	Reference Number CASE_20

Rapid Alert Notification of a Quality Defect

1. To: The Regulatory Authority	
2. Product Recall Class & Type of Defect: Class: I Type: C	3. Falsification / Fraud (specify) Not Applicable
4. Product: ROCEPHIN 1G	5. Marketing Authorisation Number: R/20.1.1/46 For use in humans
6. Brand/Trade Name: **ROCEPHIN 1G VIALS**	7. INN or Generic Name: Ceftriaxone
8. Dosage Form: Powder for Solution for Injection.	9. Strength: 1 G
10. Batch number (and bulk, if different): B0757B04	11. Expiry Date: 31/03/2024
12. Pack size and Presentation: 1 VIAL	13. Date Manufactured: 03/2021
14. Marketing Authorisation Holder: Roche products (Pty) Ltd, Building E, Hertford Office Park, 90 Bekker Road, Midrand, 1686, South Africa Contact Person: Larne Pearson larne.pearson@roche.com Telephone: + 27 11 504 4746/ +27 72 632 2142	
15. Manufacturer: 15.1 Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland	16. Recalling Firm (if different): 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: Pinholes were found on the 10ml Water for Injection that is co-packaged with the Rocephin 1g Vial. These pinholes are melting defects located at the top of the ampoule head and surrounded by concavity. Roche has decided to recall all units of this batch due to the potential leakage of the water for injection (WFI) diluent ampoules for Rocephin 1g Powder for Solution for Injection.	
19. Information on distribution including exports (type of customer, e.g. hospitals): *For more information about exporting or batch destination, please contact the 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 C) 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