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Dear Ms Lawrence

ARM 18 – Request to Reclassify a Product from POM to P

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation document. The Society welcomes the proposal to reclassify simvastatin from 'prescription-only' to 'pharmacy' category for the indications and dosage stated. Pharmacists have the professional experience and training to take customers through a self-selection process to ensure that simvastatin is appropriate for the individual concerned.

We believe that there is a clear public health benefit to be gained from making simvastatin widely available through pharmacies. The reduction in cardiac risk that simvastatin can bring is significant. It would also provide a perfect opportunity to discuss other risk factors such as smoking, obesity, diet, etc. with a customer. It would clearly be in the public interest for simvastatin to be available for self-treatment.

Simvastatin is a safe medicine, although there are some rare side effects that customers purchasing it should be made aware of. For this reason, we would expect that the initial sale of simvastatin would be performed by a pharmacist. Community Pharmacies often have quiet areas set aside for confidential consultations and we would expect that pharmacists would wish to use these areas for discussing simvastatin with a customer. Subsequent sales may be delegated to other pharmacy staff provided that they have received sufficient training to enquire about potential side effects, etc. We would further expect that the on-going monitoring of the customer would be performed by the pharmacist.

We understand that the manufacturer has developed a protocol for the sale of simvastatin to ensure that simvastatin is sold appropriately and that those at higher risk are referred to their GP. We would like to be reassured of the accuracy and specificity of this protocol. We would suggest that independent trials of the protocol are conducted in order to provide this reassurance.

We note that there is a reference in the application to the consumer being offered the opportunity to test their cholesterol levels and to receive follow up advice from their pharmacist. Although a number of community pharmacies already offer cholesterol testing in the pharmacy, it is not available in all community pharmacies. It is unclear how cholesterol testing is to be made available through these community pharmacies in order to fulfil this statement in ARM 18.

Pharmacists will need some further guidance in order to sell simvastatin confidently, safely and effectively. We understand that the manufacturer is aiming to provide training and support to pharmacists and their staff. We feel that we should not rely solely on manufacturers training when the first of a major class of medicines becomes available for pharmacy sale. We would therefore suggest that the centres for pharmacy post graduate education in the four home countries be commissioned to produce original training for pharmacists and their staff. The Society will also produce its own guidance on the sale of statins over the counter to reassure the public that there is quality in the system.

We have some concerns that there could be confusion between the level of risk that the NHS accepts for statins to be prescribed and that for self care. There is the potential that patients may demand follow on treatment from the NHS after initially purchasing simvastatin over the counter. We note that NICE has been commissioned to conduct an appraisal on statins for prevention of coronary events and that this will determine the level of risk at which the NHS should start statins. However, currently this appraisal is not due to be published until January 2005. We would urge NICE to conduct this appraisal as soon as possible in order to provide the NHS with clear guidance on when the NHS should prescribe statins and when the individual would have to purchase statins over the counter.

Yours sincerely

David Pruce
Director of Practice & Quality Improvement