

REPÚBLICA DE COLOMBIA



MINISTRY OF HEALTH AND SOCIAL PROTECTION

RESOLUTION NUMBER 005246 O F 2017

(December 20, 2017)

By which an administrative act is initiated for the study of the declaration of existence of reasons of public interest for access to direct-acting antivirals for the treatment of Hepatitis C.

THE MINISTER OF HEALTH AND SOCIAL PROTECTION

In exercise of his legal and regulatory powers, especially those conferred in section 2 of article 2.2.2.24.4 of the Unique Regulatory Decree 1074 of 2015 of the Commerce, Industry and Tourism Sector and Decree-Law 4107 of 2011, modified by Decree 2562 of 2012, and

CONSIDERING

That Decree 1074 of 2015, Unique Regulatory Decree of the Commerce, Industry and Tourism Sector, established the competence and the procedure for the declaration of existence of public interest reasons for the granting of compulsory licenses for products subject matter of patents.

That section 2 of article 2.2.2.24.4 ibidem, expects, as part of the procedure for the declaration of existence of reasons of public interest, the competent authority to stipulate, by means of motivated action, whether or not to proceed with the respective administrative action, communicating said providence to the interested party.

That Fundación IFARMA asked this Ministry "(...) TO DECLARE OF PUBLIC INTEREST ACCESS TO DIRECT-ACTING ANTIVIRALS FOR THE TRETAMENT OF HEPATITIS C, *which includes active principles teleprevir, boceprevir, sofosbuvir, simeprevir, daclatasvir, faldaprevir, ledipasvir, desabuvir, ombitasvir, elbasvir, gazoprevir, paritaprevir, ombitasvir and all those active principles of the same therapeutic group that in the future are produced for such treatment (...).*

That within IFARMA's request a series of technical arguments were submitted, aimed at the declaration of public interest by this Ministry, according to the regulations that govern the subject.

That due to the nature of the procedure that is initiated, it is necessary to indicate the impossibility of including as part of the administrative action “(...) *all those active principles of the same therapeutic group that are produced in the future for the treatment (...)*”, because it is not possible to anticipate the circumstances of manner, time and place that come up with respect to such active principles, and the possible reasons for the declaration of public interest, without this preventing that at the time, the competent authority may come to declare or not the existence of reasons of public interest with respect to the same.

That the Constitutional Court by Office Action of February 9, 2016 requested this Ministry to resolve the requests made by Fundación IFARMA on the declaration of public interest of access to direct-acting antivirals for the treatment of Hepatitis C, and the Administrative Court of Cundinamarca – Section four Subsection “A” in ruling of October 24, 2017 ordered the Entity to “(...) in a coordinated manner and within the framework of its competence, within a term of three (3) days following the notification of this decision, resolve completely and in a clear, accurate and coherent form the petitions of Fundación IFARMA (...) in the sense of informing them the status of the administrative action for the study of the declaration of public interest of access to direct-acting antivirals for the treatment of Hepatitis “C” (...).”

That for the purpose of communicating this opening to the title holders of the patents, the Medicines and Health Technologies Office, by means of filing number 201724000306763 of December 13, 2017 states that there are difficulties for such action, because it has been “(...) *evidenced that there is no relation one to one between the patents and the medicine; several patents may cover the same medicine*”, in order to comply with what is indicated in sections two and three of article 2.2.2.24.4 of Decree 1074 of 2015.

That in order to counteract the previously described situation, the decision of the opening will be communicated, in addition to the applicant, specific and indeterminate third parties, to determinable third parties, as informed by the Superintendence of Industry and Commerce and INVIMA.

That once the different documents that form the application were reviewed, it was determined that the requirements of section one of article 2.2.2.24.4 of Decree 1074 of 2015 were met, so it is considered that it is pertinent to open the administrative action, which purpose is to determine whether or not there are reasons that permit the

declaration that access to direct-acting antivirals for the treatment of Hepatitis C is of public interest, within the context of article 65 of Andean Decision 486 of 2000.

That sections two and three of article 2.2.2.24.4 of Decree 1074 of 2015 establish that the competent authority, for the case under study this Ministry, will communicate the opening decision to specific third parties, including the title holder of the patent, and to indeterminate third parties.

That the opening of the administrative action in no way means a substantive or final decision on the request, and does not predetermine the result of said administrative action. It only indicates the initiation of a process that is regulated.

According to the foregoing

DECIDES:

Article 1. Purpose.- To initiate the administrative action of declaring the existence of reasons of public interest for access to direct-acting antivirals for the treatment of Hepatitis C, for the patents granted in the country up to the date of publication of the present administrative action.

Paragraph. The documents that form the request and all the documents related to the development of the administrative action may be consulted in the web page of this Ministry.

Article 2. Communication to applicants.- To communicate the present resolution to Fundación IFARMA, as applicant

Article 3. Communication to specific third parties.- To communicate the present resolution to specific third parties when the present resolution is issued: title holders of patents, according to the information provided by the applicant and title holders of sanitary registrations of direct-acting antivirals for the treatment of Hepatitis C

Paragraph.- For the purpose of communicating to determinable third parties interested in the present action, the information provided by the Superintendence of Industry and Commerce – SIC and INVIMA, in relation to the patents and the sanitary registrations of direct-acting antivirals for the treatment of Hepatitis C in the country, respectively, will be taken into account.

Article 4.- Term for the submission of documents by specific third parties.- Specific third parties will have a term of maximum fifteen (15) business days, as of the day after the date of reception of the communication of the present administrative action to pronounce themselves in relation to the documents that form the application, according to what is provided in the paragraph of article 38 of the Code of Administrative and Contentious Administrative Procedure (CPCA).

Article 5.- *Communication to indeterminate third parties.* To publish the present administrative act in a national mass medium, for the interested indeterminate third parties to take part or intervene in the process of declaration of public interest, in accordance with what is provided in articles 37 and 38 of the CPCA.

Article 6.- *Term for the submission of documents by indeterminate third parties.* Indeterminate third parties will have a term of maximum fifteen (15) business days, as of the day after the publication date to which the previous article refers, to pronounce themselves in the terms provided in article 38 of the CPCA.

Article 7.- *Validity.*- The present resolution is in effect as of the date of its publication.

TO BE PUBLISHED AND COMPLIED WITH,

Given in Bogotá, D.C., on the 20th of December, 2017

ALEJANDRO GAVIRIA URIBE
Ministry of Health and Social Protection

