Regulator wants to put local drugmakers at front of the queue

In a move that would have significant implications for the local pharmaceutical industry, the regulator, the SA Health Products Regulatory Authority (Sahpra), has proposed the adoption of a localisation policy that would see priority being given to the registration of locally manufactured products.

Registration of medicines in SA takes a long time, and prioritisation of locally manufactured products would expedite the process for them compared with foreign products.

Stavros Nicolaou, group senior executive for strategic trade of Aspen Pharmacare, Africa's largest pharmaceutical manufacturer, welcomed the move, which he said was a significant step towards Africa developing its own capabilities. The lack of capacity was sharply demonstrated during the Covid-19 pandemic, when the continent had difficulty accessing vaccines.

Nicolaou said in an interview that if the regulator did not prioritise the registration of locally manufactured products, SA would fall behind other countries on the continent that were gearing up to produce vaccines. Egypt has seen a significant increase in local production after it adopted a prioritisation policy.

He also pointed out that the best way to ensure security of supply of medicines was to have the local capacity to produce them.

Another important element, Nicolaou added, was to align government procurement policies with those of the regulator. He was optimistic that the Public Procurement Bill passed by parliament would assist in this once it was signed by President Cyril Ramaphosa. The bill has set-asides for localisation, which generate taxes that foreign producers do not pay even if they can supply cheaper products.

Sahpra's focus on localisation coincides with the launch on Thursday last week in Paris of the African Vaccine Manufacturing Accelerator at the Global Forum for Vaccine Sovereignty and Innovation.

Funding of $1.2bn over 10 years is planned to provide financial incentives to boost vaccine manufacturing on the continent, which imports about 99% of its vaccine requirements. The aim is for Africa to produce 60% of its vaccine requirements by 2040.

At a recent meeting with the industry, Sahpra outlined the draft local manufacturing policy, which is under review by its legal committee. It envisages publishing the draft for comment between July and September and tabling it for approval by the Sahpra board and for implementation at the end of the year.

In a presentation at the meeting with industry, Sahpra CEO Boitumelo Semete-Makokotlela said that in terms of the draft policy Sahpra would prioritise local manufacturers of health products for addressing critical public health needs. It would, however, still pursue its objective of ensuring the safety, quality and therapeutic efficacy of medicines.

The policy defines a local manufacturer as a licensed entity domiciled in SA. Medicines that are locally manufactured and are of public health importance will be considered. For vaccines, fill-and-finish activities, which come at the end of the manufacturing process, would be considered local manufacture.

In terms of the draft policy, a company may not move its manufacturing business to another destination after having received priority approval of its products from Sahpra.

Sahpra is also working on a broad-based BEE policy for the industry, which has expressed concerns about it. Semete-Makokotlela said the industry would be consulted on the BBBEE qualification criteria to be used in the issuing of licences. She stressed that as an organ of state, Sahpra was obliged to comply with the BBBEE Act.

“Compliance to the policy should not affect access to safe, quality and effective health products,” she stressed in a presentation. “A licence application will never be denied because of not meeting the criteria, as BBBEE will not override the mandate of Sahpra as per the Medicines Act.”

She also said no applicant would be dispossessed of the licence on the basis of noncompliance with the BBBEE policy. Applicants for licences would not be excluded but those that met the criteria would be prioritised.

Industry has raised a number of concerns about the proposed policy, noting that under the Medicines Act the different types of licences may only be issued subject to quality assurance principles and good manufacturing and distribution practices that are related to the underlying products.

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