BUSINESS FOR SA | COVID-19

BSA COVID RESPONSE
Pharmaceuticals newsletter

ISSUE #2 | 11 April 2020

Medicines supply gaps

Thanks to everyone for taking the time to complete the data request templates with information on medicines stock-on-hand and forecasted available capacity. This information enabled us to run an initial analysis on supply gaps for critical medicines.

Over the past week we received ~70% of the data from the industry.

This data helped us understand where the gaps are and to forecast future gaps.

The initial analysis based on the data received to date suggests that there are 41 medicines on the critical needs list

Of course, this list will be updated as we receive more data on imports, manufacturing capacity and evolving epidemiological demand forecasts

41 urgent medicines needs – we have a collective responsibility to close this gap

WEEK AT A GLANCE

- Updated the gap analysis and immediate critical needs identified
- Update on demand forecasts and looming gaps
- Imports of finished dose formulations and APIs from India
- Efforts to mitigate supply shortages – your help is needed

For more details on the NDoH gap, please contact Khadija on: Khadija.Jamaloodien@health.gov.za

For private sector supply, please contact Ishara on: IRamkelawan@upd.co.za

Options for us to collectively work together as an industry to close these gaps discussed further in this edition.

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To address identified gaps and mitigate any looming shortages, we will explore opportunities to ramp up local capacity and imports, whilst exploring new supply channels

We are here

Identify shortages	Identify sources	Procurement	Order and logistics management	Downstream fulfillment	Demand management
Gap analysis based on • **Baseline demand analysis,** • **Epidemiological modelling to forecast demand,** • **supply and capacity analysis** **All gaps will be published on the dashboards**	**Explore opportunities to ramp up local supply** from registered suppliers of the product Opportunity to increase imports from registered sources Explore new credible supply channels	**Orders placed directly by NDoH, distributors or wholesalers** BSA will continue to engage the industry to ensure equitable spread of effort across all needs	**Support to debottleneck orders and logistics**	Use existing supply chain channels to distribute to downstream providers	**Working with relevant clinician associations to issue utilisation guidelines especially on critical medicines**

We've also established a regulatory sub-workstream to help facilitate S21 and imports of medicines flagged under the critical list

Potential scenario requiring regulatory interaction	Possible regulatory channel	Estimated turnaround time
I would like to **import FDF that is similar to my currently registered FDF to overcome a local shortage** I would like to **import API from a different source** to that currently on the dossier for my registered FDF given unavailability of usual API source	**Expedited variation application**	~1-7 days
I would like to **temporarily import FDF not registered in South Africa** (and not similar to another of my registered products) to overcome a local shortage	**Section 21 approval** (bulk, not named patient)	~1 week
There is a **critical shortage requiring immediate alleviation**, with other channels exhausted	**Section 36 exemption**	~3 weeks
I would like to **temporarily import FDF not registered in South Africa** (and not similar to another of my registered products[1]) to overcome a local shortage	**Expedited registration of new medicine**	~4-8 weeks
I would like **exemption from post-importation testing for my FDF (excl. vaccines)** to expedite time to market	**Post-importation testing exemption (PITE)**	~3 days

BSA pharma workstream has established a sub-workstream focusing on Section 21 and imports for medicines flagged under the critical list

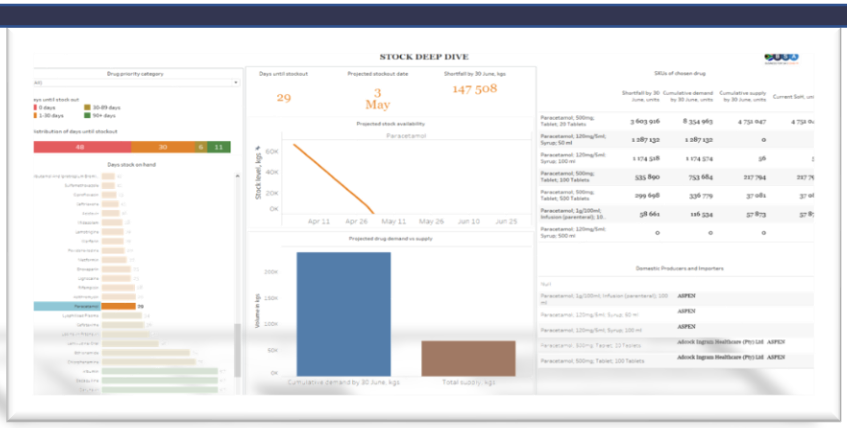
Volunteers from industry associations to support this sub-workstream are welcome

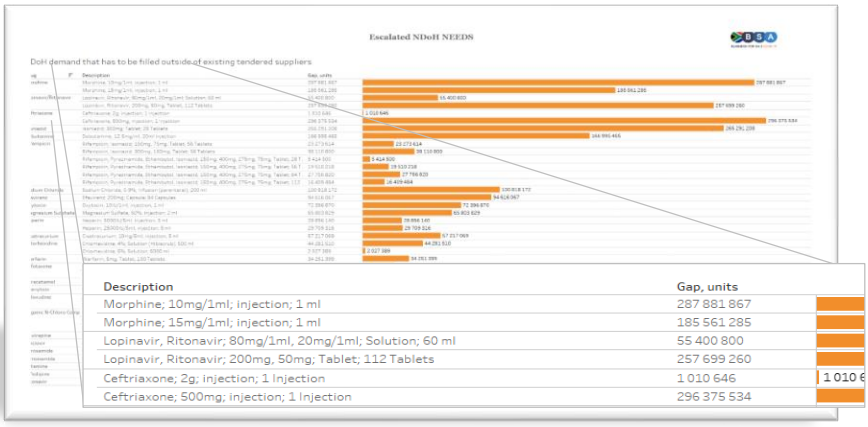
For more details, contact sub-workstream lead: Abeda Williams: awilliam1@its.jnj.com

Coming soon

We have developed an interactive dashboard with weekly updates on essential medicines, soon to be web-based to enable you to:

- Update data templates online in place of the weekly spreadsheet
- Visualise immediate needs and projected gaps
- Drill down to individual SKUs at a click.





Imports from India

Last week we circulated an email regarding an opportunity for BSA to unlock exports of finished dose formulations and APIs out of India.

Our colleague in India, confirmed he received hundreds of emails with several requests from you and it is difficult to efficiently go through all the requests in the current form.

We are also aware of the Indian government's decision to lift restrictions imposed on about a dozen products, after evaluating their internal needs, including some relief on paracetamol. This should come as a welcome relief to the industry

We however, intend to continue tracking all relevant imports from India. We will include a tab on our weekly data request template to ensure we capture relevant information and ensure consistency of reporting.

We are consolidating all requests to track held up imports from India. Look out for an additional tab on our weekly data request template asking:

1. Product name

2. Source/supplier

3. Order volume

4. Dispatch details