# FAQS – PROPOSED AMENDMENTS TO THE HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2010

## Wellness devices are not Medical Devices

1. **Are there any requirements for Telehealth products that are not intended for medical purpose[1] but are able to perform such functions (for example, Telehealth Products intended for fitness tracking that are able to monitor heart rate)?**

   Telehealth products (including devices and software) which are not intended by the Product Owner for medical purposes, but are able to perform functions such as heart rate monitoring and measurement of blood oxygen level are categorised as Wellness Devices. Wellness devices are not subject to regulatory controls as they are not regarded as medical devices.

   However, the product owner has to ensure that a "clarification statement" (or equivalent) are presented on their labels/advertisements to inform consumers that the device is not to be used for medical purposes.

   Clarification statement refers to the following text or equivalent:

   - *This device or software is intended for use only for general well-being purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose (such as the detection, diagnosis, monitoring, management or treatment of any medical condition or disease). Any health-related information provided by this device or software should not be treated as medical advice. Please consult a physician for any medical advice required.*

## "Trained User Only" Medical Device

2. **What is the difference between "Trained User only" (TUO) and "Professional-Use only" (PUO) medical devices?**

   "Trained user only" medical devices means a medical device that is to be used only by an individual, who has undergone training to use the device safely and effectively as is necessary. The training necessary for the use of device could be in the form of hands-on user training, online tutorials, briefing, technical demonstration, depending on the content as deemed appropriate by the Product Owner.

   Professional-Use Only (PUO) medical devices are intended by the Product Owner for use by or under the direct supervision of doctors or dentists.

[1] For investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process.

It is the responsibility of the registrant and suppliers to ensure that the devices are supplied to appropriate users (e.g. doctors, trained users) based on the manufacturer's intent with reference to the Instructions for Use (IFU)/user manual/product insert, where applicable.

3. **Who determines if a medical device should be a "Trained User only" (TUO) and "Professional-Use only" (PUO) device?**

   The determination of a TUO or PUO device will be based on the manufacturer's intent as presented on the Instructions for Use (IFU)/user manual/product insert of the device.

4. **Who ensures that the medical devices are appropriately categorised as TUO or PUO devices?**

   It is the responsibility of the manufacturers to determine the appropriate competency of their intended users (whether the device is for TUO or PUO) to ensure the safe and effective use of their devices. In instances where HSA disagrees with the manufacturer's intent, HSA may require additional measures in the interest of device safety or efficacy (e.g. label update).

5. **A) Are the suppliers of the TUO medical devices required to train every user themselves?**

   **B) Are we required to train the user prior to selling the device to the company? Are we allowed to sell to company then arrange for the training session later?**

   A) For more complex medical devices, HSA will require the local registrants/ suppliers to provide training for the users of these devices. Under the new regulation 13B Supply of "trained user only" medical devices, the registrant/supplier is required to make available appropriate training on the safe and efficacious use of the medical device to every user of the device. The need for training is determined by the Product Owner.

   The local registrants/ suppliers of such medical devices should work with the product owners to arrange for the appropriate training of local users, where applicable, at the point of supply of the device. The training could also be outsourced to another person, by the registrant/supplier of the medical device and the supplier is not required to train every user themselves.

   The local registrants/ suppliers are encouraged to work continually with users and user facilities to support training of new users in the facilities during the life time of the device.

   B) TUO medical devices should only be used by appropriately trained users and registrant/suppliers should arrange for such training before use of the device in the facility.

6. **What kind of evidence does HSA require local registrant to possess in order to fulfil requirement of the new regulation for Health Product Act 13B regarding "Trained user only" medical device?**

   The registrant/supplier is required to maintain records that training has been provided to the user, at or before the time the medical device is used by the user. Such records could be maintained in any format as appropriate (e.g. signed off training attendance sheet).