Consultation - Draft clinical evidence guidelines - Medical devices

Suggestions:

1. Incorporate these guidelines into the current ARGMD as it seems that the device guidelines are diverging into separate guidance documents, as they were historically. Having two separate lengthy documents causes double handling of information, and it can be overwhelming and confusing for the user.

2. Chapter 6. Requirements for specific high risk device:

For each specific high risk device, requirements for “Clinical evidence” (clinical investigations, literature review, and post-market data) and “Compiling clinical evidence” have been provided. There seems to be double up of information from Chapter 3 of the guidelines, even though reference has already been made to Chapter 3.

   a. Where possible, amend the text to remove any unnecessary repetition of information and only highlight the differences in requirements for specific high risk devices. Alternatively present the information in a table, instead of bulky paragraphs.

Minor Errors:

1. There are minor errors on page 21:
   a. “Appendix 5: Constructing the clinical evaluation report”
      The appendix number should be Appendix 2.
   b. “Appendix 6: Clinical evaluation report and supporting documents”
      The appendix number should be Appendix 5.

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