SUBMISSION OF ADDITIONAL CONTRIBUTIONS

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1. INTRODUCTION

This contributor is thankful to the United Nations Secretary-General's High-Level Panel on Access to Medicines for the opportunity to make additional inputs. This additional input briefly outlines some of the main points discussed in Contribution 73[1] and it elaborates on the brief response to the 16 March 2016 Hearing question posed to the contributor namely, 'do you not think that we need to build further, thus not just take incremental steps but instead we need to have a long term vision?'

2. BRIEF SUMMATION OF MAIN POINTS FROM CONTRIBUTION 73:

2.1. Policy incoherence is real and proven as demonstrated in:

2.1.1. Developing countries where the lack of access to medicine is keenly felt, as is the limitations imposed on such countries to grow their own means of making medicine to address these same health needs because of the current system of innovation and access to medicine;[2] and in

2.1.1. Developed countries legitimate concerns are raised about the sustainability of public health systems dependent on a profit driven system of innovation and the inability of that same system to innovate on health priorities or needs.[3]

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[1] Shamiso Zinzombe 'Contribution 73. Shamiso Zinzombe Erasmus University Rotterdam 28 February 2016' http://www.unsgaccessmeds.org/inbox/2016/2/28/shamiso-zinzombe accessed 13 March 2016 (Contribution 73. Shamiso Zinzombe).

[2] Contribution 73. Shamiso Zinzombe para 1.

[3] Mariana Mazzucato, 'Contribution 74. Mariana Mazzucato Science Policy Research Unit, University of Sussex' 28 February 2016 http://www.unsgaccessmeds.org/inbox/2016/2/28/mariana-mazzucato accessed 13 March 2016 (Contribution 74. Mariana Mazzucato) Introduction, para 1, 2, 3 demonstrates the ineffective and wasteful nature of the current system of innovation. For example, under the current system priority setting on innovation is driven by profit, not medical need, such as the prevalence of unmet medical need demonstrated by lack of research into critical areas such as antibiotics, nor true medical benefit such as prevalence of 'me too' formulations with no added therapeutic value in comparison to existing treatments. Pharmaceutical company pricing of medicine is extremely high and accessible only to the wealthy or well insured. Further pharmaceutical pricing does not reflect the cost of developing and manufacturing medicine, for example, more is spent on marketing medicine in comparison to research and development. Another example from Contribution 74. Mariana Mazzucato para 1, 'More recently, the doctrine of value based pricing is put forward, which suggests that the value and therefore price of a medicine can be equated to what it would cost to the health system to not have that medicine. For instance the $84,000 price for a 12-weeks hepatitis C treatment costing <$200 to manufacture is justified as “cheaper than a liver transplant”, the ultimate resort for people dying from chronic hepatitis C infection'. Finally, to which must be noted the undervalued and overlooked significant state investment toward research, such as through Medical Research Council in the United Kingdom among other illustrations. Leading to a situation explained in Contribution 74. Mariana Mazzucato para 3 where ' “the public” pays multiple times (funding and infrastructure for early research as well as clinical trials, various tax and other incentives to de-risk pharmaceutical companies’ R&D investments, price monopolies with limited to no price regulation and acceptance to pay high prices'. Similar concerns are highlighted in Els Toreele 'Contribution 89. Els Toreele, Open Society Foundations' 28 February 2016 http://www.unsgaccessmeds.org/inbox/2016/2/28/els-torreele accessed 13 March 2016 (Contribution 89. Els Toreele).

2.2. The current system on innovation and access to medicines is not, but should be consistent with the entitlement to access medicine which is sourced from, among other human rights, the right to health in Article 12 International Covenant on Economic, Social and Cultural Rights (ICESCR).[4] This entitlement secures access in the event of medical indication and a system of ensuring access amongst other things; thus, it also mandates a relevant legal and policy framework to accomplish this.[5]

2.3. In terms of framing a law and policy framework for such a system, Article 12 ICESCR should be read with Article 15 ICESCR, the right to among other things, science. Article 15 ICESCR reinforcess the right of the community to benefit from science such as medical innovation or inventions. It secures, among other human rights, the rights of human being inventors to moral and material interests of their inventions. It obliges the state to create a system for the development and diffusion of science like the invention of medicine. It also mandates the state to engage in international cooperation and contacts whilst doing so.[6]

2.4. In terms of Article 12 and 15 ICESCR pharmaceutical companies are implementing, rather than norm setting, duty bearers and states need to outline those specific duties in order to better hold them to account.[7]

2.5. In terms of Article 12 and 15 ICESCR intellectual property is one of the tools states may use but it is itself not a human right. For intellectual property to promote access to medicine it must be structured in a manner that best secures this, to which the Committee on Economic, Social and Cultural Rights (CESCR) has specified that among other measures in relation to the right to health, among other human rights, states may exclude certain products from patentability when their commercialisation jeopardizes realisation of the right.[8]

2.6. There is a need to elaborate on principles inherent in these existing human rights to secure access to medicine[9] within the new Sustainable Development Agenda.[10]

3. 'DO YOU NOT THINK THAT WE NEED TO BUILD FURTHER, THUS NOT JUST TAKE INCREMENTAL STEPS BUT INSTEAD WE NEED TO HAVE A LONG TERM VISION?'

3.1. The human rights framework was created with a long term comprehensive vision in mind.[11] However, in the area of access to medicine, not all human rights provisions which can bring this to fruition have been used. Instead currently the system is predominantly based on international economic law, the current framing of which in treaties like the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights[12] is one of the sources of policy incoherence.[13]

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[4] International Covenant on Economic Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR), Contribution 73. Shamiso Zinzombe para 2.
[5] Contribution 73. Shamiso Zinzombe para 2.
[6] Contribution 73. Shamiso Zinzombe para 3.
[7] Contribution 73. Shamiso Zinzombe para 4.
[8] Contribution 73. Shamiso Zinzombe para 3.8.
[9] Contribution 73. Shamiso Zinzombe para 5.
[10] UNGA 'Draft outcome document of the United Nations summit for the adoption of the post-2015 development agenda' (12 August 2015) UN Doc A/69/L.85.
[11] Charter of the United Nations (adopted 26 June 1945, entered into force 24 October 1945), Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A (III), ICESCR.
[12] Agreement on Trade Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1.
[13] Text para 2.

3.2. Thus, the proposal is for states to make more and better use of existing human rights provisions like Article 12 and 15 ICESCR. The benefits of doing this are first, this can help address existing problems for which the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)[14] does not provide solutions. Second, better and more use of the existing human rights framework can help understand the strengths and weaknesses in the existing human rights framework and how this might be best adapted to feed into initiatives such as framing a treaty on research and development as proposed by others impetus for which may be located in Article 15 (2) and (4) ICESCR. Thus, it can be used to address existing problems, whilst also building a foundation for a more long term vision. To fully appreciate the strengths and weaknesses of the existing human rights framework in the area of access to medicine it is essential to first make use of it in relation to provisions like Article 15 ICESCR and better use of it in relation to provisions like Article 12 ICESCR.

3.3. For example, this can be done by unpacking the legal principles within human rights such as the right to science Article 15 ICESCR. Colleagues, for illustration purposes, are rightly calling for a system of innovation that separates access from innovation. Article 15 ICESCR already ensures access in sub-article 1 (b) which enshrines the right of everyone to 'enjoy the benefits of scientific progress and its applications', which is reiterated in sub article 2 the obligation on the state to diffuse science. Separate from this related to innovation, among others, is Article 15 (1) (c) ICESCR. Which the CESCR has interpreted and places intellectual property within state control and regulation as one of the tools states may use by way of modalities to make this right a reality. Article 15 (2) ICESCR, which places an obligation on states to develop science and a practical proposal to make this a reality is for example Contribution 89[15] which illustrates how states can carry out their mandate in terms of this right in the area of access to medicine by offering a variety of models ranging from state sponsored such as United States of America's Defense Advanced Research Projects and other non-profit Product Development Partnerships. [16]

3.4. States can then articulate a clear set of common principles which can be applied now in tandem with the Doha Declaration. For example, these common principles can engage the human rights duty bearing role of pharmaceutical companies in the manner in which they exercise intellectual property rights. Among others, for example one such principle states could develop specifically in the context of access to medicine is the reasonableness principle.[17] Certainly, in relation to ensuring accountability among other approaches states can also support the inclusion of pharmaceutical companies within any adjudicating mechanism created in terms of the work of the Open-ended Intergovernmental Working Group on Transnational Corporations and Other Business Enterprises with respect to Human Rights.[18]

3.5. States can also use the existing human rights framework to articulate principles that engage the role of intellectual property as a tool and this can afford states the latitude they are obliged to exercise in a human rights system in order to carry out mandates in Article 12 and

[14] Declaration on the TRIPs Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.
[15] Contribution 89. Els Toreele.
[16] Contribution 89. Els Toreele para 3.3.
[17] S. Zinzombe, 'Harnessing the Human Rights Reasonableness Principle for Access to Medicine' Groningen Journal of International Law, Vol. 3, No. II, 2015.
[18] UN HRC Resolution 26/9 ' Elaboration of an international legally binding instrument on transnational corporations and other business enterprises with respect to human rights' (14 July 2014) UN Doc A/HRC/RES/26/9 mandated the Open-ended Intergovernmental Working Group on Transnational Corporations and Other Business Enterprises with respect to Human Rights which hosts its next session from 24-28 October 2016, see also website http://www.ohchr.org/EN/HRBodies/HRC/WGTransCorp/Pages/IGWGOnTNC.aspx.

15 ICESCR. For example the CESCR already confirms that states need to do everything they can to make sure intellectual property does not infringe the right to health including excluding certain products from patentability. This is a proposal also made by other contributors, such as proposal 3 in Contribution 10., '[a]uthorize exemption of essential medicines from patenting through an authoritative interpretation of articles 27 and 30 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.'[19]

3.6. In this process, as the United Nations Secretary-General and his High-Level Panel on Access to Medicines have commendably led consistently with human rights in relation to participation, space for continuous participation from civil society should be included. While input from pharmaceutical corporations in relation to which the current system of making medicine is functioning is valued, it is also proposed that it is critical for the law and policy making space, particularly the point of decision making, to be free from corporate interest, interference and influence.

3.7. An authoritative body within the United Nations should outline these principles and invest them with the necessary legal authority making them mandatory, rather than discretionary. Finally, the WTO should respect these, as these principles will have been developed from existing obligations of state parties to the ICESCR.

[19] Ellen ‘t Hoen, Brigit Toebes, Katrina Perehudoff and Frederick M Abbott 'Contribution 10. Ellen 't Hoen Global Health Law Committee of the International Law Association 22 February 2016 http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionglobal-health-law-committee-of-the-international-law-association accessed 13 March 2016.

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