

RESOLUTION TO REQUIRE THE MINISTRY OF HEALTH TO ADOPT MEASURES TO OBTAIN COMPULSORY LICENSES FOR HEPATITIS C DRUGS.

1. That "access to medicines is an indispensable part of the right to enjoy the highest possible level of health", as recognized by the Inter-American Court of Human Rights (IACHR) in its September 1, 2015 decision on the Gonzales Lluy and others v. Ecuador case and its February 26, 2016 decision on the Duque v. Colombia case.
2. That in September 2016, the United Nations Secretary-General's High-Level Panel on Access to Medicines Report (High-Level Panel) published a comprehensive report with numerous recommendations, seeking solutions for remedying "the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies." Among the recommendations made in this report there is a clear statement stating that "[g]overnments should adopt and implement legislation that facilitates the issuance of compulsory licenses."
3. That the use of the flexibilities available in intellectual property agreements, and particularly the use of compulsory licenses, was also recommended in the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Doc A/61/338, paragraph 47, published on September 13, 2006; in the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines, UN Doc A / HRC / 23/42 paragraph 19, published on May 1, 2013; and other resolutions and similar reports.
- 4.- That there is an international consensus that the World Trade Organization (WTO) intellectual property agreement, TRIPS, does not prevent or prevent WTO Member governments from taking measures to protect public health.
- 5.- That the Declaration on the TRIPS agreement and public health at the Fourth Ministerial Conference of the WTO, held in Doha (Qatar), adopted on November 14, 2001, reaffirms the right of Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility to this effect.
6. That the said Doha Declaration, in relation to compulsory licensing of patents, clearly establishes that each Member is free to determine the basis on which such licenses are

granted, without requiring for this purpose that any kind of emergency is a prerequisite for the granting of a compulsory license.

7.- That with regards to compulsory licenses, these intellectual property flexibilities to protect public health, as stated in the Doha Declaration, have been preserved in subsequent international trade agreements signed by Chile.

8.- That the Chilean industrial property legislation, Law 19039, expressly provides in Article 51 the possibility of issuing compulsory licenses based on public health grounds declared by the competent authority, and for the use of non-commercial government, among other grounds.

9. That through Resolution No. 798, dated January 11, 2017, this Chamber of Deputies, required the Ministry of Health to use compulsory licenses proactively and ex officio when necessary within its policies to facilitate the acquisition of medicines at prices competitive both by public and private services and the population that requires it, to guarantee access.

10- That on October 4, 2017, the Senate Economics Committee unanimously requested, through the Official Document Number 1200 / E-2017, that the request for declaration of public health reasons regarding medicines for hepatitis C and prostate cancer presented to the Ministry of Health by Corporación Innovarte, Fundación Nuevo Renacer, patients and legislators, and adhered to by Colegio de Químicos Farmacéuticos and Bioquímicos de Chile, be accepted for the purposes of article 51 number 3 of the Industrial Property Law 19039.

11- That on January 2, 2018, this Honorable Chamber, through Resolution No. 1014, unanimously, considering the need to ensure the sustainability and viability of treatment and coverage with the most effective drugs needed by hepatitis C patients, decided to declare that there are public health reasons that justify the granting of compulsory licenses that affect hepatitis C drugs based on sofosbuvir and in combination with other direct-acting antivirals; and required the Ministry of Health to issue the declaration in the terms requested by the petitioners indicated in the previous paragraph.

12- That the Ministry of Health, taking into account the magnitude of people already diagnosed with Hepatitis C in Chile, the recommendations and commitments with the World Health Organization for the eradication of this epidemic that causes thousands of deaths in our region, as well as the inability to access generic drugs that allow us to provide treatments in our country with adequate coverage, due to the exclusivity

granted by patent rights, among other reasons, declared by the Ministry of Health Exempt Resolution Number 399/2018, that the grant of compulsory licenses with respect to patents over hepatitis C medicines, including sofosbuvir and direct action antivirals with which sofosbuvir therapies are combined, is justified for reasons of public health.

13. - That currently, as indicated by the Ministry of Health in its Resolution No. 399, between the years 1997 and 2016, 5422 cases of hepatitis C were notified and there are currently 1058 patients with hepatitis C under control, according to the Ministry of Health Registry, all of whom must be provided effective treatment at the shortest term possible in order to safeguard their right to health and life.

14. That without prejudice to the foregoing, and to provide more details, the real number of people infected with hepatitis C including those who have not been diagnosed with the disease, for various reasons, may reach tens of thousands in Chile as indicated by studies on the subject and projections made by the World Health Organization in 2017 that establish that the average infection rate in the Americas region reaches 1% of the population [1].

15.-Once compulsory licenses for the required hepatitis C drugs have been granted, treatments based on Sofosbuvir, Daclatasvir Sofosbuvir + Ledipasvir or Sofosbuvir + Daclatasvir, among others, will be available for public procurement, with generics at extraordinarily more affordable costs, which will allow viability and continuity, and generate a greater availability of resources to increase coverage and meet other public health needs.

16. The State agencies must act governed by the principle of celerity, in particular with regards to the constitutional right to health protection, and particularly corresponds to a preferential duty of the State to guarantee the performance of health actions, obligations particularly relevant to the Ministry of Health.

THEREFORE, THE H. CHAMBER OF DEPUTIES, AGREES THE FOLLOWING PROPOSED RESOLUTION:

1.- DECLARE: The relevance and timeliness of the declaration made through the Ministry of Health Exempt Resolution Number No. 399/2018, to respond to the public health problem that represents the lack of real access to the most effective treatments needed by all people infected with hepatitis C in Chile.

2.- REQUIRE: Through His Excellency the President of the Republic to the Ministry of Health, for that this Agency, directly or through its dependent services, take the necessary acts in an urgent manner until obtaining the compulsory licenses that are required with respect to patents over hepatitis C drugs based on Sofosbuvir and their combinations with appropriate direct acting antivirals, such as Sofosbuvir + Daclatasvir or Sofosbuvir + Ledipasvir, among others.