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

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

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Minutes

Meeting of the Medical Device Coordination Group
Brussels, 28 November 2017

1) Nature of the meeting, opening, adoption of the agenda

The new Regulations (EU) 2017/745 on medical devices (MDR) and 2017/746 on *in vitro* medical devices (IVDR) establish, as of 26/11/2017, the Medical Device Coordination Group (MDCG). Its task is to provide advice and assists the Commission and Member States in implementation of both Regulations. On 28/11/2017, the first meeting of the MDCG took place. It was dedicated to organisational aspects of the MDCG and the ongoing implementation work with regard to both Regulations.

The Chair opened the meeting and thanked the experts from the National Competent Authorities for their efforts during the negotiation and for the adoption of the new Regulations and their current engagement in the implementation work. In particular, the activities of the CAMD executive and task-forces on implementation and transition enabled the preparation of a roadmap of activities and a monitoring infrastructure for implementation of the new system.

The agenda was adopted without amendments.

2) MDCG governance

Terms of Reference and Rules of Procedure *(for endorsement)*

In order to make the MDCG fully operational, certain governance documents need to be put in place, namely the Term of Reference (ToR) and the Rules of Procedure (RoP). Mid-August, draft ToR and RoP were sent to MS for comments and new versions were prepared for the meeting, together with the relevant explanations. COM summarised comments and clarifications:

- The MDCG is a 'similar entity' to an expert group, according to the Commission's Horizontal Rules for Expert Groups - [C(2016)3301]. COM reiterated that the Horizontal Rules applied to such a group and that qualification as a 'similar entity' followed from an internal consultation process within the Commission. In the area of public health, the Health Security Committee was an example of Member States forum, which – while mainly tasked with coordination of MS activities in the field of cross-border health threats – was also a 'similar entity' under the Horizontal Rules. In response, DE reiterated its reservations as to whether the MDCG should be subject to the Horizontal Rules, in particular since the agenda of the MDCG work should be set up by the Member States.

- Accordingly, the proposed ToR and RoP were prepared on the basis of templates included in the Horizontal Rules, however taking into account the provisions of

the MDR/IVDR. Some overlap between two documents resulted from those templates, however that was not to their detriment as long as both documents remained consistent with each other.

- The number of members and alternates appointed by each MS does not affect the voting rights, which are one vote per MS. While a consensus is the predominant rule for MDCG positions, in the case of a vote, a simple majority of all appointed members (either under MDR or IVDR setting, as appropriate) would be required for an outcome 'in favour'.

- In practical terms, an observer status of non-EU countries is close to that of a member, as they attend all meeting and participate in discussions. They do not however participate in formulation of MDCG positions, and in particular, they do not participate in voting.

- Stakeholders with an observer status need to be selected and invited to dedicated open sessions of the MDCG.

- ToR and RoP of the MDCG will also apply to any future WGs. In addition, a short document (ToR) will be developed for each WG, to define its tasks and composition. It is not intended to delegate to WGs any 'competences' of the MDCG, but rather any specific 'tasks'/'activities', as the need may be. The structure of WGs, once set up, will be also reflected in the Register.

- ToR/RoP do not pre-define the role and composition of the MDCG coordination group. It remains a possibility, and it will be for MS to agree on this in the next future.

A discussion followed and additional changes to ToR and RoP were introduced:

- DE raised concerns with regard to the provisions on the written procedure, voting rules, and urgency cases for distribution of documents prior to a meeting. DE emphasised that documents for a meeting need to be sent to MS sufficiently early in time, and the 'emergency clause' in point 7(2) RoP needs to be applied in a restrictive way. It was confirmed that in the case of a vote, for MDCG position to be adopted, a simple majority of all appointed members (either under MDR or IVDR setting, as appropriate) need to vote in favour in all cases. Different to the comitology rules, an absence of a vote against, or an absence of an express abstention, could not be regarded as a vote in favour. COM emphasised the need for active participation of MS if the future decision making, in particular in the case of written procedures, such as those concerning recommendations on draft designations of notified bodies that are subject to legal deadlines. For written procedures, in point 9(1) RoP, a reference to point 8 has been added.

- Several MS emphasised the need to hold more than 2 plenary meetings of the MDCG per year, and that extraordinary meetings need to be organised if so requested by MDCG members, when the situation requires. Point 5(1) RoP was amended accordingly, and any such meetings would be convened in consultation with the Chair.

- DE emphasised the need for MS leadership in WGs, to ensure the necessary expertise. COM explained that any co-chairing by COM aimed at overall coordination of the structure and application of the Horizontal Rules, including the rules on transparency.

- Following NL comment, Article 104 MDR was reflected in ToR and RoP, to emphasise that COM is to provide technical, scientific and logistic support to the MDCG.

- Modifications in points 5 and 11 ToR were introduced, to clarify the status of the non-EU countries, who may appoint observers and alternate observers. The 'alternate observer' status would not apply to stakeholders.

- Point 4(2) RoP was aligned with point 6 paragraph 2 of the ToR (i.e., as regards MDCG meetings, stakeholders participate in dedicated open sessions only).

- Following IE comment, a clause on review of RoP was introduced in point 9 ToR.

Following the discussion and additional changes made, the MDCG endorsed ToR and RoP by consensus.

In addition, COM provided clarifications as regards some operational aspects:

- Appointments to MDCG concern physical persons. These appointments take effect as of 26/11/2017 and they will need to be renewed in 3 years' time. Accordingly, for the purpose of CIRCABC communication, personal e-mail addresses, and not mail-box addresses, need to be provided.

- Following endorsement of the RoP, members/alternates and observers/alternate observers from non-EU countries should submit filled-out declarations of interest (DoI) in accordance with the template included in the RoP. DoI will be then published on the Register.

- The MDCG will be published in the Register of Commission expert groups and other similar entities, under the code: X03565, at the Register's website: http://ec.europa.eu/transparency/regexpert/ Agendas, minutes, declarations of interests will be included in the Register.

- A dedicated CIRCABC workspace will become available shortly.

Working Groups structure

Following earlier consultations, an outline of the future structure of workings groups (WG) and clusters was shared with MS prior to the meeting. After the validation by the MDCG, COM intends to launch the process for the establishment of WGs so that the new MDCG governance structure can become fully operational in 2018. In the first place, ToR of WGs will need to be set out, in order to detail their tasks and to define their composition, including the participation of stakeholders.

Following the discussions, MDCG validated the proposed structure of working groups by consensus, with a modification suggested by PT concerning the placement of the Borderline and Classification WG in Cluster C.

3) Implementation of MDR/IVDR

(a) Implementing Acts - state of play

COM updated on the progress made for the most relevant and urgent Implementing Acts.

The Implementing Regulation on the codes to be used for the designation of notified bodies was adopted on 23/11/2017, appeared in the EU Official Journal on the following day, and entered into force on 25/11/2017. Starting from 27/11/2017, notified bodies can apply for designation under MDR/IVDR. COM would have hoped to adopt it even earlier; however the discussion on IVD related issues took more time than expected. Based on this experience, any future consultations on Implementing Acts need to be subject to strict deadlines.

The Implementing Regulation on the application of notified bodies will not to be followed for the time being as the vast majority of notified bodies will have applied by the time when, at best, it could be adopted.

The Implementing Regulation on the reimbursement of costs for joint assessments was put on hold in late spring / early summer due to priorities given to the other urgencies. COM prudently envisages making a few more steps early next year. Pending the adoption of this Implementing Regulation, reimbursement of costs for joint assessments will continue to be made via the Health Programme. This path of financing is open until 2020.

Two further Implementing Regulations, dealing with Reprocessing of single-use medical devices and Devices without a medical purpose listed in Annex XVI of the MDR, are separately discussed on the agenda of the meeting.

MS expressed the wish to obtain a written overview on the various implementing measures.

(b) Implementation at national level

The EU law goes hand-in-hand with national law. Contrary to what is generally assumed, national law has still an important role to play after the shift from the Directives to the Regulations. COM explained the following four basic scenarios:

- cases in which there is an obligation to repeal contradictory and identical national law;

- cases in which there is a possibility to maintain national law which is outside the scope of the EU law (to be assessed on an abstract level, not at the level of individual requirements);

- cases in which there is a possibility to adopt or maintain national law where this is foreseen in the EU law;

- cases where there is an obligation to adopt or maintain national law where this is foreseen in EU law either explicitly or implicitly (by Directive-style provisions).

Hence MS should reflect:

- What is forbidden?

- Amongst what is not forbidden: what is useful to be regulated?

- What is mandatory?

National laws will have to be notified under Directive 2015/1535 to the COM. In addition, COM offers an informal consultation mechanism. Furthermore, COM suggests

establishing a mechanism that exchanges best practices amongst MS, if needed with the help of the COM.

In view of the resource limitations, in particular on the side of COM, DE expressed doubts on the meaningfulness of an early ex-ante screening by the COM, given that SE working document lists more than 60 empowerments for national legislation. COM observed that the vast majority of items listed in the SE working document contain references to national law, but not empowerments for national legislation. SE confirmed. Furthermore, COM observed that an early ex-ante screening reduces the overall workload both for MS and the COM, as national legislation will anyway be scrutinised under Directive 2015/1535.

PT raised doubts that issues of distribution would fall outside the competence of the national legislators. COM confirmed that the Regulations contain some particular provisions giving precise empowerments to MS legislators. However, this rather confirms the general rule that distribution is within the scope of the Regulations whilst it was not under the Directives (N.B.: hence MS need generally to withdraw their legislation on distribution).

4) Eudamed – state of play

COM presented a global overview on the implementation of the future Eudamed describing its purposes, architecture, deadlines, draft implementation plan and state of play and the role of the MDCG in this context, addressing expectations towards the Member States in order to respect the deadlines for the Eudamed implementation.

Member States expressed their concerns in relation to aspects such as functionality, engagement in development, timelines and interactions/development needs for national systems.

COM expressed the same concerns and ensured the Member States of its commitment to work in collaboration with them and to have all the tasks done within the timeline required by the Regulations. COM is aware and agrees that the interoperability of Eudamed with the national systems is a very important functional specification to have for Eudamed, A survey will be launched before end of 2017 to get from the Member States information on their national systems and their expectations towards Eudamed. However, the main concern will first be probably to have a common agreement between all Member States on what functional specifications should be developed for Eudamed and therefore, in order to speed up and facilitate the work of the COM, it would be very good if the Member States can coordinate between each otter to come with a common view within the minimum delay and before 26 May 2018 on what Eudamed should be able to do.

5) Transition to MDR/IVDR

The CAMD, in cooperation with COM, has taken some very important steps to support the implementation work, already ahead of the adoption. In particular, the CAMD has established two task-forces, one on implementation and one on clarification of transitional provisions.

Following two meetings with stakeholders, the CAMD task-force on implementation has finalised the publication of a roadmap of implementation activities which serves as a reference tool for organising and monitoring the implementation work over the next few years.

The transitional task-force has held two positive face-to-face meetings where common understanding on many transitional issues has been reached.

Representatives of IE (on implementation) and DE (on transition) presented the results of each task-force's work so far.

COM invited MS to establish a mechanism for collecting feedback on what works and what does not work with regard to the new Regulations. Collection of such information is a crucial first step for a careful management of the system change. The CAMD task-force working on transitional provisions and COM should be informed about any such feedback.

The draft Q/A paper prepared by the Transitional task-force and disseminated to MDCG members prior to the meeting was endorsed by consensus.

6) Vigilance – Manufacturer Incident Report form *(for endorsement)*

The Vigilance working group revised the Manufacturer Incident Report (MIR) form which is intended for the mandatory reporting of serious incidents by Manufacturers or their authorised representatives to national competent authorities. The MIR form is part of the MEDDEV guidelines on Vigilance and the draft revised MIR form is intended to update the current form.

This major update introduces, in particular, international nomenclatures to standardise the way incidents are reported which will allow the statistical treatment of homogeneous incident data for signal detection and trending purposes.

The draft revised MIR form has also been updated to become compatible with the new Regulations and the future Eudamed. Nevertheless, the revised MIR form is intended to be used already under the current legislation to start collecting incident data before the entry into application of the new Regulations. As presented in the "milestones" document, a transitional period of 12 months between its publication by COM and its entry into use (deadline of June 2019) is foreseen to allow the necessary adaptation of manufacturers' databases.

The draft revised MIR form was unanimously agreed at the Vigilance Working Group of 7/11/2017 by the national competent authorities and the professional organisations representing industry and notified bodies and it has been proposed for endorsement by the MDCG.

DE stressed the need not to introduce duplications and additional labelling or “data-entry” requirements for the reporting of incidents which are not in the MDR and which will be not in the Eudamed. It also expressed the views that, in particular, it would be needed to separate the UDI (a alphanumerical code) into the UDI-DI and UDI-PI or the need to provide the BASIC UDI DI on the incident reports on the registration of the UDI, and raised the extra-burden for industry generated by this comprehensive document. DE emphasised the need for alignment of the MIR form to Eudamed. However other MS recalled that the reporting form was already agreed in the Vigilance WG and therefore confirmed their agreement.

COM underlined that the revised MIR form requires specific information that is requested only for medical devices for which a serious incident occurred, and not for all medical devices registered in Eudamed. Though the revised MIR form has been developed to be in line with the future Eudamed requirements, COM proposed that the

MDCG would assess the opportunity to check again the revised MIR form once the provisions for the UDI and for Eudamed are finalised.

The revised MIR form has been endorsed by the MDCG by consensus.

7) Notified Bodies - guidance on the designation process *(for endorsement)*

As of 26/11/2017, notified bodies may apply for designation under MDR/IVDR. To facilitate the designation process, several technical guidance documents (Best Practice Guides – BPGs) and/or model forms have been discussed in the expert groups and most recently in the CAMD meeting in Tallinn, and they are now proposed for MDCG endorsement:

(a) guidance: designation and notification of conformity assessment bodies;

(b) guidance: information required for conformity assessment body's personnel involved in conformity assessment activities; forms: review of qualification for the authorisation of personnel;

(c) forms: preliminary assessment review MDR/IVDR;

(d) forms: application to be submitted by a conformity assessment bodies when applying for designation under MDR/IVDR;

(e) forms: applied-for scope of designation MDR/IVDR.

Following COM's presentation of respective documents, a discussion followed.

DE pointed out that, prior to endorsement by the MDCG, the guidance document on the competence of conformity assessment body's personnel (point 7.b of the agenda) should be consulted with notified bodies, as indicated in the CAMD meeting few days ago. On the other hand, IE supported the endorsement with no delay of the document by the MDCG, in view of the timelines of the designation process that has just started. In addition, IE pointed out to provisions of the BPG regarding the background education of internal clinicians (section 6.3.1). The provision stating that they should normally qualified physicians should remain while the reference to "alternative holders such as degree in dentistry" should be deleted to avoid potential confusion. UK and SE supported IE comments.

COM emphasised the need for certainty for the operators as regards the qualification criteria forming the basis for the joint assessment, and the urgency of the matter.

DE expressed its concerns as regards the wording of the disclaimer included in the documents, which may lead to confusion amongst applicants and the public and create difficulties for designating authorities.

MDCG endorsed all guidance documents and model forms submitted for the meeting, with the change to the BPG under point 7.b of the agenda, as described above. In the future, the guidance documents may be subject to further discussion/adjustment, as needed.

8) Harmonised standards - alignment to MDR/IVDR

The existing harmonised standards in the field of medical devices need to be aligned to MDR/IVDR. In all cases, a new so called 'Annex Z' will have to be prepared, to explain

the correlation between clauses of the standard and the essential requirements of the new legislation. In some cases, changes to the content of the standards will need to be made in account of the requirements of the new Regulations. This alignment work requires a prior Commission's request to the European Standards Organisations (ESOs) - a so called 'mandate'. Following initial discussions, ESOs propose a relatively broad mandate that covers most of the harmonised standards and which therefore allows for flexibility. On the other hand, the representation of manufacturers has indicated a selection of the standards which should be aligned as a priority in the first stage, with subsequent alignments to follow later in the process. Feedback from a representation of notified bodies is also expected. Member States have received the feedback collected so far, and as a follow up to the meeting, they will be requested for a written feedback on how, in their view, the alignment process should be planned.

9) Corrigendum to MDR/IVDR

COM informed that work on the editorial corrigendum to the two Regulations is to be launched in December. In this respect COM has already taken initiative to inform competent authorities and stakeholders about the process in order to make sure that as many inputs as possible can inform the upcoming review.

10) Scientific structures under MDR/IVDR

The two new Regulations make provisions for the establishment of scientific advisory bodies, namely expert panels and expert laboratories (MDR) and EU reference laboratories (IVDR). They will be entrusted with a range of functions, from the assessment procedures for certain high risk devices to general scientific support to MDCG, COM, MS and also the manufacturers, on matters such as the implementation of the Regulations, common specifications, targeted guidance, standards and identification of emerging safety issues. These structures will have a very important role to play in the successful functioning of the new Regulations and will need to be put in place in the near future.

11) MDR: Common specifications for reprocessing of single-use devices

At the meeting of the (comitology) Committee on Medical Devices on 5/10/2017, draft common specifications were presented. There was a large consensus on the proposal. Subsequently, COM received some comments which have been taken into account when possible, and an updated draft has been shared with MS. DK asked about the basis for a list of non-reprocessable devices introduced in an annex of the implementing act. COM pointed to Article 17(7) MDR, subject to further confirmation.

MS are invited to send any final major comments on the new version by the end of November. Then, COM intends to launch the process for the adoption of this implementing act.

12) MDR: Common specifications for the groups of products without an intended medical purpose / Annex XVI MDR

COM provided an update about the progress made with regard to the two working levels: (horizontal) requirements applicable to all six product groups listed in Annex XVI MDR and product-group specific requirements.

For the horizontal requirements, the evaluation of the second questionnaire collecting the MS feedback is in the process of being evaluated. There seems to be now a clear majority

of MS in favour of all concepts presented in the questionnaire, with the exception of one that the COM does not favour either. Whilst still considering dropping certain concepts for legal or practical reasons, COM sees this as confirmation of its initial draft of 2016 which already contained the majority of the concepts.

For the product group specific requirements, two workshops were held on 24/7/2017 and 4/9/2017. COM provided a cluster of topics based on these workshops. A teleconference on 9/11/2017 prepared further steps and ensured the coverage of all product groups by drafters, with the exception of the contact lenses, for which a leading MS is still needed.

For both horizontal and product-group specific requirements, COM will need to apply a severe legal scrutiny. Article 9(1) and 1(2) MDR are combined. This means that both sets of limitations are cumulatively applicable. Hence there is only a narrow scope for the future Implementing Regulations, while the respective safety issues need to be duly addressed.

UK wondered what will be the scenario if product-group specific requirements are not available in time for all six product groups. COM responded that, whilst it is difficult to prejudge future scenarios, there should not be a situation in which no product-group specific requirements are available for one of the product groups. Due to the workshops of this summer, some very tangible quasi-requirements are already identified for each group. The question is rather how deep these requirements will be.

FR called for a pragmatic approach, listing in the first round requirements for products on which there is already some knowledge, and supplementing other requirements later. COM agreed to this approach.

UK raised the question whether accessories to Annex XVI devices are included in the scope. COM denied this. The possibility to address this clarification in the upcoming corrigendum was mentioned.

13) IVDR: Common specifications under IVDR – update

COM explained that the common specifications (CS) will have an important role to play in the scrutiny mechanism of Class D devices. CS will replace those adopted under the Directive. There are still two Common Technical Specifications (CTS) to be adopted under the Directive. A new version of the "Common technical specifications on requirements for HCV antigen/antibody combined tests and Nucleic Acid Amplification techniques in qualitative HIV assays" has been presented following the request of some MS expressed during the vote by written procedure for its adoption, which took place in the summer.

Member States were invited to send their comments on this new version by 15/12/2017.

14) 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.	CH	Swissmedic – Swiss Agency of Therapeutic Products
5.	CZ	Ministry of Health of the Czech Republic
6.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
7.	DK	Danish Medicines Agency
8.	EE	Estonian Health Board
9.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
10.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
11.	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
12.	GR	National Organisation for Medicines
13.	HR	Agency for Medicinal Products and Medical Devices (HALMED)
14.	HU	National Institute of Pharmacy and Nutrition
15.	IE	Health Products Regulatory Authority (HPRA)
16.	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services
17.	LT	State Healthcare Accreditation Agency under Ministry of Health
18.	LU	Ministère de la Santé - Direction de la Santé
19.	NL	Ministry of Health, Welfare and Sport
20.	NO	Norwegian Directorate of Health
21.	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
22.	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
23.	RO	National Agency for Medicines and Medical Devices (ANMDM)
24.	SE	Medical Products Agency (MPA)
25.	SK	State Institute for Drug Control
26.	SI	Agency for Medicinal Products and Medical Device (JAZMP)
27.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

28.	TR	TMMDA – Turkish Medicines and Medical Devices Agency

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