promoting excellence in medicines management

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Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review

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.

SHPA strongly supports Australia's current processes for the evaluation of the safety, effectiveness and efficiency of medicinal products for subsidisation through the PBS and related schemes. We believe that this is a mature and well accepted evaluation process. This review presents the opportunity for the PBAC to move to evaluating all facets of the medicinal product, not just the medicine. SHPA would like to highlight three issues regarding the current PBAC Guidelines.

E.4 Estimate the net financial implications for the PBS and RPBS

SHPA believes that this section should be extended to include the implications for the dispensing fees payable through the Pharmaceutical Benefits Scheme (PBS), the National Diabetes Services Scheme (NDSS) and out-of-pocket expenses for the end user, usually the patient.

A preparation fee for chemotherapy medicines has been payable through the PBS since December 2011. It is possible that a preparation fee for other medicines that are not presented in a ready-to-use format could attract a similar fee in the future. We believe that any costs / fees, associated with ensuring the medicine is ready-to-use should be included in the estimate of financial implications to the Commonwealth.

Similarly some medicines / medicinal products have financial implications for the NDSS. For example the listing of insulin products for use in an insulin pump requires additional expenditure through the NDSS as the medicine is presented in a cartridge and must be transferred into a suitable reservoir (subsidised through the NDSS) before it can be administered.

Other medicine products require the use of consumables that are not subsidised by the Commonwealth, any cost is borne by either the user or the facility providing the medicine.

We note that some products have delivery devices included in the packaging, or are provided separately as an additional service to patients using the medicine (e.g. lines and cassettes required for the administration of the Veletri® brand of epoprostenol for pulmonary hypertension are delivered directly to the patient by the manufacturer).

Medicinal products that are not presented in a ready-to-use format may have additional costs in terms of patient time and out-of-pocket expenses (e.g. although subsidised through the NDSS each pump reservoir costs the patient $1.06 every 2-4 days depending on the daily doses used).
With the development of new or novel medicine delivery devices, that may or may not be included in the medicinal product, we believe that consideration should be given to how these costs are included into the Guidelines.

F.1 Quality use of medicines

SHPA supports the active post-marketing review of all medicines subsidised through the PBS and related schemes. Therefore we suggest that all submissions should include a proposal for post-marketing surveillance.

F.3 Other relevant factors

SHPA would welcome the inclusion, and therefore consideration of, the 'useability' of the medicinal product in the Guidelines.

Applicants that offer a medicinal product that has been designed and presented in a ready-to-use format or in a way that could improve the safe use of the medicine, or medication adherence should be able to include these benefits in their submission, particularly for minor submissions.

Although many of the following features are required for the medicinal product to be approved through Therapeutic Goods Australia, manufacturers are only required to meet a minimum standard. We believe applicants should be encouraged and enabled to highlight where their medicinal product exceeds the minimum standard to improve the safe and effective use of the medicine, for example:

- the ingredient name is prominent and in a large font size
- the medicinal product and / or dose administration devices is labelled with a machine-readable code with the barcode including expiry date and batch number information
- any required warnings are prominent and clearly articulated
- country of manufacture / origin is included in the label
- product information and consumer medicines information written in plain English, with a suitable level of health literacy and routinely reviewed
- product information and consumer medicines information available in languages other than English, including a comic / graphic format
- product information and consumer medicines information available in an electronic web-page format that allows the user to click into headings that takes them directly to the section they wish to read
- product packaging that includes information in braille
- product packaging that includes a suitable space for a pharmacy dispensing label, the standard label size used in Australia of 80 x 40 mm
- minimal manipulation required as product is in a ready-to-use format or dose administration device e.g. pre-loaded syringes
- if the medicine is able to be dispersed or dissolved and therefore easier to use for patients with swallowing difficulties.

If you would like to discuss the contents of SHPA's submission or require further information, please do not hesitate to contact our secretariat (shpa@shpa.org.au or 03 9486 0177).

Yours sincerely

Professor Michael Dooley
SHPA Federal President