Australian Government

Department of Health

Ref No. MC19-006776

Mr Dan Kent
Cancer Voices Australia
PO Box 713
MILSONS POINT NSW 1565

Dear Mr Kent

Thank you for your letter of 3 April 2019, to the Hon Greg Hunt MP, Minister for Health, on behalf of the Australian Cancer Consumer Network concerning equity of access for cancer patients. I am responding on behalf of Minister Hunt as the Government is now in a caretaker role pending the outcome of the federal election on 18 May 2019.

The Therapeutic Goods Administration (TGA) continues to identify opportunities to streamline and increase the flexibility of evaluations of new medicines and medical devices, following introduction of the priority review and provisional approval pathways for new prescription medicines. The TGA also has pathways, which allow the use of comparable overseas regulator reports where the evaluation is reduced to 120 and 175 days from the standard 255 days. The TGA is increasingly working with other regulatory agencies with the aim of earlier availability of therapeutics for the Australian public.

Building on the TGA's reforms to regulatory pathways, the Department is also working to improve the efficiency, transparency and timeliness of the Pharmaceutical Benefits Scheme (PBS) listing process. This work will be implemented in a staged approach from 1 July 2019. The first stage will include:

- Changes to pre-submission meetings to improve guidance, support and submission quality for complex submissions
- Introduction of a compulsory intent to apply step for submissions requiring evaluation
- Introduction of transparent pathways following a positive recommendation by the independent Pharmaceutical Benefits Advisory Committee (PBAC)
- Other improvements, including a consumer-friendly medicine status website.

Further information and opportunities to contribute to future consultations on PBS process improvements can be found under 'PBS information' at www.pbs.gov.au.

As you know, Medical Services Advisory Committee advises the Minister for Health on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. Targeted appraisal processes for innovative genetic and genomic technologies are available to applicants and further information on this can be found at www.msac.gov.au.

GPO Box 9848 Canberra ACT 2601
Telephone: (02) 6289 1555

Furthermore, the Department recognises the need for a flexible approach in ensuring access to medicines that treat less common and rare diseases with a high unmet clinical need. This is addressed through the PBAC, where it is possible for sponsors to make submissions requesting the PBS listing of medicines to treat rare conditions or cancers with low survival rates. In these such cases, the PBAC can assess the sponsors claims of the medicines effectiveness based on response rates, even in a small number of patients, and can use a range of tools to manage any uncertainty such as pricing and risk share arrangements.

A number of the issues raised in your correspondence are matters of policy, which will be a matter for the incoming Government once the outcome of the election is known.

Thank you for writing on this matter.

Yours sincerely

Ms Natasha Ploenges
Acting Assistant Secretary
Office of Health Technology Assessment Policy Branch
Technology Assessment and Access Division
16 May 2019