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Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam

Re: Senate Enquiry into the availability of new, innovative and specialist cancer drugs in Australia

The Haematology Society of Australia and New Zealand (HSANZ) is the peak professional body representing Haematologists, haematological scientists and nurses in Australia. The Council of HSANZ would like to make the following submission, in relation to the terms of reference for the Senate Enquiry into the availability of new, innovative and specialist cancer drugs in Australia.

In the treatment of haematological malignancies, the availability of new agents is often crucial in the management of patients. The past decade has seen enormous progress in the development of new agents, many of which have proven to be life-saving. However, in the early phases of development and approval, despite demonstration of benefit, many of these agents are costly to the individual and/or are only accessible through participation in clinical trials, which can be restrictive in their eligibility, and there is significant heterogeneity in the availability of such trials in different jurisdictions. Then, the subsequent availability is dependent on application by a sponsor, usually a pharmaceutical company, to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the Pharmaceutical Benefits Scheme (PBS). The determinations of the PBAC are based on four main factors - quality, safety and efficacy (assessed by the TGA), clinical and cost effectiveness (as assessed by the PBAC), and financial feasibility/acceptability (as assessed by the Minister for Health and the Cabinet).

The time period between submission to the TGA for regulatory approval and the PBS listing of the medicine is estimated to be at least 14 months, but in our experience for haematological malignancies, this period is often considerably longer, often involving multiple submissions to the PBAC. There have been instances where the approval process has been protracted with ultimately a negative result. In such situations, patients would either not have supported access to the drug or must find personal means to support the costs, which is often not feasible. Thus, while the overall process of review for listing of a cancer drug on the PBAC is made on clear, precise and well-established principles, the significant periods of time that are required before many of the submissions are successful have been the cause of significant concern, and impacted on the ability to treat patients optimally. The HSANZ is also aware of instances where there is no dispute with respect to the efficacy of the drug, but difficulties are encountered on the financial aspects of a listing, namely the price of a drug. In this respect the HSANZ believes that both the government and the pharmaceutical industry have a role to play in ensuring that they understand the difficulties of the other party, so that fruitful discussions can be made to promote the interests of the cancer patient.

We would also like to make a comment on the current standards on which efficacy is assessed. In the deliberations of the PBAC, we understand that overall survival (OS) is usually considered to be the most appropriate end-point; as such, drugs deemed to be efficacious must demonstrate an improvement in OS in Phase III clinical trials. However, OS or lack thereof, requires a much longer time to demonstrate than a benefit in progression-free survival (PFS), and it can be argued that in terms of a patient's well-being and clinical status, an improved PFS is a highly meaningful entity which is more appropriate for the assessment of the benefit of a cancer drug. Moreover, with increasing utilisation of targeted therapy, surrogate endpoints in trials, such as biomarker levels and functional imaging may be used instead of survival barometers, because the results of the trial can be measured sooner. Importantly, with the availability of more lines of treatment, many clinical trials have to rely on assessment by PFS, since OS can be confounded by subsequent treatment. For ethical reasons, many trials have also allowed patients to "cross-over" to the arm of the novel therapy, making demonstration of OS even more difficult. Such trials, even though the "gold-standard" randomised Phase III trials, may not be the ideal vehicle to demonstrate an improvement in OS in an effective drug.

In an era where developments in cancer drugs have been made at an accelerated pace, the affordability of new and effective treatments in cancer is a question that needs to be faced by the whole medical system and the country. It is clear that drug development is expensive, but the public purse is restricted and certainly not limitless. The HSANZ considers that new paradigms have to be considered in the future funding of new cancer drugs, and indeed new drugs in all aspects of medicine. This may range from separate provisions for cancer drugs which are not currently/not yet approved, such as in the model of the Cancer Drugs Fund in England (noting that this does not apply to the rest of the UK and is finite in its time application); or significant changes to the health insurance system to allow private insurance coverage for high-cost drugs, in the hope that more resources can then be directed to those who are unable to afford such insurance. The problem we face in the affordability of new cancer drugs is multi-faceted in its impact on many areas of the health system. HSANZ is of the opinion that the current system is clearly unsustainable, and an alternative means of drug funding must be sought to ensure that Australian patients receive the best available and affordable treatments for haematological malignancies.

We hope these comments will be helpful in the deliberations of the Senate Enquiry.

Yours faithfully

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for HSANZ Council