

# OTC statin may change pharmacy forever

This week, the first over-the-counter statin is launched. **Clare Bellingham** examines the practical issues surrounding the POM to P switch

**T**his week's launch of over-the-counter simvastatin is a big first for pharmacists in the UK. For one thing, it is the first OTC statin in the world. But perhaps even more importantly it marks a new step in pharmacists' role in preventing chronic disease: for the first time, they will be able to recommend starting a pharmacy medicine that can reduce the risk of heart disease occurring.

Reducing heart disease risk is what OTC simvastatin is all about. This is something that Johnson&Johnson MSD, the manufacturer of the OTC product (Zocor Heart-Pro), is keen to stress. And it is an important distinction to make. "We don't want people to get too fixated on numbers: this is about risk reduction not cholesterol reduction," says Stephen Mann, the company's vice-president of research and development in Europe.

This explains why the pharmacists' assessment of whether or not Zocor Heart-Pro is appropriate will be made on a person's risk factors rather than the results of a cholesterol test. It is probably good news since accurate cholesterol testing requires the patient to have fasted for 12 hours before the test and for a full lipid profile to be measured. Offering this kind of assessment before selling simvastatin would not be easy for many pharmacists, or convenient for patients. Even with an accurate test, pharmacists will still need to carry out the risk assessment.

The company's justification for basing the assessment on risk factors is that the beneficial effect of reducing low density lipoprotein (LDL)-cholesterol on CHD risk holds true regardless of the starting level of LDL-cholesterol. "Serum cholesterol alone is a poor predictor of risk because of the number of other factors which contribute to overall CHD risk," it states. However, Dr Mann adds: "But this is not to say that cholesterol testing isn't useful. People can use tests to see how they are progressing, which can help with compliance. Tests will also pick up the odd person who is inadequately treated."

## So what are the risk factors?

Zocor Heart-Pro is indicated for people at moderate risk of a major coronary event, defined as a 10–15 per cent risk of an event in the next 10 years. These categories are described in detail in practice guidance produced by the Royal Pharmaceutical Society and published in this week's *Journal* (see p169). But to summarise, all men aged between 55 and 70 years are eligible for treatment along with men aged between 45 and 55, and women aged over 55, who have one or more of the following risk factors: family history of CHD, smoker, overweight or of South Asian family origin. The company estimates that seven million people in the UK fall into this "moderate risk" category.



## Statin offers new choice to reduce risk

Pharmacists will use a tick-box questionnaire supplied by the company to determine whether or not simvastatin is suitable for a customer. The form covers risk factors, medical history and other medicines. "A pilot of the form showed that for a fair proportion of people, it could be completed in four minutes. For the bulk, it could be completed in eight minutes," says Dr Mann. The form has two copies: the top copy is given to the customer in a plastic wallet to be produced for repeat purchases so that sales can be made without the need for the detailed questions. The second copy is for the pharmacist to keep. One area of concern is the fact that pharmacists do not have access to patients' medical records. This means that they cannot record that a person is taking OTC simvastatin in a place that other health professionals can see; encouraging customers to inform their GP is the best alternative.

Despite cholesterol tests not being necessary, a branded Zocor Heart-Pro home cholesterol test has been developed. It is a finger-prick test, is sold through pharmacies, and the blood sample is sent away for analysis. According to the company, the test provides a full lipid profile, is as accurate as tests carried out by GPs and is returned to the customer with an explanation of what the results mean. Customers are given the option of a copy of the results to be sent to their GP.

In the run-up to the launch of OTC simvastatin, questions have been raised over the efficacy of the 10mg dose. Dr Mann responds: "Simvastatin has a log-linear dose response." This means that the 10mg dose achieves 75 per cent of the response achieved with the 40mg dose, he explains.

There is also a trade-off with safety. On the whole, simvastatin has a good safety profile but, in rare cases, serious side effects do occur. These tend to be linked either to high

doses or to interactions with other drugs. "So the 10mg dose gives the bulk of the effect with the lowest risk of adverse events," says Dr Mann. Some concerns have been raised over interactions. Dr Mann says that the only commonly used medicines that statins interact with are antibiotics. "You have to remember what the interaction does — it boosts the effect of the statin," he says. So the possibility of an interaction resulting in a toxic level of statin is greater at higher doses.

## Educational and extended role

However effective statins are, they are not the only answer to reducing CHD risk. Lifestyle changes are hugely important. This is something that Johnson&Johnson MSD has recognised. "It is not just about selling tablets. There is a big educational job, too," says Dr Mann. So when a consumer starts taking Zocor Heart-Pro, he or she is invited to join a free educational programme in which a personal action plan is developed. This includes exercise plans, steps to adopting a healthier diet and advice on stopping smoking, including referral to a pharmacist for nicotine replacement therapy. Pharmacists are also encouraged to provide lifestyle advice.

The launch of OTC simvastatin provides a new choice. For patients, it is a new approach to reducing their risk of heart disease. Although for some people, the price — at £12.99 a month or around 45p a day — will be prohibitive, many people will be persuaded that spending the equivalent of the price of a couple of cigarettes or a packet of crisps each day on a tablet that could save their lives is a price worth paying. And for pharmacists, it marks the start of a new chapter in managing chronic disease in the pharmacy.

Pharmacist Noel Wicks was a member of the panel that advised Johnson&Johnson MSD on the switch. "It is a new step for pharmacists. We are seen as the guys for minor ailments but we are moving towards having a much greater role in chronic disease management," he says. Part of this role is managing repeat prescriptions but the introduction of OTC simvastatin adds a new dimension. "In pharmacy, we tend to be reactive rather than proactive. So our biggest challenge is to be proactive in identifying who will benefit from simvastatin."

But the responsibility of ensuring OTC simvastatin is used correctly is not a light one. Tim O'Donoghue, a pharmacist at Greenlight Pharmacy in London, says that pharmacists need to rise to the challenge of demonstrating their skills. "This new category offers pharmacists the chance to develop long-term customer relationships," he comments. "This is a landmark switch and one that could change the pharmacy arena forever."