Priority question for written answer P-004117/2021
to the Commission
Rule 138
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Subject: Obstacles faced by diagnostic test manufacturers in applying the forthcoming Regulation on in vitro diagnostic medical devices

On 26 May 2022, Regulation (EU) 2017/746 on in vitro diagnostic medical devices is due to enter into force. Once it does, a number of previously self-certified medical devices will fall subject to tougher performance requirements and have to undergo a thorough assessment by a notified body.

Diagnostic test manufacturers – already placed under great strain during the health crisis – are seriously concerned about the new legislation soon to come into effect. Their main worry is the current shortage of EU-certified notified bodies, as this will mean that many tests will have to be pulled from the market in May 2022 and will therefore no longer be available to patients.

Nevertheless, the Union needs to make businesses in the sector, laboratories and hospitals sufficiently aware of the steps they need to take.

1. Given the time it takes to certify tests, does the Commission intend to set a temporary moratorium for the products already on the market that have been certified under the old system? If so, when will those in the industry be informed of the practicalities of this?

2. Is there likely to be an implementation report on the new legal framework and, if so, when?