



MAR. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Exemption from payment of registration fee and regulatory contribution

Background

With the entry into force of Ministerial Order 150/2016 of 26 May, community (retail) pharmacies became subject to the payment of fees for services provided by the Portuguese Health Regulatory Authority ("ERS"), as well as the payment of a regulatory contribution.

The application of these fees to community pharmacies that provide pharmaceutical services has proven to be particularly burdensome, as these healthcare establishments are already subject to regulatory contributions by INFARMED - Autoridade Nacional do Medicamento de Produtos de Saúde, I.P. ("Infarmed"), which is the authority responsible for regulating the activities of community pharmacies in Portugal. This results in regulatory double taxation.

The amendment

In view of this particularly damaging situation for community pharmacies, the government approved Ministerial Order 49/2023 of 15 February, which amended Ministerial Order 150/2015. The new order establishes:

- The exemption from paying the registration fee to the ERS for pharmacies providing pharmaceutical services.
- O The exemption from the payment of the regulatory contribution to the ERS by pharmacies whose services are registered with the ERS.

With this amendment, the government has recognised that community pharmacies already have to pay fees for the acts and registrations carried out by Infarmed.

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Healthcare, Life Sciences & Pharmaceuticals With this amendment, the government has recognised that community pharmacies already have to pay fees for the acts and registrations carried out by Infarmed. It has also recognised that the provision of health care by pharmacies is an ancillary activity and that their main activity is the dispensing of medicines and health products.

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Pharmaceutical services subject to registration with the ERS that are provided in community pharmacies can be registered without having to pay a registration fee.

Implications for pharmacies

With this amendment, pharmaceutical services subject to registration with the ERS that are provided in community pharmacies can be registered without having to pay a registration fee.

In addition, community pharmacies are no longer subject to the annual payment of the regulatory contribution.

This is a radical break with the past because, unlike the situation during the Covid-19 pandemic in 2020 to 2022, the exemption from these two taxes is not limited to pharmaceutical services dedicated to the response to the pandemic. Instead, it is extended to all pharmaceutical services that can be provided in pharmacies and are subject to regulation and supervision by the ERS.

In addition, these exemptions do not prevent the exercise of regulatory and supervisory powers (including inspections) by Infarmed and the ERS.

Ministerial Order 49/2023 entered into force on 16 February 2023 and applies to fees and contributions that would be due from that date. However, there is no provision for the refund of fees and contributions previously charged by the ERS. \blacksquare

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