Prescribers are increasingly circumvented

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What roles do pharmaceutical firms, healthcare organisations, and

government regulatory agencies play in switching prescription drugs to over the counter drugs? Cohen and colleagues, prompted by increased numbers of prescription drugs being made available over the counter worldwide, analyse three recent controversial switches: simvastatin in the United Kingdom, omeprazole in Sweden, and loratadine in the United States (p 39). They argue that the main motives are pharmaceutical firms' desire to expand their market, attempts to reduce drug bills, and the self care movement.

POEM*

HRT is most beneficial for women under 60

Question Is there a beneficial effect of hormone replacement therapy (HRT) in younger postmenopausal women?

Synopsis This meta-analysis represents an attempt to look at the available data on HRT in postmenopausal women to give some shading to the general (current) feeling that oestrogens are "bad." Using several databases, the investigators identified all randomised studies of HRT in postmenopausal women, including the women's health initiative study published in 2002. They included studies that lasted at least six months and reported at least one death, and used appropriate meta-analytic techniques for choosing studies, extracting the data, and assessing validity. The authors combined the results from 30 studies enrolling more than 26 000 women. Overall total deaths, cardiovascular deaths, and cancer deaths were not different between the groups receiving HRT or placebo. However, separate analysis by age showed an overall survival benefit in women younger than 60 years (odds ratio 0.61; 95% confidence interval 0.39 to 0.95). This benefit translates into a number needed to treat of 44 (29 to 88). Looking at individual outcomes, cardiovascular related or cancer related death rates were not affected by treatment. The benefit was not seen in women 60 years and older.

Bottom line Oestrogen replacement in women younger than 60 years, while not affecting an individual's likelihood of cardiovascular related or cancer related death, results in a net decrease in overall mortality. This information should reassure us that newly postmenopausal women who want to take hormone replacement therapy for symptom control can do so.

Level of evidence 1a (see www.infoPOEMs.com/levels.html). Systematic reviews (with homogeneity) of randomised controlled trials.

Salpeter SR, Walsh JME, Greyber E, Ormiston TM, Salpeter EE. Mortality associated with hormone replacement therapy in younger and older women. *J Gen Intern Med* 2004;19:791-804.

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* Patient-Oriented Evidence that Matters. See editorial (*BMJ* 2002;325:983)

Editor's choice

An important debate on the GMC

The General Medical Council—the regulatory authority for UK doctors—begins this year in crisis. Dame Janet Smith's inquiry into failures of regulation that allowed Harold Shipman to murder over 200 patients delivered bad tidings to the GMC in the last days of 2004 (see p 10). Richard Smith, close observer of the GMC during his career on this journal, argues that the GMC's failing is that it has put expediency before principle, and that further difficult reforms are essential (see p 1).

Readers may have been under the impression that the GMC was already in the business of reforming itself by increasing lay representation and allowing people who are not members of the GMC to adjudicate on fitness to practise. That impression was a reasonable one, but Dame Janet's report condemns those reforms—I paraphrase here—as ill conceived, inadequate, and unlikely to regulate the medical profession to the satisfaction of the public and parliament.

Now the government has said that the GMC's introduction of revalidation for doctors—a key plank of its regulatory reforms—may be inadequate too, and ordered a review by Sir Liam Donaldson, England's chief medical officer. The GMC has agreed to put revalidation on hold pending the review. Revalidation was a process agreed after "intense battles," and the GMC retreating from an elaborate but rigorous assessment to one that the Smiths—Janet and Richard—argue will not do its job. Expediency created a method of revalidation that left many doctors baffled as to how it related to their clinical competence, and now leaves others concerned that it will fail to protect patients.

The culture of the GMC is once again under scrutiny. In 2005, a regulatory authority pontificating on the doctor-patient relationship must put protection of patients first, however much doctors may dislike this transfer—even betrayal—of loyalties. Inevitably, another lurch towards upholding patients' rights increases pressure on the vast majority of highly committed, competent doctors, who may see more reform of the GMC as a further intrusion into their clinical practice. But self regulation in all professions has become increasingly hard to justify.

Finding fault with the current system is not rocket science. Finding a solution is more complicated. Might there be lessons from other countries, such as board recertification in the United States of America? Might we learn from the way accountants, for example, are regulated? A quick fix is impossible, which is why we are inviting contributions to a *BMJ* debate on the future of the GMC and regulation of doctors in the UK and worldwide. Over the next few months we will publish invited articles, as well as the best of the contributions that are submitted to us. Regulation of doctors is the major challenge facing UK health care in the year ahead—and resonates elsewhere. *BMJ* readers must be at the heart of this important debate.

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