10 OCT 2016

Senator the Hon Fiona Nash
Minister for Regional Development
Minister for Local Government and Territories
Minister for Regional Communications
Deputy Leader of The Nationals

Dr Rosemary Laing
Clerk of the Senate
Parliament House
CANBERRA ACT 2600

Dear Dr Laing

I write in response to an Order for the Production of Documents, agreed by the Senate on Tuesday 13 September 2016, relating to the Government's response to the Community Affairs References Committee Report "Availability of new innovative and specialist cancer drugs in Australia". The Order requires me to table a response in my capacity as Minister representing the Minister for Health.

In response to this Order for the Production of Documents, please find enclosed a letter from the Minister for Health and Aged Care, the Hon Sussan Ley MP, for tabling in the Senate. The letter provides reasons for not being in a position to comply with the Order and explains that the Government will release its response to the Committee's report in due course.

Yours sincerely

FIONA NASH

Encl

THE HON SUSSAN LEY MP
MINISTER FOR HEALTH AND AGED CARE
MINISTER FOR SPORT

Senator Stephen Parry
President of the Senate
Chairman of Committees
Senator for Tasmania
Parliament House
CANBERRA ACT 2600

7 OCT 2016

Dear Mr ~~President~~ Stephen

I refer to the motion made by the Senate regarding an Order of the Senate dated 13 September 2016 for the tabling of documents relating to the Government's Response to the Community Affairs References Committee Report "Availability of new, innovative and specialist cancer drugs in Australia". Specifically, Order 41 refers to the Production of Documents as follows:

- The Minister representing the Minister for Health and Aged Care in the Senate, by no later than 3:30 pm on 10 October 2016, table the Government's response to the report of the Community Affairs References Committee on the availability of new, innovative and specialist cancer drugs in Australia.

The Australian Government agrees that improving and streamlining existing regulatory and reimbursement processes for new medicines are key strategies which will offer the best prospects of maintaining Australia's record of timely access to cost-effective cancer medicines that deliver proven health gains. The Government is continuing to develop initiatives that will improve access to innovative and rare cancer medicines.

Since October 2013, the Australian Government has approved around 40 new cancer medicines (or amended listings) at a listing cost of over $2 billion including new treatments for advanced pancreatic cancer, melanoma, rare giant cell bone tumours and advanced breast cancer. All cancer medicines in receipt of a positive PBAC recommendation have either been listed, or are on the pathway to be listed.

On 15 September 2016, the Government released its response to the Review of Medicines and Medical Devices Regulation, which includes reforms to Australia's medicines regulation to improve access.

The Australian Government's response to the MMDR Review notes that streamlined access to medicines, including novel and lifesaving therapies, offers significant benefits to consumers, health professionals and industry. The Government has accepted a number of the recommendations including: the introduction of new expedited pathways for approval; making greater use of assessments from comparable overseas regulators; enhanced post market monitoring; and streamlined access to products under the Special Access Scheme and the Authorised Prescriber Scheme.

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7220

Patients and sponsors will benefit from these reforms with its additional pathways to market that could result in new life-saving medicines such as new cancer medicines, or existing medicines seeking approval for a new population of patients (for example, children) being available up to two years earlier. Additionally, closer alignment with comparable overseas regulators should open the door to increased opportunities to undertake work sharing and report sharing, both of which may expedite the approval process by up to three months. Where sponsors can supply unredacted assessment reports from major international regulators such as the US Food and Drug Administration then the TGA will use these reports rather than conducting their own ground-up assessment. This process has already been successfully trialled with Canada in relation to generic drugs.

Provisional approvals for marketing in Australia will be limited in duration. For these approvals, the sponsor will also be required to meet conditions imposed by the TGA. For example, a requirement will be for the sponsor to provide post-market efficacy and safety data to substantiate a request for renewal of provisional approval or for a subsequent application for ongoing approval. When enough data on the medicine are provided to confirm adequate safety, and efficacy standards, the medicine could then receive full registration. If the required data cannot be provided within the required timeframe then the provisional approval will lapse unless an extension has been granted. Full details of the new pathway will be worked through as part of the MMDR Review implementation program.

The MMDR Review did not include consideration of PBS listing and PBAC processes. However implementation activities in response to the MMDR Review will impact on these processes. The Australian Government will work to ensure that, where necessary, the PBS and PBAC processes are modified to take best advantage of the outcomes of the MMDR Review. For example, the parallel evaluation process of the TGA and the PBAC will be re-examined and modified to become more agile.

The Government is currently giving detailed consideration to the implications of the MMDR Review on its response to the Community Affairs References Committee Report, and will release its response to the Committee's report in due course.

Yours sincerely

The Hon Sussan Ley MP