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, 20 November 2018

Minutes

Meeting of the MDCG and stakeholders
Brussels, 24 September 2018

1) Opening, adoption of the agenda

2) Objectives of the meeting

MDCG met with the representatives of the competent authorities and the stakeholders to present the progress of the ongoing implementation work with regard to Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR).

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

(a) Overview

COM presented an Excel file listing various implementation measures for MDR/IVDR (implementation rolling plan). It lists 24 actions including NBs, Annex XVI, reprocessing of single-use devices, scientific bodies, helpdesk for Eudamed once launched, communication campaign, MDR governance.

The document will be made public this week on COM webpage on MD. The listing is intended to be updated on quarterly basis. It is a description of the essential tasks that are primarily under the responsibility of COM. It complements the CAMD Roadmap for which COM remains involved, in particular in the context of the Implementation and Transitional Task-Force.

(b) Reprocessing of single use devices

The results of the informal consultation were presented at the last MDCG. Positions of the main stakeholders consulted (six answers were received): five were mainly positive and asking even for stricter requirements, and one considered that the requirements were too strict. The draft Implementing Act is actually under internal revision with COM legal service before launching the inter-services consultation.

(c) Annex XVI products

A first draft text for the Implementing Regulation (IR) on Annex XVI products has been finalised by COM in collaboration with MS. The text will be published for informal consultation of stakeholders with a deadline of about 4 weeks to send comments. All comments received will be reviewed jointly by COM and MS. The informal consultation on the draft will be accompanied by a Q&A document explaining the structure and content of the draft IR, aimed at supporting stakeholders in providing their feedback. Taking into account the timelines for the application of the MDR and the time needed by notified bodies to carry out certification of Annex XVI products, the procedure for the

official adoption of the IR should start early 2019 and will include the public formal consultation stage.

With regard to the structure of the text, the articles include horizontal requirements (applicable to all or at least to five out of the six product groups referred to in Annex XVI) whilst product-specific requirements are listed in the six individual Annexes to the IR. For operational reasons, provisions applicable to Annex XVI products have been identified in three levels:

- Level 1: MDR requirements
- Level 2: Articles of the draft IR
- Level 3: Annexes of the draft IR.

4) Notified bodies designation process under MDR/IVDR

(a) Commission update (SANTE)

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

- the number of applications, deemed complete, received (COM does not avail of information about the total number of applications being processed at national level),
- the overall applied-for scope, with covers the entirety of the codes,
- the number of preliminary assessment reports received, which coincides with the number of on-site assessments carried out/scheduled, and
- the post on-site assessment activities carried out.

In relation to the number of on-site assessments in particular, COM recalled that it had committed, a few months ago, to do its best to ensure that the completion of joint assessments did not become a bottleneck step in the process of designation of conformity assessment bodies. So far, COM can confirm that joint assessments are not being a limiting factor and that, on the contrary, more joint assessments could have been carried out if there had been additional requests. Unfortunately, there were not enough requests and a number of available scheduling slots have been left empty.

MedTech asked what could be the bottleneck in the designation process, given that the rhythm of applications and assessments seem to be below what could have been expected.

COM indicated that it is difficult to pinpoint to specific factors, since this is a systemic issue.

MedTech enquired if any on-site assessments already carried out has concluded that the conformity assessment body concerned was entirely in compliance with the requirements (i.e. that there was no single non-compliance raised).

COM indicated that, so far, each and every on-site assessment has revealed non-compliances, and it must be noted that this is an entirely expected and perfectly acceptable outcome, which is not likely to change.

(b) Industry feedback (MedTech Europe)

MedTech Europe presented concerns of manufacturers about the designation process and the outlook for future NB capacity. All stakeholders are in the same boat, and sufficient NB capacity is essential for the new regulatory system, as intended by COM and Member States. Otherwise, the ability of manufacturers to CE mark most devices is endangered, presenting a risk to health institutions' and healthcare professionals' responsibility to provide continuity of care.

Since the time of Regulation 920/2013, there has been a significant decrease in the number of NBs, leading to chronic capacity shortages. Although many NBs may be working to increase their capacity, this can easily take 1-2 years per new staff member, the range of products needing NB oversight has increased, and some certifications will need more work. Brexit will exacerbate the situation, as it may put in question at least 30% of the NB system's total capacity. Given that the MDR date of application is 14 working months away (30 for IVDR), there may be insufficient time to increase NB capacity to a required level. If correct, this analysis means that there will soon be a bottleneck of certification requests.

MedTech Europe is calling for urgent action, to prevent capacity shortage and, thereby, interruption of supply. Industry is open to any solutions, by relieving NB capacity constraints, by reducing NB workload, or by allowing more time for NB to get designated and develop the needed capacity. Such solutions would be needed also for IVDs, given the expected IVD certification workload. EU-wide approach is needed, because recourse to national derogations (e.g., compassionate use) may be insufficient to address the challenge.

Until such solutions become available, MedTech Europe will continue calling for consideration of a legislative change, e.g., by extending the dates of application, or by amending the 'grace period' to (a) open to a greater range of legacy devices, and (b) reduce dependency on certificates issued under the Directives.

MedTech Europe pointed out that contingency-planning was already flagged as a 'high' priority in the CAMD Implementation Roadmap in November 2017. Member States and COM should give this work maximum possible priority and urgency, and such contingency-planning should be available within the next 3-6 months at the latest.

(c) Notified bodies feedback (NB-Med)

NB-Med presented the results of a survey carried-out by invitations sent to all MDD and AIMD notified bodies through CIRCABC tool. Focus was made on the human resources capacity, number of certificates handled and status of application process for MDR.

37 responses have been received showing capacity of around 4000 FTEs within the responders. Around 70% of the personnel was within NBs that have applied for MDR and were at various stages of the application process.

Extrapolation is made to assume that all NBs were having around 6500 full time equivalents (FTEs) and subcontractors available at the time of the survey. Substantial efforts have been made by NBs over the last five years in increasing the capacity.

Number of the MDD and AIMD certificates issued by responders is summarized and extrapolated to all NBs, which comes to around 32000 certificates. Considering various validity periods, calculation is presented to estimate around 7000 certificates per year to

be handled by all notified bodies. Therefore, any delays in designation process or insufficient number of designated NBs before the date of application of MDR will increase the workload to designated notified bodies and will surely lead to delays in certification process.

Scope of application on the level of MD codes is covered fully, with a minimum of five NBs applied for each code, and with ten NBs for most of the codes. Majority of responders are eager to provide services described in Article 16, Article 17, Annex XVI and for reusable surgical instruments.

Concerns and feedbacks on the application process were shared. The need for tight communication with COM on the gained experience from joint audits, status and progress of diverging opinions as well as the need for improved harmonization between joint audit teams was highlighted. These aspects are particularly critical for keeping the forecasted designation process duration.

Some actions by UK notified bodies in light of Brexit were presented, specifically one merger with organization in another member state and several applications for MDR submitted to other MS.

In response to the questions from the audience, statement was made that presentation reflects the current state of NBs capacity and workload estimations. But no further analysis has been performed in light of increasing amount of tasks under MDR. There is no spare capacity within NBs and additional staff is needed. Considering the increase of the workload by the new Regulations, it is very unlikely that all applications from manufacturers can be processed on time.

5) Corrigendum to MDR/IVDR

The scope of the corrigendum under preparation by the Council and the process for its adoption was outlined and discussed.

COM highlighted that Council services are exploring the possibility to conclude the exercise by end 2018. COM thanked stakeholders for their continuous contribution and input to the process.

6) New scientific bodies (JRC)

The JRC presented the key findings from the surveys on expert panels and European Reference Laboratories, focusing on the expected workload and landscape for both scientific bodies. It was noted that the response especially from Member States was poor (9 out of 28). Also only few notified bodies replied to the survey. While for the workload of EURLs reasonable estimates could be derived, additional efforts will be undertaken by JRC to obtain further data from notified bodies. The few data available so far indicate that the workload to be expected for the expert panel in the framework of the CECP is higher than previously estimated (cf. Scoping Report). The highest workload is expected for devices in the fields of cardiology, orthopaedics and neurology. But also the need for panels in the fields of endocrinology, gynaecology, gastroenterology & urology and surgical disciplines appeared to be higher than expected from earlier discussions.

The main findings for EURLs were that responders to the survey were of the opinion that a candidate EURL could candidate and be designated for more than one area of competence and that more than one EURL should be designated for a specific area of competence. However, while it is necessary to ensure a sufficient laboratory capacity, a

majority of the responders are in favour of limiting the number of EURLs in order to efficiently manage the EURL network, to keep the highest possible level of expertise and to match the limited market demand. The grouping of the EURL competences in areas is still under debate and a pragmatic approach needs to be developed.

MedTech Europe enquired whether products falling under the scope of Art. 54 can be certified under the MDR after the first NB has been designated if expert panels have not yet been designated. It was clarified that this is not possible but devices may continue to be placed on the market under the MDD during the transitional period. After the date of application, the NB must follow its obligations as per Article 54 as part of the certification process. The same applies for the EURLs.

7) Eudamed (state of play)

COM presented state of play as regards implementation of Eudamed (see PowerPoint presentation MDR Eudamed – State of Play – MDCG with Stakeholders 24.9 2018 (6_MDCG_Eudamed_State_Play_Stakeholders_20180924.pptx).

The Eudamed team is currently working on the 6 modules of Eudamed in parallel (Actor, UDI/Device, NB & Certificate, Clinical Investigation/Performance Study, Vigilance and Market Surveillance).

The Actor module is well advanced in its implementation and UDI/Device module has well progressed in its implementation, as analysis for NB & Certificate module is well advanced. It remains still much work to do for the other modules, but analysis for all of them have well progressed.

The main milestones for the Eudamed implementation are still considered within the timing requirements of the Medical Device Regulation.

COCIR: Do we know if the IT infrastructure will be able to cope with the huge amount of data to be uploaded? COM: The capacity of the IT infrastructure will have to be aligned with the needs. Stress testing and capacity analysis will be done to properly scale the Eudamed database capacity.

ESC: transparency will be crucial, especially as regards clinical evaluation reports; will healthcare professionals and patients be involved in testing? COM: yes, if you mean the Summary of Safety and (Clinical) Performance (SS(C)P), it will be publicly available and attached to the Basic UDI-DI in Eudamed. For the testing, it has to be analysed what could be possible, because it concerns the public website that we cannot open for accessibility from the Internet for test. Otherwise, in general all kinds of users could be accepted, but only for a very limited number of persons.

EAAR: possible problem with capacity at National Competent Authority level for validating quickly enough the economic operators' registrations in Eudamed, especially with non-EU manufacturer. The process must be known and harmonised between Member States enough time in advance. COM: yes it is indeed important and COM will implement some features in Eudamed for facilitating this process.

MedTech: ask for the URL that they could use for indicating where the SS(C)P can be found on the public site of Eudamed. COM: hope to have this information in October but since it is important the URL must remain stable even after a change of the COM structure (like the one that will come in 2019 after the EU elections), it could take more time because higher level and heavier procedure are required for getting a confirmation.

Vigilance data access to public: at the moment only the Field Safety Notice (FSN) will be available to the public as required by the MDR; other information could be for the public but it is still under discussion.

8) UDI (state of play)

The governance of the current work on device identification and traceability was presented. It was indicated that three task-forces have been stablished under the UDI WG, notably on UDI guidance, nomenclature and implant cards.

COM outlined the implementation progress, in particular in relation to the 5 new UDI guidelines recently submitted to the MDCG for endorsement. These cover rules for systems and procedure packs, UDI related obligations arising from Article 16, considerations on language issues, rules on software.

On nomenclature, COM highlighted that the task-force on nomenclature is currently reviewing some detailed proposals elaborated by those providers that have spontaneously shown their interest to be designated as future EU nomenclatures. The deadline for designations remains end of 2018/beginning 2019.

COM also mentioned that work has been undertaken to build up a UDI helpdesk. The objective is to make this helpdesk operational as from Q3 2019.

EU is chairing in IMDRF the WG on UDI. An update on the ongoing work and planning was provided. It was indicated that the next meeting of this WG is foreseen in October in Washington DC.

9) The standardisation request (the "mandate") to the European Standards Organisations (state of play)

COM outlined the process for the alignment of standards to MDR/IVDR, including the process for putting in place a new standardisation request to the European Standardisation Organisations – the so called ‘mandate’. COM reiterated the steps taken so far with regard to preparation of the mandate, and the next steps to follow.

As regards the first standardisation request to be prepared under MDR/IVDR, the outcome of the consultations carried out in the recent months reflects a need for prioritisation of standards, taking into account the importance of respective standards for the sector, the timelines for the application of MDR/IVDR, and the resources available to all actors. Such prioritisation approach implies selection of priority standards for the first mandate, whereby other relevant standards could be included in any subsequent mandates. The first mandate needs to include very few standards of key importance for the industry, which should be available for the starting date of the application of MDR, i.e. 26/5/2020: 13485 QMS (Quality Management System), 14155 GMP (Good Clinical Practice), 14971 (risk management), 15223/15986 (symbols). In addition, the first mandate should include some important standard families which could be aligned progressively over the coming years: biological evaluation, sterilisation, horizontal standards for medical electrical equipment.

CEN/CENELEC emphasised the need to be consulted on the draft standardisation mandate as soon as possible, and expressed its readiness to support the process for development of the mandate.

COCIR pointed out to the concerns raised by the stakeholder community with regard to draft standardisation mandate on personal protective equipment (PPE), in particular too strict criteria for development of new standards. Were the mandates in the field of medical devices be drafted on the basis of the same model, similar concerns could arise. In addition, COCIR reiterated the need to solve structural issues in the field of harmonised standards, in order to ensure timely citation in the OJEU of all standards proposed to COM for harmonisation. This even more so, in view of approaching starting date for the application of MDR, when up to date harmonised standards should be available to the sector.

ESC pointed out to the concerns of the healthcare professionals as regards the standardisation in general: standards should not indirectly impose obligations on the users, use of standards should remain voluntary, and healthcare professionals should be involved in development of standards and they should have access to standards while currently access to standards is subject to payment of a fee.

10) MDCG working groups – call to stakeholders (state of play)

COM presented the envisaged structure of new working groups (WG) which will be included under the 'umbrella' the MDCG. These WG will replace the existing WG established under the Medical Device Directives, some of which are currently separately registered in the Register of Commission Expert Groups and Other Similar Entities. The new WG will be subject to the Commission's horizontal rules on expert groups and the relevant transparency obligations apply.

A call to stakeholders for participation in respective WG of the MDCG in the capacity of observers will be launched soon. COM outlined the application procedure for participation in the WG: selection criteria, application documents, timelines, and where to look for the call (RegExp + COM website on MD).

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

The last version of the CTS on combined tests, prepared after the inter-service consultation, was accepted by the MS. It will be sent to the WTO for a TBT notification. The CTS for HIV self-test will be modified to take into consideration the modifications of the CTS on combined tests; and it will be presented to the next IVD working group on 16/10 for adoption.

Once these two CTS are adopted, the preparation of the implementing act on the Common Specifications for IVDs under the IVDR will start.

12) IMDRF – outcome of Management Committee meeting last week

COM presented a summary of the main outcomes of the CAMD Management Committee (MC) meeting the previous week.

The following points were highlighted:

- The final draft document of the GRRP WG dealing with a review of the GHTF Essential Principles of Safety and Performance of Medical Devices was endorsed following a modification of the definition of risk reduction for which a compromise wording more in line with the new EU legal framework was found.

- The guidance document of the Standardisation WG on how to improve quality of international medical device standards for regulatory use was endorsed for final publication.

- The document on "Definitions for Personalized Medical Devices" focussing on personalised, patient-specific devices including 3D printing was endorsed following an agreement on a modification of the definition of "authorised persons" more in line with the new EU Regulations.

- A new work item on Cybersecurity co-lead by the US and Canada was approved.

- A further extension of the work of the GRRP WG on Medical Device Recognition Requirements and processes aiming at developing criteria for recognition of entities that will perform the review of premarket submissions of medical devices on behalf of Regulatory Authorities was approved.

- An extension of the work of the WG dealing with Personalized Medical Devices to develop recommendations to support a harmonized approach to regulate devices that are manufactured for individual patients was approved.

- In the interest of transparency, the MC agreed to develop a document indicating the implementation of IMDRF documents by member jurisdictions, which will be made publicly available.

- The MC agreed to provide additional clarity regarding the criteria to become an Official Observer and a Management Committee member of the IMDRF.

- The MC agreed the IMDRF will provide a position statement to ISO on the proposed revision of ISO 13485.

- With regard to the MRA with Australia, we were informed that Australia intends to make the MRA operational at the moment when also the new Australian legislation has been put in place.

- There was a workshop on UDI with industry in which the work on progress of the EU-lead UFDI WG was praised.

- With regard to MDSAP, capacity questions of some participating auditing organisations had been noted. MDSAP members wish to have EU on board, but our constrains due to ongoing transition were again explained.

13) Communication campaign (update)

COM outlined the progress of the communication campaign. Six documents have been already made available on COM webpage on MD: one generic factsheet and five documents for MD and IVD manufacturers.

The translation of four of the documents for manufacturers in all EU languages as well as in Arabic, Russian, Chinese and Japanese is ongoing. The translations in EU languages shall be available mid-October.

The new architecture of the webpages on medical devices is under preparation, they should be put online beginning of November. It will be followed by a targeted communication campaign to promote the new webpages.

The second phase of the communication campaign will start by the end of this year, it will consist of new documents targeted at professionals or on some relevant topics. An assistance to offer some support will be put in place for organisation of external events organised by small stakeholders or when MS will be participating.

14) Combination products

(a) Introduction

End of July, some stakeholder organisations approached COM pointing out to the need for guidance in the field. The issue has been included in the CAMD roadmap and it is in the radar of COM and MS competent authorities.

(b) Presentation by European Biopharmaceutical Enterprises/Medicines for Europe

On behalf of the trade-associations (i.e. EBE, EFPIA, AESGP, EuropaBio, Medicines for Europe, MedTech Europe, CPC, IPAC-RS and MedTech & Pharma Platform), which co-signed the letter to DG Grow and DG Santé on the implementation of Article 117 of the Medical Devices Regulation, a presentation was made, outlining the challenges identified by the biopharmaceutical industry in respect of the implementation of Article 117 of the MDR for integral drug-device combination products. The industry proposes a multi-stakeholder workshop to discuss the concerns from the pharmaceutical industry as well as the pragmatic approach outlined in the joint industry letter. COM and the MDCG could set up a working group focusing on integral drug-device combination products.

COM recognises the concerns from the biopharmaceutical industry, but at this early stage of implementation of the new Regulations and pending establishment of the MDCG working groups, a dedicated sub-group working on combination products may not be available. Likewise, the Commission cannot commit to organise a multi-stakeholder workshop. However, there are other events, where the topic of the implementation of Article 117 could be addressed, such the CAMD meeting, or the TOPRA event on 20/11/2018.

15) Update of CIE and Vigilance WGs

A workshop on Periodic Safety Update Report (PSUR) took place in July with extended participation of MS and stakeholders, allowing significant progress on key issues. The new MIR form and its XML file have been tested by industry this summer; publication on Europa expected by end of October as well as of the revised FSN form.

16) AOB

The next MDCG session with stakeholders is expected to take place in the first half 2019.

COM referred to the ongoing Brexit negotiations and explained that a guidance documents concerning industrial products – in which category medical devices fall, explaining the general effects in this sector of a possible cliff edge Brexit was published in January 2019 and is available on COM website.

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.	CZ	Ministry of Health
7.	DK	Danish Medicines Agency
8.	EE	Estonian Health Board
9.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
10.	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
11.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
12.	GR	National Organisation for Medicines (EOF)
13.	HU	National Institute of Pharmacy and Nutrition
14.	IE	Health Products Regulatory Authority (HPRA)
15.	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
16.	LU	Ministère de la Santé - Direction de la Santé
17.	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
18.	NO	Ministry of Health and Care Services
19.	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
20.	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
21.	RO	National Agency for Medicines and Medical Devices (ANMDM)
22.	SK	State Institute for Drug Control

23.	SI	Agency for Medicinal Products and Medical Device (JAZMP)
24.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
25.	SE	Medical Products Agency (MPA)
26.	TR	TMMDA – Turkish Medicines and Medical Devices Agency
27.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Stakeholders:

- AESGP
- APPLIA EUROPE
- BEUC
- CED
- CEN-CENELEC
- COCIR
- CPME
- EAAR
- EBE
- EHIMA
- EPF
- ESC
- EUCOPE
- EUROMCONTACT
- EUROM VI
- FIDE
- GMDN Agency
- HOPE
- Medicines for Europe
- MedPharmPlast Europe
- MedTech Europe
- NB-MED
- TEAM-NB

Commission:

- JRC
- DG SANTE F5
- DG GROW D4