The Royal Australasian
College of Physicians

14 July 2008

The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Re: Royal Australasian College of Physicians (RACP) comments on the Senate inquiry to the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

The RACP welcomes the opportunity to present feedback from College members to the Senate inquiry to the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008 document. Feedback included in this process comprises information primarily from College members from the RACP Therapeutics Expert Advisory Group.

The RACP comprises over 10,000 College members, including members of the College itself (physicians and paediatricians), and members of its Faculties of Public Health Medicine, Rehabilitation Medicine, Occupational Medicine and of its Chapters of Palliative Medicine, Addiction Medicine, Community Child Health and Sexual Health Medicine. The Joint Faculty of Intensive Care Medicine is part of the RACP and the Australian and New Zealand College of Anaesthetists. In addition, the RACP encompasses 28 Specialty Societies representing the spectrum of practice in Internal Medicine and Paediatrics across 23 sub-specialties.

The RACP has evolved to bring together different groups of physicians who share common ideals in medical practice. Physicians and paediatricians are medical experts to whom patients with complex and difficult or chronic diseases are referred. They emphasise the treatment of the whole individual within a social context. This requires not only a high level of medical expertise, but high cognitive competence and the ability to communicate exceptionally well with patients, other medical practitioners such as general practitioners, other health team members and medical trainees. These ideals have led the RACP to a unique position among the specialist medical colleges. Not only is the RACP the key professional training and education body for physicians in Australia and New Zealand, it has also emerged as a key informant and influence in health policy over a range of areas.

The RACP will use the principal matters for consideration to address the submission as follows:

1.

(a) the impact of the Pharmaceutical Benefit Scheme (PBS) cost recovery on:

(i) patients' timely and affordable access to medicines;

This will likely serve as an additional barrier to the population having timely access to appropriate medicines meeting their health needs. For example, the pre-existing barriers (including, but not limited to, economic ones) to the TGA registration and PBS listing of appropriate paediatric medicines have recently been the subject of extensive discussion in Australia (see AHMAC Paediatric Pharmaceuticals Working Group Final Report, Oct 2005) and globally (see World Health Assembly resolution "Better Medicines for Children", May 2007). The Commonwealth Department of Health launched a new initiative in 2007 to help address this important issue (see Paediatric Medicines Advisory Group (PMAG) Terms of Reference, 2007). The proposal in this Bill appears to be at odds with the spirit of recent Commonwealth initiatives to improve children's access to needed medicines. While the work of PMAG is still in progress, anecdotal information indicates that at least some PBS applications for medicines addressing important paediatric health problems will need to be initiated and/or prepared by health professional groups rather than the pharmaceutical industry. Many of these will be due to commercial non-viability (at least as perceived by the pharmaceutical industry). The requirement of fees for such applications will be prohibitive, and serve as an additional barrier, unless appropriate measures are in place for fee waivers. The existing provisions under the "orphan drugs" program will not be sufficient in many cases. More explicit details of categories or conditions for fee waivers should be provided.

(ii) the Australian pharmaceutical industry;

In a number of areas the introduction of cost-recovery threatens to restrict access to important drugs for a number of groups in the Australian population. The principal reason for this is that pharmaceutical industry will no longer be prepared to develop major submissions where the medicines for a particular indication are not commercially viable.

The cost-recovery legislation fails to recognise that companies already bear significant costs in the listing process. Developing and presenting the required evidence-base in a submission to demonstrate both clinical effectiveness and cost-effectiveness is expensive (on average around $350,000 in direct costs only). Adding $110,000 dollars to the process will mean that drug companies will concentrate resources principally on those medicines where it expects significant profits – this is likely to be at the expense of medicines with only a small target population. Already, there is insufficient presentation of new data that would support extension of access to listed medicines because of the unsatisfactory "business case" from a company perspective. Assembling satisfactory clinical and economic data to accommodate a sub-set of patients previously excluded from access to a listed and increasingly commonly, expensive medication will be less likely. Thus, more patients will be unfairly discriminated against.

As the existence of the Paediatrics Medicines Advisory Group (PMAG), the Aboriginal and Torres Strait Islander medicines advisory group and the Palliative Medicines Advisory Group attests – each of which work to encourage pharmaceutical companies to register and list medicines (or formulations of medicines) for small but important indications - the PBAC already considers children, indigenous populations and the dying as underserved by existing processes.

Whilst the current proposal allows for exemptions for orphan drugs and indications, this is unlikely to be sufficient to overcome the disincentive to list or expand listing indications in many cases.

> (iv) the independence of the Pharmaceutical Benefits Advisory Committee;

It is likely to have a negative impact on this valued attribute of the PBAC, with likely negative impact on Quality Use of Medicines (QUM) in Australia. The PBS is designed to ensure medicines are available to all Australians regardless of ability to pay, and reflects the Australian government's long-term commitment to achieving both equity in access to health services and equity in health outcomes. The principal function of the PBAC is to provide independent scientifically valid advice to the Minister on what medicines should be subsidized. It is thus a process designed to assist the Government to allocate its health resources in the most efficient way according to the best available evidence. It is hard to see why the cost of this assessment process should thus be transferred to the private sector as its principal beneficiaries are (1) the government, who receive information on how best to target their scare resources; and (2) the Australian population who receive universal and affordable access to medicines that are deemed to be clinically effective and cost-effective.

> (b) cost recovery mechanisms in other countries;
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> (c) how cost recovery will improve the timeliness and effectiveness of the current PBS process for listing new medicines; and
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> (d) the modelling and consultation underpinning the decision.

The information on the "fact sheet" website claims that "consultations have been undertaken with key stakeholders, including pharmaceutical industry peak bodies, health professional groups and a consumer representative body". Given that RACP appears not to have been included in that round of consultation and many members of the College were "surprised" about the announcement in May 2008 (including several people with key roles in national medicines policy). The College would question the reliability of the previous consultation process and perhaps ask exactly which "health professional groups" and "stakeholders" were included. This consultation did not include relevant paediatric advisory groups, which again seems at odds with current Australian and global initiatives.

The cost of medicines to consumers and tax payers will increase as companies will devise methods to recoup costs and ultimately, the citizens will pay further eroding the 'Equity of Access' pillar of our National Medicines Policy.

2. That, in conducting its inquiry, the committee hear evidence, inter alia, from the pharmaceutical industry, generic medicines industry, consumer and patient health groups, the Department of Health and Ageing, the PBS Evaluation Units and the Australian Medical Association and other medical bodies.

The College also would like to express an interest the hearing on 28 July in relation to this enquiry.

If you require any further clarification of the endorsement please contact Ms Mary Osborn by email on mary.osborn@racp.edu.au.

Yours sincerely

A/Prof John Kolbe
President Elect