14th October 2019

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Consultation: Proposed changes to medical device essential principles for safety and performance

To whom it may concern,

In regards to the public consultation on proposed changes to medical device essential principles for safety and performance, Seqirus have evaluated the options listed in the Discussion Paper, and the impact of these on our business.

Please find attached our response to the TGA consultation paper for further consideration:

We appreciate the opportunity to participate in the consultation and we would like to thank you in advance for taking our comments into consideration.

Please feel free to contact me should you have any questions or require further information.

Yours faithfully,

[redacted]

Seqirus

63 Poplar Road, Parkville Victoria 3052, Australia

[redacted]

[redacted]

Seqirus

63 Poplar Road, Parkville Victoria 3052, Australia

[redacted]

Questions

1. **Do you agree with the proposal to update the Australian Essential Principles to:**

    a. **align[1] with the IMDRF Essential Principles and Labelling documents?**

Seqirus response:

Yes. Seqirus supports alignment with existing international guidelines for medical devices where possible to minimise efforts on manufacturers/ sponsors to provide different or additional information to meet local requirements. In particular, many devices are manufactured in the EU and supplied to Australia. EU manufacturers using European EC Certificates as Conformity Assessment evidence in Australia will in the majority of cases be transitioning to the same requirements, therefore impact of this change would be minimal. We believe this would be a pragmatic approach to adopt similar principles in Australia.

    b. **include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations[2]?**

Seqirus response:

Yes. Seqirus supports the inclusion of new requirements captured by the GSPR in the EU MD and IVD regulations. This will improve clarity for the manufacturer / sponsor and further improve safer and informed use for the end user.

In your answer, please provide reasons for your position.

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

Seqirus response:

Yes. Seqirus supports including additional information to improve clarity in meeting existing expectations for the mentioned areas (under Proposal 2 of the consultation).

In your answer, please provide reasons for your position.

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

Seqirus response:

FOOTNOTES

[1] Considering the Australian regulatory and legal context.
[2] As compared with the IMDRF documents.

Having separate sections for Essential Principles that only apply to non-IVD medical devices and those that only apply to IVD medical devices will make it simpler to extract the correct and relevant information.

Seqirus agrees with the proposal to move detailed requirements under Essential Principles 13 to another area of the regulation. This aligns with the IMDRF approach to separate the essential principle of providing information for a medical device from the specific detail requirement for that information. This also aligns with other Essential Principles that describe specific detail requirements pertaining to the relevant Essential Principle information.

In your answer, please provide reasons for your position.

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

Seqirus response:

Seqirus does not have any comments to this question.

In your answer, please provide reasons for your position.

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.)?**

Seqirus response:

Seqirus does not have any comments to this question currently. Further consultation would be required.

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

Seqirus response:

No. The transitional timelines appear satisfactory.

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)?**

No. Seqirus does not have additional comments.