

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

Carrying out works in pharmacies

The legislation on pharmacies provides that any works to refurbish or extend their premises, with or without a temporary transfer of the premises, must be approved in advance by INFARMED (the Portuguese National Authority for Medicines and Healthcare Products). Applications must be submitted to INFARMED through the Licenciamento+ website and the documentation to be submitted varies according to the specific type of application.

Decision 975/2021 was published in the Official Gazette on 17 September 2021 and it amends the Regulation on Refurbishment, Extension and Provisional Transfer of Pharmacy Premises to Undertake Works.

These are the highlights of the changes that have been introduced:

- i) It is now stipulated that, in the case of extension work where there are pharmacies less than 350 metres away (taking into account the area to be extended), the applicant must submit with the application a declaration from the owners of any such pharmacies that they are aware of the works and have no objection to the extension of the premises;
- ii) When carrying out works leads to a need to provisionally transfer the pharmacy's premises, it is now necessary to submit a certificate from the municipal council certifying the distance between the provisional premises and the nearest pharmacies;
- iii) When works result in the opening of a new door for access by the public, it is no longer compulsory to keep open the door originally registered in the licence. In addition, when there is an extension to the premises with the opening of a new public access door, the distance to the nearest pharmacies should no longer be measured by reference to the new door but by reference to the external limits of the pharmacy premises, including the area of the extension. If a new door with public access is opened up, an application must also be made to have this fact endorsed on the pharmacy's licence.

"When carrying out works leads to a need to provisionally transfer the pharmacy's premises, it is now necessary to submit a certificate from the municipal council certifying the distance between these provisional premises and the nearest pharmacies."

This Decision also addresses certain issues which, although they already resulted from the applicable rules or from the practice that had been followed by INFARMED, have now been expressly clarified. An example of this is the need to submit a declaration signed by the technical director or by the owner of the pharmacy who assumes responsibility for the preparation of the medicines dispensed during the period of provisional transfer of the premises, if these premises do not have a laboratory. Another example is the obligation, when the works to be carried out are exempt from municipal licensing, for the applicant to submit the document with the application proving that exemption.

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Deliberation 975/2021 came into force on 18 September 2021 and applies both to applications submitted from this date onwards and to applications which, even if they were submitted on an earlier date, are still pending at INFARMED. ■