



Fresenius Kabi South Africa

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To: South African Society of Anaesthesiologists

**Re: Product Availability**

As a responsible supplier of critical medicines to the South African public, Fresenius Kabi is aware of the current shortage of some products that may impact patient care. Here is a summary of the most pressing shortages, the reasons behind them, and the plans to address these shortages.

Currently, Fresenius Kabi is experiencing supply constraints related to the following critical products:

1. **Sodium Bicarbonate (8.5%, 4%)** The availability of specialised overwrap material required to maintain the stability of the Bicarbonate solution has been constrained since the loss of the supplier during the 2021 KZN riots. New (approved) suppliers have been sourced globally. Following autoclave sterilisation, the newly sourced product has led to inconsistent results, resulting in reduced batch yields – with as much as a 60% discard rate due to over pouch appearance. New solutions are continuously being tested.

To enhance market availability, Fresenius Kabi has decided, after evaluating the associated risks, to make use of units that were previously deemed unsellable due to product appearance. To uphold the integrity and excellence of the products, a Risk Analysis concerning the delamination of the over pouch post-sterilisation was performed. More stock is anticipated to become available in the first week of September.

2. **Narcotics (Morphine, Pethidine, Fentanyl)** Currently, only two suppliers of these medicines exist in South Africa, both of which are local manufacturers. Fresenius Kabi has traditionally been awarded 10% of the state tender units. Despite having already met, and in some cases significantly exceeded, the number of units to be supplied to the state, Fresenius Kabi

remains committed to continuing to support the Department of Health (DoH) with the additional demand that has arisen. To meet this heightened demand, the company has procured additional glass ampoules from global suppliers. Extended supply lead times have been observed due to the ongoing impact of COVID-19. Fresenius Kabi is currently ramping up production, with the anticipated availability of these increased supplies set for September onwards.

In the private market, Fresenius Kabi is considered the second supplier due to its higher Single Exit Price (SEP) compared to its competitor. As more customers have begun to procure from Fresenius Kabi due to shortages, stock levels have immediately become constrained because this additional demand was not forecasted. To address this, along with the increased demand from the state, additional units have been forecasted to meet the needs of the private market. Private hospitals continue to be fully supplied by Fresenius Kabi, the only constraint being the intermittent supply to wholesalers from time to time.

3. **Stimulants (Adrenaline)** There are 2 suppliers in SA, both local manufacturers. As with the Narcotics tender, Fresenius was awarded a minority share of the state tender – 10%. The number of units supplied versus those requested was exceeded significantly. The DOH and Fresenius have agreed to adjust the forecast. As is the case with narcotics, Fresenius Kabi is seen in the private sector as the second supplier due to a higher SEP. With a growing number of customers turning to Fresenius Kabi in response to shortages, the available stock quickly became limited due to the unanticipated surge in demand. In conjunction with the heightened demand from the state, additional production is projected to meet the requirements of the private market. Ampoules and Active Product Ingredients (API) have been ordered. Production of non-critical and non-essential medicines has been rescheduled to prioritise Adrenaline production. Private hospitals continue to be supplied in full by Fresenius Kabi, with the only constraint being to wholesalers from time to time. Additional stock will start to be released to the market by the first week of September.
4. **Anti-Infectives (Cloxacillin 250mg, Cloxacillin 500mg)** There has been a substantial increase in the demand for Cloxacillin, both in the private and state sectors, as compared to its historical usage. Cloxacillin is imported from a manufacturer in Portugal with lead times of 8 – 10 months. Several delays in production for various reasons, including the availability of raw materials, have resulted in a complete stockout in the country. Production is scheduled, and stock of both presentations will be available in the South African market at the end of October 2023.
5. **Anaesthetics (Ketamine)** In response to a worldwide alert concerning the safety of the Active Product Ingredient (API) due to elevated nitrosamine levels, the manufacturing of Ketamine (in all strengths) was suspended; however, no recall of produced or sold product was deemed necessary by the authorities. To impress on users the current shortages, supply alerts requesting prudent usage of Ketamine as per the *registered anaesthetic indications* have been forwarded to hospitals. Available product produced (pre API alert) was and is released per order to ensure that hospitals are supplied evenly, avoiding the "pooling" of stock. Wholesalers are not supplied. The modified API has subsequently been approved for production and is expected to arrive in South Africa in the last week of August. Production is scheduled, and the release of additional stock to the market is expected during October.
6. **Calcium Gluconate.** Global shortages of suitable glass ampoules and decreased batch yields from the current ampoule production line have affected the manufacturing of Calcium

Gluconate. The product is now being produced using a new ampoule production line, which has recently been approved for production, and the first batches are planned for release in September. To ensure a sufficient market supply, production on the existing line [old] will continue.

7. **Injectable Vitamin (Ascorbic Acid).** Ascorbic acid production has been rescheduled to make way for the additional production of Narcotics and Adrenaline. Stock is available but is being managed with no supply to wholesalers to avoid the “pooling” of stock.
8. **Analgesics (Paracetamol).** Demand for Paracetamol Fresenius increased by 26% in the year 2023. This sharp increase was not forecasted. Production at our plant in Austria is limited, and no additional stock can be supplied in 2023 other than what was forecasted. All supply to the state (Fresenius Kabi does not hold the tender but does supply when the state requests stock due to shortages), as well as all exports of the product, have been halted to provide for the South African Private Market. Wholesalers will also not be supplied to avoid the pooling of stock. The 50ml paediatric presentation, although registered for sale in South Africa, is not currently sold due to the linear pricing model for SEP applied by the DoH (i.e. 50ml should be priced at half of the 100ml presentation – at this price, the product would be sold well below the cost of production).

### Investments in Local Manufacture

Over the past 3 years, Fresenius Kabi has made significant investments - exceeding R300 million - in new production infrastructure at our manufacturing site in Qbergha. These investments have primarily focused on enhancing ampoule and vial production capacity.

The introduction of new vial and ampoule filling lines is expected to result in a twofold increase in ampoule production and a 30% rise in vial production.

These investments are now in the final stages of completion, having received approval from SAHPRA (South African Health Products Regulatory Authority). The implementation has been carried out in phases. The ampoule line has already commenced production, with all molecules planned to be transitioned to the new line by January 2024. Similarly, pending SAHPRA approval, the transition of vial products will begin in September 2023 to the new vial line, aiming for completion by the start of the second quarter of 2024.

Yours Truly,

Zane Langford  
Sales Director