The European Association of
Medical devices Notified Bodies

November 30th, 2024

Team-NB High level position
on
the regulatory framework for the medical devices sector

The European Association of Medical devices Notified Bodies (Team-NB) and its members fully support the objectives of the MD and IVD Regulations (MDR and IVDR) which aim 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".

Team-NB welcomes today's surveys and publications on the implementation of the Medical Devices regulations to improve the regulatory context to reach a better healthcare system ensuring a high level of patients' safety as well as confidence and promotion of innovation in the medical device industry when backed by solid safety and effectiveness data.

At the October general assembly meeting, the members aligned on a strategy including both high level objectives for the future of the sector with the aim to meet the highest level of public health and also operational aspects to respond to the concerns regarding the difficulties encountered with the implementation of the MD and IVD Regulations (MDR and IVDR).

Team-NB high level position could be summarized as

Notified Bodies are key players for the Medical Devices sector

and aim to improve the general efficiency of processes through greater harmonization amongst the members, simplification, proportionate to the risks, improvement of governance thanks to the code of conduct that we impose on ourselves and the monitoring of possible complaints and finally increased transparency.

This high level position can be divided into the following

1. **Health access thanks to NBs**
2. **Proposals to improve Health access**
3. **Harmonise designation/ monitoring of NBs**

Today, Team-NB members represent

- 42 organisations (both designated and in the designation process)
- 39 are Notified Bodies designated under the Medical Devices and/or In Vitro Diagnostic Medical Devices Regulations

- they have brought together teams representing over 5 200 employees dedicated to working to ensure that a device is placed on the market ensuring that it complies with EU safety, health and environmental protection requirements.
- they have certified over 12 000 manufacturers in Europe and outside Europe with a major attention for a response adapted to SMEs which represent 77% of our customers. Notified Bodies are conscious of the importance of the SMEs in the sector, and Team-NB are in favour of increasing the EU level financial support available to the SMEs for the certification process, as it exists in some Member States today.

Team-NB has changed their statutes in 2022 to allow organisations still in the designation process to join This was decided as a response to Authorities request to help capacity building. As part of the association, the "candidate members" have access to restricted access documents after they have proven they submitted their application to be designated. They can attend trainings and Experts sessions as well as task forces and Mirror MDCG working groups as observers.

The members are working together to provide harmonised positions.
As examples, we worked together to compile individual member checklist to get one single harmonised approach on Best Practice Guidance for the Submission of Technical Documentation under both IVDR and MDR. A consensus document on MDR Certification Process applications has also been finalised.

We also proposed templates for notified bodies such as the confirmation letter of the status of a formal application in the framework of Regulation EU 2023/607 and the transfer Agreement for Surveillance of Legacy Devices specifying the terms of the transfer of the appropriate surveillance according to Regulation (EU) 2017/7451.

As well, members harmonised views are shared on topics such as on lifetime for medical devices, reclassification of Covid-19 devices, recommendations to cybersecurity harmonised approach.

Topics for consideration
Our general views on the topics to be considered in the framework of the implementations of the regulations and ideas for improvement of the regulations are stated below.

1. **Harmonisation**
   Notified Bodies agree with other stakeholders that further harmonisation is a must. It will also enhance efficiency.

Notified Bodies would propose an adapted MDCG structure to coordinate current MDCG tasks, that could take on board the following additional coordinating tasks:

a. designation and monitoring of Notified Bodies, including reassessment and scope extensions.
b. Classification disputes and decisions
    i. A similar mechanism as described under "Special Pathways" in section 2. below could be adopted by existing MDCG WG Borderline & Classification
    ii. Could replace "Manual" and "Helsinki procedure"
    iii. Rapid publication of decisions
c. Borderline decisions
    i. Application of MDR Article 4/IVDR Article 3 provisions
    ii. Rapid publication of decisions
d. Devices under MDR Article 61(10) & Devices qualifying as WET (MDR Article 61 6(b)).
    i. Similar mechanism as described under "Special Pathways" in section 2. below could be adopted by existing MDCG WG CIE
    ii. Develop specific criteria & maintain a list of devices fitting in the pre-specified criteria
    iii. Rapid publication of decisions

Notified Bodies are working to harmonise the timelines for notified bodies processes in introducing clock stops.
Moreover, the recently adopted new version of the Team-NB Code of Conduct (version 5.0) is stating steps and duration, aiming at increased predictability.

2. Governance

Notified bodies recognize the specific needs of the medical devices and in-vitro medical devices sector. The set up of a MDCG structure to support the practical application and technical coordination of the system would be an asset. We are in favour a governance structure that is properly staffed and has the relevant expertise available, order to be able to execute all the tasks in their remit.

a. MDCG structure will be able to develop MDCG guidance documents within a reasonable timeframe.
b. MDCG structure should also be available to coordinate the drafting of Common Specifications, especially in the clinical area in cooperation with expert panels and clinical experts among the notified bodies.
c. They could also provide certain administrative functions.

In parallel, some additional structures could be established or developed, such as

a. a secretariat for Member States' joint activities in the framework of the Competent Authorities for Medical Devices (CAMD) network
b. the existing Notified Body Coordination Group (NBCG-Med) Technical secretariat funded by EU4Health should be developed to help with stating more focused documents to help notified bodies in their harmonisation. These papers should be quickly processed and published, leading to more transparency and predictability

Notified bodies are in favour of establishing in the new MDCG structure a working group dedicated to "Special Pathways", consisting of representatives from Competent Authorities. This working group will be tasked with decisions for devices for which there is a 'gap' between the clinical data required by MDR/IVDR and the clinical data the manufacturer can provide pre-market, e.g. devices for special populations and innovative devices. For these devices, notified bodies perform conformity assessment activities, but do not issue a certificate. Instead, they draft a pre-certification report with an analysis of which data are missing for full MDR/IVDR compliance, and a recommendation how these data gaps could be filled post-market (e.g. PMCF, PMPF). The MDCG "Special Pathways" working group will review the "Notified Body Pre-certification Report" (working title), including potential amendments of NB's suggestions for post-market data-collection, and issue a binding opinion. Each Member State has the right to appoint one member and one alternate to the MDCG "Special Pathways" WG. Voting will be according to the voting rules for MDCG stipulated in MDR art 103.4.

i. We see as an option to have two MDCG "Special Pathways" working group members prepare the binding opinions (analogous to CHMP working structure with Rapporteur and Co-rapporteur)
ii. We see as an option to invite the notified bodie(s) who have been involved in the "Notified Body Pre-certification Report", as observer(s). Notified bodies could have no voting rights.
iii. Once the MDCG working group "Special Pathways" has issued binding opinion(s), Common Specifications should be developed
iv. Once a Common Specification is drafted, applications for subsequent devices covered by the Common Specification will processed by a notified body.
v. In parallel, of expert panels could be involved.

Notified bodies are in favour of maintaining re-certification process of medical devices e.g., 5-years with a decision if the certificate can still be maintained but we are proposing to clarify that re-certification decision should be based an overview focusing on new aspects, safety aspects linked to post-market surveillance, vigilance and market surveillance and proportionate to the class of the risk (rather than a full repetition of the initial assessment). This will ensure continuous adoption of state of the art requirements without adding unnecessary burdensome administrative activities to well established devices with a proven safety

3. Efficiency

Notified bodies are in favour to reduce the administrative burden to the extent necessary, keeping in mind the main goal to assure patient safety. Reporting obligations, validations tasks and inconsistencies in the conformity assessment process should be reviewed to streamline the system and avoid duplication of work.
Consistent application of MDCG voting rules cf. MDR art 103.4, applicable for IVDR as well cf. IVDR art 98 could add to efficiency as well.

Notified bodies consider digitalisation as a process to achieve more efficiency. This includes e.g. the change from document to data assessment.as it will decrease duplicate review of data, streamline the process and allow reduction intime and costs. It is also a good path to prepare for application of Artificial Intelligence. In addition, it could lead to better preparation of manufacturers, as it can help for to obtain the consistent data to meet the requirements to achieve certification.

Notified bodies are supporting a process to allow early scientific advice to manufacturers following clear rules, complementing 'structured dialogue', without the risk of advice becoming consultancy. The process could include below steps:

a. After the receipt of an application from a manufacturer for early scientific advice, the notified body will draft a pre-advice.
b. New MDCG "Special Pathways" working group (see point 2 Governance above) votes on the pre-advice of the notified body. Only after a positive vote, the notified body will forward the advice to the manufacturer.
c. Before MDCG "Special Pathways" working group will vote, two members (scientific coordinators) of MDCG WG "Special Pathways" will review and, if necessary, amend the pre-advice.
d. If a manufacturer does not have a contract with a notified body, two options:
    i. the manufacturer signs a contract for conformity assessment with the notified body before applying for scientific advice
    ii. the manufacturer requests, together with the application for scientific advice, a declaration of endorsement from the notified body of his signed statement according to MDR Annex XV, Chapter II, art 4.1 (statement that all the GSPRs, except the one investigated in the Clinical Investigation, are fulfilled).
    After the notified body has issued this 'declaration of endorsement' the manufacturer can apply for scientific advice with the notified body.

Notified bodies are also proposing the establishment a Member States' committee for derogations (MDR Article 59 & Article 97, IVDR art 54 & 92) – supported by the new Member States' joint activities/CAMD Secretariat (see point 2 above).

Notified bodies are also emphasising the possibility to improve utilization of technical and scientific expertise and experience residing at notified bodies. It is also proposed to involve notified bodies representatives (e.g. via NBCG-Med with enhanced Technical Secretariat) structurally in relevant MDCG working groups, for technical and practical input.

Team-NB and its Members emphasises they actively support the improvement of the regulatory framework in the medical devices sector in order to meet the legitimate expectations of the Public Health for the well-being of the population.

In case of any further clarification needed, please contact schlemmer@team-nb.org