Pre-Accession Recommendations for Colombia

These pre-accession recommendations for Colombia are provided as updates to the OECD and its member governments in the context of the ongoing accession reviews of Colombia, following Business at OECD's 2014 statement on Colombia's business environment and the discussion papers we issued in 2015 and 2017 on market openness issues faced in the country. Additional issues may be raised at later stages throughout Colombia's accession process to the OECD.

Colombia formally began the process of acceding to the Organization for Economic Cooperation and Development (OECD) in October 2013 and committed to bring its "legislation, policy and/or practices into line with OECD instruments" and "OECD best practices."[1]

As Colombia is still under review by the OECD Trade Committee, Business at OECD members believe Colombia has an unprecedented opportunity to demonstrate adherence to the standards and best practices of the organization with regard to its trade and regulatory policies. Colombia should be required to implement effectively all of their previous commitments, including free trade agreements, to show that they are up to the practices and standards of other OECD member states, and to demonstrate their commitment to comply with their international obligations. Over the past several years, however, a number of sectors have faced a series of challenges in Colombia that remain unresolved and where appropriate implementation will be crucial. These challenges include problematic additions to its regulatory processes and the enactment of policies that ultimately translate into trade barriers and amount to trade discrimination to several sectors operating in the country. These policies do not abide by the principles of transparency, public participation and trade non-discrimination.

Summarized below are pre-accession recommendations that BIAC urges be implemented by Colombia and verified by the OECD in the context of Colombia's market openness and review of trade practices prior to Colombia's formal accession to that organization, with a formal commitment from Colombia not to roll back these policies once it joins.

[1] OECD, Roadmap for the Accession of Colombia to the OECD Convention (Sept. 24, 2013).

1. *Transparency and impact on trade*

Over the last several years, Colombia's government ministries such as the Ministry of Health (including INVIMA, the regulatory authority) and the Ministry of Transportation have regularly issued draft regulations or new policies with very short timelines for comment, depriving relevant stakeholders of a voice in the process. The public is often given insufficient time – often two weeks at best, and two days at worst – to comment on highly technical and scientific regulations which amount to unnecessary trade barriers once they are implemented. This is inconsistent not only with Colombia's obligations under the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement, which requires Colombia to afford interested stakeholders with appropriate transparency and due process in its technical regulations and conformity assessment procedures. Where the technical regulation is new or differs from international practice, the WTO TBT agreement underscores that Colombia should notify the other Party/ies through the TBT Inquiry Point mechanism and provide interested stakeholders with at least 60 days to provide comments that receive meaningful consideration.[2]

Pre-Accession Recommendation: *The Government of Colombia to issue a regulation that universally provides for sufficient notice and comment periods when implementing new rules and regulations affecting all sectors in a manner that is consistent with Colombia's commitments under international agreements. A reasonable period would be 30 days for public comment.*

2. *Market Access*

Innovative pharmaceutical companies continue to face significant challenges in getting new products approved in Colombia, despite Colombian regulations[3] that call for an expedited pharmacological review of products. That process, which requires initial review by INVIMA's new molecule committee (SEMPB) within 30 working days for all products that have previously been approved in at least two of 11 reference countries—all of them OECD countries—[4]and not denied in any of these 11 countries, is not being implemented consistently. Over the last several years, SEMPB has repeatedly rejected or requested additional information on products that are eligible

[2] See Article 2.9 of the TBT Agreement.
[3] Decreto 677 de 1995
[4] U.S., Canada, Germany, Switzerland, France, England, Denmark, Holland, Sweden, Japan and Norway

for the expedited pharmacological review, in some instances taking more than two years to make a recommendation to INVIMA, at which point the product would move to the second phase of the authorization process. Thus, the SEMPB process has created an important bottleneck that has delayed market access for many molecules, contrary to Colombia's obligations to implement technical regulations and conformity assessment procedures in a manner that does not impose unnecessary obstacles to trade.[5] Conformity assessment procedures, such as marketing authorizations for medicines, should be "undertaken and completed as expeditiously as possible"[6] wherein the competent body "promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies"; "transmits as soon as possible the results of the assessment in a precise and complete manner to the applicant so that corrective action may be taken if necessary"; "proceeds as far as practicable with the conformity assessment if the applicant so requests" "even when the application has deficiencies" and the applicant, upon request, "is informed of the stage of the procedure, with any delay being explained".[7]

Pre-Accession Recommendation: *In order to ensure that innovative products are able to obtain market access in a timely manner, the Government of Colombia to: (1) issue a resolution to modify the membership of the SEMPB to include representatives from different universities (not only National University), as well as the private sector and research groups*[8] *to increase transparency and balance in the review process;*[9] *(2) formally instruct INVIMA to comply with the time frameworks established in its regulations so that market access is granted in a timeframe more aligned with those of other OECD member countries; and (3) implement a fast track mechanism for the approval of new technologies by high surveillance sanitary agencies, as permitted by Colombian regulations.*

In 2012, truck manufacturers in the United States exported nearly 13,000 truck units to Colombia, making it one of the most important export markets in South America.

[5] See, e.g., Articles 2.5 and 5.1.2 of the TBT Agreement.
[6] Article 5.2.1 of the TBT Agreement.
[7] Article 5.2.2 of the TBT Agreement.
[8] Consistent with the recommendations from PAHO/WHO: Revisión del Funcionamiento de la Sala Especializada de Medicamentos y Products Biológicos (SEMPB) y Propuesta para su Fortalecimiento y Mejora en el Marco del Plan de Desarrollo Institutional del Institute Nacional de Vigencia de Medicamentos Alimentos (INVIMA)
[9] INVIMA recently passed Acuerdo 03, which significantly overhauls the configuration and procedures of the SEMPB. While this is a positive development, concerns will remain until it is determined that Acuerdo 3, once fully implemented, resolves the problems outlined in this paper.

Since then, the Colombian market has contracted by over 70 percent, due in part to a mandatory "one-for-one" truck scrapping program, which requires that an old truck be scrapped in order to buy a new truck. Nearly 90 percent of the trucks impacted by the scrapping program are imported, and the policy is considered to be a serious barrier to trade and a source of corruption in Colombia. In September 2016, the Government of Colombia revised the program, with the goal of eliminating the one-for-one requirement by January 1, 2019, and making a limited amount of scrapping certificates available before that date. Despite these changes, serious concerns remain and market access remains restricted.

Pre-Accession Recommendation: *The Government of Colombia to pull forward the date for the elimination of the one-for-one program to May 2018 or earlier to ensure it occurs during the administration of Colombian President Juan Manuel Santos.*

Pre-Accession Recommendation: *The Government of Colombia to remove the limit on the number of trucks that an entity can register in a single month during the transition period.*

The process for marketing approval for biosimilars negatively affects market access for innovative products, causing an un-level playing field vis-à-vis companies that have invested significant resources to conduct the necessary human trials to confirm their product's safety for human use. When adopting a biosimilar pathway in 2014 (Decree 1782 OF 2014) Colombia included three pathways for marketing approval. They included a "full dossier" pathway, a full comparability pathway consistent with World Health Organization (WHO) standards requiring a head-to-head comparability data, and an "abbreviated comparability pathway" or "third pathway." While the first two pathways are largely consistent with global standards and provide patient access to safe and effective biotherapeutics in Colombia, the third pathway is neither consistent with global standards, nor is it needed to provide patient access to biotherapeutics. This third pathway deviates significantly from global regulatory standards and guidelines, including those by the WHO. In addition to being a barrier to trade, the third pathway also:

- creates a real threat for patient safety in the country, due to the entering into the Colombian market of products that have not been tested on humans, and negatively affects market access for innovative products, resulting in an un-level playing field vis-à-vis companies that have invested significant resources to conduct the necessary human trials to confirm their products' safety for use in humans.

Pre-Accession Recommendation: *The Government of Colombia to eliminate its "third pathway" to ensure full consistency with global regulatory standards.*

On the treatment of distilled spirits, we are very pleased that Colombia passed a new law, which entered into force on January 1, 2017, that eliminates its discriminatory excise tax on distilled spirits and ensures that its state-level alcohol monopolies can no longer discriminate against imported distilled spirits. While implementation is ongoing, we are concerned by the delays taken by some departments who are still due to modify their local rules/ordenanzas to have them in line and compliant with the new law.

However, the law also introduced the "exploitation rights" levy, to be paid in addition to excise, set at 2% of sales entities operating in the monopoly, either under a permit or a production contract (to be collected in January 2018 for sales of 2017). During 2017, producing departments wielding monopoly powers have made public their interpretation under which licoreras would be exempt from this levy, given that they operate under direct designation of the departments and not by either permit or production contract. The Colombian central government confirmed in writing it shares this view. This interpretation is in direct contradiction with the non-discrimination principles included in the law, and also against a provision that includes licoreras as subjects of this levy. Departments concerned by this persistent discriminatory practice represent approximately 65% of the imported spirits market. Other discriminatory practice that stems from the same interpretation is the exemption of strip stamps for licorera within their home markets.

Pre-Accession Recommendation: *The Government of Colombia to implement the new law while fully ensuring imported distilled spirits have unimpeded and equal access to the Colombian marketplace. This means exploitation rights and strip stamps are to be applied to domestic players (licoreras) or fully eliminated for all players, prior to OECD accession taking place.*

3. ***Intellectual Property – Compulsory License Threat and Weakening of Regulatory Data Protection***

Colombia recently passed a decree (Decree 670 of 2017) that includes some small but welcome steps to address industry concerns on pricing of pharmaceuticals. The decree restricts the process of issuing a Declaration of Public Interest (DPI), the precursor to a compulsory license (CL), and also seeks to eliminate the ability of the

Ministry of Health to impose "alternative measures" to unilaterally reduce prices. While this Decree is a positive step, it fails to resolve this issue fully given that Colombia's Circular 003 continues to provide an alternative method through its establishment of a unilateral pricing mechanism for products subjected to a DPI, which can be used to impose unilateral price cuts.

Colombia already uses an international reference pricing (IRP) methodology to control prices, which has granted transparency and predictability to the process. Colombia also has other discretionary measures at its disposal, such as centralized negotiations and CLs as internationally defined. Circular 003, therefore, is unnecessary and represents a non-transparent mechanism to bypass the current pricing regime, contrary to the general practices of OECD countries, and Colombia's international obligations. In particular, alternative pricing measures that reduce prices for patented medicines to levels equivalent to those of generics appears to be inconsistent with Colombia's obligation to grant patent rights and make only limited exceptions to those exclusive rights as reflected in Article 28 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement").

Some of the alternative pricing measures appear to contravene this obligation. Innovative pharmaceutical manufacturers holding patents on medicines in Colombia have a legitimate right to expect economic returns on their investments at the levels set by the Colombian government under its existing price control systems. Imposing additional price measures that reduce prices to levels equivalent to "that of the competitors before the patent was granted" – as if the patent did not exist – "unreasonably conflict[s] with a normal exploitation of the patent".[10] Such measures are in many respects akin to Colombia issuing a *de facto* compulsory license, but without meeting all of the restrictions imposed on compulsory licensing as set forth

[10] This same phrase in TRIPS Article 30 was interpreted by a WTO dispute resolution panel in *Canada—Patent Protection of Pharmaceutical Products*. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000). The panel explained that "exploitation" is "the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent," and that "normal" encompasses both "an empirical conclusion about what is common within a relevant community" and "a normative standard of entitlement." *Id.* ¶ 7.54. The panel went on to explain that the "normal practice of exploitation by patent owners . . . is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity." *Id.* ¶ 7.55. As the panel further noted, "[p]atent laws establish a carefully defined period of market exclusivity as an inducement to innovation," and "patent owners [must be] permitted to take effective advantage of that inducement." *Id.*

in Article 31 of the TRIPS Agreement.[11] Beyond the intellectual property rights concerns, Colombia's actions could potentially constitute an impermissible import price requirement under Article XI:1 of the GATT; and an internal maximum price giving rise to prejudicial effects on exporting parties that have not been taken sufficiently into account under GATT Article III:9.

Pre-Accession Recommendation: *The Government of Colombia to revoke Circular 003/2016. The existing pricing regime is transparent and predictable and should be maintained.*

Colombia is weakening regulatory data protection (RDP) through discretionary actions that deny or fail to enforce Colombia's own requirements. Despite the protection granted by Colombia's Decree 2085 to ensure data exclusivity for all, INVIMA's Technical Committee has denied data protection rights to some new chemical entities that it has deemed are not eligible to receive RDP. This is a new, restricting action that appears to be contrary to Colombia's international obligations under Article 39.3 of TRIPS international agreements, and has taken place without appropriate industry and stakeholder consultations.

Pre-Accession Recommendation: *INVIMA to provide RDP of at least five years and in a manner that is consistent with its own regulations and international obligations.*

[11] For example, under Article 31 of the TRIPS Agreement, there must be negotiations over licensing "on reasonable commercial terms" absent a national emergency; the license's "scope and duration" must be "limited to the purpose for which it was authorized"; and the patent owner must be given "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."