



Response to [ARM 18](#) (Request to reclassify Zocor Heart-Pro from POM to P) from the NPA.

### **Response of the National Pharmaceutical Association to ARM 18**

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 18 on proposals to extend the availability of Zocor Heart-Pro from POM to P.

The NPA represents the interests of community pharmacies. We have, in voluntary membership, around 11,000 community pharmacies, which comprises the majority of the 12,000 pharmacies in the UK, with the exception of the Boots chain. The NPA provides a representative voice for its members as well as a range of services to help them with both commercial and professional aspects of running their businesses.

The NPA supports the availability of simvastatin as a Pharmacy medicine. We welcome this opportunity for pharmacists to play a wider role in helping patients to look after their health and to take on the responsibility of advising customers whether the product is right for them. Therefore we welcome the addition of this new category of product to the pharmacist's armamentarium.

Whilst welcoming simvastatin as a Pharmacy medicine, there are a number of areas where we believe further clarification is required.

#### **Indications**

The application states that the product will be targeted at patients at 'moderate' risk of CHD and goes on to state that this will be those at 10-15% risk of having a coronary event within the next 10 years. However, this does not fit with the Joint British Societies Coronary Risk Prediction definition of 'moderate' risk and we believe that the use of this terminology may be confusing for pharmacists and the public alike. The Joint British Societies define those at 10-15% risk of having a coronary event within the next five years as 'low' risk. However, the target groups described in the application are patients who are likely to be at higher risk and would therefore be referred to the GP – a 10mg dose would not be appropriate to treat them. Therefore it is unclear who the target group for OTC treatment will be. It is also unclear how the patient's risk factors will be assessed without information on blood pressure and other risk factors. We believe that pharmacists will be able to manage the safe supply of simvastatin over the counter but they must have the necessary information to enable them to identify which patients may be supplied appropriately.

## **Dose**

We believe that pharmacists will be able to supply statins to patients safely and effectively. However there must be clear guidelines to enable the pharmacist to make sure that the product is supplied only to patients for whom it is appropriate. This may be explained adequately in the accompanying training material, however as this is not part of the licence application we are unable to comment. It is essential that pharmacists have the necessary information in order to be able to identify patients at higher risk, for whom a 10mg dose will be inadequate, so that these patients may be referred to their general practitioner.

## **Cholesterol measurement**

The application makes reference to the fact that cholesterol levels will be measured. However it is not explained which type of test will be used and at what stages it will be carried out. Also it is unclear who will perform the test and who will follow up the results with the patient. Pharmacists would be well placed to carry out the test and counsel the patient. The type of test would need to be accurate and measure fasting cholesterol levels. The Heart Protection Study has shown that the benefits of statins are irrespective of initial cholesterol measurement.

It may not be useful to measure cholesterol concentration unless other risk factors are also being measured such as blood pressure. Cholesterol measurements alone are only useful if combined with other risk factors to produce a risk assessment for a patient. This would be part of a complete service that could be provided by pharmacists for the patient.

## **Heart Health Programme**

The application makes reference to the Zocor Heart Pro Heart Health Programme. However there is no further explanation of what the programme is or who will manage it. It is stated that the patient will be advised on diet and lifestyle changes but not explained who will monitor these. The pharmacist is well placed to advise patients on appropriate lifestyle and dietary changes.

## **Training material**

In our view, training material for statins needs to include reference to the assessment of cardiac risk factors and the use of appropriate risk factor tables. There must be a protocol for the supply of simvastatin so that pharmacists have clear guidelines on which patients may be supplied the OTC product safely and in accordance with the Product Licence and which patients must be referred to the practitioner. We believe it would be of tremendous benefit if proposed training material was made available as part of the consultation process.

## **Safety**

Pharmacists have been dispensing simvastatin and other statins to patients for many years and are familiar with the potential side effects and interactions. In particular, pharmacists are alert to the possibility of muscle and liver problems as they already encounter patients with adverse effects from the prescription product and already refer such patients to the prescriber.

## **Equity of access**

We also have concerns regarding equity of access. This is likely to be a relatively expensive product and this type of medication should be available to all patients at risk regardless of their income.

In summary the NPA welcomes extensions to the pharmacist's armamentarium by expansion of the 'Pharmacy' only class with the proposed pharmacy availability of Zocor Heart-Pro. However we have identified issues which need consideration to ensure the public receives the maximum benefit from this POM to P reclassification.