Consumers
Health Forum
of Australia

21 February 2012

Emeritus Professor Lloyd Sansom
Chair, Review of Anticoagulation Therapies in Atrial Fibrillation
Department of Health and Ageing
MDP 900
GPO Box 9848
CANBERRA ACT 2601

Dear Professor Sansom,

Review of Anticoagulation Therapies in Atrial Fibrillation

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide comments to the *Review of Anticoagulation Therapies in Atrial Fibrillation* (the Review). Given the long-established history of anticoagulation therapies Warfarin and Aspirin, our comments will focus on Dabigatran (Pradaxa).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF is aware of the 'Vote Against Stroke' campaign led by Boehringer Ingelheim, the manufacturers of Pradaxa, urging the listing the drug on the Pharmaceutical Benefits Scheme (PBS). While Boehringer Ingelheim has engaged consumers in this campaign, many of these participants were involved in a Pradaxa familiarisation program. These consumers were subsequently led to believe that Pradaxa would soon be listed on the PBS. While CHF supports the right of consumers to access timely medicines and treatments, this must be balanced against safety and effectiveness, as well as cost effectiveness.

It is CHF's understanding that questions have been raised as to the benefits of Pradaxa as observed in clinical trials. CHF is also aware of safety concerns relating to bleeding adverse events, resulting in the Therapeutic Goods Administration (TGA) issuing a Safety Advisory on 5 October 2011. This is consistent with growing concern internationally regarding bleeding adverse events and increased risks of acute coronary events linked to Pradaxa.

In the United States, extensive media coverage of bleeding adverse events related to Pradaxa has resulted in law firm Nadrich & Cohen investigating the possibility of a class action law suit on behalf of consumers.[1] Safety advice from medicines regulators in Japan and the United Kingdom have also warned of severe haemorrhaging as a result of the use of Pradaxa.

[1] Nadrich & Cohen (2012) *Pradaxa Side Effects*. Media release available at: http://www.personalinjurylawcal.com/pradaxa-side-effects.php

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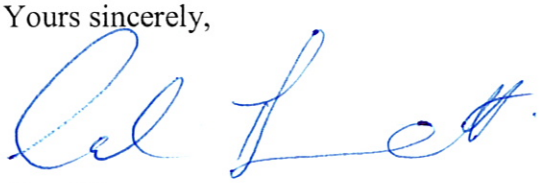
CHF is also aware of recent research linking Pradaxa to an increased risk of heart attack, angina and other serious complications in certain patients.[2] The study, published in January 2012, shows that:

- Patients who take Pradaxa are as much as 33% per cent more likely to experience a heart attack or angina compared with patients who used another type of blood thinning agent.
- Pradaxa may lack the beneficial effects that Warfarin and Aspirin have in myocardial infarction prevention.
- The cardiac risk of Pradaxa should be investigated further, especially if used in populations at high risk of certain coronary conditions.

CHF understands the disappointment experienced by consumers who began using the drug with the expectation that it would become more affordable once it became listed on the PBS. However, based on the limitations of the evidence, and the associated safety concerns in the case of Pradaxa, CHF believes that any anticoagulant therapies recommended for listing on the PBS be subject to rigorous trial to determine efficacy, mitigate potential adverse events and ensure safety for consumers. We recommend that further research be conducted prior to listing Pradaxa on the PBS.

Please feel free to contact me should you wish to discuss any aspect of these comments further.

Yours sincerely,



Carol Bennett
CHIEF EXECUTIVE OFFICER

[2] Uchino, K., and Hernandez, A.V. (2012) 'Dabigatran Association With Higher Risk of Acute Coronary Events Meta-analysis of Noninferiority Randomized Controlled Trials.' *Archives of Internal Medicine*. Volume 172(1) pp 7-84.