



**RWANDA FDA**  
Rwanda Food and Drugs Authority

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## **REPORT OF INVESTIGATION CONDUCTED DUE TO PATIENT COMPLAINT ON PURCHASED BATCH OF SUSPECTED POOR QUALITY OF ROSUVASTATIN**

### **1.0 INTRODUCTION**

Based on the report received from patient with initials UT who was prescribed Rosuvastatin 20mg On 30th January 2021 by Physician with posology of one tablet per day (OD) total dose of 30 tablets per month after the patient UT bought Rosuvastatin 20mg from Alliance Retail Pharmacy where the medicines were dispensed in the hand of UT by Mr. HABAYOMANA Prosper responsible Pharmacist at Alliance Pharmacy/Nyarugenge, the Brand of Rosuvastatin 20 mg tablet dispensed was CRESTOR with Batch No: PY489

After patient arrived at home, the client noticed that the edge of blister of Rosuvastatin 20 mg tablets containing the manufacture and expiry date was cut and this cause UT to suspect the quality of purchased medicine and reported the complaint to Rwanda FDA on 01/02/2021

### **2.0 CONDUCTED INVESTIGATION**

On 1st February 2020, Rwanda FDA staff visited the Alliance Pharmacy together with the client, the Responsible Pharmacist was requested to avail the record including Invoice for that medicines and dispensing records.

The responsible Pharmacist was asked why the information on manufacture and expire date was cut

### **3.0 FINDINGS OF INVESTIGATION**

By analyzing information provided by Responsible Pharmacist of Alliance Pharmacy, Rwanda FDA staff found that:

- ☐ The dispensed medicines was Rosuvastatin 20 mg tablets with Batch number of PY489 and expiry date 28 February 2021 which was purchased from KVCG wholesale pharmacy on 17/01/2020 and 01/02/2020 by Alliance Pharmacy
- ☐ The last dose intake of the dispensed Rosuvastatin will be coincide with the last day of the medicines' shelf-life
- ☐ The dispensing record confirmed that the all medicines with Batch No: PY489 were dispensed (no other stock of concerned batch of Rosuvastatin remain at Alliance Pharmacy)

#### **4.0 RECOMMENDATION TO RWANDA FDA**

- ☐ Rwanda FDA should plan to investigate on the same batch of Rosuvastatin 20 mg tablets available on Rwandan market to make sure that the medicines is not being dispensed for the period exceeding its shelf-life

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