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REPORT ON AN INVESTIGATION INTO ALLEGATIONS OF MALADMINISTRATION AND IRREGULARITIES ASSOCIATED WITH THE PROCUREMENT OF UNAUTHORISED MEDICINES FROM CUBA BY THE DEPARTMENT OF DEFENCE
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LIST OF ACRONYMS

The following abbreviations and acronyms are used throughout this report:

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<td>Colonel (Dr) Joseph Thabo Mnisi, Chief Medical Specialist</td>
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<td>DOD CFO</td>
<td>Mr Eric Siphiwe Sokhela, the Chief Financial Officer</td>
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<tr>
<td>DoH</td>
<td>National Department of Health</td>
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<td>General Shoke</td>
<td>General Solly Zacharia Shoke (ret), former Chief of Defence</td>
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<td>General Maphwanya</td>
<td>General Rudzani Maphwanya, Current Chief of Defence</td>
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<tr>
<td>Lt Gen Mbula</td>
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<td>Lt Gen Maphaha</td>
<td>Lieutenant General (Dr) Ntshavheni Peter Maphaha, Current Surgeon General</td>
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<td>Major General LC Ford (ret), the DOD Chief Director Military Health Force Support</td>
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<td>South African National Department of Defence</td>
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<td>SecDeF</td>
<td>Ms Gladys Sonto Kudjoe, Secretary of Defence</td>
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<td>SAHPRA</td>
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<td>SG</td>
<td>Lt General (Dr) Zola Wiseman Songo Dabula (ret), former Surgeon General</td>
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<td>Mr Sarel Jacobus Francois Marais</td>
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<td>The DOD</td>
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EXECUTIVE SUMMARY

“It is because procurement so palpably implicates socio-economic rights that the public has an interest in it being conducted in a fair, equitable, transparent, competitive and cost-effective manner.”

(i) This is a report of the Public Protector issued in terms of section 182(1)(b) of the Constitution of the Republic of South Africa, 1996 (the Constitution), and published in terms of section 8(1) of the Public Protector Act, 1994 (Public Protector Act).

(ii) The report communicates the findings and appropriate remedial action that the Public Protector is taking in terms of section 182(1)(c) of the Constitution, following an investigation into allegations of maladministration, irregular procurement and expenditure of approximately R 35 000 000.00 (thirty five million rand) of unauthorised medicines from Cuba by the Department of Defence (the DOD).

(iii) There were two complaints registered for this matter, both dealing with the same issue. The first one was an own initiative by the Public Protector emanating from media reports, registered on 17 February 2021 and the second was lodged on 19 February 2021 by Mr Sarel Jacobus Francois Marais, a Member of Parliament of the Democratic Alliance political party, who is the Shadow Minister for Defence and Military Veterans (the Complainant).

The Complainant alleged the following:

(iv) That the DOD procured drugs in excess of two hundred million rand (R 200 000 000.00) on a Cuban Covid-19 treatment, Interferon-Alpha-2B Heberon (the drug), and that the National Department of Health (DoH) had banned it.

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1 Allpay Consolidated Investment Holdings (PTY) Ltd v Chief Executive Officer of the South African Social Security Agency (No 1) (CCT 48/13) [2013] ZACC 42; 2014 (1) SA 604 (CC) paragraph 4.
from being used to treat the symptoms of the Covid-19 virus. The DOD has already paid thirty five million rand (R 35 000 000.00) for one hundred and thirty thousand (130 000) doses of the drug and was to make another payment of one hundred and eighty two million rand (R182 million) for the consignment which had already been delivered; and

(v) The DOD cannot use the drug because it did not make the necessary application to the South African Health Products Regulatory Authority (the SAHPRA) before its procurement. Furthermore, the DOD did not capture the procurement on its inventory. The procurement of the drug was done without due process.

(vi) Based on the analysis of the allegations made and information obtained from the Complainant, the following issue was considered and investigated:

(a) Whether the DOD failed to follow a proper procurement process when procuring the drug, and if so, whether such conduct constituted improper conduct in terms of section 182(1) of the Constitution and maladministration in terms of section 6(4)(a) of the Public Protector Act.

(vii) The investigation was conducted in terms of section 182(1)(a) of the Constitution and sections 6 and 7 of the Public Protector Act. It included an exchange of documentation between the Public Protector’s investigation team, the Secretary of Defence, Ms Gladys Sonto Kudjoe (SecDef), the Chief of Defense, General Rudzani Maphwanya, interviews with the DOD officials, exchange of correspondence with the relevant DOD officials, obtaining of affidavits from various witnesses, correspondence with other organs of state, analysis of relevant documents and information obtained as well as application of applicable laws, policies and related prescripts.

(viii) A Notice in terms of section 7(9)(a) of the Public Protector Act, 1994 (the Notice), was issued and served on the President of the Republic of South
Africa, President Cyril Ramaphosa (President Ramaphosa) and the SecDef on 25 October 2021, with a view of affording them an opportunity to respond to the Public Protector’s preliminary findings relating to the issues under investigation. Section 7(9)(a) and (b) of the Public Protector Act provides that persons implicated or affected in an investigation by the Public Protector, are to be allowed the opportunity to make representations regarding same.

(ix) President Ramaphosa did not respond to the Notice. The SecDef’s response was duly received by the Public Protector’s Office on 24 November 2021. A supplementary Notice (notice that covered those facts/issues/points not discussed in the original Notice issued to affected parties) was issued on 28 April 2022, to the SecDef, General Solly Zacharia Shoke (ret), General Rudzani Maphwanya, Lieutenant General Jabulani Sydney Mbuli, Lieutenant General Zola Wiseman Songo Dabula, Major General NP Maphaha and Colonel (Dr) Joseph Thabo Mnisi. The SecDef did not respond to the supplementary notice and all the listed SANDF officials responded during May and June 2022 respectively.

(x) The responses and information/evidence submitted in response to the Notice, were duly considered by the Public Protector’s Investigation Team (Investigation Team) in relation to the substance of any allegations against the person(s) concerned or the grounds for adverse comments or findings against or remedial action involving them.

(xi) Having regard to the evidence and regulatory framework determining the standard that the DOD should have complied with, the following findings are made:

(a) Whether the DOD followed a proper procurement process when procuring the drug, and if not, whether such conduct constituted improper conduct in terms of section 182(1) of the Constitution and maladministration in terms of section 6(4)(a) of the Public Protector Act.

(aa) The allegation that the DOD did not follow a proper procurement process when procuring the drug is substantiated.
(bb) The investigation revealed that the DOD procured the drug from the Cuban government based on a Bilateral Agreement signed on 10 January 2012 concerning defence relationships established between the South African and Cuban governments. In procuring the drug, the DOD senior officials confirmed that they did not follow any South African legal prescripts regulating the public procurement of goods and services, other than to rely on the said Bilateral Agreement. However, the DOD contravened the said Bilateral Agreement which they claimed to have relied on to procure the drug, because Article 1 thereof clearly states that the Bilateral Agreement is subject to each country’s domestic laws and financial constraints.

(cc) The DOD, did not record their reasons for deviation during this procurement as required in terms of National Treasury Regulation 16.A.6.4, which specifies that if in a specific case, it is impractical to invite competitive bids, the accounting officer or accounting authority may procure the required goods or services by other means, provided that the reasons for deviating from inviting competitive bids must be recorded and approved by the accounting officer or accounting authority.

(dd) The DOD did not follow the National Treasury Regulation 16A6.2 in processing this procurement. National Treasury Regulation 16A6.2 requires that a supply chain management system must, in the case of procurement through a bidding process, provide for the adjudication of bids through the establishment, composition and functioning of Bid Specification, Evaluation and Adjudication Committees.

(ee) The investigation further revealed that the drug was not registered to treat Covid-19 in South Africa and the DOD senior officials proceeded to bring it into the country on 27 April 2020, prior to them applying for its registration to the SAHPRA. The SAHPRA directed the DOD on 3 November 2021, to return the drug to Cuba, failing which the batches will be confiscated and destroyed. The SANDF reported to the SAHPRA that the unregistered/unauthorised medication in question was returned to Cuba on 20 January 2022.

(ff) The DOD spent approximately R 35 million to procure the drug without following the normal procurement processes. The DOD senior officials confirmed that the
DOD did not have additional funding to pay Cuba the approximate amount of R182 million for the drug consignment already delivered to the DOD. The drug was unregistered/unauthorized and could not be used to treat Covid-19 in South Africa. The expenditure in the amount of approximately R35 million to procure the drug from Cuba during April 2020 amounted to irregular, fruitless and wasteful expenditure, as defined in section 1 of the Public Finance Management Act (PFMA). This procurement was not economical\(^2\) and could not be obtained at a reasonable price. The DOD officials failed in their responsibilities to ensure effective, efficient, economical and transparent use of the financial resources of the DOD within their areas of responsibility\(^3\). It is noted that the R35 million paid to the Cuban government for the drug has not been refunded to South Africa.

(gg) The conduct of the former Secretary of Defence, Dr SM Gulube was in contravention of section 38 of the PFMA in terms of the failure to ensure effective, efficient, transparent systems of financial, risk management and internal control. There was a failure to ensure an appropriate procurement and provisioning system which was fair, equitable, transparent, competitive and cost-effective.

(hh) The DOD contravened sections 195(1)(a)(b) and (f) and 217 of the Constitution, Treasury Regulations 16A3, 16A3.2, 16A6.2(b) and 16.A6.4, the DOD Policy “Process and Procedures for procurement and sales in respect of commercial goods and services”, and Article 1 of the bilateral Agreement concerning defence relationships between South Africa and Cuba during the procurement of the drug.

(ii) The conduct of the DOD, in procuring the drug from Cuba constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) and (ii) of the Public Protector Act.

(xii) The appropriate remedial action taken in terms of section 182(1)(c) of the Constitution, is the following:

The Public Protector is empowered in terms of section 182(1)(c) of the Constitution

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\(^2\) PFMA section 38(1)(b)  
\(^3\) PFMA section 45 (b)
to take appropriate remedial action with a view to redressing the conduct referred to in this report where adverse findings are made.

In the matter of the Economic Freedom Fighters v Speaker of the National Assembly and Others: Democratic Alliance v Speaker of the National Assembly and Others the Constitutional Court per Mogoeng, CJ held that the remedial action taken by the Public Protector has a binding effect.

(a) The President of the Republic of South Africa must:

(aa) Take cognisance of the findings of maladministration and improper conduct mentioned in this report, in line with the authority vested on the President, in terms of section 202(2) of the Constitution.

(b) The Minister of Defence and Military Veterans must:

(aa) Take cognisance of the findings of maladministration and improper conduct mentioned in this report, in line with the authority vested on the Minister, in terms of section 202(2) of the Constitution.

(c) The Secretary for Defence must:

(aa) Take note of the Public Protector’s findings, and ensure that as the Accounting Officer contemplated in terms of section 8(a) and (e) of the Defence Act and in line with powers vested on the accounting officer in terms of section 38 of the PFMA issues a directive that any future procurement for DOD is aligned with the requirements of the Constitution, and all applicable provisions of the PFMA, the relevant Treasury Regulations and DOD’s SCM policies. The SecDef must also ensure strict compliance with the provisions of these prescripts and enforce adherence in order to efficiently and effectively manage all the DOD revenue, expenditure, assets and liabilities;

(bb) Within sixty (60) days from the date of this report, initiate an investigation in terms
of section 10 of the Defence Act and take appropriate action in terms of section 8(g) of the Defence Act against the DOD officials involved in the irregular procurement of the drug from Cuba;

(cc) Within sixty (60) days from the date of this report, include in the DOD’s Workplace Skills Plan (WSP) a training programme for functional members dealing with procurement to be trained on the relevant provisions of the Constitution, recent procurement cases done by the DOD wherein maladministration occurred, PFMA relating to procurement and the DOD SCM policies as encouraged by section 2 of the Skills Development Act 97 of 1998;

(d) The Chief of Defence must:

(aa) Take note of the findings of maladministration and improper conduct mentioned in this report and further render the necessary assistance to the SecDef in order to ensure effective implementation and fulfilment of the duties of the SecDef, contemplated in terms of section 9 of the Defence Act. The Chief of the SANDF must also adhere to all the delegated lawful instructions received from the SecDef in terms of section 10 of the Defence Act, relating to disciplinary action or departmental investigations on this matter; and

(bb) Within sixty (60) days from the date of this report and in terms of section 14(i) of the Defence Act, train the relevant members of the Defence Force to act in accordance with the Constitution and the law, including customary international law and international agreements binding on the DOD.
REPORT ON AN INVESTIGATION INTO ALLEGATIONS OF MALADMINISTRATION AND IRREGULARITIES ASSOCIATED WITH THE PROCUREMENT OF UNAUTHORISED MEDICINES FROM CUBA BY THE DEPARTMENT OF DEFENCE

1. INTRODUCTION

1.1 This is a report of the Public Protector issued in terms of section 182(1)(b) of the Constitution of the Republic of South Africa, 1996 (Constitution) and published in terms of section 8(1) of the Public Protector Act 23 of 1994 (Public Protector Act).

1.2 The report is submitted in terms of section 8(1) and 8(3) of the Public Protector Act to the following persons to note the outcome of the investigation and the remedial action taken:

1.2.1 The President of the Republic of South Africa and Commander in Chief of the South African National Defence Force (SANDF), Mr Cyril Ramaphosa;

1.2.2 The Minister of Defence, Ms Thandi Modise;

1.2.3 The Secretary of Defence, Ms Gladys Sonto Kudjoe;

1.2.4 The Chief of the South Africa Defence Force, General Rudzani Maphwanya; and

1.2.5 The Chief Executive Officer of the South African Health Products Regulatory Authority, Dr Boitumelo Semete-Makokotlela.

1.3 A copy of the report is also provided to Mr Sarel Jacobus Francois Marais, the Member of Parliament of the Democratic Alliance political party, who lodged the complaint, to inform him about the outcome of the investigation.
2. **THE COMPLAINT**

2.1 The Public Protector commenced with an own initiative investigation on 17 February 2021. Subsequently, a complaint was received on 19 February 2021 from Mr Sarel Jacobus Francois, the Member of Parliament, Democratic Alliance, who is the Shadow Minister for Defence and Military Veterans (the Complainant), dealing with the same issue as the own initiative investigation into the allegations of maladministration, irregular procurement and expenditure of two hundred and sixty million rand (R260 million) of an unregistered drug from Cuba by the SANDF.

2.2 The own initiative investigation emanated from media reports relating to the alleged irregular procurement and expenditure reported in the *Mail and Guardian* Newspaper dated 22 October 2020, with a story titled “SANDF hid R200m expenditure on ‘Covid’ drug it can’t use”⁴. It was reported in the newspaper article that a member of the SANDF reported the procurement of a drug in excess of R200m on a Cuban Covid-19 treatment, Interferon-Alpha-2B drug that the National Department of Health (DoH) had banned as treatment of symptoms of the virus. It was further alleged that the SANDF had already paid thirty five million rand (R35 million) for 130 000 doses of the drug and was to make another payment of hundred and eighty two million rand (R182 million) for a consignment which had already been delivered to the SANDF.

2.3 According to the report, the SANDF cannot use the drug because it did not make the necessary application to the South African Health Products Regulatory Authority (the SAHPRA) before its procurement. Furthermore, the SANDF allegedly did not capture the procurement on its inventory. The procurement of the drug was allegedly done without following due process.

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2.4 The Complainant alleged the following:

2.4.1 The Department of Defence (DOD) procured the drug in excess of two hundred million rand (R200 000 000.00) on a Cuban Covid-19 treatment, Interferon-Alpha-2B drug, and that the DoH had banned it from being used to treat the symptoms of the Covid-19 virus. The DOD has already paid thirty five million rand (R35 000 000.00) for 130 000 (one hundred and thirty thousand) doses of the drug and was to make another payment of one hundred and eighty two million rand (R182 million) for the consignment which had already been delivered;

2.4.2 The DOD cannot use the drug because it did not make the necessary application to the SAHPRA before its procurement; and

2.4.3 Furthermore, the DOD did not capture the procurement on its inventory. The procurement of the drug was also done without following due process.

3. POWERS AND JURISDICTION OF THE PUBLIC PROTECTOR

3.1 The investigation was conducted in terms of section 182(1) of the Constitution of the Republic of South Africa, 1996 (the Constitution) which gives the Public Protector the powers to investigate alleged or suspected improper or prejudicial conduct in state affairs, to report on that conduct and to take appropriate remedial action; and in terms of section 6(4) of the Public Protector Act 23 of 1994, (Public Protector Act), which regulates the manner in which the powers conferred by section 182 of the Constitution may be exercised in respect of government at any level.

3.2 The DOD is an organ of state and its conduct amounts to conduct in state affairs, as a result of this, the Public Protector is satisfied that the complaint falls within its competency to conduct an investigation as envisaged in section 182(1)(a) of the Constitution and sections 6(4) and (5) of the Public Protector Act.
3.3 Section 6(4)(a) of the Public Protector Act 23 of 1994 (PPA) states amongst others, that the Public Protector shall be competent to investigate on his/her own initiative or upon receipt of a complaint, any alleged act or omission by a person in the employ of government at any level or person performing a public function which results in unlawful or improper prejudice to any person.

3.4 The jurisdiction of the Public Protector was not disputed by the DOD in this matter.

4 THE ISSUE IDENTIFIED FOR INVESTIGATION

4.1 Based on the analysis of the complaint, the following issue was identified to inform and focus the investigation:

4.1.1 Whether the DOD followed a proper procurement process when procuring the drug, and if not, whether such conduct constituted improper conduct in terms of section 182(1) of the Constitution and maladministration in terms of section 6(4)(a) of the Public Protector Act.

4.2 The Public Protector has concluded the investigation and based on the information and evidence obtained during the course thereof, the Public Protector is now in a position to make findings and take appropriate remedial action.

5 THE INVESTIGATION

5.1 Methodology

5.1.1 The investigation was conducted in terms of sections 182 of the Constitution and sections 6 and 7 of the Public Protector Act.

5.1.2 The Public Protector Act confers on the Public Protector the sole discretion to determine how to resolve a dispute of alleged improper conduct or maladministration.
5.2 **Approach to the investigation**

5.2.1 The investigation was approached using an enquiry process that seeks to find out:

5.2.1.1 What happened?
5.2.1.2 What should have happened?
5.2.1.3 Is there a discrepancy between what happened and what should have happened and does that deviation amount to maladministration or other improper conduct?
5.2.1.4 In the event of maladministration or improper conduct, what would it take to remedy the wrong and what action should be taken?

5.2.2 The question regarding what happened is resolved through a factual enquiry relying on the evidence provided by the parties and independently sourced during the investigation. In this instance, the enquiry is whether the DOD failed to follow proper procurement processes when it procured the drug from Cuba during the course of April 2020.

5.2.3 The enquiry regarding what should have happened, focuses on the law or rules that regulate the standard that should have been met by the DOD and officials involved to prevent improper conduct and/or maladministration as well as prejudice.

5.2.4 The enquiry regarding the remedy or remedial action seeks to explore options for redressing the consequences of maladministration, where possible and appropriate.

5.3 **The Key Sources of information:**

5.3.1 Documents, subpoenas, letters and correspondence sent and received:
5.3.1.1 Written complaint submitted by the Complainant on 23 February 2021;
5.3.1.2 Allegations letter submitted to Ms Kudjoe dated 23 February 2021;
5.3.1.3 Ms Kudjoe’s response dated 07 May 2021;
5.3.1.4 Copy of the report dated 14 February 2021, submitted by Lt Gen Mbali;
5.3.1.5 Copies of contract no: TI 17-001 and TI 17-002;
5.3.1.6 Copy of addendum No 10 to the contract *supra* (TI 17-001);
5.3.1.7 Copy of the letter dated 28 July 2020, written by Lt Gen Mbali;
5.3.1.8 Copy of memorandum dated 30 July 2020 with reference number CFO/DBC/R/504/3/1;
5.3.1.9 Subpoena sent by the Public Protector to Lt Gen Mbali dated 14 June 2021;
5.3.1.10 Affidavit received by the Public Protector from Lt Gen Mbali dated 19 August 2021;
5.3.1.11 Copy of the report received from Major General NP Maphaha dated 23 February 2021;
5.3.1.12 Copy of the report received from Major General LC Ford dated 28 September 2020;
5.3.1.13 Subpoena sent by the Public Protector to Ms Nangamso Tyibilika dated 14 June 2021;
5.3.1.14 Affidavit received from Mr Eric Siphiwe Sokhela dated 1 July 2021;
5.3.1.15 Copy of the submission received from Major General XB Ndlovu dated 8 April 2021;
5.3.1.16 Letter dated 20 July 2021, submitted to Ms Kudjoe from the PPSA;
5.3.1.17 Copies of the Military Command Council (MCC) minutes dated 30 March 2020 to 7 September 2020;
5.3.1.18 Affidavit from Surgeon General Z Dabula dated 25 August 2021;
5.3.1.19 Affidavit from Doctor JT Mnisi dated 26 August 2021;
5.3.1.20 Copy of the report dated 8 June 2020 written by Major General M Radebe;
5.3.1.21 Copy of the letter dated 18 August 2021 written by Ms Kudjoe;
5.3.1.22 Copy of the Auditor General South Africa special report with reference number RP431/2020;
5.3.1.23 Letter dated 11 March 2021 submitted to Dr Boitumelo Semete-Makokotela from the PPSA;
5.3.1.24 Response received from Dr Semete-Makokotlela dated 13 April 2021;
5.3.1.25 Letter dated 10 December 2021 submitted to Dr Semete-Makokotlela from the Public Protector;
5.3.1.26 Response received from Dr Semete-Makokotlela dated 17 December 2021;
5.3.1.27 Subpoena sent by the Public Protector to General Solly Shoke (ret) dated 31 January 2022;
5.3.1.28 Subpoena sent by the Public Protector to Ms Nosiviwe Mapisa-Nqakula, the former Minister of Defence dated 31 January 2022;
5.3.1.29 Affidavit received from Ms Mapisa-Nqakula dated 3 February 2022;
5.3.1.30 Affidavit received from General Shoke (ret) dated 14 February 2022;
5.3.1.31 Statement of General Maphwanya dated 17 May 2022;
5.3.1.32 Further explanatory affidavit dated 27 May 2022 by General Shoke (ret).
5.3.1.33 Statement submitted by Lt Gen Mbuli dated 13 June 2022;
5.3.1.36 Copy of letter written by Lt Gen JS Mbuli with reference number LOG DIV/R/501/16/2/3 dated 23 February 2022;
5.3.1.37 Statement of Dr Joseph Thabo Mnisi dated 14 June 2022;
5.3.1.38 Statement of Lt Gen Maphaha dated 10 June 2022; and
5.3.1.39 Statement of the former SG, Zola Wiseman Songo Dabula dated 20 June 2022.

5.3.2 Meetings/Interviews/Subpoena hearings:

5.3.2.1 Subpoena hearing held on 28 June 2021 with Ms Tyibilika;
5.3.2.2 Subpoena hearing held on 12 July 2021 with Ms Kudjoe, General Mnisi, General Ndlovu and Major General Tyhalisi;
5.3.2.3 Subpoena hearing held on 13 July 2021 with Mr Sokhela;
5.3.2.4 Subpoena hearing held on 16 August 2021 with Lt Gen Mbuli;
5.3.2.5 Subpoena hearing held on 25 August 2021 with the SG, Colonel (Dr) Joseph Thabo Mnisi and Major General Mnisi;

5.3.2.6 Meeting held with Major General E Mnisi and Brig General CS Mhlauli on 8 June 2022;

5.3.2.7 Meeting held with Lt Gen Mbali, C Log, Lt Col NH Masithi, Captain TE Banda (legal) and Major JP Mashike (legal) on 9 June 2022;

5.3.2.8 Meeting held with Doctor Joseph Thabo Mnisi 9 June 2022;

5.3.2.9 Meeting held with Lt Gen Maphaha on 10 June 2022;

5.3.2.10 Meeting held with General Maphwanya, the Chief of Defence and his team comprising of Major General E Mnisi and Brig General CS Mhlauli on 13 June 2022;

5.3.2.11 Meeting held with the former SG Zola Wiseman Songo Dabula on 20 June 2022;

5.3.3 Legislation and other legal prescripts:

5.3.3.1 The Constitution of the Republic of South Africa, 1996;

5.3.3.2 The Public Protector Act No. 23 of 1994;

5.3.3.3 The Public Finance Management Act No.1 of 1999 (PFMA);

5.3.3.4 The Defence Act No. 42 of 2002;

5.3.3.5 Treasury Regulations issued under the PFMA, March 2005;

5.3.3.6 National Treasury instruction No 3 of 2020/2021; and

5.3.3.7 Medicines and Related Substances Act No.101 of 1965.

5.3.4 Case law considered:

5.3.4.1 Economic Freedom Fighters v Speaker of the National Assembly and Others; Democratic Alliance v Speaker of the National Assembly and Others 2016 (5) BCLR 618 (CC); 2016 (3) SA 580 (CC);

5.3.4.2 President of the Republic of South Africa v Office of the Public Protector and Others (91139/2016) [2017] ZAGPPHC 747; 2018 (2) SA 100 (GP); [2018] 1 All SA 800 (GP); 2018 (5) BCLR 609 (GP) (13 December 2017); and
5.3.4.3 Allpay Consolidated Investment Holdings (PTY)Ltd v Chief Executive Officer of the South African Social Security Agency (No 1) (CCT 48/13) [2013] ZACC 42; 2014 (1) SA 604 (CC).

5.3.5 Notices issued in terms of section 7(9) of the Public Protector Act to the following parties for a response:

5.3.5.1 President Ramaphosa on 25 October 2021. He did not respond to the notice;

5.3.5.2 The SecDef on 25 October 2021. She responded on 24 November 2021; and

5.3.5.3 General Rudzani Maphwanya, on 25 October 2021. He did not respond to the notice.

5.3.5.4 A supplementary notice in terms of section 7(9) of the Public Protector Act, was issued on 28 April 2022 to the SecDef, General Solly Zacharia Snoke (ret), General Rudzani Maphwanya, Lieutenant General Jabulani Sydney Mbuli, Lieutenant General ZWS Dabula, Major General NP Maphaha and Colonel (Dr) Joseph Thabo Mnisi. The SecDef did not respond to the supplementary notice and all the listed SANDF officials responded during May and June 2022 respectively.

6 THE DETERMINATION OF THE ISSUES IN RELATION TO THE EVIDENCE OBTAINED AND CONCLUSIONS MADE WITH REGARD TO THE APPLICABLE LAW AND PRESCRIPTS

6.1 Regarding whether the DOD followed a proper procurement process when procuring the drug, and if not, whether such conduct constituted improper conduct in terms of section 182(1) of the Constitution and maladministration in terms of section 6(4)(a) of the Public Protector Act
Common cause issues

6.1.1 The DOD procured approximately nine hundred and thirty nine thousand five hundred and twenty eight (939 528) vials of the drug from Cuba during April 2020, which would have expired in March, April and July 2022 respectively.

6.1.2 The total cost for the procurement of the drug was approximately (two hundred and seventeen million rand (R217 million) and as at the date of this report, the DOD had paid approximately thirty five million rand (R35 million), with an outstanding balance of approximately one hundred and eighty two million rand (R182 million) still to be paid to Cuba for the drug.

6.1.3 The DOD did not obtain prior approval from the SAHPRA for the importation of the drug into South Africa. The DOD confirmed that the drugs were returned to Cuba on 20 January 2022 and 17 February 2022 respectively.

Issues in dispute

6.1.4 The issue for the Public Protector’s determination is whether the DOD followed a proper procurement process when procuring the drug from Cuba during April 2020.

Evidence and information obtained to make a determination

6.1.5 On 23 February 2021, an allegations letter relating to the matter was submitted by the Public Protector’s investigation team to the SecDef, seeking clarity and a response on the matter.

6.1.6 On 7 May 2021, the SecDef responded through a letter, with reference number CDLS/C/1/505/6/4, dated 30 April 2021 and stated, inter alia, that the DOD did not follow any tender process for the procurement of the drug. Furthermore, the SecDef indicated that it should be noted that she assumed the role of the
DOD accounting officer “with effect from 3 August 2021” (sic). Her date of assumption was corrected in her further response as 3 August 2020.

6.1.7 In a further effort to respond adequately to the allegations, the SecDef decided to avail to the investigation team, all the relevant Chiefs and Heads of various DOD services, with the view that each should explain their role during the procurement of the drug.

6.1.8 As a result, several subpoena hearings were held with the following specified officials from the DOD to respond to the allegations:

Lieutenant General Jabulani Sydney Mbuli (Lt Gen Mbuli), the DOD Chief of Logistics:

6.1.9 Lt Gen Mbuli submitted a report dated 14 February 2021, in his capacity as the DOD Chief of Logistics (C LOG) with reference number LOG DIV/C/506/2, wherein it was stated, inter alia, that the South African and Cuban governments have a bilateral agreement regulating defence relationships. Lt Gen Mbuli stated that the DOD has a contract with the Cuban Department of Defence to provide professional and technical services under contract no: TI 17-001, as well as a contract to provide services of vocational training, under contract no: TI 17-002, with the Cuban Department of Defence.

6.1.10 The report by Lt Gen Mbuli further indicated that both these contracts were signed on 18 August 2014. Supplement No: 10 of contract no: TI 17 001 for the delivery of interferon in South Africa was signed by the Chief of the South African National Defence Force (SANDF) on 28 April 2020 which was a day after the delivery. According to the report of Lt Gen Mbuli there were twenty nine (29) Cuban military medical officers who arrived in South Africa on 27 April 2020 with the drug from Cuba and the emphasis was that there was no need for the SANDF to embark on a procurement process to acquire this medical service because it was and still is a requirement of the extension of the existing service contract between the two (2) defence forces. (Own emphasis added)
6.1.11 A copy of contract No: TI 17-001 SUID AFRICA referred to above by Lt Gen Mbuli was perused by the Investigation team and the following was noted:

(i) It was a contract between Cuba and South Africa to “Provide Professional and Technical Services”. The contract was not dated and did not have a start and end period.

6.1.12 A copy of supplement or addendum No: 10 to the contract to “Provide Professional and Technical Services” supra, was also perused by the Investigation team and the following was noted:

(i) This was a supplement or addendum to the first contract and its purpose was to render professional services in the sector of “Tanks and Transports, the Aviation and Medical Services”. Paragraph 6.2 of the contract refers to a product that will be delivered as produced under the commercial mark HEBERON ALFA R. According to the contract it was signed on 28 April 2020 and was signed in Havana, Cuba by the Cuban General Director, Mr Heriberto Sanchez Alleyne, representing Technoimport and General Solly Zacharia Shoke, representing the SANDF.

6.1.13 A copy of a letter dated 28 July 2020, written by Lt Gen Mbuli, requesting funding from the Chief Financial Officer (CFO) as per reference number LOG DIV/R/504/3/1 (20/21) was also provided to the Investigation Team. The letter referred to, inter alia, a meeting held on 02 June 2020 between the C LOG and the CFO. In the letter, the Logistics Division requested a total of R182 million to procure Interferon Alfa medicine (2nd and 3rd shipment) from Cuba. Lt Gen Mbuli further stated in the letter that Invoice S-0082 from Technoimport was submitted for payment and that the requirement was approved by means of Supplement No. 10 of the OP THUSANO contract TI 17-001 between the DOD and Cuba. (own emphasis added)

6.1.14 A copy of the memorandum (memo) dated 30 July 2020, with reference number CFO/DBC/R/504/3/1 was also perused. The memo referred to, inter alia, the letter dated 28 July 2020, supra, with the heading “Funding request for the procurement of PPE’s, other related equipment and inventory in support of OP Notlela-Logistics Division”. According to the memo, the C LOG
requested an amount of R182 million to procure the drug from Cuba. It was further stated that this was **not recommended** by the DOD Chief Director Budget Management, Ms N Tyibilika, with the reason provided: “**Not included in the original budget estimate**” and was also not approved by Mr Eric Siphiwe Sokhela, the DOD CFO. (Own emphasis added)

6.1.15 On 16 August 2021, a subpoena hearing was held at the Public Protector’s office with Lt Gen Mbuli where he stated, *inter alia*, that:

6.1.15.1 There is the Military Command Council (MCC) which is chaired by the Chief of the Defence Force and he (Lt Gen Mbuli) is the staff officer under the Chief;

6.1.15.2 During March 2020, the DOD was faced with the Covid-19 pandemic and was the last line of defence;

6.1.15.3 The DOD had bilateral agreements with the defence forces of China and Cuba and due to the experience of the armed forces of Cuba in dealing with the pandemic, the DOD requested from Cuba and China the medication they used in the fight against the Covid-19 pandemic, which information was conveyed to Surgeon General Z Dabula (SG);

6.1.15.4 The procurement of the drug came about when the SG had a discussion with the doctors from China and Cuba and **that the SG briefed the MCC, which then took a decision to purchase the drug.** He further mentioned that he, as the staff officer, implemented the decision and that there was at that stage a contract with Cuba;

6.1.15.5 The DOD decided that the C LOG would proceed with the procurement of the drug, which decision was implemented by the C LOG. The MCC had taken the decision on the efficacy of the drug against the Covid-19 virus after the briefing by the SG. He said that it was the same drug that the Cubans used when they reported to have worked in other countries. According to him, the C LOG was servicing the Cuba contracts, hence this procurement fell under the same contract;
6.1.15.6 Everything in South Africa at the time of the pandemic was done as an emergency. He indicated that his role as the C LOG was to bring the Cuban drug into the country and that was the reason his Division paid for it. According to him, the only thing they had available at the time, was the contract with Cuba and it was on those grounds that they brought the drug into the country. The details regarding the choice and procurement was done by the SG. He said that he only approved the invoice as per his C Log Finance Committee. (own emphasis) He reported that the DOD paid R35 million for the first batch of 130 000 doses. He further said that the DOD was supposed to pay R185 million more, but payment had not been processed at the date of his report;

6.1.15.7 The DOD received two (2) more batches which they still had to pay for at the date of his report;

6.1.15.8 He used his budget which the SG was supposed to refund. He said that his Division no longer has more budget to pay the remainder of the funds owed to Cuba. The second consignment had 709 594 doses and the third, 131 101 doses. He said that the expiry date for the drug, as per the SG, was in April 2022. According to him, the drug was procured as an emergency. He indicated that the SG worked out the calculation of the amount of the drug. As of the date of his report, Cuba had been demanding the remainder of the payment for the drug procured, which was R185 million. (Own emphasis added); and

6.1.15.9 The procurement of the drug was done prior to the submission of the application to the SAHPRA. He also referred to the Cuban doctors who arrived in SA, who, according to him, tested negative to Covid-19 because of the drug. He believed that they were faced with an emergency situation and the decision they took to purchase the drug at the time was correct. In conclusion, he stated that the C LOG did what the collective (MCC) tasked them to do. (Own emphasis added)
Furthermore Lt Gen Mbuli submitted an affidavit relating to the investigation dated 19 August 2021 in which he stated the following inter alia:

“… After the outbreak of the corona virus and the order by the President that the SANDF should be deployed in support of the South Africa Police Services (SAPS) to ensure that the lockdown measures are implemented countrywide in order to mitigate the spread of the virus, the MCC has been monitoring the situation and continuously received briefings from SAHMS. Based on epidemiological predictions on the spread of the corona virus among the military communities, the MCC instructed SAHMS to contact other militaries in the world for possible availability of any medical products that may be used to mitigate its spread in the SANDF as soldiers were among those who were deployed on the frontline in the fight against the pandemic.

The SG of the SAHMS is responsible for the force protection, the combat readiness as well as the health services of deployed soldiers. Subsequently SAHMS advised the MCC that there is medication that can be used to limit the spread of the virus among SANDF members. SAMHS recommended interferon B used by the Cuban government.

The MCC based on the recommendation by SAMHS, then decided that the only intervention that was available for the force protection of our vulnerable deployed soldiers against corona virus was to acquire interferon B as an immune booster to mitigate the wide spread of the virus amongst SANDF members. This requirement was an emergency as it was a matter of life and death for our deployed soldiers. The only possible quicker avenue available at the disposal of SANDF at that time was to acquire interferon B was through existing bilateral agreement between RSA and Cuba. The SA government and the Cuban government have bilateral agreement on defence to defence relationship. Subsequent to this agreement, Project Thusano was born and placed under the control of Logistics Division with its main function to facilitate services that ought to be provided to both countries on specific professional and technical services required by each country. The SA DOD has contract No
TI 17-001-SUID AFRICA tomprovide professional and technical services and contract No. TI 17-002-SUID AFRICA to provide services of vocational training with the Cuban Department of Defence. Therefore it was under this bilateral agreement, specifically Project Thusano that interferon B was delivered to South Africa. It should also be noted that Logistics Division is only involved with purchases internally, within the country and not external purchases.

Invoice for medication was forwarded through the office of the Chief of the SANDF to Logistic Division. The Logistic Division Finance Committee took a decision to make payment thereof, using Project Thusano funds as supplement number 10 for medication. The payment which was made through Project Thusano was as a result of the bilateral agreement between the SA government and Cuban government, which includes the Defence to Defence co-operation. Later it was rectified that the funds to be used be the Ops Notlela funds and not Project Thusano funds…" (sic)

Report of Major General NP Maphaha, the DOD Chief Director Military Health Force Preparation:

6.1.17 Major General NP Maphaha (Gen Maphaha) submitted a report dated 23 February 2021, in his capacity as the DOD Chief Director Military Health Force Preparation with reference number SG/CDMHFP/IGSAMHS/AGSA/505/1/3, wherein it was stated, inter alia, that at the beginning of the Covid-19 pandemic, there was no single drug that could cure Covid-19. According to the report of Gen Maphaha, all possible treatment options were experimental in terms of the novel. Gen Maphaha said that the Cuban drug was found to be potentially useful as it offered protection to the Cuban medical personnel deployed at different hotspots globally. According to Gen Maphaha, it was then decided that since the SANDF was going to be deployed in hotspots, the drug could be the best medication to boost the body’s immune system, as the Covid-19 virus was known to target natural Interferon. Over 900 000 vials were procured.
Submission of Major General LC Ford, the DOD Chief Director Military Health Force Support (Maj Gen Ford)

6.1.18 In response to a subpoena dated 13 May 2021, Maj Gen Ford submitted a report with reference number SG/CDMFFS/C/505/17/6, dated 28 September 2020, in his capacity as the DOD Chief Director Military Health Force Support, wherein he stated the following, *inter alia*:

6.1.18.1 That the South African Military Health Service (SAMHS) was presented with invoice No. TEC 002/2020 to the value of two million and eighty United States dollars ($2 080 000.00) but rejected the responsibility for the payment thereof on the basis that the unexpected delivery of the drug did not form part of the foreseen treatment protocols for Covid-19 and that the SAMHS would not be in a position to do so as the drug was not registered for use by the SAHPRA. (Own emphasis) Maj Gen Ford said that the Logistics Division paid the invoice in the amount of R35 262 500.00 against financial authority 12298052. Subsequently, second and third shipments of the drug were delivered to the Military Health base depot at a potential cost of R182 908 497.41;

6.1.18.2 That it was not clear who created the demand for the drug and it was understood that the said requirement was not initiated by the SAMHS. “*This would make sense as the drug is not SAHPRA approved for use within South Africa. A post facto application had been made to SAHPRA for the first batch of Interferon as at the date of this report*”; and

6.1.18.3 That the Logistics Division approached the CFO for funding for the second and third batches, but this was declined. Maj Gen Ford reported further that the system of financial management and internal control established for the DOD required that no contract, or extension thereof, can be entertained without the commensurate funding having been secured prior to contractual agreement or receipt of the goods. (Own emphasis added)
Submission of Ms Nangamso Tyibilika, Chief Director: Budget Management (Ms Tyibilika)

6.1.19 On 27 May 2021, Ms Tyibilika responded to the subpoena and stated, *inter alia*; that she was employed by the DOD as the Chief Director: Budget Management. Ms Tyibilika said that she was not involved in the procurement of the drug from Cuba. Ms Tyibilika indicated that she played no role in the matter at all. Furthermore, Ms Tyibilika stated that she was advised that Invoice S-0080 for USD 2 015 000.00 was paid and that Invoices S-0082 for USD 10 998 707 and S-0086 for USD 2 032 065.50 were outstanding and not paid by the DOD.

6.1.20 On 28 June 2021, a subpoena hearing of Ms Tyibilika was held at the Public Protector’s Office. Ms Tyibilika stated, *inter alia*, that when the Covid-19 pandemic started, a list of items and budget that were going to be procured were submitted to the National Treasury (NT). According to Ms Tyibilika, the request was for the funds for Operation Notlela (code name for COVID by the DOD). The NT allocated R3 billion to the DOD for this operation. Ms Tyibilika confirmed that the drug was not on the list and she stated that their unit was not involved in the procurement of the drug and that the procurement was done by the Chief of Logistics, using its own budget. Ms Tyibilika further indicated that she has no control on how a particular division spends its own budget.

6.1.21 According to Ms Tyibilika, the Logistics Division had already paid approximately R35 million for the drug at the date of her report. Ms Tyibilika reported that when the Chief of Logistics requested approval of further funds amounting to approximately R182 million, she did not recommend approval as this was not in the NT list. (own emphasis added)

Submission of Mr Eric Siphiwe Sokhela, Chief Financial Officer (Mr Sokhela)
6.1.22 An affidavit dated 01 July 2021, was received from Mr Sokhela, who stated, \textit{inter alia}, that his duties and responsibilities relate to financial management in the whole of the DOD. He said that unlike other departments, the responsibilities of the CFO in the DOD excludes the supply chain management. The procurement of goods and services falls under the DOD Logistics Division. Mr Sokhela said that he was not involved in the procurement of the drug from Cuba and did not have any information regarding the procurement process that was followed. (Own emphasis) According to Mr Sokhela, the total amount spent on the procurement was R33 496 973.60.

6.1.23 On 13 July 2021, a subpoena hearing was held at the Public Protector office with Mr Sokhela and he confirmed what is contained in his affidavit. Mr Sokhela explained that the CFO also deals with payments, in that he only pays once the end user has confirmed that the service has been rendered. Mr Sokhela said that his office also deals with the Auditor General of South Africa (AGSA) and risk management within his division. Mr Sokhela indicated that he is not consulted when procurement takes place in the various DOD units. (Own emphasis)

6.1.24 With reference to the procurement of the drug, Mr Sokhela indicated that he had no knowledge of how it was procured and he said that each unit is responsible for its own budget and procurement. According to Mr Sokhela, if a unit exceeds its budget, it may request further funds from the CFO who may allocate more funds or decline the request. With reference to the procurement of the drug, Mr Sokhela said that the Chief of Logistics was the one responsible. Mr Sokhela said that as the CFO, he did not know anything about the procurement of the drug. Mr Sokhela explained that the reason that he did not approve further funds to the C LOG for the procurement of the drug was because he could not buy the drug if his Division did not have a budget for it. (Own emphasis added)

Submission of Major General XB Ndlovu, Logistics (Maj Gen Ndlovu)
6.1.25 During the first week of July 2021, a submission dated 8 April 2021 regarding the allegations was received from the Chief Logistics, compiled by Maj Gen Ndlovu which stated, *inter alia*, that the procurement of the drug was under a bilateral agreement between the South African and Cuban governments on defence to defence relations. No tender process was entered into for the procurement of the drug due to the bilateral relationship.

*Additional evidence obtained from the DOD*

*Subpoena hearing of the SecDef and DOD team*

6.1.26 On 12 July 2021, a subpoena hearing of the SecDef, Adjutant General Major General Mnisi (Legal: DOD), General Ndlovu (Logistics: DOD), Major General Tyhalisi (Projects: DOD) was held at the Public Protector’s office. The DOD team discussed the process followed and the background to the procurement. They stated, *inter alia*, that procurement in the DOD is conducted by the Logistics Division and done in terms of the Public Finance Management Act, 1999 (the PFMA). They further stated the following:

6.1.26.1 The DOD has a bilateral agreement or Memorandum of Understanding (MoU) with Cuba signed in 2012. Due to the Covid-19 pandemic, the DOD was ordered during March 2020 to assist other law enforcement agencies to ensure that the public complied with the Covid-19 Regulations. According to the DOD team, this order was taken to the highest decision making body in the SANDF, the MCC, which had to ensure the deployment of the army across the country. They advised that the MCC also had to address the safety and protection of the force and this was by means of providing Personal Protective Equipment (PPE) and medical protection. According to the DOD team, the MCC took a decision to instruct the SAMHS to find the means to protect the members during this deployment. They reported that the SAMHS had to research what could be used for Covid-19 and it found that in Cuba, the drug was available and was presented to the MCC; (Own emphasis added)
6.1.26.2 The DOD relied on Articles 3 and 6 of the MoU to obtain the drug and a contract, thereafter, followed between the two (2) countries to procure it, hence in this case, the normal procurement process was not followed;

6.1.26.3 That based on this MOU, the DOD felt that they did not have to follow the normal procurement process because at the time, the drug was seen as a strong immune booster that was used in various countries. The team explained that the DOD went on the strength that the drug was used by other countries and that it was recognized by the World Health Organization (WHO). The team further reported that the SAMHS recommended the use of the drug and it (SAMHS) applied for the registration for the use of the drug with the SAPHRA. It was reported that the drug was bought on the principle of necessity, which is being used for research purposes. The DOD team confirmed that nearly R38 million has been spent already in the purchase of the drug. (Own emphasis added)

**Minutes of the MCC**

6.1.27 On 20 July 2021, a letter from the Public Protector's Investigation Team was forwarded to the SecDef which requested, amongst others, copies of the minutes of the MCC's meetings regarding the procurement of the drug.

6.1.28 On 10 August 2021, the Adjutant General, Major General EZ Mnisi, provided extracts of the MCC minutes related to the procurement. The minutes stipulate the following:

6.1.28.1 The MCC minutes dated 30 March 2020 stated, *inter alia*, that the Chief of the SANDF confirmed that both China and Cuba were ready to support South Africa. The MCC directed that Cuba and China were officially requested to assist the SANDF in terms of an immune system booster, protective and medical equipment and skilled personal. The Chief of the SANDF reported that an immune booster (Interferon) was being utilised in Italy. The A/SG agreed that the drug will be obtained and utilised in the SANDF;
6.1.28.2 The MCC minutes dated 2 April 2020 stated, *inter alia*, that the A/SG confirmed the urgent requirement to collect the drug from Cuba as the SANDF treatment. **He indicated that the drug was not part of the National Treatment Protocol** (Own emphasis added);

6.1.28.3 The MCC minutes dated 13 July 2020 stated, *inter alia*, that the SG confirmed that there was no SAHPRA accreditation for the medication. (Own emphasis added);

6.1.28.4 The MCC minutes dated 16 July 2020 stated, *inter alia*, that the SG again indicated that the medication was not accredited by the SAHPRA. The Chief of the SANDF indicated that the SANDF is not subject to the accreditation of the SAHPRA and confirmed that the drug is approved by WHO. (own emphasis added);

6.1.28.5 The MCC minutes dated 20 July 2020 stated, *inter alia*, that the CFO advised that funds must be obtained to pay the invoice of R180 million. No financial authority was granted; (Own emphasis added);

6.1.28.6 The MCC minutes dated 24 July 2020 stated, *inter alia*, that the SG reported that the Cuban and SAMHS experts met on 24 July 2020 to agree on a joint clinical protocol for the administering of the drug. In response to the Chief of the SANDF’s concerns, the SG explained that the SAMHS cannot administer the drug without any clinical basis. The Chief of the SANDF enquired why the administration related to the drug was not confirmed before the medication was ordered. **The SG confirmed that the required clinical protocol had not been confirmed before the medication was ordered:** (Own emphasis added);

6.1.28.7 The MCC minutes dated 3 August 2020 stated, *inter alia*, that the SG reported that the drug was not registered in South Africa as a treatment for the Covid-19 virus. However, he confirmed that the registration process was being pursued. The Chief of the SANDF questioned why the SAMHS ordered the drug, but refused to administer it. **The CHR summarised that the drug had**
been ordered on the advice of the SG and the SAMHS. He said that **the procedural and legal issues should have been addressed before the medication was ordered.** The CHR also explained **the predicament of medical practitioners who have to adhere to professional regulatory legislation and bodies** while adhering to the MCC instructions. (Own emphasis added);

6.1.28.8 The MCC minutes dated 3 September 2020, stated *inter alia*, that the SG reported that the SAHPRA had turned down the Section 21 application based on the requirement for a name list of the members who would be treated with the drug. The SAMHS was awaiting approval for the research proposal. (Own emphasis added); and

6.1.28.9 The MCC minutes dated 7 September 2020 stated, *inter alia*, that the SAMHS was awaiting approval for the research proposal. The SG pointed out that the research proposal will require minimal vaccines and he anticipated that only 5000 doses would be used for research purposes and other medication. He said that the bulk of the vaccines would, probably, expire. In response to PMG’s questions on the related costs and decisions, the SG concurred that an investigation was required into the decision to order the vaccines and the reasons why the medication cannot be administered as Covid-19 treatment. The SG said that the SANDF was not working in isolation as far as health matters are concerned and that contravention of the National Health Regulations constitutes medical malpractice. He said that a formal investigation will get to the truth of the matter. The IG enquired if other countries use the drug as an antidote against Covid 19, IG also enquired on the involvement of the DoH. The SG confirmed that the DoH process to evaluate medication is standardised and that the DoH does not recommend the use of the drug as a Covid-19 treatment. (Own emphasis added).

**South African Military Health Services (SAMHS)**

6.1.29 On 25 August 2021, a subpoena hearing was held at the Public Protector’s office with the SG, Colonel (Dr) Joseph Thabo Mnisi and Major General Mnisi.
The discussions at the hearing are set out below by their statements and supporting documents provided:

**The former Surgeon General, Lt General (Dr) Dabula (ret)**

6.1.30 On 25 August 2021, the former SG submitted a statement relating to the investigation which stated, *inter alia*, that towards the end of March 2020, he was sent to Cuba to address issues pertaining to the South African students doing military medical studies in that country. During this visit, the Cuban authorities invited him to a plant that was producing Interferon, the drug in question. The indication was that, in all the countries that had requested assistance from Cuba to fight the disease, they used the drug to prevent Covid complications. According to the former SG, he advised the MCC that given the circumstances on the ground, the SANDF could use the drug to protect the soldiers from the adverse effects of possible infection during deployments. The procurement of all the assets needed for this operation was given to the C LOG.

6.1.30.1 The former SG stated that the first consignment arrived on 27 April 2020. He said that he was assured that all the necessary and required processes for the procurement of the consignment were followed. He reported that it was only after a number of months that it was discovered that certain steps had been regrettably missed in the process. He explained that these were the registration of the drug for use in the SANDF community, with the relevant regulatory authority. According to him, the SAMHS was not well equipped with the management of the process of procurement of drugs from outside the country since their military to military co-operation, with outside fraternal bodies had been through the exchange of training of military health forces.

6.1.30.2 It was the former SG’s evidence that the drug was stored at the ‘*military health base depot*’, until the matter was resolved. He indicated that the regulatory authority gave them the conditions that must be fulfilled, prior to the administration of the drug to patients.
Colonel (Dr) Joseph Thabo Mnisi

6.1.31 On 26 August 2021, Dr Mnisi provided a statement relating to the investigation which stated, *inter alia*:

6.1.31.1 That he began interactions with his military counterparts on strategies, prevention and treatment options, internally and externally, including specialists from China, Vietnam and Cuba. According to statement of Dr Mnisi, the drug, as a protection agent not a Covid Pneumonia treating drug, was chosen as a suitable immune-modulator for deploying soldiers and was procured from Cuba by the Military in 2020, as an emergency response for the South Africa’s own force protection. Furthermore, he indicated that the use of this medicine was successful on one patient who was treated on the section 21 application with the SAHPRA.

6.1.31.2 Dr Mnisi advised that there was an ongoing dialogue between the SAHPRA and SAMHS regarding the use and registration of this drug. According to Dr Mnisi, a decision was taken to agree on the use in research so that it does not go to waste.

6.1.32 Attached to Dr Mnisi’s statement *supra*, was a document labelled Annexure (C) with the heading “Q & A on interferon”. The following paragraphs of importance are listed below *inter alia*:

“…What was the need analysis on procurement of these drugs?

*At the beginning of covid 19 pandemic, there was no single drug that could cure covid 19. All drugs were experimental. Force protection became the best option against a pandemic that had no cure by admission of experts and available evidence then. Additional biological measures to supplement known etiquettes such as sanitization, social distancing, cough etiquettes and others in the absence of credible vaccine were explored. We looked into what countries that seemed to have lower mortality rates per 1000 were using. The Cuban interferon was found to be potentially useful as it offered protection for*
Cuban medical personnel deployed at different hotspots globally. We felt that since we were going to be deployed in hotspots, we needed interferon boost as the virus is known to target natural interferon. (sic)

What was urgent about procuring such a huge consignment at once?

The interferon and other covid 19 related drugs where sought after by many countries affected by the pandemic. It was during the time Zinc and Chloroquine were procured by other countries in such large quantities that they were scarce. It was imperative then in March 2020 with borders closing and China procuring Cuban interferon in large quantities to procure the drug before it is either not available or escalate in price due to demand. The Cuban Medical brigade also requested to be deployed with the medication they best know how to use and have proven efficacy in prevention worsening of symptoms in covid 19 infection. (sic)

Over 900 000 vials were procured, what was the rationale for such quantities?

Heberon R confers protection after administration of 10 vials per individual over 10 days. This needs to be repeated after six months for the duration of the pandemic to maintain optimum interferon levels. Our active force members bit uniformed and PSAPS, reserve force members and our VPA members and other SAMHS beneficiaries who will need interferon boosting are well above what could be procured at the time. This could only cover 23 000 members active and call-ups for a period of 2 years with consistent cover. The total number of SAMHS beneficiaries stands over ten times this figure at above 230 000. With procured figures we could prioritize active members and call-ups up to 23 000 for the first two years of the pandemic. (sic)

How much has been administered to date and has it been beneficial?
10 vials were administered on a patient, and the patient fully recovered without any complications within 7 days if its administration, in that he regained energy and symptoms disappeared. We regard this as beneficial. (sic)

Did the procured drugs serve the need, and what impact did they have on the soldiers?

Psychologically the morale of the soldiers was heightened by the awareness of available protective drugs, the impact could have been more positive with fewer sick leave days had we been granted bulk approval for military use. The impact was going to be financially positive as our soldiers were needed during operations like notlela and in assistance to NDoH. (sic)

How is the drug administered and stored?

One vial of 5 MU Heberon R is diluted with 2ml of saline and sprayed nasally with a syringe daily over 10 days. It is stored and transported at 2 to 8 degrees Celsius. (sic)

Was SAHPRA approval obtained prior to importation and transportation to the depot?

The SANDF understanding at the time was that due to the State of Disaster Declaration and shared information on intention to use a number of drugs on emergency basis as lockdown was at level 5, SAHPRA would clear emergency procured drugs upon application of section 21 of act 101 of 1965. It became apparent to SANDF that the normal application processes which included section 22 of the aforementioned act ought to have been fully explored irrespective of the urgent state it found itself as many sectors were either shut or working with skeleton staff. However normal port of entry requirements and clearing at Airport with complied with. The Cold chain and handling of the drug were fully complied with in a joint effort of Pharmacists
and Medical Logistics personnel. The integrity of the drugs was protected. (sic)

It was reported in the AG interim report and media that about 40% of the consignment could have been potentially be destroyed, how did this come about?

SAHPRA came to inspect the consignment more than once and even took samples for testing. None of our drugs were damaged in any manner as we monitor conditions under which they are stored according to manufacturer’s specifications. Access is controlled by high security and multiple entry gates and doors with keys to each held by separate personnel. We are open to further sample testing to disprove this false and unfortunate assertion. (sic)

SAHPRA says they disapproved your application, what is your comment?

SAHPRA was engaged several times the first approval was sent back as it had no specific name of patient…a resubmission was approved with a patient name for 10 vials dated 05/10/2020. Subsequent bulk approval was rejected on basis inadequate data of individual patient application of section 21. Further section 21 reapplications on individual patients needing the medication on same basis as the approved one were sent to SAHPRA and no replies were received…further contact via emails and telephone calls enquiries drew blank to date. (sic)

How does the SANDF intend to use Heberon R and who will administer it?

The SANDF intends to smooth relations with SAHPRA through dialogue and optimise communication with the NDoH at all levels in order to utilize the Medication for Force Protection before the onset of the 3rd wave of the pandemic so that soldiers can be healthy to support the government whenever required. (sic)
Was there consultation and interaction with others including NDoH and support within SAMHS?

Two webinar clinical discussions were held with Cuban Specialist, 1 was held with China and another with Vietnam. The NDoH was invited to the Cuban webinar but could not attend. SAMHS had informal interaction with NDOH at Ministerial level on interferon. The national protocols did not have a position on the use of interferon for immunomodulation but encouraged clinical trials on its use beyond Hospitalized patients where consensus remains undisputed. Within SAMHS the responsible clinical department with Cuban outreach and Preventative Medicine in covid 19 outside hospital. The Department of Family Medicine and Primary Health Care is fully behind its use and is in the forefront of development of its clinical trials and section 21 applications. (sic)

What is SAMHS position regarding the SAHPRA mandate and Authority?

SAMHS observes all governing institutions and regrets not having representation in some of these bodies to be abreast and update legal requirements as contemplated in the uniquely challenging and austere military environment. SAMHS would embark on engagements to normalize relations and find common ground through open interactions. (sic)

What is the planned consequence management for any laws broken?

It is categorically stated that the SANDF is not a rogue entity and is subject to constitutional requirements. In carrying its mandate to serve, it may find itself operating in a mode of survival instinct and inadvertenty overlook normal peacetime procedure without any bad intention to undermine the law in expediency. Discussion with legally mandated people to update operational legal framework under stressful and Disaster Management Act conditions such as new normal brought by covid 19 are afoot to ensure compliance without failing on delivering on its mandate to secure the country without fail
under any circumstances. There are several investigations and possible prosecution under way in the SANDF under way on identified corrupt activities and criminalities where evidence is being collected by our intelligence to ensure successful prosecution. (sic)

Conclusion: Covid 19 presented new challenges where there is no single department that was never affected or effected adjustments in order to function under the new normal. Lessons learnt and areas of improvement need to be constructively harnessed. SANDF delivered as the leader of operations to repatriate from hotspots and to serve in support of other departments in Operation Notlela and in Eastern Cape deployments…while ensuring protection of members. Wartime planning and executions can always be viewed and judged harshly with benefit of hindsight and peacetime perspective. SANDF promotes discipline and professionalism within itself and is ready to evolve from its erstwhile past to serve our flagging democracy under civilian rule. May the space to self-correct be afforded without adversarial prosecution and destructive engagements. We are open to remedial appraisals…” (sic)

6.1.33 Reference is made to the following paragraphs of a report written by Dr Mnisi dated March 2021 (specific date omitted from report) which stated, inter alia, that:

6.1.33.1 The aim of the report was to solicit the SG’s approval on the **recommended research strategy** regarding the use of the drug in clinical trial as directed by the SAHPRA. According to the report, the DoH and its regulatory authority on the use of medicines and medical products as well as their registration in South Africa, the SAHPRA, **directed the SAMHS to use the drug only under clinical research** in accordance with protocols in the management of Covid-19 (Own emphasis added); and

6.1.33.2 According to the report of Dr Mnisi, the SAMHS was, therefore, previously allowed to use on one patient under section 21 which governs application for special use of unregistered medicines. The report indicated that the SAHPRA
could, however not grant the bulk use permission owing to limited randomised clinical trial literature on the use of the drug for immunomodulation in Covid-19. According to the report, the agreement reached was to embark on a clinical research project to investigate the safety and efficacy of the drug as an immunomodulatory in Covid-19.

6.1.34 Reference is also made to the following paragraphs of the report dated 8 June 2020, written by Maj. General (Dr) M Radebe (ret) the Health Attache, Havana. In the report the following was stated inter alia:

6.1.34.1 There was an urgent need to treat infected cases in order to minimize further spread of the disease and Cuba found a way to do this. This approach could potentially support our country to reduce mortality rates in the coming weeks before the expected peak. His report reviewed a proposal by the Cuban government to the South African DOD;

6.1.34.2 Maj. Gen (Dr) Radebe (ret) advised that it was against this background that the Cuban Surgeon General made contact with the South African DOD, offering possible collaboration, particularly around sharing experience with the innovative treatments that Cuba has employed, to bring the pandemic under control. The proposal was for South Africa to acquire doses of interferon a2b and jusvinza for treatment of Covid-19 as soon as possible to control the pandemic, in order for it not to overwhelm our healthcare system (Own emphasis added); and

6.1.34.3 In the report, Maj. Gen (Dr) Radebe (ret) recommended that South Africa should as soon as possible consider the proposal of obtaining supplies of the treatment developed by Cuba.

6.1.35 Reference is further made to the following letter dated 18 August 2021, written by the SecDef to the NT, in which it was stated, inter alia, that the SAMHS had recommended the drug to the MCC. The letter indicated that following
those recommendations, the MCC instructed the SAMHS and the Logistics Division to look at the possibility of getting the drug from Cuba. According to the letter, the SANDF ordered the drug from Cuba which was brought to the country when Cuban clinicians arrived in the country. According to the letter, it was an emergency procurement which the SANDF had to embark on. According to the SAMHS, in bringing the drug to South Africa, they were of the view that section 22 (c) of the Medicines and Related Substances Act 101 of 1965 was silent on the requirement for registration by an institution like the SANDF, therefore, if the legislation was silent there was no need for them to apply to the SAHPRA. (Own emphasis)

6.1.35.1 In the letter the SecDef indicated that the drug would expire in 2022 and it cost the DOD, R225 million (two hundred and twenty five million rand). She reported in the letter that the amount paid so far was R35 million (thirty five million rand) and that the outstanding balance was R180 million (one hundred and eighty million rand). The letter further indicated that the DOD does not have the funds to settle the outstanding balance and the NT was requested to assist the DOD with funds to settle the debt. (Own emphasis added)

AGSA Report on the matter

6.1.36 The AGSA second special report on the financial management of government Covid-19 initiatives\(^5\), particularly an audit on the procurement of the drug, was perused. Amongst others, the following was noted:

“…With Operation Notlela (the department's response to the covid-19 pandemic), the department prioritised procuring medicine for frontline workers – health workers, VIPs, vulnerable groups with comorbidities, and dependants – to support other government departments in the fight against covid-19. The department compiled a covid-19 management protocol, which includes a formal list of medicine for covid-19 treatment. The protocol also

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deliberated on candidate drugs undergoing investigation, including the **unregistered medical drug** Heberon® Alfa R (Heberon), which contains the active ingredient interferon alpha 2b. The department procured 970 895 vials of Heberon (three million international units per vial) from a Cuban supplier at a cost of US$15 048 872, 50 (approximately R260, 59 million), as per the invoices and importation packing lists up to 17 August 2020. Of this amount, only R34, 86 million has been paid to the supplier as at 30 September 2020…

**…Covid-19-related medicine**

The audit on covid-19-related medicine covered the planning to procure medicine for the period from 23 March to 30 September 2020 and focused on the procurement, transportation, warehousing and recording related to the medical drug Heberon…

**Inadequate needs analysis to support required levels of covid-19-related medicine**

The department did not submit the planning parameters, including the rationale and assumptions used to estimate the number of covid-19 patients and medicine required, for audit purposes. It was also not clear from the medicine planning documentation provided how the department determined the required quantities of medicine for the treatment of, and clinical trials for, covid-19.

**Recommendations**

The accounting officer should ensure that medicine is procured based on a defined needs assessment to limit the over-procurement and excessive stockpiling of medicine. The need should also be continuously updated as the pandemic unfolds to reflect the changes in the initial assumptions.

**Auditee’s response**

The accounting officer noted the auditors’ observation and explained that the department decided to protect its soldiers by boosting their immune system during their deployment. The accounting officer also stated that the high
demand for Heberon worldwide informed the department's decision to procure as much Heberon as was practically available.

Auditors' response
The department did not submit any supporting evidence to refute the finding or to support the accounting officer's claim of high demand worldwide. The World Health Organization also did not recommend the use of Interferon, the active ingredient of Heberon, in the clinical management of covid-19.

...Deficiencies with procurement of, and accounting for, Heberon

Approval process not followed prior to the procurement of Heberon

The department did not provide evidence that it had adhered to the import regulations for unregistered medicine by obtaining authorisation from the South African Health Products Regulatory Authority (Sahpra) before importing the Heberon.

On 5 October 2020, Sahpra reauthorized the department’s application to import and use 10 vials of Heberon on a single patient. The original application that should have accompanied the reauthorisation letter was not submitted for audit purposes. As at 4 November 2020, the department had approval to use 10 vials only, as Sahpra rejected the department’s bulk stock application on 21 October 2020 and no further clinical trial application was submitted. The 10 vials equate to 0,001% of the 970 895 vials the department had already imported by 17 August 2020...

...Shortcomings in the procurement process
The department has an overarching international contract with a Cuban supplier to provide technical services, which provides for further supplements to the contract. An additional supplement was entered into to allow for the procurement of Heberon. However, this supplement was signed on 28 April 2020, while the first consignment of Heberon was received at the warehouse
on 27 April 2020. In addition, the supplement did not stipulate the total quantities or value of Heberon to be procured.

The department did not submit all evidence supporting the international procurement transactions, i.e. orders, airway bills, customs tax clearance certificates, packing lists and commercial invoices, for audit purposes. As such, we could not inspect and conclude on the procurement transactions, including the possible incurrence of penalties for delayed payments.

**Insufficient record keeping for the transportation and warehousing of Heberon**

We could not determine whether the shipments of Heberon were safely and appropriately transported from the port of entry to the warehouse, as the department did not submit supporting evidence for audit purposes.

None of the 970 895 vials of Heberon was accounted for on the department’s inventory system and bin numbers were not allocated for the shelved stock. This, together with the non-accounting of the stock, contributed to the staff being unable to corroborate precise delivery dates.

**Incorrect classification of expenditure**

The department did not correctly classify payments for some of the covid-19 expenditure items in accordance with the accounting rules (Standard Chart of Accounts) for recording transactions and accounting classification. Medication worth R34, 86 million was classified as agency and outsourced services instead of inventory: medicine in the department's books.

**Recommendations**

The accounting officer should:

- ensure that all requested information is readily available and submitted for audit purposes when requested
- institute a formal process to monitor compliance with legislation before and during medicine procurement
- put measures in place to ensure that accounting transactions are classified in accordance with their nature and characteristics
• implement a monitoring control to assess the correct classification of covid-19-related transactions and apply the classification principles as detailed in the Standard Chart of Accounts guidance.

Auditee’s response
The accounting officer indicated that:
• all requested information is not readily available and everything practical is being done to locate the required information
• the department has not been charged possible penalties for not paying the supplier on time
• the department is in the process of improving the inventory recording system
• She agreed with the finding on the misclassification of covid-19-related transactions. A new financial authority of R34 859 500, 00 will be captured under the correct classification to correct the error.

Post-importation testing procedures for Heberon not performed as required

The department did not perform post-importation testing procedures to confirm the integrity of the product upon arrival and prior to release into the country. The testing would have included checking whether the drug was transported and stored at the required temperature (2 – 8 °C) as per the product specifications. The department also did not apply to Sahpra for an exemption. As such, Sahpra did not confirm the safety, effectiveness and quality of the drug before it was released for use into the country, which may pose a risk to patients receiving the drug.

The department did not monitor and evaluate the transportation of the shipments according to Sahpra’s post-importation guidelines despite an internationally recognised temperature monitoring device being attached to batches of the medication shipped from Cuba to South Africa. The department also did not submit stability data on the integrity of the product to Sahpra, as required by the post-importation guidelines.
As a result, approximately 387,000 (39.8%) of the 970,895 vials were exposed to temperatures outside of the required range (temperature as well as duration) during transportation and/or warehousing. The department did not detect and investigate this breach in the cold chain to determine the effect on the drug’s integrity and whether the shipment should have been accepted where the cold chain was compromised before the department received the Heberon.

The audit revealed that, where breaches occurred, the drugs were, in most instances, exposed to temperatures above 8°C for more than 20 hours. Device measurements showed that some vials were exposed for up to 94 hours and 23 minutes.

Recommendations

The accounting officer should:
• Institute a formal process to monitor compliance with legislation before, during and after medicine is procured
• monitor and measure temperature-related events relating to the cold chain transportation and storage of Heberon and other medicine. Where cold chains are compromised, the impact on the drug’s effectiveness and integrity should be investigated and documented
• institute consequence management in instances where officials have not adequately safeguarded medicine.

Auditee’s response
The accounting officer’s response did not include a response on this finding.

Conclusion

The accounting officer took note of the shortcomings and committed to locate the outstanding information and improve the inventory recording system. However, she did not indicate any timelines for the implementation of
remedial actions or possible consequence management. Because of the unavailability of some of the key information relating to the Sahpra approval and procurement of this unregistered medicine, we were unable to conclude on whether the department adhered to the required processes. Furthermore, the accounting officer did not provide a response to the non-compliance with Sahpra requirements in relation to post-importation testing procedures. This is concerning because the effect of the compromised cold chain on the drug’s integrity must be investigated before it can be used in the clinical management of covid-19. Ultimately, this may result in a large portion of the drugs not being used and the money spent being wasted…”

**Correspondence with the SAHPRA**

6.1.37 On 11 March 2021, an enquiry letter was submitted to Dr Semete-Makokotlela, the Chief Executive Officer of the SAHPRA regarding the SAHPRA’s involvement into the matter, the registration of the drug processes and whether the DOD applied for the drug registration.

6.1.38 On 13 April 2021, Dr Semete-Makokotlela responded through a letter and two attachments, and explained as follows:

6.1.38.1 The SAHPRA confirmed that the drug was **not registered for use in South Africa** and was not aware of the registration of the drug with other global regulators for the purposes of treating Covid-19. The **SANDF did not apply to the SAHPRA** for registration of the product prior to its procurement. The **applications for Section 21 use were received once the product had arrived in the country**. There were no feasibility studies/medical reports done in relation to the efficacy of the drug: (Own emphasis added)

6.1.38.2 Annexure (A) from the SAHPRA listed, **inter alia**, the following:

“… Background on INF alpha2b
INF alpha 2b is an antiviral/antineoplastic drug.

- Used for the treatment of hairy cell leukemia, malignant melanoma, kaposi’s sarcoma caused by AIDS etc
- Registered in SA for the above conditions.
- Not recommended for use in treatment of COVID 19 hospitalized patients, but could be considered under clinical trial.
- WHO also did not recommend its use outside of a clinical trial.
- Included in the Solidarity trial for COVID 19 treatments.
- Had little or no effect on hospitalized COVID 19 patients in terms of overall mortality, initiation of ventilation and duration of hospital stay.

What approvals were granted/Not granted

- 27 August 2020- SAHPRA received a new application for bulk stock of Heberon (Recombinant Human Interferon alpha-2b), no quantities were mentioned, no further was information supplied on clinical benefit, the application was rejected.
- 5 October 2020-SAHPRA received a named-patient authorisation request ‘to boost defence against COVID-19 complications’ for the use of 10 vials of Heberon (Recombinant Human Interferon alpha-2b), the application was approved...
- 21 October 2020- SAHPRA received a bulk stock authorisation request for Heberon (Recombinant Human Interferon alpha-2b), no quantities were mentioned, no further information was supplied and the application was rejected with recommendation that all relevant details about the application be submitted to SAHPRA through section21@sahpra.org.za
- There has been no further supporting details submitted to SAHPRA to date.
Inspection of facility

- SAHPRA became aware of the matter of the product interferon alpha 2B being in the possession of the SANDF in November 2020.
- The product was imported by SANDF without SAHPRA authorization in November 2020…”

6.1.38.3 The procedure for “Authorization for the use of unregistered medicines” was set out below, inter alia:

“…Procedure

Authorization for the use of unregistered medicines for the purpose of this procedure may fall in one of the following categories:

Named patient applications

- Investigational medicines showing prospect of benefit for the individual (specific person).
- Patients suffering from a serious but not life-threatening illness where a serious clinical need can be demonstrated and where scientific evidence exists to support the request.
- Continued access to medicines provided to specific participants during clinical trials on completion of the trial provided that it is evidenced that the participant has benefitted from the investigational product indefinitely or until the medicinal product is available in the state sector. The responsibility for this arrangement lies with trial sponsor. Progress reports must be submitted on a six-monthly basis demonstrating the findings of safety and efficacy monitoring.
- Clinical need exists for a medicine available and or registered in other countries, but not marketed in South Africa.
Bulk stock applications

• In certain exceptional cases, specific unregistered medicines need to be available urgently at an institution i.e. ICU unit. In such cases the physician involved as well as the superintendent of the institution may apply for a certain amount of emergency stock to be held in the pharmacy of the institution to be made available when required. (this is to prevent the constraints of normal office hours)

Process

• A Section 21 application can either be a New Application (named patient or bulk stock) or a Re-authorization (named patient or bulk stock). A New Application is submitted, when a health care practitioner (HCP) applies for a specific medication for the first time. A Re-authorization is applied for, 6 months after a prior New Application was approved and a reference number has been issued.

• A HPC, identifies the need for a Section 21 application in his/her practice or hospital, for a specific patient/a number of patients. This need will arise, when a required medication is not registered within South Africa or is currently out of stock or a medicine is discontinued.

• The HCP needs to ensure that all available relevant medications within the country have been used and did not deliver the required clinical benefit anticipated before a Section 21 application can be submitted.

• Should a registered medication be out of stock, the HCP will be required to supply the Section 21 Department with an out of stock letter from the Manufacturer of the medication or the holder of registration certificate.

• The unregistered medication which the HCP will apply for, needs to be registered in the country of origin, for the same indication that is intended to be used by the HCP. The Country from which the unregistered medicine is sourced from, needs to be affiliated with Pharmaceutical Inspection Co-operation Scheme (PICS), which is a body that
**SAHPRA aligns itself with.** This is to ensure that, there is harmonised GMP standards and quality systems in the field of medicinal products. The HCP needs to supply a Package Insert of this unregistered medication, if not already in the possession of the Section 21 Unit.

- If an indication is off label, a Peer Reviewed Article will have to be provided by the HCP, in support of this medication for the indication.

- A Section 21 application is valid for a maximum period of 6 months and no applicant can apply for a period exceeding 6 months. A re-authorization application may be submitted by the HCP where a patient requires chronic usage of the medicine exceeding 6 months.

- The quantity requested, needs to be a justifiable amount. The quantity is justified by the duration, frequency, dose, and number of patients intended to treat (in the case of bulk stock) over a maximum period of 6 months.

- The HCP needs to provide a clinical motivation for the use of the medication, as well as an indication or diagnosis, which is in line with the indications the medication is registered for in the country of origin.

- The application fee for a Section 21 application is R330.00 (2019 / 2020). Each application should make mention of the reference number for this payment. Public institutions are exempted from paying an application fee. Proof of payment must be emailed to section21@sahpra.org.za

- Only one medication can be applied for per application.

- The Affordable Medicines Unit at the National Department of Health applies for large quantities of unregistered or out of stock medication. The applicant in this case can be the Director of the Affordable Medicines Unit. This is the only exception permitted where the applicant is not a Medical Officer. These applications need to be accompanied by a Memo from the NDOH, supporting the application and are to be placed in the “Deputy Director Review” mailbox.

- All Colistin applications must be accompanied by a Microbiological Culture and Sensitivity (MC and S) report. This must be emailed to section21@sahpra.org.za …"
6.1.39 On 10 December 2021, an enquiry letter was submitted to Dr Semete-Makokotlela regarding the progress on the application for registration of the drug by the SANDF. On 17 December 2021, she responded through a letter and stated, inter alia, that the SAHPRA did not receive an application for registration of the drug from the SANDF and confirmed that the SAHPRA did instruct the SANDF to return the drug to Cuba, failing which the batches would be confiscated and destroyed. (Own emphasis)

6.1.40 A letter dated 3 November 2021, directed to the SAMHS was also attached to the SAHPRA submission. The SAHPRA’s letter to SAMHS stated the following:

“…SAHPRA has been in engagement with the South African Military Health Services (SAMHS) since November 2020 through numerous engagements as evidenced by the respective letters that have been shared.

As per Section 2A of the Medicines and Related Substances Act, Act 101 of 1965, as amended (“the Medicines Act), the objects of the Authority (SAHPRA) are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest. As per Section 2B(1)(e) of the Act, SAHPRA must ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation.

Regarding import of medicines or scheduled substances:

(i) Section 22C(6) of the Act stipulates that no manufacturer, importer or exporter shall import or export any medicine unless he or she is the holder of a licence as contemplated in section 22C(1)(b) of the Act. (ii) Regulation 1(xvii) of the Act states that no person shall import any medicine or Scheduled substance, including medicines imported in terms of section 15C of the Act, read together with regulation 6, into the Republic except through one of the following ports of entry:
a) Cape Town Airport or harbour;  
b) Port Elizabeth (Gqeberha) Airport or harbour;  
c) Durban Airport or harbour; and  
d) Oliver Tambo International Airport (Johannesburg)

Section 14(1) of the Act prohibits import of any medicine, medical device or IVD subject to registration but is not registered nor has authorization in terms of sections 21 or 22A.

To date, SAMHS has failed to submit the following:

- **The scientific basis for the use of Heberon alpha in the management of COVID-19**

- An explanation of how Hebron alpha was brought to into South Africa and proof thereof. This will assist SAHPRA to determine compliance with Section 22C(1)(b) and/or Section 21(1) and (2), as well as Regulation 6, of the Medicines and Related Substances Act, Act 101 of 1965, as amended.

  Despite SAHPRA invoking the provisions of the Intergovernmental Relations Act (IGRF Act) SAMHS failed to seize the opportunity to have this matter speedily resolved.

Due to SAMHS’ lack of adequate response and in light of the contravention of sections Section 14(1), 22C(1)(b) Section 22C(6) of the Medicines Act and Regulation 6 of the General Regulations, SAHPRA, **as the Regulator has therefore declared Hebron alpha as an unauthorised medicines.**

Accordingly, Hebron Alpha would be handled in terms of Section 23 of the Medicines Act.
Section 23(1) of the Medicines Act stipulates that, if the Authority is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be made available to the public, it may —

(a) by notice in writing transmitted by registered post to any person direct that person; or

(b) by notice in the Gazette direct any person, to return any quantity of such medicine, medical device or IVD which he has in his possession to the manufacturer thereof or (in the case of any imported medicine, medical device or IVD) to the importer concerned or to deliver or send it to any other person designated by the Authority.

(2) The Authority may by notice in writing direct any medical device or IVD establishment, manufacturer or importer of any such medicine, medical device or IVD who has in his possession any quantity thereof (including any quantity returned, delivered or sent to him in pursuance of a direction under subsection (1)), or any other person to whom any quantity of such medicine, medical device or IVD has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) No person shall sell any medicine, medical device or IVD which is the subject of a notice under subsection (1) which has not been set aside on appeal.

With powers vested to SAHPRA in accordance with its mandate, SAHPRA hereby directs SAMHS to return Hebron alpha to Cuba. SAMHS must ensure that it complies with the aforesaid instruction on or before 30 November 2021. Should SAMHS fail to comply with the aforesaid instruction, SAHPRA will be left with no other option but to seize Hebron alpha as contemplated in section 29 of the Medicines Act order to destroy the Hebron alpha in terms of section 30 (3) the Medicines Act…” (Own emphasis)
Response to the Public Protector's Notice issued in terms of section 7(9)(a) of the Public Protector Act:

6.1.41 The Public Protector issued and served a Notice in terms of section 7(9)(a) of the Public Protector Act to the DOD on 25 October 2021, to afford it an opportunity to respond to the Public Protector's preliminary findings and the intended remedial actions thereto.

6.1.42 The SecDef, responded on 24 November 2021, and stated the following inter alia:

6.1.42.1 There was no evidence in the report that justified the recommendation of disciplinary action to be taken against herself. She stated that she commenced with her appointment in the DOD on 3 August 2020 and that payment for the procurement was done before 28 July 2020. It was also common cause that the DOD has not yet paid and seemingly does not intend to pay the excess amount of R182 million to Cuba for the drug;

6.1.42.2 The DOD has comprehensive policies and prescripts dealing with revenue, expenditure, assets and liabilities. The DOD has failed to follow normal procurement procedures to procure the drug. The fact that the DOD intentionally decided not to follow normal procurement procedures, should not in turn infer that there was a lack, or there is not in place, legal and policy prescripts for procurement; and

6.1.42.3 She advised that the following witnesses should have been interviewed:

(a) The former Minister of Defence to determine her knowledge of the procurement;

(b) The former SecDef (late) Dr SM Gulube: who retired at the end of July 2020, and tragically passed on during July 2021. She questioned if Dr Gulube signed any deviation from normal procurement processes to pay, as required inter alia by National Treasury Instruction No 3 of 2020/21;
(c) The former C SANDF, General Shoke, retired at the end of May 2021 and was the Chairperson of the MCC, the forum that dealt with the procurement of the drug. She advised that General Shoke should have reported on the reasons for obtaining the drug; content of the instructions issued by him to the SG and other DOD officials; extent of discussions with the former Minister and (late) SecDef; whether he was aware that prior SAHPRA approval was necessary, if known why was the SAPHRA approval processes circumvented; how was the number of vials derived at and their intended use; why was the Supplement No 10 of contract No TI 17 0001 only signed after delivery of the drug and why was the commencement and end date of the contract not included;

(d) Former SG Lt Gen Dabula: She advised that the drug was ordered on the advice of the former SG, what was the instructions received from the MCC and the former SG’s understanding thereof; why was the Cuba drug considered and not for example drugs provided by China; the former SG’s denial of not having been aware that the drug first had to be approved by the SAHPRA to her was highly questionable. It was highly improbable that a person with his years of experience was unaware of prior SAHPRA’s approval;

(e) Medical Doctor Col Mnisi: She advised that it was highly improbable that a person with his years of experience in the medical field as a medical doctor was unaware of prior SAHPRA’s approval; and

(f) National Treasury Instruction No 3 of 2020/21: It was clear to her that this instruction only applied to the emergency purchase of PPE goods, items and services and not the importing of medicines.

Submission of Ms Nosiviwe Mapisa-Nqakula

6.1.43 A subpoena was issued on 31 January 2022, to Ms Mapisa-Nqakula, the former Minister of Defence to obtain her version of the events in the matter. In
an affidavit dated 3 February 2022, submitted to the Public Protector, she stated *inter alia*, the following:

6.1.43.1 That she is currently the Speaker of the National Assembly and that she was the Minister of Defence and Military Veterans from 12 June 2012 to 5 August 2021. During the outbreak of Covid-19 worldwide in the beginning of 2020, South Africa declared a national state of disaster on 15 March 2020 and the SANDF was deployed as of 26 March 2020 to assist the SAPS to maintain law and order, to assist other State Departments and to control the border line to combat the spread of Covid-19;

6.1.43.2 That she was briefed during this time by General Shoke that the SANDF had been in engagements with, amongst others, the militaries of the Republic of Cuba and Russia about their roles in the fight against the spread of Covid-19. She was told that it was within this context that the Cubans offered to the SANDF the supply of the drug as an immune booster to the forces who were in the frontline. The immune boosting effects of this medicine sounded very promising in the manner it was described by General Shoke and as such she did not hesitate to raise the matter of importing the drug for all South Africans, not just to the members in uniform, not less than three (3) times at the level of the National Coronavirus Command Council (NCCC). A decision in support or against such a proposal was however never recorded in her presence on the NCCC;

6.1.43.3 That she advised that members of the Executive do not play a role in the procurement or acquisition done by their respective Departments. They have a political oversight role and are accountable to Parliament by tabling the annual reports of a particular Department within the prescripts of the PFMA. Once irregularities have been detected, the provisions of this Act dictate that appropriate consequence management is taken against those identified, by the Executive Authority, as well as the Director-General as the case may be. She was not aware at the time of the procurement of the drug of the processes followed in such procurement as documentation does not get processed in a Ministry. She was also not aware of the fact that the SAMHS
had to register the drug with the SAHPRA before it could be imported or administered in the country;

6.1.43.4 That she only became aware of the alleged irregularities in the procurement of the drug and the importation thereof into South Africa through media reports based on a reportedly leaked memorandum prepared by Major General Ford, the Chief Director: Military Health Force Support. She viewed these allegations in a serious light and therefore took a decision to appoint an external task team to investigate the veracity of these allegations and to prepare a report with recommendations to address any wrong doing uncovered, whether of a criminal or disciplinary nature and to also include broader recommendations on how to stop such behaviour and prevent it going forward, should any of the allegations be confirmed. She wanted the task team to start its investigation in January 2021, but due to the non-availability of individuals, approached to serve on the external team as a result of prior commitments or health reasons, she was only able to finally appoint a team to start working as of 01 March 2021;

6.1.43.5 That she advised that the task team was chaired by Mr Zola Ngcakani and the other two (2) members were Dr RC Lubisi and Mr B Masethla. The task team was supposed to finish its investigation after six (6) months, but she noted an extension of their term after she left the position of Minister of Defence; and

6.1.43.6 That she advised that she appeared twice before the Portfolio Committee of Defence and Military Veterans, on 17 and 24 February 2021, when the SANDF was requested to account for the procurement processes followed and non-registration with SAPHRA. She reiterated during these engagements that she was aware of the offer by Cuba to use this drug to boost immunity amongst their uniformed members and that the MCC was acting on this offer, but that she was not aware of the alleged failure to follow procurement processes, the need to register with SAPHRA before importation, the quantities or costs involved. She indicated that she took political responsibility upon learning of these serious allegations, as contained in the memorandum
by Maj Gen Ford and media reports and she took steps towards the appointment of an external task team to investigate and prepare a report. She also in those meetings confirmed that she requested the DOD to fully cooperate with the investigation of the AGSA, by providing all requested documentation without delay. She also informed the AGSA of the appointment of the external task team to investigate the matter.

**Submission of General Solly Shoke (ret) also chairperson of the MCC at the time.**

6.1.44 A subpoena was issued to General Shoke (ret) on 31 January 2022 to obtain his version of events. General Shoke responded by way of an affidavit dated 14 February 2022 and stated the following:

6.1.44.1 That he was the retired Chief of the SANDF as at 31 May 2021. General Shoke referred to the SANDF’s mandate and its functions as per section 200(2) of the Constitution, being to defend and protect the Republic, its territorial integrity and its people in accordance with the Constitution and the principles of international law regulating the use of force;

6.1.44.2 General Shoke advised that at the outbreak of Covid-19 in November 2019 in China, the SANDF developed a keen interest in that the emergence, outbreak and/or detection thereof in South Africa was a matter of time. Therefore, the SANDF and MCC closely monitored the developments of Covid-19 globally. Based on medical intelligence and reports from affected countries at the time, the SANDF developed a view that the drug was helpful in mitigating against fatalities in the fight against Covid-19. General Shoke submitted that although the blame was put squarely at the SANDF’s door for having acted swiftly by procuring the drug, the SANDF has recently been criticised that it was slow to react during the July 2021 unrest when the SANDF had to ensure that all internal processes, regulations and applicable policies were complied with before the SANDF could be deployed to defuse the July 2021 unrest that engulfed South Africa;
6.144.3 General Shoke submitted that immediately after the outbreak of Covid-19, the SANDF had to quickly convert into operation mode and had to fetch South Africans that were trapped in China and who could not be flown by any other airline company due to the global lockdown by various countries. In view of the MCC, the members of the SANDF were sent to China without any protection and had anyone contracted Covid-19, no doubt he, as the then Chief SANDF, would have been labelled as irresponsible and having no regard for the lives of the soldiers. The minutes of the MCC’s meetings include the instructions that all members of the SANDF had to be protected as people that were in the front line of fighting the Covid 19 and also protecting members of the public;

6.144.4 General Shoke advised that the decisions of the MCC are binding on each and every member of the SANDF. In other words, the decisions of the MCC, in their nature, constitute decisions to members of the SANDF and they must act in accordance with such instructions obviously within the confines of the law. In the procurement of the drug, no monetary or pecuniary gain was realised or derived by any member of the SANDF. General Shoke indicated that the criticism or complaint that there was no Covid 19 budget by the SANDF, and by extension the DOD was meritless. No other state department had a Covid 19 budget when the first case of Covid 19 was detected in South Africa. General Shoke submitted that it was also documented in all forms of media that countries had to mobilise funds to invest in research and in procuring PPE. General Shoke insisted that, indeed there was no Covid 19 budget in 2019 since no one could have foreseen the outbreak of Covid 19 before November 2019;

6.144.5 According to General Shoke the mandate of the SG appears in the General Regulations of the SANDF, chapter XIV amendments to the General Regulations for the SANDF and reserve, promulgated in terms of the Defence Act, section 87 (1)(h) and amended by GNR1174GG759829/5/81 (the regulations). It was submitted by General Shoke that in terms of regulation 2, the SG or a medical officer designated by him/her, must from time to time, in
consultation with the CSANDF or staff division or supporting service concerned determine the standard of physical and mental fitness required in peace or war time for efficient work performance of a member in every service or division;

6.1.44.6 General Shoke referred to the execution of the SG’s functions in terms of regulations 2(a) to (c) and to section 2 of the Medicines and Related Substance Act 101 of 1965 (MRSA) that establishes SAHPRA as an organ of state within the public administration but outside the public service. He also referred to public service as defined in section 1 of the Public Service Act 1994 (PSA) and section 8 of the PSA regarding composition of the public service and to section 38 of MRSA). Based on the above, it did not appear that MRSA binds and applies to the SAMHS and SANDF, more so section 2 of MRSA is expressive on its applicability “being outside the public service” (to SAMHS and SANDF) whom are units or divisions within the DOD, and a department contemplated in section 8 of the PSA;

6.1.44.7 General Shoke advised that to demonstrate on reading of the MRSA, the MRSA does not cater and/or deal with the outbreak of global pandemics such as Covid 19 and the treatment of persons including the expeditious procurement thereof in instances where there were or are no known manufactures of vaccines concerned. The MRSA is primarily aimed (if not sorely directed) at people and pharmacists who are in the business of selling and distributing medical health related products for monetary gain, whilst entities such as SANDF and SAMHS are not;

6.1.44.8 General Shoke advised that the CSANDF is the chairperson of the MCC or any person so delegated by the CSANDF. The MCC is constituted by the Chiefs of four (4) arms of services and all support divisions and at MCC level, they all look at issues from all angles and advise the SANDF accordingly on the basis of their professional advice and recommend to the SANDF the best available course to embark upon so that a decision can be made by the MCC. When such decisions are taken, the MCC also looks at the gravity of the matter and decision-making and depending on the gravity thereof or an issue
confronting the SANDF, both the Minister of Defence and the President of the Republic may be informed. The decisions of the MCC are collective decisions. General Shoke argued that at no point did he take decisions which were not informed by the collective nature of decision making within the SANDF. General Shoke submitted that it was a worldwide fact that Covid 19 was initially detected in China, in the province of Wuhan as early as November 2019, prior thereto, was an unknown phenomenal globally;

6.1.44.9 General Shoke advised that there were no treatments and/or vaccines for Covid 19 in November 2019 such as Pfizer, Johnson & Johnson etc. Fundamentally there were no vaccine manufacturers of Covid-19 in existence in November 2019. The vaccines that were used or are in use in South Africa were only approved and/or registered and/or accredited by the SAHPRA as late as between June/July 2021, approximately 19 months after the first case of Covid 19 was detected in China. Before then (in November 2019 and June/July 2021) the applicability of section 217 of the Constitution was subjectively and objectively impossible on account of no accredited Covid 19 vaccine manufactures at the time. Therefore to accuse the SANDF and the MCC of not having followed the procurement process as contemplated in section 217 of the Constitution in procuring the drug is ignorant of the fact that there were no Covid 19 vaccine manufacturers who could have been invited and/or approached to provide the vaccines by the SANDF or any other organ of state;

6.1.44.10 General Shoke advised that it was also factually untrue that the drug was banned in South Africa. On the contrary, a strand of the interferon drug is used in South Africa for treatment of cancer. However, the strand of the interferon drug (interferon B) has less side-effects compared to the one that is being used for cancer treatment in South Africa. As at March 2020, countries such as China and Venezuela had procured the drug from Cuba. Countries such as Italy also allowed Cuban doctors to administer the drug on Italian nationals. Cuba had deployed so many of its medical doctors and soldiers in various hotspots in different countries of the world and not one of them died on account of having contracted Covid-19. On 20 March 2020,
South Africa imposed a state of national disaster owing to the outbreak of Covid-19. On 26 March 2020, the level 5 hard lockdown was imposed by the President. Between November 2019 and until present, millions of people have died whilst the countries and the WHO were busy searching for solutions and other medical treatment of Covid-19;

6.1.44.11 According to General Shoke, in the exercise of the discretion afforded to the MCC, in his capacity as the then CSANDF, and the legal framework that was employed in the procurement of the drug, he wished to reassure the Public Protector that the procurement of the drug, took into account several measures and factors into account. He also wished to deal with the apparent conflation of section 217 of the Constitution and the deviation process for procuring. In law, he was advised that the two concepts were mutually exclusive;

6.1.44.12 General Shoke advised that the SANDF military strategy also includes defence against biological and/or chemical attack and SANDF must devise defensive measures against the employment of biological agents or chemical products by an adversary to produce casualties in or animal and damage to plants or material to obtain military advantage. In addition, SANDF is enjoined as per its military strategic document, to provide support for the preservation of life, health and property in emergency situations which exceeds the capacity of the civilian authority. He stated that the SANDF consists of four (4) services, being the three (3) combatant services and one (1) supporting service, which are: the South Africa army, the SA Air Force, the SA Navy, the SAMHS, which was established as the SA medical service in 1979 and support divisions;

6.1.44.13 General Shoke stated that it was common cause that around January 2012, a lawfully concluded bilateral agreement came into existence between South Africa and Cuba. Evidently, when the bilateral agreement was concluded between South Africa and Cuba in 2012, the outbreak of Covid-19 was not and could not have been within the contemplation of officials of both countries. Thus, before the outbreak of Covid-19, South Africa and Cuba had
been exchanging information on military health, health, technical and other related fields. Therefore, the exchange and/or procurement of the drug must be seen in that light;

6.1.44.14 It was also indicated by General Shoke that the consignment of the drug arrived in South Africa at the time when the movement of people, globally was prohibited. The reason why the supplementary agreement was signed after the delivery of the drug was precisely because there were no people who were able to travel between the two (2) countries on account of level 5 hard lockdown. The Cuban authorities acted on trust, by delivering the drug before the supplementary agreement could be counter-signed by him, in his capacity as the CSANDF. The supplementary agreement was counter-signed by the CSANDF on 28 April 2021 whilst the Cuban authorities had already done so;

6.1.44.15 The supplementary agreement was concluded between the SANDF and the Foreign Trade Enterprise called Import and Export Cuban Company of Technical Products (Technoimport) a Cuban state enterprise. He represented the SANDF in his capacity as the CSANDF;

6.1.44.16 General Shoke advised that the drug was never clinically tested in South Africa by the SAHPRA. The drug’s efficacy should be viewed as an aim and/or means to reducing the fatalities to members of the SANDF that were brought about by Covid-19 given the number of people that had died since November 2019 until April 2021, when the drug was procured. The drug was rejected by the SAHPRA on the basis that it was imported into South Africa without being registered with the SAHPRA and that the SANDF took longer to provide the SAHPRA with clinical reports on the drug. In fact, the mandatory clinical trial exercise was never completed when the SAHPRA demanded that the drug should be repatriated back to Cuba;

6.1.44.17 It was submitted by General Shoke that the former Minister in her affidavit raised the issue of importing the drug on no less than three (3) occasions at the level of the National Corona Virus Command Council (NCCC) although a decision that was either in support and/or against such a proposal was not recorded in her presence at the NCCC meetings. The extent that it was
alleged that the SANDF acted on a frolic of its own was also untrue since the issue of the procurement of the drug formed a subject matter at the National Joint Operational and Intelligence Structure (NATJOINTS) discussion which included the DoH;

6.1.44.18 General Shoke advised that section 201(3) of the Constitution which deals with the political responsibility of the SANDF and it, *inter alia*, provides that when the SANDF is deployed for any purposes mentioned in section 201(2) of the Constitution, the President must inform Parliament promptly and in appropriate detail. He referred to section 237 which obligates every person and organ of state that performs a constitutional obligation (compliance with section 201(3) of the Constitution) to perform it without delay. The deployment of the SANDF during March 2020 was an emergency response to an emergency crisis, brought about by the unfolding Covid-19 pandemic at the time. South Africa was under hard lockdown and to expect the SANDF to sit idle, during the outbreak of Covid-19 and in circumstances where there were no accredited vaccine manufacturers for Covid-19 was at odds with section 36 of the Constitution, which deals with the limitation of rights. Section 201(3) is echoed in section 18 of the Defence Act, in particular section 18(1)(a) *inter alia*, provides that the SANDF must be deployed where the President or Minister has authorised same for service inside the Republic, in order to preserve life, health or property in emergency or in humanitarian relief operations;

6.1.44.19 General Shoke advised that on 15 April 2020, the NT’s Director General issued the NT Instruction which was aimed at providing guidance on disaster management central emergency procurement process for the PPE that may be implemented by accounting officers of departments and institutions and accounting authorities of public entities listed in schedule 2 and 3 of the PFMA. In terms of clause 2.5 of the NT Instruction it was, *inter alia*, provided that in light of the lockdown, emergencies may occur where normal procurement practices are impractical and moreover where there is a high demand within a short time frame for goods or services required, and therefore the need to make special arrangements with service providers with
proven capability and capacity to assist, thus mitigating against dangerous, perilous situations or misery;

6.1.44.20 General Shoke stated that Covid-19 was a global novel phenomenon and in that regard clause 2.6 of the NT Instruction also acknowledged and recognised the difficulty of sourcing critical and essential health products during the Covid-19 emergency and the fact that whilst some products were produced locally, many specialized products needed to be imported. The SANDF did inform the NT of its intention on urgent or emergency procurement of Covid-19 military products and services by the SecDef, around August 2021 which was addressed to the DG of the NT. According to him, the procurement of the drug was done in terms of the NT Instruction and the approval of R4 billion by the NT in favour of the SANDF;

6.1.44.21 General Shoke advised that during the procurement of the drug, they had countless interactions as members of the MCC (including the then SecDef, the late Dr Sam Gulube) and collectively, the following process and factors were taken into account: there was no need for the SANDF to have procured the drug or any other medication in terms of section 217 of the Constitution because such was procured under the bilateral agreement concerning the defence relationship between SA and Cuba. There was no sufficient time, let alone the absence of Covid-19 vaccine manufacturers, to experiment and/or speculate and/or to ponder on the immediate threat that confronted the SANDF and members of the public in general. When Covid-19 was first identified there were no drugs and/or vaccines that could prevent and/or treat Covid-19 and based on the interactions by SAMHS and medical experts in foreign jurisdictions, it was concluded that the Cuba drug was potentially useful as it offered protection to the Cuban medical personnel. On the reasoning that members of the SANDF were to be deployed throughout the Republic, it was imperative to procure the drug, the aim of which was to protect the members of the SANDF when they were called upon to assist the public;

6.1.44.22 According to General Shoke, it was the decision that was taken by the MCC as it appears in the minutes of the MCC, that required the SAMHS to explore
means to protect members of the SANDF during deployment and as he has already alluded to, the SAMHS research led to SANDF and the MCC in particular to procure the Cuban drug. WHO recognised the drug as one of the accredited immune boosters in the fight against Covid-19. Around 24 July 2020, the SG in the company of the SAMHS expert met with the Cuban medical experts and they agreed on a joint clinical protocol for the administration of the drug. On 03 August 2020, the SANDF had embarked on a registration process of the drug with SAHPRA, yet on 03 September 2020, the SAHPRA turned down SANDF’s section 21 application;

6.1.44.23 General Shoke advised that the procurement of the drug should be seen in three (3) distinct, yet correlated phases. He referred to the Ministerial Task Team, the procurement of the drug regarding the urgent and/or procurement thereof was a constitutional imperative if regard was had to section 200(2) of the Constitution, read with section 237, which enjoin that all constitutional obligations must be performed diligently and importantly, without delay. The third phase involved the registration of the drug through the SAHPRA; and

6.1.44.24 General Shoke submitted that the MCC and SANDF’s conduct in procuring the drug was, on the facts, aimed at avoiding cataclysmic consequences at the time which resulted in the loss of lives of both members of the military community and civilians. The SANDF acted in concert with its counterparts in other countries and closely with affected countries before the very first case of Covid-19 was recorded in SA and heavy reliance was placed on intelligence and medical reports that were received from the said countries and the said information was analysed and it led to the procurement of the drug. In conclusion, he referred to the High Court litigation, wherein SANDF and other applicants sought an interdict against the SAHPRA, following SAHPRA’s decision on 03 December 2021 to reject, confiscate and destroy the drugs that were kept at the SANDF depot.
SAHPRA’s submission to the Portfolio Committee

6.1.45 A letter was perused dated 26 January 2022, from Dr Semete-Makokotlela to the Portfolio Committee on Defence and Military Veterans (the Committee) which stated, *inter alia*, that on **25 January 2022**, the SAHPRA was informed by the SANDF that the unregistered medicine in question had been **returned to Cuba on 20 January 2022**. (Own emphasis added)

AGSA’s submission to the Portfolio Committee

6.1.46 A letter dated 24 January 2022, from Ms Zolisa Zwakala, the Acting Head of Portfolio, AGSA to the Committee *inter alia*, stated the following regarding the AGSA audit finding:

“...In the second special report, we indeed highlighted shortcomings relating to procurement of the drug. These included the use of an open-ended contract under operation Thusano for procuring the drug. During the final audit, we further reported in the management report that the process followed to implement the bilateral agreement with Cuba through operation Thusano was not compliant with section 217 of the Constitution or with National Treasury Regulations and instruction notes. As a result, all expenditure incurred under operation Thusano, which was in excess of R1 billion as at 31 March 2021, was irregular (the total expenditure includes payment for the Heberon drug). The department disagreed with this finding, which also contributed to the qualification on completeness of irregular expenditure...” (Own emphasis added)

6.1.47 On 26 January 2022, the Investigation team further became aware that the drugs have since been returned to Cuba from various media reports, including an online media article ⁶ which reported the following:

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“...The SA National Defence Force (SANDF) on Wednesday confirmed that it has returned 500,000 vials of the Heberon interferon alpha-2B Covid-19 drug to Cuba.

This follows instructions and recommendations by a ministerial task team and the SA Health Products Regulatory Authority (Sahpra) on the illegal procurement of the drug which cost the taxpayer millions of rand.

SANDF Chief Gen Rudzani Maphwanya told parliament’s portfolio committee on defence and military veterans that the defence force was instructed to either return the medicine or have it destroyed as it was due to expire. The SANDF has complied and sent the medicine back to Cuba. We are writing to Sahpra and the auditor-general as the interested parties that we felt we should be re-engaged after we complied,” said Maphwanya...”

Meeting with SecDef to discuss the provisional findings and remedial action

6.1.48 On 29 March 2022, a further meeting was held with the SecDef and her legal team in order to communicate the Public Protector’s provisional findings and remedial action as stated in the first Notice issued on 25 October 2021 and her response dated 24 November 2021. Discussions were held on her powers as the DOD Accounting Officer. The SecDef made her inputs with regard to the proposed remedial action. As a result of the discussion with the SecDef, the Public Protector issued supplementary Notices to General Shoke (ret), General Rudzani Maphwanya, Lt Gen Mbuli, Lieutenant General Zola Wiseman Songo Dabula, Major General NP Maphaha and Colonel (Dr) Joseph Thabo Mnisi. The SecDef did not respond to the supplementary notice and all the listed SANDF officials responded in May and June 2022, respectively.

6.1.49 In a letter dated 30 March 2022, the SecDef was requested to advise, inter alia, on the undermentioned, but no response had been received at the date of this report:

6.1.49.1 Whether the DOD returned all of the drugs to Cuba; and
Whether Cuba will refund the R35 million already paid by the DOD, or whether the DOD will be engaging with Cuba on a process to recover the R35 million.

Response to the Supplementary Notice:

The Public Protector’s supplementary notice was issued to the SecDef, General Shoke (ret), General Rudzani Maphwanya, Lt Gen Mbuli, Lieutenant General ZWS Dabula, Major General NP Maphaha and Colonel (Dr) Joseph Thabo Mnisi on 28 April 2022, with a view to afford them an opportunity to respond to the Public Protector’s provisional findings and remedial action.

Submission of General Maphwanya (current Chief of the SANDF)

General Maphwanya responded to the section 7(9) notices on 17 May 2022 and stated, *inter alia*, that the spread of the Covid-19 took the whole world by surprise and that not a single country could provide any medical solutions against it. General Maphwanya said that vaccines against the Covid-19 came late. According to General Maphwanya, the SANDF, being the last line of defence, was faced with an unprecedented challenge of not only protecting its members from Covid-19, but there was also an expectation that it must also play a huge role in containing the spread of the virus among the communities.

General Maphwanya referred to the following legal sections and advised that the Constitution of South Africa provides that the “… primary object of the Defence Force (South African National Defence Force) is to defend and protect the Republic. Its territorial integrity and its people in accordance with the Constitution and the principles of international law regulating the use of force…”

General Maphwanya also stated that the secondary mandate of the Defence Force is found in section 18(1) of the Defence Act 42 of 2002. According to the
provisions of section 18(1) of the Defence Act, the SANDF may be deployed to: “…

(a) preserve life, health or property in emergency or humanitarian relief operations;
(b) ensure the provision of essential services;
(c) support any department of state, including support for purposes of socioeconomic upliftment; and
(d) effect national border control…”

6.1.51.3 General Maphwanya advised that as mandated by the Constitution and the Defence Act, the SANDF was the first organisation in SA to be tasked to do anything related to Covid-19. General Maphwanya referred to the SANDF being tasked to conduct one of the complex operations in repatriating South Africans who were trapped in different parts of Wuhan province in China. He advised that it was a case of emergency and there was no manual to guide the SANDF on how to respond to the call by the SA government. The SANDF could not say “no”, when instructed by the President, however, he confirmed that the mission was a great success.

6.1.51.4 General Maphwanya indicated that the MCC closely monitored the situation and continuously received briefing from the SG regarding estimates of possible deaths that the virus could cause in military communities. General Maphwanya further stated that based on epidemiological predictions on the spread of Covid-19 among the military communities, the MCC instructed the SG to contact other fraternal militaries for possible availability of any medical products that may be used to mitigate its spread in the SANDF, as soldiers were among those who were deployed in the front line in the fight against the pandemic.

6.1.51.5 According to General Maphwanya, until then, no single approved drug which actively treated Covid-19 was available in the whole world. Clinicians from SAMHS contacted their counterparts from other militaries. He said that the...
former SG found that countries like China and Cuba use a drug called Interferon-B as an immune booster and application in family medicine and primary health care for disease prevention and recommended the drug to the MCC.

6.1.51.6 General Maphwanya further indicated that following these professional recommendations, the MCC instructed SAMHS and the Logistic Division to work together and procure the drug for the sole use by members of the SANDF. All these decisions, according to him, were not taken in secret, they were recorded in the minutes of the MCC meetings.

6.1.51.7 General Maphwanya explained that the MCC only decided on what should be done to protect their troops and does not get involved in any procurement processes and said that any involvement in any procurement processes by the MCC would have been grossly irregular.

6.1.51.8 General Maphwanya in reference to paragraph 9.1.7 of the notice in terms of section 7(9) of the Public Protector Act, further stated that sadly, in the findings in of the report the Public Protector which stated that:

“The conduct of the DOD officials involved in the irregular procurement of the Interferon-Alpha-2B drug from Cuba, which include but not limited to the roles played by General Solly Zacharia Shoke (ret), Surgeon General Dabula, Lieutenant General Jabulani Sydney Mbuli, Major General Maphaha, Colonel (Dr) Joseph Thabo Mnisi and members of the MCC at the time that the procurement was approved constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(i) and (ii) of the Public Protector Act…”.

6.1.51.9 General Maphwanya stated that he respectfully submits that by including all members of the MCC at the time to have been involved in the irregular procurement of the drug, the office of the Public Protector has “misled itself”. General Maphwanya indicated that the MCC is not a DOD procurement structure therefore members of the MCC cannot be accused of irregular
procurement. General Maphwanya argued that the finding is reviewable and he made a request to reconsider same as far as including all members of the MCC;

6.1.51.10 According to General Maphwanya, paragraph 10.4 of the report, the Public Protector instructed the SecDef to “...Investigate in terms of section 10 of the Defence Act and take appropriate disciplinary action in terms of section 8(g) of the Defence Act against the DOD officials involved in the irregular procurement of the Interferon-Alpha-2B drug from Cuba. This will include but not limited to the roles played by General Solly Zacharia Shoke (ret), Surgeon General Dabula, Lieutenant General Jabulani Sydney Mbuli, Major General Maphaha, Colonel (Dr) Joseph Thabo Mnisi and members of the MCC at the time that the procurement was approved...”, Again the office of the Public Protector has included members of the MCC at the time that the procurement was approved;

6.1.51.11 The question raised by General Maphwanya was whether the remedial action was based on the MCC having accepted the former SG’s professional recommendations or on the irregular procurement of the drug. The MCC decided on what should be done to protect their soldiers. The “how” part (procurement process) was never and it is still not the role of the MCC. General Maphwanya said the Public Protector should reconsider this remedial action in as far as it includes all members of the MCC;

6.1.51.12 General Maphwanya advised that the remedial action in paragraph 10.5 was of no effect as members of the MCC are not members of any DOD procurement Board. The remedial action stated that, “...Within sixty (60) working days from the date of the final report, include in the DOD’s Workplace Skills Plan (WSP) a training programme for members of the MCC (the Chiefs of the four (4) arms of service) to be trained on the relevant provisions of the Constitution, PFMA relating to procurement and the DOD SCM policies as encouraged by section 2 of the Skills Development Act 97 of 1998...”,


6.1.51.13 According to General Maphwanya, this remedial action was relevant to anyone that the office of the Public Protector had found to have failed to follow procurement processes. Members of the MCC by sitting at the MCC meetings did not commit any misconduct or there is no evidence that they committed any misconduct. Therefore, they must be spared from the indignity of a remedial action that they must be disciplined or a disciplinary action should be taken against them. The Public Protector should reconsider this remedial action in as far as it includes all members of the MCC; and

6.1.51.14 General Maphwanya submitted that the MCC took a decision to try to preserve the lives of deployed soldiers who were deployed without any form of protection. The MCC decision should be completely separated from the procurement processes that were allegedly not followed.

6.1.51.15 General Maphwanya further advised that on 9 May 2022, the MCC sat to discuss the matter. According to him, during deliberations Lt Gen Mbuli informed attendees of the meeting that Logistics Division was not involved in the procurement process of the drug, except for payment. He said that Lt Gen Mbuli further advised that only the former SG (Lt Gen Dabula) knew what procurement processes the SAMHS followed. (Own emphasis added)

**Further submission of General Shoke (ret)**

6.1.52 On 27 May 2022, General Shoke (ret) responded to the supplementary notice with a further explanatory affidavit and stated the following:

6.1.52.1 That he had already submitted a comprehensive affidavit to the Public Protector. In this affidavit, he explained that the Public Protector’s notice in terms of section 7(9) dated 22 October 2021, is substantially similar with the latest section 7(9) dated 28 April 2022 (latest notice);

6.1.52.2 General Shoke stated that what the Public Protector had done, in the latest notice, was to regurgitate the contents of the initial notice and the Public
General Shoke advised that at paragraphs 8.1.25 to 8.1.30 of the Public Protector’s latest notice, the Public Protector seems to place heavy reliance on the interactions that she had with Major General Ford (Gen Ford), the previous Chief Director: Military Health Force Support. What the Public Protector’s latest notice specifically omits to mention is the fact that Gen Ford whilst at the employ of the SANDF sat in SAMHS Command Council and it was expected of him to be well versed with the decisions that are being made by the SAMHS. The SAMHS Command Council is the highest decision-making body in the Military Health Services. The SG represents the entire SAMHS at the MCC which he chaired. He expected Gen Ford to have been well versed with the decisions that were made at the SAMHS and the MCC. The decisions of the MCC are then cascaded to all members of the SANDF, through their respective command councils;

That the issues around the procurement of the drug were discussed at the SAMHS Command Council as well. He was dismayed by Gen Ford’s purported ignorance of what transpired at the MCC and the SAMHS Command Council. Gen Ford’s perceived act of “whistle-blowing”, was designed and aimed at diverting attention away from him. At the relevant time, when Gen Ford levelled allegations of improper conduct against members of the SANDF, Gen Ford was, to the best of his knowledge a person of interest by the investigative structures of the SANDF;

General Shoke advised that at paragraphs 10 to 31 of his initial affidavit, he gave the following context within which his initial affidavit had to be construed by the Public Protector:
(a) The SANDF had relied on medical intelligence and reports from affected countries at the time, by the Covid-19 pandemic;

(b) The said countries shared intelligence that explained what the Interferon drug was all about;

(c) Lots of people had lost their lives and were losing their lives on account of the outbreak of Covid-19;

(d) The criticism or complaint that there was no Covid-19 budget by the SANDF is meritless because no other State department had Covid-19 budget when the first case of Covid-19 was detected;

(e) The MRSA establishes SAHPRA as an organ of State within the public administration, but outside the public service;

(f) The DOD, of which the SANDF is a subsidiary of, is an entity that is contemplated to be in the public service; and

(g) In any event the procurement of the drug was achieved on the basis of the bilateral agreement that governs the relationship between South Africa and Cuba.

6.1.52.6 General Shoke stated that the Public Protector’s notice was silent on the respective mandates of the SANDF, SAMHS and SAHPRA. He indicated that although at paragraph 9.1.2 of the Public Protector’s latest notice and elsewhere therein, it is recorded that the DOD had failed to record its reasons for deviation “from inviting competitive bids”, the Public Protector has completely disregarded paragraphs 40 and 41 of his initial affidavit. He had deposed, in those paragraphs, as follows:

“…40 Therefore to accuse SANDF and MCC of not having followed the procurement process as contemplated in section 217 of the Constitution in procuring the interferon drug is ignorant of the fact that there were no Covid
19 vaccine manufacturers who could have been invited and/or approached to provide the vaccines by SANDF or any other organ of State.

41 to that end I invite the Complainant to share with the PP’s office and the rest of the world a list and/or names of accredited entities, countries and/or individuals (nationally or globally) that had the requisite Covid 19 vaccines as at November 2019 including and leading to the period March 2020 when the interferon drug was procured by SANDF from Cuba…”

6.1.52.7 General Shoke indicated further that based on the above quoted portions of his initial affidavit, it would appear that the Public Protector has not applied her mind to the inapplicability of section 217 of the Constitution.

6.1.52.8 General Shoke advised that to the extent that the Public Protector intends to make a finding of improper conduct on the part of the SANDF and members of the MCC in particular, he raised these aspects that appeared in the initial affidavit and in this affidavit.

6.1.52.9 General Shoke advised that the Public Protector has failed to draw a direct link on contravention of section 217 of the Constitution by members of the MCC. He argued that the Public Protector’s report does not explain or detail how has the MCC contravened section 217 of the Constitution or any applicable procurement legislation or policies that govern the SANDF.

6.1.52.10 General Shoke further said that at paragraph 8.1.35 of the Public Protector’s latest notice, it is observed and correctly so, that the DOD, at the time, regarded the drug as a strong immune booster that was used in various countries. Importantly the WHO, regarded the drug as an immune booster.

6.1.52.11 General Shoke also indicated that at paragraph 49 of his initial affidavit, he specifically deposed that:

“…49 It is also factually untrue that the interferon drug is banned in South Africa. On the contrary, a strand of the interferon drug is used in South Africa
for treatment of cancer. However, the strand of the interferon drug (Interferon B) has less side-effects compared to the one that is being used for cancer treatment in South Africa…”

6.1.52.12 General Shoke argued that this aspect is not dealt with in the Public Protector’s latest notice. In conclusion, he reiterated the contents of his initial affidavit and he persisted with what he has already deposed therein, as well as the contents of his latest affidavit.

6.1.52.13 General Shoke stated in his affidavit that he invites members of the public, Gen Ford and the Complainant, including the Public Protector to demonstrate if there was any other solution to the outbreak of the Covid-19 (by service providers, companies and countries) which subsequently became a global pandemic, immediately as at November 2019 to June 2020.

6.1.52.14 General Shoke further contended that if there was such a solution, which was hidden or remain hidden in the face of millions of people having lost their lives, such service providers, companies and countries must be held liable for genocide.

6.1.52.15 General Shoke further contended that the SG’s professional advice to the MCC had the interest of the people and the country at heart. According to him, it is very much unfair to politicise the noble intentions of the SANDF. In the premise, he contended that there was no contravention of any procurement laws of the Republic of South Africa as alleged by the Public Protector.

**Further meetings with the SANDF:**

6.1.53 On 8 June 2022, a meeting was held with Major General E Mnisi and Brig General CS Mhlauli following the supplementary notices issued by the Public Protector.
Maj Gen Mnisi’s submission

6.1.54 The following was stated by Maj Gen Mnisi in which he sought to clarify certain issues in relation to the supplementary notice, and also based on the letter written by the Chief of Defence dated 17 May 2022:

6.1.54.1 Maj Gen Mnisi stated that he is responsible for the legal services in the SANDF and wanted to clarify the procedural issues regarding the procurement of the drug. On record and even in Parliament, the DOD officials conceded that a procurement process was not followed. He divided the process into four (4) parts, namely the need, the procurement process, the registration and the bringing of the drug into SA. He was not going to discuss the procurement process in detail. The DOD was instructed to deploy at the time, the former SG was the authority for advising the DOD on medical issues. The MCC instructed the former SG to go out into the world and advise on what other countries were doing in this crisis. Maj Gen Mnisi further reported that:

(a) That prior to this, the former SG had advised the MCC on predications of scenarios that could occur in regard to the Covid-19 pandemic. The former SG was tasked to find out from other militaries on what measures they were taking and he came back and advised that some countries were using a drug as an immune booster called interferon. The MCC then accepted the advice provided. They accepted the recommendation from the former SG that the drug be purchased;

(b) That the MCC does not deal with procurement processes at all and only identifies and approves the need. Once this is decided, all the procurement processes will then be followed by the relevant officials/structures at lower and higher levels. After the MCC confirmed the need, then the SG and C LOG will then have to follow the procurement process. A number of steps will then have been taken for the procurement that would not have taken place within the space of the MCC. Those officials involved in the procurement process must explain
as to what occurred and what went wrong. The MCC only identified a need and the officials were responsible for the procurement process that was not followed. Functional processes were supposed to be followed. The Chief of Defence cannot be held accountable for the process followed by the former SG; and

(c) That once the MCC identified the need that was the end of the process for the MCC. The specifications and procurement process will then have been carried out by the SG and C LOG. On 9 May 2022, the MCC sat and discussed the matter. Furthermore Lt Gen Mbuli informed the MCC that C LOG was not involved in any procurement process and was only involved in payment. They were under the impression that the bilateral contract was used for the procurement, until C LOG informed the MCC that he just paid and was not involved in any procurement process. One of the lessons learned was that processes must be followed. There were gaps that will have to be corrected. The issues of registration regarding the drug fell under the responsibility of the SG. He was informed that the drugs were returned back to Cuba. However he was not sure about the return of the R35 million and that will be addressed between discussions between South Africa and Cuba. (Own emphasis added)

Further submission of Lt Gen Mbuli, C LOG

6.1.55 On 9 June 2022, a meeting was held with Lt General Mbuli, C LOG, Lt Col NH Masithi, Captain TE Banda (Legal) and Major JP Mashike (Legal). This meeting was followed by a statement submitted by Lt General Mbuli dated 13 June 2022, which stated inter alia, that he read the affidavit of the C SANDF (Gen Shoke) dated 14 February 2022 sent to the Public Protector and aligned himself with the contents thereof and requested the Public Protector to regard it as incorporated into his statement. Lt General Mbuli stated the following with regard to his role on the acquisition of the drug:
6.1.55.1 That on 30 March 2020 at the MCC meeting, the SG presented his report on the availability of immune booster (interferon) that was utilised by the Cubans and Chinese. The C SANDF re-emphasised the need to ensure protection of soldiers that were deployed in support of the National State of Disaster that had been announced by the Commander in Chief. The C SANDF furthermore stated that an immune booster interferon had been utilised in Italy and many more countries. The acting SG agreed that interferon will be obtained and utilised in the SANDF. The minutes bear proof that the MCC agreed and instructed that the SG should acquire the drug from Cuba. The DOD has an existing bilateral agreement between the SANDF and the Cuban Defence Force. This bilateral agreement is managed under OP THUSANO;

6.1.55.2 That in terms of the agreement, any DOD arm of service or division that requires services from the Cubans, the service representative will forward the requirement to the Director of OP THUSANO. The Director of OP THUSANO will then consolidate the requirements and forward it to the South African Military Attache in Cuba. The Attache will then forward the requirements to the Cuban Military, then the Cuban Military will process the submission from the SANDF. The submission is then converted into a supplement to the main contract as per agreement. In cases where clarity is required, the Attache will therefore seek for clarification directly from the service representative. Once the supplement is finalised with the Attache and the Cuban Military the senior Cuban Military official will sign the supplement. It will then be forwarded to SA for signature in order to seal the supplementary agreement. The signed supplement will then be forwarded to the Logistics Division; and

6.1.55.3 That once services are rendered, the invoice and a copy of the supplement will be forwarded to the office of the C SANDF for perusal. The invoice will then be brought to the Logistics Division for payment. The Director OP THUSANO will then verify the invoice and all available reports, then forward it to the Budget Manager for capturing. The Budget Manager will then table the invoice before the Logistics Division Finance Committee. The Finance Committee will approve the invoice and Budget Manager will process the
invoice for payment. The Budget Manager will forward the invoice to the Financial Division under the CFO at the Poyntons Building in Pretoria. After further verification the Finance division will forward the invoice to the Reserve Bank. The Logistics Division, as the appointed manager of the contract, would get funding from the Services or Divisions either in advance or later pay for the services rendered. The Logistics Division played no role in the acquisition of services from the Cubans.

Procurement processes in the DOD:

6.1.55.4 Lt Gen Mbuli advised that there are two (2) types of procurement processes to follow, namely: Standard Procurement and Emergency Procurement which was set out as *inter alia*:

(a) **Standard Procurement**: A demand is created by the end-user and forwarded to a procurement centre (Central Procurement Service Centre in Pretoria and Simon’s Town Procurement Service Centre). This demand is coupled with confirmation of availability of funds for the requirement. The procurement unit captures the requirement into the system for further processing. A Specification Committee sits and drafts specifications including terms of reference for the requirement of which when done, the requirement is advertised in the state tender bulletin for invitation of interested bidders to bid for requirements above R1 million. On receipt of the offers, an Evaluation Committee sits and evaluates the offers following the Preferential Procurement Points System. This system is an 80/20 point system for bids up to R 50 million and 90/10 system for bids above an estimate of R 50 million. On completion of the evaluation, the bid is forwarded to a bid Adjudication Committee that will award to the highest scoring bidder of which the combined maximum score is 100. The winning bidder is then awarded the tender through a letter of acceptance given by the procurement unit on behalf of the accounting officer (Secretary of Defence). On accepting the letter of acceptance, the supplier is then given a contract to go ahead in delivering the goods or service.
(b) **Emergency Procurement:** It is informed by NT Regulation 16A which allows procurement entities to procure outside competitive means due to the nature of requirement. In this case when the demand is actioned, the procurement entity can approach suppliers who are registered on the NT Central Supplier (CSD) database that can be accessible in a short space of time in order to save life and property. On receiving the offer by one or more suppliers, the procurement entity will evaluate and adjudicate the bid. The process of interacting with the winning bidder are the same as that of standard procurement. In early 2020 when Covid-19 struck, the NT issued Instructions 8 of 2019 and 5 of 2020/21 for emergency procurement of Covid-19 related protection equipment. As a military institution, the MCC, went through an appreciation process that came to the conclusion that this was a biological warfare related matter which needed a special operation including acquisition of medical supplies for force protection purposes.

6.1.55.5 Lt Gen Mbuli advised that this acquisition did not follow a procurement process as it was military driven operation and faith was put upon the MCC to make a judgement as to where resources will be acquired. This happens with great military expediency and secrecy by the nature of the organisation.

6.1.55.6 Lt Gen Mbuli advised that when it comes to the acquiring of the drug from Cuba, it would not have been expected from Logistics Division to start any procurement process without a requirement from the end user, even if C LOG was instructed directly by the MCC. Furthermore, at the time there were no approved suppliers throughout the world who could supply any medicine or vaccine that could protect humans from Covid-19. As a result the DOD could not talk about a tender process since there were no known suppliers of any medication to remedy the situation at hand, therefore there was no procurement process.

6.1.55.7 Lt Gen Mbuli advised that during the outbreak of this pandemic, the Cuban doctors were deployed throughout the world assisting other countries to
manage the spread of Covid-19 and they were protected through the use of the drug which was proved to be an effective immune booster. As a result, the SANDF who had a mandate to be on the frontline of combating the existing health threat posed by Covid-19, soldiers were vulnerable and at risk of contracting Covid-19. This would have been catastrophic since more lives would have been lost especially those of soldiers who were supposed to enforce the regulations under the State of Disaster. This would have ultimately resulted in the failure to achieve the required mandate. Logistics Division chartered a flight to Cuba, which left South Africa on 23 April 2020, to deliver commodities and PPE to the SANDF students who were in Cuba and returned on 27 April 2020, with doctors who were requested by the South African Government (DoH).

6.1.55.8 Lt Gen Mbuli indicated that after the return of the flight, the Logistics Division was presented with the invoices from Cuba to process. The interferon invoice was among the OP THUSANO invoices. At the time it became evident that the medicine was acquired and that was impliedly confirmed to C LOG by the SG when the SG asked for C LOG to pay for the medication, which according to C LOG’s understanding was acquired under the bilateral agreement between South Africa and Cuba.

6.1.55.9 Lt Gen Mbuli stated that it should be noted that Logistics Division as the Manager of this contract has been paying the Cuba invoices under OP THUSANO and this was nothing new or strange to C LOG, and furthermore that C LOG knew that the MCC approved the acquiring of the medicine. The C LOG had no reason to refuse to pay for the medicine when the end user impliedly confirmed that he had received the medicine. It may be that the use of the medicine in South Africa was not approved by SAHPRA but it would be unfair to expect the C LOG to have known that fact since C LOG was not the end user and neither was C LOG an expert in that field.

6.1.55.10 It was indicated by Lt Gen Mbuli that the first batch of 130 000 doses came with an invoice of approximately R35 million which was processed by the C
LOG for payment. After payment of an amount of R35 million, there were two (2) more batches of the drug that came into South Africa with invoices totalling approximately R181 million which was not paid. The MCC instructed that the invoices should be paid (Attached MCC minutes of 20 July 2020 para 12 c) however the C LOG did not have the money to pay for the second and third batches of the drug and wrote a memorandum to the CFO requesting for additional funds to pay the outstanding balance in the amount of R181 million to Cuba. The DOD did not pay for the second and third batches of the drug until the matter was in the media and the Parliamentary Portfolio Committee raised questions about it. Furthermore, there were multiple enquiries from the AGSA. Subsequently, the Ministerial Task Team (MTT) investigated the matter and a full report was presented to the Portfolio Committee on Defence and subsequently, the DOD received enquiries from the office of the Public Protector.

6.1.55.11 Lt Gen Mbuli advised that on 19 January 2022, the C LOG returned the medication back to Cuba as per the recommendations of the MTT (attached annexure F, return of Heberon [interferon] drugs to Cuba). The payment that has already been effected for the medicine should be a matter to be discussed with Cuba on the bilateral between the two (2) political offices. The MTT report made it clear that the C LOG was not involved in the acquiring of the drug and only processed payment for services rendered.

Annexures attached to Lt Gen Mbuli’s submission:

6.1.55.13 **Annexure B:** Copy of National Treasury Regulations: PFMA 16 A Supply Chain Management.

6.1.55.14 **Annexure C:** Copy of National Treasury Instruction NO: 8 of 2019/2020.

6.1.55.15 **Annexure D:** Copy of National Treasury Instruction NO: 5 of 2020/21.

6.1.55.16 **Annexure E:** Copy of the minutes of the special MCC meeting dated 30 March 2020, 2 April 2020, 4 May 2020, 22 May 2020 and 30 July 2022. Some of the relevant minutes are reflected at paragraph (5.1.25) of this report. Furthermore the following minutes reflected the following *inter alia:*

a. **22 May 2020:** The SG reported on a virtual engagement with the People’s Republic of China (PRC) specialists and SANDF *Reg f and Res F* specialist. He surmised that the PRC was; because of the socio-economic structure, able to successfully enforce the lockdown; social distancing; and treatment of the infected. Interferon B was found to be successful in conjunction with (malaria prophylaxes) chloroquine. Interferon A was used to strengthen patients’ immune systems. Ventilation must be available in abundance. The important thing is to prevent the spreading of the virus through a lockdown.

b. **23 July 2020:** A/SG reported that work was in progress. CoS directed SG to brief C SANDF before Monday, 27 July 2020. *CJ Ops* recalled C SANDF’s direction that Interferon B must be administered within the SANDF with immediate effect. C SANDF again directed SG to administer Interferon B (approved by WHO) as a matter of urgency. C SANDF directed SG to ensure that Medical Practitioners are trained in the administering of Interferon B. He confirmed that the SANDF had procured the medication weeks ago.

c. **27 July 2020:** A/SG reported that the Cuban and SAMHS experts had met on 24 July 2020 to agree on a joint clinical protocol for the
administering of Interferon. The clinical protocol will be the basis of the
roll-out plan which will focus on the frontline personal in the fight against
Covid 19. It was hoped that the programme will start on or before 1
August 2020. In response to C SANDF concerns, A/SG explained that
the SAMHS cannot administer Interferon B without any clinical basis. C
SANDF enquired why the administration related to interferon B was not
confirmed before the medication was ordered. A/SG confirmed that the
required clinical protocol had not been confirmed before the medication
was ordered.

d. 3 August 2022: In response to CoS report that the interferon B was not
administered to the MCC at SADIC, as scheduled on 31 July 2020, A/SG
reported that Interferon B was not registered in SA as a treatment for the
Covid 19 virus. However A/SG confirmed that the registration process
was being pursued. C SANDF questioned why SAMHS ordered
Interferon B but refused to administer it. CJ ops confirmed that the MCC
had instructed the administering of Interferon B and this should have been
carried out. CHR summarised that Interferon B had been ordered on the
advice of SG and SAMHS. He said that the procedural and legal issues
should have been addressed before the medication was ordered. CHR
also explained the predicament of medical practitioners, who have to
adhere to professional regulatory legislation and bodies while adhering to
MCC instructions. CoS instructed SG to correct the situation.

e. 3 September 2020: A/SG reported that SAHPRA had turned down the
section 21 application based on the requirement for a name list of the
members who would be treated with the drug. The SAMHS was awaiting
approval for the research proposal.

f. 7 September 2020: The SAMHS was awaiting approval for the research
proposal. A/SG pointed out that the research proposal will require
minimal vaccines and he anticipated that only 5000 doses would be used
for research purposes and other medication. He said that the bulk of the
vaccines would probably expire. **Formal Investigation:** In response to PMG’s questions on the related costs and decisions, A/SG concurred that an investigation was required into the decision to order the vaccines and the reasons why the medication cannot be administered as Covid 19 treatment. A/SG said that the SANDF is not working in isolation as far as health matters are concerned and that contravention of National Health Regulations constitutes medical malpractice. He said that a formal investigation will get to the truth of the matter. IG enquired if other countries use Interferon as antidote against Covid 19. He also enquired on the involvement of the Department of Health (DoH). A/SG confirmed that the DoH process to evaluate medication is standardised and that the DoH do not recommend the use of Interferon as a Covid 19 treatment. **Defence intelligence investigation:** CDI confirmed that he had been tasked to investigate the matter including the sequence of the decision to procure the medication.

6.1.55.17 **Annexure F:** Copy of the letter written by Lt Gen Mbuli with reference LOG DIV/R/501/16/2/3 dated 23 February 2022. The letter *inter alia*, stated that all the drugs were returned to Cuba. The Cuban authorities accepted all medication returned to them.

**Colonel (Dr) Joseph Thabo Mnisi’s submission**

6.1.56 On 09 June 2022, a meeting was held with Dr Joseph Thabo Mnisi. This meeting was followed by his written statement, dated 14 June 2022. Colonel (Dr) Mnisi stated the following *inter alia:*

6.1.56.1 That he was appointed as the Chief Medical Specialist and Clinical Head of Department by the SANDF for the SAMHS Department of Family Medicine and Primary Health Care. He has been practicing as a Medical Doctor in various positions outside the current employer from 2001. He joined the SANDF as a Medical Specialist in 2010 April and holds the following Qualifications: MBChB (MEDUNSA, 2001); B. FCFP (CMSA, 2009); C.
M.MED (FAM. MED)( UL. 2010); D. MBL ( UNISA, 2011); E. Cert in Medical Law (UP/UNISA, 2008); F. PGDDS (SU, 2019); Senior Commander and Staff Qualifications (SA WAR COLLEGE); Appointed as Senior Officer to substantial rank of Colonel;

6.1.56.2 That he was appointed as a Clinician and played no role except advisory to the SAMHS, within the SANDF in procurement of Medical or any products, neither was he in the procurement part of the drug. He provided clinical advice on the drug mode of action and use as an immune system modulator in the context of Covid-19 outside Hospital use, which is part of his expertise. The acquisition of Interferon for own Force Protection as Covid-19 depletes natural Interferon thus rendering victims vulnerable to Covid 19 Pneumonia and death was clinically rational after various interaction with Global specialists. This position was his clinical advice to the SG;

6.1.56.3 Colonel (Dr) Mnisi advised that Interferon Alpha 2b to which Cuban HEBERON R belongs is neither banned nor useless in Covid 19. Cuba was and is the only country in the world that has produced this pure form of Interferon by Human Specific Anti HSA standards. The SAHPRA approved its use on an application he made under Section 21 because it was not banned in South Africa. Its use is not illegal. The SAHPRA further recommended and directed the SANDF to use it under research, pointing that it was erroneous to view it as banned and useless. He was the only doctor in the country that used it during Covid 19 to help a patient survive and the positive results were reported to the SAHPRA, thus dispelling opposition dim view on its usefulness;

6.1.56.4 Colonel (Dr) Mnisi advised that the interaction with the SAHPRA was when permission was sought to use the medicine under bulk use of Section 21. This was not granted as the information for individual patients was required. Subsequently a name was given and permission was granted. If the SANDF is believed to have broken any law in this regard where he was personally
involved, he challenged the party that makes such a finding to state the specific written law so traversed;

6.1.56.5 That the intentions to use the drug under research are still on and SAHPRA welcomes applications. According to Colonel (Dr) Mnisi the drug purchased will still be re-imported once procedures are clear to all. Colonel (Dr) Mnisi submitted that it is preserved in Cuba as it was directed to be returned before expiry by SAHPRA. None of the drug procured was destroyed by heat exposure and samples taken from the batches for testing by the SAHPRA can attest. That there was no objective finding to support the idea of destruction by heat and that even Cuba has not reported such on receipt of returned medicine. Thus the idea of wastage of medicine is unfounded according to Colonel (Dr) Mnisi;

6.1.56.6 Colonel (Dr) Mnisi advised that there was no drug to date that was registered by the SAHPRA as a cure for Covid-19 Pneumonia specifically. All drugs under protocol were registered for other use but were useful in symptomatic treatment in patients with Covid-19;

6.1.56.7 Colonel (Dr) Mnisi advised that Interferon Alpha 2B Heberon R was not banned or useless in mitigation of Covid-19. Other than under Section 21, the SAHPRA recommended its use under Clinical Research which was still the intention of its use after clearing importation requirements. He advocated the clinical use of the drug as an immune modulator now as he did prior to its initial importation; and

6.1.56.8 Colonel (Dr) Mnisi stated that although he was not in the medical procurement processes itself he however supported the acquisition of the Interferon as he does now. That the procurement processes should not cast any shadow of doubt on its clinical importance save to say the piece of legislature or process against which the SANDF was judged was not established without contextual and legal contestation, which is a domain to be objectified by the Constitutional experts. Colonel (Dr) Mnisi finally submitted that in the context of Level 5 lockdown and absence of cure for Covid-19, as well as
permutations of Section 21 use and Research allowance by the SAHPRA, he has broken no law in advocating for Interferon clinical use prior to its acquisition and actually using it after procurement. Colonel (Dr) Mnisi averred further that the process of procurement which he was not involved in is itself sterile of any objective contravention of rules from his analysis point of view unless established by specific unambiguous act or directive.

Submission by Lieutenant General (Dr) Ntshavheni Peter Maphaha, the current SG

6.1.57 On 10 June 2022, a meeting was held with Lt Gen Maphaha, he submitted a written statement dated 10 June 2022. At the meeting Lt Gen Maphaha stated the following:

6.1.57.1 That he was serving as the Surgeon General of the SANDF with effect from 01 November 2021 and his submission are in relation to when he was the Chief Director Military Health Force Preparation of the SAMHS with effect from 01 June 2020 until 31 October 2021. He explained the context of his involvement as it referred to the supplementary notice in terms of section 7(9)(a) of the Public Protector Act, paragraph 8.1.24 of the document;

6.1.57.2 Lt Gen Maphaha advised that the document being referred to by the Public Protector, reference SG/CDMHFP/IGSAMHS/AGSA/505/1/3 and dated 23 February 2021, was in response to the request for information by the AGSA in their audit investigation on the procurement of the drug;

6.1.57.3 That it was his responsibility to ensure that the troops were combat ready at all times, part of which was Force Health Protection. This involved protecting the troops from any health threats, and Covid-19 was one of the threats identified. Lt Gen Maphaha was informed that there was, in the Military Health Base Depot, a drug by the name of Interferon, which had apparently been procured as an immune booster for their troops. After making enquiries, he found that this drug was not registered for the treatment of Covid-19 in South Africa. Lt
Gen Maphaha therefore had to get it registered before he could authorize its utilization as an immune booster to protect the troops; and

6.1.57.4 That the SAHPRA instructed them to first conduct research trial to prove the efficacy of the drug, before they could register it as an immune booster. The process of applying for the research trial proved to be lengthy and expensive, and during this period, the SAHPRA approached the High Court for an order that the drug be returned to Cuba. Subsequently, at the end of 2021, the High Court of North Gauteng, issued an order for the SANDF to return the drug to Cuba, which order was adhered to. His involvement in the use of the drug was therefore solely to attempt to obtain registration of the drug as an immune booster for Covid-19.

**General Rudzani Maphwanya, the Chief of Defence**

6.1.58 On 13 June 2022, a meeting was held with General Maphwanya, the Chief of Defence and his team consisting of Major General E Mnisi and Brig General CS Mhlauli. The Chief explained the role of the Chief and the SecDef within the DOD. General Maphwanya explained his responsibilities and gave the background regarding the start of Covid-19 and the trip to Wuhan, China. General Maphwanya once again confirmed that decisions of the MCC and activation of those decisions must be separated. General Maphwanya said that the decision of the MCC was to ensure that the members will be protected.

6.1.59 It was reported by General Maphwanya that with the advice of the SG and having engaged with China and the Cubans, they took that decision which must be separated from the process of procurement. On the matter of decisions of the MCC, General Maphwanya explained that individuals cannot be held responsible as they were not involved in any procurement processes. General Maphwanya confirmed that the SG gave advice to the MCC regarding the drug and C LOG dealt with its procurement. With regard to the R35 million that was paid to Cuba and the return of the drugs, General Maphwanya advised that a transaction was entered into by South Africa and Cuba. General
Maphwanya said that it will have to be a high level engagement between the political heads in resolving the issue and not at his level.

**Former SG, Lt General (Dr) Zola Wiseman Songo Dabula (ret)**

6.1.60 On 20 June 2022, a meeting was held with the former SG. This was followed by his written statement, dated 23 June 2022. Lt Gen Dabula (ret) stated in his statement *inter alia*:

6.1.60.1 That he is a retired General, who was the SG of the SANDF, appointed on 1 November 2019 and retired on 31 October 2021. Towards the end of March 2020, he was sent to Cuba to address issues pertaining to the students doing Military Medical studies in that country. The purpose of the visit was to finalise the issue of what would happen to them after completion of their medical degrees in Cuba. During this visit, the Cuban authorities invited him to a plant that was producing Interferon, the drug in question. This followed an in-depth discussion with them on the utilization of the drug, its efficacy and the results of research that was conducted in humans in a number of countries across the world;

6.1.60.2 Lt Gen Dabula (ret) advised that the Cuban specialists had even used the drug in patients with Covid-19 with good results. They were using it as an immune booster/modulator in these patients with the result that these patients did not need hospital admission and the patient response to the drug was that it was of value for them. In fact, the indication was that in all the countries that had requested assistance from Cuba to fight the disease they carried the drug to use it themselves (the medical doctors and specialists) to prevent Covid-19 complications and also, in those countries that allowed them, to use the drug in the general population. On coming back to SA, he found that the first case of Covid 19 had been reported in the country. There were frequent MCC meetings whose purpose was to map out a response to the disease, to which very little was known about at the time;
6.1.60.3 Lt Gen Dabula (ret) advised that the general approach of the MCC was to use everything that had been proved not to be having any adverse effects on humans to protect the DOD population. At the time, President Ramaphosa had declared a State of National Disaster and deployed the armed forces to assist the SAPS to enforce compliance with the regulations under lockdown level 5. The rest of the world was at pains to find the appropriate drugs/vaccines to combat the spread of disease and the decimating effect it had on the populations of the different countries. The SANDF epidemiologists predicted that SA would be no exception—and this was indeed the case;

6.1.60.4 Lt Gen Dabula (ret) stated that he advised the MCC that given the circumstances on the ground, the SANDF could use this drug to protect the soldiers from the adverse effects of possible complications of infection during deployments. The procurement of all the assets needed for this operation was given to C LOG. All the funds that could not be used by services and divisions of the DOD, due to these restrictions had to be reprioritized and given to C LOG for the purchase of all the covid-19 requirements;

6.1.60.5 Lt Gen Dabula (ret) advised that at the time of discussing how to obtain the drug, he had a bereavement in his family and was forced to take compassionate leave during which time someone else, the Deputy Surgeon General, was acting on his behalf. On his return from compassionate leave on 25 April 2020, the first consignment of the drug came with the “Cuban Brigade” that landed at Airforce Base Waterkloof on 27 April 2020. He was assured that all the necessary and required processes for the procurement of this consignment were followed. It was after a number of months later, when it was discovered that certain steps had been regrettably missed in the process. These were the registration of the drug for use in the SANDF community with the relevant authority (DoH and SAHPRA);

6.1.60.6 Lt Gen Dabula (ret) advised that the SAMHS was not well equipped with the management of the process of procurement of drugs from outside the country since their military to military co-operation with outside fraternal bodies had
been through the exchange of training of military health forces and exchange of medical information;

6.1.60.7 Lt Gen Dabula (ret) stated that the SANDF, as being the last line of defence, had the national responsibility of defending the safety and territorial integrity of the Republic and its sovereignty had to be performed using all means at its disposal within the confines and prescripts of the law. This was one of the forms of aggression against the state which had in fact been predicted in previous environmental analysis or the Defence Force around 2017/18 that in the foreseeable future we should be prepared for the possible biological, radiological and chemical insult to this country. When Covid-19 hit the world, the predictions by the environmental experts not only predicted them, but we were faced with the reality not only at our doorstep but on an international basis. It would be unkind and inconsiderate for the Public Protector to even consider the exigency of the situation that the country faced at the time. As the National Defence Force (Military Health Service), they had an urgent responsibility to act prudently and pragmatically to make sure of the life and survival of the deployed troops as part of their Force Health Protection role, and that was done within the constraints of the global lockdown;

6.1.60.8 Lt Gen Dabula (ret) advised that on recognizing that there was a problem in the utilization of the medicine within the Defence community, a process was immediately set in motion to find an amicable solution of dealing with the challenge with the DoH, which referred them to the SAHPRA. Communication with the regulatory authority was done to the extent that the consignment of medicine that they had, had to be used only within the confines of a research environment, to the extent that the SAMHS was given the use under Section 21 on one patient. The goal posts for the use of this drug in the SANDF became an ever-shifting target. This continued until he retired on 31 October 2021; and

6.1.60.9 Lt Gen Dabula (ret) believed that had everything not been normal and not interfered with by external forces outside the National Defence Force, this
drug would have been a ground breaking success in improving the mortality rate and death of the people in this country.

6.1.61 During the course of the meeting, Lt Gen Dabula (ret) further advised, *inter alia*, that funds were redirected from his unit to C LOG. The purchase of everything fell under the C LOG’s duties. He reported that he went on leave on 15 April 2020 and came back on 25 April 2020. According to him, during his absence Major General Ndlovu (Dr) and Major General (Dr) Ntshavheni Peter Maphaha acted on his behalf and when he arrived back at work, he was told by Chief SANDF to go to Waterkloof Airforce base on 27 April 2020 to welcome the Cuban Brigade and to receive twenty seven (27) doctors to his unit. He said that when he arrived at the base he met Major General Tyhalisi from Logistics Division who informed him that the drug arrived as well. He reported that he went to verify this with both acting SGs who said that they knew nothing about the delivery of the drug; and

6.1.61.1 Lt Gen Dabula (ret) indicated that he discovered that certain steps were missed during purchasing of the drug after consultations with Colonel (Dr) Mnisi. According to him, Dr Mnisi advised him that the drug needed to be registered first. He advised that what went wrong was getting the drug inside the country without registering it first. He believed that the MCC as a whole was responsible. He advised that if the MCC, chaired by the Chief of the SANDF, gives an instruction, if it is not followed, there are consequences. He said that moving forward, a remedy that can correct the situation is for the SAMHS to have a seat on the bodies that the DoH sits on as well, in order for better communication.

6.1.62 In a letter dated 27 June 2022, submitted to the SecDef and General Rudzani Maphwanya respectively by the Investigation Team, they were requested to advise, *inter alia*, on the undermentioned, but no response has been received at the date of this report:

“… It is unclear who specifically placed the order for the Interferon drugs from
Cuba. Kindly provide the name or names of the officials who prepared and processed the order, including the one who authorised it; Furthermore the submissions from the SANDF did not include copies of the order, letters, emails or correspondence confirming the drugs to be procured or the volume. Kindly forward the copies of correspondence relating to the order; and Provide the criteria used to determine the volume of the Interferon drugs to be procured…”

6.1.63 In a letter dated 28 July 2022, submitted to the SecDef by the Investigation Team, she was requested to advise, *inter alia*, on the undermentioned, but no response had been received at the date of this report:

“…We further refer to our letter dated 27 June 2022, and remind that the requested information/evidence is still outstanding. Attached, find a copy of the letter for ease of reference.

The Public Protector is in the final stage of finalising the report, however the following is requested:

A copy of the final report of the Ministerial Task Team investigation on the same matter…”

6.1.64 On 14 September 2022, Ms Mukona Mphidi, the SAHPRA Office Manager, provided documentation through email relating to the court case no: 61569/2021, Gauteng Division. The papers in the matter were perused. Of importance was the court order by the Honourable Judge Bam, dated 28 December 2021, which stated *inter alia*, that the Applicants (Chief SANDF, SecDef, SG) undertook to repatriate the drugs to Cuba by not later than 31 December 2021.

6.1.65 In a letter dated 21 September 2022, from Dr Boitumelo Semete-Makokotlela, CEO, SAHPRA she stated as follows *inter alia*, that Heberon contains the active pharmaceutical ingredient, Interferon-alpha 2b, which appears in a number of other registered products in South Africa, however, the finished
product Heberon, is not registered in South Africa. It is a requirement that every single finished product must be registered. She advised that the SANDF cannot import unregistered products, without the approval of the South African regulator. (own emphasis added)

**Application of the relevant legal framework:**


6.1.66 Section 200 of the Constitution stipulates *inter alia*:

(1) “The defence force must be structured and managed as a disciplined military force”.

6.1.67 Section 201 of the Constitution is titled *Political responsibility* and stipulates *inter alia*:

(1) “A member of the Cabinet must be responsible for defence”

6.1.67.1 In terms of section 202 of the Constitution, the President as head of the national executive is Commander-in-Chief of the defence force and the command of the defence force must be exercised in accordance with the directions of the Cabinet member responsible for defence, under the authority of the President.

6.1.67.2 The relevant provision of the Constitution that relates to the DOD’s accountability in the public administration is section 195(1) (a)(b)(f) and (g), which provides that the public administration must be governed by the democratic values and principles enshrined in the Constitution, including a high standard of professional ethics which must be promoted and maintained; efficient, economic and effective use of resources which must be promoted; public administration must be accountable and transparency must be fostered by providing the public with timely, accessible and accurate information.
6.1.67.3 Section 217 of the Constitution is the basis upon which all procurement processes within the public sector, including the DOD, are developed, as it demands that certain standards and practices should be complied with when an organ of state contracts for goods and services.

6.1.67.4 Section 217(1) of the Constitution provides that when an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost effective. (Own emphasis)

6.1.67.5 The general rule under section 217 of the Constitution is that all public procurement must be effected in accordance with a system that is fair, equitable, transparent, competitive and cost-effective and that is the standard which was expected of the DOD in procuring this drug. Therefore, the DOD is compelled to comply with the five (5) key procurement principles enunciated in section 217(1) of the Constitution.

6.1.67.6 By following a competitive bidding process, the DOD would have ensured that there was a benchmark with other service providers in the industry and in other countries. Furthermore, a proper process would have entailed feasibility studies (on the drug use to fight Covid-19 and cost involved) research (which countries were using the drug, which countries or companies were selling the drug, market-related cost) and consultations (with the DoH, SAHPRA and health universities). This would have then assisted the DOD in understanding that they were not allowed to procure the drug which was not registered for use in South Africa.

6.1.67.7 The version of the DOD is that due to the Covid-19, section 217 of the Constitution was not applicable as the drug was not part of the National

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7 Steenkamp NO v Provincial Tender Board of the Eastern Cape [2006] ZACC 16; 2007 (3) SA 121 (CC) para 33.
Treatment Protocol for Covid-19 but for exclusive use by soldiers who had to be deployed to enforce Covid-19 Regulations. This was improbable as the drug was not registered for use to treat Covid-19 in South Africa, and could not be used. It is also noted that the DOD had to return the drug to Cuba.

**The Defence Act 42 of 2002 (Defence Act)**

6.1.68 Section 7 of the Defence Act *inter alia*, states that:

“…

7. Secretary for Defence

(1) The President must, subject to the laws governing the public service, appoint a person to the post of Secretary for Defence as head of the Defence Secretariat…”

6.1.69 Section 8 of the Defence Act highlights the functions of the Secretary for Defence and states the following:

“…

8. Functions of Secretary for Defence

The Secretary for Defence-

(a) is the Head of the Department as contemplated in the Public Service Act, 1994 (Proclamation No. 103 of 1994), and the accounting officer for the Department as contemplated in section 36 of the Public Finance Management Act, 1999 (Act No. 1 of 1999);

(b) is the principal departmental adviser to the Minister on defence policy matters;

(c) must advise the Minister on any matter referred to him or her by the Minister;
(d) must perform such functions as may be entrusted to the Secretary for Defence by the Minister, in particular those necessary or expedient to enhance civil control by –

(i) Parliament over the Department;
(ii) parliamentary committees having oversight over the Department; and
(iii) the Minister over the Department;

(e) must provide the Chief of the Defence Force with comprehensive instructions requiring the Chief of the Defence Force to issue orders and directives and to give commands to any specified member regarding the exercise of any power delegated or the performance of any duty assigned to that member by the Secretary for Defence as head and accounting officer of the Department of Defence; (Own emphasis)

(f) must monitor compliance with policies and directions issued by the Minister to the Chief of the Defence Force and report thereon to the Minister; and

(g) is responsible for the discipline of, administrative control over and management of employees, including their effective utilisation and training…" (Own emphasis)

6.1.70 In terms of section 9:

“…Delegation of powers and assignment of duties by Secretary for Defence
(1) The Secretary for Defence may, subject to such conditions as he or she may impose, in writing delegate any power and assign any duty conferred upon him or her in terms of this Act to –
(a) any employee or member contemplated in section 6(3);
(b) the Chief of the Defence Force; and
(c) with the consent of the Chief of the Defence Force, any member of the Defence Force.
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(2) A delegation or assignment under subsection (1) does not prevent the Secretary for Defence from exercising the power in question himself or herself…”

6.1.71 In terms of section 10:

“…10. **Departmental investigations by Secretary for Defence**

The Secretary for Defence may in respect of any matter concerning his or her capacity as head or accounting officer of the Department –
(a) instruct any employee or member contemplated in section 6(3) to carry out an inspection or investigation within the Defence Secretariat;
(b) if such matter affects or concerns the Defence Force, instruct the Chief of the Defence Force to convene a board of inquiry or to have such matter investigated by the Military Police;
(c) otherwise deal with it or have it dealt with in accordance with the law; or
(d) institute such investigation as may be provided for in law…”

6.1.71.1 In terms of section 14(a) of the Defence Act, the functions of the Chief of Defence Force, without derogating from any function of the Secretary for Defence contemplated in section 8, are stated as including *inter alia*:

“...
(a) *is the principal adviser to the Minister on any military, operational and administrative matter within the competence of the Chief of the Defence Force*…”

6.1.72 It is noted *supra*, that the SecDef is the accounting officer for the DOD and is responsible for the discipline of employees and has administrative control over and management of employees within the DOD. Furthermore, the SecDef has the necessary powers to conduct departmental investigations.
The Public Finance Management Act, 1999 (the PFMA).

6.1.73 The key instrument regulating procurement in the public service is the PFMA. The key objective of this legislation is to regulate financial management in the national government and provincial governments; to ensure that all revenue, expenditure, assets and liabilities of those governments are managed efficiently and effectively; to provide for the responsibilities of persons entrusted with financial management in those governments; and to provide for matters connected therewith.

6.1.73.1 Fruitless and wasteful expenditure is defined by section 1 as: “expenditure which was made in vain and would have been avoided had reasonable care been exercised.”

6.1.73.2 Irregular expenditure is defined by section 1 as:

“...expenditure, other than unauthorised expenditure, incurred in contravention of or that is not in accordance with a requirement of any applicable legislation, including—
(a) this Act; or
(b) the State Tender Board Act, 1968 (Act 86 of 1968), or any regulations made in terms of that Act; or
(c) any provincial legislation providing for procurement procedures in that provincial government…”

6.1.73.3 Unauthorised Expenditure is defined by section 1 as:

“(a) overspending of a vote or a main division within a vote;
(b) expenditure not in accordance with the purpose of a vote or, in the case of a main division, not in accordance with the purpose of the main division…”
6.1.73.4 Section 36 of the PFMA provides that “… Accounting officers.—(1) every department and every constitutional institution must have an accounting officer…”

6.1.73.5 Section 38 of the PFMA provides that the accounting officer of a department, trading entity or constitutional institution must, *inter alia*, ensure that the department, trading entity or constitutional institution has and maintains an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost-effective, must ensure that there is a system for properly evaluating all major capital projects prior to a final decision on the project. Furthermore, **he or she must take effective and appropriate steps to prevent unauthorized, irregular and fruitless and wasteful expenditure.** (Own emphasis)

6.1.73.6 Section 38(1)(a) prescribes that the accounting officer must ensure that a department has, and maintained, effective, efficient and transparent systems of financial and risk management and internal control.

6.1.73.7 Section 38(1)(b) provides that the accounting officer of a department is responsible for the effective, efficient, economical and transparent use of the resources of the department.

6.1.73.8 Section 38(1)(c)(iii) stipulates that the accounting officer must take effective and appropriate steps to manage available working capital efficiently and economically. Overall, the accounting officer should ensure that the whole department complied with the provisions of the PFMA, as the proper management of the Department’s resources fell with the accounting officer’s responsibilities.

6.1.73.9 Section 38(h) stipulates that the accounting officer “… must take effective and appropriate disciplinary steps against any official in the service of the department, trading entity or constitutional institution who-
(i) contravenes or fails to comply with a provision of this Act;
(ii) commits an act which undermines the financial management and internal control system of the department, trading entity or constitutional institution; or
(iii) makes or permits an unauthorised expenditure, irregular expenditure or fruitless and wasteful expenditure…”

6.1.73.10 Section 38 (n) stipulates that the accounting officer must comply, and ensure compliance by the department, trading entity or constitutional institution, with the provisions of this Act.

6.1.73.11 Section 44(1) states that the accounting officer of a department may:

   “
   (a) in writing delegate any of the powers entrusted or delegated to the accounting officer in terms of this Act, to an official in that department, trading entity or constitutional institution; or
   (b) instruct any official in that department, trading entity or constitutional institution to perform any of the duties assigned to the accounting officer in terms of this Act…”

6.1.73.12 Section 44(2)(d) of the PFMA provides that a delegation or instruction to an official in terms of subsection (1), does not divest the accounting officer of the responsibility concerning the exercise of the delegated power or the performance of the assigned duty.

6.1.73.13 Section 45 provides that “…Responsibilities of other officials.—An official in a department, trading entity or constitutional institution—(b) is responsible for the effective, efficient, economical and transparent use of financial and other resources within that official’s area of responsibility…”

6.1.73.14 The SecDef is the accounting officer of the DOD for the purposes of PFMA as envisaged above.
6.1.73.15 In terms of section 76 “…Treasury regulations and instructions.—(1) The National Treasury must make regulations or issue instructions applicable to departments, concerning: (g) the cancellation or variation of contracts to the detriment of the state…”

6.1.73.16 In terms of sections 81(1) (b) of the PFMA, an accounting officer commits an act of financial misconduct if that accounting officer makes or permits an unauthorised expenditure, an irregular expenditure or a fruitless and wasteful expenditure.

**National Treasury Practice Note**

6.1.73.17 With regard to government procurement, the National Treasury Practice Note 8 of 2007/2008 provides that all contracts with a high value (greater than R500 000.00) should invite competitive bids. The DOD, had to afford all potential suppliers the right to compete for this project through competitive bidding.

6.1.73.18 The DOD confirmed that it did not follow the public procurement process as prescribed by the PFMA.

6.1.73.19 The process of procurement of goods and services in respect of the drug should have been guided by the Constitution, the PFMA, Treasury Regulations as discussed in this report and related prescripts and the DOD Supply Chain Management Policies.

6.1.73.20 The value of the drugs bought was more than R500 000.00 and a competitive bidding process should have been followed. The DOD had spent R35 million on drugs that they were unable to use. The drugs have since been returned to Cuba at a loss of R35 million to South Africa.
Treasury Regulations

6.1.74 The Supply Chain Management (SCM) framework is set out in Regulation 16A of the Treasury Regulations.

Regulation Supply Management:

“16A6 Procurement of goods and services” provides that:

“…”

16A6.1 Procurement of goods and services, either by way of quotations or through a bidding process, must be within the threshold values as determined by the National Treasury.

16A6.2 A supply chain management system must, in the case of procurement through a bidding process, provide for –

(a) The adjudication of bids through a bid adjudication committee;

(b) The establishment, composition and functioning of bid specification, evaluation and adjudication committees;

(c) The selection of bid adjudication committee members;

(d) Bidding procedures; and

(e) The approval of bid evaluation and/or adjudication committee recommendations…”

6.1.74.1 Regulation 16.A3.2 “…A supply chain management system referred to in paragraph 16A.3.1 must – (a) be fair, equitable, transparent, competitive and cost effective…”

6.1.74.2 Regulation 16.A6.4: “If in a specific case it is impractical to invite competitive bids, the accounting officer or accounting authority may procure the required goods or services by other means, provided that the reasons for deviating from inviting competitive bids must be recorded and approved by the accounting officer or accounting authority”.

6.1.74.3 Regulation 16A8 “Compliance with Ethical Standards” provides that:
“16A8.1 all officials and other role players in a supply chain management system must comply with the highest ethical standards in order to promote –
(a) Mutual trust and respect; and
(b) An environment where business can be conducted with integrity and in a fair and reasonable manner…”

6.1.74.4 The DOD did not follow a procurement as outlined in the regulations to the PFMA during procurement of the drug. There are circumstances when it is impractical to invite competitive bids and a state organ can deviate from the normal procurement process. One such reason of deviation is an emergency circumstance. However, in this case no deviation process was even followed. This was neither urgent, timeous, nor practical. It was not expected of the DOD to use the Covid-19 pandemic narrative to disregard procurement procedures for a fair, equitable, transparent, competitive and cost-effective procurement process.

National Treasury instruction No 03 of 2020/21

6.1.75 The NT Instruction no. 03 of 2020/21 provides as follows inter alia:

“…5 Procurement of covid 19 related items and services not covered by this instruction

5.1. If an item or service is not covered in this instruction and is considered to be a specific requirement for the institution to combat COVID-19, the emergency procurement prescripts may be followed:

i. Accounting officers of national and provincial departments and accounting authorities of national and provincial public entities may deviate from inviting competitive bidding in cases of emergency-paragraphs 8.1 and 8.2 of National Treasury SCM Instruction 3 of 2016/17 (Prevention and combating abuse in SCM). This does not require National Treasury’s approval.
ii. Accounting officers/authorities are required to report within 10 working days to the relevant treasury and the Auditor-General all cases where goods and services above the value of R 1 million (VAT inclusive) were procured in terms of Treasury Regulation 16A6.4. The report must include the description of the goods or services, the name/s of the supplier/s, the amount/s involved and the reasons for dispensing with the prescribed competitive bidding process.

“…”

Department of Defence: Process and Procedures for procurement and sales in respect of commercial goods and services: Joint Defence Publication: ACQ NO 00003/2004 (EDITION 1)

6.1.76 The DOD submitted the above policy as its Supply Chain Management Policy and the following sections are of importance in respect of this matter:

“This publication is issued under the authority of Department of Defence Instruction DODI/ACQ/00002/1999 (Edition 2) dated 1 August 2004 and must be implemented in conjunction with the instructions prescribed therein.

This publication prescribes the process and procedures to be followed with respect to procurement and sales in the Department of Defence (DOD)…”

**BACKGROUND**

“…”

The DOD also has a responsibility towards industry by having a procurement and sales system that is fair, competitive, transparent, equitable and cost-effective, as reflected in the Constitution of the RSA (Reference B) and the PFMA (Reference C)…”

6.1.76.1 The DOD has confirmed that none of the domestic procurement legal prescripts, including its own policy, was applied when it procured the drug.
6.1.76.2 It was observed that the DOD has a Supply Chain Management Policy *supra*, which is detailed and speaks to every aspect of the Supply Chain Management process, but it chose not to follow it when it procured the drug.

*The Agreement between the Government of South Africa and the Government of Cuba concerning Defence Cooperation*

6.1.77 The DOD Senior officials reported that the procurement of the drug was done based on the Agreement between South African and Cuba, particularly articles 3 and 6. The Agreement dated 10 January 2012, is reflected below:


…

**ARTICLE 1**

**PURPOSE**

This Agreement shall establish a bilateral defence relationship between the two Parties subject to each Party’s *domestic law* and international obligations, as well as each Party’s *financial constraints in this regard*.

…

**ARTICLE 3**

**IMPLEMENTATION**

(1) The Parties shall entrust the Secretary for Defence of the Republic of South Africa, and the Ministry of the Revolutionary Armed Forces of the Republic of Cuba with the overall implementation of this Agreement. For regular coordination of cooperation, the Parties shall designate a Focal Point in their respective Armed Forces, after which its Terms of Reference could be agreed upon by the Parties.

(2) The Parties shall cooperate on the principle of reciprocity as follows:

(a) Exchange of information on science and technology in specified defence related fields;
(b) exchange of students, lecturers and training staff;
(c) exchange of information and expertise in the fields of defence intelligence, aviation, electronic warfare, weapon systems, defence logistics and military health;
(d) exchange of information and expertise on the use, maintenance and repair of weapon systems as well as facilities and infrastructure management;
(e) exchange of high-level visits as well as ship and aircraft visits; and
(f) any other defence-related area mutually agreed upon by the Parties.

... 

ARTICLE 6
SUPPLEMENTARY ARRANGEMENTS

With regards to any particular matter covered by the provisions of this Agreement, the Parties may enter into such further agreements of a general or a specific nature, as would in their opinion promote the effective implementation of this Agreement...”

6.1.77.1 Article 1 provides for the purpose of the Agreement. It provides that the Agreement’s purpose is to establish a bilateral defence relationship between the two countries, subject to each country’s domestic law...as well as its financial constraints. (Own emphasis)

6.1.77.2 It is evident from this Agreement that any undertaking done in terms of this Agreement was expected to be in compliance with the applicable South African and Cuban legal prescripts. Furthermore any undertaking done must be subject to each country’s financial constraints, meaning, inter alia, funding must be available for any undertaking done in terms of the Agreement.

6.1.77.3 With reference to the procurement of the drug, the DOD was expected to comply with every applicable procurement legal prescript of South Africa before it agreed with Cuba to procure the drug. All the DOD Senior Officials confirmed through interviews and through sworn declarations that the South
African procurement legal prescripts were not complied with when procuring the drug.

6.1.77.4 Secondly, it was expected of the DOD to ensure that there was budget available when procuring the drug. The DOD Logistics Division officials confirmed that there was no budget to pay for the other batches of the drug already delivered by the Cuban government.

Skills Development Act 97 of 1998

6.1.78 Section 2 of the Act states *inter alia*; that

“...

2. (1) The purposes of this Act are—

(a) to develop the skills of the South African workforce—

(i) to improve the quality of life of workers, their prospects of work and labour mobility;

(ii) to improve productivity in the workplace and the competitiveness of employers;

(iii) to promote self-employment; and

(iv) to improve the delivery of social services;

(b) to increase the levels of investment in education and training in the labour market and to improve the return on that investment:

(c) to encourage employers—

(i) to use the workplace as an active learning environment;

(ii) to provide employees with the opportunities to acquire new skills;

(iii) to provide opportunities for new entrants to the labour market to gain work experience; and

(iv) …

(d) to encourage workers to participate in leadership and other training programmed;

(e) …

(j) to ensure the quality of education and training in and for the workplace…”
Medicines and Related Substances Act, Act 101 of 1965, as amended (the Medicines Act)

6.1.79 As per section 2A the objects of SAHPRA are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

6.1.80 As per section 2B (1)(e) of the medicines act “…ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation…”

6.1.81 As per section 14 (1) of the medicines act “…Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration…”

6.1.82 As per section 22 (C) (6) “…No manufacturer, wholesaler or distributer referred to in subsection (1)(b) shall manufacture, import or export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection…”

General regulations under the Medicines Act

6.1.83 In terms of the regulations under the Medicines Act, regulation 6 states “…that no person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, into the Republic except through one of the following ports of entry:

(a) Cape Town International Airport or harbour;
(b) Port Elizabeth International Airport or harbour;
(c) King Shake International Airport or Durban harbour; and
(d) O.R. Tambo International Airport…”
6.1.84 It was observed that the SANDF brought the drugs into South Africa through Waterkloof Airforce Base.

**Case law**

6.1.85 *Allpay Consolidated Investment Holdings (PTY)Ltd v Chief Executive Officer of the South African Social Security Agency (No 1) (CCT 48/13) [2013] ZACC 42; 2014 (1) SA 604 (CC)*

6.1.85.1 In his judgment on 29 November 2013, Justice Froneman held that:

“It is because procurement so palpably implicates socio-economic rights that the public has an interest in it being conducted in a fair, equitable, transparent, competitive and cost-effective manner.” [Paragraph 4]

6.1.85.2 The Court further held that:

“…deviations from fair process may themselves all too often be symptoms of corruption or malfeasance in the process. In other words, an unfair process may betoken a deliberately skewed process. Hence insistence on compliance with process formalities has a three-fold purpose: (a) it ensures fairness to participants in the bid process; (b) it enhances the likelihood of efficiency and optimality in the outcome; and (c) it serves as a guardian against a process skewed by corrupt influences.” [Paragraph 27]

6.1.85.3 With regard to compliance with the regulatory framework in procurement, the court held that:

“Compliance with the requirements for a valid tender process, issued in accordance with the constitutional and legislative procurement framework, is thus legally required. These requirements are not merely internal prescripts that SASSA may disregard at whim. To hold otherwise would undermine the demands of equal treatment, transparency and efficiency under the
Constitution. Once a particular administrative process is prescribed by law, it is subject to the norms of procedural fairness codified in PAJA. Deviations from the procedure will be assessed in terms of those norms of procedural fairness. That does not mean that administrators may never depart from the system put into place or that deviations will necessarily result in procedural unfairness. But it does mean that, where administrators depart from procedures, the basis for doing so will have to be reasonable and justifiable, and the process of change must be procedurally fair.” [Paragraph 40]

The SAHPRA process

6.1.86 As highlighted above, there is a detailed process which the DOD was expected to follow prior to procuring and bringing an unregistered drug into South Africa. This was stated, inter alia, as follows:

“…Process

A Section 21 application can either be a New Application (named patient or bulk stock) or a Re-authorization (named patient or bulk stock). A New Application is submitted, when a health care practitioner (HCP) applies for a specific medication for the first time. A Re-authorization is applied for, 6 months after a prior New Application was approved and a reference number has been issued.

A HCP, identifies the need for a Section 21 application in his/her practice or hospital, for a specific patient/a number of patients. This need will arise, when a required medication is not registered within South Africa or is currently out of stock or a medicine is discontinued.

The HCP needs to ensure that all available relevant medications within the country have been used and did not deliver the required clinical benefit anticipated before a Section 21 application can be submitted.
Should a registered medication be out of stock, the HCP will be required to supply the Section 21 Department with an out of stock letter from the Manufacturer of the medication or the holder of registration certificate.

The unregistered medication which the HCP will apply for, needs to be registered in the country of origin, for the same indication that is intended to be used by the HCP. The Country from which the unregistered medicine is sourced from, needs to be affiliated with Pharmaceutical Inspection Co-operation Scheme (PICS), which is a body that SAHPRA aligns itself with. This is to ensure that, there is harmonised GMP standards and quality systems in the field of medicinal products. The HCP needs to supply a Package Insert of this unregistered medication, if not already in the possession of the Section 21 Unit.

If an indication is off label, a Peer Reviewed Article will have to be provided by the HCP, in support of this medication for the indication.

A Section 21 application is valid for a maximum period of 6 months and no applicant can apply for a period exceeding 6 months. A re-authorization application may be submitted by the HCP where a patient requires chronic usage of the medicine exceeding 6 months.

The quantity requested, needs to be a justifiable amount. The quantity is justified by the duration, frequency, dose, and number of patients intended to treat (in the case of bulk stock) over a maximum period of 6 months.

The HCP needs to provide a clinical motivation for the use of the medication, as well as an indication or diagnosis, which is in line with the indications the medication is registered for in the country of origin.”

(Own emphasis added)

6.1.87 It was expected of the DOD to comply with the national legislation regulating the registration/use of health products in the procurement of the unregistered drug.
Conclusion

6.1.88 Based on the information and evidence gathered, it can be concluded that the DOD did not comply with any South African procurement legal prescripts when it procured the drug, particularly the NT regulations/instruction notes and the PFMA, including those that are specifically established for the procurement of goods and serves on an emergency basis. It was not expected of the DOD to use the Covid-19 pandemic narrative to disregard procurement procedures for a fair, equitable, transparent, competitive and cost-effective procurement process.

6.1.89 It can also be noted from the SecDef’s letter dated 18 August 2021 to the NT, that the DOD did not have funds for the procurement that they committed themselves to R225 million. It is against all procurement processes for the DOD to conclude a procurement process when there was no budget or funds available. The SecDef stated that it was an emergency procurement which the SANDF had to embark on. Furthermore, this letter was written to NT approximately 17 months after the procurement had occurred. The DOD did not confirm the availability of funds before the procurement of the drug.

6.1.90 Accounting officers are therefore required to implement control measures to ensure that all expenditure in their respective institutions are necessary, appropriate, cost-effective and recorded and reported, as prescribed by the relevant legislative framework. Evidence and information obtained show that there was a lack of control in that the drug was irregularly procured and brought into the country by the DOD.

6.1.91 The evidence further reflects that the drug was not registered for use to treat Covid-19 in South Africa when it was delivered in the country. It was also observed that the DOD was unable to use this drug. It paid approximately R35 million for a drug that they could not use in South Africa, and still owed Cuba approximately R182 million for the drug.

8 National Treasury Instructions No. 2 of 2016/2017.
6.1.92 The following are the observations made from the AGSA report:

(a) The DOD did not provide evidence that it had adhered to the import regulations for unregistered medicine by obtaining authorisation from the SAHPRA before importing the drug; and

(b) An additional supplement was entered into to allow for the procurement of Heberon. However, this supplement was signed on 28 April 2020, while the first consignment of Heberon was received at the SANDF warehouse on 27 April 2020. In essence the drug was delivered prior to the agreement/supplement being signed.

6.1.93 It was noted that the SAHPRA directed the DOD on 3 November 2021, to return the drug to Cuba, failing which the batches were to be confiscated and destroyed. In terms of a letter dated 26 January 2022, from Dr Semete-Makokotela to the Portfolio Committee on Defence and Military Veterans (the Committee), the SANDF reported to the SAHPRA that the unregistered medicine in question had been returned to Cuba on 20 January 2022.

6.1.94 In essence, the DOD paid approximately R35 million for a drug that they could not use and had to return to Cuba. This was a material loss that resulted in fruitless and wasteful expenditure. The drug expired in March 2022, April 2022 and July 2022 respectively.

6.1.95 In terms of section 38 the PFMA, the former SecDef as the accounting officer should have ensured that the DOD had an appropriate procurement and provisioning system which was fair, equitable, transparent, competitive and cost-effective. He should have played a greater role in preventing this financial misconduct. This was a major capital project and there was a lack or no proper evaluation prior to a final decision being taken. He should have ensured that there was an effective, efficient, economical and transparent use of the financial resources. This would have ensured that the SANDF did not commit...
themselves to R182 million procurement when they did not have any funds/budget available.

6.1.96 Furthermore there was a failure by the former SecDef to take effective and appropriate steps to prevent the irregular, fruitless and wasteful expenditure. The DOD confirmed that it did not follow the public procurement process as prescribed by the PFMA. The drug was unregistered for use to treat Covid-19 and still procured it. The drug has since been returned to Cuba however the R35 million paid has not been refunded to South Africa. The former SecDef should have investigated this matter and taken effective and appropriate disciplinary steps against all officials who were involved in the irregular procurement. The NT had provided a Covid-19 emergency budget for the SANDF to procure however this unregistered drug was not on the list.

6.1.97 It was noted that the funds were initially used from Project Thusano (use of the bi-lateral contract) however on the DOD’s own version this was then shifted to Operation Notlela (code name for the Covid operation by the DOD).

6.1.98 In response to the lack of budget by the DOD for Covid-19, the NT had allocated R3 billion to the DOD for this operation (Notlela). This included all PPEs and other items required by the DOD. C LOG had used funds from their initial budget the R35 million before they shifted from Project Thusano to Notlela. The further payment of R182 million was stopped as this unregistered drug was not on the NT list. There were no funds for this irregular procurement of unregistered drugs. When the current SecDef, a year, later requested funds from the NT to pay for the reminder of the money owning, R182 million, this was not approved by the NT.

6.1.99 With regard to the response and version provided by General Shoke (ret), it is noted and common cause that the DOD has confirmed that a procurement process was not followed and that the drugs have since been returned to Cuba. According to General Shoke, he advised that the NT was informed, however it was noted that the DOD wrote to the NT requesting additional funds on 18 August 2021, when the procurement had already occurred the previous year.
in April 2020. The version of General Shoke in his response, did not follow the true chronology order of the events as they unfolded. Furthermore, there was no deviation process followed by the SANDF, it only embarked on a registration process after the drug was brought into the country. The SAHPRA had also advised that WHO did not recommend its use outside of a clinical trial.

6.1.99.1 In regard to General Shoke reliance on clause 2.5 of the NT’s instruction No 03 of 2020/2021, “…inter alia, provided that in light of the lockdown, emergencies may occur where normal procurement practices are impractical and moreover where there is a high demand within a short time frame for goods or services required, and therefore the need to make special arrangements with service providers with proven capability and capacity to assist, thus mitigating against dangerous, perilous situations or misery…”, clause 2.16 of the same instruction is quite clear that the core values of fairness, transparency, competitiveness, cost-effectiveness and equitability, as enshrined in section 217 of the Constitution are adhered to.

6.1.99.2 Furthermore this was for central procurement, and a Central Implementing Agent should have been used. It is noted that the DOD did not follow this process and conducted this irregular procurement on its own. If the DOD had followed this instruction they would have had access to a procurement team consisting of officials from the DoH and National Treasury’s Office of the Chief Procurement Officer (NT-OCPO). It was also noted that the DOD reported the procurement in a letter to the NT nearly one (1) year later after the procurement.

6.1.99.3 The version that there was a lack of vaccines in the world, which allowed DOD to circumvent section 217 of the Constitution is not accepted. The DOD at a later stage advised that they had purchased an immune booster. Section 217 of the Constitution stipulates that the DOD when contracting for goods, should have done same in accordance with a system which is fair, equitable, transparent, competitive and cost-effective. The DOD did not even negotiate for a fair price, did not test the market for other products that could have been
used as immune boosters. The DOD even confirmed that the required clinical protocol had not been confirmed or followed before the drug was ordered.

6.1.99.4 A transparent process would have entailed a procurement process being followed or under emergency circumstances a deviation process to have unfolded. This was procurement for an R182 Million, even if reliance was to be placed by the DOD on the Bi-lateral contract, the DOD would still have to have identified the need, did a feasibility study and established that there was a budget in place for the procurement. In essence the DOD bought the drug with no budget confirmed or in place. There was no feasibility studies/medical reports done in relation to the efficacy of the drug.

6.1.99.5 It was noted that General Shoke indicated that there were no accredited Covid-19 vaccine manufactures at the time. However by the DOD’s admission, the drug they procured was an immune booster, hence proper feasibility studies could have been done to establish what immune boosters could be used and what was allowed to be used in South Africa. The version of the DOD is that due to the Covid-19, section 217 of the Constitution was not applicable as the drug was not part of the National Treatment Protocol for Covid-19 but for exclusive use by soldiers who had to be deployed to enforce Covid-19 Regulations. This is not accepted as the drug was not registered for use to treat Covid-19 in South Africa.

6.1.99.6 The DOD did not inform the NT of the procurement within the required time (10 days) after receiving the drug on 28 April 2020, but only during August 2021, nearly one (1) year and four (4) months later after the procurement had taken place. General Shoke stated that the procurement was in line with the NT instruction but this version was not correct as the procurement did not go through the Central Allocation Committee or follow the emergency process as stated in the NT instruction.

6.1.100 It was noted that as part of C LOG’s evidence he stated that “…In terms of the agreement, any DOD arm of service or division that requires services from the Cubans, the service representative will forward the requirement to Director OP
THUSANO. The Director OP THUSANO will then consolidate the requirements and forward it to the South African Military Attache in Cuba. The Attache will then forward the requirements to the Cuban Military, then the Cuban Military will process the submission from the SANDF. The submission is then converted into a supplement to the main contract as per agreement. In cases where clarity is required, the Attache will therefore seek for clarification directly from the service representative. Once the supplement is finalised with the Attache and the Cuban Military the senior Cuban Military official will sign the supplement. It will then be forwarded to SA for signature in order to seal the supplementary agreement. The signed supplement will then be forwarded to the Logistics Division…”

to date the DOD were unable to prove any requirement, need, order, detailed specification document or that they had availability of funds at the time of procurement.

6.1.101 With regard to the version of General Shoke in relation to the Medicines and Related Substance Act 101 of 1965 (MRSA), and that “it does not appear that MRSA binds and applies to SAMHS and SANDF,” this matter is moot as the SANDF has returned the unregistered drugs back to Cuba as per the instructions of SAHPRA in terms of the MRSA. Furthermore it is noted that SAMHS used the MRSA when they submitted their application to SAHPRA for use of the bulk stock of the drug on 27 August 2020. It was also noted that SAHPRA on 5 October 2020 approved an application from SAMHS to use ten vials of the drug in terms of section 21 of MRSA. It was also noted that in the High Court matter as per case number 61569/2021 between the Applicants (Minister of Defence, Chief SANDF, SecDef and the SG) and the Respondent (SAHPRA), it stated inter alia, in the SG’s affidavit at paragraph 42, that he himself states “… It is submitted that if the honourable court were to grant the interdict, the impugned medicine will ultimately be repatriated property to the republic of Cuba and the SANDF will in due course and once all the processes in terms of section 21 of the Medicine and Related Substance Control Act have been complied with, receive replacement drugs or medicine for research purposes within SANDF…”

It thus follows that the
SANDF and SAMHS have followed and applied the MRSA when dealing with the unauthorised drug.

6.1.102 Furthermore from the court papers SAHPRA had raised the issue that the SANDF had a “… duty to protect members of the public, including members of the SANDF against the usage of unauthorized medication which has not been subjected to the rigorous scientific testing to ensure its safety and efficacy, and thus confiscation and destruction of same would serve as a means of protection…” (Own emphasis added)

6.1.103 It was noted as per the court case no: 61569/2021, in the High Court of South Africa (Gauteng Division) that the court order dated 28 December 2021, held inter alia, that the Applicants (Chief SANDF, SecDef, SG) undertook to repatriate the Heberon Alpha drug to Cuba by not later than 31 December 2021. The drugs have since been returned to Cuba.

7. FINDINGS

7.1 Whether the DOD failed to follow a proper procurement process when procuring the drug, and if so, whether such conduct constituted improper conduct in terms of section 182(1) of the Constitution and maladministration in terms of section 6(4)(a) of the Public Protector Act

7.1.1 The allegation that the DOD failed to follow a proper procurement process when procuring the drug is substantiated.

7.1.2 The investigation revealed that the DOD procured the drug from the Cuban government based on the Bilateral Agreement signed on 10 January 2012 concerning defence relationships established between the South African and Cuban governments. In procuring the drug, the DOD senior officials confirmed that they did not follow any South African legal prescripts regulating the public procurement of goods and services other than to rely on the said Bilateral Agreement. However, the DOD contravened the said Bilateral Agreement
which they claimed to have relied on to procure the drug, because Article 1 thereof clearly states that the Bilateral Agreement is subject to each country’s domestic laws and financial constraints.

7.1.3 The DOD failed to follow the National Treasury Regulation 16A6.2 in processing this procurement. National Treasury Regulation 16A6.2 requires that a supply chain management system must, in the case of procurement through a bidding process, provide for the adjudication of bids through the establishment, composition and functioning of Bid Specification, Evaluation and Adjudication Committees.

7.1.4 The investigation further revealed that the drug was not registered to treat Covid-19 in South Africa and the DOD senior officials proceeded to bring it into the country on 27 April 2020 prior to them applying for its registration to the SAHPRA. The SAHPRA directed the DOD on 3 November 2021, to return the drug to Cuba failing which, the batches will be confiscated and destroyed. The SANDF reported to the SAHPRA that the unregistered/unauthorized medication in question was returned to Cuba on 20 January 2022.

7.1.5 The DOD spent approximately R35 million to procure the drug without following normal procurement processes. The DOD senior officials confirmed that the DOD did not have additional funding to pay Cuba the approximate amount of R182 million for the drug consignment already delivered to the DOD. The drugs were unregistered/unauthorized and could not be used to treat Covid-19 in South Africa. The expenditure in the amount of approximately R35 million to procure the drugs from Cuba during April 2020 amounted to irregular, fruitless and wasteful expenditure, as defined in section 1 of the PFMA. This procurement was not economical⁹ and could not be obtained at a reasonable price. The DOD officials failed in their responsibilities for an effective, efficient, economical and transparent use of the financial resources of the DOD within their areas of responsibility¹⁰.

⁹ PFMA section 38(1)(b).
¹⁰ PFMA section 45 (b).
7.1.6 The conduct of the former Secretary of Defence, Dr SM Gulube was in contravention of section 38 of the PFMA in terms of the failure to ensure effective, efficient, transparent systems of financial, risk management and internal control. There was a failure to ensure an appropriate procurement and provisioning system which was fair, equitable, transparent, competitive and cost-effective. There was a failure to ensure a system for properly evaluating all major capital projects prior to a final decision on the project.

7.1.7 The DOD contravened sections 195(1)(a)(b) and (f) and 217 of the Constitution, Treasury Regulations 16A3, 16A3.2, 16A6.2(b) and 16.A6.4, the DOD Policy “Process and Procedures for procurement and sales in respect of commercial goods and services”, and Article 1 of the bilateral Agreement concerning defence relationships between South Africa and Cuba during the procurement of the drug.

7.1.8 The conduct of the DOD, in procuring the drug from Cuba constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) and (ii) of the Public Protector Act.

8. REMEDIAL ACTION

8.1 The Public Protector is empowered in terms of section 182(1)(c) of the Constitution to take appropriate remedial action with a view of redressing the conduct referred to in this notice upon the conclusion of an investigation where adverse findings are made.

8.2 In the matter of Economic Freedom Fighters v Speaker of the National Assembly and Others: Democratic Alliance v Speaker of the National Assembly and Others 2016 (5) BCLR (CC) at paragraph 76, the Constitutional Court per Mogoeng CJ held that the remedial action taken
by the Public Protector has a binding effect.\textsuperscript{11} The Constitutional Court further held at paragraph 73 that:

“When remedial action is binding, compliance is not optional, whatever reservations the affected party might have about its fairness, appropriateness or lawfulness. For this reason, the remedial action taken against those under investigation cannot be ignored without any legal consequences.”\textsuperscript{12}

**The President of the Republic of South Africa must:**

8.3 Take cognisance of the findings of maladministration and improper conduct mentioned in this report, in line with the authority vested on the President, in terms of section 202(1) of the Constitution.

**The Minister of Defence and Military Veterans must:**

8.4 Take cognisance of the findings of maladministration and improper conduct mentioned in this report, in line with the authority vested on the Minister, in terms of section 202(2) of the Constitution.

**The Secretary for Defence must:**

8.5 Take note of the Public Protector’s findings, and ensure that as the accounting officer contemplated in terms of section 8(a) and (e) of the Defence Act and in line with powers vested on the accounting officer in terms of section 38 of the PFMA issues a directive that any future procurement for DOD is aligned with the requirements of the Constitution, and all applicable provisions of the PFMA; the relevant Treasury Regulations and DOD’s SCM policies. The SecDef must also ensure strict compliance with the provisions of these prescripts and enforce adherence in order to efficiently and effectively manage all the DOD revenue, expenditure, assets and liabilities;

\textsuperscript{11} [2016] ZACC 11; 2016 (3) SA 580 (CC) and 2016 (5) BCLR 618 (CC) at para [76].

\textsuperscript{12} Supra at para [73].
8.6 Within sixty (60) days from the date of this report, initiate an investigation in terms of section 10 of the Defence Act and take appropriate action in terms of section 8(g) of the Defence Act against the DOD officials involved in the irregular procurement of the drug from Cuba;

8.7 Within sixty (60) days from the date of this report, include in the DOD’s Workplace Skills Plan (WSP), a training programme for functional members dealing with procurement to be trained on the relevant provisions of the Constitution, recent procurement cases done by the DOD wherein maladministration occurred, PFMA relating to procurement and the DOD SCM policies, as encouraged by section 2 of the Skills Development Act 97 of 1998.

The Chief of Defence must:

8.8 Take note of the findings of maladministration and improper conduct mentioned in this report and further render the necessary assistance to the SecDef, in order to ensure effective implementation and fulfilment of the duties of the SecDef contemplated in terms of section 9 of the Defence Act. The Chief of the SANDF must also adhere to all the delegated lawful instructions received from the SecDef in terms of section 10 of the Defence Act relating to disciplinary action or departmental investigations on this matter; and

8.9 Within sixty (60) days from the date of this report, and in terms of section 14(i) of the Defence Act, train the relevant members of the Defence Force to act in accordance with the Constitution and the law, including customary international law and international agreements binding on the DOD.
9. MONITORING

9.1 The Secretary for Defence must submit an Implementation Plan to the Public Protector within sixty (60) days from the date of receipt of this report indicating how the remedial action referred to in paragraph 8 above will be implemented.

ADV KHOLEKA GCALEKA
ACTING PUBLIC PROTECTOR OF
THE REPUBLIC OF SOUTH AFRICA
DATE: 30 SEPTEMBER 2022

Assisted by: Ms P Mogaladi
Executive Manager: Investigations Branch