

Terms of Reference – Review of the Efficient Funding of Chemotherapy arrangements

Chemotherapy medicines listed on the Pharmaceutical Benefits Scheme (PBS) are supplied as a specialty service through public and private treatment settings in Australia. Remuneration for chemotherapy medicines is paid to the supplying pharmacy in accordance with the Efficient Funding of Chemotherapy (EFC) measure, which was established in 2011. Generally, chemotherapy medicines are prescribed, compounded and administered at a specific dose calculated for each individual patient to ensure optimum outcomes.

Since the establishment of the EFC measure, and increasingly in recent years, stakeholders have expressed varying views regarding the:

- Appropriateness of the compounding fees provided compared to the cost of compounding (including operational costs in relation to compounding in Therapeutic Goods Administration (TGA) licenced production facilities)
- Administrative burden associated with the claiming and receiving payment for chemotherapy medicines dispensed from a range of pharmacy settings, and
- Appropriateness of the current EFC approach in ensuring all participants in the chemotherapy medicines supply chain are reimbursed fairly and appropriately.

As part of the 2020-21 Budget, the Australian Government agreed to a review of current EFC arrangements. The EFC review will look at the impact and continuing suitability of current EFC arrangements and associated practices within the supply chain to ensure continuing access to these medicines.

In conducting the EFC review, the Government will examine whether the EFC Program supports patient access to chemotherapy medicines in an efficient and cost-effective manner. The Government may also consider whether a new or adjusted reimbursement framework is required to ensure ongoing access to these medicines and whether a new or adjusted framework may encourage innovation and collaboration across the EFC supply chain.

The EFC review will produce a final report for consideration by the Minister for Health and Aged Care no later than 30 June 2022.

In making its recommendations, the EFC review will consider:

- The patient experience, including expectations, priorities and experiences related to accessing EFC medicines across different States and Territories
- The activities and experiences of the participants in the EFC supply chain in supporting patient access to chemotherapy medicines and related pharmaceutical benefits as defined in the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, including:
 - Current arrangements and models of delivery that support access for Australians in rural and regional areas, Aboriginal and/or Torres Strait Islander peoples, and older Australians, and
 - PBS prescribing, claims processing and the administrative burden associated with providing access to chemotherapy medicines.

- The distribution of costs and Government remuneration through the EFC supply chain, including:
 - Current remuneration structures that support the provision of products and services by the EFC supply chain
 - Whether all participants in the supply chain are funded effectively and equitably to provide products and services to patients while meeting regulatory and compliance requirements
 - Opportunities to promote market competition and innovation within the EFC supply chain, and
 - Options for alternative funding mechanisms to support access for Australians in rural and regional areas, Aboriginal and/or Torres Strait Islander peoples and older Australians.
- How appropriate transparency of product flow and funding may be supported, including through systems and data flows used by Government and supply chain participants
- The outcomes of current Commonwealth reviews into national standards, policies and guidelines of relevance to EFC medicines supply and access, such as the National Medicines Policy and the TGA PIC/S9 Guide to Good Manufacturing Practice for Medicinal Products
- The possible impact of new and/or emerging technologies on future operation and funding of EFC arrangements
- How access to chemotherapy medicines is provided globally, and whether these international models could be incorporated appropriately in the Australian context, and
- The classification of items listed in the EFC Instrument and on the general PBS Schedule, including potential for adjustments to improve the patient and health professional experience.

In conducting the EFC review, the following will be undertaken at a minimum:

- Call for public submissions
- Consultation with stakeholders on discussion papers and an interim report
- Consideration of approaches to funding of chemotherapy across all jurisdictions
- Analysis of costs incurred in the manufacture, logistics, handling, compounding and dispensing of chemotherapy medicines, and
- Examination of new and emerging technologies associated with the manufacture, logistics, handling, compounding and dispensing of chemotherapy medicines.

Matters to be considered out of scope for the EFC review include:

- a) Considerations relating to ancillary cancer treatment costs (such as travel and accommodation);
- b) Costs and access arrangements for non-EFC listed cancer treatments (e.g. oral chemotherapy medicines and non-PBS medicines).