29 March 2019

Via Electronic Submission
Therapeutic Goods Administration (TGA)
PO BOX 100
Woden ACT 2606
Australia

Re: Regulation of software, including Software as a Medical Device (SaMD)

Dear Sir or Madam:

Roche, a world-wide leader in pharmaceuticals and *in vitro* diagnostics (IVDs), applauds TGA's goal to develop a risk-based, fit-for-purpose regulatory paradigm for software.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Today, Roche creates innovative medicines and diagnostic tests that help millions of patients globally. As a leader in healthcare, Roche is committed to the digital transformation of healthcare and has taken a number of proactive steps to drive our investment and capabilities in software development and new data-driven solutions that deliver clinical decision support and advanced patient-level and population-level analytics to customers.

We respectfully submit the following comments on TGA's consultation focused on regulation of software.

General Comments

Given the rapidly evolving and innovative nature of the development, delivery, and frequency of innovation in software, especially SaMD, the increasingly complex IT and data interconnections within healthcare systems, the advent of "big data," and artificial intelligence/machine learning, TGA has an incredible opportunity to create a regulatory framework more appropriately tailored for development of software now and into the future. **We strongly support TGA's goal to adopt a risk-based, streamlined regulatory approach to SaMD in order to allow more efficient oversight while speeding patient access to these technologies.**

Qualification

- We believe TGA has missed a core issue regarding appropriate regulation of software – qualification. There continues to be confusion in many jurisdictions regarding which software qualifies as a medical device and is therefore regulated, and which does not. While TGA touches on some of these issues in Appendix 1, it is critical that TGA provide greater clarification to software developers. We encourage TGA to **exclude certain low-risk software from regulatory oversight**, which is an approach similar to the United States and Canada. This can be accomplished either through changing the definition of medical devices to explicitly carve out certain software functions, such as software intended for general health and wellness purposes, or through excluding low risk software from regulatory oversight. Importantly, such an approach would focus limited TGA resources on those software functions that present the highest risk to patients. Roche has proposed such exclusions in our specific comments in Appendix A.

Classification

- Roche generally supports use of the IMDRF categories of SaMD for risk classification, and we fully support efforts to promote global convergence. We also agree that risk should be assessed by the significance of the information to the healthcare decision and the state of the healthcare disease/condition.[1] Yet, it is important to note that IMDRF categories generally do not fit within the statutory framework of most countries, including Australia. We encourage TGA to **adapt the IMDRF definitions to align with the Australian medical device framework.** While traditional risk classification of medical devices is focused on the intended use/purpose, IMDRF classification relies on both the intended use/purpose (significance of the information to the healthcare decision) as well as the indications for use (state of the healthcare disease or condition). Such an approach introduces complexities and can make it difficult to differentiate when SaMD should be "drive" vs. "inform" and even variations to regulatory oversight within a single risk classification, such as "drive." We have shared additional language in Appendix A to help in clarifying and adapting the IMDRF model to account for these differences.

- Under the SaMD classification scheme proposed in this consultation, the number of Class I software products will be minimal; only one type of software functionality results in a Class I determination, and the others result in either Class IIa, IIb, or III classification. This will result in significant administrative and regulatory burdens to both TGA and software developers. We recommend that TGA **adopt a risk-based approach to SaMD classification**, such as those under consideration by the U.S. FDA and Health Canada, to enable TGA to focus its regulatory oversight on the highest risk products while maintaining an appropriate level of regulatory control over all other SaMD products.

[1] *See* International Medical Device Regulators Forum Guidance: *"Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations.*

- We recommend TGA **rely on IMDRF guidance,** both N12 SaMD Risk Categorization and N41 SaMD Clinical Evaluation, as opposed to EU MDR 2017/745, as they are primarily focused on risk-based, tailored classification. Reliance on IMDRF guidance rather than approaches from the EU will ensure that Australia does not lag behind other countries in bringing high quality software to patients and physicians in a timely manner.

SaMD in the Australian Register of Therapeutic Goods (ARTG)

- Roche applauds TGA's efforts to ensure that all SaMDs have the necessary regulatory oversight and meet safety, quality and performance requirements. As TGA assesses the "Personal Importation" provisions in light of the technological evolution taking place in healthcare, we encourage TGA to **strike a careful balance** to maintain access to innovative health care solutions by patients/health care providers with the necessary licensing requirements to protect those same software users. We support robust real world performance monitoring by software developers to ensure the safety and quality of their products.

- The same careful balance must also be addressed when **determining an appropriate transition period** for the regulations to ensure enough time for companies to comply without unnecessarily preventing patient and clinician access to important, innovative technologies.

- Roche continues to strongly support **TGA's recognition of marketing approvals and clearances by comparable overseas regulators**, such as the EU, U.S., and Canada. To maximize use of TGA resources, we urge TGA to take the same approach regarding regulated software and allow inclusion of such approvals/clearances into the ARTG. This should assist in reducing potential bottlenecks that might prevent innovative technologies from reaching Australian patients and clinicians in a timely manner.

Essential Regulatory Principles for SaMD

- As TGA continues to significantly revise and reform its regulatory framework for software, we agree with TGA that additional regulations, beyond just qualification and classification of software, need to change. Roche urges TGA to develop **"fit for purpose" regulatory requirements** for the lifecycle management of software, including streamlined submission pathways with iterative, flexible modification pathways. SaMD is expected to undergo routine changes and modifications. An effective regulatory framework that allows timely and efficient introduction of software changes (i.e. introducing different oversight between minor changes vs changes that would have an impact on the clinical interpretation of results) is important to quality, safety, and availability of innovative software products. It is acknowledged that software changes vary from low to high potential risk with respect to their impacts on product safety and/or efficacy. The regulatory reporting mechanisms associated with the changes should be commensurate with the potential risk. We encourage TGA to consider an alternative regulatory

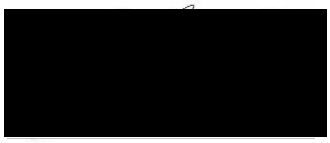
pathway, such as the U.S. FDA's software precertification pilot program which focuses on software developers demonstrating a culture of quality and organizational excellence (CQOE) and commitment to monitoring real-world performance of products in order to provide a more agile regulatory approach suited to fast-paced software development and iteration.

- SaMD regulation should be **dependent on the developer's intended use/purpose** and be regulated the same way without regard to its platform (e.g., mobile medical application; cloud; server; or as a module on an analyzer).

- To maintain patient and public trust in these important digital technologies, it is critical that TGA **maintain robust risk-based standards for safety and performance** while providing a regulatory pathway more suited to the unique needs of software. This includes ensuring that SaMD be appropriately licensed within Australia and included on the ARTG.

We appreciate the opportunity to provide our comments on this important issue and are committed to working with TGA to support a flexible regulatory pathway for SaMD that allows for innovative products that meet established standards for safety and effectiveness to reach patients and providers in a timely manner.

Yours sincerely



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Appendix A: **Specific Roche Comments on TGA SaMD Consultation**

#	Page	Proposed Change	Rationale
#1	4	For additional clarity, we recommend providing the following definition of "health and lifestyle apps" either in this document (such as the Appendix) or in separate guidance: "'A health or lifestyle app' has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition." Additionally, provide examples of apps that would fall within this "health and lifestyle" category, such as: - Weight management apps - Physical fitness apps - Relaxation or stress management apps - Breathing technique apps for managing migraine headaches - Apps for tracking sleep for coping with stress - Diet apps for living well with diabetes	The consultation makes reference to "health and lifestyle apps," but this term is not defined elsewhere within the consultation or in the regulations. In order to ensure a common understanding on the functionalities and claims associated with these types of products and to avoid confusion by software developers, we recommend that TGA define this term and provide examples of such apps. This may best be accomplished in the Appendix or a separate guidance, and the US FDA's "General Wellness: Policy for Low Risk Devices" guidance may serve as a helpful model.
#2	4	Replace "The term SaMD refers to software that functions on a general computing platform, such as a laptop computer, smartphone or tablet, and that has an intended purpose consistent with the definition of a medical device." with: "The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. Such software is capable of running on commercial off-the-shelf computing platforms (e.g. applications on mobile phones, tablets, personal computers, etc.); may be used in combination (e.g. as a module) with other products, including medical devices;" may be interfaced with other medical devices, including	As a member of the IMDRF, we recommend that TGA harmonize its definition of SaMD to be consistent with IMDRF guidance N10. U.S. FDA and Health Canada have taken a similar approach. TGA can provide greater clarification following use of the IMDRF definition by explaining that this includes software that "functions on a general computing platform, such as a laptop computer, smartphone or tablet, and that has an intended purpose consistent with the definition of a medical device." We have included language used by Health Canada for describing such capabilities.

#	Page	Proposed Change	Rationale
		hardware medical devices and other SaMD software, as well as general purpose software; and has an intended purpose that meets the definition of a medical device."	
#3	5	Add the following as the first key issue regarding the regulation of SaMD: "The first issue regarding the regulation of software as a medical device is determining if the software qualifies as a medical device."	Before a classification decision for software can be made, it must first be determined if the software qualifies as a medical device. In many situations, this determination is as complex as the classification decision and should also be addressed by TGA.
#4	5	Amend the definition of "medical device," as provided in section 41BD of the Therapeutic Goods Act 1989, to the following: (1) A medical device is: (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological process; (iv) control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or (aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or	We recommend TGA focus its regulatory oversight on the highest risk SaMD products in order to achieve a suitable balance between regulatory requirements and the risk of harm to the patient. To accomplish that, we recommend that TGA amend the definition of "medical device" to exclude low risk software where TGA or third party review does not add significant value. This is an approach similar to ones taken in the 21st Century Cures Act US legislation and in the principles described within Health Canada's recent SaMD draft guidance. Specifically, we believe it is important to clarify that software containing certain functionality, even when used in a clinical environment, is not considered to be SaMD. Amending the "medical device" definition will bring greater clarity with respect to software functions that are and are not considered to be medical devices. We strongly recommend that this be described within the consultation.

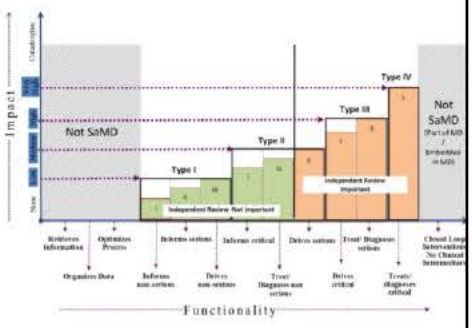
#	Page	Proposed Change	Rationale
		(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab). (c) The term "medical device" shall exclude a software function that is intended: (i) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow; (ii) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; (iii) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, or similar tools used by patients to track and organize health information for personal use or to interact with a health care provider. (iv) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or (v) for a function that meets all of the following criteria:	

#	Page	Proposed Change	Rationale
		(aa) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system; (bb) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (cc) supporting or providing recommendations to a health care professional, patient, or caregiver about prevention, diagnosis, or treatment of a disease or condition; and (dd) not intended to replace the clinical judgement of a health care professional to make a clinical diagnosis or treatment decision regarding an individual patient, for the purpose of allowing the user to reach a recommendation independently without primarily relying on the software function.	
#5	5-6	Revise sections to more appropriately characterize the risk of SaMD, which ranges from low to high.	We support TGA's effort to develop a risk-based approach to SaMD classification and regulation. However, we believe some of the risks that SaMD presents are over-stated in the consultation. As noted on page 6, SaMD does not have direct physical interaction with the patient, and many types of SaMD are used only to inform a physician's or patient's decision. While we agree that it is critically important to ensure that the appropriate regulatory controls are in place to ensure the safety and effectiveness of SaMD, it is not clear that "more and more of

<table>
<tr><th>#</th><th>Page</th><th>Proposed Change</th><th>Rationale</th></tr>
<tr><td></td><td></td><td></td><td>them present a moderate or high risk to patients and consumers" or have the possibility of causing "great harm." This is highly dependent on a SaMD's intended purpose and related risk.</td></tr>
<tr><td>#6</td><td>8-9</td><td>Replace the proposed classification rules on page 8 or 9 with the following table indicating the appropriate TGA medical device classification for the IMDRF categories based on level of potential harm:

<table>
<tr><th rowspan="2">State of Healthcare situation or condition</th><th colspan="3">Significance of information provided by SaMD to healthcare decision</th></tr>
<tr><th>Treat or Diagnose</th><th>Drive Clinical Management</th><th>Inform Clinical Management</th></tr>
<tr><td>Critical</td><td>III</td><td>IIb</td><td>I</td></tr>
<tr><td>Serious</td><td>IIb</td><td>IIa</td><td>I</td></tr>
<tr><td>Non-serious</td><td>I</td><td>I</td><td>I</td></tr>
</table></td><td>While we appreciate TGA's effort to take a risk-based approach to SaMD classification, we believe the classification rules should take into account the "State of Healthcare Situation or Condition" and the "Significance of the Information Provided by SaMD to the Healthcare Decision," as described in IMDRF's N12 Risk Categorization guidance.

Using these two factors as a starting point, we mapped the SaMD categories from the IMDRF N12 guidance to TGA's classification scheme, using Figure 13 from IMDRF's N41 Clinical Evaluation guidance to inform our effort:

Section 8 of IMDRF's N41 guidance describes the importance of independent review in relation to a SaMD's risk category; the greater the SaMD risk, the more important the independent review. In the context of TGA's medical device classification scheme, we can view independent review as review by TGA or a notified body, which is required for all devices that are classified above Class I. As</td></tr>
</table>

#	Page	Proposed Change	Rationale
			signified in Figure 13 and the supporting discussion in the IMDRF N41 guidance, independent review is less important for SaMD that fall to the left of the red line. Therefore, we recommend that, based on the TGA medical device classification scheme, all SaMD to the left of the red line be classified as Class I and that all SaMD to the right of the red line be classified as Class IIa, IIb, or III, depending on their level of potential harm. This approach is reflected in our proposed table. By classifying SaMD in this manner, TGA will be able to focus its regulatory oversight on the highest risk SaMD products and achieve a suitable balance between regulatory requirements with risk of harm to the patient. It is unnecessary and unsustainable for a health authority to require review of every SaMD product, specifically those that IMDRF has identified are less important for external review. As this approach also follows IMDRF, it promotes global convergence rather than development of an entirely new risk classification scheme by TGA, which could lead to delays in patients and clinicians accessing important SaMD technologies.
#7	8-9	Provide examples of software in each risk classification and a rationale for why the risk classification is appropriate.	We appreciate the examples provided in the table. To provide additional clarity, TGA should include a broader variety of examples of different types of software for each appropriate risk classification and the rationale for the classification. Examples should also include software that "mitigates" or "prevents" a disease or condition.

#	Page	Proposed Change	Rationale
#8	8-9	We suggest TGA provide clearer interpretations of the IMDRF definitions related to the significance of the information, i.e. treat/diagnose, drive, and inform. Language for each is included below, with language added to the IMDRF language denoted in red. **To treat or to diagnose** - To provide therapy to a human body; - To diagnose/screen/detect a disease or condition Output of the SaMD is intended to be used to: - Definitively diagnose a disease or condition; - Provide direct treatment or definitive treatment information for a disease or condition; Output of the SaMD is the sole determinant for clinical action and requires no further steps or confirmatory testing. **To drive clinical management** - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device. - To aid in making a definitive diagnosis. - To triage or identify early signs of a disease or conditions. Output of the SaMD is intended to be: - One of several inputs used for clinical action and/or decision-making; - Necessary for clinical action or decision-making or for understanding progression of the disease by the health care professional or patient that cannot be derived from standard clinical assessment, i.e. determinative. **To inform clinical management** - To inform of options - To provide clinical information by aggregating relevant information	We have provided the language in red to better delineate differences between the IMDRF risk categories and to appropriately classify SaMD within each category. For example, SaMD that treats/diagnoses is the sole source of information a clinician or patient uses for clinical decision-making, and provides a definitive diagnosis or information without any need for confirmatory tests. On the other hand, SaMD that is one of several pieces of information can be considered to either drive or inform clinical action by a clinician or patient. Only if the SaMD is necessary for use by the user and cannot be derived from standard clinical assessment should it be considered "driving" clinical action. This means the user has no other way to obtain the information provided by the SaMD, which is different than software that is merely meant to "inform." For example, a SaMD that assists a clinician in determining a certain functional score to assess a patient's disease state or changed disease state (e.g. disease progression) using an algorithm that relies on a variety of patient inputs or tests which could not have been derived from the physician's sole assessment (using existing clinical outcomes or tools) would not be categorized in the "inform" category and fall into the "drive" category. The proposed language in red has been vetted by a multitude of software

#	Page	Proposed Change	Rationale
		Output of the SaMD is intended to be: - One of several inputs used for clinical action and/or decision-making; and - Not necessary for clinical action or decision-making by the health care professional or patient or for understanding progression of the disease by the health care professional or patient; may or may not lead to direct clinical action or be derived from standard clinical assessment, i.e. informative or adjunctive. In addition, we recommend TGA provide clearer interpretations for state of the healthcare situation/condition, i.e. critical, serious, and non-serious.	developers and clinicians for its applicability. In addition to this language, we suggest TGA develop a classification tool for SaMD, similar to the tool that already exists on the TGA website.
#9	11	Recommend replacing essential principles (EP) # 2, 4, and 5 with the following: "that cybersecurity risks associated with the intended use environment be evaluated and mitigated, as needed, according to internationally recognized risk management principles."	We recommend that EPs # 2, 4, and 5, which are all related to cybersecurity measures, be combined into a single overarching cybersecurity principle. Our suggested language outlines the overarching cybersecurity principles and allows flexibility for a sponsor to demonstrate compliance with such principles.
#10	13	For on-market products that are in the ARTG, we suggest TGA add language to leverage the Conformity Assessment by the NB in a GHTF jurisdiction and post market data in order to support TGA requirements. This includes recognition and reliance on other comparable regulatory authorities for marketing approvals and evidence as consistent with current TGA regulations including "Use of market authorization evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)," and the goals of the Expert Review of Medicines and Medical Devices Regulation (MMDR) related to streamlining TGA processes to improve access by Australian consumers to new devices.	Manufacturers of SaMDs will be required to assess (or re-assess) the classification of the SaMD under the new regulations. Transitioning from the current Class 1 to the new level may require manufacturers and sponsors to generate additional data even though the product is already in use in Australia. We recommend TGA consider the least burdensome path (proposed in the left column) to mitigate patient impact, including recognition of SaMD approvals/clearances and reliance on clinical evidence from comparable overseas regulators.

#	Page	Proposed Change	Rationale
			Such an approach will allow TGA to focus its review where it is most needed and also to reduce regulatory burdens for SaMD developers. For example, if a manufacturer has a SaMD in the EU that was reviewed by a NB and if the manufacturer uses the same NB in Australia, we suggest TGA allow the manufacturer to use the Conformity Assessment evidence used in the EU to support the transition of the product classification as necessary. Similarly, if a manufacturer has a 510(k) clearance for a SaMD product in the US or an approval in Canada or Japan, we suggest that TGA enable this clearance to be leveraged in support of TGA requirements, similar to its approach with other medical devices.
#11	17	Please add the following section to the Appendix: Some standalone software may break down into a significant number of applications for the user where each of these applications is correlated with a module. Some of these modules have a medical purpose, some not. Such software may be intended to cover many needs, e.g.: - Collect and maintain administrative patient details; - Keep on file the medical history of the patient; - Invoicing and other accounting functions; - Provide a link to the social security system for reimbursement; - Provide a link to drug prescription systems (with possible link to drug dispensing outlets); - Provide expert system assistance for medical decision making (e.g. radiotherapy dose planner). This raises the issue as to whether the whole product must be qualified as a medical device when not all applications have a medical purpose.	In support of global convergence, we propose that the recommended text be included to ensure the understanding that, for software products with multiple functions, only those functions with medical device functionality will be regulated by TGA. This approach is consistent with approaches utilized by the US FDA (as described in the 21st Century Cures Act legislation and the supporting FDA draft guidance *"Multiple Function Device Products: Policy and Considerations"*), Health Canada (as described in its recent SaMD draft guidance document), and the EU (as described in MEDDEV 2.1/6, *Guidelines on the Qualification and Classification of Stand Alone Software Used in Healthcare within the Regulatory Framework of Medical Devices."*

#	Page	Proposed Change	Rationale
		Computer programs used in healthcare mostly have applications which consist of both medical device and non-medical device modules. The modules which are subject to the Australian Therapeutic Goods Regulation for Medical Devices must comply with the requirements of this Regulation. The non-medical device modules are not subject to the TGA medical device Regulation. It is the obligation of the manufacturer to identify the boundaries and the interfaces of the different modules. The boundaries of the modules which are subject to the TGA medical device Regulation should be clearly identified by the manufacturer and based on the intended use. If the modules which are subject to the TGA medical device Regulation are intended for use in combination with other modules of the whole software structure, other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the modules which are subject to the Regulation.	

Answers to TGA Consultation Questions

1. **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?**

   Response:

   In principle, Roche supports the proposal to change the way medical device software is currently regulated in Australia. A regulatory framework for SaMD that considers the unique nature of software has the potential to support rapid innovation and more robust digital health integration. A more predictable, risk-based regulatory pathway can also help reduce the time and cost of market entry, ensuring an appropriately streamlined path to increasingly advanced – and increasingly connected – digital health technology. These changes are intended to minimise public health and safety risks as well as align with international best practice.

We acknowledge that the current Australian regulations do not specifically address software that is used to diagnose or treat a medical condition, or that directly provides therapy through patient interaction in any detail. In general, we are supportive of the introduction of a risk-based regulation, based on the IMDRF framework. The three proposed areas of change to some extent reinforce this framework, but some aspects of the proposal are not yet sufficiently detailed. We have included some comments on this in our answers to the below questions.

Roche would like to highlight the potential for the changes to create a barrier to the local customisation of software and applications to meet the needs of the Australian healthcare providers and patients and to the risk of delays as local developers will need to acquaint themselves with the new regulations and its associated requirements. In order to avoid assigning a higher classification than is justified by the nature of the software and the setting in which it is used, it will be important to consider the classifications rules carefully.

Instead of creating an entirely new regulatory classification framework that seemingly limited in scope, Roche recommends the TGA to adopt the SaMD categories published by the IMDRF. For example, the current classification framework does not cover software functionalities that "mitigate" or "prevent" a disease or condition. Specific examples with different software functionalities and their corresponding classifications would ensure regulatory clarity.

2. What do you consider to be the benefits and disadvantages of the particular proposals for change?

Response:

Generally, it is suggested that the transition period shall coincide with the transition in Europe to the Medical Device Regulation 2017/745. Some of the proposed changes might have rather high impact, for example the new classification of SaMD leading to a high number of SaMD requiring related conformity assessment. Particularly since some software (e.g. dosing calculations) have only recently been classified as SaMD by the TGA. The new changes to classification will lead to a number of software products requiring a higher classification requiring significantly more resources related to obtaining conformity assessment by the TGA or Notified Bodies.

We are of the opinion that a reasonable transition period (i.e. 5 years) need to be given to ensure continued access to medical device software for the Australian patients/consumers.

Further, a recommendation would be for the TGA to conduct a series of training sessions (e.g. Roadshows) for the local developers as well as sponsors of SaMD to familiarise them with the new requirements.

Proposal 1: Changes to the classification rules:

Roche supports unambiguous, internationally-recognised, risk-based classification rules that are based on the IMDRF framework. We have proposed additional clarity related to the definition of SaMD as well as the interpretations for IMDRF risk classifications.
We suggest clearer definitions, based on the IMDRF definitions and examples, for the following:

- Inclusion of examples on software that would NOT be considered medical devices.
- The suggested wording repeatedly refers to software that "processes" data for the purpose of providing information for diagnosis or treatment. Is this equal to "performing an action on data" and thereby generating tailored output e.g. based on matrixes, or is the idea to also include mere storage of data (e.g. database)?
- "Screen" patients to determine the need for further assessment. What types of actions would be considered "screening"?
- "Debilitation" - How to distinguish from the general "harmful" that would result in a lower class?
- "Non-interactive intervention"- What is meant in this context: *"The software directs patient activity based on a non-interactive intervention."*

Also, based on the proposed classification rules, there seem to be only very few class I SaMD. This may result in a significant amount of SaMD that would need to be re-classified, which would require significant resources not only from manufacturers, but also from notified bodies and the TGA.

We suggest specifically addressing this topic in dialogue with SaMD manufacturers to ensure continued access to such SaMD for the Australian patients/consumers. We also suggest including more examples of class I SaMD.

Additionally, it's important that the TGA provide a clarification to industry about who, in TGA's opinion, would be an appropriate third party that will be providing conformity assessment to apps that are developed here in Australia. The sponsors of those devices that will be reclassified to a higher class will need to have a third party oversight through application of the conformity assessment procedure required.

Proposal 2: Requiring SaMD to be included in the ARTG:

Roche agrees with the TGA proposal to include SaMDs in the ARTG and for the TGA to have the necessary regulatory oversight and meet safety, quality and performance requirements. As TGA assesses the "Personal Importation" provisions in light of the technological evolution taking place in healthcare, we encourage TGA to strike a careful balance to maintain access to innovative health care solutions by patients/health care providers with the necessary licensing requirements to protect those same software users. We support robust real world performance monitoring by software developers to ensure the safety and quality of their products.

Proposal 3: Changes to the essential principles:

Roche is in agreement with the proposal to update the essential principals (EP) to capture SaMD, to align with good software development practices, high-level security principles and the EU regulatory framework. However, Roche is of the opinion that a clear and distinct subset of EP, that are only applicable to SaMD should be prepared.

It will be also expected that the TGA would provide clear guidance regarding the information needed for the technical file for assessment of SaMD, as it is expected that there may be an increased need for documenting related processes.

3. **Do you believe there will be any unintended consequences arising from the proposed changes?**

Response:

Roche would expect that there will be unintended consequences arising from the proposed changes as follows:

1- Availability of new applications or SaMD in the Australian market will be delayed as a result of re-classification of SaMD. The resource (time and cost) needed to prepare for these applications under the new classification rules (e.g. assessment by a notified body, organising of a technical file), could delay the availability of SaMD to patients, in comparison to the current environment. There is a significant risk for bottlenecks, i.e. capacity constraints in notified bodies as well as the TGA evaluation.
2- The increase in complexity of the dossier requirements might lead to fewer locally and globally developed systems that are customised to meet the AU regulations. This might discourage the development of local applications that are deemed necessary for the quality use of therapeutic products in Australia.

4. **What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?**

Response:

Roche believes that, in order to meet the new arrangement, manufacturers and sponsors would need to review our current software and prepare the required documentation to support reclassification and submission. This will result in a significant workload for local sponsors.

5. **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.**

Response:

There will be an increase in the cost of the developing applications locally, which will be an additional barrier to the local introduction of locally suitable applications.

There will be a financial impact as developer cost will be increased accounting for the:

- Increase in the cost to prepare technical file. This, coupled with the
- submissions costs, will result in increase in the cost per unit.

It is also anticipated that there will be an increase in the cost of subscriptions to third party systems, which will increase the cost per App/SaMD.

The proposed change may have an impact on the organisational structure of a company. An additional headcount may be required in order to comply with the new requirements.

6. **What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.**

   Response:

   For reasons discussed in this document, it is anticipated that a transition period of a minimum of 5 years would be adequate to account for the implementation of the newly proposed changes. The TGA granted the industry a 5-year grace period when device requirements changed in 2002 and that was very helpful to the industry at that time to ensure compliance.

There is one more questions that arises from the new proposals as follows:

- Does the TGA have plans for expediting assessment and approvals of all reclassifications of devices that are currently classified as Class I SaMD?