Testing as a strategy to limit the impact of COVID-19 in the European Union

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COVID-19 has a profound impact on society. The health consequences are severe and the virus can be transmitted during normal social behavior by symptomatic and asymptomatic individuals. Therefore, control has proven to be extremely difficult and requires profound limitations of human interaction. This also affected the exchange of people within the European Union.

To remain in control of the virus with limited impact on society there are basically two strategies. One is an effective vaccine and second is the early detection and subsequent isolation of infected individuals. Vaccines are being developed but their availability and effectiveness are as yet uncertain. Diagnostic methods for COVID-19 based on PCR have been available since a few weeks after the virus was discovered. These PCR based methods are now being used on an unprecedented scale all around the world. They are extremely reliable but require a relatively complicated laboratory infrastructure and the time to result is often 24-48 hours.

Recently new methods have become available which are less complicated. Rapid antigen tests that can be performed at the point of care have proven to be reliable to detect infectious individuals within 15 minutes. These tests do not require a laboratory environment and sampling can be performed by well instructed individuals themselves. These rapid antigen tests are being produced in large quantities for a relatively low price and have the potential to be performed at home by most citizens. Frequent and widespread testing would enable the early detection of infectious individuals with targeted control measures. This would limit the impact of COVID-19 on society substantially while remaining in control of the virus.

However, the current European regulations for the use of in vitro diagnostic devices as a so-called "self-test" pose a barrier to this application. The transition of IVD-directive (IVDD) to IVD-regulation (IVDR) is ongoing at this moment. This new IVDR increases the regulatory review for the majority of diagnostic tests. Under the new IVDR, 80% of diagnostic tests will require notified body review and approval prior to market entry. The increased amount of certifications that will be reviewed by the notified bodies, will delay the entry of novel diagnostic tests and increase the costs for diagnostic companies. Unfortunately, there is currently no strategy in place to quickly launch new tests in case of an emergency. Upon discussion with regulatory experts, a COVID-19 home test under IVDR, would result in a review process by a notified body that is expected to last 12-15 months. In the US, FDA has such a process called the Emergency Use Authorization (EUA). This process drastically reduces this time to 3 months. Although this process is still strictly controlled and monitored by FDA, it allows companies to release new products much faster on the US market compared to the EU market. Such an emergency situation is currently not foreseen in the EU regulation.

A joined effort of the Benelux and Germany could take these hurdles.
What is needed is

1) to develop a reliable method including instruction or active guidance for "self-testing"
2) to develop criteria to be used for the selection of rapid antigen tests
3) to develop protocols for different settings to use rapid antigen tests in combination with other diagnostic tests (e.g. hospitals, nursing homes, schools, industry, entertainment sector)
4) to accelerate the regulatory options to allow self-testing for this unusual situation

Furthermore, EU countries should align testing strategies and explore the possibilities to develop a joined COVID-19-free passport to support the safe exchange of people between countries. Effective testing strategies will play a key role in ensuring the free movement of people and allowing the smooth functioning of the internal market.
As long as we don't have an effective vaccine available on a wide scale, testing is the most reliable method to limit the impact of COVID-19. New methods offer new opportunities which can only come to full fruition by European collaboration.