

Romania: Online pharmacies - a new benefit for the pharma business

Although Law 160/2018 granted pharmacies and drugstores the possibility to sell over-the-counter drugs (“OTCs”) in July of last year, the detailed regulations governing online sales are only now being finalised.

On 15 January, the Romanian Ministry of Health (“**MoH**”) held a meeting to discuss public observations to its draft Order for the approval of the Norms regarding the establishment, organisation and operation of the pharmaceutical units, including the online pharmacies, which was published on the MoH website in mid-December 2018 (“**MoH 2019 Draft Norms**”).

Of particular relevance to pharmacies / drugstores wishing to sell OTCs online, the MoH 2019 Draft Norms, in conjunction with applicable law, states:

→ In order to undertake online sales of OTCs, community pharmacies and drugstores must:

- o be authorised according to the provisions of the pharmacy law no. 266/2008;
 - o notify the MoH of their intention to sell medicines online; and
 - o submit the required documentation with the county public health directorates (details of the dossier can be found in the MoH 2019 Draft Norms).
- Applicants need to appoint a pharmacist responsible for the online sale and release of medicines, and include the pharmacist’s name in the notification to the MoH.

→ Applicants will be required to undergo an inspection by the MoH. The MoH will have 30 days from the inspection date to issue its decision granting/denying authorisation to sell online. Neither Law 160/2018 nor the MoH 2019 Draft Norms address procedures to challenge a decision of the authority rejecting the authorisation.

→ Applicants exclusively dedicate at least 10 sq.m. to the functioning of the online service, featuring: furniture adequate for packaging and storing; equipment ensuring temperature and humidity monitoring; other means for storing the medicines in accordance with the producer’s specifications; computer and Internet connection.

→ The pharmacy/drugstore’s website must comply with applicable e-commerce legislation and contain a page dedicated to the online business, with following minimum information:

- o the contact details of the MoH and a hyperlink to its website (note: no hyperlink to the website of pharma companies is permitted);
- o the common European logo for the online release of medicinal products (with a hyperlink to the entry number of the pharmacy/drugstore in the list of online pharmacies/drugstores to be published by the MoH on its website);
- o a hyperlink to the page on the website of the Romanian National Drug Agency regarding reporting on adverse reactions;
- o the data from the annex to the authorisation issued by the MoH regarding the online business;
- o the statement of consent for the processing of personal data to be filled in by each visiting patient; and
- o a mandatory questionnaire in which patients indicate their: age, weight, height, sex, whether they are undergoing treatments, allergies, and pregnancy or breast-feeding status.

→ The pharmacy/drugstore’s website must ensure that sales are only possible after an interactive exchange of information between the patient and the pharmacist, either by email or online. It is the responsibility of the pharmacist to ensure the confidentiality of the data exchanged and to ‘validate’ each response of the patient by

‘specific means’.

→ Online sales are only permitted for patients over 18 years old.

→ The pharmacy/drugstore may outsource its website’s technical activity. Transportation can also be outsourced to contractors ensuring controlled temperature. Note however, the sale and release of medicines cannot be outsourced.

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