

**Number 522**

**RAFAEL CORREA DELGADO**

**CONSTITUTIONAL PRESIDENT OF THE REPUBLIC**

**CONSIDERING:**

Whereas Article 32 of the Constitution of the Republic of Ecuador states that health is a right guaranteed by the Government through economic, social, cultural, educational and environmental policies;

Whereas Article 52 of the Constitution of the Republic of Ecuador states that people have the right to enjoy good quality goods and services and to choose with freedom, as well as to have precise and not misleading information about its content and characteristics;

Whereas Article 361 of the Constitution of the Republic of Ecuador states that the Government shall command the system through the national health authority and shall be responsible of devising a national health policy, shall rule and control all activities related to health, as well as the operations of the entities of this sector;

Whereas Numeral 7 of Article 363 of the Constitution of the Republic of Ecuador states that Government is responsible to guarantee the availability and access to good quality medicines that are safe and effective, oversee their marketing and encourage their national production as well as the use of generic drugs that meet the epidemiological needs of the population;

Whereas Article 259 of the Organic Health Law states that a generic drug is the one that is registered and marketed under the International Nonproprietary Name (INN) of the active ingredient, proposed by the World Health Organization, or in its absence, with a generic denomination that would be internationally known;

Whereas in the health norms there is reference to branded drugs even though in the legal system there is no definition about it, confusion that has generated distortions in the drug market and, as a consequence of it, a discrimination towards generic drugs, fact that causes confusion among consumers because of ignorance of the true nature and qualities of the product;

Whereas once ended the term of protection of a patent, time from which is it public domain, it is essential that the Government performs all needed actions so that the drugs that use such active ingredients, can contribute to the health of the Ecuadorian population; and,

In use of the attributions provided in numeral 13 of the Article 147 of the Constitution of the Republic of Ecuador,

**DECREES:**

**Unique Article.-** After Article 30 of the Regulation for the Application of the Law of Production, Importation, Commercialization and Marketing of Generic Medicine for Human Use, add the following:

**“Art. ... .-** Drugs shall be registered and marketed mandatorily as generics, once their invention patent has expired, and must have in the tag the International Nonproprietary Name (INN) and the denomination of the “Generic Drug” on top of the manufacturer name.

Once the patent is expired, reference drugs shall be registered as such and shall be marketed as generic. Reference drugs are those that had the invention patent that expired.

It is forbidden to exclusively market generic drugs under only one brand.”

**Transitory provision.-**The ones obligated to comply this decree, shall implement appropriate measures to adjust themselves to the valid norms within the lapse of one year.

This decree is valid from its publication in the Official Records.

Given in the National Palace, in Quito, December 17th, 2014

Rafael Correa Delgado

Constitutional President of the Republic