Examples of consumer information about medicines listed under a managed entry framework are provided below.

Example 1: If data is being collected as part of a managed entry framework

This medicine has been listed on the PBS via a managed entry framework. This managed entry framework provides a mechanism to address the uncertainty over [description of the nature of the uncertainty, eg the size of the additional clinical benefit of this medicine] while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a managed entry framework does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

The relevant information for this drug is being collected about selected patients from their prescribing doctor. Patients are being selected on the grounds that [insert any specific recruitment criteria].

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each selected patient receiving PBS-subsidy for this medicine.

For more information on managed entry framework, please visit [link to finalised information].

For more information on the PBAC's consideration of this medicine and its managed entry framework: [link to relevant Public Summary Document]

Example 2: If data is being collected outside the managed entry framework (eg through an on-going study or trial)

This medicine has been listed on the PBS via a managed entry framework. This managed entry framework provides a mechanism to address the uncertainty over [description of the nature of the uncertainty, eg the size of the additional clinical benefit of this medicine] while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a managed entry framework does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of this drug, the relevant information is being collected [description of how information is being collected, eg from an ongoing clinical trial outside the PBS].

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS subsidy for this medicine.

For more information on managed entry framework, please visit [link to finalised information].

For more information on the PBAC's consideration of this medicine and its managed entry framework: [link to relevant Public Summary Document]