

OFFICIAL GAZETTE OF BOLIVIA

SUPREME DECREE No. 29004

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EVO MORALES AYMA **CONSTITUTIONAL PRESIDENT OF THE REPUBLIC**

WHEREAS:

Subparagraph (a) of Article 7 of the Political Constitution of the State states that any person has the fundamental right to life, health and safety; Articles 158 and 164 also stipulate that the State has the obligation to defend human capital by protecting the health of the population, and that the rules on public health are binding and compulsory.

One of the fundamental principles is the Right to Health, in accordance with international agreements such as the International Covenant on Economic, Social and Cultural Rights; the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS; and the Doha Declaration on the TRIPS Agreement and Public Health of the World Trade Organization – WTO, which states that the TRIPS Agreement must be interpreted and applied in a way that protects public health and promotes access to all medicines.

The World Health Organization – WHO reaffirms the right of its member countries, which include Bolivia, to make full use of the flexibilities included in the TRIPS Agreement to protect public health and boost access to medicines.

It is necessary to protect Public Health and access to medicines for all Bolivians and foreigners living or staying in the national territory, reaffirming the obligations established in the Political Constitution of the State.

Article 2 of the Health Code, approved by Decree Law No. 15629 of July 18, 1978, states that health is a public interest good, and that it is the duty of the State to protect the health of the individual, the family and the population as a whole.

Article 4 of Law No. 3351 of February 21, 2006 – Organization of the Executive Branch Act, establishes the responsibilities of the Ministry of Health and Sport as including the regulation, planning, control and leadership of the National Health System and the private and public subsectors of Social Security.

Law No. 1737 of December 17, 1996, Medicines Act establishes, in Articles 1 and 3, mechanisms for the regulation and control of medicines, in accordance with the Medicines Policy established in Articles 1 and 3 of Supreme Decree No. 25235 of November 30, 1998, Regulations under the Medicines Act.

The Ministry of Health and Sport, subject to Ministerial Resolution No. 580 of August 29, 2006, approves the Organizational Structure of the Unit of Medicines – UNIMED, so that it complies with the obligations stipulated in the Medicines Act and the Regulations thereunder.

Supreme Decree No. 27938 of December 20, 2004, amended by Supreme Decree No. 28152 of May 16, 2005, establishes the jurisdiction of the National Intellectual Property Service – SENAPI, as the competent national office to administer the intellectual property regime, and for the monitoring and effective protection of the rights of exclusivity in relation to industrial property.

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The State must protect the public interest, guaranteeing the social function that must be fulfilled by private ownership; in this sense, it is necessary to establish a special procedure for the treatment of pharmaceutical products, as differentiated social goods.

IN COUNCIL OF MINISTERS,

D E C R E E S:

ARTICLE 1. (OBJECTIVE). The objective of this Supreme Decree is to establish a prior consent procedure in a product patent application and/or pharmaceutical invention process.

ARTICLE 2. (PRIOR CONSENT). For the purposes of this Supreme Decree, Prior Consent shall mean the concrete mechanism to determine whether the content and scope for which protection is sought in the patent application do not interfere with the right to health and access to medicines.

ARTICLE 3. (GRANTING OF PATENTS). The granting of pharmaceutical invention patents for products and procedures shall depend on the Prior Consent given by the Unit of Medicines and Health Technology – UNIMED.

ARTICLE 4. (COMPETENT ENTITIES). The Competent Entities are as follows:

- (a) the National Intellectual Property Service – SENAPI, which is responsible for analyzing the requirements for the award of patents and the registration procedure.
- (b) The Unit of Medicines and Health Technology – UNIMED, of which the main responsibility is to issue Prior Consent in response to a patent application for a pharmaceutical invention.

ARTICLE 5. (RESPONSIBILITY). Responsibilities of competent entities:

- (a) SENAPI, following the award of an invention patent in the pharmaceutical area, shall refer the relevant procedure to UNIMED.
- (b) when the result of the Prior Consent is positive, UNIMED shall refer to SENAPI the pharmaceutical invention patent application, giving the grounds for the result of the Prior Consent. If the result of the Prior Consent is negative, UNIMED shall refer the patent application to SENAPI, giving the grounds for the refusal and supporting it with documentation.

ARTICLE 6. (TECHNICAL COMMISSION FOR PRIOR CONSENT). In accordance with Article 1 of this Supreme Decree, UNIMED will form a Technical Commission for Prior Consent, to enable objective decisions to be made to analyze the pharmaceutical invention patent application referred by SENAPI.

TRANSITIONAL PROVISIONS

SINGLE TRANSITIONAL PROVISION. The Ministry of Health and Sport shall draft and approve, 90 (ninety) days from the publication of this Supreme Decree, the supplementary regulations needed to apply this rule.

All the provisions that contradict the present Supreme Decree are repealed and abolished.

The Ministers of State for the Offices of Production and Micro-enterprise and Health and Sport shall be responsible for the implementation and enforcement of the present Supreme Decree.

Done at the Palace of Government in the city of La Paz, on the ninth day of the month of January of the year two thousand and seven.

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SIGNED BY EVO MORALES AYMA, David Choquehuanca Céspedes, Juan Ramón Quintana Taborga, Alicia Muñoz Alá, Walker San Miguel Rodríguez, Casimira Rodríguez Romero, Hernando Larrazábal Córdova, Luís Alberto Arce Catacora, Abel Mamani Marca, Celinda Sosa Lunda, Salvador Ric Riera, Hugo Salvatierra Gutiérrez, Carlos Villegas Quiroga, José Guillermo Dalence Salinas, Santiago Alex Gálvez Mamani, Félix Patzi Paco, Nila Heredia Miranda.