New legal framework on Sars-Cov-2 antigen self-tests

Ordinance No. 56/2021 of March 12 established an exceptional and temporary regime for the performance of rapid antigen tests, intended by its manufacturers to be performed in samples of the internal anterior nasal area.

For the prevention of the contamination of the new coronavirus (SARS-CoV-2), rapid antigen tests for the detection of cases of infection will be made available to the public, on the contrary to what has been verified so far, which was used exclusively by professionals.

This measure will allow the availability of antigen tests on the market, without the need of a medical prescription, in health system units, pharmacies, places of sale of medicines not subject to medical prescription authorized and other places to be defined by order of the member of the Government responsible for health.

The extension of the use of these antigen tests to a non-professional level is aimed for enabling self-testing by the population, at a time when the strategy undertaken is to intensify Covid-19 infection screening.

The provision of rapid tests to the public for non-professional use represents a measure of public health protection which is thought to be exceptional and temporary. It will be up to define, in a joint circular of INFARMED - National Authority of Medicines and Health Products, I. P. (INFARMED, I. P.), and the General-Manager for Health and INSA – National Institute of Health Doctor Ricardo Jorge, the criteria for inclusion of antigen tests in this exceptional regimen within a maximum of five working days in a list made available on the website of INFARMED, I.P.

The maximum maintenance period for rapid antigen tests in this exceptional legal framework shall be six months from the date of the decision of INFARMED, I.P. to include the antigen test in the referred list, available on its website. However, Ordinance No. 56/2021 consecrates the possibility of extension by INFARMED, I.P., for a period of another six months, at the request of the manufacturer, provided that the submission of a request for conformity assessment to a notified body is duly confirmed.

In this sense, and since the population's access to these tests, as a measure of protection of public health, is not in line with the exclusive use by professionals, Ordinance No. 56/2021 allows the availability of antigen tests on the market for the self-test by the population in general, approach already adopted by other countries, namely Austria and Germany.

Contacto
Rita Roque de Pinho - rita.pinho@pbbr.pt
Rita Serpa Viana - rita.viana@pbbr.pt

www.pbbr.pt