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January 15, 2018

The Honorable Alejandro Gaviria Uribe
Minister of Health and Social Protection
Republic of Colombia
Carrera 13 No. 32-76, piso 1
Bogotá. Código Postal 110311

Dear Minister Gaviria,

On behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), I am writing to request that the Colombian Ministry of Health and Social Protection ("MinSalud") revoke Resolution Number 005246 ("Resolution 5246"), and the initiation of this administrative action to assess whether a declaration of public interest ("DPI") is required to ensure access to direct-acting antivirals for the treatment of Hepatitis C.

PhRMA represents the world's leading research-based biopharmaceutical companies, and is devoted to advancing public policies around the world that support innovative medical research, deliver progress for patients, and provide hope for tomorrow's treatments and cures. Our industry is a partner in healthcare solutions around the world and is ready to continue constructively working with the Colombian Government to address patient needs.

MinSalud issued Resolution 5246 on December 20, 2017, in response to a petition filed by Fundación IFARMA on October 28, 2015 (hereinafter "petition"), thereby initiating the procedure for declaring public interest over "direct action antivirals for the treatment of Hepatitis C, for the patents granted in the country up to the publication of this administrative act."

Resolution 5246 is both legally and procedurally deficient, and also appears inconsistent with Colombia's international obligations and aspirations. First, Resolution 5246 is based on a petition that failed to identify the patents for which the DPI is being requested, clearly falling short of the standard set forth in Decree 1074 of 2015 ("Decree"). There is no provision in the Decree that allows for MinSalud to unilaterally correct omissions in the petition. On the contrary, Article 2.2.2.24.4 of the Decree expressly places the burden of proof on the petitioner to identify the patented technologies that are supposedly affecting the public interest.

Second, a DPI on a broad category of medicines, namely "antivirals for treatment of Hepatitis C" would be baseless for a number of reasons, including that: a) the petition itself identifies an entire class of medicines, which demonstrates that competition already exists in this market segment; b) Hepatitis C drugs were just recently the subject of significant price reductions in Colombia, and the Ministry itself has asserted in the media, over the course of months, that the price reduction was between 80 and 90%; and c) there is no indication that a health-related emergency regarding Hepatitis C exists in Colombia; to the contrary, as discussed more fully below, the incidence of Hepatitis C, a disease that has affected people for centuries, is quite low in Colombia.

Third, the DPI, if issued, would be inconsistent not only with Colombia's international obligations and its interest in acceding to the rules-based Organization for Economic Co-operation and Development ("OECD"), but its own domestic laws, namely the Decree. Mere enjoyment of a patent cannot be the basis for issuing a DPI.

Petitions:

We urge MinSalud to revoke Resolution 5246. In the event that the review proceeds, for the reasons stated in this submission MinSalud and the Interinstitutional Technical Committee should expeditiously determine that there is no basis to issue a DPI for Hepatitis C drugs.

I. This Administrative Action to Initiate Consideration of a DPI Fails to Satisfy the Colombian Government's Own Procedural Rules

MinSalud has exceeded its authority by accepting a petition that fails to fulfill the minimum legal requirements for such petitions. In particular, when a third party requests a DPI for the purposes of the issuance of a compulsory license ("CL"), the petitioner is expected to identify the patents over which they request public interest be declared, with reasons to support their petition.[1]

As Resolution 5246 itself acknowledges, however, the petition fails to identify any of the patents relevant to its request; instead, the petition simply notes *a number of active ingredients* that exist to treat Hepatitis C, and provides no information of the inventions, *i.e.*, the patents in question.

MinSalud's willingness to move forward with an incomplete and vague petition that fails to identify the patents at issue creates an uncertain and non-transparent environment that favors third party petitioners at the expense of innovators.

The petitioner's failure to meet the minimum requirements of the Decree also should have resulted in a rejection of the petition in the first instance. Instead, however, MinSalud sought to correct these deficiencies under its own auspices by requesting the missing patent information from the Colombian Patent Authority. This seemingly unusual action by MinSalud to correct voluntarily a third party's otherwise flawed petition is not based on any rules that regulate either the issuance of a DPI or of CLs.

II. Petitioner's Request for the Issuance of a DPI is Without Basis

The Petitioner's request also fails to identify any justifiable basis on which a DPI should be granted. MinSalud's willingness to move forward with such an unjustifiable petition raises serious questions regarding Colombia's commitment to the development and delivery of innovative medicines and treatments in Colombia.

First, the petition fails to demonstrate that there is insufficient supply of products in the market to treat Hepatitis C patients in Colombia, nor does it provide any specific data suggesting that Colombian patients are not using the current products available on the market. To the contrary,

[1] "Unique Regulatory Decree 1074 of 2015 of the Commerce, Industry and Tourism Sector".

the petition itself enumerates a long list of products used to treat this condition, thereby highlighting the existence of competition in the market.

Second, rather than demonstrating any lack of access to Hepatitis C medicines in Colombia, the petition appears to be driven solely by a desire to use the DPI process to secure drastic and arbitrary price reductions for an entire class of medicines. Such an extraordinary action is requested despite the fact that these medicines have been subject to recent price negotiations with the Colombian Government. Specifically, Colombia recently secured medicines to treat Hepatitis C through a pooled-procurement process that resulted in reductions of approximately 90% of the price of treatments.[2] Neither the petition nor the resolution appear to acknowledge these significant price reductions. The acceptance of a petition that seeks to expropriate patents on purported "price" grounds despite recently negotiated price reductions by the government drastically undermines any legitimacy of the DPI process and business certainty for medical innovators.

Third, new Hepatitis C treatments – which in many cases cure rather than just treat the disease – are currently cost-effective treatments that advance the public interest. Since 2014, several new all-oral direct-acting antiviral agents have been developed and approved for use. These new treatments are reported to have cure rates exceeding 90% for those who complete treatment.[3] A number of studies have also determined that treatment of genotypes 2 through 6 of Hepatitis C with direct-acting antivirals is cost-effective.[4] Prior to the developments leading up to these direct-acting antivirals, treating Hepatitis C required significantly higher costs regimens, sometimes including life-long dependence on interferon drugs and even liver transplants. A DPI that leads to either a CL or arbitrary price cuts on such medicines would not appropriately value the patents on these innovative cures. As a result, such actions would significantly undermine the incentives needed to develop and deliver new treatments and cures to patients who need them, thereby undermining rather than advancing the public interest.

Lastly, the petitioners fail to demonstrate any ongoing public health emergency now or in the future related to Hepatitis C in Colombia that would justify a DPI. In contrast, the incidence of Hepatitis C in Colombia is well below the average, based either on the global standard or the regional standard. According to the most recent global estimates, the incidence rate in Colombia is between 1.3% and 1.5%. This puts Colombia in the "low" category – along with the United States and Canada, among others.[5]

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[2] *See* Press Release, Paho, *Colombia Procures High-cost Medicines for Hepatitis C Through the Strategic Fund*, Aug. 21, 2017.

[3] Deborah Hollzman, Infectious Diseases Related to Travel: Hepatitis C, CENTERS FOR DISEASE CONTROL AND PREVENTION, (Jan. 12, 2018, 10:16 AM), https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-c.

[4] HEP, Hepatitis C Treatment is Cost Effective for Genotypes 2 Through 5, Nov. 25, 2017.

[5] Hollzman, supra note 3.

III. The DPI Appears Inconsistent with Colombia's International Commitments

In light of the serious deficiencies highlighted above, a DPI for access to direct-acting antivirals for the treatment of Hepatitis C would likely be inconsistent with Colombia's commitments under the U.S.-Colombia Trade Promotion Agreement (CPTA). Specifically, Article 16.9(3) of the CTPA permits the Parties to "provide limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner."

Issuing the proposed DPI would contravene this obligation. Biopharmaceutical patent holders in Colombia have a legitimate right to expect reasonable economic returns on their investment. Imposing a CL or additional price reduction scheme that fails to acknowledge existing negotiated price reductions "unreasonably conflict[s] with a normal exploitation of the patent." The extraordinary measures Colombia is contemplating with respect to Hepatitis C medicines would effectively destroy the value of the patent, in a manner contrary to its "normal exploitation".

More broadly, Colombia's acceptance of this deficient petition without evidence of a sufficient basis to justify the use of such an extraordinary process as the DPI questions Colombia's very commitment to the laws and agreements that protect intellectual property and incentivize innovation. This is particularly concerning in light of Colombia's accession process to the OECD, an organization committed to advancing global trade and innovation and to promoting principles of open government including transparency. The OECD recommends, for example that its members:

> "[a]dhere to principles of open government, including transparency and participation in the regulatory process to ensure that regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation. This includes providing *meaningful* opportunities (including online) for the public to contribute to the process of preparing draft regulatory proposals and to the quality of the supporting analysis. Governments should *ensure that regulations are comprehensible and clear and that parties can easily understand their rights and obligations*.[6]

For the reasons discussed above, Resolution 5246 is inconsistent with such notions of transparency and due process.

The issuance of a DPI for Hepatitis C medicines also would establish a dangerous precedent that, if followed more broadly, could lead to significant harm to the Colombian market and potentially more limited access to life-saving medicines. Under the current proposal, any patented medicine, regardless of whether there are concerns about access to the medicine, the presence of competition in the market or the reasonableness of current prices set by the government, could be subject to a CL or unilateral price cut simply because a third party suggests the government

[6] OECD, Recommendation of the Council on Regulatory Policy and Governance (2012), p. 4, http://www.oecd.org/gov/regulatory-policy/49990817.pdf (emphasis added).

should no longer pay a price the government already agreed to pay. Such actions are inconsistent with international trade rules and undermine the certainty needed to create the conditions for innovators to bring their products to the patients that need them.

IV. The Resolution Process Failed to Provide Procedural Fairness and Transparency for Stakeholders

Resolution 5246 provided an impractically short 15-day window for interested stakeholders (both specified and indeterminate) to comment and was issued just before a major holiday and the New Year. As such, the notice provided by Resolution 5246 was not reasonably sufficient to provide potentially impacted stakeholders with a meaningful opportunity to respond. Such a rushed process is in serious conflict with the basic notion of due process, especially given the grave implications of the DPI, if issued.

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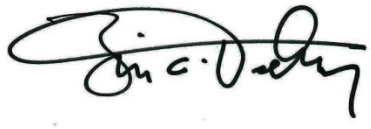
For the above reasons, PhRMA strongly urges the Colombian Government to rescind Resolution 5246. We appreciate the opportunity to provide these comments and look forward to engaging with you on ways to build and strengthen an intellectual property system that fosters innovation, investment and the interests of patients in Colombia.

Sincerely,



Brian Toohey
Senior Vice President, International Advocacy

cc: H.E. Juan Manuel Santos Calderón, President of the Republic
H.E. María Lorena Gutiérrez Botero, Minister of Commerce, Industry and Tourism
H.E. Catalina Crane, High-Level Contact for Colombia's OECD Accession Process