EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
**Medical devices, Health Technology Assessment**

# Minutes of the expert groups

Brussels, 13 July 2021

## Minutes

**Meeting of the Medical Devices Coordination Group[1] (MDCG)**
**27/5/2021 and 28/5/2021**

### 1. Opening, adoption of the agenda

COM welcomed participants to the meeting, in virtual format due to the COVID-19 pandemic, noting the milestone of 26 May, date of application of Regulation (EU) 2017/745 (MDR). The Chair thanked MDCG members for the great work that has been achieved so far and noted that work will continue to support an effective implementation.

The agenda was adopted with addition of some AOB points. The minutes of the meeting held on 4-5 March 2021 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

### 2. MDR implementation

The Chair announced that exchange on governance aspects in MDCG will be followed up in a future meeting. COM considers this a very relevant discussion and they reminded of the questions shared with MDCG members prior to the MDCG meeting 4-5 March; MDCG members were reminded that they can provide their comments in writing.

#### 2.1 MDCG Sub-groups Work Programmes – *for endorsement*

MDCG endorsed the Work Programmes for 2021 of MDCG sub-groups Annex XVI, EUDAMED, International Matters and Standards.

MDCG members aim to seek more harmonisation across procedures and a more top down approach in future work programmes development.

#### 2.2 Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

COM introduced the topic of application of MDR requirements to the so called 'legacy devices' and to 'old' devices, i.e. devices that have been placed on the market in accordance with Directive 90/385/EEC or Directive 93/42/EEC prior to 26 May 2021. It was noted that the issue has come up in various MDCG sub-groups or task-forces; questions have been raised by competent authorities and stakeholders. The legal assessment of the Commission services (SANTE B6) was presented and the purpose to ensure an aligned and legally sound approach

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

was reiterated. In essence it was explained that MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices apply to 'legacy devices' to the extent that "corresponding requirements" exist in Directives 90/385/EEC or 93/42/EEC.

The MDR does not apply to devices placed on the market before 26 May 2021 in accordance with Directive 90/385/EEC or Directive 93/42/EEC. The control over those 'old' devices is governed by the relevant provisions of Directives 90/385/EEC and 93/42/EEC.
A number of Member States expressed concerns about a too restrictive interpretation of "corresponding requirements" with regard to 'legacy devices' and considered that the entire chapter VII of the MDR should apply to 'legacy devices', including the requirements on PSUR. One Member State considered that a more narrow interpretation is possible. Some Member States referred to the unfortunate timing of the discussion and the Commission explained the necessity in order to ensure a coordinated approach across MDCG WGs. During the discussion, suggestions for a mitigating approach were made distinguishing between manufacturers' obligations and the involvement of notified bodies.

As regards 'old' devices, no objections were raised regarding the approach outlined by the COM services. However, two Member States highlighted that it should be ensured that incidents regarding 'old' devices can be reported through EUDAMED in order to avoid the use of different vigilance reporting systems, in line with recital 98 of the MDR.

COM took note of the concerns raised by MDCG members. It was agreed that an *ad hoc* Task-Force reporting directly to MDCG should be set up to quickly find a solution that is legally defendable and pragmatic. Member States were invited to nominate participants to the task force within one week from the meeting and to ensure that nominated task force participants represents their MDCG members.

### 2.3 European Medical Device Nomenclature (EMDN)

#### 2.3.1 Update and governance

The EMDN nomenclature was agreed upon by Member States at the last Nomenclature MDCG sub-group meeting of 31 April 2021 and was subsequently published on 5 May 2021. This project was supported by the Italian Ministry of Health and only the Italian version of the EMDN is considered the official. In order to render the English version also official, the European Commission is currently holding a month-long online consultation on the English version until 4 June 2021.The aim is to collect feedback from users and the wider healthcare community on any translation errors and or syntax suggestions. EMDN will be used in the UDI module of EUDAMED but also support transparency to patients and other activities such as post-market surveillance, vigilance, data analysis, market analysis, etc.

MDCG decided for the first two following years that they would welcome a technical report by the Nomenclature MDCG sub-group. The process will be re-evaluated after this period.

COM welcomes nomination of experts / candidates for the validation of EMDN in national languages.

#### 2.3.2 Frequently Asked Questions – *for endorsement*

MDCG endorsed the FAQ document already approved by the Nomenclature MDCG sub-group. Following relevant requests for translations COM informed that this action is currently on-going.

#### 2.3.3 Implant card – "Device types" – *for endorsement*

MDCG endorsed this document which intends to provide a non-exhaustive list of implantable medical 'device types' in order to aid manufacturers in allocating an appropriate term for this requested information within the implant card indication of device types. MDCG subgroups of UDI, CIE and NET have been consulted and this is considered as a living document that will be updated as appropriate with MDCG approval.

### 2.4 UDI

#### 2.4.1 Guidance on the status of appendixes E-I of IMDRF 48 – *for endorsement*

MDCG endorsed this document which intends to provide clarifications as to how certain principles and examples outlined in IMDRF N48 Appendices E-I apply under the MDR/IVDR. The examples provided within the Appendixes are for informative purposes and should not be interpreted as the sole manner for complying with UDI obligations. The document also highlights that certain principles and terminology set out within the IMDRF N48 Appendixes are not applicable under the MDR/IVDR.

#### 2.4.2 Position Paper on the implementation of UDI requirements for contact lenses, spectacle lenses, spectacle frames and ready readers – *for endorsement*

MDCG endorsed this Position Paper confirming and summarising the applicability of UDI requirements to certain eyewear products and related timelines. The allocation of specific UDI assignment rules for certain product types (e.g. eyewear products) has been deemed necessary to ensure relevant regulatory information is captured in EUDAMED, and that disproportionate data entry for certain products is avoided. Whilst a solution is under development by the UDI MDCG sub-group in collaboration with stakeholders and the UDI Issuing Entities, it was deemed necessary to clarify applicable obligations for concerned stakeholder until a solution is concluded.

COM informed that the UDI Helpdesk has been launched to support obligations and requirements introduced by the UDI and to provide information on EMDN. It has a user friendly platform in five languages with content uploaded already; at present most questions received are by manufacturers / consultancies, mainly on labelling.

### 2.5 Implementing acts

Standardisation request: after the positive opinion of the Committee on Standards delivered on 12 March 2021, the Commission Implementing Decision was adopted on 14 April and accepted by CEN and Cenelec on 12 May. A joint work programme is to be submitted by CEN and Cenelec by 28 May. On that basis, two Commission Implementing Decisions for the first publications in the OJEU of references of harmonised standards for the new Regulations are under preparation, with about 10 references for MDR and IVDR, likely by June.

Annex XVI products: a final draft of the common specifications (CS) on products without an intended medical purpose has been agreed by the Task Force of MDCG sub-group on Annex XVI. COM informed that the content and structure of the document has changed, mainly for legal reasons. As compliance with CS provide presumption of conformity with the legal requirements covered by the CS, the relevant MDR requirements must be clearly identified and the CS be formulated in a way that compliance with them is deemed sufficient for compliance with the relevant MDR requirements. So far, this has not been achieved for requirements on clinical evaluation. COM considers that it is a priority to adopt the CS as soon as possible even if they focus at this stage on the application of risk management requirements in order to ensure that the MDR can eventually become applicable to Annex XVI products. COM clarified that the CS can be updated/new CS adopted as soon as the discussions on additional requirements have been concluded. COM also reminded about the legal deadline set out in MDR, 26 May 2021, for adopting the CS. While this date has already passed, the delay should be kept as short as possible. The final draft has been shared for consultation with members and observers of Annex XVI sub-group. MDCG will be consulted afterwards.

Some MDCG members expressed concerns about the classification of certain devices under Annex XVI. COM explained the lack of legal mandate to include reclassification under the Annex XVI CS and referred to the option of a separate implementing act on reclassification of devices (Article 51(3)(b) MDR). Sufficient scientific evidence or data from market surveillance or vigilance is however needed in order to justify a reclassification decision derogating from the classification rules laid down in Annex VIII MDR. COM invited MDCG to collect and submit this kind of information to allow preparation of an implementing act reclassifying certain Article XVI products.

## 3. Notified bodies under MDR/IVDR

### 3.1 MDCG recommendation on the draft designation of a notified body

#### 3.1.1 Final assessment report of the designating authority and draft designation – summary presentation by the competent authority

#### 3.1.2 Final opinion of the joint assessment team – summary presentation by SANTE

#### 3.1.3 MDCG recommendations under Article 39(9) MDR

Following description of the outcome of the relevant joint assessment processes, MDCG issued positive recommendations for the designation of two notified bodies under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified bodies should be designated within the scope proposed by the designating authority.

### 3.2 Joint Assessments Progress Report

COM shared an overview of notified bodies' activities at each stage of the joint assessment/designation process. COM informed that a total of 50 applications for the MDR and 16 for the IVDR are progressing at various stages throughout the joint assessment process. Again, COM encouraged MSs to engage with their notified bodies that have not yet applied, in particular those who plan on applying for the IVDR. In addition, COM informed that it is awaiting submission from MSs of a number of preliminary assessment reports some of which have been outstanding since early 2018. Member States were encouraged to do what is possible to speed up these processes. There have been 47 on-site assessments completed to-date in

addition to 3 preliminary remote assessments completed. A further 6 assessments have been/are currently being scheduled to be conducted over the coming months. The MDCG will be kept informed on the composition of joint assessment teams for individual cases. MSs were reminded to continue their efforts in the review of CAPA plans (as DAs and National Experts) in as timely a manner as possible. At the time of the meeting, a total of 24 notified bodies were notified in NANDO under the Regulations (20 MDR and 4 IVDR).

3.3 Commission Notice 2021/C 8/01 – Follow up on conformity assessment performed by notified bodies in COVID-19 circumstances

During the previous meeting, the inability for notified bodies to carry out on-site audits and the consequent risk for possible delay in certifications and risk of shortages of devices was extensively discussed. Commission Notice 2021/C 8/01 issued earlier in the year provides for the needed flexibility to perform, under certain conditions, temporary extraordinary measures where availability of devise could otherwise be put at risk. Following the agreement at MDCG NBO sub-group, the Commission set up a dedicated CIRCABC workspace to allow Member States to share information on temporary extraordinary measures taken by individual notified bodies. In addition, the MDCG NBO sub-group also agreed on a common template in order to harmonise the approach as requested by Member States. However, no notification has been submitted so far by the Member States. COM welcomed any feedback by MDCG members on notified bodies in their territories and their application of Notice 2021/C 8/01. Some MDCG members reported that although some remote audits took place they are still waiting for feedback by their notified bodies and then will use the template and report back.

3.4 Market readiness; data on notified bodies certifications

COM presented the outcome of the survey on notified bodies 'certifications and applications and compared the replied obtained in May with replies from February this year. A total of 48 notified bodies replied, in particular all notified bodies designated under the Regulations provided their feedback.

Concerning the MDR, it was noted that vast majority of certificates issued under the Directives will expire at the end of the transition period. COM highlighted the need to ensure manufacturers continue to progressively apply, not waiting to get closer to the end of the transition period, it order to prevent possible unmanageable peaks of workload.

Data concerning IVDR show particular concerns since, whilst the number of applications filed seems to increase, only a total of 11 certificates were issued.

3.5 Certification activities according to Article 16 MDR/IVDR

COM introduced this topic which relates to the requirements introduced by Article 16 MDR/IVDR on the quality management system to be established by distributors and importers concerning relabelling and repackaging of devices. The same Article provides for a notified body to certify that the quality management system of the distributor or importer complies with the requirements laid down in the abovementioned Article. Distributors or importers are also required to submit to the relevant competent authorities such a certificate at least 28 days prior to making the relabelled or repackaged device available on the market. COM invited any feedback by MDCG members including any information on potential lack of awareness among distributors and importers, since according to information received, no relevant certificates were issued by notified bodies.

Discussions with MDCG members showed that there is a lot of uncertainty regarding the scope and application of Article 16 among authorities, distributors and other entities. MDCG members stressed the need for a guidance document. MDCG members and COM highlighted that Article 16 MDR should be read in conjunction with recital 37, aiming to regulate in particular 'parallel trade', i.e. sale of devices outside the manufacturers' official distribution chain. COM informed that two separate guidance documents are under preparation. In particular, one document is mainly focused on activities to be performed by notified bodies whilst the other is intended to address distributors and importers. Both drafts are currently at the consultation stage and are expected to be submitted to MDCG for endorsement, after the agreement of NBO WG and MS WG, ideally in the coming weeks.

## 4. Expert Panels update

COM informed on the extensive work that has been done for the opening and operation of expert panels. Two files have been received by the panels at the time of this MDCG meeting. A number of meetings took place to support the launch of the panels and sub-groups and various actions taken to assist their operation: internal workflow documents, expert guidance, Standard Operating Procedures, policy on management of conflict of interest, guidance and instructions for notified bodies and expert training. Preparations for the launch of the IVD panel are also ongoing.

MDCG members expressed concerns for the possibility of extra workload to the panels due to new obligations stemming from the Commission proposal for Health Technology Assessment and the Commission proposal for a reinforced role of EMA in crisis preparedness and management for medicinal products and medical devices. The expressed concerns focused primarily on the possibility to create extra work for the panels adding to their primary tasks stipulated in MDR/IVDR. COM reassured that the two proposals are not assigning new tasks to the panels than those already set out under MDR/IVDR. As regards the HTA proposal, the reference to expert panels is used to define which devices will be subject for joint clinical assessment under the HTA Regulation. It was also clarified that the expert panels' members will not be involved in the HTA processes set out in the HTA Regulation as this regulation sets up its own coordination group of HTA experts for this.

## 5. Eudamed update

COM presented the state of play of the Eudamed development and the roadmap. The planning is under constant review and update. A new version of the Playground is foreseen for July 2021, and the release of the UDI/Device module and Certificate module is foreseen for September 2021 with all key functionalities to allow the use of the modules.

The development of the MIR form for the Vigilance module has started and is at initial stage.

COM mentioned that a set of questions regarding the Eudamed gradual roll-out has been sent via CIRCABC, and reminded that they invited for comments by MDCG members in writing.

COM explained that the setting up of the new CIRCABC work spaces according to MDCG 2021-1 Rev 1 is ongoing and invited the members who did not answer yet, to provide their response to the message sent on 5 May 2021 on nomination of contact points for such work spaces. Training material for the use of CIRCABC will be shared if deemed useful.

## 6. IVDR implementation

6.1 Joint Implementation Plan – *for endorsement*

MDCG endorsed in principle the Joint Implementation Plan for the IVDR acknowledging this is an evolving document/process.

The JIP as examined in previous MDCG meetings identifies a number of essential and high priority actions that should be completed in collaboration between COM and competent authorities of Member States before the date of application of IVDR. It also contributes to a monitoring of compliance of the sector.

Some MDCG members underlined the importance of continued discussions of possible solutions and mitigation measures especially in relation to availability of devices after the date of application.

6.2 Discussion of specific IVDR transition issues

COM recognised the concerns regarding the readiness of the sector in view of the date of application IVDR. The key issues include low notified body capacity and low numbers of applications from manufacturers. Some of these concerns have been transmitted at a higher political level and a relevant discussion will take place at the next Health Ministerial Council (EPSCO) on 15 June.

COM invited MDCG members to reflect on possible actions to address the root causes of insufficient preparedness of the sector and ensure the functioning of the system. Member States exchanged experiences of encouragement of candidate notified body applications and expressed proposals for actions such as guidance on conformity assessment and information campaigns for manufacturers and authorised representatives.

COM proposed to follow up this discussion in a dedicated MDCG meeting in June/July.

6.3 EU Reference Laboratories

COM informed on the updated versions of implementing acts on tasks, criteria and fees. An open public feedback mechanism will follow during July-August; in parallel translations will be launched. A comitology procedure including voting by Member States will follow at a later stage. Other streams of work include processing results from the survey on EURL demand, answering frequent questions from Member States, preparation of the call for application and revision of the landscape of scopes of designation. The new landscape includes 8 categories with subdivisions (groups). It is envisaged to designate laboratories for the entire categories.

## 7. COVID-19 and IVDs

COM informed of ongoing regular exchanges in the context of MDCG IVD group. In addition:

- A notice to manufacturers and authorised representatives on genetic variants was endorsed and published. It will be disseminated in particular to authorised representatives to increase awareness of third country manufacturers of their obligations;
- Common Specifications on tests for professional use – work on technical content is finished, preparing for publication as MDCG guidance and also for adoption as CS

- Common Specifications on self-tests – processing results of stakeholder consultation

List of rapid antigen tests established by Council in Jan 2021, developed by HSC (Health Security Committee), published on JRC Database; https://covid-19-diagnostics.jrc.ec.europa.eu/; collaboration with ECDC for criteria for validation;

The EU Digital COVID-19 Certificate Regulation has been agreed by co-legislators and is to be formally adopted and published soon. Certificates will be issued for vaccinated people, those who have recovered from COVID-19 or those with a negative test result. For tests, PCR or rapid antigen tests in the HSC list will be accepted. Suitability of antibody tests is to be reviewed by COM in 4 months' time.

## 8. AOB

- COM reminded that they are expecting to receive notifications from competent authorities regarding obligations under Articles 111 and 113 MDR on Fees & Penalties;

- COM briefly informed on the COM Proposal for a Regulation laying down harmonised rules on artificial intelligence; MDCG members were invited to liaise at national level with their colleagues who will be following the file to ensure consistent approach;

- COM reminded MDCG members of invitations to the workshop "Scope of the medicines legislation, interplay and classification aspects" organised in the context of the Pharmaceutical Strategy on 1 June 2021 with the participation of pharmaceutical legislation regulators, representatives from authorities responsible for blood, tissues and cells and medical devices regulators;

- Customs Union Agreement with Turkey: the final steps to update the EU-Turkey Customs Union for medical devices, including the signing of an Administrative Arrangement for the transfer of personal data between the European Commission and the Turkish Medicines and Medical Devices Agency, and the Customs Union Joint Committee Statement confirming Turkey's alignment with the MDR, have been concluded. This confirms the continued integration of Turkey to the EU market on medical devices and the facilitation of trade. A similar alignment to enable the continuation of EU-Turkey Customs Union for *in vitro* diagnostic medical devices with the IVDR will follow.

- Mutual Recognition Agreement with Switzerland: in the absence of a deal on the EU-Switzerland Institutional Framework Agreement, a full update of the MRA cannot be considered, including the medical devices chapter. To prevent possible disruptions, the EU proposed to Switzerland a limited modification of the medical devices chapter focusing on transitional provisions for validity of certificates; however, despite consistent efforts and EU readiness to conclude such a transitional arrangement, the proposed modification was not agreed. Therefore, the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland ceased to apply on 26 May 2021. See the press release https://ec.europa.eu/commission/presscorner/detail/en/IP_21_2684 with the information notice to stakeholders.

**Next meeting**

An extra-ordinary MDCG IVD meeting should be organised before the next MDCG meeting which is scheduled for 18 and 19 October 2021.

**List of participants**

**MDCG members:** AT, BE, BG, HR, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HU, IE, IT, LU, LT, LV, MT, NL, PL, PT, RO, SI, SK, SE.

**Observers:** IC, LI, NO, TR.

**Commission:** SANTE B6, SANTE F5, JRC F2, SANTE A4.