Most recently, publicly available data from both the EMA and the FDA has created debate about both the appropriate dose of the oral anticoagulant dabigatran and the need to monitor its concentration.[8] Review of the FDA's reports revealed that an advisory committee had voted six to four in favour of a 110 mg formulation. However, despite this advice only a 150 mg dabigatran product was approved in the USA. The material also revealed at least one committee member raised concern about whether dabigatran required laboratory monitoring, given that the data showed variability in plasma concentrations. Review of information from the EMA also revealed individual committee members had concerns about the large variability in plasma concentrations. Appraisal of the materials from both regulatory agencies also highlighted their different responses to the same evidence. The Europeans approved the 110 mg dose to reduce the risk of bleeding, while the FDA was concerned about the efficacy of this dose and therefore approved the 150 mg dose.[8]

These examples demonstrate the challenges for regulatory agencies in assessing evidence. However, this challenge is not limited to regulatory agencies – even re-analysis of trial results by the original study investigators has resulted in changes in interpretation. There has been a study of 37 re-analyses of randomised controlled trials, 86% of which were undertaken by the same research group that published the original trial. Most commonly, the re-analyses used a different method of analysis or used a different definition of the outcome. In 35% of cases, the re-analysis led to different interpretations as to which patients should be treated.[9]

The release of trial data by the EMA in 2015 increases the transparency of the data on which regulatory decisions are made. Future planned developments include the release of individual patient level data, which may further assist in decision making, and potentially enable additional analyses.

Given that there is often uncertainty about either the safety or efficacy of drugs when they first come to market, the provision of trial data in the public domain will spark much more robust debate about the place of medicines in practice. This will allow us to make more informed decisions that meet patients' needs. ◀

Conflict of interest: none declared

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Letters to the Editor

Pharmaceuticals, pharmacists and profits

Editor, – In his article, 'Pharmaceuticals, pharmacists and profits: a health policy perspective' (Aust Prescr 2014;37:148-9), Professor Philip Clarke highlights the importance of the price disclosure policy in reducing government spending on pharmaceuticals. However, Professor Clarke blatantly disregards the important role that community pharmacists play by comparing pharmacies to 'firms that sell computers or mobile phones'. He asks why community pharmacy should have the support of taxpayer funds in order to remain viable while electronics stores do not. What a ridiculous comparison!

Community pharmacies are staffed by highly trained health professionals and are essential in providing timely access to prescription medicines. This is an essential service that must remain a viable business for those involved. In addition to this, community pharmacists also provide a range of

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important services including counselling on the use of medicines, drug information and advice, primary health care, medication management services and delivery of medicines to the elderly and disabled. These services are generally provided free of charge and help to reduce medication-related hospital admissions which cost $1.2 billion annually.

Australian pharmacists are well attuned to the need to ensure that the Pharmaceutical Benefits Scheme (PBS) remains sustainable, especially in the context of our ageing population. They are calling for increased opportunities to provide funded health care and medication management services.

Pharmacists remain one of the most accessible health professionals with anyone being able to walk into a pharmacy (often open long hours) and obtain advice within 10 minutes. Community pharmacies are ideally placed to provide an expanded range of services where current gaps exist.

Melanie Frodsham
Pharmacist
Melbourne

Dr Philip Clarke, the author of the article, comments:

I fully agree with Ms Frodsham that community pharmacies are staffed by highly trained professionals who can play an important role in providing advice and information on the use of medicines to improve health outcomes. However, it is very unclear why this role depends on the pharmacy owners continuing to receive government subsidies from 'discounts' on the wholesale cost of generic drugs. These discounts mean that payments from government to pharmacies exceed the regulated markups of many generic drugs. This costs taxpayers hundreds of millions of dollars each year.

Paying high prices for generic drugs not only has a financial impact on some patients, but it also increases the chance they may discontinue their treatment, which may put them at risk. A far better way to remunerate pharmacists would be to look at ways to directly pay for the services they provide, rather than the current system, where profitability largely depends on the volume and margins on drugs sold.

Smoking and preoperative assessment

Editor, – The article on preoperative assessment (Aust Prescr 2014;37:188-91) was a good review, but unfortunately omitted the critical issue of smoking. Smoking causes increased cardiorespiratory complications, intensive care admissions, mortality, wound infections and poorer wound healing after surgery. Smoking cessation before elective surgery can significantly improve postoperative outcomes.[1] The perioperative period is a teachable moment when patients are more motivated to quit,[2] and some patients who quit may remain abstinent after discharge. However, many opportunities to assist smokers are being missed and most continue to smoke up to the day of surgery.[3]

The Australian and New Zealand College of Anaesthetists recommends a simple and brief intervention known as the A-A-R strategy.[4] It involves:

- Asking about smoking status
- Advising smokers to quit
- Referring them for smoking cessation support.

Smokers can be referred to Quitline (137 848), general practitioners or Tobacco Treatment Specialists (www.aascp.org.au). A brief smoking intervention such as Ask Advise and Refer should be a routine part of preoperative elective surgery care for all anaesthetists and surgeons.

Colin Mendelsohn
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Colin Mendelsohn has received honoraria for teaching, consulting and travel from Pfizer, GlaxoSmithKline, and Johnson & Johnson. He sits on Pfizer's Champix Advisory Board.

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Austin Ng and Leonard Kritharides, the authors of the article, comment:

We appreciate the important comments made by Dr Mendelsohn. We certainly agree smoking cessation is important for all patients including those undergoing surgery. It should be incorporated into a protocol-driven documentation of the patient's risk factors during preoperative assessment as recommended by the Australian and New Zealand College of Anaesthetists.