

EXECUTIVE BOARD

RESOLUTION - RDC Nº 14, OF APRIL 10, 2015

Concerning the health warning that must occupy 30% (thirty percent) of the lower front surface of packages of smoking products derived from tobacco.

The Executive Board of the National Agency of Health Oversight (ANVISA - *Agência Nacional de Vigilância Sanitária*), in the exercise of the authority conferred upon it by sub-paragraphs III and IV, of Art. 15 of Law n.º 9.782, of January 26, 1999, sub-paragraph V, and §§ 1 and 3 of Art. 5 of the Internal Regimen approved pursuant to the terms of Annex I of Edict n.º 650 of ANVISA, of May 29, 2014, bearing in mind sub-paragraphs III, of Art. 2, III and IV, of Art. 7 of Law n.º 9.782, of 1999, the Agency's Program for Improvement of the Process of Regulation, as instituted by Edict n.º 422, of April 16, 2008, and in accordance with what was decided at a meeting held on April 02, 2014, adopts the following Resolution of the Executive Board and I, Acting Chief Executive Officer, order its publication:

CHAPTER I

INITIAL PROVISIONS

Art. 1 The requirements for the use of the health warning that must be printed in such a way to occupy 30% (thirty percent) of the lower front surface of packages of all smoking products derived from tobacco sold in the country, whether of national manufacture or imported, are hereby established.

Art. 2 The message of the health warning addressed by this Resolution must be printed in the following manner:

I- "THIS PRODUCT CAUSES CANCER," printed in high resolution, in a legible manner and prominently displayed, with white letters, in bold upper case, in the Arial font, with simple spacing, against a BLACK background (PANTONE scale Process Black C), accompanied by the seal of the Ministry of Health "STOP SMOKING DIAL HEALTH 136" as per the template provided in the Annex, and at the web portal of ANVISA.

II- The health warning described in the preceding sub-paragraph must occupy 30% (thirty percent) of the height of the package in the lower front surface visible to the public, and the full extent of the width of this surface, without altering the proportions among its elements.

§1 The health warning cannot be broken into sections.

§2 What is set forth in this provision also applies to products sold by unit.

§3 The health warning can only be reduced up to a proportion of 65% of the dimension provided in order to maintain its legibility.

Art. 3 The use of any kind of wrapping or element that blocks, obscures or breaks up, in whole or in part, the visibility of the health warning, including the opening of the package, is hereby prohibited.

Sole paragraph. The seal of control of the Federal Bureau of Revenue of Brazil (SRFBr – *Secretaria da Receita Federal do Brasil*) on packages also cannot be placed over the health warning.

Art. 4 The printed health warning can be applied through adhesives exclusively in cases where the package is made of material that renders printing on it unfeasible, as long as the terms set forth in this Resolution are adhered to.

Sole paragraph. The adhesive must be made in such a way so as to ensure its attachment and the preservation of the graphic parameters, even after the opening of the package.

CHAPTER II

FINAL AND TRANSITORY PROVISIONS

Art. 5 After January 01, 2016, only packages that are in compliance with this Resolution can be provided for retail sale.

Sole paragraph. Packages that are not in compliance with this Resolution must be withdrawn by the responsible company by June 30, 2016.

Art. 6 Changes made to packages, exclusively in implementing compliance with this Resolution must be submitted ahead of time to ANVISA through a memorandum, and are subject to immediate implementation, without requiring a prior statement by ANVISA.

§ 1 The changes discussed in the heading of this Article may not modify packages by suppressing or including new elements.

§ 2 Immediate implementation does not imply the approval of ANVISA, which may at any time analyze the changes made and notify companies in the event of non-compliance with the legislation.

§ 3 Any changes not related to this legal provision remain subject to the laws in force concerning packages of smoking products derived from tobacco.

Art. 7 Failure to comply with this Resolution constitutes a health violation, subjecting offenders to the penalties of Laws n.º 9.294, of July 02, 1996, and n.º 6.437, of August 20, 1977, and other applicable sanctions.

Art. 8 This Resolution of the Executive Board shall enter into force on the date of its publication, without impairment to other laws and regulations concerning packages of smoking products derived from tobacco.

ANNEX

THIS PRODUCT CAUSES CANCER

STOP SMOKING

DIAL HEALTH

(136)

Auditor General of the SUS (Health Service)

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