Exchange of information between medical device competent authorities on borderline and classification cases

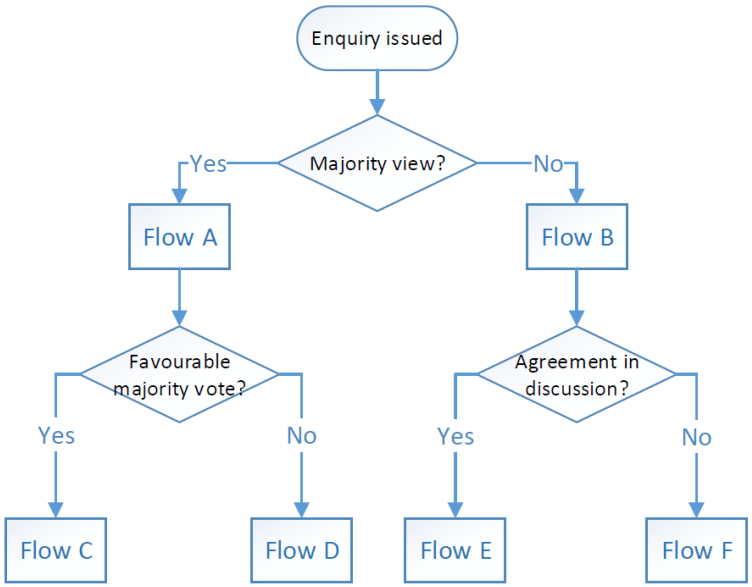
Helsinki Procedure 2021

Introduction

This document is an updated version of the system agreed at the Medical Device Competent Authorities Meeting in Helsinki in October 2002. The purpose of the system is to allow consultation among competent authorities (CAs) on borderline and classification issues concerning medical devices and to ensure that appropriate guidance is published in the Manual on Borderline & Classification for Medical Devices (hereafter referred to as the Manual). The system was revised following the entry into application of the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) by the Borderline & Classification Working Group (BCWG)[1] of the Medical Devices Coordination Group (MDCG) in 2021. The operation of the BCWG and its cooperation with other MDCG Working Groups takes place according to the relevant Terms of Reference[2].

Procedure

The diagram below gives an overview of the procedure with flows A-F. The numbering in the following text corresponds to the accompanying flowcharts. In what follows the 'MDCG Borderline & Classification Working Group' refers to the group's members and 'extended MDCG Borderline & Classification Working Group' refers to the group's members and observers.



1. Enquiries or requests for decision on borderline or classification issues are frequently received by CAs. In the majority of cases, these issues are easily and quickly resolved. However, consultation with other Member State CAs may be necessary where there is a complex issue, or when a CA is requested by a third party (e.g. a trade association or a manufacturer) to obtain an EU-wide opinion on a particular issue.
2. In the first instance, where a CA identifies a borderline or classification issue it will try to resolve it by:
    - Reference to the MDR and/or IVDR
    - Precedent

[1] https://ec.europa.eu/docsroom/documents/32069/attachments/1/translations/en/renditions/native
[2] Medical Device Coordination Group Working Groups | Public Health (europa.eu)

- Reference to various guidance documents published by the EU Commission (e.g. the Manual, MDCG documents)

3. If the issue is resolved, the CA does not need to contact other CAs.
4. However, where this fails to resolve the matter it may seek input from other CAs by means of the Helsinki Procedure.
5. Before launching an enquiry, on a case-by-case basis, stakeholders may be consulted by the initiating CA so as to provide extra information. The initiating CA will determine the parties to be consulted. The consultation may include either specific national or EU-level organisations in that Member State or a broad range of stakeholders, e.g. those on the extended mailing list of the MDCG Borderline & Classification Working Group. A call for data may be initiated.
6. The enquiry should be launched by means of a standard request form (template in Annex 1). Using this form (in English) the initiating CA will:

    - describe the issue (including an adequate description of the device, its intended purpose as described by the manufacturer and the problem to be resolved)
    - present its opinion on the issue (and that of the manufacturer and / or notified body, if applicable)
    - describe the rationale behind their opinion and a proposal for solution
    - make reference to all available and relevant guidance, reference documents and scientific literature
    - if helpful, provide the instructions for use or other information; however, this should be anonymised (e.g. the manufacturer's name and address, device trade names etc. should be removed)

    The information included in the form should be as full and clear as possible. The CA should send the enquiry to all other CAs for comments by e-mail.

7. The standard period to be given for replies is 1 month. This may be extended if there is a holiday period or if the enquiry is considered to be complex. The initiating CA may also issue an extension to the time period if requested to do so by another CA (see below).

    The other CAs shall respond to the enquiry by giving their opinion on the proposed solution. The answer may be positive, negative, or a new proposal. A rationale shall be provided in complex cases and particularly in the case of a negative answer or a new proposal. CAs should respond to all enquiries, even if only to state that they have no opinion on the issue. If additional time is required in order to respond to the enquiry, then the concerned CA should advise the initiating CA of this to enable an extension to be issued.

    The reply should be sent to all CAs.

    If additional information becomes available during this process, this should be circulated to all CAs, preferably by updating the original CA enquiry. Additional information may be supplied by any CA.

8. Within 1 month after the end of the consultation period, the initiating CA shall prepare a **summary** of the replies received (see Annex 2). This shall include the position taken by each CA and the rationale given. It shall also produce a redacted summary where the identification of the individual CAs and any information that might identify a specific manufacturer or device is removed.
9. The initiating CA shall add an **overall summary** of the responses indicating the majority view to both full and redacted summary. In this context a majority view shall exist if more than 75% of the CAs who transmit an opinion agree. Depending on whether or not a majority view exists after this initial CA consultation, flows A or B will be followed. If no draft entry is needed, the procedure shall stop at this point (for example if there is a request to amend an already existing entry which is rejected).

Flow A. Majority view exists following initial CA consultation

10. If a majority view exists, the initiating CA shall also prepare a draft entry to the Manual within the deadline for point 8.
11. Within the deadline for point 8 (unless an extension is granted), the initiating CA will distribute the summary to the other CAs and the redacted summary to the extended MDCG Borderline & Classification Working Group, both containing the draft entry to the Manual.
12. The recipients will have one month to comment on the summary and first draft entry to the Manual.

13. Within two weeks after the end of the commenting period, the initiating CA should incorporate the comments in the summary and the second draft entry (as appropriate). The draft entry should then be sent to the EU Commission for review.

14. Within two weeks, the initiating CA and the EU Commission should agree on the text to be presented for voting.

15. Within one week, the initiating CA should then issue the draft entry to all other CAs for voting on a voting form.

16. The CAs shall respond within 2 weeks providing one of the following responses:

- accept proposal for the Manual
- reject proposal for the Manual
- abstention

17. The initiating CA shall provide the results of the voting procedure to all CAs and the EU Commission within one week.

18. A favourable majority vote shall exist if 75% or more of all voting CAs are in favour. Abstention (including non-responding CAs) will be considered to be in agreement with the majority.

Depending on whether a favourable majority vote has been achieved, flows C or D shall be followed.

Flow C. Favourable majority vote achieved

19. Where a favourable majority vote exists, the CAs should submit their final editorial comments to the initiating CA within two weeks. It should be understood that amendments to the draft entry should only relate to the wording used and not to the fundamental decision reached.

20. The initiating CA will then produce a final entry in collaboration with the EU Commission, incorporating CA editorial comments where appropriate.

21. Subject to its agreement, the EU Commission will publish the entry in the Manual.

Flow D. No favourable majority vote achieved

The initiating CA shall inform the EU Commission that this issue should be placed on the agenda for the next CAs-only meeting or teleconference. The process will then follow flow B (no majority view following initial CA consultation) from point 25.

Flow B. No majority view exists following initial CA consultation

22. Within 1 month of the end of the consultation in point 7, the initiating CA shall issue the summary to all CAs and the redacted summary to the extended BCWG, without a draft entry. The initiating CA shall invite the CAs and the extended BCWG to comment on the summary and submit any additional information that may help resolve the issue.

23. Within 2 months, the CAs and the stakeholders in the extended BCWG submit any additional information in order to support their arguments on the specific issue to the initiating CA.

24. Within 1 month after the end of the submission period, the initiating CA shall summarise the input and transmit the summary of arguments and accompanying documents in a collated form to all the CAs and the EU Commission.

25. The EU Commission will place the item on the agenda for the next available CAs-only meeting or teleconference for further discussion. Copies of relevant documents (copy CA enquiry, summary arguments, documents submitted, course of action proposed by the initiating CA etc.) shall be issued at least one month before the date of the meeting.

26. The initiating CA will present the case at the meeting or teleconference. The aim of the discussion should be to examine the various issues involved in the matter to try and reach an agreement on the substance of the case.

27. Depending on the outcome of the discussion, flows E or F should be followed.

Flow E. Preliminary agreement reached in the CA discussion

28. Within three weeks, the initiating CA shall prepare or revise the draft entry taking account of the discussion at the meeting or teleconference.

29. The initiating CA should send the draft entry to the CAs and the extended BCWG for a 2-week editorial consultation. It should be understood that proposed amendments to the draft entry should only relate to the wording used and not to the fundamental agreement reached.

30. Within 2 weeks after the end of the consultation period, the initiating CA should take account of any comments received and, if it considers this necessary, amend the entry. It should then send it to the EU Commission for review.

31. The procedure should then continue from step 14 (preparation for voting).

32. If no favourable majority vote is achieved after two cycles of voting in total, the procedure should continue from point 33.

Flow F. No preliminary agreement reached in the CA discussion

33. If no majority agreement is achieved, the members of the working group should clearly decide what the next steps in resolving the matter should be. This may include, for example:

34. Obtaining further information (by further research or by referring the matter to an *ad hoc* or established group of medicines / devices representatives (where a determination is required on which regulatory regime should apply).

35. Setting up a Task Force as described above. Such a Task Force will be led by the initiating MS and will include volunteers from other CAs as well as representatives from other regulatory fields, both at national and EU level, as needed.

36. Requesting an opinion of the EMA / ECHA / EFSA, where appropriate. In this case the EU Commission will make an official request to the EMA / ECHA / EFSA. This does not prevent the consultation of relevant national competent authorities by the CA members of BCWG. The procedure will be suspended until the opinion is received.

Where the working group decides that additional information is required in order for a majority agreement to be achieved (for example presentations, scientific or legal advice, input from the *ad hoc* group on medicines / devices etc), a clear timeline should be set for further discussions, taking into account the complexity of the issue.

37. The issue should be discussed a second time at a subsequent meeting, taking into account all the relevant information presented. The aim should be to reach majority agreement. If successful, the same process as set out above for publishing the agreed entry should be followed.

In specific cases and on request of the initiating CA the timeline for any step, except the voting, may be extended. The CA will communicate the specific reason behind this request and the duration of the extension to CA members, or to all members of the BCWG depending on the step in the procedure. Examples may include: complex scientific matter, need to consult experts, information becoming available during the procedure, difficulties in processing the information.

A centralised document indicating the status of each enquiry will be made available to the entire BCWG in CIRCABC and will be updated by the EU Commission at least every 3 months. This will constitute a reminder mechanism for unduly delayed entries.

At the end of the procedure the initiating CA will submit to the EU Commission an archived file containing all the relevant information linked to the enquiry. The EU Commission will place this file in CIRCABC.

If at any step in the procedure the appropriate action is not taken by the initiating Member State for more than 3 months and no request for an extension is submitted, the case will be considered as stopped and will be archived. Nevertheless, best endeavours should be used by all to bring the enquiries to completion to ensure effective use of the time and resources invested in each case.

The EU Commission shall update the manual at a fixed frequency of every 3 months.

Cooperation with other MDCG Working Groups:

For some cases, cooperation between the BCWG and other MDCG Working Groups may be necessary, for example the In Vitro Diagnostics Working Group, the New Technologies Working Group, the Annex XVI Working Group etc.

In case the BCWG identifies a need for consulting another MDCG Working Group, it may initiate the necessary exchange in the appropriate form, e.g. by submitting a technical question or a Helsinki enquiry for circulation in the other Working Group.

If a borderline or classification case is identified by one of the other Working Groups, the concerned member of that Working Group should inform their national counterpart in the BCWG of the need to launch an enquiry. The Member State should decide internally who, among the national nominees in the Working Groups concerned, should be responsible for managing the enquiry in question. The enquiry, summary and any other documents should be circulated concurrently in that group and the BCWG. The respective stakeholders should be included at the appropriate step. For voting, each Member State should decide on a national position and submit a single vote.

Contact Points:

In order for the updated system to work correctly it will be necessary for a full list of e-mail addresses to be maintained for both the initial circulation to CAs and for circulation to the full BCWG.

All CAs and stakeholders will be responsible for informing the EU Commission of the correct contacts and e-mail addresses.

E-mail addresses should include at least one nominated individual's direct e-mail address, however may also include one ‘generic’ e-mail address.

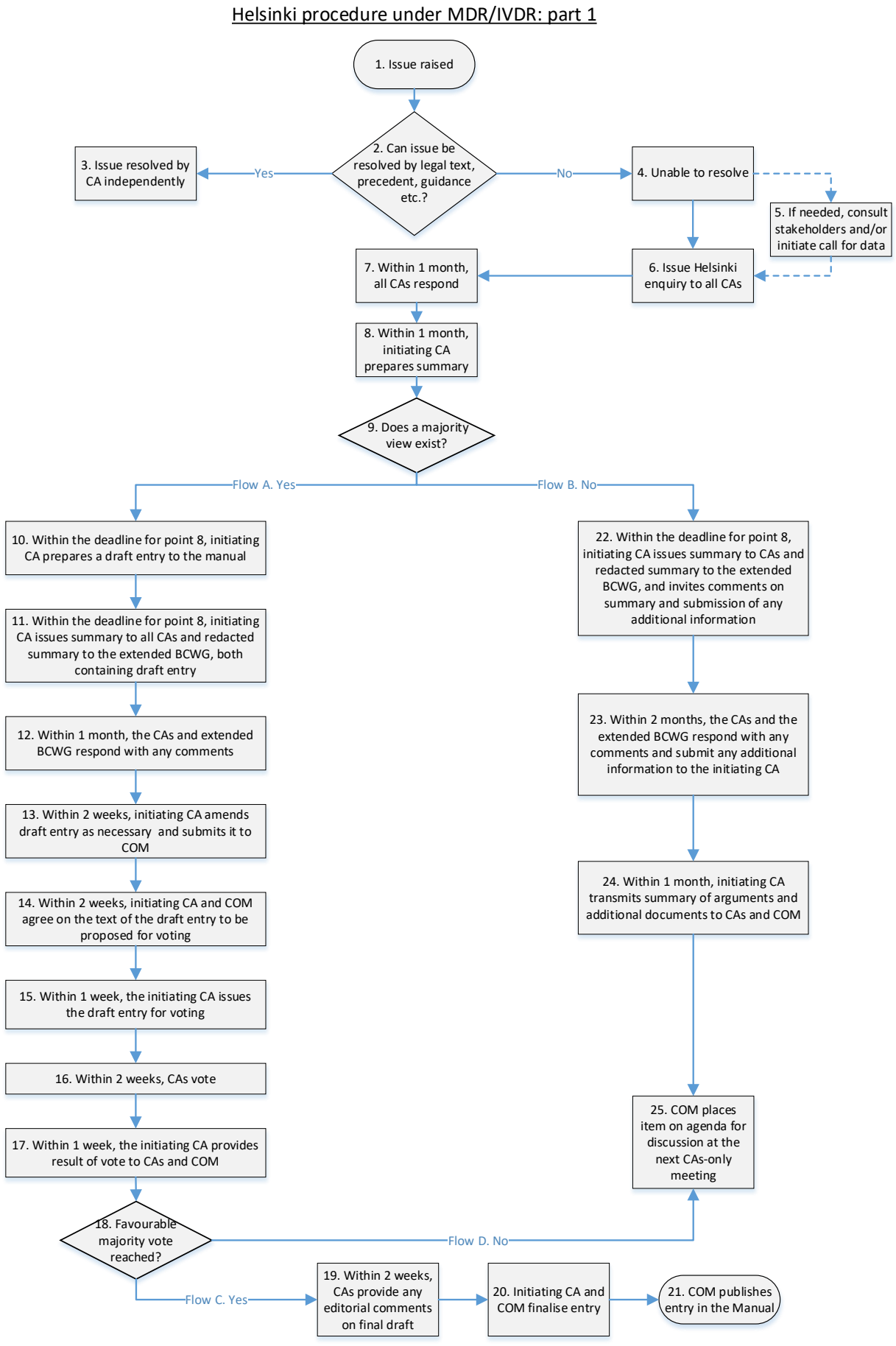
The EU Commission will maintain the lists of contact points for all stages of the Helsinki system in CIRCABC and keep them up to date. There will therefore be one list maintained for the first part of the Helsinki procedure (i.e. CAs only) and one list for the extended BCWG (CAs plus stakeholders). All CAs and stakeholders shall be responsible for informing the EU Commission of any changes to contact points. In case of involvement of other MDCG Working Groups the lists of members and observers will be used. For all questions related to contact lists CAs may contact the EU Commission.

Overview of the timelines:

- ✓ Enquiry to be sent via e-mail for comments;
- ✓ 1 month to respond;
- ✓ 1 month to prepare a summary of responses + first draft entry;
- ✓ 1 month to comment on the first draft entry (extended BCWG involved);
- ✓ 2 weeks to amend the entry;
- ✓ 2 weeks to agree on the text with the EU Commission;
- ✓ 1 week to issue the draft entry for voting;
- ✓ 2 weeks for voting the second draft entry (Accept, Reject, Abstention) - 75% or more, agreement achieved – less than 75%, no agreement achieved.
- ✓ 1 week for the initiating CA to communicate the result
- ✓ 2 weeks for editorial comments;
- ✓ Finalisation and publication (update of the Manual every three months).

Total length of procedure is 5 months, 2 weeks + publication time.

Annex I – Helsinki Procedure flowcharts



Helsinki procedure under MDR/IVDR: part 2