



SOUTH CENTRE STATEMENT ON ACCESS TO BIOSIMILARS / BIOGENERIC MEDICINES AT THE WHA 72

By Germán Velásquez

At the 2014 World Health Assembly (WHA), World Health Organization (WHO) Member States, through Resolution WHA67.21 on ‘Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy’, requested the WHO Secretariat :

"to convene the WHO Expert Committee on Biological Standardization to update the 2009 guidelines on similar therapeutic products, taking into account the technological advances for the characterization of biotherapeutic products and considering national regulatory needs and capacities and to report on the update to the Executive Board"

The process of drafting and adoption of Resolution WHA67.21, approved by consensus, were largely influenced by the experiences of and proposals from Argentina and Colombia. The drug regulatory agency of Argentina adopted in 2011 a regulation for the registration and marketing approval of biosimilars (Resolution ANMAT 7729/11). In the case of Colombia, after several years of discussion and heated debate, Decree 1782/ 2014 on the registration of biological medicines, including biosimilars was adopted in 2014.¹ The regulation included an abbreviated procedure for the registration of biosimilar products.²

The revision of the guidelines on similar therapeutic products mandated by Resolution WHA67.21 is crucial for promoting the availability of and access to biosimilars. The reduction in prices ensuing from the introduction of these products has become essential to address public health needs in developed and developing countries.

The WHO Document A72/59 under consideration by the WHA 72 (agenda item 21.3) states in paragraph 80 that “WHO expert committees have approved guidance on (...) biotherapeutics, including an update of the 2009 similar biotherapeutic products guidelines”. This statement is not accurate, as the guidelines were not updated as mandated by Resolution WHA67.21.

The South Centre issued the following statement in relation to this issue:

¹ https://www.minsalud.gov.co/Normatividad_Nuevo/Decreto%201782%20de%202014.pdf

² See Carolina Gómez, “Colombia's Biogenics Regulation: A Preliminary Court Decision in favour of Public Health”, South Views No. 180, 20 May 2019, South Centre. Available from <https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=98d2b094a7>.

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The South Centre takes this opportunity to highlight the importance of access to biotherapeutics, especially similar biotherapeutics. In this regard, we call upon the Secretariat to implement OP 2(4) of the WHA67.21 on "Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy" (WHA67.21). It requests the Director-General: "to convene the WHO Expert Committee on Biological Standardization to update the 2009 guidelines on similar therapeutic products, taking into account the technological advances for the characterization of biotherapeutic products and considering national regulatory needs and capacities and to report on the update to the Executive Board". The Secretariat, however, only issued a Question and Answer (Q&A) document apparently aimed at providing clarifications to said guidelines, which falls short of an update of the Guidelines as explicitly mandated under the WHA 67.21.

Document A72/59 under consideration in this agenda item 21.3 states in paragraph 80 that "WHO expert committees have approved guidance on (...) biotherapeutics, including an update of the 2009 similar biotherapeutic products guidelines". This report on last year's activities seems to suggest that the 2018 document on Questions and Answers on the 2009 guidelines is, in fact, the update of such guidelines as demanded in Resolution WHA67.21, but this is not the case. We kindly demand that language on paragraph 80 of document A72/59 be amended to objectively reflect the current situation, i.e., that the WHO Secretariat has not fully performed yet the referred to mandate of Resolution WHA67.21.

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