



February 23, 2018

Mr. John Melle, AUSTR for the Western Hemisphere  
Ms. Dawn Shackelford, AUSTR for WTO and Multilateral Affairs  
Office of the United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

### **Regarding Colombia's Regulatory Pathway for Similar Biotherapeutic Products**

Dear Mr. Melle and Ms. Shackelford:

The Biotechnology Innovation Organization (BIO) is the world's largest biotechnology trade association representing over 1,100 diverse biotechnology organizations, including companies, academic institutions, public biotechnology research centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in researching, developing, and commercializing biotechnology products across different sectors, including food and agriculture, healthcare, industrial, and environmental technologies. Our members are committed to working collaboratively with institutions globally to accelerate innovation and help Heal, Feed, and Fuel the world through biotechnology.

BIO has collaborated with the Colombian government on the development of a globally competitive innovative biotechnology sector and has expressed concern on policy developments in recent years that run counter to Colombia's broader, more ambitious and praiseworthy goals of cultivating an environment for the sustainable growth and development of a competitive biotech sector. Ongoing challenges to Intellectual Property rights of BIO members in the biopharmaceutical space, for example, continue to disrupt the collective efforts of the private and public sectors to ensure Colombia's biotechnology aspirations become a reality.

The main purpose of this letter, however, is to raise our biopharmaceutical membership's concerns with respect to Colombia's abbreviated pathway for the registration of candidate similar biotherapeutics, or biosimilars.<sup>1</sup> This regulatory pathway raises discriminatory market access barriers to U.S. products and, furthermore, does not appropriately safeguard the public health of Colombians due to its inadequacy in assessing safety, efficacy and quality of biosimilar candidates. The abbreviated pathway compromises patient safety because it diverges from globally accepted minimum safety standards as established by the WHO.<sup>2</sup>

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<sup>1</sup> See Article 9 of Decree 1782 of 2014

<sup>2</sup> WHO Guidelines on Evaluation of Similar Biotherapeutic Products,  
[http://www.who.int/biologicals/areas/biological\\_therapeutics/BIO\\_THERAPEUTICS\\_FOR\\_WEB\\_22APRIL2010.pdf](http://www.who.int/biologicals/areas/biological_therapeutics/BIO_THERAPEUTICS_FOR_WEB_22APRIL2010.pdf)



BIO for several years has encouraged the Colombian government to revisit this regulatory policy and revise it in order to bring Colombia's approach to regulating biologic drugs in line with globally accepted regulatory standards. Given Colombia's growing ambitions to more actively contribute to broader economic policy discussions at the global level, we urge USTR to engage in any appropriate bilateral or multilateral forum on this issue and encourage Colombia to revoke its policies regarding this regulatory pathway in order to, first and foremost, protect patient safety in Colombia and to correct potentially unanticipated market access barriers for similar biotherapeutic candidates. BIO would welcome this engagement and a showing from the Colombian government that it is taking steps to ameliorate these concerns and improve its regulatory environment for biosimilars.

Innovative biotherapeutic products, in which the U.S. is the world leader, are subject to robust safety, efficacy and quality standards in Colombia, as they are in all other major global markets, including the United States. In nearly all other major markets, biosimilar products are also subject to rigorous safety, efficacy and quality standards. Complying with such standards – which is necessary for the safeguarding of human health – entails a lengthy and expensive regulatory process for manufacturers. In contrast, under Colombia's abbreviated pathway the approval of biosimilars is permitted to circumvent and not conform to minimum international standards for safety, efficacy, and quality. Not only does this create an uneven and discriminatory regulatory playing field and could jeopardize patient health, but it could also discourage biotherapeutic candidates with more robust data demonstrating safety and efficacy from entering and competing in the Colombian marketplace for biotherapeutics. This regulatory regime may therefore distort the Colombian marketplace for biotherapeutics by discriminating against those biosimilar candidates that have invested time and resources to demonstrate safety and efficacy according to minimum global standards as provided for by the WHO.

Furthermore, and as it pertains to ensuring the safety, efficacy and quality of biosimilars, the "abbreviated comparability pathway" articulated in Article 9 of the Decree establishes concerning precedent insofar as it relates to the safety of patients in Colombia and potentially to patients in other countries that misguidedly embrace this regulatory pathway. Chief among BIO's concerns, the abbreviated pathway:<sup>3</sup>

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<sup>3</sup> For a more complete review of the scientific considerations expressed in previous BIO communications that support the claims made above, please see:

- <http://www.minsalud.gov.co/Politic%20Farmaceuticas/Biotecnol%20gicos/Comentarios%20recibidos%20biotecnologicos%20-%2001%20ronda/BIO%20Comments%20on%20Colombia%20Biologics%20Regulations%20FINAL.pdf>
- <http://www.minsalud.gov.co/Politic%20Farmaceuticas/Biotecnol%20gicos/Comentarios%20recibidos%20-%202%20ronda/BIO%20Comments%20on%20Revised%20Colombia%20Biologics%20Regulations%20FINAL.pdf>
- <http://www.bio.org/advocacy/letters/bio-comments-colombia-biologics-and-biosimilars-regulations>
- <https://www.bio.org/advocacy/letters/bio-comments-colombia%E2%80%99s-proposed-biologics-and-biosimilars-regulations-submitted-ju>



- Continues to permit inappropriate reliance on pharmacopeia public reference standards in contradiction to the clear positions of prominent pharmacopeia organizations provided to the Ministry of Health prior to the issuance of the Decree;
- Does not require head-to-head clinical pharmacology (pharmacokinetic/pharmacodynamics [PK/PD]) studies, thereby deviating from minimum requirements of even the most streamlined similar biotherapeutic product pathways in other jurisdictions with strong science-based regulatory frameworks;
- Introduces the unprecedented concept (in global regulatory frameworks) of a collective comparison of a candidate biologic with a “group of medicines with highly similar active ingredients”; and,
- Introduces a requirement for “no clinically meaningful differences” with the above mentioned collective group of medicines, without providing a scientific basis (e.g., head-to-head clinical testing) to support such a determination.

Given these divergences with global standards and the unlevel playing field they create for U.S. companies operating or that plan to operate in Colombia, BIO strongly encourages USTR to engage with the Colombian government in any appropriate bilateral or multilateral forum and urge that the Colombian government make commitments to align this policy with international standards to remove the market access challenges. Taking into account Colombia’s emergence and interest in greater integration in global economic fora, a commitment to address this longstanding issue would send a positive signal to BIO membership about Colombia’s commitment to policy supportive of innovation and in alignment with global best practices.

We hope that this letter has been helpful in articulating the challenges we at BIO see with respect to Colombia’s Abbreviated Pathway and its divergence from international standards. Should there be any questions, please feel free to contact me directly or my colleague Justin Duarte Pine at (202) 962-6694 and at [jpine@bio.org](mailto:jpine@bio.org).

Yours sincerely,

A handwritten signature in black ink that reads "Joseph M. Damond". The signature is written in a cursive, flowing style.

Joseph Damond  
Executive Vice President, International Affairs  
Biotechnology Innovation Organization (BIO)