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Market supply obligations - Responsibilities of the players of medicines distribution chain

With the publication in Infarmed's website of the Drug Availability Management Regulation approved by Infarmed's board of directors (the "Regulation")[1], occurred yesterday, the recent revision of the legal framework of medicinal products supply obligations contained in Decree-Law nr. 112/2019 of 16 August ("Decree-Law 112/2019") that amended the Medicinal Products Legal Act[2] , was completed.

With this legislative change, the main activities required to ensure access to medicines, which is a mission of Infarmed under the terms of its statutory law, now assume the nature of an essential public service duty of all the players of medicines distribution chain.

Market supply obligations of the players in the medicines distribution chain were already contemplated in the Medicinal Products Legal Act, previously, but Decree-Law 112/2019 has strengthened the duties of the various players, from the marketing authorization holders ("MAH"), passing through wholesale distributors, to pharmacies and entities authorized to dispense medicines to the public. Following the approval by Infarmed of Informative Note nr. 012 / CD / 100.20.200 of 08.01.2019[3], which dealt with these matters, the new regulatory framework established more stringent obligations for all the players in the medicines chain,

especially for MAH's, being now provided in art. 6 of the Medicines Statute, the legal principle of continuity of service to the community.

Please find herebelow a brief description of the changes introduced by this new regulatory framework to the supply obligations of each of the referred players in the medicines distribution chain.

- ***MAH***

MAHs are now bound by an effective obligation of market monitoring in order to assess market needs on a continuous manner, and to maintain permanent communication with other players of the supply chain.

The MAH's supply obligations now include the obligations to,
(i) supply the other players in the medicine distribution chain on a continuous manner and in quantities necessary to meet patients' needs;
(ii) fulfill orders submitted by wholesale distributors that have supply orders submitted by national pharmacies and hospital pharmaceutical services, as well as
(iii) develop strategies to prevent medicines shortages.

Furthermore, the new regulatory framework provides that MAH's cannot refuse to fulfil the supply orders submitted by wholesale distributors that have supply requests from pharmacies and hospital pharmaceutical services.

Abusive bargaining practices in the supply of medicinal products and the use of discriminatory conditions are also prohibited. Examples of these, are the unilateral refusal to supply ordered products, or the use different timings to meet medicines orders.

MAH's are bound to ***notify Infarmed*** *of* ***shortages*** *of medicines through the Health Technology Assessment Information System (SIATS) portal, at least* ***2 months*** *before the estimated date of the beginning of the relevant shortage.*

If the medicines shortage entails medium or high risks to public health, such notification shall be accompanied by additional information, including with respect to the development of strategies address thereto, such as the identification of therapeutic alternatives for the medicinal products concerned.

The MAH's are also required to have, permanently, elaborated and ready to be provided to Infarmed, a very comprehensive set of information on shortage prevention measures, related to medicinal products that have no therapeutic alternatives, or have limited alternatives, and where the interruption of supply may result in a public health risk. This obligation of MAH's is permanent, regardless of whether or not, the medicinal products concerned are in shortage.

- ***Wholesale Distributors***

Wholesale distributors of medicines have to ensure the adequate and continuous supply of pharmacies and other entities authorized to dispense medicines to the public, and are bound to maintain ***minimum stocks of not less than the monthly average*** *ordered on the previous year, or the monthly average on the effective marketing period, if shorter.*

The export of medicines by wholesale distributors, or the supply of medicines to other distributors, is only allowed provided that the full accomplishment of the supply requests submitted by the authorized medicines dispensing entities is assured. In addition, now Infarmed is empowered to determine the temporary suspension of exports of certain medicinal products when public health protection reasons are at stake.

In case MAH's do not meet medicines orders submitted by wholesale distributors, the latter shall inform Infarmed thereof through the Medicines and Health Products Information Center ("CIMI"). This notification is accompanied by information on volumes ordered and supplied, as well as quantities exported by the wholesale distributor in the previous 2 months period.

- ***Pharmacies***

Pharmacies' duties of continuous service to the community, include the notification of medicines shortages resulting from the unfeasibility to meet a certain medicines prescription, or to fulfill a non-prescription medicines request for a period of more than 12 hours.

It should be noted as a final remark that the Regulation expressly provides for the application of the sanctions contained in the Medicines Statute in the event of any breach of the rules contained in the Regulation, which entail the application of fines of up to 15% of turnover, or EUR 180,000, whichever is lower.

In this regard it is noteworthy that in addition to the application of fines, the agent failing to comply with this new regulatory framework may also incur in civil, criminal or disciplinary liability under the general terms of law.

In addition to the provisions of Decree-Law 112/2019, the Regulation has strengthened the obligations of supply of medicines within the medicines market, qualifying such duties as of an essential public service nature. The compliance with the legal principle of continuity of service to the community results from the activities developed by the various market players. In order to meet such objective, the new regulatory framework integrates the regulation of each of the stages of the medicine distribution chain, with the underlying materialization of the obligations of each player, and establishing for MAH's more stringent obligations than such applicable to the remaining players.

[1] Drug Availability Management Regulation approved by resolution of Infarmed's board pf directors nº 93/CD/2019 (https://www.infarmed.pt/web/infarmed/gestao-da-disponibilidade-do-medicamento)
[2] Medicinal Products Legal Act approved by Decree-Law nr. 176/2006 of 39 August, as amended.
[3] See pbbr newsletter of 10.01.2019 (https://www.pbbr.pt/pt/actualidade/newsletters/obrigacao-de-fornecimento-do-mercado-responsabilidades-dos-intervenientes-no-circuito-do-medicamento/207/)

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