



All correspondence should be
addressed to the Director General

In reply, please quote

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 19th August 2026

To: Distributors, Wholesalers, Public and Private Hospital Pharmacies, Retailers,
Healthcare Professionals

MEDICAL PRODUCT ALERT:

URGENT MEDICAL DEVICE RECALL, CLASS I TYPE B: SMARTBAG, FLEXPACK ACID CONCENTRATES (SEVERAL BATCHES) MANUFACTURED BY FRESENIUS MEDICAL CARE (PTY) LIMITED, SOUTH AFRICA

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to ensure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

On this background, the Authority wishes to notify all distributors, wholesalers, public and private hospital pharmacies, retailers and healthcare professionals on the recall of the above-mentioned product following the testing of prior-produced Smartbags which revealed the sporadic presence of neodymium, a lanthanide metal. The manufacturer of the product has established that the metal leached from the magnetic drive in a defective pump that was used during the manufacturing process of the affected batches.

Product details:

S/N	Name of Product	Manufacturer	Batch Number	Mfg. Date	Expiry Date
1.	Smartbag, Flexpack Acid Concentrates	Fresenius Medical Care (Pty) Limited, South Africa	Several Batches (See Annexure)	Various	2027-04 to 2028-03

RISK OF NEODYMIUM CONTAMINATION

Neodymium is a lanthanide metal used in magnets. The legal limit for neodymium is not known, however, considering the worst-case scenario and high safety margins, potential bioaccumulation as well as toxicological effects cannot be excluded. Therefore, usage of the product should be avoided to minimise any potential risks.

Head Office

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Off Kenneth Kaunda International Airport Road.
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351
E-mail: pharmacy@zamra.co.zm

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356

E-mail: npvu@zamra.co.zm
Website: www.zamra.co.zm

HOW TO IDENTIFY THE AFFECTED PRODUCT BATCHES

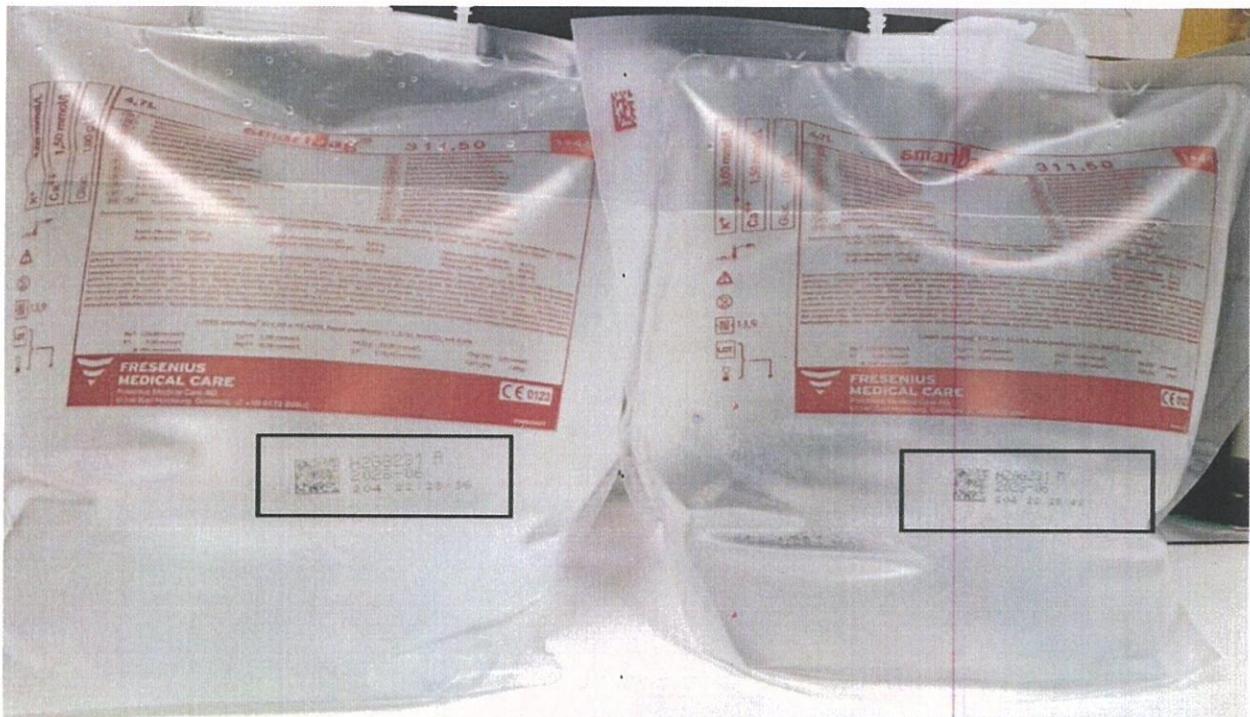
SMARTBAGS, FLEXPACK ACID CONCENTRATES, are flexible bags filled with liquid acid concentrate for extracorporeal bicarbonate hemodialysis or, when applicable, bicarbonate Fresenius Medical Care ONLINE hemodiafiltration. They are intended for the correction of blood electrolytes and acid-base balance in patients on dialysis following kidney problems.

During production of the product, two separate filling machines (Lines A and B) process one batch. **The defective pump was only located in line M.** The bags are labelled to indicate whether they were filled in line A or M (see picture 1 for an overview and picture 2 for more details).

Only bags from line M should no longer be used, while bags from line A are not affected!

One box of Smartbags can contain bags from both filling lines, A and M. This identification letter is not part of the batch number printed on the box. Thus, it is necessary to:

1. Identify if you have affected batches on stock – refer to Annex I.
2. Open the boxes (i) with the first letters G2G or H2G on the printed batch and (ii) with an expiry date from 2027-04 to 2028-03 (see picture 2).
3. Inspect the variable data printed on the bags (see picture 1).
4. Identify the affected Smartbags with M and separate (see picture 2).
5. Follow the instructions provided by our local contact person for the return or discarding of Smartbags with M.



Picture 1: Smartbags labeling – batch number overview. The bag print shows whether the Smartbags were filled on line A or M.



Picture 2: Smartbags labeling – details. “A” after the batch number represents Smartbags filled from line A that are OK to be used. **“M” after the batch number represents Smartbags from line M that must not be used!**

In view of the above, if you are in possession of the affected product batches (provided in Annexure 1), please do not use or sale the product. All pharmaceutical outlets and health facilities in possession of this product should place it in quarantine and return it to their supplier(s).

If you suffer any adverse drug reaction having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL

ANNEXURE ONE (01): LIST OF AFFECTED BATCHES

SKU	Batch	SLED
F0000065D	G2GG021	2027/06/30
F0000065D	G2GG033	2027/06/30
F0000065D	G2GK083	2027/09/30
F0000065D	G2GL071	2027/10/31
F0000065D	G2GL191	2027/10/31
F0000065D	G2GL193	2027/10/31
F0000065D	G2GL301	2027/10/31
F0000065D	G2GM013	2027/11/30
F0000065D	G2GM092	2027/11/30
F0000065D	G2GM094	2027/11/30
F0000065D	G2GM095	2027/11/30
F0000065D	G2GM101	2027/11/30
F0000065D	G2GM181	2027/11/30
F0000065D	G2GM182	2027/11/30
F0000065D	G2GM193	2027/11/30
F0000065D	G2GM194	2027/11/30
F0000065D	H2GA161	2027/12/31
F0000065D	H2GA162	2027/12/31
F0000065D	H2GA163	2027/12/31
F0000065D	H2GA164	2027/12/31
F0000065D	H2GA221	2027/12/31
F0000065D	H2GA222	2027/12/31
F0000065D	H2GA223	2027/12/31
F0000065D	H2GA224	2027/12/31
F0000065D	H2GA225	2027/12/31
F0000065D	H2GA231	2027/12/31
F0000065D	H2GA232	2027/12/31
F0000065D	H2GA233	2027/12/31
F0000065D	H2GA234	2027/12/31
F0000065D	H2GA251	2027/12/31
F0000065D	H2GA261	2027/12/31
F0000065D	H2GB054	2028/01/31
F0000065D	H2GB055	2028/01/31
F0000065D	H2GB061	2028/01/31
F0000065D	H2GB062	2028/01/31
F0000065D	H2GB063	2028/01/31
F0000065D	H2GB164	2028/01/31
F0000065D	H2GB165	2028/01/31
F0000065D	H2GB171	2028/01/31
F0000065D	H2GB172	2028/01/31
F0000065D	H2GB193	2028/01/31
F0000065D	H2GB194	2028/01/31
F0000065D	H2GB195	2028/01/31
F0000065D	H2GB201	2028/01/31
F0000065D	H2GB202	2028/01/31
F0000065D	H2GB203	2028/01/31
F0000065D	H2GB204	2028/01/31
F0000065D	G2GM012	2027/11/30
F0000065D	G2GM022	2027/11/30
F0000065D	G2GK079	2027/09/30
F0000065D	G2GL074	2027/10/31
F0000065D	G2GL091	2027/10/31
F0000065D	G2GM014	2027/11/30
F0000065D	G2GM091	2027/11/30
F0000065D	G2GL062	2027/10/31
F0000065D	G2GM095	2027/11/30

SKU	Batch	SLED
F0000065D	G2GL186	2027/10/31
F0000065D	G2GM022	2027/11/30
F0000065D	G2GM091	2027/11/30
F0000065D	G2GM093	2027/11/30
F0000065D	G2GL184	2027/10/31
F0000065D	G2GM014	2027/11/30
F0000065D	G2GL186	2027/10/31
F0000065D	G2GL191	2027/10/31
F0000065D	H2GA233	2027/12/31
F0000065D	G2GL185	2027/10/31
F0000065D	G2GL186	2027/10/31
F0000065D	G2GM021	2027/11/30
F0000065D	G2GM101	2027/11/30
F0000065D	G2GL186	2027/10/31
F0000065D	G2GL091	2027/10/31
F0000065D	G2GL186	2027/10/31
F0000065D	H2GA233	2027/12/31
F0000232D	G2GE161	2027/04/30
F0000232D	G2GE163	2027/04/30
F0000232D	G2GF162	2027/05/31
F0000232D	G2GH255	2027/07/31
F0000232D	G2GK131	2027/09/30
F0000232D	G2GL181	2027/10/31
F0000232D	G2GL182	2027/10/31
F0000232D	G2GL272	2027/10/31
F0000232D	G2GL273	2027/10/31
F0000232D	G2GL275	2027/10/31
F0000232D	G2GM111	2027/11/30
F0000232D	G2GM112	2027/11/30
F0000232D	G2GM113	2027/11/30
F0000232D	G2GM115	2027/11/30
F0000232D	G2GM121	2027/11/30
F0000232D	G2GM122	2027/11/30
F0000232D	G2GM123	2027/11/30
F0000232D	G2GM124	2027/11/30
F0000232D	G2GM185	2027/11/30
F0000232D	G2GM186	2027/11/30
F0000232D	G2GM191	2027/11/30
F0000232D	G2GM192	2027/11/30
F0000232D	H2GA072	2027/12/31
F0000232D	H2GA073	2027/12/31
F0000232D	H2GA074	2027/12/31
F0000232D	H2GA075	2027/12/31
F0000232D	H2GA081	2027/12/31
F0000232D	H2GA082	2027/12/31
F0000232D	H2GA083	2027/12/31
F0000232D	H2GA084	2027/12/31
F0000232D	H2GA085	2027/12/31
F0000232D	H2GA273	2027/12/31
F0000232D	H2GA274	2027/12/31
F0000232D	H2GA275	2027/12/31
F0000232D	H2GA281	2027/12/31
F0000232D	H2GA282	2027/12/31
F0000232D	H2GA283	2027/12/31
F0000232D	H2GA284	2027/12/31
F0000232D	H2GA285	2027/12/31

SKU	Batch	SLED
F0000232D	H2GA291	2027/12/31
F0000232D	H2GB262	2028/01/31
F0000232D	G2GM112	2027/11/30
F0000232D	G2GK064	2027/09/30
F0000232D	G2GK065	2027/09/30
F0000232D	G2GK071	2027/09/30
F0000232D	G2GK072	2027/09/30
F0000232D	G2GK073	2027/09/30
F0000232D	G2GK074	2027/09/30
F0000232D	G2GL181	2027/10/31
F0000232D	G2GM114	2027/11/30
F0000232D	G2GH252	2027/07/31
F0000232D	G2GH253	2027/07/31
F0000232D	G2GH254	2027/07/31
F0000232D	G2GL182	2027/10/31

SKU	Batch	SLED
F0000232D	G2GL273	2027/10/31
F0000232D	G2GM111	2027/11/30
F0000232D	G2GF171	2027/05/31
F0000232D	G2GM113	2027/11/30
F0000232D	G2GM115	2027/11/30
F0000232D	G2GI221	2027/08/31
F0000232D	G2GI224	2027/08/31
F0000232D	G2GH255	2027/07/31
F0000232D	G2GL272	2027/10/31
F0000232D	G2GI222	2027/08/31
F0000232D	G2GM186	2027/11/30
F0000232D	G2GM111	2027/11/30
F0000232D	G2GM123	2027/11/30
F0000232D	G2GE281	2027/04/30
F0000232D	G2GE283	2027/04/30