EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate D – Consumer, Environmental and Health Technologies
Unit D4. – Health Technology and Cosmetics

Brussels, 31 January 2019

Draft Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 30 November 2018

1) Opening, adoption of the agenda

Agenda was adopted. The agenda item concerning new scientific structures was moved to the next meeting of the MDCG.

2) Adoption of the minutes of the previous meetings

Minutes of 17/7/2018 were endorsed. Minutes from 24/9/2018 (open session with stakeholders), 25/9/2018 (session with Member States), and 11/10/2018 were not yet endorsed, awaiting MS comments

3) Implementation of MDR/IVDR (state of play)

a) Overview

The updated rolling plan was provided to reflect major developments after 25/9/2018:

- notified bodies: the updated data about applications received and joint assessments scheduled have been added. In parallel, this information is made publicly available on Europa website;
- MDCG expert groups: the call for stakeholders has come to an end on 15/11/2018 and the applications will be reviewed in the coming weeks;
- new scientific structures: JRC has completed the consultation of stakeholders and MS and the report is being finalised;
- Nomenclature: the established task-force completed its work earlier this November.

On 25/10/2018, Commissioner Bieńkowska took part in the plenary session of the European Parliament to address an oral question on the implementation of the new Regulations. An extension of the existing traditional periods was not supported by some MEPs.

b) Annex XVI products

In view of the ongoing discussions of MS, public consultation on the draft implementing act has been postponed.

Comments on the draft implementing act received from MS in September have been discussed during two web meetings and one physical meeting on 29/11/2018. Further web meetings will be set the following week and later in order to complete the review of the product-specific annexes. On this basis, a revised text of the implementing act will be drafted. Once the review of product-specific annexes is completed, the draft will be sent for comments to stakeholders.

4) Notified bodies under MDR/IVDR

a) joint assessments - progress report

COM provided updated information on the state of play of the joint assessment process, including:

- the number of applications that COM had received and the overall applied-for scope,
- the number of preliminary assessment reports received,
- the number of on-site assessments carried out/scheduled (also sorted out per week)
- the average number of days elapsing from the submission, at national level, of the notified body's application, to the COM receipt of the preliminary assessment report,
- information on the diverging opinions raised, in particular what they are (both in plain terms and as described in the Best Practice Guide NBOG 2017-01), how many per assessments and the issues at stake, and
- the activities following the on-site assessment completion.

Taking advantage of the fact that an updated list of experts participating in joint assessments has just been uploaded into CIRCABC, COM reminded that there is still a lack of information about the availability of national experts. In particular, this availability has been indicated in relation to less than half of the experts participating in MDR assessments and for around a quarter of the experts participating in IVDR assessments. Hence, COM encouraged again MS to provide the expert's availability for the specific slots allocated to schedule joint assessments.

b) legal requirements for notified bodies – diverging opinions

Following the discussion in the meeting of NBOG on 13/11/2018 on diverging opinions concerning certain requirements for designation of notified bodies, MDCG took the following positions:

- content of the certificate under MDR / IVDR Annex XII, Chapter II, section 10

The suggestion that certificates would not need to include reference to relevant common specifications or harmonised standards as long as such information on all examinations and tests performed is traceable and available from e.g. report(s) which are mentioned in the certificate, was discussed. It was noted that while on the one hand, there is a need for transparency, on the other hand, that it may not be practical to include on the certificate large amount of information which may eventually not be clear to the third parties. MDCG endorsed the proposed position:

Certificates do not need to include reference to relevant common specifications or harmonised standards as long as such information on all examinations and tests performed is traceable and available from e.g. report(s) which are mentioned in the certificate.

In the future, it should be seen how the practice develops and – depending on the class and type of the device, the conformity assessment route and the resulting available documentation – which could be suitable means to address transparency needs.

– voluntary certificate transfer under MDR Article 58 / IVDR Article 53

Two options were presented, with 'Option A' putting emphasis on the recognition of the already issued certificate ('incoming NB *does not need* to carry out new full conformity assessment'), and 'Option B' putting emphasis on the responsibility of the incoming NB ('incoming NB *may decide* not to carry out new full conformity assessment').

A discussion followed.

DK was in support of COM proposal presented at NBOG meeting of 13/11/2018: 'Article 58 establishes the conditions for the agreement to be put in place between the manufacturer and the incoming notified body in case of transfer. As this article does not include any exemption for the conduct of a regular conformity assessment procedure, Article 52 and therefore the relevant requirements set out in the annexes should apply from application to issuing of certificate, including surveillance activities when applicable.' (Document circulated to NBOG on 3/10/2018, Q. 26 'What are the applicable requirements for transfer').

Some MDCG Members supported 'Option A'. The majority supported 'Option B' which has been endorsed:

While MDR Article 58(1) / IVDR Article 53(1) sets out the requirements for a transfer agreement, it does not specify the conformity assessment activities to be performed by the incoming NB. The incoming NB may decide not to carry out full conformity assessment activities according to Article 52 MDR / Article 48 IVDR, as long as it does have sufficient information in respect to the conformity activities performed by the outgoing NB.

For quality management system certificates, the incoming NB needs to perform appropriate on-site audit(s) and assessments to ensure that the manufacturer in question applies the approved QMS and the post-market surveillance plan prior to the issue of any certificate. In respect to the assessment of technical documentations on a sampling basis, the oncoming NB shall review the previous assessment results together with a sample of a technical documentation and draw up or amend a sampling plan. For product certificates (Annex IX Chapter II/Annex X), new certificates without a comprehensive (initial) review may be issued as long as the documentation received does not identify ongoing existing or other concerns.

The incoming NB assumes full responsibility for the new certificates issued following the transfer.

– the meaning of the term "employed" in MDR Article 36(1) / IVDR Article 32(1)

A first discussion of the MDCG on the subject took place. In the absence of a majority support for any of the discussed positions, no decision was taken. The issue will be discussed further in another MDCG meeting.

c) MDCG recommendation on the draft designation of a notified body

The designating authority and COM summarised different steps in the designation process of the notified body. As this was the first discussion on a designation under MDR

it also touched upon procedural issues. Following the discussion, MDCG adopted a recommendation to designate the applicant notified body.

5) UDI

a) update

An update on the state-of-play of different UDI activities was provided by COM.

b) discussion on check digit and maximum length for Basic UDI-DI and possible adoption of MDCG guidance

COM presented the rationale behind the proposed guidance.

Some MDCG members asked more explanations about the concerns of industry on this point.

COM highlighted the importance of this guidance for the quality of the data in the EUDAMED database and indicated that a meeting with industry took place ahead of this MDCG meeting where COM explained to industry the rationale of the requirements and its intention to support issuing entities in ensuring necessary adaptations.

No objection was raised to the guidance.

c) nomenclature: discussion and MDCG views on the report on evaluation of providers

By requiring COM to "make available" a nomenclature, the co-legislator has granted the necessary discretion for COM to choose the nomenclature that it deems to be more appropriate, taking into account the requirements laid down in the Regulations and the needs associated to the functioning of the EUDAMED database and the important function that a medical device nomenclature is deemed to exert in a medical device regulatory system.

COM, in order to exert its faculty with the maximum possible level of knowledge and information and having due regard to the role held by the MDCG under the new Regulations on medical devices, has established, in cooperation with the MDCG, a process comprising the following steps:

1. Establishment of a task-force of MS, operating under the UDI Work Group, supporting COM in information gathering process and evaluation procedure (spring 2017);

2. Adoption of an MDCG document (03/2018), providing a detailed mapping/description of the requirements and criteria for the new nomenclature arising from the new Regulations on medical devices;

3. Evaluation by COM (04/2018), in cooperation with the task-force, of available alternatives/options;

4. Production by the task-force of a report for consideration and discussion by the MDCG (11/2018);

5. MDCG's views (this meeting);

6. Final decision by COM and integration of the new nomenclature in the EUDAMED database (Q1 2019).

The final report produced by the task-force for consideration and discussion by the MDCG was presented by COM. As GMDN and CND stand as the two main options, it was clarified that, for reasons of opportunity, IT and UK did not take part in the evaluation process and in the preparation of the final report.

The first part of the discussion took part at the presence of all MDCG members.

IT and UK explained the reasons for their respective preference for CND and GMDN. EL and PT explained their positive experience with the CND.

For the second part of the discussion, where MDCG members were asked to provide a preference or strong indications on the findings of the report, UK and IT, for reasons of opportunity, did not take part in the discussion. DE, ES, AT, EL, PT expressed a strong preference for CND. IE and FR indicated that, while being in principle ready to accept either of the option, the higher level of international spreading of GMDN should be taken into account. All other members expressed neutrality.

DK asked the reason why SNOMED was not considered for further engagement. COM explained that the task-force judged the SNOMED application much less mature than the others. Moreover, it was estimated that the time to ensure the necessary adaptations of SNOMED for its fitness as EU nomenclature for medical devices would not be compatible with the COM's timelines.

6) Corrigendum to MDR/IVDR

A document for the services of the Council containing the list of all the points has been disseminated prior to the meeting. Following the last written consultation, work has been undertaken to verify whether and which other parts of the two Regulations should be changed to achieve consistency within each text. In addition, some minor changes have been made to parts discussed in the MDCG meeting on 11/10/2018 having pure editorial nature.

DK confirmed its concerns related to the changes made to a transitional provision on the grace period.

EL and PT also indicated some reservations in respect to corrections made to that same provision.

SE expressed reservation as to the changes made to the provision related to the sampling plans of Notified Bodies.

COM highlighted that all points had been agreed unanimously at the meeting of 11 October (with the only exception of the DK) and some new considerations expressed at today's meeting do not facilitate progress on this important file.

COM indicated that, as all points identified received the approval of a very large majority of members, the document will be transmitted in its current version to the Council which will ensure the follow-up. COM also declared its full availability to provide necessary technical clarifications at the bilateral level in a view to clear remaining reservations and facilitate consensus on all points.

7) Registration of MDD devices after May 2020

COM explained that the possible registration obligations for legacy products has been one of the subjects most raised by the operators and competent authorities during the last few months. It is very urgent to provide guidance in this context.

To this purpose, COM presented the results of a first legal analysis.

DE indicated that the views presented by COM are overall acceptable, though they do not believe that legacy products should be recorded in EUDAMED at all.

Other MDCG members recognised the need to deal with this issue but their view is that the availability of information of legacy devices in EUDAMED should not be voluntary, notably looking at vigilance and market surveillance needs.

COM indicated that, based on comments received, it will reflect on next steps. In any event, this issue should be clarified by the next MDCG meeting.

8) Eudamed (update)

A quick presentation on the state of play of the Eudamed implementation was presented by COM. It was first foreseen to have all requirements for Eudamed defined by end of October 2018 but it has been now postponed to April 2019 due to the time it is taking to get a common view and stable requirements for a compliant to the Regulations and workable system.

As an answer to a question, the public website of Eudamed will be delivered in due time for accessing information that will be available in Eudamed and considered as accessible to the public.

9) The standardisation request (the "mandate") to the European Standards Organisations (update)

Following the previous discussions on the draft list of standards for the first standardisation mandate under MDR/IVDR, a draft Commission Implementing Decision has been submitted to the MDCG for comments by the end of the year. The draft follows the ‘blue print’ developed by the horizontal unit in DG GROW for all product sectors. MDCG Members are especially invited to indicate any technical requirements on any specific standards, as requirements could be then added in the annex to the decision.

10) Common specifications under IVDR and CTS under IVDD (update)

The CTS on combined tests have been sent to WTO for comments. The deadline for comments is 15 December, and then the draft will be submitted to a written comitology vote. As soon as we get the approval on the CTS for combined tests we will launch the adoption of the CTS for HIV self-test, for which Member States have received an updated version.

11) AOB

a) media – recent developments

The negative media campaign on the new Regulations launched by different media throughout Europe earlier this week reflects continuous fragility of topics related to public health. Efforts should be made to continue to provide comprehensive information to the public and avoid miscommunication.

b) communication campaign (update)

Recently three new factsheets have been shared with the MDCG. The translations of the factsheets are ongoing. The next factsheet to be drafted will target healthcare professionals and health institutions.

The webpages dedicated to medical devices will be put online in the coming weeks; MDCG members are invited to check the webpages in order to update, complement or correct the information provided.

Banners are developed to be used in meetings A proposal will be sent to MDCG members to order banners for their own use

c) MIR-form – date of application of new version

At the MDCG meeting in March 2018, the new Manufacturer Incident Report (MIR) form has been endorsed as well as a timeframe for its implementation. A transition period of 12 months from the publication on the Europa website (until June 2019) was agreed in order to enable the industry to adapt their internal databases. However, the publication was postponed for 7 months (December 2018) due to difficulties to develop an XML file compatible with the future Eudamed. Therefore, the new date for implementation by the industry would be December 2019, meaning that the MIR form would be implemented only 5 months before the date of application of the MDR. Following the discussions at the Vigilance WG on 8/11/2018, MedTech and EAAR (authorised representatives) sent a position paper explaining the need to align the date of implementation of the MIR form to the date of application of the MDR. However, the MDCG unanimously decided to keep the date of December 2019 to implement the new MIR form.

d) miscellaneous

NL reiterated its invitation to the participants to attend a dedicated meeting on possible Brexit consequences organised by NL on 12 December.

Due to time constraints the participation of CAMD Chair in MDCG meetings was not discussed and it will be addressed in a future meeting.

Next MDCG meeting will take place early 2019, the exact date to be confirmed. Three MDCG meetings are expected in the first half 2019 with five to six meetings in total.

COM reminded of the call for nomination of national experts to MDCG working groups. The documents are available on CIRCABC of the MDCG and should be sent by the end of the year at the latest.

List of participants

No	MDCG Member/ Observer	Institution/Organisation
1.	AT	Federal Ministry of Health and Women's Affairs
		Austrian Federal Office for Safety in Health Care / Austrian Agency for Health and Food Safety (BASG / AGES)
2.	BE	Federal Agency for Medicines and Health Products (AFMPS)
3.	BG	Bulgarian Drug Agency
4.	HR	Agency for Medicinal Products and Medical Devices (HALMED)
5.	CY	Cyprus Medical Devices Competent Authority
6.	DK	Danish Medicines Agency
7.	EE	Estonian Health Board
8.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
9.	FR	National Agency for the Safety of Medicines and Health Products (ANSM), General Directorate for Health, Ministry of Health and Solidarities
10.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
11.	GR	National Organisation for Medicines (EOF)
12.	HU	National Institute of Pharmacy and Nutrition
13.	IE	Health Products Regulatory Authority (HPRA)
14.	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
15.	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
16.	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
17.	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
18.	SK	State Institute for Drug Control
19.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
20.	SE	Medical Products Agency (MPA)
21.	TR	TMMDA – Turkish Medicines and Medical Devices Agency
22.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- JRC
- DG SANTE F5
- DG GROW D4