COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR concerns in the event of a no-deal Brexit

Open letter to the European Commission & National Competent Authorities

for Medical Devices

Brussels, 7 March 2019

The date of withdrawal of the United Kingdom from the European Union - 29 March 2019 - is drawing ever-closer. While we sincerely hope that both parties will continue to do their utmost to find an agreement, our industry is increasingly concerned over preparations for a "no-deal scenario". Such an outcome means that the UK will no longer remain part of the European Single Market. Given recent communications by the European Commission[1], this will have detrimental consequences for our industries in the European Union. Our major concerns are that:

- UK Notified Bodies, which currently play a critical role in certifying medical devices placed on the EU-27 market, will no longer be able to issue EU certificates.
- Non-EU manufacturers that currently have an Authorised Representative based in the UK will have to change to one based in the EU-27.
- Manufacturers transferring to a new – EU-27-based - Notified Body will need to change how their devices are labelled to reflect the new Notified Body number or face non-compliance with the Medical Device Directives.

Unfortunately, it appears that the European Commission and the EU-27 Member States are currently not planning to adopt a specific transition period for medical devices (similar to the one planned by the UK). However, we would like to point out that the current timing is insufficient to allow for manufacturers to receive certification by a new Notified Body. Even where a transfer is possible, and new CE certificates from EU-27 based Notified Bodies have only been issued in the last few weeks, re-labelling all their devices would be challenging at best and unfeasible in many cases, particularly for manufacturers with large product portfolios. If devices are not available, even temporarily, the resulting impact on European healthcare systems – and the safety of EU citizens - could be substantial.

Therefore, in the best interest of citizens, we call on the European Commission, together with Member States, to agree on a limited transition period. This will allow those manufacturers directly impacted by any no-deal Brexit to continue to place devices certified by a UK Notified Body on the market.

Standard practice for medical devices[2] when changing to a different Notified Body would be to provide six months following the Date of Withdrawal. This would allow the re-labelling of devices after the certificates transition to a new Notified Body. Even 12 to 18 months could be necessary in case manufacturers have to switch to a completely new Notified Body to ensure the necessary time for the re-certification process.

Such a transition would give manufacturers much-needed certainty and ensure that hospitals, healthcare professionals and citizens in the EU see reliable and predictable access to these devices.

This, however, provides a short-term solution to a long-term challenge. We therefore encourage the EU and the UK to expedite negotiations on a trade agreement that includes the mutual recognition of medical device certification.

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[1] https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf
[2] http://www.doks.nbog.eu/Doks/NBOG_BPG_2006_1.pdf