



**RWANDA FDA**

Rwanda Food and Drugs Authority

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Kigali,

Ref N°

18/12/2019

1756

/Rwanda FDA/2019

**District Pharmacy (All)**  
**District Hospital (All)**  
**Referral Hospital (All)**  
**Pharmaceutical Wholesalers (All)**  
**Importers (All)**  
**Retail Pharmacies (All)**  
**Private clinics/ (All)**

**Title: Recall for Helicobacter Pylori Antibody test strip batch N° HPB11303B**

The role of Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the Law N° 003/2018 of 09/02/2018 to health professionals and to other concerned organs. The Authority takes into considerations every serious information from partners to ensure availability of safe and quality products.

Referring to the spontaneous reports from different health facilities, district pharmacies and further investigation conducted by Rwanda FDA using Gold standard test, the product was found to have low sensitivity where the mentioned tests give many false positive results. Therefore, we regret to notify that the following batch was found with that quality issue.

| Name                                    | Batch N°  | Manufacture date | Expiry date | Importer | Manufacturer                          |
|---|-----------|------------------|-------------|----------|---------------------------------------|
| Helicobacter Pylori Antibody test strip | HPB11303B | 14/03/2019       | 03-2021     | DUPHAR   | QINGDAO HIGHTOP BIOTECH CO.,LTD/CHINA |

**Action to be taken**

Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesale pharmacies, District Pharmacies, retail Pharmacies, Public and Private Health Facilities in possession of the incriminated batch to stop distribution, using these tests and return them to their suppliers

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Rwanda FDA instructs all importers to provide a report on the quantities imported, distributed, returned and stock on hand within 7 calendar days.

Sincerely,



**Dr. Charles KARANGWA**  
**Ag. Director General**



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