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Strategic plan for a pan-European centre on medical device metrology

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1. Executive summary

In May 2021 the Medical Device Regulation (MDR) will supersede the Medical Device Directive (MDD). Both, MDD and MDR were developed in order to harmonise the requirements for medical devices in the EU region. While for certain aspects in the cycle of a medical device this was achieved, issues arise for medical devices with a measuring function (MDMF), during the introduction of the devices on the market as well as during the market surveillance. One reason for this, is that aspects not fully covered by the MDR are left at the discretion of individual countries:

MDR, Recital (40): "*Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation.* ***However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation."***

As a consequence, certain countries developed national by-laws that regulate such unclear aspects (e.g. the metrological check of MDMF in operation) and define additional requirements (in form of periodical mandatory metrological checks of such devices), thus leading to a heterogeneous situation and an unclear context for manufacturers, calibration offices and operators of MDMF.

Additionally, MDR demands a coordinated approach towards market surveillance: *"The principle of* ***coordinated exchange and assessment should also apply across other authority activities described in this Regulation …and should be encouraged in the area of market***

surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level*"*.

Contrary to this specific request, no coordinated European approach exists concerning the metrological verification of MDMF as part of market surveillance. This undermines the manufacturers' free access to the market. Furthermore, no established procedure exists to ensure that the metrological requirements imposed by Notified Bodies during the conformity assessment, (when devices are placed on the market), and those imposed by NMIs for metrological checks (as part of market surveillance) are identical or compatible. This undermines the expectation of citizens and device manufacturers that EU legislation is consistent and uniformly applicable.

To correct this unsatisfactory state, we propose a coordinated approach for MDMF metrology by establishing a long-lasting European network for MDMF metrology and in parallel a physical pan-European Centre for Medical Device Metrology (ECMDM). This network will facilitate a platform for regular and standardised exchange between network partners and a broad range of stakeholders: regulating authorities and legislators at the European and national level, device manufacturers, external NMIs, calibration offices, and health-care professionals.

Initially, the network will concentrate on two MDMF: eye tonometers and blood pressure devices and will incorporate five central European countries. Over time, the proposed network will extend its services to different types of MDMF and to different European territories. The planned network and the EMCDM as a physical construct will, for the first time, establish a coordinated approach to MDMF metrology despite varying national regulatory requirements. The centre will become the metrological authority in this field and a service provider for other NMIs and stakeholders. Thus, improved and harmonised metrology services for MDMF will be ensured, with manifold benefits for partners and stakeholders alike.

To ensure the traceability of MDMF, the proposed joint strategy will provide clear and unified guidelines for the metrological verification of such devices. Such a harmonised context will benefit particularly test and verification offices, and manufacturers. Test offices will be enabled to perform their business according to the latest state-of-the-art and ensure a uniform and high-quality metrological service throughout Europe. Manufacturers of new medical devices and distributors will deal with a homogenously developed regulatory situation not only at market introduction but also with respect to market surveillance. They will have access to unified guidelines and to a competent partner for assistance. This is expected to prevent bureaucratic delays and to facilitate faster innovations and shorter times-to-market in this highly dynamic technology segment

2. Legal background

At present, European legislation on medical devices is undergoing a major reorganisation as the existing Medical Devices Directive (MDD, 93/42 EEC) is being replaced by a new Medical Device Regulation (MDR, 2017/745 EEC). While it was planned for the MDR to enter into force on the 26th of May 2020, on the 3rd of April 2020 the European Commission proposed a one-year delay. On the 23rd of April this proposal was adopted by the European Parliament and the Council.

The MDR sets binding, harmonised rules for placing medical device on the market.:

Recital (2): "this Regulation *harmonises the* ***rules for the placing on the market*** *and putting into service of medical devices and their accessories on the Union market*"

The MDR also encourages a coordinated approach towards market surveillance without making specific requirements. This explicit call for a coordinated approach also in market surveillance is new, it was not present in the MDD and is one of the distinctive new features of the MDR:

Recital (80): "***Rules on market surveillance should be included*** *in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures*."

Recital (84): "*The* ***principle of coordinated exchange and assessment*** *should also apply across other authority activities described in this Regulation … and* ***should be encouraged in the area of market surveillance of devices****. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level*".

While the new MDR introduces a wide variety of changes, minimal changes concern metrological aspects of the MDMFs. The requirements continue to be formulated rather vaguely, the only improvement the MDR brings is the reference to appropriate scientific and technical methods.

Annex I, Article 15.1: "*Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient* ***accuracy, precision and stability*** *for their intended purpose, based on* ***appropriate scientific and technical methods****. The limits of accuracy shall be indicated by the manufacturer."* In accordance to the general rules of the Regulation the responsibility to assess "*the conformity of the devices with the metrological requirements*" is assigned to **Notified Bodies** in Article (52) 7b.

Nevertheless, the regulation does not specify what is meant by "appropriate" and which institutions or documents decide what the appropriate scientific and technical methods are. As a consequence, important decisions will continue to be taken subjectively and will vary from country to country.

While MDR was developed to ensure unified regulations in the field of medical devices, the regulation allows EU states to develop their additional national regulations containing additional requirements to the EU legislations.

Recital (40): *"Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation."*

This fact will lead to a heterogeneous European context with respect to aspects not covered by MDR. On one hand, requirements will vary from country to country, on the other hand, conflicting requirements between market introduction and market surveillance will be

introduced. This will create an unclear context for various players in the field of medical devices (e.g. manufacturers, importers, operators of medical devices, calibration offices, etc.).

Whether or not the accuracy, precision and stability of an MDMF in the field, i.e. a device already in professional use by a healthcare provider, is subjected to metrological checks (verifications), is a matter of market surveillance. Hence it is not uniformly regulated by the MDR but governed by national legislation in the member states. Some member states require periodical metrological checks, others do not. In member states where metrological checks of selected MDMFs are required (e.g. Czech Republic, Germany), traceability of all calibrations to national standards is often required. This brings the NMIs into play: both the procedures and the equipment used for the verification for MDMFs must have been approved by an NMI.

A survey performed by the European Association of the NMIs - EURAMET confirmed that medical device metrology is a very heterogeneously developed field. The results showed that in 16 out of 23 responding countries legal metrological requirements exist for medical devices in operation. The survey also showed that the list of medical devices with a measuring function subjected to traceability requirements differs vastly from country to country as more often than not it is determined by the respective financial resources and NMI capabilities rather than by national policy or societal needs. Furthermore, the metrological verifications are performed according to different requirements in different countries (e.g. national guidelines, ISO standards, OIML recommendations, manufacturer specifications).

In the current EU legislation context, two main issues are arising :

- In contrast to the specific request of the MDR, no coordinated approach exists across member states concerning the metrological verification of MDMFs as part of market surveillance.
- In contrast to the spirit and the intentions of the MDR, no established mechanism or procedure exists to ensure that the metrological requirements imposed by the Notified Bodies during the conformity assessment, i.e. when the device is placed on the market, and imposed by the NMIs for metrological checks, i.e. as part of market surveillance in some member states, are identical or at least compatible.

3. The scope of the pan-European centre

A harmonisation of the current metrological context can only be reached by offering all European countries the possibility to work together, develop common requirements and offer all interested parties access to high standard capabilities. In this sense, a European Centre for Medical Device Metrology (ECMDM) will be established. Its main role is to ensure a coordinated approach to MDMF metrology and will play both a provider and a guidance role for interested NMIs and stakeholders. The centre will provide basic and advanced trainings and facilitate access to reliable services at the highest metrological standards for all relevant parties from NMIs to manufacturers, test and calibration offices as well as members of the medical community. While on a short-term (first 5 years), the centre will offer services focused on intraocular pressure metrology and blood pressure metrology, the centre will continue to expand its expertise in a mid- to long-term (10-15 years) to other MDMF (e.g. audiometers, thermometers). The ECMDM will address those MDMFs which are relevant for market surveillance from a metrological point of view (in other words, the devices for which recalibration is relevant and meaningful) and their metrological requirements are predominantly defined by the MDR and not preceded by other EU regulations.

The first steps in this quest were made by the consortium of the EMPIR project inTENSE by establishing a centre for intraocular pressure metrology at CMI premises in Most. This centre has been successfully offering trainings and metrological services (e.g. periodical calibrations, full traceability for most types of eye tonometers, certification of new test devices and testing procedures for new types of eye tonometers) to other European NMIs and their customers (mainly manufacturers of eye tonometers and test devices for eye tonometers as well as test and calibration offices).

In the mid- to long-term, it is intended that the centre will not only concentrate on the market surveillance aspects of medical devices, but will also address the existent discrepancies between the requirements for the MDMFs entering the market and the requirements for those in use and in this way to reach synergic effects in coordinating the conformity assessments and certain aspects of the market surveillance. In this scope, CMI started the process towards becoming a Notified Body under the MDR and it is estimated that by the end of 2022, a notified body office will be established by CMI.

To support the ECDMD, a network for MDMF metrology will be established. The initial core of the network will be composed of NMIs with expertise in intraocular and blood pressure metrology (Czech Republic - CMI, Germany - PTB, Slovakia - SMU, Austria - BEV). In the mid- to long-term, the network will be geographically expanded; the ultimate geographical scope of the network will be determined by the membership pool of EURAMET and WELMEC, but is open to extend beyond the European borders.

The network will have an essential role in devising future strategies for the ECMDM (e.g. prioritising MDMF, developing strategies for achieving a harmonised traceability for the respective MDMF, ensuring a smooth cooperation with stakeholders). To keep up to date with the new development and technologies in the field of medical devices as well as addressing the real needs of the stakeholders this network will be in close contact with all relevant players in the field of medical devices: manufacturers of medical devices, notified bodies, competent authorities, test offices and medical professionals.

4. Creating the network for MDMF metrology

The overarching purpose of the network for MDMF metrology is to provide support and metrological underpinning for the MDR. Specifically, the primary long-term goals are:

1. to coordinate and harmonise the different national approaches towards metrological checks of MDMFs as a part of market surveillance,
2. to work towards harmonised metrological requirements for conformity assessment (responsibility of Notified Bodies) and market surveillance (responsibility of NMIs).

Traceable calibration of medical devices is a promising and rewarding area of metrological activity, but it is not an easy field for newcomers to enter, since competence in the metrological core sector of physical quantities alone is not sufficient. In addition, a fair amount of medical competence and connections into the respective community are required. The network will contribute its medical expertise while the basic physical-quantity metrology could remain at the local NMIs. This way the smaller metrology institutes would get access to at least a share of this market segment. Effective harmonisation of medical device metrology on a European scale requires the collaboration of NMIs in three functional classes:

1. those with an established expertise in the field,
2. emerging institutes aiming to adopt this knowledge and ambitious to become the new leaders in the field and to provide medical device traceability to other institutes in the future,
3. "customer" NMIs required or interested to provide medical device metrology to their country but lacking the resources to develop the complete traceability chain on their own.

In the common network theory, a network consists of nodes and links. Particularly important nodes, i.e. those with a high number of links in general or nodes which are the single-entry point to the network for other smaller nodes, are called hubs.

The **nodes** of the proposed network are:

- The NMIs which are required or interested to provide —directly or indirectly— traceability for MDMFs in their country; this may affect the complete traceability chain or only parts of it;
- All other offices, institutes, laboratories, etc., which are involved in providing metrological services in the MDMF context. This could include state verification offices, accredited calibration laboratories, notified bodies, etc.

The **hubs** of the proposed network are:

- One NMI which hosts and maintains a web-based virtual platform serving as the central gateway for all communication between the network and the outside world of stakeholders (national and international manufacturers, regulatory authorities at the European and national level, external NMIs and calibration offices and health-care professionals, e.g. represented via their professional societies).
- The competence centre(s) for MDMF metrology, i.e. an NMI laboratory which

- has the expertise, the equipment and the resources to provide the *complete* traceability chain for a given medical measurands;
- is able and willing to provide the higher end of that traceability chain to all other network nodes who request that service;
- is capable to develop and validate new measurement/verification procedures and equipment upon stakeholder request; to make those procedures available to calibration offices; to establish a route to make the developed equipment commercially available to calibration offices;
- is capable to assess procedures and/or test equipment developed by other parties, e.g. calibration offices or tonometer manufacturers, with respect to their suitability to be used for metrological checks;
- is actively involved in training and knowledge transfer for the other network nodes, e.g. by temporarily hosting other metrologists as trainees or as external experts, by organising workshops and comparisons, etc.

The **links** between the nodes are:

- Common research projects; Development of Strategic Research Agenda and Road Maps
- Resource sharing (i.e. smart specialisation of capabilities);
- Knowledge transfer; training; best practice guidelines; advice;
- Any customer-provider relationship;
- Any other cooperation.

5. The starting configuration of the network

The first steps in the establishment of the network and of the ECMDM were made during the "inTENSE" project (EMPIR 16RPT03) which started in 2017. During the project, a **competence centre for IOP metrology** was established at the location of CMI, laboratory in the city of Most. This centre comprises all the expertise to provide the complete IOP traceability chain. This centre is not only able to test and verify all existing equipment in the field, but is also capable and available to develop and/or assess new test procedures and the new test devices (transfer standards) in the field of eye tonometry. The services, the trainings and the expertise of this competence centre are available to all European NMIs or calibration offices who are interested to use it.

With the purpose of extending the scope and the size of the network, the core partners initiated in 2019 a second European project "adOSSIG" (EMPIR 18RPT02), concentrating on blood pressure measurements metrology. At the end of this project, a **competence centre for blood pressure metrology** will be established at CMI, laboratory in the city of Brno.

Building on existing work and knowledge, the following starting configuration exists:

Devices: tonometers, sphygmomanometers;

Hubs: CMI as a hub running the web platform;
CMI as a competence centre for tonometers and sphygmomanometers;

Nodes: all NMIs willing and capable to actively contribute to the network's development. At the moment these are BEV (Austria), GUM (Poland), PTB (Germany), SMU (Slovakia), TÜBITAK UME (Turkey), IPQ (Portugal).

The starting phase will end in June 2022 with the ending of the EMPIR project adOSSIG.

6. Mid- to long-term perspective

It is expected that up to ten European NMIs will join the MDMF metrology network before 2025 and define its priorities and commit either to becoming a competence centre/hub or a node in the network. The new discovered hubs will start to build their centres of excellence, while the already established hubs (sphygmomanometry, eye-tonometry) will serve as the pathfinders for the advanced tasks as interlaboratory comparisons in the respective quantities, development of methods for the new techniques (e.g. cuffless digital sphygmomanometers) and the new adjacent measurands and the cooperations with the international organisations like OIML in the development of new guidelines. The network will also liaise with other networks and initiatives in the field of the MDMF (e.g. "The European Metrology Network for traceability in laboratory medicine") in order increase its visibility, expand the pool of stakeholders and most importantly, to promote the uptake of results and knowledge transfer across organisations and sectors.

The fast, regular and constructive dialogue between the members of the network and the stakeholders in the field of medical devices will be supported by creating a dedicated web platform which will be run by the CMI.

To ensure the success of the network, a smooth cooperation between the members of the network, as well as to confirm their commitment, a legal framework between the network partners will be created. Therefore, bylaws will be developed and signed in order to create a long-lasting binding contract between the partners.

On a long-term perspective (the next 15 years) the network will become a true pan-European network, covering the key EU countries from all the regions and having cooperations with NMIs outside the EU as well. It is expected that the scope of the network will be expanded to over ten medical quantities and that minimum five hubs will be established at the end of this period. As a consequence, a pan-European centre for MDMF metrology would have been established. As not many medical quantities can be ensured by a direct traceability to a relevant physical quantity, new approaches (e.g. using the collections of the representative sample signals, the clinically tested "transfer standards") will be employed. Hence, the network will put emphasis on a very close cooperation with academia, notified bodies and manufacturers. At this moment, it is expected that a critical mass will be reached to attract a wide variety of laboratories and experts to tackle the new challenges in the field of medical devices (e.g. emerging new measurands, softwares as medical devices).