

DECREE No. 3,181 OF 23 SEPTEMBER 1999

Regulates Law no. 9,787 of 10 February 1999, 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, in the use of the attributions vested in him under article 84, item IV of the Constitution, and in view of provisions in article 57 of Law No. 6,360 of 23 September 1976 and in article 4 of Law No. 9,787 of 10 February 1999,

DECREES:

Article 1. The terminology of the Brazilian Common Denomination – DCB or, in its absence, the International Nonproprietary Name – INN, must be used in all packaging, labels, leaflets, handouts, texts, or in any other type of marketing and medical information material referring to medicinal products.

Article 2. The generic denomination of medicinal products must be placed in the same printing field and below the trade mark.

Article 3. The lettering used must maintain due proportion in terms of distance between letters, with a view to easy reading and highlighting, especially with respect to the generic denomination for the base substance, which must correspond to half the size of the letters and characters of the trade mark.

Article 4. The carton used in the packaging of medicinal products, dietetic products, and related products, which may only be sold under medical prescription, must have a red strip in all of its extension, in its bottom middle third part, and its placement at the bottom of the packaging is forbidden, its width must not be inferior to one fifth of the largest total face, containing the statement: "Sold under medical prescription."

Article 5. Whenever the medicinal product contains an association or combination of active ingredients in a fixed dose, the Brazilian Health Regulatory Agency, by means of an administrative deed, shall determine the correspondences with the generic denomination.

Article 6. The use of the generic denomination in the forms or marketing authorization petitions, and authorizations related to production, commercialization, and imports of medicinal products is mandatory.

Article 7. The laboratories currently producing and commercializing medicinal products with or without a trade mark shall be granted a four-month period to carry out the alterations and adaptations required to comply with the provisions in Law No. 9,787 of 10 February 1999 and in this Decree.

Sole Paragraph. The similar medicinal product may only be commercialized and identified by its trade mark.

Article 8. The Brazilian Health Regulatory Agency shall regulate the labeling criteria regarding the Brazilian Common Denomination – DCB in all medicinal products, in compliance with the provisions in articles 3 and 5 of this Decree.

Article 9. This Decree enters into force on the date of its publication.

Article 10. Decree No. 793 of 5 April 1993 is hereby revoked.

Brasília, 23 September 1999; 178th year from the Independence and 111th 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 24 September 1999