	Reference Number CASE_17

Rapid Alert Notification of a Quality Defect

1. To: The Regulatory Authority	
2. Product Recall Class & Type of Defect: Class: I Type: A	3. Falsification / Fraud (specify) Not Applicable
4. Product: **Coryx Throat Spray**	5. Marketing Authorisation Number: W/16.3/58 For use in humans
6. Brand/Trade Name: Coryx Throat Spray	7. INN or Generic Name: Benzocaine and chlorhexidine gluconate solution 20 %
8. Dosage Form: solution	9. Strength: (20 % w/v)
10. Batch number (and bulk, if different): See Appendix A	11. Expiry Date: See Appendix A
12. Pack size and Presentation: 100 ml	13. Date Manufactured: See Appendix A
14. Marketing Authorisation Holder: Cipla Medpro (Pty) Ltd, Parc du Cap Building 9 Mispel Street Bellville 7530, South Africa Contact Person: Nicole.Carter@Cipla.com Telephone: +27 21 943 4200/ +27 83 543 7579	
15. Manufacturer: 15.1 Cipla Medpro (Pty) Ltd, Parc du Cap Building 9 Mispel Street Bellville 7530, South Africa	16. Recalling Firm (if different from 15.1): Not Applicable Contact Person: Not Applicable Telephone: Not Applicable
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Not Applicable	
17. Recall Number Assigned (if available): Not Applicable	
18. Details of Defect/Reason for Recall: Quality defect: The company received two product complaints from two customers who purchased Coryx Throat Spray. *1st complaint:* The spray nozzle came off and got stuck in the patient's throat. The patient was not able to remove it and swallowed the cap. The patient further explained that his throat was damaged trying to remove the cap. *2nd complaint*: The spray nozzle of the bottle came off while the patient was using it and he involuntarily swallowed it.	
19. Information on distribution including exports (type of customer, e.g. hospitals): *For more information about exporting or batch destination, please Marketing Authorisation Holder and/ or local Regulatory Authority (SAHPRA).* portia.nkambule@sahpra.org.za / maphutheho.selikane@sahpra.org.za	

20. Action taken by Issuing Authority: Conduct a recall (Class I, Type A)
https://www.sahpra.org.za/product-recalls/

21. Proposed Action: SAHPRA is monitoring the recall.

22. From (Issuing Authority):

South Africa Health Products Regulatory Authority (SAHPRA) Loftus Park, Building A, 402 Kirkness St, Arcadia, Pretoria, 0083, South Africa.

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Signed: Digitally Signed by: Deon Poovan, Senior Manager: Inspectorate and Regulatory Compliance, 70dd9ebc-b1cb-4422-af5c-ae27ede429f1, Powered By RealSign

Date: 15/09/2022 10:23:16 AM

Deon Poovan – Senior Manager: Inspectorate & Regulatory Compliance

Appendix A

Batch number, Date of Manufacturing and Date of expiry of impacted batches

Batch No.	Date of Manufacturing	Date of Expiry
ZB000156	11/2020	10/2022
ZB000157	11/2020	10/2022
ZB000158	11/2020	10/2022
ZB000159	11/2020	10/2022
ZB000160	11/2020	10/2022
ZB100105	03/2021	02/2023
ZB100107	03/2021	02/2023
ZB100172	04/2021	03/2023
ZB100173	04/2021	03/2023