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Ms. Tania Plibersek
Federal Minister for Health
Canberra

Dear Minister Plibersek,

I am writing to you on behalf of all elderly Australians. Over the last 20 years we have seen a dramatic improvement in the health of our population which has resulted in many people living to an older age and being healthy and active in their senior years. This increase in life expectancy has been due to the development and availability of better medication to treat cardiovascular disease in conjunction with decreased smoking and promotion of healthier lifestyles and diets.

With the aging of our population there is an increase in diseases associated with advanced age and atrial fibrillation (AF) is one of these. This is a disorder of heart rhythm that is characterised by an irregular heartbeat that often causes no symptoms. Despite this, AF increases the risk of stroke in the elderly, and if a stroke occurs in the context of AF, it is more likely to be fatal or disabling than in a patient with a normal (regular) heart rhythm.

The standard treatment for stroke prevention in AF is the blood thinner warfarin which is a highly effective medication but is difficult to use and control in many patients. It needs regular blood tests to monitor the effectiveness of its action so that the patient is not over anticoagulated (increasing the risk of bleeding) or under anticoagulated (increasing the risk of stroke). Warfarin has multiple food and medication interactions as well as individual genetic variation in metabolism which contributes to

the less than ideal control seen in most patients. Many of the problems with warfarin have been overcome with the advent of the novel anticoagulants, and in particular dabigatran, which has proven benefits over warfarin. It is more effective than warfarin in reducing stroke in patients with AF and has similar or reduced risk of bleeding depending on the dose used. It does not need to be monitored as it gives consistent and reliable anticoagulation, and has no significant food or drug interactions.

This drug was evaluated by the TGA who approved its registration for this indication. It was then evaluated by the PBAC who recommended it be funded through the PBS. In the past, medication that has passed these two hurdles has been funded but unfortunately the Gillard Government has chosen to break with precedent and has commissioned a review of how to improve the effectiveness of current therapies (warfarin) for this indication. To many physicians this would seem to be a waste of time as even in the best managed countries such as Sweden, control of patients is less than ideal with on average 30% of patients inadequately anticoagulated and thus at risk.

Dabigatran has been approved and recommended for subsidisation by the Government appointed independent TGA and PBAC, and is currently available in many countries globally, including the USA, Canada, Europe, and even in NZ and the UK where the regulatory processes are as rigorous if not more so than ours. It is disappointing and frustrating that your government has chosen not to subsidise this medication and allow Australian patients to access this potentially life saving therapy.

I appreciate there is a cost associated with the introduction of new therapies, but in this case most of the costs will be offset by the reduction in stroke and subsequent institutionalisation of patients who are disabled due to stroke related to AF. The Govt. estimates that this will be a billion dollar drug are misleading as this a 5 year

cost rather than annually. In an audit by Deloitte the annual costs of new strokes related to AF were in the order of \$250 million per year, making dabigatran an attractive and cost effective therapy, not only to reduce strokes, death and disability but to improve the quality of our elderly patients with AF who have paid taxes all their lives and deserve to be treated with the best available medication.

I am asked on a daily basis why this medication is not available by my many patients who have AF and are on warfarin with less than ideal control. All I can tell them is that their Government has chosen to ignore the advice of their independent scientific advisors and has chosen not to fund this potentially lifesaving drug despite solid evidence of its benefits over warfarin. I have encouraged them to discuss this with their local member to make them aware of the problem and issues.

Many patients in Australia are needlessly having strokes due to the unavailability of dabigatran, which has unequivocal evidence of benefit over current best practice for stroke prevention in AF. I thus implore you to discuss this issue with Ms. Gillard, Mr. Swan and Cabinet so that elderly patients in Australia have access to medication that is more effective and safer than current best practice, and which is available in most countries in the world for this indication.

Yours sincerely,



John Amerena
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