COLLEGIATE BOARD RESOLUTION – RDC 769 OF 12 DECEMBER 2022

Amends Collegiate Board Resolution – RDC no. 47 of 8 September 2009, which establishes rules for the preparation, harmonization, updating, publication, and availability of medicine package inserts for patients and health professionals.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraphs 1 and 3 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 7 December 2022, and I, Director-President, determine its publication.

Article 1. Collegiate Board Resolution – RDC no. 47 of 8 September 2009, published in the Federal Official Gazette no. 172 of 9 September 2009, Section 1, page 31, comes into force with the following amendments:

“Art. 26……..

Paragraph 1 .....

Paragraph 2. The inclusion of a digital mechanism in the primary and secondary packaging of medicinal products is allowed for the provision of information authorized by Anvisa with access to the most up-to-date patient and health professional package inserts in accordance with Anvisa's Electronic Medicine Leaflet Compendium."(New Wording)

.....

“Article 29. Multipacks, packages intended for hospitals, and packages for institutional destination must contain a minimum number of inserts, as defined in the subsequent paragraphs:

Paragraph 1. In the case of medicinal products for acute use that are dispensed to the patient in the primary packaging, the number of inserts for the patient in the multiple packaging must be equivalent to, at least, 10% (ten percent) of the number of primary packages.

Paragraph 2. In the case of medicinal products for continuous use that are dispensed to the patient in the primary packaging, the period of 90 (ninety) days of treatment must be used as a reference to calculate the number of leaflets for the patient to be made available in the secondary packaging.

Paragraph 3.....

Paragraph 4..... ..." (New Wording)

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ANNEX I

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PATIENT INFORMATION:

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6. HOW SHOULD I USE THIS MEDICINE? ...

According to the characteristic of the pharmaceutical form, include the following sentence, in bold:
....

"The xx mg tablet can be split. The unused part of the tablet must be kept in the original package and administered within a maximum period of xx day(s)". (New Wording)

Article 2. The inclusion of a digital mechanism for the provision of information authorized by Anvisa in the primary and secondary packaging of medicines must comply with Collegiate Board Resolution – RDC no. 768 of 12 December 2022, and its updates.

Article 3. This Resolution shall enter into force on 2 January 2023.

ANTONIO BARRA TORRES
Director-President