SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Communication to Industry Monday, December 20, 2021

Contact details for Guideline 8.04 Recall, Adverse Event And Post-Marketing Vigilance Reporting Of Medical Devices And IVDs

Attention All Stakeholders

Reporting of Adverse Events

Reportable adverse events, as per Guideline 8.04, must be emailed to the following email addresses:

Medical Devices contact email:

Bafana.malaza@sahpra.org.za and

Dimakatso.mathibe@sahpra.org.za

Recalls and Market Actions

Currently, Section 6 of Guideline 8.04 states that the following:

If the HCR / licensed manufacturer / licensed distributor is contemplating any of the following:

- *correcting product on the market*
- *removing product from the market, or*
- *advising users of an issue with a medical device*

contact the Vigilance Unit at the office of the CEO for advice.

Stakeholders are hereby informed to communicate any recall or market action information to the following email addresses and **not** the Vigilance Unit:

Maphutheho.Selikane@sahpra.org.za

Copy: Mokgadi.Fafudi@sahpra.org.za

Deon.Poovan@sahpra.org.za

Bafana.malaza@sahpra.org.za

Dimakatso.mathibe@sahpra.org.za

Guideline 8.04 Recall, Adverse Event And Post-Marketing Vigilance Reporting Of Medical Devices And IVDs will be updated accordingly in early 2022.