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REPORT OF THE SAFETY INSPECTION ON SUSPECTED POOR QUALITY

MEDICINES

INTRODUCTION

On Friday 06th November 2020 Rwanda FDA through the Division of Pharmacovigilance and Food safety Monitoring we have conducted safety inspection due to received reports on suspected poor quality of Hyoscine butyl bromide and Phytomenadione injectables reported by RMS due to presence of particulate matters in both Batches of Hyoscine Butyl bromide and Phytomenadione.

The inspection was also conducted in different wholesale Pharmacies to investigate the reported suspected poor quality which are batches of the following medicines: Kofflyn syrup and Meftal cream with suspicious of being counterfeited

Complaint of suspected poor quality medicines

This complaint was received via PV reporting form from RMS LTD who purchased that product at SIAAN INTERNATIONAL where during reception of these medicines they identified the complaints of particulate matters within Ampoule and they refuse to receive these medicines and immediately report to Rwanda FDA, unfortunately the reported batch of Hyoscine butyl bromide (**BN:3H20001**) we did not find where the rejected quantities were located and we requested RMS Ltd to continue finding where these products are located.

The available batch of Hyoscine butyl bromide rejected also by RMS Ltd was **CH-1981** the sample of this batch was also conducted to lab to test their quality so that the decision should be taken accordingly

For Phytomenadione inj it has the batch number of **SA20C008E** the sample for this batch was taken and conducted to the lab for testing its quality.

All the rejected medicines were received by PARAAS on behalf of SIAAN we found that for phytomenadione the total quantity was 800 boxes and for Hyoscine butyl bromide the total quantity was 724 boxes

Complaint of suspected counterfeit of Meftal forte Cream

This complaint was received through a well detailed letter of Manufacturer addressed to Rwanda FDA stating that there are Meftal forte cream available at the market of Rwanda different to the one designed by Manufacturer to Rwanda Market.

As on Monday 26th October 2020 we conducted investigation for the case of Meftal cream where we met with the Pharmacist of PHILLIPS so as to have a complete information on their complaints and telling that the suspected Meftal cream as counterfeit was distributed by ESCORT PHARMACY, on 06th November 2020 we conducted the investigation in different pharmacies retail and wholesale pharmacies to find out these suspected meftal cream, retail pharmacies were inspected where we did not find the suspected batch of meftal cream.

The inspection was also extended to wholesale pharmacies but also at that level we did not find the suspected batch of meftal cream.

The inspected pharmacies were: a Lincoln Pharmacies, SANO Pharmacies, JYAMBERE Pharmaceuticals, ESCORT Pharmacy, GYNOVA Pharmacy, SURYA, SUN, AIVEN, BIOGEN

For the complaint of Kofflyn syrup we have noticed that for all brands of Kofflyn Raspberry the manufacturer wrote wrongly on the recommended dosage at outer package where they mentioned that child of 0-1 year can use 2.5ml and 0-5ml can use 5ml as this information can confuse the patient at all visited pharmacies who were having this brand the information on the outer package was wrongly written.

Recommendation

- ☐ As for the case of reported suspected counterfeit of Meftal cream reported by Phillips we did not find the suspected products in all inspected pharmacies the other inspection targeting many retail pharmacies should be prepared for deep investigation.

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