

Ref: CCC/CP/CA/07/2024

4 July 2024

### WARNING NOTICE TO THE GENERAL PUBLIC

#### **RECALL OF BATCH NO. A4042 OF EFFERALGAN VITAMINE C 500mg/200mg (commprimé effeverscent) MANUFACTURED BY UPSA/SAS, FRANCE.**

The COMESA Competition Commission (the Commission) has become aware of the recall notice by Rwanda Food and Drug Authority (Rwanda FDA), Ref. No. DD/PVCT/2986/FDA/2024 dated 30 June 2024, recalling Efferalgan Vitamine C 500mg/200mg (commprimé effeverscent), Batch No. A4042, manufactured by UPSA/SAS, France. The notice states that the product has been recalled due to colour changes from white to brown which compromises quality standards of the product.

The Rwanda FDA wrote to all stakeholders involved in the importation, distribution, prescription and consumer of the drug requesting:

- to stop distribution and dispensing of the recalled drug with immediate effect
- to report to the Rwanda FDA within 10 working days from the date of publication of this recall, the quantities imported/procured, quantities distributed, quantities returned and final stock at hand (returned +undistributed).
- anyone in possession of the recalled batch to stop using the medicine.

#### **Image of the recalled product:**



Preliminary investigations by the Commission have established that the recalled drug is also distributed in Burundi and the Democratic Republic of Congo. The Commission is therefore concerned that the recalled batch might have been imported in other COMESA Member States.

In this regard, pursuant to Article 30(1)(b) of the COMESA Competition Regulations, the Commission wishes to warn consumers in the Common Market of the risks associated with the recalled product as specified in the notice by Rwanda FDA.

The Commission also requests any person who establishes that the above recalled product, batch No. A4042, is being sold in other COMESA Member States to avoid its purchase or use, and report the matter to the Commission by contacting **Mr. Steven Kamukama, Director Consumer Welfare and Advocacy Division** on +265 (0) 111 772466 or by email on: [skamukama@comesacompetition.org](mailto:skamukama@comesacompetition.org)

Affected persons within the Common Market may also contact their national consumer institutions or any other body with the mandate on consumer protection in their countries.



**Meti Demissie Disasa**  
**Registrar**

**COMESA Competition Commission**  
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**Rwanda Food and Drugs Authority**  
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Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)  
website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

QMS N°: FDISM/PVSM/FMT/034  
Revision No: 0  
Effective Date: 31/03/2023

## GUHAGARIKA UMUTI

*Kigali ku wa 30 / 06 /2024*

Ref. No.: DD/PVCT/2986/FDA/2024

**Abafite ububiko bw'imiti n'amashami yayo (Bose)**  
**Abinjiza imiti mu Rwanda, farumasi ziranguza n'izidandaza (Bose)**  
**Amavuriro ya Leta n'ayigenga (Yose)**  
**Abaganga n'Abahanga mu by'imiti (Bose)**  
**Abakoresha imiti (Bose)**

**Impamvu: Guhagarika gukwirakwiza no gukoresha nimero A4042 y'umuti witwa EFFERALGAN VITAMINE C 500mg/200mg ("comprimé effervescent"), ukorwa n'uruganda rwitwa UPSA SAS rwo mu Bufaransa**

**Ubwoko bw'ihagarikwa : Ihagarikwa ritegetswe**  
**Icyiciro cy'ihagarikwa : icyiciro cya II**  
**Urwego rw'ihagarikwa : Kugeza ku bakoresha imiti**

Hashingiwe kuri raporo zitandukanye zakiriwe na Rwanda FDA zakemangaga ubuziranenge bw'umuti witwa EFFERALGAN VITAMINE C 500mg/200mg ("comprimé effervescent") ufite nimero A4042 wakozwe mu kwa 04/2022 uzarangira mu kwa 3/2025 n'uruganda rwitwa UPSA SAS rwo mu Bufaransa,

Rwanda FDA yakoze ubusesenguzi isanga nimero y'umuti wavuzwe haruguru, warahinduye ibara ; *aho kuba umweru, ibara ry' iyi nimero y'umuti ryahindutse ikigina*, binyuranye n'ibipimo by'ubuziranenge ugomba uba wujuje.

### **Ibigomba gukorwa :**

- Guhagarika gutanga no gukoresha nimero yavuzwe haruguru bakayisubiza aho bayiranguye.
- Gushyikiriza Rwanda FDA mu gihe cy'iminsi icumi y'akazi (10) uhereye ku itariki y'iri hagarikwa, raporo igizwe n'imibare y'ingano y'uwo muti baranguye, iyo bagurishije, iyagaruwe ndetse n'ingano yose bazaba bafite igomba kwangizwa (iyagaruwe + itaracurujwe).
- Umuntu waba agifite umuti wa EFFERALGAN VITAMINE C 500mg/200mg ("comprimé effervescent") ufite nimero A4042 guhagarika kuwukoresha.

**Icyitonderwa:** Ku bindi bisobanuro ndetse no gutanga amakuru ajyanye n'ubuziranenge bw'imiti bukemangwa cyangwa ingaruka ku miti mwahamagara kuri **0788771663**; mushobora no kutwoherereza email kuri [pv\\_sm@rwandafda.gov.rw](mailto:pv_sm@rwandafda.gov.rw)

**Prof. Emile BIENVENU**  
**Umuyobozi Mukuru**



Digitally signed by Rwanda  
FDA (Director General)  
Date: 2024.06.30 18:08:04  
+02'00'

**IFOTO IGARAGAZA UMUTI WAKUWE KU ISOKO**

