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Discussion Paper 2 - Pharmaceutical and health care issues

This discussion paper is provided as an update to the OECD in the context of the ongoing accession reviews of Colombia, following BIAC's 2014 statement on Colombia's business environment. The views expressed herein are based on inputs received from a number of BIAC members and do not necessarily reflect a final BIAC position. Additional issues may be raised at later stages throughout Colombia's accession process to the OECD.

I – Update of the main issue

Earlier this year, Colombia introduced its 2015 National Development Plan (NDP), which includes many policy changes that would negatively impact the research-based pharmaceutical industry, and establish harmful precedents that could lead to other countries seeking to control healthcare costs by undermining IPRs and disregarding international trade commitments.

1. Potential violations of TRIPS Agreement

Article 71 of the NDP establishes a right for the Ministry of Health and Social Services (MHSS) to submit non-binding opinions on pharmaceutical patent applications, which is likely inconsistent with WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS). This proposal requires that an additional bureaucratic procedure in the patent examination that goes beyond the patent's office assessment of whether the invention is new involves an inventive step and is capable of industrial application. This additional procedure likely violates TRIPS Article 27.1, which requires that patent rights shall be enjoyable without discrimination as to the field of technology. The MHSS submissions will create a burdensome "dual examination", increase patent backlogs and introduce subjectivity into patent reviews.

Article 71 2 also provides for the systematic and pro-active review by the MHSS of all patented health technologies against their potential to be the subject of a request for a compulsory license, in potential contradiction with TRIPS Article 31(a) that establishes that each grant of a compulsory license must be considered on its individual merits.. Article 70 furthermore provides the MHSS with the ability to declare a sanitary emergency based on a broad set of factors, including the "risk" of a medicine shortage.

2. Regulatory approvals subject to price determination

Article 73 from the NDP would require that the MHSS provide a technology assessment and price determination to Colombia's medicines and device regulator before the regulator can issue a marketing authorization grant or renewal., The globally accepted best practice for approving a new medicine for marketing is to review safety, efficacy, and quality. Article 73 would undermine the scientific basis by which Colombia currently and rightly grants marketing authorization by adding to the review process subjectivity and unpredictability. Pricing is irrelevant to whether medicines and medical devices meet the relevant technical requirements Article 73 might be contrary to Articles 2.2 and 5.1.2 of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement, which provide that technical regulation shall not be more trade-restrictive than necessary to fulfil a legitimate objective.

3. Substandard biologics regulation

On September 18, 2014, Colombia issued Decree 1782, establishing an unprecedented "abbreviated comparability pathway" for registration of similar biologic medicines ('biosimilars'). Such abbreviated pathway is inconsistent with international regulatory guidance/standards and could result in the approval of medicines that are not safe and/or effective. Several OECD members raised these concerns as part of a WTO TBT consultation, to no avail. Furthermore, per the Decree, a product approved via this pathway will use the same non-proprietary name (INN) as the innovator. Under current pharmacy practices in Colombia, the shared INN means that the proposed

similar product would likely be substituted for the prescribed innovator product, despite the fact that the products have not been compared in head-to-head clinical pharmacology studies.

II – How the issues impact business and society

The implementation of these articles could prevent or delay the introduction of new medicines in Colombia. They could also discourage foreign investment, international trade, and technological innovation in Colombia. Linking regulatory approval to price determination processes would also increase uncertainty, and by surpassing the regulatory requirements for products also create significant risks for patient health. Substandard biologic regulations risks facilitating the introduction of medicines that are not safe and/or effective and diverge from established international standards.

III – Why it matters for trade policy

Several provisions in Articles 73 and 71 may violate the WTO TRIPS Agreement. Linking regulatory approval process to price determination procedures could violate parts of the WTO TBT Agreement and Article 73 of the EU-Colombia FTA, US-Colombia FTA Article 16.9(6)(a).