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EFORT position on revision of the Medical Device Regulation

The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) welcomes the European Commission's proposal 2025/0404 (COD) for a targeted evaluation and revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). EFORT, representing 41 National Orthopaedic and Traumatology Societies cross Europe, and by this more than 60.000 clinical active orthopaedic surgeon, nearby daily implanting medical devices in patients, are much depending on high safety and sustainability in certificated for use on the EU market.

The targeted evaluation and revision of the Medical Device regulation have several positive incitements to stimulate both innovation as well as safe implants available for our patients. EFORT notably welcomes the fact that:

- The revision aims to **prevent shortages** of devices by simplifying rules and creating new and shortened pathways for orphan and breakthrough devices.

- The revised proposal aims to **reduce the administrative burden.** Since the MDR was introduced unpredictable certification timelines and disproportionate costs to manufacturers, which mainly effected innovative products of SME in Europe, resulting in removal of their long-time used surgical medical devices from the market (e.g. special -low volume- fracture plates to be used in bone cancer patients).

- Reduced costs for certification by Commission for **micro and some small enterprises (i.e. start-ups** from **EU academia** with innovative ideas**).**

- The revision intends to **increase involvement of EMA Expert Panels** in the revised MDR. The use of these independent Expert Panels with clinical and scientific expertise in both the evaluation of complex orthopaedic implants as well as evaluations of orphan and breakthrough devices safeguards reliance on scientific clinical evidence for certification. . accelerated evaluations of orphan and breakthrough devices

- The possibility for **manufacturers to receive scientific advice** from Expert Panels early in the development phase is for scientific umbrella organisation within the field, like EFORT, important in order to educate colleagues during symposia on scientific clinical evidence and advocating guidelines on the use of innovative technologies, such as 3D-printed or smart implants.

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- The definition and extended list on **well-stablished technologies (WET).** This creates a more proportionate regulatory pathway for standard orthopaedic medical devices that have shown proven performance and safety for decades. Thus, reducing the overall administrative burden to the regulatory system and preventing the need for expensive new clinical trials for devices that are already SATO (state of the art) in clinical daily practice.

- **Grandfathering of orphan devices under MDD** can now be easier used under the proposed revision MDR, which has a positive effect on patient care. For that matter hip, knee implants with good to excellent results (5-10% failure at 10 years) based on documentation of high completeness (> 95%) national implant registries are in daily clinical practice state-of-the-art (SOTA).

- **EUDAMED**, is promising and may help healthcare professionals and patients in their evidence-based choice for an implant if EUDAMED provides enough granularity on performance and adverse events. This in combination with outcome data from the independent orthopaedic implant registries with > 95% completeness safeguards optimal choice for a certain implant, which is better than relying solely on manufacturer implant brochures.

Nevertheless, EFORT has some concerns on the proposed revision of the MDR, which need a closer look from an orthopaedic and traumatology perspective to prevent avoidable adverse events:

- Excluding the **5-year validity limit of certificates** may impact patient safety negatively. As for orthopaedic joint replacement medical devices like hip, knee etc it is known that loosening of the implant is only visible beyond 5 years. Therefore, EFORT recommends a science-based approach to be used beyond 5-years: request from industry to deliver a report of real-world data from national or regional arthroplasty registries with a completeness of at least 95 % . If not available, observational data from a different source must be provided on the number of implanted and revised implants. These data can be interpreted by Notified Bodies and / or Expert Panels.

- Market entry based on **equivalence.** History has shown that devices which were introduced based on “equivalence” (i.e. the 510k pathway FDA) with no pre-certificate clinical studies, e imposed a high risk on patient safety. Two examples on this, first the metal-metal hip (i.e. under 510k pathway) disaster with up to at least a 5 times higher revision risk of these hip implants implanted in young patients compared to a conventional hip implant[1]

1. Ardaugh BM, Graves SE, Redberg RF. The 510(k) ancestry of a metal-on-metal hip implant. New Engl J Med. 2013;368:97–100.

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as well as a 8% higher mortality at 10 years follow-up (Pijls et al[2]). Secondly, equivalence is not identical, in orthopaedics this issue is known as camouflage where the same (i.e. similar) product name has several subtypes with a fourfold higher revision rate of a certain knee implant (Wilton et al[3]). These are just two examples on the "equivalence" pathway, both the orthopaedic and cardiologic community have more examples on this concern. In the proposed revised MDR, manufacturers can claim equivalence to another device in the conformity assessment application, permitting them to rely on clinical data for that specific alternative device, and removing the requirement to perform a clinical investigation. Thus creating preventable risks to patients as mentioned above. This can be prevented by following established guidelines for clinical evidence as proposed by the CORE-MD (Co-ordination of Research and Evidence for high-risk Medical Devices) consortium (Fraser et al[4]).

In view of the above, EFORT recommends that:

- orthopaedic colleagues in the **expert panel**, must be involved in the evaluation and decision, when equivalence is claimed for new devices with no earlier clinical date to support the devices entry to the EU market.

- To secure patient safety, **clinical evidence** must be presented for class III and class IIb with medicinal effects high-risk medical devices before the device enters the EU market. The evidence must be balanced (i.e. proportionate) according to severity and rarity of the conditions as well as the device which is intended to treat it. The latter was also stressed by the outcomes of CORE-MD, co-lead by ESC and EFORT [4].

[2] Pijls BG, Meessen JM, Schoones JW, Fiocco M, van der Heide HJ, Sedrakyan A, Nelissen RG Increased **Mortality** in Metal-on-Metal versus Non-Metal-on-Metal Primary Total Hip Arthroplasty at 10 Years and Longer Follow-Up: A Systematic Review and Meta-Analysis. .PLoS One. 2016 Jun 13;11(6):e0156051. doi: 10.1371/journal.pone.0156051. eCollection 2016.PMID: 2729503

3. Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? Bone Joint J. 2023 Mar 1;105-B(3):221-226. doi: 10.1302/0301-620X.105B3.BJJ-2023-0145. PMID: 36854320.

[4]Fraser AG, Buccheri S, Byrne RA et al. Recommended methodologies for clinical investigations of high-risk medical devices-Conclusions from the European Union CORE-MD Project. Lancet Reg Health Eur. 2025 Sep 15;58:101460. doi: 10.1016/j.lanepe.2025.101460.