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Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606, Australia

28 March 2019

Dear Sir/Madam,

Consultation: Regulation of software, including Software as a Medical Device

AstraZeneca welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation paper 'Regulation of software, including Software as a Medical Device (SaMD)'.

AstraZeneca's feedback on the guidance, is contained in Attachment 1, having given consideration to the specific questions included in the consultation paper. The responses include suggestions for changes to provide better clarity on requirements which will support practical implementation as well as identifying key areas of concern.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments.

Yours sincerely

AstraZeneca Pty Ltd

[redacted]
E: Regulatory-Affairs-Sydney@astrazeneca.com

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Item	Comments and Rationale
General Comments	• Approaches that would enable greater utilisation of marketing approvals for software as a medical device in an overseas market in circumstances where the device has been approved by a comparable overseas regulator would be highly welcomed. This has the potential to help facilitate the process of reclassification of software currently registered as Class I if required. • The consultation document provides descriptions and a number of examples of how TGA intends to classify software as a medical device when that software fulfils traditional medical device functionality, however the document does not specify if these classification considerations change when the software application is associated or labeled for use with a medicinal product. The combined use of medical device software and medicinal product raises regulatory jurisdictional questions as well as practical considerations around the risk (and perhaps the classification) of the software functionality. Any changes made by TGA to the construct of the regulations or authoring of new guidance should describe how the TGA intends to regulate medical device software when it is used with a medicinal product.
Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?	• The proposal for the Australian medical device regulatory scheme to be further aligned with international requirements/best practice is welcome and will help to ensure a level of harmonisation for software as a medical device. It should be noted that any Australian requirements that may be non-harmonised or inconsistent with international best practice do not create an additional regulatory burden for Sponsors
What do you consider to be the benefits and disadvantages of the particular proposals for change?	• A harmonised approach where the same types of regulatory requirements need to be satisfied across markets will reduce the impacts on organisations developing and distributing software as a medical device in multiple jurisdictions.

Item	Comments and Rationale
Do you believe there will be any unintended consequences arising from the proposed changes?	• The TGA should be mindful to ensure that it is adequately resourced and the transition period is of sufficient duration to allow for the possible reclassification of existing Class I devices as required as well as a possible increase in evaluation of applications of software as a medical device due to the changes in classification.
What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?	• Not applicable as AstraZeneca does not currently hold any registrations for software as medical device.
What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.	• Not applicable as AstraZeneca does not currently hold any registrations for software as medical device.
What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.	• Not applicable as AstraZeneca does not currently hold any registrations for software as medical device.