EFORT position on revision of the Regulations on Medical and In Vitro Diagnostic Devices

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 regulation have several positive incitements to have both innovation and 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**, which has been evident through the years with the initiation of the new MDR. This has resulted in unpredictable certification timelines and disproportionate costs to the manufactures, with an impact of innovation and thereby certification of medical devices, especially from SMEs.
- Reduced costs and administrative burden to **micro and small enterprises**, since they bring innovation after being start-ups from **EU academia.**
- The revision intends to **increase involvement of expert panels** in the revised MDR. Hereby, clinical expertise is involved in the evaluation of complex orthopaedic implants through an independent, high-level review of the clinical evidence for high-risk and novel devices. This ensures that "sufficient clinical evidence" is judged by specialists who understand the practical realities of joint replacements and trauma medical devices as well have scientific knowledge to interpret this.
- The possibility for **manufacturers to receive scientific advice** from Expert Panels early in the development phase is for umbrella organisation within the field, like EFORT, who delivers experts for the panels important in order to educate colleagues with symposia and guidelines on innovative technologies, such as 3D-printed or smart implants. Improvements by manufacturers can be done before they reach the expensive final certification stage.
- The **overall increased involvement of experts** in various aspects like specific support and accelerated evaluations of orphan and breakthrough devices.
- the revised MDR focus on **well-stablished technologies (WET),** where the definition of WET has been expanded to more devices, because it creates a more proportionate regulatory pathway for standard orthopaedic medical devices that have decades of proven safety, reducing the overall burden to the regulatory system and prevents the need for expensive new clinical trials for devices that are already "standard of care". Orthopaedic and traumatology surgeons daily use several devices, that has been to market over decades without any reported concerns on patient safety.
- **Grandfathering of orphan devices under MDD** can now be easier used under the proposed revision MDR , which has a positive effect on patientcare
- **EUDAMED**, when operational will replace a fragmented, paper-heavy system with a centralized "source of truth" that prioritizes clinical evidence and patient safety, to improve clinical transparency where surgeons can access the Summary of Safety and Clinical Performance (SSCP) for high-risk

implants. This allows EFORT members to review a device's objective clinical data and complication rates before choosing it for a patient, rather than relying solely on manufacturer brochures.

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However, EFORT also have some concerns on the revised MDR, and ask the EU Commission to take a closer look at these.

- Excluding the **5-year validity limit of certificates** may impact patient safety negatively by posing i.e. late negative outcomes of devices, since for joint replacement joints it is known that adverse events are only visible beyond the 5 years. Therefore, EFORT recommends a science-based approach by using beyond the 5-year validity mark, the request to industry to deliver a report of real-world data from national or regional arthroplasty registries with a completeness of at least 95 % on their product (medical device). If not available, observational data from a different source have to be provided on number of implanted and revised implants. These data can be interpreted by Notified Bodies and / or Expert Panels within s Such data are not needed for devices on the market for decades with proven long-term results in national arthroplasty registers which have at least 95% completeness without any safety concerns. This accounts for several total hip and knee replacement devices. In contrast, novel devices and devices with modifications must be clinically followed and investigated, optimal by a conditional certification and a defined post-market follow-up investigation. The orthopaedic colleagues in the expert panel could propose guidelines to ensure a harmonised issuance of certificates, thus improving patient safety and predictability for industry. Communication with colleagues from the notified body could be done, creating a learning EU network.
- History has shown that devices with no pre-certificate clinical studies, entering the market based on **equivalence** to other devices already certificated, imposed a risk on patient safety. In orthopaedics this issue is known as camouflage where the same (i.e. similar) product name has subtypes with a fourfold higher revision rate of a certain knee implant[1]. For example, the DePuy ASR ASR XL Acetabular metal-on-metal hip replacement system was approved on the basis of equivalence in the EU, and by the 510(k) pathway in the US, meaning it has never been clinically tested in patients before it was approved and sold[2]. In 2008, the Australian Orthopaedic Association National Joint Replacement Registry reported a high rate of complications, with a revision rate at 5 years of about 13%. The device was taken off the market. It had been approved on claims related to long-discontinued prostheses, and to predicates that had different combinations of characteristics. The orthopaedic and cardiologic community have more examples to this concern. In the 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. As a result of this, new high-risk implantable devices may be marketed without any form of pre-market clinical investigation. EFORT notice this as a clear negative approach, and with an increased risk and safety concerns for patients, surgeons and hospitals.

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.

[1] 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.

[2] 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.

- 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-ordination of Research and Evidence for high-risk Medical Devices) co-lead by ESC and EFORT [3]. This project showed that clinical evidence was insufficient for high-risk medical devices used in cardiology, orthopaedics and diabetic medicine.

[3] Fraser A, Buccheri S, Byrne R et al. **Recommended methodologies for clinical investigations of high-risk medical devices—Conclusions from the European Union CORE–MD Project** The Lancet Regional Health – Europe, 2025; 58