

NEW RESTRICTIONS ON ADVERTISING PHARMACEUTICAL PRODUCTS

On December 5, 2015, Supreme Decree No. 01 of the Ministry of Health (S.D. No. 01/2015) –which modifies Supreme Decree No. 466, of 1984, Regulations for Pharmacies, Pharmaceutical Wholesalers, Pharmaceutical Stores, Medicine Cabinets and Authorized Deposits, No. 405, of 1983, Regulations for Controlled Drugs, and No. 03, of 2010, Pharmaceutical Products Regulations– was published.

Through this supreme decree, the Ministry of Health has modified several provisions regarding the commercialization of pharmaceutical products contained in various normative bodies, including:

- Prescription and expenditure or sale of pharmaceutical products to the public
- Exhibition and sale of direct sale products in pharmacies
- Fractioning of medicine packages
- Pharmacies shifts
- Price information in pharmacies
- Advertisement and promotion of pharmaceutical products

Please be aware that S.D. No. 01/2015 includes important modifications concerning advertisement and promotion of pharmaceutical products in S.D. No. 03/2010, including:

1. PREVIOUSLY AUTHORIZED ADVERTISEMENT AND PROMOTION

The first paragraph of article 200 of S.D. No. 03/2010 is replaced by a new provision which includes a requirement to obtain prior authorization from the ISP for every advertisement regarding the direct sale of pharmaceutical products, with an obligation to, “reproduce the exact content, partial or complete, of the informative brochures for patients and labeling, authorized in the relevant sanitary registration”.

2. NO MORE ANNOUNCEMENTS FOR PROFESSIONALS

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Paragraph two of article 201, which used to authorize announcements for professionals regarding the existence and introduction of a pharmaceutical product in the market, has been eliminated.

3. EXTENSION OF LIABILITY FOR NON AUTHORIZED ADVERTISEMENT

In order to increase the prohibitions and obligations regarding promotion of pharmaceutical products, a new article 207 A has been added to S.D. No. 03/2010, through which the liability derived from unauthorized advertisement is extended beyond the holder of the sanitary registration, including, “every person or entity that participates in the diffusion of such advertisement and without which the same would not be possible”.

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