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, 20.06.2018

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 2 May 2018

1) Opening, adoption of the agenda

The meeting of the representatives of the competent authorities to the MDCG was dedicated to the ongoing implementation work with regard to Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR).

The agenda was adopted without modifications.

2) Adoption of the minutes of the MDCG meeting on 5-6/3/2018

The minutes of the open session of the MDCG with the stakeholders on 5/3/2018 were adopted without modifications. As regards the minutes from the session for the competent authorities on 6/3/2018, ES and IT indicated the requested changes, and DE indicated the parts of the minutes with regard to which DE would provide the modified wording by the end of the week.

NL enquired whether the documents endorsed by MDCG were available at any single location. COM explained that all documents endorsed by the MDCG were available in the 'Guidance' section of the COM's website dedicated to medical devices (https://ec.europa.eu/growth/sectors/medical-devices/guidance_en).

3) Implementation of MDR/IVDR: Implementing Acts (state of play) – update

a) Overview

COM provided an overview of the implementation measures taken so far, the obligatory implementing acts to be adopted, and the ongoing work on implementing acts.

b) Annex XVI products - feedback to the third MS enquiry

COM presented the state of play, emphasising the need to obtain from the Member States first drafts regarding the product group specific requirements by June, to keep the deadline set-up by the legislator. The 'reverse' timing for the process was outlined:

- May 2020 - application date intended by the legislator
- Early Sept 2019 – latest adoption date when combining procedural requirements and the lead-time needed for certification
- Jan 2019 - start of formal adoption procedure (Inter-service consultation, formal public consultation, Committee vote, modifications following Committee vote, translations, transmission to EP and Council, formal adoption by Commission, publication)
- End Dec 2018 - two meetings with MS are planned for evaluation of feed-back from public consultation
- Early Nov 2018 - evaluation of feedback from public consultation
- Mid-Sept 2018 - launch of informal public consultation
- Jul-Aug 2018 - workshops with MS for finalisation of draft product group specific requirements; last workshop of linguistic polishing
- End June 2018 - deadline for submissions of product-group specific requirements by MS' teams
- June 2018 - establishment of requirements for product group I (contact lenses)
- June 2018 - linguistic polishing of horizontal requirements, preferably from MS
- 10/5/2018 - MS' feedback chart planned to be sent to MS

DE puts into doubt that MS' feedback chart reflects the MS' views, the more so as only 10 MS responded.

COM replies that MS' feedback chart is the best guess regarding the MS' majority views and thus the best basis for increasing likelihood of acceptance of future Implementing Regulation. The Commission does not base product-group requirements "on its own wisdom", but, in case of absence of timely contributions by the product-group teams, on the findings of the two workshops held with MS in summer 2017.

FR, DE and ES believe that there is a need for a smooth phasing in.

NL tried to finalise the questionnaire, but found it very difficult. They cannot agree on it and requests an integral text.

ES agrees to the comments of NL and to the remark of DE that 6 month period is too short for the industry.

COM understands the need for operators to adapt. However, the transition period should be determined at the end of the process in the Committee. Subject to the scope of last-minute amendments, more or less transition time will be needed.

c) Reprocessing - update

COM informed the MDCG that an informal consultation of stakeholders is planned before the analysis of the text with the Legal Service.

4) UDI – update on the state-of-play of work

COM presented the work of the two task-forces of UDI guidance and medical device nomenclature, the content of guidance documents published and the next steps.

Next meeting of WG will be on 17/5/2018.

5) Eudamed

a) Draft functional specifications for all modules

b) Draft implementation plan

COM gave an update regarding the state of play for the setting up of the functional specifications and related implementation plan.

As explained, the aim is to have first an implementation plan made by COM to be provided by 26 May.

Main questions and issues raised:

COM needs to have from the COEN templates with details on data to be entered in Eudamed for functional specifications for market surveillance.

The MS members of the Eudamed WGs on clinical investigation, vigilance and market surveillance cannot determine what information should be accessible to the public beside the few ones clearly mentioned as such by the MDR. They consider the MDCG must be involved to determine what can be disclosed to the public.

NL raised the questions whether the implementation plan will be sent to Member States, when the acceptance testing will be done and whether Member States will be involved in this.

COM replied that the implementation plan will be sent to all MDCG members and MDCG members may participate to acceptance testing and will be informed about the acceptance testing 1-3 month in advance. This is planned for September 2018.

IE agreed on three priority models and raised the question if the priorities are still the same and if all three will be included in the first release. IE also wondered whether COM is waiting for further feedback.

ES asked the same questions and stressed that the questions need to be more structured (a questionnaire was mentioned).

DK agreed on the main specifications and expressed some worries about the timing. They questioned the criteria and the timing for the definition of priorities and asked about the definition of audit criteria.

DE expressed similar concerns as DK. The functional specifications are only discussed in the WG, but there are different views. There need to be a forum to make decisions. The basis of the decisions is not clear. DE questioned whether there is a way of having a Eudamed steering group or if the MDCG needs to be involved, considering diverging opinions in this respect.

AT complained about the fact of not being informed or invited for the market surveillance related work.

COM highlighted the priority of complying with the timing. Timing priority "High (1)" applies for the first release to be audited. To agree on the priorities is probably the first challenge. The functional specifications for Eudamed will be ready in time although some aspects will need to be fine-tuned at a later stage. COM needs Member States input to discuss the priorities, which impact directly the implementation plan.

About 100 pages with the current functional specifications exist, which are not drafted in details. If also the details were introduced, it would end up in more than 1000 pages, which would not be manageable. The system is too big to decide all details in the MDCG.

The decision of the WG and COM may not always be in line with each single Member State position.

A Eudamed market surveillance WG was set up a long time ago after sending a call for interest. In the last MDCG meeting it was asked about the involvement of the COEN; however Eudamed was not mentioned in the last COEN meeting.

PT mentioned that they do not have capacity to attend the WG and the Eudamed Steering Group. They can join only the MDCG meetings. It is therefore needed to involve the MDCG more into the decisions for those MS who cannot attend to all TF.

AT mentioned the need to find a solution and asked to update the address-list to include the MS into the contributions. AT likes to contribute, but was not sufficiently informed.

IT agrees to AT and PT positions. IT members are bombarded by questions after the MDCG meetings, which cannot be answered. IT asked to send PowerPoint presentations immediately after the MDCG.

DK believes that it is difficult to manage such a group and it is understandable that the Commission needs to take decisions sometimes. But it was promised that the participants will examine and approve the system. They wondered whether the process can be considered as delayed by 6 months.

PT suggested that COM identifies the main questions and concerns and send them to the MDCG members to find a solution. Member States need to have an active role in the MDCG for the future Eudamed.

COM committed, in light of IT request, to send the PP earlier in the future, i.e. the days immediately after the MDCG. A document will be prepared for reply on the main questions/issues, especially on the public accessibility on data for CI/PS, vigilance and market surveillance. It is clear that not all Member States can be in all ad hoc WG on Eudamed and that therefore the MDCG is the group to contribute at the top level.

There is no delay to the plan. The Commission will provide the implementation plan before 26 May. The whole system will continue to rely on everybody's participation and contribution.

6) The new scientific bodies – next steps

COM gave a presentation on the next steps concerning novel scientific bodies under the new legislation, showing generic and specific pathways towards the establishment of expert panels, expert laboratories and EU reference laboratories. The specific pathway includes elements of a participatory approach involving MS and stakeholders via surveys of Member States competent authorities and stakeholders and in view of gathering data, opinions, proposals, ideas and preference with respect to various aspects of the establishment and operation of the scientific bodies. Stakeholders survey would address industry associations, notified body associations, medical/clinical associations and patient associations; COM asked whether the MDCG had proposals for additional other

stakeholders. The surveys are based on a scoping study providing background to technical/scientific aspects.

COM outlined that there would be two phases with respect to the surveys:

1. MDCG consultation: Initially the MDCG will be consulted regarding the surveys and scoping paper. The purpose of this consultation is to get MDCG views on the completeness, adequacy and clarity of the survey questions on the background of the scoping paper and to amend the surveys where necessary. The draft survey documents and scoping paper will be circulated next week.

2. Actual surveying: Following input by MDCG, the surveys and scoping paper will be circulated amongst MS competent authorities and stakeholders to gather information and views.

COM further highlighted some differences regarding the pathways of establishing expert panels and laboratories (EURLS and expert laboratories) and provided examples of eligibility criteria for all three bodies as well as measurable criteria based on the selection criteria outlined in the Regulations what concerns expert laboratories and EURLs. Further, MDCG members were invited to volunteer for a joint COM/MDCG task force on scientific bodies which would work on solutions to be presented to the MDCG. The first meeting is envisaged in the near future in Ispra.

In the ensuing discussion, DK, FR, DE, NL and PT expressed their interest in joining the task force. NL expressed their wish to share their expertise in particular on expert laboratories, and has already prepared a paper on the topic. FR and DE noted that expert laboratories should be treated as a lower priority. DE pointed out the importance of checking the adequacy of the survey questions prior to distribution. FR and PT noted that expert panels should be phased in gradually, beginning with 1-3 panels in the most high-demand specialities such as cardiology, orthopaedics, neurology. PT noted that it already has national expert laboratories for pharmaceuticals and would be happy to share their expertise. COM agreed with the remarks of the MS and thanked them for their engagement. With regard to the gradual phase-in of panels, COM noted that this is an issue that will be discussed in the Task Force, and that the scope of products classified as class III implantable and class IIb drug delivery and removal devices is wider than the specialities named earlier. In response to a question from PT concerning the relationship of the expert panels under the MDR and IVDR and those to be set up under the upcoming HTA legislation, COM noted that any possible relationship with the work under the HTA proposal is yet to be discussed.

7) HTA legislative proposal

COM gave a presentation on the proposal for a Regulation on health technology assessment (HTA) for medicinal products and medical devices. The proposal is now reviewed by the European Parliament and the Council. The following aspects were addressed: Definition of HTA, the current HTA practices across the EU, background of the HTA initiative, key milestones leading to adoption of the proposal, objectives and expected benefits of the Regulation, HTA cooperation under the proposal with emphasis on MS–driven approach and differentiation between an assessment *vs* appraisal, and finally proposed timelines for the application of the Regulation.

IE pointed out to possible overlaps of the proposal with the new legislative framework on medical devices as regards clinical investigations. COM explained that no such overlaps were intended as the HTA process is performed after the CE marking, but that attention would be paid to it in further works.

8) Joint assessments of notified bodies - state of play

COM presented and update on the joint assessments under the new Regulations. In order to ensure a smooth organisation of joint assessments, COM invited MSs to make use of the available on-site assessment dates with regard to applications which may be under review at national level. COM encouraged MSs to aim at striking the right balance between thoroughness and pragmatism when drawing up the preliminary assessment reports.

The revamped procedure for the appointment of joint assessment teams (JATs) had been already communicated to MS, and no comments were received. Nevertheless, COM took also this opportunity to present the new approach, which aims at increasing the robustness of the appointments (which are fully documented), transparency and clarity in the decision-making process:

- As regards the robustness, a new document is now produced recording the appointment of a JAT (which is added to the already existing recording of the JAT proposal).

- As regards transparency, delegations' objections are discussed with all MDCG members and discussions on delegations' clarifications, which are addressed bilaterally with the MS concerned, are reflected in the document recording the JAT appointment, hence keeping all MDCG members fully informed.

- As regards the decision-making process, COM re-iterated that Consensus remains the default procedure. As recorded in the minutes of the MDCG meeting held on 6 March 2018, if a delegation has objections to a given appointment, the onus in on that very delegation to explicitly request a vote on the matter.

On other matters concerning JATs, COM explained the following:

- The dates of the on-site assessment set out in the document recording the JAT appointment are tentative (as explicitly indicated therein) and provided for information purposes only. Therefore, if there are no changes in the JAT, but the dates of the on-site assessment end up being different, no new documentation will be circulated to the MDCG at that stage.

- The replacement of member(s) of a given JAT, for force majeure reasons (e.g. if an expert does no longer work in a designating authority), results in the production of a new JAT proposal, to which MDCG members will have the opportunity to comment upon (Clarifications/Objections, if any), prior to the issuing of the document recording the JAT appointment.

- In contrast, the addition of further experts to a given JAT (usually these are experts in training) without modifying the core of the JAT results in the corresponding notification of the enlarged JAT to MDCG members, but a new proposal is not made. For the file, such enlargements of the teams are always subject to be discussed with and agreed by the receiving designating authority.

No comments were made by the MDCG members to any of the above issues.

UK pointed out the need for further MDCG discussion on the application of some requirements for notified bodies laid down in the new Regulations, since it seems that joint assessments are already revealing some diverging views between JATs and the designating authorities. DE suggested that these issues could be discussed at technical level and the corresponding fora (i.e. the Joint Assessments Coordination Group and NBOG) with a view to suggest pragmatic solutions. While agreeing with this approach, COM noted that the remaining diverging opinions will have to be resolved, ultimately, at the MDCG level, giving due consideration to the respect of the legal provisions.

NL raised some concerns about the requirements related to the location of notified bodies' staff. COM explained that in accordance with the fundamental freedoms in the internal market, there are no restrictions as regards the location of the staff. However, the legislators laid down specific requirements as to which staff needs to be employed by the notified body, and these requirements have to be respected, taking into account the criteria developed by the Court of Justice.

DK expressed concerns about the number of preliminary assessment reports issued following conformity assessment bodies' applications, which might be a reflection of the complexity of the new requirements for notified bodies laid done by the Regulations. COM pointed out that it is undeniable that the requirements are now much more complex and, therefore, challenging. However, COM reiterated its conviction that the number of preliminary assessment reports reflects also due diligence from the designating authorities, and that the process can be considered on track.

9) Harmonised standards - alignment to MDR/IVDR - progress for the standardisation request to the European Standardisation Organisations

COM provided an update on the development of a standardisation mandate. Further to the outline in the previous MDCG meeting, a list of approx. 240 standards to be covered by the future mandate was compiled, and disseminated to the MDCG through CIRCABC prior to the present meeting. In parallel, the list was informally transmitted to Cen/Cenelec, primarily with a view of verifying the accuracy of the list; their feedback is expected in the second half of May.

In response to questions raised by DE and ES, COM explained the structure of the list, which differentiates between new standards to be developed, published standards, and standards undergoing a revision. Only standards published by the European Standardisation Organisations could be considered for harmonisation, and any reference to ISO standards was for identification purposes only. The future mandate would cover the standards relevant for both MDR and IVDR, whereas two separate lists for each Regulation are already included in the draft.

DE and NL raised concerns as regards the deadlines proposed for the alignment of the standards to the new Regulations, in view of the broad scope of the mandate. At the same, standards should be cited in OJ prior to the application dates of the new Regulations.

COM reiterated that the list of standards was prepared on the basis of input from Cen/Cenelec. Depending on the topic, standards are developed in different technical committees, who work independently from each other. The most important standards should be published by Cen/Cenelec by the application dates of MDR/IVDR, so that the 'state of the art' is available to different actors using the standards. The only exception are

the standards on the labelling of symbols, which should be published by Cen already in 2019, so that they can be cited in the OJ by the application date for the MDR.

DE questioned the scope of the mandate. The alignment of 240 standards to the new Regulations within the next 2-4 years is not realistic. Some of the standards on the list are not needed and the approach for having such a large number of harmonised standards should be overall reconsidered. Conformity with the essential requirements does not require use of harmonised standards. Moreover, the mandate should not only list the relevant standards, but also specify their content.

PT agreed that the mandate should be based on priorities. A realistic mandate could include 20-30 horizontal standards, such as QMS, labelling symbols, good clinical practice / good study practice, biocompatibility.

COM explained that, initially, it invited Cen/Cenelec to prioritise among the standards for the purpose of the first mandate. Due to specifics of internal organisation within Cen/Cenelec, they asked for a broad mandate (separate technical committees). Moreover, it was not always possible to rate the importance of certain devices or processes against the other.

In view of the overall MS feedback of the draft list of the standards, COM asked for specific comments by the end of May. The standardisation mandate would be drafted on this basis.

DE, IT, ES and AT pointed to the need for developing a symbol for a medical device, and for COM and the MDCG to be involved in the process. DE explained that the time necessary to agree on any such symbol at ISO level be much longer than what is envisaged for the alignment of the existing standard on symbols. DE is working on such a symbol at national level and exploring the possibilities of harmonising the symbol through a European standard.

10) MDCG governance: set up of working groups – transition to the new scheme

Draft Terms of Reference (ToR) of respective working groups (WG) of the MDCG were disseminated to MS prior to the meeting. Following the establishment of the WG, COM intends to ask MS to appoint their representatives to the respective WGs and to launch a call for stakeholders to participate in the relevant WG as observers.

IE enquired whether ToR would be reviewed by the WG. COM explained that the ToR should be laid down by the MDCG, because in accordance with the MDR, MDCG establishes the WG. As regards the already existing expert groups under the Medical Device Directives, not all MS are represented in each WG, while a discussion within the MDCG gives an opportunity for each MS to be involved.

IE and PT pointed to the need for consistency of the documents, a varying level of detail as regards the scope of activities in the remit of respective WG, and the need to explain the interlinks between WGs and the co-operation within clusters.

AT emphasised the need for more frequent meetings of the WGs to meet up to the implementation tasks.

NL pointed out that the roles of stakeholders required clarification.

UK, FR, DE provided examples where modifications of draft ToR would be necessary, including the WGs on UDI, market surveillance, post-market surveillance and vigilance, clinical investigation and evaluation, borderline and classification and *in vitro* diagnostics.

COM asked MS to provide comments on the draft ToR by mid-May 2018.

11) IVDR

COM presented an update on the ongoing specific activities for IVD.

a) Adoption of the last two Common Technical Specifications (CTS) for IVD

The CTS for combined tests is undergoing the inter services consultation and will then be sent for consultation to WTO and will be adopted subsequently. The CTS for HIV self-test will closely follow the same process of adoption. It will be the two last CTS to be adopted under the IVD Directive. It will be followed by the adoption of these CTS as Common specification (CS) under the IVD Regulation. There is already a draft for CS for Chagas disease and Syphilis which should be incorporated.

Following a question by DE, COM made clear that the CS will have to be adopted via an implementing act.

b) Update about the CIE/IVD taskforce

A task force between the IVD technical group and the CIE working group has been created to provide guidance on performance evaluation and performance studies for IVD. The terms of reference of this task force have been drafted and a work plan will be adopted during the next meeting of the task force.

c) Update about the classification guidance for IVD

The subgroup of the IVD technical group is busy preparing classification guidance for IVD under the Regulation. The work is progressing well and the guidance should be ready by the end of the year for adoption by the MDCG.

PT, supported by IT, insisted on the fact that classification issues for IVD should be addressed by the Borderline and Classification WG.

COM indicated that classification issues concerning IVDs shall be discussed in the IVD working group, which has the knowledge and expertise, rather than in the general Borderline and Classification WG; but agreed that the borderline issues should be addressed by the Borderline and Classification WG.

12) Communication campaign – update and question

An update was presented on the status of the communication campaign on the new Regulations:

A questionnaire has been sent to 76 EU stakeholders associations to check their knowledge and needs regarding the Regulations. The questionnaire also aims to collect information on existing documents and webpages about the Regulation and to create a database of stakeholders at EU and international level;

The first target groups of the campaign will be:

- Manufacturers,
- Persons in charge of procurement of medical devices,
- Competent authorities in third countries,
- Authorised representatives, importers and distributors,
- Healthcare professionals and health institutions,
- Reprocessors of single use medical devices,
- Manufacturers of Annex XVI devices.

COM asked MS to provide information on how procurement is organised in their MS and how to reach people in charge. COM also wanted to receive the views of MS regarding the need to target customs officers in the EU. If the answer is yes, MS are asked to provide COM with information on how to reach them.

A new architecture for DG GROW webpages is under preparation and should be online in June.

There will be webpages dedicated to specific topics, such as: UDI, in-house devices, 3D printing, transitional provisions and financing for SMEs.

Members of the MDCG will receive a questionnaire regarding the need to target customs officers and the organisation of procurement of MD. The contact points on DG GROW webpages will need to be updated, including TSE-BSE contact points. The members will also receive the draft factsheets for manufacturers in order to provide comments.

DE insisted on the fact that no commercial links shall be put on the website of DG GROW, which COM agreed to.

UK expressed its concern that COM does work in parallel to the MS, which may be confusing for stakeholders. COM replied that the documents produced are factual and not interpretative. There is a will from COM to avoid duplication, which is the reason why MS are requested to provide links to what they have already produced, so it can be put on DG GROW website.

Following a request from NL, COM indicated that some documents are already online (Guidance from MDCG), but the new webpages should be online in June together with the firsts factsheets.

ES and AT supported the need to fill the gap with a good information campaign, but were afraid about the consistency on some subjects, which are hotly debated. COM reassured that MS will be consulted on documents put on line.

IT underlined that the work of the COM is very helpful. There is a need for a step by step approach and simple communication. If this information comes from COM it is more official.

COM reminded that the campaign will not go into detailed information but that the goal is awareness raising and providing a hub for finding relevant information for the stakeholders.

13) Update on IMDRF and other international developments

An update was provided on the EU multilateral cooperation in the IMDRF framework and the outcome of the recent management committee meeting in Shanghai and its follow up as well as on bilateral relations with a number of important trade partners. There was also a brief update on MDSAP – the MD Single audit Programme that is operational on the international level also involving several notified bodies, and, as observers, two MS and COM.

It was indicated that there is a need for additional EU members in the WGs of IMDRF and for additional MS to join the MDSAP.

14) Brief update on CAMD and its task forces

The person who has been requested to present this agenda item could not attend the meeting.

DE representative informed that the CAMD meeting is scheduled in two weeks' time. The Agenda will include the implementation of Eudamed. Next Friday the implementation TF will meet again and decide on a rapid alert system. The TF will open a FAQ sheet for the transitional period. It will be in the webpage of the CAMD. New questions are included.

A major discussion had taken place on the timely implementation of Eudamed. Some interventions had stressed the crucial importance to make sure that Eudamed is ready on time. Parts of the legislation could not be applied without Eudamed in place.

The CAMD will vote on a new executive group during the next meeting.

NL asked to receive more information and clarification about the proposed market surveillance and goods package Regulation.

COM explained that a proposal has been submitted to the Council and the European Parliament, where discussions are ongoing.

DE mentioned that they consider Medical Devices should not be covered under the scope of the new horizontal proposal. DE expressed doubts whether medicinal products would be excluded but medical devices are included.

PT also referred to the need to bring clarity in this respect.

COM stated that medical devices are not out of the scope of the horizontal proposal. Further decisions on this belong to the co-legislators.

NL mentioned that they are already confronted with some problems of shortage of medical devices due to the MDR implementation and that therefore a soft transition is needed.

COM replied that there might be a lack of knowledge about the transitional provisions and insisted on the need to spread accurate information at national level and to the industry, notably as regards the transitional provisions.

ES has witnessed some degree of ignorance about the MDR especially in hospitals. They invited hospitals and industry to a meeting to provide mutual information.

IT underlined the need to pay close attention to avoid misunderstandings. Some manufactures would be in the process of applying to new notified bodies in order to limit the risk of shortage of devices.

15) AOB

a) The Chair reminded the participants about the deadlines for contributions from Member States' side on the relevant points of the agenda.

b) At least two more MDCG meetings are planned for 2018. At this stage, the next MDCG meeting is planned after the summer, likely in September, subject to confirmation. The last 2018 MDCG meeting should take place towards the end of the year.

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.	DK	Danish Medicines Agency
6.	EE	Estonian Health Board
7.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
8.	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
9.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
10.	IE	Health Products Regulatory Authority (HPRA)
11.	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
12.	LV	Ministry of Health
13.	LU	Ministère de la Santé - Direction de la Santé
14.	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
15.	NO	Ministry of Health and Care Services
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.	CH	Swissmedic – Swiss Agency of Therapeutic Products
22.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- DR JRC F2
- DG SANTE F5
- DG GROW D4