Issuance of certificates of recovery based on rapid antigen tests

2022/2561(DEA) - 22/02/2022 - Non-legislative basic document

This Commission delegated act amends Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery (EU Digital COVID Certificate) based on rapid antigen tests.

Background

Regulation (EU) 2021/9531 establishes a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

According to Regulation (EU) 2021/953, a certificate of recovery confirms that, following a positive result of a molecular nucleic acid amplification test (NAAT) carried out by health professionals or by skilled testing personnel, the holder has recovered from a SARS-CoV-2 infection.

In May 2021, the Health Security Committee, established by Decision No 1082/2013/EU, set up a technical working group on COVID-19 diagnostic tests. This technical working group aims to review proposals put forward by Member States and manufacturers for COVID-19 rapid antigen tests to be included in the EU common list of rapid antigen tests agreed by the Health Security Committee. Only COVID-19 rapid antigen tests included in that list can form the basis for the issuance of a test certificate in the EU Digital COVID Certificate format.

The EU common list includes CE-marked rapid antigen tests that are in use and have been validated in at least one Member State, and the clinical performance of which was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. The list only includes rapid antigen tests conducted by trained healthcare personnel or, where appropriate, trained operators.

On 11 January 2022, the technical working group on COVID-19 diagnostic tests discussed the use of rapid antigen tests for certificates of recovery, taking into account the worsened epidemiological situation, with record high numbers of COVID-19 cases due to the ‘Omicron’ variant of concern, as well as shortages of NAAT capacities in various Member States as a result of a high testing demand.

Given these circumstances, the technical working group agreed that rapid antigen tests included in the EU common list could be used to issue certificates of recovery. The technical work group stressed that only the results of rapid antigen tests conducted by medical professionals or other trained personnel should be used to issue such certificates.

Content

The draft delegated act:

- adds to the definition of certificates of recovery a **reference to rapid antigen tests** listed in the EU common list of COVID-19 rapid antigen tests agreed by the Health Security Committee;

- provides that Member States may issue **certificate of recovery also following a positive result of a rapid antigen test** listed in the EU common list of COVID-19 antigen tests agreed by the Health Security Committee carried out by health professionals or by skilled testing personnel;

- removes the explicit references to NAATs from the data fields set out in point 3 of the Annex, which concern the personal data to be included in certificates of recovery, to ensure that the data fields can also include data on the positive result of a rapid antigen test

To facilitate free movement, in particular of citizens who have been infected during the Omicron wave, Member States should be able to issue certificates of recovery retroactively, that is, based on rapid antigen tests carried out as from **1 October 2021**, provided that the rapid antigen test concerned was included in the EU common list at the time the test result was produced.

Certificates of recovery shall be issued at the earliest **11 days** after the date on which a person was first subject to a NAAT test or rapid antigen test that produced a positive result.