



BLACK PHARMACEUTICAL INDUSTRY ASSOCIATION (BPIA)

**PRESENTATION TO THE HEALTH PORTFOLIO
COMMITTEE ON THE NATIONAL HEALTH INSURANCE
BILL (B11 - 2019)**

27th July 2021

ABOUT THE BLACK PHARMACEUTICAL INDUSTRY ASSOCIATION (BPIA) - Unreserved Support for NHI

- ▶ The BPIA was incorporated as a NPO in 2016 an Association representing aspirations of majority Black owned Pharmaceutical Manufacturers, Wholesalers & Distributors, Retail & Courier Pharmacies registered and operating in South Africa
- ▶ Our core objective is the Transformation of the SA Pharmaceutical Value Chain to facilitate entry of Black owned pharmaceutical industry players into the mainstream economy of our country.
- ▶ Advocacy Group that demands SAHPRA to recognise or use BBBEE Certificates in the registration of Dossiers which prioritise locally manufactured products.
- ▶ The BPIA supports the Govt's Universal Healthcare System for all South African's which will introduce a single equitable and accessible healthcare system for its people irrespective of Colour, Creed and social standing.



EXECUTIVE SUMMARY

- ▶ The South African market is currently worth R56,4 billion and Black Owned companies constitute less than 1% of the market.
- ▶ The vast majority of Active Pharmaceutical Ingredients (API), greater than 95%, and a significant portion of finished products are imported into South Africa. The country produces 35% of the volume of pharmaceuticals consumed locally, with 65% imported.
- ▶ This dependence on imports has translated into a negative pharmaceutical trade balance, currently in excess of ZAR 28,5 Billion in 2019. The pharmaceutical trade deficit totalled R 230.3 billion between 1993 and 2017 (Quantec: SA Pharma Trade – Import and Exports).
- ▶ Imported goods are subject to currency fluctuations as the US dollar is the currency used to trade. This leads to a continuous stream of product shortages (Stock Outs) especially of products in the Essential Drug List (EDL), and poses a threat to procurement and the availability of products under the National Health Insurance (NHI)



EXECUTIVE SUMMARY CONTINUED

- ▶ **The Covid -19 pandemic and the breakdown in Global Value Chains, coupled with export restrictions on priority essential medicines and medical consumables by countries like India has clearly highlighted the threat faced by the nation in securing the supply of medication.**
- ▶ Security of supply of medication for all South Africans at the dawn of the NHI, requires the Local Production of both API and finished goods of the EDL.
- ▶ Pursuing a strategy of ensuring a greater supply of South Africa's healthcare needs from local suppliers, presents the country with an opportunity to transform the healthcare sector, as new Black owned enterprises form part of the Supply chain.
- ▶ Black individuals were not allowed to own pharmaceutical companies by law legislated by the apartheid government.
- ▶ Only one black company (Be-Tabs) was allowed to operate in 1978 with a special ministerial consent and only to sell their drugs to black dispensing doctors.



SAHPRA DOES NOT RECOGNIZE OR USE BB-BEE CERTIFICATES IN THE REGISTRATION OF PRODUCT DOSSIERS, AS MANDATED BY LAW

IMPACT:

1. The pharmaceutical private sector, which comprises 80% of the SA market value, continues to trade as per pre- 1994, with no pressure to transform.
2. Currently SAHPRA takes in excess of 4 years to register a product dossier. Local white owned pharmaceutical companies, established pre-1994, and multinational companies, have large existing product portfolio's and equally massive product pipelines.
3. They can absorb the lost opportunity cost incurred from the delays in product registration.
4. **By contrast, Black owned new enterprises cannot endure the latter as they Do Not have large product portfolio's and product pipelines; this limits new market entrants.**
5. Key to retention of the status quo is the failure to recognize BB-BEE as part of the product dossier registration process by SAHPRA.



PROPOSED SHORT TERM SOLUTIONS OF REGISTRATION OF PRODUCT DOSSIERS

1. **The Dept of Health should work in conjunction with the DTIC to enact a Health Charter (covering Pharmaceuticals) – within a stipulated and strict time-frame**
2. Make the BB-BEE scorecard part of the pharmaceutical product dossier registration process at SAHPRA.
3. Expedite the registration of products from Black-Owned companies (defined as companies that have a minimum of 51% black ownership). Specifically, we are proposing that SAHPRA must give priority to Black Owned pharmaceutical companies in the registration of product dossiers.
4. Under No Circumstances, should Black Owned companies be exempt from the full regulatory assessment of product dossiers to ensure product Safety and Efficacy. For the sake of clarity, we are only advocating for the administrative addition of the BB-BEE certificate in the Screening phase of the current SAHPRA Regulatory process.



THE SOUTH AFRICAN PHARMACEUTICAL VALUE CHAIN REMAINS UNTRANSFORMED.

► Background

Market access is key to the transformation of the Healthcare sector! Black Owned companies constitute less than 1% of the sector, in a country where greater than 90% of the population is Black. In the pharmaceutical sector, registration of product dossiers is the obligatory market entry requirement (see above).



THE SOUTH AFRICAN PHARMACEUTICAL VALUE CHAIN REMAINS UNTRANSFORMED.

► Proposed Short Term Solutions (1-2 years):

- 1. The Dept of Health should work in conjunction with the DTIC to enact a Health Charter (covering Pharmaceuticals) – within a stipulated and strict time-frame**
2. As in other industry sectors, we propose that in the Healthcare sector, with emphasis in the key pharmaceutical sector, that a minimum of 30% set asides be an Obligatory requirement in both the public and the private sector this is as per the PPPFA Act of 2000.
3. In the Private sector, **there should be a minimum Obligatory 30% set aside for all pharmaceutical trade by corporate pharmaceutical companies**, retail and courier pharmacy chains, and hospitals with Black Owned companies in the healthcare space. Punitive measures should be applied to corporates that do not pursue trade with Black owned companies in a given year, such as withholding of new licenses and restricting the renewal of existing licenses, until there is satisfactory resolution of the matter by the noncompliant company.



SHORT TERM SOLUTIONS CONTINUED:

3. In the Public sector, there should be an Obligatory minimum 30% set aside in ALL NDoH state tenders. Currently, the NDoH allows and accepts imported products from (for example) Indian companies, with a small local representative office in SA. For example, Macleods won the biggest percentage of ARV tenders and are currently failing to supply timeously – **forcing the state into emergency procurement at higher prices, increasing the actual cost of the ARV programme.** Despite this, they have just been awarded the largest portion of the TB tender.
4. We propose that Black Owned companies instead be permitted to import products within the minimum Obligatory 30% set aside on state Tenders.



ESTABLISHING THE PHARMACEUTICAL HUB THROUGH LOCAL PRODUCTION OF API AND PHARMACEUTICAL FORMULATIONS (MEDIUM TERM, WITHIN 5YEARS)

Background:

South Africa imports almost 100% of API's to formulate its products locally. In for example, the largest volume product in SA on state tender, the ARV tender, the API's are 100% imported.

The state tender requires a BBBEE certificate to submit a bid. However, the 10 points allocated for BB-BEE are insufficient given that price accounts for 90 points.

Indian manufacturers in particular who are fully backward integrated, will continue to offer the lowest price until such time as we can manufacture our own API. **Local manufacture of API will result in a minimum of 12% reduction in costs.**



ESTABLISHING THE PHARMACEUTICAL HUB THROUGH LOCAL PRODUCTION OF API AND PHARMACEUTICAL FORMULATIONS (MEDIUM TERM, WITHIN 5YEARS): CONTINUED

The capability to manufacture both API and finished goods will be critical to the Universal coverage mission of the NHI.

Immediate steps should be taken to incentivize the local production of API and finished goods of pharmaceutical products in the EDL.

The NDoH should implement a forward-looking target of State procurement of 50% of its healthcare needs being supplied from Black owned companies by 2026. The success of a manufacturing Enterprise is reliant on consistent, large production volumes, such as will be offered through the NHI.



ESTABLISHING THE PHARMACEUTICAL HUB THROUGH LOCAL PRODUCTION OF API AND PHARMACEUTICAL FORMULATIONS

Proposed Solutions:

1. Establish a R & D capability, led by the CSIR, at the CSIR and additional partnering universities; hub and spokes model.
2. Increase the number of pharmaceutical product registration of the EDL submitted by Black owned pharmaceutical companies. This will establish the product volumes required for local manufacture of both finished goods and the associated API's.
3. Establish a target of 50% of NHI procurement of the EDL products from Black owned companies by 2026 and 80% by 2036.
4. All NHI suppliers should procure their EDL product API from local manufacturers. Failure to do so should result in exclusion from future procurement from NHI.



LOCAL PRODUCTION OF API AND PRODUCT FORMULATIONS

► Background.

Existing Black Owned companies and new Black Owned entrants in the pharmaceutical sector need support. The support should be in the form of Obligatory set asides for Black Owned companies. The sale of API are directly linked to the product formulation.

Regulatory tenets require that product dossiers submitted for receipt of market authorization should identify the source of the API manufacturer. Thus, for example a registered TLD product dossier consisting of 3 separate API's in a single tablet, must indicate the source of the API.



LOCAL PRODUCTION OF API AND PRODUCT FORMULATIONS CONTINUED:

- ▶ To gain a foothold in the market with the local manufacture of API, we propose the following:
 1. A minimum 30% allocation for Black Owned companies of the ARV Tender through 3 Tender cycles beginning with the next ARV Tender. This would result in a savings of more than R2 billion for the government.
 2. The Black Owned companies will be Obligated to source their API from the local API manufacturer of the respective API for TLD.
 3. The official 30% allocation by the NDoH will be used by the Black Owned companies to raise funding for the development of the following:
 - a) An API manufacturing plant in one of the provincial IDZ dedicated for/to Pharmaceuticals;
 - b) A Formulation plant with high speed equipment to manufacture the high product volumes;



LOCAL PRODUCTION OF API AND PRODUCT FORMULATIONS CONTINUED:

- c) Both facilities will be established with state of the art manufacturing technology, endorsed by international regulatory bodies.
- 4. The NDoH should also identify specific products that are chronically in short supply, such as key antibiotics in the EDL for local manufacture. These should also be made available for local manufacture by one or more Black Owned manufacturing facility, over 3 Tender cycles. For the less profitable EDL products that are chronically in short supply, these should be manufactured locally in partnership with the government, as they will very likely require some form of government subsidization.
- 5. The NDoH should work with the Department of Trade and Industry to develop a restricted list of products that can only be procured locally, with a minimum of 30% to be procured from Black Owned company suppliers.



LOCAL PRODUCTION OF API AND PRODUCT FORMULATIONS CONTINUED:

6. Importation of products should be prohibited as soon as they are produced in sufficient quantity to meet the local demand. This will continue to foster local production, maintain local jobs, facilitate technology transfer and lead to increasing pharmaceutical R & D, and in the process giving effect to the Minister's vision to convert South Africa into a pharmaceutical manufacturing hub, whilst reversing the pharmaceutical trade deficit.



THE WAY FORWARD:

1. Health Charter is crucial – within a stipulated time (July 2022)
2. Covid-19 has exposed the danger of reliance on imported products (GBC collapse and restrictions on exports)
3. **Urgent need for intentional, bold and thoughtful interventions to create Health security for the country**
 - a) **Expedited registrations**
 - b) **Legislated and Mandatory Procurement Preferences encompassing public and private sector**
 - c) **Restricted lists**
 - d) **Directed support at building local API and Formulation capability and capacity working with research institutes and universities**





THANK YOU