Feedback to Therapeutic Goods Administration Discussion Paper on *Communication plan for patients and health professionals on priority and provisionally registered medicines.*

Thank you for the opportunity for Cancer Council and the Clinical Oncology Society of Australia to review the draft communication plan for patients and health professionals on priority and provisionally registered medicines. Below is a joint response by the two organisations.

Distinction between priority and provisionally approved:

It's essential that there is a clear distinction in the difference between medicines registered through the priority pathway and medicines with provisional approval. The similarity is the improved time to market for serious and life-threatening conditions, however, there is a significant difference in the level of certainty of the data on which the approval is based. Medicines approved through the priority pathway have demonstrated a high level of efficacy and safety, comparable with medicines approved through the traditional pathway, whereas provisionally approved medicines are yet to demonstrate a high level of certainty in their outcomes.

Partnership between consumer and health professional:

Treatment plans are managed by a health professional and prescription medicines can only be accessed after consultation with a health professional. Patients on provisionally approved medicines may require additional visits to ensure continued effectiveness, identification of side effects or adverse events, and early action plan for alternative care in case the medicines provisional approval status is not extended, and/or the sponsor does not register the product on the ARTG within the allocated time.

Conditions of using a provisionally approved medicine:

Sponsors of provisionally approved medicines are required to commit to the ongoing collection of clinical trial information and data with the intention to complete a full registration. It is unclear whether patients who are prescribed to provisionally approved medicines are required to participate in the ongoing data collection process. If so, the patient would need to receive information relating to the collection of their data. This would require an additional conversation regarding the sign up to data collection or clinical trial environment. The patient should not be coerced into providing consent to their information to be used in return for access to the provisionally approved medicine.

De-registration, lapsing of registration or narrowing of indication will impact patients who received a benefit from the medicine. For these patients, there must be an explicit plan for

ongoing access to the drug which must require a commitment from sponsors to exploring and assisting these patients with off label access.

Communication strategies:

Accessing health professionals through professional opportunities such as conferences, journal articles and via Colleges is appropriate to reach that target audience. However, social media intended to reach the consumer population will miss many people who do not frequently use these mediums, including older people who are more likely to have cancer. Information on the expedited review pathways can be distributed through consumer organisations and integration into consumer materials however, the crucial communication point is between the health professional and the consumer when discussing treatment options. Industry cannot market prescription medicines directly to consumers, and consumers cannot access prescription medicines without health professional consultation. Therefore, along with integration within general communication about how medicines can be registered in Australia, a focus should also be on the communication tools for health professionals to use in their conversations with patients.

Cost:

Although the TGA does not regulate price, health professionals and patients should discuss the cost of cancer treatment when deciding on a cancer care plan. Cost, particularly potential out-of-pocket expenses or claims made to private health insurers, is a critical component to their decision making and the health professionals requirement to obtained informed financial consent prior to treatment. Patients want to know the implications that their treatment options will have on their lives and families. As they are not fully registered on the Australian Register for Therapeutic Goods (ARTG), it is not understood whether provisionally approved medicines can be considered for subsidy on the Pharmaceutical Benefits Scheme (PBS), or other means such as compassionate access. As part of the informed financial consent process patients should be clear about the expected costs associated with all treatment options, as well as other risks and benefits.

The communication plan:

<u>Goals and Objectives</u>

- The goal of the proposed communication plan should include *creating awareness and inform* to support the implementation of the priority and provisional registration pathways.
- Objective 6. Should include awareness of the importance of *identifying* and reporting adverse events. Particularly for provisionally approved medicines, there should be greater communication with patients about the risks and benefits and how to recognise a potential adverse event.

<u>Target audience:</u>

The target should mostly focus on health professionals as communicators of treatment options. It is entirely appropriate to integrate information into consumer resources which discuss how prescription medicines are approved for use in Australia, and that, particularly for patient groups with serious and life-threatening conditions, to understand this may be an option. There should be a focus on the development of consumer targeted resources which can be used within a consultation between the patient and health professional.

<u>Key messages:</u>

We cannot appropriately choose only five key messages and rank in priority order both the health professionals, and patients and consumer lists. Each key message cannot be used in isolation or without context. Each key message provides a snap shot that could be accessed as approved text for use for all parties wishing to communicate about priority and provisionally approved pathways and medicines. The key messages can naturally be grouped together based on information about the process of approval, conditions of approval, and safety of the medicine. Above all, we would highly recommend priority use of the key messages relating to safety and access.

A few additional points to consider:

- Acknowledge that in the event a provisionally approved drug is not extended or registered, that the health professional and consumer will discuss alternative options in partnership and make an alternative treatment plan. Must be clear that alternatives will be sought and that this is not the responsibility of the patient.
- Explain the meaning of the Black Triangle symbol.
- As part of post market monitoring activities, that particular attention will be given to the patient's response to treatment and any adverse events.
- Include the need for practitioners to discuss the cost implications for the patient, whether this is the market price, a compassionate access arrangement or other means, such as clinical trial participation.
- Indicate that a patient accessing a provisionally approved product may consulted to provide their consent to their clinical information to contribute to the sponsors requirement for ongoing data collection to support a full registration of the drug in the future.

Materials:

- Health professional to consumer material, such as a pamphlet, should be developed to enable discussion between the two individuals and then the consumer can take this information home with them.

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