

**LAW No. 9,787 OF 10 FEBRUARY 1999**

Alters Law No. 6,360 of 23 September 1976, which provides for health surveillance, establishes the generic medicinal product, provides for the use of generic names in pharmaceutical products, and gives other provisions.

THE PRESIDENT OF THE REPUBLIC: I hereby make it public that the National Congress decrees and I sanction the following Law:

Article 1. Law No. 6,360 of 23 September 1976 is hereafter in force with the following amendments:

"Article 3 .....

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"XVIII – Brazilian Common Denomination (DCB): denomination of the pharmaceutical or of the active pharmaceutical ingredient approved by the federal organization responsible for health surveillance;

XIX – International Nonproprietary Name (INN): denomination of the pharmaceutical or of the active pharmaceutical ingredient recommended by the World Health Organization;

XX – Similar Medicinal Product: the one that contains the same active ingredient or ingredients, presenting the same concentration, pharmaceutical form, administration route, dosage, and therapeutic, preventive, or diagnostic indication, and is equivalent to the medicinal product authorized by the federal organization responsible for health surveillance, and it may differ solely in terms of characteristics related to size and form the product, its shelf life, packaging, labeling, excipients, and vehicles, having its efficacy, safety, and quality confirmed, and it must always be identified by a brand name or trademark; **(Wording given by Law no. 13,235 of 2015)**

XXI – Generic Medicinal Product: a medicinal product similar to a reference product or to an innovative product intended to be interchangeable with the latter, normally produced after validity or waiver of patent protection or of other exclusivity rights, once its efficacy, safety, and quality are confirmed, and it is designated by DCB or, in its absence, by INN;

XXII – Reference Medicinal Product: an innovative product, authorized by the federal organization responsible for health surveillance and commercialized in Brazil, the efficacy, safety, and quality of which have been scientifically confirmed with the competent federal organization, on the occasion of its marketing authorization;

XXIII – Interchangeable Pharmaceutical Product: product therapeutically equivalent to a reference medicinal product, having the same effects in terms of efficacy and safety essentially confirmed;

XXIV – Bioequivalence: the demonstration of pharmaceutical equivalence between products

presented under the same pharmaceutical form, containing identical qualitative and quantitative composition in terms of active ingredient(s), with comparable bioavailability, when studied under the same experimental design;

XXV – Bioavailability: it indicates the speed and the extent of absorption of an active ingredient in a form of dosage, starting from its time/ concentration curb in the systemic circulation or in its excretion in urine.”

“Article 57 .....

~~“Sole Paragraph. The medicinal products that display fantasy or brand name must also display, with the same highlight and in a legible way, on the parts referred to in the caption of this article, on packages and promotional materials, the Brazilian Common Name or, in its absence, the International Nonproprietary Name, with letters and characters the size of which shall not be smaller than one half the size of the letters and characters of the fantasy or brand name.~~

Paragraph 1. In addition to the fantasy or brand name, the medicinal products must display, on the parts referred to in the caption of this Article, on packages and promotional materials, the Brazilian Common Name or, as appropriate, the International Nonproprietary Name, with letters and characters the size of which shall never be smaller than one half the size of the letters and characters of the fantasy or brand name. **(Wording given by Law no. 13,236 of 2015)**

Paragraph 2. The labels of medicinal products, pharmaceuticals, and related products must have characteristics that make them clearly different from each other and that inhibit dispensation and administration mistakes, unwanted exchanges, or wrong use. **(Included by Law no. 13,236 of 2015)**”

~~Article 2. The federal agency in charge of health surveillance shall regulate, in up to ninety days:~~

Article 2. The federal agency in charge of health surveillance shall regulate, in up to one hundred and eighty days, from 11 February 1999: **(Wording given by Provisional Measure no. 2,190-34 of 2001)**

I – the criteria and conditions for the marketing authorization and quality control of generic medicinal products;

II – the criteria for bioavailability tests of pharmaceutical products in general;

III – the criteria for the assessment of therapeutic equivalence, through bioequivalence tests of generic medicinal products, in order to characterize their interchangeability.

IV – the criteria for dispensing generic medicinal products in government and private pharmaceutical services, and the prescribing professional’s expressed decision of non-interchangeability must be respected.

Article 3. The acquisition of medicinal products, under any purchase modality, and medical and dental medicinal product prescriptions, within the scope of the Unified Health System – SUS, must adopt the Brazilian Common Denomination (DCB) or, in its absence, the International Nonproprietary Name (INN).

Paragraph 1. The federal agency in charge of health surveillance shall edit, periodically, the list of medicinal products with marketing authorization in Brazil, according to the pharmacological

classification of the National List of Essential Medicinal Products (Rename, in Portuguese) in force and according to the Brazilian Common Denomination or, in its absence, the International Nonproprietary Name, followed by the trade marks and the corresponding manufacturing companies.

Paragraph 2. In the acquisition of medicinal products referred to in the caption of this article, the generic medicinal product, when available, shall be given preference over others in the same price equality conditions.

Paragraph 3. In announcements, bidding proposals, and contracts of acquisition of medicinal products, within the scope of SUS, the technical specifications of the products, the respective quality control methods, and the system for compliance certification shall be required, when applicable.

Paragraph 4. The delivery of the acquired medicinal products shall be accompanied by the respective quality reports.

Article 4. The Federal Executive Power is allowed to promote special measures concerning marketing authorization, manufacturing, taxation system, distribution, and dispensation of generic medicinal products, object of this Law, with a view to encouraging their adoption and use in the country.

Sole Paragraph. The Ministry of Health shall provide mechanisms to ensure broad communication, information, and education on generic medicinal products.

Article 5. The Ministry of Health shall promote technical-scientific development support programs applied to the improvement of medicinal product quality.

Sole Paragraph. The cooperation of national and international institutions related to the assessment of the quality of medicinal products shall be sought.

Article 6. Laboratories that produce and commercialize medicinal products with or without trade mark shall carry out the alterations and adaptations required to comply with this Law in up to six months.

Article 7. This Law enters into force on the date of its publication.

Brasília, 10 February 1999; 178<sup>th</sup> year from the Independence and 111<sup>th</sup> year from the Proclamation of the Republic.

FERNANDO HENRIQUE CARDOSO

José Serra

This text does not replace the one published on the Federal Official Gazette of 11 February 1999.