

## **2.3.R REGIONAL INFORMATION/ FOR EU**

### **- Process Validation Scheme for the Drug Product**

Process validation protocol for Bimatoprost-Timolol/Pharmathen 0.3mg/mL + 5mg/mL, Preservative Free, Eye drops solution, multidose container is enclosed in *Module 3, Section 3.2.R. "Regional Information/ For EU"*.

### **- Medical Device**

Not applicable

### **- Certificates of Suitability**

Current Certificate of Suitability Timolol maleate by FDC is enclosed in *Module 3, Section 3.2.R. "Regional Information/ For EU"*.

### **- Medicinal Products containing or using in the manufacturing process materials of animal and/or human origin**

The excipients used in the manufacture of Bimatoprost-Timolol/Pharmathen 0.3mg/mL + 5mg/mL, Preservative Free, Eye drops solution, multidose container do not pose a TSE risk.

Information supporting this statement is provided in *Module 3, Section 3.2.R. "Regional Information/ For EU"*.