promoting excellence in medicines management

ABN 54 004 553 806

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Re: Access to cancer medicines in Australia report

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practising in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists wherever they may practice.

SHPA strongly supports Australia's National Medicines Policy and acknowledges the crucial role the pharmaceutical industry has in ensuring medicines are available for use.

SHPA strongly supports Australia's evidence based approach to the approval of medicines through Therapeutics Goods Australia (TGA) and the funding of medicines through the Pharmaceutical Benefits Scheme (PBS).

We believe each of the multiple steps in the approval process is essential to protect the public, support the responsible use of medicines, provide reasonable value for expenditure of public monies and maximise the benefit to the community as a whole.

SHPA provide the following comments regarding the content and findings of the report.

1. SHPA strongly supports an evidence based approach to the approval of medicines by the TGA and the indications listed as part of that approval process. In principle we would not support any move to reduce the level of evidence required for the approval of any medicine and do not necessarily consider that process differentiation for cancer medicines is required in Australia. However, for rare diseases, it is not always be possible to meet the required levels of evidence to even have a TGA listed indication, resulting in lack of effective treatment for some of these diseases until these medicines are old or cheap enough to be prescribed in a more unrestricted manner. Since treatments for rare diseases are most likely to continue to be considered "experimental", **in order to meet funding challenges in a consistent manner,** a collaborative approach with industry and across jurisdictions may need to be pursued into the future. SHPA supports the need for further investigation into alternative approaches to research being considered, i.e. to test for drugs active in particular disease with mutant or over-expressing genetics, regardless of anatomical location. Perhaps regulators need to be approached to consider these and other alternative means of providing evidence including outcome-based research, and not rely solely on trials based upon the location of a tumour.

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2. SHPA strongly supports a health economic approach to the approval of medicines to be funded through the PBS and the notion of all medicines being considered using a common construct and evidence requirements.

   We believe this approach is crucial to ensuring the long-term viability of the PBS and the future listing of cancer medicines developed in the medium to long term. Gaining approval for a medicine to be funded through the PBS is a cost of doing business just like the cost of advertising of a medicine or undertaking clinical trials.

   SHPA does not believe that a protracted approval process for some medicines or the number of rejections is necessarily an indicator of system inefficiency. It may reflect the quality of submissions or unrealistic price expectations.

3. SHPA acknowledges that as the cost of older medicines falls, the gap in the cost benefit of new medicines over the established treatments widens and that this impacts on the pharmacoeconomic equation i.e. the cost benefit of the new medicine over current therapy is more difficult to demonstrate. However, we do not believe that the response by government should be to change the assessment process or the 'willingness to pay' factors as these are designed to ensure that only medicines with a demonstrated and quantifiable cost to benefit ratio are funded using public monies.

   SHPA notes that advances in the treatment of cancer in recent years now requires clinicians to think beyond cancer medicines as being 'curative' with one end point: patient survival and to think of cancer as a chronic disease in many patients.

   Perhaps one issue with the approval of cancer medicines for funding through the PBS is the continued focus of submissions based on preventing a death rather than: absence of disease activity, slowing disease progression / life extension or symptom control and the associated price placed on the medicine.

   As the paper notes the medicines industry may have to change their expectations from 'profit-maximising' to 'profit-making' for some medicines.

4. The report highlights that "the TGA-approved list of indications is not always in line with the evidence development since the initial approval" and that many cancer medicines are used in evidence based treatment guidelines that are considered as 'off-label' indications.

   We agree that this is less than optimal and would encourage sponsors to ensure that the TGA-approved list of indications reflect contemporary cancer practice rather than applying for approval for new indications only when it is required for changes to funding. The reference paper cited details the use of these medicines in "evidence-based treatment guidelines" which are usually developed and endorsed over a period of years; this implies sponsors have sufficient time to seek approval for these indications.

   This is a perennial problem in medicines used in children.

5. SHPA holds concern about structural changes that reduce the universality of the PBS. Changes such as those that would allow one group of consumers to gain access to a medicine based on their health insurance status or the introduction of a 'health savings account' will require broad stakeholder collaboration in order to ensure support across the Australian community, and to ensure that they do not adversely affect the likelihood that medicines will be made available through the PBS if they meet eligibility criteria.

5. The report includes several comments about hospital services. SHPA would like to point out that the move to an activity based funding model for public hospitals has already begun.

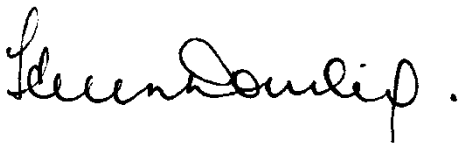
As the report remarks many medicines are considered by public hospital medicines advisory committees for listing on the hospitals formulary. SHPA notes that many of these committees would welcome access to information similar to that submitted to the PBAC including cost-effectiveness data.

In section 6.5 the comment is made that the private sector will not be able to provide access to medicines through compassionate or early access programs with resulting equity of access issues. SHPA is unaware of the basis for this statement.

6. SHPA notes that the Coalition's *Policy to Support Australia's Health System* includes that "the Health Minister will have to authority to list medicines recommended by the PBAC that do not cost more than $20million in any of the first four years of listing". We assume that this might remove concerns about 'political interference' with the PBS listing process for most drugs.
7. SHPA agrees that there are issues regarding the assessment and approval of co-dependent technologies and the concurrent PBAC and MSAC approval processes and that these processes could be streamlined.
8. SHPA agrees that investment into the treatment for rare cancers could be increased.

If you would like to discuss the issues raised in this submission or require further information please contact Karen O'Leary (koleary@shpa.org.au or 03 94860177).

Yours sincerely,



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