13 May 2020

RE: Response to TGA Consultation: Scope of Regulated Software based products

Hydrix Limited is strongly supportive of the TGA initiative to address the risk of patient harm where information is the source of harm, by considering measures that would clarify the boundary for software-based products that are captured under the regulatory framework for medical devices in Australia.

Our specific comments on the issues that we consider of greatest concern or require TGA elaboration (numbered as per the consultation document) are below.

Questions

- **What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?**

    1. **helps patients self-manage a specific disease/ condition**

        Hydrix Feedback: Could be considered under an exemption where it is not related to provision of information that directs a patient to take or not take a drug.

        If TGA can elaborate on 'self-manage' a specific disease/condition. Does it involve the software recording information entered by the patient? Does the software provide recommendations to patient based on the information entered e.g. take or not take drug?

        Can TGA elaborate on what disease/condition would be considered for self-management that could be exempted?

    2. **Lab Support Software that is intended to be used in an accredited pathology laboratory**

        Hydrix Feedback: Can be exempted when supplied to a certain type of facility or for a specified purpose.

- **What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?**

    1. **helps patients manage stress for mental health**

        Hydrix Feedback: For management of stress only, can be considered for an exclusion with conditions (not if the patient has any significant mental conditions e.g. major depression, schizophrenia, bipolar). TGA oversight is not required.

2. **monitors a condition**

   Hydrix Feedback: Would depend on analysis of which conditions.

   If the condition relates to the common cold, mild asthma, or hay-fever, with symptoms that are seasonal and self-limiting, software to monitor these conditions can be excluded. TGA oversight is not required.

   Can TGA elaborate on what disease/condition would be mild/self-limiting?

3. **Software that provides "class-based analyses" rather than patient-specific diagnosis or management**

   Hydrix Feedback: Could be excluded because it provides analysis of common trends or diagnostic indicators for review by health professionals. TGA oversight is not required.

Please provide details:

of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or

describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

- **Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?**

Hydrix Feedback: Can TGA consider providing a guidance or oversight like the Draft FDA guidance "Clinical Decision Support Software" issued on September 27, 2019. The guidance document elaborates on the software that are not Clinical Decision Support on which FDA intends to focus its regulatory oversight. TGA can provide information on similar lines.

Kind regards,

[redacted]
Michelle Knight
Clinical and Regulatory Manager