Based on the product's intended use and risk, determine whether the product is excluded, exempt, or not exempt under the Therapeutic Goods Administration (TGA) regulatory pathway for medical devices.

Excluded products that meet certain exclusion criteria are not regulated by the TGA.

OR

Exempt software qualifies as a medical device but is not subject to all regulatory requirements.

OR

Not exempt products are subject to all applicable regulatory requirements.

Class: I, IIa, IIb, III

Mental health tools that meet exclusion criteria *and* display key information on the system are **excluded** and not required to register on the Australian Register for Therapeutic Goods (ARTG).

Note: National Safety and Quality Digital Mental Health (NSQDMH) Standards requirements may apply.

Clinical decision support software (CDSS) that meet certain criteria *and* display key information on the system are **exempt** and are not required to register on the ARTG; however, developers must notify the TGA and products are subject to post market requirements.

Manufacturer demonstrates compliance with the Essential Principles for medical devices through a conformity assessment.

OR

During any phase of the conformity assessment process, manufacturer may apply for expedited Priority Review if the device represents a breakthrough technology or provides a clinical advantage for an unmet need. This process provides 'front-of-queue' priority status.

Class: IIa, IIb, III

Clinical evidence evaluation and ***clinical investigation*** may be required.

Achieve medical device self-declaration of conformity.

Class: I

Clinical evidence evaluation may be required.

OR

Obtain Conformity Assessment Certification from TGA or a third party Australian conformity assessment body (Australian CAB).

Class: IIa, IIb, III

Clinical evidence evaluation and ***clinical investigation*** may be required.

OR

Obtain Conformity Assessment Certification from a comparable overseas regulator (i.e., European Union (EU) Notified Body).

Class: IIa, IIb, III

Clinical evidence evaluation and ***clinical investigation*** may be required.

Leverage specific overseas assessments and approvals for an abridged assessment for a TGA conformity assessment certificate.

OR

Leverage specific overseas assessments and approvals as the documentation required for passing the preliminary ARTG inclusion assessment.

Comply with disclosure requirements ahead of proceeding to various patient access routes.

Sponsor submits certificate to TGA as evidence of manufacturer's compliance. TGA may approve the inclusion of a device based on the information provided in the application or may select an application for audit. Audit reviews may include product labelling, instructions for use, technical documentation, advertising materials, clinical evidence, or risk management documentation.

Sponsor submits application to be listed on the Australian Register for Therapeutic Goods (ARTG).

DHT pricing, reimbursement, patient access, and product assessment by purchasers is primarily conducted at the **local** level on a case-by-case basis (i.e., states, insurers, health systems, healthcare providers, employers).

NO national Health Technology Assessment (HTA) process for DHTs

NO national pricing or reimbursement processes for DHTs

NO national prescribing requirement or patient access pathways for DHTs

Key

Step that applies to a **national** process

Step that applies to a **local** or **regional** level

Details regarding clinical data:

Clinical evidence evaluation *refers to the review of published data.*

Clinical investigation *refers to a systematic investigation or study undertaken to verify the safety and performance of a device.*

NO **national** pathways for DHTs