COCIR Position

Proposed actions to enhance Notified Bodies capacity and preparedness

Current situation

With the adoption of the Regulation (EU) 2017/745 (MDR), the regulatory framework for medical devices has changed significantly. The main objectives of this Regulation are to "establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". However, despite the significant effort from the European Commission and the Medical Devices Coordination Group (MDCG), there is a growing concern for the readiness of the sector on 26 May 2024, when the transitional provisions allowing medical devices certified under the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) and the Medical Device Directive 93/42/EEC (MDD) to be placed on the market will expire.

As noted by EU Health Commissioner Stella Kyriakides at the June EU Health Ministers meeting, 24.000 certificates will expire in 2024. In order to avoid shortages of and interrupted access to medical devices for EU patients, Kyriakides has called on manufacturers to increase their preparedness and plan ahead of the deadline, as well as to ensure that sufficient numbers of Notified Bodies (NBs) are approved within Member States to give enough time for reviews to take place. The MDCG has already agreed on a list of actions aiming, among other, to enhance NBs capacity and preparedness.

COCIR members, representing medical device manufacturers in medical imaging, radiation therapy and digital health sectors, are well advanced in MDR certification. However, concerns remain in the following areas:

- Delays in scheduling of audits
- Length of technical documentation review as well as time to formally obtain certificate after review
- Resource constraints / capacity by Notified Bodies
- Different interpretation and level of scrutiny between reviewers within the same NBs (time needed for NBs to train reviewers)
- Expected bottleneck in MDR certification towards 2024 (as outlined by Notified Bodies here)

COCIR believes that it is paramount to avoid bottlenecks in MDR certification towards 2024 and to ensure availability of medical devices to guarantee the continuity of care, including all those certified under the Medical Devices Directives, on the European market. To this end, we are enclosing a list of measures to support the MDCG work to increase capacities of existing Notified Bodies and work more efficiently. These proposed solutions target specific areas for improvement, such as MDR certification process; Clinical evaluation requirements; Technical documentation review; and Designation of Notified Bodies.

In particular, we would primarily recommend to:

- Expand the use of remote audits to all products generally (without need for specific justification)
- Use Medical Device Single Audit Program (MDSAP) reports to introduce efficiencies
- Allow Notified Bodies more flexibility in defining the appropriate technical documentation sampling (e.g. lower number of technical files based on risk class and not on groups)
- Provide guidance on use of performance data and interpret equivalence provisions as pragmatically and flexibly as possible (within legal framework).

Please find below a full list of proposed actions.

Area for action	Proposed solution	Impact / Remarks
MDR certification process	Extend MDD certification	Consider an extension of the MDD certification, especially if the manufacturer can prove that all documents for certification process have been submitted in time, and delays are caused by the backlog of Notified Bodies or other authorities.
	Accelerate procedures	Faster/less intense procedure can mitigate the risk of lower number of medical devices on the market after the Grace Period. Such an action would increase the review coverage compared to the MDD/AIMDD and, at the same time, would allow a more efficient use of resources.
	Decide whether specific conditions or provisions need to be defined for the certification	Consider actions to allow for more pragmatic (less formalistic) assessment, especially clinical evaluation/evidence in case of devices already certified under MDD/AIMDD.
	Promote flexibility	Consider actions to enhance capacities of existing NBs and use existing capacities more efficiently (e.g. alleviate the burden coming from the joint assessment process; less restrictive application of staff requirements; hybrid audits; leverage of evidence obtained under MDD/AIMDD for same requirements).
	Accelerate conditional approvals	Consider actions to promote provisional certificates for MDD and conditional certificates for new MDR products. One the one hand, this solution would allow Notified Bodies to issue provisional MDR certificates that will become final MDR when the Notified Body will finalise its review of the technical file. On the other, NBs will have the green light to deliver conditional certificates for new MDR products under certain conditions (CAPA mode). Once the NB will verify that those conditions are fulfilled, the conditional certificate will become a final certificate.
	Reduce Notified Body review time	Reduce the amount of time to complete a technical file review by allowing Notified Bodies to only have to review the delta between the MDD and MDR tech file, when a MDD device is converted to MDR version.
		AIMDD and MDD medical devices are already placed on the market and being found safe and performing under the AIMDD and the MDD. The MDR has no article for surveillance audits and reviews, nor has the MDR a grandfather provision for already certified devices. However, it can be argued that the initial review can be reduced. The following is possible within the MDR regulation:

		• Reducing the review amount of the Quality Management System. • Reducing the review amount of the Technical Documentation. • Allow more devices under a device group where possible. • Reduce the audit and review frequency where possible.
	Create a fast Track Pathway for Well Established Technologies Products	This action will free up capacities of Notified Bodies and give them the ability to focus on other products.
		Remove the requirement for the NBs to approve the introduction of a new device when this device enters inside the product category/group covered by the certificate. The technical review should simply be assessed by sampling during surveillance audits.
	Enable full remote audits	Consider actions to allow NBs to expand use of remote audits to all products generally. During the COVID -19 pandemic remote audits were used with good results. This reduces travel times and allow more flexibility in audit schemes for NBs.
		Consider actions to allow NBs to use MDSAP report, to avoid duplication in the audited topics.
Clinical evaluation requirements	Provide complete clinical evaluation guidance	The clinical evaluation requirements within the MDR are the most complex in the world and have been significantly updated under the MDR. The guidance MEDDEV 2.7.1 rev 4 has not been updated. COCIR has reviewed this guidance based on the changes under the MDR, which can be used for this. An updated and complete clinical evaluation guidance for the MDR would avoid a lot of issues with the review of clinical evaluations.
	Make use of all sources of clinical and technical evidence	The MDR has restricted significantly what Clinical Evidence can be used for market approval. Usable clinical data or technical data can be used through article 61(10). The article 61(10) could be more promoted. For example, not all clinical data is published, and clinical data of similar devices also could be useful to show the safety and performance of certain medical devices. This has to be well justified under article 61(10). The MDR would then be in line with the IMDRF guidance for MDR Class IIb and lower classification devices.
	Promote the use of the Clinical Evaluation Assessment Report (CEAR) for manufacturers	The CEAR is used by Notified Bodies to check the Clinical Evaluation. The CEAR is also useful as checklist for the manufacturer. However, this is not widely known. To promote the CEAR as

		checklist for manufacturers, might avoid a lot of issues in the Clinical Evaluation.
Technical documentation review	Accelerate technical file application	Faster/ stricter technical file application does not resolve the risk of a lower number of medical devices on the market after Grace Period.
	Reduce technical files required per sample	With this action, the total scope of work is reduced; it also relieves the risk of lower number of medical devices on the market after the Grace Period.
	Enhance predictability	Consider actions to enhance predictability, e.g. gradual and consistent application of guidance; extend list of harmonized standards; allow pre-submission dialogue between notified bodies and manufacturers.
		Consider that technical documentation under review is not re-reviewed when guidance is released. This is a major delay factor.
		Consider actions to allow Notified Bodies to give precise input to manufacturers where a correction is needed in the Quality Management System and the Technical Documentation, and do not consider that consultancy. Currently, there is a very strict interpretation, while there should be no limit on the review cycle of a Notified Body. Consultancy activities are under the MDR strictly separated, and the concern for conflicting interests have disappeared.
	Allow certification when resolution of comments or observations is not completed. Please note, this is not applicable to non conformances	During the audit or technical documentation review many comments or observations are made, of which the source in the MDR is not clear. The MDR is very new and this is part of the learning process of Notified Body and Manufacturer. Open comments and observations delay significantly the certification process. Since there is not a compliance issue, certification should be allowed. Non conformances should be checked with the MDR if they are nonconformance or are an observation. The Notified Body could set an acceptance criterion for the Technical Documentation, based upon risk, GSPR etc, and agree that some needed corrections are minor and do not constitute an unsafe product. This may alleviate prolonged reviews and enable continued market access.
Designation of Notified Bodies	Reduce the burden of re-designation of Notified Bodies	Consider delaying the re-assessment process to ensure that Notified Bodies can fully focus on the MDR certification of Medical Devices. Under MDR, after 3 years Notified Bodies have to be re-assessed, which requires resources and slows

		down Notified Bodies to focus on working on Certification dossiers for Medical Devices.
	Limit unannounced audits during critical periods	Limit unannounced audits for the critical periods (2023-2024) or limit the requirement of conducting unannounced audits to high-risk devices, new technologies or newly certified manufacturers. Unannounced audits are adding burden on Notified Bodies.
	Appoint more Notified Bodies	Further accelerate the designation of new Notified Bodies by the European Commission and Competent Authorities and increase their capacity.