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OTC statins: a bad decision for public health

From July, simvastatin will be available without a prescription in the UK. The Department of Health has accepted the advice of the Committee on Safety of Medicines (CSM) that simvastatin 10 mg can be sold through pharmacies to people at moderate risk of coronary heart disease. The UK is the first country to make a statin available over the counter (OTC).

The decision followed a 10-week public consultation with 100 responses referred to the CSM. The reclassification summary concludes "The overall risk to benefit to the community of Pharmacy availability of Zocor Heart-Pro 10 mg tablets (simvastatin) is regarded as favourable".

Let's examine the facts. There are no trials of OTC statins for primary prevention of heart disease. There are no data on compliance with OTC statins, which for products that need to be taken daily longterm is a concern. Will those who buy simvastatin also stop smoking, lose weight, and do more exercise, or will they substitute drug use for lifestyle modification? Will pharmacists have the time to determine the individual's risk of coronary heart disease before selling the drug and also to give lifestyle advice? All these are unknowns, which is unfortunate for the UK public, who will be the guineapigs in this large-scale OTC experiment. Americans have escaped this role, with two applications for OTC statins (pravastatin 10 mg and lovastatin 10 mg) being rejected in 2000 because of insufficient evidence that either drug could be used safely and effectively in an OTC setting.

Without data on the self-medicating population, the reclassification report relies on a 2003 systematic review of data comparing simvastatin 10 mg with placebo, which gives a 27% reduction in LDL-cholesterol. However, some of these data come from short-term trials, and some trials included patients with coronary heart disease. The 27% reduction in LDL-cholesterol is associated with a reduction in risk of a major coronary event (death or non-fatal myocardial infarction) by about one-third after 3 years of treatment. But, according to an appraisal by the University of British Columbia, if the five major statin primary-prevention trials are combined (and none studied simvastatin), then 71 patients with cardiovascular risk factors have to be treated with a statin for 3–5 years to prevent one heart attack or stroke. However, total mortality and total serious adverse events are similar in the treated and control patients. Prescribed statins (pravastatin 40 mg, atorvastatin 10 mg, and lovastatin 20-40 mg) have not been shown to provide an overall mortality benefit in primary-prevention trials. It is unlikely that a low dose of OTC simvastatin will do what has not been found in controlled settings.

And what about the hazards of OTC simvastatin? Again, since no studies have been done in this setting, any hazards are unknown. Myopathy or rhabdomyolysis, although rare in trials, remain concerns. Pharmacists will need to be vigilant about the potential for interaction with prescribed drugs such as other cholesterol-lowering drugs, anti-coagulants, antifungals, or antibiotics.

In the absence of evidence of the overall mortality benefits of OTC simvastatin, it is difficult to avoid concluding that the motive behind the Government's decision is saving money. Statins are currently prescribed to about 1·8 million people in the UK, costing the NHS £700 million a year. With the NHS bill for statins predicted to be more than £2 billion a year by 2010, transferring costs to patients might seem timely. But privatising the prevention of heart disease will increase inequalities, with many unable to afford the likely £10–15 per month longterm. For the manufacturer, of course, the motive is clear. With simvastatin now off patent, creation of a new market (perhaps 8 million more people in the UK) will please shareholders.

What is now needed is a surveillance system for OTC simvastatin. Evidence of benefit and risk must be collated in this primary-prevention setting, and used to decide on applications for increased doses of simvastatin or other statins to be available OTC. In the meantime the planned National Institute for Clinical Excellence appraisal of statins for prevention of coronary events due to be published in June, 2005, should be fast-tracked to provide updated guidance on statin prescribing. If the Government is serious about preventing heart disease, then privatisation of that prevention is not the answer. And if the UK public is to be used in an OTC experiment, then the evidence must be collected and used for the benefit of all.

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