promoting excellence in medicines management

ABN 54 004 553 806

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Re: Public Consultation on the Terms of Reference for the Post-market Review of the Life Saving Drugs Programme

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 core 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, especially in hospitals. SHPA supports pharmacists to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians, as individuals, for the community as a whole and for healthcare facilities within our systems of healthcare.

Preliminary comments

SHPA welcomes this review of the Life Saving Drugs Programme (LSDP) and the exploration of how the LSDP fits within other funding mechanisms of medicines at a federal level. The current plethora of funding mechanisms and rules for medicines cause confusion, increase the risk of medication error and diverts prescribers and pharmacists attention away from direct patient care.

The administrative burden for pharmacists is onerous, particularly for hospital pharmacists, and the number of funding mechanisms and categories has continued to expand in recent decades. In addition, there has been a failure to take advantage of new technologies that could be used to streamline most processes, improve information sharing between health care professionals and the data available to the Department and the PBAC (Pharmaceutical Benefits Advisory Committee).

In principle, SHPA believes that quality use of medicines principles are paramount and should be the major determinants for restricting access to medicines through the Pharmaceutical Benefits Scheme (PBS) and LSDP.

Terms of Reference

Review the clinical effectiveness and safety of medicines subsidised through the LSDP.
Consistent with SHPA's previous submissions to the Therapeutic Goods Administration (TGA), we believe that the role of assessing the safety and effectiveness lies with the TGA.

Reviewing the efficiency and decision to subsidise these medicines is appropriate and within the scope of the Reference Group.

Review emerging clinical treatments and diseases, including those that identify sub-groups by molecular target, which could potentially seek subsidisation through the LSDP in the future.
While SHPA supports in principle the necessity to subsidise treatments for life-threatening and / or

rare conditions with expensive treatments, the Reference Group should consider if the LSDP is necessarily the best construct in which to fund some medicines.

SHPA believes that while it is worthwhile reviewing emerging clinical treatments and diseases that may potentially seek subsidisation through the LSDP, the Reference Group should also seek to clarify and define the inclusion criteria for medicines subsidised through the LSDP.

Conduct an international comparison of subsidisation of drugs for rare diseases and the definitions for a rare/ultra-rare disease.
SHPA supports an international comparison of subsidisation of drugs for rare diseases. Given the small population sizes of patients diagnosed with these conditions, it is imperative the Reference Group looks internationally to compare funding constructs and mechanisms to improve the operation of the LSDP, and compare the programme requirements and inclusion criteria of similar programmes internationally.

Compare the subsidisation and equity principles of the PBS and the LSDP.
SHPA is cognisant that one of the core distinctions between the LSDP and the PBS, is that medicines listed on the LSDP fail the cost-effectiveness criteria used by the PBAC. It seems that medicines applying for listing on the LSDP undergo similar evaluations, but have a lower threshold for cost-effectiveness.

SHPA notes that some medicines which have been approved for subsidisation on the LSDP are not necessarily 'life-saving', such as eculizumab for the treatment of paroxysmal nocturnal haemoglobinuria, which can be treated with regular blood transfusions. It appears that perhaps concepts such as quality of life are now a factor when considering the subsidisation and equity principles of the LSDP. In this sense, robust evaluation of medicines applying for LSDP listing must occur.

Assess the value for money of the medicines subsidised on the LSDP by evaluating the benefit of each drug's treatment outcomes, including in terms of quality of life achieved through the programme, and their cost.
While the medicines on the LSDP have unacceptable cost-effectiveness for inclusion on the PBS, the review should also consider the costs that would be incurred through **not** treating these conditions. For example, not treating these patients may have significant impacts such as, but not limited to:

- Death, rapid deterioration, severe / permanent disability, development of secondary conditions as a result of inadequate treatment
- More frequent visits to general practitioners, public and private hospitals, emergency departments, allied health practitioners and other health services
- Requiring carer services, either from professionals or from family/friends who exit the workforce as a result
- Limiting the patient's potential for attaining an education or participating in the workforce
- Impact negatively on the patient's and their family's quality of life

The points above are provided as a snapshot of how not treating some conditions through the LSDP, has the potential to introduce other costs to federal, state and territory governments, given both levels of government invest significantly into primary care, public hospitals and carer services.

Review the administration of the LSDP, including the Guidelines with which the programme is administered for each condition, and assess alternative administration systems.
SHPA believes that the administrative burden for prescribers and pharmacists is resource-intensive and should be minimised. We believe that:

1. The administration of the LSDP should be automated and electronic / web-based as much as possible. The application and approval process for new patients should at the very least utilise electronic forms and not require prescribers to handwrite applications and allow inclusion of mandatory fields that are required to assess the application. This would enable prescribers to seek and confirm approval prior to prescribing the medicines which would prevent the need for the cost of the medicine being borne by the hospital while applications are pending review by the Department of Health. It may also eliminate the need for individual Disease Advisory Committees and allow a single committee to oversee all conditions treated through the LSDP. This may also deliver economies of scale, consistency and minimise variations in the assessment of new patient applications and variable/extra dose applications.

2. The approved pharmacy should have the ability to nominate a 'permanent' individual as the contact person for the pharmacy service of each health organisation. Currently, a hospital pharmacy contact must be identified for each new patient application and their consent to manage the LSDP for that individual is sought with each application. As this is usually the pharmacy manager, this step is unnecessary, repetitive and onerous for hospitals which have multiple patients accessing medicines through the LSDP.

3. The approved pharmacy should have the ability to order directly from the supplier once approval has been obtained. Payment for the medicine could be managed by either:
   - The Department of Health pays the invoices for all LSDP medicines provided to approved patients; or
   - The approved pharmacies order the medicine and make a claim for reimbursement through the Department of Human Services.

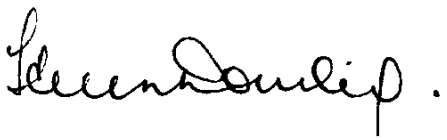
Establish a framework for data collection on rare diseases in Australia and assess how this could function properly.

SHPA believes streamlined data collection on rare diseases in Australia is important and essential for the stakeholders at home and abroad, given the small population sizes of patients diagnosed with these rare conditions.

To obtain more meaningful data in larger sample sizes to aid researchers and funders of these medicines, a centralised and singular mechanism, independent of pharmaceutical companies, should be utilised.

If you would like to discuss the issues raised in this submission or require further information, please contact Jerry Yik. (JYik@shpa.org.au or 03 9486 0177)

Yours sincerely,



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