Comments on particular items from the current list of 'authority required' items of the Pharmaceutical Benefits Scheme (PBS)

I write these comments in support of the maintenance of a prior approval process across a range of pharmaceutical items from the current list of 'authority required' items. The grounds for these comments are mainly that the abolition of the current process for funding of these items will adversely affect the longevity of the PBS in that a range of medication, and often expensive medication, will be used for inappropriate indications or will cause harm

Currently a third party – be it a pharmacist or a administration officer working under the supervision of a pharmacist – reviews the proposed treatment prior to funding being made available. This review of the treatment involves the prescriber submitting a 'case' for the use of the drug. This can involve a simple telephone conversation or a more complex submission for a Highly Specialised Drug where a range of details are provided and where the prescriber signs off on the treatment. In either case the prescriber is making a set of claims about the patient, the patient's condition and the intended use of the drug in question.

I consider that the lifting of these requirements on a range of medications would present an unacceptable risk to the integrity of current PBS system and open the way to abuse of taxpayer funded medication. I would prefer to see problems with the current system clearly identified and solutions applied to those problems in such a way that the system is not compromised.

This submission provides a set of examples to illustrate the points I am making. It is not an exhaustive list, however it provides some examples of the potential of either cost blow out or harm that could eventuate with the abolition of the current system.

Drug or drug group	Comments or effects of removing the 'authority required' listing
Cancer therapies	Many of these are new entities and are very expensive. TGA approval is usually restricted to a narrow list of cancer diseases. The management of cancer treatments can often become somewhat experimental when options are reduced as the disease progresses. Pressure often mounts from the patient and family for clinicians to resort to therapies that don't yet have proven efficacy or safety in a particular type of cancer. The removal of 'authority required' for these items could easily result in their use beyond TGA and PBS approved indications often without real benefit but with increased cost blow out.

Drug or drug group	Comments or effects of removing the 'authority required' listing
TNF alfa inhibitors	These are expensive drugs to treat a range of autoimmune diseases such as rheumatoid arthritis. There are very effective in these diseases but are very expensive – around $1700 for a monthly injection. I have recently heard of trials taking place for the treatment of Alzheimer's Disease with the drug etanercept. There are large numbers of Australians suffering from this disease and even a small 'leak' of the use of this drug for this off-label experimental treatment would be costly to the community.
Vancomycin capsules	Oral Vancomycin is listed on the PBS for the treatment of antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance or resistance to metronidazole. As a pharmacist I have been and continue to be amazed that some medical practitioners do not understand that vancomycin in its oral form cannot be absorbed into the blood stream and treat a systemic infection in the bone or elsewhere. This 'authority required' listing protects patients being harmed by not getting proper treatment in such cases and it protects the public purse in cases where a treatment becomes ineffective.
Esomeprazole 40mg	This drug is a highly potent proton pump inhibitor. The current 'authority required' listing prevents inappropriately high doses of this medication from being prescribed especially in view of its propensity to reduce the absorption of magnesium particularly in the elderly.
Epoiten	The removal of the 'authority required' listing could lead to its use as a performance enhancer in sport.
Tadalafil and sildenafil	These drugs are listed for the treatment of pulmonary hypertension. The removal of the 'authority required' listing could lead to their use to treat erectile dysfunction.
Terbenafine	This drug is listed to treat nail infections. It has the propensity to cause liver damage if taken for long periods. A number of medical practitioners consider that long term treatment is needed if the infection from the nail has not totally disappeared, whereas this is not needed if clean non-infected nail is visible at the base. The current 'authority required' listing prevents its misuse in this way.

Drug or drug group	Comments or effects of removing the 'authority required' listing
Testosterone products	The removal of the 'authority required' listing could lead to its use as a performance enhancer in sport or misuse in the body building sport and industry.
Ciprofloxacin	Australia (like many other countries) is facing a problem of escalating antibiotic resistance. The removal of this 'authority required' listing would add to this problem.
Benzodiazepines	These drugs are listed in greater quantities as 'authority required' for the treatment of patients in palliative care and in aged care facilities etc. The removal of these listings has the potential to increase the current benzodiazepine addiction problem of this country.

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