Consultation input: Draft clinical evidence guidelines – medical devices

This response relates to the utility of the guidelines document (such as scope, structure, expression, etc.).

The guidance could be improved with respect to:

- **user-focus**
- **findability**
- **scannability**
- **readability**
- **accessibility**

**User-focus**

The guidance contains information for sponsors and manufacturers of higher-risk medical devices. However, it would be useful to make it clear near the beginning of the guidance:

- Is it the manufacturer who submits this as part of conformity assessment, or the sponsor as part of inclusion – what is the role of the sponsor in relation to clinical evidence?
- Is this meant to be guidance for a clinician writing the clinical report?
- What is expected for lower class medical devices? Surely a report by a medical practitioner is not required for a new manufacturer of bandages? When are clinical reports always required? Is a justification for not requiring clinical evidence sometimes sufficient?
- What is meant by clinical evidence for IVDs?
- When I put myself in the place of a clinician writing a report, I found it difficult to work out quickly what was required. Does the report start with a discussion of the essential principles? Is the literature review an appendix to the report? What does a clinician need to consider when evidence is from predicate and similar marketed devices – what does the TGA want assurance of?
- The common errors section could be rephrased as a positive list of things to make sure have been addressed in the report.
- Who compiles the clinical evaluation report? Appendix 5 implies that it is a multi-author document.

**Findability**

This document has been written as a stand-alone document, to be read in isolation from the rest of the TGA website. Nowadays, information is usually presented in the context of the website, so that general information, for example the essential principles, does not need to be repeated.
This enables the reader to get to the relevant information quickly and is more efficient from the point of view of the organisation (in this case the TGA).

Some of the information in the appendices is actually key to understanding some of the text, such as the flowchart for preparing a clinical report.

**Scannability**

The headings are scannable, being descriptive and short (mostly). However, the text consists of dense paragraphs. It is also difficult to follow a flow of logic. The information all appears to be relevant, but there is no clear ‘journey’ and no easy way to discern who should be looking at what.

**Readability**

According to the Microsoft Word check:

- words per sentence 14.2
- passive sentences 16%
- Flesch reading ease 19.6
- Flesch-Kincaid grade level 13.7.

These scores are considerably better than some guidance produced by the TGA in the past. However, there is still scope for some improvement.

Some lists have been itemised in the guidance, but there are some lists in sentence format.

**Accessibility**

When checking accessibility using Microsoft Word, some of the findings could have been corrected, for example ‘skipped heading level’.

The word 'see' is used 16 times – a term that is preferred not to be used, because it implies that the document is being seen, not heard.