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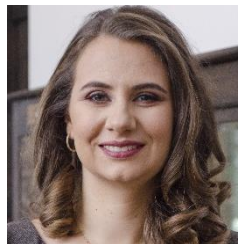
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New rules on the establishment, organization and operation of pharmaceutical units

Alexandra Radu
Partner

Phone: +40 21 408 89 10

E-mail: alexandra.radu@bulboaca.com



Roxana Șerbănescu
Associate

Phone: +40 21 408 89 89

E-mail: roxana.serbanescu@bulboaca.com





New rules on the establishment, organization and operation of pharmaceutical units

On March 25, 2019, the Ministry of Health issued Order no. 444/2019 for the approval of the Rules on the Establishment, Organization and Operation of Pharmaceutical Units (the "Rules"). The Rules were published in the Official Gazette no. 270bis of 9 April 2019 and entered into force on 24 April 2019. Order no. 444/2019 repeals the Order of the Minister of Health no. 962/2009 for the approval of Rules regarding the establishment, organization and operation of pharmacies and drugstores.

Among the changes that emerged as a result of the implementation of the Rules, we mention the following:

The operating authorization

According to the previous provisions, the operation authorization was issued by the Ministry of Health ("MH") based on the favorable inspection report drawn up by MH pharmacists inspectors.

Currently, the Rules state that the operating authorization is also issued by the MH, but based on a decision issued by the executive director of the Public Health District Authority ("PHDA"). In addition, this decision will be accompanied by an inspection report, which will no longer be prepared by the pharmacist inspectors, but by the PHDA empowered staff.

Voluntary suspension of the operating authorization

The Rules also regulate the possibility of voluntary suspension of the operating authorization of a pharmaceutical unit as a result of the interruption of the activity for more than 30 days. This suspension shall be registered as a mention in the annex to the operating authorization, and no inspection is necessary.

MH may approve the interruption of the pharmacy activity for up to 180 days for certain reasons (*i.e.* expiration of the headquarters contract, changes to the space etc.). The pharmaceutical unit may continue its activity only after it registers the mention of resumption of the activity on the annex to the operating authorization.

Reducing the term regarding the notification of the Ministry of Health

If any change to the conditions underlying the issuance of the operating authorization occurs, the MH must be notified. Under previous provisions, the term for notification was up to 20 days. Currently, this term is reduced to 5 business days.

Surveillance inspection

Surveillance inspection at the pharmacies, dispensaries and drugstores will be exercised by NAMMD (National Agency for Medicines and Medical Devices), at least once every 5 years. Previously, the provisions indicated that the inspection was carried out by MH pharmacists inspectors at least every 3 years.



Transfer of medicines

The Rules regulate the possibility to transfer medicines and other products which are under the management of pharmaceutical units under the following conditions:

- between the points of work of the same company;
- between the pharmacy and the local distribution dispensary listed on its operating authorization;
- between 2 companies in the situation of change of the authorization holder;
- between 2 sanitary units with beds.

Online trading

Rules have been adopted to implement the existing provisions in the Pharmaceutical Law no. 266/2008 on the possibility of pharmacies and drugstores to sell online.

In this context, pharmacies that want to sell online must have at least 10 sqm in addition to the minimum required for operation in order to store and package the products online.

The activity on the pharmaceutical unit's website can be outsourced only in terms of technical operations, not the sale and release of medicines.

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