May, 2020

MODIFICATION OF DECREE Nº 466, OF 1984, OF THE MINISTRY OF HEALTH, WHICH APPROVES THE REGULATION OF PHARMACIES, DRUGSTORES, PHARMACEUTICAL WAREHOUSES AND AUTHORIZED PHARMACEUTICAL DEPOSITS, IN THE MATTER OF ELECTRONIC COMMERCE OF MEDICINES

On May 7, 2020, the amendment to Decree No. 466 was published in the Official Gazette, which approves the Regulation of Pharmacies, Drugstores and other pharmaceutical establishments, regarding the **sale of medicines through electronic means**.

Particularly, article 8 of said Decree is modified, in order to allow the electronic sale of medicines **in pharmacies**, incorporating the following sentence:

"Pharmacies may dispense medicines through electronic means. For these purposes, they must comply with the provisions of Title VI bis and others that are applicable to these regulations."

In this regard, the following modifications are also incorporated in relation to pharmacies that sell medicines through electronic means:

1. The responsibility of the technical director is established to ensure that home delivery ensures the preservation, stability and quality of pharmaceutical products (article 24, new literal h).
2. They must have an electronic registry available to the public through the pharmacy's website. In said electronic record, the observations of the users may be recorded, as well as the claims contained therein (article 22, last paragraph, new).
3. In the case of dispensing fractionated medicines, the technical director or whoever he supervises, must send, along with the products, the respective information brochures (article 40 E, last paragraph, new).
4. They must make available to the Ministry of Health (MINSAL) the prices of the pharmaceutical products that are sold, which will be done through the interconnection of the information that the pharmacy provides with the informational price system of the MINSAL. Any changes that may occur in the prices and discounts offered for the pharmaceutical products that they have for sale must be reported as soon as possible. The Minister of Health shall fix, by resolution, the form of data entry into the system, interoperability and other technical delivery conditions (Article 45 I, new).

If you have any questions regarding the matters discussed in this news alert, please contact the following attorneys or call your regular Carey contact.

Ignacio Gillmore
Partner
+56 2 2928 2612
igillmore@carey.cl

Alejandra Del Rio
Regulatory Affairs Manager
+56 2 2928 2766
adelrio@carey.cl

Javiera Péndola
Patent and Regulatory Affairs Specialist
+56 2 2928 2766
jpendola@carey.cl

Carey y Cía. Ltda.
Isidora Goyenechea 2800, 43rd Floor.
Las Condes, Santiago, Chile.
www.carey.cl

Likewise, article 56 is amended, adding a new third paragraph, which allows the electronic sale of medicines **in pharmaceutical warehouses**:

"Pharmaceutical warehouses may sell medicines through electronic means. For these purposes, they must comply with the provisions of Title VI bis and others that are applicable to these regulations and reconcilable with, considering the nature of the means by which they carry out the sale."

In this sense, as indicated in the new articles 8 and 56, a new Title VI bis is added to Decree No. 466, after Article 87 and before Title VII, called "**On the sale of medicines by electronic means**", in which the following is regulated:

1. Medicine sales by electronic means and the requirements for said authorization; Imports of medicines for sale by electronic means;
2. Minimum pharmaceutical stock for those establishment selling medicines through electronic means;
3. Sale according to approved sale conditions for the electronic sale of medicines;
4. Dispensing of medicines that must demonstrate Bioequivalence;
5. Necessary information of the buyer for the sale of the product (name, surname, contact telephone number, email and address);
6. Dispatch under conditions that guarantee product quality;
7. Return of products in accordance with Law 19.496 on the protection of consumer rights;
8. Pricing information in a clear, timely, transparent and truthful way;
9. Minimum information on the pharmaceutical product, which must be available on the electronic site (photograph of the secondary packaging, brand name and active ingredient, pharmaceutical form, dosage per pharmaceutical form, among others);
10. Pharmaceutical information that must be available on the electronic site (infographics that promote the rational use of medications, warnings about the proper use and dosage of medications with direct sales conditions, adverse reactions to medications and telephone numbers of existing lines that provide information free toxicology, such as the MINSAL remote assistance center);
11. Regulatory information that must be available on the website through a link (S.D. No. 466/1984 that approves the Regulation of Pharmacies, Drugstores, Pharmaceutical Warehouses and S.D. No. 3/2010 that approves the Regulation of the National Control System of Pharmaceutical Products for Human Use).

It should be noted that, with regard to the **sale condition** for the electronic sale of medicines, the following considerations must be kept in mind:

1. In the case of medicines which sale condition is a **simple prescription**, the sale will be performed either by means of an **electronic prescription** (complying with the requirements of article 101 of the Sanitary Code) or a **digitized copy of a prescription issued by physical means** (in this case, in addition to complying with the requirements of article 101 of the Sanitary Code, whoever distributes the medication must verify the correspondence between the physical support and its digitalization).
2. In the case of medications that require a **retained prescription**, as in the previous case, the dispensing may be done through an **electronic prescription**, or through a **digitalized copy of a physical prescription**. In the case of a digitized copy, the physical prescription **must be delivered** upon receipt of the pharmaceutical product by the consumer.
3. In the case of medicines which condition of sale is **"prescription-check" they are not included among those that can be dispensed by electronic means**.

Finally, this amendment establishes changes in Decrees No. 404, which approves the regulation of narcotic drugs, and No. 405, which approves the regulation of psychotropic products, both dated 1983 by the Ministry of Health, in order to allow the sale of psychotropic or narcotic drugs through electronic means.

In this sense, in both Decrees, the following new final paragraph is incorporated in article 26 and 25, respectively:

"In the case of sale through electronic means with a prescription held, the provisions of Title VI bis of Decree No. 466, of 1984, of the Ministry of Health, which approves Regulations of pharmacies, drugstores, pharmaceutical warehouse and authorized pharmaceutical deposits, will be followed."

All the aforementioned modifications are effective as of May 7 of this year. With the exception of those indicated in Article VI that are related to the availability of medicine prices to MINSAL, for which a Resolution should be expected to set the conditions for the delivery of data to the system.