Bijlage 1 - Tekst Publieke Consultatie- Gerichte Evaluatie MDR-IVDR

The MDR and IVDR were adopted to better ensure patient safety and transparency of the system. The Ministry of Health, Welfare and Sports (MoH) continues to fully support these values and goals.

Over the years it has become clear that the balance between safety, availability and innovation of medical devices, each of which contribute to patient safety, has not been sufficiently secured in the regulations. The Dutch MoH believes that this evaluation of the regulations should have the goal to ensure a better balance between these three factors.

Any proposal which comes forth from this evaluation should clearly contribute to the reliability and credibility of the regulatory system and should benefit those who have invested in compliance with the system**. Extended transitional timelines have**, although sometimes needed, **not contributed to the reliability of the regulatory framework**. Any such future proposals should take those who have invested in compliance into serious consideration and should not provide ambiguity or possibilities for evasion for those unwilling to comply.

With that, The Dutch MoH wants to express concerns regarding **the impact of horizontal legislation** on the availability of medical devices on the EU market. The MoH supports proposals for adequate regulation of topics such as sustainability, (chemical) substances, data, digital markets, cybersecurity, responsibilities of economic operators and the like, but sees the need to ensure that horizontal legislation is harmonized as much as possible with the MDR and IVDR. The MoH supports the need for a better coordination mechanism, and a clear overview of horizontal legislation that have an interplay with the MDR and IVDR.

The MoH values the efforts of notified bodies in harmonizing their ways of working and their efforts in the realization of the attributed action points of MDCG 2022-14 on notified body capacity. For some time now, the capacity of notified bodies has been sufficient for those seriously pursuing regulation certification. The MoH is of the opinion that the legislative institutions, such as the European Commission and MDCG should continue to develop tools which would allow for more **efficient certification** as described in MDCG 2022-14.

Moreover, the MoH wants to reiterate **the importance of EUDAMED** and the considerable role this database will have in making the regulations fit for their goal. EUDAMED will increase transparency on the medical devices and make cooperation between member states more efficient.

To conclude, the MoH is in favor of the creation of a **political steering group under the CAMD** structure consisting of the Heads of Medical Devices to further improve the efficiency and transparency of the system. The MoH would value one representative body, with experts on medical devices that could give input on priorities, address long term development of the regulatory system and coordinate international activities to ensure consistency, predictability, sustainability and confidence.