

# Is pharmacy ready for OTC statins?

The consultation on making simvastatin available over the counter closes next week. **Clare Bellingham** raises some questions for consideration

**M**aking a statin available over the counter seems to be a good move: improved access to an undoubtedly useful medicine for patients, a new clinical role for pharmacists and a reduction in workload for GPs. But underneath the gloss, is it really such a good idea? Who will benefit from such a switch? And what are the risks that come with it?

Perhaps the most important question is this: is pharmacy ready for OTC simvastatin? If the answer is “no”, and the switch goes ahead, then the result could be shambolic which would do nothing but hinder the current development of professional roles that pharmacy is enjoying. If the answer is “yes”, then it represents a significant move forward in the management of chronic disease in pharmacy. Although pharmacists — with the new training already proposed as part of the switch — do have the skills to provide statins over the counter, the question mark is over the supporting infrastructure.

## Records and protocols

The consultation document that outlines the proposed POM to P switch of 10mg simvastatin (to be called Zocor Heart-Pro) suggests that it is intended to reduce the risk of a first major coronary event in people at moderate risk of coronary heart disease. These groups are all men aged 55 years and over, and men aged between 45 and 55 years and women aged over 55 years with certain risk factors (family history of CHD, smoker, obese or of South Asian ethnicity).

Provided pharmacists can identify that patients fit into one of these at-risk groups, the consultation document states that there is no need for any tests or referral to medical records before the statin is sold. Instead, it recommends that pharmacists follow a pharmacy protocol for determining the suitability of the statin for the patient. This involves:

- Establishing the likely level of CHD (by assessing risk factors such as sex and age)
- Checking that there is no pre-existing condition which indicates high CHD risk and requires management by a doctor
- Checking that simvastatin is not contraindicated
- Checking that the patient is not taking other cholesterol-lowering drugs and checking for interactions with other prescription medicines

Since the vast majority of pharmacists do not have access to patients' medical records, not only can they not check a patient's medical history but they cannot add information, either. So it is difficult for the pharmacist to communicate to the doctor that the patient is

buying OTC statins, and the doctor may not ever know unless the patient chooses to tell him or her. In addition, the number of purchases the patient makes will not be recorded so compliance will be difficult to monitor.

This is a concern for the Royal College of General Practitioners: “The proposed move underlines the need for sharing of relevant clinical information between pharmacists, GPs and other members of the primary health care team. Pharmacists currently do not have access to a patient's medical records which would help them judge whether statins were necessary. There would also need to be a system in place for pharmacists to inform GPs about patients to whom statins have been prescribed.”

The problem could be solved by giving pharmacists access to patients' records but IT difficulties have so far prevented this. Contracts to develop the NHS Care Records Service in England were announced last month, and pharmacists have been promised access to the NHSnet, but this will not happen overnight. A push for pharmacists to have access to patient records has taken place in Wales and also in Scotland, where connection of all community pharmacies to the NHSnet is under way. Until these IT developments move forward, pharmacist access to records will remain unusual, although direct computer access has been achieved by some pharmacists (*PJ*, 7 June 2003, p787).

“The Royal Pharmaceutical Society would like pharmacists to have access to patients' medical records and this consultation emphasises the importance of that access,” says David Pruce, the Society's director of practice and quality improvement. In the meantime, he suggests that pharmacists, with the patient's permission, make a record of the sale in the pharmacy and inform the GP that the patient is taking a statin.

Not everyone believes that access to records is essential. Colette McCreedy, director of pharmacy practice, National Pharmaceutical Association, says: “Pharmacists do not need medical records to build up a picture of whether an OTC statin would be appropriate rather than referral to the doctor. The relevant information can be obtained by asking appropriate questions.” She adds: “It is good practice to build up a full picture of a person's medication history but this applies to all non prescription medicines and complementary medicines. There is no need to make a special case for simvastatin.”

John Blenkinsopp, research fellow at the school of pharmacy, University of Bradford, and chairman of Johnson & Johnson MSD's (simvastatin's manufacturer) pharmacy advisory panel, says that the company will give people buying simvastatin a record card to



**Will this man benefit when simvastatin becomes available OTC?**

record all the medicines they take. “The only thing that will work at the moment is a customer-held record that can be given to whichever health professional they see,” he explains.

## Tests and monitoring

Before prescribing a statin, GPs measure a patient's cholesterol level. Yet under the new proposals, for someone buying simvastatin over the counter a cholesterol test is not necessary before treatment or for monitoring afterwards. The reason for this, according to the Medicines and Healthcare products Regulatory Agency, is: “The current evidence suggests that, for adults in Western societies, it can be beneficial to reduce cholesterol levels whatever the starting point.”

Dr Blenkinsopp says that a distinction has to be drawn between patients treated with statins on the NHS according to the National Service Framework for CHD and those people who buy a statin over the counter. Those who buy statins will be at moderate risk, falling short of the NSF guidelines, he explains. “For these people, their cholesterol level is irrelevant. It is their risk factors that are important so this is why a cholesterol test is not needed,” he says. Dr Blenkinsopp expands on this in a letter to the editor (p13).

However, there is another dilemma raised by Professor Sir Charles George, medical director of the British Heart Foundation. “On one hand, it is clear that benefits in terms of cholesterol lowering occur whatever the starting level. But if you really want to determine CHD risk over the next five or 10 years then you need to know someone's cholesterol

level," he says. "My concern is that unless people are given a proper risk assessment then someone may be deprived the full efficacy of simvastatin [ie, higher doses] because their risk is underestimated." One way in which this could be prevented would be for a full screening of all risk factors, including testing both blood pressure and cholesterol levels, as well as considering factors such as age, sex, weight, ethnicity and smoking status.

The consultation document states: "The pharmacy protocol allows the pharmacist the opportunity to offer a range of supportive information and/or testing services, including blood pressure and cholesterol management." Of course, this is dependent on the pharmacist or more likely the pharmacy premises being able to provide these services. The Society will query this in its response to the consultation. "The consultation document states that people will be offered the opportunity to have a test but it is unclear how that will be done," comments Mr Pruce.

There is also the question of long-term monitoring of people taking a statin. At the moment, this is carried out by GPs but who this responsibility will fall to for people who buy a statin is unclear. The NPA says that responsibility for long-term monitoring of cholesterol levels should lie with the patient, with encouragement from the pharmacist.

Some of these questions could be ironed out by a pilot study that Johnson & Johnson MSD began in December in 10 pharmacies to test the feasibility of the pharmacy protocol. The pharmacist uses the questionnaire that will form part of the protocol for sale of simvastatin (along with some guidance for pharmacists) and then makes a recommendation as to whether or not simvastatin is suitable, or if the patient should be referred to the GP. Feedback from the customers is collected. The pilot runs until the end of January and its findings, it is hoped from 100 people, will be submitted to the MHRA.

In addition to the pilot, Johnson & Johnson MSD is developing a training package for pharmacists and assistants as part of the proposed switch. It will include information about CHD, simvastatin (its mode of action, contraindications, precautions for use and possible adverse effects) and review other interventions to reduce CHD risk. The Society is also developing guidance on the sale of OTC statins.

### Questions over efficacy

There are other clinical concerns, as well. A question mark exists over the efficacy of the 10mg dose of simvastatin, for example. There have been some suggestions that it is too low and that evidence to support the 10mg dose in low-risk patients appears to be lacking.

According to the Royal College of General Practitioners: "There is very little research evidence of statins being beneficial for those at low risk." This is backed up by Neal Maskrey, medical director of the National Prescribing Centre, who comments: "The problem is that the big trials have almost all

used larger doses, in other words the evidence rests with the 20 and 40mg doses."

The consultation document states that treatment with simvastatin 10mg will produce a 27 per cent reduction in low density lipoprotein-cholesterol. However, it concedes that there are no trial data for this population: "While no specific clinical trials have been conducted with simvastatin 10mg in this particular patient population, it is reasonable to assume that these benefits would also apply to this group of people given that the effect of lowering LDL-cholesterol by simvastatin is consistent between populations, and the relation of LDL-cholesterol to risk is linear."

The NPA is concerned that the proposed indications for use are unclear. Ms McCreedy says that the definition used of moderate risk does not tally with the definition in the Joint British Societies Coronary Risk Prediction Chart. This might lead to confusion over how appropriate a 10mg dose is for some patients.

Perhaps the dose comes down to a question of balance. Sir Charles says that although higher doses are more effective, choice is about safety and efficacy. "The 10mg dose is unlikely to have significant adverse effects," he points out.

### Safety concerns

One of the biggest concerns of the anti-OTC lobby is over the safety of statins. Overall, the safety profile of simvastatin is excellent. However, there are some potential adverse effects of concern. In particular, they are muscular effects (myopathy and rhabdomyolysis) and liver function abnormalities.

The consultation document states that the contraindications and cautions listed in the pharmacy protocol and product labelling address the concerns about myopathy. It says that modest elevations of liver enzymes are common with statin use and do not reflect hepatotoxicity. It adds that hepatic injury is extremely rare so routine testing of liver function tests before and during treatment with OTC simvastatin is not required.

If liver function tests are not necessary for patients taking statins, why do GPs carry them out? Sir Charles suggests that the reasons for GPs continuing to monitor liver enzymes are historical. Although conducting liver function tests had been reasonable when statins were first launched, the usefulness of monitoring is no longer clear, he says.

Ms McCreedy comments: "The NPA is confident that pharmacists will be able to handle non prescription supply of simvastatin safely. They have been supplying it on prescription for many years and are well aware of the drug's side effects."

Perhaps the most difficult question is the fact that it is not possible to predict accurately who will fall into the small minority of people who develop these adverse events. This is of concern for two particular pharmacists.

Pamela Brompton, a community pharmacist in Yorkshire whose father suffered a severe adverse reaction to a statin, is concerned about their safety. "If statins are to be made

available over the counter then patient registration is needed at the pharmacy not only to prevent people shopping around for statins but also to keep track of potential or developing problems," she says.

A year ago, an academic pharmacist wrote to *The Journal* about his disappointment with suggestions that statins might become OTC medicines. His opposition to the proposed POM to P switch was prompted by the adverse effects he had experienced as a result of taking statins (*PJ*, 16 November 2002, p711). This week, he told *The Journal* that he remains opposed to the switch. "I am not sure that the general public knows enough about statins and their side effects to make reasoned, intelligent decisions about buying them," he comments. "I am more than happy for GPs to prescribe statins on the basis of a patient's risk category but not for people to be able to turn up and buy them."

According to researchers writing in this week's *Journal*, many adverse effects associated with statin use can be explained by coenzyme Q10 depletion caused by statins (p23).

### Costs and inequalities

Some people believe that making statins available over the counter is no more than the Government avoiding paying for treatment for this group. Simvastatin accounted for 3.75 per cent of the drugs budget in England in 2002. Shifting some of this cost to patients' pockets will certainly save the Government money in terms of the drugs budget. Whether or not it will lead to other costs, through encouraging more people to go to the GP for a cholesterol test or even to request a statin, is not known.

However, as the Royal College of General Practitioners points out, having an OTC statin "raises the issue as to whether we, as a society, want health care costs to be financed by society as a whole or if we want some health care costs moved to patients as individuals".

And this in turn leads to health inequalities. If it is decided that some health care costs for treating chronic conditions should be moved to individuals then some people with low incomes will be denied treatment. Is this acceptable? Another issue is advertising and a debate over advertisements for simvastatin, as an OTC medicine, is likely.

Then there are ethical issues. Will easier access to statins mean that people use them instead of making lifestyle changes? After all, given a choice between losing weight, giving up smoking and taking exercise or popping a pill, many people are likely to be tempted by the easiest option.

Even the POM to P consultation document admits: "It is recognised that there are uncertainties about the effect of taking a statin on compliance with behavioural risk-modifications (such as healthy eating, exercise and smoking cessation)." But if the choice was between people doing nothing at all or taking a statin, then how detrimental is it for people to take a statin?

If the switch takes place, simvastatin will be available over the counter in the spring.