RWANDA FDA
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REPORT OF THE REPORTED CASE OF SUSPECTED POOR QUALITY MEDICINES

CASE REPORTED BY RMS LIMITED

RMS reported to Rwanda FDA the case of Hyoscine Butyl bromide with BN 3H20001 and the case of Phytomenadione injectable with BN SA20C008E both of the products were reported due to presence of particulate matters in vials

INVESTIGATION DONE

By our investigation conducted at 26th October 2020 we found that the products were rejected by MPPD due to this defect and the defected products were taken by PARAS on behalf of SIAAN who supplied the medicines at RMS Ltd, unfortunately after our deep investigation we have found that the Batch of Hyoscine butyl bromide that was in the hand of PARAS was different to the batch reported by RMS.the batch which was in the hand of PARAS during inspection was BN:CH-1981. For Phytomenadione the product on hand of PARAS was compatible to the reported batch which is SA20C008E

ACTION TAKEN DURING INVESTIGATION

- ✔ We continued our investigation by asking RMS why the reported batch is not compatible to the rejected batch unfortunately they fail to give us explanation as they were not having the record mentioning where PARAS receive this batch of Hyoscine butyl bromide BN 3H20001
- ✔ We took sample of reported batch of Hyoscine butyl bromide(3H20001) and the one found in the hand of PARAS(CH-1981)for quality control analysis lab
- ✔ We took also the sample of reported batch of Phytomenadione injectable (BN SA20C008E)for quality control analysis lab

FINDINGS AFTER LAB RESULT

- ✔ After lab result we found that Hyoscine butyl bromide with BN 3H20001 and

Phytomenadione injectable with BN SA20C008E do not comply with the performed specification they all contain particulate matters.

- ✔ For batch of Hyoscine butyl bromide BN CH-1981 found in the hand of Paras which was different to the reported batch lab result reveal that it was comply with specification of performed test

PROPOSED ACTION TO BE TAKEN

- ✔ To give PARAS feedback letter requesting him the disposal of unfit batch of phytomenadione injectable
- ✔ As the batch of Hyoscine butyl bromide BN CH-1981 that was in the hand of PARAS as the lab result show that it complies with the performed test our Division have to discuss on the feedback to give to PARAS

NB.PARAS is the one who took the rejected batches of Hyoscine butyl bromide inj and Phytomenadione injectable by RMS Ltd on behalf of SIAAN who supplied these batch to RMS Ltd

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