Consultation Paper - Potential reclassification of active medical devices for diagnosis and patient therapy

Question Number	Question	Roche Comments
1	What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?	- We recommend deleting Artificial Pancreas from the example list for the reasons listed in item 3.
2	Are there any further issues and questions we should consider when implementing this change (i.e. areas that need to be clarified in our guidance)?	- No further comment.
3	Other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include: – external pacemakers – continuous positive airway pressure (CPAP) devices – intravascular heating/cooling system control units – hyperthermia systems, temperature mapping units – intraperitoneal-circulation hypothermia system control units – mechanical bloodstream indicator injectors. We seek your feedback whether reclassification of any or all of these devices in Australia to Class III is appropriate.	- We recommend TGA delete the artificial pancreas as an example of a Class III closed loop system as future generations of an artificial pancreas may qualify for a different classification. - Additionally, mentioning "artificial pancreas" as an example of a Class III medical device limits TGA's opportunity to implement innovative pathways to ensure access to life saving medical devices. - For example, FDA is creating a new regulatory scheme for AID systems that will be differentiated from the previously established closed-loop artificial pancreas regulatory scheme. In USA, AID systems and their components may not be classified at the highest level of regulatory requirements. In 2018 FDA created a new device classification regulation for Integrated Continuous Glucose Monitors that defined these devices as Class II, with several

		regulatory special controls, rather than as Class III. (21 CFR 880.5730) - The FDA's AID regulatory scheme initiative is supported by domestic and international diabetes patient advocacy organizations, e.g., JDRF. If FDA is successful in creating the new AID system regulatory scheme, other global health authorities may be asked by these advocates to follow their lead. - It is therefore recommended to delete artificial pancreas as example of closed loop Class III device from this paper.
4	Are there any other groups of devices that we have not considered which might fall within the scope of this proposed change?	We recommend that the TGA create a new regulatory scheme for Automated Insulin Delivery systems (AID) that will be differentiated from the previously established closed-loop artificial pancreas regulatory scheme. Although TGA's regulatory policies follow EU rather than USA FDA, if EU Competent Authorities and TGA may decide to establish new device classifications for AID systems that are differentiated from closed-loop artificial pancreas specified and/or developed by a single company. If mentioning "artificial pancreas" as an example of Class III medical device limits your opportunity to place AID systems and components in Class II, then it may be prudent to delete artificial pancreas as example of closed loop Class III device from this paper.
5	Do you have any comments regarding the transitional arrangements proposed in this paper?	We welcome the TGA's proposal regarding the transitional arrangements in this paper.