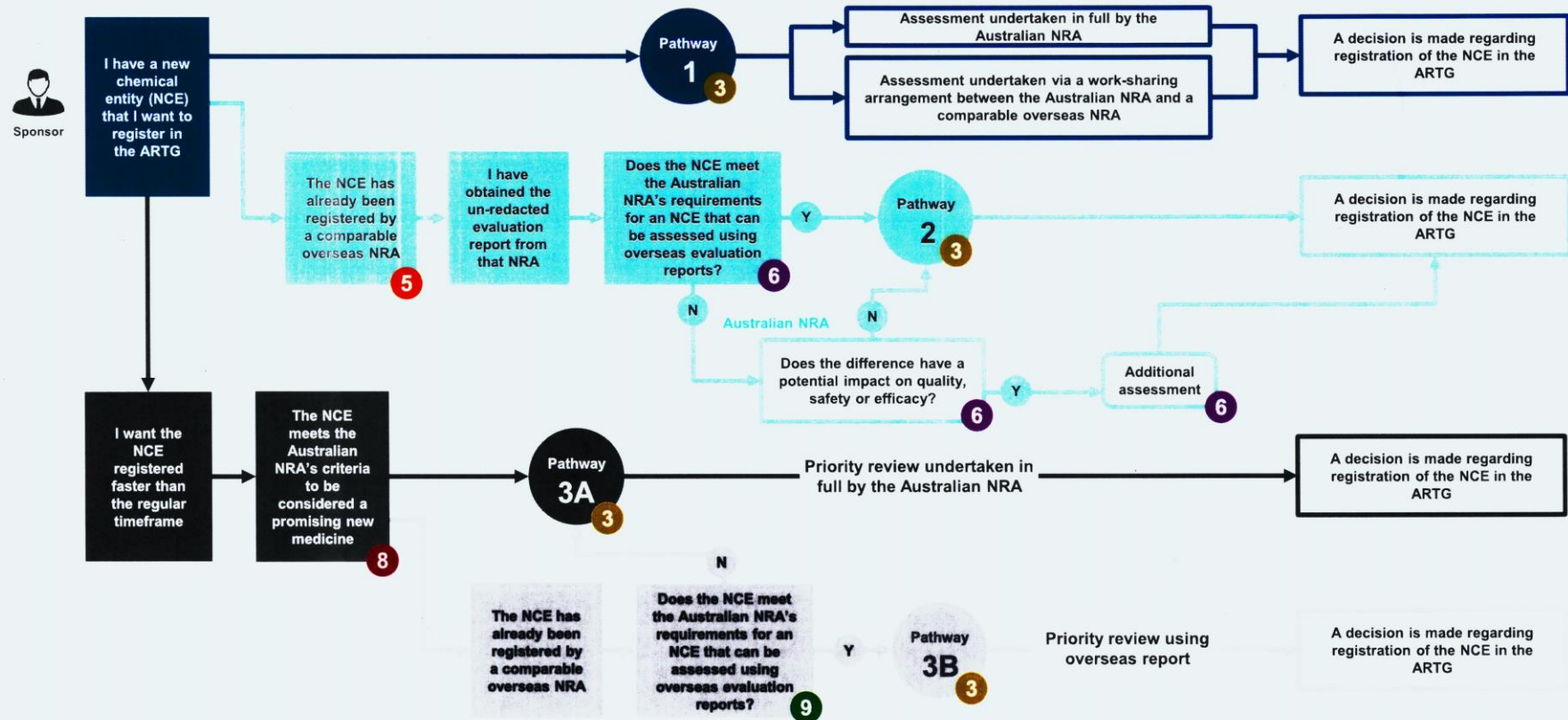


Overview of three pathways to register NCEs



- 3 Recommendation 3**
 Three pathways to registration of new chemical entities (NCE),
 1) Submission of complete dossier for de novo assessment
 2) Submission of an evaluation report from a comparable NRA
 3) Expedited approval in certain circumstances

- 5 Recommendation 5**
 Transparent criteria for identifying comparable overseas regulators for the purpose of registering NCEs (also generics and biosimilars)

- 6 Recommendation 6**
 Requirements to be satisfied before registration of a new chemical entity via Pathway 2, based on a comparable overseas NRA report and what else needs to be done if the NCE does not fulfil the requirements

- 8 Recommendation 8**
 Transparent criteria under which application may be made for 'promising new medicines'

- 9 Recommendation 9**
 Requirements to be satisfied before expedited approval process for registration of a new chemical entity via Pathway 2 based on the overseas NRA report.