Inquiry into the equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer

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Sydney Hearing –31 January 2024

Question on Notice from Senator Louise Pratt

Private Cancer Physicians of Australia

1. How best to capture data, using myHealth record

The question asked by Senator Pratt regarding how best to capture data, using myHealth records, is beyond the immediate scope of the PCPA (a members' based Not-for-profit peak body) and requires considerable research with the input and knowledge of key stakeholders, data analysts, ICT experts, hospitals and medical researchers. It may also be a question best directed back to the Department of Health and Aged Care.

February 05, 2024

Equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer.

Senate Community Affairs References Committee

Additional information from the Private Cancer Physicians of Australia

Repurposing of cancer medicines – a priority list and the benefits to cancer patients

Introduction

The Private Cancer Physicians of Australia welcomes the invitation to present a priority list of cancer medicines that we believe should be repurposed for the urgent and equitable access for Australian cancer patients.

These recommendations have also been made – on request – to the Therapeutic Goods Administration and *Medicines Repurposing Program implementation update and targeted consultation* paper.

The issue of repurposing is complex.

The reasons behind the lack of PBAC approval for each individual medicine is different.

In this context and for this submission to the TGA and for the consideration of this Senate inquiry, repurposing does not include the use of higher cost drugs for other indications (eg: the use of immune checkpoint inhibitors for non-TGA approved or PBS funded indications)

The medications that are likely candidates for repurposing include older, cheaper medications that are used as anticancer therapy or as supportive care medications.

We agree with many other of our cancer advocate colleagues that the current plans for the proposed Medicines Repurposing Program, represents incremental progress towards realising the true opportunities and benefits that repurposing cancer medicines could provide to all Australians with cancer.

For more than a decade, the PCPA has advocated to the Government to remove the existing regulatory and time-delay barriers for cancer specialists to safely prescribe the medical oncology and haematology medicines our patients need.

The recommendations made to the TGA are included as attachment A as it maybe beyond the scope of this committee but provides context nonetheless, to the existing structural regulatory challenges to repurposing.

February 05, 2024

Priority list of oncology drugs for repurposing

Below is our recommended priority list of oncology drugs, used in cancer care, that are potential candidates for repurposing and should be considered.

As requested, this list has been provided to the Senate Reference committee inquiring into the

We recommend the PCPA collaborate closely with the TGA, and other cancer care advocates to prioritise the first tranche of cancer medicines to be repurposed. These could include:

Dacarbazine to treat Hodgkin lymphoma	**Mitomycin C** to treat anal cancer and bladder cancer	**Lomustine** to treat children with brain tumours.	**Goserelin** 3 monthly vs monthly for ovarian suppression during chemotherapy in premenopausal women.	**Danazol** to treat haematological disorders eg thrombocytopenia in patients with AMML.
Olanzapine to prevent and treat treatment-induced nausea and vomiting	**Valaciclovir** to prevent viral infections in immunocompromised patients	**Infliximab** to treat patients with immunotherapy-related colitis	**MESNA** to prevent bladder toxicity due to high dose cyclophosphamide	**ATRA** to treat patients with APML (acute leukaemia)
Thiotepa to treat patients with CNS lymphoma	**Carmustine** to treat lymphoma	**Procarbazine** to treat Hodgkin lymphoma		

Background to the priority medicines for repurposing

1. Dacarbazine

An intravenous cytotoxic chemotherapy drug used in the curative treatment of Hodgkin lymphoma (in combination with other therapies). Dacarbazine has been standard of care for Hodgkin lymphoma since the mid 1970s.

Dacarbazine is not TGA approved for the treatment of Hodgkin lymphoma.

Dacarbazine is not PBS subsidised for any indication.

Thus, the PBAC is unable to consider dacarbazine for repurposing as it is not TGA approved for HL.

Dacarbazine is not used for the approved TGA indications.

Pfizer only manufacturer (was Hospira).

2. Mitomycin C

An intravenous cytotoxic chemotherapy drug used in curative treatments for anal cancer and bladder cancer. Used with 5FU in combination with radiotherapy.

Also used as intravesical treatment in patients with superficial bladder cancer.

Mitomycin is TGA approved for the palliative treatment of carcinoma of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder.

Mitomycin is not TGA approved for the treatment of patients with anal carcinoma.
Mitomycin is not on the PBS for any indication.

3. Lomustine

Lomustine is an oral chemotherapy drug used in the treatment of patients with brain cancer. It forms part of standard second line therapy for some tumours. Lomustine is used to treat children with brain tumours.

Lomustine is TGA approved for these indications (although ongoing supply is under threat).
Lomustine is not PBAC approved for any indication.
Lomustine is currently being discontinued by the sponsor, Bristol Myer Squibb.

4. Olanzapine

Olanzapine is TGA approved only for the following indications:

- Treatment of schizophrenia and related psychoses
- Short-term treatment, alone or in combination with lithium or valproate, of acute manic episodes associated with Bipolar | Disorder
- Preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder

Olanzapine is now used as for the prevention and treatment of treatment-induced nausea and vomiting. It is now included as standard, second line therapy in international supportive care guidelines of the management of treatment-related nausea and vomiting.

In addition, olanzapine has been demonstrated to improve appetite, cachexia and weight gain in patients on chemotherapy, in comparison with placebo.
Olanzapine is not on the PBS for the management of nausea, vomiting or cancer related cachexia.
Patients pay for private prescriptions.

5. Valaciclovir

PBS listed for the treatment of herpes virus infections (eg Herpes Zoster (shingles) and recurrent genital herpes simplex (HSV)).

Routinely used for the prophylaxis of HSV and VZV HSV prophylaxis in immunocompromised patients (eg during treatment for leukaemia, lymphoma, myeloma and after stem cell transplantation.)

Not PBS subsidised for prophylaxis in this setting but is on the PBS for other indications.

Derestriction would be possible here.

6. Infliximab

(with potentially other DMARDS) for the management of immunotherapy toxicity eg Immune checkpoint inhibitor related colitis.

This is usually a single dose of infliximab given to patients who are unwell and leads to rapid improvement.

Infliximab is not TGA or PBAC approved for this indication.

7. Goserelin

TGA and PBAC approved for men with prostate cancer but also used in women with breast cancer and used in female patients with other cancers as a fertility preservation tool.

Changing from 1 month injections to 3 monthly.

8. Danazol

Danazol can be used in patients with haematological conditions such as AMML

Not commonly prescribed but it is no longer on the PBS (company making a commercial decision not to list) Cost is $265 per bottle of 100 capsules on SAS.

9. Thiotepa

Part of the standard of care for Primary CNS Lymphoma (PCNSL).

PCNSL is a rare disorder.

Thiotepa is TGA listed but has not been put through the PBAC process due to it being an old drug and it not financially viable for sponsors to do so under the current arrangements.

10. Carmustine

A chemotherapeutic drug used in BEAM conditioning chemotherapy for autologous stem cell transplantation.

Carmustine is TGA listed but has not been put through the PBAC process due to it being an old drug and it not financially viable for sponsors to do so under the current arrangements.

11. Probcarbazine

Procarbazine is used in Hodgkin lymphoma which is highly curable.

Procarbazine is TGA listed but has not been put through the PBAC process, due to it being an old drug and it not financially viable for sponsors to do so under the current arrangements.

12. MESA (oral formulation)

MESNA is used as a chemo-protective agent. The IV formulation is PBS listed but the oral formulation is not. This results in many unnecessary admissions to hospital, as patients cannot afford oral MESNA.

MESNA (oral formulation) is TGA listed but has not been put through the PBAC process due to it being an old drug and it not financially viable for sponsors to do so under the current arrangements.

13. All Trans Retinoic Acid (ATRA)

This drug is standard of care for a rare sub-type of Acute Myeloid Leukaemia (AML) called Acute Promyelocytic Leukaemia (APML).

APML treated with ATRA has a very high cure rate.

ATRA is TGA listed but has not been put through the PBAC process due to it being an old drug and it not financially viable for sponsors to do so under the current arrangement.

Conclusion

We thank the Senate committee members for their collective consideration of these important issues and barriers that are currently unacceptable barriers to Australians with rare and uncommon cancers, having equitable and timely access to older but vital and safe anticancer therapies.

We look forward to the committee's final report of recommendations.

Warm regards
Associate Professor Christopher Steer

President
Private Cancer Physicians of Australia

Who we are

The Private Cancer Physicians of Australia

The Private Cancer Physicians of Australia (PCPA) Limited is a not-for-profit organisation dedicated to the improvement of the health system for all cancer patients, but particularly for private cancer patients in Australia.

Although the majority of cancer patients are treated in the private system, there are many anomalies in funding and regulation that disadvantage private patients. Private cancer physicians also face issues in accessing drugs for their patients and sometimes beds. Barriers also exist to the participation of private physicians in research and training. The PCPA has been established to address these issues.

Established in 2007 the PCPA is a membership organisation for medical and radiation oncologists and clinical haematologists in private practice in Australia. The PCPA has a pivotal role in the Australian community for the implementation, delivery and planning of improved cancer services in the Private Health Sector. The PCPA collaborates closely with policy makers, funding bodies, health providers, and, of course, patients themselves.

Our Mission

To promote and work towards a health system that provides high quality, fair, integrated cancer treatment that benefits patients and supports medical practitioners.

Our Vision

All cancer patients in Australia will receive a high quality, timely and personal care from a physician of their choice.

Our Values

- Quality care for patients
- Personal, patient centred care
- Well educated professionals
- Evidence based medicine
- Collegiality and peer support

Attachment A

Recommendations to the TGA (consultation on the proposed Medicines Repurposing Program)

The PCPA requests the TGA considers the following:

- The proposed fee waivers and dossier support may provide some incentives for sponsors to progress an application. However, the financial cost and administrative and resource burden to the intended sponsor of providing the required data and evidence to support and progress an application, remains a significant barrier to a successful outcome.

- The TGA needs to consider how it can proactively collaborate with interested sponsors – industry, clinicians and patient advocates - to alleviate, or offset, the cost burden of providing the data and evidence required to meet the current eligibility criteria.

- We understand this program is limited to repurpose up to five medicines each year.
- However, we recommend all cancer related medicines should be considered for this program if they can be repurposed safely. At the very least, treatments intended for cancer patients should be prioritized.
  These repurposed medicines are potentially lifesaving and, at the very least, are intended to improve the outcomes for our most vulnerable of patients.

  Prioritising cancer patients has the potential to improve equity of access to urgently needed low-cost treatments and will deliver a significant public health and economic dividend.

- The PCPA requests cancer clinicians and cancer patient advocates should be appointed to a Medicines Repurposing Advisory Board or Expert Panel to provide the Government with ongoing advice on medicines they consider a high priority, regardless of whether these medicines meet the existing eligibility criteria.

- We believe the TGA needs to adopt some level of flexibility with the consideration of medicines that are already long approved by the PBAC but for other indications, do not quite meet the existing repurposing criteria.

- The TGA must undertake to actively help cancer clinicians, and patient advocates, pursue and connect potential industry sponsors, with a request for a medicine to be repurposed.

- The TGA should consider investing in an internal, dedicated unit of pharmacovigilance experts, embedded into this program, to adopt the responsibility and be legally responsible for meeting pharmacovigilance reporting requirements for the medicine it approves for repurposing. This should be done without compromising patient safety.

- Removing this significant legal and administrative burden and cost may further encourage clinicians and the (low value, high volume) generic medicines industry, in particular, to apply as the sponsor of a proposed medicine for repurposing.

- Cancer patients do not have the luxury of time to wait for an unduly long approval regulatory process to be undertaken. We ask that the TGA's Repurposing Program is sufficiently resourced as to limit unnecessary delays in the approval process.