
**RESPONSE**

**Therapeutic Goods Administration**

**CONSULTATION: Scope of regulated software-based products**

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# Introduction

GPC Systems (Australia) is an independent organisation representing GPC Systems based in the United Kingdom who are the developers of innovative technologies across a number of industries but having based its growth and experience through substantial involvement in the development of 3D Depth Camera and information management technologies in cooperation with the NHS.

# Comments and Observations

## Exclusion/Exemption Profile

The GPC Systems (AUS) response is focussed on exclusion and exemption criteria to supplement the proposed principles of the scoping document.

Although a complex issue is at hand, the definition of software-based product for exclusion or exemption, could be determined in simple terms by describing a product's risk profile as follows: -

- Any dependency on an invasive process to acquire the expected outcomes.
- Any dependency on passive or active intervention to drive an expected outcome or remedial action.
- The delivery of passive outcomes that are dependent on further assessment to determine further intervention or remedial action.
- Providing outcomes that are aligned with predictive analytics based on machine learning to support clinical expertise.
- Software does not actively change the current state of the subject under examination but delivers information upon which expert determination will drive actions to be undertaken in an immediate timeframe or a clearly defined period of currency.
- Where necessary quantifiable and qualified calibration of any integrated image, weights, and measures to within acceptable tolerances, are documented and committed by the supplier/ manufacturer.
- The purpose is defined as supporting remote capture and dissemination of information not requiring clinical intervention and post useability training for unqualified/non-clinical users.

A significant danger exists that products classified under self-assessment could enter the marketplace without any registration or commitment from the developer/distributor. A simple set of

criteria as described above where low to no direct risk to a patient can be achieved where a product is passive in nature and outcomes only activated through expert diagnosis either through clinicians knowledge and experience or highly qualified machine learning technology which would be subject to the inclusion on ARTG.

## ARTG Registration – Carve-out Mechanisms

As stated within the scoping document there is a dependency on the ARTG to deliver confidence that software-based product is safe and fit for purpose when used.

Exempt product should meet the criteria of SaMD or fit the description of Clinical Decision Support or Patient Decision Support.

Excluded product would be product that is not a medical device but has a clinical purpose.

In addition to the principles proposed the following is offered for broader industry understanding and acceptance: -

### Exempt/Excluded Product for Inclusion on the ARTG

The "Scope for regulated software-based products" suggests that excluded products would *not* be included in the ARTG.

To assist the risk assessment of Software as a Medical Device by purchasers, separate registration categories of Exempt and Excluded should be created with inclusion based on a supplier/ developer/ manufacturer self-regulated assessment and compliance for exclusion/exemption.

This premise aligns with the basic purpose of the US FDA 510(k) Pre-Market authorisations.

## Other Jurisdiction Guidance Material

In GPC's view the approaches that have merit for consideration can be summarised as follows: -

- Health Canada

  Section 2.1 Software as a Medical Device – inclusion criteria. The interpretation for defining SaMD and the intended key use are appropriate to Australian guidelines. The use of an "intended use" statement should be included in submission for exclusion under the Australian guidelines.

  Section 2.2 including Table 1 clearly defines process and description for exclusion and would be appropriate for adoption in the Australian circumstance.

# Summary

It is GPC's observation and recommendation that the criteria for exclusion/exemption should be aligned and where the product has a medical purpose then it must be registered for inclusion in the ARTG under an Exempt or Excluded category and domiciled accordingly with an identifier to be readily identified within product documentation including license to use and/or affixed to the product hardware.