How to avoid a real risk of shortage of essential medical devices in case of implementation of EU Regulation 2017/45?

Preamble

On May 31, 2022, the French National Academies of Medicine, Pharmacy and Surgery [1] and the Royal Academy of Medicine of Belgium (ARMB) alerted the political and administrative world, all healthcare professionals and the patient community to **the risk of a shortage of medical devices (MDs), particularly implantable medical devices (IMDs)**, by May 26, 2024. This risk is real if no measures are taken to **overcome the bottleneck** constituted essentially by the notified bodies (NBs) responsible for CE marking of these devices in application of the new EU regulation 2017/745, as they are too few in number and have insufficient means. Indeed, any device that is not labelled by this deadline can no longer be marketed and therefore used for the benefit of patients.

Three recommendations were made**: (1) an extension of the transitional period by at least two years, (2) an increase in the resources made available to NBs, and finally (3) a real assessment of the risk for certain patients of being deprived of these MDs or IMDs essential to their health.**

Development

Having become aware of this risk, the French Ministry of Health officially requested on 22/09/22 from the European Commission **an extension of the transitional period [2]**. This proposal must now be validated by all 27 countries of the European Union.

The Federation of European Academies of Medicine (FEAM), also concerned by this important public health issue, wishes to endorse this recommendation and has joined the ongoing process.

This deferral of implementation should only apply to products for which manufacturers have shown their determination to be re-listed by submitting a validation file (even if incomplete) by the initial deadline of May 2024 and identifying, within the same timeframe, products considered essential, i.e., with no alternative solution.

On the other hand, concerned about the guarantees of safety, transparency, and traceability needed for the necessary confidence of users, the four National Academies and FEAM have identified the compulsory registration of marketed MDs , on registers, as a particularly suitable means of ensuring their monitoring.

Recommendations

The French National Academies of Medicine, Pharmacy and Surgery, ARMB and FEAM jointly recommend:

1) **The extension of the transitional period for the implementation of the EU Regulation 2017/745 by at least two (2) years**, as already advocated by six EU Member States in addition to France.

2) That this extension **essentially** concerns **perfectly proven MDs and IMDs***, already CE marked from 1991 to 2021 and for which their manufacturers have expressed the wish to keep them on the market by submitting a validation file, even a partial one.

3) That practitioners using these IMDs should ensure that they are **systematically registered** in monitoring registers, in relation with the manufacturers responsible for their material monitoring

4) That the list of **essential MDs and IMDs**, i.e., **those without valid alternatives and not yet registered or in difficulty of registration, be determined rapidly** in relation to their users, in order to avoid their disappearance, which would be detrimental to patients' health.

*Without safety problems identified by the annual inspection carried out by the notified body (NB) or on the basis of material vigilance data (Manufacturers, NBs, Health Agencies, etc.)

References

[1] Press release of the National Academies of Medicine, Surgery and Pharmacy of May 31, 2022

[2]. APM news of Thursday 22/09/22 at 15h25