EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 10 May, 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) 21-22/3/2022

1. Opening, adoption of the agenda

The Chair welcomed the MDCG members to the meeting and introduced the draft agenda. The draft agenda was endorsed with the addition of the Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 and three AOB items: national measures on safety issues, the Commission proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act) and national measures regarding reprocessing of single-use devices.

The minutes of MDCG meeting of 6 December 2021 were endorsed prior to this meeting through written procedure and published on the Commission's Registry for expert groups.

2. MDCG governance

2.1 Annual Work Programmes MDCG & MDCG sub-groups – *for endorsement*

In the context of the MDCG governance related discussions, the Commission had shared prior to the meeting the annual work programmes (AWPs) of all MDCG sub-groups together with identified new work item proposals (NWIPs) as appropriate for relevant MDCG sub-groups.

All of the above had been previously examined, discussed and endorsed by the respective MDCG sub-groups.

MDCG endorsed the proposals taking into consideration that:

- small adaptations would be required on one of the submitted AWP as regards timelines of a deliverable;
- some work streams like the capacity building for notified bodies, so called orphan devices and significant changes would be directly handled under MDCG and not in the context of any of the sub-groups;
- Overall the AWPs were considered extremely ambitious and priorities should be better linked with available resources and overall be identified in a clearer way;

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

- MDCG asked to ensure that they would always have the opportunity to reflect overall objectives in relation to core priorities like safety and support for innovation while ensuring access to training to facilitate implementation.

The Chair welcomed the input, invited participants to identify work items that could be de-prioritised in case of insufficient resources or lack of available representatives from national competent authorities to engage in the work. The Chair also concluded that this is a first step of improving governance and priority setting and further streamlining will follow.

The Chair also informed that the Commission services are working on the development of an SoP (Standard Operating Procedures) document to map and reflect in a practical way the work of MDCG in the context of governance, procedures and avoid potential duplications.

2.2 Coordination group to support the work of MDCG

A dedicated coordination group (CG) to support the work of MDCG was launched following a relevant MDCG discussion and decision. The CG met two times with the seven MDCG members who volunteered for this task that involves active participation and engagement.

CG reiterated their commitment to stay inclusive and transparent vis-à-vis all MDCG members every step of the way and consider before the end of the year how to encourage a rotation system in order to allow participation of more MDCG members while ensuring agile working methods.

3. Opportunity for financial support relevant for the Medical Devices sector/authorities

3.1 EU4Health

The Commission presented possibilities for financial support under the EU4Health Program for actions of potential interest for MDCG members. One of the proposed action is a Joint Action for the reinforcement of market surveillance – a grant to competent authorities co-financed to 60%. The process was launched and a timeline was shared for the expression of interest. Member States are expected to indicate if they are interested in taking part to the Joint Action by 1 September. An Information day to support Member States in the appointment process is planned for May. The deadline for submission of a possible proposal is 13 January 2023. A dedicated workshop to support the proposal submission is planned for 13-15 September 2022. For other information and opportunities MDCG was invited to regularly monitor https://ec.europa.eu/health/funding/eu4health-2021-2027-vision-healthier-european-union_en?msclkid=fd41dadeb11911ec897d89183671b1cf

3.2 Technical support Instrument (TSI)

The Technical Support Instrument - managed by DG REFORM - was also presented to MDCG. TSI is a tool to provide technical support (technical expertise) to design or implement structural reforms in a tailor-made approach. TSI supports activities such as exchange programmes between the identified authorities or bodies, training activities, etc. Implementation of EU regulatory framework is considered as eligible

to benefit from TSI. To benefit from such support, national authorities will need to indicate the authorities and/or bodies which would need to benefit from the support and submit a proposal outlining the type of support needed. The call for projects is on yearly basis. The Call opens in June and closes by 31 October of the same year. If interested, MDCG members are encouraged to contact the Commission. The submission of requests by each Member State is done through a national coordinating authority who is responsible to filter and prioritise as they see fit and then submit to the Commission. Multi Countries proposals are also possible and encouraged.

Implementation MDR / IVDR

4. Market surveillance and vigilance

4.1 Framework for a European market surveillance programme (EMSP) – *for endorsement*

MDCG endorsed (with some slight modifications agreed in the meeting) a European Market Surveillance Framework (EMSP) Programme developed and endorsed by the Market Surveillance MDCG sub-group.

MDCG recognised that this is a dynamic document meant to facilitate collaboration between national competent authorities and harmonisation of market surveillance activities in the Union; aspects relating to IVDR will be incorporated after its date of application

4.2 Notification of market surveillance measures

Commission presented the differing implications of notifying market surveillance measures under Articles 95 – 98 MDR/Article 90 -93 IVDR (including procedural and potential union-wide implications of measures e.g. Art 95-96 MDR/Article 90-91 IVDR), noting the efforts made to promote harmonised application of articles. Discussions will continue under the Market surveillance subgroup, including in a dedicated task force and monthly teleconferences as relevant.

4.3 The coordination of medical device safety issues

MDCG agreed in principle on a general approach for the coordination on specific cases related to vigilance, safety issues based on a concept paper developed by three MDGC members (IE-FR-SE). It was concluded that cooperation and coordination between national competent authorities in this area, especially in relation to high profile safety cases with European impact is essential. The important role of MDCG in vigilance coordination as well as of the MDCG sub-groups on Market Surveillance and on Post-market Surveillance and Vigilance was underlined and competent authorities were invited to ensure dedicated resources at national and EU level.

Based on the input provided in the concept paper and previous discussions, the Commission presented its preliminary reflections on vigilance coordination. The Commission invited MDCG members to nominate contact points for these issues by 8 April. MDCG will be consulted further and the Commission will soon circulate a draft SoP covering vigilance coordination.

4.4 Information on the state of play on the Manufacturer Incident Report (MIR)

The Commission informed about the revision of the MIR form as examined and approved by the PMSV sub-group at its meeting on 17-18/3.

5. Notified Bodies under MDR / IVDR

5.1 Capacity of notified bodies

France leading the Task Force on notified bodies' capacity gave an update on the state of play of their work, in cooperation with the Commission. Main activity is currently the market monitoring. The overall objective is to launch surveys with manufactures and notified bodies in parallel and shortly, collection of data to facilitate identification and implementation of appropriate measures.

MDCG was also informed on the establishment of a Task Force under NBO on hybrid audits to agree on a definition and draft a position paper on the possible use of a hybrid approach for notified body audits of quality management systems under MDR/IVDR.

5.2 Availability of national experts

The Commission provided a brief overview on the state of play for the availability of national experts in JAT (Joint Assessments Teams) appointments. Currently, such availability is extremely limited, with the result that the average time required for these appointments has significantly increased over time.

The Commission reminded that joint assessments are a legal obligation shared with the Member States, and that the presence of national experts in JATs is a prerequisite for such assessments which, in turn, are essential for notified bodies (be it their designation or re-assessment). The Commission invited MDCG members to liaise internally with their colleagues and see how to address the situation.

Several delegations requested the Commission to facilitate training of more national experts via their participation as observers in joint assessments. The Commission noted that it remains ready to continue this practice, which has been in place since the start of the joint assessment process.

Some delegations requested the Commission to notify the calendar of assessments as soon as possible, so that national experts can plan their work accordingly. The Commission will submit an indication of the approximate dates when re-assessments could take place (noting that the dates have to be firmed up by the national designating authorities), as this is known given that re-assessments follow a cycle. However, assessments for the designation of notified bodies cannot be planned (much) in advance, as they are organised based on demand (upon receipt of the corresponding preliminary assessment report).

5.3 MDCG recommendation on the draft designation of a notified body

Following description of the outcome of the relevant joint assessment process, MDCG issued a positive recommendation for the designation of a notified body under Article 35(9) of Regulation (EU) 2017/746, according to which the applicant notified body should be designated within the scope proposed by the designating authority.

The Commission also informed about one additional MDCG recommendation under Article 39(9) of Regulation (EU) 2017/745 which will be sent for endorsement via written procedure shortly after the meeting.

5.4 Update on Joint Assessments

The Commission shared an overview of notified bodies' activities at each stage of the joint assessment/designation process and informed that a total of 56 applications for the MDR and 18 for the IVDR are progressing at various stages throughout the joint assessment process. Member States were encouraged to do what is possible to speed up these processes. There have been 56 on-site assessments completed to-date and a number of on-site assessment are scheduled for the coming months. At the time of the meeting, a total of 33 notified bodies were notified in NANDO under the Regulations (27 MDR and 6 IVDR).

6. Exchange of views with NBCG–Med (Notified Bodies Coordination Group)

MDCG initiated a structured interaction with the coordination group of notified bodies for medical devices (MDR Article 49 and IVDR Article 45) – NBCG – Med. At this meeting NBCG-Med had been asked to identify and inform the greatest challenges for certifications. NBCG-Med had identified two main areas that seem to create most challenges for them: application of guidance docs and hybrid audits.

On guidance documents: they noted different interpretations between NCAs (national competent authorities) as well as different expectations; many guidance documents issued for MDR but less for IVDR. NBCG-Med requested some type of consistent EU interpretation and/ or common understanding on application of guidance documents. The Commission reminded about the non-legal status of MDCG guidance and committed to discuss further with MDCG members with the aim of ensuring a common understanding.

On hybrid audits: NBCG-Med informed that in their views these are audits partially performed off-site using ICT while at least one auditor is on site simultaneously and that these hybrid audits comply with MDR/IVDR requirements. According to NBCG-Med they can perform more audits with the same people as they do not have to travel. MDCG requested from NBCG-Med to provide for future meetings an estimation of time saved or number of additional audits performed when using hybrid audits model.

The structured discussion with NBCG-Med will continue in future MDCG meetings.

7. IVDR implementation

7.1 IVDR Joint Implementation Plan

An updated version was presented to MDCG of the Joint Implementation Plan (JIP). The updates mainly concerned the amendment of the IVDR transitional provisions by Regulation 2022/112 and the new NWIPs (new work item proposals), some of them specifically related to the gradual roll-out of the IVDR (e.g. planned guidance on legacy devices). MDCG will be consulted for a week and the updated version of the JIP will be published on the European Commission website for medical devices. [Meanwhile, the updated version of the JIP has been published on the Commission website.]

7.1.1 Guidance on significant changes under Article 110(3) IVDR – state of play

The work is ongoing in a Task Force led by Germany. At present, comments on the draft guidance submitted by NCAs and stakeholders are being processed. A revised version will be submitted to the Task Force with a view to sending the draft guidance to MDCG for endorsement in April.

7.2 EU reference laboratories

Preparation of the implementing acts on EU Reference laboratories' tasks and criteria and on fees is very advanced and ready for submission to the Medical Device Committee (comitology committee). More information regarding the date of the committee meeting and other details will be communicated to MDCG in the following days. [After the MDCG meeting, the date for the comitology committee meeting was set on 26 April 2022.]

7.3 Performance studies that started under IVDD

The Commission informed about an issue discussed in the context of the IVD sub-group as regards performance studies that started before 26 May 2022 under the Directive (IVDD) and will continue after the IVDR's date of application. While the IVDD does not lay down any requirements for authorisation, registration or notification of performance studies, the IVDR has requirements for authorisation or notification of certain performance studies (Article 58). After discussion in the IVD sub-group, the following way forward is proposed which is supported by the MDCG:

Pursuant to the principle of legal certainty that includes the principle of non-retroactivity of rules, the IVDR requirements regarding authorisation or notification of performance studies do not apply to performance studies that have been approved or have started before 26 May 2022 in accordance with the applicable (national) rules, including in cases where no national rules exist.

However, any serious adverse event (SAE) or device deficiencies that may lead to a SAE occurring in a performance study referred to in Article 58 after 26 May 2022, regardless of when the performance study started, should be reported in accordance with Article 76 IVDR. A SAE or device deficiency is a new event that occurs after the entry into application of the IVDR. Its application to those events would therefore have no retroactive effect. Eventually, this approach corresponds to the approach laid down in Article 120(11) MDR for clinical investigations started before 26 May 2021 (i.e. the MDR's date of application). The means to report SAEs and device deficiencies occurring in a performance study in the absence of EUDAMED are to be elaborated in the context of the guidance on technical alternatives to EUDAMED currently under being prepared.

8 MDCG 2019-9 Summary of safety and clinical performance – A guide for manufacturers and notified bodies, Rev. 1 – *for endorsement*

MDCG endorsed the revised version of guidance MDCG 2019-9 in relation to the association of the SSCP with the Basic UDI-DI(s) and adaptation to EUDAMED requirements.

Furthermore, in order to prepare the manufacturers for the requirements of EUDAMED, the manufacturer's internal reference number is added to the template. This reference number will also be asked by EUDAMED.

9 EUDAMED – update on state of play

The Commission presented the state of play of the EUDAMED development and the roadmap.

Currently, the first three modules (Actors, UDI/Device and Notified bodies and Certificate modules) are deployed in Production and still subject to some development, and the last three (Clinical investigation and Performance study, Vigilance and Post market surveillance and Market surveillance modules) are in development and only planned to be released in Playground until EUDAMED full functionality.

The Commission is planning two releases at the end of Q1/2022, one for the first three modules, which will be deployed in Production, and one for all modules, to be deployed in Playground and that will be available for testing and providing feedback. The Commission explained also the scope of such releases. [The releases took place in the beginning of April.]

In addition the Commission gave an overview on the EUDAMED customer service and explained that the next steps will be to close the remaining open requirements as soon as possible and encouraged the members to liaise with their expert colleagues and invite them to test and provide feedback on the new modules. In doing so, the Commission reminded to keep in mind the MVP approach. Documentation will be made available for both the Production and Playground releases.

MDCG raised questions in relation to the time to be provide for feedback on Playground release and support when testing, i.e. have a list of functionalities to test and enough test data, so to give a better feedback. MDCG members also inquired about the planning after the MVP development finalisation, and the functionalities outside MVP scope.

The Commission clarified that the time for feedback will be communicated at the moment of the release to all involved parties, and that some test users with different profiles will be provided to the competent authorities in order for them to create different test data and be able to simulate different scenarios. There will be a release note with the list of functionalities deployed. It was also underlined that the feedback expected relates to the expertise of the authorities in the domain relevant for the specific modules and functionalities to be confirmed or reviewed, if necessary.

As regards the planning after the MVP, it was noted that all resources are focused on the finalisation of the MVP, and that a planning for additional features will be made at a later stage. Commission reminded that after MVP delivery, EUDAMED development will continue and will address other functionalities, which were not included in the MVP scope.

Finally, MDCG was informed about the agreement reached at the meeting of MDCG EUDAMED sub-group of 17 February 2022 on the implementation of the CTIS (Clinical Trial Information System) interoperability after delivery of the Eudamed MVP.

10 Annex XVI MDR - reclassification of certain active devices without an intended medical purpose – for information

The Chair presented the state of play as regards the work in MDCG sub-group of Annex XVI and reclassification. Some members of the subgroup on Annex XVI have expressed concerns regarding the current classification set out in MDR stipulating that certain Annex XVI active products, such as laser or intense pulsed light devices intended for hair removal or skin treatment, liposuction equipment and brain stimulation devices would be classified in the lowest

risk class I. The Commission invited formal requests for reclassification, including justifications, from Member States. The Commission expressed willingness to continue discussions on possible reclassification in the subgroup and consider an implementing act to reclassify those products in the same higher class of analogous devices with a medical purpose based on adequate justifications from Member States.

11 MDCG task force on orphan/niche devices – state of play

Germany, as chair of the task force set up by the MDCG, provided a progress report of the task force's work. The scope of the task force is to collect and analyse information regarding concerns related to the application of MDR and IVDR requirements to certain 'orphan' devices and/or 'niche' devices. This should lead to a detailed problem description with identification of possible root causes and the elaboration of recommendations of possible measures to address the problems with a view to prevent risks for patient safety and public health. For this purpose the term 'orphan device' would need to be clarified and should encompass also 'niche devices'.

Besides many complaints, there is not yet a lot of well substantiated evidence that the new MDR/IVDR requirements are the actual cause for the (planned) discontinuation of devices.

The task force will aim to get a better data basis by reaching out to (European or national) relevant healthcare professionals asking for information about (announced) discontinued devices.

On a preliminary basis, possible root causes could be linked to the following challenges:

(1) to obtain sufficient clinical data for new (orphan or niche) devices but also for legacy (orphan or niche) devices; and

(2) to have a sustainable business also for low volume devices (e.g. with limited number of applications per year for rare diseases or special treatments) when the external (regulatory) costs have significantly increased.

MDCG recognised the complexity and importance of the topic, which should be addressed focussing on patient safety and public health.

12 Expert Panels – state of play – for information

MDCG was updated on the state of play and hand over of expert panels from the European Commission JRC to the European Medicines Agency (EMA). The extended mandate of the Agency (EU) 2022/123 provides EMA with the legal basis for the coordination role for the expert panels on medical devices and in vitro diagnostics.

EMA provided an overview on the provisions of the Regulation (EU) 2022/123 on the extended mandate on the reinforcement of EMA's role in crisis preparedness and management of medicinal products and medical devices that came into effect on the 1st March 2022. EMA provided a background on the status of EMA's coordination on the expert panels and EMA`s preparatory work for the implementation of the Regulation in relation to the monitoring and mitigating shortages of critical medical devices in the context of a public health emergency. EMA presented background information on the status of the roadmap for the handover and highlighted that the secretariat managing the medical devices' panels is fully functional and accepting applications. The members discussed aspects related to the future work of the expert

panels (e.g. scientific advice, consultation on common specifications) and the transparency policy of confidential information in the opinions of the expert panels.
Regarding medical device shortages, EMA highlighted that the establishment of interactions and collaboration with relevant existing groups responsible for medical devices and National Competent Authorities is pivotal for the successful implementation of the Regulation, and subsequent activities. A high-level overview on the preparatory work was provided, including methodological aspects related to the establishment of the list of categories of critical medical devices and the identification of existing data sources.
The importance of the methodological aspects related to the establishment of the list of categories of critical medical devices was discussed with MDCG members. Further details on all activities can be provided at the next MDCG meeting.

13 **Standardisation** – for information

The latest publications in the OJEU took place in January 2022, including the harmonised standards on quality management EN ISO 13485 and on symbols EN ISO 15331-1; the next publication is under preparation, to take place in coming month, including the standard on risk management EN ISO 14971. More publications each three or four months. Also under preparation: amendment to the standardisation request to add and remove some items according to the inputs from CEN and CENELEC; should be completed by Q3 2022.

14 Guidance on borderline between medical devices and medicinal products under (EU) 2017/745

A written endorsement was launched in December 2021, but interrupted since one Member State asked for a discussion in MDCG.

MDCG exchanged views on the draft guidance. Two MDCG members expressed reservations, namely Italy and Germany, while the rest of MDCG wished to proceed with the endorsement. It was agreed that exceptionally a dedicated workshop would be organised as an additional effort to find consensus. The scope of this workshop, to which the involvement of stakeholders was expected, was to define a one year mechanism for enhanced coordination on the usage of this guidance document. The aim of such a mechanism should be that based on input from the stakeholders, notified bodies and regulators' experience coming from the usage of the guidance document, the involved actors exchange views so as to ensure a harmonised understanding of the text. The finalisation of the written procedure for endorsement will be launched after this workshop.

Addendum post meeting: The workshop mentioned above took place on 4 April 2022 and the proposal was meet with broad support. The written endorsement procedure was finalised on 12 April 2022 and the document was endorsed. Italy and Germany maintained their reservations.

15 AOB

15.1 National measures on safety issues

France had requested the addition of this point as an AOB to take the opportunity and inform other MDCG members on national measures taken, further to the recall of ventilators devices by the company Philips, because of potential health risks. French authorities proposed replacement of faulty devices based on a 12 month plan and asked Philips to monitor long term

risks. French authorities will continue monitoring the situation and asked for more coordinated approach at EU level.

MDCG will consider including this topic for further discussion in the context of their regular meetings on coordinated vigilance activities.

15.2 Proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)

The Commission raised as an information point a proposal of 08/02/2022 on a comprehensive set of measures called "European Chips Act" with a fund of around 43 Billion € for strengthening the EU semiconductor production. The legislative proposal focuses primarily on EU's security of supply, resilience and innovation capacity to address recent global semiconductor shortages which had a severe impact on various industrial sectors including medical device production and maintenance. The Commission has also launched a "European Chips Survey" to better know the specific needs of each sector with a deadline for responding of 20 March 2022. MDCG members had previously been informed on the survey and were asked to provide input.

15.3 National measures regarding reprocessing of single-use devices

The Commission thanked Member States who already provided their notifications on national measures on whether they permit or not the reprocessing of single-use devices. The information collected is publicly available on Commission's website National rules on reprocessing of single-use devices | Public Health (europa.eu). In case of any follow up amendments of these national rules they were invited to communicate as well in order to keep updated the published information.

Next meeting

The next MDCG meeting is scheduled for 19-20 May 2022.

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. NBCG-Med (dedicated session)

European Commission and Agencies: SANTE B6, SANTE F5, SANTE A4, JRC F2, and European Medicines Agency (EMA).