ALLG Australasian Leukaemia & Lymphoma Group — Better treatments... Better lives.

9 February 2024

Standing Committee on Community Affairs
References Committee
PO Box 6100
Parliament House
Canberra ACT 2600
community.affairs.sen@aph.gov.au

Dear Committee

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

Response to question on notice

The Australasian Leukaemia & Lymphoma Group (ALLG) is the only not-for-profit, collaborative clinical research group in Australia and New Zealand dedicated to designing and conducting independent clinical trials for the treatment of blood cancers. For 50 years, the ALLG has provided the infrastructure and governance necessary for Australian clinicians and scientists to work together to conduct multi-disciplinary clinical research into blood cancers.

The ALLG's mission is to create better treatments and better lives for blood cancer patients. Since 1973, the ALLG and its members have helped over 13,000 patients access the best global treatments through our clinical trial research program.

Question on notice: *We heard evidence from some of the pharmaceuticals yesterday about their desire to have a temporary fund developed once the drugs are TGA approved but before the evidence has actually been gathered in Australia to make the drugs available to be able to build that evidence so that they can monitor it. Would you support something like that being invested in by the government?*

Thank you for allowing us to take this question on notice. Without know the exact proposal being put forward by the pharmaceuticals we can contribute the following comments regarding expedited drug pathways.

For Australia to be dynamic and responsive but retain necessary diligence and fiscal management, the Government could:

- Provide a simplified pathway to TGA registration for novel therapeutics or technologies, e.g. if it is approved in a similar jurisdiction have a process to accept that review. The example would be of drugs already registered in similar jurisdictions (e.g. EMA in Europe) which reduces duplication, costs, and improved efficiency.

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- Implement a pathway to expand the TGA labels for TGA registered drugs. E.g. drug available in Australia for a disease indication, and subsequently we discover a reputable agency oversees accepts its use in another indication, the TGA add that indication label for Australia. The example is if a registration label is present in a similar jurisdiction (e.g. FDA in USA), sponsors can add that label to an already TGA approved drug without undue process or cost.
  Or for already TGA approved drugs, professional societies or national research groups could apply to have a label added without undue cost or complexity. These options are not unreasonable given that the majority of new drug assessment would have already occurred as part of the initial submission to the TGA. e.g. BRAF inhibitors in hairy cell leukaemia, Crizotinib in ALK+ lymphomas, bortezomib in AL amyloidosis. Rituximab in Mantle cell lymphoma maintenance.

- Establish a pathway of conditional drug reimbursement, whereby ongoing reimbursement after a period was dependent on generation of supportive data from internationally or from Australian use. This could be best achieved via drug access linked to data acquisition via a clinical trial of national registry.

In closing we wish to reiterate the importance of generating evidence through quality data collection methods such as clinical trials and registries. The ALLG remains available to contribute further to this inquiry and welcomes the opportunity to consider and provide further input as required.

Yours Sincerely

Delaine Smith

Chief Executive Officer
Australasian Leukaemia & Lymphoma Group

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