

DRUG ACCESS

UK decision to sell statins over the counter criticized

The UK's drug regulatory agency approved the world's first over-the-counter (OTC) statin on the basis of inconclusive evidence, according to the UK's influential *Drug and Therapeutics Bulletin* (DTB).

The Medicines and Healthcare products regulatory Agency reclassified simvastatin (Zocor Heart-Pro) from prescription-only to OTC status for a 10-mg dosage in July 2004.

The regulatory agency made the move to improve access to a medication that reduces the risk of a first major coronary event in people at moderate risk of coronary artery disease. Patients targeted are those at a 10% to 15% risk of an event in 10 years.

Simvastatin is available without a prescription but requires consultation with a pharmacist.

In reviewing the change to OTC status, the DTB states that the lack of long-term efficacy trials to support the regulator's rationale is "alarming."

"People are, in effect, being used as guinea pigs for such treatment, and being charged for the privilege," says Dr. Ike Iheanacho, DTB's editor.

The regulatory agency acknowledges there have been no trials of simvastatin 10-mg in the target population, but says there is good evidence it will reduce the risk of a coronary event by a third after 3 years' use.

"To advocate a new controlled clinical study with the precise dose and population selected for self-medication is not supportable ethically, since the

result is completely predictable on the basis of the existing body of evidence," said a spokesperson for McNeil Ltd., a subsidiary of Johnson & Johnson MSD, the manufacturer of simvastatin.

DTB says that claim may be too optimistic because it is based on studies of people who already had coronary heart disease.

DTB also says the OTC protocol used to assess risk is flawed. Pharmacists rely on gender, age and self-reported risk factors before deciding whether to sell patients the drug. But they are not taking blood pressure.

"Some could be wrongly classed and treated as being at only moderate risk of a heart attack, when in reality their risk is very much higher," states DTB.

The Royal College of General Practitioners says that without stricter rules, consumers may be sold medication they don't need.

While simvastatin has a good safety profile, myopathy, rhabdomyolysis and hepatic reactions are rare but severe side effects. The medication is also contraindicated if taken with certain other drugs.

DTB also criticized the move on the basis of cost. Zocor Heart-Pro costs £170.00 (Can\$402) annually. "If it works as well as is being claimed, then why is it only being made available to those who can afford it?" Iheanacho asked.

McNeil Ltd. says the National Health Service does not have un-



Simvastatin is available over the counter in the UK despite a lack of trial data to support the move.

limited resources and must prioritize whom it treats.

"OTC statins give otherwise healthy consumers the opportunity to take proactive steps to reduce their risk of a heart attack," says the company spokesperson.

Prof. Sir Charles George, medical director of the British Heart Foundation said he is confident OTC statins will save lives.

The US Food and Drug Administration is considering whether statins should be made available OTC. — *Colin Meek*, Wester Ross, Scotland