Response to Questions:

1. **Do you agree with the proposal to update the Australian Essential Principles to:**
    a. **align[20] with the IMDRF Essential Principles and Labelling documents?**
    b. **include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations[21]?**

    From a medical device usability engineering perspective, anything that mandates that processes are in line with those applied in other regions of the world is a positive step. Human factors issues and use errors related to usability are becoming increasingly identified as a key problem in the field, leading to injuries and deaths.

    By ensuring Australian Essential Principles are in keeping with other nations, we can be more confident that medical devices entering the Australian market are of a high-quality and limit the potential for use errors.

2. **Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?**

    I completely agree with this proposal, particularly area no.5 related to human and social factors. It is essential that medical device manufacturers consider the physical and cognitive capabilities of the intended user groups, particularly within the context of the use environments. Potential regional differences in this, specific to the Australian market, need to be considered to ensure quality, usable and safe products are delivered.

3. **Do you agree with the proposal to restructure the Essential Principles and Labelling requirements for clarity and readability?**

    Yes, agree with this proposal. Anything that reduces ambiguity in the essential principles and labelling requirements is a positive. Reducing this ambiguity is likely to reduce issues during the submission process, supporting faster outcomes.

4. **Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label?**

    I agree with this proposal. This seems to be a commonsense approach for these products.

5. **What financial or other effects—including any that are unintended—do you anticipate the changes to the Essential Principles may have for yourself, your business, and other stakeholders (such as consumers, healthcare professionals, health organisations, industry, etc.)?**

    As a medical device usability specialist, I anticipate these changes will have no effect financially or otherwise. In my approach I ensure my work is compliant with existing international usability engineering standards (i.e. IEC62366) to ensure a safe and usable product. Compliance with these standards ensures compliance with the changes proposed.

I do not foresee these changes affecting other stakeholders.

6. **Do you have any comments regarding the transitional arrangements proposed in this paper?**

   No.

7. **Are there any further issues, questions, or requirements we should consider when implementing this change (including areas that can/should be clarified in our guidance)?**

   I am not aware of any.