The Society of Hospital Pharmacists of Australia
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50 YEARS National Organisation
ABN 54 004 553 806

21st February 2012

PBS Post Market
Department of Health and Ageing
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Dear Sir / Madam

Re: Review of Anticoagulation Therapies in Atrial Fibrillation

SHPA is the national professional organisation for nearly 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. These pharmacists work within healthcare teams with a focus on supporting the safe and effective use of medicines as their core business.

SHPA welcomes the review of the availability and safe use of anticoagulants across the continuum of care, in particular the use of newer agents such as dabigatran. SHPA supports decision making processes of the Pharmaceutical Benefits Advisory Committee (PBAC) and notes the recommendation made with regards to the listing of dabigatran on the Pharmaceutical Benefits Scheme (PBS).

SHPA also notes that the use of dabigatran in the community through a Product Familiarisation Program (PFP) has given decision makers and many clinicians a better understanding of the risks and benefits of using this medicine outside clinical trials, in a wider context with 'real' patient populations, without practice guidelines on the use of the medicine. This experience has highlighted the difficulty GPs have in managing anticoagulant therapies and reinforced the need for and benefits of specialist anticoagulant clinics.

SHPA and our members have always supported the use of evidence-based treatment guidelines for the introduction and maintenance of warfarin therapy. We have worked with numerous national groups and locally within hospitals, to develop a mechanism for the safe and effective use of warfarin for a variety of patient groups. These national and local approaches have required prescribers and pharmacists to have a deep understanding of both the medicine and the inherent risks of using anticoagulants in specific patient groups when used in the short term and for long term therapy.

SHPA believes that we have failed to translate the lessons learnt from the widespread use of and risks associated with warfarin to the introduction of newer anticoagulants.

Feedback from our members has been unequivocal: there is a need to review the conditions for the availability of agents such as dabigatran to reflect the actual and potential risks and costs associated with the use of this medicine.

SHPA notes that at this time few, if any, public hospitals have approved the use of these medicines - patients are usually commenced these medicines in the community setting through a PFP. Therefore hospital-based practitioners have limited experience in the initiation of these medicines, but growing expertise in managing the complications and adverse effects of these medicines and managing patients during inpatient admissions.

Anecdotally we have received reports of hospitalisations within as little as two days of the commencement of therapy with dabigatran. We are also aware that the use of these newer agents is impacting on the delivery of elective surgery and emergency care, increasing patient length of stay and overall hospital costs. These bleeding events, hospitalisations, cancelled elective care and deaths appear to be linked to a poor understanding of the risks associated with newer anticoagulants and the 'down playing' of these risks and the need for ongoing monitoring and review.

Our members have highlighted that a lack of guidelines: on the initiation of these medicines, day-to-day management and the treatment of complications is compromising patient care. It has been suggested that access to these agent through a PFP should be accompanied by evidence-based guidelines on their use.

SHPA believes that three key facts are ignored / unappreciated in the decision making process with the newer anticoagulants. This is compounded by the access of medicines through a PFP mechanism with little or no restriction on the use of these medicines or guidelines on the management of the inherent risks with their use.

1. There is **no proven antidote** / **reversal agent** for dabigatran. Bleeding events are difficult to manage: this accentuates complications, leads to problems with managing patients scheduled for elective surgery and the management of patients requiring emergency care.
2. Patients at high risk of excessive bleeding are at **high risk of excessive bleeding irrespective of the anticoagulant being used**. The risk is linked to patient-specific factors, as is the need for a suitable monitoring regimen.
3. The dosage adjustment required for patient with **renal impairment**, in particular patients with severe renal function. Anecdotally many patients transitioning to newer anticoagulants are elderly, many have impaired renal function and some a pre-existing gastro-intestinal disease.

Specifically dabigatran has dose-form properties that complicate its use in real patients and increases the likelihood of adverse events:

- The dose form is not stable outside its own packaging which should preclude its use in patients that require dose administration aids of any kind and prevents its repackaging to unit dose systems in hospitals.
- The administration method can have a significant impact on clinical effect and bleeding times, for example if the patient spreads the contents of the capsule onto food there is an increased anticoagulant effect.

SHPA believes the Department will receive numerous examples of local treatment guidelines and detailed information from a range of clinicians. For this reason we have focused our comments on detailing the principles that should drive the availability and clinical use of these medicines.

- The use of all anticoagulants should be driven by evidence-based treatment guidelines. The availability of these medicines through the PBS (and any restrictions on their use) should be linked to these treatment guidelines.
- All anticoagulants have inherent risk and these risks should be clearly articulated and drive the approach to initiating, monitoring and withdrawing these medicines. The approach used

for warfarin should remain the 'standard' until there is sufficient information to develop a different approach for newer anticoagulants.

- Patients at high risk of adverse events when using anticoagulants are at risk irrespective of the anticoagulant being used.
- There is a need to articulate protocols / treatment guidelines for:
  - transferring patients from warfarin to newer anticoagulants
  - commencing therapy and reaching desired clinical parameters
  - managing patients prior to surgical / invasive procedures and reversing the anticoagulant effect of each agent
  - dose reduction in renal impairment, concurrent conditions (e.g. ischaemic heart disease, gastro-intestinal disease) and monitoring.
- For medicines like dabigatran there needs to be an informed consent process prior to its use. Patients should be informed that:
  - there is no proven antidote
  - patients with previous bleeding events should be informed of the level of ongoing monitoring required and additional risks associated with the medicine for them to allow them to understand any change in benefit / risk and
  - patients with renal impairment and severe renal impairment should be aware of the additional risks associated with the use of the medicine for them.
- Many of Australia's public hospitals offer anticoagulation clinics and the new Activity Based Funding (ABF) system for public hospitals lists these clinics *Anti-coagulant Screening and Management* as a specific service for ambulatory patients. In addition, many private pathology providers are offering monitoring programs (anecdotally leading to a devolution of care to these providers). SHPA believes that to maximise effectiveness and minimise adverse events all patients receiving anticoagulant therapy should have access to a monitoring program equivalent to that offered in dedicated anticoagulant clinics.
- Patients with bleeding events often require ongoing care and monitoring in the immediate post-discharge period. Where clinically required these patients should have access to a hospital initiated post-discharge home medicines review.

As most anticoagulants are commenced in hospital, SHPA suggests that hospital pharmacists would be ideal to educate hospital staff about any final agreed national protocol and also to administer those protocols in collaboration with local therapeutics committees. When such oversight of protocols is devolved to hospital pharmacists, evidence is clear that both morbidity and mortality is improved (Bond CA, Raehl CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. Pharmacotherapy 2007; 27: 481-93).

Please contact me via email: shpa@shpa.org.au if you require any further information about how SHPA may assist to improve the use of anticoagulants.

Yours sincerely,

Sue Kirsa

SHPA Federal President