Fact Sheet:
Real-world data and evidence

HTA Review recommends developing a framework, infrastructure and access to a nationally coordinated RWD/RWE data set to support HTA submissions, managed entry agreements and post-listing reviews.

The HTA Review recognises that RWD and RWE can supplement clinical trial data to demonstrate the efficacy, safety and cost-effectiveness of new technologies. This is especially relevant for new technologies for rare conditions or small patient populations, and where clinical trial evidence may not be robust or even feasible. RWD can also be used to demonstrate long-term efficacy, safety and cost-effectiveness of new technologies as part of managed access programs, DUSC reviews and post-market reviews.

The HTA Review makes the following reform recommendations:

- Develop and implement an Australian-specific, co-designed framework to optimise timely access to relevant RWD for HTA as a supplement to randomised control trial (RCT) evidence (Recommendation 27).
- Develop a whole-of-government data infrastructure, with oversight by a multi-stakeholder advisory group (Recommendation 28).
- Promote State and Territory Government collaboration and participation in cross-jurisdictional data-sharing to support nationally cohesive HTA (Recommendation 29).
- Develop a multi-stakeholder coordinated approach to transparent evidence development for HTA using best-practice methods, spanning standardised data, analytics and reporting (Recommendation 30).
- Ensure early identification and configuration of data collections suitable to support the resolution of uncertainties where it is expected that an application is likely to result in a Managed Entry Arrangement (MEA) (Recommendation 31).

Access to nationally coordinated RWD and RWE will assist sponsors in supporting HTA applications and addressing residual uncertainties about the safety, efficacy and cost-effectiveness of novel health technologies. These are positive recommendations for industry but must be implemented with broad consultation.