explicitly accompanied by the possibility of using compliance mechanisms based on binding rules. With regard to the transparency of the application of the IHR at the national level, the non-paper calls for improved collaboration and strengthening of the system for reporting outbreaks or PHEICs. The immediate reporting of such problems should be mandatory.

[46] Reddy, S., Mazhar, S. & Lencucha, R., "The financial sustainability of the World Health Organization and the political economy of global health governance: a review of funding proposals". *Global Health* 14, 119 (2018). Available from https://doi.org/10.1186/s12992-018-0436-8.

THE SPECIAL MEETING OF THE EXECUTIVE BOARD ON 5–6 OCTOBER 2020

In the context of the health crisis caused by the COVID-19, the resolution WHA 73 "COVID-19 Response" (May 2020) and the non paper presented by France and Germany, the extraordinary meeting of the Executive Board on 5–6 October 2020 became a kind of forum on how to address the reform of WHO.

At the extraordinary meeting, several countries referred in their interventions to the non-paper presented a few weeks earlier; it, hence, became an important element of a diplomatic strategy aiming at starting a debate on the WHO reform.

The second day of the extraordinary meeting was dedicated to the review of the progress of two committees and one panel that are in charge of the implementation of resolution WHA 73: COVID-19 Response, of May 2020:[47]

1. The Independent Panel Pandemic Preparedness Response (IPPR)
2. The IHR Review Committee
3. The Independent Oversight and Advisory Committee on WHO Emergencies Programme

The two committees and the panel are composed of recognized international experts appointed by the WHO Director General. Proposals for the implementation of resolution WHA73, now assumed to be part of a WHO reform, are expected to go to these bodies, or at least to the second "IHR Review Committee" that is considering the IHR review.

[47] WHA 73 Draft Resolution on COVID-19 Response, May 2020. Available from https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf.

CONCLUDING REMARKS

The three main problems identified in relation to the inability of WHO to respond to situations such as the one posed by the COVID-19 crisis require a discussion of:

1. The public nature and role of WHO.

2. The absence of binding mechanisms for the enforcement of its directives, norms and standards.

3. The dilemma between the normative and the humanitarian role of WHO.

A reform of WHO that aims to respond to the existing structural problems should then: define mechanisms to progressively regain the public character of the organization, so as to control at least 51 per cent of the budget in a period, for instance, of 7 years. This means that the regular mandatory assessed contributions of the Member States should represent at least 51 per cent of the agency's total budget.

Effective coordination by WHO of global health issues requires the use of articles 19, 20 and 21 of its Constitution for the approval of binding instruments and compliance mechanisms that ensure the effective application of directives, regulations and standards issued by the organization.

The third point of the reform is perhaps the most complex and controversial – the dilemma between the normative and the humanitarian role of WHO. For the reasons explained throughout this paper, and taking into account the multiplication of actors addressing health issues, and the mistakes and delays in the management of previous epidemics (H1N1, Zika, Ebola), WHO should concentrate as a priority on its normative work.

The more than 400 high-quality and relevant documents produced by WHO during the first six months of 2020 are a clear and positive sign of what this agency can do. If the tools and instruments were found to make the relevant standards enforceable, the world would be much better off.

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Chemin de Balexert 7-9
1219 Vernier
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

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