RWANDA FDA
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REPORT OF POST MARKETING SURVEILLANCE INSPECTION ON SUSPECTED POOR QUALITY SENSOCAIN SPINAL 0.5% INJECTION THAT WAS REPORTED BY BYUMBA DISTRICT HOSPITAL

1.	**Name, Post and Service of the person who went on in country mission**	• **Frederic Muhoza**, Clinical Trial Specialist, Rwanda FDA • **Axelle Mutezinkwano**, PV-PMS Specialist, Rwanda FDA • **Dr Egide Buregeya**, Consultant Anaesthetist, Rwanda Military Hospital
2.	**Institution &Authority Who Proposed the Mission**	Rwanda Food and Drugs Authority, Rwanda FDA Acting Director General
3.	**Duration of the Mission**	**19-20 January 2021**
4.	**Mission Objectives**	The main objective mission was to: • To assess the current practices by Anesthesiologist while using SENSOCAIN (Bupivacaine hyperbare) 0.5% during daily surgical operations at Byumba Hospital to avoid therapeutic failure • To provide necessary coaching and mentorship to anaesthetists of Byumba Hospital on the use of hyperbaric Bupivacaine for patient safety • To take an informed decision in relation of 800 quarantined hyperbaric Bupivacaine 0.5% due to suspicion of poor quality after cases of therapeutic failure.
5.	**Place of Mission**	**Byumba District Hospital** Located in GICUMBI District, Northern Province
6.	**Targeted People To Meet**	Director General of Byumba Hospital Team of non-physician anesthetists of Byumba Hospital Pharmacist of Byumba Hospital Director of RMS Ltd, Gicumbi Branch

7.	**Expected Outcome Of The Mission**	• To improve clinical practices of non-physician anesthetists of Byumba Hospital when using hyperbaric Bupivacaine 0.5% injection during the surgical operations • To remove 800 Vials of SENSOCAIN (Heavy Bupivacaine) 0.5% injection that were in quarantine based on findings
8.	**Description of Suspected Product**	The suspected product is SENSOCAIN (Heavy Bupivacaine) 0.5% vial for injection reported to have therapeutic failure after administration of normal dose: • Batch No**: 105G9** • Manufacturing date: **07/2019** • Expiry Date: **07/2021** • Storage conditions: **Do not store above 30˚C** • Route of Administration: **intrathecal single use only** • Manufacturer: **BROOKES PHARMA (PRIVATE) LIMITED, 58/15 Korangi Industrial, Area Karachi, Pakistan** • Importer: **SUN ENTERPRISES LTD/ RWANDA** • Quantity imported**: 10.000vials** • Quantity issued to RMS Gicumbi**: 1,200 vials** • **Quarantined quantity: 800Vials** • **Quantity used by Hospitals: 8800 Vial** • Reference standards used**: USP (United states pharmacopoeia)**
9.	**Process Of Pv Pms Inspection**	After warm welcome by Director General of Byumba Hospital Dr. Uwizeye Marcel, we introduced ourselves and presented the objectives of our visit. Later, DG invited the hospital pharmacist and Anesthetists for a short discussion and way forward leading to the informed decision. They stated the difficulty they had with SENSOCAIN (Heavy Bupivacaine) 0.5% vial for injection reported to have therapeutic failure after administration of normal dose. This experience was also shared by the anesthesiologist who used the same drug. The issue was raised by Byumba Hospital while other hospitals in different corner of Rwanda have already consumed all quantities of this batch. The consultant Anaesthesiologist confirmed that this batch was used during the Army Week operations where they used to perform a gentle shaking for the drug uniformity. This technique was confirmed by Hospital Anaesthetist who informed that it was borrowed from Kacyiru Hospital Anaesthtist. They are now using this technique in the daily practices on other bupivacaine 0.5% vials which were failing after administration of normal Dose without gentle shaking. This technique was not known before quarantining incriminated because it is not mentioned in product notice. The gentle shaking technique for the drug uniformity was just information shared between the health professionals (Anesthetists) who used it and

		actually use this product in daily surgical operations. This was also confirmed by the Consultant anaesthesiologists from CHUK. After this information, we concluded that since we have information that the batch was tested in third party quality control laboratory and found to meet quality specifications, we should carry out a test using the quarantined batch in order to take an informed decision. After the assisted operation using the incriminated batch of Bupivacaine 0.5% injection with gentle shaking for drug uniformity, it was successfully done with an onset of about 15-17 minutes (without adjuvant). Therefore, the team concluded that the SENSOCAIN (Bupivacaine 0.5%) injection can be used after gentle shaking for drug uniformity to be used after shaking.
10.	**Findings From the PV PMS Inspection**	• It was found that the SENSOCAIN (Bupivacaine 0.5%) injection produce desired therapeutic effect after gentle shaking for drug uniformity as new technique adopted by health professionals (Anesthetists) of different hospital • The technique of gentle shaking for drug uniformity is not mentioned neither in the product leaflet nor on the product label • The 800 quarantined bupivacaine 0.5% vial that will expire in July 2021 may be used after adoption of shaking technique.
11.	**Acceptance/Rejection Criteria of the Product**	The investigations carried on SENSOCAIN (Heavy Bupivacaine) 0.5% vial for injection Batch No**: 105G9 include** • **Laboratory quality control results which revealed that the product meets quality specification** • **Deep investigation, based on distribution list provided by the importer, revealed all quantities distributed in other health facilities were successfully utilized** • **Further investigation carried out in Byumba district Hospital revealed that the product produce desired therapeutic effect after a gentle shaking for drug uniformity.**
12.	**Conclusion**	Based on findings of different investigations as stated above the SENSOCAIN (Heavy Bupivacaine) 0.5% vial for injection Batch No**: 105G9 fit for its purpose after gentle shaking for drug uniformity.**
13.	**Action Taken**	All remaining batches of SENSOCAIN (Heavy Bupivacaine) 0.5% vial for injection **Batch No: 105G9 in Byumba Hospital and RMS Ltd Gicumbi Branch may be used before the expiration date by adopting the technique of gentle shaking for drug uniformity**

14.	**Recommendations**	For patient safety and public health protection: • All importers distributors, consumers and health professionals should always report to the regulatory authority any suspected poor-quality products issues, ADR or any other problem related to the use of a medical products • Rwanda FDA should request the manufacturer to explore the effect of gentle shaking technique for drug uniformity before use and consider to put in the label and/or in relevant section of the product leaflet • Rwanda FDA should consider to issue safety information on Bupivacaine injection • Director of RMS Ltd Gicumbi Branch should consider to distribute this product before its expiration date

<u>Note</u>: All activities related to this investigation were carried out by respecting all measures to prevent the spread of COVID-19 pandemic.

Done at Kigali, 21/01/2021

Prepared by:		
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