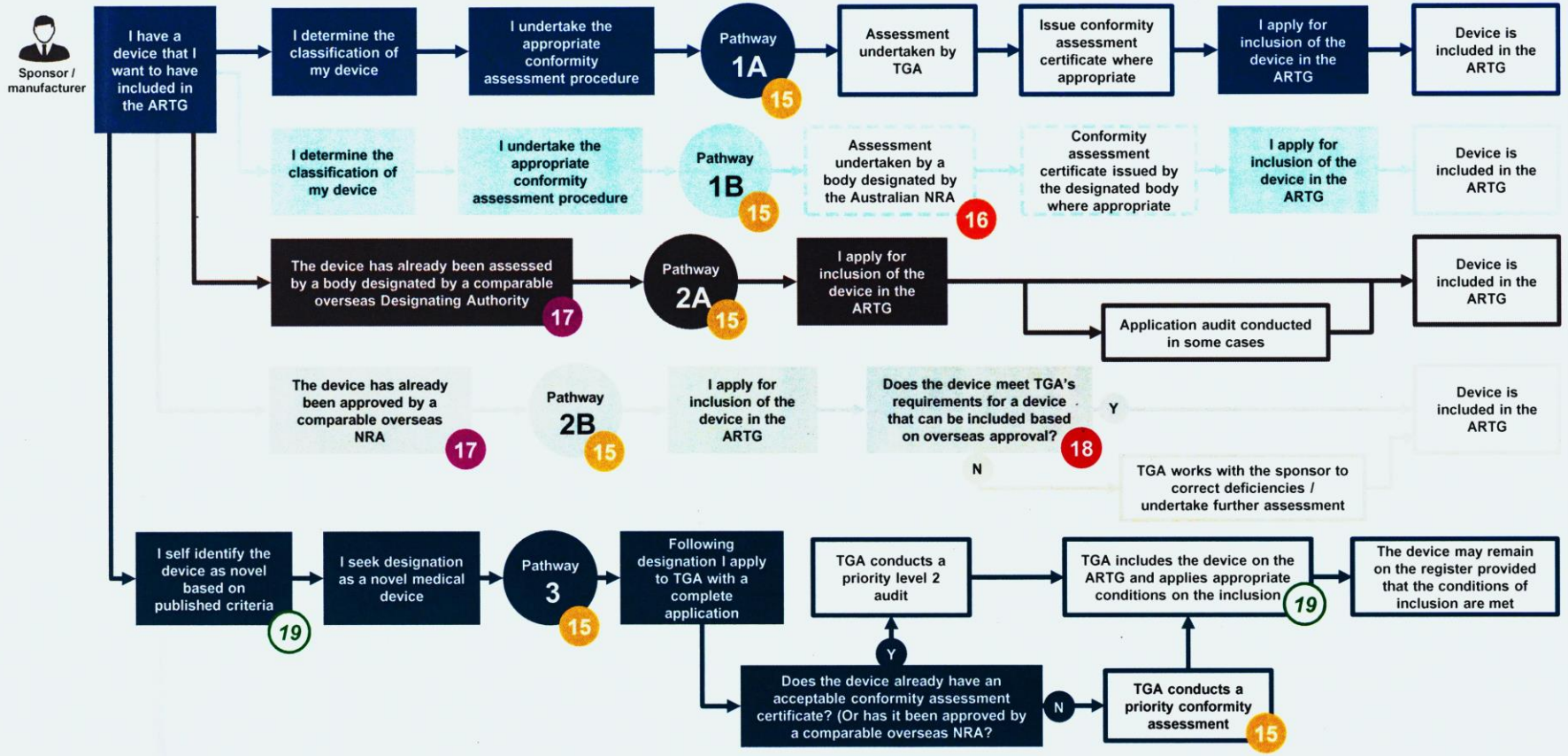
Australian Government
Department of Health

THINKPLACE

Overview of Three pathways to include medical devices



15 **Recommendation 15**
Three pathways to registration of new medical devices 1) Conformity assessment done in Australia by the NRA or a designated body 2) utilisation of market approval by comparable overseas NRA or designating authority 3) Expedited approval in certain circumstances

16 **Recommendation 16**
Transparent criteria for designated bodies in Australia

17 **Recommendation 17**
Transparent criteria for identifying comparable overseas NRA's and designating authorities for the evaluation of medical devices

18 **Recommendation 18**
Checklist for registration of medical devices using pathway two

19 ***Recommendation 19 – EARLY OPPORTUNITY***
Transparent criteria conditions for expedited approval of new medical devices

20 **Recommendation 20**
Aligning the regulation of medical devices with the EU wherever possible

21 **Recommendation 21**
Target timeframes that reflect international benchmarks for the registration of medical devices