EU RMP Part VI	
Drug Substance	Rosuvastatin calcium
Version Number of EU RMP when last updated	4.0
Data lock point for this module	15 April 2018

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR ROSUVASTATIN

This is a summary of the RMP for rosuvastatin. The RMP details important risks of rosuvastatin, how these risks can be minimised, and how more information will be obtained about rosuvastatin's risks.

Rosuvastatin's Prescribing Information (PI) and package leaflet give essential information to healthcare professionals and patients on how rosuvastatin should be used.

Important new concerns or changes to the current ones will be included in updates of rosuvastatin's RMP.

VI: 1 THE MEDICINE AND WHAT IT IS USED FOR

CRESTOR is authorised for treating hypercholesterolemia and prevention of cardiovascular events. It contains rosuvastatin as the active substance and it is given by oral route of administration. Rosuvastatin is presented as film-coated tablets in strengths of 2.5 mg, 5 mg, 10 mg, 20 mg and 40 mg.

VI: 2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of rosuvastatin, together with measures to minimise such risks and the proposed studies for learning more about rosuvastatin's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PI and package leaflet addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks

Together, these measures constitute routine risk minimisation measures.

VI: 2.1 List of important risks and missing information

Important risks of rosuvastatin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient evidence of causal association with the use of rosuvastatin. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

VI: 2.2 Post-authorisation development plan

There are no studies required for rosuvastatin.