MDCG 2022-14

MDCG Position Paper

Transition to the MDR and IVDR

Notified body capacity and availability of medical devices and IVDs

August 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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The MDCG recognises that significant and urgent challenges remain in ensuring sufficient capacity of notified bodies and readiness of manufacturers in order to allow medical devices and *in vitro* diagnostic medical devices to be certified in accordance with the MDR and the IVDR within the transition periods provided for in the Regulations. The data gathered to date indicate that there are multiple causes which require a mix of solutions.

At the EPSCO Council meeting on 14 June 2022, Health Ministers expressed their concerns that these challenges, if left unaddressed, may lead to disruption of supply of devices needed for health systems and patients and may jeopardise the access of innovative medical devices to the European market. Health Ministers called on the MDCG to propose solutions to address immediate challenges as a matter of urgency. The proposed actions outlined in this document are intended to improve the efficiency of application of the regulatory requirements, rather than reducing, avoiding or removing requirements, in particular in relation to safety.

For this purpose, the MDCG lists the following actions to enhance notified body capacity, access to notified bodies and manufacturers' preparedness in order to facilitate transition to the MDR and IVDR and to avoid shortage of medical devices. The MDCG will implement and/or support the implementation of the actions listed in a timely manner, assess the progress and the impact of those actions, and assess whether further actions are needed. To this end, the MDCG counts also on the full commitment of all actors involved, including notified bodies and industry, to implement the actions and provide the data necessary for the monitoring of the market by the MDCG.

Even though the above mentioned challenges are currently more pressing in the area of the MDR, most of the actions listed in this document also apply in the area of the IVDR. Supporting the transition to the MDR and IVDR is a continuous process, which may require adding actions to those listed in this position paper.

- *Increase notified bodies' capacities*

1. The MDCG advises notified bodies to make **use of hybrid audits** where they consider that this would contribute to conducting the conformity assessment in a timely and efficient manner in compliance with the Regulations.

2. In order to avoid unnecessary duplication of work, the MDCG encourages notified bodies to develop a framework for **leveraging evidence, or components thereof, from previous assessments conducted with regard to requirements under the Directives** for the purpose of conformity assessment procedures under the Regulations, provided that duly qualified notified body personnel deem the previous assessments by the same or another notified body valid and properly substantiated also with regard to the MDR/IVDR requirements and the device under assessment. *[actor: NBCG-Med, NBO]*

3. With regard to **'appropriate surveillance' of legacy devices**, the MDCG calls on notified bodies to make full use of the flexibility described already in MDCG 2022-4 on 'appropriate surveillance under Article 120(3) MDR. This includes combining audits under the Directives and the Regulations for 'legacy devices' whose application for MDR/IVDR certification is being reviewed by the notified body; focussing on assessment of compliance with MDR/IVDR requirements instead of surveillance of compliance with Directives' requirements; and also abandoning sampling plans for technical documentation assessments under Directive 93/42/EEC. The MDCG commits to develop

guidance on 'appropriate surveillance' under Article 110(3) IVDR and to update MDCG 2022-4. *[actors: MDCG, NBO]*

4. The MDCG will **review its guidance** with a view to eliminate administrative workload of notified bodies or undue limitations regarding the scope of documentation not required by MDR/IVDR[1]. *[actors: NBCG-Med to identify workload not required by MDR/IVDR; relevant MDCG sub-groups]*

5. The MDCG considers that in the framework of the development of **Eudamed** it should be ensured as soon as possible that notified bodies can upload relevant information **machine-to-machine**. Moreover, generally the MDCG acknowledges that double registrations should be avoided to the extent possible[2]. *[actors: MDCG, Eudamed WG, European Commission]*

6. MDCG calls upon all parties involved to **foster capacity-building** of existing and potential new notified bodies by means of training, coaching and internship activities for their personnel[3]. In addition, notified bodies should **rationalise and streamline internal administrative procedures**, and ensure that proper conformity assessments are carried out in a timely and efficient manner in accordance with the Regulations. [*actors: notified bodies*]

7. The MDCG welcomes the preparation of **Commission Delegated Acts to modify the frequency of complete re-assessments of notified bodies**, based on Article 44(11) MDR and Article 40(11) IVDR. Currently, a complete reassessment with a joint assessment team needs to be carried out 3 years after notification and then every 4th year. According to current planning, 10 re-assessments are due to be launched in 2022, 12 re-assessments in 2023 and 11 re-assessments in 2024. The timing for the first complete re-assessment after notification could be deferred to up to 5 years after notification, while providing certain flexibility as regards the exact timing and addressing re-assessments that have already been launched. It would allow national designating authorities to focus on the assessment of new notified bodies and alleviate notified bodies from being subject to a complete re-assessment in a moment when they need their resources to process high amount of first MDR/IVDR certifications. In order to foster mutual trust in the system, the designating authorities will provide details of the outcome of their monitoring and on-site assessment activities regarding notified bodies to the MDCG and the Commission in their annual reports in accordance with Article 44(12) MDR / Article 40(12) IVDR. *[actors: European Commission, MDCG, NBO]*

8. At the same time, the MDCG calls upon all parties involved in the **assessment, designation and notification of conformity assessment bodies** to continue to make all efforts to **speed up this process**, while preserving the level of requirements to be met by notified bodies under the Regulations. Especially in respect of conformity assessment bodies that are in an advanced stage of assessment, the European Commission, designating authorities and conformity assessment bodies should reduce, where

[1] E.g. review of MDCG 2019-9 rev.1 on SSCP requiring notified bodies to upload SSCP translations in Eudamed within certain deadlines of receiving them from the manufacturer. However, translations are not verified by the notified body. Article 32 MDR/Article 29 IVDR require the notified body "after its evaluation" to upload the SSCP in Eudamed, but do not require to upload also (non-validated) translations. Moreover, review of MDCG 2019-13 on sampling of devices for the assessment of the technical documentation is already planned.

[2] See also MDCG 2020-15, in which members of the MDCG agreed that double registration requirements for actors should be avoided as much as possible.

[3] A call for proposals to increase notified body capacity was launched in the framework of the EU4Health 2022 work programme.

possible, the timing to complete activities in order to allow timely designation of additional notified bodies under MDR and IVDR. *[actors: European Commission, Designating Authorities, Joint Assessment Teams, Conformity Assessment Bodies]*

9. The MDCG will explore means to **add codes to the designation of notified bodies**[4] in a timely manner in accordance with the Regulations. For this purpose, the MDCG will consider the depth of the assessment and possibilities of an expedited process. The MDCG notes that the lifting of conditions or limitations of designations as well as changes within codes should not be considered as extension of the scope of designation. *[actors: European Commission, MDCG, NBO]*

10. The MDCG commits to prioritise actions that are ongoing in the MDCG or its sub-groups, which aim at contributing to enhancing notified body capacity, such as the **revision of section III.6. of MDCG 2019-6 revision 3** regarding the meaning of 'personnel employed by the notified body' referred to in Article 36(1) MDR / Article 32(1) IVDR. *[actors: MDCG and its subgroups]*

11. As regards the **status of MDCG guidance documents**, MDCG reminds that their main objective is to assist economic operators, notified bodies and competent authorities to apply the legal requirements in a harmonised way, providing possible solutions endorsed by the MDCG. Having regard to the status of guidance documents[5], economic operators and notified bodies should be allowed flexibility as to how to demonstrate compliance with legal requirements. Moreover, reasonable time needs to be given to integrate new guidance in the relevant systems and/or to apply them. That means that new guidance should not be applied to ongoing processes or applications already launched by a conformity assessment body for designation and/or a manufacturer for conformity assessment, unless application of such guidance yields increased efficiency of the process.

- *Access to notified bodies*

12. The MDCG reminds notified bodies of their obligation to make their standard fees publicly available (Article 50 MDR / Article 46 IVDR), **taking into account the interests of SMEs** in relation to fees (section 1.2.8 of Annex VII MDR / IVDR). The MDCG also encourages notified bodies that fees published are easy to compare.

13. Moreover, the MDCG calls on notified bodies to develop schemes in order to **allocate capacity for SME manufacturers and first-time applicants** and ensure access of SMEs and first-time applicants to notified bodies for conformity assessment. *[actors: NBCG-Med, MDCG]*

- *Increase preparedness of manufacturers*

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[4] See Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council.

[5] A distinction should be made between different types of guidance documents. For example, MDR/IVDR (e.g. Annex IX, section 2.3) refer to certain MDCG guidance that notified bodies 'shall take into account', e.g. MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation. MDR/IVDR also refer to standard formats for reports of notified bodies containing minimum elements determined by the MDCG (Annex VII, section 4.6, 4th indent), e.g. MDCG 2020-13 Clinical evaluation assessment report template. MDCG guidance concerning the requirements to be met by notified bodies represent the authorities' common understanding of how they will apply those requirements.

14. The MDCG reminds manufacturers of its notice **MDCG 2022-11**[6] calling on manufacturers to ensure timely compliance with MDR requirements. The MDCG also calls on manufacturers to ensure timely compliance with IVDR requirements *as soon as possible, making use of available notified body capacities, and not wait until the end of the transition periods.* The MDCG is committed to supporting the transition to the Regulations and avoid shortage of devices.

15. The MDCG encourages notified bodies and manufacturers to organise **structured dialogues** before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body. Such dialogues should not be considered consultancy service[7]. *[actors: MDCG, NBO]*

16. In order to **increase preparedness of manufacturers**, especially SMEs and first-time applicants, to adapt to the high-level standards set up by the Regulations, the MDCG calls on all parties involved to continue and, where possible, to step up communication with manufacturers by means of webinars, workshops, targeted feedback and informative sessions[8]. E.g. notified bodies are invited to work on common guidelines for manufacturers to assist them in the application phase, including information about typical non-conformities and preparation and content of technical documentation. National authorities are invited to continue to promote awareness and engagement with relevant stakeholders at national level, and to exchange between them best practices about information campaigns[9]. Also industry associations are invited to promote and ensure awareness of economic operators of the legal requirements. *[actors: CAMD, NCAs, NBCG-Med; EU business associations]*

- *Other actions facilitating transition to MDR/IVDR and/or avoiding shortage of devices*

The MDCG considers that, in particular for **safe and effective legacy devices**, including orphan devices, the **complexity of conformity assessments should be reduced and more pragmatism ensured** with regard to the demonstration of compliance with the applicable requirements. For this purpose, the MDCG commits to undertake the following additional actions with highest priority:

17. Provision of **additional guidance to notified bodies and manufacturers** to assist with the practical application of Article 61 MDR (clinical evaluation)[10], and possibly Article 56 IVDR (performance evaluation and clinical evidence), and to make appropriate use of MDCG guidance on clinical evidence for legacy devices[11] and clinical evaluation –

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6 Notice to manufacturers to ensure timely compliance with MDR requirements (MDCG 2022-11).

7 In accordance with Section 1.2.9. of Annex VII to the MDR, the independence and impartiality requirements laid down in Section 1.2. "*in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment*".

8 See call for proposals to increase notified body capacity launched in the framework of the EU4Health 2022 work programme, referred to in footnote 2. See also factsheets on the European Commission website.

9 See also the factsheets in several languages produced for the European Commission's information campaign financed under the EU4Health programme.

10 To be noted that it is the manufacturer that shall specify the level of clinical evidence necessary to demonstrate conformity with the relevant safety and performance requirements, having regard to the characteristics of the device and its intended purpose.

11 MDCG 2020-6 on clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC and 90/385/EEC already clarifies that "*the pre-market and post-market clinical data generated for the purposes of the MDD / AIMDD can be taken into account*" for the first conformity assessment under the MDR. It also states that CE-marked devices under the Directives are "*presumed to have been supported by*

equivalence[12]. In combination with the possibility for notified bodies to issue certificates under conditions[13] or combined with the requirement to carry out PMCF / PMPF studies[14], this action will increase the necessary flexibility to apply the reinforced clinical evidence requirements to devices that have a demonstrable track record of safety. *[actors: MDCG, NBO, CIE, NBCG-Med]*

18. The MDCG acknowledges the specific situation of **'orphan devices'** and will pursue work with a view to providing a definition for 'orphan devices' and suggesting specific guidance or other means of assistance for those products to be able to meet the legal requirements. Sustainable solutions are also needed in the mid- and long-term for orphan devices. [*actors: MDCG TF on orphan devices]*

19. The MDCG urges **medicines authorities to accept and efficiently process consultations by notified bodies regarding medical devices incorporating an ancillary medicinal substance**[15] **and regarding companion diagnostics**. Medicines authorities should ensure that in case of devices already certified following a medicines authority's consultation under MDD/AIMDD[16], an **expedited review** is carried out following the recommendation in MDCG 2020-12[17]. Medicines authorities are invited to support notified bodies in identifying availability of medicines authorities for determined devices. The MDCG calls upon the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) to take action ensuring that the consultation of medicines authorities is carried out in a cost-efficient and timely manner, in particular as regards devices that had undergone the consultation under MDD/AIMDD. [*actors: EMA, HMA]*

Finally, the MDCG recalls that derogations from applicable conformity assessments procedures may be granted by competent authorities only if the use of the device concerned is in the interest of public health, patient safety or patient health. Mechanisms provided in Chapter VII of the Regulations, such as market surveillance measures, may only be applicable for devices for which manufacturers can demonstrate that they have undertaken all reasonable efforts to transition to the Regulations[18]. MDCG will explore the application of such measures and, where relevant, work towards a coordinated, transparent and coherent approach.

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clinical data". It provides practical advice how to establish or update the clinical evaluation plan, to identify and appraise existing clinical data, to generate new clinical data and to analyse the clinical data. Among other things, it is stated that class III and implantable 'legacy' devices should have sufficient data that stems, as a minimum, from studies with potential methodological flaws but where data can still be quantified and acceptability justified (see appendix III of MDCG-2020-6).

12 MDCG 2020-5 on clinical evaluation - equivalence

13 The MDR/IVDR mention the possibility to issue certificates with conditions several times: 'conditions of the certificate's validity', see Annex IX, section 4.9; Annex X, section 4; 'conditions for or limitations to the validity', see Annex XII, chapter II, point 14; 'specific conditions or limitations associated with the certification', see Annex VII, section 4.8).

14 See Article 56(3) MDR / Article 51(3) IVDR.

15 Currently, only 14 medicines authorities seem to accept consultations regarding devices incorporating an ancillary medicinal substance, see Heads of Medicines Agencies: Combination products (hma.eu).

16 This includes consultations of the MHRA when the UK was EU Member State.

17 MDCG 2020-12 states: "*The medicinal products authority may consider the depth of its review given the extent of the changes since the previous consultation under the MDD/AIMDD. It is at the discretion of the medicinal products authority to issue its opinion in less than 210 days. If many elements concerning the substance remain identical, the medicinal products authority is highly recommended to expedite its review.*" (p. 3-4).

18 See also MDCG Notice to manufacturers to ensure timely compliance with MDR requirements (MDCG 2022-11).