

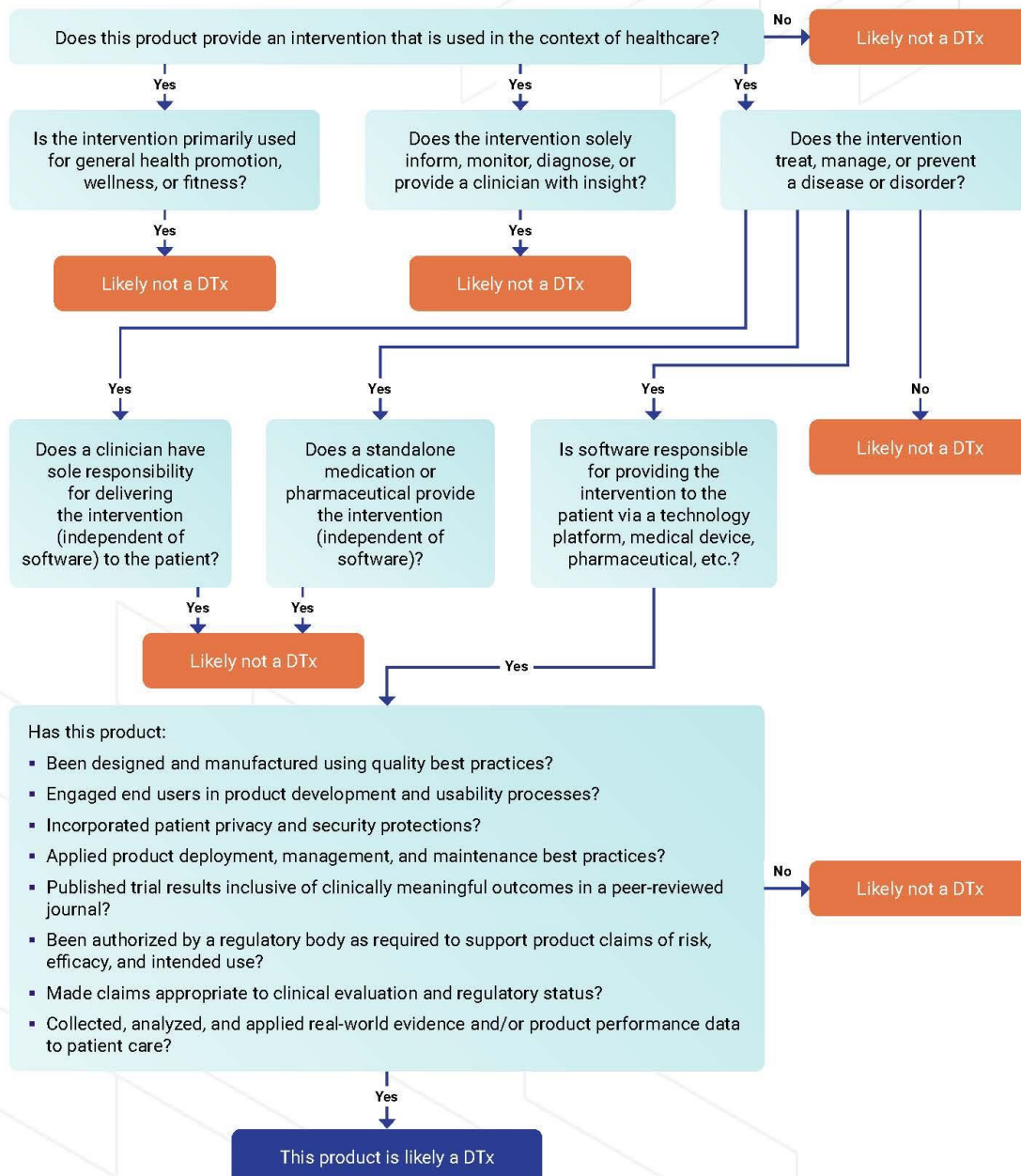
Further notification of evidence relating to Software as a Medical Device (SaMD) to the Health Select Committee from the Digital Health Association (DHA)

To help the Health Select Committee further, we have found a flow chart from the [Digital Therapeutics Alliance](https://dtxalliance.org/wp-content/uploads/2022/09/DTA_FS_Is-This-Product-a-DTx.pdf) that defines a clear path of what constitutes SaMD (Digital Therapeutic (DTx)) and what does not https://dtxalliance.org/wp-content/uploads/2022/09/DTA_FS_Is-This-Product-a-DTx.pdf



Is This Product a DTx?

Given the proliferation of products available to patients, caregivers, and clinicians for use in healthcare, it can be difficult for end users to determine which products are digital therapeutics vs. other types of DHTs. This flow chart helps HCDMs and end users understand which products qualify as a digital therapeutic and therefore are best suited to be evaluated using this Guide.



Please also find below the link to a recent report on the European Union (EU) Medical Device Regulation (MDR), *MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation*:

<https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

Key findings of the report:

- The survey represents an estimated 60-70% market revenue coverage.
- MDR certificates have not been issued yet for >85% of the >500,000 devices previously certified under the MDD or AIMDD.
- Larger companies are actively filing under MDR. Review is still ongoing for 70% of submitted industry applications.
- The time-to-certification with MDR-designated Notified Bodies is taking 13-18 months on average. This is double the time historically needed for certification under the Directives.
- >50% of respondents plan portfolio reductions. 33% of these companies' medical devices are currently planned for discontinuation.
- All product categories are impacted by potential device discontinuations.
- At least 15 % and up to 30% of Small and Medium Enterprises (SMEs) still have no access to an MDR-designated Notified Body.
- ~50% of respondents are deprioritising the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices.
- >20% of respondents attribute delays in MDR certification to the publication of new or revised MDCG guidance.

This report should raise significant concerns around how not fit-for-purpose regulation can impact negatively and cause significant unintended consequences. We understand that there are less medical device companies and products available in the EU now and that patient safety relating to products that cannot get a timely authorisation is compromised where clinical staff are having to create their own off-the-cuff workarounds.

We believe New Zealand has a unique opportunity to create a regulatory framework for SaMD that is agile and up-to-date and become global leaders in this space.

We urge the Committee to consider the above evidence when investigating and deciding on next steps for SaMD regulation in New Zealand. The Digital Health Association and its members are committed to working with Government to help provide consultation, advice, and guidance on the regulation of SaMD.

Ngā mihi,

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