Question for written answer E-000151/2022
to the Commission
Rule 138
Izaskun Bilbao Barandica (Renew)

Subject: Improvements to approval processes in the EU for in vitro diagnostic kits

The arrival of the Omicron variant, the exponential growth in cases and the rejigging of track-and-trace techniques have triggered demand for antigen tests throughout the EU. However, the slow pace of approval procedures for those tests is making it difficult for diagnostic kits manufactured by European SMEs to reach the market in time to meet that demand, which has repercussions for sale prices. In fact, in the wake of Brexit, and now that the relevant legislation has been tightened, we have gone from having 140 approval bodies in the EU to 26, while the number of products requiring approval has been growing. Of the 26 bodies, only 6 are equipped to certify in vitro tests. As a result, it takes more than half a year to get tests on the market. Small companies that invested in innovation and development to manufacture self-testing kits also find it more difficult to obtain approval than large firms do.

1. Is the Commission aware of those problems?

2. Given the urgent need to step up the supply of COVID-19 self-testing kits, what steps are being taken to remedy the problems?

3. Do any measures to bring about price controls on these tests exist?