Reply to additional comments of the Commission after inspection meeting on a request for information from the European Ombudsman –complaint ref. 2132/2022/KR

1. I appreciate that the Commission acknowledges that draft versions of documents prior to their endorsement are included in the wording “other relevant background documents”.

2. I still do not agree with the Commission’s interpretation of possible exceptions to the publication of documents as described in Art 26(2) of Commission Decision C(2016) 3301 with reference to Article 4 of Regulation No 1049/2001.
   The Commission reiterates that the publication of documents “such as MDCG guidance documents, MDCG position papers, MDCG recommendations for designation of notified bodies, which are still at a draft stage” are not proactively published because “such a publication would seriously undermine the ongoing decision-making process within the MDCG” without adding further information why this should be generally the case.
   While it is possible that some documents fall under the exceptions, this decision still needs to be taken on a case-by-case basis and must be carefully considered to comply with the general principles of transparency. The mere fact that positions taken in draft documents are not final and subject to change does not automatically undermine the authority of the MDCG but lies in the nature of the decision-making process. On the contrary: Providing the public with an insight into this decision-making in a transparent way in my opinion strengthens the position of the expert group.
   In this context I would like to take up two examples that were given by the Commission during the inspection to point out concrete detrimental effects of the publication of draft versions.
   In the first example the commission argues that the publication of a draft version of a guidance on significant changes might have caused confusion in the sector because these views were not final and changed over time. This assumes that not only the general public but also trained professionals are not able to discriminate between finalized, published documents and draft versions that might contain preliminary views. I do not think that this is a realistic estimation of a possible effect and as stated in my previous reply, the Court of Justice of the European Union in a slightly different context stated that “Public opinion is perfectly capable of understanding that the author of a proposal is likely to amend its content subsequently.” (T-163/21, ECLI:EU:T:2023:15, paragraph 79). If this is the case for the public opinion, it surely is true for professionals working in the field.
   In the second example the Commission argues that premature publication of a draft of Commission Implementing Regulation (EU) 2022/2347 with respect to reclassification of certain active products without an intended medical purpose might have led to pressure by stakeholders aiming at favorable changes for their products. While this may be true, transparency in this case would help defend against stakeholder pressure and does not further it. If there is no published proposal, then the public is not able to judge if any changes were made due to inevitable pressure by stakeholders. It is important to see what the original intent of the proposal was and how it changed over time to be able to determine if any product was favored by this change and to be able to question why this was the case. To assume that respective stakeholder pressure would only occur with respect to information made publicly available and that secrecy in the proceedings is a good way to prevent this, seems unrealistic and runs contrary to the well-established principles of transparency.
   Overall I do not think the two examples provided support for a general exemption of certain draft documents from publication as possibly detrimental to the decision-making process. On the contrary they show that an exception would not have been justified in those two cases. The

decision needs to be made on a case-by-case basis and it needs to be well-funded if publication is denied.

3. I do not think that the additional reference to Article 109(2) of Regulation (EU) 2017/745 and Article 102(2) of Regulation (EU) 2017/746 with respect to information "exchanged on a confidential basis" adds anything to the argument.
   The section stating that "information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority" is not specific to the MDR or the IVDR, but can be found in several recent EU regulations or draft regulations (e.g. Regulation (EU) 2023/1230, Regulation (EU) 2022/123, proposal for an EU AI Act).
   The information that is covered by this section is limited to the cases, where the information was exchanged "on a confidential basis". This limitation does not cover every non-public information exchange (which would basically be every exchange) but introduces an additional qualifier. There should be significant reasons why this information should fall under the protection of confidentiality, e.g. the information pertaining to commercially confidentiality or information publication of which might affect the effective implementation of the Regulation. This essentially is already covered by the exceptions to transparency allowed by Article 4 of Regulation No 1049/2001. Even though there might be some additional cases that are covered by this Article, the interpretation of the Commission is again overly broad. There needs to be an objective, individually established reason why confidentiality is applicable for specific cases.
   Basically the argument of the Commission here is identical to the previous argument: Publication of certain types of draft documents might impact the correct implementation of the Regulation regardless of the details of the case, therefore it generally cannot be done. And like before, this generalization does not hold up to scrutiny: The decision must be made on a case-by-case basis. Just stating that in all cases every authority contributing to a draft needs to be considered as an "originating authority" for the piece of information contributed and therefore must agree to publication is not sufficient.
   Overall, this argument seems like another version of the first argument in trying to find a general exception rule for all draft documents of certain types.

4. To ensure that the use of the exceptions according to Article 4 of Regulation No 1049/2001 and reliance on information exchange on a confidential basis according to Article 109(2) of Regulation (EU) 2017/745 or Article 102(2) of Regulation (EU) 2017/746 is done in a transparent manner, I would like to propose that a list of relevant documents should be included in the minutes of the respective meeting together with the decision on publication of the document with the respective rationale (either Article 4 or the authority/authorities denying publication due to the information being exchanged on a confidential basis).