Review of the Efficient Funding of Chemotherapy (EFC) program
Discussion Paper and Call for Submissions

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1. Introduction and Background

In the 2020-21 Budget, the Government announced a review of the current Efficient Funding of Chemotherapy (EFC) program. The review will look at the impact and continuing suitability of the current EFC program and associated practices within the supply chain to ensure continuing access to medicines under this program.

Chemotherapy medicines listed on the Pharmaceutical Benefits Scheme (PBS) are supplied as a specialty service, legislatively underpinned by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*. Chemotherapy medicines are supplied through public and private treatment settings in Australia. Remuneration for chemotherapy medicines is paid to the supplying pharmacy in accordance with the EFC program, which was established in 2011 with the aim of achieving greater efficiency in the use of injectable and infusible chemotherapy medicines used in the treatment of cancer.

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 program, and increasingly in recent years, stakeholders have expressed varying views regarding the:

- Appropriateness of the compounding fees provided as part of chemotherapy remuneration 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 claiming and receiving payment via the EFC program for chemotherapy medicines dispensed from a range of pharmacy settings, and
- Appropriateness of the current EFC approach in ensuring all participants in chemotherapy medicines provision are reimbursed fairly and appropriately.

In conducting the 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 (including, but not limited to, medicines manufacturers, wholesalers, chemotherapy compounders, prescribers, and people involved in chemotherapy preparation and administration). The Government is seeking to ensure, through this review process, that the access and funding arrangements for chemotherapy services reflect a transparent, accountable, efficient and equitable model of service.

In forming this review, consultation with stakeholders of the EFC supply chain has been sought and the Terms of Reference for the review finalised and endorsed by the Hon Greg Hunt, Minister for Health and Aged Care (the Minister).

To achieve the aims of the review, the Department of Health (the Department) will be conducting a period of stakeholder consultation on matters including, but not limited to:

- Access to chemotherapy medicines in the EFC program

- Processes impacting the manufacturing, supply and claiming of EFC medicines, and
- Strategies for implementation of models which may improve the EFC program

Throughout this Discussion Paper, the Department will seek your feedback and recommendations on accessing chemotherapy medicines under the EFC program.

Through this consultation the Department is seeking to understand: who you are and what industry you belong to within the EFC supply chain; your perspectives regarding the questions posed about the EFC supply chain and the EFC program; and how this review will affect you, your organisation and other members of the industry.

The feedback received as a result of the consultation on this Discussion Paper will support the Department in developing a final report for the Minister to consider by 30 June 2022. Details on how to make a submission are provided under section 7 of this paper, 'Process for Providing a Submission'.

2. Aim of Consultation

This consultation aims to bring together the perspectives of stakeholders to formulate potential changes, if any, across the supply chain of chemotherapy medicines to ensure equitable and efficient access to these medicines for all stakeholders.

Stakeholders in this case include, but are not limited to:

- manufacturers
- delivery and logistics partners
- patients
- chemotherapy compounders
- hospital pharmacists
- prescribers, and
- other Commonwealth and State Government Departments.

3. Reporting

The review aims to conduct consultation workshops following close of the Discussion Paper consultation period. An interim report for stakeholder consultation will be produced from consolidated feedback prior to 31 December 2021, before a final report for consideration by the Minister no later than 30 June 2022.

4. Terms of Reference

The review will address areas in which the Government requires further information to determine the most appropriate approach for providing access to chemotherapy medicines through the EFC supply chain.

The Terms of Reference were published on 1 May 2021 through the PBS Website , and can be found at https://www.pbs.gov.au/info/reviews/efficient-funding-of-chemotherapy-review.

5. Questions for Stakeholder Input

The following questions have been designed to address the Terms of Reference for the review, having regard to particular issues raised in previous consultations.

You may wish to respond to all or some of these questions as they apply to your experience with accessing and/or providing chemotherapy medicines or services. In considering the Terms of Reference, please note that these are not meant to be exhaustive, nor do they intend to limit stakeholder opinions with respect to individual opinions on the Terms of Reference. Should you wish to provide information that is not specifically captured by the following questions, please feel free to provide the information in the section you feel most relevant.

Please use the template available on the Department's Heath Consultation Hub which can be found on the Australian Government Website at https://consultations.health.gov.au/

In providing your feedback, you are welcome to consider the impact on other stakeholders, including providers of chemotherapy medicines and consumers of medicines via the EFC program.

5.1: Patient Access to Chemotherapy Services

The Government is committed to ensuring the needs of consumers and access to EFC medicines. This is particularly important in regards to the 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.

The Government is seeking to understand the patient experience, including expectations and priorities related to accessing EFC medicines across different States and Territories, and the options for alternative funding mechanisms.

Questions:

1. Does access to chemotherapy services vary in rural and remote areas compared to urban areas? What, if anything, could be changed about current access arrangements? Please provide a case example if possible.
2. Are there differences in the costs or processes for receiving chemotherapy services in rural and remote areas? How do access arrangements vary between public and private sectors, States and Territories and what is the effect on accessibility of services? Please provide any details you have to support your position.
3. What additional may limit access to chemotherapy services in rural and remote areas?
4. What changes, if any, could be made to current pharmacy arrangements to improve access to chemotherapy services in rural and remote areas? Can you suggest ways in which those changes could be managed?
5. Describe the challenges you have faced with current access arrangements to chemotherapy for Rural and Remote areas, Aboriginal and Torres Strait Islander People, and older Australians. How could these be improved?

6. When compared to urban/metro areas, are there significant differences in treatment facilities which may impact chemotherapy services for rural and remote areas? Please provide any details you have to support your position.

5.2 Chemotherapy Services as 'Specialty Services'

Chemotherapy pharmacy services could be recognised as a 'specialty area of practice with unique requirements, arrangements and expertise'. The Terms of Reference include language to support examination of specific regulatory and quality factors related to the provision of chemotherapy services, and recognition of these services as a 'specialty service'.

The Government is seeking to understand the possible impact of how new and/or emerging technologies and international models of this 'specialty service' area may be incorporated appropriately in the Australian context for future operations.

Questions:

1. Describe what regulatory and quality challenges you have faced when delivering chemotherapy services. What, if anything, could be changed to improve chemotherapy services?
2. How have the unique characteristics of chemotherapy services (including but not limited to unique requirements, arrangements and expertise in the compounding/handling of these medicines) challenged you over the past years?
3. What strategies have been used to overcome these challenges? Describe any implementation challenges you faced.
4. How have you aimed to minimise wastage and improve cost-effectiveness of infusible chemotherapy medicines over recent years. Which strategies have been practical and why? Are there other strategies you could use, but have not been able to implement? If not, why?
5. In terms of improved access to these medicines for patients, what implementation challenges have hindered the use of innovative technologies, such as chemotherapy compounding automation solutions, in the EFC supply chain? How could these be resolved?

5.3: Terminology and Definition of Medicine Types

Over recent years, the EFC program has expanded to include medicine types other than cytotoxic chemotherapy agents, such as immunotherapies. The term 'chemotherapy' traditionally refers to medicines that are considered to be cytotoxic medicines. The classification of chemotherapy agents listed in both the EFC Instrument and on the general PBS Schedule may include the potential for adjustments to improve the patient and health professional experience.

Question:

1. Is "Efficient Funding of Chemotherapy" the most appropriate name for this program? If not, what alternative name would you suggest for a program that covers injectable/infusible anti-cancer medications?

5.4 Referencing Standards, Guidelines and Policies

Manufacturers and compounders of chemotherapy medicines have many standards, guidelines and policies to ensure compliance. These include but are not limited to:

- The National Medicines Policy
- The National Safety, Quality, Health, Service Standards User Guide for Medication Management in Cancer Care, and
- The TGA Compounded Medicines and Good Manufacturing Practice Guidance.

Additionally, there can also be Parliamentary processes and/or enquiries, such as the current House of Representatives Inquiry into the Approval Process for New Drugs and Novel Medical Technologies in Australia that may influence current and/or future practices.

Acknowledgement of, and reference to, the outcomes of current reviews into national standards, policies and guidelines of relevance to EFC medicines supply and access is important to ensure a contextually aware environment that acknowledges the interplay between the standards of quality, safety, and efficacy of chemotherapy treatments in use across the sector that underpin the provision of chemotherapy treatments.

Questions:

1. What guidelines and standards apply to the preparation, supply, and administration of chemotherapy services across States and Territories? How are these standards regulated?
2. Is further development of current standards required? If so, in which area is work needed?
3. Is other work, such as the development of quality assurance programs, required?
4. Should meeting any of these standards be a mandatory requirement for Commonwealth funding under the EFC program? If so, which? How would this be managed or enforced?

5.5 Funding of EFC across the Supply Chain

Ensuring appropriate reimbursement, remuneration and payment for chemotherapy medicine providers (including manufacturers, logistics and handling organisations, compounding service providers and dispensers) is an area of importance for the EFC review. This includes appropriate transparency of product flow and funding including through systems and data flows used by Government and supply chain participants.

The distribution of costs and Government remuneration through the EFC supply chain may include:

- 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 and
- Opportunities to promote market competition and innovation within the EFC supply chain

However, the primary focus of the EFC review is not remuneration matters, rather it is patient access and chemotherapy service provision (i.e. operational and administrative), and how to best ensure equitable access to these services for all Australians.

To inform this, the review will consider whether alternate funding models to support different modes of chemotherapy medicine treatment delivery may improve patient access.

Questions:

1. What are the main challenges in having medicines listed in the EFC program compared to non-EFC drugs/other PBS listed drugs?
2. What are the key barriers for wholesalers in ensuring equitable access to EFC medicines for all Australians?
3. Are there significant differences in the costs or processes for providing chemotherapy services in rural and remote areas compared to urban areas? If yes, what are they?
4. How do arrangements vary between the public and private sectors, States and Territories and what is the effect on accessibility of services? Please provide any details to support your position.
5. Do consumers or providers have additional costs or other factors that limit access to services in rural and remote areas (excluding ancillary costs such as travel and accommodation, and oral chemotherapy medicines)? Please provide any details to indicate the difference in costs or other factors for consumers.
6. Do you hold, or are you aware of, any datasets, analyses, databases, or registries that might inform recommendations of the review? If yes, please provide the details for the relevant person/s to contact regarding access to those data if possible.

5.6 PBS Access and Claims Processing of EFC Medicines

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*, includes PBS prescribing, claims processing and the administrative burden associated with providing access to chemotherapy medicines.

The PBS EFC claims process could be considered complex from an administrative perspective for prescribers and/or dispensers regarding PBS item codes based on setting (Public or Private), and prescribing chart matters such as Chemotherapy Medication Charts and Infusion Prescriptions, which could be viewed as impacting consumer access and overall health professional experience.

Questions:

1. What concerns are there in relation to the current administrative processes surrounding the provision and claiming of EFC medicines?
2. What could be addressed in relation to these matters?
3. Are there other matters not mentioned in this paper that could be considered in developing a sustainable, transparent and equitable model for access to chemotherapy medicines?
4. Are there other consumer issues that could be considered in developing a sustainable, transparent and equitable model for access to chemotherapy medicines?
5. What are the key administrative challenges in relation to prescribing and claiming EFC medicines? For example, via the Private vs Public settings?

6. Are the current remuneration arrangements appropriate? Should they be amended, and how? What strategies could be implemented to create greater equity in remuneration across the EFC supply chain?

6. Glossary

Chemotherapy	Chemotherapy is a type of cancer treatment that uses one or more anti-cancer drugs as part of a standardized chemotherapy regimen
Cytotoxic	Cytotoxic refers to a substance or process which results in cell damage or cell death. The term is often used to describe chemotherapy drugs that kill cancer cells
EFC	Efficient Funding of Chemotherapy
Immunotherapy	Immunotherapy is the treatment of disease by activating or suppressing the immune system
PBS	Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration

7. Process for Providing a Submission

Stakeholders are invited to answer as many of the questions raised in this discussion paper that they feel pertain to them (your response does not need to address all questions if they are not relevant to you).

While these questions reflect the areas of focus for the Department in preparing recommendations for the Commonwealth Government about future arrangements for the EFC program, stakeholders are encouraged and welcome to provide additional feedback to more specific responses. Please provide these responses in the section that you feel is most relevant to the subject matter you wish to provide information on.

Stakeholders and groups interested in providing a submission should prepare and forward the submission via the Australian Government Department of Health Consultation Hub from 21 May 2021 to 2 July 2021. The Consultation Hub can be found at https://consultations.health.gov.au/

If you wish your submission or part of your submission to be kept confidential, you must notify the Department. Any submission not identified to the Department as confidential will be placed on the Department's web site, and may also be mentioned or quoted in a summary of submissions.

For any questions relating to submissions please email EFCreview@health.gov.au

8. Next Steps

Throughout the Discussion Paper consultation period, the Lead Reviewer (Professor Sanchia Aranda), and the Health Economics & Policy Analysis Unit (University of Sydney Centre for Health Economics Research and Evaluation) will also be conducting a series of consultations with industry.

Following the Discussion Paper consultation period, and the consultation process during that period, the review team will analyse the responses and other information received from consultations in order to produce a summary of matters raised. This summary will go on to form the basis of a series of workshops that will be held by the review team, and will form the basis of an Interim Report due to be published before 31 December 2021.

The Interim Report will then guide the next steps in regard to further consultations that will be required in the early months of 2022, prior to submission of a final report to the Minister by 30 June 2022.