GSK Comments on TGA Consultation: Scope of Regulated Software based products May 2020

Overall Comment

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the TGA consultation Scope of Regulated Software based products.

The purpose of this consultation is to consider the boundaries for software-based products that are captured under the regulatory framework for medical devices in Australia, and to ensure that sponsors and manufacturers are not subjected to unnecessary regulatory oversight.

It is recognised that the TGA is not proposing any changes but rather seeking input from impacted sponsors and manufacturers on scoping the boundaries on software-based products regulated in Australia. GSK welcomes the opportunity to comment on the type of software-based product that should be exempted from inclusion in the ARTG.

Specific Comments to the Consultation Questions

GSK's responses to specific questions on the consultation paper are provided below and are preceded by the consultation question.

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

GSK Comments

GSK does not have any specific examples of type of software-based products that should be exempted from being included in the ARTG. However, based on the TGA's consultation document further guidance is required on the following two points.

- The guidance and classification rules rely heavily on the term "public health," however the scope and definition of public health is not clearly defined. These definitions are essential for sponsors to correctly classify their products according to TGA's classification rules, and to consider exempted or excluded software.
    - Certainly COVID-19, HIV and other highly infectious diseases are considered to be public health risks. It is not clear whether the TGA considers other health risks such as obesity, heart disease and stroke as public health risks even if they are public health risks in other countries.

- It is noted that the guidance identifies software that serves as electronic patient records is not classified as a medical device. However, it is not clear whether patient surveys and self-assessment questionnaires may also be considered as software as medical devices. These are common features of medical software which typically require clinician input for a definitive diagnosis or assessment.
    - For example, would the presence of a patient-completed Hospital Anxiety and Depression Scale alone be considered a functionality that would meet the TGA's criteria of "Diagnosing and screening for a disease or condition". Similarly, would the

> Asthma Control Test alone be a functionality that would meet the criteria of "Monitoring the state or progression of a disease, condition, etc." Would it make a difference if the results of those surveys or questionnaires are automatically shared with the clinician, or it is up to patient discretion?

In relation to the other questions outlined in the consultation document regarding the software-based products that should be excluded from regulation by the TGA or which approaches from international jurisdictions should be used, GSK does not have any comments.

We thank the TGA for providing GSK with the opportunity to participate in this consultation process.