



## **national treasury**

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Mr. David Lewis  
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Dear Mr. Lewis

### **CLARITY REGARDING EMERGENCY PROCUREMENT OF COVID-19 VACCINES**

1. Reference is made to your letter dated 12 January 2021 requesting clarity regarding the procurement of Covid-19 vaccines and requiring a response by 18 January 2021.
2. National Treasury acknowledges the crucial role of Corruption Watch in its fight against the abuse of public funds, and the promotion of transparency and accountability to protect the beneficiaries of public goods and services.
3. Treasury believes the vaccination programme is a public good and supports that all should be able to access it in line with need and the Department of Health's rollout plan.
4. South Africa has, like many other countries, entered into a strong second wave of COVID-19 infections. Vaccines will play a pivotal role in saving lives and facilitating the country's economic recovery. Ensuring access to COVID-19 vaccines is of highest priority to the South African Government.
5. The South African Government has already entered into a committed purchase agreement with the Gavi Alliance for South Africa to access vaccines through the COVAX Facility. Government has signed a binding financial commitment for the future payments to Gavi (approximately 85% of the total cost of approximately R2.2 billion) and this has already been included in the preliminary allocation letter to the National Department of Health. The Solidarity Fund generously made a donation to cover the required upfront payment of approximately 15 per cent of the total cost. It must be appreciated that the COVAX purchase agreement involved complex legal provisions and the time it took to finalise it was to enable National Treasury, the Department of Health and Gavi to jointly ensure that it was permissible within South African law and that all due compliance processes were followed in the interest of good governance and safeguarding against corruption. PFMA provisions and related processes are in place to ensure accountability, sound financial management and fairness in procurement.



6. In addition to purchasing vaccines through COVAX, which will reach South African shores during Q2 of 2021 (April – June 2021), the National Department of Health has engaged vaccines manufacturers to explore the possibility to purchase vaccines from them directly. As recently announced, the Department of Health is close to finalising an initial purchase agreement for 1.5 million doses from Serum Institute of India. National Treasury and the National Department of Health are in continuous contact on the vaccine rollout strategy and formalised this process by establishing a joint working group on COVID-19 vaccines.
7. National Treasury's Office of the Chief Procurement Officer has timeously and rapidly provided guidance to the Department of Health on simple and swift procurement procedures and has already provided the necessary approvals to proceed with sourcing and procurement of vaccines.
8. The Office of the Chief Procurement Officer has provided guidance to the National Department of Health on procurement procedures which need to be followed where it is impractical to follow a competitive bidding process in line with prevailing public procurement legislation. Such legislation includes departures from treasury regulations, instructions or conditions in terms of Section 79 of the PFMA, procurement deviations allowed in Treasury Regulation 16A6.4, Practice Note 8 of 2007/2008, par. 3.4.3 and SCM Instruction 03 of 2016/2017 (Preventing and Combating Abuse in the SCM System), par. 8.5.
9. Accordingly, we now respond as best we can to the specific questions raised.

**9.1. Has National Treasury provided the National Department of Health with input about best practices for emergency procurement as it pertains to vaccine and health products?**

Yes. The Department of Health engaged with National treasury early to determine the best course of action within the PFMA. The Department of Health was advised that there were two options that the Department of Health (DoH) could elect to use, namely:

- Emergency procurement method, or
- Procurement based on urgency which makes it impractical to issue an open competitive bid.

Treasury Regulation 16A6.4 states that if in a specific case it is impractical to invite competitive bids, the Accounting Officer may procure the required goods or services by other means, provided that the reasons for deviating from the competitive bids must be recorded and approved by the Accounting Officer.

In terms of SCM Instruction Note 3 of 2016/2017 (Preventing and Combating Abuse in the SCM System) paragraph 8.1, the Accounting Officer must only deviate from inviting competitive bids in cases of emergency and sole supplier status. Paragraph 8.2 of SCM Instruction Note 3 of 2016/2017 states that an emergency procurement may occur when there is a serious and unexpected situation that poses an immediate risk to health, life, property or environment which calls for an agency to action and there is insufficient time to invite competitive bids.

Paragraph 8.5 of the same instruction note states that any other deviation will be allowed in exceptional cases subject to the prior written approval from the relevant treasury.



The Department of Health was advised to seek approval from National Treasury, on a case-by-case basis, to deviate from procurement processes based on urgency which makes it impractical to invite competitive bids.

**9.2. Has the National Department of Health requested permission to deviate from accepted supply chain management prescripts in respect of procuring vaccine?**

Yes, they have.

- i. Covid-19 Vaccine Global Access (COVAX) Facility: In a letter dated 29 September 2020, the Department of Health requested approval to deviate from the normal procurement process and procure vaccines through the Covid-19 Vaccine Global Access (COVAX) Facility.

The motivation provided for the deviation is that Government has a responsibility to implement intervention measures quickly and efficiently to minimise the negative impact of the Covid-19 pandemic on the health care of its citizens and the economy. The introduction of an effective vaccine has been identified as a key intervention to mitigate the public health and economic impact of the pandemic. The COVAX Facility has been established to support developing countries such as South Africa, to access the vaccine in a fair and equitable manner, in partnership with the World Health Organisation, UNICEF, the World Bank, Gavi and the Bill & Melinda Gates Foundation. According to the Department of Health, experience has shown that more well-resourced countries are better able to acquire the limited volumes of vaccines available at exorbitant prices, thereby creating inequality in the global distribution of the vaccines. Therefore, due to limited supply, South Africa may be at risk of not receiving vaccines when they are available after clinical trials have been concluded.

National Treasury approved the application to deviate from the competitive process and use the COVAX Facility to procure the Covid-19 vaccines on 23 November 2020.

- ii. Procurement of Covid-19 vaccines from individual vaccine producers for a period of six months: In the letter dated 6 January 2020, the Department of Health requested approval to deviate from normal procurement processes and procure vaccines from Pfizer, AstraZeneca (through their marketing agents Cipla and SII), Moderna and Johnson and Johnson for a period of six (6) months as and when the stock is available.

The motivation provided for the deviation was based on urgency and the impracticality to issue a competitive bid. Given the severity of the second wave and its impact on the health system, access to vaccines is required to urgently vaccinate frontline health care workers. At present there are very few vaccines that have come to market and there is a huge global demand for the limited number of doses available of these vaccines. Most countries that have successfully procured vaccines have done so by negotiating supply agreements directly with manufacturers. It is for these reasons that alternative procurement mechanisms were being considered in order to secure the vaccines for immediate use. It will not be practical to procure vaccines in the immediate short-term using an open competitive bidding process. The Department will source available Covid-19 vaccines from the four mentioned companies, and the



option to engage with other manufacturers as stock becomes available in order to secure the vaccines.

The Department of Health undertook to:

- negotiate prices with suppliers to achieve the best available prices for South Africa,
- inform National Treasury of the processes followed and the agreements reached with manufacturers, and
- advertise a tender for these vaccines to secure supply in the longer term.

National Treasury approved the application on 6 January 2021 to approach the four suppliers and the option to engage with other manufacturers as stock becomes available in order to secure the vaccines. The Department must ensure that the regulatory requirements in terms of registration of the vaccines are complied with.

**9.3. Will the permission to proceed with a deviation be contingent on the regulator providing the appropriate regulatory approvals of vaccines? What metrics will National Treasury be using (or has it used) to satisfy itself prior to granting approval to proceed?**

Yes, the deviation approval by the OCPO explicitly states that the Department of Health must comply with the regulatory requirements for the registrations of vaccines with South African Health Products Regulatory Authority (SAHPRA) in terms of the the Medicines and Related Substances Act.

**9.4. Has National Treasury received any other deviation requests in respect of the vaccine rollout?**

Yes. The Department of Health also requested for deviation from procurement processes for the transport, storage and distribution of the Covid-19 vaccines for the short term. In a letter dated 07 January 2020, the Department of Health requested approval to deviate from normal procurement processes for the following:

- i. To use the single source procurement method to appoint the Biovac Institute for the short term (3 months) to provide storage and distribution services for vaccines procured urgently to immunise frontline health care workers; and
- ii. To request approval to issue a closed bid to four service providers that specialise in cold storage and distribution of medicines in order to secure the services of transport and logistics providers that comply with regulatory requirements to store and distribute Covid-19 vaccines for a period of 6 months. These companies are Biovac Institute, Imperial Health Sciences, DSV and United Pharmaceutical Distributors.

The motivation provided for the deviation was based on urgency in order to procure vaccines to support front line health care workers in the short term (3 months) and the urgency required to contract for storage and distribution of vaccines procured through the COVAX Facility.



National Treasury approved the application on 7 January 2021 to appoint Biovac Institute in the short term (three months) only to expedite the necessary vaccine authorisation in terms of Section 21 of the Medicines and Related Substances Act. In terms of the Section 21 application process, because NDoH is the applicant, they needed an importer/distributor to be listed on the application before SAHPRA would consider the approval.

National Treasury, furthermore, approved the closed bid procurement process to the four service providers mentioned above in the medium term (6 months). The Department of Health must ensure that the closed bid process does not in any way prejudice any other potential supplier who has the required storage and distribution capabilities.

It should be noted that it is envisaged that more vaccine suppliers / manufacturers may come to the fore in the near future, hence the long-term solution by Department of Health will be an open competitive bidding process where the contract terms will be for the total cost, i.e the cost of the vaccines, including the cost of logistics (transport and distribution). This however depends on vaccine efficacy data of more vaccine manufacturing candidates and the registration of vaccines.

**9.5. What regulations, instruction notes and circulars are relevant or are planned to be issued, in relation to the vaccine procurement process?**

In this specific case regarding the procurement of Covid-19 vaccines, current procurement legislation will prevail. National Treasury do not currently foresee issuing any instructions related to the procurement of Covid-19 vaccines, as the funding and procurement of the vaccines are kept central (through the National Department of Health). This allows for comprehensive central control of procurement, governance and the spending of funds. This approach also minimizes the opportunities for corruption, provides for central record keeping of agreements and centralized contact with manufacturers. It further allows for a more focused negotiation strategy based on combined volumes for the public and private health sectors.

**9.6. What oversight measures are being taken to safeguard the vaccine procurement process from corruption risks, including whether the Auditor-General will be engaged to conduct real-time audits of vaccine procurement?**

In so far as procurement of vaccines, it will be subject to the monitoring and oversight framework of all public procurement and expenditure. PFMA provisions and related processes are in place to ensure accountability, sound financial management and fairness in procurement.

The Auditor-General will be engaged at the appropriate time to conduct real-time audits on the procurement process of the Covid-19 vaccines.

**9.7. Will the Auditor-General have access to non-disclosure agreements signed by government with pharmaceutical companies to ensure compliance with South African law and rules around public expenditure?**

The National Department of Health is better placed to respond to this question.



It must be appreciated that these agreements are complex and it is important to ensure that the agreements are permissible within South African law and that all due compliance processes are followed in the interest of good governance and safeguarding against corruption.

**9.8. Besides National Treasury, which other departments / institutions have an oversight function in relation to the vaccine procurement process and is Treasury interfacing with them?**

Besides National Treasury and the Accounting Officer of the National Department of Health itself, important institutions with oversight of procurement and budget execution are the Auditor-General, the Parliament of South Africa, the South African Health Products Regulatory Authority and provincial treasuries and legislatures for provincial health departments.

**9.9. Which programme in the Health Department's budget vote or budget source is being used to fund vaccine procurement?**

Detailed budgetary allocations, including which budget programmes in the Health Vote funds will be allocated to, will be announced in the 2021 Budget. Funding will likely come from a combination of additional budgets, reprioritization within budgets, and potentially from partnerships with the private sector. The bulk of the funding will likely be required in the 2021/22 financial year, and funding requirements for the remaining months of the current financial year will be sourced from underspending areas within existing budgets.

**9.10. What type of rigours will procurement of vaccines via the COVAX facility be subjected to, given that COVAX is conducting negotiations as opposed to a tender process of the nature envisaged in the PFMA?**

In the case of COVAX, it is correct that Gavi conducts negotiations with vaccine manufacturers on behalf of participating countries. A key strength of COVAX is the purchasing and negotiating power that Gavi has by pooling the demand of over 189 participants. While the South African Government is not directly involved in these negotiations and therefore has limited insight, the Gavi Alliance has vast experience of vaccine price negotiations and we are confident that the Facility will offer competitive prices. In November 2020, the OCPO approved a procurement deviation request, allowing for the NDOH to procure vaccines via the COVAX Facility.

**9.11. Will the public sector funds to be spent on vaccine be handled via the Solidarity Fund or the Health Department or transferred to a central fund like the NHI fund?**

The public sector funds will be allocated to the National Department of Health, which will be the department responsible for procuring and paying for the vaccines. This allows for central control of procurement, governance and spending of funds.

**9.12. What transparency arrangements is National Treasury and the National Department of Health and other relevant entities making so that there can be public oversight of the vaccine procurement?**

In so far as procurement of vaccines, it will be subject to the monitoring and oversight framework of all public procurement. The National Department of Health is better placed

to respond to which specific information pertaining to supply agreements that will be made available to the public. National Treasury examines the expenditure of the Department of Health on an ongoing basis and will monitor vaccine expenditure closely. We also submit quarterly expenditure reports to Parliament's Standing Committee on Appropriations and will report expenditure on COVID-19 vaccines therein.

Please don't hesitate to contact me if you have any questions or if I can be of further assistance.

Yours sincerely



**DONDO MOGAJANE**  
**DIRECTOR GENERAL**  
DATE: 18/1/2021