# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 3304**

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**(INTERNAL QUESTION PAPER NO. 36)**

**Mrs M O Clarke (DA) to ask the Minister of Health:**

(1) What measures has his department put in place to address the (a) current yellow fever vaccine shortages plaguing the Republic and (b) contingency plans of the Republic to prevent future shortages;

(2) (a) how is his department expediting the release of the Sanofi stock of yellow fever vaccines that is currently with the (i) National Control Laboratory and/or (ii) SA Health Products Regulatory Authority (SAHPRA) in Bloemfontein and (b) by what date does his department envisage the release date of the Sanofi stock of yellow fever vaccines;

(3) whether the SAHPRA has been approached to licence and/or register yellow fever vaccines from different manufactures; if not, why not; if so, what is the status of the Sanofi yellow fever vaccine? **NW4101E**

**REPLY:**

1. (a) The National Department of Health manages contracts for approximately 1 200 line items including vaccines. Currently, there are no supply constraints in the public sector related to yellow fever vaccines.

(b) To ensure that there are no supply constraints at facilities, a number of interventions are implemented. These interventions are informed by the cause of the supply challenge.

* Where the supply constraint is due to operational matters, re is a delay e.g. machine breakdown, labour unrest, theft, post importation testing, etc., the National Department of Health (NDOH) would source products from alternative local suppliers with registered products using the quotation process.
* Should the supply constraint result in a longer term supply challenge, such as regulatory matters including amendments to the dossier that requires approval from South African Health Products Regulatory Authority (SAHPRA), including a change/addition of an active pharmaceutical ingredient source and/or manufacturing site, the transfer of ownership of dossiers which results in a change of marketing authorization, delays in the issuing of the permits for imported medicines, manufactured products requiring additional quality checks by SAHPRA, etc. and no alternative local suppliers with registered products are available; an application would be made to SAHPRA for the acquisition of unregistered medicines for human use in South Africa Act use in terms of Section 21 of the Medicines and Related Substances Act.
* During the contracting for medicines, it is a special contractual condition that suppliers provide the NDoH with information related to their buffer stock holding, plans within the pipeline and data related to deliveries made to facilities. The DoH uses this information to manage supplier performance including the imposition of penalties where appropriate. Furthermore, the data is used for planning purposes including demand and supply planning.

1. (a) It must be noted that the National Control Laboratory and SA Health Products Regulatory Authority (SAHPRA) are independent of the NDoH. Nevertheless, written communication was sent to SAHPRA from the NDOH to request that the release of yellow fever vaccine stock be expedited.

(b) SAHPRA has subsequently approved the Yellow Fever Vaccine on the 23rd of September 2022 and the stock is currently with the distributor for delivery to facilities that have placed orders.

1. Yellow fever vaccine is a low volume product. The low demand for the vaccine resulted in the current contracted supplier writing-off 1 505 units. The low demand makes market entry very difficult.

With regard to the status of the Sanofi yellow fever vaccine, SAHPRA has subsequently approved the Yellow Fever Vaccine on the 23rd of September 2022 and the stock is currently with the distributor for delivery to facilities that have placed orders.

END.