Import and distribution of rapid antigen tests

Article by Miriam Schuh

With vaccination off to a slow start, rapid antigen tests have become a key part of the efforts to combat the coronavirus pandemic. This is reason enough to comment on the difference between the various testing methods, the special approval procedure for self-administered tests, the import and distribution of testing kits and, above all, the associated liability risks.

Tests, Tests, Tests

The PCR test method is still considered to be the "gold standard" when it comes to detecting infection with the SARS-CoV-2 virus. Samples can only be taken by medical personnel, or "members of the medical profession." PCR tests can only be evaluated in labs, and it can take several days for the results to become available. PCR tests are valued for their high degree of accuracy and reliability, but these are not "rapid tests."

Rapid antigen test are used in addition to PCR tests. As with PCR tests, these tests also involve taking nasal and/or throat swabs. In this case as well, samples are taken only by trained personnel, ideally members of the medical profession. However, these tests do not have to be evaluated in a lab, but rather can be evaluated right at the point of care. The disadvantage of rapid tests is that they are less accurate than PCR tests: the percentage of "false negatives" is higher with the rapid test method. The first rapid antigen tests to be approved were sent exclusively to professional users, so that the labeling and use information for the products included the phrase, "for professional use only."

As the pandemic has progressed, there have been more and more calls for "self-tests," i.e. tests which can be self-administered by (untrained) laypersons. However, rapid tests which were designated by their manufacturer as for professional use only cannot simply be distributed to medical laypersons.

Regulatory conditions for rapid antigen tests

All of the tests mentioned above for the detection of coronavirus infections qualify as in-vitro diagnostics (IVDs), which are subject to harmonized regulation within the EU. In-vitro diagnostics are defined as any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, and is intended by the manufacturer to be used in vitro for the

examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state. The manufacturing, placement on the market, importation and distribution of in-vitro diagnostics within the EU are governed by the In-Vitro Diagnostics Directive, Directive 98/79/EC, which was implemented into national law by the Medical Devices Act (only in German). As of 26 May 2022, the Directive will be replaced by the In-Vitro Diagnostics Regulation (IVDR) (PDF) and, at the national level, the Medical Devices Act will be replaced by the Implementing Act for Medical Devices Law [Medizinprodukterecht-Durchführungsgesetz].

Accordingly, rapid antigen tests still need to satisfy the requirements of the Directive and the national legislation in the member states for the time being. In particular, they need to comply with the essential requirements for the safety and performance of these devices. Part of product safety is that the devices must be examined for the manufacturer for safe use by members of the medical profession or by laypersons, as the case may be, and designed accordingly. Tests which are to be made available to laypersons may require a more user-friendly design than products which are slated for distribution to medical professionals only, or the use information may have to be worded differently.

Given the demand for rapid tests for distribution to medical laypersons, which was not provided for until a few weeks ago but is now to occur as soon as possible and in the greatest possible numbers, manufacturers can apply to the competent federal agency (the Federal Institute for Drugs and Medical Devices, BfArM) for special approval in accordance with § 11 of the Medical Devices in order to make their devices available to laypersons. The tests which received this special approval are listed on the BfArM website.

The tests listed here may be made available to laypersons under the amendment which has already been made to the German Medical Devices Supply Ordinance [Medizinprodukteabgabenverordnung] (only in German).

Liability risks for importers and distributors

What this means for importers and distributors of rapid antigen tests for self-use by laypersons is that, in general, only approved tests may be distributed as self-tests for the time being. It is in their own interest for importers and distributors to ensure that they do not make tests available to laypersons which are designated by their manufacturer as for use by medical professionals only.

It is also to be expected that, that manufacturers will also strive for proper CE certification for tests for self-use. They are working on building up the directive-compliant production of regularly published tests, which can then be introduced to all EU member states, in addition to the tests brought into circulation by way of the temporary special approval.

With regard to these products, importers should be aware of the provision in § 5 of the Medical Devices Act: if a non-European manufacturer has failed to designate an authorized representative in Europe, the importer is responsible for the placement of these medical devices on the market in the European Economic Area, and is therefore subject to the duties specified in the Medical Devices Act. Not infrequently, the competent supervisory authorities are already enforcing the requirements for importers and distributors of IVDs which are only set to take effect in the future, when the IVDR takes effect. Violating these requirements may result in official sanctions (halting sales, recall orders or the destruction of stocks), as well as consequences in criminal law.

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