25 October 2016

WIPO, WHO, WTO Joint Technical Symposium on AMR

Panel 3 – Trade policy in support of antimicrobial access and stewardship

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Intervention

1. Allow me at the outset to thank WHO, WTO and WIPO for organizing this Joint Technical Symposium and for inviting Brazil to contribute to the debate on Antimicrobial Resistance.

2. AMR is a new discussion that deserves serious and adequate consideration taking into account the issue's manifold dimensions.

3. I will focus my presentation on access to and stewardship of antimicrobials, exploring how a future AMR framework could have access to medicine at its core, including R&D related aspects. I will also try to point differences between AMR and the broader access to medicine agenda, and the need, therefore, to balance and include safeguards for human rights and development.

4. Brazil participated actively in the negotiations of the WHO's Global Action Plan on AMR, adopted last year by the Health Assembly, and the Political Declaration that came out of the UNGA high level meeting on AMR, last September. We follow closely also discussions in the Codex Alimentarius, BRICS, G20 and other UN fora. In Brazil, an inter-ministerial working group was established in 2014 to develop a national action plan on AMR, which is expected to be finalized next May.

5. We welcome that the New York political declaration reinforces fundamental elements of the WHO Action Plan. It acknowledges, for example, the relevance of interagency collaboration within the UN system through the "One Health approach".

6. As a tentative concept, however, “One Health approach” should not lead to a “one size fits all” framing of solutions. Rather, WHO, FAO and OIE should continue to work within their respective mandates and frameworks of commitments. Similarly, the human, animal and phytosanitary dimensions need to be mapped and framed in accordance with their specificities.

7. We believe discussions on options for a global stewardship and development framework for AMR should neither duplicate nor extrapolate the WHO Global Action Plan.

8. Moreover, any options “in support of access to and stewardship of antimicrobials” should balance monitoring, control and conservation, on the one hand, and access and affordability where antibiotics are needed, on the other hand.

9. From a development perspective, it would seem far too drastic to start off advocating for stringent measures of control, such as limiting consumer access to antimicrobials, curtailing wholesales of antimicrobials or withholding life saving antibiotics for human use under a concept of conservation.

10. Avoiding unnecessarily restrictive policies is particularly important for developing countries, where the lack of access to antimicrobial medicines kills more than the resistance itself. And we must bear in mind that undue restrictions on prescription and use of antibiotics, or imposing a ban on sales, would result in greater barriers to access and could, in practice, undermine flexibilities provided for public health objectives in international agreements.

11. It would go against the Doha Declaration on TRIPS and Public Health and the 2030 Agenda for Sustainable Development, violating the human right to health and jeopardizing food security and nutrition, with significant negative social consequences for many.

12. Less drastic but effective initiatives, as a mandatory retention of antibiotic prescriptions for human use, could be considered to

monitor rational use. Brazil made this practice of the public sector mandatory also for private pharmacies from 2011 onwards.

13. The core objective must be to ensure access to existing and new antimicrobials for all, alongside with food security and nutrition, access to water and sanitation, and improving the R&D landscape.

14. Further work on the definition of "appropriate use" would be needed, if this term is to become the standard for decisions on prescription and use of antibiotics, because what is "appropriate" will vary enormously according to the degree of disease burden, diagnostics capacity, overall strength of national health systems, social groups and levels of development.

15. Improved training of physicians and a health workforce commensurate with the challenges faced are also paramount.

16. As recognized by the political declaration and the WHO GAP, AMR needs to be contextualized according to the sector and be grounded on scientific evidence and risk analysis.

17. I must emphasize that scientific evidence and risk analysis are crucial to addressing the human-animal interface, particularly in order to avoid manipulation of the AMR agenda as a smokescreen for protectionism and unfair trade.

18. We should be scientific and objective, avoiding also the temptation of overstating AMR as a threat in security terms, and instead focus on raising awareness of it as a public health challenge of international concern.

19. The UN is well suited, as a major first step, to run awareness campaigns to improve public understanding of the need for more rational use of antimicrobials. At the same time, we should agree to focus on preventing infections to reduce the need for antibiotics in the first place, paying particular attention not to sound the alarm so high, that it might jeopardize international travel, trade and migration.

20. Research and Development and scientific investigation in a broad sense must take center stage of a AMR global stewardship framework, since at the origin of the debate is the lack of dynamic innovation for more effective medicines.

21. This issue is not exclusive to AMR, and solutions for stepping up R&D on antimicrobials should encompass other life threatening and underserved illnesses especially affecting developing countries - in particular neglected tropical diseases. Solutions should be based on needs assessment and priority setting by relevant multilateral mechanisms, notably the WHO.

22. We feel there is a lack of analysis of the shortcomings of the IP System to induce innovation on antimicrobials based on needs, rather than market reward.

23. Additionally, a credible AMR global stewardship framework would require giving the public sector agenda a greater role in this respect, particularly in countries that have high levels of public health R&D investment.

24. Even if we take into account the AMR review estimate of 10 million annual deaths due to AMR in 2050, we must recognize that the public health burden can be also high for other existing diseases that have not gotten the same level of international attention as AMR.

25. According to WHO fact sheets, approximately 3,2 billion people – nearly half of world's population – are at risk of malaria and, in 2015 alone, 214 million cases were registered resulting in 438 thousand deaths. If you add up the number of deaths by malaria until 2050, you would reach a total of 15 million; if you take Hepatitis C and its estimated annual number of deaths of 700 thousand, this is the same as the current number of deaths due to AMR; if you consider diarrhoeal disease and its approximately 1,7 billion cases every year, resulting in 1,4 million deaths, this is twice the current burden of AMR and mostly preventable.

26. This is not to downplay the concern on AMR, but rather to highlight that the AMR momentum should be used to tackle

systemically the problem of access to medicines: for all humans; for all illnesses disproportionately affecting the population; and to revisit the innovation system where it is clearly failing to deliver.

27. From a public health perspective, generics should continue to be recognized as part of the solution, not the problem. TRIPS flexibilities should be reaffirmed as a legitimate resource tool to encourage early entry into market of new relevant medicines, as well as generics, upon patent expiry and exhaustion of rights, under conditions of affordability and access.

28. Much has been discussed about de-linking the cost of R&D and the price and volume of sales for antimicrobials, but a first step would be to better understand what kind of linkages exist between the two, if any, and how they operate.

29. Since so much of the argument for IP monopolies and corporate pricing policies are based on allegations of R&D cost recovery, and so very little is disclosed in terms of actual company expenditures, and public subsidies that feed into the process, we should take on the challenge of a serious informed discussion on this critical issue.

30. R&D costs urgently need a common, workable definition, and the UN is the appropriate body to carry out this task.

31. It would seem logical that in the determination of cost for R&D associated with a particular medicine, or vaccine, we should avoid adding up disbursements disconnected from the production chain, such as: the cost of unrelated unsuccessful streams of R&D within a particular corporation; the cost of advertisement; dividends to share-holders; the cost of unsuccessful financial market portfolio operations; unreasonable profit margins for unreasonable wages and bonuses at the expense of availability and affordability of medicine where most needed.

32. Similarly, we should consider subtracting from R&D cost calculations direct and indirect subsidies received, as well as tax-breaks and other such possible subsidy equivalents, because these are

expenditures that have been borne out by the general public, not the brand corporation.

33. A balanced global stewardship for AMR should favor all in need, and we see with concern that some existing voluntary patent pooling mechanisms have been limited in scale by the commercial interests and market strategies of participating rights-holders. More often than not, they will restrict voluntary licensing of their products by excluding large middle-income countries, where the world's poor and needy live in largest number.

34. To conclude, AMR is an all-encompassing agenda, which will demand a UN system-wide response, but one that is separate from the traditional access to medicine agenda, and will require its own framework for discussion, balancing of rights and obligations, and norm-setting.

35. Any solution will need to take into consideration the different capacities of States to tackle AMR and the need for evidence-based R&D, capacity building, technology transfer, technical assistance and cooperation.

36. The access to medicine and equity challenge which we have been discussing over 20 years, since the early days of the HIV response, must continue to be examined in its own broad terms, with a view to an appropriate response at the coordinated multilateral level, involving WHO, WIPO, WTO, Human Rights Council and other relevant institutions of the UN family.

37. It could be complemented with, but should not be replaced by an AMR global stewardship discussion that could risk overriding the hard-earned balances embedded in the Doha Declaration on TRIPS and Public Health, and other such provisions and declarations that make up the acquis of the access to health movement.

38. AMR is a new discussion, with little multilateral precedent to draw from. It potentially involves restricting access to antimicrobials under the guise of "conservation"; and rewarding innovation through

innovative mechanisms that could eventually have an IP-plus effect on market control and prices.

39. The AMR agenda has been conceived in a small group of discussions, located in the G-7, and promoted more recently on the basis of the AMR review and an economic-financing perspective.

40. To become a matter of global agreement, it will need to respond and be accountable to the social-equity dimensions of the 2030 Agenda for Sustainable Development, its goals and targets.

41. We must be aware that AMR is a different discussion because it involves interplay between human needs and rights, animal health and agriculture, nutrition and food security, business and trade.

42. The stakes may be higher, and, therefore, the balances and safeguards for human rights and development have also to be more solidly discussed and cared for.

Thank you.