	Reference Number: Case 63
Rapid Alert Notification of a Quality Defect	
1. To: The Regulatory Authority	
2. Product Recall Classification: **Class: II Type: A**	3. Falsification / Fraud (specify) Not Applicable
4. Product: **YAZ Plus**	5. Marketing Authorisation Number: **45/21.8.2/0534**
6. Brand/Trade Name: **YAZ Plus**	7. INN or Generic Name: **Drospirenone + Ethinylestradiol + Levomefolate calcium**
8. Dosage Form: **Tablets**	9. Strength: **24 tablets containing drospirenone 3,0 mg, ethinylestradiol (as betadex clathrate) 0,02 mg plus levomefolate calcium 0,451 mg** **4 tablets containing levomefolate calcium 0,451 mg**
10. Batch number (and bulk, if different): **WEW96J**	11. Expiry Date: **03/2026**
12. Pack size and Presentation: **28's Tablets**	13. Date Manufactured: **7 – 9 August 2023** (packaging date)
14. Marketing Authorisation Holder (MAH): **Bayer (Pty) Ltd, 27 Wrench Road, Isando** Contact Person: **Mr. Eric Chauke** Telephone: **011 921 5549**	
15.1 Manufacturer: **Bayer Weimar GmbH und Co. KG,** **Döbereinerstr.20, 99427 Weimar, Germany**	16. Recalling Firm (if different from 15.1): **Bayer (Pty) Ltd, 27 Wrench Road,** **Isando** Contact Person: **Mr. Eric Chauke** Telephone: **011 921 5549**
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. Summary of Quality Defect and Reason for Recall:

This recall is initiated due to a limited number of packs found in retail Pharmacy, with mix-up of the sequence of hormone-containing and hormone-free tablets, wherein some packs had

- 24 light orange hormone-free, and
- 4 pink film-coated hormone tablets

Instead of

- 24 pink film-coated hormone tablets and
- 4 light orange hormone-free tablets.

19. Distribution including export to other markets:

According to the MAH, distribution of the affected batch was as follows:

***Botswana** = 115 units, **Namibia** = 1 472 units, **Mauritius** = 1 500 units, **Zimbabwe** = 200 units and **Lesotho** = 100 units*

For more information about exporting or batch destination, please contact Marketing Authorisation Holder and/ or local Regulatory Authority (SAHPRA) tsakane.mashaba@sahpra.org.za and mokgadi.fafudi@sahpra.org.za then copy *deon.poovan@sahpra.org.za*

20. Action taken by Issuing Authority: Conduct a recall (**Class II, Type A**)
The information is published on the SAHPRA recall webpage 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.

Deon Poovan – Acting Chief Regulatory Officer

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Mokgadi Fafudi – Manager: Regulatory Compliance

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Signed: Deon Poovan Date: 21 November 2024

Deon Poovan – Acting Chief Regulatory Officer