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Overcoming the "Soft vs Hard Law" Debate in the Development of New Global Health Instruments

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On 30 March 2021, the President of the European Council, the Director-General of the World Health Organization (WHO), and twenty-six Heads of State and Government called for a new treaty for pandemic preparedness and response. The World Health Assembly (WHA) will convene a special session at the end of November to evaluate the benefits of such an international agreement. Since global health law can be described as a sophisticated patchwork of hard and soft law standards, the doctrinal dispute revolving around the preferable choice between the two is not new. The discussion is likely to arise again with this forthcoming convention.

Building on this premise, this post will begin with a thorough analysis of the use of soft and hard law in the realm of global health law. It will then argue that rather than focusing on the *a priori* debate on which of the two approaches is better suited to tackle global health challenges, in the development of new global health instruments more attention should be paid to: a) how soft and hard law can interact with each other; and b) how to foster respect for the norms, irrespective of whether they are legally binding. In the latter regard, capacity-building, compliance mechanisms and engagement with non-State actors should be given due consideration.

Soft vs Hard Law: The Debate and the Status Quo in Global Health Law

Although the definition of soft law is highly debated, with some academics even denying the notion itself portraying it as redundant and illogical, soft law could be considered as "a convenient description for a variety of non-binding normatively worded

instruments used in contemporary international relations by States and international organizations". Examples of soft law include recommendations, guidelines, codes of conduct, non-binding resolutions, and standards. In contrast, hard law refers to legally binding instruments, which in international law typically take the form of treaties.

Soft and hard law present both advantages and disadvantages. Soft law is generally developed and adopted relatively quickly. It is also commonly less time-consuming and thus less costly, more flexible, and more ambitious than hard law. Conversely, hard law is deemed to be more legitimate and democratic than soft law, more precise and detailed, related to strong powers of enforceability and its applicability is also possible against domestic actors, such as individuals and businesses.

There are different views on which of the two approaches is the more appropriate to address global health problems. For instance, Sekalala is strongly in favour of the adoption of soft law in this area and supported this claim by proving that soft law has been particularly effective in dealing with HIV/AIDS, malaria and tuberculosis. Klock holds similar views, arguing that soft law might be more powerful in affecting conduct. Yet, various scholars believe that global health hard law measures could be efficacious too, and numerous health treaties have been proposed in the literature. By way of illustration, there have been calls for a Framework Convention on Alcohol Control and for an International Treaty on Antimicrobial Resistance.

This post contends that a one-size-fits-all solution exclusively promoting either soft or hard instruments in global health law should be avoided, as both can be valid. The successful use of soft law by the WHO in the fight against HIV/AIDS and of hard law in addressing the tobacco epidemic would seem to demonstrate this. Indeed, various soft instruments, such as WHA resolutions (e.g. WHA resolution 40.26 (1987)), conceivably played an essential role in limiting the spread of HIV/AIDS, in protecting the human rights of people with the disease and in increasing access to anti-retroviral drugs. On the other hand, several high-level studies suggest that the Framework Convention on Tobacco Control (FCTC) contributed to the rapid enactment of domestic tobacco control legislation.

Even though both soft and hard instruments can arguably be effective, it must be noted that in the sphere of global health law, more specifically when the document is adopted under the auspices of the WHO, soft law appears to be the rule rather than the exception. Although the Constitution of the WHO grants the organization relevant normative powers, the WHA has only adopted three legally binding instruments since the birth of the agency in 1948: two regulations (the Nomenclature Regulations and the International Health Law Regulations, hereinafter IHR) and one convention (the FCTC). In other words, the WHO has historically given preference to the production of soft law.

The reasons for this can be many. The predilection of the WHO for soft law might be rooted in the culture of the organisation, composed of doctors and scientists not comfortable with exercising legislative authority. Another explanation could be that health has been (and continues to be) perceived mainly as a domestic, rather than an international, matter. Other reasons can be identified in the advantages of soft law mentioned above, and especially the fact that soft law can be easily modified, keeping pace with the scientific progress in medicine.

The Development of New Global Health Instruments: Overcoming the Debate

Although the "soft *versus* hard law" debate is critical, this post maintains that any discussion on the development of new global health law instruments should pay more attention to two other elements. It should: a) consider the potential relations between hard and soft rules; and b) focus on how to ensure adherence to the norms, regardless of whether they are legally binding or not.

The first point wants to stress that any debate that remains at the *a priori* level "soft *versus* hard law", without exploring the possibility that the two types of instruments can be connected to and potentially reinforce each other, is a poor one. This does not mean that soft and hard law must necessarily be intertwined to be effective, but that this is an option and proper consideration should be given to it. Indeed, in the reality of global health law, examples of this phenomenon are already present. A very good illustration of this interconnection is given by the Pandemic Influenza Preparedness Framework (PIP Framework), which is not legally binding but can create legal obligations through enforceable contracts.

Its purpose is to facilitate the sharing of influenza viruses with human pandemic potential and to increase the access of developing countries to vaccines and other pandemic related supplies. The Framework includes "Standards Material Transfer Agreements" (SMTAs), which are binding contracts that regulate the transfer of the biological material between the WHO and biotechnology firms and universities. Interestingly, once signed, SMTAs produce contractual duties to dispense particular benefits, such as pandemic influenza vaccines, antiviral medicines or other pandemic-related products or technologies, in exchange for receiving the pathogens. The Framework has been praised as an innovative and creative global health law tool.

The second point aims to shed light on the complex topic of how to foster compliance with the (soft or hard) norms. This post argues that any discussion on the matter cannot but considers three main factors. The first one refers to the need to ascertain whether the State possesses the resources necessary for the implementation of the norms. The second one is that the WHO and States are normally not very keen on hard models of enforcement

when global health issues are concerned. The third is that non-State actors, such as NGOs, civil society groups, businesses, foundations, and academia, are increasingly relevant in the global health governance picture and can play a fundamental role in ensuring that States observe their obligations.

Low- and middle-income countries (LMICs), should be put in a position that allows them to respect the norms in the first place. Many global health instruments demand the States to develop implementation capacities, which frequently requires substantial economic resources. They may also contain provisions that encourage the international community to offer assistance both in pecuniary and technical terms, but the latter are typically and purposely vague. Both the IHR and the FCTC have been criticised for not including a proper strategy for capacity building. According to Gostin, the reluctance of States to finance capacity building in LMICs is one of the major limitations of global health law, regardless of it being hard or soft.

Furthermore, any debate on how to achieve respect for global health norms should recognise that States are not very keen on hard models of enforcement in the context of global health law adopted under the aegis of the WHO. For instance, both the IHR and the FCTC lack strong enforcement mechanisms, despite being legally binding instruments. One reason behind this predilection might be the fact that hard types of enforcement do not traditionally characterize WHO's institutional culture. Another motive could be that States are highly aware of the complexities that global health challenges entail, and consequently, that it is better to refrain from accusing each other when it is so easy to be the one committing violations.

Finally, the potential of non-State actors in enhancing State compliance with global health norms should not be underestimated. Contemporary global health architecture features a high variety of players. Not acknowledging (and making the most of) this reality could mean losing an opportunity. There is no doubt that engaging non-State actors raises serious concerns with regards to questions of, *inter alia*, legitimacy and conflict of interests. Nonetheless, involving non-State actors remains crucial. Not only because non-State actors can help address global health problems, but also because if not engaged by the States and international organizations, they might operate on their own anyway. Moreover, inclusive compliance tools could contribute to re-build trust between individuals and institutions, trust which may have been significantly affected by how the Covid-19 pandemic has been handled.