

18 October 2013

Oncology Industry Taskforce
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

Dear Sir/Madam

Submission on initial findings of Oncology Industry Taskforce Report

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to Medicine Australia's public consultation on the Oncology Industry Taskforce Report (the Report).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF has an interest in sustainable patient access to cancer medicines. While CHF has not undertaken comprehensive consumer consultation on this subject specifically, our submission draws on recent community consultations that CHF undertook to provide input into the Department of Health review of chemotherapy funding. Our recommendations also draw on ongoing consultation with our broader membership, including cancer organisations.

CHF welcomes the objective of the Report to inform a wider discussion around patient access to cancer medicines in Australia, and supports the view that we need to find solutions that are mutually agreeable to stakeholders, beneficial to patients and sustainable for Australia's health system in the short and long term. Our comments and recommendations in relation to each of the issues raised in the Report are provided below.

Issues arising from regulatory and reimbursement processes

CHF notes that the Report identifies the complex and technical barriers that make it difficult to demonstrate the cost-effectiveness of new medicines under the current regulatory and reimbursement system in Australia.

While CHF understands the need to ensure timely access to these medicines, we are supportive of continuing the rigour and consistency provided through the current Australian approval processes including those of the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC). The Pharmaceutical Benefits Scheme (PBS) process, which is a tax-payer funded initiative, needs to ensure equitable and cost-effective access to medicines for all Australians. The current processes are well-understood and well-respected, and are viewed as transparent and independent.

As the Report notes, the development of a new medicine following discovery requires a period of 10-15 years. Compared to the overall development period, the regulatory and reimbursement process to access public funding is a relatively small amount of time, and time that is critical to ensuring consumer access to evidence-based medicines is being provided in a cost-effective way. ***CHF recommends that transparent and independent processes remain in place to assess the appropriateness of publicly funded access to new cancer therapies.***

Issues arising from evidentiary requirements to support access

CHF notes that the Report highlights the difficulties in measuring the ‘value’ of clinical benefit in oncology, considering that there are seemingly small benefits which may be of great significance to patients, but which may otherwise not demonstrate ‘value for money’.

CHF is supportive of an approach that would better reflect perceived societal preferences for funding end-of-life medicines, and recognises that further exploration of approaches adopted in the other international jurisdictions mentioned in the Report may be warranted. CHF believes there is a need for a broader community conversation regarding these issues, and what the community expects in relation to life prolonging treatments and the relative costs of these.

CHF recommends more research occurs to compare how new medicines are being assessed in other international settings for cost effectiveness, clinical trial efficacy endpoints and quality of life outcomes. CHF further recommends that the community be supported to engage with these issues and participate in conversation regarding the expectations in relation to ‘value for money’ around cancer therapies in an Australian context.

Issues relating to coverage of indications on the PBS- TGA and PBAC

The Report details the process by which it is a prerequisite for PBS reimbursement of a medicine to first obtain TGA approval for particular indications. The Report highlights that the TGA-approved list of indications may not always reflect the most up-to-date evidence which may have been gained since the initial approval. This can result in a difference between the conditions for which patients can access particular medicine with a PBS subsidy and the clinical evidence-based advice which may include an increased number of conditions that the medicine is effective in treating.

As mentioned previously, CHF is supportive of a rigorous process that ensures Australian consumer access to safe and effective medicines. The TGA’s risk-benefit approach to pre-market assessments is designed to ensure that medicines and indications listed on the Australian Register of Therapeutic Goods are consistently safe, effective and of high quality. However, we understand that the current processes may de-incentivise sponsors seeking approval of already assessed medicines to treat additional conditions as new evidence emerges. CHF recognises that there may be a case to explore refinement of processes to address these issues.

However, if any change is to be considered, it is paramount that there is no compromise to ensuring the highest standard of quality and safety. Consumers need to continue to have confidence that the products they are using for the recommended clinical indications are safe and efficacious, and comply with quality and established regulatory standards.

CHF recommends that if the TGA explores a refinement of current processes to support further approval process for new indicators, high thresholds around ensuring the maintenance of standards and quality are built into this process.

Issues relating to inadequate remuneration for the supply of chemotherapy

CHF recently undertook community consultations to provide input into the broader Department of Health review of funding arrangements for chemotherapy services. These consultations found that consumers want chemotherapy funding arrangements that are transparent, equitable and good value for money. They want arrangements to explicitly outline which services are being purchased through these agreements, and believe that only the cost of medicines should be funded through the PBS.

CHF regards that it is inappropriate for the Government to pay inflated costs for drugs in order to cross-subsidise other elements of the delivery of cancer drugs or other pharmacy services. It has never been the intention of pharmaceutical pricing to fund anything other than the cost of the drug.

CHF recommends that that the PBS subsidy for chemotherapy drugs reflect the market price of the medicine and that these subsidies should not be used to cross-subsidise other aspects of the provision of chemotherapy drugs.

Issues relating to the value of Cancer medicines

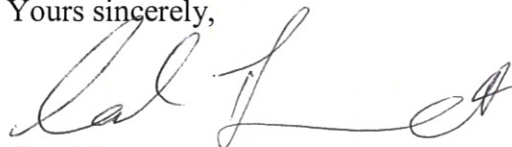
As noted in the Report, there has not been meaningful debate in Australia about what the community considers to be acceptable levels of funding for caring for palliative patients, including those with advanced and rare cancers.

CHF also notes that while the consultation process for the Report involved consumer organisations, the complexity and sensitivity of the issue warrants a broader level of community conversation and engagement.

CHF values access to new cancer medication, however sustainability and access to other medicines and treatments also needs to be considered in these conversations. CHF is supportive of an approach that encourages a broader level community conversation on this complex issue. ***CHF recommends an informed public debate on access to new medicines be supported as part of the next phase of this work.***

CHF appreciates the opportunity to provide a submission on the Report. If you would like to discuss these comments in greater detail, please contact CHF Policy Office, Priyanka Rai.

Yours sincerely,



Carol Bennett
CHIEF EXECUTIVE OFFICER